SCOTTISH HOSPITALS INQUIRY

Bundle of documents for Oral hearings commencing from 19 August 2024 in relation to the Queen Elizabeth University Hospital and the Royal Hospital for Children, Glasgow

Bundle 19 – Documents referred to in the Quantitative and Qualitative Infection Link expert reports of Sid Mookerjee, Sara Mumford and Linda Dempster

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SCOTTISH HOSPITALS INQUIRY

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SCOTTISH HOSPITALS INQUIRY

E:[redacted]

Dr Sara Mumford
[redacted]

4th October 2022

Dear Doctor Mumford,

The Scottish Hospitals Inquiry

1. I am writing on behalf of the Chair to the Scottish Hospitals Inquiry, Lord Brodie PC QC, with instructions for the preparation of a report on a number of matters related to healthcare associated infections caused by environmental organisms at Queen Elizabeth University Hospital, Glasgow, by members of a panel of experts. You have kindly agreed to convene this panel for the purpose of this report. The other initial members of the panel are Ms Linda Dempster and Dr Jimmy Walker. I have provided copies of this letter to them. Additional members may be appointed to the panel at any time by the Chair.

2. The purpose of the report is to provide evidence and expert opinion about matters within the expertise of the panel that may assist the Chair in fulfilling the Inquiry's Terms of Reference. I set out in more detail below the topics and questions that the Chair asks you to address at this stage. The Inquiry will provide a copy of the report to the Core Participants to the Inquiry, and it will be published on the Inquiry's website. The Chair may ask one or more contributors to the report to speak to its content at a public hearing of the Inquiry at a later date.

3. The members of the panel are instructed as expert witnesses to the Inquiry, and accordingly are required to exercise reasonable skill and care in carrying out these instructions. They should also comply with any relevant professional code of practice (which the panel follow as part of their professional responsibility). Their overriding duty is to assist the Inquiry and to provide your unbiased opinion as an independent witness in relation to those matters which are within your expertise.

4. This letter sets out instructions for the work of the panel that reflect the current understanding of the Inquiry. The Inquiry's investigations are not yet complete, and indeed the work of the panel forms a crucial part of that investigation. It is therefore possible that in due course, members of the panel, or the panel as a whole, may be asked to undertake further

work to assist the Inquiry. This may include answering questions raised by the Inquiry or by Core Participants, preparing further reports, conducting discussions with or providing opinions to other experts instructed by the Inquiry, giving oral evidence at the Inquiry's public hearings, and carrying out other duties appropriate to the role of an expert to the Inquiry as directed by the Chair.

The Inquiry's remit and terms of reference

1. As you are aware, the remit of the Scottish Hospitals Inquiry requires it to consider the planning, design, construction, commissioning and, where appropriate, maintenance of two hospitals: the Queen Elizabeth University Hospital Campus, Glasgow (the QEUH) and the Royal Hospital for Children and Young People and Department of Clinical Neurosciences, Edinburgh, with a view to the Inquiry determining –

1.1 how issues relating to adequacy of ventilation, water contamination and other matters adversely impacting on patient safety and care occurred;
1.2 if these issues could have been prevented;
1.3 the impacts of these issues on patients and their families;
1.4 whether the buildings provide a suitable environment for the delivery of safe, effective person-centred care.

2. The Inquiry must then report to the Scottish Ministers and make recommendations as to ensure that any past mistakes are not repeated in future NHS infrastructure projects as soon as reasonably practicable. The Inquiry is an independent public inquiry under the Inquiries Act 2005 ('the 2005 Act').

3. The Inquiry's remit is followed by specific terms of reference that the Inquiry is to fulfil as the means by which it is to carry out its remit. These terms of reference include the following:

> "1. To examine the issues in relation to adequacy of ventilation, water contamination and other matters adversely impacting on patient safety and care which arose in the construction and delivery of the QEUH and RHCYP/DCN; and to identify whether and to what extent these issues were contributed to by key building systems which were defective…
>
> 6. To examine, during the life cycle of the QEUH and RHCYP/DCN projects, how the Boards of NHS Greater Glasgow and Clyde and NHS Lothian secured assurance and supporting evidence that:
>
> A. All necessary inspection and testing had taken place;
> B. All key building systems had been completed and functioned in accordance with contractual specifications and other applicable regulations, recommendations, guidance, and good practice and;
> C. Adequate information and training were provided to allow end-users effectively to operate and maintain key building systems.
>
> 7. To examine what actions have been taken to remedy defects and the extent to which they have been adequate and effective.
>
> 8. To examine the physical, emotional and other effects of the issues identified on patients and their families (in particular in respect of environmental organisms linked to infections at the QEUH) and to determine whether communication with patients and

their families supported and respected their rights to be informed and to participate in respect of matters bearing on treatment.

9. To examine the processes and practices of reporting healthcare associated infections within QEUH and determine what lessons have been or should be learned.

10. To examine whether the choice of sites was appropriate or gave rise to an increased risk to patients of environmental organisms causing infections."

4. The full Terms of Reference may be found on the Inquiry's website.

5. The decision by the Cabinet Secretary to cause a public inquiry to be held was made in the light of, among other concerns, a history of infections and water contamination at the QEUH. As appears from the Inquiry's remit there have been concerns over the hospital's ventilation and water systems as possibly adversely impacting on patient safety. There has also been concern over drainage and plumbing systems. The hospital site is close to a water treatment plant which periodically is the source of unpleasant odours. This has given rise to a concern that it might also be a source of infection.

6. For the avoidance of doubt, while the Inquiry is charged with examining issues at both QEUH and the Royal Hospital for Children and Young People/ Department of Clinical Neurosciences, Edinburgh, this instruction relates solely to the situation at QEUH (in this instruction, as more generally "QEUH" is used to comprehend both the adult hospital and the immediately adjacent and linked Royal Hospital for Children ("RHC")). It is concerned with the issues of whether and to what extent the incidence of infection that has been experienced in that hospital can be linked to the built environment. It is further concerned to determine whether the buildings present a current environmental risk. It is particularly (but not exclusively) concerned to determine whether the state of the water supply has contributed to the incidence of infection and whether the current state of the water supply gives rise to risk.

Background

7. There is a history of concern over the effectiveness of infection prevention and control in the QEUH. That concern has focused on the paediatric haemato-oncology wards within the RHC. These wards (2A/B) are referred to as the Schiehallion Unit. In September 2018, Schiehallion patients were decanted to ward 6A in the adult hospital in order to allow extensive reconstruction work to be carried out.

8. In addition, there is a history of concern of risks to patients posed by environmental factors at the QEUH, particularly in relation to the ventilation and water and drainage systems. These systems have been thought to be implicated in contributing to infections affecting children and young people in the paediatric haemato-oncology service at the QEUH and the RHC over a number of years. A handful of cases of children and young people with infections occurred in 2016 and 2017, but concerns mounted between January and September 2018 when the number and diversity of type of infections increased. According to Health Protection Scotland (HPS), there were at least 23 cases, involving 11 different organisms.

9. Water testing in Ward 2A in 2018 identified contamination of water outlets and drains, and as a result, control measures were put in place, including sanitisation of the water supply to Ward 2A and installation of point-of-use filters in wash hand basins and showers. Despite these measures, concerns remained and in September 2018, more drastic steps were taken when Wards 2A and 2B in the RHC were closed and the children and young people were moved to the main QEUH building (principally to ward 6A).

10. Concerns about the water supply led to installation of an enhanced water-testing regime and a chlorine dioxide dosing system, first operating across the RHC in late 2018, then in the QEUH in 2019.

11. An additional series of infections in 2019 in Ward 6A in the QEUH heightened concerns, and eventually led to the temporary closure of that ward to new patient admissions. Media reports claimed that several deaths of patients were linked to infection in the hospital, raising further concerns among patients and families about safety. In addition, internal NHS GGC water testing reports came to light that suggested that some of the problems with the QEUH site had been identified as early as 2015, but did not appear to have been acted upon at the time (although they were at a later stage).

12. This occurred against a background of concerns that had been consistently raised by several clinicians at the QEUH about the potential environmental risks of the building and the link to emerging infections. Some of these concerns dated back to the period of the completion and handover of the new building in 2015.

13. Finally, there have been a number of relevant reports by external bodies over the period that underlined these various concerns. These include the report undertaken by HPS, which was invited to examine the infection incidents by the Health Board. Its report – Queen Elizabeth University Hospital/Royal Hospital for Children: Water Contamination Incident – was published in February 2019. As well as setting out a number of recommendations for NHS GGC and for national action, the report recognised that the environmental risks of the hospital could not be discounted.

14. In an oral hearing session in September 2021, the Inquiry heard from patients and families of patients who were affected by healthcare associated infections. Many of those giving evidence referred to issues with the water supply at QEUH. The tone of that evidence was summarised by Counsel to the Inquiry in his closing submission at the end of that hearing in the following terms:

> "(iv) An escalating pattern of concerns about water and drainage is consistently reported by patients and families within the Schiehallion Unit up until its relocation in September 2018. There is more limited evidence of concerns about ventilation during this period. While there is some evidence of concerns on the part of patients and families about water and drainage as far back as 2015/2016, it was only in 2017 that these became more widespread and more serious (and not only within the Schiehallion Unit). That year there were a number of reported infections within the hospital.
>
> (v) Despite attempts by the Scottish Government and by Greater Glasgow Health Board ("GGC") to provide reassurance, evidence of issues with the water supply and with drainage only increased in the eyes of patients and families during 2018. That evidence included a number of very serious infection incidents, including some where clinical staff and/or managers appeared to acknowledge a link between the infection and the hospital environment…
>
> (xii) The Inquiry has been provided with a substantial body of evidence said to indicate the possibility of links between serious patient infections and the built hospital environment. Some of that evidence proceeds on the basis of suspicion: links between infection are suspected or assumed to exist because of circumstantial evidence thought to support those links. That circumstantial evidence includes the various issues with

key building systems already discussed; and it includes perceived increases in the incidence of line infections.

(xiii) But not all the evidence of possible links between infection and hospital environment can be said to be based only on suspicion or assumption. Several witnesses say that they were told either by clinical staff or via reports provided by the Case Note Review ("CNR") that the possibility (at least) of a link had been established. Against that background, and given also the findings of the CNR, Core Participants may wish to consider the questions below.

(xiv) The potential consequences of an infection for a vulnerable patient and for an immunocompromised child in particular can be very serious indeed. Some parents suspect infections linked to the hospital environment contributed to the deaths of their children. Parents witnessed with their own eyes – and children experienced – the consequences of an infection: rapid and terrifying deterioration; suffering; additional illness. In some cases, parents assumed that they were watching the final moments of their child's life."

Instructions

15. The Chair has determined that in order to fulfil its terms of reference, and in view of the concerns over the incidence and source of infection outlined above, among the issues the Inquiry must address is whether there is a causal link between the incidence of healthcare associated infections experienced in the QEUH since 2015, and the condition of the hospital building and its systems. As indicated above, the infections to which attention has been drawn have almost exclusively been those suffered by the paediatric haemato-oncology patients in the Schiehallion Unit, but, in the view of the Chair, the Inquiry must also consider the incidence of infections in other parts of QEUH and any link between these infections and the state of the building. In so far as practicable, the Inquiry would wish to ascertain how rates of healthcare associated infection (and particular types of such infection) compare with other equivalent hospitals (all as further explained below). The Inquiry appreciates the potential difficulty of investigating any infection/ building link, particularly in the light of the various concerns over the available data, reporting and record keeping which have been identified elsewhere. In consequence, the Inquiry's conclusions may have to be couched in terms of increased risk or possibility rather than scientific certainty or balance of probability, in which case the Inquiry would wish to be in a position to explain why that is so.

16. The Chair is conscious that the members of the panel have great expertise and experience in your respective fields. The topics and questions set out in the paragraphs that follow are intended to provide a focus and structure to your work for the Inquiry. However, if

you feel that the topics or questions could helpfully be rephrased, or are too limiting in some respect, or if there are matters that you consider should be added or omitted from those set out below, then please provide any suggestion in that regard to me. The Chair will consider any points that you raise (and may wish to discuss them with you). As noted above at paragraph 4 above it is entirely possible that we will revert with further questions on which your advice is required as our investigations proceed. Please note, however, that you are not being asked to express an opinion on the circumstances of any particular individual patient treated at QEUH and nothing that follows should be taken as suggesting the contrary.

17. As far as possible, your report should cover the following topics and questions insofar as they are within your areas of expertise and it is possible to address them on the evidence and data available to you:

Investigating the significance of the previously identified and investigated groups of cases in the wider context of comparisons with other similar units.

17.1 The panel should identify similar units comparable to the Schiehallion Unit with a view to determining whether the incidence of infection that was seen in the Schiehallion Unit was unusual, particularly in relation to types of infection and number of cases. The panel will be aware that the Schiehallion Unit comprises wards 2A/2B of RHC, and then after the September 2018 decant, ward 6A which was located in the (adult) QEUH. The views of the panel are invited as to whether any meaningful comparator (i.e. children from a specialised paediatric oncology unit re-located in adult wards which were not designed for paediatric oncology patients) exists for the period following the decant.

17.2 This investigation should include a review of the Health Protection Scotland Summary of Incident and Findings of the NHS GGC: QEUH/RHC water contamination incident and recommendations for NHS Scotland (20 Dec 2018); the Health Protection Scotland Review of NHS GGC paediatric haemato-oncology data (Oct 2019); the Oversight Board Final Report Timeline section 9 Heat Map of Infections; and the CNR Overview Report.

17.3 Those reports make references to “outbreaks”, “incidents” and “unusual infections”, which appear to have been noticed as of being of significance by at least March 2018. The opinion of the panel is sought on what was unusual or remarkable about these outbreaks, incidents or unusual infections. The Inquiry requires help in understanding what was the significance of the numbers or types or locations (i.e. a paediatric haemato-oncology ward and/or a general adult ward) of these reported cases.

Determining whether there have been other unreported blood stream infections in the Schiehallion patients and whether or not these are significant and why they have not been previously included in other investigations.

17.4 The Inquiry suspects that there will have been infections suffered by Schiehallion patients that have not, for whatever reason, been included in the cases referred to in the various reports referred to above. The panel should report on whether there is evidence of other unreported healthcare associated infections in the Schiehallion Unit.

17.5 If so, the Inquiry would wish to know:

17.5.1 the types, frequency and numbers of infection;
17.5.2 why they were not included in previous reports; and
17.5.3 whether or not the previously unreported cases are significant or unusual.

17.6 The panel should identify similar units comparable to the Schiehallion Unit with a view to determining whether the incidence of infection that was seen in the Schiehallion Unit was unusual, particularly in relation to types of infection and number of cases. The panel will be aware that the Schiehallion Unit comprises wards 2A/2B of RHC, and then after the September 2018 decant, ward 6A which was an adult ward. The views of the panel are invited as to whether any meaningful comparator (i.e. children from a specialised unit re-located in adult wards) exists for the period following the decant.

Reviewing the blood stream infections seen in other areas of QEUH/RHC and determining if the incidence of such infections is unusual or significant either in organism or frequency, requiring a review against peer comparator hospitals across the UK.

17.7 The Inquiry suspects that there will have been infections suffered by patients in QEUH outwith the Schiehallion Unit which have not been the subject of previous reports. The Inquiry would wish the panel to examine the types, numbers and locations of healthcare associated infections arising from environmental factors in the whole of QEUH. In particular, the Inquiry would be interested in the panel's views on the incidence of infections of the types found in the Schiehallion Unit in the wider QEUH.

17.8 The panel should identify similar patient populations comparable to the QEUH with a view to determining whether the incidence of infection that was seen in the QEUH was unusual, particularly in relation to types of infection and frequency and number of cases.

17.9 The panel's views are invited as to whether there is anything unusual or remarkable in relation to the types, frequency and number of infections found in the QEUH.

If any unusual findings are seen, investigating how this might relate to the built environment.

17.10 If it be the case that has been something unusual, unexpected or otherwise remarkable either in the type, frequency or number of infections in the Schiehallion Unit or in the experience of the hospital more generally, then the panel should investigate to what extent that may have been the result of any of the features of the built environment. These would include the design and maintenance of the water system which have been the principal focus of attention so far.

Identifying the potential risks of infection related to the design and build of the built environment irrespective of whether a causal relationship is identified.

17.11 Even if it is not possible to identify causal relationships, the Inquiry needs to understand the risks of infection associated with the following features of the building: design and maintenance of the water system; lower than recommended air change rates in patient rooms; inadequate positive pressure; the lack of particulate (HEPA) filtration in some areas; and the use of chilled beams for temperature control in rooms for immuno-compromised patients.

17.12 The panel should advise on potential vectors of infections which occurred and evaluate the information contained in the available reports (perhaps particularly , the HFS Water Management Issues Technical Review of March 2019) and advise on whether further investigation would be of value.

17.13 The panel should advise whether the proximity of the location of the QEUH and RHC to the Shieldhall water treatment plant gave rise to an increased risk to patients of environmental organisms causing infections

Reviewing the information gathered by the Inquiry to date related to contamination, design and operation of the system to advise on next steps in the investigation.

17.14 The Inquiry has accumulated a certain amount of information in relation to the water supply to the QEUH, findings of contamination and possible defects in the design and operation of the system. The panel should advise on how that information might best be built on with a view to focusing further investigation on the possible relationship between the state of the water and design of the water supply system, on the one hand, and the incidence of infection and/ or the risk of infection, on the other.

Reviewing the reporting of healthcare associated infections.

17.15 The panel should review the processes and practices of reporting and recording healthcare associated infections at QEUH (both within the Schiehallion Unit and the wider hospital). In addition, the views of the panel are invited upon:

17.15.1 Whether the processes and practices adopted during the period 2015 – 2019 were appropriate to dealing with incidents of the type experienced at QEUH, having regard to processes and practices followed elsewhere and whether appropriate guidance was followed;

17.15.2 Whether improvements to practices and processes made during that period and thereafter have, or are likely to, improve management of incidents to achieve better patient outcomes, including whether recommendations made by previous reviews have been implemented; and

17.15.3 What lessons have been or should be learned.

Assessing the current situation.

17.16 The panel should advise on whether, in their opinion, there are any risks to patient safety and care arising from either (i) the built environment as it currently exists or (ii) current healthcare associated infection reporting processes and practices.

Provision Of Material To The Panel

18. The Inquiry will provide such documentary evidence as is available to it to enable you to provide your report. We will provide instructions separately on how to access the Inquiry's document management systems by means of which we will give access to the evidence that you require. In so far as the Inquiry does not have evidence that you feel is necessary to enable you to reach a conclusion on any of the topics set out above, then the Inquiry will

attempt to obtain it for you and, where practicable, may use its statutory powers to do so.

19. The Inquiry will use its best endeavours to facilitate a site visit or visits to QEUH should that be desirable to facilitate your consideration of the issues noted above. In addition, either during those visits or otherwise, if you consider it appropriate to speak directly to staff of NHS Greater Glasgow and Clyde or any other person, the Inquiry will endeavour to facilitate those conversations.

20. Such material as may be provided to the panel members by the Inquiry, or that comes into the possession of panel members by reason of this instruction, is subject to Restriction Order No. 1. In short, that prohibits the use of material provide by the Inquiry for any purpose unrelated to the Inquiry, including publication of any material received from the Inquiry, without the express consent of the Inquiry unless or until that material is published by the Inquiry itself (though the prohibition does not apply in respect of material that is otherwise in the public domain). Accordingly, you should not use any material provided by the Inquiry for any purpose other than the provision of the report to the Inquiry without the Inquiry's prior written consent.

21. Please note that this restriction does not apply in relation to any reference to appointment as a member of the panel that you may wish to make in any publicly accessible material (including social media). However, you should not do so until the Inquiry has published

its own notice of that appointment. The Inquiry would like to publish a short biography of you on its website subject to your prior approval of the content.

Format of the Report

22. The report should be reasonably concise and expressed as far as possible in straightforward language. Where technical or clinical terms are used, and their meaning may not be obvious, please provide a brief explanation as to their meaning.

23. Subject to that general observation, the manner in which you address the topics set out is a matter for you, as is the way in which you express your conclusions and any qualifications that accompany them. However, in preparing your report please make sure that:

23.1 It sets out details of the qualifications of all members of the panel contributing to the report and their clinical and/or academic experience.
23.2 It gives details of any literature or other material that you have relied on.
23.3 It contains a statement setting out the substance of all facts that are material to the opinions expressed.
23.4 It contains a summary of your conclusions.
23.5 It sets out any qualification to an opinion or conclusion provided.

24. If there is a range of professional opinion on a particular issue covered in the report that must be made clear and the range of opinions summarised. The report should explain why you have reached the particular conclusion that you have. Similarly, If there is a disagreement among panel members about any matter within the report, then this too should be made clear. The report should summarise the range of opinions, attribute them to the relevant panel

members, and provide the reasons explaining the views expressed.

25. Where appropriate, the report should make clear if there are any matters on which it is

not, or may not be, possible to provide an expert opinion, for example due to (for example) the lack of available information or gaps in the documentation. The report should give the reasons for any such limitation.

26. The final report must be verified by statements from all panel members who have contributed to the report, saying: “I confirm that in respect of those parts of this report to which I have contributed: (i) I have made clear which facts and matters referred to in this report are within my knowledge and which are not. (ii) Those that are within my knowledge I confirm to be true. (iii) The opinions I have expressed represent my true and complete professional opinions on the matters to which they refer.”

27. You should let me know immediately if at any time after producing your report and before the conclusion of the Inquiry you change your views. It is also important that you notify me promptly if you feel it is necessary to update your report after it has been finalised, for example because new evidence has come to light.

Timetable

28. You will appreciate that the Inquiry is keen to make progress and would therefore value production of your report at the earliest possible date. Equally, however, the Inquiry acknowledges that until you have had an opportunity to assess the initial information that it is able to provide and the scope of the task, it is difficult for you to commit to a specific timetable.

In addition, the panel's ability to provide the report in a timely manner will depend on the availability of information requested from third parties external to the Inquiry. Accordingly, we will agree a date by which a draft copy of your report should be provided after you have had an opportunity to assess those matters. I ask for the report to be provided in draft in the first instance so that I can approve its format, check that the formal requirements for an expert report mentioned above are fulfilled correctly and ask for any queries that the Chair may have to be addressed before the report is signed.

29. Once the report is finalised, a copy will be disclosed to the Core Participants (who are listed on the Inquiry's website) and will be published on the Inquiry website. It may be that once Core Participants have reviewed your report they will identify further issues that the Chair may wish to raise with you.

30. One or more panel members will be asked to attend the Inquiry to give oral evidence at a hearing of the Inquiry. The date of any such hearing is not yet fixed. I would currently anticipate at this stage that it is unlikely to occur before late 2023. I will keep you updated as to the date on which the hearing will take place as soon as possible.

General

31. As a matter of general practice, the Inquiry will copy all correspondence relating to the work of the panel to all members. The principal point of contact on the Inquiry side will be Kirsten McMillan (Assistant Solicitor, Legal Team). In her absence, the principal point of contact will be me, James Logie (Solicitor to the Inquiry).

32. Should the circumstances of any panel member change such that they are unable or unwilling to continue to carry out this instruction, they should inform me as soon as reasonably practicable. Panel members may be removed from the panel only at the direction of the Chair of the Inquiry, who may do so at any time.

33. The Inquiry will make arrangements for providing whatever administrative or other support may be required by the panel from time to time. Any requests for such support should be made in writing to me.

34. May I thank you and the other panel members once again for agreeing in principle to assist the Inquiry. If there is anything that I can do to assist or there are any aspects of these instructions that you would like to clarify then please do not hesitate to contact me.

Yours sincerely,

James Logie,
Solicitor to the Scottish Hospitals Inquiry

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What Does the Odds Ratio Estimate in a Case-Control Study?

NEIL PEARCE[*,†]

Pearce N (Department of Medicine, Wellington School of Medicine, PO Box 7343 Wellington, New Zealand). What does the odds ratio estimate in a case-control study? *International Journal of Epidemiology* 1993; **22**: 1189–1192.
The use of the term 'odds ratio' in reporting the findings of case-control studies is technically correct, but is often misleading. The meaning of the odds ratio estimates obtained in a case-control study differs according to whether controls are selected from person-time at risk (the study base), persons at risk (the base-population at risk at the beginning of follow-up), or survivors (the population at risk at the end of follow-up). These three methods of control selection correspond to estimating the rate ratio, risk ratio, or the odds ratio respectively, by means of calculating the odds ratio in the subjects actually studied. None of these estimation procedures depends on any rare disease assumption. Where the rare disease assumption is relevant is whether the effect which is estimated (e.g. the odds ratio) is approximately equal to some other effect measure of interest (e.g. the risk ratio or rate ratio) in the underlying study base. To avoid confusion on this issue, authors should be encouraged to not only specify the manner in which controls have been selected (e.g. by density sampling) but also the corresponding effect measure which is being estimated (e.g. the rate ratio) by the 'odds ratio' which is obtained in a case-control analysis.

In this paper I will argue that the use of the term 'odds ratio' in reporting the findings of case-control studies is technically correct, but is often misleading. I will first briefly review the commonly used measures of disease occurrence and measures of effect in cohort studies, before discussing measures of effect in case-control studies.

MEASURES OF DISEASE OCCURRENCE

Epidemiological studies should be based on the experience of a particular group of people followed over a particular period of time. Miettinen[1] has termed this study population the 'base population' and its experience over time the 'study base'.

Table 1 shows the findings of a hypothetical cohort study of 100000 people exposed to a particular risk factor, and 100000 people who are not exposed; both groups are followed for 10 years. For simplicity, I will assume that the outcome of interest is mortality from any cause in a fixed cohort; similar arguments apply when studying specific causes of death (or incidence of a non-fatal disease) in an open (dynamic) population, but the estimation procedures are less straightforward.

Three measures of disease occurrence are commonly used in cohort studies. These have been extensively discussed in standard texts[2] and will only be briefly reviewed here, using the findings for the non-exposed group.

TABLE 1 *Findings from a hypothetical cohort study of 200 000 persons followed for 10 years*

	Exposed	Non-exposed	Ratio
Deaths	18 127 (a)	9516 (b)	
Survivors	81 873 (c)	90 484 (d)	
Base population	100 000 (N_1)	100 000 (N_0)	
Person-years	906 346 (Y_1)	951 626 (Y_0)	
Incidence rate	0.0200 (I_1)	0.0100 (I_0)	2.00
Cumulative incidence	0.1813 (CI_1)	0.0952 (CI_0)	1.90
Incidence odds	0.2214 (O_1)	0.1052 (O_0)	2.11

Perhaps the most common measure of disease occurrence is the (person-time) *incidence rate* (or incidence density[3]) which is a measure of the disease occurrence per unit time. In this example, the non-exposed group contributed 951626 person-years during the 10 years of follow-up (this is less than the total possible person-time of 1000000 person-years since people who died before the end of the 10-year period stopped contributing person-time at the time of their death) and there were 9516 deaths during the same period; thus, the incidence rate in the non-exposed group (b/Y_0) was 9516/951626 = 0.0100 (or 1000 per

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100 000 person-years). The incidence rate is a rate per unit time, and has the reciprocal of time as its dimension.[2]

A second measure of disease occurrence is the *cumulative incidence* (incidence proportion[3]) which is the proportion of study subjects who experience the outcome of interest at any time during the follow-up period. In this instance, there were 9516 deaths among the 100 000 people in the non-exposed group, and the cumulative incidence (b/N_0) was therefore 9516/100 000 = 0.0952. The cumulative incidence is a proportion and is dimensionless, but it is necessary to specify the time period over which it is being measured.[2] When the outcome of interest is rare over the follow-up period, then the cumulative incidence is approximately equal to the product of the incidence rate times the follow-up period (in this instance this product is 0.1000 whereas the cumulative incidence is 0.0952).

A third measure of disease occurrence is the *incidence odds*[4] which is the ratio of the number of subjects who experience the outcome (b) to the number of subjects who do not experience the outcome (d). In this instance, the incidence odds (b/d) is 9516/90 484 = 0.1052. As for the cumulative incidence, the incidence odds is dimensionless but it is necessary to specify the time period over which it is being measured.[2] When the outcome is rare over the follow-up period then the incidence odds is approximately equal to the cumulative incidence.

These three measures of disease occurrence all involve the same numerator: the number of deaths (b). They differ in whether their denominators represent person-time at risk (Y_0), persons at risk (N_0), or survivors (d).

MEASURES OF EFFECT IN COHORT STUDIES

Corresponding to these three measures of disease occurrence, there are three principal multiplicative measures of effect which are used in cohort studies.

The measure of primary interest is often the *rate ratio* (incidence density ratio) which is the ratio of the incidence rate in the exposed group (a/Y_1) to that in the non-exposed group (b/Y_0). In the example in Table 1, the incidence rates are 0.02 per person-year in the exposed group and 0.01 per person-year in the non-exposed group, and the rate ratio is 2.00.

A second effect measure is the *risk ratio* (cumulative incidence ratio) which is the ratio of the cumulative incidence in the exposed group (a/N_1) to that in the non-exposed group (b/N_0). In this example, the cumulative incidence ratio is 0.1813/0.0952 = 1.90. When the outcome is rare over the follow-up period the risk ratio is approximately equal to the rate ratio.

A third possible effect measure is the (incidence) *odds ratio* which is the ratio of the incidence odds in the exposed group (a/c) to that in the non-exposed group (b/d). In this example the odds ratio is 0.2214/0.1052 = 2.11. Once again, when the outcome is rare over the study period the incidence odds ratio is approximately equal to the incidence rate ratio.

Each of these effect measures involves the ratio of a measure of disease occurrence in the exposed group to that in the non-exposed group. The various measures of disease occurrence all involve the same numerators (deaths), but differ in whether their denominators are based on person-time, persons, or survivors. They are all approximately equal when the disease is rare during the follow-up period (e.g. a cumulative incidence of less than 10%). The rate ratio is sometimes regarded as the primary effect measure on theoretical grounds,[5] but the risk ratio is perhaps the easier to conceptualize, especially by non-epidemiologists, whereas the odds ratio has been severely criticized as an effect measure.[4,6] These three multiplicative effect measures are sometimes referred to under the generic term of *relative risk*.

MEASURES OF EFFECT IN CASE-CONTROL STUDIES

Suppose that a nested case-control study is conducted in this study base, involving all of the deaths and a group of controls. The effect measure which this case-control study will estimate depends on the manner in which controls are selected. Once again, there are three main options.

One option is to select controls from those who do not experience the outcome during the follow-up period, i.e. the *survivors* (at the end of follow-up). In this instance, a sample of controls chosen from the survivors will estimate the exposure odds (b/d) of the survivors, and the odds ratio obtained in the case-control study will therefore estimate the odds ratio in the base population. Early presentations of the case-control approach were often presented in this context,[7] and it was emphasized that the odds ratio was approximately equal to the risk ratio when the disease was rare.

It was later recognized that controls can be sampled from the entire *base population* (those at risk at the beginning of follow-up), rather than just from the survivors (those at risk at the end of follow-up). This approach which was previously used by Thomas[8] and Kupper *et al*,[9] has more recently been termed 'case-base' sampling,[10] or the 'case-cohort' design.[11] In this

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instance, the controls will estimate the exposure odds in the base population of persons at risk at the start of follow-up (N_1/N_0), and the odds ratio obtained in the case-control study will therefore estimate the risk ratio in the base population (in this instance the method of calculation of the odds ratio is the same as for any other case-control study, but minor changes are needed in the standard methods for calculating confidence intervals and *P* values to take into account that some cases may also be selected as controls[12]).

The third approach is to select controls longitudinally throughout the course of the study;[5,13] this is sometimes described as 'risk-set sampling',[14] 'sampling from the study base' (the person-time experience),[3] or 'density sampling'.[15] In this instance, the controls will estimate the exposure odds in the study base (i.e. the person-time at risk, which can be conceptualized as 'person-years', 'person-months' or even 'person-days'), and the odds ratio obtained in the case-control study will therefore estimate the rate ratio in the study base. Although case-control studies have traditionally been presented in terms of sampling from the survivors,[7] it has been pointed out[5] that most case-control studies actually involve density sampling (with matching on a time variable such as calendar time or age), and therefore estimate the rate ratio without the need for any rare disease assumption[5,13,16] (it should be noted that density sampling does not involve a random sample of the person-time in the study base since controls are only sampled for the 'instantaneous' time periods in which cases occur; thus the odds ratio obtained from density sampling may not be the same as that obtained by selecting controls at random from the study base, but the two odds ratios will be equivalent if 'time' is controlled in the analysis—in this instance 'density sampling' involves matching and then controlling for time in the analysis whereas 'random sampling' can be followed by directly controlling for time in the analysis).

DISCUSSION

Thus, the meaning of the odds ratio estimates obtained in a case-control study differs according to whether controls are selected from person-time at risk (the study base), persons at risk (the base-population at risk at the beginning of follow-up), or survivors (the population at risk at the end of follow-up). These three methods of control selection correspond to estimating the rate ratio, risk ratio, or the odds ratio respectively, by means of calculating the odds ratio in the subjects actually studied. None of these estimation procedures depend on any rare disease assumption. Where the rare disease assumption is relevant is whether the effect which is estimated (e.g. the odds ratio) is approximately equal to some other effect measure of interest (e.g. the risk ratio or rate ratio) in the underlying study base.

Thus, the use of the term 'odds ratio' in reporting the findings of case-control studies is technically correct, since it does involve calculating the odds ratio in the subjects actually studied. However, the traditional presentation of case-control studies and the universal use of the term 'odds ratio', has led to some confusion as to what is being estimated, whether a rare disease assumption is required, and whether the 'odds ratio' is a measure of intrinsic interest.

One solution would be to define a new term to refer specifically to the odds ratio in a case-control study (e.g. 'case-control odds ratio'). This would perhaps be inadvisable, given the exponential increase in new names for old concepts in epidemiology in recent years. Nevertheless, the situation would be clarified if authors were encouraged to not only specify the manner in which controls have been selected (e.g. by density sampling) but also the corresponding effect measure which is presumably being estimated (e.g. the rate ratio) by the 'odds ratio' which is obtained in a case-control analysis.

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Causality and the Interpretation of Epidemiologic Evidence

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There is an ongoing debate regarding how and when an agent's or determinant's impact can be interpreted as causation with respect to some target disease. The so-called criteria of causation, originating from the seminal work of Sir Austin Bradford Hill and Mervyn Susser, are often schematically applied disregarding the fact that they were meant neither as criteria nor as a checklist for attributing to a hazard the potential of disease causation. Furthermore, there is a tendency to misinterpret the lack of evidence for causation as evidence for lack of a causal relation. There are no criteria in the strict sense for the assessment of evidence concerning an agent's or determinant's propensity to cause a disease, nor are there criteria to dismiss the notion of causation. Rather, there is a discursive process of conjecture and refutation. In this commentary, I propose a dialogue approach for the assessment of an agent or determinant. Starting from epidemiologic evidence, four issues need to be addressed: temporal relation, association, environmental equivalence, and population equivalence. If there are no valid counterarguments, a factor is attributed the potential of disease causation. More often than not, there will be insufficient evidence from epidemiologic studies. In these cases, other evidence can be used instead that increases or decreases confidence in a factor being causally related to a disease. Even though every verdict of causation is provisional, action must not be postponed until better evidence is available if our present knowledge appears to demand immediate measures for health protection. *Key words:* causality, epidemiology. *Environ Health Perspect* 114:969–974 (2006). doi:10.1289/ehp.8297 available via *http://dx.doi.org/* [Online 27 March 2006]

The principle of causality, so deeply embedded in humans' minds that it has been thought of as immediately evident, is the very foundation not only of all three monotheistic world religions but also of the first staggering steps of science [*de nihilo nihil* (nothing can be born of nothing); Lucretius 1951]. Hume (1739) was the first to note that there is no logical foundation in the assumption that if in the past every event has had a cause, this will also be the case in the future and, furthermore, that what we perceive in daily life as well as in science is only a sequence of events but not cause and effect. Although Hume deeply believed in the truth of the principle of causality, he pointed to the role of the human mind in constructing reality and the futility of scientifically proving its validity. Kant (1791), as he became acquainted with Hume's thoughts, was awakened from his metaphysical slumber, or so he kept saying, and set out to solve the problem of how Newton's physics, which he thought of as eternally true, could be possible in the face of Hume's demonstration that it cannot be inferred from experience. The Copernican turn in Kant's reasoning was to imply the principle of causality from the assumption that it is among the conditions of every experience. Indeed, if A is a necessary condition of B, then B is a sufficient condition of A. Hence, if for every experience we make (B) it is a precondition that everything has a cause (A), then from the fact that we do have experiences (B), it follows that everything has a cause (A). However, to make this a logically coherent theory, Kant had to sacrifice "objective knowledge"—that is, the *Ding an sich* (the "thing in itself") remains incomprehensible for the human mind. For more than 100 years, the philosophy of science circled around either the assumptions or the (untoward) consequences of Kant's solution. When in 1905 Einstein published his special theory of relativity and his theory of the interaction of electrons and light (Einstein 1905a, 1905b), the very foundation of Kant's philosophy was called into question: the universal truth of Newton's mechanics (Newton 1726) and the validity of the deterministic concept. These considerations not only profoundly changed modern science but also resulted in an open-ended controversy within epistemology. And last but not least, epidemiology and the interpretation of epidemiologic evidence are deeply connected to these fundamental considerations about the nature of human knowledge.

Defining Cause and Causality

The most advanced sciences, physics and chemistry, have altogether abandoned the concepts of cause and effect. These terms are no longer used in these sciences. Newton had already replaced cause and effect with functional relationships; however, to make himself understood to his contemporaries, in the third book of his *Principia* (1726) he spoke about causes (especially to defend his position of what can be called a minimal sufficient cause). Nevertheless, "cause and effect" remained terms used in physics, somewhat anachronistically, especially for scholarly purposes until the end of the 19th century. Mach (1883), alluding to Hume, stressed the psychological nature of these concepts and pointed out that "in nature there is no cause and no effect" and that these concepts are results of an economical processing of perceptions by the human mind.

The notion that diseases have natural causes and are not God's punishments or trials or curses of malicious beings or results of supernatural forces has not even fully penetrated Western culture, let alone become the prevailing view worldwide. Despite its metaphysical character, the etiologic axiom that every disease has an endogenous and/or exogenous cause was extremely successful and is still the foundation of scientific medicine. However, what actually "causes" a disease has from the very beginning been a matter of controversy. Indeed, a single clinical phenomenon can have quite different "causes," and one "cause" can have quite different clinical consequences (Table 1). These facts are not consistent with the original concept of causation, which states that a cause is an object that is followed by another, and where all objects similar to the first are followed by objects similar to the second (Hume 1739). Not even for infectious diseases does this (strong) concept of causation hold. (Hume gave several "definitions" of a cause, among these also what has been called the counterfactual approach, discussed below.)

How, then, should cause and causation be defined? In a review of definitions of "causation" in epidemiologic literature, Parascandola and Weed (2001) delineated five categories. However, all of these definitions (summarized in Table 1) have severe deficits. Not totally unexpected, the definitions found in the literature are insufficient to provide a basis for the notion of disease causation. As pointed out above for physical phenomena, it is also impossible for disease processes to draw an ontologic demarcation within the indefinite stream of events between causal and noncausal associations.

Consider a human being as a complex input–output system that is described by a path

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through a state space (of likely very high dimensionality) that may or may not explicitly depend on time. The task is to solve the equations that relate the input stream, the output stream, and the internal states to each other. The solution could give the probability that the human being will be in some internal state of disease at some point in time given a set of initial and/or side conditions. If we were in possession of such a tool, we would not need the crutch of a concept of causation. Meanwhile, in a pragmatic sense, it is reasonable to stay with this concept but hold in mind that it is just an economical way to organize the otherwise unfathomable stream of events and to take the necessary steps to counteract or prevent the disease process. The process of diagnosis itself is one of abstraction and generalization because no two diseased human beings given the same diagnosis have exactly the same features.

In this pragmatic sense, disease cause can be defined as follows: Given two or more populations of subjects that are sufficiently similar for the problem under study, a disease cause is a set of mutually exclusive conditions by which these populations differ that increase the probability of the disease. In some cases, the similarity must be high, such that only homozygous twins can be studied; in other cases, maybe only sex and age must be considered, or the state of immunity. To avoid encumbering the definition with unnecessary complexity, we use the term "conditions" and the active verb "increase." What is meant is that a number of extrinsic and/or intrinsic factors (i.e., conditions) can be discerned that are present before diagnosis of the disease and that prevail at a time and for a duration that is compatible with what is known about the natural history of the disease. Hence, this temporal relation is a precondition for an agent to be considered a causal factor. The "conditions" must be mutually exclusive (e.g., groups of males characterized by one of the following conditions: smoking or having smoked cigarettes, cigars, pipes only, more than one of these, or none), because otherwise the increase in the probability of the disease cannot be uniquely related to any one of them.

This definition is in line with the main designs of epidemiologic studies: the cohort, the case–control, and the randomized controlled trial. It is also in line with the pragmatic definition that assessment of causality affords more than just the observation of an increased incidence or prevalence in some group or the other. This is the point from which Sir Austin Bradford Hill started his considerations that led to what are now commonly called the "Bradford Hill criteria" (1965).

Taking Refuge in Causality

It seems that the first time causality entered the discussion on epidemiologic results was during the tobacco controversy in the late 1950s and early 1960s. In particular, the criticism of Fisher (1959) concerning the conclusions drawn from the British Doctors Study by Doll and Bradford Hill (1954) initiated a detailed consideration of the concept of causality that led to the famous presidential address by Bradford Hill to the Section of Occupational Medicine of the Royal Society of Medicine in 1965. In this talk, Bradford Hill discussed nine issues that should be addressed when deciding whether an observed association is a causal relationship. These issues, now called the "Bradford Hill criteria"—although they were not intended as criteria and not all of them have stood the test of time—are still the starting point of many a treatise on the subject today.

The Bradford Hill criteria were established such that, in the case they are met for a specific factor, this would increase our confidence in this factor being causally related to the disease. However, they were not intended to dismiss a factor as potentially causing the disease: "None of my nine viewpoints can bring indisputable evidence for or against the cause-and-effect hypothesis and none can be required as a *sine qua non*" (Bradford Hill 1965).

Some statements in the past few years about the relationship between environmental or occupational factors and human health have used the terms "causality" or "causal" in a negative sense—that is, claiming that there is no evidence for a causal relationship. First, one has to discriminate between evidence for no causal relationship, and no evidence of a causal relationship (Altman and Bland 1995). The former expresses an important piece of evidence that may have substantial consequences on steps taken to prevent health hazards, whereas the latter simply expresses lack of knowledge. It is, however, often misunderstood as an exculpation of the agent in question and is readily misused by interested parties to claim that exposure is not associated with adverse health effects.

Some examples of such statements illustrate the point:

- A "formal causation analysis based on an application of the Hill criteria confirms that there is no causal relationship between diesel exhaust and multiple myeloma" (Wong 2003).
- "Applying a weight-of-evidence evaluation to the PCB [polychlorinated biphenyl] epidemiologic studies can only lead to the conclusion that there is no causal relationship between PCB exposure and any form of cancer" (Golden et al. 2003).
- "Results of these studies to date give no consistent or convincing evidence of a causal relation between RF [radiofrequency] exposure and any adverse health effect" (Ahlbom et al. 2004).

There are significant differences between these statements. The last one claims that there is no "consistent or convincing evidence" (whatever this may be) of a causal relation. Hence, it points mainly to the lack of knowledge accumulated so far. The second one goes a step further: It claims that risk assessment based on the weight-of-evidence approach [as applied by the U.S. Environmental Protection Agency (U.S. EPA 1999) or the International Agency for Research on Cancer (IARC 2004)] leads to the conclusion of no causal relationship. However, there is no category of this type in the weight-of-evidence approaches. Either the category "not likely carcinogenic to humans" (U.S. EPA 1999) or "evidence suggesting lack of carcinogenicity" (IARC 2004) may be used. Because of the by far higher demands on quality and size of studies set out to dismiss the assumption of carcinogenicity, there is an inherent imbalance of classification concerning carcinogenicity and lack of carcinogenicity. The first statement goes still further: It claims that an analysis

Table 1. Definitions of causation from the epidemiologic literature (modified from Parascandola and Weed 2001).

Definition	Main criticism
A cause is something that produces or creates an effect.	Tautological because "production" and "creation" are synonyms of "causation"
A cause is a condition without which the effect cannot occur.	Only very few diseases could then have a cause[a]
A cause is a condition with which the effect must occur.	Again, only few diseases could then have a cause[b]
A cause is made up of several components, no single one of which is sufficient of its own, which taken together must lead to the effect.	Introduces unnecessary complexity in cases of simple dose response and in cases of interaction between components
A cause is a condition that increases the probability of occurrence of the effect.	Does not distinguish between an association and a "cause"[c]
A cause is a condition that, if present, makes a difference in (the probability of) the outcome.	Is, in the strict sense, unprovable because there is only one world and one cannot observe it twice—once with and once without the condition

[a]Many disease definitions already include a cause (e.g., AIDS is a clinical syndrome in the presence of HIV infection of CD4 cells), but this must not be confused with a necessary cause. All clinical symptoms that occur in AIDS patients can have a variety of other "causes." [b]For example, falling from the 27th floor onto the pavement is not a necessary cause for breaking the skull because many other processes can lead to this effect; however, it can be seen as a sufficient cause. Except for injuries due to extreme physical or chemical conditions and exposure to extremely contagious infectious agents that lead to death (e.g., rabies) or do not result in immunity (e.g., gonorrhea), there are no sufficient causes in this strict sense. [c]Following this definition, male sex would be a cause of lung cancer.

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based on the Bradford Hill criteria confirms that there is no causal relationship. Because the only Bradford Hill criterion that is essential is "temporal relation," the only way to confirm—based on these so-called criteria—that there is no causal relation is to demonstrate that exposure commenced after disease onset. All other evidence may reduce the weight in favor of a causal relationship but cannot confirm that there is no causal relationship.

Are There Criteria for Causation?

During the past decades, Bradford Hill's criteria have played almost the same role in occupational and environmental risk assessment as Koch's postulates for microbiology (Koch 1882). As was the case with Koch's postulates, which cannot be fulfilled for many infectious agents, so Bradford Hill's criteria are supportive (for the assumption of a causal relation) only if fulfilled, but cannot be used to dismiss the assumption of a causal relation. It is a complete misinterpretation of the nine issues considered by Bradford Hill that they can be a type of checklist to establish causation. But it may turn out that they owe their popularity, still persisting after 40 years, exactly to this misconception.

Because the definition of a disease cause given above affords the existence of mutually exclusive conditions, in a strict sense, causation can be indicated only by (experimental) production and control of all (relevant) conditions. This, however, leads to ethical problems if the factor is potentially debilitating or lethal. And it is practically impossible if the latency is long, as it is for chronic diseases. Resorting to animal experimentation can reduce some of these problems but introduces new ones, because inference from results in animals to effects in humans is far from trivial. Hence, we are often left with a number of problems that cannot be optimally solved, and therefore there is no set of criteria that, if fulfilled, would result in attributing a factor as either causally related or not. This does not mean that we cannot, to the best of our present knowledge, come to a decision concerning the relationship of an agent and a disease. Or, as Bradford Hill (1965) said 40 years ago:

> All scientific work is incomplete—whether it be observational or experimental. All scientific work is liable to be upset or modified by advancing knowledge. That does not confer upon us a freedom to ignore the knowledge we already have, or to postpone the action that it appears to demand at a given time.

A Pragmatic Approach

Concerning a particular chemical or physical factor, general medical knowledge may suffice to attribute it as harmful and as causing illness or death (but even in extreme cases such derivations may not be altogether valid—e.g., the statement that it is impossible to climb Mt. Everest without respiratory aid). But in a developed society, obviously, hazardous conditions are likely to have been detected already and are subject to an individual and/or public risk–benefit evaluation. So we are dealing with either less obvious hazards or those that occur only rarely or in a small proportion of the population. The evidence may stem from all kinds of sources, but often we start only from the pessimistic assumption that an agent either not present in the natural environment or present only at much lower levels may be harmful to health. Or it may be that during routine surveillance, a high prevalence of a (rare) disease is observed that coincides with a (rare) environmental condition. How should we come to a conclusion whether the suspected environmental condition is causing disease? It might be worthwhile to stress that there are cases where we do not need the verdict of causation before we take action (e.g., a not very important food additive may be banned on weak evidence of harmful effects). An important part, and a much ignored one, of Bradford Hill's article deals with such situations, as Phillips and Goodman (2004) pointed out.

Starting from the definition of a disease cause stated above, it is obvious that three main issues need to be addressed (to simplify the discussion, let us speak of the set of exclusive conditions as of an agent or determinant A):

- Is the probability of the disease conditional on the presence of A higher than in the absence of A? (association)
- Is the set of conditions to which the source populations are exposed sufficiently similar except for A? (environmental equivalence)
- Are the features of the populations that differ with respect to exposure to A such that, for the problem under investigation, they can be considered equivalent? (population equivalence).

Association. Although we can to some degree rely on statistical decision theory concerning an observed difference, some problems need to be addressed: First, there are cases where we observe an incidence only in those exposed to A and contrast it to the overall incidence in the population (as was the case with hepatic angiosarcoma in workers exposed to vinyl chloride monomer). If the disease is extremely rare in the population, it may not be feasible to do a conventional epidemiologic study. However, if a plausible mechanism of action can be delineated, the observation of an unexpectedly high incidence of the disease may suffice for a verdict of causation. Second, in the case–control approach, we estimate not the conditional probabilities of the disease but their ratio. Furthermore, it is questionable whether statistical decision theory based on random sampling can be applied without further consideration. Typically, all cases of the target disease occurring within a specified region (or even only those diagnosed in one or several hospitals) and during a specified period of time are intentionally included, and only controls are sampled (either from the population or from hospital cases presenting with other than the target disease). To apply statistical decision theory, we have to assume that the cases are a random sample from the distribution of all samples related to all time/space intervals. Furthermore, the population from which the cases and controls originate has, in general, not been stable during the relevant past. Cases of the target disease that occurred before study onset are not included, and also migration in and out of the target area may play an important role, as might deaths from other and maybe related causes. Because of these circumstances and the additional problem of reliably assessing the presence of A retrospectively, case–control studies are often denied the potential to form the basis of a causal interpretation. However, this is exaggerating the difficulties associated with this study type. Especially if several case–control studies from different areas and time periods are available, a generalization about the ratio of incidences can be made if the different sources of bias have been thoroughly addressed. Finally, even if the relative risk (whether estimated from rate ratios, odds ratios, or hazard ratios) is high, statistical significance may not be reached if the number of cases exposed to A is low.

Environmental equivalence. Ideally, those exposed to A should share the same conditions, besides A, with those not exposed to A. If not, all relevant conditions that are potentially related to both A and the outcome (i.e., confounding conditions) must be included in the data set to account for them in the analysis. Failing to do so—that is, controlling for some but not others—may increase confounding instead of removing it (e.g., Maldonado and Greenland 2001); on the other hand, controlling for a variable that is downstream of A may remove the effect of A (Kaufman and Poole 2000). Because the number of potentially confounding factors is indefinite and judgment about the degree of similarity between environmental conditions depends on limited experience, there is always the possibility that an observed association is due to confounding. On the other hand, the mere suspicion that an observed association is due to confounding does not conform to scientific reasoning because it cannot be refuted by a finite sequence of empirical tests. Analysis of uncontrolled confounding (Greenland 2003; Robins et al. 1999) can give an idea about the strength of the association between the confounding variable and both A and the outcome required to substantially alter inferences about the existence of an association between A and the outcome. These approaches may replace the earlier procedures, as already applied by Bradford Hill.

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Population equivalence. The counterfactual approach to causality (last statement in Table 1), although of questionable empirical content, has great heuristic strengths. A counterfactual cause is defined as something that leads to a difference in the disease propensity with respect to the same target (population). Although, of course, it is then impossible to ever empirically demonstrate such a cause, it points to the importance of considering all features of the populations that are substitutes for the target exposed to A or not exposed to A, respectively. Ideally, all features of these substitutes should be equal. However, this would afford restriction to homozygous twin studies with twins who shared the same experiences except for exposure to A. However, for practical purposes, it will suffice to demonstrate equivalence with respect to the features that determine susceptibility to A, disposition to develop the target disease, and the interaction between disposition and susceptibility (i.e., the joint distribution of these features).

Unfortunately, as a National Cancer Institute workshop has stressed (Carbone et al. 2004), there is insufficient evidence to stratify populations based on susceptibility to develop cancer. For other chronic diseases, such as atherosclerosis, Alzheimer's disease, and obstructive pulmonary disease, there might be even fewer evidence-based criteria for disposition and susceptibility. Therefore, a still more modest approach must be followed that is embedded in the universal scientific scheme of bold trial-and-error correction. As a minimum requirement, we must address the features that are known to be related to disease incidence (in most cases, age will be among these features); features that indicate early steps of the target disease (e.g., polyposis for colon cancer), thereby keeping in mind that agent A may be effective only during certain steps of the pathologic process; and features that may determine the potential to counteract or aggravate the disease (e.g., social class). Scientific discussion may reveal that potentially important features have been left out. In this case, considerations of the potential bias thereby introduced may reveal that the effect of A has been underestimated (e.g., if those exposed to A can be considered less prone to develop the target disease). If the investigation resulted in a positive association between A and the target disease, we might conclude that no further investigation is needed; if, on the other hand, no association was revealed, there is indeed a need for error correction. An analogue procedure follows from a suspected overestimation of the association.

Environmental equivalence and population equivalence are usually termed the *ceteris paribus* condition and are often jointly discussed. It is, however, important to discriminate between environmental and population characteristics. Only the former can be targets of change; the latter, although not stationary at all, must be taken as side conditions that can be controlled only by active selection. It is also important to consider self-selection processes in observational studies where features of the environment may determine to some degree features of the population and vice versa.

It goes without saying that all investigations that are assessed for a causal interpretation must be scrutinized for potential biases (especially exposure and outcome misclassification and response or observer bias). However, it is insufficient merely to point to a potential bias without considering the effect this bias may have had on the results. For example, in cohort studies, exposure misclassification can lead to a bias only in the opposite direction of the reported association.

Under the precondition that all investigations have been thoroughly assessed concerning association, environmental equivalence, and population equivalence, and potential biases, and still the following set of statements can be derived, then it is reasonable to allocate A among the potentially causal factors of the target disease:

- The temporal relationship between exposure to A and disease onset (or diagnosis) conforms to what is known about the natural history of the disease.
- There is an association between exposure to A and the target disease.
- Environmental characteristics in which exposed and unexposed populations live can be considered equivalent during the etiologically relevant period except for A.
- Characteristics of exposed and unexposed populations are sufficiently similar to consider them equivalent.

Only the first two statements are essential; the latter two can be substituted by evidence from experimental or other research demonstrating a mechanism of action that does not depend on individual characteristics or environmental factors. Furthermore, if it is impossible to demonstrate the equivalence condition, then other considerations and evidence can be substituted to support the assumption of a causal relation (see below).

Temporal relation, association, and environmental and population equivalence suffice for a verdict of potential causation. This assertion can only be refuted by the following:

- Evidence that demonstrates that A is a downstream condition of some other factor B (e.g., *Helicobacter pylori* infection instead of gastritis as a potential causal factor for atherosclerosis)
- Evidence that A is associated with B, the essential causal agent (e.g., technical tetrachloroethene contaminated with epoxybutane)
- Evidence that essential side conditions have been overlooked that need to be present to make A effective or to make non-A preventive (e.g., a specific receptor phenotype).

It is not necessary to demonstrate a mechanism of action. Bradford Hill (1965) and others pointed to the landmark 1854 study of John Snow, who demonstrated that the rate of cholera deaths in London was 14 times higher in households supplied with water from the Southwark and Vauxhall Company compared with households supplied with water from the Lambeth Company (Snow 1855). Although Snow suspected a living organism contaminating

Table 2. A pragmatic dialogue approach to causal inferences about an agent or determinant A with respect to a disease D: Evidence from epidemiologic studies.

	Counterarguments	
In favor of causation	Valid	Invalid
Temporal relation	Exposure to A commenced after onset of D.	No mechanism of action of A on any or all stages of D has been established.
Association	A is a downstream factor of agent/determinant B that has been indicated as a causal factor of D.	Exposure to A has not been precisely assessed.
	A is associated with B that has been indicated as a causal factor of D.	There could be exposure misclassification.
	There is differential bias (response or observer bias) in the direction of an association between A and D.	There is a potential bias (response or observer bias) with unknown effect on the association between A and D.
	There has been differential disease misclassification in cohort studies.	There has been disease misclassification in case–control studies but not associated with exposure.
Environmental equivalence	Confounding conditions with a combined effect exceeding that of agent A have not been considered.	There could have been confounding.
Population equivalence	A is associated with selection into the study population.	There is a potential selection bias with unknown effect on the association between A and D.
	Risk of A applies only to a subgroup of the population.	
	Exposure is associated with *a priori* risk to develop the disease.	

At this stage no further evidence is necessary for establishing causation unless valid counterarguments have been put forward.

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drinking water by proximity to sewage, another 30 years elapsed before Robert Koch isolated *Vibrio cholerae*, and more than 100 years before the mechanism of action of the cholera toxin was established. The original observation of Snow sufficed to state that something in the water supplied by one company potentially caused cholera and to take appropriate action (closing the pump), and there was no need to wait until a mechanism of action had been demonstrated (thereby probably sacrificing the lives of thousands of people). However, if a mechanism of action can be established, the requirements for epidemiologic evidence outlined above can be somewhat relaxed.

Because of difficulties inherent in observational studies, it may be impossible to demonstrate environmental and/or population equivalence to a sufficient degree, and therefore additional evidence and considerations are necessary to support the notion of a causal relation between agent A and the target disease. There is no possible evidence beyond the three points stated above that will refute epidemiologic evidence in favor of a causal relation besides more and "better" epidemiologic evidence. Stakeholders tend to "flood" the scientific literature with inconclusive (powerless and/or biased) studies in the hope that the balance of evidence will turn in favor of a less strong association between agent A and the target disease. Assessment of evidence must take this into consideration and make proper use of such information (which in most cases will result in disregarding it altogether).

There is an extensive literature about "criteria" for causal inferences in the health sciences, most of which goes back to the seminal work of Bradford Hill (1965) and Mervyn Susser (1973). Although neither author meant to establish a checklist, but only to formulate issues that aid in this task, application has been more or less schematically following these criteria. However, there is no rule that can guide the decision. How many of the criteria must be fulfilled? Is one counting more than the other? What to do if none is fulfilled? There is no straightforward answer to these questions, and every single case merits its own specific line of argumentation.

Tables 2 and 3 propose a dialogue approach to causal inference. It is assumed that epidemiologic evidence has been put forward that is evaluated along the criteria outlined above. A scientific dialogue of conjecture and refutation at first tries to dismiss the notion of a causal relation between agent/determinant A and disease D along the four issues "temporal relation," "association," "environmental equivalence," and "population equivalence." There are valid and invalid counterarguments. If the dialogue ends without valid counterarguments, no further evidence for the verdict of causation is necessary. More often than not, epidemiologic evidence will be insufficient (e.g., due to short duration of exposure). In this case, other evidence may support or weaken the assumption of a causal relation between A and D. The most important of these arguments favoring or against causation are shown in Table 3. Arguments against causation are often not symmetrical to arguments in favor of causation. For example, a long-term experiment in animals that results in a higher incidence of the target disease in exposed animals supports causal inference, whereas a negative result does not support the assumption of no causal relation, because the tested species or strain may lack a decisive feature (e.g., an enzyme) that is present in humans and necessary for A to produce D. There are, however, cases where a positive result in animal experiments cannot be taken as evidence for causation because of processes not present in humans.

Most risk assessment procedures demand that for chronic diseases such as cancer there must be epidemiologic evidence before an extrinsic agent can be ascribed a hazardous potential for human health. Considering the long latencies involved in these diseases, there is a need to define procedures that give answers about a potential causal relationship in a more rapid fashion. Traditional epidemiologic evidence can be provided only *ex post*, when the health impairment has already occurred in a significant fraction of the exposed population. There is an urgent need to connect the disciplines of molecular biology and epidemiology (Carbone et al. 2004). Such collaboration should result in *a*) a better characterization of the study participants with respect to susceptibility and *b*) early markers of responses to the agent in question that can be assessed long before occurrence of manifest disease. With regard to such new approaches, it is of paramount importance to investigate the mechanism of interaction of the extrinsic agent with the organism in order to define potential cofactors and sensitive end points. For chemical substances, *in silico* methods and structure–activity considerations may provide

Table 3. A pragmatic dialogue approach to causal inferences about an agent or determinant A with respect to a disease D: Evidence increasing or decreasing confidence in a potential causal relation between A and D.

Type of evidence	Increasing confidence	Decreasing confidence
From prior knowledge	Results conform to predictions from theoretical considerations and/or prior knowledge about specificity of outcome, specificity of type of exposure, or specificity regarding the outcome in different subgroups of the population.	Although there are sound arguments for specificity of outcome, specificity of type of exposure, or specificity regarding the outcome in different subgroups of the population, data do not conform to these expectations.
	Association between A and D is coherent with biologic knowledge and/or a plausible mechanistic model of action can be delineated.	There is knowledge about mechanism of action that indicates lack of effect of A on D.
From epidemiology	Strength of association between A and D exceeds that of potential confounders.	There are known confounders not considered in existing investigations strong enough to explain the observed effect.
	Association between A and D is consistently observed in different populations, with different types of studies, or in different time intervals.	There is substantial heterogeneity in the effect of A on D in different populations, different study types, or different time intervals.
	Manipulating A in the population changes pattern and/or frequency of D.	Manipulating A in the population does not affect occurrence of D.
	In the case a meaningful meter of the "dose" of A can be defined, there exists a dose–response relationship.	A meaningful "dose" meter can be defined but the relationship between "dose" and response is not monotonous.
From animal studies	Long-term animal studies in different species indicate an association between A and D (or D*, an analogue of D in these species).	There exist animal models of the disease D, and in none of these models A is effective.
	A enhances the effect of a known pathogen B.	No promoting or antagonizing effect of A with a variety of other agents could be found in different exposure regimes relevant for human exposures.
	In animal experiments, intermediate steps of the pathogenic process can be evoked by exposure to A.	In different species that are sensitive to other exposures producing effects expected to be similar to those of A, the latter is ineffective.
From *in vitro* studies	Exposed cells or tissues react or get damaged by exposure to A consistent with the pathogenic process of D.	In cell lines or tissues sensitive to exposures similar to A, no effect of exposure to A is found.
	Upstream events can be observed by exposure to A that may lead to D in the intact organism.	No changes in cellular processes or alterations of signaling pathways can be evoked by exposure to A.
	A enhances the effect of a known cellular pathogen B.	No promoting or antagonizing effect of A with a variety of other agents could be found.

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first answers to a potential path of action (e.g., binding to a receptor). For physical factors such as electromagnetic fields, knowledge is more limited, and new approaches must be designed.

Despite its metaphysical character, the principle of causation or, more specifically, the notion that every disease has a cause has been of great heuristic value and likely will govern our future endeavors for better understanding of the relationship between the environment and human health until we have accumulated more knowledge and may describe the process by a system of equations. However, the complexity of the problem may be too great ever to lend itself to complete description.

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The missed lessons of Sir Austin Bradford Hill

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Abstract

Austin Bradford Hill's landmark 1965 paper contains several important lessons for the current conduct of epidemiology. Unfortunately, it is almost exclusively cited as the source of the "Bradford-Hill criteria" for inferring causation when association is observed, despite Hill's explicit statement that cause-effect decisions cannot be based on a set of rules. Overlooked are Hill's important lessons about how to make decisions based on epidemiologic evidence. He advised epidemiologists to avoid over-emphasizing statistical significance testing, given the observation that systematic error is often greater than random error. His compelling and intuitive examples point out the need to consider costs and benefits when making decisions about health-promoting interventions. These lessons, which offer ways to dramatically increase the contribution of health science to decision making, are as needed today as they were when Hill presented them.

Introduction

One of the most cited papers in health research is Austin Bradford Hill's "The Environment and Disease: Association or Causation?" [1], Hill's 1965 Presidential Address to the Section of Occupational Medicine of the Royal Society of Medicine, where he presented what are now commonly called the "Bradford-Hill criteria." This paper ironically gains its fame for providing a checklist for inferring causation, something Hill did not claim to be creating. Meanwhile, largely ignored are its great insights and potential contributions to critical methodological and policy issues.

Hill outlined a systematic approach for using scientific judgment to infer causation from statistical associations observed in epidemiologic data, listing nine issues to be considered when judging whether an observed association is a causal relationship. Despite widely distributed and clearly elaborated advice to the contrary [2], Hill's nine considerations are still frequently taught to students of epidemiology and referred to in the literature as "causal criteria." Typically presented as a checklist approach to assessing causation (though without a method for deciding whether to assign a particular checkmark, let alone how to make a final assessment), Hill's list is commonly taught in epidemiology courses and is probably invoked more often than any other method for assessing causation. At a time when the discussion of the nature of causation and methods for identifying causal effects are reaching new levels of sophistication in epidemiology [3-5], this is particularly unfortunate.

Hill never used the term "criteria" and he explicitly stated that he did not believe any hard-and-fast rules of evidence could be laid down, emphasizing that his nine "viewpoints" [1](p. 299) were neither necessary nor sufficient for causation. His suggestions about how to intuitively assess causation are almost completely lost when his address is distilled into a checklist (See endnote 1).

Causal criteria are an intriguing subject for the history of science, including the question of why Hill's list seems more popular than others [7-10] and whether causal conclusions that explicitly appealed to criteria are more likely to be borne out by subsequent evidence. (To our knowledge, there has been no such validation study of causal criteria.) But it is not the main purpose of this analysis to join the extensive discussion of the history and merits of causal criteria. We will say only that Hill's list seems to have been a useful contribution to a young science that surely needed systematic thinking, but it long since should have been relegated to part of the historical foundation, as an early rough cut. Yet it is still being recited by many as something like natural law. Appealing in our teaching and epistemology to the untested "criteria" of a great luminary from the past is reminiscent of the "scientific" methods of the Dark Ages. Hill's own caveats suggest a similar opinion (though such a claim requires some caution, given that Hill repeated his list in his medical statistics textbooks until the time of his death, adding neither an evolution in his perspective nor arguments to support the validity or usefulness of the list [11-14]).

This brief analysis of Hill's "criteria" and what has been made of them can add little new to that topic (though we will argue that Hill deserves more credit than he is usually given by critics of "criteria" for the nuances and examples he presented). Our purpose is to call attention to the seldom-cited last page and a half of the article, which presents lessons that remain overlooked today.

Analysis

Hill eloquently warned about overemphasis on statistical significance testing, writing "the glitter of the *t* table diverts attention from the inadequacies of the fare" [1](p. 299). The mistake of drawing conclusions from inadequate samples had been replaced with the mistake of treating statistical significance as necessary and sufficient for action. An intellectual generation passed after 1965 with almost no improvement [15], and little has changed in another generation after that. Researchers still frequently present results as if statistical significance and p-values are useful decision criteria, and decision makers are left with inadequate information.

One implication of Hill's advice is well understood. Emphasis on the p-value (let alone dichotomous statements of significance) has been soundly denounced for decades [16,17]. Estimation of effect sizes, presented as point estimates with confidence intervals, is the preferred method in current textbooks [18] and these are generally reported, though in practice confidence intervals tend to be interpreted as mere tests of statistical significance by ignoring their range except to note whether or not they include the null value (see endnote 2).

A further inadequacy of the fare is less well appreciated, stemming not from the question of p-values versus confidence intervals, but from systematic errors. No statistical test of random sampling error informs us about the possible impacts of measurement error, confounding, and selection bias. Methods for quantifying such errors (and perhaps more importantly, arguments for why we need to do so) have been developed in epidemiology, particularly over the last five years [19-25]. Hill hinted at this more than three decades before the recent spate of attention when he noted that one of his own studies [26], like many studies, had great potential for selection bias (though he does not use this term). In effect, he asks "why would I bother to do an exaggeratedly precise statistical test when I know that the other sources of error are likely so large?" Rather than emphasize low p-values, he concluded that simple cell counts made both random error and plausible systematic error unlikely to account for the observed association. While his solution was inadequate – indeed, it might even be called hubris (see endnote 3) – he did issue a clear warning about mistaking statistical precision for validity. Despite the influence of Hill's article, the fact that it contained this point is forgotten (and the point, while obviously true, remains widely ignored).

Even as modern epidemiologic analysts become less dazzled by the t-table, replacing significance testing with confidence intervals and introducing quantification of systematic errors, there is still a tendency to completely overlook Hill's other important insight. Hill sought to address the question how to decide whether to take action once causal inferences are made. In his last few paragraphs, he offers an important commentary on the policy recommendations that flow from decisions regarding cause and effect in epidemiology. Since "our object is usually to take action" [1](p. 300), policy considerations are central to the importance of the science. While epidemiology has its roots in specific policy questions ("can we do something to prevent cholera outbreaks?"), epidemiologists have ambivalent attitudes towards the policy decisions associated with their research [31]. In grant applications and introductions to research reports, it is typical for epidemiologists to justify expensive research based on immediate practical benefits. But in presenting the results, they often deny, implicitly or explicitly, the need to assess the policy contributions [32], defending the

value of science for its own sake (sometimes even as they issue press releases calling for policy responses).

Even when policy implications are presented explicitly, they are seldom carefully analyzed. Analyzing the implications of a health research finding for decision making is often not terribly difficult, but making recommendations without such analysis can lead to absurd suggestions [33]. One epidemiology journal famously goes so far as to instruct authors to avoid the common practice of tacking on policy recommendations at the end of research reports. The argument is that policy analysis is too complicated and too serious to be an afterthought by researchers whose expertise lies elsewhere [34,35]. Judging from Hill's comments, he might have preferred more careful policy analysis be included in epidemiologic research reports, rather than none at all, though it is not clear he could solve the challenge of fitting it into the standard 3000-word, single-result health research paper. The present journal offers a solution by publishing policy analyses that are based on health research results, and allowing the articles to be whatever length they need be [36].

Hill, who was educated in economics, argued that in order to take policy action, we ought to pay attention to the absolute costs and benefits of potential actions. It would clearly be reading too much into the text to suggest that he had a prescient vision of modern probability-weighted cost and benefit based policy analyses and decision theory (those fields were in their early stages at the time of his writing and he never used any of those terms). But, in another memorable phrase, he did make the case for having "differential standards before we convict" [1](p. 300), based on costs and benefits. Moving another step beyond statistical significance testing, we need to consider more than the degree of certainty that there is *some* health hazard, and act based on the expected gains and losses, with or without statistical certainty.

Hill points this out (in an example sufficiently ill-chosen that it may have contributed to his important message being ignored): "On relatively slight evidence we might decide to restrict the use of a drug for early-morning sickness in pregnant women. If we are wrong in deducing causation from association no great harm will be done. The good lady and the pharmaceutical industry will doubtless survive [1](p. 300)."

Setting aside the impolitic dismissal of women's preferences and the unsupported assertion that there is no great harm at stake (as well as the irony of the popularity, withdrawl, and rehabilitation of the morning sickness drug, Bendectin) the underlying point might be his most important lesson: Policy actions that appear to create a net benefit (on average, considering all costs and benefits) should be taken, even without statistical "proof" of an association, while actions that entail great costs should only be taken with sufficient certainty of substantial benefit.

Hill goes on to strengthen his argument: "On fair evidence we might take action on what appears to be an occupational hazard, e.g. we might change from a probably carcinogenic oil to a noncarcinogenic oil in a limited environment and without too much injustice if we are wrong. But we should need very strong evidence before we made people burn a fuel in their homes that they do not like or stop smoking the cigarettes and eating the fats and sugar that they do like [1](p.300)."

Hill clearly stated that the science and data analysis should not be influenced by what is at stake. But health researchers should recognize that the stakes matter, and incorporate a consideration of them into their work. The alternative to carrying out the policy analysis is to leave the weighing of costs and benefits to an unreliable post-science political process.

The observation that the costs and benefits matter, despite being rather obvious, is frequently – indeed, typically – overlooked in public health discussions. The popular decongestant phenylpropanolamine was banned on weak evidence without regard to the high cost to consumers [37]; dietary recommendations are made without considering absolute benefits, let alone the cost to people of avoiding their favorite foods; and health and safety regulations are tremendously uneven in their cost effectiveness, to cite just three examples. The "policy recommendations" paragraph found in many health research papers sometimes quantifies medical costs, but typically ignores lifestyle, psychological, or productivity costs. It is even rare to find quantification of the absolute aggregate benefit that would result from a policy or behavioral change.

Making a good decision does not depend on having studies with confidence intervals that exclude the null. A best decision can be based on whatever information we have now, and indeed a decision will be made – after all, the decision to maintain the status quo is still a decision [20,38]. Hill offered his clearest condemnation of overemphasizing statistical significance testing, not when he discussed p-values, but when he concluded by saying: "All scientific work is incomplete – whether it be observational or experimental. All scientific work is liable to be upset or modified by advancing knowledge. That does not confer upon us a freedom to ignore the knowledge we already have, or to postpone the action that it appears to demand at a given time [1](p. 300)."

The pursuit of the low p-value (or confidence interval that excludes the null) leaves our society postponing apparently useful policy choices while we do more research to try to show what we already believe to be true. It also creates the incentive to use dubious methods (e.g., unstated multiple hypothesis testing, choosing models or transforming data to maximize the effect size [39]) in order to squeeze out significant results. Those same methods can be used by those who would prefer to make real causal relationships disappear below the p = .05 horizon. Making the best of the knowledge we have would reduce such temptations. If epidemiologists help empower policy makers to ban an easily-replaced chemical when we believe there is, say, a 50-50 chance that it is a health hazard (based on an honest assessment of all uncertainty), then the payoff for fiddling with the data to show the certainty is a bit higher or a bit lower would be eliminated.

This would release us from the trap of letting ignorance trump knowledge. Regulators often fail to act because we have not yet statistically "proven" an association between an exposure and a disease, even when there is enough evidence to strongly suspect a causal relationship. There is a growing movement to escape this mistake by making a similar mistake in the other direction: adopting precautionary principles, which typically call for restrictions until we have "proven" lack of causal association – a decision based on ignorance that merely reverses the default. If we can escape from the false dichotomy of "proven vs. not proven," facilitated by the nonexistant bright line implied by statistical hypothesis testing and by the notion that causality can be definitively inferred from a list of criteria, then we can make decisions based on what we do know rather than what we don't.

Conclusions

The uncritical repetition of Hill's "causal criteria" is probably counterproductive in promoting sophisticated understanding of causal inference. But a different list of considerations that can be found in his address is worthy of repeating:

• Statistical significance should not be mistaken for evidence of a substantial association.

• Association does not prove causation (other evidence must be considered).

• Precision should not be mistaken for validity (non-random errors exist).

• Evidence (or belief) that there is a causal relationship is not sufficient to suggest action should be taken.

• Uncertainty about whether there is a causal relationship (or even an association) is not sufficient to suggest action should not be taken.

These points may seem obvious when stated so bluntly, but causal inference and health policy decision making would benefit tremendously if they were considered more carefully and more often. The last point may be the most important unlearned lesson in health decision making.

In fairness to those who do not appreciate these points even today, it overinterprets Hill's short paper to claim that he clearly laid out these considerations, or that he was calling for modern decision analysis and uncertainty quantification. But the fundamental concepts were clearly there (and the overinterpretation is not as great as that required to derive a checklist of criteria for determining causation). Several generations of advancement in epidemiology and policy analysis provide much deeper exposition of his points. But Hill still offers timeless insightful analysis about how to interpret our observations. Strangely, these forgotten lessons, which are only slowly and grudgingly being appreciated in modern epidemiology, are hidden in plain sight, in what is possibly the best known paper in the field.

Endnotes

1. Interestingly, there are more extreme cases of a scholar's name being immortalized for something contrary to his beliefs. The "Coase Theorem" in economics, from one of the most cited article in the economics and legal literatures [6] (often identified as the most cited article in one of those fields or in their intersection), is usually invoked to make worldly claims that certain beneficial transactions will occur (which, among other things, reduce the need for regulation). But much of Coase's work (including that paper) focuses on how the circumstances required for those transactions to take place are absent in the real world.

2. Reporting confidence intervals provides more information about the estimated association of an exposure and outcome. For example, a large measured effect with a wide confidence interval and a small measured effect with a narrow confidence interval may have the same p-value, but the confidence intervals suggests that a large association is likely in the former case, but not the latter. This has implications for both scientific conclusions and decision making. However, the reporting of confidence intervals addresses only this limitation, not others described subsequently.

3. In effect, Hill claimed that the association was so strong that neither the random nor the systematic error could explain it. In doing so, he failed to heed his own observa-

tion that systematic errors might explain an association no matter how low the p-value, and invoked the strength of the statistical association to rule out the possibility it was caused by systematic error. More important, Hill made the mistake of overestimating his ability to intuitively assess complicated quantitative relationships. In Hill's defense, his remark predated the research, primarily from the 1970s and 1980s, that demonstrated that both lay people and experts have poor quantitative intuition (most of the key papers from that literature can be found in a few collected volumes [27-30]). Current researchers who argue that their intuition obviates the need for modern methods for quantifying uncertainty have no such excuse.

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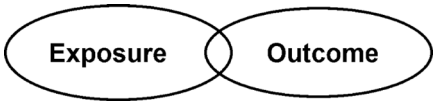
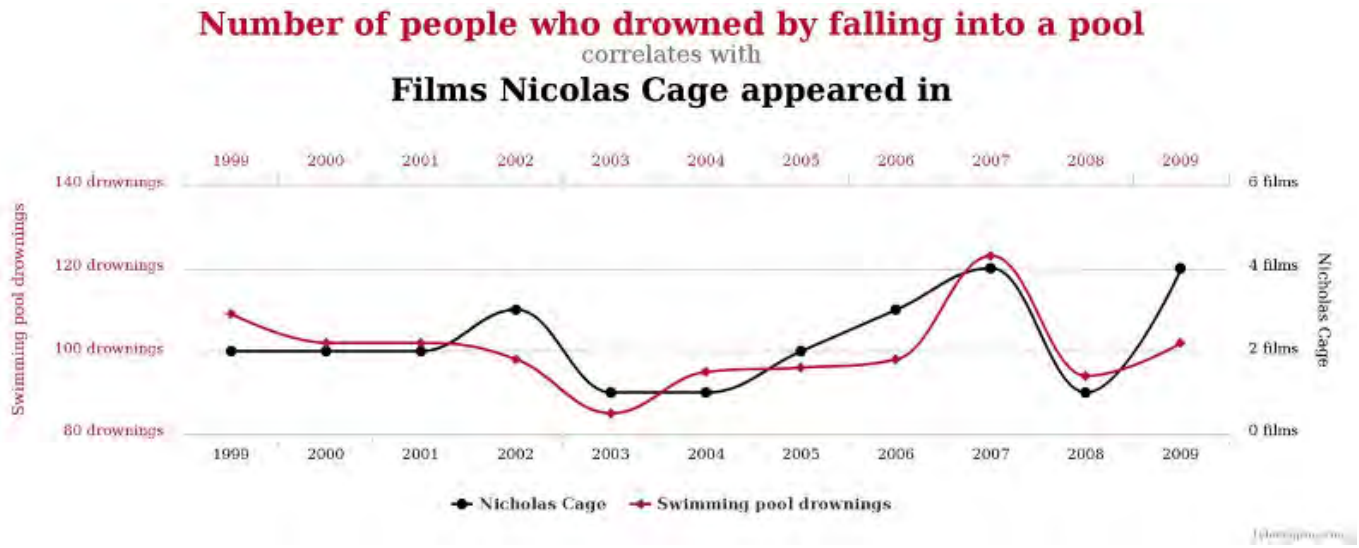
Association versus Causation

When considering the relationship between exposures and health outcomes, it is important to distinguish between association and causation. Epidemiologists ultimately want to be able to draw conclusions about causation, but most epidemiologic studies focus on establishing associations.

Association: Is a specified health outcome *more likely* in people with a particular "exposure"? Is there a link? Association is a statistical relationship between two variables.



Two variables may be associated without a causal relationship. For example, there is a statistical association between the number of people who drowned by falling into a pool and the number of films Nicolas Cage appeared in in a given year. However, there is obviously no causal relationship.



Jewish women have a higher risk of breast cancer, while Mormons have a lower risk. However, one's religion is not a cause of breast cancer. There are other explanations.

It has been convincingly demonstrated that people of lower socioeconomic status (SES) have a higher risk of lung cancer, i.e., there is a clear association, but does that mean that low SES is a cause of lung cancer? A more plausible explanation is that people of lower SES are more likely to smoke and to be chronically exposed to air pollution and that exposure of the respiratory tract to these contaminants causes mutations in bronchial cells that can eventually produce a cancer.

Risk Factor	Component Causes	Biological Effect	Health Outcome
Low SES (a social determinant)	Tobacco smoke, pollution	Mutations in respiratory cells	Lung cancer

Causation: Causation means that the exposure *produces* the effect. It can be the presence of an adverse exposure, e.g., increased risks from working in a coal mine, using illicit drugs, or breathing in second hand smoke. Causative factors can also be the absence of a preventive exposure, such as not wearing a seatbelt or not exercising. A cause must be associated with the outcome, but simply demonstrating an association is not enough. To conclude that lack of exercise is a cause of heart disease, one needs to review the body of evidence suggesting a causal relationship and also consider other criteria. For example,

- Does exposure to tobacco smoke and air pollution *precede* the occurrence of lung cancer?
- Is there a *strong association* between smoking and subsequent occurrence of lung cancer?
- Is it possible that having lung cancer causes one to smoke?

It is interesting to note that when lifelong smokers are told they have lung cancer or emphysema, many of them quit smoking. This makes it seem as if ex-smokers are more likely to die of emphysema or lung cancer than current smokers.

Meeting January 14 1965

The Environment and Disease: Association or Causation?

by Sir Austin Bradford Hill CBE DSC FRCP(hon) FRS
(*Professor Emeritus of Medical Statistics, University of London*)

Amongst the objects of this newly-founded Section of Occupational Medicine are firstly 'to provide a means, not readily afforded elsewhere, whereby physicians and surgeons with a special knowledge of the relationship between sickness and injury and conditions of work may discuss their problems, not only with each other, but also with colleagues in other fields, by holding joint meetings with other Sections of the Society'; and, secondly, 'to make available information about the physical, chemical and psychological hazards of occupation, and in particular about those that are rare or not easily recognized'.

At this first meeting of the Section and before, with however laudable intentions, we set about instructing our colleagues in other fields, it will be proper to consider a problem fundamental to our own. How in the first place do we detect these relationships between sickness, injury and conditions of work? How do we determine what are physical, chemical and psychological hazards of occupation, and in particular those that are rare and not easily recognized?

There are, of course, instances in which we can reasonably answer these questions from the general body of medical knowledge. A particular, and perhaps extreme, physical environment cannot fail to be harmful; a particular chemical is known to be toxic to man and therefore suspect on the factory floor. Sometimes, alternatively, we may be able to consider what *might* a particular environment do to man, and then see whether such consequences are indeed to be found. But more often than not we have no such guidance, no such means of proceeding; more often than not we are dependent upon our observation and enumeration of defined events for which we then seek antecedents. In other words we see that the event B is associated with the environmental feature A, that, to take a specific example, some form of respiratory illness is associated with a dust in the environment. In what circumstances can we pass from this observed *association* to a verdict of *causation*? Upon what basis should we proceed to do so?

President's Address

I have no wish, nor the skill, to embark upon a philosophical discussion of the meaning of 'causation'. The 'cause' of illness may be immediate and direct, it may be remote and indirect underlying the observed association. But with the aims of occupational, and almost synonymously preventive, medicine in mind the decisive question is whether the frequency of the undesirable event B will be influenced by a change in the environmental feature A. *How* such a change exerts that influence may call for a great deal of research. However, before deducing 'causation' and taking action we shall not invariably have to sit around awaiting the results of that research. The whole chain may have to be unravelled or a few links may suffice. It will depend upon circumstances.

Disregarding then any such problem in semantics we have this situation. Our observations reveal an association between two variables, perfectly clear-cut and beyond what we would care to attribute to the play of chance. What aspects of that association should we especially consider before deciding that the most likely interpretation of it is causation?

(1) *Strength.* First upon my list I would put the strength of the association. To take a very old example, by comparing the occupations of patients with scrotal cancer with the occupations of patients presenting with other diseases, Percival Pott could reach a correct conclusion because of the *enormous* increase of scrotal cancer in the chimney sweeps. 'Even as late as the second decade of the twentieth century', writes Richard Doll (1964), 'the mortality of chimney sweeps from scrotal cancer was some 200 times that of workers who were not specially exposed to tar or mineral oils and in the eighteenth century the relative difference is likely to have been much greater.'

To take a more modern and more general example upon which I have now reflected for over fifteen years, prospective inquiries into smoking have shown that the death rate from cancer of the lung in cigarette smokers is nine to ten times the rate in non-smokers and the rate in heavy cigarette smokers is twenty to thirty times

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as great. On the other hand the death rate from coronary thrombosis in smokers is no more than twice, possibly less, the death rate in non-smokers. Though there is good evidence to support causation it is surely much easier in this case to think of some features of life that may go hand-in-hand with smoking – features that might conceivably be the real underlying cause or, at the least, an important contributor, whether it be lack of exercise, nature of diet or other factors. But to explain the pronounced excess in cancer of the lung in any other environmental terms requires some feature of life so intimately linked with cigarette smoking and with the amount of smoking that such a feature should be easily detectable. If we cannot detect it or reasonably infer a specific one, then in such circumstances I think we are reasonably entitled to reject the vague contention of the armchair critic 'you can't prove it, there *may* be such a feature'.

Certainly in this situation I would reject the argument sometimes advanced that what matters is the absolute difference between the death rates of our various groups and not the ratio of one to other. That depends upon what we want to know. If we want to know how many extra deaths from cancer of the lung will take place through smoking (i.e. presuming causation), then obviously we must use the absolute differences between the death rates – 0·07 per 1,000 per year in non-smoking doctors, 0·57 in those smoking 1–14 cigarettes daily, 1·39 for 15–24 cigarettes daily and 2·27 for 25 or more daily. But it does not follow here, or in more specifically occupational problems, that this best measure of the effect upon mortality is also the best measure in relation to ætiology. In this respect the ratios of 8, 20 and 32 to 1 are far more informative. It does not, of course, follow that the differences revealed by ratios are of any practical importance. Maybe they are, maybe they are not; but that is another point altogether.

We may recall John Snow's classic analysis of the opening weeks of the cholera epidemic of 1854 (Snow 1855). The death rate that he recorded in the customers supplied with the grossly polluted water of the Southwark and Vauxhall Company was in truth quite low – 71 deaths in each 10,000 houses. What stands out vividly is the fact that the small rate is 14 times the figure of 5 deaths per 10,000 houses supplied with the sewage-free water of the rival Lambeth Company.

In thus putting emphasis upon the strength of an association we must, nevertheless, look at the obverse of the coin. We must not be too ready to dismiss a cause-and-effect hypothesis merely on the grounds that the observed association appears to be slight. There are many occasions in medicine when this is in truth so. Relatively few persons harbouring the meningococcus fall sick of meningococcal meningitis. Relatively few persons occupationally exposed to rat's urine contract Weil's disease.

(2) *Consistency:* Next on my list of features to be specially considered I would place the *consistency* of the observed association. Has it been repeatedly observed by different persons, in different places, circumstances and times?

This requirement may be of special importance for those rare hazards singled out in the Section's terms of reference. With many alert minds at work in industry today many an environmental association may be thrown up. Some of them on the customary tests of statistical significance will appear to be unlikely to be due to chance. Nevertheless whether chance is the explanation or whether a true hazard has been revealed may sometimes be answered only by a repetition of the circumstances and the observations.

Returning to my more general example, the Advisory Committee to the Surgeon-General of the United States Public Health Service found the association of smoking with cancer of the lung in 29 retrospective and 7 prospective inquiries (US Department of Health, Education & Welfare 1964). The lesson here is that broadly the same answer has been reached in quite a wide variety of situations and techniques. In other words we can justifiably infer that the association is not due to some constant error or fallacy that permeates every inquiry. And we have indeed to be on our guard against that.

Take, for instance, an example given by Heady (1958). Patients admitted to hospital for operation for peptic ulcer are questioned about recent domestic anxieties or crises that may have precipitated the acute illness. As controls, patients admitted for operation for a simple hernia are similarly quizzed. But, as Heady points out, the two groups may not be *in pari materia*. If your wife ran off with the lodger last week you still have to take your perforated ulcer to hospital without delay. But with a hernia you might prefer to stay at home for a while – to mourn (or celebrate) the event. No number of exact repetitions would remove or necessarily reveal that fallacy.

We have, therefore, the somewhat paradoxical position that the different results of a different inquiry certainly cannot be held to refute the

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original evidence; yet the same results from precisely the same form of inquiry will not invariably greatly strengthen the original evidence. I would myself put a good deal of weight upon similar results reached in quite different ways, e.g. prospectively and retrospectively.

Once again looking at the obverse of the coin there will be occasions when repetition is absent or impossible and yet we should not hesitate to draw conclusions. The experience of the nickel refiners of South Wales is an outstanding example. I quote from the Alfred Watson Memorial Lecture that I gave in 1962 to the Institute of Actuaries:

'The population at risk, workers and pensioners, numbered about one thousand. During the ten years 1929 to 1938, sixteen of them had died from cancer of the lung, eleven of them had died from cancer of the nasal sinuses. At the age specific death rates of England and Wales at that time, one might have anticipated one death from cancer of the lung (to compare with the 16), and a fraction of a death from cancer of the nose (to compare with the 11). In all other bodily sites cancer had appeared on the death certificate 11 times and one would have expected it to do so 10–11 times. There had been 67 deaths from all other causes of mortality and over the ten years' period 72 would have been expected at the national death rates. Finally division of the population at risk in relation to their jobs showed that the excess of cancer of the lung and nose had fallen wholly upon the workers employed in the chemical processes.

'More recently my colleague, Dr Richard Doll, has brought this story a stage further. In the nine years 1948 to 1956 there had been, he found, 48 deaths from cancer of the lung and 13 deaths from cancer of the nose. He assessed the numbers expected at normal rates of mortality as, respectively 10 and 0·1.

'In 1923, long before any special hazard had been recognized, certain changes in the refinery took place. No case of cancer of the nose has been observed in any man who first entered the works after that year, and in these men there has been no excess of cancer of the lung. In other words, the excess in both sites is uniquely a feature in men who entered the refinery in, roughly, the first 23 years of the present century.

'No causal agent of these neoplasms has been identified. Until recently no animal experimentation had given any clue or any support to this wholly statistical evidence. Yet I wonder if any of us would hesitate to accept it as proof of a grave industrial hazard?' (Hill 1962).

In relation to my present discussion I know of no parallel investigation. We have (or certainly had) to make up our minds on a unique event; and there is no difficulty in doing so.

(3) *Specificity:* One reason, needless to say, is the specificity of the association, the third characteristic which invariably we must consider. If, as here, the association is limited to specific workers and to particular sites and types of disease and there is no association between the work and other modes of dying, then clearly that is a strong argument in favour of causation.

We must not, however, over-emphasize the importance of the characteristic. Even in my present example there is a cause and effect relationship with two different sites of cancer – the lung and the nose. Milk as a carrier of infection and, in that sense, the cause of disease can produce such a disparate galaxy as scarlet fever, diphtheria, tuberculosis, undulant fever, sore throat, dysentery and typhoid fever. Before the discovery of the underlying factor, the bacterial origin of disease, harm would have been done by pushing too firmly the need for specificity as a necessary feature before convicting the dairy.

Coming to modern times the prospective investigations of smoking and cancer of the lung have been criticized for not showing specificity – in other words the death rate of smokers is higher than the death rate of non-smokers from many causes of death (though in fact the results of Doll & Hill, 1964, do not show that). But here surely one must return to my first characteristic, the strength of the association. If other causes of death are raised 10, 20 or even 50% in smokers whereas cancer of the lung is raised 900–1,000% we have specificity – a specificity in the magnitude of the association.

We must also keep in mind that diseases may have more than one cause. It has always been possible to acquire a cancer of the scrotum without sweeping chimneys or taking to mule-spinning in Lancashire. One-to-one relationships are not frequent. Indeed I believe that multi-causation is generally more likely than single causation though possibly if we knew all the answers we might get back to a single factor.

In short, if specificity exists we may be able to draw conclusions without hesitation; if it is not apparent, we are not thereby necessarily left sitting irresolutely on the fence.

(4) *Temporality:* My fourth characteristic is the temporal relationship of the association – which is the cart and which the horse? This is a question which might be particularly relevant with diseases of slow development. Does a particular diet lead to disease or do the early stages of the disease lead to those peculiar dietetic habits? Does a

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particular occupation or occupational environment promote infection by the tubercle bacillus or are the men and women who select that kind of work more liable to contract tuberculosis whatever the environment – or, indeed, have they already contracted it? This temporal problem may not arise often but it certainly needs to be remembered, particularly with selective factors at work in industry.

(5) *Biological gradient:* Fifthly, if the association is one which can reveal a biological gradient, or dose-response curve, then we should look most carefully for such evidence. For instance, the fact that the death rate from cancer of the lung rises linearly with the number of cigarettes smoked daily, adds a very great deal to the simpler evidence that cigarette smokers have a higher death rate than non-smokers. That comparison would be weakened, though not necessarily destroyed, if it depended upon, say, a much heavier death rate in light smokers and a lower rate in heavier smokers. We should then need to envisage some much more complex relationship to satisfy the cause-and-effect hypothesis. The clear dose-response curve admits of a simple explanation and obviously puts the case in a clearer light.

The same would clearly be true of an alleged dust hazard in industry. The dustier the environment the greater the incidence of disease we would expect to see. Often the difficulty is to secure some satisfactory quantitative measure of the environment which will permit us to explore this dose-response. But we should invariably seek it.

(6) *Plausibility:* It will be helpful if the causation we suspect is biologically plausible. But this is a feature I am convinced we cannot demand. What is biologically plausible depends upon the biological knowledge of the day.

To quote again from my Alfred Watson Memorial Lecture (Hill 1962), there was

'. . . no biological knowledge to support (or to refute) Pott's observation in the 18th century of the excess of cancer in chimney sweeps. It was lack of biological knowledge in the 19th that led a prize essayist writing on the value and the fallacy of statistics to conclude, amongst other "absurd" associations, that "it could be no more ridiculous for the stranger who passed the night in the steerage of an emigrant ship to ascribe the typhus, which he there contracted, to the vermin with which bodies of the sick might be infected". And coming to nearer times, in the 20th century there was no biological knowledge to support the evidence against rubella.'

In short, the association we observe may be one new to science or medicine and we must not dismiss it too light-heartedly as just too odd. As Sherlock Holmes advised Dr Watson, 'when you have eliminated the impossible, whatever remains, *however improbable*, must be the truth.'

(7) *Coherence:* On the other hand the cause-and-effect interpretation of our data should not seriously conflict with the generally known facts of the natural history and biology of the disease – in the expression of the Advisory Committee to the Surgeon-General it should have coherence.

Thus in the discussion of lung cancer the Committee finds its association with cigarette smoking coherent with the temporal rise that has taken place in the two variables over the last generation and with the sex difference in mortality – features that might well apply in an occupational problem. The known urban/rural ratio of lung cancer mortality does not detract from coherence, nor the restriction of the effect to the lung.

Personally, I regard as greatly contributing to coherence the histopathological evidence from the bronchial epithelium of smokers and the isolation from cigarette smoke of factors carcinogenic for the skin of laboratory animals. Nevertheless, while such laboratory evidence can enormously strengthen the hypothesis and, indeed, may determine the actual causative agent, the lack of such evidence cannot nullify the epidemiological observations in man. Arsenic can undoubtedly cause cancer of the skin in man but it has never been possible to demonstrate such an effect on any other animal. In a wider field John Snow's epidemiological observations on the conveyance of cholera by the water from the Broad Street pump would have been put almost beyond dispute if Robert Koch had been then around to isolate the vibrio from the baby's nappies, the well itself and the gentleman in delicate health from Brighton. Yet the fact that Koch's work was to be awaited another thirty years did not really weaken the epidemiological case though it made it more difficult to establish against the criticisms of the day – both just and unjust.

(8) *Experiment:* Occasionally it is possible to appeal to experimental, or semi-experimental, evidence. For example, because of an observed association some preventive action is taken. Does it in fact prevent? The dust in the workshop is reduced, lubricating oils are changed, persons stop smoking cigarettes. Is the frequency of the associated events affected? Here the strongest

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support for the causation hypothesis may be revealed.

(9) *Analogy:* In some circumstances it would be fair to judge by analogy. With the effects of thalidomide and rubella before us we would surely be ready to accept slighter but similar evidence with another drug or another viral disease in pregnancy.

Here then are nine different viewpoints from all of which we should study association before we cry causation. What I do not believe – and this has been suggested – is that we can usefully lay down some hard-and-fast rules of evidence that *must* be obeyed before we accept cause and effect. None of my nine viewpoints can bring indisputable evidence for or against the cause-and-effect hypothesis and none can be required as a *sine qua non*. What they can do, with greater or less strength, is to help us to make up our minds on the fundamental question – is there any other way of explaining the set of facts before us, is there any other answer equally, or more, likely than cause and effect?

Tests of Significance

No formal tests of significance can answer those questions. Such tests can, and should, remind us of the effects that the play of chance can create, and they will instruct us in the likely magnitude of those effects. Beyond that they contribute nothing to the 'proof' of our hypothesis.

Nearly forty years ago, amongst the studies of occupational health that I made for the Industrial Health Research Board of the Medical Research Council was one that concerned the workers in the cotton-spinning mills of Lancashire (Hill 1930). The question that I had to answer, by the use of the National Health Insurance records of that time, was this: Do the workers in the card-room of the spinning mill, who tend the machines that clean the raw cotton, have a sickness experience in any way different from that of other operatives in the same mills who are relatively unexposed to the dust and fibre that were features of the cardroom? The answer was an unqualified 'Yes'. From age 30 to age 60 the cardroom workers suffered over three times as much from respiratory causes of illness whereas from non-respiratory causes their experience was not different from that of the other workers. This pronounced difference with the respiratory causes was derived not from abnormally long periods of sickness but rather from an excessive number of repeated absences from work of the cardroom workers.

All this has rightly passed into the limbo of forgotten things. What interests me today is this: My results were set out for men and women separately and for half a dozen age groups in 36 tables. So there were plenty of sums. Yet I cannot find that anywhere I thought it necessary to use a test of significance. The evidence was so clear-cut, the differences between the groups were mainly so large, the contrast between respiratory and non-respiratory causes of illness so specific, that no formal tests could really contribute anything of value to the argument. So why use them?

Would we think or act that way today? I rather doubt it. Between the two world wars there was a strong case for emphasizing to the clinician and other research workers the importance of not overlooking the effects of the play of chance upon their data. Perhaps too often generalities were based upon two men and a laboratory dog while the treatment of choice was deduced from a difference between two bedfuls of patients and might easily have no true meaning. It was therefore a useful corrective for statisticians to stress, and to teach the need for, tests of significance merely to serve as guides to caution before drawing a conclusion, before inflating the particular to the general.

I wonder whether the pendulum has not swung too far – not only with the attentive pupils but even with the statisticians themselves. To decline to draw conclusions without standard errors can surely be just as silly? Fortunately I believe we have not yet gone so far as our friends in the USA where, I am told, some editors of journals will return an article because tests of significance have not been applied. Yet there are innumerable situations in which they are totally unnecessary – because the difference is grotesquely obvious, because it is negligible, or because, whether it be formally significant or not, it is too small to be of any practical importance. What is worse the glitter of the t table diverts attention from the inadequacies of the fare. Only a tithe, and an unknown tithe, of the factory personnel volunteer for some procedure or interview, 20% of patients treated in some particular way are lost to sight, 30% of a randomly-drawn sample are never contacted. The sample may, indeed, be akin to that of the man who, according to Swift, 'had a mind to sell his house and carried a piece of brick in his pocket, which he showed as a pattern to encourage purchasers'. The writer, the editor and the reader are unmoved. The magic formulæ are there.

Of course I exaggerate. Yet too often I suspect we waste a deal of time, we grasp the shadow and

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lose the substance, we weaken our capacity to interpret data and to take reasonable decisions whatever the value of P. And far too often we deduce 'no difference' from 'no significant difference'. Like fire, the χ^2 test is an excellent servant and a bad master.

The Case for Action

Finally, in passing from association to causation I believe in 'real life' we shall have to consider what flows from that decision. On scientific grounds we should do no such thing. The evidence is there to be judged on its merits and the judgment (in that sense) should be utterly independent of what hangs upon it – or who hangs because of it. But in another and more practical sense we may surely ask what is involved in our decision. In occupational medicine our object is usually to take action. If this be operative cause and that be deleterious effect, then we shall wish to intervene to abolish or reduce death or disease.

While that is a commendable ambition it almost inevitably leads us to introduce differential standards before we convict. Thus on relatively slight evidence we might decide to restrict the use of a drug for early-morning sickness in pregnant women. If we are wrong in deducing causation from association no great harm will be done. The good lady and the pharmaceutical industry will doubtless survive.

On fair evidence we might take action on what appears to be an occupational hazard, e.g. we might change from a probably carcinogenic oil to a non-carcinogenic oil in a limited environment and without too much injustice if we are wrong. But we should need very strong evidence before we made people burn a fuel in their homes that they do not like or stop smoking the cigarettes and eating the fats and sugar that they do like. In asking for very strong evidence I would, however, repeat emphatically that this does not imply crossing every 't', and swords with every critic, before we act.

All scientific work is incomplete – whether it be observational or experimental. All scientific work is liable to be upset or modified by advancing knowledge. That does not confer upon us a freedom to ignore the knowledge we already have, or to postpone the action that it appears to demand at a given time.

Who knows, asked Robert Browning, but the world may end tonight? True, but on available evidence most of us make ready to commute on the 8.30 next day.

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Causal criteria and counterfactuals; nothing more (or less) than scientific common sense

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Abstract

Two persistent myths in epidemiology are that we can use a list of "causal criteria" to provide an algorithmic approach to inferring causation and that a modern "counterfactual model" can assist in the same endeavor. We argue that these are neither criteria nor a model, but that lists of causal *considerations* and formalizations of the counterfactual *definition* of causation are nevertheless useful tools for promoting scientific thinking. They set us on the path to the common sense of scientific inquiry, including testing hypotheses (really putting them to a test, not just calculating simplistic statistics), responding to the Duhem-Quine problem, and avoiding many common errors. Austin Bradford Hill's famous considerations are thus both over-interpreted by those who would use them as criteria and under-appreciated by those who dismiss them as flawed. Similarly, formalizations of counterfactuals are under-appreciated as lessons in basic scientific thinking. The need for lessons in scientific common sense is great in epidemiology, which is taught largely as an engineering discipline and practiced largely as technical tasks, making attention to core principles of scientific inquiry woefully rare.

Background

An interesting persistent myth in epidemiology is that Austin Bradford Hill, the committee preparing the original United States Surgeon General's report on smoking, Mervyn Susser, or other authors have provided us a set of criteria for identifying cause-effect relations. This notion is remarkably robust given that these lists clearly do not meet usual definitions of criteria, which imply some sort of rule or test. Even when authors who invoke the "Bradford Hill criteria" yield to the scolding of various authors (including us [1]), and dutifully use Hill's word – "considerations" – rather than "criteria", they still seem to be in search of the elusive criteria.

A mythology to come into vogue more recently is that there is some "counterfactual model" that can help us to better recognize and understand causation in epidemiology. Just as causal criteria are not criteria, formal presentation of counterfactuals does not meet the definition of model, which can be thought of as a schematic or representation that captures part of the essence of a more complicated system in a way that leads to emergent properties.

In these pages, Höfler [2] took on the goal of trying to better understand Hill's considerations [3] by invoking a counterfactual model. As might be surmised from the above, we do not consider this to be a promising pursuit. We argue that causal considerations and the counterfactual conceptualization are both useful, but not in ways

that support an analysis like Höfler's. Nevertheless, Höfler does provide what is possibly the best one-sentence assessment of the concept of causal criteria, and nicely (though perhaps inadvertently) helps argue the case that causal considerations and counterfactuals are, more than anything else, guideposts on the road to common sense.

Analysis

Not criteria

"Criteria" is sometimes defined overly broadly to include anything you might want to think about when making a decision (that is, as a synonym for "considerations"). But most definitions include a reference to a test, basis for judgment, or condition (and anyone trying to "apply" a set of criteria to make a determination must have such a definition in mind). Clearly, causal considerations do not meet these tighter definitions of criteria. There is no method for determining whether or how well each consideration is met (for example, researchers seem able to concoct some biological story to explain any association in their data; how absurd does it have to be before there is no biological plausibility?), let alone how we would aggregate any such scores for individual considerations into an ultimate decision about cause and effect. This tends to be obscured when commentators' main criticisms are that the proposed conditions are neither necessary nor sufficient, overlooking the salient fact that they are not actually well-defined conditions (and thus can be neither necessary nor sufficient, nor can they be non-necessary or non-sufficient).

With that in mind, it is instructive to consider the implications of authors providing worldly examples of causal conditions being met as evidence for the conditions being either informative or misleading, or of attempts like Höfler's to improve the application of criteria. Those authors clearly have in mind some standard for judging whether a condition is met and whether a relationship is causal. The latter assessment must be independent of the criteria (since it is meant to validate the usefulness of the criteria) and, most importantly, is presumably meant to be something most readers would agree upon. This suggests a presumption of shared common sense. Poole [4,5], inspired by Thomas Kuhn [6,7], suggests that rather than criteria, causal considerations are "values" which different scientists can hold to different degrees. Values are bases for making worldly conclusions, but tend to lack scoring systems and other elements of algorithms, and any claims based on them are subject to interpretation and scrutiny. Indeed, the empirical and experimental evidence Poole cites makes clear that epidemiologists' interpretations of the considerations vary substantially [8-14]. But debates among scientists about which values are legitimate suggest a feeling that there should be some shared scientific common sense, rather than persistent heterogeneity of values.

Neither Hill's nor any other list can codify common sense, but it can introduce some of it and thereby provide a starting point. This is quite useful since common sense is disturbingly uncommon and thus in need of whatever help it can get. For researchers who fail to consider, say, consistency across studies or coherence with previous knowledge in their assessment of causation, and proudly declare that "our research is the first to show that exposure E causes disease D, contrary to numerous previous findings," Hill's lesson in common sense has immediate value. Attending to Hill's or others' causal considerations would encourage anyone writing, "our research is the first to show X...," to follow it – as they almost always should – with, "...so X is probably not true."

Of course, common sense is most useful in simple cases, while modeling (e.g., drawing diagrams of causal pathways) becomes more critical as a system becomes more complex. Höfler observes that "the heuristic value of Hill's considerations converges to zero as the complexity of a causal system and the uncertainty about the true causal system increase" [2]. This may be the definitive observation about causal criteria/considerations. To venture a simpler paraphrase, lists of causal considerations are pretty good rules of thumb when the system being assessed is simple, but in cases where an assessment of causation demands more than common sense, these lists are not going to be terribly useful. Höfler goes on to try to improve on Hill's list to make it more useful in complicated cases, but we think he was right the first time: in a complicated system the list can only serve as a tool for teaching scientific common sense, and no matter how we try to dress it up, it cannot serve as a checklist, algorithm, or method.

Not a model

The use of the term "model" in the previous paragraph illustrates its meaning. Causal diagrams take as inputs some of the known or postulated elements of a worldly system of causes and effects and schematize them in a way that new knowledge (i.e., beyond the inputs themselves) can be extracted. In this sense, a small three-dimensional scale version of an airplane is a model (because, for example, we can put it in a wind tunnel and learn something about the actual airplane that we did not know when we made the model) but a photograph of the plane is not a model (at least not in any obvious way). Neither is the phrase "heavier-than-air, fixed-wing, self-propelled flying vehicles" a model. The phrase is informative about airplanes, but in a different way from a model: it is the definition of airplanes. We need to have that phrase (or some variation) in mind before it even makes sense to talk

about airplanes, let alone model them. It might be useful to refer back to the definition if, during an assessment of airplanes, we somehow lost touch with the class of things we are talking about. But the definition is not a model; it does not offer a way to extract any information that is not merely an input into it, such as assessing how airworthy a particular airplane is. Indeed, it cannot in itself help us determine if a particular object really makes the cut (e.g., that it can really fly).

In that spirit, what many authors, including Höfler, mistakenly call the "counterfactual model of causation" can easily be seen to be a definition, not a model. There is an extensive philosophical literature on what the verb "cause" means (including when it is implicit in many other verbs or phrases such as "increases", "leads to", and "protects against" [15]). These discussions include alternative definitions as well as arguments that the word actually has no definitional teeth. But in the everyday practical world of epidemiology (a field we define broadly to include empirical and experimental research on diseases and health-related exposures with people as the unit of analysis), we would venture to say that most everyone who uses causal language is implicitly invoking the counterfactual definition, "but for E, D will not occur or would not have occurred, but given E it will/would have" (described in more detail and with more symbolic logic by Höfler and many other authors; see in particular Maldonado and Greenland's "Estimating Causal Effects"[16]). We cannot think of any use of the word "cause" in epidemiology (in the research and its policy implications, excluding purely philosophical discussions) where the author seemed to have something else in mind.

This does not mean that careful attention to the definition is worthless. Maldonado, a leading proponent and teacher in epidemiology of the formal counterfactual definition and its implications (and who refers to the "counterfactual approach", "concept", or "definition", but not "model"), has pointed out that it aids us in, among other things, specifying epidemiologic questions, assessing which statistics are genuine measures of effect, designing studies, and defining confounding. Much of this, however, is arguably scientific common sense (see further discussion below), not of the "values" sort, but in the form of first- or second-order logical inferences that scientists should intuitively grasp. But, again, since common sense may be woefully uncommon, the formalizations by Maldonado and others are valuable.

Invoking counterfactuals in pursuit of better causal criteria

We thus agree with Höfler's assessment that Hill probably had a counterfactual concept – *definition*, not model – of causation in mind (consciously or subconsciously) when he gave his famous (and under-appreciated [1]) talk [3], not merely because of some specific phrase he used but because it is difficult to imagine anything else he could have had in mind. Though Höfler argues that "counterfactual causality [presumably meaning the counterfactual definition of causality] ... only became standard in epidemiology from the 1980s" [2], it seems very unlikely that epidemiologists (or economists or statisticians, for those who prefer those characterizations of Hill) had some other definition in mind before that. Like Newton "discovering" gravity, those who formalized the definition of causation in philosophy, mathematical statistics, and applied sciences did so in a context in which most people already grasped the basic idea and made use of it (to make scientific inferences or to keep from floating away into space).

With the counterfactual concept providing merely the definition, one that Hill shared with most of us, it seems unlikely that it can teach us much new about Hill's list. Indeed, it does not appear that Höfler finds any teeth in the notion of counterfactuals.

Höfler's analysis begins with the strength of association condition, a particularly good heuristic when a system is simple (e.g., a large, well-designed randomized trial with results that are easily measured soon after the intervention). But strength of association is considerably less definitive when confounding and other errors add complexity to our assessment. Höfler addresses the uncertainty that results from study errors, asking "Would the interval estimate that properly accounts for not only random, but also systematic error...allow for the desired conclusion...?" adding, "high uncertainty about bias parameters requires larger associations than modest uncertainty does." That is, whether or not an association is strong is a matter of context.

There are analytic methods being developed to put some numbers to that context, and we appreciate and encourage the attention to quantification of epidemiologic uncertainty from errors other than random sampling, a line of thinking in epidemiology that one of us helped to launch [17] (see endnote 1). But despite the fact that this line of thinking sprang from Maldonado's work on causal contrasts (a line of thinking he traces proximately to Greenland and Robins [19], and which also traces to Rubin, Neyman, Hume, and other thinkers) we have to say that Höfler's assessment seems to have nothing to do with counterfactuals. It primarily supports his thesis that complicated systems defy the simple rules of thumb. This conforms to what we have argued previously: uncertainty about input assumptions (e.g., the assumptions that measurement is accurate and confounding is controlled for) is almost always ignored in epidemiologic results, and people (including experts) have been shown to be

quite bad at quantifying the possible magnitude of error without mathematical aids [17,18,20,21]. Höfler tries to improve upon the simplest statement of the strength of association consideration, but provides nothing that is any more operationalizable, leaving us again with values or common sense.

Höfler structures his analysis around "what if" questions, calling them counterfactuals, but this gets no apparent traction from formally representing the counterfactual definition or pursuing its implications. For example, after observing that the consistency criterion suffers because different studies of different populations are expected to produce inconsistent results, Höfler asks questions including, "If the causal effect varied across the studies," (presumably actually meaning if it varied across the different study populations, exposure definitions, etc. that are implicitly defined by the studies) "would one expect to observe different associations...?" This is a useful lesson on consistency, replacing the hobgoblin of foolish consistency with systematic prediction of inconsistency. This is used when, for example, authors find it reassuring that the association with an exposure is stronger for histologically-confirmed cancers than it is for an alternative (presumably noisier) definition of disease status. Since we would expect to see a stronger association (more likely than not) when there is less (independent, non-differential) measurement error, this inconsistency could make us more comfortable with a causal conclusion. However, the role of counterfactuals in this lesson, beyond the implicit definition of causation, is unclear.

It appears that any value in Höfler's analysis lies not in counterfactuals, but in *hypotheticals* – that is, *ex ante* hypotheses about what data would show if a certain assumption were true. Perhaps this puts a finer point on "common sense," replacing it with the systematic scientific thinking that epidemiology needs much more than it needs improved causal checklists. Our example, that different disease definitions should result in inconsistent associations (in a predictable way), introduces a testable hypothesis. Höfler presents another under the specificity criterion, borrowing the example [22] that wearing helmets, if it reduces injury rather than just being a proxy for an unmeasurable tendency to act more carefully, should result in reduced injuries of the head, but not other body parts. Both of these examples are useful and, though immediately compelling when presented, may be a step beyond mere common sense. There is clearly value in teaching health researchers to think more about proposing and testing hypotheses (in the genuine sense discussed below). Conversations about evidential clues (e.g., lists of causal considerations) provide one good starting point for teaching such lessons. Indeed, there is every reason to believe that this was what Hill was trying to do when he gave his talk.

Problems result when people mistakenly treat Hill's lessons as being from the wrong branch of philosophy, interpreting them as rules of logical rather than worldly philosophy of science and the ethics of decision making [1]. Höfler (quoting Rothman and Greenland [[23], p.27]) notes that one condition – that cause must precede effect – is "the only *sine qua non* for a counterfactual effect" (see endnote 2). Although temporal ordering is a necessary condition according to the physics we understand, or even simple semantics (the condition follows directly from some phrasings of the definition of cause), this does not make this consideration any more or less useful than others as a lesson in common sense. Lessons such as, "if a measured upward trend in cancer rates leads (rather than lags) the measured increase in the exposure that you think is causing it, you are probably wrong about your causal conclusion," are not fundamentally different from other common sense applications of Hill's considerations.

The need for lessons in common sense

Why do health researchers, seemingly much more than those in other fields, cling to rules for assessing causation to the point that we have several such lists as well as a secondary literature that tries to assess and improve the rules? Why, as suggested by Kaufman and Poole [5], did Susser [24] provide five strategies for assessing causation – strategies for testing hypotheses alongside his list of causal criteria – but respond to greater interest in the criteria list by subsequently focusing on the list and de-emphasizing the other strategies? Part of the answer may lie in the emphasis on observational data (since well-designed interventions provide simpler support for causal claims, at least for some types of inquiry). However, this cannot be the whole story, since physics and biology (to say nothing of economics) quite often rely on observation alone.

Probably more importantly, the desire to find answers to countless different policy, social science, and biological questions creates the desire to study something once (in a particular population, at a particular time, with particular variable definitions), declare an answer, and move on. This does not provide much opportunity to actually test hypotheses. It encourages health researchers to conduct simplistic statistical calculations that are described in the language of hypothesis testing, and mistake this for actually testing a worldly hypothesis. It discourages genuine hypothesis testing, along the lines of, "If we have observed a true causal relationship, then we would also expect to see.... Let's do more research to check that before reporting our result." We would certainly expect such testing from another science before it declared, say, the discovery of cold fusion or that unfettered free markets make people's

lives better (bad examples, perhaps – call them exceptions that emphasize the value of the rule).

Epidemiology sees few studies designed to chip away the ambiguities resulting from the Duhem-Quine problem (which, roughly speaking, is the quandary that any study used to test a particular claim is simultaneously testing many ancillary hypotheses about the study methodology – e.g., that the right measures were used, the instruments do what they are supposed to – and thus we cannot be sure the observed result informs the causal hypothesis of interest). Studies are seldom repeated with improved (or even different) instruments (see endnote 3). Validation studies are occasionally conducted, quite often finding substantial measurement error, but the results are almost never incorporated into the primary analysis. Even easy analyses that require no further fieldwork, such as assessing whether an effect estimate is highly dependent on the particular functional form used in the quantitative analysis (i.e., statistical model assumptions, cutpoints for categorizing variables, etc.) are rarely reported.

Similarly, new studies on a topic almost never actually replicate a result, failing to take the simple step of using a previously defined model on a different dataset. Instead they use a new *ad hoc* model, ensuring that too many things vary at once for us to be able to distinguish our result of interest from the ancillary hypotheses. (Epidemiologists may find this point most familiar in the context of meta-analysis, where careful researchers often discover that there are many more dimensions of variation among study methods than there are studies.) Claims of causation in this context are rather strained, whatever models, criteria, or equations we might have.

What is worse is that there is not just negligence about doing good science, but actual attempts to subvert it. Not only is there no attempt to conduct and report alternate analyses that test the robustness of a statistical model and use the findings of such tests to address uncertainty, but in many cases, many statistical calculations are performed and the one reported is chosen *because* it is an outlier (i.e., because it shows a dramatic result), making it most likely to be an artifact of false ancillary hypotheses about the model [25]. Thus, not only do researchers fail to further test the causal conclusions they draw based on their data, but their causal conclusions are often not even supported by their data (since most calculations using the data would produce less extreme results than the ones reported). This approach violates common-sense norms of scientific inquiry, including Hill's often-overlooked preamble consideration, that the data must show an association in the first place. Unfortunately, this subversion is not terribly surprising when the desire to get an interesting result is not tempered by concern about replicablility and consistency (there is very little chance anyone will ever attempt to actually replicate a result, and health researchers show an unfortunate tendency to cite an outlier result as evidence of an association, regardless of how many other studies found a null association), or by real scientific training that imparts an ethic about what constitutes good science.

The desire to substitute what is ostensibly a checklist of criteria for real scientific analysis and thinking seems to reflect the practice of health science rather than the nature of epidemiologic data. Just as most health science ethics classes offer legalistic checklists, rather than serious analysis of ethics, most epidemiology pedagogy offers a set of tools, without much scientific thinking. There is nothing inherently wrong with training people to be engineers – skilled users of complicated tools they can adapt to specific practical applications. The field of epidemiology was largely created by members of one field of engineering, physicians (who, incidentally, constituted most of Hill's original audience, a telling bit of context that is usually ignored), with sage advice from various sciences (Hill's approach reflects his background as an economist).

Epidemiologic training is almost always designed to create engineers, practitioners who produce tangible results, but who devote little attention to questions about the nature of inquiry or scientific truth. Moreover, health science practice is dominated by those who lack even adequate skills in epidemiologic engineering; they tend toward rote application of particular techniques and use of off-the-shelf software they do not really understand – a pattern that describes technicians, not engineers or scientists. One might be tempted to counter that most practitioners of every science spend most of their time carrying out technical tasks. But the education and expectations of scientists in most fields include fully understanding the models and methods they use and trying to advance the methods in pursuit of inquiry; those who mechanically operate conceptual or physical tools they cannot explain and would not have been able to create from scratch are not generally called "doctor" and do not dominate the scientific output of other fields. This is particularly true in sciences that are as immature as modern health research (see endnote 4).

In this context, health "science" tends to avoid and even disdain scientific thinking: There is little interest in rigorously challenging conclusions before expressing comfort with them. Initiating vigorous learned debate or suggesting that researchers should be required to defend their claims against criticism is frequently considered impolite or even hostile. Pursuit of better methods of research and analysis, despite how terribly primitive our methods are, is considered an esoteric sideline rather than the lifeblood

of the science. Results of published studies are cited as if they were definitive, without adequate regard to the quality of the research, even when there is clear reason for doubt. Methods sections in research reports do not provide even remotely sufficient detail to understand what was done. Datasets are seldom re-analyzed, no matter how important the implications. And on top of these problems (or perhaps because of them), the cursory peer-review process is treated as if it – rather than a crucible of further study and debate – determines the truth of a claim.

Epidemiology education is seldom designed to produce scientists. In our experience, if two professors present conflicting views on proper methodology, students typically react with discomfort, or even hostility, insisting that someone just tell them what is right so they can use it and move on. From what we have seen, most training in epidemiology indulges (or even helps create) this mindset, catering to students who are clearly budding technicians, not scientists. Students are usually taught to use computational black-boxes and describe the results with rote language. Some of them want to be scientists, and try to engage in scientific analysis and inquiry, but being taught (or even forced) to conform to the dominant modes of practice makes that difficult. A student who masters a typical program in epidemiology will be a competent engineer, but will have learned little about the nature of scientific inquiry.

To be sure, engineers could be considered the bedrock of modernity and technicians undoubtedly produce more total day-to-day benefits than scientists, so this is not a pronouncement about comparative worth. But it does explain why scientific thinking needs a boost in the field. We would be surprised if even 1/1000th of the person-time spent doing epidemiology is devoted to critical analysis.

Conclusion

It is in this context, a field of scientific inquiry that is dominated by non-scientists, that lessons in scientific common sense have immense value. Four years before "Estimating Causal Effects" was published, Maldonado presented a seminar on the usefulness of formalizing counterfactuals, and following it one of us (CVP), new to epidemiology at the time, asked, "what part of that was I not supposed to already know?" In retrospect, the question clearly missed the point: Like Hill's contemplations, the formalization of counterfactuals is not a new discovery or even a new lesson, but rather an articulation of a concept that deserves more attention (or basic awareness) than it gets in health research. Indeed, we emphasized the need for further analysis of what is "known" in the field (in the sense of having been said some time, in some way), but seem to be remembered far too infrequently, as a major reason for starting a new journal [26,27]. As every teacher knows, spending time contemplating previous lessons is usually a lot more valuable than introducing a novel idea every minute of every lecture.

Attention to a formal definition of causation and to a list of clues that might help us draw conclusions about causation can be valuable. Such attention can help promote the active thinking that leads to scientific common sense. So long as the message is interpreted as the need to contemplate and investigate before drawing scientific conclusions, these lessons are valuable. But when they degenerate into black-box algorithms, this enables health researchers to avoid the intellectual work of being scientists.

Endnote 1

We find it unfortunate that Höfler used the term "Monte Carlo sensitivity analysis," to describe some uncertainty quantification methods. Phillips has pointed out that this is a misnomer since those methods differ fundamentally from sensitivity analysis and "Monte Carlo" confuses the calculation tool with the analysis [18].

Endnote 2

It is worth mentioning that the temporality condition is also a perfect fit for counterfactual-avoiding definitions of causation such as "predictable patterns of one event following another", suggesting again that nothing is learned about causal considerations by invoking counterfactuals.

Endnote 3

Ironically, as we were writing this paper, one of us attended a workshop on getting health research grants from the Canadian government; part of the advice was that the exposure-disease relationship being studied needs to be novel. The message was that checking the robustness of previous results was such a low priority that it would not attract this funding.

Endnote 4

To add concreteness to the point about conceptual machinery, consider how many of those who are considered scientists in epidemiology ever learned how to calculate the statistics they report without depending on a black-box software package or, for that matter, how many can even define confounding, let alone explain why their mathematical model was the best choice or calculate the impact of measurement error. In a science that is profoundly still under development, we would expect that scientists would be educated and conversant in the entire process of inquiry so that they could contribute to the development. Epidemiology is clearly immature and under development: most epidemiologic research in history has been done within the lifetimes, often even the

professional lifetimes, of current researchers, and the list of known glaring failures of the methods is long.

Competing interests

The authors have previously written on related topics and have an incentive to support their previously published points of view. Their views are influenced by a high level of frustration with current scientific standards in health research. CVP was trained largely as an economist, and his praise for Hill somewhat reflects a shared disciplinary outlook.

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Risks, Rates and Odds: What's the Difference and Why Does It Matter?

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"The little things are infinitely the most important."—Sherlock Holmes, *A Case of Identity*, 1892

Clinicians, as consumers of clinical research, seek to understand the association between treatment and outcome in providing the best care for their patients. Measures of association frequently encountered include risks, rates and odds, and their relative terms of risk ratios, rate ratios and odds ratios. Too often, these terms are used interchangeably, yet they all have important distinctions.

Definitions

Let's begin by defining the terms and then proceed to explore what other information we can obtain from these measures of association.

Risk

Risk is defined as the number of new cases that occur during a specified time period in a population at risk of becoming a case (the study population). Because risk includes only *new* cases, individuals must be free from the condition at the start of the time period. This is also referred to as the absolute risk.

An example would be the risk of C5 palsy within 1 week following a laminoplasty for cervical myelopathy. To calculate, all patients must be free of C5 palsy before surgery, and therefore, "at risk" of having a C5 palsy after surgery (denominator). The number of new cases becomes the numerator.

Risk ranges from 0 to 1, and in the spine literature, risk is often expressed as a percent. For example, one might read that C5 palsy occurred in 15.7% of patients (16/102) within 1 week following laminoplasty for cervical myelopathy.

Use risk when studying the effect of an intervention or risk factor when the follow-up period is the same for all participants.

Rate

Rate is defined as the number of new cases that occur per the total amount of time a person is at risk of becoming a case. It differs from risk in that it accounts for the sum total of time that study members are at risk of developing the outcome of interest. Rate ranges from 0 to ∞, and is expressed as cases per person-time.

For example, in Figure 1 below we have a study trying to determine the frequency of revision surgery in 10 patients. The investigators have 3-year follow-up. Note that one died before the end of the follow-up. The *risk* of revision surgery over 3 years is 44% (4/9, 4 cases out of 9 possible, excluding the person who died). The *rate* of revision surgery is 17.8 per 100 person-years. This is calculated by dividing the 4 cases by the sum of the time each patient has not had a revision and converting to 100. Patient 1 contributed 0.5 years; patients 2, 3, 6, 8, and 10 contributed 3 years each; patient 4 contributed 2 years; patient 5, 2.5 years; patient 7, 1year; and patient 9, 1.5 years before dying. The rate of revision in our example is 4/22.5 person-years or 17.8 per 100 person-years.

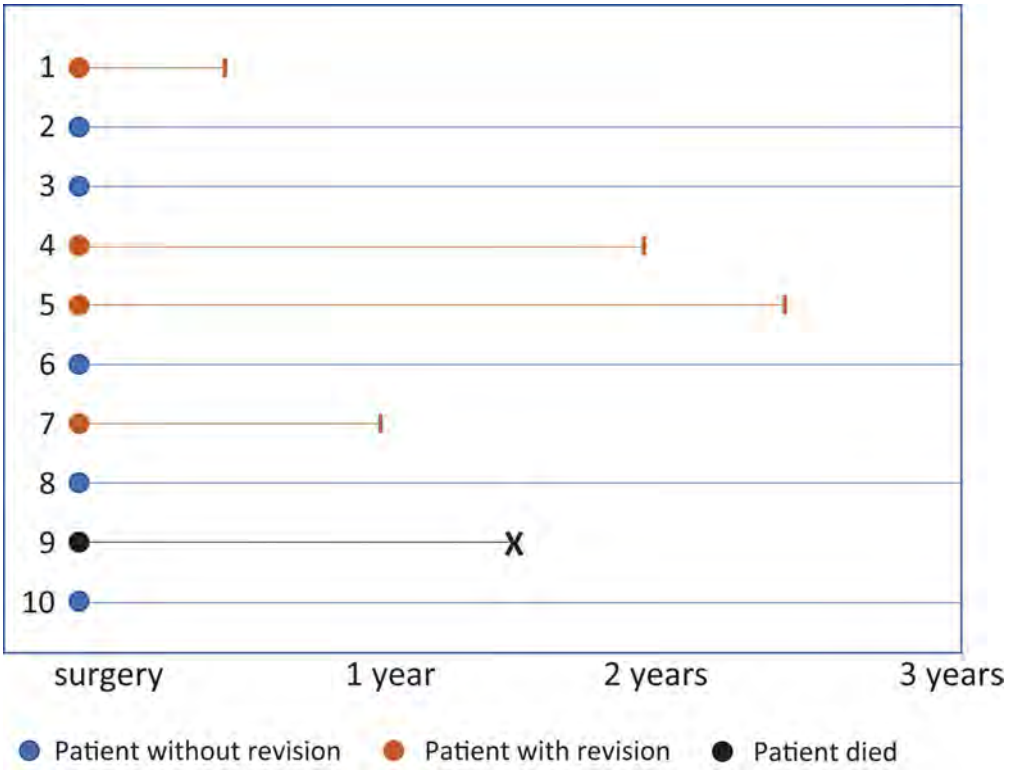

Figure 1. Frequency of revision in 10 hypothetical patients.

Use rates when participants have different lengths of follow-up or to handle a high loss to follow-up or loss to competing risks such as death.

Odds

Odds is the likelihood of a new case occurring rather than not occurring. It is the probability that an event will occur divided by the probability that the event will not occur. It differs from risk in that the denominator does not include the patients with the condition. In our example in Figure 1, the odds of revision is 80%, (4/9)/(5/9). Note that the odds of revision (80%) is markedly different than the risk of revision (4/9, 44%). However, odds approaches risk when the risk is small. If the risk of a pulmonary embolism following a surgery is 1/100, the odds are 1/99, which is nearly the same. The general rule of thumb is that the odds approaches risk when the risk is less than 10%.

Odds are not intuitive and you rarely see absolute odds in the spine research. Therefore, use odds when you go to the racetrack.

Ratios

"Everything is relative except relatives, and they are absolute."—Alfred Stieglitz, photographer

Ratios are used to describe the relative effect of a certain intervention or risk factor compared with another.

Risk Ratios or Relative Risk (RR)

The formula for RR equals (risk of an event in one group)/(risk of an event in a second group). It is an indication of the strength of the association between the 2 risks. Its interpretation is intuitive. If there is a 15% risk of revision surgery after treatment A but only 6% following treatment B, the RR is 15%/6% = 2.5. The interpretation is that a patient is 2 and half times more likely to receive revision surgery with treatment A compared with B. Given the RRs are ratios, their values are ≥0. Therefore, the closer the RR is to 1, the smaller difference between groups.

In addition to calculating the absolute risks (15% and 6%) and the risk ratio (2.5), one can also calculate the risk difference (RD) between the groups. The RD is simply the difference between the absolute risks. In our example, the RD equals 9% (15%-6%) and represents the extra risk associated with treatment A above the risk associated with treatment B, Figure 2. From the RD, the number of patients needed to be treated (NNT) in order to prevent one revision can be calculated. The formula is 1/RD; in our example 1/.09 = 11. In plain language, for every 11 patients treated with treatment B, one revision can be prevented compared with treatment A.

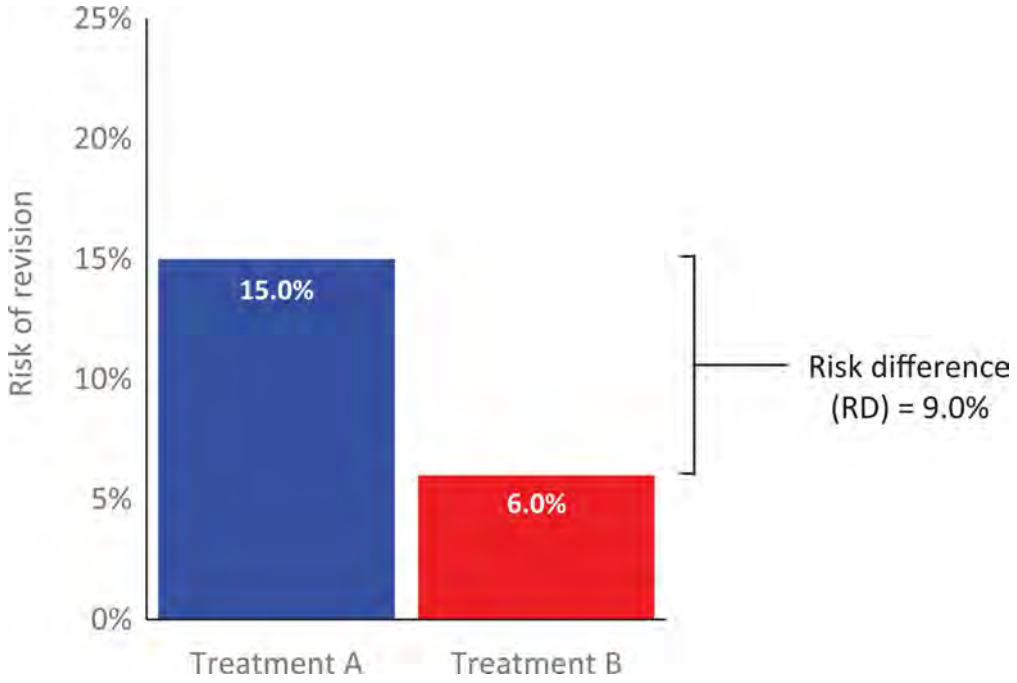

Figure 2. Risk difference.

Rate Ratios and Odds Ratios (OR)

Like the RR, rate ratios and odds ratios divide the rate or odds in one group by the rate or odds in a second group to provide a relative effect. Unlike absolute odds, the OR is used frequently in the spine literature, in part because of its unique statistical properties. And, if the risk is low, ≤10%, it is good estimator of the relative risk. But in general, beware how you interpret the OR when the risk of an outcome is higher than 10%, as the OR will overstate the risk effect size.

Summary

- Absolute risk, rate and odds and their ratios are different measures of association between exposure (treatment or risk factor) and outcome.
- Risk is the number of new cases that occur during a specified time period divided by a population at risk of becoming a case. It is often expressed as a percent.
- Rate is the number of new cases that occur per the total amount of time a person is at risk of becoming a case. It is expressed as person-time such as 17.8 cases per 100 person years.
- Odds is the likelihood of a new case occurring rather than not occurring. It differs from risk in that the denominator does not include the patients with the condition.
- Ratios (risk, rate and odds) provide a relative effect of an intervention or risk factor.
- The risk difference (RD) is the difference between the absolute risks of 2 interventions or risk factors. The RD represents excess risk attributed to the group with the higher risk.
- The odds ratio can estimate the risk ratio when the probability of an event is ≤10%.

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Contents

Aims and Objectives

The overarching aim of the Gram negative bacteraemia (*Escherichia coli* bacteraemia (ECB), *Klebsiella* species (spp.) bacteraemia (KSB), *Pseudomonas aeruginosa* bacteraemia (PAB)) and *Staphylococcus aureus* bacteraemia (SAB) national bacteraemia programmes is to monitor the burden of bacteraemia and to inform interventions/changes in practices. This has been achieved by implementing a mandatory and voluntary surveillance programmes identifying patient characteristics, history of healthcare and risk factors (potential primary infection source, potential cause of bacteraemia) and making these data available in a relevant context in order to:

- Support the NHS boards in strategic planning, implementation of targeted intervention and quality improvement in clinical areas, and to monitor the impact of these activities.
- Provide a national expert role in epidemiology to underpin and support improvement of infection management, antimicrobial treatment and effective prevention and control of bacteraemia to the NHS Boards, other NSS divisions, Scottish Government and other relevant clinical networks/ forums, including the National urinary tract infection (UTI) programme, Scottish Microbiology and Virology Network (SMVN) and Scottish Antimicrobial prescribing Group (SAPG), by identifying risk factors and populations at risks.
- Align with research and support the development of national guidance and quality improvement tools for facilitating reduction in bacteraemia incidence.
- Provide epidemiological support to NHS boards in outbreak and incident investigations.

Case Definitions

The following blood specimens are excluded from the surveillance:

- Post mortem blood/pathology reports
- Clotted blood
- Plasma
- Serum
- Ascitic fluid

Esherichia coli bacteraemia

A case of bacteraemia is a patient from whom *Escherichia coli* (*E. coli*) has been isolated from the patient's blood, and who has not previously had the same organism isolated from blood within the same 14-day period (i.e. 14 days from date last positive sample obtained).

This surveillance includes all laboratory reported cases except *E. coli* O157 or other serotype samples

Klebsiella species bacteraemia

A case of bacteraemia is a patient from whom *Klebsiella* spp. has been isolated from the patient's blood, and who has not previously had the same organism isolated from blood within the same 14 day period (i.e. 14 days from date last positive sample obtained).

If a patient has had more than one *Klebsiella* e.g. *Klebsiella pneumoniae* and *Klebsiella oxytoca* within the same rolling 14-day period this is coded to be the same episode, rather than two episodes.

Pseudomonas aeruginosa bacteraemia

A case of bacteraemia is a patient from whom *Pseudomonas aeruginosa* (*P. aeruginosa*) has been isolated from the patient's blood, and who has not previously had the same organism isolated from blood within the same 14-day period (i.e. 14 days from date last positive sample obtained).

Staphylococcus aureus bacteraemia

A case of SAB is a patient whom *Staphylococcus aureus* (*S. aureus*) has been isolated from the patient's blood, and who has not previously had the same organism isolated from blood within the same 14-day period (i.e. 14 days from the date last positive sample obtained).

Borderline oxacillin resistance *S. aureus* (BORSA) are coded as MSSA.

S. aureus Reference Laboratory samples take priority in the episode.

Enhanced surveillance datasets

Core data fields

- CHI Number
- Forename
- Surname
- Gender
- Postcode
- NHS health board of residence
- NHS health board of laboratory
- Episode date
- Specimen number
- Date of birth
- Date of admission to hospital during episode
- Ward where positive blood culture aspirated
- Health board where positive blood culture aspirated
- Hospital where positive blood culture aspirated
- Clinical Speciality where blood culture taken
- Health board bacteraemia attributed to
- Hospital bacteraemia attributed to
- Clinical Speciality bacteraemia attributed to
- Origin of infection
- Notes

ECB data fields

- Hospital Admission History (30 Days Prior)
- Specific source of *E. coli* bacteraemia
- Other source of *E. coli* bacteraemia
- Bacteraemia by system involved or external factor
- Other bacteraemia by system involved or external factor
- Urinary catheter inserted/removed in last 30 days prior to bacteraemia
- Urinary catheter manipulated 30 days prior to bacteraemia
- Duration of urinary catheter
- Reason for urinary catheter insertion
- Treatment for UTI 30 days prior to bacteraemia
- Prostate biopsy 30 days prior to bacteraemia
- Hepatobiliary procedure 30 days prior to bacteraemia
- Type of hepatobiliary procedure
- Prophylactic antibiotics given for hepatobiliary procedure

KSB data fields

- Hospital Admission History (30 Days Prior)
- Specific source of *Klebsiella* spp. bacteraemia
- Other source of *Klebsiella* spp. bacteraemia

PAB data fields

- Hospital Admission History (30 Days Prior)
- Specific source of *P. aeruginosa* bacteraemia
- Other source of *P. aeruginosa* bacteraemia

SAB data fields

- *S. aureus* susceptibility (methicillin-resistant staphylococcus aureus (MRSA) or methicillin-sensitive staphylococcus aureus (MSSA)
- SAB entry point
- SAB entry point other: please specify
- Deep-seated/metastatic infection
- Deep-seated/metastatic infection other: please specify
- Device risk factors
- Skin and soft tissue risk factors
- Other risk factors

Methods

Process for information capture

NHS Boards should coordinate the completion of the HPS enhanced ECB/SAB surveillance.

Each NHS Board is responsible for capturing the data required by the enhanced surveillance in the enhanced surveillance tool within ECOSS (www.ecoss.scot.nhs.uk). Information should be collected on a prospective basis. Data can be obtained from local Laboratory Information Management Systems (LIMS) or Patient Administration Systems (PAS) as applicable.

Case Validation

To ensure data quality, validation rules have been built in to the web tool

RED

Essential data corrections/Essential fields missing.

The case cannot be saved as complete until these have been resolved.

AMBER

Desirable data checks/Unlikely cross-field combinations to be checked.

These messages are advisory and the case can still be saved as complete.

Deadlines for completion of Enhanced data on ECOSS

Quarter	Completion date
January – March (Quarter 1)	1st Friday in May
April – June (Quarter 2)	1st Friday in August
July – September (Quarter 3)	1st Friday in November
October – December (Quarter 4)	1st Friday in February

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Core Surveillance Data Definitions

Data item:	CHI Number
Response required:	Essential
Definition:	
Choices:	
Rationale:	
Comments:	

Data item:	Forename
Response required:	Essential
Definition:	
Choices:	
Rationale:	Part of unique record
Comments:	

Data item:	Surname
Response required:	Essential
Definition:	
Choices:	
Rationale:	Part of unique record
Comments:	

Data item:	Gender
Response required:	Essential
Definition:	
Choices:	Male, Female
Rationale:	Part of unique record
Comments:	

Data item:	Date of birth
Response required:	Essential
Definition:	
Choices:	
Rationale:	Part of unique record
Comments:	

Data item:	Postcode
Response required:	Desirable
Definition:	
Choices:	Multiple
Rationale:	Part of unique record
Comments:	

Data item:	NHS health board of residence
Response required:	Essential
Definition:	
Choices:	AA (NHS Ayrshire and Arran), BR (NHS Borders), DG (NHS Dumfries & Galloway), FF (NHS Fife), FV (NHS Forth Valley), GR (NHS Grampian), GGC (NHS Greater Glasgow & Clyde), HG (NHS Highland), LN (NHS Lanarkshire), LO (NHS Lothian), OR (NHS Orkney), SH (NHS Shetland), TY (NHS Tayside), WI (NHS Western Isles), Non NHS Scotland
Rationale:	Part of unique record
Comments:	Non NHS Scotland should be used for residents from the rest of the UK or those who are visiting from other countries.

Data item:	NHS health board of laboratory
Response required:	Essential
Definition:	
Choices:	AA, BR, DG, FF, FV, GR, GGC, HG, LN, LO, NWTC, OR, SH,
TY, WI	
Rationale:	To allow data to be searched by Health Board
Comments:	

Data item:	Episode (specimen) date
Response required:	Essential
Definition:	
Choices:	
Rationale:	Required to identify origin of bacteraemia
Comments:	

Data item:	Specimen number
Response required:	Essential
Definition:	
Choices:	
Rationale:	
Comments:	

Data item:	Date of admission to hospital during bacteraemia episode
Response required:	Essential for SAB/ECB, Voluntary for KSB/PAB
Definition:	If the patient was first admitted to A&E, the A&E admission date should be used.
Choices:	
Rationale:	
Comments:	If patient has not been admitted to hospital, enter 09/09/9999 in this field and complete the location of sample aspiration within the notes field. Contact the SSHAIP team to override validation.

Data item:	Ward where positive blood culture aspirated
Response required:	Optional
Definition:	
Choices:	Individual Infection Prevention and Control Teams will need to identify wards in their own NHS Board
Rationale:	
Comments:	For local use only.

Data item:	Health board where positive blood culture aspirated
Response required:	Essential for SAB/ECB, Voluntary for KSB/PAB
Definition:	
Choices:	AA, BR, DG, FF, FV, GR, GGC, HG, LN, LO, NWTC, OR, SH,
TY, WI	
Rationale:	
Comments:	

Data item:	Hospital where positive blood culture aspirated
Response required:	Essential for SAB/ECB, Voluntary for KSB/PAB
Definition:	
Choices:	Hospital code*
Rationale:	
Comments:	If the sample was taken in a hospice, the 'hospital at home' option should be used, name of care home/location can be entered into the comments.

* The hospital code list included in the web tool will be refreshed on an annual basis. If a change is required please contact Information Services Scotland

Data item:	Clinical speciality where blood culture taken
Response required:	Essential for SAB/ECB, Voluntary for KSB/PAB
Definition:	
Choices:	Multiple (See Appendix 1)
Rationale:	
Comments:	

Data item:	Health board bacteraemia attributed to
Response required:	Optional
Definition:	For patient transfers positive blood culture MUST be obtained within 48 hours of transfer to the new health board If infection source/entry point is surgical site infection (SSI) (refer SSI protocol definitions), attribute to health board of surgery If infection source/entry point is dialysis, attribute to health board of dialysis
Choices:	AA, BR, DG, FF, FV, GR, GGC, HG, LN, LO, NWTC, OR, SH, TY, WI, Non NHS Scotland
Rationale:	Option available for HAI bacteraemia only
Comments:	Non NHS Scotland should be used where the infection is attributed to a hospital within the rest of the UK or in other countries.

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Data item:	Hospital bacteraemia attributed to
Response required:	Optional
Definition:	For patient transfers positive blood culture MUST be obtained within 48 hours of transfer to the new hospital If infection source/entry point is surgical site infection (SSI) (refer SSI protocol definitions), attribute to hospital of surgery If infection source/entry point is dialysis, attribute to hospital of dialysis
Choices:	Hospital code
Rationale:	Option available for HAI bacteraemia only
Comments:	The hospital code list included in the web tool will be refreshed on an annual basis. If a change is required please contact Information Services Scotland

Data item:	Clinical speciality bacteraemia attributed to
Response required:	Optional
Definition:	For patient transfers positive blood culture MUST be obtained within 48 hours of transfer to the different speciality
Choices:	Multiple (See Appendix 1)
Rationale:	
Comments:	

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Data item:	Origin of infection
Response required:	Essential for SAB/ECB, Voluntary for KSB/PAB
Definition:	**Hospital acquired infection (HAI):** Positive blood culture obtained from a patient who has been hospitalised for ≥48 hours. If the patient was transferred from another hospital, the duration of in-patient stay is calculated from the date of the first hospital admission. If the patient was a neonate/baby who has never left hospital since being born. OR The patient was discharged from hospital in the 48hr prior to the positive blood culture being taken. OR A patient who receives regular haemodialysis as an out-patient. OR Contaminant if the blood aspirated in hospital. OR If infection source/entry point is surgical site infection (SSI). **Healthcare associated infection (HCAI):** Positive blood culture obtained from a patient within 48 hours of admission to hospital and fulfils one or more of the following criteria: Was hospitalised overnight in the 30 days prior to the positive blood culture being taken. OR Resides in a nursing, long term care facility or residential home. OR IV, or intra-articular medication in the 30 days prior to the positive blood culture being taken, but **excluding IV illicit drug use**. OR Had the use of a registered medical device in the 30 days prior to the positive blood culture being taken e.g. intermittent self-catheterisation or percutaneous endoscopic gastrostomy (PEG) tube with or without the direct involvement of a healthcare worker (excludes haemodialysis lines see HAI). OR Underwent any medical procedure which broke mucous or skin barrier i.e. biopsies or dental extraction in the 30 days prior to the positive blood culture being taken. OR Underwent care for a medical condition by a healthcare worker in the community which involved contact with non-intact skin, mucous membranes or the use of an invasive device in the 30 days prior to the positive blood culture being taken e.g. podiatry or dressing of chronic ulcers, catheter change or insertion.

	Community infection: Positive blood culture obtained from a patient within 48 hours of admission to hospital who does not fulfil any of the criteria for healthcare associated bloodstream infection. **Not known:** Only to be used if the bacteraemia is not an HAI, and unable to determine if Community or HCAI.
Choices:	Hospital acquired infection (HAI) Healthcare associated infection (HCAI) Community Not known
Rationale:	
Comments:	

Data item:	Notes
Response required:	Optional
Definition:	
Choices:	Variable and patient specific
Rationale:	
Comments:	Can be used to provide additional information or qualifying information. **In addition, for SAB** it can be used to specify what multiple sites of metastatic infection have been picked in “Deep-seated metastatic infection”

E. coli Bacteraemia Surveillance Data Definitions

Data item:	Hospital admission history (30 days prior)
Response required:	Essential
Definition:	Any hospital admission in prior 30 days to the current admission being recorded including A&E admissions.
Choices:	Yes / No / Unknown
Rationale:	
Comments:	

Data item:	Specific source of *E. coli* bacteraemia
Response required:	Essential
Definition:	Specific source of the *E. coli* bacteraemia.
Choices:	Multiple (See Appendix 2)
Rationale:	
Comments:	

Data item:	Other source of *E. coli* bacteraemia
Response required:	Optional
Definition:	
Choices:	Free text
Rationale:	If the specific source is not present on the drop down menu
Comments:	

Data item:	Bacteraemia by system involved or external factor
Response required:	Essential
Definition:	System involved or external factor to help identify the entry point of the bacteraemia.
Choices:	Multiple (See Appendix 3)
Rationale:	
Comments:	

Data item:	Other bacteraemia by system involved or external factor
Response required:	Optional
Definition:	
Choices:	Free text
Rationale:	If the system involved or external factor is not present on the drop down menu
Comments:	

Data item:	Urinary catheter inserted/removed in last 30 days prior to bacteraemia
Response required:	Optional
Definition:	
Choices:	Yes / No / Unknown
Rationale:	
Comments:	Voluntary risk factor question.

Data item:	Urinary catheter manipulated 30 days prior to bacteraemia
Response required:	Optional
Definition:	
Choices:	Yes / No / Unknown
Rationale:	
Comments:	Voluntary risk factor question.

Data item:	Duration of urinary catheter
Response required:	Optional
Definition:	
Choices:	Intermittent self catheterisation / Short (<30 days) / Long (≥30days) / Unknown
Rationale:	Only available for completion if ‘yes’ is selected for ‘Urinary catheter inserted in last 30 days prior’ or ‘Urinary catheter removed in last 30 days prior’ or ‘Urinary catheter manipulated 30 days prior’.
Comments:	Voluntary risk factor question.

Data item:	Reason for urinary catheter insertion
Response required:	Optional
Definition:	
Choices:	Fluid balance / Urinary retention / Urinary obstruction / Neurogenic bladder Surgery / Incontinence / Not documented / Other (please specify)
Rationale:	Only available for completion if 'yes' is selected for 'Urinary catheter inserted/removed in last 30 days prior' or 'Urinary catheter manipulated 30 days prior'.
Comments:	Voluntary risk factor question. If 'other: specify' is selected complete the free text field.

Data item:	Other reason for urinary catheter insertion
Response required:	Optional
Definition:	
Choices:	
Rationale:	Only available for completion if 'yes' is selected for 'Urinary catheter inserted/removed in last 30 days prior' or 'Urinary catheter manipulated 30 days prior', and then "Other (please specify)" selected for "Reason for urinary catheter insertion".
Comments:	Voluntary risk factor question. If 'other: specify' is selected complete the free text field.

Data item:	Treatment for UTI 30 days prior to bacteraemia
Response required:	Optional
Definition:	Patient has received medical care in 30 days prior to onset of bacteraemia with intention of treating a urinary tract infection.
Choices:	Yes / No / Unknown
Rationale:	
Comments:	Voluntary risk factor question. If 'yes (other: specify)' is selected complete the free text field.

Data item:	Prostate biopsy 30 days prior to bacteraemia
Response required:	Optional
Definition:	Patient has received procedure in 30 days prior to bacteraemia
Choices:	Yes / No / Unknown
Rationale:	
Comments:	Voluntary risk factor question.

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Data item:	Hepatobiliary procedure 30 days prior to bacteraemia
Response required:	Optional
Definition:	Any procedure performed on hepatobiliary organs, such as Magnetic Resonance Cholangiopancreatography (MRCP) or Endoscopic Retrograde Cholangio-Pancreatography (ERCP).
Choices:	Yes (ERCP) / Yes (MRCP) / Yes (Stent insertion) / Yes (other please specify) / No / Unknown
Rationale:	
Comments:	Voluntary risk factor question.

Data item:	Other hepatobiliary procedure 30 days prior to bacteraemia
Response required:	Optional
Definition:	
Choices:	
Rationale:	Only available for completion if 'yes (other please specify)' is selected for "Hepatobiliary procedure 30 days prior to bacteraemia" field.
Comments:	Voluntary risk factor question.

Data item:	Type of hepatobiliary procedure
Response required:	Optional
Definition:	
Choices:	Elective / Emergency / Unknown
Rationale:	If 'yes' answered to 'Hepatobiliary procedure 30 days prior'
Comments:	Voluntary risk factor question.

Data item:	Prophylactic antibiotics given for hepatobiliary procedure
Response required:	Optional
Definition:	Prophylactic antibiotics given before/during/after procedure
Choices:	Yes / No / Not recorded
Rationale:	If 'yes' answered to 'Hepatobiliary procedure 30 days prior'.
Comments:	Voluntary risk factor question.

Klebsiella spp. Bacteraemia Surveillance Data Definitions

Data item:	Hospital admission history (30 days prior)
Response required:	Voluntary
Definition:	Any hospital admission in prior 30 days to the current admission being recorded including A&E admissions.
Choices:	Yes / No / Unknown
Rationale:	
Comments:	

Data item:	Specific source of *Klebsiella* spp. bacteraemia
Response required:	Voluntary
Definition:	Specific source of the *Klebsiella* spp. bacteraemia.
Choices:	Multiple (See Appendix 2)
Rationale:	
Comments:	

Data item:	Other source of *Klebsiella* spp. bacteraemia
Response required:	Optional
Definition:	
Choices:	Free text
Rationale:	If the specific source is not present on the drop down menu
Comments:	

P. aeruginosa Bacteraemia Surveillance Data Definitions

Data item:	Hospital admission history (30 days prior)
Response required:	Voluntary
Definition:	Any hospital admission in prior 30 days to the current admission being recorded including A&E admissions.
Choices:	Yes / No / Unknown
Rationale:	
Comments:	

Data item:	Specific source of *P. aeruginosa* bacteraemia
Response required:	Voluntary
Definition:	Specific source of the *Pseudomonas aeruginosa* bacteraemia.
Choices:	Multiple (See Appendix 2)
Rationale:	
Comments:	

Data item:	Other source of *P. aeruginosa* bacteraemia
Response required:	Optional
Definition:	
Choices:	Free text
Rationale:	If the specific source is not present on the drop down menu
Comments:	

S. aureus Bacteraemia Surveillance Data Definitions

Data item:	*S. aureus* susceptibility
Response required:	Essential
Definition:	When there is a difference in sensitivities between the laboratory results then the result from the Reference Laboratory should be used.
Choices:	MSSA / MRSA
Rationale:	
Comments:	

Data item:	SAB entry point
Response required:	Essential
Definition:	
Choices:	Multiple (See Appendix 5)
Rationale:	Identifies the proven or probable entry point of *S. aureus* into the blood stream and can be used to target interventions.
Comments:	Where the SAB is a continuation of a previous episode, the primary entry point should be used.

Data item:	SAB entry point – other: please specify
Response required:	Essential if SAB entry point = “other: please specify”
Definition:	
Choices:	Free text
Rationale:	If the entry point is not present on the drop down menu
Comments:	

Data item:	Deep-seated/metastatic infection
Response required:	Essential
Definition:	
Choices:	Multiple (See Appendix 6)
Rationale:	Useful for the clinical management of a patient and can be linked to patient outcome data.

Data item:	Deep-seated/metastatic infection – other: please specify
Response required:	Essential if deep-seated/metastatic infection = “other: please specify”
Definition:	
Choices:	Free text
Rationale:	If the entry point is not present on the drop down menu
Comments:	

Data item:	List all the device risk factors
Response required:	Essential
Definition:	List all devices risk factors in the 30 days prior to the date the positive blood culture was aspirated but do not include devices inserted to treat the current SAB episode.
Choices:	Multiple (See Appendix 7)
Rationale:	May identify practices where interventions can be targeted to reduce SAB
Comments:	If a device risk factor is selected as the Entry Point, then it must also be selected from risk factor list.

Data item:	Skin & soft tissue risk factors
Response required:	Essential
Definition:	List all skin and soft tissue risk factors at the time the blood culture was aspirated
Choices:	Multiple (See Appendix 7)
Rationale:	May identify practices where interventions can be targeted to reduce SAB
Comments:	If a skin & soft tissue risk factor is selected as the Entry Point, then it must also be selected from risk factor list.

Data item:	Other risk factors
Response required:	Essential
Definition:	List all other recognised risk factors at the time the blood culture was aspirated
Choices:	Multiple (See Appendix 7)
Rationale:	May identify practices where interventions can be targeted to reduce SAB
Comments:	

Appendix 1: Systematic classification of clinical specialties for enhanced surveillance

Specialty	Sub-specialties within specialty classification
Accident & emergency	
Cardiology	
Cardio-thoracic surgery	
Care of the elderly	
Ear, Nose and Throat	
General surgery	Including: upper and lower bowel surgery, acute surgery and Surgical High Dependency Unit
Haematology	
Hospital at home/community	Including: patients managed in their own home, but receiving extra care provided by care of the elderly consultants or services beyond the scope of GPs, OR obtained in a community setting by healthcare worker i.e. GP surgery or patients home or OPAT service
Infectious disease	
Intensive care	
Maxilo-facial surgery	
Medicine	Including: General medicine, Acute medicine, Respiratory medicine, Dermatology, Palliative care, Medical high dependency unit
Mental health	
Neurosurgery	Including: spinal surgery
Obstetrics & gynaecology	
Oncology	
Ophthalmology	
Orthopaedic surgery	
Paediatrics and neonatology	Including: SCBU, neonatal ICU
Plastic surgery	Including: burns units
Rehabilitation Medicine	
Renal medicine	
Transplant surgery	
Urology	
Vascular surgery	

Appendix 2: Specific source of ECB / KSB / PAB

Specific source	Definition
Contaminant	To call *E. coli* / *Klebsiella* spp. / *P. aeruginosa* a contaminant it must conform to the definition below: Blood culture obtained from a patient with no clinical signs of infection and is not prescribed an antibiotic which is active against *E. coli* / *Klebsiella* spp. / *P. aeruginosa*. Or The patient has signs and symptoms of infection with or without objective markers for infection AND is treated by the clinical team for another pathogen. Or The surveillance team along with the clinical team agree *E. coli* / *Klebsiella* spp. / *P. aeruginosa* is a contaminant.
Cystitis	Inflammation of the bladder
Device - CAPD	Continuous ambulatory peritoneal dialysis - A permanent soft flexible plastic tube (catheter) inserted in the abdomen under local or general anaesthetic. Dialysis fluid are run via the catheter into the peritoneal cavity, and remain in the cavity for several hours before being drained out into an empty bag by gravity.
Device - Dialysis line	All types of dialysis except CAPD
Device - Suprapubic Catheter	Sterile tube used to drain urine from your bladder when you cannot urinate
Device - Urinary Catheter	Includes all urethral catheters used to drain the bladder and collect urine
Device - Other: please specify	Any device that has not been specified already
Endocarditis	Inflammation of the inner layer of the heart usually involving the heart valves
Hepatobiliary	Infections involving liver plus the gallbladder, bile ducts, or bile.
Hydronephrosis	Condition where one or both kidneys become stretched and swollen as the result of a build-up of urine inside them.
Lower urinary tract infection	Infection of the bladder and urethra
Mediastinitis	Inflammation of the tissues in the mid-chest, or mediastinum
Nephrostomy	Artificial opening created between the kidney and the skin which allows for the urinary diversion directly from the upper part of the urinary system (renal pelvis)
Osteomyelitis	Inflammation of bone or bone marrow
Pneumonia	Swelling (inflammation) of the tissue in one or both of your lungs
Pyelonephritis	Inflammation of the kidney tissue, calyces, and renal pelvis
Renal abscess	Collection of pus around one or both kidneys
Septic arthritis	Infection of a joint that causes arthritis
Skin - Abscess	Collection of pus under skin

Specific source	Definition
Skin - Burns	Burn / scald to skin
Skin - Necrotising fasciitis	Infection of the deeper layers of skin and subcutaneous tissues
Skin - Ulcer	Open wound on skin
Surgical site infection (superficial)	See definitions for SSI surveillance
Surgical site infection (deep)	See definitions for SSI surveillance
Surgical site infection (organ/space)	See definitions for SSI surveillance
Not known	Source not known.
Other: please specify	Any infection source that has not been specified already

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Appendix 3: Classification of the ECB source by system involved or external factor

System involved or external factor	Specific infections (not exhaustive)
Cardiovascular infection	Infections of native valves and other structures related to the heart and vasculature i.e. thrombophlebitis.
Central nervous system infection	Infections related to the meninges, subdural or extradural, and involving the spinal column.
Congenital infection	Infection acquired while in-utero i.e. as a result of chorioamnionitis or traversing the birth canal.
Contaminant	To call *E. coli* a contaminant it must conform to the definition below: Blood culture obtained from a patient with no clinical signs of infection and is not prescribed an antibiotic which is active against *E. coli*. Or Has signs and symptoms of infection with or without objective markers for infection AND is treated by the clinical team for another pathogen. Or The surveillance team along with the clinical team agree *E. coli* is a contaminant.
Genital tract including prostate in males and the reproductive organs in females	Would include infections and abscess related to the reproductive organs including; ovaries, salpinx, uterus, cervical canal and vagina in females. In males the testis, epididymis and prostate.
Hepatobiliary system	Infections related to the liver, gallbladder, hepatic duct and bile duct.
Intra abdominal infection (other than HB system)	Infections related to the GI tract including presumed translocation in the context of ischaemic bowel, pancreas, gastroenteritis, diverticulitis and perforations of the oesophagus, stomach, small and large bowel.
Procedure related bacteraemia	Would include all *E. coli* bacteraemia related to an invasive procedure (i.e. post ERCP, post invasive radiological procedure, post cystoscopy) in the previous 48hr, but not related to a surgical procedure.
Related to IV illicit drug use	Would include any infection caused by IV illicit drug use such as injection site abscess, cellulitis and endocarditis.

System involved or external factor	Specific infections (not exhaustive)
Related to medical device other than VAD	Would include supra-pubic catheters, urethral catheters, PEG tubes, surgical drains, chest drains, nephrostomy tubes, tracheostomy tubes, epidural anaesthesia, peritoneal dialysis. NOTE: implanted devices such as vascular grafts, prosthetic joints, prosthetic valves, pacing wires and ventricular shunts infections may be classified under this group if arise sometime after the surgery. Alternatively, may be classified under surgical site infection if the infection occurred at time of surgery.
Renal tract infection	Structures related and including the kidney, ureter, bladder and urethra.
Respiratory infection	Lower and upper respiratory tract and associated structures.
Skeletal or joint infection	Would include septic arthritis, osteomyelitis, discitis and abscess/collections related to a bone or disc infection.
Skin & soft tissue infection	Includes pressure sores, chronic wounds necrotising fasciitis folliculitis, cellulitis, myositis and abscess within soft tissue.
Source not known	Source not known.
Surgical site infection	Infections resulting from or the result of surgery. Can be superficial, deep or organ/space related. See definitions for SSI surveillance. This would include dental extraction.
Vascular access device	Would include PVC, CVC, PICC, dialysis lines and dialysis fistulas.
Other	Any source by system that has not been specified already

Appendix 4: Voluntary risk factors for ECB

Risk factor	Qualification and examples	Time period
Urinary catheter inserted/removed	Includes intermittent self catheterisation	30 days prior to bacteraemia
Urinary catheter manipulated	Includes intermittent self catheterisation	30 days prior to bacteraemia
Duration of urinary catheter	Only available for completion if 'yes' is selected for 'Urinary catheter inserted in last 30 days prior' or 'Urinary catheter removed in last 30 days prior' or 'Urinary catheter manipulated 30 days prior'.	-
Reason for urinary catheter insertion	Only available for completion if 'yes' is selected for 'Urinary catheter inserted in last 30 days prior' or 'Urinary catheter removed in last 30 days prior' or 'Urinary catheter manipulated 30 days prior'.	-
Treatment for UTI	Patient has received medical care in 30 days prior to onset of bacteraemia with intention of treating a urinary tract infection.	30 days prior to bacteraemia
Prostate biopsy	Patient has received procedure in 30 days prior to bacteraemia	30 days prior to bacteraemia
Hepatobiliary procedure	Any procedure performed on hepatobiliary organs, such as Magnetic Resonance Cholangiopancreatography (MRCP) or Endoscopic Retrograde Cholangio-Pancreatography (ERCP).	30 days prior to bacteraemia
Type of hepatobiliary procedure	If 'yes' answered to 'Hepatobiliary procedure 30 days prior'	-
Prophylactic antibiotics given for hepatobiliary procedure	If 'yes' answered to 'Hepatobiliary procedure 30 days prior'	-

Appendix 5: Classification of SAB entry point

Infection prevention is interested in identifying the proven or probable entry point of the initial bacteraemia because if they can be prevented then the primary and secondary bacteraemia can be prevented.

Entry Point	Definition or comment
Contaminant	To call a SAB a contaminant it must conform to one of the definitions below after all other systems or external factors have been excluded: Blood culture taken from a patient with no clinical signs of infection and is not prescribed an antibiotic which is active against the *S. aureus.* Or Has signs and symptoms of infection with or without objective markers for infection AND is treated by the clinical team for another pathogen e.g. UTI with Gram negative bacillus. Or The surveillance team along with the clinical team agree the SAB is a contaminant.
Dental	Infection of the mouth, gums or teeth.
Device (A) to (E)	Vascular access devices.
Devices (F) to (M)	Medical devices other than VAD. Invasive ventilation includes endotracheal and tracheostomy tubes. NOTE: implanted devices cannot be entered as an SAB entry point only as a deep-seated/metastatic infection. Infections associated with implanted devices will be due to metastatic spread or SSI.
Device (N)	Other: please specify (free text box) in Device Risk Factors
ENT	Infections of the ear, nose or throat.
Injection site related to illicit drug use	Includes any infection caused by illicit IV or IM drug use at the injection site e.g. abscess, cellulitis, thrombophlebitis.
Nephrostomy	Tube, stent or catheter inserted into kidney through the skin.
Respiratory infection	Infection in the lower and upper respiratory tract and associated structures.
Skin & soft tissue (A) to (H)	Includes infections of skin, subcutaneous tissue, fascia and muscle.
Skin & soft tissue (I)	Other: please specify (free text box) in Skin Risk Factors
Surgical site infection	Infections resulting from or the result of surgery. Can be superficial, deep or organ/space related. See definitions for SSI surveillance. This would include dental extraction.

Entry Point	Definition or comment
Urinary tract infection	Infection of the bladder or urethra. If “Device (J) Urinary Catheter” is selected as risk factor then UTI entry point must be amended to Device (J) Urinary Catheter, since UTI would be Catheter Associated UTI (CAUTI).
Other: see specify	Free text box.
Not known	

Appendix 6: Deep-seated/metastatic infection associated with SAB

Clinicians are interested in the source of the bacteraemia either superficial or deep because it influences the antibiotic regimen and length of treatment.

Deep-seated/metastatic infection type	Site of deep-seated/ metastatic infection	Specific infections (not exhaustive)
Cardiovascular	Endocarditis	Inflammation of the inner layer of the heart usually involving the heart valves.
	Myocarditis	Inflammation of the heart muscle.
	Pericarditis	Inflammation of the pericardium (fibrous sac surrounding the heart).
	Thrombophlebitis	Inflammation of the wall of a vein related to thrombosis.
Bone & Joint	Bursitis	Inflammation of one or more bursae of synovial fluid in the body.
	Discitis	Inflammation of the invertebral disc space
	Osteomyelitis	Inflammation of bone or bone marrow.
	Septic arthritis	Infection of a joint that causes arthritis.
Implanted device - infection of these devices within 30 days of the implant surgery are likely to have occurred at the time of surgery and therefore recorded under the SSI entry point.	Prosthetic valve Pacemaker	Infection of subcutaneous pocket or pacemaker lead.
	Prosthetic joint	Infection at the site of prosthetic joint.
	Prosthetic valve	Infection at the site of prosthetic valve.
	Vascular graft	Infection at a site of graft, patch, stent, etc.

Deep-seated/metastatic infection type	Site of deep-seated/ metastatic infection	Specific infections (not exhaustive)
Deep abscess(es)/ haematoma	Central nervous system infection	Infections related to the meninges, subdural or extradural, and involving the spinal column.
	Genitourinary infection system	Infections and deep abscesses in reproductive and urinary system organs, including kidneys.
	Hepatobiliary infection system	Infections related to the liver, gallbladder, hepatic duct and bile duct.
	Intra abdominal infection (other)	Infections related to organs within the abdomen, excluding the hepatobiliary system. This would include the stomach, pancreas and small and large intestines (excluding the kidneys).
	Lung abscess	Collection of pus in/around one or both lungs.
	Mediastinitis	Inflammation of the tissues in the mid-chest, or mediastinum.
Multiple site of metastatic infection	Multiple site of metastatic infection	More than one deep-seated/ metastatic infection – please record sites in comments section.
Not known	Not known	Site not known.
None	None	No evidence of deep-seated/ metastatic infection.
Other: see comments	Other: see comments	Any infection source that has not been specified already.

Appendix 7: Risk factors for SAB

These include likely entry points for a *S. aureus* bacterium which could give rise to a localised infection which may go on to result in a *S. aureus* bacteraemia, plus risk factors in the patient which make a localised infection more likely to result in haematogenous spread.

Risk factor	Qualification and examples	Time period
Indwelling vascular access devices (VAD)	Device (A) Arterial Line Device (B) PVC Device (C1) CVC non-tunnelled Device (C2) CVC tunnelled Device (D1) Dialysis line – non-tunnelled Device (D2) Dialysis line – tunnelled Device (D3) Dialysis line – fistula Device (E) PICC/Midline	In the 30 days prior to the date the positive blood culture was taken.
Indwelling medical device other than VAD	Device (F) Invasive ventilation Device (G) CAPD Device (H) Surgical drain Device (I) Chest drain Device (J) Urinary catheter Device (K) Suprapubic catheter Device (L) PEG Device (M) External shunt	In the 30 days prior to the date the positive blood culture was taken.
Other Devices	Device (N) Other: please specify	In the 30 days prior to the date the positive blood culture was taken.
Skin & soft tissue: Infections of skin but does not include deep seated/metastatic skin & soft tissue infection.	Skin & soft tissue (A) Abscess Skin & soft tissue (B) Cellulitis Skin & soft tissue (C) Pressure ulcer Skin & soft tissue (D) Skin break Skin & soft tissue (E) e.g. Eczema Skin & soft tissue (F) Necrotising fasciitis Skin & soft tissue (G) Ulcer Skin & soft tissue (H) Burns Skin & soft tissue (I) Other: please specify	At the time the positive blood culture was taken.

Risk factor	Qualification and examples	Time period
Other risk factor (A): Medical/surgical instrumentation	Interventions which require breaking the skin such as muscle or bone biopsy, or endoscopic procedure where a biopsy was taken i.e. prostate biopsy, dental extraction.	In the 30 days prior to the date the positive blood culture was taken.
Other risk factor (B): Previous hospital admission	Overnight stay in hospital.	In the 30 days prior to the positive blood culture being taken.
Other risk factor (C): Diabetes mellitus		At the time the positive blood culture was taken.
Other risk factor (D): IM, IV, subcutaneous intra-articular medication, or venepuncture	i.e. insulin, dalteparin, steroid injections into joints, vaccination.	In the 30 days prior to the date the positive blood culture was taken.
Other risk factor (E): Immunosuppressed	This would include medical conditions such a HIV and haematological malignancy, but also drug induced immunosuppression by azathioprine, ciclosporin, leflunomide methotrexate, cyclophosphomide, prednisolone or immunosuppressive chemotherapy **TNFα inhibitors:** (Analimumab, etanercet, infliximab, certolizumab, golimumab) Cytockine modulators: (Anakinra, Tocilizumab) **B-cell inhibitors:** (Belimumab) **T-cell inhibitors:** (Abatacept).	At the time the positive blood culture was taken.
Other risk factor (F): Related to IV illicit drug use	Includes Intra muscular (IM) illicit drug use	
Other risk factor (G): Patient admitted from care home/institutional facility/other hospital	Would include nursing homes, care homes, prisons, residential homes, military barracks, transfers from peripheral hospital.	Immediately prior to hospital admission when the *S. aureus* bacteraemia occurred.
Other risk factor (H): Non healthcare cosmetic procedure breaking skin or mucous membrane	Includes, but not exclusively: skin piercing, tattoos and botox injections.	In the 30 days prior to the positive blood culture being taken.
Other risk factor (I) Implanted devices (risk for deep focus/ metastatic spread)	Includes, devices such as vascular grafts, prosthetic joints, prosthetic valves, pacing wires, ventricular shunts and pacemakers.	In place at the time the positive blood culture was taken.

NICE National Institute for Health and Care Excellence

Healthcare-associated infections

Last revised in July 2023

Management

Scenario: Management (/topics/healthcare-associated-infections/management/management/)

Background information

Definition (/topics/healthcare-associated-infections/background-information/definition/)

Causes (/topics/healthcare-associated-infections/background-information/causes/)

Prevalence (/topics/healthcare-associated-infections/background-information/prevalence/)

Transmission (/topics/healthcare-associated-infections/background-information/transmission/)

Risk factors (/topics/healthcare-associated-infections/background-information/risk-factors/)

Impact (/topics/healthcare-associated-infections/background-information/impact/)

Prognosis (/topics/healthcare-associated-infections/background-information/prognosis/)

Healthcare-associated infections: Summary

- A healthcare-associated infection is a problem which develops as a direct result of healthcare interventions for example, medical or surgical treatment, or as a result of direct contact with a healthcare setting.
- Healthcare-associated infections are caused by a wide range of microorganisms, which have gained entry into the body by an invasive device or procedure, including:
  - Meticillin-resistant *Staphylococcus aureus* (MRSA).

    - Meticillin-sensitive *Staphylococcus aureus* (MSSA).
    - *Clostridium difficile* (*C. difficile*).
    - *Escherichia coli* (*E. coli*).
- Around 300,000 people a year in England acquire a healthcare-associated infection as a result of NHS care.
- The most common types are respiratory infections (including pneumonia and infections of the lower respiratory tract; 22.8%), urinary tract infections (17.2%) and surgical site infections (15.7%).
- They are transmitted via blood, body fluids or excretions, and can result from:
    - Contact with non-intact skin or mucous membranes, and any equipment or items in the care environment that could have become contaminated.
    - Inhalation of droplets or airborne infections.
    - Inoculation incidents.
- Healthcare-associated infections can exacerbate existing or underlying conditions, delay recovery and adversely affect quality of life.
- Standard infection control precautions are the basic minimum standard of hygiene to be applied throughout all contact with blood and body fluids from any source to control the spread of infection within clinical practice and should comprise:
    - Assessment of the risk to and from individuals.
    - Hand hygiene measures.
    - Appropriate use of personal protective equipment.
    - Respiratory and cough hygiene.
    - Safe management of equipment
    - Maintenance of environmental cleanliness.
    - Safe management of laundry, and blood and body fluid spillages.
    - Safe disposal of waste and sharps.
- All people involved in providing care should be:
    - Educated about the standard principles of infection prevention and control.
    - Trained in hand decontamination, the use of personal protective equipment and the safe use and disposal of sharps.
- Additional precautions should be used when inserting and managing invasive devices, including:
    - Ensuring all equipment is sterile, packaging is intact and within the expiry date.
    - Performing skin decontamination prior to inserting a device through the skin (for example using 2% Chlorhexidine in 70% alcohol).

    - Maintaining a ‘closed’ system with as few connections as possible to reduce the risk of contamination.
    - Applying standard precautions and aseptic technique when manipulating the device.
- Additional transmission based precautions may be necessary for people with a known/suspected infectious agent, including:
    - Scheduling people to attend for a procedure at the end of the session to allow for environmental cleaning.
    - Wearing disposable gloves and apron when in contact with body fluids and disposing of these after each procedure.
    - Wearing long sleeved fluid repellent gowns if there is a risk of extensive splashing of body fluids.
    - Cleaning the treatment couch and immediate area with detergent and warm water followed by a hypochlorite solution or a disinfectant wipe.
    - Disposing of waste contaminated with body fluids as infectious waste.

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Review Article

User's guide to correlation coefficients

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ABSTRACT

When writing a manuscript, we often use words such as perfect, strong, good or weak to name the strength of the relationship between variables. However, it is unclear where a good relationship turns into a strong one. The same strength of r is named differently by several researchers. Therefore, there is an absolute necessity to explicitly report the strength and direction of r while reporting correlation coefficients in manuscripts. This article aims to familiarize medical readers with several different correlation coefficients reported in medical manuscripts, clarify confounding aspects and summarize the naming practices for the strength of correlation coefficients.

1. Introduction

Medical research is naturally based on finding the relationship between the known and the unknown.[1] Clinicians gather information via history, physical examination, laboratory tests and imaging; then, they use this information to infer clinical diagnosis, outcomes and treatment choices. Therefore, an endless struggle to link what is already known to what needs to be known goes on. We try to infer the mortality risk of a myocardial infarction patient from the level of troponin or cardiac scores so that we can select the appropriate treatment among options with various risks. We are trying to calculate the risk of mortality from the level of troponin or TIMI score. The most basic form of mathematically connecting the dots between the known and unknown forms the foundations of the correlational analysis.

Correlation is defined as *a relation existing between phenomena or things or between mathematical or statistical variables which tend to vary, be associated, or occur together in a way not expected by chance alone* by the Merriam-Webster dictionary.[2] A classic example would be the apparent and high correlation between the systolic (SBP) and diastolic blood pressures (DBP). The correlation between two variables (eg., systolic and diastolic pressures) is called a bivariate correlation and can be shown on a scatterplot diagram if both are continuous (scale) variables (Fig. 1). It is clear from the figure that SBP and DBP increase and decrease together, therefore, they are highly correlated. If we want to remove the effect of a third variable from the correlation between two variables, then we have to calculate a Partial correlation. It is a form of correlation which quantifies the relationship between two variables while controlling the effect of one or more additional variables (eg., age, sex, treatment received, etc.). In the figure male and female subjects are colored separately to examine if sex affects the correlation between SBP and DBP, or not.

The most important fact is that correlation does not imply causation. As the ice-cream sales increase, the rate of deaths from drownings, and the frequency of forest fires increase as well. These facts happen at the same period, doesn't cause one another.[3]

The relationship (or the correlation) between the two variables is denoted by the letter r and quantified with a number, which varies between -1 and $+1$. Zero means there is no correlation, where 1 means a complete or perfect correlation. The sign of the r shows the direction of the correlation. A negative r means that the variables are inversely related. The strength of the correlation increases both from 0 to $+1$, and 0 to -1.

When writing a manuscript, we often use words such as perfect, strong, good or weak to name the strength of the relationship between variables. However, it is unclear where a good relationship turns into a strong one. The same strength of r is named differently by several researchers. Therefore, there is an absolute necessity to explicitly report the strength and direction of r while reporting correlation coefficients in manuscripts.

This article aims to familiarize medical readers with several different correlation coefficients reported in medical manuscripts, clarify confounding aspects and summarize the naming practices for the strength of correlation coefficients.

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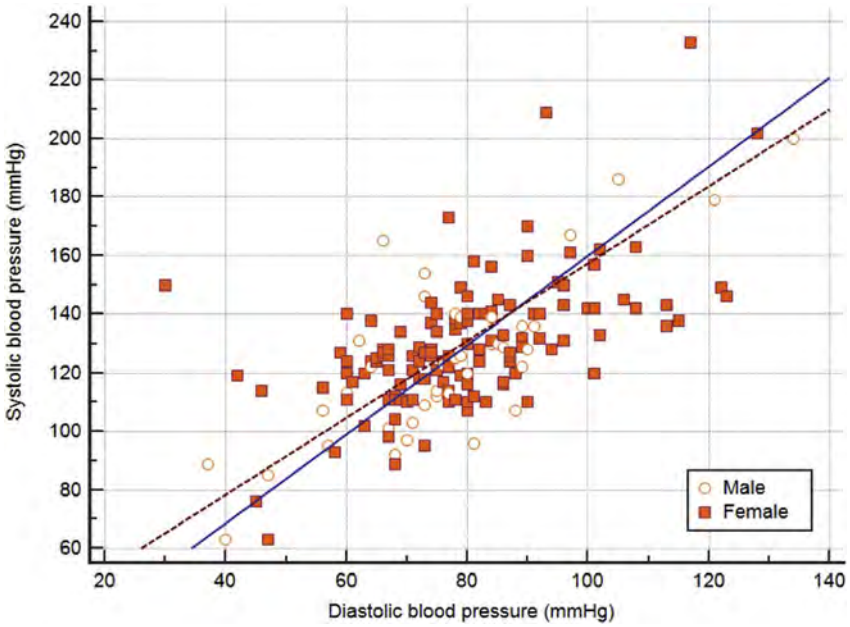

Fig. 1. Scatterplot of systolic and diastolic blood pressures of a study group according to sex.

2. How to name the strength of the relationship for different coefficients?

2.1. Bivariate correlation coefficients: Pearson's r, Spearman's rho (r_s) and Kendall's Tau (τ)

Those tests use the data from the two variables and test if there is a linear relationship between them or not. Therefore, the first step is to check the relationship by a scatterplot for linearity. Pearson's r is calculated by a parametric test which needs normally distributed continuous variables, and is the most commonly reported correlation coefficient. For non-normal distributions (for data with extreme values, outliers), correlation coefficients should be calculated from the ranks of the data, not from their actual values. The coefficients designed for this purpose are Spearman's rho (denoted as r_s) and Kendall's Tau. In fact, normality is essential for the calculation of the significance and confidence intervals, not the correlation coefficient itself. Kendall's tau is an extension of Spearman's rho. It should be used when the same rank is repeated too many times in a small dataset. Some authors suggest that Kendall's tau may draw more accurate generalizations compared to Spearman's rho in the population.

After the calculation of the above coefficients, an interesting question arises: how can we name this strength? All researchers tend to report that there is a strong relationship between what they have tested. However, most of the time, the significance is incorrectly reported instead of the strength of the relationship. A statistically significant correlation does not necessarily mean that the strength of the correlation is strong. The p-value shows the probability that this strength may occur by chance. In the dataset shown in Fig. 1, the correlation coefficient of systolic and diastolic blood pressures was 0.64, with a p-value of less than 0.0001. This r of 0.64 is moderate to strong correlation with a very high statistical significance ($p < 0.0001$). In the same dataset, the correlation coefficient of diastolic blood pressure and age was just 0.31 with the same p-value. Even though, it has the same and very high statistical significance level, it is a weak one. The low level of the p-value reassures us that 99.99% of the time the correlation is weak at an r of 0.31.

In this context, the utmost importance should be given to avoid misunderstandings when reporting correlation coefficients and naming their strength. In Table 1, we provided a combined chart of the three most commonly used interpretations of the r values. Authors of those definitions are from different research areas and specialties.

Table 1
Interpretation of the Pearson's and Spearman's correlation coefficients.

Correlation Coefficient		Dancey & Reidy (Psychology)	Quinnipiac University (Politics)	Chan YH (Medicine)
+1	−1	Perfect	Perfect	Perfect
+0.9	−0.9	Strong	Very Strong	Very Strong
+0.8	−0.8	Strong	Very Strong	Very Strong
+0.7	−0.7	Strong	Very Strong	Moderate
+0.6	−0.6	Moderate	Strong	Moderate
+0.5	−0.5	Moderate	Strong	Fair
+0.4	−0.4	Moderate	Strong	Fair
+0.3	−0.3	Weak	Moderate	Fair
+0.2	−0.2	Weak	Weak	Poor
+0.1	−0.1	Weak	Negligible	Poor
0	0	Zero	None	None

The naming on the 1) Left: Dancey & Reidy.,[4] 2) Middle: The Political Science Department at Quinnipiac University, 3) Right: Chan et al.[5].

2.2. Phi Coefficient and Cramer's V Correlation

Phi is a measure for the strength of an association between two categorical variables in a 2 × 2 contingency table. It is calculated by taking the chi-square value, dividing it by the sample size, and then taking the square root of this value.[6] It varies between 0 and 1 without any negative values (Table 2).

Cramer's V is an alternative to phi in tables bigger than 2 × 2 tabulation. Cramer's V varies between 0 and 1 without any negative

Table 2
Interpretation of Phi and Cramer's V.

Phi and Cramer's V	Interpretation
> 0.25	Very strong
> 0.15	Strong
> 0.10	Moderate
> 0.05	Weak
> 0	No or very weak

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Table 3
Interpretation of Lin's CCC according to McBride et al.[7].

Value of the Lin's CCC	Interpretation
> 0.99	Almost Perfect
0.95 to 0.99	Substantial
0.90 to 0.95	Moderate
< 0.90	Poor

values. Similar to Pearson's r, a value close to 0 means no association. However, a value bigger than 0.25 is named as a very strong relationship for the Cramer's V (Table 2).

2.3. Concordance Correlation Coefficient (CCC)

Lin's concordance correlation coefficient (ρ_c) is a measure which tests how well bivariate pairs of observations conform relative to a gold standard or another set.[7] Lin's CCC (ρc) measures both precision (ρ) and accuracy (Cβ).[8] It ranges from 0 to ± 1 similar to Pearson's. Altman suggested that it should be interpreted close to other correlation coefficients like Pearson's, with < 0.2 as poor and > 0.8 as excellent. On the contrary, McBride suggested another set for the interpretation (Table 3).

3. Conclusion

Interpretation of correlation coefficients differs significantly among scientific research areas. There are no absolute rules for the interpretation of their strength. Therefore, authors should avoid over-interpreting the strength of associations when they are writing their manuscripts.

Funding

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Conflicts of interest

HA reports no conflict of interest.

Author contributions

HA performed the literature search, designed the manuscript, drafted and approved the final version. HA take responsibility for the paper.

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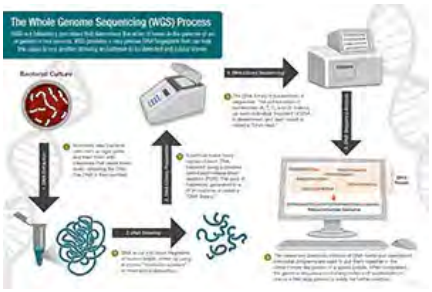
Whole Genome Sequencing



WGS Workflow: Larger View
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What is whole genome sequencing (WGS)?

All organisms (bacteria, vegetable, mammal) have a unique genetic code, or genome, that is composed of nucleotide bases (A, T, C, and G). If you know the sequence of the bases in an organism, you have identified its unique DNA fingerprint, or pattern. Determining the order of bases is called sequencing. Whole genome sequencing is a laboratory procedure that determines the order of bases in the genome of an organism in one process.

How does whole genome sequencing work?

Scientists conduct whole genome sequencing by following these four main steps:

1. **DNA shearing**: Scientists begin by using molecular scissors to cut the DNA, which is composed of millions of bases (A's, C's, T's and G's), into pieces that are small enough for the sequencing machine to read.
2. **DNA bar coding**: Scientists add small pieces of DNA tags, or bar codes, to identify which piece of sheared DNA belongs to which bacteria. This is similar to how a bar code identifies a product at a grocery store.
3. **DNA sequencing**: The bar-coded DNA from multiple bacteria is combined and put in a DNA sequencer. The sequencer identifies the A's, C's, T's, and G's, or bases, that make up each bacterial sequence. The sequencer uses the bar code to keep track of which bases belong to which bacteria.
4. **Data analysis**: Scientists use computer analysis tools to compare sequences from multiple bacteria and identify differences. The number of differences can tell the scientists how closely related the bacteria are, and how likely it is that they are part of the same outbreak.

How has whole genome sequencing improved disease detection?

Since 2019, whole genome sequencing has been the standard PulseNet method for detecting and investigating foodborne outbreaks associated with bacteria such as *Campylobacter*, Shiga toxin-producing *E. coli* (STEC), *Salmonella*, *Vibrio*, and *Listeria*. Since being launched, whole genome sequencing of pathogens in public health laboratories has improved surveillance for foodborne disease outbreaks and enhanced our ability to detect trends in foodborne infections and antimicrobial resistance. Whole genome sequencing provides detailed and precise data for identifying outbreaks sooner. Additionally, whole genome sequencing is used to characterize bacteria as well as track outbreaks; this greatly improves the efficiency of how PulseNet conducts surveillance.

PulseNet established the structure to support whole genome sequencing at state public health laboratories through:

- Training public health laboratory scientists to perform whole genome sequencing
- Purchasing equipment and supplies
- Updating data analysis systems and software

As the use of whole genome sequencing expands, CDC's national surveillance systems and laboratory infrastructure must keep pace with the changing technology. With modernization, CDC and its public health partners can continue to successfully detect, respond to, and stop infectious diseases. Whole genome sequencing is a fast and affordable way to obtain detailed information about bacteria using just one test. Together, we can ensure rapid and less costly diagnoses for individuals and collect the evidence needed to quickly solve and prevent foodborne outbreaks.

The implementation of whole genome sequencing of pathogens for detecting and tracking foodborne outbreaks was made possible through collaborations with CDC's Advanced Molecular Detection (AMD) Office, Food Safety Office, and Antimicrobial Resistance Solutions Initiative.

*For latest PulseNet laboratory protocols, please e-mail pulsenetngslab@cdc.gov

Page last reviewed: August 15, 2022

Establishing whole genome sequencing at the core of epidemiological surveillance

Over the last two decades, genome sequencing has become an important tool for understanding and tracking the spread of pathogens. Genomic epidemiology is now a preferred method of surveillance and recent years have seen pathogen sequencing at an unprecedented scale, pushing the underlying technologies to the limit. This has brought major innovations and opportunities to public attention, as well as identifying new research areas. However, major challenges remain in public health settings. These include: incorporating new sequencing technologies and data types for real-time surveillance; developing platforms and nomenclatures for genome-based typing and epidemiology; understanding pathogen evolution and the emergence of virulence and antimicrobial resistance; contextualizing knowledge of clinical microbiology with One Health ecological genomics. In this collection, we bring together recent studies that are establishing pathogen genomics as a major part of contemporary disease control efforts.

Collection Contents

13 results

Sort: ALL Go

Pangenomic analyses of antibiotic-resistant *Campylobacter jejuni* reveal unique lineage distributions and epidemiological associations

Jose A. Rodrigues, Heather M. Blankenship, Wonhee Cha, Sanjana Mukherjee, Rebekah E. Sloup, James T. Rudrik, Marty Soehnlen and Shannon D. Manning

+ More

Enteric fever cluster identification in South Africa using genomic surveillance of *Salmonella enterica* serovar Typhi

Anthony Marius Smith, Linda Kathleen Erasmus, Nomsa Pauline Tau, Shannon Lucrecia Smouse, Hlengiwe Mimmy Ngomane, Bolele Disenyeng, Andrew Whitelaw, Charlene Ann Lawrence, Phuti Sekwadi and Juno Thomas

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+ More

Impact of social disparities on 10 year survival rates in paediatric cancers: a cohort study

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Summary

Background Studies reporting on the impact of social determinants of health on childhood cancer are limited. The current study aimed to examine the relationship between health disparities, as measured by the social deprivation index, and mortality in paediatric oncology patients using a population-based national database.

Methods In this cohort study of children across all paediatric cancers, survival rates were determined using the Surveillance, Epidemiology, and End Results (SEER) database from 1975 to 2016. The social deprivation index was used to measure and assess healthcare disparities and specifically the impact on both overall and cancer-specific survival. Hazard ratios were used to assess the association of area deprivation.

Findings The study cohort was composed of 99,542 patients with paediatric cancer. Patients had a median age of 10 years old (IQR: 3–16) with 46,109 (46.3%) of female sex. Based on race, 79,984 (80.4%) of patients were identified as white while 10,801 (10.9%) were identified as Black. Patients from socially deprived areas had significantly higher hazard of death overall for both non-metastatic [1.27 (95% CI: 1.19–1.36)] and metastatic presentations [1.09 (95% CI: 1.05–1.15)] compared to in more socially affluent areas.

Interpretation Patients from the most socially deprived areas had lower rates of overall and cancer-specific survival compared to patients from socially affluent areas. With an increase in childhood cancer survivors, implementation of social determinant indices, such as the social deprivation index, might aid improvement in healthcare outcomes for the most vulnerable patients.

Funding There was no study sponsor or extramural funding.

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Keywords: Social determinants of health; Survival outcomes; Social deprivation index; Socioeconomic status

Introduction

Childhood cancer is the leading cause for death by disease in the United States,[1] despite 85% of children surviving past five years.[2] The gap in childhood health care outcomes is greatest among racial and ethnic minorities particularly for cancers that are most amenable to treatment.[3] These differences are thought to be due in large part to social determinants of health (SDoH),[4] which are the environmental factors that impact well-being with four commonly cited examples being income, education, employment, and social support.[5] Poverty has been found to have the single most profound effect on SDoH.[6] In the United States (US) alone, 16% of children were determined to be living in poverty according to the US Census Bureau in 2020.[7] While most of the published literature on SDoH focuses on poverty, inequalities in terms of educational attainment, food insecurity, health care access, housing, and transportation have been demonstrated to have an impact on healthcare outcomes.[8–11]

Although SDoH have been reported to have a significant impact on a host of cancer outcomes in adults,[5] studies reporting on the impact of SDoH in childhood cancer have been limited.[12–15] In a systematic review by Tran et al., in 2022, inconsistent findings have been found on the association of SDoH and paediatric cancer.[16] In a prospective study on the topic, Bona et al. found that 20% of the 99 families with children

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Research in context

Evidence before this study

Health disparities have been described in the United States for several paediatric cancers; however, the association between social determinants of health and paediatric cancer has been inconsistently reported. We searched PubMed and Google scholar for relevant articles written in English. There have been several studies reporting lower overall survival in paediatric cancer patients with acute lymphoblastic leukaemia and tumours of the central nervous system using the area deprivation index. Due to being derived from geographical data from the census tract, the area deprivation index has been unable to be applied beyond the state level. Limited studies have reported on the impact of health disparities and their outcomes in patients with paediatric cancer using national data.

Added value of this study

We used a national cancer registry to provide estimates of paediatric cancer mortality across the United States at the county-level for patients based on degree of social inequity. Using the social deprivation index, we show significantly worse overall and cancer-specific survival in paediatric cancer patients residing in areas of lower socioeconomic status. We found significantly worse outcomes for patients who reported being racially Black or who presented with nonmetastatic cancer.

Implications of all the available evidence

Among paediatric cancer patients, social inequities impact health outcomes. Social determinants of health screening tools would likely benefit the patient. While there are several available social determinants of health assessment tools, the social deprivation index can be uniquely applied to four geographical levels—county, census tract, aggregated Zip Code Tabulation Area, and Primary Care Service Area—therefore, the social deprivation index may be a valuable tool used in clinical practice to assess for health disparities at the patient, community, and national level.

receiving chemotherapy for a primary cancer had income ≤200% the federal poverty line and at least one episode of a food, energy, or housing insecurity.[17] With an increasing incidence of paediatric cancer and rising minority population as described by Aristizabal et al., there is an increased need to address cancer health disparities in paediatric populations.[12] Moreover, there is a need for practical interventions to improve outcomes in the paediatric population.[18] Limited studies have assessed the impact of SDoH in paediatric cancer using the area deprivation index, using geographical data based on census tracts, in patients with acute lymphoblastic leukaemia[19,20] and primary central nervous system tumours.[21] Due to the lack of census tract data in large cancer databases, studies looking at national survival outcomes are unable to be performed using such data, however. The social deprivation index (SDI) is a similar measure of area level deprivation that has multiple levels of disaggregation including county.[22] While the SDI has been defined and subsequently validated to assess healthcare outcomes in adults,[22,23] the SDI has not been assessed in children. The SDI is based on a composite of weighted factors based on geographic data using income, education, employment, housing, household characteristics, and transportation. Importantly, the SDI is valuable in being able to quantify SDoH measures.[22]

Using the SDI, the purpose of this project is to stratify survival outcomes across all paediatric cancers and to describe differences in survival outcomes based on SDoH. The hypothesis is that patients from the most socially deprived areas will have worse oncological survival outcomes compared to patients from less socially deprived areas.

Methods

Data source and study population

The Surveillance of Epidemiology and End Results (SEER) database represents one of the largest datasets in describing outcomes in cancer, accounting for 30% of the population in the US.[24] SEER importantly contains data that is valuable for an analysis on a population level to describe survival outcomes including for childhood cancer.[25] The SEER 18 dataset is based on 18 population-based cancer registries from 13 states.[24] After IRB approval (1871434-3), the SEER data was used to analyse paediatric patients (≤19 years old) diagnosed between 1975 and 2016. Patients were included using the International Classification for Oncology, third edition (ICD-O-3) to classify patients with a paediatric cancer.[26] Primary cancer type was defined by the World Health Organization based on the International Classification of Childhood Cancer (ICCC).[27] A total of 1223 cases were excluded due to missing census SDI demographic data from Honolulu county, Kauai county, Hawaii county, Maui county, or Alaska county. A total of 72 cases were excluded with missing county data. A total of 281 cases with survival months missing were excluded. A summary of patients included in the study can be found in Fig. 1. This study adhered to the Strengthening the Reporting of Observational Studies in Epidemiology (STROBE) reporting guideline.

Social deprivation index (SDI)

Social deprivation for each patient was determined using the 5-year American Community Survey (ACS) county level data from 2011 to 2015. The ACS provides population-level estimates of the US population annually based on random sampling of housing units. Further

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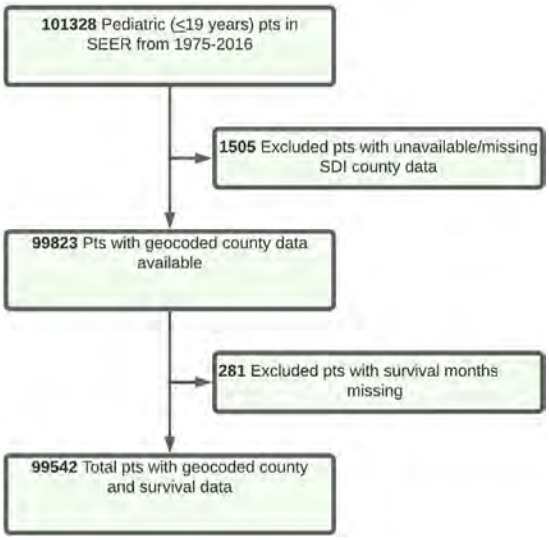

Fig. 1: Flow diagram for study participants.

information on the collection of the data and survey methods can be found on the ACS website: https://www.census.gov/programs-surveys/acs. The latest SDI scores were quantified as originally described by Butler et al., in 2015.[22] The SDI uses seven SDoH characteristics: percent living in poverty, percent with less than 12 years of education, percent single parent household, percent living in rented housing unit, percent living in overcrowded housing unit, percent of households without a car, and percent non-employed adults under 65 years of age.[22] The SDI scores are weighted based on the SDoH characteristics with a range given of 1–100 from national county percentile rankings.[22] Higher SDI scores are associated with worse social conditions. We defined SDI based in quartiles for analysis (Quartile 1 = 0–25, Quartile 2 = 26–50, Quartile 3 = 51–75, Quartile 4 = 76–100), as published previously.[23]

Variables

Patient demographic data included age (in years), gender, race, and ethnicity. As healthcare outcomes based on racial and ethnic status are recognized to have an impact on social determinants of health,[28] these variables were included.

Endpoints

The primary endpoint in our study was overall survival with the secondary endpoint of cancer-specific survival among patients with a paediatric cancer diagnosis. Based on the SEER classification, cancer-specific survival was defined based on survival from the primary cancer with other causes of death censored.[29] Survival time is based on the period from cancer diagnosis to either mortality or loss to follow-up. Survival time was evaluated up to a period of 10 years.

Statistical analysis

For continuous variables the median and interquartile range were recorded while for categorical variables the frequency and percentage were recorded. Patient demographics were assessed using the Chi-square test for categorical variables and Kruskal–Wallis test for continuous variables to assess overall differences in SDI quartiles. Kaplan–Meier curves were performed to assess both overall and cancer-specific survival based on SDI quartiles for up to 10 years. To assess statistical differences in the survival curves, the log-rank test was utilized. Separate sub analyses were performed using metastatic (M) stage and race/ethnicity. A cox proportional hazard regression model was performed of factors associated with overall survival. A backward stepwise technique was used with elimination of nonsignificant covariates to produce a multivariable model. Significance was defined for all tests using a two-tail p-value of <0.05. Basic analysis in this study was conducted using both the Social Sciences version 28.0 (IBM Corporation) and Stata version 17 (Stata Corporation). The RCommander package of R version 4.1.0 was used for statistical analysis.[30]

Results

Patient population and characteristics

A total of 99,542 paediatric oncology patients met inclusion criteria. In the entire cohort, patients had a median age of 10 years old (IQR: 3–16) with 46,109 (46.3%) identified as being female sex. Based on race, 79,984 (80.4%) patients were recorded as white while 10,801 (10.9%) patients were Black. According to metastatic (M) stage, 45,776 (46.0%) of patients had defined M0 stage disease while 38,551 (38.7%) of patients had defined M1 stage disease in the population.

In Table 1, a summary of the patient demographics can be found based on SDI quartiles. Significant differences ($p < 0.001$) in patients being recorded as Black was found across SDI quartiles. Black patients were most likely to be from the most socially deprived area (17.1% vs. 4.1%) compared to the least deprived area. There were similarly significant differences ($p < 0.001$) in patients having M1 stage disease at presentation across SDI quartiles. Patients with M1 stage disease at presentation were most often to be from the most socially deprived area (42.2% vs. 35.5%).

SDI-related risk of death

Survival differences were determined based on quartiles. 10-year overall and cancer-specific survival hazard ratios are described based on quartiles in Table 2. Based on overall survival, patients had significantly ($p < 0.001$) higher hazard of death [1.15 (95% CI: 1.11–1.19)] in the most socially deprived area

Characteristics	No. (%)				Total	p-value[b]
	Quartile 1[a]	Quartile 2	Quartile 3	Quartile 4		
No.	23,239	24,906	24,343	27,054	99,542	
Age, Median (IQR), y	9.8 [3–16]	9.7 [3–16]	9.7 [3–16]	9.6 [3–16]	10.0 [3–16]	0.001
Sex						
Female	10,941 (47.1)	11,467 (46.0)	11,151 (45.8)	12,550 (46.4)	46,109 (46.3)	0.032
Male	12,298 (52.9)	13,439 (54.0)	13,192 (54.2)	14,504 (53.6)	53,433 (53.7)	
Race						
White	21,245 (91.4)	19,854 (79.7)	18,561 (76.2)	20,324 (75.1)	79,984 (80.4)	<0.001
Black	946 (4.1)	2036 (8.2)	3204 (13.2)	4615 (17.1)	10,801 (10.9)	
Other[c]	1048 (4.5)	3016 (12.1)	2578 (10.6)	2115 (7.8)	8757 (8.8)	
Ethnicity						
Hispanic	1715 (7.4)	4001 (16.1)	6787 (27.9)	11,692 (43.2)	24,195 (24.3)	
M Stage						
M0	10,729 (46.2)	11,304 (45.4)	11,544 (47.4)	12,199 (45.1)	45,776 (46.0)	<0.001
M1	8257 (35.5)	9197 (36.9)	9677 (39.8)	11,420 (42.2)	38,551 (38.7)	
Unknown	4253 (18.3)	4405 (17.7)	3122 (12.8)	3435 (12.7)	15,215 (15.3)	
Primary Site						
Leukaemia	5537 (23.8)	6133 (24.6)	6474 (26.6)	7811 (28.9)	25,955 (26.1)	<0.001
CNS	4278 (18.4)	4273 (17.2)	3942 (16.2)	4214 (15.6)	16,707 (16.8)	
Lymphoma	3407 (14.7)	3754 (15.1)	3358 (13.8)	3594 (13.3)	14,113 (14.2)	
Miscellaneous[d]	2900 (12.5)	3267 (13.1)	3078 (12.6)	3471 (12.8)	12,716 (12.8)	
Carcinoma	1949 (8.4)	2144 (8.6)	2120 (8.7)	2117 (7.8)	8330 (8.4)	
Germ Cell	1395 (6.0)	1511 (6.1)	1602 (6.6)	1875 (6.9)	6383 (6.4)	
Soft Tissue	1431 (6.2)	1604 (6.4)	1537 (6.3)	1803 (6.7)	6375 (6.4)	
Bone	1401 (6.0)	1369 (5.5)	1448 (5.9)	1594 (5.9)	5812 (5.8)	
Skin	892 (3.8)	807 (3.2)	714 (2.9)	520 (1.9)	2933 (2.9)	
Unspecified	49 (0.2)	44 (0.2)	70 (0.3)	55 (0.2)	218 (0.2)	
Follow-up time, Median (IQR), y	8.3 (2.4–17.8)	8.0 (2.3–16.8)	6.1 (1.9–12.3)	6.6 (1.8–13.8)	7.1 (2.1–14.8)	<0.001

[a]Increasing quartiles indicate increasing levels of social deprivation. [b]p values detected overall differences using ANOVA for continuous variables and Pearson Chi-Square for categorical variables. [c]Includes American Indian/Alaska Native, Asian/Pacific Islander. [d]Includes Wilms, neuroblastoma, embryonal, paragangliomas, myeloma, mast cell or other lymphoreticular tumours.

Table 1: **Baseline patient demographics among all paediatric cancer patients by Social Deprivation Index Quartiles.**

compared to the least deprived area. A linear trend was found based on overall survival with worst survival in the most deprived areas. Based on cancer-specific survival, patients had significantly ($p < 0.001$) higher hazard of death [1.15 (95% CI: 1.10–1.19)] in Q4. Patients from Q4 similarly had worse cancer-specific survival than in each of the other quartiles. Kaplan–Meier curves for overall and cancer-specific survival based on quartiles for all paediatric cancer patients can be found in Fig. 2. Patients in Table 2 from Q4 had a 10-year overall survival of 73.8% (95% CI: 73.3–74.4%) and cancer-specific survival of 77.1% (95% CI: 76.5–77.7%).

Metastatic stage of presentation-related risk of death

Survival differences were further defined based on metastatic disease for the cohort. In Table 3, 10-year

SDI Quartile	Overall survival			Cancer-specific survival		
	Survival % (95% CI)	Hazard ratio	p value	Survival % (95% CI)	Hazard ratio	p value
Quartile 1	76.7 (76.1–77.3)	1 [referent]	NA	79.6 (79.1–80.2)	1 [referent]	NA
Quartile 2	75.9 (75.3–76.4)	1.04 (1.00–1.07)	0.07	79.0 (78.4–79.5)	1.04 (0.99–1.08)	0.086
Quartile 3	75.8 (75.2–76.4)	1.05 (1.01–1.09)	0.014	79.3 (78.7–79.8)	1.02 (0.97–1.06)	0.45
Quartile 4	73.8 (73.3–74.4)	1.15 (1.11–1.19)	<0.001	77.1 (76.5–77.7)	1.15 (1.10–1.19)	<0.001

SDI, Social deprivation index; NA, Not applicable.

Table 2: **10 year overall and cancer-specific survival with hazard ratios stratified by Social Deprivation Index quartiles.**

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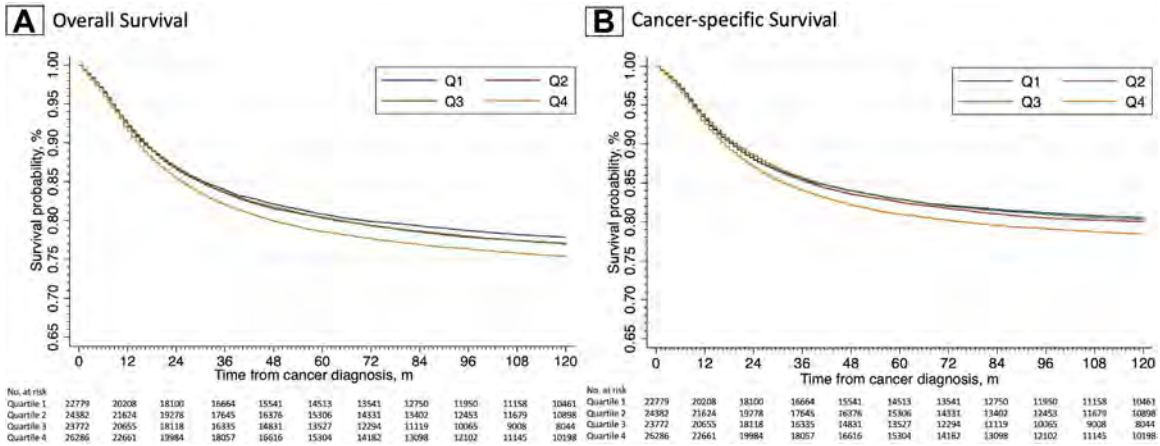

Fig. 2: Kaplan–Meier estimates by social deprivation quartile based on (A) overall and (B) cancer-specific survival.

overall and cancer-specific survival hazard ratios are described for quartiles based on the presence or absence of metastatic disease. Patients from Q4 with non-metastatic cancer were found to have a significantly ($p < 0.001$) higher risk of overall [1.27 (95% CI: 1.19–1.36)] and cancer-specific [1.28 (95% CI: 1.19–1.38)] hazard of death. Patients from Q4 with metastatic cancer were similarly found to have a higher risk of both overall [1.09 (95% CI: 1.05–1.15)] and cancer-specific hazard of death [1.08 (95% CI: 1.02–1.14)] with significant differences ($p = 0.001$ overall and $p = 0.007$ cancer specific). Kaplan–Meier curves for overall and cancer-specific survival based on quartiles for both non-metastatic and metastatic disease can be found in Fig. 3. In metastatic presentations, there is no statistical difference noted between Q1, Q2 and Q3. The only difference is seen in the most deprived Q4 population. Non-metastatic patients in Table 3 had a 10-year overall survival from Q4 of 81.3% (95% CI: 80.6–82.1%) and cancer-specific survival of 83.8% (95% CI: 83.1–84.5%). Metastatic patients in Table 3 had a 10-year overall survival from Q4 of 66.9% (95% CI: 66.0–67.9%) and cancer-specific survival of 70.7% (95% CI: 69.8–71.6%).

Race/ethnicity-related risk of death

Patients were separately subdivided by race and ethnicity in Table 4. Black patients had lower 10-year overall [67.6% (95% CI: 66.1–69.0%) vs. 75.2% (95% CI: 74.5–75.8%)] and cancer-specific [71.5% (95% CI: 70.1–72.9%) vs. 78.2% (95% CI: 77.6–78.8%)] survival in Q4 compared to non-Black patients. In contrast, patients of Hispanic ethnicity had similar 10-year overall [74.3% (95% CI: 73.4–75.2%) vs. 73.5% (95% CI: 72.7–74.3%)] and cancer-specific [77.5% (95% CI: 76.7–78.4%) vs. 76.7% (95% CI: 76.0–77.5%)] survival in Q4 compared to non-Hispanic patients.

SDI Quartile	No. (%)	Overall survival			Cancer-specific survival		
		Survival % (95% CI)	Hazard ratio	p value	Survival % (95% CI)	Hazard ratio	p value
M0 Disease							
Quartile 1	10,729 (23.4)	85.0 (84.2–85.7)	1 [referent]	NA	87.1 (86.4–87.8)	1 [referent]	NA
Quartile 2	11,304 (24.7)	84.1 (83.3–84.5)	1.06 (0.99–1.13)	0.1	86.4 (85.7–87.0)	1.05 (0.98–1.14)	0.17
Quartile 3	11,544 (25.2)	82.4 (81.6–83.2)	1.19 (1.11–1.27)	<0.001	85.5 (84.8–86.1)	1.13 (1.05–1.22)	<0.001
Quartile 4	12,199 (26.6)	81.3 (80.6–82.1)	1.27 (1.19–1.36)	<0.001	83.8 (83.1–84.5)	1.28 (1.19–1.38)	<0.001
M1 Disease							
Quartile 1	8257 (21.4)	69.1 (68.1–70.2)	1 [referent]	NA	72.5 (71.5–73.5)	1 [referent]	NA
Quartile 2	9197 (23.9)	67.7 (66.7–68.7)	1.05 (0.99–1.10)	0.1	71.5 (70.5–72.5)	1.04 (0.98–1.10)	0.24
Quartile 3	9677 (25.1)	69.8 (68.8–70.8)	0.97 (0.92–1.03)	0.29	73.7 (72.7–74.6)	0.95 (0.89–1.00)	0.06
Quartile 4	11,420 (29.6)	66.9 (66.0–67.9)	1.09 (1.04–1.15)	0.001	70.7 (69.8–71.6)	1.08 (1.02–1.14)	0.007

M, Metastases; SDI, Social deprivation index; NA, Not applicable.

Table 3: **10 year overall and cancer-specific survival stratified by metastatic and non-metastatic disease.**

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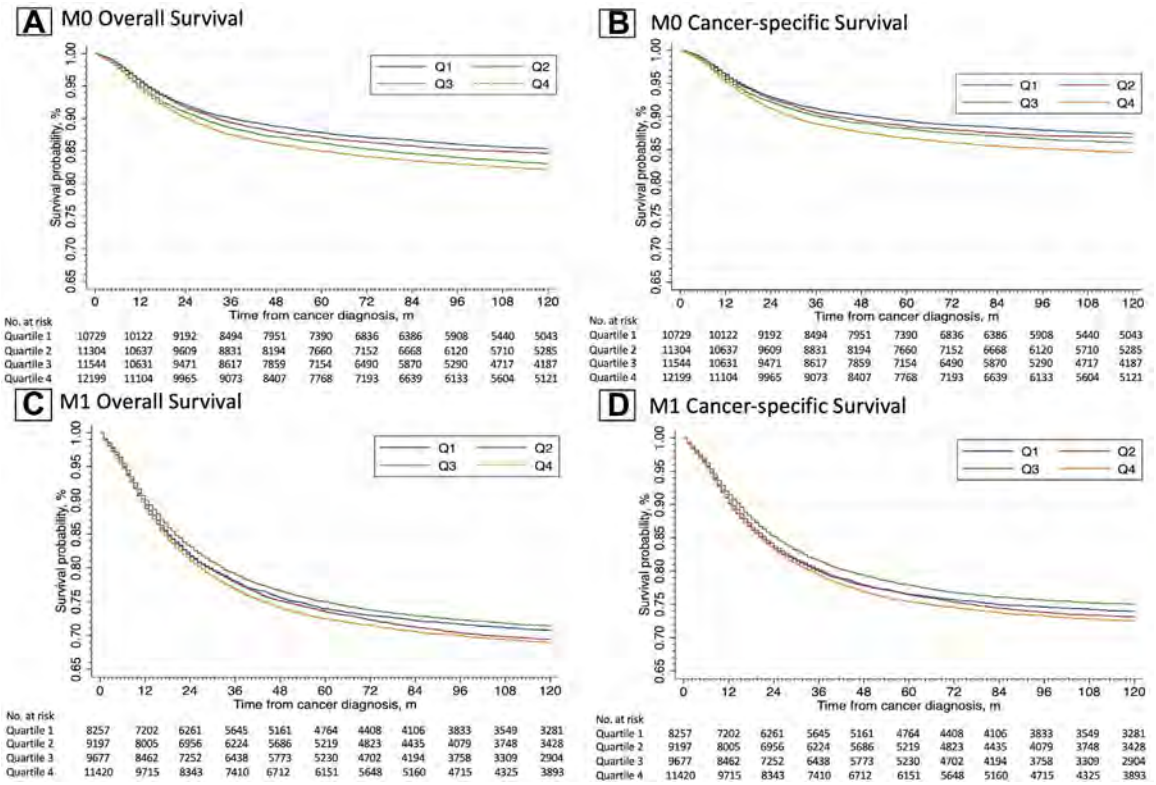

Fig. 3: Kaplan–Meier estimates based on metastatic disease and social deprivation quartile. Denoted is (A) overall and (B) cancer-specific survival for localized disease along with (C) overall and (D) cancer-specific survival for metastatic disease.

Univariate and multivariate cox proportional hazards regression analysis

To identify predictors of overall survival, a univariate analysis was performed with significant factors included into the multivariate analysis in Table 5. SDI was significantly associated with overall survival ($p < 0.001$). Q4 was significantly associated with a higher hazard of death [1.08 (95% CI: 1.04–1.12)]. Patients of Black race [1.36 (95% CI: 1.31–1.41)] as well as Hispanic ethnicity [1.07 (95% CI: 1.04–1.11)] had a higher hazard of death. As SDI is based on ACS data from 2011 to 2015, a separate cox proportional hazards regression was performed with patients exclusively diagnosed during this period. This data shows similar findings and is provided in the Supplementary Table S1.

Discussion

This is one of the first studies to quantify SDoH to assess a national cohort of paediatric oncology patients.[31] The results of this study show that patients from the most socially deprived areas consistently have worse overall and cancer-specific survival compared to patients from more socially affluent areas. These data were evaluated in numerous ways and across different timelines to try and make the series more contemporary. Ultimately, the findings remained consistent whether the evaluation focused on a specific subset of malignancy, a more limited timeframe, or a more contemporary series. Most striking, paediatric oncology patients from Q4, the most socially deprived with non-metastatic disease had roughly 30% higher risk of death for both overall and cancer-specific survival compared to patients from Q1, the most socially affluent quarter of the cohort. These findings emphasize that health outcomes are impacted by social and community contexts.

Inequities based on race were found among patients from the most socially deprived areas, with patients more likely to be Black. In a SEER study by Tehranifar et al., racial and ethnic minorities were found to have worse survival in cancers that were more amenable to medical interventions.[32] When Q4 was subdivided in our study, both non-Black and Black populations still were found to have lower survival rates than Q1, but the decrease in survival was more profound in the Black population. While Butler et al. excluded percent Black from the constructed SDI model, the disproportionately higher percentage of Black patients in Q4 and associated worse survival outcomes in this population cannot be completely accounted for currently.[22] Although patients of Hispanic ethnicity were found to be disproportionately higher in Q4, this did not translate to worse

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SDI Quartile	No. (%)	Overall survival			Cancer-specific survival		
		Survival % (95% CI)	Hazard ratio	p value	Survival % (95% CI)	Hazard ratio	p value
Race							
non-Black							
Q1	22,293 (25.1)	76.9 (76.3–77.5)	1 [referent]	NA	79.8 (79.2–80.3)	1 [referent]	NA
Q2	22,870 (25.8)	76.3 (75.7–76.9)	1.02 (0.98–1.06)	0.24	79.4 (78.8–79.9)	1.02 (0.98–1.07)	0.29
Q3	21,139 (23.8)	76.8 (76.2–77.5)	1.00 (0.96–1.04)	0.87	80.2 (79.5–80.8)	0.97 (0.93–1.02)	0.24
Q4	22,439 (25.3)	75.2 (74.5–75.8)	1.09 (1.05–1.13)	<0.001	78.2 (77.6–78.8)	1.08 (1.04–1.13)	<0.001
Black							
Q1	946 (8.8)	72.1 (68.8–75.1)	1 [referent]	NA	76.6 (73.5–79.5)	1 [referent]	NA
Q2	2036 (18.9)	70.5 (68.3–72.6)	1.01 (0.87–1.17)	0.91	74.3 (72.2–76.3)	1.06 (0.89–1.25)	0.52
Q3	3204 (29.7)	68.9 (67.1–70.7)	1.09 (0.95–1.25)	0.24	73.6 (71.9–75.3)	1.11 (0.95–1.29)	0.21
Q4	4615 (42.7)	67.6 (66.1–69.0)	1.15 (1.01–1.31)	0.04	71.5 (70.1–72.9)	1.21 (1.05–1.41)	0.01
Ethnicity							
non-Hispanic							
Q1	21,524 (28.6)	76.7 (76.1–77.3)	1 [referent]	NA	79.6 (79.0–80.2)	1 [referent]	NA
Q2	20,905 (27.7)	76.0 (75.4–76.6)	1.03 (0.99–1.07)	0.18	79.0 (78.4–79.6)	1.04 (0.99–1.08)	0.11
Q3	17,556 (23.3)	76.2 (75.5–76.9)	1.03 (0.98–1.07)	0.22	79.5 (78.9–80.2)	1.00 (0.95–1.05)	0.99
Q4	15,362 (20.4)	73.5 (72.7–74.3)	1.17 (1.12–1.22)	<0.001	76.7 (76.0–77.5)	1.16 (1.11–1.22)	<0.001
Hispanic							
Q1	1715 (7.1)	76.7 (74.3–78.9)	1 [referent]	NA	79.9 (77.6–82.0)	1 [referent]	NA
Q2	4001 (16.5)	74.9 (73.4–76.4)	1.08 (0.95–1.22)	0.23	78.9 (77.5–80.3)	1.05 (0.92–1.21)	0.46
Q3	6787 (28.1)	74.5 (73.3–75.7)	1.10 (0.98–1.24)	0.11	78.6 (77.4–79.7)	1.08 (0.95–1.22)	0.26
Q4	11,692 (48.3)	74.3 (73.4–75.2)	1.12 (1.01–1.25)	0.04	77.5 (76.7–78.4)	1.14 (1.01–1.29)	0.04

Q, Quartile; SDI, Social deprivation index; NA, Not applicable.

Table 4: **10 year overall and cancer-specific survival stratified by race/ethnicity.**

survival outcomes. The question of how to connect both race and ethnicity in a disparity index will need to be evaluated with future research endeavours.

This study utilized SDI as a method to evaluate degree of social deprivation of a geographic area based on county data and followed patients over a 10-year period. The SDI is currently available at four geographical levels: county, census tract, aggregated Zip Code Tabulation Area (ZCTA), and Primary Care Service Area.[33] Indexes that have previously been applied to the paediatric oncology population are available at only a single geographical level such as the area deprivation index which is based on census block groups or the composite index of socioeconomic status which is based on census tract groups.[34,35] Data generated exclusively from smaller geographical regions offer more precise information, but increasingly raise concerns of patient information being reidentifiable; this data requires protective methods to maintain compliance.[36] Moreover, the unavailability of census block group data in national cancer databases for the paediatric population has precluded its application beyond the state level. As socioeconomic data for census tracts in SEER have only been collected since 2000, follow-up time is limited.[29]

Overall, the findings in this manuscript can help push for improvements in patient access and screening, the delivery of health care, future research, and policy changes. In the literature, social needs screening and referrals in clinical workflows are the most cited tools for addressing SDoH issues.[37,38] Community-level SDoH assessments can be used to inform health care policies based on lack of facilities or even provide detailed information on medical professional shortages that may affect care in a geographic area.[39] Similarly, community-level SDoH assessments can be incorporated into the medical health record to stratify patient risk in a multitude of health care settings such as inpatient or outpatient.[40,41] With most children surviving a primary malignancy, assessments that focus on childhood cancer survivorship is increasingly more relevant due to a higher incidence of not only secondary malignant neoplasms[42] but also cardiovascular complications[43] in this population. Both general and subspecialty medical health care providers have a valuable role in both risk-based surveillance and preventative medicine.[44]

This study has several limitations of note. While SDI is a composite measure to assess factors related to SDoH, this is not comprehensive by any means in measuring patient level healthcare inequities. Having more local or even block level metrics to measure SDoH would provide greater specificity to individual inequities, however, oftentimes at the risk of becoming too granular and only describing community pockets. Outcomes in this study are limited to county-level data

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Factor	HR (95% CI)	p value
Age		
Adolescent (>11 years old)	1 [referent]	<0.001
Children (2–10 years old)	0.71 (0.69–0.73)	
Infant (<2 years old)	0.94 (0.90–0.99)	
Sex		
Male	1 [referent]	<0.001
Female	0.86 (0.84–0.88)	
Race		
White	1 [referent]	<0.001
Black	1.36 (1.31–1.41)	
Other	1.06 (1.01–1.12)	
Ethnicity		
Non-Hispanic	1 [referent]	<0.001
Hispanic	1.07 (1.04–1.11)	
Metastasis		
M0	1 [referent]	<0.001
M1	3.31 (3.19–3.43)	
Unknown	2.07 (2.0–2.16)	
Primary site		
Leukaemia	1 [referent]	<0.001
CNS	2.96 (2.82–3.11)	
Lymphoma	0.88 (0.83–0.93)	
Miscellaneous	1.49 (1.41–1.56)	
Carcinoma	1.18 (1.10–1.26)	
Germ cell	0.79 (0.73–0.85)	
Soft tissue	2.42 (2.29–2.56)	
Bone	2.90 (2.82–3.11)	
Skin	0.92 (0.82–1.04)	
Unspecified	2.23 (1.77–2.82)	
SDI Quartile		
Q1	1 [referent]	<0.001
Q2	1.02 (0.98–1.06)	
Q3	1.01 (0.97–1.05)	
Q4	1.08 (1.04–1.12)	

Q, Quartile; SDI, Social deprivation index.

Table 5: **Multivariate cox proportional hazard model for overall mortality.**

but as there are varying levels of affluence and access across neighbourhoods the available data are further removed from the experience of an individual patient. Cancer treatments and outcomes have changed over the 40 years of the SEER database and some geographic areas 40 years earlier may have been different from a socioeconomic standpoint than they are today. Patient factors including comorbidity are unavailable in SEER, and therefore could not be accounted for in our study. While the data in SEER is robust in accounting for a large patient sample of oncology patients, it is by no means inclusive of the entire United States and as such data are primarily collected from academic hospitals and metropolitan areas. As such, the study is limited to patients recorded in the SEER registry. Future prospective studies will be needed to apply and use SDI scores as an intervention in practice.

Conclusions

Social determinants of health are a contributor to disparities in healthcare outcomes among paediatric oncology patients. Patients from the most socially deprived areas had significantly worse 10-year overall and cancer-specific survival rates across all paediatric cancers. After separating out patients with metastatic disease, the differences in survival were present but not as disparate as for non-metastatic disease. Of important note, a higher proportion of patients from the most socially deprived quartile had metastatic disease. This is in alignment with other studies that found the greatest differences in outcomes in patients with disease were most amenable to medical interventions. With a lack of any standard SDoH metric in clinical practice, patients would likely benefit from implementation and screening using electronic medical records. The social deprivation index may be a useful tool to stratify individual patients and communities who should be the target of more focused medical attention and support. This could be an especially valuable tool in healthcare models that are driven by value-based care. More focus needs to be diverted towards paediatric patients who are vulnerable, particularly those from socially deprived areas, to create more equitable outcomes in the field.

Contributors

VC and AAS were responsible for project conceptualization. VC, CR, and AAR were responsible for data curation and data analysis. AAR and SMB provided project administration, supervision, and resources. VC and AAR wrote the original draft. All authors edited the final version. VC and CR had access to all the data and had final responsibility for the decision to submit for publication.

Data sharing statement

The SEER 18 data is publicly available at https://seer.cancer.gov/data/. The dataset creation plan for this study is available from the corresponding author upon request.

Role of the funding source

There was no study sponsor or extramural funding.

Declaration of interests

The authors declare that they have no conflicts of interest.

Appendix A. Supplementary data

Supplementary data related to this article can be found at https://doi.org/10.1016/j.lana.2023.100454.

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Water testing summary for the whole Queen Elizabeth University Hospital campus, 2015-2020

Sample numbers and test results for the new and retained buildings

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Background and scope

The Queen Elizabeth University Hospital (QEUH) campus consists of two new hospital buildings that opened to patients in May 2015, QEUH Adults and the Royal Hospital for Children (RHC), as well as numerous buildings that were already present on the site (referred to as retained buildings), including the Neonatal and Maternity buildings, Neurology and Neurosurgery, Spinal, Podiatry, and the Teaching & Learning block, among others.

This report gives a broad overview of microbiological water testing numbers and results for the period January 2015 to December 2020. It covers water sampling conducted across the whole QEUH campus (new and retained buildings) for all routine and reactive microbiological testing, including Legionella, Pseudomonas, potable, fungi, Gram negative bacteria, atypical mycobacteria, and other organism-specific tests. More detailed summaries of specific areas of the new buildings, including key wards, are outwith the scope of this report but are the subject of a separate report focusing on the new buildings, *Microbiological testing of water and environmental samples from the Queen Elizabeth University Hospital (Adults) and Royal Hospital for Children, 2015-2020* (DL Chaput). Legislation and guidance applicable to water testing on the QEUH campus are outwith the scope of this report but are summarised in a separate document, *Summary of legislation and guidance for routine microbiological water tests carried out at QEUH Adults and RHC* (DL Chaput).

Data were obtained from the QEUH Estates Department, from DMA Canyon Ltd, and from TelePath, the GG&C Laboratory Information Management System (see Supplemental Information for a detailed list of data sources). Data processing and analyses were carried out in R version 4.2.0, as detailed in Supplemental Information, and this report was written in Rmarkdown.

Protocols: Water sampling and microbiological testing

Water sampling

Collection of water samples from across the QEUH campus over the period 2015-2020 was carried out by two contractors, ALcontrol Laboratories and DMA Canyon Ltd, and by GG&C clinical staff in specific areas.

ALcontrol Laboratories (2015-2017)

ALcontrol Laboratories (hereafter referred to as ALcontrol) were a UKAS accredited water and environmental analysis service, contracted to carry out sampling and testing in the QEUH new buildings from April 2015 to January 2017. They were acquired by ALS Global in November 2016, and their website (www.alcontrol.com) now redirects to SGS Analytics.

ALcontrol collected water samples from the new buildings for Legionella testing on a monthly basis from April 2015 to June 2017. They sampled for potable water testing in April-May and Oct-Nov 2015, and again in Jan 2017. They also sampled for Pseudomonas

testing every month from Nov 2015 to Mar 2016, with some additional Pseudomonas sampling in Sept 2016.

DMA Canyon Ltd (2015-2020)

DMA Canyon Ltd (hereafter referred to as DMA) are specialists in plumbing, water treatment, and water hygiene monitoring, contracted by GG&C to carry out water sampling on the QEUH campus over the period 2015-2020 (continuing to the present day). They are registered with SNIPEF (Scottish and Northern Ireland Plumbing Employers' Federation), WaterSafe, and the Legionella Control Association, and hold ISO 9001 (quality management system), OHSAS 18001 (occupational health and safety), and ISO 14001 (environmental management system) certifications.

From January 2015 to August 2016, DMA conducted water sampling only in the retained buildings, while ALcontrol Laboratories sampled water from the new buildings. From September 2016 onward, DMA's sampling schedule included the new buildings, but only for Pseudomonas or specific organism testing at the request of Infection Prevention & Control (IPC) and/or Incident Management Teams (IMTs) (e.g. Serratia, *Elizabethkingia miricola*, Stenotrophomonas). DMA began collecting samples on a monthly basis for routine Legionella testing in the new buildings in July 2017 (taking over from ALcontrol), and began sampling for potable testing in the new buildings in April 2018.

DMA follow industry standard methods for water sample collection, with protocols specific to the type of outlet being sampled (tap, shower, storage tank, etc., hot, cold or mixed, with or without point-of-use filter, etc.) and to the type of microbiological analysis required (e.g. potable, Pseudomonas, Legionella). Where applicable, DMA's protocols aligned with those described in the Scottish Health Technical Memoranda (SHTM), notably SHTM 04-01 Water safety for healthcare premises Part B: Operational management (2014), as well as meeting the requirements set out in relevant Health and Safety Executive documents specific to Legionella control (see separate report for overview of applicable guidance and legislation).

Specialist units (new buildings)

A small number of specialist units in the QEUH new buildings had specific sampling and testing arrangements: the aseptic pharmacies in QEUH Adults and RHC, and the RHC Theatre 8, for cardiology procedures. In these areas, waters were (and continue to be) sampled routinely by GG&C clinical teams onsite. There is no involvement of Estates or external sampling contractors in this arrangement.

Testing laboratories

ALcontrol

Water samples collected by ALcontrol over the period 2015-2017 were analysed by their own UKAS accredited microbiological testing laboratory. The results were not entered into the GG&C TelePath system. Data sheets generated by ALcontrol were held by QEUH Estates.

GG&C Environmental Laboratory

The NHS GG&C Environmental Laboratory (hereafter referred to as the Environmental Laboratory) forms part of the Clinical Microbiology Department, located in the New Lister Building at the Glasgow Royal Infirmary. It is UKAS-accredited to ISO/IEC 17025:2017 for analysis of potable, endoscopy and renal waters, and air samples. Target microorganisms covered by this accreditation include *Legionella* species, coliforms and *Escherichia coli*, *Pseudomonas* species, atypical mycobacteria, as well as yeasts and moulds. Gram negative investigations are not specifically covered by the current UKAS accreditation, as they are not standard tests for water samples, but most of the methods involved are covered by other accredited protocols. The Environmental Laboratory has been UKAS-accredited for *Legionella* testing for many years and has therefore maintained high quality, training and calibration standards. Accreditation for the other tests was granted in April 2020 following a UKAS assessment in September 2019. Prior to this, the Environmental Laboratory was working towards UKAS accreditation for these tests and was therefore operating to these standards.

The Environmental Laboratory has had a long-standing arrangement with the clinical teams in the specialist units described above (the aseptic pharmacies and RHC Theatre 8). From 2015 onward, samples collected from these units were sent to the Environmental Laboratory for testing. Results were reported directly back to the clinical teams.

The Environmental Laboratory was also the main microbiological testing laboratory for both routine and reactive samples collected by DMA throughout the period 2015-2020. Results were reported back to DMA, who incorporated the microbiological findings into spreadsheets with sampling metadata (sampling date, location, type of outlet, etc.) and then sent the completed data sheets to QEUH Estates Department and, from mid-2018 onward, to contacts in Microbiology and IPC.

In addition to sending testing results back to the requestor (specialist unit clinical teams or DMA), the Environmental Laboratory maintained paper copies from 2015 to March 2017. From April 2017, all results from the Environmental Laboratory were uploaded to the GG&C TelePath system, and earlier results from 2015 to March 2017 were retrospectively entered into TelePath.

Intertek

Intertek is a global quality assurance company that provides testing services for numerous industries, including water and air quality monitoring. Its water microbiology analysis service is carried out to Drinking Water Directive 98/83/EC standards (Council Directive 98/83/EC of 3 November 1998 on the quality of water intended for human consumption, European Union legislation).

From December 2018 onward, due to the large increase in the number of water samples collected from the new buildings for microbiological analysis, some of the routine water samples collected by DMA from predetermined sentinel outlets (approximately 142 samples per month) were sent to Intertek for testing instead of the Environmental Laboratory, who tested the remaining routine and reactive samples.

Intertek reported its results to DMA, who incorporated them into the data sheets with sampling metadata and results from the Environmental Laboratory, then disseminated to Estates and contacts in IPC and Microbiology. Since Intertek is an external contractor, its microbiological test results were not uploaded to the GG&C TelePath system, which only holds water testing data from the Environmental Laboratory.

Microbiological test types

Water testing can be broadly classified as either routine (for monitoring purposes) or reactive (for investigation). Routine water samples collected by ALcontrol, DMA, or clinical teams in specialist units underwent one or more of the standard microbiological investigations listed in Table 1. Routine Legionella, Pseudomonas, and potable testing occurred throughout 2015-2020, while other routine tests were added at various points in specific areas of the campus. Testing for Cupriavidus and other Gram negative bacteria (GNBs) began with a large reactive sampling effort in early 2018, followed by implementation of routine testing for these organisms from Dec 2018. Routine fungal testing began in Dec 2018, and testing for atypical mycobacterial species (AMS) in specific areas of the new buildings began in Apr 2019. Where reactive sampling was carried out specifically to assist IPC/IMTs, *ad hoc* tests for specific microorganisms were instead ordered, often in conjunction with one or more of the routine tests.

Table 1 shows the routine water tests commonly carried out on the QEUH campus. All three laboratories (Environmental Laboratory, ALcontrol, and Intertek) performed the standard potable, Pseudomonas and Legionella tests, though Intertek did not include a separate PA100 in its Pseudomonas testing, and the Environmental Laboratory and ALcontrol included it only in a subset of their Pseudomonas tests. Routine fungal testing was carried out by both the Environmental Laboratory and Intertek, whereas routine testing for other organisms, some of which was bespoke to GG&C (e.g. GNBs, Cupriavidus) was carried out by the Environmental Laboratory. The Environmental Laboratory SOP entitled *LP538 Non Legionella Water Testing: Potable Water & Endoscopy Analysis (LP538)* details its testing, control, and reporting procedures, as well as its operating thresholds for out-of-spec results. The SOP has a procedure in place for *ad hoc* investigations requested by IPC teams. Legionella testing is covered by the Environmental Laboratory's SOP entitled *LP532 Detection & Enumeration of Legionella by Filtration*.

For the purpose of microbiological water testing and reporting, specific areas on the QEUH campus have been designated as high risk by the QEUH Estates Department and IPC, as detailed in the QEUH Estates Department SOP entitled *WQS-017 Procedures in the event of out of specification sample for Legionella and other monitored bacteria, moulds etc.*. High-risk areas are predominantly located in the new buildings. They include transplant and haematology units, intensive care and high dependency units, and others (see Supplemental Information for details on which wards are classified as high risk). Stricter water testing thresholds are applied in these areas (Table 1). In addition, the specialist units within the new buildings (aseptic pharmacies and RHC Theatre 8) that have their own testing arrangements also have different thresholds. Outwith these high-risk and specialist areas, general microbiological thresholds are applied across the QEUH campus.

Table 1. Routine water tests and count thresholds for out-of-spec results

Test	Type	Description	Thresholds (general)	Thresholds (high risk)	Thresholds (specialist)
Legionella	Legionella	Legionella count per 1L (any species/serogroup)	Any count	Any count	Any count
PS100	Pseudomonas	Pseudomonas species count per 100 ml	10 CFU/100 ml	Any count	Any count
PA100	Pseudomonas	Pseudomonas aeruginosa count per 100 ml	10 CFU/100 ml	Any count	Any count
TVC37	potable	Total viable count (37°C) per 1 ml	100 CFU/ml	10 CFU/ml	10 CFU/ml
TVC22	potable	Total viable count (22°C) per 1 ml	100 CFU/ml	10 CFU/ml	100 CFU/ml
CF100	potable	Coliform count per 100 ml	Any count	Any count	Any count
EC100	potable	*Escherichia* count per 100 ml	Any count	Any count	Any count
SAB30	fungi	Fungal count at 30°C	10 CFU/100 ml	10 CFU/100 ml	NA
SAB22	fungi	Fungal count at 22°C	10 CFU/100 ml	10 CFU/100 ml	NA
GNB	Gram negative bacteria incl. Cupriavidus	GNB count per 100 ml	Any count	Any count	NA
AMS	Atypical mycobacteria	AMS count per 100 ml	Any count	Any count	Any count

The thresholds shown in Table 1 are those currently applied to different areas of the QEUH campus. Not all of these thresholds would have been in place throughout the period 2015-2020. Routine fungal and GNB testing began in Dec 2018, whereas AMS testing began in Apr 2019, and the more stringent TVC22 threshold for high-risk areas was introduced in Dec 2018. A large amount of reactive testing specifically for Cupriavidus and other GNBs was carried out in March-Apr 2018, but routine testing for these organisms was only described in WQS-017 in Dec 2018. An outline of the thresholds used for each routine test throughout the period 2015-2020 can be found in the report entitled *Summary of legislation and guidance for routine microbiological water tests carried out at QEUH Adults and RHC*.

Overview of water testing numbers 2015-2020

Table 2 shows the annual numbers of water samples collected and the numbers of different microbiological tests that were carried out. There was a marked increase in sample and test numbers in 2019-2020 compared with the earlier years, due to the expanded programme of sampling and testing that was implemented in the new buildings in Dec 2018 to coincide with the installation of on-site chlorine dioxide dosing systems.

Table 2. Annual numbers of water samples and microbiological tests carried out across the whole QEUH campus (new and retained buildings)

Year	Number of samples[1]	Legionella tests	Pseudomonas tests	Potable tests	Fungal tests	Cupriavidus/ GNB tests[2]	AMS tests	Other specific tests
2015	3781	2262	749	889	0	0	0	0
2016	3248	2393	782	413	0	0	0	194
2017	2335	1480	620	390	0	0	0	258
2018	5406	2605	554	810	400	2148	0	81
2019	6118	3947	3939	4507	3217	657	412	81
2020	8203	4154	5577	5996	2429	3525	517	124
Total	29 091	16 841	12 221	13 005	6046	6330	929	738

[1]Samples were frequently booked in for more than one type of test.
[2]Reactive testing for Cupriavidus and other GNBs was predominantly carried out in Mar-Apr 2018, with routine testing for these organisms implemented in Dec 2018.

Samples were often booked in for more than one type of test, so there is some incomplete overlap between test numbers. The largest number of samples underwent only Legionella testing, followed by the number of samples that underwent two or more of the standard routine tests (Legionella, Pseudomonas, potable, fungi). Monthly test numbers in the new versus the retained buildings for each of the routine tests are shown in the following section (Microbiological test results).

Although a broad distinction can be made between routine and reactive water testing, in reality, over the period 2015-2020, this distinction was more nuanced due to variations in the tests ordered by IPC teams during reactive sampling, which differed among IPC doctors and also with the nature of the IMT investigation. In some instances, the reactive tests ordered were for one or two specific microorganisms, but in other cases, a broader suite of general tests was requested instead of or alongside specific microorganism tests. Occasionally, rather than requesting tests for a specific organism, IPC/IMTs requested an *ad hoc* version of a general test, notably TVC per 100 ml, which is carried out by filtration and allows subsequent identification of any colonies that grow, rather than the standard TVC per ml, carried out by the pour plate method, where colonies are embedded in agar and cannot subsequently be identified.

A summary of all test requests in the new and retained buildings is shown in Figure 1. This includes the routine tests as well as each of the reactive tests for a specific named microorganism and *ad hoc* tests, such as TVC per 100 mL.

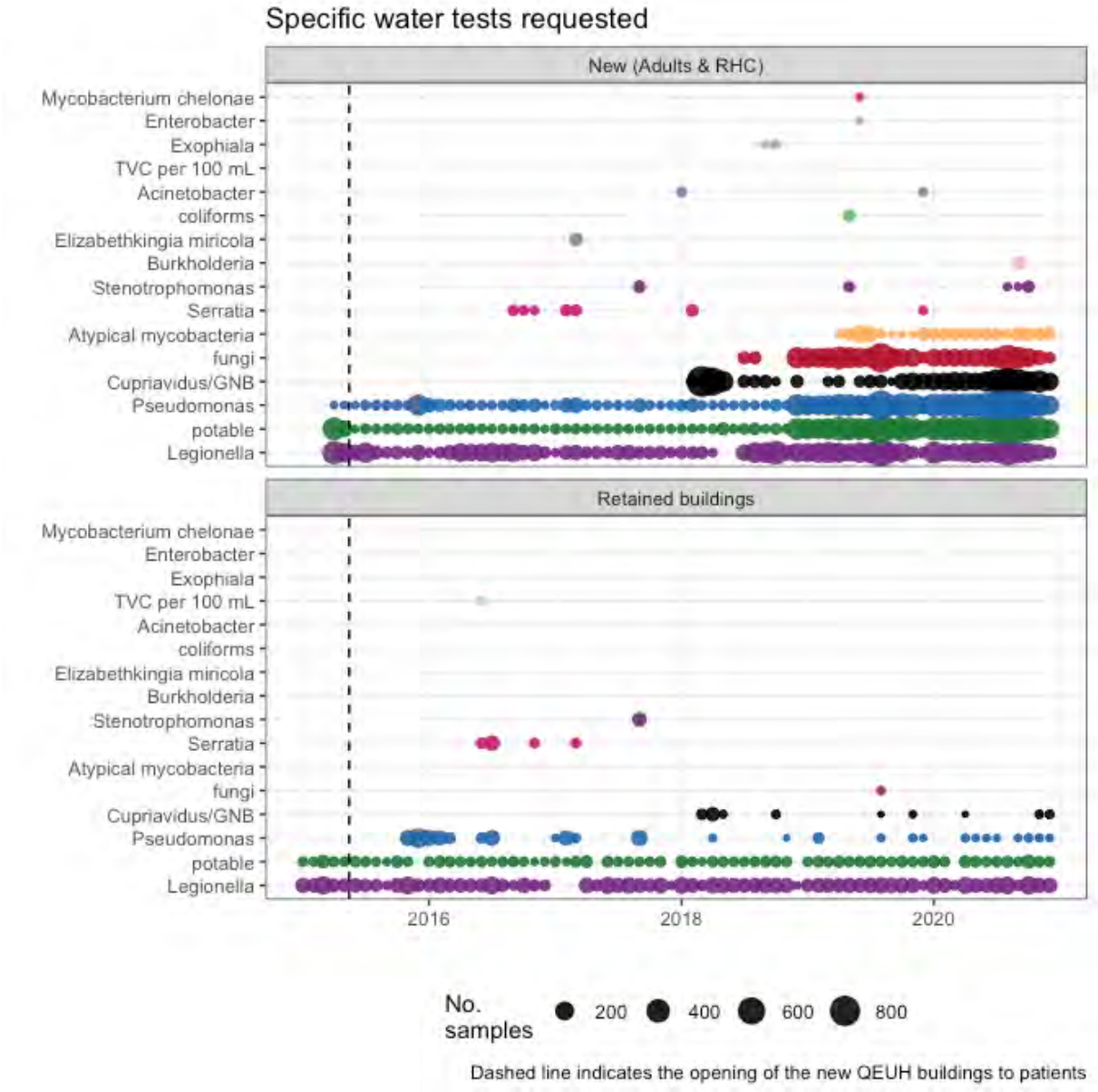


Figure 1. Types of microbiological tests requested across the QEUH campus, 2015-2020. Circle size is proportional to the number of tests per month.

Figure 1 shows tests that were requested at the time of sampling, not an indication of the microbiological results that were subsequently reported (microbiological results are presented in the next section). The test(s) requested on the sample login sheets did not generally constrain the identification of microorganisms, as the Environmental Laboratory regularly identified organisms that grew in general tests, as well as non-target species that grew in specific tests (see below).

Microbiological results: Out-of-spec samples

This section shows the number of samples classified as passes or out of spec on Legionella, Pseudomonas, potable, fungal, Cupriavidus/GNB, and AMS tests over the period 2015-2020 (a sample is deemed out of spec when the microbial counts exceeded the thresholds set by GG&C, outlined in Table 1). More detailed named organism results will be shown in the following section. This section gives a broad overview of sample numbers but does not delve further into the nature of the out-of-spec samples or the sampling context - whether a point-of-use (POU) filter was fitted and if so, whether the sample was taken through the POU filter or after its removal, whether the sample was collected before or after outlet flushing, whether it was a repeat sampling following an earlier out-of-spec result, etc.

Of the routine microbiological water tests carried out by GG&C, only those for Legionella and Pseudomonas have required or recommended thresholds in applicable legislation and guidance, and the GG&C thresholds in Table 1 meet or exceed those requirements or recommendations (for more details, refer to the report entitled *Summary of legislation and guidance for routine microbiological water tests carried out at QEUH Adults and RHC*). Coliform and E.coli tests, included in the potable water panel of tests, also have legal thresholds for water to meet potable standards (any count is considered out of spec), but routine potable testing is not required in healthcare settings, except in specific circumstances (see the summary of legislation and guidance report).

The thresholds used in this section to classify samples as passes or out of spec are those currently in place for the QEUH campus and listed in Table 1, with appropriate thresholds applied to samples depending on whether they were from general, high-risk, or specialist areas. However, it is important to note that here, in order to allow a valid comparison of water results over the period 2015-2020, the current thresholds are being applied retrospectively to samples that were collected before some of these thresholds were in place, including the more stringent high-risk TVC22 threshold (10 CFU/mL) that was implemented in Dec 2018. This will classify some samples as out of spec that would not have been considered out of spec at the time, but a temporal comparison is only valid if the same thresholds are applied throughout the period under consideration.

The current process for dealing with out-of-spec water results on the QEUH campus is detailed in the QEUH Estates Department SOP WQS-017. Briefly, when the Environmental Laboratory and Intertek send microbiological results to DMA, any out-of-spec samples are flagged and their details entered in a dedicated spreadsheet (out-of-spec summary sheet). Full results, including the out-of-spec summary sheet, are shared with QEUH Estates, GG&C Microbiology, and contacts in IPC. Any serious issues are immediately reported to the Lead Authorised Person (LAP) in QEUH Estates. For all out-of-spec samples, the LAP logs an Incident Report, which triggers a work request for remedial action. All remedial work is logged on the out-of-spec summary sheet, and DMA continue sampling the affected outlets until a minimum of three clear results are obtained.

Legionella test results

Overall, 16 841 samples underwent Legionella testing. Here, any detection of Legionella is considered out of spec, regardless of location, species or serogroup, a stricter threshold than in applicable legislation and guidance. Over the period 2015-2020, there were 1096 out-of-spec samples in total (6.5% of samples). The older retained buildings had a higher prevalence of Legionella-positive samples (718 samples out of 5923, or 12.1%), compared with the new buildings (378 Legionella-positive samples out of 10 918, or 3.5%). Monthly numbers of Legionella samples that were out of spec versus those that passed are shown in Figure 2.

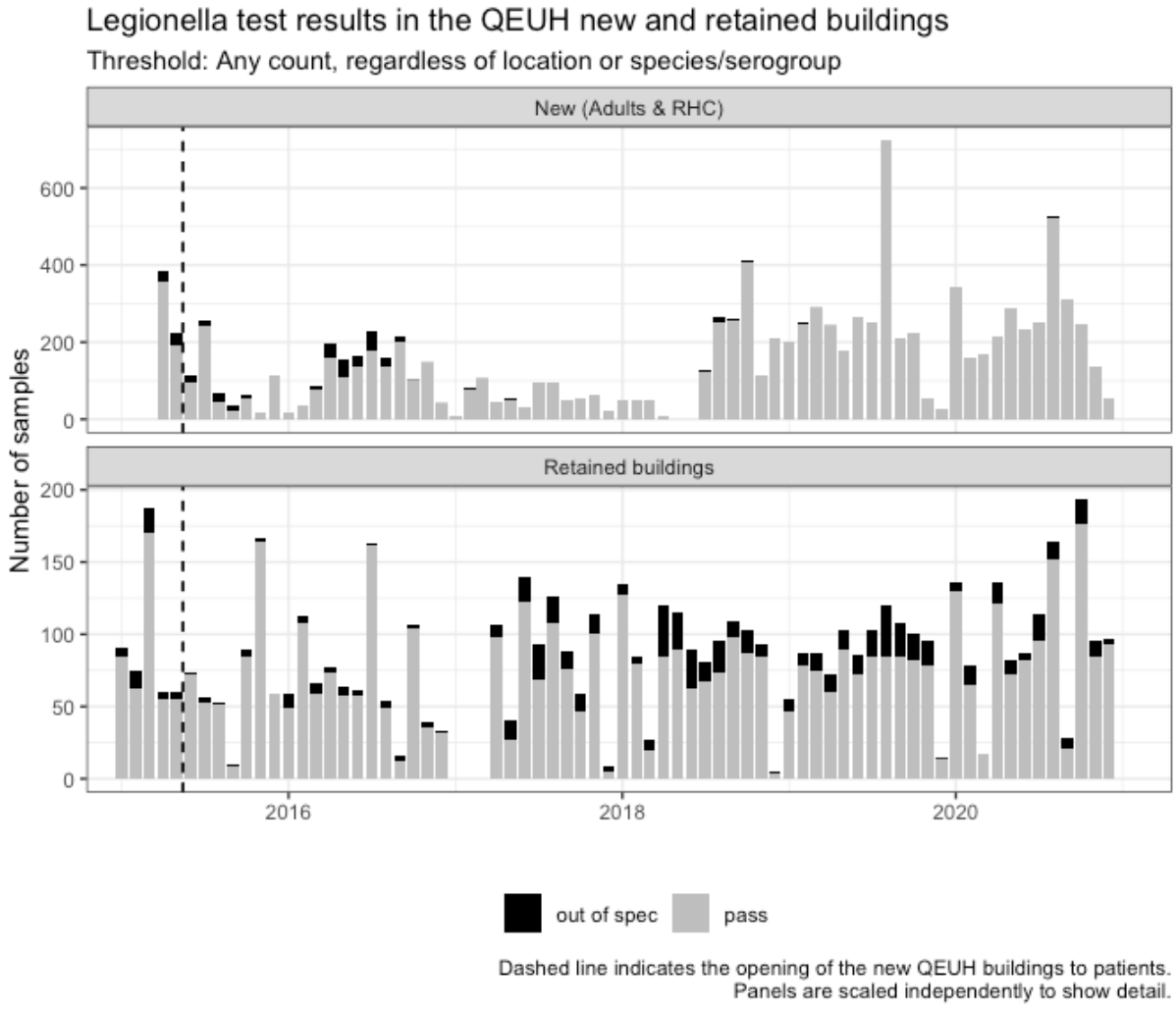


Figure 2. Number of Legionella tests out of spec per month across the QEUH campus (new versus retained buildings). Panels are scaled independently to show detail.

Figure 2 gives the number and distribution of samples that had any Legionella count, regardless of species and serogroup. However, when Legionella counts are detected, the testing laboratories provide additional species and serogroup information to distinguish between the following: *Legionella pneumophila* serogroup 1, the variant that causes

approximately 95% of human cases (Lp.1), *Legionella pneumophila* serogroups 2 to 14 (Lp.2-14), or other Legionella species (L.species). Figure 3 shows the species/serogroup results for these out-of-spec samples.

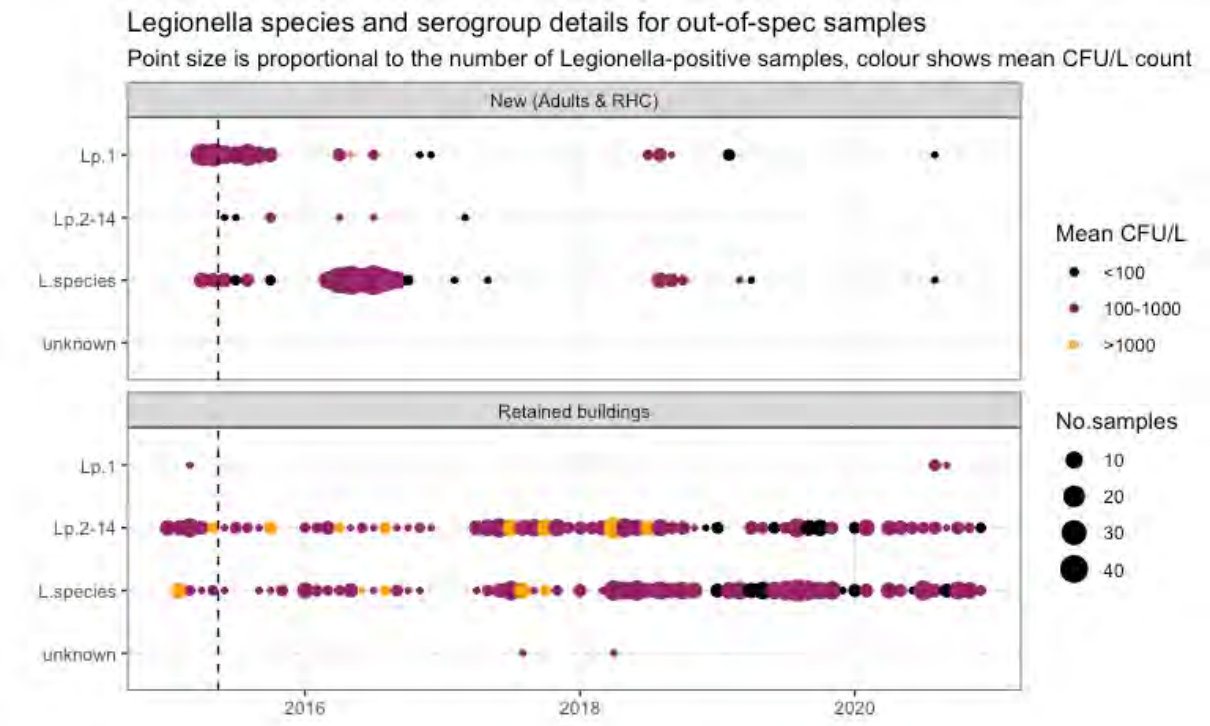


Figure 3. Legionella species and serogroup details for out of spec samples across the QEUH campus.

Legionella pneumophila serogroup 1 (Lp.1) was rarely detected in the new buildings after late 2015. Samples testing positive for Lp.1 were concentrated in the months prior to and immediately following opening. *Legionella pneumophila* serogroups 2-14 were almost absent from the new buildings over the entire period, and other Legionella species were detected only sporadically, with the largest occurrence in 2016. Across the retained buildings, Lp.1 was almost absent, whereas Lp.2-14 and L.species were detected more frequently.

Pseudomonas test results

It is important to note a possible data entry or transcription error that might be inflating the Pseudomonas out-of-spec results in the new buildings in 2015-2016. In the new buildings, out-of-spec Pseudomonas results were reported mostly over the period Jul 2015 to Sep 2016, with few out-of-spec Pseudomonas results after that date. Most of these samples were from the new building aseptic pharmacies, apart from the larger number collected in Dec 2015 from other areas. Closer inspection of the data recorded in TelePath shows that for most of the CFU counts recorded for the aseptic pharmacies in the PS100 column over this period (the Pseudomonas species test), an identical number is also entered in another data column reserved for other named organisms, next to a named species (often *Cupriavidus pauculus* but occasionally other species, including *Comamonas testosteroni*, *Achromobacter denitrificans*, and *Alcaligenes faecalis*). This exact duplication of counts suggests that the numbers reported in the PS100 column from Jul 2015 to Sept 2016 (excluding Dec 2015) were the total number of colonies on the agar plate, not those that had been confirmed as Pseudomonas, and that these colonies were subsequently identified as being other species. If this were the case, most of the samples flagged as out-of-spec for Pseudomonas over this period would instead be passes. This section shows both the reported Pseudomonas results, including these likely transcription errors, and the corrected Pseudomonas results, where these duplicated counts are excluded.

Overall, 12 221 samples from across the QEUH campus underwent Pseudomonas testing (Figure 4). Thresholds for Pseudomonas tests (PS100 or PA100) differ by location (Table 1): 10 CFU/100 mL in general areas, and no count in high-risk and specialist areas. Over the period 2015-2020, there were 221 out-of-spec samples in total (1.8% of samples), though this number drops to 131 out-of-spec samples (1.1%) when likely transcription errors are corrected (transcription errors only affected samples from the new buildings). New buildings had a lower percent out of spec (1.8% / 0.95% corrected) than retained buildings (2.3%).

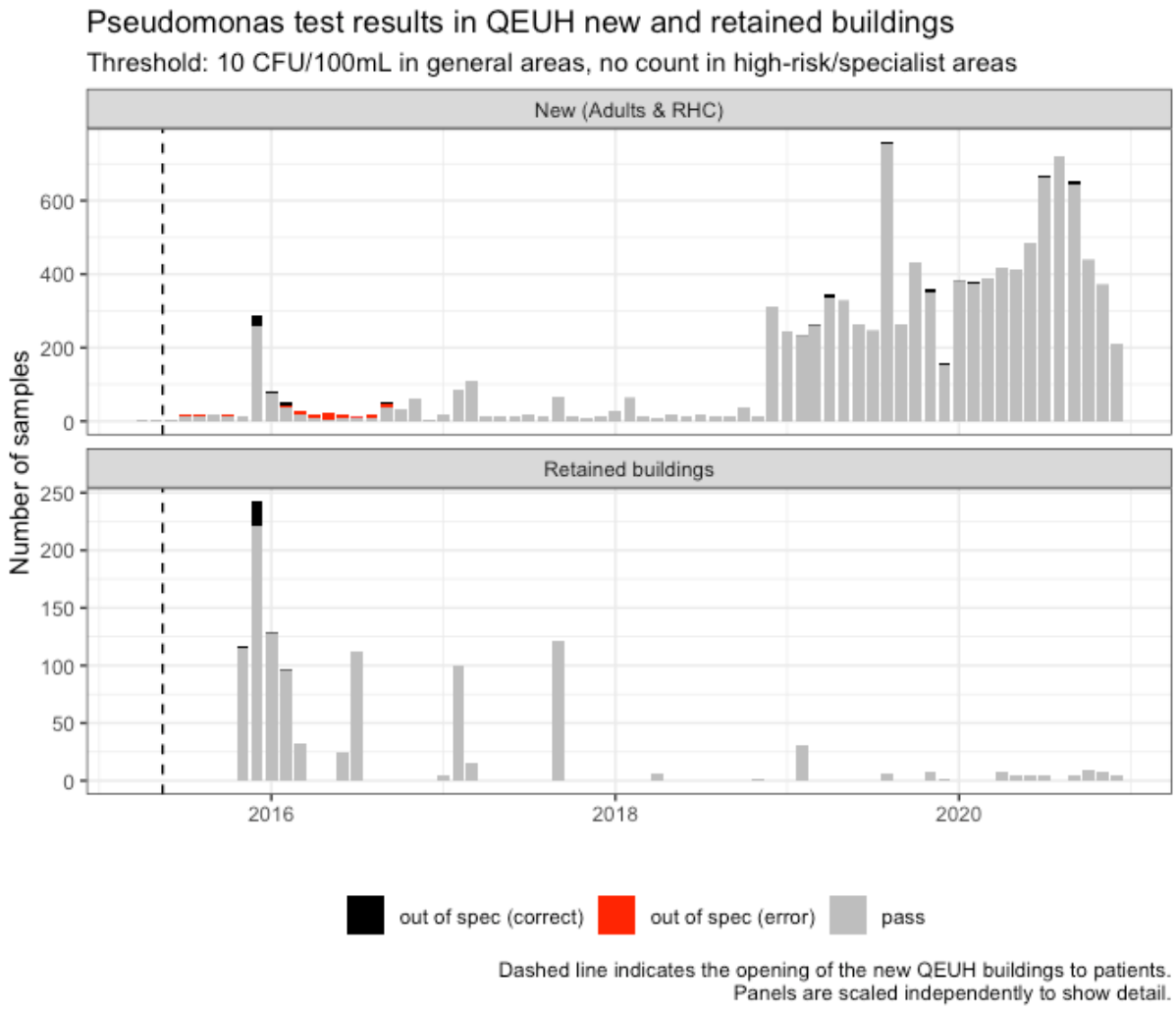


Figure 4. Number of Pseudomonas tests out of spec per month in the QEUH new and retained buildings. Panels are scaled independently to show detail.

Potable test results

Potable water samples include all those with microbiological results for TVC37, TVC22, CF100 and EC100. Of the 13 005 potable tests carried out across the whole QEUH campus over the period 2015-2020, 722 were out of spec (5.6%). The majority of out-of-spec samples failed due to elevated TVC22 (514 samples in total, i.e. 4.0%) and/or TVC37 (389 samples in total, i.e. 3.0%) (Figure 5). CF100 (coliforms per 100 mL) counts were less often responsible for out-of-spec results (63 samples in total, i.e. 0.48%), and EC100 counts (*Escherichia coli* per 100 mL) were only observed in three samples (0.023%).

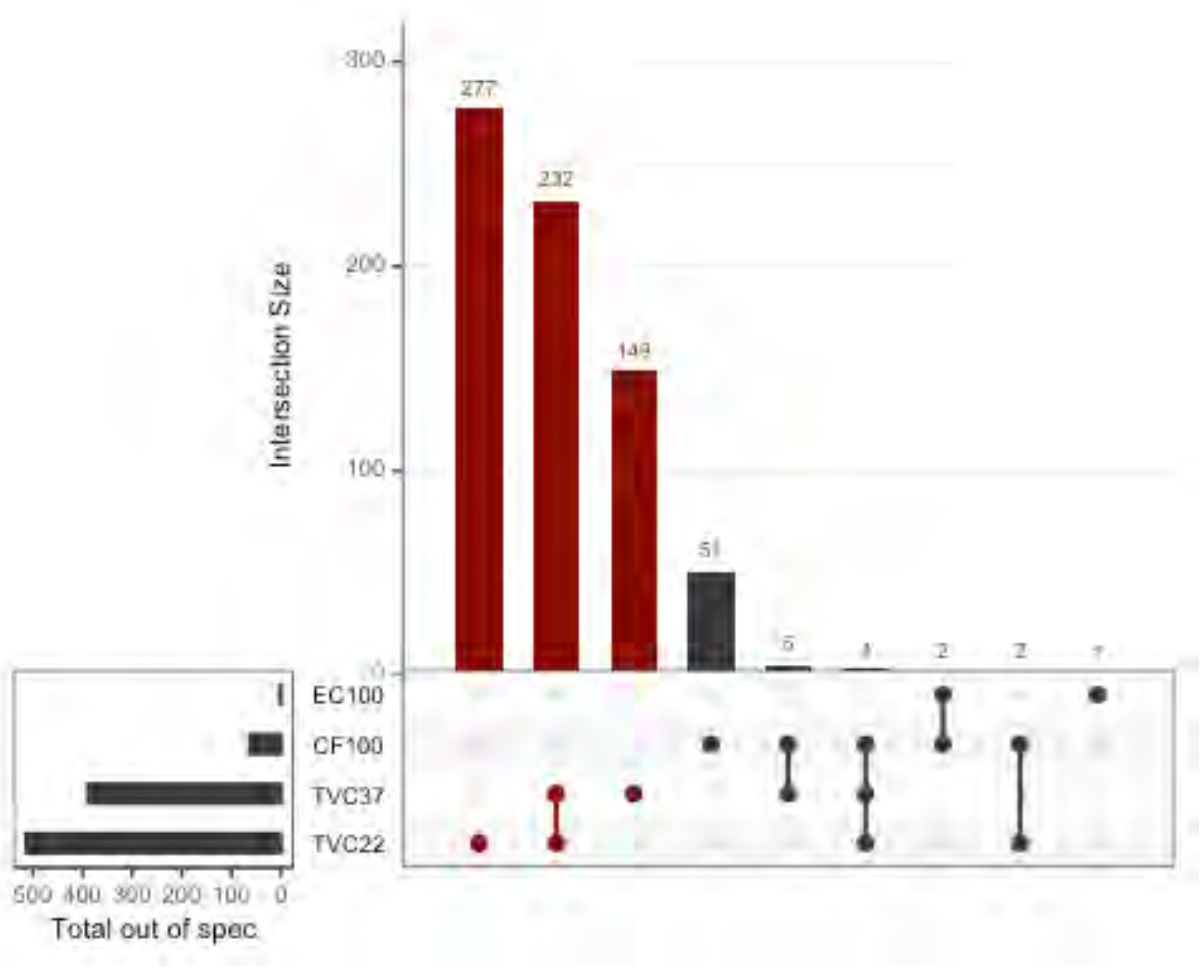


Figure 5. Specific tests responsible for potable water out-of-spec results across the QEUH campus 2015-2020. Red bars indicate the number of samples that failed on TVCs only, black bars show number of samples with out-of-spec results in CF100 and/or EC100

Thresholds currently in place for potable testing vary by location, with the strictest ones being applied in high-risk areas (10 CFU/mL on both TVC22 and TVC37), intermediate ones in specialist units (10 CFU/mL on TVC37, 100 CFU/mL on TVC22), and less stringent ones in general areas (100 CFU/mL on both TVC37 and TVC22). Coliform and E.coli counts must be zero in all areas.

Figure 6 shows the number of potable water samples from the new and retained buildings, grouped by month, that passed all four potable tests, versus the number that were out of spec (i.e. exceeded thresholds on one or more of the four tests). Of the 11 360 samples tested from the new buildings, 667 (5.9%) were out of spec, whereas in the retained buildings, 55 samples out of 1645 (3.3%) were out of spec.

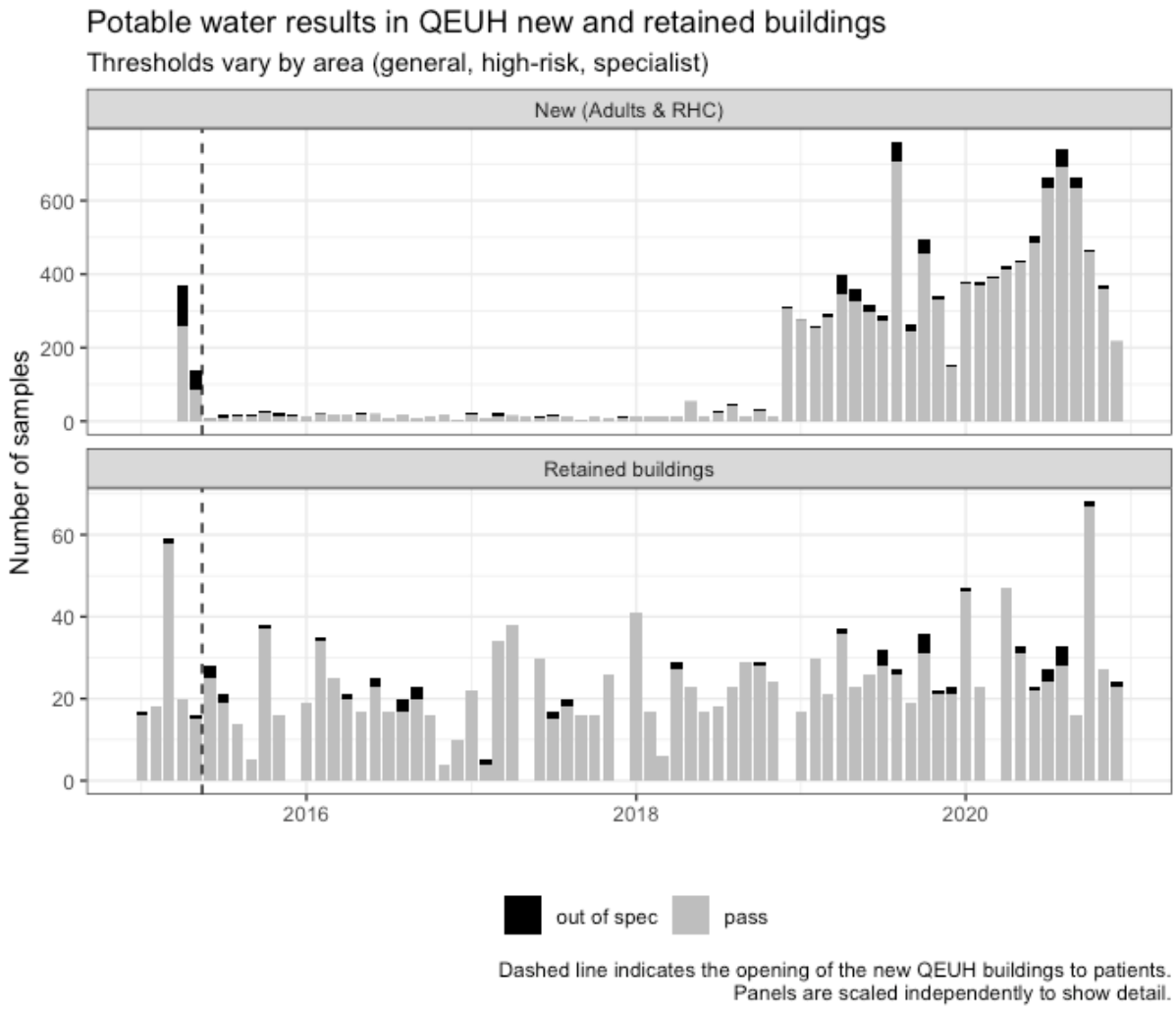


Figure 6. Number of potable tests out of spec per month across the QEUH new and retained buildings. Panels are scaled independently to show detail.

Fungal test results

Routine fungal testing began in the new buildings in Dec 2018, though reactive fungal testing occurred earlier in 2018 on a smaller scale (Figure 7). Overall, 6046 samples underwent routine fungal testing (SAB30 and SAB22), of which 6040 were from the new buildings. Of the 6 samples from the retained estate, 2 were out of spec (33.3%), whereas in the new buildings, 605 samples (10.0%) were out of spec.

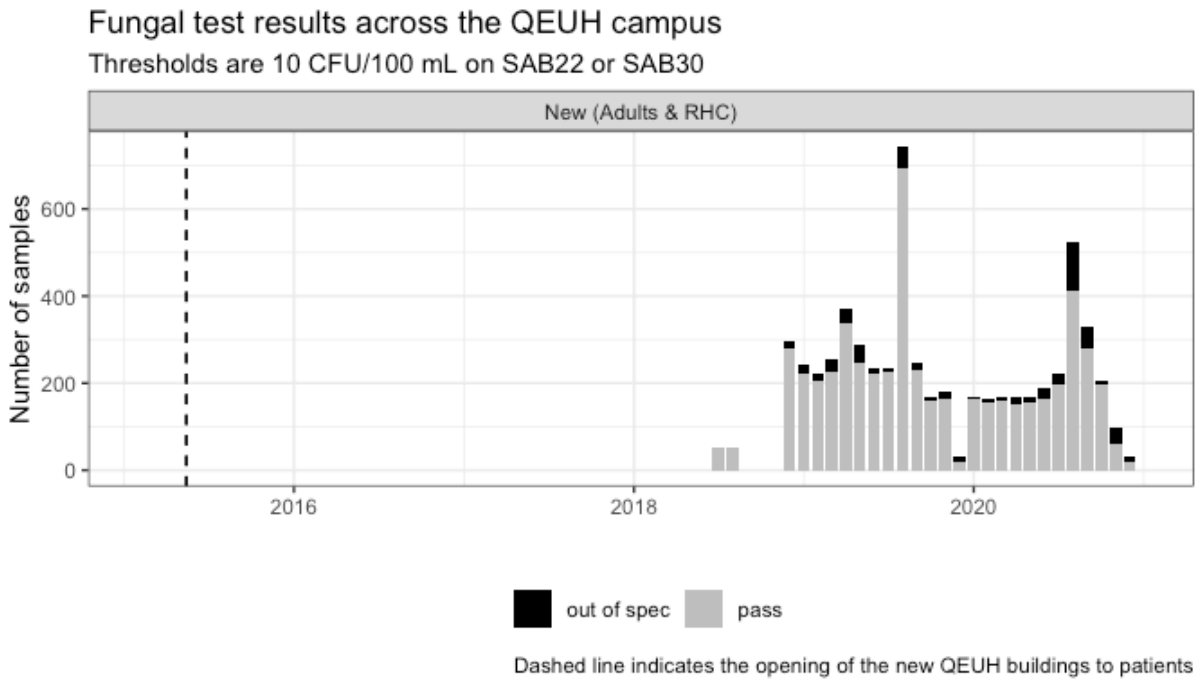


Figure 7. Number of fungal tests out of spec per month across the QEUH campus. Fungal testing was only carried out in the new buildings.

Cupriavidus and other Gram negative bacteria

Overall, 6330 samples from across the QEUH campus underwent specific testing for Cupriavidus and other GNBs. The vast majority of these, 6183 samples, were from the new buildings, with only 147 samples from retained buildings (Figure 8).

Across all these samples, 4.4% were positive for Cupriavidus (280 samples) and a further 15.6% (988 samples) were negative for Cupriavidus but positive for at least one other GNB, giving an overall positivity rate for any GNB of 20.0%. The percent of samples that were Cupriavidus-positive was similar in the new and retained buildings (4.4% and 3.4%, respectively), but the percent of additional samples with other GNBs was much higher in the retained buildings (36.1%) than in the new buildings (15.1%).

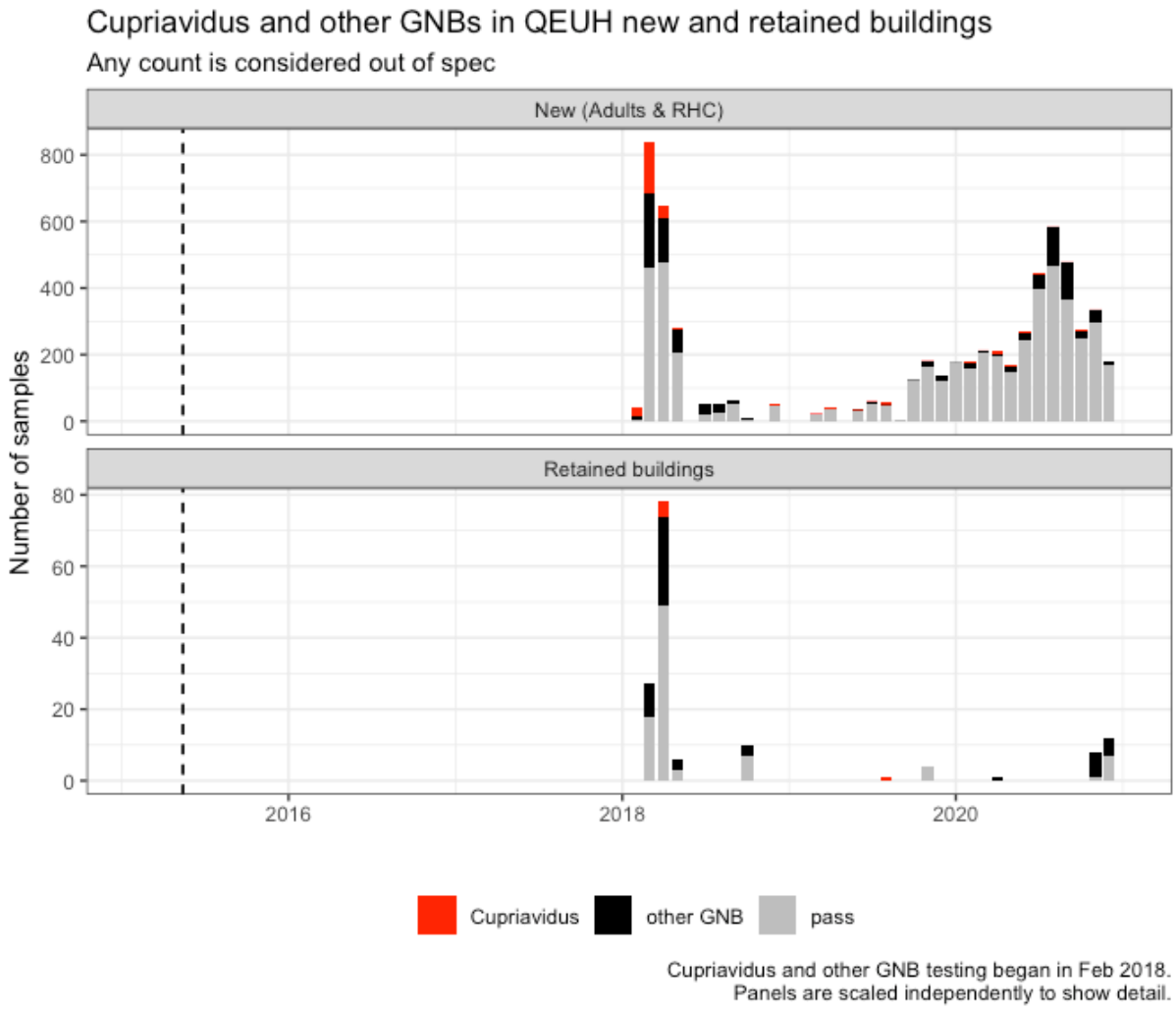


Figure 8. Number of Cupriavidus and other GNBs out of spec per month in QEUH new and retained buildings. Testing for these organisms was almost exclusively carried out in the new buildings.

Atypical mycobacteria test results

Overall, 929 samples underwent specific testing for AMS, which was limited to the new buildings but not carried out in the specialist units. There were 85 out-of-spec samples in total (9.1% of samples). Total AMS passes and out-of-spec results, grouped by month, are shown in Figure 9.

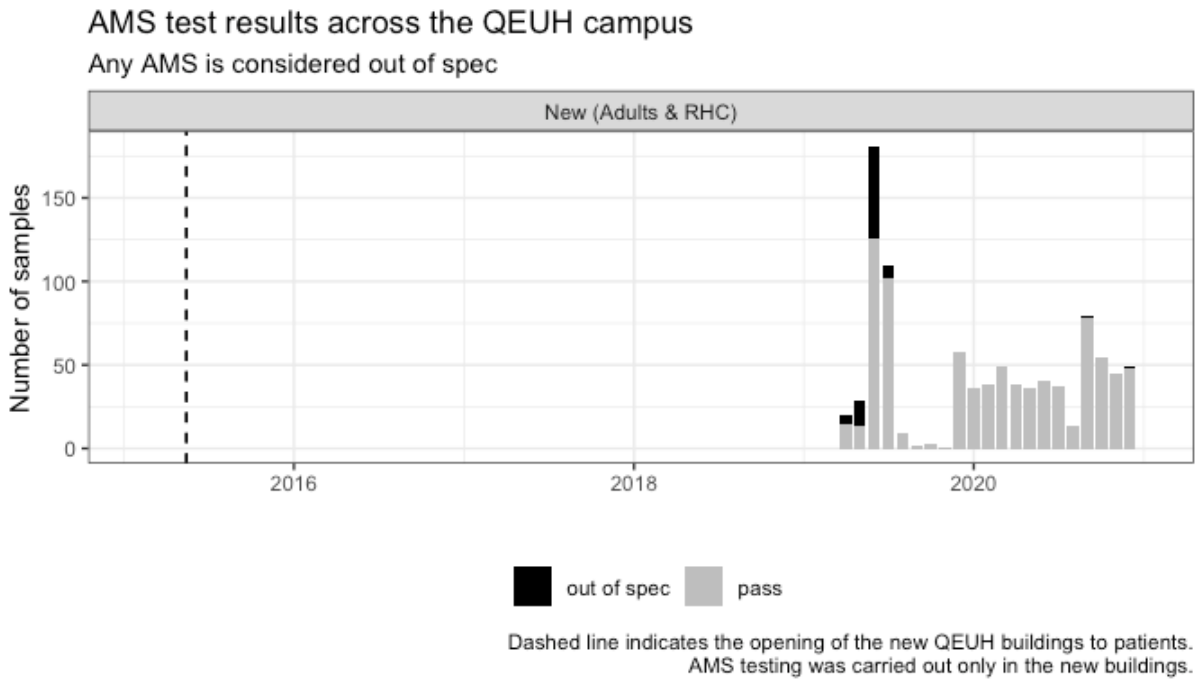


Figure 9. Number of AMS tests out of spec per month across the QEUH campus. AMS testing was carried out only in the new buildings.

Microbiological results: Named microorganisms

In routine potable, Pseudomonas and fungal testing, as well as in other microbiological tests, a water sample of a specified volume is either mixed directly with molten agar and allowed to solidify (for standard TVC37 and TVC22 tests), or filtered through a sterile membrane, which is placed on the surface of a solidified nutrient agar plate. Cells that had been present in the original water sample are thus immobilised in or on top of the solidified growth media. During incubation at a set temperature for a specified amount of time, some of these cells will replicate and form visible colonies, which are counted and reported as colony-forming units per volume of the original sample. The composition of the growth media can select for certain types of bacteria or fungi - for example, the media used in TVC tests is a general nutrient agar, since the goal is to encourage the growth of any organism in the sample, whereas Pseudomonas medium is selective, containing compounds that encourage Pseudomonas species and inhibit others. However, selective growth media are not perfect. Non-target organisms can also grow in organism-specific tests, so laboratory staff carry out further tests to confirm the identity of the colonies. Depending on the laboratory, its reporting practices and criteria, and the requests of the sample sender, non-target organisms may or may not be recorded and reported to the sender. For example, where a request is for Pseudomonas testing, a standard report would summarise how many, if any, confirmed Pseudomonas colonies were detected. Non-target organisms would not automatically be included in such a report.

With regards to the water testing carried out across the QEUH campus over the period 2015-2020, ALcontrol and Intertek did not report non-target organisms from colonies obtained during routine potable, Pseudomonas or fungal testing. However, for testing

carried out by the Environmental Laboratory, all the data recorded in TelePath were available, including any information recorded by laboratory staff on the identification of non-target organisms. As such, data shown in this section are from the routine and reactive samples analysed by the Environmental Laboratory.

Some of these data, notably in the earlier part of the time period (2015-2017), were recorded in a field called 'Laboratory Comments Not Reported', suggesting that the sample sender would only have received the results specific to the test they had requested (e.g. 'Pseudomonas - not detected'). In other cases, the non-target organism IDs were recorded under various 'Laboratory Comments' fields, so it is unclear whether these would have been communicated with the sample sender. Finally, as there is no requirement to report non-target organisms, there is likely an amount of variability in how and when the non-target organism information was recorded, or whether it was recorded at all. However, once testing for Cupriavidus/GNBs and fungi began in 2018, the recording of organism IDs and their CFU counts into specific database fields was standardised.

Environmental organisms with mandatory reporting

The National Infection Prevention and Control Manual (NIPCM), Appendix 13, describes the nationally agreed mandatory minimum list of alert organisms for infections to be reported to Infection Prevention and Control Teams and includes certain organisms under the heading "Environmental bacteria". The NIPCM does not mandate routine testing for or reporting the presence of these organisms in environmental samples outwith investigations into clinical cases. The four organisms currently listed under this heading in Appendix 13 are: *Pseudomonas aeruginosa*, Acinetobacter species, *Stenotrophomonas maltophilia*, and *Serratia marcescens*, though the guidance recognises that this list is not exhaustive. These environmental organisms were added to the NIPCM on 30 June 2017, and were added to the GG&C ICNet alert list in August 2017 after going through the necessary IPC governance committees.

Across all 12 526 water samples tested by the Environmental Laboratory from 2015-2020, excluding the samples tested only for Legionella, no *Serratia marcescens* were detected, and *Pseudomonas aeruginosa* were found in a total of 8 samples (only those out-of-spec Pseudomonas tests that confirmed the identification as *P. aeruginosa* are included here, since other Pseudomonas species can grow in those test). *Stenotrophomonas maltophilia* occurred in 76 samples, whereas 8 distinct Acinetobacter species were observed across 79 samples, with *Acinetobacter lwoffii* and *Acinetobacter ursingii* being the most common ones (38 and 23 samples, respectively).

Other environmental organisms

The NIPCM guidance recognises that the list of environmental alert organisms is not exhaustive. As expected with potable water, which is not naturally a sterile environment, many more taxa were identified in all test types. Across all 12 526 samples from the QEUH new and retained buildings tested by the Environmental Laboratory over the period 2015-2020, 105 bacterial taxa were identified. Of these, 32 were rare, occurring in only one sample across the entire data set. Furthermore, 30 fungal taxa were reported, with 9 occurring in a single sample. While routine fungal testing did not begin until Dec 2018, specific fungal taxa were reported prior to that date.

Table 3 shows all bacterial taxa detected across the QEUH campus and Table 4 shows all fungal taxa, in decreasing order of total abundance (number of samples). Some of the entries are not true taxonomic groups, but broad categories that likely encompass a wide diversity of organisms (e.g. Environmental GNB, Saprophytic fungi). True taxonomic names are shown in italics, and entries ending in 'species' were resolved only to the coarser genus level.

Table 3. All bacterial taxa detected in water samples from the QEUH campus, with number of positive samples from new and retained buildings.

Bacterial ID	New buildings	Retained buildings	Total[1]
Cupriavidus pauculus	440	7	447
Environmental GNB (unspecified)	193	37	230
Sphingomonas paucimobilis	206	20	226
Delftia acidovorans	168		168
Comamonas testosteroni	119	1	120
Stenotrophomonas maltophilia	76		76
Atypical mycobacteria	56		56
Sphingobium xenophagum	47		47
Cupriavidus gilardii	41	4	45
Pseudomonas veronii	45		45
Acinetobacter lwoffii	36	2	38
Pseudomonas fluorescens	30	3	33
Acidovorax delafieldii	18	12	30
Mycobacterium chelonae	29		29
Brevundimonas species	22	3	25
Brevundimonas diminuta/vesicularis	21	3	24
Acinetobacter ursingii	22	1	23
Enhydrobacter aerosaccus	22		22
Blastomonas ursincola	15	6	21
Bordetella bronchiseptica	19		19
Achromobacter xylosoxidans	18		18
Acidovorax temperans	7	9	16
Chryseobacterium indologenes	12		12
Rhizobium radiobacter	8	3	11
Roseomonas mucosa	11		11

Bacterial ID	New buildings	Retained buildings	Total[1]
Sphingobium yanoikuyae	11		11
Achromobacter denitrificans	9		9
Bordetella hinzii	9		9
Roseomonas gilardii	9		9
Brevundimonas diminuta	8		8
Brevundimonas vesicularis	8		8
Pantoea agglomerans	5	3	8
Pseudomonas aeruginosa	8		8
Acinetobacter johnsonii	7		7
Staphylococci	6	1	7
Alcaligenes faecalis	6		6
Enterobacter cloacae	5	1	6
Microbacterium oxydans	6		6
Pseudomonas anguilliseptica	6		6
Pseudomonas oleovorans	6		6
Pseudomonas species	6		6
Pseudoxanthomonas mexicana	5	1	6
Lelliottia amnigena	5		5
Pseudomonas putida	5		5
Ralstonia pickettii	5		5
Achromobacter species	4		4
Acinetobacter species	4		4
Alcaligenes species	4		4
Cupriavidus species	4		4
Microbacterium flavescens	4		4
Microbacterium flavescens/laevaniformans	4		4
Acinetobacter junii		3	3
Burkholderia gladioli	3		3
Klebsiella pneumoniae	3		3
Morganella morganii	3		3
Pseudomonas chlororaphis	3		3
Ralstonia insidiosa	3		3

Bacterial ID	New buildings	Retained buildings	Total[1]
Raoultella terrigena	3		3
Serratia fonticola	3		3
Sphingobacterium thalpophilum	3		3
Sphingomonas species	3		3
Aeromonas salmonicida	2		2
Burkholderia species	2		2
Cronobacter sakazakii	2		2
Gardnerella species	2		2
Gram positive		2	2
Pantoea species	2		2
Pseudomonas alcaligenes	2		2
Pseudomonas pseudoalcaligenes	2		2
Shewanella putrefaciens	2		2
Sphingobacterium multivorum	2		2
Sphingomonas adhaesiva	2		2
Sphingomonas melonis	2		2
Acinetobacter calcoaceticus	1		1
Acinetobacter gyllenbergii	1		1
Acinetobacter haemolyticus	1		1
Acinetobacter radioresistens	1		1
Aeromonas media	1		1
Aeromonas species	1		1
Bacillus species	1		1
Burkholderia cepacia	1		1
Burkholderia mallei	1		1
Cedecea lapagei	1		1
Chryseobacterium species	1		1
Citrobacter species	1		1
Clostridium beijerinckii	1		1
Clostridium sporogenes		1	1
Corynebacterium species	1		1
Delftia species	1		1

Bacterial ID	New buildings	Retained buildings	Total[1]
Enterobacter species	1		1
Klebsiella oxytoca		1	1
Kluyvera intermedia	1		1
Leclercia adecarboxylata	1		1
Microbacter species	1		1
Moraxella species	1		1
Mycobacterium szulgai	1		1
Myroides species	1		1
Neisseria animaloris	1		1
Paenibacillus durus	1		1
Paenibacillus species		1	1
Paracoccus yeei	1		1
Pseudomonas oryzihabitans	1		1
Raoultella species	1		1
Rothia dentocariosa	1		1
Sphingobacterium spiritivorum	1		1

[1]Out of 12 526 samples tested by the Environmental Laboratory 2015-2020 (10 311 from the new buildings and 2215 from the retained buildings), excluding those tested only for Legionella.

Table 4. All fungal taxa detected in water samples from the QEUH campus, with number of positive samples from new and retained buildings.

Fungal ID	New buildings	Retained buildings	Total[1]
Saprophytic fungi	800	68	868
Mycelia sterilia	239	2	241
Dematiaceous hyphomycete	239		239
Hyaline hyphomycete	154	1	155
Cladosporium species	60		60
Fungi	57	2	59
Exophiala species	57		57
Aspergillus fumigatus	54	2	56
Aspergillus niger	27	1	28

Fungal ID	New buildings	Retained buildings	Total[1]
Purpureocillium lilacinum	26		26
Aspergillus versicolor	24		24
Acremonium species	21		21
Penicillium species	20		20
Exophiala equina	15		15
Rhodotorula species	15		15
Fusarium species	11		11
Aspergillus species	8	1	9
Yeast	9		9
Exophiala dermatitidis	8		8
Paecilomyces species	8		8
Mould	4		4
Absidia species	1		1
Aspergillus flavus	1		1
Aspergillus glaucus	1		1
Candida famata	1		1
Candida parapsilosis	1		1
Neoscytalidium dimidiatum	1		1
Phoma species	1		1
Scytalidium hyalinum	1		1
Verticillium species	1		1

[1]Out of 12 526 samples tested by the Environmental Laboratory 2015-2020 (10 311 from the new buildings and 2215 from the retained buildings), excluding those tested only for Legionella.

The distribution of named bacterial and fungal taxa over time are shown in Figures 10 and 11, with samples split depending on whether they were collected for reactive testing, whether they were routine samples that passed on all standard tests (Legionella, Pseudomonas, potable, fungi), or whether they were routine samples that were out of spec on one or more of these tests. In general, the same taxa were observed in routine out-of-spec samples as in routine samples that passed on all tests, indicating that the out-of-spec results were largely due to total counts rather than to different taxa being found. There was a large reactive sampling effort in Mar-Apr 2018, during which the Environmental Laboratory was asked to look for Cupriavidus and other GNBs. This required identification of any colonies that grew, and as a consequence, numerous bacterial taxa were reported at this time.

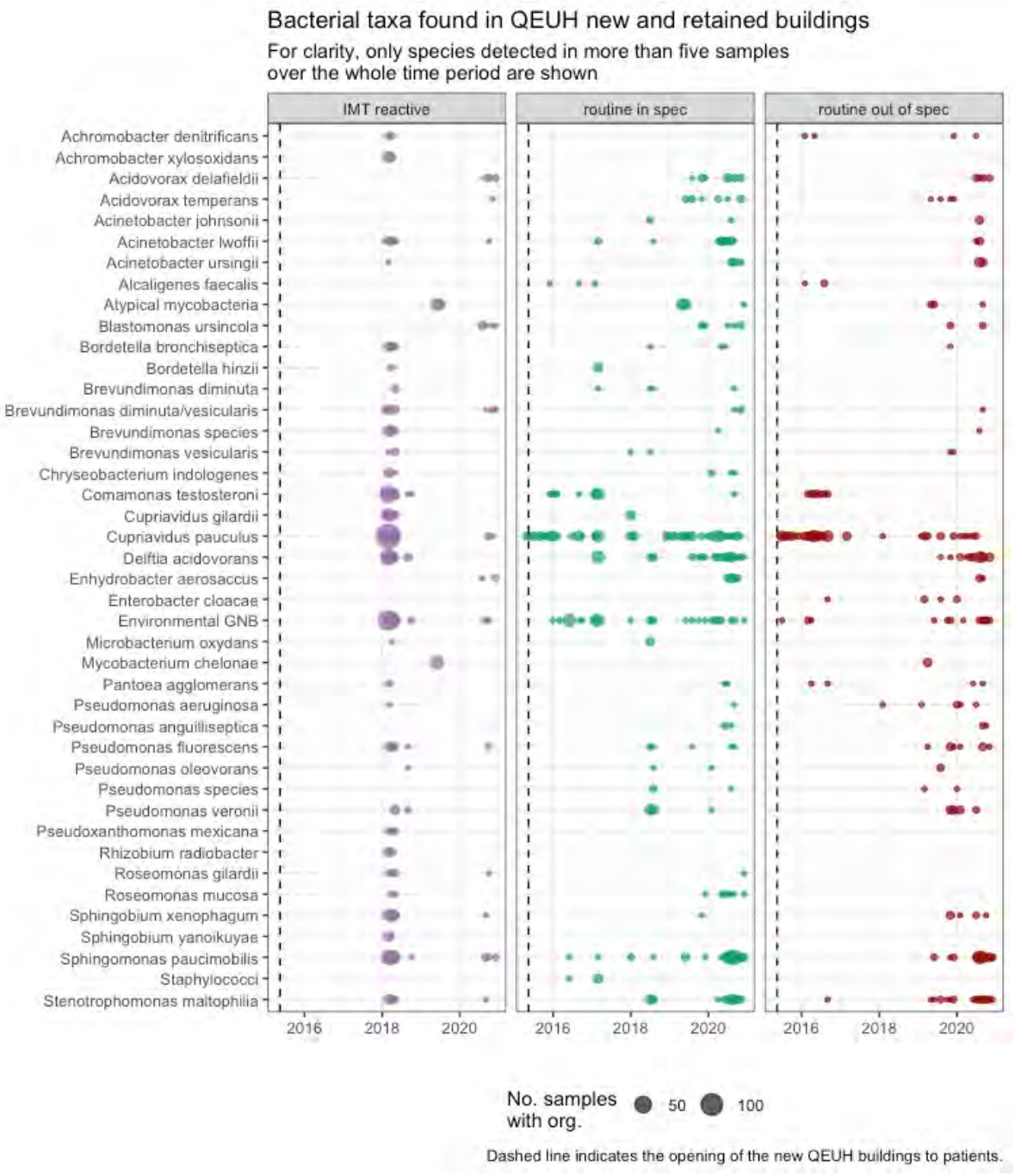


Figure 10. Bacterial taxa identified in reactive samples, and in samples that were in or out of spec on routine tests, 2015-2020.

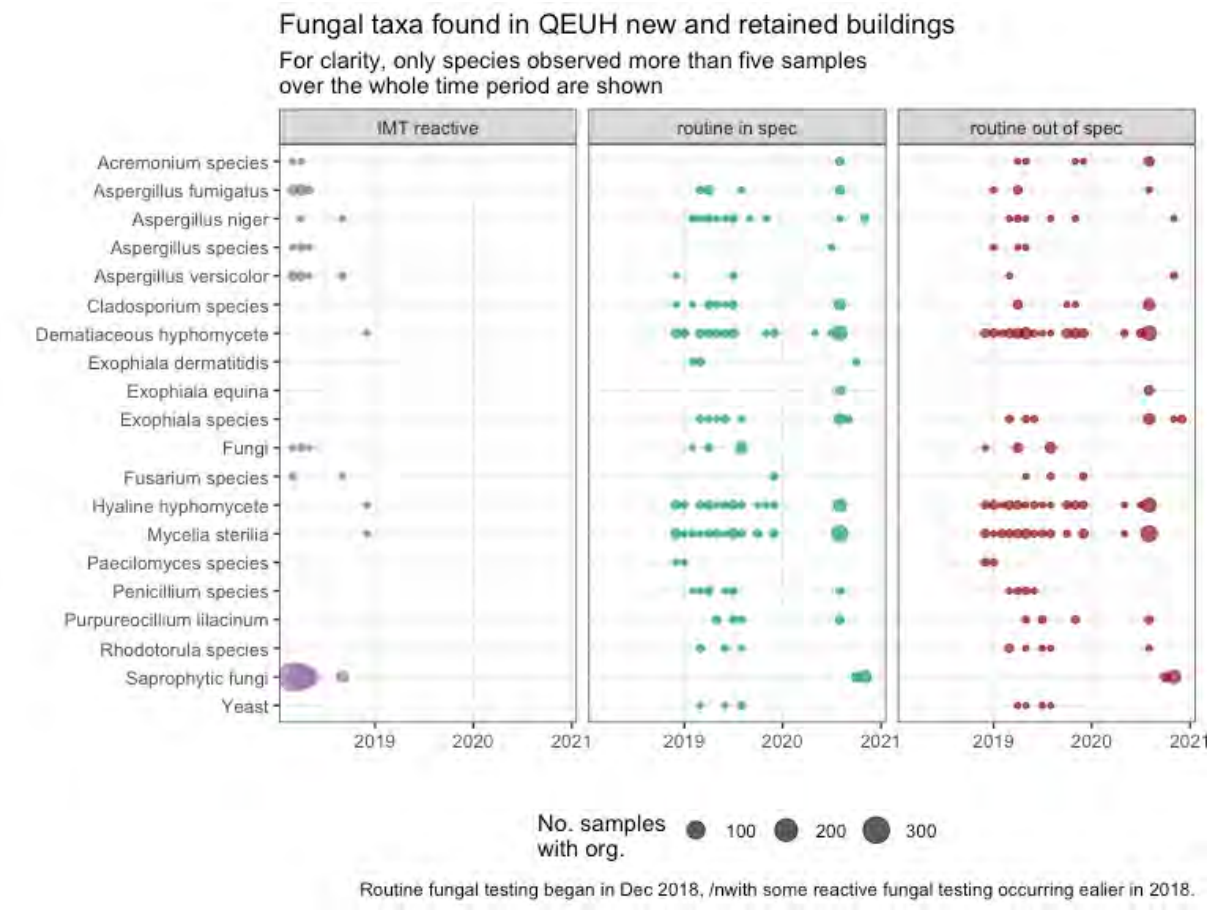


Figure 11. Fungal taxa identified in reactive samples and in samples that were in or out of spec on routine tests, 2015-2020.

The vast majority of named organisms were reported in the new rather than the retained buildings. However, this finding could be explained by the concentration of high-risk wards in the new buildings (where sampling effort is concentrated), by differences in sample numbers between new and retained buildings, and by the microbiological tests that were performed only in the new buildings, notably those tests that specifically look for Gram negative bacteria and fungi, reporting not only CFU counts but also organism IDs on a routine basis.

It is important to note that identifying environmental organisms is not always straightforward, as the procedures used in routine laboratories are optimised for clinical isolates. The Environmental Laboratory identifies unknown organisms using a MALDI-TOF MS system (Biomerieux), which compares spectra obtained from unknown colonies to those in databases of reference organisms. When the MALDI-TOF system fails to identify an organism, a second system, Vitek (Biomerieux), is used, which carries out a series of biochemical tests in an automated manner to give an organism ID.

Both the MALDI-TOF MS and the Vitek perform well in a clinical laboratory setting, but as their reference databases are heavily biased towards human pathogens, they may perform less well at identifying environmental organisms that are rarely found in a clinical context. For example, further typing by whole genome sequencing showed that

numerous isolates identified as *Cupriavidus pauculus* were either other Cupriavidus species, or were not members of the genus Cupriavidus at all but belonged to other genera. Furthermore, when both systems failed to give an organism ID, the Environmental Laboratory reported 'Environmental GNB'. Table 3 shows that Environmental GNB was the second most common bacterial group detected in the new buildings over the period 2015-2020, with 230 occurrences out of 2043 reports of named bacterial taxa. This means that for 11.3% of the organisms that grew from these water samples, a reliable identification could not be obtained using the MALDI-TOF MS and Vitek platforms.

Summary

1. *Background*: The QEUH campus encompasses two new buildings (Adults and RHC), plus a number of retained buildings. Specific areas on campus (transplant and haematology units, intensive care and high dependency units, among others) have been classified as high risk, where stricter water microbiological thresholds are applied. Outwith the high-risk areas and a few specialist units (aseptic pharmacies and RHC Theatre 8), general microbiological thresholds apply.
2. *Sampling and testing*: Water sampling across the QEUH campus over the period 2015-2020 was carried out by ALcontrol Laboratories, by DMA Canyon Ltd, and by GG&C clinical teams, depending on the location. Most microbiological testing was performed by the GG&C Environmental Laboratory, with a subset of samples tested by ALcontrol and by Intertek.
3. *Types of test*: Water samples were either routine (for monitoring) or reactive (for investigation). Samples were booked in for one or more of the following tests: Legionella, Pseudomonas, potable water (consisting of four separate tests for TVCs, coliforms and *E.coli*), and from 2018 onward, fungal, Gram negative bacteria including Cupriavidus, and atypical mycobacterial species, as well as *ad hoc* tests for other specific organisms.
4. *Test thresholds*: While there are required or recommended thresholds for Legionella and Pseudomonas tests in healthcare settings, no such thresholds exist for the other routine tests carried out across the QEUH campus. GG&C set its own thresholds for these tests, with more stringent thresholds in specified high-risk areas.
5. *Test numbers 2015-2020*: Regular Legionella testing was carried out across the new and retained buildings over the entire period 2015-2020. Routine potable water testing was mainly carried out in the retained buildings and specialist areas of the new buildings from 2015-2018, while periodic Pseudomonas testing and reactive testing were carried out in the new buildings. An expanded programme of sampling was implemented throughout the new buildings in December 2018, resulting in a large increase in monthly sampling and a broader range of routine tests.
6. *Out-of-spec Legionella tests*: There were 1096 out-of-spec samples in total (6.5% of samples). The retained buildings had a higher prevalence of Legionella-positive samples (718 samples out of 5923, or 12.1%), compared with the new buildings

(378 Legionella-positive samples out of 10 918, or 3.5%). *Legionella pneumophila* serogroup 1 was rarely detected anywhere on the QEUH campus, and *L.pneumophila* serogroups 2-14 were almost absent from the new buildings. Serogroups 2-14 and other Legionella species accounted for most of the Legionella detected in the retained buildings.

7. *Out-of-spec Pseudomonas tests*: Overall, 12 221 samples underwent Pseudomonas testing. Over the period 2015-2020, there were 221 out-of-spec samples in total (1.8% of samples). New buildings had a lower percent out of spec (1.8% / 0.95% corrected) than retained buildings (2.3%).
8. *Out-of-spec potable tests*: Of the 13 005 potable tests carried out across the whole QEUH campus over the period 2015-2020, 722 were out of spec (5.6%). The majority of out-of-spec potable samples failed due to elevated TVC22 (514 samples in total, i.e. 4.0%) and/or TVC37 (389 samples in total, i.e. 3.0%).
9. *Out-of-spec fungal tests*: 6046 samples underwent routine fungal testing, of which 6040 were from the new buildings. 10.0% of these were out of spec.
10. *Out-of-spec Cupriavidus/GNB tests*: 6330 samples from across the QEUH campus underwent specific testing for Cupriavidus and other GNBs (6183 from new buildings and 147 from retained buildings). 4.4% overall were positive for Cupriavidus and a further 15.6% were negative for Cupriavidus but positive for at least one other GNB.
11. *Out-of-spec AMS tests*: AMS testing was limited to the new buildings. 929 samples underwent AMS testing, of which 9.1% were out of spec.
12. *Prevalence of notifiable taxa*: The mandatory alert organism list for infections in the NIPCM contains four taxa, for which, when clinical cases are identified, an environmental source should be considered. Of these, Acinetobacter species were detected in 79 samples, *Stenotrophomonas maltophilia* in 76 samples, *Pseudomonas aeruginosa* in 8 samples, and *Serratia marcescens* was not detected at all, across all 12 526 water samples tested by the Environmental Laboratory from 2015-2020 (excluding those tested only for Legionella).
13. *Total number of bacterial taxa detected*: Across all 12 526 water samples tested by the Environmental Laboratory over the period 2015-2020, 105 bacterial taxa were identified, with 32 of these occurring in only one sample across the entire data set. In addition, 30 fungal taxa were identified, with 9 of these occurring in only one sample.
14. *Most prevalent bacterial taxa*: Across all 12 526 water samples tested by the Environmental Laboratory over the period 2015-2020, the most prevalent taxa were *Cupriavidus pauculus* (447 samples), Environmental GNB (unspecified) (230 samples), *Sphingomonas paucimobilis* (226 samples), *Delftia acidovorans* (168 samples), *Comamonas testosteroni* (120 samples), and *Stenotrophomonas maltophilia* (76 samples).

Supplemental information

Glossary

Table 5. Acronyms and abbreviations used in this report

Abbreviation	Definition
AMS	Atypical mycobacteria
CF100	Coliform counts per 100 mL
CFU	Colony-forming unit
DMA	DMA Canyon Ltd, water monitoring contractor
E.coli	*Escherichia coli*
EC100	*E.coli* counts per 100 mL
GG&C	NHS Greater Glasgow & Clyde
GNB	Gram negative bacteria
IEC	International Electrotechnical Commission
IMT	Incident Management Team
IPC	Infection Prevention & Control
ISO	International Organization for Standardization
LIMS	Laboratory Information Management System, i.e. TelePath
Lp	*Legionella pneumophila*
MALDI-TOF MS	Matrix-assisted laser desorption/ionization time-of-flight mass spectrometer, an instrument for rapid identification of unknown organisms in the clinical microbiology laboratory
NIPCM	National Infection Prevention and Control Manual
PA100	*Pseudomonas aeruginosa* counts per 100 mL
POU	Point of use, e.g. POU filter attached to a tap
PS100	Pseudomonas counts per 100 mL
QEUH	Queen Elizabeth University Hospital
RHC	Royal Hospital for Children
SAB	Sabouraud's agar (used for selective culturing of fungi)
SAB22	Fungal counts after incubation at 22°C, which encourages the growth of moulds
SAB30	Fungal counts after incubation at 30°C, which encourages the growth of yeasts
SOP	Standard Operating Procedure
TVC	Total viable count
TVC22	Total viable count (CFU/mL) after incubation at 22°C, which selects for environmental organisms

Abbreviation	Definition
TVC37	Total viable count (CFU/mL) after incubation at 37°C, which selects for organisms that might be more adapted to human body temperature
UKAS	UK Accreditation Service

Locations and associated out of spec threshold categories

The following location codes were used to recode and standardise location data across all samples. The associated out of spec thresholds, based on risk level, are as outlined in WQS-017 Water Management Procedure (QEUH Estates Department). Recoding of location data was based on unique outlet ID, where available, and on data in various other fields, which varied across the years and data sources. There were occasional inconsistencies among data sheets from different years, where the same unique ID was associated with entries from different wards, buildings, new vs retained, and/or risk levels. Where inconsistencies were identified, these were repaired based on the following hierarchy:

1. Unique IDs on dedicated location sheets (e.g. PICU, Ward 6A)
2. Consensus location based on numerous separate sheets
3. Clarity of entries in other fields on the same sheet
4. Most recent sheets

Table 6. Buildings, wards, and associated microbiological threshold categories

New or retained	Building	Ward[1]	Threshold category
new	Adults	4B	high risk
new	Adults	4C	high risk
new	Adults	6A	high risk
new	Adults	7A	high risk
new	Adults	7D	high risk
new	Adults	HDU	high risk
new	Adults	other	general
new	Adults RHC	basement bed wash	general
new	Adults RHC	basement tanks	general
new	Adults RHC	drains risers calorifiers	general
new	Adults RHC	external	general
new	RHC	1D PICU	high risk
new	RHC	2A 2B	high risk
new	RHC	2C	high risk

New or retained	Building	Ward[1]	Threshold category
new	RHC	3A	high risk
new	RHC	3B	high risk
new	RHC	3C	high risk
new	RHC	NICU	high risk
new	RHC	other	general
new specialist	Adults	Aseptic pharmacy	specialist
new specialist	RHC	Aseptic pharmacy	specialist
new specialist	RHC	Theatre8	specialist
retained	AE retained	other	general
retained	AMB	other	general
retained	CMB	other	general
retained	ICE	other	general
retained	Lab building	other	general
retained	Langlands	other	general
retained	MIU	other	general
retained	Neo Natal	NICU	high risk
retained	Neo Natal	other	general
retained	Neurology	other	general
retained	Neurosurgery	other	general
retained	Office block	other	general
retained	Old Maternity	other	general
retained	Outpatients	other	general
retained	Pathology	other	general
retained	PDRU	other	general
retained	Podiatry	other	general
retained	Spinal	other	general
retained	Surgical wards	other	general
retained	Teaching Learning	other	general
retained	Therapy Centre	other	general
retained	Westmarc	other	general

[1]Wards not specifically listed as high risk were grouped under 'other'.

Raw data sources

Water sampling data sheets used in this report were obtained from QEUH Estates Department, from the GG&C TelePath system, and directly from DMA. All raw data files are listed below.

Table 7. Original water testing data files included in this summary report

Original data file	Year	Source
2015 Potable Water Master File Complete 13.11.20.xls	2015	LIMS
NHS Southern General Sample Login (Office) 01 2015.xls	2015	DMA
NHS Southern General Sample Login (Office) 02 2015.xls	2015	DMA
NHS Southern General Sample Login (Office) 03 2015.xls	2015	DMA
NHS Southern General Sample Login (Office) 04 2015.xls	2015	DMA
NHS Southern General Sample Login (Office) 05 2015.xls	2015	DMA
NHS Southern General Sample Login (Office) 06 2015.xls	2015	DMA
NHS Southern General Sample Login (Office) 07 2015.xls	2015	DMA
NHS Southern General Sample Login (Office) 08 2015.xls	2015	DMA
NHS Southern General Sample Login (Office) 09 2015.xls	2015	DMA
NHS Southern General Sample Login (Office) 10 2015.xls	2015	DMA
NHS Southern General Sample Login (Office) 11 2015.xls	2015	DMA
NHS Southern General Sample Login (Office) 12 2015.xls	2015	DMA
Alcontrol 18 08 2015 samples.xls	2015	Alcontrol
2016 Potable Water Master File Complete 13.11.20.xls	2016	LIMS
NHS Southern General Sample Login (Office) 01 2016.xls	2016	DMA
NHS Southern General Sample Login (Office) 02 2016.xls	2016	DMA
NHS Southern General Sample Login (Office) 03 2016.xls	2016	DMA
NHS Southern General Sample Login (Office) 04 2016.xls	2016	DMA
NHS Southern General Sample Login (Office) 05 2016.xls	2016	DMA
NHS Southern General Sample Login (Office) 06 2016.xls	2016	DMA
NHS Southern General Sample Login (Office) 07 2016.xls	2016	DMA
NHS Southern General Sample Login (Office) 08 2016.xls	2016	DMA
NHS Southern General Sample Login (Office) 09 2016.xls	2016	DMA
NHS Southern General Sample Login (Office) 10 2016.xls	2016	DMA
NHS Southern General Sample Login (Office) 11 2016.xls	2016	DMA

Original data file	Year	Source
NHS Southern General Sample Login (Office) 12 2016.xls	2016	DMA
Alcontrol Water Sample 06 01 2016.xls	2016	Alcontrol
2017 Potable Water Master File Complete 13.11.20.xlsx	2017	LIMS
2017 NHS QEUH Sample Login Template (Inc Ps).xls	2017	DMA
Alcontrol 20 01 2017 samples.xls	2017	Alcontrol
2018 Potable Water Master File Complete 13.11.20.xlsx	2018	LIMS
2018 NHS QEUH Adult Sample Login Template (Inc Ps&R).xls	2018	DMA
2018 NHS QEUH Childrens Sample Login (Inc Ps&R).xlsm	2018	DMA
2018 NHS QEUH CMB Sample Login Template (Inc Ps&R).xlsm	2018	DMA
2018 NHS QEUH Ice Sample Login Template (Inc Ps&R).xlsm	2018	DMA
2018 NHS QEUH Lab Building Sample Login Template (Inc Ps&R).xlsm	2018	DMA
2018 NHS QEUH Neo Natal Sample Login Template (Inc Ps&R).xlsm	2018	DMA
2018 NHS QEUH Neurology Sample Login Template (Inc Ps&R).xlsm	2018	DMA
2018 NHS QEUH Neurosurgery Sample Login Template (Inc Ps&R).xlsm	2018	DMA
2018 NHS QEUH Office Sample Login Template (Inc Ps&R).xlsm	2018	DMA
2018 NHS QEUH Old Maternity Sample Login Template (Inc Ps&R).xlsm	2018	DMA
2018 NHS QEUH PDRU Sample Login Template (Inc Ps&R).xlsm	2018	DMA
2018 NHS QEUH Podiatry Sample Login Template (Inc Ps&R).xlsm	2018	DMA
2018 NHS QEUH Spinal Sample Login Template (Inc Ps&R).xlsm	2018	DMA
2018 NHS QEUH Teaching & Learning Sample Login Template (Inc Ps&R).xlsm	2018	DMA
2018 NHS QEUH Westmarc Sample Login Template (Inc Ps&R).xlsm	2018	DMA
2019 Potable Water Master File Complete 13.11.20.xlsx	2019	LIMS
2019 (01-06) QEUH A&C Sample Login (Inc AMS).xls	2019	DMA
2019 (07-12) QEUH A&C Sample Login (Inc AMS).xls	2019	DMA
2019 NHS QEUH CMB Sample Login Template (Inc Ps&R).xlsm	2019	DMA
2019 NHS QEUH ICE Sample Login Template (Inc Ps&R).xlsm	2019	DMA
2019 NHS QEUH Lab Building Sample Login Template (Inc Ps&R).xlsm	2019	DMA
2019 NHS QEUH Neo Natal Sample Login Template (Inc Ps&R).xlsm	2019	DMA
2019 NHS QEUH Neurology Sample Login Template (Inc Ps&R).xlsm	2019	DMA
2019 NHS QEUH Neurosurgery Sample Login Template (Inc Ps&R).xlsm	2019	DMA
2019 NHS QEUH Office Sample Login Template (Inc Ps&R).xlsm	2019	DMA
2019 NHS QEUH Old Maternity Sample Login Template (Inc Ps&R).xlsm	2019	DMA

Original data file	Year	Source
2019 NHS QEUH PDRU Sample Login Template (Inc Ps&R).xlsm	2019	DMA
2019 NHS QEUH Podiatry Sample Login Template (Inc Ps&R).xlsm	2019	DMA
2019 NHS QEUH Spinal Sample Login Template (Inc Ps&R).xlsm	2019	DMA
2019 NHS QEUH Teaching & Learning Sample Login Template (Inc Ps&R).xlsm	2019	DMA
2019 NHS QEUH Westmarc Sample Login Template (Inc Ps&R).xlsm	2019	DMA
DC QEUH NON-DMA SAMPLES 1.1.20 - 31.12.20.xlsx	2020	LIMS
2020 NHS QEUH AC (01-06) Sample Login Sheet (002) 210720.xlsm	2020	DMA
2020 NHS QEUH AC (07-12) Sample Login Sheet (016) 301220.xlsm	2020	DMA
2020 NHS QEUH Ward 1D PICU Samples (008) 241220.xlsm	2020	DMA
2020 NHS QEUH Ward 6A Samples (00A) 241220.xlsm	2020	DMA
2020 NHS QEUH CMB Sample Login Sheet.xlsm	2020	DMA
2020 NHS QEUH ICE Building Sample Login Sheet.xlsm	2020	DMA
2020 NHS QEUH MIU Sample Login Sheet.xlsm	2020	DMA
2020 NHS QEUH Neo Natal Sample Login Sheet.xlsm	2020	DMA
2020 NHS QEUH Neurology Sample Login Sheet.xlsm	2020	DMA
2020 NHS QEUH Neurosurgery Sample Login Sheet.xlsm	2020	DMA
2020 NHS QEUH Office Block Sample Login Sheet.xlsm	2020	DMA
2020 NHS QEUH Old Maternity Sample Login Sheet.xlsm	2020	DMA
2020 NHS QEUH PDRU Sample Login Sheet.xlsm	2020	DMA
2020 NHS QEUH Podiatry Sample Login Sheet.xlsm	2020	DMA
2020 NHS QEUH Spinal Sample Login Sheet.xlsm	2020	DMA
2020 NHS QEUH Teaching & Learning Sample Login Sheet.xlsm	2020	DMA
2020 NHS QEUH Westmarc Sample Login Sheet.xlsm	2020	DMA

Data curation and re-coding for consistency

The data sheets from ALcontrol were first processed in Excel to separate Legionella from potable and Pseudomonas test results, remove formatting and non-numeric symbols from numeric test result entries, and re-code the locations manually by cross-referencing with location data from DMA, since ALcontrol provided only outlet ID numbers with little additional information about which building or ward the sample had been collected from.

All other data sheets (those from DMA and TelePath) were locked to prevent editing, and were instead read directly into R version 4.2.0 using the readxl package, along with the processed ALcontrol data sheets. Data preparation and curation were carried out entirely in R, as detailed in the separate Rmarkdown notebook 01_Water_data_upload_and_preparation_v3_2021.Rmd.

Briefly, it involved the following:

1. Loading each Excel file, adjusting variable names so as to be consistent across the data set, and joining files into a single data object
2. Removing duplicate entries, i.e. those that were present in both the TelePath data and DMA sheets
3. Removing entries for samples that were not collected or tested, or for which results were not recorded, indicated by free text 'No sample taken', 'No access', 'Results not available', or similar character strings in one or more of the metadata columns
4. Moving character strings from numeric columns into free-text columns
5. Re-coding location data into new consistent variables (New or retained, Ward) using a series of automated string detection steps
6. Re-coding test requested data into consistent variables, based on the results in the numeric columns as well as string detection steps in free-text columns.

Named organism data were re-coded manually from the main data set into a separate Excel sheet, as there was no consistency in how these data were entered. This Excel sheet was subsequently loaded into R and joined to the main data set. Final curation steps corrected obvious errors, including duplicate Lab.Reference numbers for samples that were clearly different, mis-typed sample dates where digits were reversed or added to the year of sampling, and entries where an organism was reported using an outdated name (e.g. *Pseudomonas paucimobilis*, which is an old name for *Sphingomonas paucimobilis*).

The final data set was loaded into the Rmarkdown script used to generate this report.

Bacteraemia rates and Resistance patterns in Paediatric Haematology /oncology patients 2014 -2018

Draft Report 10/10/2018

Dr Christine Peters : Clinical Lead Microbiology QEUH

Kathleen Harvey-Wood Clinical Scientist

Pharmacy data provided by Ysobel Gourlay : Antimicrobial Pharmacist

BACKGROUND

An IMT into increased rates of infections with water borne organisms in Haemato-oncology patients prompted an analysis of bacteraemia resistance rates and antibiotic usage on the unit by the Microbiology department. The Unit moved to RHC new premises over a number of weeks from May 2015 .

AIM

- To describe the epidemiology of bacteraemia rates on the Haem-onc unit, before and after the move from Yorkhill to RHC.
- To determine antibiotic resistance rates
- Analyse antibiotic patterns of use in relation to resistance and empirical policy

METHODS

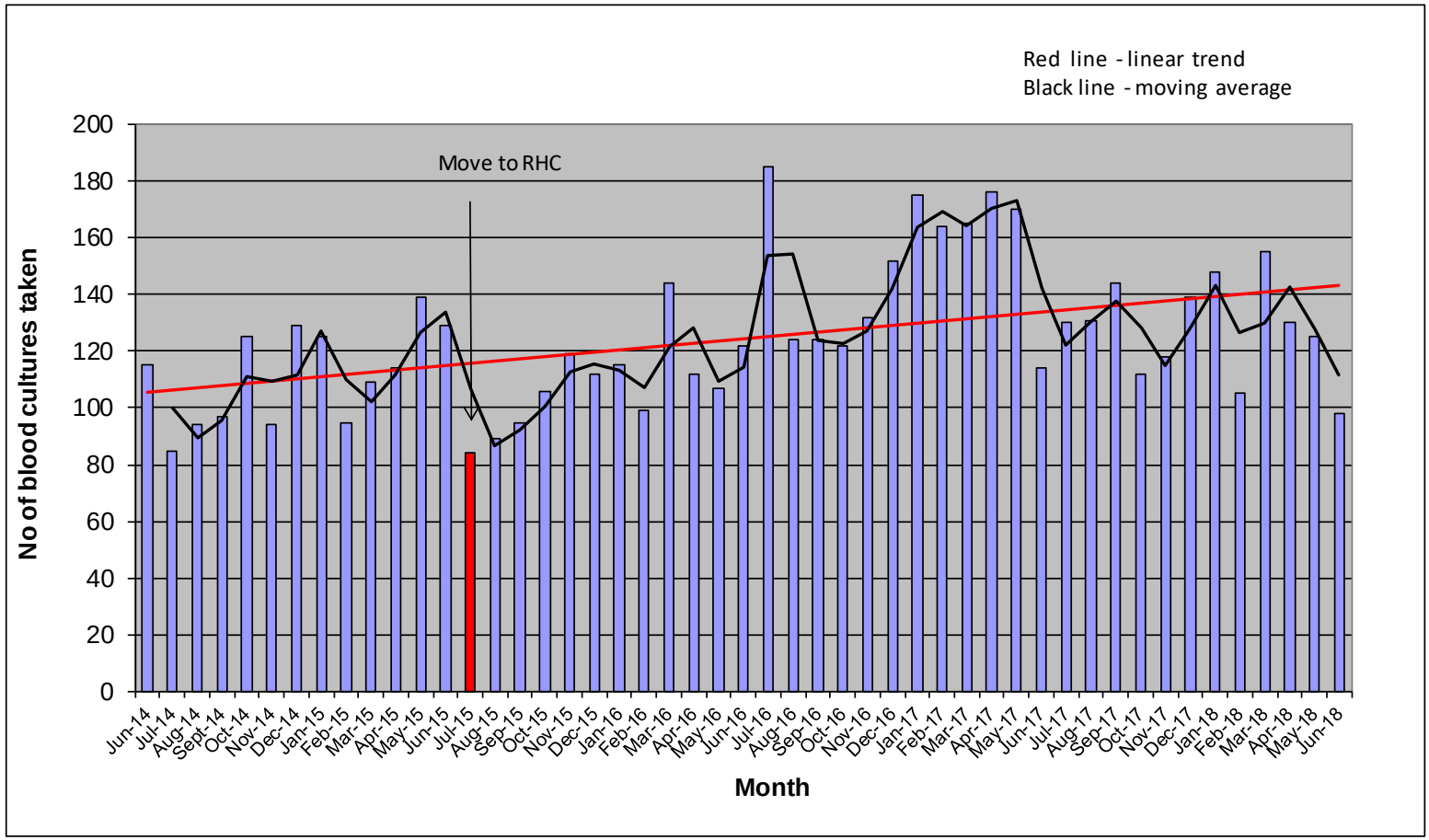
A retrospective 4 year audit of blood cultures from 10 th June 2014 - 9 th June 2018, with subsequent addition of July data (not included in antibiotic resistance analysis).

A LIMS Telepath extract was carried out by a trained Clinical Scientist with many years experience of data extraction form Telepath. The data captured was all Blood cultures sent to the department of Microbiology from patients linked to Haematology and Oncology Paediatric Consultants. This data was transferred to Excel and subsequently analysed using Excel software.

De-duplication was carried out with an episode defined as an organism isolated from a blood culture in a patient more than 14 days from any previous culture with the same organism, including identical antibiogram.

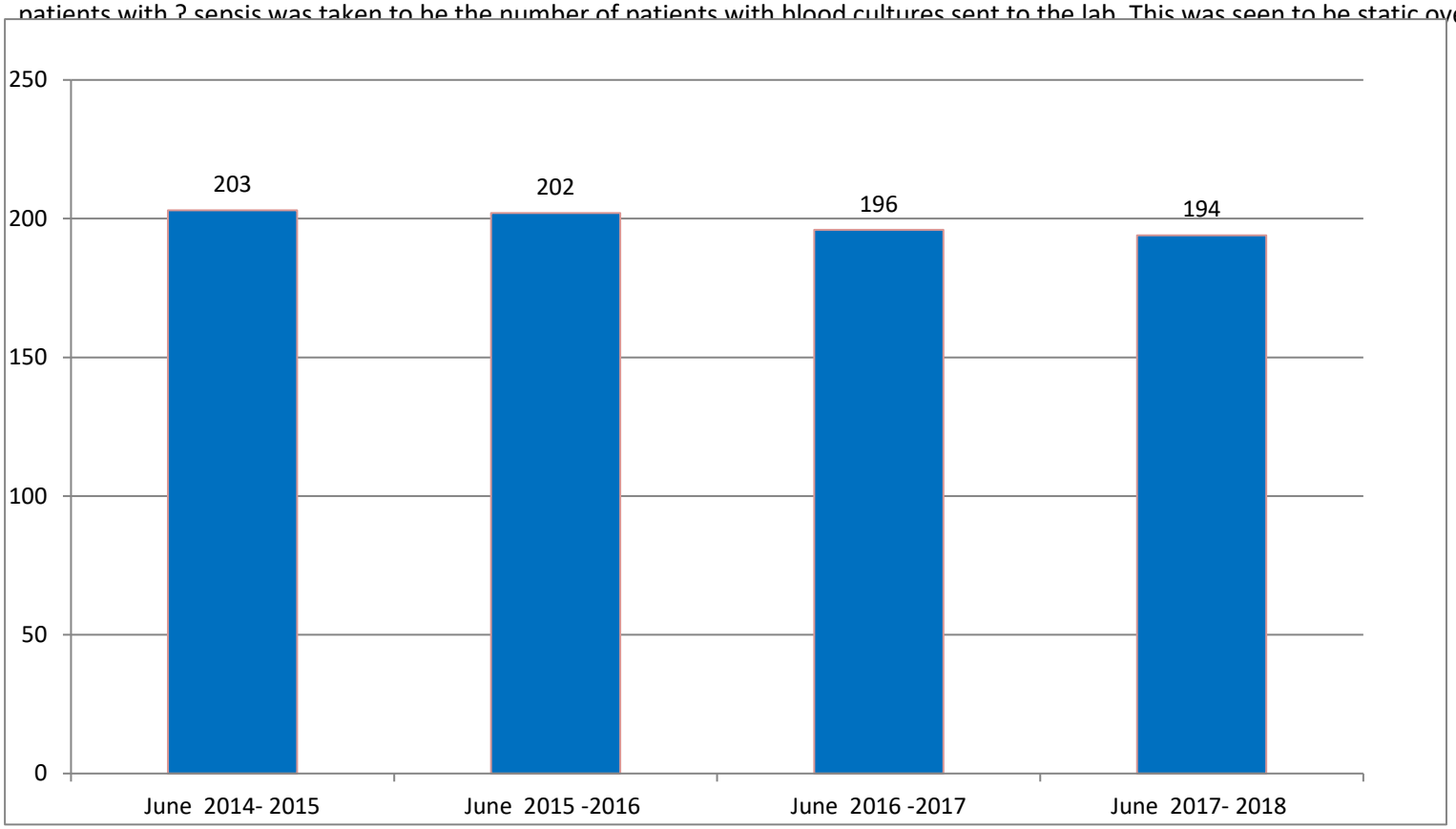
RESULTS

Overall Number of blood cultures sent to Microbiology June 2014 – June 2018



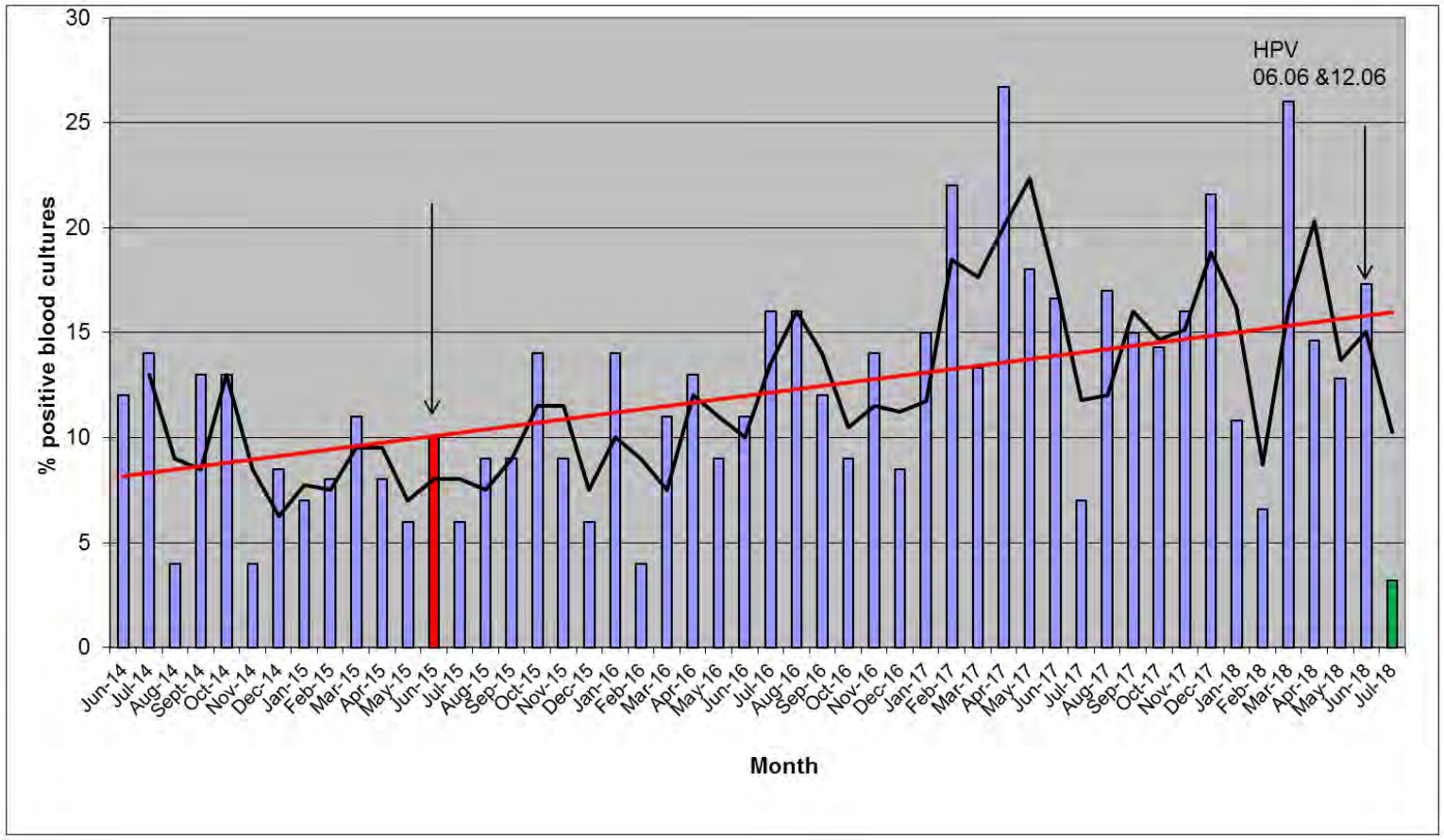
2. Number of patients with blood cultures taken per year

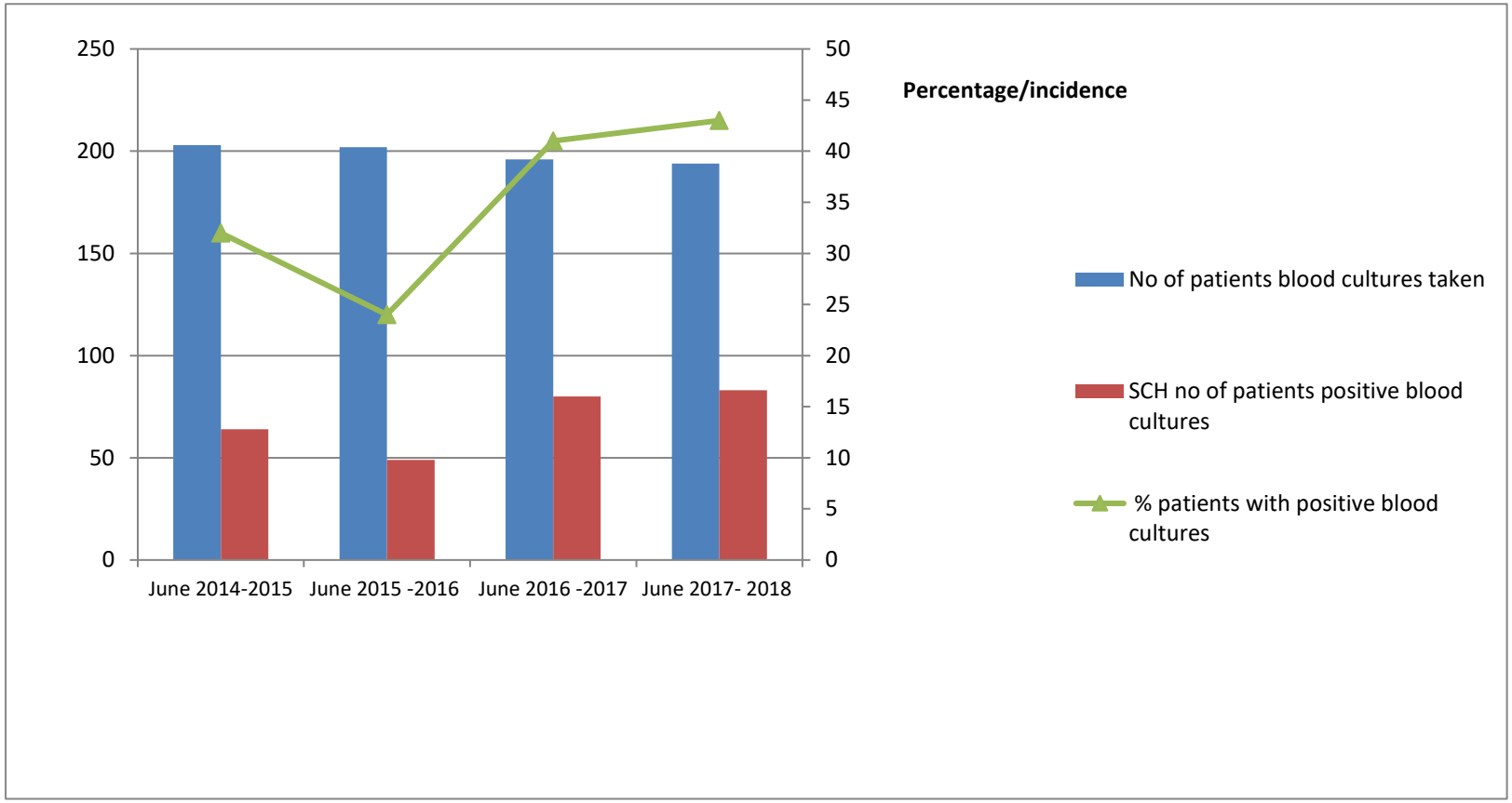
In order to determine if increases in positive cases was related in increases in numbers of patient case load , a plausible denominator of number of patients with ? sepsis was taken to be the number of patients with blood cultures sent to the lab. This was seen to be static over the years, in



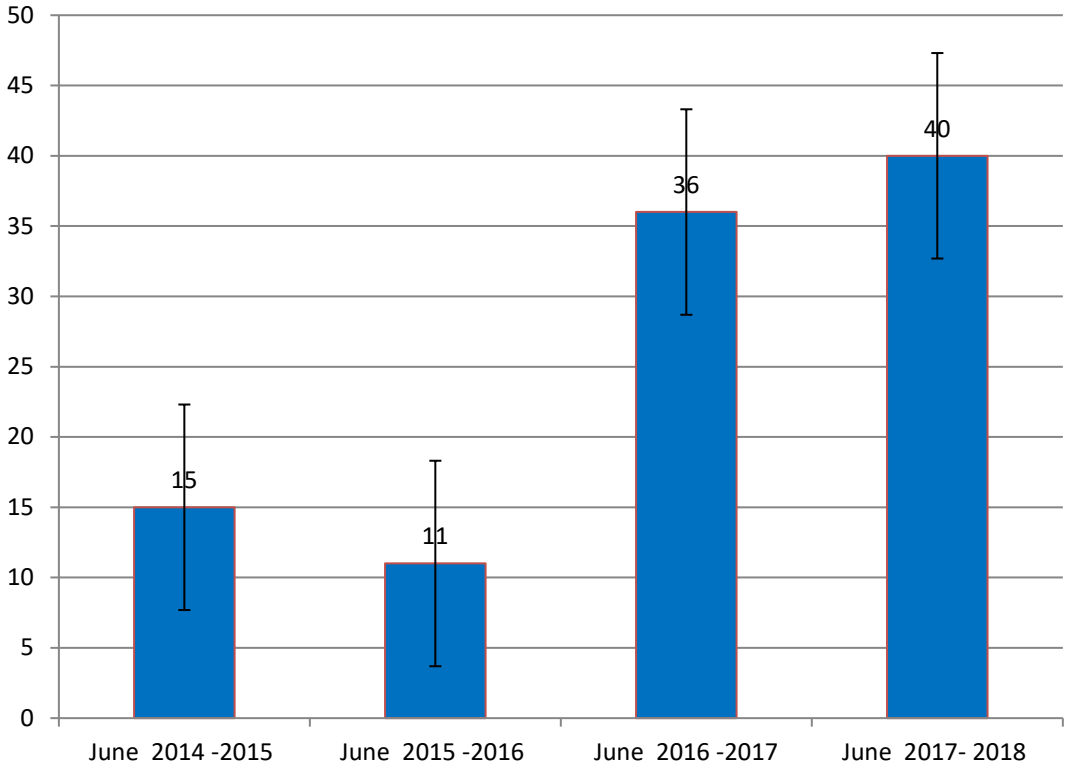
3. Percentage positive Blood cultures per month

Increasing rates of positivity in Blood cultures seen , with spikes in April 2017, December 2017 and April 2018

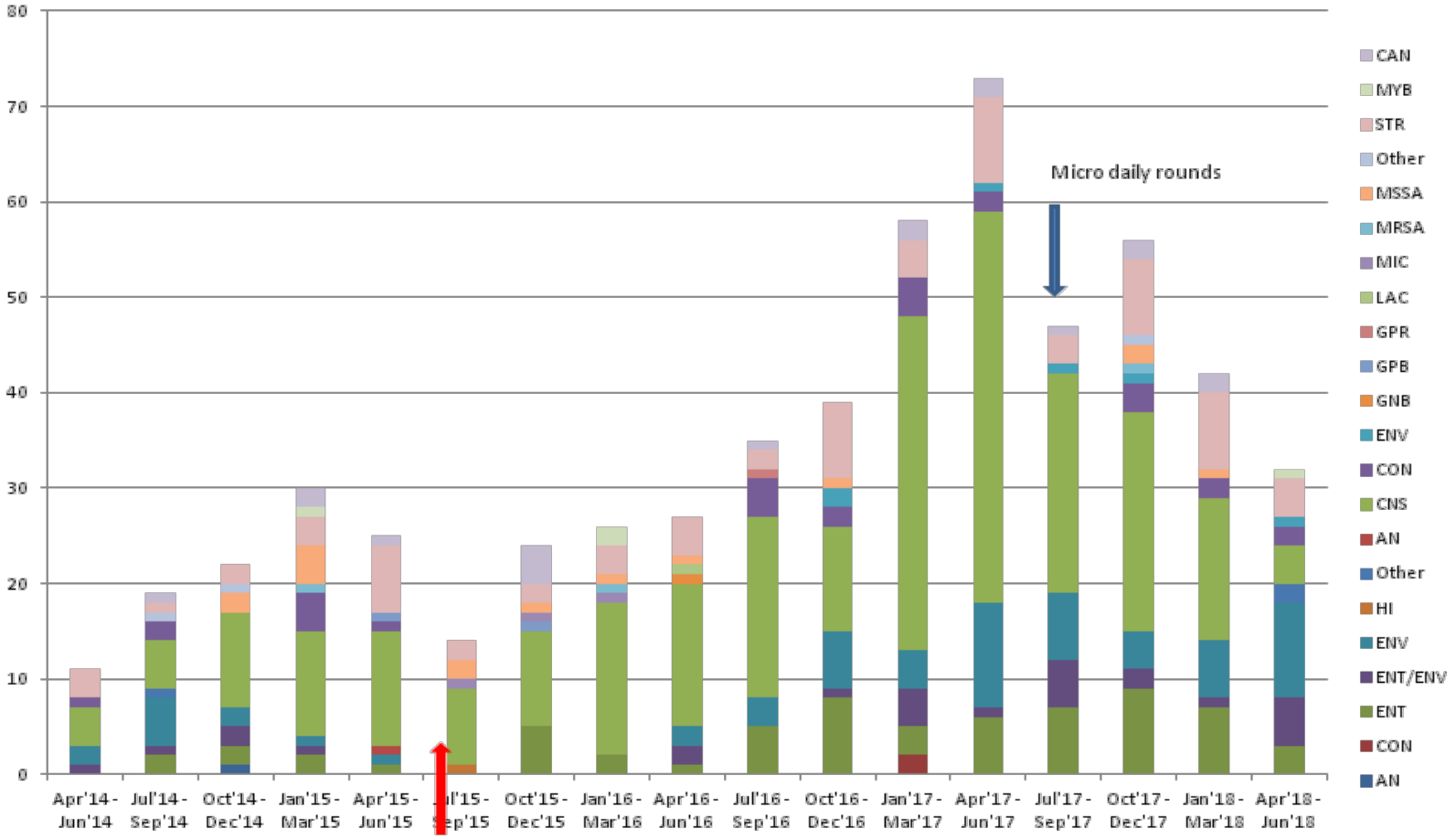



250
200
150
100
50
0
50
45
40
35
30
25
20
15
10
5
0
Percentage/incidence
June 2014-2015
June 2015 -2016
June 2016 -2017
June 2017- 2018
No of patients blood cultures taken
SCH no of patients positive blood cultures
% patients with positive blood cultures

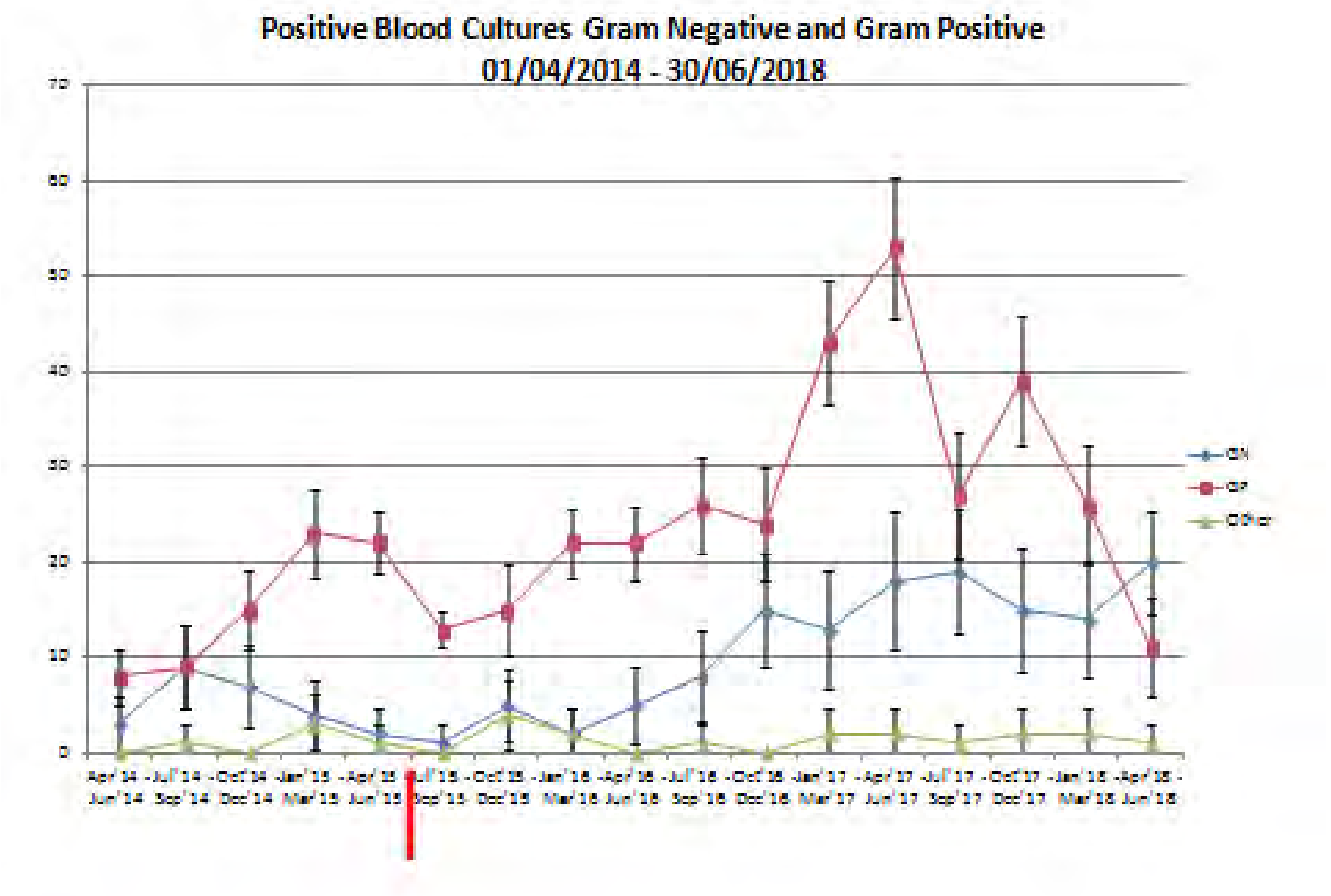
4. Number of mixed blood cultures per year
   Fourfold increase in number of mixed blood cultures – ie more than one organism in single blood culture sample in 2016 -2018



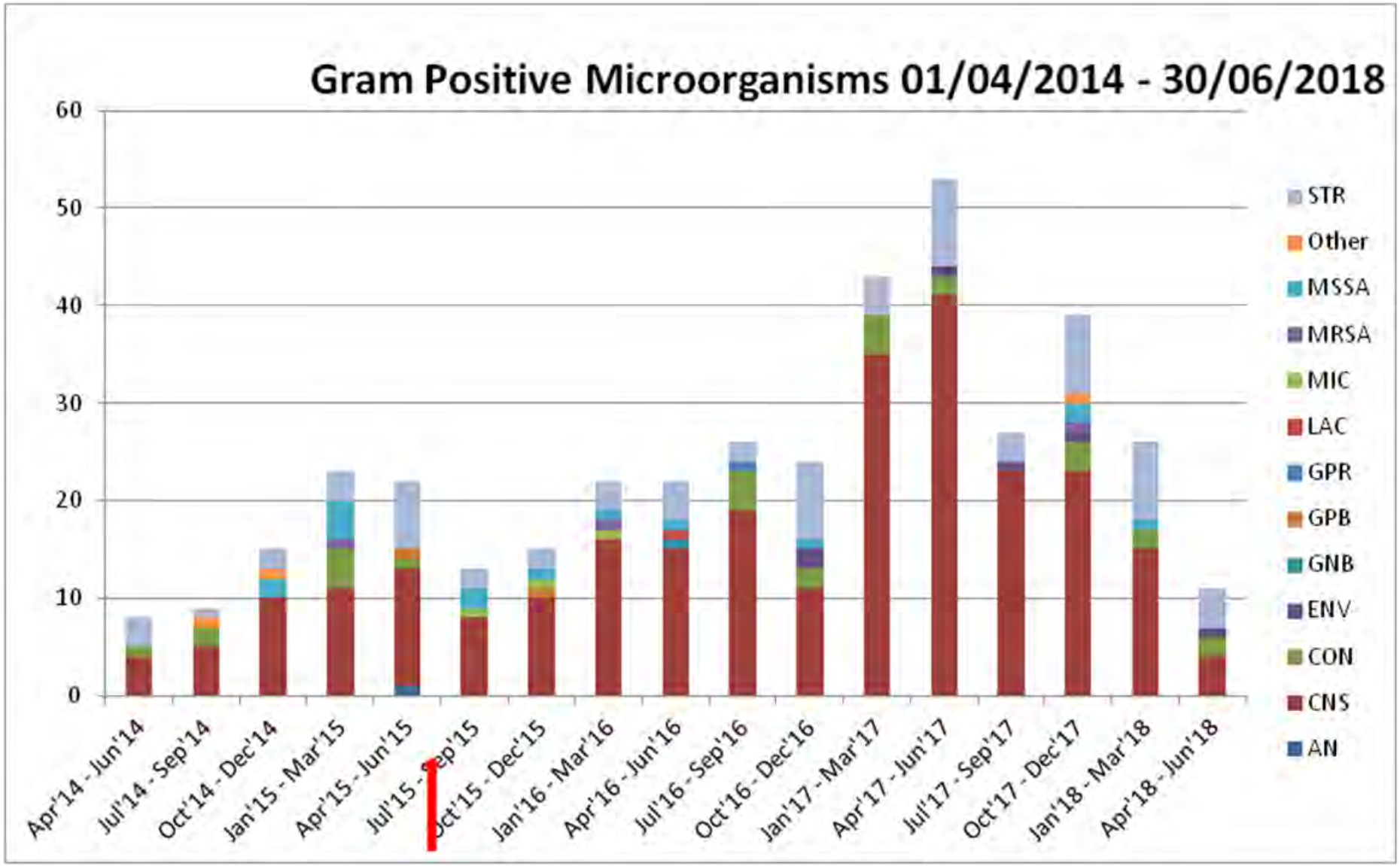
5. Quarterly Deduplicated Blood cultures – all organisms
   Red arrow denotes move to the New hospital premises completed



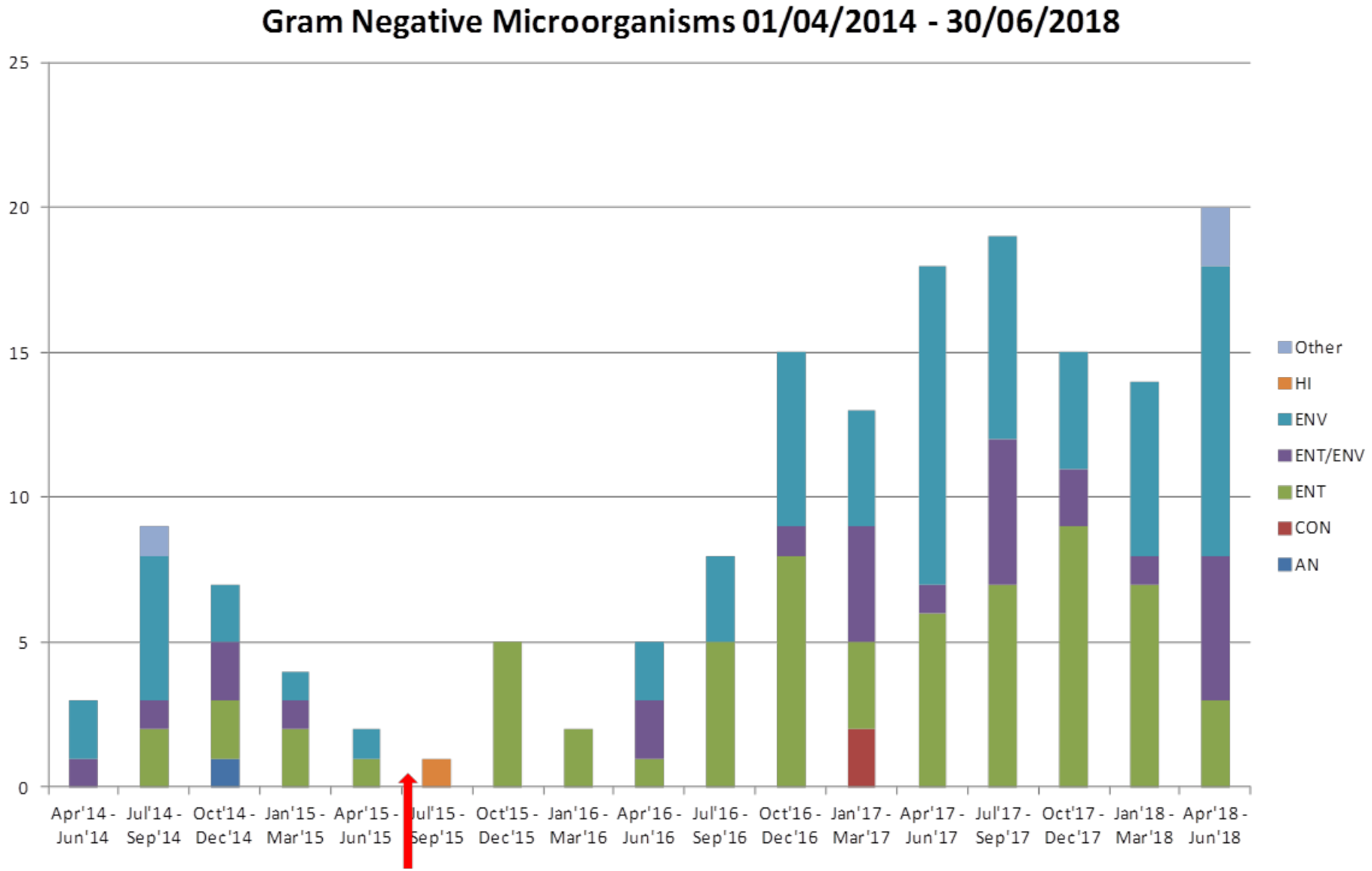
6. Change in ratio of gram positive to gram negative isolates



7. Gram Positive organisms
   Of note Coagulase negative staphylococci reduce in line with QIS project on line infections

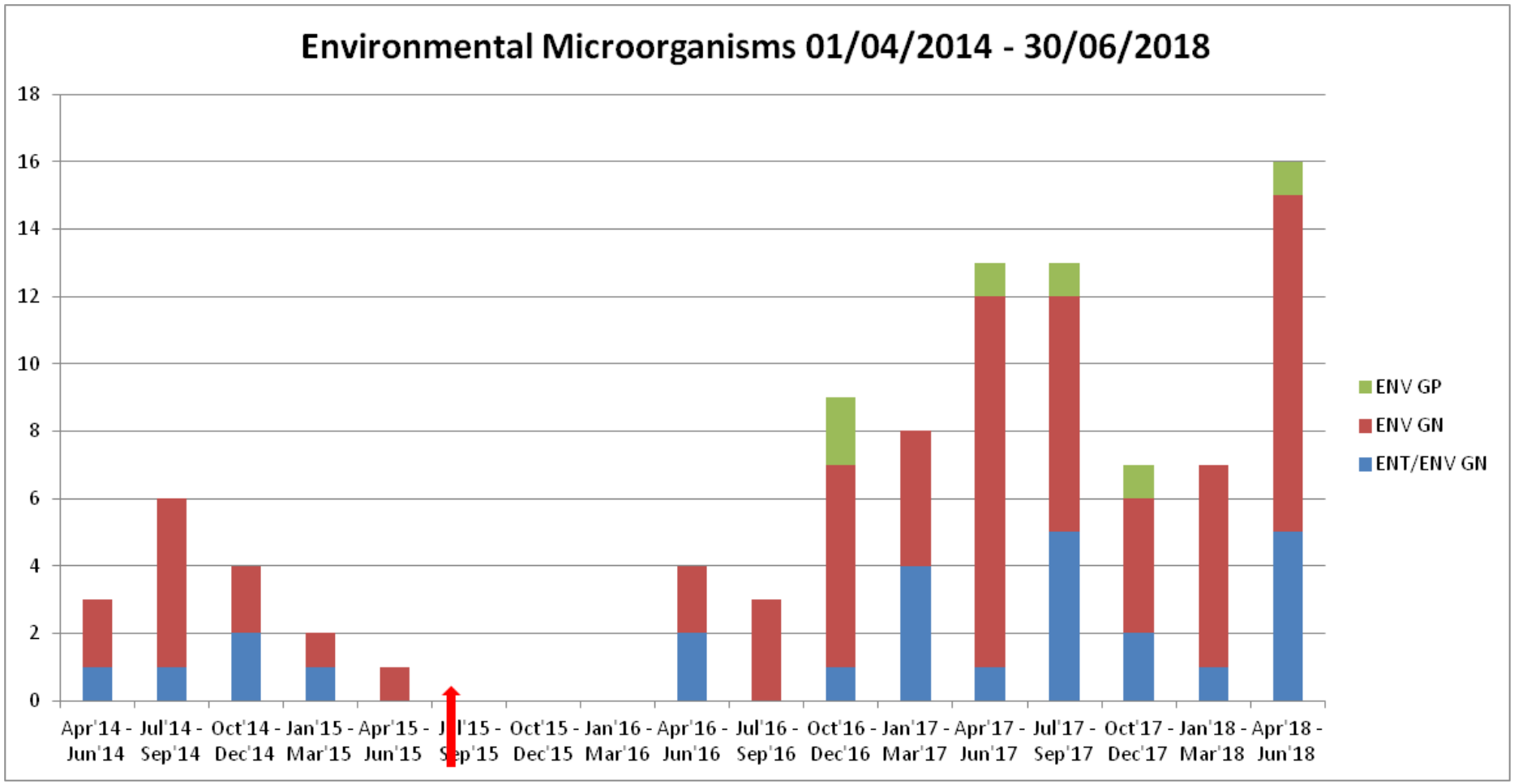

Gram Positive Microorganisms 01/04/2014 - 30/06/2018
60
50
40
30
20
10
0
Apr'14 - Jun'14
Jul'14 - Sep'14
Oct'14 - Dec'14
Jan'15 - Mar'15
Apr'15 - Jun'15
Jul'15 - Sep'15
Oct'15 - Dec'15
Jan'16 - Mar'16
Apr'16 - Jun'16
Jul'16 - Sep'16
Oct'16 - Dec'16
Jan'17 - Mar'17
Apr'17 - Jun'17
Jul'17 - Sep'17
Oct'17 - Dec'17
Jan'18 - Mar'18
Apr'18 - Jun'18
STR
Other
MSSA
MRSA
MIC
LAC
GPR
GPB
GNB
ENV
CON
CNS
AN

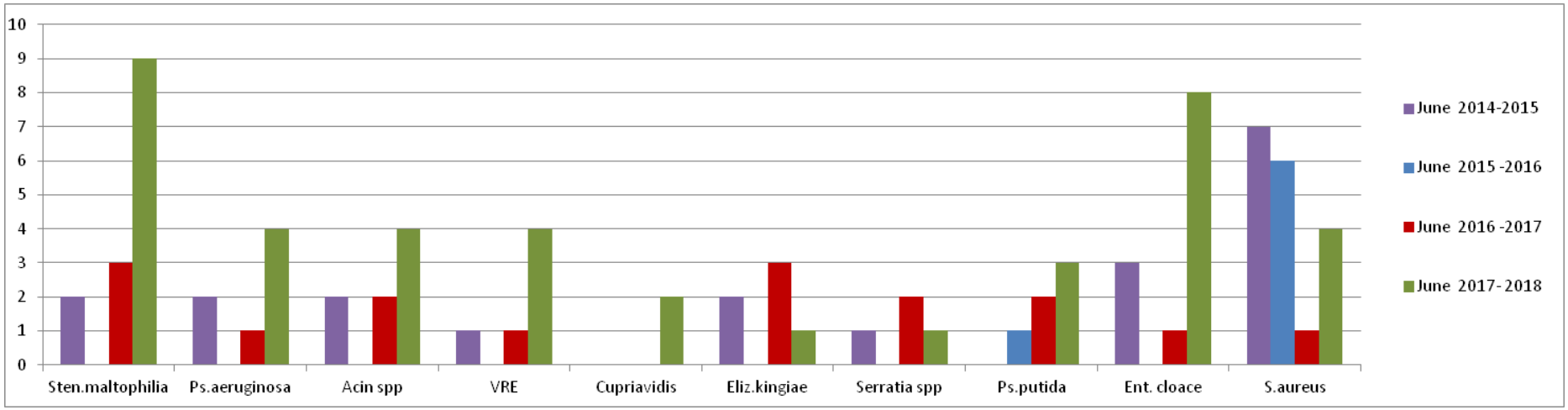
8. Gram Negative organism s
   Four fold increase between final quarter 2015 and second quarter 2018


Gram Negative Microorganisms 01/04/2014 - 30/06/2018
25
20
15
10
5
0
Apr'14 - Jun'14
Jul'14 - Sep'14
Oct'14 - Dec'14
Jan'15 - Mar'15
Apr'15 - Jun'15
Jul'15 - Sep'15
Oct'15 - Dec'15
Jan'16 - Mar'16
Apr'16 - Jun'16
Jul'16 - Sep'16
Oct'16 - Dec'16
Jan'17 - Mar'17
Apr'17 - Jun'17
Jul'17 - Sep'17
Oct'17 - Dec'17
Jan'18 - Mar'18
Apr'18 - Jun'18
Other
HI
ENV
ENT/ENV
ENT
CON
AN

9. Environmental organisms

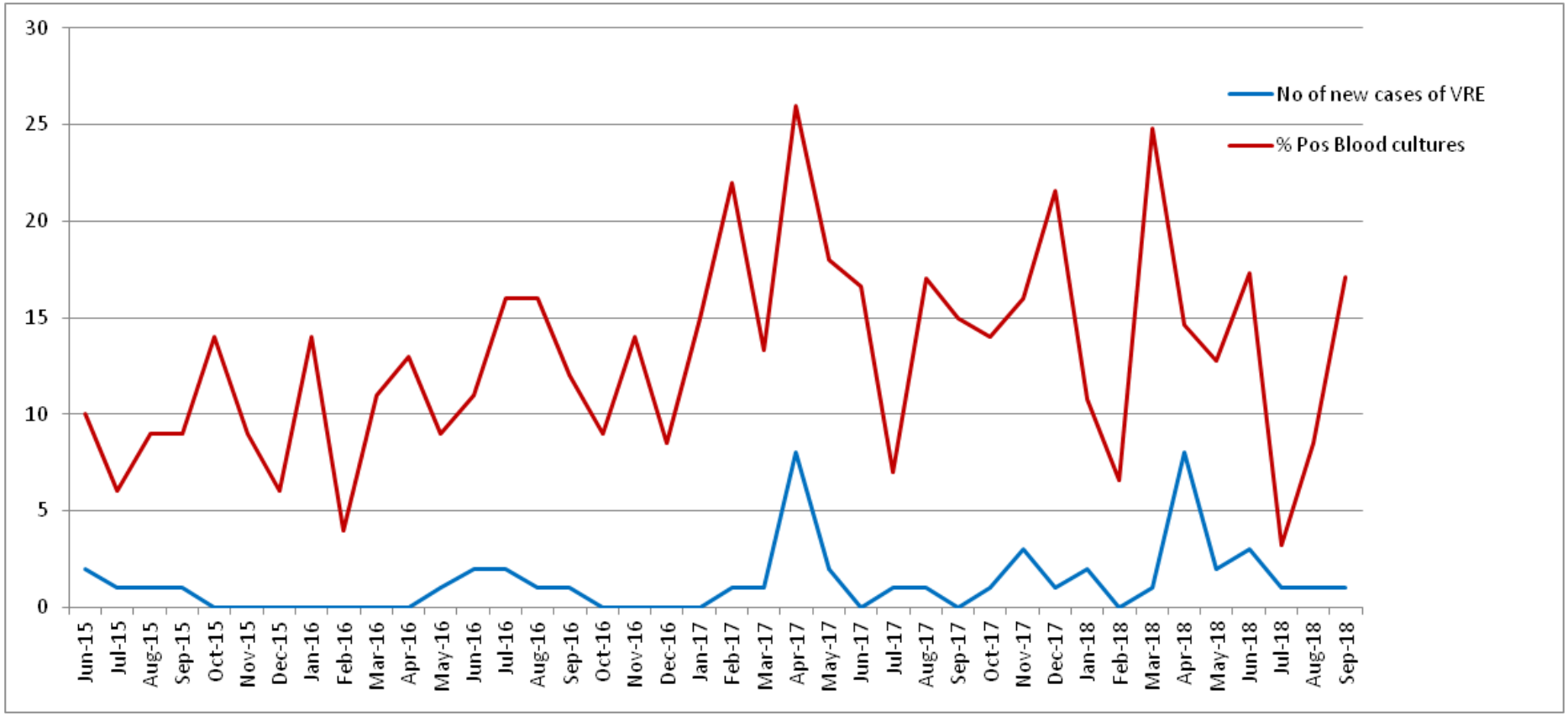
No Environmental organisms isolated for 9 months post move. Followed by biphasic peak . A total of 80 bacteraemic episodes from April 2016 to Jun 2018 with Environmental organisms .



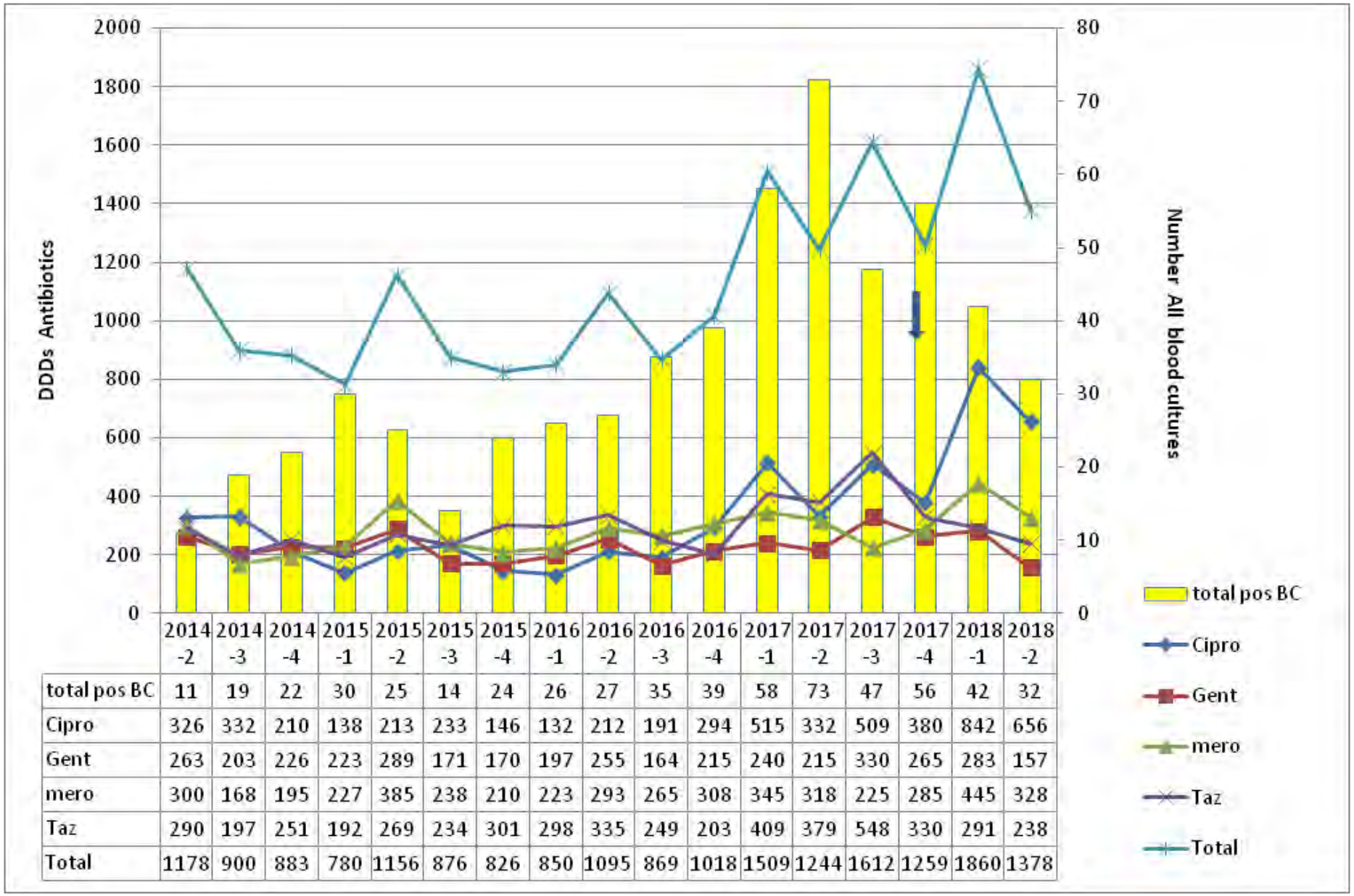

10
9
8
7
6
5
4
3
2
1
0
Sten.maltophilia
Ps.aeruginosa
Acin spp
VRE
Cupriavidis
Eliz.kingiae
Serratia spp
Ps.putida
Ent. cloace
S.aureus
June 2014-2015
June 2015 -2016
June 2016 -2017
June 2017- 2018

10. Haematology/Oncology Patients

Number of new cases of VRE (colonisations included – ie not bactaeraemias) and percentage positive blood cultures June 2015 – Sept 2018 (18.09), spikes associated in time with spikes in environmental BC isolates indicating common environmental factors.

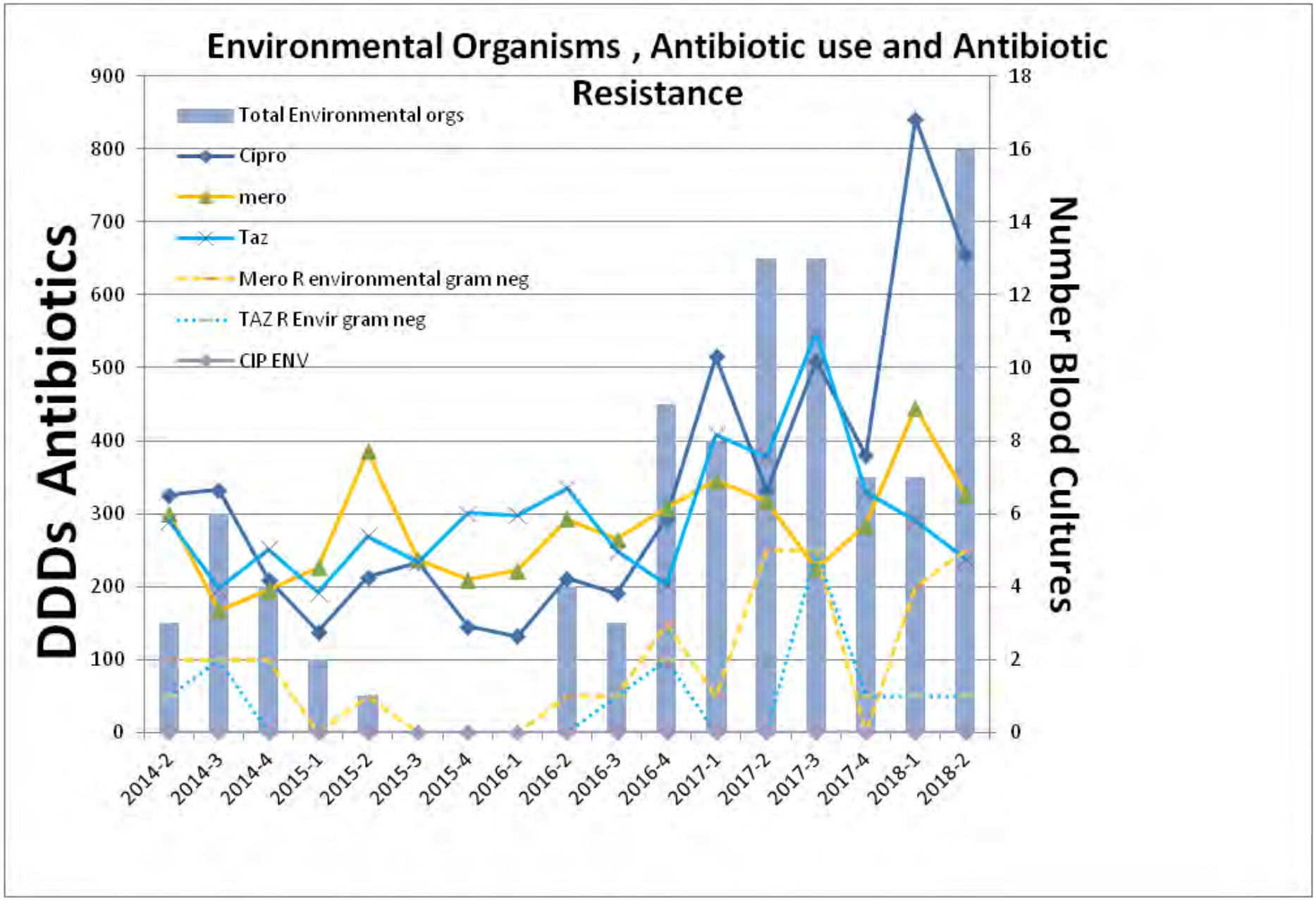


11. Antibiotic Use in DDDs against back ground bacteraemia rate

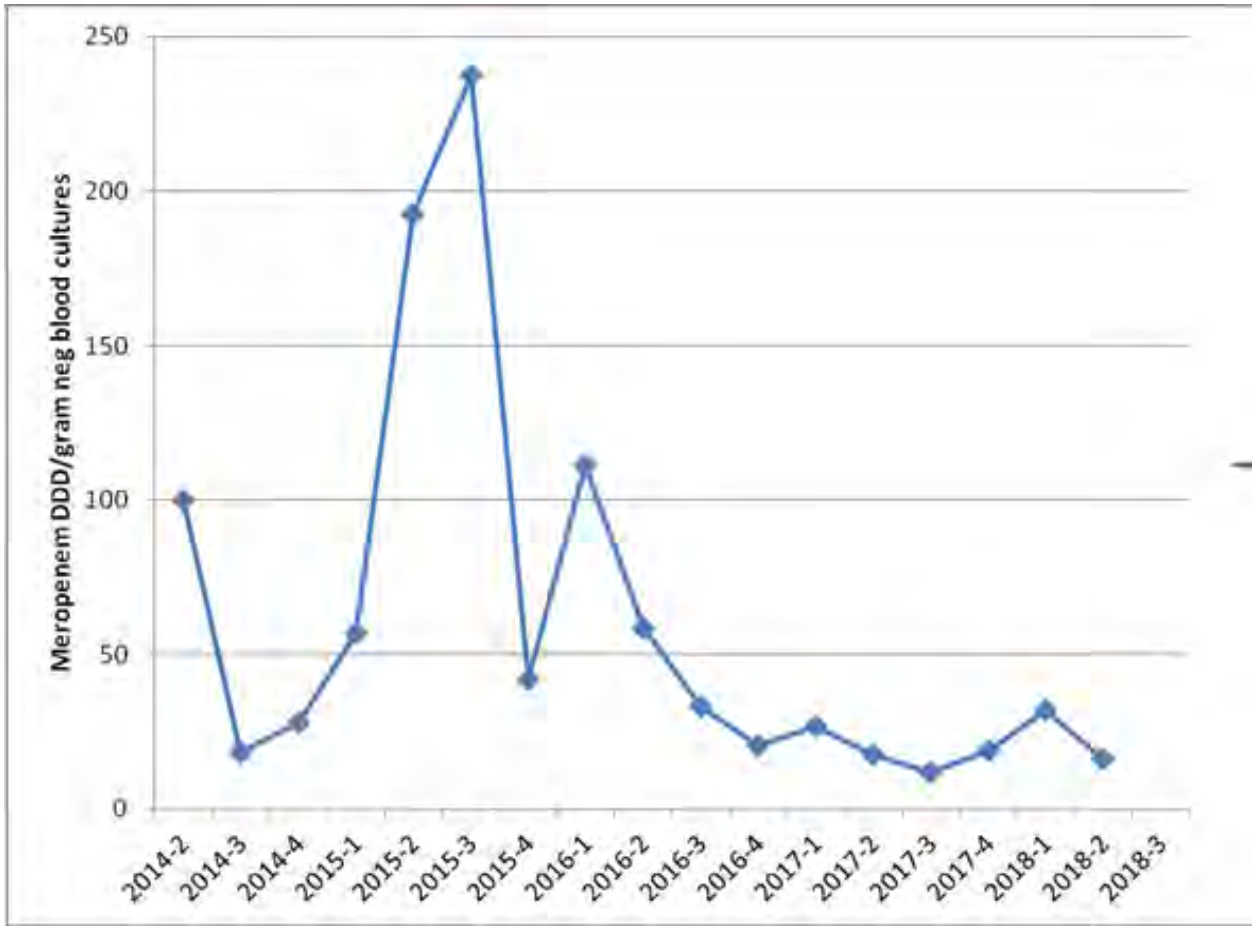


	2014-2	2014-3	2014-4	2015-1	2015-2	2015-3	2015-4	2016-1	2016-2	2016-3	2016-4	2017-1	2017-2	2017-3	2017-4	2018-1	2018-2
total pos BC	11	19	22	30	25	14	24	26	27	35	39	58	73	47	56	42	32
Cipro	326	332	210	138	213	233	146	132	212	191	294	515	332	509	380	842	656
Gent	263	203	226	223	289	171	170	197	255	164	215	240	215	330	265	283	157
mero	300	168	195	227	385	238	210	223	293	265	308	345	318	225	285	445	328
Taz	290	197	251	192	269	234	301	298	335	249	203	409	379	548	330	291	238
Total	1178	900	883	780	1156	876	826	850	1095	869	1018	1509	1244	1612	1259	1860	1378

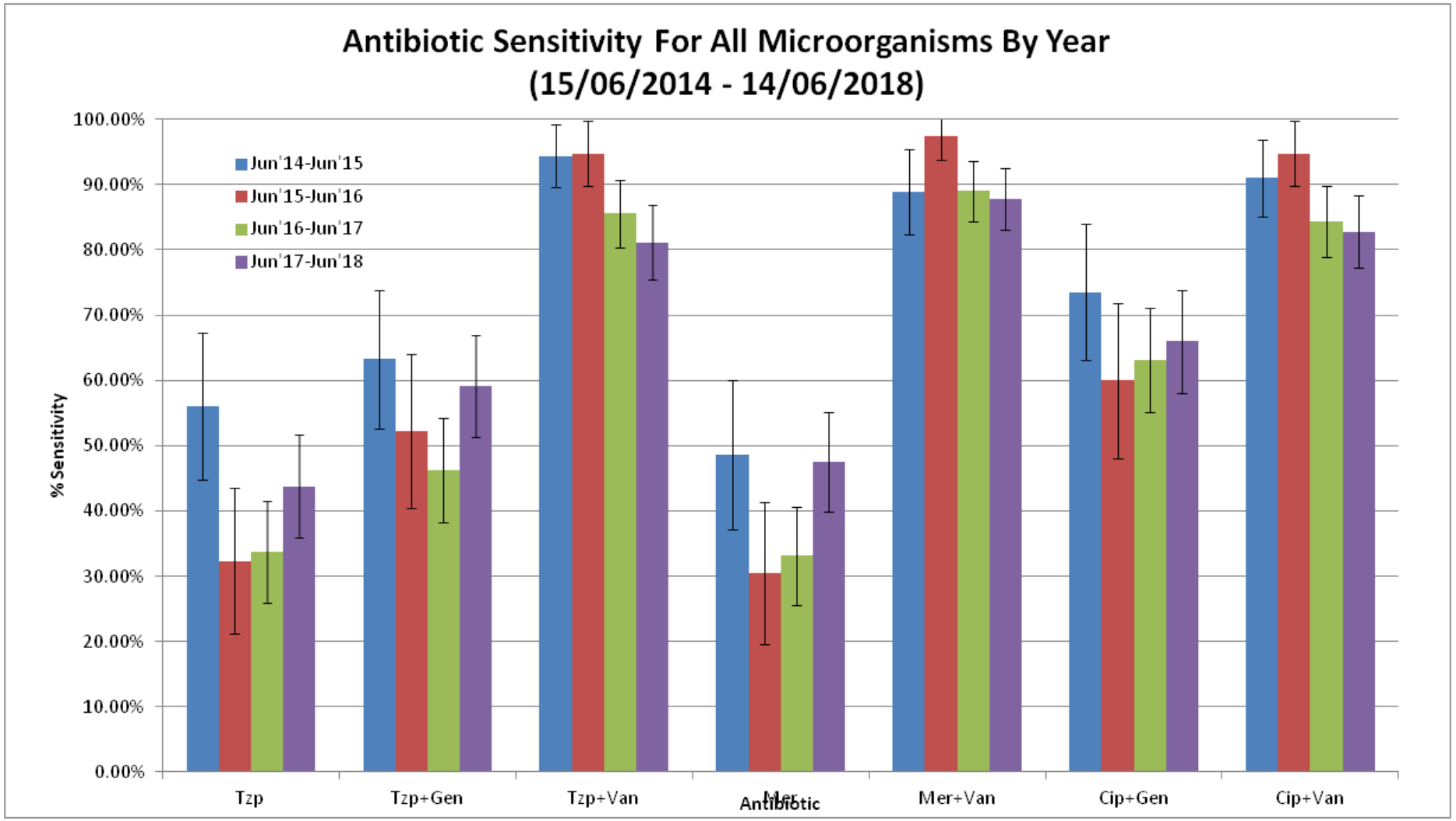
12. Antibiotic use against Environmental organisms and antibiotic resistance rates

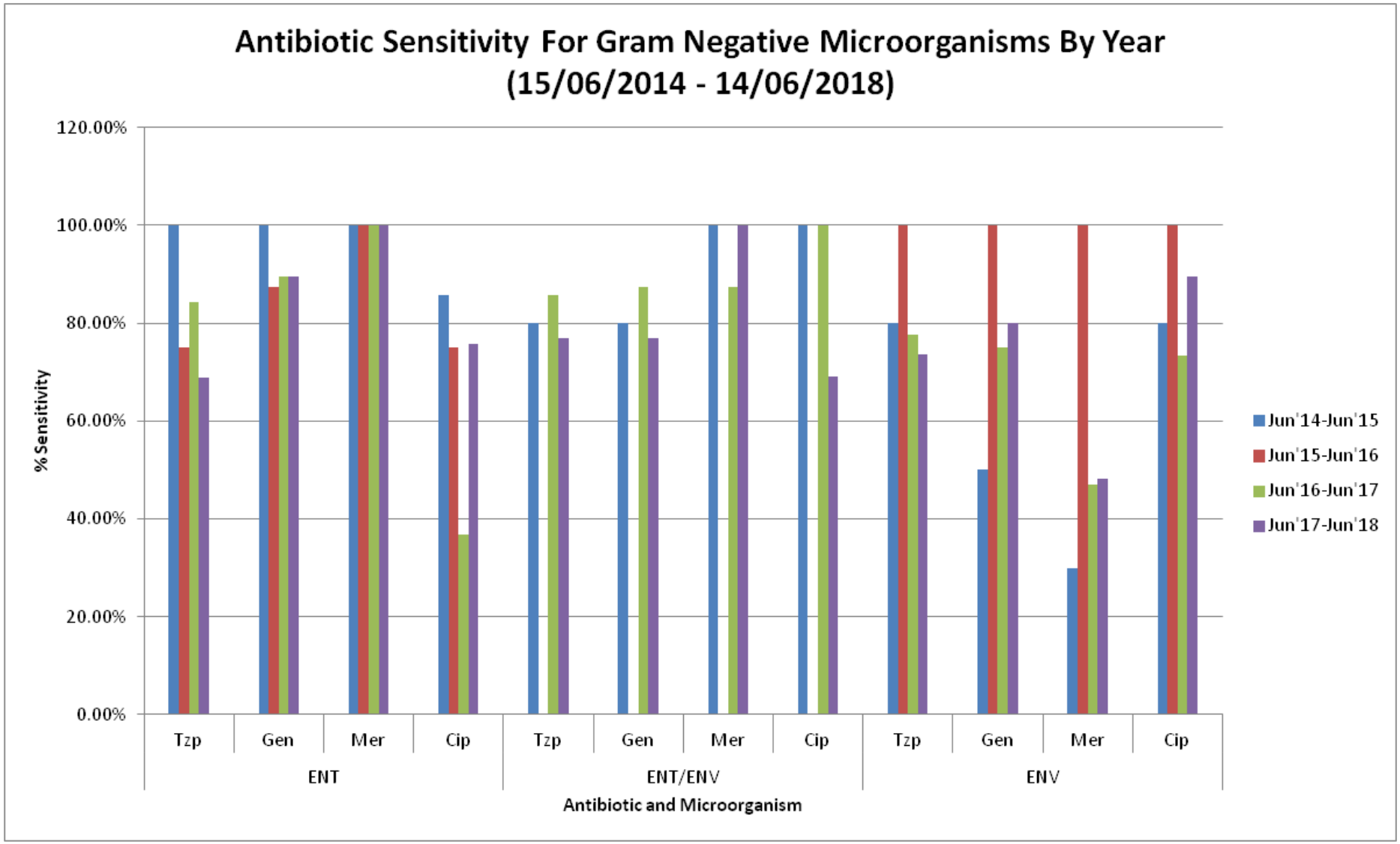

Environmental Organisms , Antibiotic use and Antibiotic Resistance
DDDs Antibiotics
Number Blood Cultures
Total Environmental orgs
Cipro
mero
Taz
Mero R environmental gram neg
TAZ R Envir gram neg
CIP ENV
900
800
700
600
500
400
300
200
100
0
18
16
14
12
10
8
6
4
2
0
2014-2
2014-3
2014-4
2015-1
2015-2
2015-3
2015-4
2016-1
2016-2
2016-3
2016-4
2017-1
2017-2
2017-3
2017-4
2018-1
2018-2

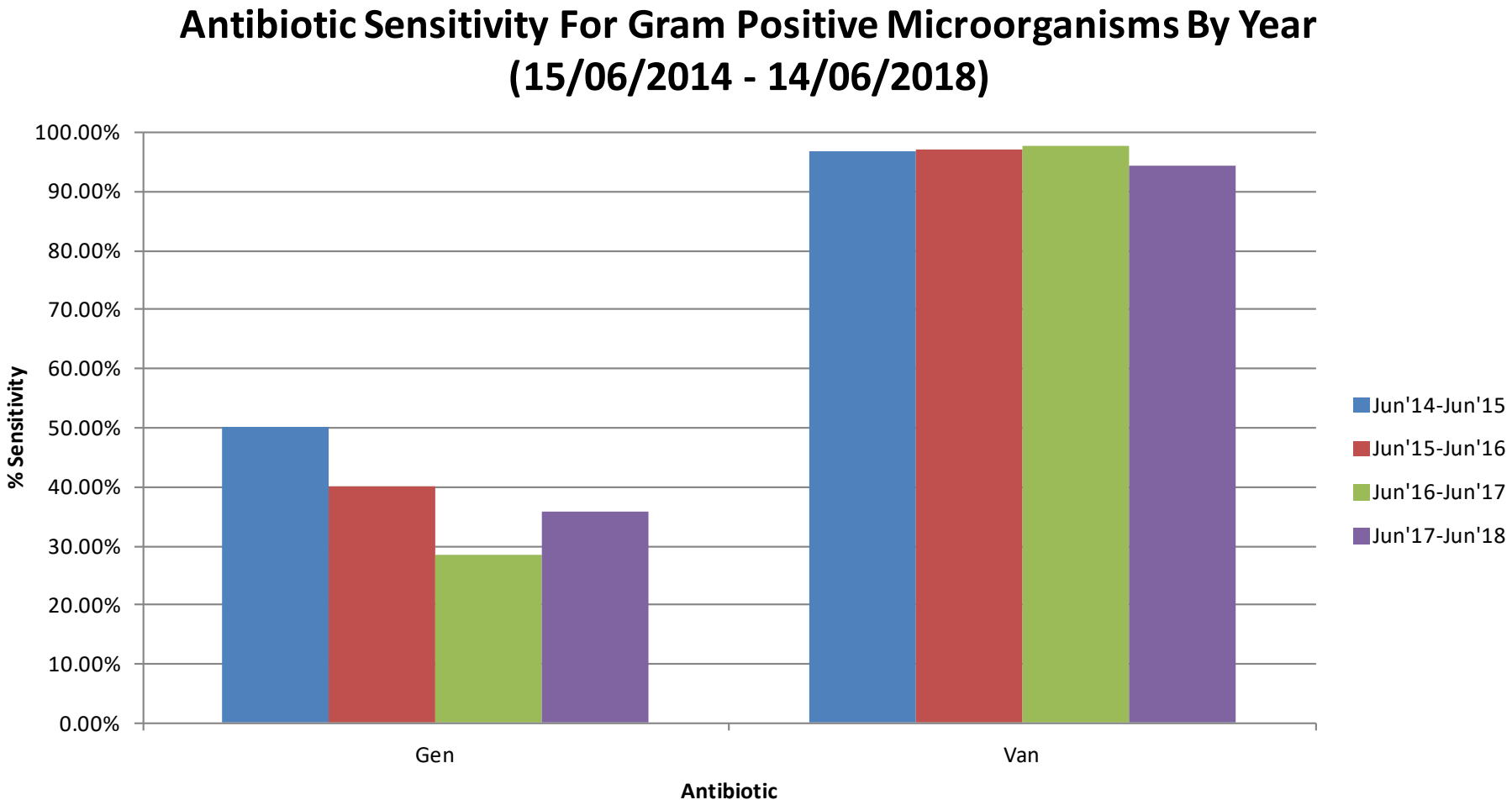
13. Meropenem Use in DDD divided by number of Gram negative bacteraemias.
    Rate of mero use per gram neg blood culture stable since third quarter 2016.



14. Antibiotic Sensitivity rates




Antibiotic Sensitivity For Gram Negative Microorganisms By Year
(15/06/2014 - 14/06/2018)
120.00%
100.00%
80.00%
60.00%
40.00%
20.00%
0.00%
% Sensitivity
Tzp
Gen
Mer
Cip
ENT
ENT/ENV
ENV
Antibiotic and Microorganism
Jun'14-Jun'15
Jun'15-Jun'16
Jun'16-Jun'17
Jun'17-Jun'18


Antibiotic Sensitivity For Gram Positive Microorganisms By Year
(15/06/2014 - 14/06/2018)
100.00%
90.00%
80.00%
70.00%
60.00%
50.00%
40.00%
30.00%
20.00%
10.00%
0.00%
% Sensitivity
Gen
Van
Antibiotic
Jun'14-Jun'15
Jun'15-Jun'16
Jun'16-Jun'17
Jun'17-Jun'18

Summary of Results

Epidemiology

- Significant increases in bacteraemia rates since 2015 with a peak in April –June 2017, with a static at risk population
- Of note NO significant changes in laboratory practices occurred throughout the audit period
- Reduction in Gram positives bacteraemia cases since 2017 – in line with QIS programme on line related infections (data not shown)
- Notable Double peak in environmental organisms in third quarter 2017 and second quarter 2018
- Change in predominance from gram positive to gram negative organisms, with more gram negatives for first time in second quarter 2018
- Striking increase in mixed infections with multiple environmental organisms – in keeping with environmental sources of infection
- Increases in the number of different species isolated ie diversity of organisms increases associated with peaks (data not shown), including unusual and rarely isolated organisms.

Antibiotic Use

- Total antibiotic use peaks associated with increase in cipro use –possibly linked to use of Cipro as prophylaxis in context of water incident
- Peak in BCs associated with peak in resistance rates to taz and mero and cipro , in keeping with the types of organisms isolated
- Meropenem use static in comparison to number of gram negative organisms isolated

Resistance Patterns

- Large variability in year to year resistance patterns
- When organism is unknown TAZ plus Vanc gives 80% cover , Gent plus taz less than 60% (current policy)
- Within the Gram negative there are significant differences in resistance rates between environmental vs coliform

- Gram positives – vancomycin better cover till teic sens known due to 23 % resistance to Teicoplanin (data not shown)

CONCLUSIONS

1. There has clearly been an increase in the incidence of gram negative organisms in the haematology/ Oncology paediatric patients, most strikingly in unusual non- coliform environmental organisms which cannot be explained by increased number of at risk patients , laboratory practices or selection pressure of meropenem use.
2. Overall this data supports the hypothesis that environmental factors have been driving rates of bacteraemias in this cohort
3. As the organisms and resistance rates are volatile the most crucial component of managing sepsis is rapid diagnosis and identification or organisms with daily microbiology and clinician discussions regarding therapy.
4. Empirical guidelines will not cover environmental organisms well, but when these are removed meropenem offers 100 % cover as an escalation antibiotic. Further discussions regarding empirical policy are warranted and are ongoing.
5. Antibiotic use is driven by increases in infections and serious bacteraemias.
6. Further work is required to look at amikacin resistance, different combinations of antibiotics for different groups of pathogens.
7. Resources need to be identified in order to maintain a close and timely monitoring of this level of epidemiological data.

Questions for Professor Evans based on the 3 reports which have been provided by NHS GGC to the Inquiry, in relation to:

1. Cupriavidus – *Report on Cupriavidus Infection at Queen Elizabeth Hospital University Glasgow* by Prof T Evans (5 March 2023)
2. Stenotrophomonas – *Report on Stenotrophomonas Infection at Queen Elizabeth Hospital University Glasgow* by Prof T Evans (5 March 2023)
3. Enterobacter – *Report on Enterobacter Infection Queen Elizabeth Hospital University Glasgow* by Prof T Evans (5 March 2023)

The Expert Group instructed by the Inquiry have considered these reports and have identified some further information that we are now seeking from Professor Evans to allow us to better understand his reports.

A. For all reports

We note that the reports provide a discussion of the results, but not the results themselves which the Expert Group has indicated makes them difficult to evaluate.

As such, in order to consider the reports further, for each report can Professor Evans please provide the results on which the analysis is based, by which we mean:

1 A table of sample characteristics (human, water, other environment), their date of collection and location. In this regard we note that there is a reference to a sample from GRI. A table showing location would reassure us that all samples included in the study are relevant. See report by Prof Alistair Leanord and Dr Derek Brown for details. If further information is required please contact NHSGGC.

2 Where a WGS family tree is referred to, the tree itself. Attached

3 We would also like to see copy of the Standard Operating Procedure for collection and processing of water samples. Available from NHSGGC.

4 A flow chart illustrating the sifting process would also be useful. I am unsure what exactly this means.

B. Queries specific to each report

In addition to this we have some specific queries for each of the three reports, although some of these may be answered should the above results be made available.

1. Cupriavidus

1.1 Section 3.1 – "*total of 10,331 water samples were analysed by the environmental lab…*" . Does this refer to QEUH and RHC samples or everything the lab has processed? Please see the report by Dr Dominique Chaput for details of the sampling.

1.2 Section 3.1 – "*In the period 2015 – 2020 a total of 485 isolates of Cupriavidus were isolated from QEUH Adults and RHC water samples.* "

- How does this figure of 485 tally with the figure of '275? (the author goes on to note – "*Of these 10,311 water samples, 6183 looked…Cupriavidus of which 275 (4.4%) were positive for this genus*" Please see the report by Dr Dominique Chaput for details of the sampling and results.

1.3 Section 3.1 – "*275 (4.4%) were positive for this genus. 56 isolates of Cupriavidus species were isolated from other environmental sources…8 isolates were from human cultures*"

- Does this mean that the total number of samples at this point is = 275 + 56 + 8 (two patients had duplicate sets, so 6 unique samples)= 337? Please see the report by Dr Dominique Chaput for details of the sampling and results. Please see the report by Prof Alistair Leanord and Dr Derek Brown for details of the availability of isolates for sequencing.

1.4 Section 3.1 – "*Of note, prior to March 2018, in general, isolates of Cupriavidus spp from water and other environmental sources were not routinely stored and hence such samples are not available for whole genome sequencing*"

- Does this mean that only water and other environmental samples (275 + 56 = 331) which were taken after March 2018 were taken into account? In general only isolates available for sequencing were from March 2018 onward. As above please see reports by Dr Dominique Chaput and Prof Alistair Leanord and Dr Derek Brown for details on sampling and isolates for sequencing.

1.5 Section 3.2 – "*we analysed 133 of the Cupriavidus isolates…*" –

- Is this of 337 samples? What is the breakdown here of water, other environmental and human samples? 133 isolates were from the collected isolates generally after March 2018. Of the sequenced isolates, 8 were human samples, The rest were predominantly from water sampling. Please see the report by Prof Alistair Leanord and Dr Derek Brown for further details on the isolates that were available for sequencing.
- How does this tie in with the 485 isolates of Cupriavidus between 2015-2020 from water samples noted in section 3.1? As described above.
- **133 isolates analysed** how were these 133 selected? Are they a mixture of water and environmental samples? Did they include the 8 patient samples? (We assume so because they are referred to later.) As described above, they include the human samples and the available stored isolates.

1.6 Section 3.3 – "*As all the human isolates were C. pauculus or the new Cupriavidus species, we focussed on these species. The 75 C. pauculus isolates were highly diverse*" –

- Can you advise why these 75 were focused on? Because these were the isolates from patients. None of the other *Cupriavidus* species were found in the human isolates.
- C. pauculus and 'new' Cupriavidus species isolates make up = 75 + 6 = 81
    - What happened to the 52 *C. (various species)* isolates? These are sequenced and annotated on the phylogenetic tree.
- Did the author purposely chose the C. pauculus + 'new' species isolated because all 8 human samples were contained within these 2 groups? If so is the total therefore 81? Yes as clearly stated in paragraph 3.3.
- Regarding the new species group – based on them being 'new', was the process of taking them through WGS different to those 'previously known isolate species? No

1.7 Section 3.5 – "*All the Cupriavidus spp genome sequences were analysed and a family tree of their relatedness to one another was constructed. Of the 6 unique human isolates, 2 were isolated prior to 2018*" –

- Is this WGS family tree available for scrutiny? Yes
- How many Cupriavidus samples were analysed? 81? No. 133 as set out above and on the tree.

1.8 Section 3.5 – "*Of the 6 unique human isolates, 2 were isolated prior to 2018. One was isolated on 16/2/16; the clinical details note this was thought to be a contaminant. The other was isolated on 22/9/17. One of the sequenced samples was from Glasgow Royal Infirmary and not considered further here*"

- How was it that a Glasgow Royal infirmary sample was included? We were sent all available sequenced samples - this isolate from GRI was excluded from my analysis.
- If a GRI sample was included can we be sure if all the others were indeed from QEUH/RHC? Only QEUH/RHC samples were part of my analysis.
- A table of all samples 337 , their sample location and date of collection would have been useful in order for the reader to scrutinise and answer such questions. Is there one that could be made available? 337 is not the number of samples isolated as set out above. Please see the report by Prof Alistair Leanord and Dr Derek Brown for further details on the isolates that were available for sequencing.

1.9 Section 3.8, 3.9 and 3.10 and conclusion sections–

The author then goes onto compare human and environmental samples' WGS which are at least 8 months apart, with one example of a pair (human and environmental sample) 2 yrs 1 month apart.

- What is the justification behind comparing the WG-sequences of these human and environmental isolates to each other? That was the main aim of the study – to establish if there was any relatedness between human and environmental isolates which could indicate a possible transmission event.
- How many human samples were included in the WGS comparison, however far apart the human and environmental samples? All the human samples excluding duplicates.
- **Section 4.6 and 4.7 –** Ultimately only 4 human samples seemed to have been compared to environmental samples using WGS. Comparisons were made where there was a likelihood of close relationship. As set out in paragraph 3.8, there were few water/environmental samples available to make a meaningful comparison for the 2 human isolates obtained prior to 2018.
    - The author noted in **section 3.7** – "*a large number of environmental isolates of C.pauculus were isolated between February and March 2018"*
        - What do we know about the 'extent' and 'frequency' of water sampling at the timepoints where we see these 6 unique human isolates, other than the months of Feb and March 2018 which the author flags? Please see the report by Dr Dominique Chaput for details of the sampling and results.

2. Stenotrophomonas

2.1 Section 3.2

- **T**he author notes that of 10,331 water samples, 76 isolates of S. maltophilia, were found. 75 of these water S. maltophilia, positive were isolated > = 2018, apart from 1 in 2016. Later on the report says "*Of these 10,311 water samples, 6,183 looked*

specifically for Gram negative organisms including S. maltophilia (STM), of which 71 (1.1%) were positive for this species".

- Is the figure of 76 or 71 STM positive water samples over the period 2015 – 2020 correct? Please see the report by Dr Dominique Chaput for details of the sampling and results.

- 40 further STM isolates is noted from "…*other environmental sources such as drains*" The author notes - "*Although as outlined, different locations and extents of testing were carried out, there is no reason to suppose that this level of the presence of S. maltophilia in water samples is not representative*"
  - On what information does the author base the above comment regarding the level of presence of STM in water samples? Is this based on a 'baseline prevalence' figure which is not referenced within this report? This is based on the details of the testing regimens and samples obtained as set out in the report by Dr Dominique Chaput. The distribution of different types of *Stenotrophomonas* within the water and environmental samples was very similar to the published analysis by Groschel et al.
- The author then notes – "Over this time period, there were 23 isolates of clinical relevance isolated from blood cultures."
  - What is meant by the term 'of clinical relevance' Deemed to be associated with clinical disease.
- So far the figures of STM positive from water, other environmental and 'clinically relevant blood cultures' tallies up to either

  76 + 40 + 23 = 139, or
  71 + 40 + 23 = 134.
  - Can the author confirm which is correct? The number of positive water and other environmental samples positive for *Stenotrophomonas maltophilia* is described in the report by Dr Dominque Chaput. 23 clinical isolates were available for sequencing.

2.2 Section 3.3

- The author notes: "*We were able to carry out a detailed analysis of the genomes of 84 these organisms and related them to available epidemiological data, notably time and place of isolation. 79 of these sequences were from samples at the QEUH campus (including the Royal Children's Hospital)"*
- The author notes detailed analysis of genomes was carried out on 84 of these organisms
  - Does this refer only to STM organisms, or to all samples? If the latter, is this from all sources (ie, patient, water and environmental). This question is not clear to me. We were given sequence information on 84 *Stenotrophomonas maltophila* isolates from both human, water and environmental sources.
- The author then provides a tally - "*79 of these sequences… 56 from isolates of water…*".
  - This implies 79 of 84 were from QEUH (incld. RHC) What about the remaining 5 samples? Were they outwith QUEH? Yes, the other 5 were not from the QEUH/RHC.
- The author then notes – "*Of these, 23 of the isolates were from blood cultures, and 56 from isolates of water samples and environmental samples taken from drains from a variety of outlet points (which represents 48% (56/116) of the total water/environmental S. maltophilia isolated at the QEUH campus). The human samples were collected between 2015-2020, the water and environmental samples from 2018-2020*"
  - Can the author confirm whether he means 23 blood cultures and 56 isolates from water and environmental samples of 79? Yes

- The author then notes that the 56 isolates makes up 48% of the total water/environmental STM isolated.
    - What was the reason behind not including the remaining 52% of the water/environmental samples? Are we to assume that the 56 is a purposeful sample? Isolates were not available for sequencing. Please see the report by Prof Alistair Leanord and Dr Derek Brown for details on the isolates that were available for sequencing.
    - Again. a results section detailing the samples by ward, collection date (even by year) would have been helpful. Is there one that could be made available? Please see the report by Prof Alistair Leanord and Dr Derek Brown for details on the isolates that were available for sequencing.

3. Enterobacter

3.1 Section 3.1

- There is a table of 'other environmental' samples taken by ward area is provided.
- There is a table providing the number of 'samples containing Enterobacter' which we presume is the 'number of positive samples for Enterobacter' by sample location. Yes
- The total positive samples from 'other environmental samples' = 60
    - Where is the number of positive samples from 'water samples' provided? See 3.1- 6 isolates which were not analysed further.

3.2 Section 3.2

- The author notes: "*6 isolates of Enterobacter from environmental samples were serendipitously retained and whole genome sequences obtained*" .
- So of the 60 'other environmental samples', 10% - 6 isolates of Enterobacter are put through WGS
    - Can the author clarify the timeframe over which the 60 environmental samples spanned, and the monthly incidence over that time period. Please see the report by Dr Dominique Chaput for details of the sampling and results.
    - Can the author clarify how representative the 10% of samples finally put through WGS are of the total, for example, is there assurance that that they aren't all from a single month where water sampling was done at a high frequency? I understand that these were from a very limited time frame in around Sep/Oct 2018. Please see the report by Prof Alistair Leanord and Dr Derek Brown for details.
- The author notes: "*Over this period, 29 patient samples were identified from blood cultures from patients within the QEUH/RHC*"
    - Can the author clarify the period being referred to? 2016 - 2019
    - Can the author confirm whether these 29 patient samples from this period were also put through WGS? Does that mean the total put through WGS was actually 6+29 = 35? Yes as set out in 3.1
- Can the author cl 6 samarify what they mean when they say: "… *29 patient samples were identified from blood cultures..*" ? Exactly that
    - Can we infer that this the total number of Enterobacter blood culture samples to come out of QEUH and RHC over this period? No. Please contact NHSGGC for details on the number of is positive blood cultures.
    - Is this number identified or available to the author? As above
    - Is there assurance on either point? As above

3.3 Section 3.3

- The author notes**: "**The whole genome sequences of these human and environmental Enterobacter isolates were assembled and a phylogenetic tree constructed to show their

evolutionary relationships. As expected, the species as identified by ribosomal multilocus sequence typing grouped together."

- Is there a results section available providing the phylogenetic tree and, if so, can this be provided? Yes attached

3.4 Section 3.10 – "*None of the isolates from environmental sources were closely related to any of the isolates from patients*"

- Can the author clarify how this conclusion is validated? By SNP analysis

3.5 Section 4.1 to 4.4

- Can the author clarify whether there is any information available on the 'spread', 'representativeness' of the 29 bloodstream isolates of all patient / human Enterobacter isolates As above
- Can the author provide further information on which human and environmental samples were compared? As above

Report on the findings of the NHS Greater Glasgow and Clyde:

Queen Elizabeth University Hospital/Royal Hospital for Children water contamination incident and recommendations for NHS Scotland

DRAFT

Report prepared on behalf of HPS/HFS by:

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Contents

Executive summary

NHS Greater Glasgow and Clyde (NHSGGC) have been investigating a potentially contaminated water system with linked clinical cases since January 2018. Health Protection Scotland and Health Facilities Scotland have been supporting this investigation since March 2018. An initial report into the investigation was prepared for Scottish Government and NHSGGC in June 2018.

This final report is based on the interpretation of the data and information made available by NHS GGC including that found within the electronic operating and maintenance manual (ZUTEC) during the course of the investigation. Only Information presented by NHS GGC up to 25th July 2018 has been taken into account.

This report summarises the findings from the information provided and the investigation to date and seeks only to consider the hot and cold water installation and the associated issues and does not consider in detail any issues with the operation of the Energy Centre other than to note its potential impact on the hot and cold water installation within QEUH and RCH.

The Contractor was not directly involved in the production of this report nor requested to verify the contents, although the Contractor has responded to some questions posed directly to them by NHS GGC and these are included where relevant.

This report reviews a number of activities including design, installation, commissioning and handover and makes an assessment on whether practice was compliant with best practice/guidance and the impact on the water system.

Recommendations are made for NHSGGC, HPS, HFS and Scottish Government

Introduction

NHS Greater Glasgow and Clyde (NHSGGC) are currently investigating a potentially contaminated water system across the Queen Elizabeth University Hospital (QEUH) and Royal Hospital for Children (RHC) with possible linked cases of bloodstream infections associated with ward 2A RHC. NHSGGC requested support from HPS with this incident on 16th March 2018 and Scottish Government invoked the national support framework[144] on 20th March 2018 which requires HPS to lead an investigation and provide board support. An initial summary of the findings from this investigation was prepared in a summary report, shared with Glasgow for factual accuracy on 3rd May 2018 and submitted to Scottish Government 31st May 2018 (Appendix 1). This full report contains a more technical review and shared with NHSGGC for factual accuracy on 6th August 2018 and submitted to Scottish Government on 17th August 2018.

HPS worked with the support of Health Facilities Scotland (HFS) as the technical engineering experts to support this investigation and report production. This report is based on information provided by NHSGGC, HPS and HFS. Responses for information requests by NHSGGC and third parties are detailed in Appendix 3. A number of hypothesis are discussed within the report and concludes with recommendations for NHSGGC, NHS Scotland and HFS/HPS.

Background

Queen Elizabeth University Hospital

NHS Greater Glasgow and Clyde's (NHSGGC) Queen Elizabeth University hospital (QEUH) is a 1109 bedded hospital located in Govan in the South West of Glasgow. One of the largest acute hospitals in Europe, it is home to major specialist services such as renal medicine, transplantation, vascular surgery and diagnostic services. It comprises 100% en suite single side rooms on 14 floors. The hospital was handed over to the Board on 26th January 2015 with patient migration commencing from 24th April 2015 until 7th June 2015.

Royal Hospital for Children

The adjoining Royal Hospital for Children (RHC) is a 256 bedded childrens hospital in an adjoining building to the QEUH which was handed over to the Board on 26th January 2015 with migration of patients occurring between 10th and 14th June 2015.

The QEUH and RHC were both fully occupied from 15th June 2015 There are a number of additional healthcare facilities in the surrounding grounds including the maternity unit, neurosurgical unit, elderly care unit and the national spinal injuries unit.

Organisms linked to cases of infection in this incident

In the initial stages of this incident, three organisms were identified as organisms of concern (Cupriavidas, Stenotrophomonas and Pseudomonas). As the investigation continued the case definition was extended to include all gram negative bacteria which had been indentified within the water/drains.

Summary of Incident

Since the incident was identified in January 2018 there have been 17 patient cases identified all linked to ward 2A/B RHC. There have been no new reported cases since 31st May 2018. Whilst a number of these cases gave clinical cause for concern and some had treatment delays there has been no associated mortality.

Ward 2A RHC is a haemato-oncology unit, also known as scheihallion, and houses the national bone marrow transplant unit. Many of the children within ward 2A/B are immunocompromised and as such are the most vulnerable patient population to infection.

In 2016 a patient within ward 2A RHC was identified as having a blood stream infection (BSI) as a result of cupravidas pauculus. NHSGGC investigations included water samples from outlets within the aseptic suite of the pharmacy department where the parenteral nutrition was made that the child had received. Cupriavidas pauculus was isolated from water samples taken from a tap on a washhand basin within this area. The wash hand basin was subsequently removed as a result. A further single case of Cupriavidas pauculus was identified in 2017 however no environmental or water sampling was undertaken at this time.

On 29th January 2018 cupriavidus pauculus was identified from a blood stream infection (BSI) in a patient in ward 2A. A series of investigations were undertaken including water

sampling from outlets within the ward area. On 21st February pseudomonas was identified from a BSI and between 11th and 16th March 2018 4 cases of stenotrophomonas maltophilia were identified from patients in ward 2A and 1 patient in Paediatric ICU. Cupriavidas, pseudomonas and stenotrophomonas (amongst other gram negative bacillus and fungi) were identified. This led to enhanced control measures being applied within ward 2A and an extensive investigation into the potentially contaminated water system across the QEUH and RHC. Testing of the organisms in this incident have not provided an exact link to the patient cases and the water system. Testing in an incident like this can be difficult and should only be used to include cases rather than exclude. To attain appropriate representation of the bacteria within the water would require significant sampling of each organism identified to ensure a representation of strains was identified. The clinical component of this incident was declared over and a debrief was held 15th May 2018. On 18th May an internal problem assessment group (PAG) was convened following the identification of 2 cases of enterobacter BSI linked to wards 2A/2B. Following the report of a new case in a child who became unwell as a result the incident management team reconvened on 4th June 2018. It was reported that there was evidence of a black substance being visible at the outlet of the drains in some clinical wash hand basins in ward 2A/B thought to be biofilm. A programme of drain cleaning of all drains in all high risk wards across QEUH and RHC was commenced, staring with wards 2A/B. In addition both these wards underwent a series of environmental decontamination using hydrogen peroxide vapour. The point of use filters in place have resulted in the water from the outlet being closer to the washhand basin and causing splash. The hypothesis is this splash caused by the filter was a factor in environmental and person contamination with enterobacter present within the drains. No further cases have been reported within these wards since drain cleaning has been completed. Whilst the clinical IMT has been stood down since 21st June 2018, weekly water IMT is being held by NHSGGC and supported by HPS/HFS. This group will continue to meet on a weekly basis throughout the year and meeting schedules will be reviewed early 2019.

This report was due to be published in June 2018 however due to the complexity and volume of information required and requested from NHSGGC an extension to the delivery date was agreed and the report was produced on 17th August 2018. A further detailed review on wards 2A/B will be produced by mid October 2018. HPS worked with the support of Health Facilities Scotland (HFS) as the technical engineering experts to support this investigation and complete both interim and final report production.

Biofilm

Water and water systems harbour a diversity of microorganisms and whilst the majority are considered harmless to healthy individuals, some, such as Pseudomonas aeruginosa, can cause serious opportunistic infections, particularly in individuals with a weakened immune system ((Lyczak JB, 2000) as cited in (G Moore, 2015)). Biofilm is a group of microorganisms in which the cells adhere to each other and often to a surface. These cells then become embedded within a slimy substance and can be prevalent in natural, industrial and hospital settings. Multiple environmental conditions such as oxygen availability, water temperature and the flow rate of water across the biofilm, will determine the extent to which a biofilm grows (Nocker, 2014).

Once a biofilm has advanced, it forms a complex structure in which different bacteria occupy different environments. This sophisticated approach means bacteria towards the outside of the community have a very different structure from those deep within the matrix. These physiological differences together with delayed penetration of chemical agents through the biofilm matrix result in an increased tolerance to antimicrobial agents, including disinfectants and other chemical biocides (Bridier et al. 2011, cited in (G Moore, 2015)).

There is a multitude of information in the published literature which directly links biofillm production/biofilm producing organisms to water source related outbreaks. In addition, three recent review articles focussed on the role of water in healthcare associated infections, with specific mention of biofilm formation as a key mechanism for sustained contamination of water systems.[57-59] Biofilm formation has been described for Cupriavidus species and Pseudomonas spp, particularly in association with water systems. Biofilm formation with Stenotrophomonas on a variety of surfaces has also been demonstrated.[32]

Control Measures

Throughout this incident patient safety has been paramount and the focus of the investigation by NHSGGC, HPS and HFS. A number of control measures have been implemented to ensure this as much as possible. These include:

Point of use filters

Point of use (POU) filters were installed as one of the main control measures initially in high risk areas (wash hand basins and showers) to ensure a safe water supply at the point of use. These filters have been installed across all areas within QEUH and RHC where there are likely to be immunocompromised patients or in identified clinically higher risk areas. POU filters require to be changed every 30 days and are a costly approach, however in the interim until the water contamination can be addressed, is the only feasible approach to ensure safe delivery of water. A number of studies found that installation of point of use filters reduced either infection rates in associated healthcare settings[60;61] or pathogen counts within tested water samples.[62]

Drain Cleaning

A programme of drain decontamination using a hypochlorite (bleach based) disinfectant was undertaken in all high risk areas across the QEUH and RHC commencing with wards 2A/B RHC. An ongoing programme of drain cleaning will be considered.

Water treatment

It is well recognised that drinking water distribution systems contain a diverse range of microorganisms.[134-136] The presence of microorganisms is affected by various factors including; the disinfection processes employed, the location and age of the system as well as pipe material.[137]

There are a number of options to be explored for longer term water treatment and NHS GGC are preparing a feasibility report on the most appropriate solution: these options are discussed in the initial report. NHS GGC are currently exploring the preferred option of

chlorine dioxide however it is recognised that this may take up to 2 years to ensure the water system is within acceptable parameters from a microbiological perspective.

Appendix 5 contains a rapid review of the literature and summary of issues associated

Hypothesis

There are a number of workable hypothesis that continue to be explored, it is currently considered the most likely cause of the widespread contamination is a combination of hypothesis B and C

A: Ingress contamination
A small low level number of micro-organisms may have been present in the water supply at the point of entry. Lack of temperature or chemical control may have enabled biofilm formation. Due to the increasing biofilm throughout the system this may have allowed any subsequent micro-organisms present at point of entry an opportunity to flourish and cause widespread contamination of the system.

B: Regressional contamination
This may have occurred due to contamination occurring at the taps/outlets or flow straighteners and contamination has regressed backwards throughout the system causing widespread contamination. The widespread positive results and array of bacteria point to contaminated outlets at installation or contamination of high risk components in the tap from ingress as opposed to the patient contact route

C: Contamination at installation/commissioning
Contamination may have occurred due to presence of contaminated pipework or outlets. Prior to handover the system required to be sanitised due to high TVC counts. It is unclear what infection control input was to this process and the counts at handover. It is also unclear if a robust flushing regime was in place from installation to handover and from handover to occupancy to prevent contamination.

Contract

Type

- The contract type was a NEC3 Engineering and Construction Contract (ECC).
- This contract type is common and generally used for the appointment of a contractor for large scale engineering and construction work, including portions of design responsibility.
- The contract was awarded 18th December 2009, with a total value of the project at £610 million (including QEUH, RCH, Labs, car parks, Institute of Neuro Science etc) with an approximate value of the mechanical and electrical works of approximately £184 million.

- The sectional completion certificate for the works associated with QEUH and RCH is dated 26th January 2015.

Roles

- The following organisations were employed under the above noted contract to deliver the project for NHS GGC.

Team	Role	Name
Contractor	Main contractor	Brookfield Multiplex
	M&E subcontractor	Mercury Engineering
	Architect	Nightingale Associates (now IBI)
	M&E services engineer (Design Engineers)	ZBP Associates, subsequently taken over by TUV SUD (Wallace Whittle)
	Water Services Commissioning	H&V Commissioning Services Ltd
	Construction (Design and Management) Regulations 2007 (CDM)	Brookfield Multiplex Health & Safety Team

Table 2.1 Roles and responsibilities for design, installation and commissioning

- It is noted that as the Contract was a design and build type, the NHS GGC Estates team were not part of the Client's project team and had no influence with regard to the design of the mechanical and electrical services or any input into the practicality of maintaining these services.
- One member of the NHS GGC Estates Team and one member of NHS GGC Infection Control were involved during the commissioning period to review method statements.
- The QEUH did not go through the NHS Scotland Design Assessment Process (NDAP). At the time of planning and design for this project, NDAP assistance was voluntary at the discretion of the Boards.

Information requested

- To assist with the technical appraisal requests were made by HFS and HPS for information to NHS GGC and various third parties. The responses by NHS GGC to the information requests are shown in Appendix 3 as are responses from third parties.
- The hypotheses, conclusions and recommendations in this report are based on the information received, discussions with various specialists and technical research.

Design and Construction

Guidance and specifications

- Legal reference documents for water systems are as follows, however we have not been provided with evidence that these documents have been referenced in detail within either the NHS GGC Employer's Requirements or the Contractor's proposals:

  Health and Safety at Work Act 1974

  Management of Health and Safety at Work regulations 1999

  Control of Substances Hazardous to Health (COSHH) 2002

  Approved Code of Practice (ACOP) L8

  Legionnaires' disease Technical Guidance HSG 274

- These documents set out the legal requirements and guidance which must be observed with respect to water systems during design, construction, commissioning and maintenance.
- NHS GGC set out the design parameters and guidance to be followed in their Employer's Requirements (ER). In section 8.2.8 Water Systems and Filtration, the ER details the requirement for two new water supplies, storage and full compliance with certain guidance documents. An image of this section is detailed in Appendix 2[1]. Some of the documents referred to in this section are incorrectly referenced, superseded at the time of construction and therefore could be misleading.
    - The Health Technical Memorandum is noted as (S) HTM 04-01. It is therefore unclear if the Scottish Health Memorandum (SHTM) or the NHS England version (HTM). It should be noted that all project in Scotland should follow guidance given in SHTMs.
    - SHTM 2027 should not have been cited as it was superseded by SHTM 04-01 (published August 2011)
    - SHTM 02 refers to medical gases (and therefore would not provide guidance on the safe operation of water systems).
    - SHTM 2040 should not have been cited as it was superseded by SHTM 04-01 (published August 2011)

[1] Appendix 2 Item reference 1

- The Health Guidance Note (HGN) “Safe Water Temperatures” noted was incorporated into SHTM 04-01.

- The ER also details the test and certification requirements to be handed over for all services, but lists the water services documentation specifically as:-
  - Flushing and Chlorination test certificates.
  - Testing of all hot water TMV etc
  - Mechanical pipe work pressure tests
  - Water systems in accordance with CIBSE Code W
  - Domestic water bacteriological tests
  - Legionella testing (including incoming mains)
  - Chemical clean and inhibitor dosing
- Contractor stated compliance with SHTM and specifically SHTM 04-01
  - The contractor has identified which guidance documents they intended to comply with in their submission response document, section 7.1 “NHS Mandatory Documentation”[2]. It is noted that the contractor’s proposal complies with SHTM 04-01 A and SHTM 04-01 B but there is no mention of any of the other parts which were published at this time (SHTM 04-01 parts C to F). The only deviation noted is the reduction in capacity of the storage tanks.
  - The contractor has also noted that they intend to comply with the NHS England HTM 04-01 A and HTM 04-01 B. It should be noted that these documents are not applicable in Scotland. The Contractor has also noted compliance with superseded water related SHTM (SHTM 2027).
  - The theme of compliance with superseded and English documentation is consistent through the contractor’s proposal document for other services. It is also noted that there are duplicate references to various items of guidance on the full table contained within section 7.1 “NHS Mandatory Documentation”.
  - It is not clear therefore what health care design guidance took precedence from the information provided.
  - The contractor has noted in their document “Design strategy for engineering systems reserve capacity” that an additional 25% capacity was allowed in the distribution pipe work, pump systems, mains and risers[3]. This same document notes that there is “nil reserve capacity” for the cold water storage system. It should be noted that over sizing water pipe distribution systems may lead to stagnation in parts of the water system which may contravene Health and Safety guidance as well as the guidance given in SHTM 04-01.
  - Larger diameter pipe work will have less velocity than smaller pipe work, which may lead to biofilm adhering to the pipe surfaces. Most designers build in a certain amount of capacity in their design (and this should be defined by

[2] Appendix 2 Item 2 Extract from Contractors Proposals
[3] Appendix 2 Item 22

assessment[4] to avoid stagnation), but the issue of biofilm formation may be exacerbated by adding 25% on to the main pipe work distribution.

Specification of water system

- The contractor has specified that "The incoming water main service systems will comply with the relevant clauses of the NHS Model Engineering Specification Parts C01, C07, C82, D08, addendums to Part C, SHTM 2027, 2040, BS 6700, Scottish Water Byelaws 2004, and descriptions and requirements set out below" in their specification document section 4.45-4.47. These are outdated references even at the time of the specification was written.
- The specification for the hot and cold water supply systems is detailed in TUV SUD (Contactor's specialist mechanical and electrical (M&E) designer) specification reference ZBP-XX-XX-SP-500-103. This document makes it clear that the specialist sub-contractor has to develop the installation, setting to work and commissioning. The applicable guidance is noted as SHTM 04-01.
- The document refers to thermostatic mixing valves (TMV) rather than thermostatic mixing taps (TMT). This (TMV) means a separate device for mixing the hot and cold water was envisaged rather than combing this unit with the tap (TMT) at the time the specification was written.
- The cold water storage is sized for 24 hours with 10% spare capacity which is different from the nil noted above.
- The hot water is designed for 60°C flow and 55°C return. It has been advised by NHS GGC that these temperatures are not what is being found in practice due to issues with the Energy Centre (this is discussed elsewhere in this document).
- The specification states that "All main distribution and dropper connections will be provided with isolating valves, with local isolation valves installed to isolate and shut down individual ward/department areas". This is not what has been provided onsite as this level of isolation cannot be achieved.
- The specification states that the Domestic Hot Water Service (DHWS) distribution system will be configured with a pumped return to maintain temperatures within the system in accordance with SHTM 04-01. The pumped return system will minimise "dead legs" and reduce water consumption by providing the correct temperature of water at the outlet with minimum delay. From the contractor's description and reports from the Project Supervisor, dead-legs have been introduced into the systems rather than be minimised.
- Water flow regulators are specified to reduce flow on both the hot and cold outlets. These have the potential to become colonised with bacteria and guidance issued after the commencement of this contract advised against using these devices.

[4] CIBSE Design Guide G

- With respect to completion of the project,
  - the specification calls for the following:-

COMPLETION

The Sub-contractor shall protect the system from damage or interference during the works.

The Sub-contractor shall Test, flush and clean the system as per section Y12, Y50, SHTM/ HTM's and TR/20.

The Sub-contractor shall submit O&M's (Operating and Maintenance Manuals) as required by The Contractor

The Sub-contractor shall provide training as per section Y12, Y40 & Y50.

The Sub-contractor shall provide spares as per section Y12, Y40 & Y50

The pressure testing of the system is to be to BS 6700.

- The ZBP/TUV SUD specification "Common Mechanical Clauses[5]", details Y12, Y40 and Y50 noted above amongst other requirements. Selected clause extracts from this specification are highlighted below as reference to points raised later in this report as follows:-

Y10 Pipelines

Purpose made cap ends to prevent dirt and rodent infestation.
Protect against frost, building works, or the operation of others.
Keeping clean, tidy, and free from waste and superfluous material all of their areas.
For water services, pipe runs should not be excessively long and dead legs should be kept to an absolute minimum to avoid stagnation.

Y12 MECHANICAL CLEANING AND CHEMICAL TREATMENT

Water analysis: Analyse water samples before treatment.

The use of stainless steel, PVC-U, PVC-C, PB or PE-X piping requires a leachate flushing regime to reduce the level of contaminants leaching from the piping material into the water. Details of this regime are given in SHTN 2. All parts in contact with the water must be non-dezincifiable. It is recommended that a specialist firms are engaged for the disinfecting and water sampling process. NOTE chlorine should NOT be used for the disinfection of stainless steel piping or membrane filters manufactured from polypropylene.

Disinfection and subsequent flushing should be carried out as a continuous and consecutive operation without any intermediate delays.

[5] ZBP/TUV SUD Specification ZBP-XX-XX-SP-520-307

Flushing: In accordance with BSRIA AG 1/2001.1.
Installation checks: Thoroughly inspect pipework.
Water treatment: Standard: To BS 6700.
Samples for analysis: Provide after flushing.
Water quality tests: Standard: To BS 6700.

Samples: Submit samples for bacteriological analysis.
Water temperature: Record the temperature of the water at each sampling point, at the time of taking the sample.
Test results: Submit

Y50 Mechanical commissioning

Completion

The Sub-contractor shall provide instruction to the clients engineers and maintenance staff in the safe operation of all systems and items of equipment for an adequate and reasonable period of time based on the manufactures' recommendations and best practice. The Sub-contractor shall provide adequate and qualified staff in order to carry out their maintenance and repairs during the defects liability period.

Demonstrations

Running of plant: Run, maintain and supervise the installations under normal working conditions.
Duration: 4 weeks.
Instruction: Instruct and demonstrate the purpose, function and operation of the installations.

Seasonal commissioning

Seasonal commissioning of plant and systems shall be undertaken over the first 24 month period in accordance with the requirements of the BREEAM Assessment. Measurement and recording of criteria for thermal comfort (temperature and humidity where applicable), ventilation rates and effectiveness, lighting levels and controls, etc shall be carried out at three monthly intervals. A representative from the Hospital shall also give subjective feedback for consideration in the monitoring process.

- It is noted that water supplies are allowed for the courtyards. These could potentially be little used outlets and introduce dead-legs into the system. NHSGGC have advised that the outlets have been removed, but the pipe work has not been completely removed.
- The stage 3 instruction to proceed log makes it clear that flexible hoses are prohibited. This is also highlighted in Invitation to Participate in Competitive Dialogue: Volume 2. It would appear that there may be 2 instances of flexible hoses having been used in areas retro-fitted by contractors employed by charitable organisations. It is not clear how a third party contractor managed to install these, attach them to the water system

and commission them. In addition flexible hoses have been installed in several locations for rise and fall baths and sinks.

System description

- NHS GGC negotiated two new water supplies from Scottish Water for the QEUH and RHC. One is known as Hardgate Road and the other is Govan Road. Each of these supplies can accommodate the full combined demand of the QEUH and RHC. These enter the building at basement level and connect to two "raw" water storage tanks. A simplified schematic for the cold water distribution system is shown in Appendix 1[6].
- Each supply connects to both raw water tanks via water meters which are connected to the Building Management Systems (BMS). The metering allows checks against the provider's water meters. The supplies alternate every seven hours to ensure no stagnation in the mains and assist in the Scottish Water distribution network.
- Each raw water storage tank has a capacity of 100,000 litres, giving a total raw water storage of 200,000 litres.
- The output of the raw water tanks links to filtration plant. This filtration plant removes dirt, debris and organisms to 0.2 micron.
- From the filtration plant, the water is routed to one of two filtered water storage tanks. Each of these tanks has a capacity of 225,000 litres, giving a total filtered water storage of 450,000 litres.
- The output of the filtered water tanks serves two booster pumps. Each booster pump serves different areas of the facility. The higher pressure systems (7.7 bar) serves mainly the tower of the QEUH (plant rooms 31, 32 and 33) and the lower pressure system (5.0 bar) serves mainly the RHC (plant rooms 21, 22 and 41) - although the floor distribution is not as simplistic as this. It should be noted that the designer (TUV SUD) describes two 7.7 bar systems in their specification and there is no audit trail to advise how the final solution was arrived at.
- It should also be noted that the as-installed drawings on ZUTEC show a different pump distribution system to that which has been installed.
- This Boosted Cold Water Supply (BCWS) into each plant room is metered and routed to either the vertical risers to the calorifiers. The water in the calorifiers is heated via plate heat exchangers with Medium Temperature Hot Water (MTHW) from the Energy Centre. It should be noted that the expansion vessels associated with the calorifiers are not of the flow through type as recommended in The Health and Safety Executive's guidance document HSG 274 part 2[7]. These devices[8] introduce a potential problem of microbial colonisation as plant room temperatures generally exceed that of the incoming water and the internal lining of the diaphragm is made of a material which has been shown to increase the risk of organism growth.

[6] Appendix 1 Simplified water schematic for QEUH and RHC
[7] Appendix 2 item 30
[8] Appendix 2 item 31

- The BCWS pipe work and the HWS pipe work are routed together horizontally in the ward corridors on each floor.
- There is no return on the BCWS, but there is a return pipe work distribution network on the Hot Water Supply (HWS) (which is normal). The BCWS does have temperature controlled end-of-line dump valves. These have been installed to allow water to flow to the drain when the BMS detects a cold water temp of 23°C; this has been installed to prevent conditions which are favourable to the growth of legionella, however the trigger point is set at the start of the legionella growth curve.
- With respect to the return on the hot water pipe work, this has not been installed to the requirements of SHTM 04-01 or HSG 274. The installed hot water pipe loop is created in the corridor or ceiling void and then a spur drops down behind the removable panel to the outlet. This method of installation creates a dead leg to the outlet. Both SHTM 04-01 and HSG 274 part 2 show the hot water circulation pipe work branching as close as practically possible to the outlet so that dead legs and stagnation are avoided. SHTM 04-01 part A notes:-

  Paragraph 8.6

  All pipework should be insulated, except for any exposed final connections to sanitary appliances, and should be arranged to eliminate or minimise dead-legs.

- In addition there is a third system known as the Trades Water Supply. The Trades Water System supplies various outlets such as bib taps in plant rooms, irrigation connections points and the 12th floor helipad fire suppression system.

Pipe work

- The manufacturer of the pipe work installed for the cold water system is noted in ZUTEC as Pegler Yorkshire. There is contact information for the manufacturer and wholesaler. There is a general Pegler Yorkshire XPRESS brochure which covers various materials (copper, low carbon steel and stainless steel).
- This system is installed using crimp joint connections made using a bespoke tool.
- There is no information on the compatibility of the pipe work or joint connection seals and chemical disinfectants. The manufacturer has no published data on this aspect of the pipe system installed (either on their website or via their technical department); there is no assurance regarding the suitability of the chemical used by the Contractor for disinfection of the water systems with the pipe, seals, pumps etc.
- The water services pipe work was integrated into pre-fabricated modules and erected on site along with other services. Due to the density of services in certain locations, it may prove difficult to replace the water services pipe work at any future date without significant disruption to the QEUH and RCH services.

Pipe work installation

Appendix xx details summaries from various Capita Symonds Supervisors reports.

It is noted from these summaries however that:

> There was concern expressed relating to a number of open ends being left on the main pipework installations as well as damaged sections of ductwork noted on arrival to the site. Open ended pipework can become wet and contaminated and if not cleaned before fitting an lead to the development of biofilm and corrosion. In addition this may lead to debris or other material restricting the operation of the systems. The contractors response was to seal all open ends on site, however this was not until 30th March 2012. There is evidence that the pipework was not adequately protected from contamination during construction and the issue with open ended pipework continued to be highlighted as an issue in 2013. There is no evidence that the open ended pipes were subject to any additional checks or decontamination. The open ended pipes were non compliant with the requirements of the specification, SHTM 04-01 or other guidance documents referenced.
>
> It is also noted that at no time in the description of the supervisor's reports are specific standards, specifications or guidance cross referenced for compliance, other than noting the systems are compliant. The terms used are subjective and not quality related.

Comment [a1]: Ian: is this correct?

Comment [a2]: Ian what are the other documents referenced.

Building Management System

- As part of the design[9] a Building Management System (BMS) was designed, installed and commissioned. This system comprises of a network of various sensors, controllers, meters, interfaces and a graphical interface to allow NHS GGC to monitor the plant condition, various water temperatures, energy readings and alarm conditions.
- It is noted that the specification calls for a server to be provided, the storage of which was to be sized to accommodate (amongst other things) access of system archive information for a period of 53 weeks on a rolling basis. It is further noted that the storage should have been a Redundant Array of Independent Disks (RAID) configuration with automatic redundancy. A RAID is a data storage technology that combines multiple physical discs drive components into one or more logical components to improve data security and performance. A RAID server has not been supplied under the contract and NHS GGC is not aware of any specification change regarding this.
- The contractor who was selected to carry out these works under the contract was Schneider Ltd and they have been retained by NHS GGC to carry out the maintenance of the system as well as any operational adjustments required.
- Schneider Ltd utilise a "cloud" based data system for their solution

[9] TUV SUD Specification for Building Management Systems and Automatic Controls Rev F March 2014. Document ref: ZBP-XX-XX-SP-660-401

- At the early part of 2018 NHSGGC were advised by Schneider that the site database was “lost” as well as historical data relating to various trend logs pertaining to energy and temperature monitoring (for QEUH, RCH and the Energy Centre). At the time of writing (July 2018) the historical data has still not been recovered by Schneider; any data pre-dating this is not recoverable due to extended trend logging criteria not being enabled on the standard BMS configuration.
- Schneider are currently modifying the extended logging criteria to resolve this issue moving forward but to confirm the historic data is **NOT** recoverable before 1st January 2018.
- It is noted that there is no record available of the training (off site and on site) required by the specification to NHS GGC staff.
- It is also noted that NHS GGC do not have a process in place for addressing any of the alarms which are generated by the BMS.

Flexible hoses

- Flexible hoses are used to connect items of equipment which are required to change height (i.e. rise and fall sinks, specialist bathing equipment, etc) or equipment which vibrates (i.e. pumps, motors, etc).
- These hoses have been installed in potential contravention to Safety Action Notice SAN(SC)09/0310 “Flexible water supply hoses: risk of harmful micro organisms”. The independent contractor and the Authorising Engineer have expressed concern in their reports regarding the type of hoses that have been installed.

  HSG 274 Part 2 notes:

  > *2.35 In buildings where there are those with an increased susceptibility to infection or with processes requiring specific water characteristics, materials of an enhanced quality may be required. Healthcare buildings and care homes should specifically take note of alerts and advice from the Department of Health and Health Facilities Scotland. For example, healthcare premises are advised against the use of ethylene propylene diene monomer (EPDM) lined flexible hoses (tails) as these have been shown to be a risk of microbial colonisation. Such flexible connections should therefore only be used in healthcare premises where an installation has to move during operation or is subject to vibration.*

- The designers, TUV SUD, have stated in their “Specification Hot and Cold Water Systems11” and section “Flexible Supply Hoses for Final Connections” on page 10 that no flexible hoses (or tails) connections shall be used. This is also highlighted in Volume 2 of NHS GGC’s Invitation to Participate in Competitive Dialogue document.

[10] Safety Action Notice SAN(SC)09/03 “Flexible water supply hoses: risk of harmful micro organisms”
[11] TUV SUD Specification Hot and Cold Water Systems Rev C April 2014. Document ref: ZBP-XX-XX-SP-500-103

- It is noted in the "2010 Instruction to Proceed Log-FINAL"[12] agreement was made to prohibit the use of flexible hose connections by all parties.
- It would appear that the Contractor installed flexible hoses in rise and fall sinks and baths or the connection to certain items of equipment. The contractor has advised that all the hoses installed are Water Regulations Advisory Scheme Approved (WRAS) approved, however that does not mean that they are acceptable in the connection of the healthcare environment and specifically SAN (SC) 09/03. If the hoses contain EPDM (ethylene propylene diene monomer) there is the possibility that pseudomonas and legionella bacteria may exist. The SAN notes that these hoses should be risk assessed and should be changed to a suitable alternative to EPDM as well as being WRAS approved.
- Where installed these hoses should be part of the planned maintenance and replacement procedures.

Outlets

- The Mechanical and Electrical Services designer did not specify the type of tap to be installed. Their specification[13] refers to the Architect's schedules. The room datasheets compiled by the Architect detail the requirements for each room. An example of this is shown in Appendix 2. The Architect has noted the guidance document the sanitary ware should comply with, but not the actual manufacturer. This is also reflected in the layout drawings.
- There are no records to confirm the TMT and TMV associated with the outlets were initially commissioned satisfactorily or that the adjustments required for in-service tests at 6/8 weeks and 12/15 weeks have been carried out.

Dust during construction

- The Control of Substances Hazardous to Health Regulations 2002 (COSHH) gives advice on precautions which may be required or prevent exposure to dust (amongst other things).
- Dust will be a 'substance hazardous to health' for the purposes of COSHH if it is a substance:

  Which is listed in Table 3.2 of part 3 of Annex VI of the CLP Regulation[14]; and

  For which an indication of danger specified for the substance is very toxic, toxic, harmful, corrosive or irritant; or

  If it is a substance to which a workplace exposure limit (WEL) applies.

- If not falling within any of the above categories, paragraph (d) of the definition of 'substance hazardous to health' in regulation 2 of COSHH states that any dust when

[12] Extract from NHS GGC 2010 Instruction to Proceed Log - FINAL
[13] TUV SUD Specification ZBP-XX-XX-SP-500-103
[14] The Classification, Labelling and Packaging of Chemicals Regulations 2015

present in the workplace at a concentration in air equal to or greater than 10 mg/m^3 of inhalable dust or 4 mg/m^3 of respirable (as a time-weighted average over an 8-hour period) is considered to be a substance hazardous to health.

- If the dust falls within the definition of 'substance hazardous to health' then the requirements of COSHH will apply, including the need to assess the risk to workers and to ensure exposure is prevented or adequately controlled.
- The dust measurements taken by the Contractor did not consider the dust expressed as a weight per volume, but rather the percentage coverage of a "DustDisc" sample and the results expressed as Absolute Area Coverage (AAC) and Effective Area Coverage (EAC). These can be combined to indicate possible annoyance caused by dust deposition. There are no formal limits for dust annoyance published.
- There was only one monitoring point on the QEUH/RHC building[15]. This is known as point 6 and is where the higher levels were recorded.
- The risk assessments made available for this report all note the risk as very low.
- Previously suggested EAC% assessment criteria are as follows:

EAC% per day	**Outcome**
0.2	Noticeable
0.5	Possible complaints
0.7	Objectionable
2.0	Probable complaints
A5.0	Serious complaints

Table 3.1 EAC percentage assessment criteria

- It is noted that some results are tending towards EAC % of 0.7 (objectionable) on particular days.
- It was advised during the compilation of this report that there was anecdotal evidence of complaints regarding the levels of dust prior to and post handover of the facility, but no written evidence was available.
- It should be noted that NHS GGC are cleaning the chilled beam system within the campus between once and twice a year due to dust accumulation. The manufacturer recommendation for cleaning the chilled beams is noted in ZUTEC as five years. Additional it has been reported, particularly in Wards 2A and 2B that there appears to be intermittent condensate dripping from the chilled beams to the floor.

[15] Appendix 2 Image 16

- In addition, although there is no empirical evidence regarding particulate, certain buildings were demolished during the construction period of the QEUH and RCH. The demolition of older buildings can release fungal spores (including *aspergillus*) and it should be noted that the water samples from 2018 record high levels of fungi across all areas sampled including the main water tanks. There is no evidence that any tests were carried out for *aspergillum* or fungi as a result of an demolitions in the vicinity of QEUH and RCH.

Commissioning of water systems

Scottish Water

- The incoming water supply for the QEUH and RCH together with the existing supply to the site was tested by Scottish Water on 20th February 2012 and was reported as bacteriologically satisfactory. Heterotrophic colony counts at 22°C and 37°C were reported as <1 CFU/ml for both locations.
- Scottish Water also provided water quality data for their distribution network point (Milngavie) from 2014 to 2015 and show results taken from a selection of mains points and customers outlets and are all within Scottish Water's operating limits.

Standards

- The main industry standards applicable to the commissioning of the water services and as noted in the specification[16] are:

  SHTM 04-01

  CIBSE Guide W

  BS EN 806 Specifications for installations inside buildings conveying water for human consumption

  BS 6700 Design, installation, testing and maintenance of services supplying water for domestic use within buildings and their curtilages.

  BS 8558 Guide to the design, installation, testing and maintenance of services supplying water for domestic use within buildings and their curtilages - Complementary guidance to BS EN 806.

Disinfectant used and effectiveness

- As part of the commissioning process, the contractor used a water treatment disinfection product known as Sanosil[17] to disinfect the hot and cold water pipes. Sanosil is a patented formula made from a unique blend of hydrogen peroxide and silver. It is widely used for surface disinfection and water treatment and the product used by the Contractor was "Sanosil Super 25.

[16] ZBP/TUV SUD ZBP-XX-XX-SP-520-307
[17] www.sanosil.co.uk

- The manufacturer notes that the product has “low corrosivity – protects pipe work” and is approved under Regulation 31 of the Water Supply (Water Quality) Regulations 2000. It should be also noted that Sanosil Super 25 also is approved under regulation 27(4)(a) of the water Supply (Water Quality)(Scotland) Regulations 2001.
- Within this product the active substance is hydrogen peroxide. The manufacturer recommends[18] the following for cleaning and disinfecting of pipes:
    - 500mg/l (equivalent to 500ppm) for smooth pipe surfaces (PVC or metal), with a contact time of between 6 and 12 hours.
    - 1000 ml/m^3 (equivalent to 0.1% or 1000ppm) for pipeline and tank disinfection (shock disinfection). The manufacturer also suggests 10% concentration to combat mould (mycelium), bacteria, yeasts and fungi and a 6% concentration where there is a high degree of contamination.[19] The contact times for these concentrations are between 12 and 24 hours.
- The manufacturer of Sanosil is not aware of any issues with compatibility of “at use concentrations” of Sanosil with Brass or Neoprene[20].
- In the Health and Safety Executive’s (HSE) guidance document HSG 274 part 2[21] it is noted that “Silver stabilised hydrogen peroxide has a history of use in the control of legionella in water systems. A silver hydrogen peroxide solution is injected directly into the water system and if applied and maintained according to the manufacturers’ instructions, can be an effective means of control. However, this should not be used in water systems supplying dialysis units.”
- The concentration of Sanosil used (150 ppm) seems have been agreed by the Contractor and the manufacturer of the Mains Filtration plant as this is noted in the risk assessment method statement Sterilisation of Water Services/DHW/TMV Temp Checks[22]. There is no record of dialogue between the Contractor any other equipment manufacturer. It is also noted that the main 0.2 micron protection filters were not in place at the time the Sanosil was used.
- There appears to be a discrepancy with the recommended concentrations of the solutions from the manufacturer and their main supplier in Scotland (Water Treatment Scotland) which may have led to the 150ppm dosage. The manufacturers recommended dosage is as noted above (500ppm to 1000ppm); however the agent’s recommendation is 150ppm[23].

[18] https://www.sanosil.com/en/produkte/sanosil-super-25-2/ Disinfection of drinking water
[19] https://www.sanosil.com/en/produkte/sanosil-super-25-2/ Manual
[20] Email correspondence from Water Treatment Products to HFS 9th May 2018
[21] HSG 274 Legionnaires’ disease Part 2: The control of legionella bacteria in hot and cold water systems.
[22] Document 0037-MS-MER-GB10008-186 REV02
[23] http://www.watertreatmentproducts.co.uk/pdf/Sanosil_MS_Sterilisation.pdf

Impact of chemicals on pipe work

- Published independent and academic studies researched during the course of this report did not highlight any major detrimental impact from hydrogen peroxide on 316 stainless steel, gaskets or sanitary ware components at the concentrations or pH noted. The only exception to this are the comments made by Horne Engineering and Armitage Shanks/Ideal standard regarding their taps noted later in this report.
- If the contact time is prolonged and the pH of hydrogen peroxide is increased to pH10 there is evidence of pitting of the surface of the steel and rubber gaskets.
- The manufacturers of the taps have noted the impact of various chemicals on their products and this is discussed elsewhere in this report.

Results

- The information noted below is located in ZUTEC under “Operation and Maintenance Information – Mechanical-Water Services” and ” Operation and Maintenance Information – Water Services-Above Ground Drainage - Test and Commissioning”
- The above ground drainage stacks have been tested, however the testing standard is not quoted and the test gauge model and calibration certificate are marked as “N/A”. It is noted elsewhere that a “water gauge was used – no calibration certificate”.
- The following are records from ZUTEC detailing some of the commissioning results from specific areas or plant rooms.

Basement Water Services

- It is noted that only one calibration certificate is presented in ZUTEC, which is surprising given the physical size of the installation. It is also noted that the date on the calibration certificate is 20th April 2012, but the actual static tests were carried out on in November 2013. One of the tests (BS03 TCWS) was carried out in May 2014 with a gauge different from the one supplied with a calibration certificate.
- The drawings associated with BS03 show bib taps on the roof and courtyards. These taps and associated pipe work have the potential to be classed as little used outlets and significant dead legs. NHS GGC have advised that these have been removed, but some of the associated pipe work is still in place.
- There is a method statement for the “Sterilisation of Water Services/DHW/TMV Temp checks”. This notes the following parameters:-

  BS 8558 (Flushing and disinfection of domestic water services)

  SHTM 04-01 (Water safety for healthcare premises)

  Agreed Sterilising medium: Hydrogen Peroxide (Sanosil Super 25) @: 150ppm

  Acceptable parameters

  Total Coliforms 0 (zero) per 100ml

E.coli	0 (zero) per 100ml
TVC @37 Degrees Celsius	Minimum achievable
TVC @22 Degrees Celsius	Minimum achievable

- It should be noted that SHTM 04-01 part A makes reference to CIBSE commissioning guide W, which is not mentioned above.
- In addition SHTM 04-01 part C details the actions to take when various concentrations of TVC are found. This is not referenced in the Contractor's documentation.
- There is no record of the pre commissioning checks as noted in SHTM 04-01 Part A.
- There is no record available of the analysis of the water prior to treatment as required by the specification[24].
- From the information provided, it would appear that there is no record of the results for the tests noted in the either the method statement or the SHTM.
- The temperatures at the outlets when the tests were taken are not recorded.
- The contact time for the disinfectant chemical is noted as one hour. This is not as per the manufacturers recommendations of six to twelve hours.
- The concentration of disinfectant chemical used by the contractor is equivalent to 0.015% or 150ml/m^3 and does not reflect the recommendations made by the manufacturer.
- The following non-zero results (Table 4.1) are recorded for TVC on the certificates of analysis associated with the serialisation certificates for Plant room 32 (please note: TVC results of 10 and above recorded in all plant room systems. SHTM 04-01 Part C requires action to be considered for TVC counts of 10 and above).
- There is evidence from the contractor that percentages of the Horne taps failed the initial disinfection tests, were disinfected and retested (a month-and-a-half) later[25] and failed the second test. There is no evidence with ZUTEC of any additional testing to resolve these failures. There is also evidence that as a result of re-disinfection, some retested outlets passed the second test (after first failure).[26]

Area/Sample ref	Date	TVC (2 days @ 37^0C) cfu/ml	TVC (3days @ 22^0C) cfu/ml
32k L9 WS9-021 MIX	22-12-14	~2000	~1400
32F L5 GENWD-065 MIX	22-12-14	Escherichia coli 5 cfu/100ml	
32f l6 genwd-029	22-12-14	~2800	~1200

[24] ZBP/TUV SUD ZBP-XX-XX-SP-520-307
[25] Appendix 2 Item 10
[26] Appendix 2 Item 11

Area/Sample ref	Date	TVC (2 days @ 37^{0}C) cfu/ml	TVC (3days @ 22^{0}C) cfu/ml
MIX		Escherichia coli 5 cfu/100ml	
32F L6 GENWD-065 MIX	22-12-14	~500	216
		Escherichia coli 5 cfu/100ml	
32F L8 GENWD-001 MIX	22-12-14	~2100	~2200
		Escherichia coli 5 cfu/100ml	
32f l9 genwd-001 mix	22-12-14	~2000	~940
		Escherichia coli 5 cfu/100ml	
32f l11 genwd-065 MIX	22-12-14	~2800	~3100
32f l7 genwd-001 mix	22-12-14	~320	~1600

Table 4.1 Extract from sterilisation results in ZUTEC

- The results within ZUTEC are extremely difficult to interpret with respect to whether a retest of the outlet has been carried out and successfully passed (it would appear the majority have passed). The Contractor has changed the references of the outlets and there is no correlation of any reference changes on ZUTEC. For example 31H GENWD-028 MIX changed to zhl11t5genwo-028mws. NHS GGC has had to carry out some considerable work to analyse this data to try and ensure that this cross referencing is valid. Notwithstanding this, the data in ZUTEC is at best difficult to reference and is incomplete as NHS GGC has had to ask the contractor for some of the results not contained within ZUTEC. Some of these “new” certificates have the same test date as the test results which show E-coli and high TVC located within ZUTEC.
- It should be noted that the European Drinking Water Directive (98/83/EC), The Water Quality (Scotland) Regulations 2010 and Scottish Water By-Laws, do not permit any *E.Coli* readings at the consumers outlets. There is no evidence the E-coli was type tested.
- There is no evidence to suggest that the *E.Coli* found in the water system was escalated to NHS GGC Project Team, NHS GGC Infection Control, Health Protection Scotland or any other agency. If any amount of E. coli bacteria is found in a water sample, it is an indication that human sewage or animal faeces has contaminated the water supply[27].

[27] MyGov.Scot

- Although Scottish Health Technical Memorandum (SHTM) 04-01 Part B paragraph 9.1 states that routine quality control microbiological testing for TVCs is no longer considered to be necessary (other than where there are taste or odour problems), many NHS Estates personnel invariably have them undertaken on a regular basis after acceptance of installations as a 'rule of thumb' indicator by which an abnormal change assists in identifying potential problems at an early stage. SHTM 04-01 Part C provides a TVC testing protocol. There is no evidence to suggest that the actions highlighted in this document were followed.

Water management between commissioning and handover

- There is some documented evidence presented with respect to the water management of the system between the various parts of the system being commissioned by the contractor and NHS GGC taking over the system. The contractor advised in a response to NHSGGC[28] that "*Water Management is the term we use for the process of managing the water system after disinfection leading up to handover to ensure the water is not left stagnant in the system for long periods of time. Typically this would involve flushing water through tap outlets regularly.*" NHS GGC has obtained[29] a sampling methodology from the Contractor together with a sample recording sheet. Neither of these is contained within ZUTEC.
- HSG 274 notes

  2.45 If water turnover is anticipated to be low initially, it may be advisable not to commission certain parts of the system, such as cold water storage tanks, until the building is ready for occupation. This will ensure flushing during low use periods will draw directly on the mains supply rather than intermediate storage. The manufacturer of any component to be bypassed should be consulted for any requirements, such as whether it needs to be filled or can remain empty until it is brought into use.

  2.47 If there is a prolonged period between pressure testing using water and full occupation of the development, a procedure should be adopted to maintain water quality in the system. Weekly flushing should be implemented to reduce stagnation and the potential for microbial growth, keep temperatures below 20 °C and to ensure residual chemical treatment levels eg the low level of chlorine in the incoming water supply, is maintained throughout the system.

  2.48 In large systems where a long period of time from filling to occupation cannot be avoided, continuous dosing with an appropriate concentration of biocide as soon as the system is wetted combined with regular flushing at all outlets can control the accumulation of biofilm more effectively than flushing and temperature control alone. While other disinfection methods could be used, maintaining 1–3 mg/l of chlorine dioxide is generally effective, however dosing at such high levels may reduce the life of the system pipe work and components. This initial high level disinfection should not be confused with ongoing dosing at lower levels in

[28] NHS GGC email 14 05 18
[29] NHS GGC email 19 07 18

operational systems where the water is intended for human consumption. National conditions of use require that the combined concentration of chlorine dioxide, chlorite and chlorate in the water entering supply do not exceed 0.5 mg/l as chlorine dioxide.

Handover

Professional accountability[30]

Team	Role	Name	Handover responsibilities
Contractor	Main contractor	Brookfield Multiplex	To provide a zero defects, fully commissioned building to relevant standards To provide certification of tests and inspections (To provide plumbers for continuation of flushing regime - 6 weeks)
	M&E subcontractor	Mercury Engineering	N/a - contract was with Brookfield
	Architect	Nightingale Associates (now IBI)	N/a - contract was with Brookfield
	M&E services engineer	TUV SUD (Wallace Whittle)	N/a - contract was with Brookfield
	Water Services Commissioning	H&V Commissioning	N/a - contract was with Brookfield
	CDM	Brookfield Multiplex Health & Safety Team	Brookfield internal arrangement
	ZUTEC collation	Zutec Brookfield All sub-contractors	To assist contractor/sub contractors to upload all certification and PPM information (Allowance of 60 days post handover to

[30] Provided by NHS GGC

Team	Role	Name	Handover responsibilities
		Capita	complete certification upload)
NHS GGC	Project Supervisor	Capita	(extract[31]) • Carry out test and inspections • Assist NHS Named Project Manager • Be central liaison between Contractor and NHS re defects/incorrect works/quality issues/outstanding items • To agree timescales for completion of outstanding works
	Mechanical & Electrical advisor	Capita (review of RDD drawings TUV SUD (Wallace Whittle) – pre construction, specialist input during design development (prior to ZBP going into liquidation)	As above None as contract was with Brookfield
	Architectural advisor	HLM (pre-construction only)	No input - commission was pre-construction as design developed through User Group meetings between NHS and Contractor

[31] Pages from NSGH Supervisor Brief Final

Team	Role	Name	Handover responsibilities
	Construction (Design and Management) Regulations 2007 (CDM)	URS (now Aecom)	To check the (CDM) H&S File is complete (noting allowance of 60 days post handover for doc upload)
	Independent commissioning		NHS GGC gave instruction to omit this service[32]. The detail of the omission of the Independent Commissioning Engineer is given here[33]
		NHS GGC Estates	• Obtain Legionella Risk Assessment • Water quality manager programme • Fire tests • To provide Access Cards to NHS contractors • To agree RAMS[34] for NHS Contractors • Hydropool maintenance, monitoring & equipment • NHS water testing and commissioning
		NHS GGC Infection control	Pre-handover - to witness the flushing and sterilisation of water system and to undertake 4 weeks of testing. Advise if any issues

[32] Removal of Commissioning Engineer instruction #2073
[33] Pages from NSGACL - ITPD Volume 2_iss1_rev1
[34] Risk Assessments and Method Statements (RAMS)

Team	Role	Name	Handover responsibilities
		NHS GGC Public Health	No input re water
		NHS GGC Decontamination Engineering Team	Scope Decontamination Commissioning • induct contractors • install washers and dryers • water quality manager programme

Table 5.1 Roles and responsibilities at handover

- The role of the Independent Commissioning Engineer (ICE) differs from that of a commissioning manager in that the ICE would normally incorporate a review of the design, and suitability of systems to be practically commissioned. In addition it is normal that the ICE would ensure compliance with the requirements of the ER, specifications, guidance and codes of practice as well as witnessing commissioning activities and certifying documentation. From the above table it is noted that NHS GGC relinquished governance of the testing and commissioning of all systems (not just water) to the Contractor and the independent third party check on the commissioning was lost as a result.

NHS GGC Infection Control.

- There is no documented evidence of NHS GGC Infection Control being involved in the commissioning or handover process of the project. However NHS GGC has provided a statement from the Lead Infection Control doctor at the time[35] to confirm that he was involved in reviewing the water testing methodology and the results for QEUH and RHC during commissioning and handover. It should be noted that this at variance from the table of responsibilities noted above.

  The Lead ICD has confirmed being involved in:

  1. QA of the water testing methodology used by the commissioning engineers.
  2. Liaising with Facilities Colleagues in reviewing the water testing results supplied by the commissioning engineers.
  3. Recommending further actions (dosing), for a small number of outlets with TVCs above the acceptable limits.

[35] Statement from Professor Craig Williams 15th June 2018

ZUTEC

- The project data management system, ZUTEC[36], should be a repository for all design and construction information for the Queen Elizabeth University Hospital (QEUH) and any other projects which are recorded there. Access is by registration and is password protected per user.
- There appears to be different access levels and it is recommended that all NHS GGC Estates staff that have access to ZUTEC have the appropriate level of visibility to folders, especially the data relating to maintenance instructions.
- There is no reference to any recognised industry standard for the production or content of the project data management system as an operating and maintenance manual i.e.

  BS EN 82079-1:2012. Preparation of instructions for use. Structuring, content and presentation. General principles and detailed requirements

  CIBSE Guide M. Maintenance engineering and Management

  BSRIA BG 1/2007. Handover, O&M Manuals, and Project Feedback. A toolkit for designers and contractors.

- On interrogation of ZUTEC and in particular the sections under Adult and Children Hospital; General Project Information A&C; the information relating to the following are all empty (see Appendix 2[37]):

  Building description

  Public and Local Authority Consents

  QA/QC

  Schedule of Guarantees and Warranties

  Residual Hazards

  Statutory Requirements

  Employers Requirements

  Principals of Design

  Compliance Documentation

  Third Party Approvals

- The Health and Safety File, required under the Construction (Design and Management) Regulations 2007 (CDM 2007), which was current at the time of the project, is located within ZUTEC in a separate electronic folder titled “Health and Safety File A&C”. This should contain information relating to the project which is likely to be needed during any subsequent construction work to ensure the health and safety

[36] https://www.zutec.com/site/
[37] Appendix 2 Item 12

of any person. The Health and Safety File should not generally contain design information, although it is noted that there are planning documents and design statements included within this section of the ZUTEC information. The CDM files contained within ZUTEC have only been considered with regard to the water incident.

- Within the section for residual risk under Building Services Engineer there is no risk noted for water (residual risks noted for working at height, high voltage cabling, the major plant replacement strategy and the dangers of electric shock).
- The section “Access and Maintenance Strategies” only deals with access to the roof and its maintenance. It does not address the maintenance access required for isolating water service behind panels, ceiling voids or plant rooms.
- Within the “Health and Safety File” section under Project Development and description there is a document titled “Design Strategy Final”. This notes that:

  > *Quantities of clinical handwash basins complies with HFN30 (one per single bedroom, two per four-bed bay, one per critical care bedroom, one per consult exam.*
  >
  > *Procedure rooms as a rule have, as a minimum, a clinical handwash basin, or- where appropriate a scrub trough*
  >
  > *Clinical wash basins are equipped with thermostatically controlled, single lever action taps; spray taps are not to be used.*

- Within the “Health and Safety File” section under Design Description there is a document titled “WW Design Description A&C” (WW refers to TUV SUD Wallace Whittle who were the M&E designers for the project). This notes that:

  > *Domestic Cold Water System Wholesome cold water is derived from 2 No. separate incoming water main supplies entering the basement tank room. Each supply is capable of isolation by valves within the building. A water meter is incorporated on each supply within the tank room with direct reading and a BMS interface.*
  >
  > *From the bulk storage tanks, the wholesome boosted cold-water service is routed via the main distribution routes to roof plant level and vertical risers to feed the various departments.*
  >
  > *In the plant rooms, the wholesome boosted cold water service feeds un-vented HWS plant, and a number of direct connections to demand points within the building, including system pressurisation units, and dedicated water service systems storage tanks, via type AB air gaps for prevention of cross contamination.*

- Air gaps are required by the Scottish Water Byelaws[38] in water tanks to prevent backflow. There are five fluid categories, with fluid category 5 being the most onerous (includes water containing pathogens, human waste, etc). The type AB air gap is one where a physical air gap is maintained between the lowest water inlet point and the highest level of the water in the tank at overflow.

[38] Scottish Water byelaws

- It should be noted that there is no mention of taps or any sanitary ware in the aforementioned documentation.
- Also within the “Health and Safety File” section under Residual Risks there is a document titled “WW Residual Risks A&C”. There are no risk assessments contained within this document, merely statements and there is no noted residual risk of the water systems.
- Within the “Client Training and Familiarisation” section under Mechanical Services Training there are two documents associated with “Water Services”. One is a PowerPoint presentation and the second is a register of attendance for the water services training. Within the PowerPoint presentation it is noted that there are temperature controlled dump valves installed throughout the installation. The detailed specification of the water tanks are not part of this presentation, therefore clarity is sought on the type of tank lid support. There is a basic schematic within the PowerPoint presentation showing the non-domestic water system and associated cold water feed, strainers, valves and expansion vessels.
- It is noted that there are several entries contained within ZUTEC which appear not to have reached final approval stage and are still reviewed with comments status[39].

Training at handover

- The only evidence of formal training on the water system by the Contractor to NHS GGC is recorded in ZUTEC as follows:
  - Domestic and Trade water systems 24th November 2014. Attended by eleven NHS GGC employees.
  - MTHW and LTHW Detailed training – systems & Equipment 16th December 2014. Attended by twelve NHS GGC employees.
- Each training session comprised of a presentation on each system, detailing incoming services, risers, distribution pipe work and equipment. From the documentation contained within ZUTEC there does not appear to have been a practical element to the training on any of the water systems or associated equipment. There is no mention of system sterilisation/disinfection or water management and the risk of legionella or other pathogens.
- The specification[40] calls for the sub-contractor to “provide instruction to the clients engineers and maintenance staff in the safe operation of all systems and items of equipment for an adequate and reasonable period of time based on the manufactures’ recommendations and best practice”. There is no evidence that this happened.
- In the Building Management System (BMS) Specification[41], there is a significant amount of on-site and offsite training specified. There is no record of this being provided and NHS GGC has confirmed that system familiarisation only was provided

[39] Appendix 2 Item 44
[40] ZBP/TUV SUD ZBP-XX-XX-SP-520-307
[41] ZBP/TUV SUD ZBP-XX-XX-SP-660-401_F

on site. NHS GGC confirmed they arranged additional training for the KNK (Konnex) data bus system as part of their maintenance contract with the supplier.

- Horne Engineering has advised in their email of 4th May 2018[42] that "*With regards to training we have made multiple offers of training for both Estates/FM and clinical staff users (see attached example). Maintenance Training was also offered as a specified item on our quotation for the project. Our Applications Engineer who is our principal provider of maintenance training is currently off work but he has advised me that a training event was organised which he attended but unfortunately no Estates personnel appeared and the session was abandoned*".

Initial Risk Assessment

- DMA produced an initial Legionella Risk Assessment on 29th April 2015.
- DMA noted several points which required to be actioned and some of these are noted as follows (extracts from Executive Summary):

> DMA were advised the NHS sampling programme has highlighted a number out of specification Legionella and Potable results and a responsive programme of daily flushing and local disinfections was underway in affected areas. Neither the actual microbiological results returned after sampling nor the method statement for disinfections was not submitted for comment or review by DMA.
>
> At time of assessment there was no formal management structure, written scheme or communication protocols and there were significant communication issues between parties involved
>
> It should be noted that there is no separate dedicated supply to the Renal (or other medical) systems, with all being fed from the Bulk Water system. This means that system disinfections will require to be very carefully scheduled or carried out locally as the disinfection procedure/chemical may interfere with the renal/medical systems and impact on patient welfare.
>
> There are various issues with the calorifiers including temperatures being low due to a heating failure on 21st April, individual calorifiers running at lower temperatures than the linked vessels and returns not achieving the design temperatures of 55°C.
>
> The cold water temperatures recorded by DMA vary considerably with the majority being more than 5°C higher than those recorded at the water tanks and with peak temperatures of 30°C being noted. Additional control measure such as flushing, disinfections and background dosing flushing should be implemented until such times as the area/department fully occupied, storage and distribution temperatures and microbiological results are consistently satisfactory.
>
> There are various other risk systems fitted throughout the hospital building

[42] Horne Engineering Ltd Email 4th May 2018

including Hydrotherapy Pool, Arjo Baths, Dental equipment, Emergency showers, Irrigation systems, Sprinkler/Wet fire fighting systems, Renal dialysis (x 2), Endoscopy Wash, Water softeners, Medical Gases/Medical Equipment (e.g. Nebulisers, incubators, etc.),

Dry/Wet (Adiabatic) Cooling (e.g. MRI chillers), Closed heating systems, Closed chilled water systems, Steam Humidification, Air Conditioning

Table 5.2 Extract from DMA Executive Summary: Report April 2015

- It is noted that even at this early stage DMA considered that the site should be considered for background dosing[43].
- The DMA report highlights in detail various risks associated with the water system at handover with a significant number to be dealt with either immediately, as soon as reasonably practicable or within three months. There is no evidence presented that any of the actions identified have been addressed. There are a significant number of items to be addressed and these cannot be replicated here, however the following points should be noted:

  When DMA were on site on the 21st of April there was a significant drop on the temperatures of the calorifiers which we understand was caused by a failure on the heating system. Temperatures recorded on these calorifiers on this day were 40-45°C. This represented a significant break in the control system and there were no records of any remedial or corrective actions and no records of additional control measures.

  There are numerous connection points onto other "nondomestic" outlets such as renal dialysis, endoscopy wash, pressurisation units, steam humidifier units and MRI chiller cooling which are connected to the Bulk Water system. It is advised that Estates (or Brookfield/Mercury) confirm these systems have suitable backflow protection installed or if necessary suitable backflow protection fitted.

  DMA have been advised by Estates there are ongoing commissioning problems on the cold water dump valve system and the system is not operating as intended. DMA have noted during site surveys there were areas with cold water temperatures in excess of 20°C and dump valves are fitted, but the valves not discharging. Corrective action should be taken and once fully operational the control set points and parameters for discharging should be referenced in site written scheme.

  DMA have been advised by Mercury Engineering that the domestic hot water systems do not operate on a conventional flow and return system, with principle, sub-ordinate and tertiary loops, instead utilising a reverse return circuit. This means that there are longer "deadlegs" to the outlets than SHTM 04-01 advises. However, it was noted that hot temperatures generally rose very quickly when DMA were recording temperatures throughout the building and the flow and return circuits appear to be circulating hot water to all areas, with only a few

[43] DMA L8 Risk Assessment (pre occupancy) 29th April 2015 p18 and Appendix 2 Item 3

exceptions noted.

Flexible hoses have been noted in Kitchen/Pantry areas where there are flexible connections to dishwashers (not all fitted at present), in Facilities rooms (connections to double level sinks), in Dirty Utility rooms (connections to sluice machines) with the only patient areas DMA have noted as having flexible hoses being the connection to Arjo baths (both connections to the hot/cold system and internally within the actual bath). Wherever possible DMA would recommend all flexi hoses are removed and connections hard piped. Where flexible hoses cannot be removed then replacing with alternative WRAS approved hoses with linings other than EPDM should be considered. In healthcare premises additional guidance on the replacement and use of flexible hoses is provided in the "safety action notice SAN(SC)09/03[44]".

Flexible hoses have also been noted on the boosted bulk water system on pressure reducing valves. If possible these should be hard piped (stainless steel) or WRAS approved hoses with linings other than EPDM should be considered. Should these not be available for these types of units/connections then a regular inspection and replacement schedule should be implemented for these. DMA were advised by Mercury Engineering and Estates that all materials fitted during the construction are

WRAs approved and therefore do not support bacterial growth. In particular Horne TMV taps were designed specifically with Legionella and Pseudomonas control in mind. The use of EPDM flexible hoses in some areas may contradict this statement and their use should be reviewed to ensure compliance.

The steam humidifiers do not appear to have been commissioned as yet (and DMA were informed by Estates these may not actually be commissioned in the immediate future) creating deadlegs on the cold system within the relevant plantrooms. It is advised that these have suitable backflow protection installed on the lines where the tee-off from the main line or are included in the site flushing regime until such times as the units are commissioned and fully operational.

General management structure in place though not specific to legionella. Formal Legionella management roles and responsibilities have yet to be documented. Documentation should also include communication routes between NHS Estates, NHS Projects and Building Contractor(s).

DMA have been informed by Estates personnel there have been breakdowns in communication between Estates, Projects and Building Contractor(s) where defects highlighted by NHS Estates to other parties are being acted upon without Estates without Estates being informed to allow proper consideration of bacterial control to be made, or to review/sign off that actions have been carried out in a compliant manner minimising any potential bacterial control impacts.

[44] Safety Action Notice SAN(SC)09/03 "Flexible water supply hoses: risk of harmful micro organisms"

Examples include:

- A direct and open connection installed by the Building Contractor(s) between the Hardgate Road mains supply and the PR 41/22/21 distribution pipe bypassing the filtration plant running for an unknown length of time which NHS Estates were previously unaware of.
- A calorifier which appeared to have been offline for over three months being reinstated by the Building Contractor(s) with no evidence of flushing/pasteurisation/disinfection. In addition to problematic cold water temperature control (highlighted in section 7) and other mechanical concerns, a lack of defined communication between involved parties may be a contributing factor to the out of specification bacterial and legionella results recently recorded by NHS Estates.

Photographs of various installation points described in the report are highlighted in the DMA Report. Three have been extracted and are shown in Appendix [45]2.

Table 5.3 Extracts from DMA Report April 2015 highlighting risk

- DMA produced a second legionella risk assessment in 2017 and this is discussed in section 6 of this document.

Post handover

Maintenance software

- NHS GGC utilise an Estates and Facilities Management Software called Fmfirst(R)[46]. Certain maintenance tasks are written into the software database and are then allocated to staff based on the Planned Preventative Maintenance (PPM) Schedule (or planner). The NHS GGC operatives have a hand held device which the daily tasks[47] allocated to them are loaded. The operatives can sign the work as completed on the mobile device, but any associated forms are completed manually.
- It was observed that the forms are returned to the NHS GGC engineer responsible for managing the PPM, however these are left in a filing stack for the Engineer to go through and there is no formal mechanism or process in place to highlight any defects or discrepancies found by the operatives. There is the potential for items to be missed.
- The PPM schedule made available, only consider critical care areas of both the RHC and QEUH, with the exception of shower heads which cover the whole hospital (except the ARJO baths which are currently not maintained by NHS GGC Estates).
- It is noted that NHS GGC are piloting a newer PPM system in other sites.

[45] Appendix 2 Item 4
[46] https://fmfirst.co.uk/
[47] Typical PPM job card

Seasonal commissioning

- Seasonal commissioning involves re-commissioning heating systems in winter and mechanical ventilation and cooling systems in summer. Seasonal commissioning may also be applied to other systems, such as motorised actuators for windows and active solar-shading devices any other building services system affected by seasonal changes.
- The specification calls for seasonal commissioning at QEUH and RCH to be carried out over a 24 month period. NHSGG&C has confirmed they have no records of any seasonal commissioning haven taken place.

Maintenance

- The contractor has provided, within ZUTEC, comprehensive details of plant and equipment planned preventative maintenance (PPM) routines, general maintenance instructions and fault finding instructions. These PPM instructions include maintenance instructions on all pipe work and equipment associated with the hot and cold water services.
- It is not clear how or if these have been transferred to NHS GGC PPM package (FMFirst).
- The maintenance of the water systems in critical areas has been sub-contracted recently to DMA Canyon (DMA). DMA produce a record sheet (sample records from 2017 and 2018 provided) of their inspections and this includes:

  Temperatures (hot, cold, mix)

  Fails safe test

  Filter cleaning & disinfection

  Isolation valve operation

  Any issues found.

- On the DMA reports inspected (snapshot in Appendix), there are issues found and reported during the maintenance[48], but no indication if they have been resolved or signed off by NHSGGC.
- In house water maintenance records for certain (high risk) wards from 2016 and 2017 were provided[49]. The records for non critical care areas were not available.
- The records of the shower chlorination from FMfirst are for critical areas and are from 2016 and 2017. They show the results of the chlorination of the shower heads and record the mixed water temperature and the cold water temperature. It is noted that a significant number of the cold water results show temperatures in excess of 20^0C[50]. We have been advised that a program of replacing the shower hoses and shower

[48] Appendix 2 Image 18
[49] Appendix 2 Image 19
[50] Appendix 2 Image 20

heads in the critical care areas is about to commence, however the disinfection program for the showers will remain in the rest of the hospital.

Water Management Hierarchy

- SHTM 04-01 Part B[51] identifies the Boards structure for the safe management of water systems. In addition his document gives comprehensive advice and guidance to healthcare management, design engineers, estate managers and operations managers on the legal requirements, design applications, maintenance and operation of hot and cold water supply, storage and distribution systems in all types of healthcare premises. It is equally applicable to both new and existing sites.
- Section 2 covers management responsibility, section 5 covers operational management and section 6 details the hierarchy and designated staff functions.
- Since handover, no formal appoint was available for any of the positions noted in Section 6 of SHTM 04-01 Part B. This has also been identified by the Authorising Engineer (Water) and independent contractor in their reports/audits which are detailed elsewhere. It is noted that the updated Written Scheme has the positions identified and as of 5th June 2018 an Authorised Person has been appointed and operatives have been trained.

Authorising Engineer (Water)

- NHS GGC has appointed Legionella Control as the company who provide the Authorising Engineer (Water) (AE (W)) duties for the whole of NHSGGC Estate. Mr Dennis Kelly is the Authorising Engineer who represents Legionella Control.
- The AE (W) produced the only audit[52] of the installation in May 2017. This document is with respect to Legionella Management and Compliance Audit – Domestic Water Systems.
- The audit highlights fifty six points of recommendations (there are two duplicates). In addition there is a supporting document[53] developed by NHS GGC with details of relevant dates costs associated with the various recommendations. There is no evidence of any of the points raised have been closed by NHS GGC.
- Points raised by the AE (w) in the 2017 audit include (not exhaustive):-
    - Ensure the new risk assessment covers all the ancillary water systems on site such as renal dialysis.
    - The competency of all named, involved personnel should be reviewed at the time of the new risk assessment.
    - Create an up to date set of schematics for the QEUH. Maintain these in electronic format and ensure that they can be accessed by the responsible person and any others who may need access.

[51] SHTM 04-01 Part B Water safety for healthcare premises Part B: Operational management.
[52] Legionella Control AE Audit – Queen Elizabeth University Hospital – May 2017
[53] NHS GGC Action Plan - Timescales

- There are very few hot water temperatures measured in the records. Most of the temperatures recorded are from mixed outlets. In future temperatures need to be taken of the hot water system and not from mixed temperature outlets.
- It was noted that there is a water storage tank in a 12th floor plant room. There are no monitoring or risk reduction processes and procedures in place for this tank. The tank should be risk assessed and appropriate procedures put in place if required.
- No evidence that the risk assessment remedial actions have been completed. Once a new risk assessment has been completed a plan for addressing the remedial actions should be implemented.

- NHS GGC has noted that "Initial AE audit was postponed by the AE due to site commissioning, migration and site establishment. Subsequent audit was carried out on 4th May 2017". This is unusual as it is normal for the Board to instruct the Authorising Engineer (regardless of discipline) to carry out audits of the facility they require; the AE would not normally reject these instructions.

DMA

- DMA were instructed by NHS GGC to carry out a second risk assessment[54] in September 2017.
- The points raised in the Executive summary of this report are similar to those highlighted in their report of April 2015.
- DMA continued to highlight that (not exhaustive)
  - There were issues with the calorifier temperatures
  - The expansion vessels were not of a flow through design as highlighted in SHTM 04-01 and HSG 274
  - Very dirty water is being purged from calorifier drains.
  - Double check valves locations could not be verified due to insulation coverage.
  - NHS Estates have fitted 'Emergency Dialysis' points on cold water system since the initial installation. NHS should confirm location of all Emergency Dialysis Points and ensure System Drawings and Asset Lists are updated to reflect this.
  - Cold water temperature gain was again noted.
  - The thermal facility to maintain and service the Horne taps has not been completed or commissioned.
  - Maintenance of TMV taps in non clinical areas not being serviced.
  - DMA Gap Analysis identified gaps in the PPM program.

[54] DMA L8 Risk Assessment September to October 2017.

- In the Gap Analysis, DMA note the following:-
    - The information gathered highlights significant gaps in the Legionella (and potentially other bacterial) control on site both in terms of management processes and the implementation of the recommended planned preventative maintenance tasks.
    - The Estates Manager placed in the role of 'AP Water' has not undergone any training in Legionella control (or other bacteria) and has limited knowledge of the water systems on site and the requirements of L8, HSG 274 and SHTM 04-01.
    - We would advise corrective actions are taken as a matter of immediate urgency to ensure an accurate and compliant Written Scheme is compiled and the appropriate PPM schedule implemented.
    - We would describe the Legionella Management on site as being High Risk until remedial actions highlighted within the legionella risk assessment and within this Gap Analysis are implemented.
- As part of the Gap Analysis DMA provided a"Summary of L8 Management Tasks Required for L8 and SHTM 04-01 Compliance". Several of the comments note that various items are not documented therefore there is no evidence to support and there is no Authorised Person training in place (at the time of the DMA reports being written).
- It is noted that (as of July 2018) NHSGGC have put in significant effort to address and resolve the vast majority of the issues raised in AE (W) Audit and in the two DMA reports. NHS GGC anticipates that all matters will be addressed fully by October 2018 and have already instructed the AE (W) to conduct a new audit.

Written Scheme QEUH

- A Written Scheme has been produced for QEUH dated December 2016 and is based on a DMA template. Assurance is sought that the items noted as part of the action lists is being carried out and recorded for all areas of the QEUH and RCH.
- It is recognised that this written scheme is specifically oriented towards legionella, but in light of recent incidents it should consider wider organism infection.

Water tanks

- The turnover of the raw water tanks has been calculated as approximately 442m^3 on average daily. This will mean that (providing the tanks are working balanced) the raw water tanks will turnover twice per day and the filter storage tanks approximately once per day. From the information provided the Hardgate Road tank is not turning over as much as the Govan Road tank. It is suggested that the tanks are checked for balancing as the water meter results show one tank turnover less the other and therefore a risk of stagnation exists.

- As noted in the DMA reports various items of debris were found in the water tanks[55]. NHS GGC had all tanks cleaned in July 2018 and addition material was recovered from the tanks.

Water treatment

- There has been no documented evidence provided of any system wide or area wide water treatment post handover. It is noted however that there is anecdotal evidence of targeted water treatment on certain parts of the RCH as a result of water quality issues.

Water samples

- Evidence has been provided[56] of water sampling of water outlets at various times during from April to December 2015 with sampling of the main raw water tanks in October 2016.
- The sampling was carried out by NHS GGC and processed by ALcontrol Laboratories (a United Kingdom Accreditation Service (UKAS) accredited testing facility).
- There are positive results for *legionella* species (*spp*) in certain areas in April 2015. For example the spreadsheet shows 41 samples taken between the 18th and 22nd August 2015 with 15 of the samples shown as being "out of specification". A screen shot of this spreadsheet is shown in Appendix 2 Item 6[57]**.** These show positive *legionella spp* results ranging from 20 cfu/l to 1360 cfu/l.
- The results from November/December 2015 detailed as "potable" show 5 outlets out of specification from a sample of 151 and returning positive *legionella* results between 23cfu/l and 101cfu/l.
- The results from November/December 2015 detailed as "Healthcare" show 124 outlets out of specification from a sample of 2392 and returning positive *legionella* results between 20 cfu/l and 4800 cfu/l. It is noted that some outlets which have positive *legionella spp* results have not been included in the overall percentage (or highlighted). These results also note TVC counts in some areas (highest 620 cfu/ml 2days at 37^0C and 320 cfu/ml 3 days at 22^0C).

  From the spreadsheet provided, a typical set of results for particular tap outlets is as follows

Area	**area**	**Result cfu/l**
GENW - 034 A H1	09-04-15	None detected
	10-	None

[55] Appendix 2 Item 41
[56] Alcontrol 18 08 2015 samples spreadsheet
[57] Appendix 2 Item 6

Area		area	Result cfu/l
		04-15	detected
		29-05-15	None detected
	29-05-15	40	
	12-06-15	None detected	
	11-09-15	1480	
WSG-005 CORE A H1	18-08-15	80	
	21-08-15	20	
	07-05-15	120	
	07-05-15	100	
	08-06-15	100	
	28-06-15	160	
	13-07-15	80	
	31-07-15	20	
	31-07-15	None detected	
	31-07-15	140	
	31-07-15	320	
	28-08-15	240	
	28-08-15	640	
GENW - 065 A H1			
5th floor	09-04-15	1460	
9th floor	10-04-15	Not detected	
5th floor	29-05-15	20	
5th floor	12-06-15	20	
WSG-005A H1			
11th floor	21-08-15	Not detected	
11th floor	07-05-15	100	

Area	area	Result cfu/l
10th floor	07-05-15	100
11th floor	19-05-15	3280
10th floor	19-05-15	140

Table 5.4 Extracts from Alcontrol 18 08 2015 samples spreadsheet

- The ward 1D of the RHC Paediatric Intensive Care Unit (PICU) test result[58] was taken on 29th September 2015 and tested on 4th October 2015. The results show the presence of *Cupriavidus pauculus* in the pre and post flush samples. The results also note positive results for *Pseudomonas spp* and *Steno Maltophilia*.
- Test results for Ward 4A[59] were also provided from July and August 2017. These show initial *legionella spp* positive results post disinfection of the system. Thermal disinfection and replacement taps were installed to overcome the issue. All final test results for the outlets show that they passed.
- The raw water tank tests in June 2016 do not show any positive *legionella spp* results.
- There has been no evidence presented to advise what control measures or actions were put in place (as per SHTM 04-01 Part C) as a result of the various positive results in 2015.
- Samples were taken from the water tanks in April 2018 before NHS GGC implemented a cleaning program for the water tanks as noted in the DMA reports. The results of these tests are shown on the following table.

Date	Sample location	Outlet Type	Description	Cupriavadus (CFU\100ml)	Species (isolates)	Fungi
16\4\2018	Basement Tank room	CWST	Bulk Filtrate tank 2A	0	N\A	0
16\4\2018	Basement Tank room	CWST Drain Cock	Bulk Filtrate tank 2A	0	N\A	>100 fungi saprophytic Aspergillus
16\4\2018	Basement Tank room	CWST	Bulk Filtrate tank 2b	0	N\A	0

[58] PICU Pseudomonas test results 04.10.2016 spreadsheet
[59] Latest Ward 4 A Samples Re-Tests spreadsheet

Date	Sample location	Outlet Type	Description	Cupriavadus (CFU\100ml)	Species (isolates)	Fungi
16\4\2018	Basement Tank room	CWST	Bulk Filtrate tank 1a	1	Cupriavadus pauculus	0
16\4\2018	Basement Tank room	CWST	Bulk Filtrate tank 1b	0	N\A	3 fungi Saprophytic
16\4\2018	Basement Tank room	CWST	Raw 1A	0	N\A	3 fungi Saprophytic
16\4\2018	Basement Tank room	CWST Drain Cock	Raw CWST 1A	0	N\A	>100 fungi saprophytic Aspergillus
16\4\2018	Basement Tank room	Govan Rd In-coming Mains	Raw CWST 1B	>100	environmental GNB	>100 fungi saprophytic Aspergillus
16\4\2018	Basement Tank room	CWST	Raw CWST 1B	0	N\A	5 fungi Aspergillus versicolor Saprophytic
16\4\2018	Basement Tank room	CWST Drain Cock	Raw CWST 1B	0	N\A	>100 fungi Saprophytic
16\4\2018	Basement Tank room	Hard Gate road In-coming Mains	Raw CWST 2A	0	Delftia acidovorans environmental GNB	>100 fungi Saprophytic
16\4\2018	Basement Tank room	CWST	Raw CWST 2A	$6*10^2$	Cupriavadus pauculus, Pseudomonas xanthomonas Mexicana	4 fungi Saprophytic

Date	Sample location	Outlet Type	Description	Cupriavadus (CFU\100ml)	Species (isolates)	Fungi
16\4\2018	Basement Tank room	CWST Drain	Raw CWST 2A	0	S paucimobilis, M oxydans	>100 fungi Saprophytic
16\4\2018	Basement Tank room	CWST	Raw CWST 2B	0	no Cupriavadus	2 fungi Saprophytic
16\4\2018	Basement Tank room	CWST Drain	Raw CWST 2B	0	Delftia acidovorans	>100 fungi Saprophytic

Table5.5 Water samples from water tanks April 2018

- NHS GGC's Infection Control's interpretation[60] of the results detailed above concludes:

  There are several hypothesis for these findings;

  1) *Low level contamination of the incoming water supply - unlikely given we have a 0.2micron filter*
  2) *Contamination at the time of construction/installation e.g. pipework*
  3) *Back seeding from contaminated outlets because the outlets themselves were contaminated at installation*
  4) *Back seeding from contaminated outlets from organisms found in patients via hands of healthcare workers or patients themselves*

  Given the range of bacteria and fungi found 2 and/or 3 seem most likely.

Water coolers

- Water coolers are provided under the contract at various locations throughout QEUH and RCH. The mechanical and electrical specification[61] notes:

  > Water coolers, drinks and vending machines shall be supplied and installed by others.
  >
  > The Sub-contractor shall supply services to the coolers and vending machines at locations shown on drawings and agreed with the Contractor.

- These units are supplied by third parties and either connected on to the mains cold water system or stand alone units with water bottles. It is noted that these units are not under the control of NHS GGC Estates and therefore not part of any scheduled PPM. It is not clear which NHS GGC department has maintenance responsibilities for these water coolers.

[60] NHS GGC Email 25-07-18
[61] TUV SUD Specification Hot and Cold Water Systems Rev C April 2014. Document ref: ZBP-XX-XX-SP-500-103

- As a result of a poor standard of microbiological quality of the water sampled for these coolers, NHS GGC Lead Infection Control Doctor produced an SBAR[62] the recommendations of which were as follows:-

  NHSGGC should apply the draft document SUP 05. Whilst only in draft form this is based on expert opinion and the advice is in keeping with policies in England.

  Water coolers already in the high risk areas listed above can remain but may be removed if deemed an infection control risk i.e. implicated in an outbreak.

  No new mains coolers should be installed in high risk areas.

  IPCT and estates should be alerted to purchases of new water coolers.

  Mains coolers should be subject to regular quarterly maintenance and weekly cleaning.

  Users should ensure that water is not consumed directly from the cooler and that drip trays are kept clean and dry on a daily basis. Water should not be allowed to pool as this will create stagnant conditions.

  Stand alone water bottle coolers should be removed .The only agreed exception should be maternity Ultrasound Scan (USS) clinics or urology clinics where patients may be required to drink water pre procedure and no mains fed cooler is in the vicinity. These coolers should be identified and a cleaning regime should be agreed with the IPCT.

- The document referred to in the recommendations SUP05[63] is a "Standard Unified Procedure" which is seen as best practice (rather than guidance) and is currently available in draft for NHS Boards to discuss and amend as necessary to reflect their own situations.
- It is noted that NHS GGC Estates proactively disconnected all the water coolers when evidence of contamination was found.
- It should be noted that the Department of Health (DoH) revised their guidance (Health Technical Memorandum (HTM) 04-01) in 2016 which included the following regarding water coolers et al

  HTM 04-01 Part A

  Vending, chilled water and ice-making machines

  Note

  These should not be installed in augmented care areas.

  9.24.1 The design, installation, location and risk assessment of all equipment should be approved by the WSG (see also HBN 00-09 – 'Infection control in the built environment'). The risk assessment should consider:

[62] NHS GGC SBAR Water coolers 2nd March 2017
[63] SUP05 Drinking Water Procedures

- *carbon filtration in these devices, which are a high nutrient source for bacteria;*
- *cleanability and maintenance of the machine.*

9.25 The water supply to this equipment should be taken from a wholesome supply via a double-check valve to prevent backflow, and be upstream of a regularly used outlet with the minimum of intervening pipe-run, that is, less than 3 m. The supply should not be softened. Additionally, it should be established that the usage is sufficient to avoid deterioration in water quality, for example that the inlet water temperature does not exceed 20°C. The equipment should be positioned so that the warm air exhaust does not impinge directly on taps or hoses supplying cold water and to provide access for maintenance.

9.26 Design considerations include, for example:

- *no drinking fountain or vending machine should be installed at the end of the line (potential dead-leg);*
- *the pipework should be as short as possible from take-off point (mains water tee);*
- *the cold water supply pipework should be copper and fitted with a local isolation valve and drain valve;*
- *the flexible pipe connector should be kept as short as possible (see paragraphs 3.39–3.41).*

Note

Flexible EPDM should not be used (see Estates and Facilities Alert DH (2010) 03 – 'Flexible water supply hoses').

9.26 Reference should also be made to the Food Safety (Temperature Control) Regulations 1995 and Food Safety (General Food Hygiene) Regulations 1995.

HTM 04-01 Part B

Vending, chilled-water and ice-making machines

8.3 See paragraphs 9.24–9.27 in HTM 04- 01 Part A for guidance on installation of this equipment.

8.*4 Where equipment is hand-filled, there should be clear instructions on the water used; it should be hygienically collected and decanted into the equipment from a clean vessel.*

8.5 Chilled-water drinking fountains normally include a reservoir to assist in the cooling cycle; if machines are turned off, water quality can

deteriorate. Provision of bottle dispensers should be approved only by the WSG. Where carbon filters and/or UV are fitted, these should be maintained as per the manufacturer's instructions. Additional cleaning to ensure adequate hygiene of nozzles etc should be put in place as recommended by the WSG.

Note

Proprietary water containers for water dispensing machines should be returned to the supplier.

8.6 Ice machines should not be placed in augmented care units. Where ice is needed for treatment purposes, it should be made using water obtained through a microbiological POU filter or boiled water in sterile ice trays or ice bags.

8.7 Ice should not be allowed to stagnate in an ice-making machine's storage bin, but should be changed frequently. Appropriate cleaning and hygienic procedures, agreed by the WSG, including the cleaning and disinfection of scoops etc should be put in place. For guidance on infection-control precautions with regard to ice-making machines, see HBN 00-09 – 'Infection control in the built environment'.

8.8 Maintenance for ice-making machines should be carried out in accordance with the manufacturer's recommendations. Care should be taken to ensure that the water supply to the ice-making machine is not subjected to heat gain.

HTM 04-01 Part C Advice for augmented care units

3.0 Protecting augmented care patients

3.1g. All other uses of water used in augmented care units should be considered and appropriate action/ changes to operational procedures taken. Uses of water to be considered include:

i. drinking water fountains;

ii. bottled water dispensers;

iii. wet shaving of patients who have a central venous catheter inserted into the jugular vein;

iv. washing patients with in-dwelling devices.

Notes:

1. Tap water should not be used in neonatal units for the process of defrosting frozen breast milk.

2. Water features should not be installed in augmented care units.

3. Chilled water and ice-making machines should not be installed in augmented care units. Where ice is needed for treatment purposes, it should be made using water obtained through a microbiological POU filter or boiled water in sterile ice trays or ice bags.

- It should be noted that the Scottish Engineering Technology Advisory Group (SETAG) has agreed that the Water Guidance in Scotland (SHTM 04-01) should be updated to mirror HTM 04-01 (with Scottish amendments as necessary detailed in Appendices).

Dishwashers

- In a separate but related incident it was noted that certain patient groups were colonised by fungi. These fungi did not cause clinical infection. The Infection Control Doctor (ICD) had the dishwashers (amongst other areas and equipment) swabbed and tested. These were found to be positive and matched the fungi colonised on the patients.
- Issues were noted with cleaning practices and the plumbing of the units, which were addressed. The dishwashers are currently not being used and will not be put back into service until acceptable results are achieved. The ICD has requested point of use (POU) filters on the incoming water lines to the dishwasher before re-swabbing and testing.

Water temperatures

- At the early part of 2018 NHSGGC were advised by Schneider that the site database was “lost” as well as historical data relating to various trend logs pertaining to energy and temperature monitoring (for QEUH, RCH and the Energy Centre). At the time of writing (July 2018) the historical data has not been recovered by Schneider; any data pre-dating this is not recoverable due to extended trend logging criteria not being enabled on the standard BMS configuration.
- Schneider are currently modifying the extended logging criteria to resolve this issue moving forward but to confirm the historic data is **NOT** recoverable before 1st January 2018.
- As a result it is not possible to confirm that water temperature records for the period when NGSCCC took possession of the QEUH and RCH until January 2018.
- The BMS Contractor provided snapshot logs of the hot and cold water temperatures for both the QEUH and RCH recorded between the 10th April 2018 and 15th April 2018. There is unfortunately no reference point with respect to the incoming water temperatures at the mains or tanks, however, the following are noted:

  Level 0 DMV1 to 6 and 10; constant value indicating possible faulty sensors and all above 20^0C.
  Level 0 DMV7, 8, 9 and 12; constantly over 20^0C

- This pattern is mirrored to a greater or lesser degree in the logs for the other levels. The temperature in the cold water system rises during night hours when consumption

is lower. This would suggest thermal pickup for heat sources (lighting equipment, heating pipes and low/zero ventilation) in the ceiling voids.

- With respect to the hot water trend logs made available for the period noted above no sensor location information is given so it is impossible to comment on specific temperatures. There are some sensor showing constant temperatures (no fluctuation) and these may be faulty. It is noted that the temperature fluctuates on all floors between 65^0C and 52^0C. It should be noted that SHM04-01 Part A notes:-

  9.43 *The minimum flow temperature of water leaving the calorifier/water heater should be 60°C at all times, and 55°C at the supply to the furthermost draw-off point in the circulating system. The minimum water temperature of all return legs to the calorifier/water heater should be 50°C.*

  Note 14: A minimum of 55°C may be required for the operation of suitable mixing devices required to provide 'safe' hot water at the upper limit of the recommended range.

- The cold water temperature is also noted on the NHS Estates Department and DMA maintenance records for the thermostatic mixing taps (TMT). It can be seen[64] that these temperatures are approaching 20°C. The significance of this temperature is it is recognised as the temperature which legionella (and other organisms) begin to multiply.

Dump valves

- The Contractor has included what is commonly known as "dump valves" on the cold water system on each floor. These comprise of a solenoid valve controlled with a temperature sensor and the Building Management System (BMS). The purpose is to instigate flow in the cold water circuit if the cold water temperature exceeds 20°C as above this point legionella bacteria begin to grow. The water is literally dumped to drain.
- The set point for the solenoids at QEUH and RHC is advised as opening at 23°C and closing at 20°C.
- It is noted that there is no maintenance schedule for these items and there is no metering to establish the volume of water being put to drain or indeed if there are any equipment (solenoid) failures. If the sensor accuracy if +/-2°C then this may mean that the open action could be initiated as high as 25°C.
- There is anecdotal evidence that these solenoids can "weep" into the drains and can be the site of bacterial growth.
- HFS has been advised of several new healthcare buildings which are experiencing cold water temperatures being elevated. The main contributory factors to thermal gain in the cold water systems are:

  Proximity of other services (typically the hot water pipe work)

[64] Appendix 2 Item 20 and item 24

Proximity of lighting control gear (particularly LED control gear).

Lack of ventilation in ceiling voids.

Higher than anticipated incoming water temperatures from Scottish Water.

Over sizing of storage tanks and pipe work systems.

Lack of flow through water pipe work (particularly at weekend and night).

Many wash hand basins used very infrequently.

Training (specific to water systems)

- Training records have been provided for eight operatives who completed a one day training course on "legionella awareness HTM 04-01" by PPL training on various dates in March 2018. It is noted that this course is not with respect to SHTM 04-01 which has some different requirements to the HTM. It is not clear how many of the operatives are employed directly at QEUH and RCH.
- Horne Engineering have advised[65] that "With regards to training we have made multiple offers of training for both Estates/FM and clinical staff users. Maintenance Training was also offered as a specified item on our quotation for the project. Our Applications Engineer who is our principal provider of maintenance training is currently off work but he has advised me that a training event was organised which he attended but unfortunately no Estates personnel appeared and the session was abandoned."

Point of Use Filters

- Point of use (POU) filters were not specified as part of the project. SHTM 04-01 Part A (paragraph 5.19) provides guidance on the use of POU filters.
- A POU filter is a disposable device which fits on to an existing tap or shower, which has internal membrane which acts as a barrier to material and organisms above 2μm (generally). The lifespan of the POU filter varies from manufacturer to manufacturer but is typically 31 days.
- The connection to the tap may be via a connector, rather than a direct fit onto the tap.
- The chosen POU filter installed in the critical care areas (taps and showers) of both QEUH and RCH when NHS GGC discovered there was an issue with the water system is manufactured by PALL Medical (PALL), who presented technical and microbiological papers to support the efficacy of their filters.
- The cost to NHS GGC of installing these filters is significant as is the ongoing costs of the monthly replacement program. Some filters are being replaced every seven days as an added protection measure requested by clinicians.
- The filters will not eradicate the issue but will (providing they are not dislodged) remove bacteria and fungi by acting as a barrier.

[65] Email Horne Eng to HFS 4th May 2018

- Due to the configuration of the taps[66] and sinks, with the adaptor fitted and the POU filter in place, it was reported that some clinical staff, patients and parents experienced difficulty in hand washing as the outlet of the POU filter was in close proximity to the bottom of the sink.
- During practical tests, it was noted that "normal" washing also caused splashing back from the sink on to the filter.
- There was confusing and conflicting information provided regarding the cleaning of the filters by the manufacturer. Initially a cleaning specification was provided by PALL Medical[67] to HFS as a result of a direct question, but the NHS GGC was given the advice not to clean the filters. The latter was adopted to prevent the filters being dislodged which potentially could result in contamination.
- Water tests continued once the POU were installed and all but two came back negative. The POU filters were sent back to the manufacturer for detailed analysis to determine the cause of the failure. The manufacturer's letter[68] dated 1st May 2018 confirmed that there was no fault found in either filter, therefore any contamination would have been retrograde (i.e. contamination after the POU was fitted).

Sanitary ware

Taps

- There are two main manufacturers of thermostatic mixing taps (TMT) in both the QEUH and RCH with one main manufacturer of showers in both buildings.
- The first TMT and most prevalent is the manufactured by Horne Engineering and is from their "Optitherm" range.
- The second is Ideal Standard/Armitage Shanks TMT from their "Markwik 21" range.
- The showers are mainly manufactured by Horne Engineering and from their "TSV-1" range. Other showers are integral as part of the specialist baths from Arjo Huntleigh.
- In and around July 2012 the Contractor proposed the Horne Optitherm tap to NHS GGC Project Team.
- NHSGGC produced a paper "Installation of Taps" dated 27th July 2012 as a review of the proposed taps with respect to functionality, maintenance and infection control issues. The paper also considered a benchmarking exercise with NHS Fife and NHS Lanarkshire. The summary of the paper is as follows:

[66] Appendix 2 Image 32
[67] PALL Medical Surface disinfection letter May 2017
[68] PALL Medical letter reference 1673-CY18-POR & 1907-CY18-POR Final Closeout Letter

TAP	INSTALLATION	POINTS TO CONSIDER
Horne Optitherm	Clinical wash hand basins Scrub sinks Pantry wash hand basin	Thermal disinfection is recommended by the manufacturer. Chemical disinfection not recommended - will degrade internal components within the tap.
Markwick Sensor Tap	Public areas ? Staff toilets & staff change	Nil noted
Armitage Shanks disabled basin tap	Patients en-suites Assisted bathrooms	'Screaming' taps following chemical disinfection. Likely to be related to manufacturing, storage or installation issues.
Need to consider the type of tap for equipment wash up sink, discard sink in clean utility, & treatment sinks in dermatology.		

Table 5.6 Tap type summary for QEUH and RCH July 2012

- As part of the benchmarking it is noted from correspondence provided by NHS GGC, that the Horne tap was installed at Monklands Hospital and Vale of Leven Theatre Suite. "*Vale of Leven provided information direct from the company who have recommended thermal disinfection of the taps instead of chemical disinfection which is currently used for other taps. Monklands have reported that this has not been an issue in practice.*" Also "*Monklands did however advise that we accept the training sessions offered by the company to train staff on the use of the taps as the design is different from what we currently use*."
- In August 2012, there was discussion regarding the NHS representative Currie and Brown, Brookfield and Horne Engineering regarding chemical sanitisation of the Optitherm tap. From the email correspondence referenced It is noted that the manufacturer stated in response to technical questions on the correct method of disinfection posed by NHS GGC that:

  Horne have confirmed[69], and evidenced, that point of use filters can be fitted to the Optitherm tap and it is recommended that these are for maximum 14 day use.

  They have further confirmed that the tap can be chemically disinfected subject to the correct processes and concentration of product. Their tap has shown no greater degradation than other parts of systems where incorrect treatment has been undertaken.

  In relation to the combined flow conditioner and regulator, which is not an aereator, they do not recommend its omission on a risk assessed basis

  - Also[70]

  "There are no materials or components in any of our products which makes them peculiarly susceptible to chemical damage".

  He goes on to state that in isolated cases where damage has occurred " I think that what has really happened is that chemicals which have traditionally been used in the food production process sector have been offered as pipework sanitizing chemicals but insufficient consideration has been given to the fact that the materials of which a domestic water system is typically composed are substantially different from those found in process applications."

  he goes on to say

  "However I would not wish to cause any undue alarm on this point and would suggest that it is a risk easily managed and controlled once understood. Domestic pipework systems in healthcare applications are widely, if not universally, occasionally exposed to chemical

[69] Email Currie and Brown to NHS GGC 3rd August 2012
[70] Email Currie and Brown to NHS GGC 6th August 2012

disinfectants and the correct use of the appropriate chemical should pose no risk whatsoever. "

- The above is different to what NHS GGC noted in the July 2012 tap type summary table and in any other correspondence which Horne Engineering has provided either verbally or in writing.
- Horne Engineering has advised in correspondence to HFS that each of their products (including those provided to QEUH and RCH) is shipped with their document reference 10378 which states "*HORNE PRODUCTS MUST ONLY BE EXPOSED TO POTABLE WATER SUPPLIES. ANY EXPOSURE TO HARMFUL CHECMICALS MAY CAUSE DAMAGE AND WILL INVALIDATE THE WARRANTY*". There is no detail on what, in this context, is a "harmful chemical".
- Horne Engineering has also advised that they had commissioned a report in the course of investigating product failures. They believed these failures to be a consequence of exposure to oxidising chemicals used in the course of sanitising and commissioning domestic water services. With regard to the impact that chemicals may have on lifespan of product and components it is very difficult to say since the type of chemical used, the concentration of the chemical, temperature and duration of exposure are all important factors. As a result of this report, a summary of which was made available to the contractor, Horne Engineering advise that "*Any cleaning or sanitisation regimes that have been proven not to damage valves in the past will not damage them now. It is just that we are aware of a plethora of new chemicals that we KNOW are likely to damage our valves, and also damage other items in the domestic hot water system. We believe that anything that contains hydrogen peroxide is likely to come into that category. Thus we suspect that hydrogen peroxide, silver peroxide, peracetic acid and all derivatives of this type of product can certainly pose a risk to Horne valves. However, we have consciously decided not to recommend any one chemical treatment over another. We have experience where even chlorination can cause very similar damage if excessive concentrations are used. We do recommend thermal disinfection for our products, where appropriate, and our website has details on this*."
- The design of the Horne Optitherm tap is unique in the market place. There is a flow straightener included at the outlet which they advise is an integral flow regulator and a flow conditioner. This is a plastic device which retains water at the mouth of the tap due to surface tension created by the lattice network of the straightener. An exploded image of this device can be seen in Appendix 2. Horne Engineering advice that this prevents contaminants from being introduced into the body of the tap.
- SHTM 04-01 Part A (2014) note 15 advises *".....the type of tap should be carefully selected to minimise the formation of aerosols. The water flow profile must be compatible with the shape of the wash hand basin. Rosettes, flow straighteners and aerators have been found to be heavily colonised with biofilm but their removal can create turbulent flow at increased pressure resulting in splashing of surrounding surfaces and flooring. Current advice is that they should be removed but this should be subject to risk assessment.*"

- In April 2014 NHSGGC requested advice from HPS on removal of the flow straighteners. As a result HPS produced an SBAR[71] (Situation-Background-Assessment-Recommendation) which highlighted three options, namely:

  1. Instruct the contractor to install the procured taps in all clinical areas across the SGH. This would subsequently require NHS GG&C to commence a water sampling regimen to monitor for Pseudomonas in high risk units.

  2. Instruct the contractor to install the:

  Procured taps in all clinical areas across the hospital excluding high risk units;

  and

  Procured taps without flow straighteners in high risk units.

  3. Instruct the contractor to install:

  The procured taps in all clinical areas across the hospital excluding high risk units; and

  New compliant taps (without flow straighteners) in high risk units.

- *The recommendation of the SBAR was as follows:*

  The HPS Guidance for NNUs, adult and paediatric ICUs in Scotland is designed to minimise the risk of infection with Pseudomonas aeruginosa – the risk however can never be eliminated.

  Based on the above assessment and the extant national guidance on water safety and potential infection risks to patients, particularly in high risk units1, 2 HPS recommend NHS GG&C to progress with option 2 or 3.

- As a result of the revised Guidance noted above, NHS GGC requested a meeting to discuss the implications as the Contractor had already purchased or ordered the majority of the outlets for the project. This meeting took place on 5th June 2014 with representatives from NHSGGC, Public Health England, Golden Jubilee National Hospital, NHS Ayrshire and Arran, HPS, HFS and Horne Engineering. It was agreed that the development and the specification of the taps at the time complied with the guidance published at the time of specification and procurement. It was agreed any residual perceived or potential risks would be identified and form part of the routine maintenance.
- During the early stages of the investigation (2nd March 2018 and 14th March 2018) taps and showers were sampled by NHS GGC microbiologists and an internal report[72] produced to aid the investigation. The showers and taps were dismantled under laboratory conditions to sample specific components within the outlets. These tests returned positive results for *Cupriavadis pauculus*, *Sphingimonas Paucimobilis*, *Ochrobactrum anthropi* and Bevundimonas *sp* amongst others (detail of location and species are presented in the report).

[71] HPS SPAR "Pseudomonas – Taps" April 2014
[72] REPORT on Environmental Sampling on 2A and 4B

- The above noted report confirms the results from the tap samples taken by NHS GGC and processed by their laboratory at Glasgow Royal Infirmary. The samples were at first only taken from RCH wards 2A and 2B, but it was decided that in order to determine the extent of the contamination samples were taken from all levels of QEUH and RHC, including the water tanks and risers. These results indicated that the majority of the water system was contaminated with various organisms and fungi.
- It is noted that the laboratory struggled to cope with the volume of additional testing being requested of it and maintain business-as-usual. NHS GGC advised there was no other accredited lab available to assist with the testing.

Maintenance issues

- In the ZUTEC "Manufacturers' Literature" section, the following Horne documents are located:-

  Optitherm INSTALLATION, COMMISSIONING, OPERATING AND MAINTENANCE INSTRUCTIONS

  TSV1-A108A DUAL CONTROL SHOWER PANEL

  TSV1-A108A2L DUAL CONTROL SHOWER PANEL
- In the Optitherm document, the following observations are made:-

  The tap operating conditions are noted as hot: 52^{o}C to 65^{o}C and cold: 5^{o}C to 20^{o}C with a minimum differential between mixed and supply temperatures of 11^{o}C (between 1 and 5 bar). Horne will not guarantee operation out with these conditions.
- There is evidence that some cold water temperatures are in excess of the *20^{o}C noted above.*
- There are two methods of flushing the pipe work described prior to installation of the tap. There is no evidence within the commissioning documentation contained within ZUTEC that these have been followed.
- There is no evidence contained within ZUTEC that the various checks noted (flushing, hot temp, cold temp, mixed, mixed temp and cold water failure test) were carried out at commissioning. The contractor has provided a series of drawings within ZUTEC which appear to indicate various taps and outlets being checked-off as operational; but this does not replicate the manufacturers commissioning requirements. There are also blue crosses annotated on these drawings, the meaning of which is unclear (i.e. has the tap/shower failed the test?) A sample image[73] is shown in Appendix 2.
- Thermal disinfection is noted as the method of disinfection for the Horne tap.
- It was noted that the during routine maintenance functions, the brass isolating screws of the Horne tap are being damaged when NHS GGC operative are using the manufacturer's approved tools as they are constructed of soft brass. These isolating

[73] Appendix 2 Item 21

screws are also difficult to access given their location. A series of photographs of the maintenance of the tap is shown in Appendix 2[74].

- The flow straightener was taken apart and the components can be seen in Appendix 2[75].
- The other taps installed in the project (mainly non clinical) are manufactured by Armitage Shanks/Ideal Standard.
- These taps are from their Contour range. A comprehensive maintenance document is available on ZUTEC for this product. It has the same temperature operating parameters as the Horne Optitherm tap.
- These taps have a flow similar flow straigtener but this tap does not retain water as the Horne Engineering tap does.
- There is a comprehensive installation and commissioning process. There is no evidence that these were carried out from the ZUTEC information.
- From the documentation it is recommended that these taps should be audited :

  6 to 8 weeks and 12 to 15 weeks after commissioning

  If all OK then 6 monthly servicing cycle

- There is no evidence that the above recommendations have been carried out for areas out with critical care areas.
- The Contour 21 tap has two flow control devices installed (one on the TMT and one on the incoming supply to the outlet). This may increase the risk of promoting biofilm formation due to the resultant restrictions in water flow.
- There is no internal means of isolating the Contour 21 tap. The isolation valve, strainers, check valve and flow regulator are located in the service void behind the IPS panel, therefore outlet isolation for servicing requires the IPS (Integrated Plumbing System) panel to be removed which can be difficult in an operational hospital. The manufacturer requires that the strainer is cleaned every six months.
- It has been reported that IPS panels have caused injury to operatives as they have fallen as a result of the type of fixing employed on the panels.
- It is noted that this tap meets the requirements of HBN 64 and HTM 04 as noted by the manufacturer.

HSG 274 Part 2 notes

2.34 It is important that there should be ease of access to all parts of the system, components and associated equipment for management and maintenance purposes, eg tanks, calorifiers, thermostatic mixing valves (TMVs), blending valves, circulation pumps etc. Isolation valves should be included in all locations to facilitate maintenance and the implementation of control measures. The pipework and any

[74] Appendix 2 Item 13
[75] Appendix 2 Item 14

components should be easy to inspect so that the thermal insulation and temperature monitoring can be checked.

SHTM 04-01 Part A notes as follows:-

7.46 Strainers should be fitted within the water pipework system to protect thermostatic valves etc against ingress of particulate matter. The installation of these fittings should allow adequate access for maintenance/replacement, and they should be provided with means of upstream and downstream isolation. (see also paragraph 5.4, however) Strainers can be a source of Legionella bacteria and should be included in routine cleaning, maintenance and disinfection procedures (see Section 7, Part B).

7.47 Service isolation valves should be fitted to all pipework preceding sanitary tapware and WCs etc for servicing, repair or replacement. Drain-valve provision may also be appropriate for certain installations, for example, service pipework to en-suite facilities etc.

Recommendations (Page 12)

It is preferable that thermostatic mixing devices are fitted directly to the mixed temperature outlet, or be integral with it, and be the method of temperature and flow control.

Notes 14:

a. in all new installations thermostatic mixing devices shall be fitted directly to the mixed temperature outlet or be integral with it, and be the method of temperature and flow control, i.e. the mixing device should not be separate and supply water via second tap or manual mixer since there will be many cases where draw-off of cold water will not occur;

- Given the lack of suitable isolation at the tap itself, this solution is operationally difficult to maintain in an operational hospital. In addition the inclusion of additional in line isolation, flow control and strainers which, due to the installation are difficult to maintain, may prove an additional risk for biofilm growth.

Warranty issues

- As a result of the use of chemicals to disinfect the Horne Engineering Ltd taps rather than the manufacturers recommended thermal disinfection methods, the warranty on these taps are null and void. There is contradiction in the advice given previously by the Contractor in August 2012 and that provide in ZUTEC and subsequently given by Horne Engineering as noted above.

- Armitage Shanks/Ideal Standard do not share the same general concerns regarding chemical disinfection of their taps, providing the dosage is to the World Health Organisations (WHO) and manufacturer's recommendations. Armitage Shanks/Ideal Standard note that hydrogen peroxide (main active component of SANOSIL) is detrimental to the system and do not recommend its use[76]. Horne Engineering has also noted the detrimental impact of hydrogen peroxide.

Wash hand basins

- The Mechanical and Electrical Services designer did not specify the type of sink to be installed. Their specification[77] refers to the Architect's schedules. The room datasheets compiled by the Architect detail the requirements for each room. An example of this is shown in Appendix 2. The Architect has noted the guidance document the sanitary ware should comply with, but not the actual manufacturer. This is also reflected in the layout drawings.
- The range of clinical and non clinical wash hand basins chosen by the contractor are manufactured by Armitage Shanks from their Contour 21[78] healthcare range. There is no facility to connect the tap on the sink as the taps are panel mounted. The drain connection is at the rear of the sink bowl and there is no overflow all as per guidance.
- The connection to the drainage pipe work from the sink is via an aluminium spigot with a silicone gasket or washer.
- A clinical incident was identified around the 4th of June 2018 in wards 2A and 2B. On investigation it was noted that the sink drains had a build up of biofilm and the aluminium spigot was corroding. Images of one sample from a sink can be seen in Appendix 2[79].
- It is noted that around the time of procurement and installation of the sinks in 2013/2014, the manufacturer changed the aluminium spigot to a PVC spigot. It is not known the extent of the aluminium spigots across QEUH or RHC.
- Further investigation is required on this matter and NHS GGC has submitted an incident report to HFS Incident Reporting and Investigating Centre (IRIC). In addition HFS, HPS and NHS GGC are arranging discussions with Public Health England (PHE) who are currently investigating (unrelated) drainage issue in healthcare environments.
- NHS GGC have analysed the material in the sink from a microbiological perspective and have identified the following organisms across a number of sinks.

Drain swabs wards 2A AND 2B RCH

Area	**Organisms**

[76] Appendix 2 Item 17
[77] TUV SUD Specification ZBP-XX-XX-SP-500-103
[78] Appendix 2 Item 26
[79] Appendix 2 Item 25

Drain swabs wards 2A AND 2B RCH

Consulting room 4 trough sink drain	*Enterobacter cloacae and Pseudomonas fluorescens*
Consulting room 2 sink drain	*Pseudomonas aeurginosa*
Clean prep room sink	*Pseudomonas aeurginosa and Cupriavidus pauculus*
Room 5 sink plug hole	*Enterobacter hormacechei, Sphingomonas paucimobilis and Pseudomonas fluorescens*
Rm A bathroom sink	*Acinetobacter haemolyticus and Fungi*
Rm A sink plug	*Acinetobacter haemolyticus and Fungi*
Large clean prep room sink	Klebsiella oxytoca, Cupriavidus pauculus, Enterobacter cloacae, Pseudomonas aeurginosa

Table 7.1 Summary of drain swabs for wards 2A and 2B

- In addition to the above, NHS GGC has had a sample of the sink spigots as well as the flow straighteners from several taps analysed by an independent laboratory (Intertek). As a result an interim report[80] has been produced and this details some of their findings. The main points to note from this very comprehensive report are:

  From 17 of the flow straighteners tested 11 were found to have biofilm[81].

  CFU were recorded in excess of 1000 in the biofilm samples.

  CFU were estimated to be in excess of 200million per flow straightener.

  Pseudomonas sp and CFU were recorded in a flow straightener which was unused.

  The microbiological analysis of the spigot was similar to that observed by NHS GGC.

  Plastic film, hair and other organic matter was found to be in the drain spigot and on the spigot seal.

  The material found[82] in the water tanks indicted the presence of biofilm.

- It is noted that the Contractor's as installed information relating to the drainage detail loaded into ZUTEC is actually not what has been installed. An extract from drawing

[80] Intertek Interim Report ITSS-0718-0001W
[81] Appendix 2 Item 43
[82] Appendix 2 Item 41

ZBP-XX-XX-DT-581-0061[83] shows the "as-installed information" in ZUTEC. Some of the differences observed in the installed versus the drawings are :-

Thermostatic Mixing Valve (TMV) shown rather than the Thermostatic Mixing Tap (TMT) installed.

Isolating/commission valves not installed.

Traditional "U" bend shown rather than the bottle trap installed.

The rodding access point has not been installed.

Main access panels not practically accessible (noted in DMA reports)

The bottom access panel is only around 200mm high which leads to the plumber having to lie on the floor in order to reach up to access the bottle trap.

- NHS GGC have advised "*The DWS (Domestic Water Services) 'as fitted' layout drawings are generally consistent with the actual installation, however minor discrepancies have been found during various investigators pertaining to general services*".

Energy centre

- To provide an efficient source of heating and power for QEUH, RCH and other parts of the QEUH campus a new separate Energy Centre was built to house the Combined Heat and Power Unit (CHP) and boilers.
- Hot water is distributed to the building plant rooms from the energy centres via a Medium Temperature Hot Water (MTHW) heating system derived from seven MTHW dual fuel boilers and 3 gas fired CHP units. The CHP system is designed to be the lead system and provide a high portion of the campus heating requirement.
- In the QEUH and RCH plant rooms there are plate heat exchangers which convert the MTHW to Domestic Hot water (DHW) and Low Temperature Hot Water (LTHW) to serve the hot water and heating circuits respectively, for the wards and ancillary spaces.
- The CHP plant was not commissioned within the original project time line and was subject to contractual penalties. A summary of the current situation is as follows:

Question	NHS GGC response
Intended project completion	January 2015.

[83] Appendix 2 Item 29

Question	NHS GGC response
Actual project completion	January 2016. All 3 CHP units were brought on line, there was no sign off on the compliance of the CHP with the contract as Multiplex still required to prove the control strategy and energy performance, to date (July 2018) this has not been provided.
First indication not working as intended	January 2016.
Date changes made to control software	These changes have been ongoing since January 2016 under the control and instruction of Multiplex, current configuration was implemented Aug 2017 by Multiplex (not proven or signed off as working).
Have all software changes been documented	No these software changes have not been documented despite requests for this documentation and sign off by the system control philosophy changes by the design engineers. Following pressure (from NHS GGC Estates) a user guide was issued (by the Contractor) for use by the operational Estates Team.
Training provided	System familiarisation training was provided on site. The offsite BMS training specified under the contract was not provided.

Table 8.1 Energy centre summary

- NHS GGC have advised they have not been able to operate the plant as intended due to numerous failures of the system, which are highlighted in the following documents:-

  QEUH Energy Centre Forensic Analysis Report[84]

  QEUH Building Presentation[85]

  Comments on BMS Graphs[86]

[84] Innovated Design Solutions QEUH Energy Centre Forensic Analysis Report 10th May 2018
[85] Innovated Design Solutions QEUH Building Presentation 22nd May 2018
[86] Innovated Design Solutions Comments on BMS Graphs 11th June 2018

- The Contractor has indicated[87] that they and their advisors can see no consistent issues with temperatures although there may be some control issues which were instigated in 2017 and it has been these changes which have caused the potential issues with the hot water temperatures at QEUH and RCH.

Temperature issues

- NHS GGC has advised that the main issue is that the MTHW flow and return temperatures are not as specified. This in turn means that on occasion that the DHW temperatures on the wards will fall[88] below the specification and parameters set out in SHTM 04-01. The DHW graph shown in appendix 2 (item 27) shows a set point of approximately 65^0C however this drops off to a mean of about 60^0C over a period of 43 days with minimums of approximately 53^0C.
- The plots for the CHP[89] show flow temperatures generally of 105^0C and return of generally 70^0C, however there are temperatures outside of this band which will have a negative impact (albeit for a short time) on the LPHW and DHW in QEUH and RCH.
- It should be noted that there are no test or commissioning results for the water services in the Energy Centre contained in ZUTEC.

BMS issues relating to the Energy Centre

- From the preliminary information available at this time, it would appear that there are several issues relating to the Building Management Software.
- As noted previously the BMS maintenance contractor's database was lost and to date has not been fully recovered.
- The alterations made to the plant in the energy centre have not been documented; therefore it is unclear if the current control strategy has changed from the design intent.
- From the various graphs and reports provided it is evident that there are some sensors which are malfunctioning.
- NHS GGC does not have a process in place for BMS alarm prioritisation, reaction or resolution.

[87] Email Multiplex to NHS GGC 16th June 2018
[88] Appendix 2 Item 27
[89] Appendix 3 Item 28

Proposed solution

- NHS GGC has been in discussion with various specialists to consider an appropriate response to the current situation with the water system at QEUH and RCH.
- Various chemical treatment solutions were researched and considered, including a new technology called CLORIOUS 2 which is a variant of chlorine dioxide, but as yet is untried in large scale healthcare environments. The chosen solution is based on Chlorine Dioxide (ClO_2)
- A full analysis of various chemical treatments is given in SHTM 04-01 Part D[90].
- The solution is detailed in the following NHS GGC's documents:

  Potable Water System: Proposed Sanitisation Strategy Paper (5/06/2018)[91]

  Proposed SOE for ClO2 Disinfection and Dosing (D5 180613)[92]

  Water Quality Incident Action Plan 2018 (DW 180612)[93]

  Appendix 1 Distribution Zone Map[94]

  Appendix 1A-1D Shock Dosing Schedule of Areas Affected[95]

- The basis of this proposal is the installation of new Chlorine Dioxide (ClO_2) plant external to the RCH in a new purpose built housing. Pipe work will be routed from this new housing in existing ducts to various existing pipe work risers to the various plant rooms.
- The ClO_2 plant requires to be procured as it is not an "off the shelf" item and therefore this will delay the implementation of the solution. This delay will however be used to carry out any enabling works, such as planning consent for the housing, surveying connection points, cleaning and disinfection of plant. There will be a total of nine dosing systems (one for the bulk storage tanks and eight others distributed through both hospitals).
- The ClO_2 will be introduced to the RCH in the first instance and then to QEUH. The dosage limits will be within the World Health Organisation Guidance, EU Drinking Water Directive and Scottish Water Bylaws. The initial dosage of ClO_2 will be approximately 0.1ppm at the taps and other outlets.
- Once the ClO_2 is established in the water system a shock dosing of the system using ClO_2 to assist in the removal of biofilm. The concentration of the shock dosing and contact time will depend on specialist advice as the contact time of a high concentration may have a detrimental impact on the pipe work and fittings.

[90] SHTM 04-01 Part D: Disinfection of Domestic Water Systems
[91] QEUH sanitisation strategy paper 05-06-2018
[92] Proposed SOE for ClO2 Disinfection and Dosing (D5 180613)
[93] Water Quality Incident Action Plan 2018 (DW 180612)
[94] Appendix 1 Distribution Zone Map
[95] Appendix 1A-1D Shock Dosing Schedule of Areas Affected

- After the shock treatment the residual level of ClO_2 will be reduced to 0.2ppm at the outlet to provide protection to the system.
- During these works wards will have periods of time (up to 24hrs) when there is no water available through the system and a ward-by-ward contingency is required and is being developed by NHS GGC.
    - It may take up to two years before the ClO_2 has had a significant impact on the level of organisms within the system.
    - NHS GGC will put in place a testing regime to ensure the dosage of the ClO_2 is maintained to between 0.2ppm and 0.1ppm and the microbiological results are acceptable.
    - The current cost of the protective measures to date expended by NHS GGC is circa £500k.
    - The preliminary estimate cost from NHS GGC associated with the installation of the ClO_2 plant is in the region of £1.3 million including VAT (and includes pipe work modifications, POU filters, microbiological testing, review of all control and legislative documentation, etc). This excludes any whole scale replacement of taps across QEUH and RCH but includes tap replacement in critical care wards.
    - NHS GGC estimate the recurring cost associated with the solution circa £720k (including VAT) per annum.
    - Until the microbiological levels are returned to normal there will be a need to utilise point of use filters in certain high risk clinical areas such as RCH wards 2A and 2B and QEUH wards 4A and 4B. Other areas may also require POU filters, but this will be determined and advised by NHS GGC microbiologists and clinical staff.
    - Consideration is being given to removing the Horne Engineering taps in critical care areas as it is not possible to remove the flow regulator and the Manufacturer is not prepared to modify the design to accommodate the removal of this device as they do not share the same view on its function or role in the microbiological event surrounding this incident. This is discussed in the paper presented to the Water Group Meeting on 8th June 2018[96].

Conclusions and hypothesis

The NHS GGC Estates team were not part of the Client's project team and had no influence with regard to the design of the mechanical and electrical services or any input into the practicality of maintaining these services. Only one member of the Estates team was seconded to the project team during the pre-commissioning and handover phases of the project.

In view of the evidence provided and as detailed in this report, it is likely that the hot and cold water distribution pipe work installation was contaminated at one or more times during the installation process.

The Scottish Water main incoming supplies were tested in February 2012 and were reported by Scottish Water as being bacteriologically satisfactory.

[96] QEUH High risk area TMT Review paper 05-06-2018

There is good evidence that pipe work was not adequately protected from contamination during construction.

The Project Supervisor has noted in several of the reports that various pipes were left open-ended and unprotected during the installation period. There is no evidence to suggest that this pipe work was rejected, therefore the pipe work was probably subject to contamination and the introduction of moisture via condensation.

There is evidence that water was in pipe work in some areas of the building in August 2014. Commissioning of the systems was not until November 2014.

NHS GGC relinquished the independent governance of the testing and commissioning of all systems (not just water) to the Contractor and the independent third party check on the commissioning was lost as a result.

The commissioning certification shows identification of *E.Coli* and high (Total Viable Count) TVC at the initial disinfection stage. There is no evidence to suggest that the fact that *E.Coli* was present in the system was brought to the attention of NHS GGC Infection Control or Project Supervisor by the contractor. It would appear that the post disinfection results show that the *E.Coli* was eliminated and TVC in some areas reduced at the second disinfection, but there is the potential that the level of chemical used was not adequate to remove all the organisms and any established biofilm. Some outlets failed the second disinfection test and no results are available to prove they subsequently passed. This suggests that the system may have been handed over in a failing condition.

There is also evidence that work was carried out by the contractor on the main incoming water tanks, calorifiers and pipe work post handover, which may have introduced contaminants into the hot and cold water systems. NHS GGC Estates were not aware of these works taking place; therefore there was no control of the methodology of the installation or re-commissioning, disinfection and re-testing of these parts of the water distribution system.

NHS GGC's specialist contractor, used to produce the legionella risk assessment, also noted that there were visible signs of contamination immediately after handover and highlighted issues with the water sampling test results.

Since handover the maintenance of the hot and cold water systems has not followed the manufacturers' recommendations or guidance.

There is no evidence that the maintenance procedures set out by the Contractor in ZUTEC for taps, showers and drains have been implemented.

NHS GGC employed an independent company (DMA) to carry out legionella risk assessments at handover and again in 2017. These highlighted numerous actions required to be taken to resolve issues with the water management at QEUH and RCH. NHS GGC also employed an Authorising Engineer (AE) to Audit the management of the water systems at QEUH and RCH. The AE' audit highlighted several items required to be resolved.

NHS GGC has now (July 2018) resolved the majority of the outstanding items on the three reports noted in the paragraph above and as a result have reduced the risks associated with the management of the water systems at QUEH and RCH.

- It is impossible to determine the exact cause of the various organisms and fungi which have been found to be present in the water system as both QEUH and RCH. From the information provided to both HPS and HFS the following is a plausible scenario.
    - The incoming water supply from Scottish Water was not infected with any organism.
    - The incoming mains pipe was identified as being contaminated with soil and debris.
    - There is evidence that the water tanks were not clean at the time of handover.
    - The hot and cold water system pipe work at both QEUH and RCH were contaminated during the installation process. This contamination could have come from dust and debris on the site as there is documented evidence of open ended pipes. Moisture may have entered the open-ended pipes and started to provide a basis for biofilm proliferation.
    - There is evidence that flushing took place without the main water system filters in place. These filters are designed to prevent organisms above 2μm entering the water supply.
    - From the manufacturers information the strength of the disinfectant agent used was potentially insufficient to be effective against the organisms and biofilm established before the commissioning process occurred.
    - The manufacturers of the taps have record that hydrogen peroxide will have detrimental effects on their products, should not be used and will void their warranty.
    - The water system commissioning results show initial high levels of TVC and certain other organisms. These results are not isolated to particular areas of the water system and included E-coli. New test results have been produced to indicate that subsequent test cleared these outlets of E-coli, but it is likely that the biofilm survived the chemical dosing applied.
    - There are no records of the commissioning of the dump valves therefore the potential has existed for these to become dead legs if the valves are not functioning or the set point for actuation is set too high.
    - The pipe work had water in since July 2014 and there is no evidence that this was circulated or flushed.
    - The commissioning of the system was completed in stages from November 2014 to January 2015, with some individual outlets being re-tested in February 2015.
    - During the commissioning period there is no evidence that the outlets (all taps, showers, external taps, connections to equipment or water coolers were flushed). This may mean that the biofilm had an opportunity to grow and establish.
    - As part of the commissioning some outlets failed the tests. Some of these passed subsequent tests, but others did not. There is no evidence in

ZUTEC of certain outlets passing the disinfection process (indeed some are marked as failing).

- There is evidence that undocumented work was being carried out on the water system post handover (as noted in the DMA reports) which may have introduced contamination into the system. There is no record of this work or if the section or system was disinfected.
- As the system was colonised, the type of flow straightener on the Horne tap became a site for certain organisms to grow, particularly gram negative organisms such as *pseudomonas and cupriavados*. As a result of the investigations by NHS GGC, the contamination of the tap body and components was shown to be wide spread. This biofilm may have cause retrograde contamination back into the water system.
- Prior to any POU filters being installed it is probable that the drainage system (via the sinks) became contaminated and biofilm began to colonise the drains.
- There is no evidence of NHS GGC Infection Control Team being involved in the handover process of the hospitals to review the water test results.
- There is some evidence to suggest that the Contractor was flushing the taps in the hospitals in April 2015. Some records have been provided for flushing by NHS GGC in March and April 2015. Subsequent to 2015, there are records for critical care areas, but not for other wards or general areas.
- It is clear from the DMA report dated April 2015, that the water system did have a significant number of deficiencies at the time of the initial legionella risk assessment. These included (but not limited to):-

  Issues with the MTHW from the energy centre

  Cold water temperature were recorded as high

  Dump valve not operating as per design

  EPDM flexible hoses installed with are contrary to SAN(SC)09/03

  Areas could not be accessed for flushing

  Areas still under construction

  Water tanks had various degrees of detritus at handover

  Very few, if any, of the actions noted in the DMA report of April 2015 were actioned.

  Very few, if any, of the actions noted in the DMA report of September/ October 2017 were actioned.
- These points are again picked up in DMA's report of 2017 and the Authorising Engineers report of 2017.
- It is therefore suggested that there was a lack of routine maintenance on the water system with the exception of critical care areas. This included a

failure to replace flow straightners as per the manufacturer's recommendations.

- As noted in DMAs reports there were issues reported at the time with the MTHW supply to QEUH and RCH from the Energy Centre. This may have contributed to the LTHW temperatures to the outlets dropping below the minimum 50°C required and into the legionella growth zone (which would have also aided other organism growth). There is evidence from the BMS logs that the LTHW temp is low. This situation has not been resolved at the time of writing (July 2018). Issues with the function of the CHP are being addressed directly by NHS GGC to the Contractor.
- Indicators that a system wide contamination issue may be present manifested in the positive organism results in 2015. Due to the focus on critical care areas the scale of the problem was missed.
- It took a significant amount of time to establish the extent of the contamination because NHS GGC laboratory became swamped with requests for test results and the sheer volume of results and data was problematic to manage.
- As a result of the biofilm and organisms in the water, the drains have become infected prior to the POU filters being installed. This has been exacerbated by organic material, plastics and other material being flushed down the sinks. There is a possibility that cross contamination has occurred from "misting" from the drain on-to hands being washed.

Recommendations

Recommendations NHS GGC

NHSGGC should consider:

- Formal appointment letters issued to all the relevant members of NHS GGC water management team as detailed in SHTM 04-01 Part B and put in place the managements systems described in the guidance (this should be the case for all other engineering services too).
- All AP and CP training to allow competent operation and management of the water system should be completed and recorded (this should be the case for all other engineering services too).
- Resolve outstanding issues with Energy Centre.
- The Employer's Requirements for future projects should detail accurately the guidance applicable in Scotland at the time of writing the ER.
- All the points noted by DMA in their Risk Assessments are addressed and all remedial work carried out.
- All points raised by NHS GGC Authorising Engineer (Water) are addressed and all remedial work carried out.

- Have a formal process in place to prioritise, manage, record and react to any BMS alarms from anywhere in the campus network.
- Check turnover of all water tanks is balanced and there is no stagnation.
- Carry out routine maintenance and reactive maintenance on the hot and cold water systems and components as per PPM schedules in ZUTEC and specific manufacturers' recommendations.
- Have the seasonal commissioning as required by the specification carried out by the Contractor.
- Provision of competent building services Clerk of Works (CoW) for all building contracts.
- Ensure quality and competency checks for all projects
- Ensure the Estates Department have a collaborative roll at all stages of capital construction projects.
- Ensure that all infrequently used outlets are managed and flushing is recorded.
- Ensure all pipe work to removed external bib taps has been removed.
- Confirm all EPDM flexible hoses have been removed
- Ensure that a RAID server or equivalent is provided as specified for the BMS and provide assurance that the BMS historical data is protected and stored for the appropriate time.
- Have all ZUTEC records checked and any missing or incorrect documentation rectified.
- Check dump valves operation and ensure there is no route for bacteria to grow at the valve or the tundish (if there is one). If the tundish detail is missing or incorrect this should be rectified.
- Point of use filters will continue to be in place in ward 2A and other areas identified by the IMT/IPCT until the risk to patients from the current situation of water contamination has been minimised
- NHSGGC IPCT work closely with the facilities team ensuring:
    - Attendance at every water group meeting
    - Regular updates on the condition of the water, including review of any water samples and offering advice on remedial solutions.
    - Provide input into every stage of the water review including as a minimum continual dosing, tap replacement, water cooler review
    - The ICM provides the HAI executive lead with assurance relating to water safety from an IPC perspective
    - Water safety is an agenda item at local and board infection control committee meetings
    - Early identification of any potentially water linked clinical cases

Recommendations for HPS/HFS/Scottish Government

- HPS/HFS will continue to provide support to NHSGGC relating to the current water incident and provide input into the weekly meetings until 2019 (and reviewed thereafter)
- Review of construction management guidance to establish how it can provide assurance that similar issues will not occur in future projects.
- Consideration to be given to production of updated "standard" Employer's Requirements (also known as Authority Contract Requirements (ACR) or Board Contract Requirements (BCR) as a National resource for all Boards.
- Consideration for updated water and other guidance to include:-
    - Thermal disinfection in sections of water distribution systems
    - Handover checklists
    - Contract management procedures
    - Design guides to eliminate thermal pickup in cold water systems
    - Update advantages and disadvantages of chemical disinfection techniques
    - What organisms to test for and action to take on defined levels
    - Drain cleaning regimes
    - Biofilm growth in drainage systems
- Consideration to be given to HFS providing Authorising Engineer capabilities as a service to all Boards in Scotland.
- HPS via the existing Infection Control Built environment programme will, in conjunction with HFS:

    A. Prioritise water safety and undertake a review of NHS Scotland current approach to water safety

    B. Review existing National and international guidance relating to water safety and consider robust requirements for building handover requirements in relation to the water systems.

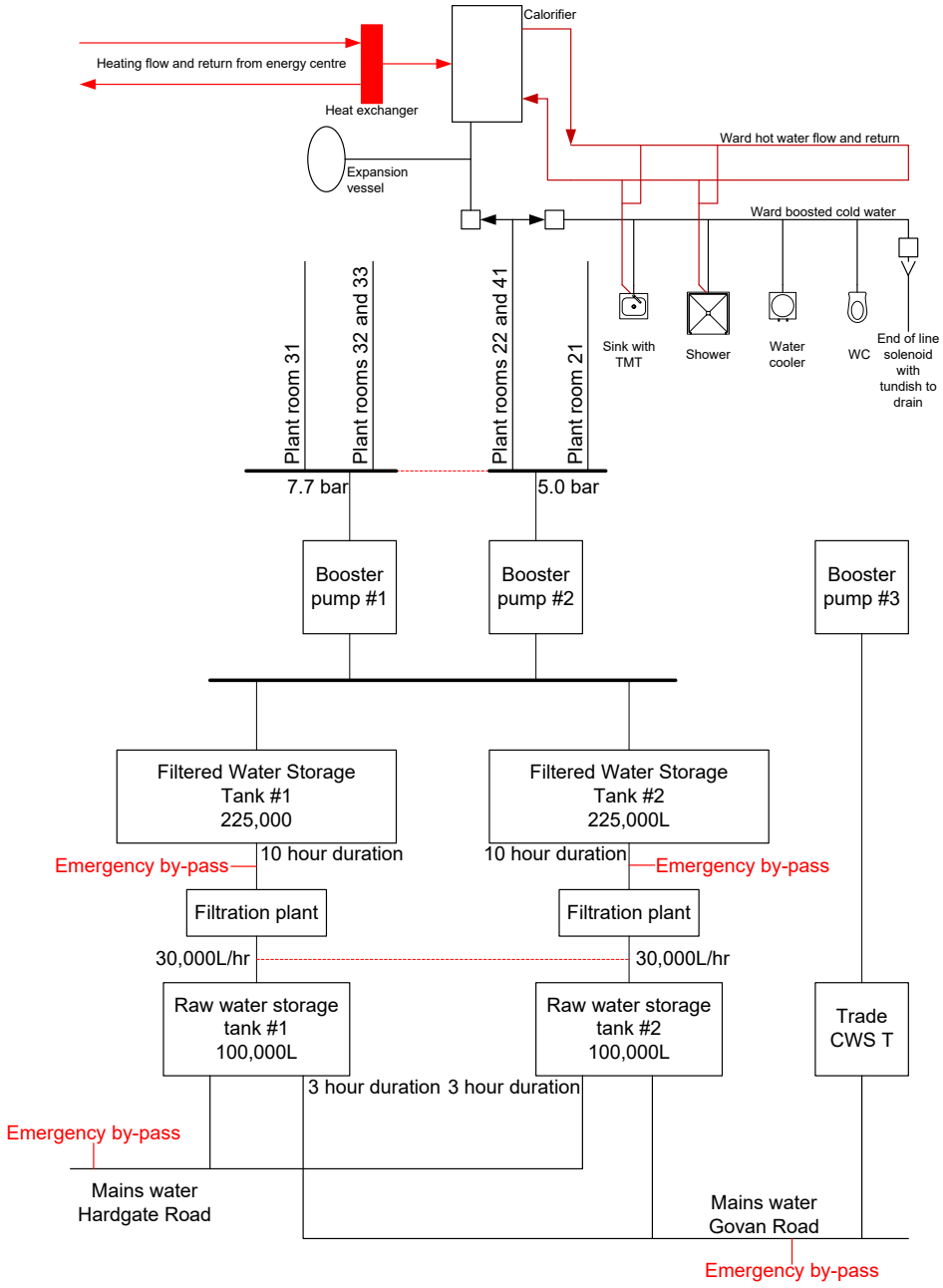
    C. Review the role of the IPCT into the built environment, including day to day activities, refurbishments and new builds

    D. Give consideration to the development of an evidence based/best practice built environment manual which will cover as a minimum the technical requirements from a clinical and HAI perspective

    E. Establish a risk based approach to water testing and any remedial action required, including roles and responsibilities.

Appendices

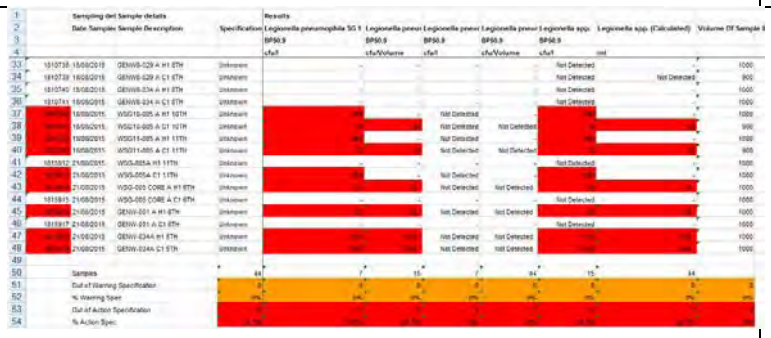
Appendix 1 Simplified water schematic



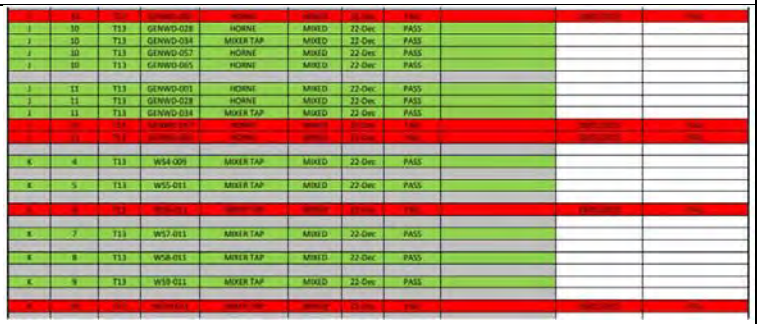
Simplified water schematic for QEUH and RHC

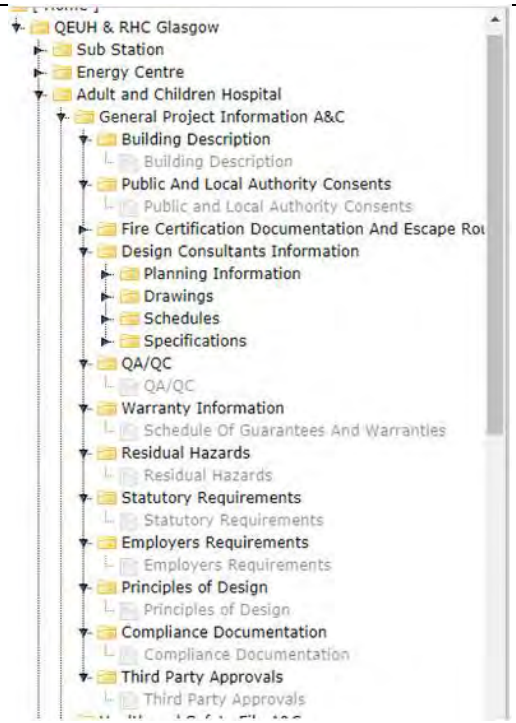
Appendix 2 Images and screen shots

Item	Image	Comments
1	8.2.8. **Water Systems and Filtration** 8.2.8.1. Cold Water Supply 8.2.8.2. The water supply system for The Works shall include two new supplies and also incorporate on-site segregated bulk water storage (24-hours). Treatment of potable cold water supplies is not acceptable and the provision of a wholesome supply from Scottish Water's mains with the minimum of storage and handling is required. 8.2.8.3. The Contractor shall design and install the domestic cold and hot water supply installations to fully comply with the requirements of; a) (S)HTM04-01; b) SHTM 2027; c) SHTM 02; d) SHTM 2040 "The control of legionella in healthcare premises - a code of practice"; and e) Health Guidance Note "Safe Hot Water and Surface Temperatures." 166	Extract from NHS GGC Employers requirements (ER) showing guidance required to be complied with respect to the domestic hot and cold water systems
2	 Document / Title / Proposals Comply? (Yes/No) / Compliance Narrative (How compliance is being Achieved) SHTM 04-01 Part A — Control of Legionella - drinking systems Part A — yes — Hot and cold water services are described in Design Strategy for Hot and Cold Water Services Volume 3 Section 3.7 and specification sections Volume 4 Sections 4.27, 4.28 & 4.51. However, the following adjustments are proposed:- Fig 2 shows A small CWS break cistern serving each cold water system, prior to the main filtration plant will be provided. However, a secondary break cistern before each bulk storage cistern will not be provided. At least two equally sized bulk storage cisterns with a total of 100% of the design capacity in each location have been provided. The recommended quantities of water storage given in Table A1 are considered excessive for modern hospitals. Therefore, reduced levels have been used. Refer to Design Strategy for Hot and Cold Water Services Volume 3 Section 3.7 for further details. Clauses 9.13/9.23 recommend providing peak continuous hot water output for 20 minutes. Following the recommendations of the SHTM, results in excessive storage capacity, which can increase energy consumption and increase the risk of Legionella, the HTM approach is also outdated and relates back to when there was high usage of baths at set periods of the day. Modern hospitals predominantly use showers, which use less water and have a much higher diversity factor. This approach will not be followed, but diversity will be considered using the principles of BS 6700. SHTM 04-01 Part B — Control of Legionella - drinking systems Part B — yes — Hot and cold water services are described in Design Strategy for Hot and Cold Water Services Volume 3 Section 3.7 and specification sections Volume 4 Sections 4.27, 4.28 & 4.51.	Extract from contractors response section 7 NHS Mandatory Documentation "Table 2 (extract from ITPD Vol 2/1 Section 5.1.2) – ITSFB Clarification Appendix 1"
3	Should background dosing be considered for this site? — Yes. However as renal dialysis, and other medical systems, are fed directly from the Raw/Bulk Water supply any background dosing system would have to be fully risk assessed and approved prior to installation.	Extract from DMA initial legionella risk assessment April 2015

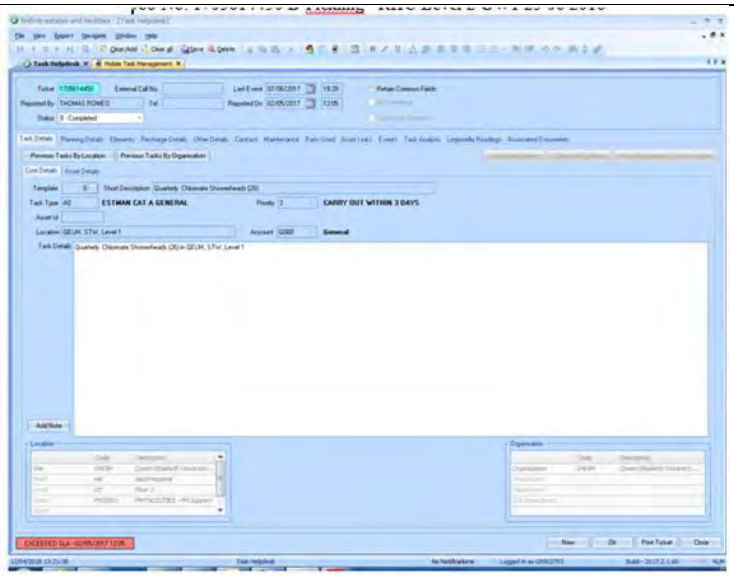
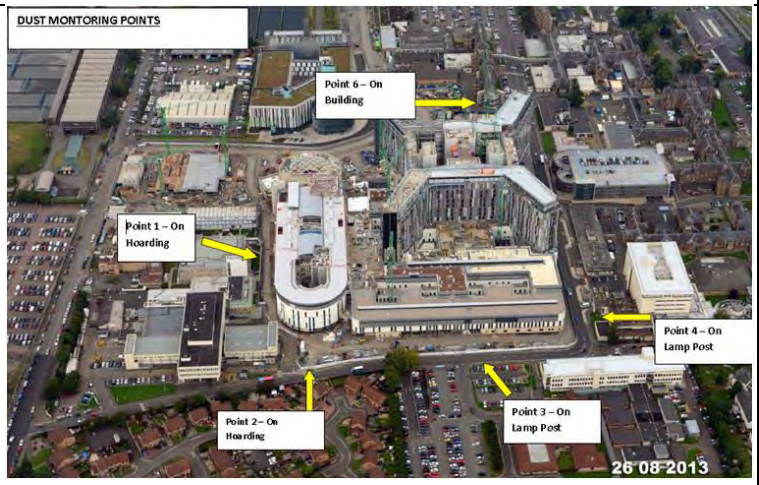
Item	Image	Comments
4	  Raw 1B CWST Raw 2A CWST  Trade LHS CWST	Images from DMA initial legionella risk assessment April 2015 showing debris in water tanks
5	7.9.6(h) Make a note in H&C specs about prohibited use of flexible hose connections Prohibition to remain and be enforced + noted in specifications by BCL Agreed	Extract from "The 2010 Instruction to Proceed Log - FINAL
6		Extract screen shot from water sampling test result summary August 2015.

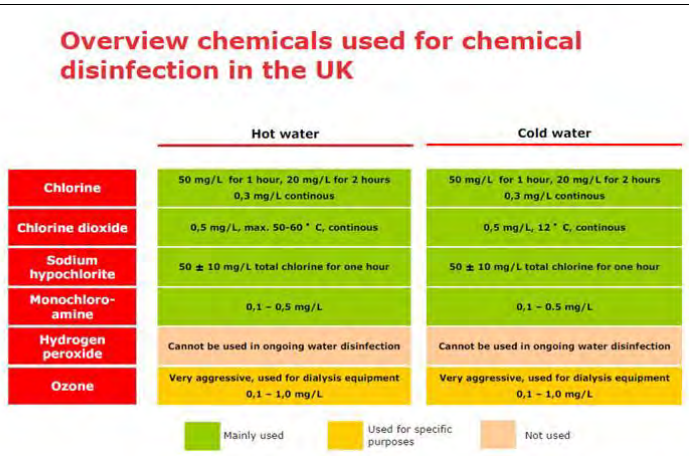
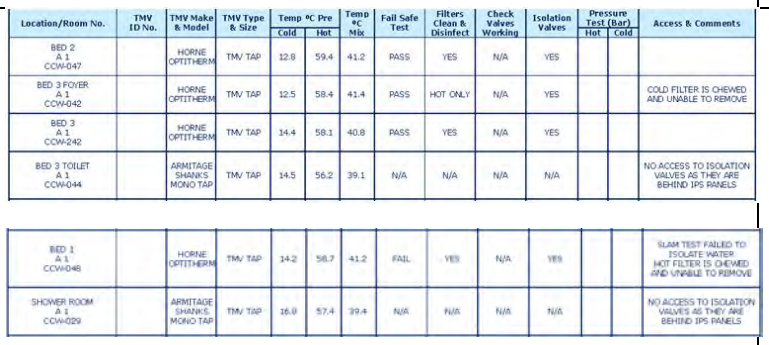
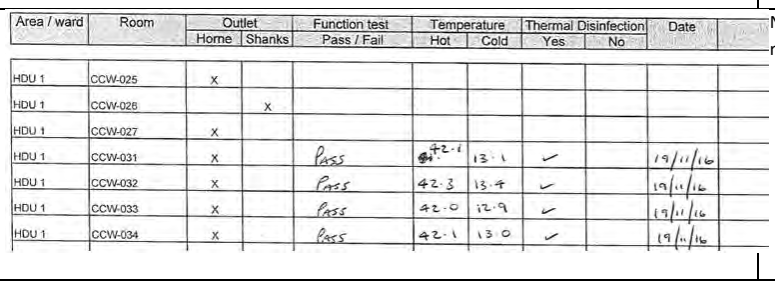
Item	Image	Comments
7		Photograph 6 from Capita Symonds Supervisors Report number 12 dated March 2012, showing open-ended pipe.
8		Photograph from Capita Symonds Supervisors Report number 19 October 2012, showing open-ended pipe.

Item	Image	Comments
9	W0.9 Commissioning Records It is essential that the results of all checks and measurements are recorded in writing at the time they are made. Breaks in the continuity of commissioning operations are likely and proper records will show the state of progress at any stage. It is most important that commissioning records are provided as part of the 'hand-over' information. It is therefore recommended that a standardised format be compiled from this Code for a particular project (see sections W5.5, W6.6, W7.10 and W8.4). W6.4.1 General Care should be taken during construction to keep the internal surfaces of pipework as clean as possible. Blockages in equipment may prove difficult to locate and expensive to rectify. It is therefore most important that the system is thoroughly cleaned of all detritus. In order to minimise the risk of corrosion and biofilm development, flushing and cleaning should commence as soon as possible after the initial system fill, ideally within 48 hours.	Extract from CIBSE Commissioning Guide W
10		Plant room 32 This shows taps which have failed the sanitisations in December and January.

Item	Image	Comments
11		Image showing initial failures of Horne taps, with retest passing a month-and-a-half later.
12		Image of ZUTEC file structure showing empty folders.

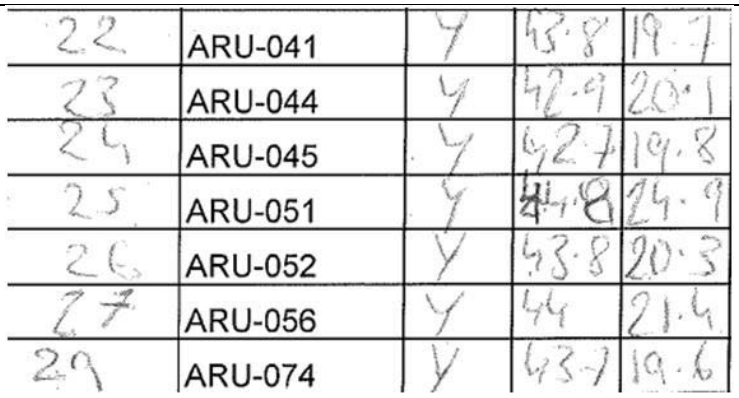
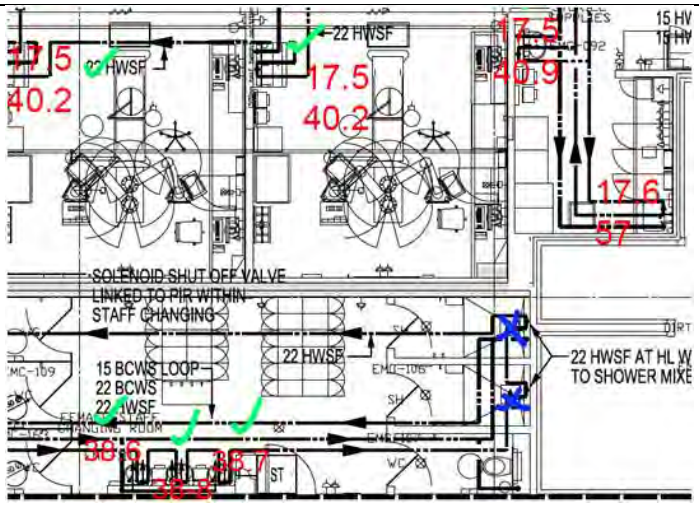
Item	Image	Comments
13		Routine maintenance of Horne Tap. Image (top left) show damage to brass isolating screws. Image (bottom right) shows old and new flow straightener.
14		Exploded view of Horne flow straightener

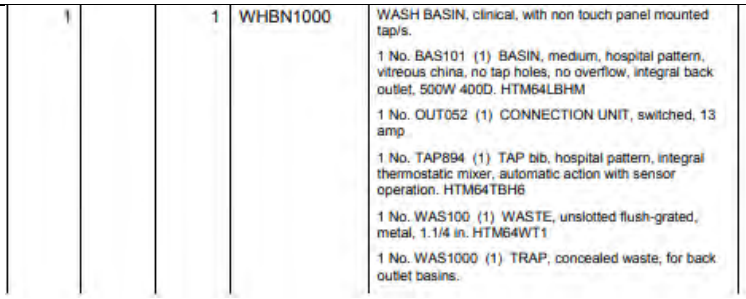
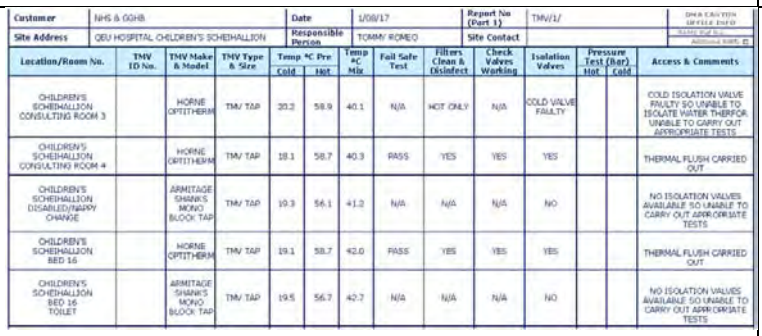
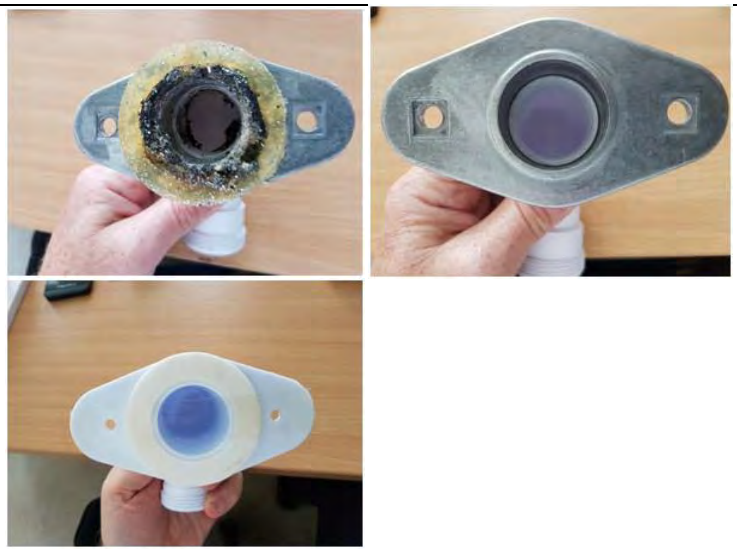
Item	Image	Comments
15		Image of a typical FMfirst(R) job card
16		Image showing the dust monitoring points.

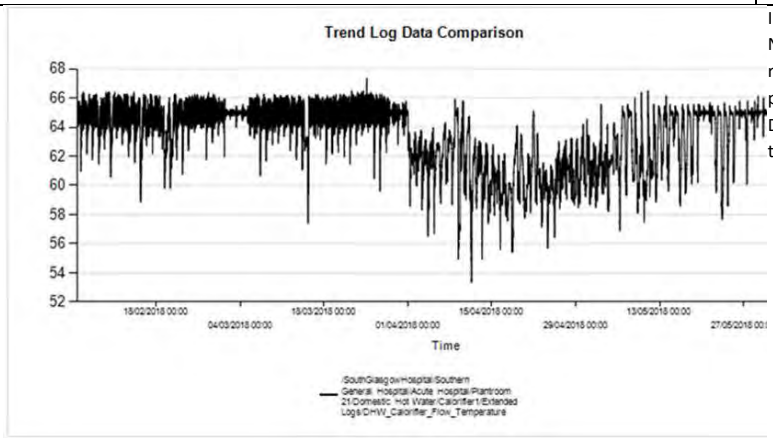
Item	Image	Comments
17		From Armitage Shanks / Ideal Standards regarding the concentration of chemicals which can be used with their taps without detrimental impact.
18		DMA Canyon report
19		NHS GGC report

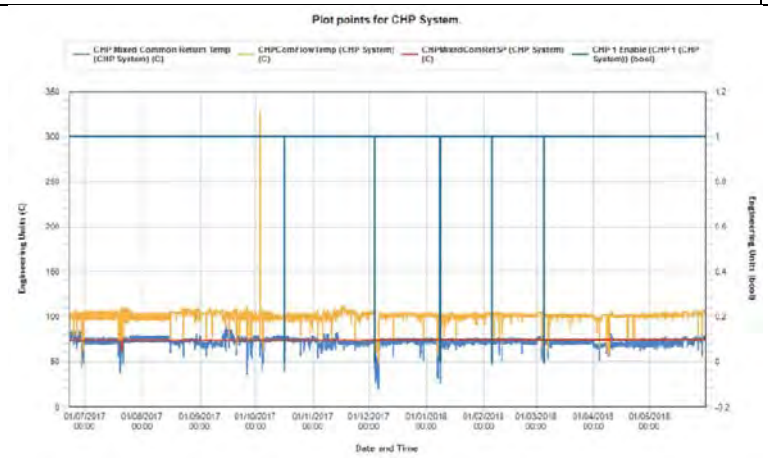
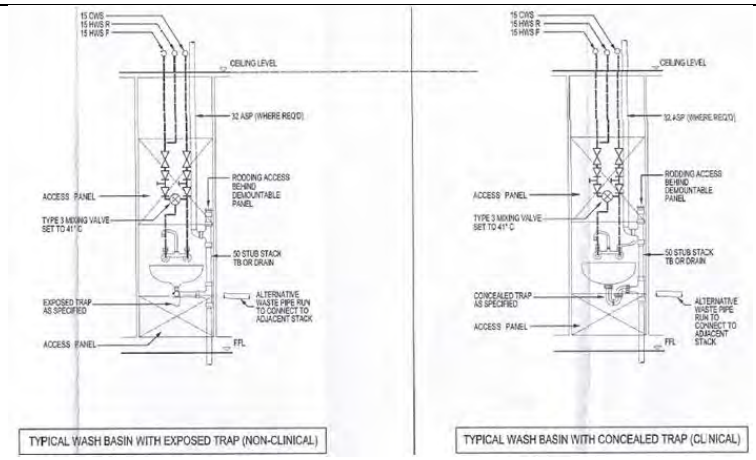
Location/Room No.	TMV ID No.	TMV Make & Model	TMV Type & Size	Temp °C Pre Cold	Temp °C Pre Hot	Temp °C Mix	Fail Safe Test	Filters Clean & Disinfect	Check Valves Working	Isolation Valves	Pressure Test (Bar) Hot	Pressure Test (Bar) Cold	Access & Comments
BED 2 A 1 CCW-047		HORNE OPTITHERM	TMV TAP	12.8	59.4	41.2	PASS	YES	N/A	YES			
BED 3 FOYER A 1 CCW-042		HORNE OPTITHERM	TMV TAP	12.5	58.4	41.4	PASS	HOT ONLY	N/A	YES			COLD FILTER IS CHEWED AND UNABLE TO REMOVE
BED 3 A 1 CCW-242		HORNE OPTITHERM	TMV TAP	14.4	58.1	40.8	PASS	YES	N/A	YES			
BED 3 TOILET A 1 CCW-044		ARMITAGE SHANKS MONO TAP	TMV TAP	14.5	56.2	39.1	N/A	N/A	N/A	N/A			NO ACCESS TO ISOLATION VALVES AS THEY ARE BEHIND IPS PANELS
BED 1 A 1 CCW-048		HORNE OPTITHERM	TMV TAP	14.2	58.7	41.2	FAIL	YES	N/A	YES			SLAM TEST FAILED TO ISOLATE WATER HOT FILTER IS CHEWED AND UNABLE TO REMOVE
SHOWER ROOM A 1 CCW-029		ARMITAGE SHANKS MONO TAP	TMV TAP	16.0	57.4	39.4	N/A	N/A	N/A	N/A			NO ACCESS TO ISOLATION VALVES AS THEY ARE BEHIND IPS PANELS

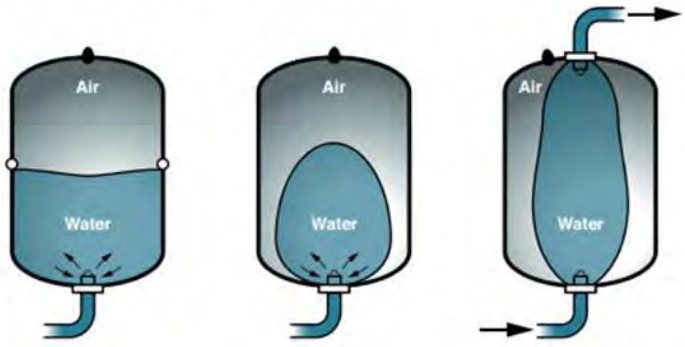
Area / ward	Room	Outlet Horne	Outlet Shanks	Function test Pass / Fail	Temperature Hot	Temperature Cold	Thermal Disinfection Yes	Thermal Disinfection No	Date
HDU 1	CCW-025	X							
HDU 1	CCW-026		X						
HDU 1	CCW-027	X							
HDU 1	CCW-031	X		Pass	42.6	13.1	✓		19/11/16
HDU 1	CCW-032	X		Pass	42.3	13.4	✓		19/11/16
HDU 1	CCW-033	X		Pass	42.0	12.9	✓		19/11/16
HDU 1	CCW-034	X		Pass	42.1	13.0	✓		19/11/16

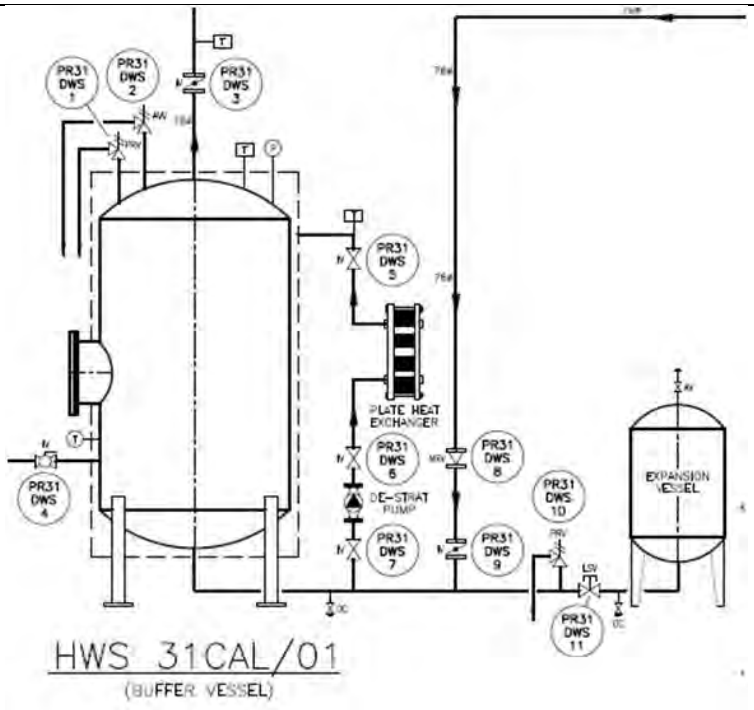
Item	Image	Comments
20		Image from FM First record of shower chlorination. This shows the cold water temperature on the right hand column.
21		Image showing areas served from plant room 21. Hot water noted as 57^{0}C. Some blue crosses noted and unclear if this means failure of the temperature record or equipment.
22	**Brookfield** New South Glasgow Hospitals Project **DESIGN STRATEGY FOR ENGINEERING SYSTEMS RESERVE CAPACITY** In respect of Clause 8.1.3.2 of Volume 2/1 of the ITPD documents the following reserve capacity is proposed for each of the major engineering services systems: **System** / **Proposed Reserve Capacity** / **Description** Cold water storage / 25% capacity / Water storage volume should not exceed 24 hours usage and ideally be less. Storage capacity could be reduced by lowering the ball valve floats. There is 25% additional capacity on the distribution pipework and pump systems, mains and risers, O% on local pipework systems. Hot water storage / 25% per description 0% in calorifiers / The provision of spare volume capacity in hot water systems is discouraged as this can lead to increased risk of Legionella. Plate heat exchangers and primary heating pipework will include a 25% output reserve. Main runs and risers will include 25% reserve capacity	Image showing spare capacity built into water system.

Item	Image	Comments
23		Image from room datasheet for children's bed room showing guidance requirements for sanitary ware.
24		TMT servicing reports showing cold water temperatures close or over 20C and issues with taps preventing maintenance.
25		Images of drain spigot connections from clinical wash hand basins. The left hand image shows corrosion and biofilm. The middle is a non contaminated sample. The right hand side image is the new plastic design for the spigot.

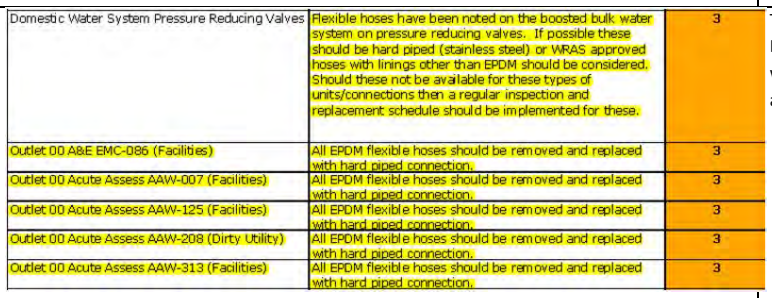
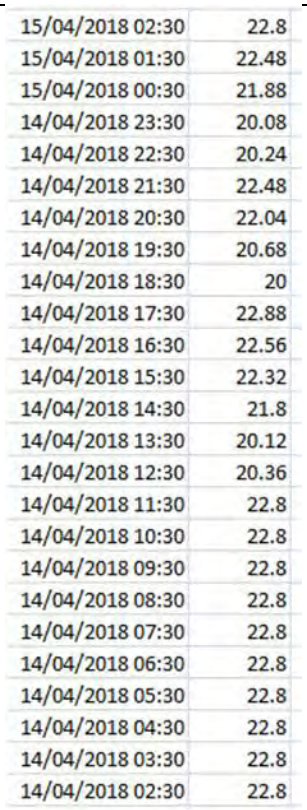
Item	Image	Comments
26		Image of Armitage Shanks Contour 21 and aluminium spigot with drainage connection.
27		Image from NHS GGC CHP report showing plant room 21 DHW flow temperature.

Item	Image	Comments
28		Image from NHS GGC CHP report showing MTHW flow and return temperatures for CHP 1.
29		Image showing the contractors as installed drawing (in part) for the drainage connections detail at the wash hand basins. This is not what is installed.

Item	Image	Comments
30	There are several types of vessel available including diaphragm or bladder type, with fixed and interchangeable (replaceable) bladders, as shown below. These internal bladders are often made of synthetic rubber such as EPDM and may support the growth of microorganisms including legionella, so check to see if these are approved against BS 6920. Vessels with a 'flow through' design should provide less opportunity for water to stagnate and become contaminated (as in the latter design).  **Expansion vessels**	Extract from HSG 274: info box 2.1. The type recommended is the flow through which is not as per installed. This was also recommended in SHTM 04-01 part A 2011.

Item	Image	Comments
31		Extract from Plantroom 31 - Domestic Water Pipework Valve Chart 1 of 3 drawing showing expansion vessel type installed.
32		Image showing the POU fitted to the Horne Engineering tap and the relationship to the sink.

Item	Image	Comments
33	**Comments:** There was bypass pipework set up to run from the Hardgate Road mains to the domestic (Bulk) water supply system connecting in after the Booster Pumps (5.0 Bar set). This was noted during DMAs initial site walk round and reported to Estates. DMA again noted this during the site survey of the CWSTs on 02/04/15 and again reported this to Estates. DMA were advised in mid-April this had been removed by Mercury/Brookfield. This line could potentially have introduced debris to the distribution system which would otherwise have been removed by the filtration units and could be a contributory factor to any out of specification microbiological results.	Text from DMA initial water risk assessment
34	Calorifier 32-03 was offline when DMA had an initial site familiarisation walk-round with Mercury Engineering in early January 2015. This calorifier was still offline when DMA were on site on 21st April 2015. This was creating deadlegs on the cold supply, hot flow and hot return to the calorifier and Estates staff were unable to confirm the reason for this calorifier being offline. This calorifier had been reinstated when DMA revisited on 27/04/15 though Estates not aware of any flushing, pasteurisation or disinfection of calorifier being carried out prior to reinstatement. DMA would recommend the calorifier (and hot system) is disinfected/pasteurised legionella samples taken from the calorifier and system prior to reinstatement to confirm these corrective actions have been effective.	Text from DMA initial water risk assessment
35	Legionella Management | Significant gaps were identified in the Legionella Management on site. Please refer to the Gap Analysis for further information. | 2	Text from DMA second water risk assessment
36	There are no records that manufacturers recommendations have been implemented to date regarding commissioning and component changes. Estates advised there is currently no mechanism in place for 'no access' reports to be reactioned to ensure all valves are completed in the necessary time frame.	Text from DMA second water risk assessment
37	**Competency** **11. A list of named management personnel, with the details of their responsibility should be created and added to the on site written scheme for the QEUH.** **12. Lines of communication should be clearly defined and added to the written scheme.** **13. A full written scheme, in accordance with the requirements as outlined in Appendix 2 of the HSG 274 document should be created for he site.** **14. Consideration should be given to creating a form which carries the training details of the on site involved staff.** **15. The involved Estates' staff should ask for copies of proof of competency for contractor's staff.** **16. It is recommended that any contractors who are working on the water systems on site are able to show proof of competency for the work being completed. This would include plumbing contractors who may be used on the site.** **17. NHS GGC should consider what contractor management process should be introduced to ensure the quality and standards of the contractors are acceptable.**	Text from AE audit 2017
38	General System | It may be prudent to consider installing a background dosing system on this site (e.g. Chlorine Dioxide) due to control issues identified during this assessment. | 2	Text from DMA initial water risk assessment

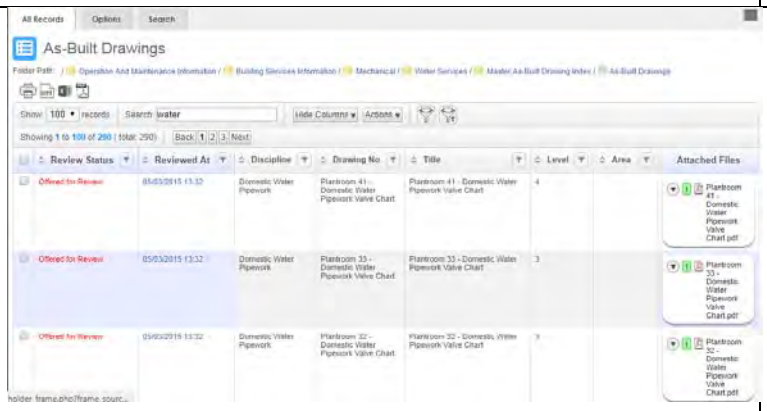
Item	Image	Comments
39		Text from DMA initial water risk assessment
40		Image of BMS Extended log of cold water sensor in level 0.

Domestic Water System Pressure Reducing Valves	Flexible hoses have been noted on the boosted bulk water system on pressure reducing valves. If possible these should be hard piped (stainless steel) or WRAS approved hoses with linings other than EPDM should be considered. Should these not be available for these types of units/connections then a regular inspection and replacement schedule should be implemented for these.	3
Outlet 00 A&E EMC-086 (Facilities)	All EPDM flexible hoses should be removed and replaced with hard piped connection.	3
Outlet 00 Acute Assess AAW-007 (Facilities)	All EPDM flexible hoses should be removed and replaced with hard piped connection.	3
Outlet 00 Acute Assess AAW-125 (Facilities)	All EPDM flexible hoses should be removed and replaced with hard piped connection.	3
Outlet 00 Acute Assess AAW-208 (Dirty Utility)	All EPDM flexible hoses should be removed and replaced with hard piped connection.	3
Outlet 00 Acute Assess AAW-313 (Facilities)	All EPDM flexible hoses should be removed and replaced with hard piped connection.	3

15/04/2018 02:30	22.8
15/04/2018 01:30	22.48
15/04/2018 00:30	21.88
14/04/2018 23:30	20.08
14/04/2018 22:30	20.24
14/04/2018 21:30	22.48
14/04/2018 20:30	22.04
14/04/2018 19:30	20.68
14/04/2018 18:30	20
14/04/2018 17:30	22.88
14/04/2018 16:30	22.56
14/04/2018 15:30	22.32
14/04/2018 14:30	21.8
14/04/2018 13:30	20.12
14/04/2018 12:30	20.36
14/04/2018 11:30	22.8
14/04/2018 10:30	22.8
14/04/2018 09:30	22.8
14/04/2018 08:30	22.8
14/04/2018 07:30	22.8
14/04/2018 06:30	22.8
14/04/2018 05:30	22.8
14/04/2018 04:30	22.8
14/04/2018 03:30	22.8
14/04/2018 02:30	22.8

Item	Image	Comments
41		Images of materials found in water tank. Left and image from raw water tank 1A and right hand image from raw water tank 2B.

Item	Image	Comments
42	5.5 Where water quality sampling in a water system confirmed (acceptable) Legionella results less than 100 CFUs/Litre – the Authorised Person (Water) would be informed and provided with copies of the samples in writing and associated record keeping. The Authorised Person (Water) would provide interpretation (with the Consultant Microbiologist when and where required) on the results and confirm if any actions are required. 5.6 Where water quality sampling in a water system confirmed Legionella results in excess of 100, but less than 1,000 CFUs/Litre – the Authorised Person(Water) and Consultant Microbiologist must be informed and provided with copies of the samples in writing. The Consultant Microbiologist would provide interpretation on the results and confirm the necessary actions prior to bringing the water system into use. 5.7 Where water quality sampling in a water system confirmed Legionella results in excess of 1,000 CFUs/Litre immediate action must be taken and the Consultant Microbiologist and Authorised Person (Water) must be informed and provided with copies of the samples in writing. They will immediately confirm the necessary actions prior to re-sampling and bringing the water system into use when (acceptable) Legionella results are reliably less than 100 CFUs/Litre. Note: Where continued water system sampling is required, this would be undertaken on a weekly frequency. 5.8 Where the results of three consecutive weekly water system samples remained below 100 CFUs/Litre, the Authorised Person (Water) and Consultant Microbiologist would be informed and sampling would revert to a monthly sampling frequency. 5.9 Where the results of three consecutive monthly Water System samples remained below 100 CFUs/Litre, the Authorised Person (Water) and Consultant Microbiologist would be informed and sampling would revert to a 3-monthly sampling frequency.	Extract from SHTM 04-01 Part C detailing the TVC testing protocol.

Item	Image	Comments
43		Extract from Intertek interim report showing tests on tap flow straigteners.
44		One example of document which has not been finalised contained within ZUTEC.

Appendix 3 Information requested

Health Facilities Scotland / Health Protection Scotland

Healthcare Infection, Incident and Outbreak Reporting

Information required for Final Report on incident at NHS Greater Glasgow and Clyde QEUH March 2018

UPDATED: 28-06-18

Item	Description	Information required	Date required	Date received	Not received	Comments
1	Design information	List of all design standards, guidance and reference documents cited in the contract relevant to the water installation (including SHTM, SHPN, British Standards, Approved Codes of Practice, etc).	11-04-18	01-05-18 partial		Extract from employers requirements section 8.2.8 only.

Item	Description	Information required	Date required	Date received	Not received	Comments
2	Commissioning information	Test results and certificates for incoming water			✓	There is nothing regarding the Scottish Water tests **NHS GGC Response:** To include the test certs once received from BMCL/Capita. Note no certification received but statement from Scottish Water.
		Test results and certificates for water tanks		13-04-18		
		Test results and certificates for hot and cold pipe work		13-04-18		
		Test results and certificates for hot water system		13-04-18		
		Water treatment test results and certification		13-04-18		

Item	Description	Information required	Date required	Date received	Not received	Comments
		Contractors pre handover risk assessment		18-05-18		**NHS GGC response:** As the water system is subject to regular/routine planned preventative maintenance and the contractor has provided PPM and manufacturer information a contractor risk assessment would not be expected.
		Water system handover documentation		01-05-18		
		Evidence of any issues with water system during construction or handover		18-08-18		There is nothing in writing of any issues with the water system, pipe work, fitting, fixings, sterilisation, flushing etc. **NHS GGC response:** No evidence found of any issues with water system during construction or handover
		Extent of flexible hose installations		01-05-18 partial		None to be installed under contract but these have been installed in rise and fall sanitary ware and by third party contractor.

Item	Description	Information required	Date required	Date received	Not received	Comments
		Commissioning documentation for flexible hose installations		01-05-18 partial		None installed under contract but these have been installed in rise and fall. No details of where the third party installation was/is.
		Pressure testing records		13-04-18		On Zutec
		O&M instructions for water system including any recommendations for PPM		01-05-18 partial	✓	There are no specific recommendations in ZUTEC that I can see for either thermal or chemical water treatment of the system. Other PPM in ZUTEC. There are different access levels within ZUTEC. IGS will recheck when access level changed. **28-06-18** ZUTEC checked. No specific mention of chemical or thermal treatment to the system. Specific recommendations on PPM for sanitary ware and equipment and water sampling and analysis.

Item	Description	Information required	Date required	Date received	Not received	Comments
		Specification for water services pipe work		01-05-18		316 stainless steel and Pegler Yorkshire "XPRESS"
		Records of pipe work inspection during construction		01-05-18		None available **NHS GGC response:** Capita were the appointed Project Supervisors. Capita had representation within the Project Site Offices on an almost daily basis. Capita undertook regular site visits. Capita had regular informal meetings with Brookfield and monthly formal meetings with the NHS Project team. Updates on pipework installation were included within their formal monthly reports.
3	Post handover	NHS GGC initial water risk assessment		01-05-18		DMA 2015 **NHS GGC response:** No NHSGGC written scheme (3.1)

Item	Description	Information required	Date required	Date received	Not received	Comments
		NHS GGC subsequent water risk assessments to date		01-05-18		DMA only **NHS GGC response:** These are required for both critical care and non critical care areas of the RSC and QEUH. First draft was done 2015 and has been a live document since. (3.2)
		Authorising Engineer (water) initial audit with recommendations		01-05-18		AE only no follow up **NHS GGC response:** Initial AE audit was not carried out until the hospital was fully operational as agreed with the previous SEM (Jim McFadden). However this was unfortunately delayed and subsequent audit was carried out on 4th May 2017 (3.3). A further audit is planned for June 2018.

Item	Description	Information required	Date required	Date received	Not received	Comments
		Authorising Engineer (water) subsequent audits with recommendations		01-05-18		None only one audit **NHS GGC response:** Audit date 4th May 2017. A further audit is planned for June 2018. (3.4)
		Appointment letters for Competent Persons (water)		18-05-18		**NHS GGC response:** No formal appointments made to date. AP is in process of assessing competent staff.
		Appointment letters for Authorised Persons (water)		18-05-18		**NHS GGC response:** No formal appointments made to date. Copy of AP letter for Mel MacMillan sent to HFS on 6/6/18
		Appointment letters for Designated Person (water) Responsible Person (water) Deputy Responsible Persons (water)			✓	**Additional** **NHS GGC response:-** This are still to outstanding.

Item	Description	Information required	Date required	Date received	Not received	Comments
		Training records for all AP(W) and CP(W)		01-05-18 partial		Training records for 8 operatives in 2018 on HTM not SHTM. Not clear how many operatives are at QEUH. No training records prior to 2018
		Minutes of all water safety group meetings since handover		01-05-18		Minutes of Board Water Safety Group meetings received
		Results of any organisms found and water treatment to eradicate same		15-05-18 partial	✓	This relates to before the current incident and post handover Organism results received. Water treatment outstanding. **NHS GGC response:** Results of testing are contained within folder 3.9. Further results after handover to be forwarded when J.Guthrie returns from A/L next week. (3.9)

Item	Description	Information required	Date required	Date received	Not received	Comments
		Cold water temperature records (system)		13-04-18 01-05-18 partial	✓	Critical care areas only received CWS tanks received **NHS GGC response:** Water storage tank trends submitted in folder 3.10. An example of the CW temperatures recorded on taps in non critical areas are also included. Full extensive records available if required. (3.10) IGS note: these are sentinel points from 2015.

Item	Description	Information required	Date required	Date received	Not received	Comments
		Hot water temperature records (system)		13-04-18 01-05-18 18-05-18		Critical care areas only received DHW **<u>NHS GGC response:</u>** Calorifier trend logs submitted in folder 3.11. An example of the HW temperatures recorded on taps in non critical areas are also included. Full extensive records available if required. (3.11) IGS note. These are for 2018. It would be useful to have records indicting deviations in DHW system.

Item	Description	Information required	Date required	Date received	Not received	Comments
		Tap temperature records (mixed, hot, cold)		13-04-18 01-05-18 partial	✓	Critical care areas only received 2015 sentinel **NHS GGC response:** Examples in folder 3.12 (3.12)
		Main filtration system PPM		01-05-18 18-08-18		PPM by third party for filtration plant some for 2016 and 2017. **NHS GGC Response:** Examples in folder 3.13 Next due May 2018. (3.13)
		Water storage tank turnover versus storage volume		01-05-18		Figures for October 2016 hardgate road and govan road **NHS GGC Response** Table contained in folder 3.14 (3.14)

Item	Description	Information required	Date required	Date received	Not received	Comments
		Competency of company and individuals carrying out risk assessment		13-04-18		For DMA NHS GGC response Contained in folder 3.15 (3.15)

Item	Description	Information required	Date required	Date received	Not received	Comments
4	Water treatment	Details of PPM water systems		13-04-18 partial	✓	Received for critical care areas. PPM for other areas required (excel sheet shows showers for all areas and taps only for critical areas).
					Additional	Who maintains the showers as part of the rise and fall baths and frequency? **NHS GGC Response:** There is possibly only 1 bath affected and this will be checked.
					Additional	Main water tank has a DMA report (2017) which has various points to be addressed...have these been dealt with satisfactorily? **NHS GGC Response:** Order issued for tank cleaning on Feb 2018. Cleaning and disinfection of main water tanks has been scheduled to address any issues. Due to restrictions for isolation and draining of the tanks a comprehensive RAMS is required. This work is now underway and DMA Water are mobilising to deliver this works as the first stage of the 'longer tem solution' Have the items in the DMA L8 report 2017 been auctioned satisfactorily and provide evidence for same. **NHS GGC response:**

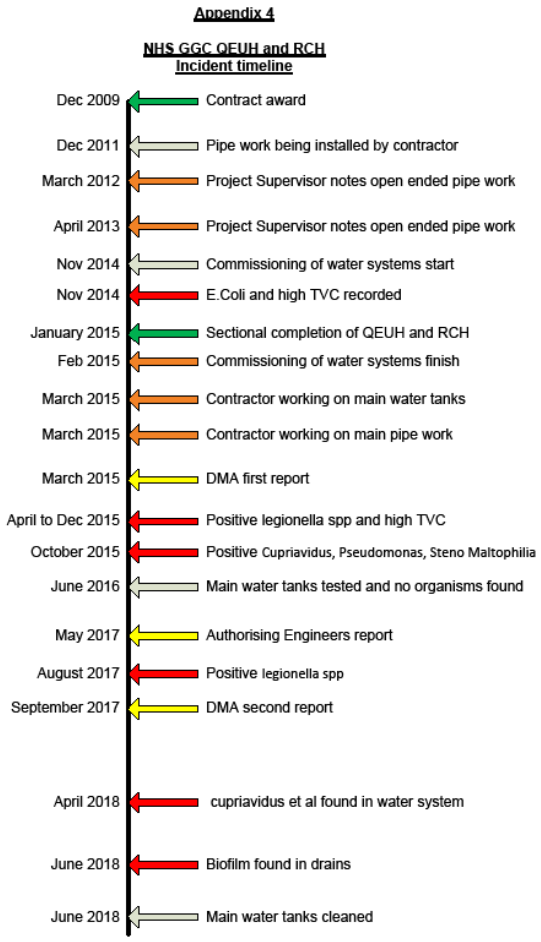
Item	Description	Information required	Date required	Date received	Not received	Comments
		Details of chemical treatments on any part of the water system post hand over			✓	**NHS GGC response:** There were 3 recorded events Pharmacy Aseptic Unit Feb 2016 PICU Dec 2016 Adult Renal June 2016 Records of the actions in relation to these events will be available when J.Guthrie returns from leave.
		Details of thermal treatments on any part of the water system post hand over			✓	
		Details of testing regime (frequency, for which organisms, TVC results, organism results etc)		13-04-18 partial	✓	Sample results from 13-01-18 and 13-02-18 for 4B and critical areas for 2017. Program info required
		Details of company taking water samples, training records, methodology.		13-04-18 partial	✓	DMA taking samples in critical care areas; who is taking samples in non critical areas; details of competency, methodology, etc.

Item	Description	Information required	Date required	Date received	Not received	Comments
5	Horne Taps	Adult hospital commissioning results for taps		13-04-18		
		Children hospital commissioning results for taps		13-04-18		
		PPM records for taps		13-04-18		**NHS GGC Response:** Non critical area TMTs, TSVs have not been included in the service plan. Non-critical area sampling not required as per SHTM04-01.
		Drop tests for taps		13-04-18		
6	Contour Taps	Adult hospital commissioning results for taps		13-04-18		
		Children hospital commissioning results for taps		13-04-18		
		PPM records for taps		13-04-18 18-05-18		**NHS GGC Response:** Non critical area TMTs, TSVs have not been included in the service plan.
		Drop tests for taps		13-04-18		

Item	Description	Information required	Date required	Date received	Not received	Comments
7	Showers	Adult hospital commissioning results for showers		13-04-18		
		Children hospital commissioning results for showers		13-04-18		
		PPM records for showers		13-04-18		
		Drop tests for showers		13-04-18		
		Details on all shower types		13-04-18		
		Records for shower hose and head replacements since handover		01-05-18 partial	✓	No replacement records, but chlorination records 2017
8	Wash hand basins (clinical and non-clinical)	Design brief for requirements including dimensions		01-05-18		
		Details of what has been installed		13-04-18		

Item	Description	Information required	Date required	Date received	Not received	Comments
9	Drains (WHB and Showers)	Records of PPM		18-05-18		**NHS GGC response:** None recorded and no actions required. Estates do not routinely carry out sampling in drains. This would only be done as requested by Infection Control.
		Records of any organisms found and treatment to eradicate.		18-08-18		**NHS GGC Response:** None recorded and no actions required as per SHTM04-01 This would only be done as requested by Infection Control
10	Point of use filters	Cleaning regime		13-04-18		**NHS GGC Response:** Current recommendations passed to NHSGG&C from PALL Europe indicate that no cleaning should be carried out on filter casings. This is to eliminate the possibility of cross contamination or breaching the integrity of the filter membrane.
		Replacement regime		13-04-18		Discussed and recorded at meetings

Appendix 4 NHS GGC QEUH and RCH Incident timeline



Appendix 5 Rapid literature review of water associated HAI incidents

Rapid literature review of water associated HAI incidents in support of NHS GGC

Health Protection Scotland

August 2018

Contents

1. Objectives

A rapid literature review of reported infection incidents associated with water in the healthcare setting was conducted with the objective of identifying the:

- Organisms associated with waterborne healthcare associated infection incidents,
- At risk patient groups/care settings,
- Most frequently identified sources and transmission routes,
- Most frequently reported control measures and their effectiveness.

2. Methods

A rapid review of the risk factors associated with HAI outbreaks associated with healthcare water systems was performed. Academic databases were searched to identify relevant academic and grey literature from the past twenty years. The search found 798 articles (see Appendix 1 for the search strategy), and following the screening process resulted in the selection of 98 articles. Additional hand searching and expert recommendation resulted in the identification of an extra 34 papers which met the criteria for inclusion. In total 132 articles were included in the final literature review. This included outbreaks reports, case-control studies, pseudo-outbreak reports, and intervention studies in both outbreak and endemic situations linked to water systems.

In addition, ad hoc literature searching and hand searching was carried out to inform specific research questions e.g. the infection risk from automated sensor taps. Full search strategies are available in appendix 1.

3. Results

3.1 What organisms are associated with outbreaks due to healthcare water systems?

A broad range of microorganisms are associated with water system contamination which can lead to healthcare outbreaks or endemic situations. From the articles included within this review, the organisms most frequently isolated from hospital water systems and associated fittings, fixtures and equipment include: *Pseudomonas aeruginosa* which was discussed in 51 articles;[1-50;51] *Legionella pneumophila* discussed in 24 studies;[1;52-74] nontuberculosis mycobacteria (NTM) discussed in 19 studies;[1;75-92] *Klebsiella pneumoniae* discussed in 9 studies;[50;93-100] and *Acinetobacter baummannii* discussed in 5 studies.[101-105]

Other causative organisms included *Achromobacter* spp.,[106] *Acinetobacter junii,*[107] *Burkholderia* spp.,[108-110] *Citrobacter freundii*,[111] *Elizabethkinga meningoseptica*,[112;113] *Enterobacter cloacae*,[50;114-116] *Klebsiella oxytoca*,[117-119] *Pantoea agglomerans,*[120] *Pseudomonas fluorescens,*[121] *Pseudomonas putida,*[2] *Staphylococcus aureus,*[122] *Serratia marcescens,*[100;123] *and Stenotrophomonas maltophilia.*[124-126] Fungi including *Aspergillus* spp.,[127] *Fusarium* spp.,[128;129] *Exophiala jeanselmei,*[130] *and Rhizomucor* spp.[127] were additionally identified as the cause of HAI outbreaks, as well as viruses such as Norovirus and an unidentified small round structured virus, which were isolated from or on water system fittings in two studies.[131;132]

3.2 What clinical settings and patient populations are affected?

There were several clinical settings which were frequently affected with waterborne outbreaks, with one of the most common being haematology and oncology units,[2;11;16;21-23;32;34;37;38;41;52;55;56;62;75;78;79;85;88;106;107;115;119;127-130] with additional outbreaks involving patients within bone marrow and stem cell transplant wards.[36;37;39;50;53;57;58;64;74;78;84;85;91;121;130] This was followed by outbreaks within adult and paediatric intensive care units (ICUs)[4;5;10;12;17;18;27-29;34;42;46;48;51;52;57;64;66;68;93;94;96;98;101;105;114;123;126] and neonatal units (NNUs).[3;6;7;15;24;25;29;35;45;67;113;124]

Waterborne colonization and infection of high-risk patients occurred in several other clinical settings such as surgical units performing cardiac surgery,[76;85] general surgery,[63] neurosurgery,[73] paediatric surgery,[40] and transplant units[62] (including lung,[18;85] liver[1] and kidney[59;61]) as well as a pacemaker implantation unit.[82] A range of other clinical locations implicated in outbreaks were a bronchoscopy suite,[54] burns units,[19;122] cardiac wards,[55;56;63;68;74] an ears, nose throat department,[20] an HIV unit,[87] long term care facilities,[72;92] nephrology wards,[13;49] private or military hospitals,[77;83] respiratory wards,[8;63] and a re-education facility.[132]

It was also noted that water system contamination could result in outbreaks across different clinical settings[9;10;18;21;28;34;37;46;52;55-57;60;61;63-66;68;69;74;78;80;85;90;110;128;131] and between two or more geographically distinct hospitals.[3;70;95;98;99]

In addition to patients, staff and visitors also became colonized and/or infected in several outbreaks of *L. pneumophila*. This occurred in staff within a haematology-oncology unit in one outbreak,[62]

whilst in another hospital staff in multiple locations including the chest department and laboratory were affected.[63] In another, visitors were infected after contact with a contaminated decorative fountain in a hospital lobby.[71]

3.2.1 Haematology-Oncology Units

Colonization or infection of patients within haematology and oncology wards was frequently reported within the retrieved literature,[2;11;16;21-23;32;34;37;38;41;52;55;56;62;75;78;79;85;88;106;107;115;119;127-130] nine of the included studies involved paediatric patients.[2;16;78;79;89;106;107;127;129] The organisms implicated were *Achromobacter* spp.[106] *A. junii,*[107] *Aspergillus spp.,*[127] *E. cloacae,*[115] *E. jeanselmei,*[130] *F. oxysporum,*[129] *F. solani,*[128;129] *P. aeruginosa,*[2;11;16;22;23;32;34;38;41] *P. putida,*[2] *K. oxytoca,*[119] *L. pneumophila,*[52;55;56;62] *M. mucogenicum*[75;79;88] and *Rhizomucor spp..*[127]

In two further studies, haematology and oncology outpatients acquired a waterborne HAI. Firstly, outpatients with malignant tumours acquired infections with *P. agglomerans*[120] and, secondly, patients with sickle cell disease developed infection with *M. mucogenicum*[89] following infusions or IV flushes respectively using liquids which had come into contact with contaminated with sink water.

Several additional cases of nosocomial infection occurred in patients assumed to be undergoing bone marrow or stem cell transplantation or preparatory conditioning procedures.[36;37;39;50;53;57;58;64;74;78;84;85;91;121;130] Infection and/or colonization was associated with *E. cloacae,*[50] *E. jeanselmei,*[130] *F . solani,*[128] *P. fluorescens,*[121] *P. aeruginosa,*[36;37;39;50] *K. pneumoniae,*[50] *L. pneumoniae,*[53;57;58;64;74] or Non-Tuberculous Mycobacteria.[84;91]

Multivariate analysis identified neutropenia,[130] long duration of hospital stays,[130] and use of corticosteroids[74;130] as risk factors for patient acquisition of outbreak pathogen within haematology and bone marrow transplant units. Additionally, during an outbreak of *B. cepacia*, patients with cancer was found to be at a significant risk of acquisition.[110]

Importantly, many of the outbreaks of infection within adult and paediatric haematology and oncology wards were associated with central venous catheters (CVC) becoming contaminated during patient bathing.[2;16;23;75;79;88;106]

3.2.2 Intensive Care Units (ICUs)

The second most common clinical setting in which waterborne outbreaks occurred was the ICU. This included colonization and/or infection of patients within general ICUs,[34;51;52;57;64;66;68] surgical ICUs,[4;10;12;17;28;47;98;101;123;126] neurosurgical ICUs,[42;94;96] burns ICUs,[5;27;104] cardiac ICUs,[18;114] and paediatric ICUs.[66;93;105]

Organisms implicated included *A. baumannii,*[101;104;105] *P. aeruginosa,*[4;5;10;12;17;18;27;28;34;42;48] *K. pneumoniae,*[93;94;96;98] *K. oxytoca*,[114] *L. Pneumophila,*[64;66;68] *S. marcescens,*[123] and *S. maltophilia.*[126]

The characteristics of patients at risk of colonization and/or infection with pathogens associated with waterborne outbreaks within healthcare facilities were analysed in several case-control studies. Significant risks factors ($p \leq 0.05$) for patients included: undergoing dialysis or haemodialysis,[17;47]

longer stays within ICU,[47;48;104] surgery prior or during ICU stay,[31;48] mechanical ventilation,[48;123] presence of central lines,[123] length of time with a CVC,[31;48] arterial catheterisation, urinary catheterisation,[48] warming up with warm air blanket,[31] antibiotic use during admission,[31] preceding infection,[47] frequency of bronchial lavage,[31] intracranial pressure catheterisation,[123] nebulisation therapy,[123] peripheral nutrition solution/number of days receiving solution,[48;123] medication received orally,[123] and receiving multiple doses of medication.[123]

3.2.3 Neonatal Units (NNUs)

Neonatal units were also regularly host to outbreaks associated with water systems in healthcare facilities.[3;6;7;15;24;25;29;35;45;67;113;124] The majority of outbreaks discussed (75%) were caused by *P. aeruginosa*[3;6;7;15;24;25;29;35;45] however, there were also cases of infection in neonates due to *E. meningoseptica*[113], *L. Pneumophila*[67] *and S. maltophilia*.[124]

Case-control studies identified the gestational age and mean birth weight as risk factors, with those with a lower birth weight[7;24] and lower gestational age[24] at a higher risk of colonization and/or infection. Additionally case patients were more likely to have exposure to a peripherally inserted catheter[24] or invasive ventilation or respiratory support.[7;24] These clinical risk factors were noted in additional outbreak reports with at least half of neonates colonized/infected with extremely low birth weight (<1000g),[6;15] pre-term (<37 weeks),[15;124] and were ventilated or requiring respiratory support.[15;124] Additionally, neonates who had received blood transfusions were found to be at a higher risk of infection, however, this was found ultimately to be due to the use of a contaminated water bath used to heat transfusion products.[45]

3.3 What are the potential sources of waterborne outbreaks?

There were multiple elements of healthcare water systems which are the potential source during outbreaks, with the potable water supply most commonly found to be the source of patient colonization and/or infection. The potable water supply was most commonly identified, alongside fixtures and fittings such as sinks, showers, taps and drains, and water based medical equipment. However, in some cases no single source was identified.[22;25;76;131] It was not always clear how these sources initially became contaminated. This may have been due to low levels of intrinsic microorganisms within the potable water supply or, as several studies suggested, may be due to contamination following contact with initial index case patient, or hands of healthcare workers treating index patient.[14;15;26;38;72;98;102;117;122] Fixtures may also become contaminated due to the improper disposal of bodily fluids, such as the emptying the contents of dialysis bags into sinks also used for hand hygiene.[8;17;51;94;98;100;108;111;118;119]

3.3.1 Water Distribution Systems

Water distribution systems supplying contaminated water within healthcare facilities were the most frequently cited source of outbreaks. Colonization and/or infection of patients was often due to direct contact with contaminated tap water, or through exposure to equipment, fluids and infusates which had been contaminated with non-sterile tap water supplied by the water system.[1;2;24;30;36;41;49;50;52;53;53;55-57;59-66;68;70;72-75;77-79;82;83;85;88;90-92;99;106;109;110;128;129;132;133] Water tanks and

reservoirs were frequently implicated[75;82;83;129] with contamination associated with sediment and stagnation,[75;83] which likely attributed to biofilm formation.

Several studies detailed environmental risk factors which may have led to the microbial contamination of water systems such as favourable water temperatures for microbial growth (45-50°C);[56;61;62;68] inadequate disinfectant levels (i.e. low residual chlorine, <1 ppm);[56;60;62;75;82;85;88;90;92] contamination of the public water supply;[77;78;85] reduced water usage;[65;85;92] slow delivery or low flow rates water to outlets;[85;92] and dead end pipes.[64;65;68] In one study there was no disinfection programme for the hospital water system which led to an outbreak of *L. pneumophila.*[63] Whilst others had used disinfection systems incorporating ultraviolet light[49] or copper-silver ionization[60] but had failed to prevent water system contamination.

The recent construction of hospital water systems was implicated in subsequent outbreaks of *L. pneumophila*[53;62;72] and *P. aeruginosa.*[24;62] This was hypothesised to have occurred due to water stagnation and biofilm formation for several months before the building was completed and opened.[24;53;62] Recent interruption or renovation of water systems was also implicated during outbreaks[30;57;64] which may have disrupted established biofilms within older sections of pipe work or caused an increase in the number of dead legs. An outbreak of *Fusarium* spp. occurred after reintroduction of the maintenance of water reservoirs in one report, which had been neglected for several years prior.[129]

Additionally, waste water systems were implicated in two hospital outbreaks. In one hospital a leaking waste pipe was thought to have caused environmental contamination of a haematology unit.[34] Whilst in another facility, slow drainage and blocked drains resulted in backflow of dirty water into toilets and showers which were improperly cleaned, leading to contamination of environment.[34] Additionally, an unsealed floor drain in a cytoscopy suite used to drain fluids from patients was also indentified as a source, which due to its design allowed blood and urine to float back up to floor level.[13]

3.3.2 Taps; Sensor taps, aerators and flow straighteners

Taps (faucets) and aerators (flow-straighteners) of water outlets were also cited in 29 studies as the source of waterborne outbreak within healthcare facilities.[3;4;12;14;23;26;27;29;31;35;40;42-44;46-48;89;96;103;107;112-114;123;124;126;134;135] In many reports it was likely that water faucets had acted as long-term environmental reservoirs, and use had resulted in the subsequent transmission to patients, staff and medical infusions.

Electronic sensor taps have been implicated in outbreaks of *Acinetobacter baumannii*,[103] *Pseudomonas aeruginosa*[35;44;136] and *Mycobacterium mucogenicum.*[88] A study by Sydnor et al assessed microbiological contamination in water samples from newly installed sensor taps compared with existing manual taps over one year.[137] Median heterotrophic plate counts (HPCs) were significantly higher in sensor taps compared to manual taps.[137] In addition, *Legionella* spp. were more frequently isolated from sensor taps compared to manual taps and nearly all sensor taps had at least one sample positive for *Legionella* spp. compared to less than half of manual taps.[137] The authors suggested that the additional components of sensor taps may provide 'points of concentrated bacterial growth'.[137]

Following the deaths of four neonates as a result of *P. aeruginosa* bacteraemia in hospitals in Northern Ireland, thirty taps and eight flow straighteners were collected from the relevant hospitals, dismantled, and their components assessed for microbiological contamination.[3] It was found that sensor taps had significantly higher odds of having at least one component positive for *P. aeruginosa* compared with non-sensor taps ($p>0.05$).[3] A study by Moore et al also investigated colonisation of hospital tap components but using an experimental water distribution system; *P. aeruginosa* was injected into 27 individual tap 'assemblies'.[138] Taps were subsequently flushed twice daily and contamination levels monitored over two years. Tap assemblies were dismantled and individual components were assessed for colonisation; the effect of removing potentially contaminated components from the assemblies was also determined. *P. aeruginosa* was repeatedly recovered from the tap water at concentrations above the augmented care alert level. The organism was recovered from all dismantled solenoid valves (component used to control water flow in sensor taps). Removing the solenoid valves reduced *P. aeruginosa* counts in the water to below detectable levels, implicating the solenoid valve as the primary contamination source. The authors conclude that these findings support the removal of sensor taps from augmented care units. The Water Group Scotland (*Pseudomonas*) short-life working group was convened in 2017 for the scheduled update of the Scottish guidance for control of *Pseudomonas* spp. from water in NNUs, adult and paediatric ICUs.[139] Based on the most recent (January 2018) review of the evidence base (which included the study by Moore et al)[138] it was agreed that the guidance should be updated to recommend that the removal of sensor taps from augmented care areas is considered.[139] This change has not yet been made but will be included in the updated guidance due to be produced before end March 2019.

Aerators within taps have been implicated in outbreaks of infection,[29;96;107;112;124;126] with organic matter and debris collecting on the wire mesh of these components, resulting in water stagnation and contamination via low levels of microorganisms within potable water.[29;107;126] One study stated cultures should be performed on faucet aerators when water sources are suspected as the reservoir for a nosocomial outbreak.[126] If additional clusters of infected or colonized patients are linked to contaminated aerators, consideration should be given to routine disinfection or removal of the aerators.[126] One study found contaminated faucet aerators on the ICU probably served as a persisting source, while inter-patient transmission by medical staff was a likely way of spread.[31]

Limited information from the published literature was identified in relation to use of flow straighteners. One study confirmed that poor flow regulation may lead to splashing, and that turbidity of flow and the resulting shear forces may enhance sloughing of attached bacteria.[135] Walker et al found that biofilms were isolated from flow straighteners, suggesting they may have acted as a reservoir during the outbreak.[3]

3.3.3 POU filters

No studies were found that identified POU filters as a source or reservoir of infection during a waterborne outbreak. However, two studies were identified that highlight the risk of unintended consequences i.e. retrograde contamination of the filters.

One study found that patient colonization and infection significantly decreased following implementation of POU filters on three outlets within a liver transplant unit.[1] Results demonstrated that none of the circulating organisms identified in unfiltered water, including *Legionella* spp., *Mycobacterium* spp. or fungal spp., were isolated in filtered water samples up to 14 days after implementation.[1] However sampling of filtered water recovered positive HPCs in 2.9% of samples after 3 days, 42.1% samples after 7 days, and 33.3% of samples after 10 days of use; in the final samples after 14 days of use, 69.2% were positive, with 2.6 x 10^3 CFU/L recovered.[1] The authors suggested that the retrograde contamination of filters may have occurred due to water splashing from basin or contamination through hands and clothes.[1] The second study identified positive samples from two taps after 2 weeks use of POU filters, which had replaced the initial set of POU filters used for 2 weeks prior.[30] Sampling identified HPC bacteria as well as >300 CFU/100 mL *P. aeruginosa*. As the *P. aeruginosa* identified was a unique strain, not identified elsewhere, this demonstrated that retrograde contamination of the filtered had occurred.[30]

3.3.4 Sinks (Basins, Drains and Siphons)

Sinks and associated structures were frequently associated with waterborne HAI. Sink units, siphons (sink traps), and drains were implicated in 36 studies,[7-11;15-19;21;28;32;37;39;42;46;51;93-98;100;101;104;108;111;114;115;117-120;124] as well as a soap dispenser in another.[36] These fixtures and fittings were often one of several environmental reservoirs.[11;18;19;28;39;95;97;102;104;114]

Poor design, which allowed splashing, aerosol formation and inadequate infection control, was frequently cited as the reason as to why sinks became the source of waterborne outbreaks. These design features included small and/or shallow sinks;[93;100;105] short taps;[16] taps directing water over drains;[100;115] location of sinks close to countertops used for medical preparations or patient care products;[108;120] sinks located in close proximity to patients;[10] drainage systems which impaired adequate drainage;[117;118]drains with internal grooves thought to have promoted biofilm formation;[32] improperly sealed joints between walls and sinks;[66] grouted tiles surrounding sinks;[7] poor quality sinks with damaged porcelain.[100] The shallow design of a sink and high water pressure in one study led to staff to place towels around the sink to prevent a damp environment, which resulted in the sink and towels becoming an environmental reservoir and preventing adequate hand hygiene.[105] Additionally, in two outbreaks of *P. aeruginosa* reusable hair washing basins were implicated as additional sources of transmission during outbreaks.[28;31] In several cases it was thought that waste products poured down sinks used for hand hygiene resulted in the contamination of the sink drains. Waste included water used during patient cleaning, bodily fluids, residual antibiotics and dialysis fluids, with resultant outbreaks of *Citrobacter freundii*,[111] mixed Carbapenem-resistant *Enterobacteriaceae* (CRE),[100] *Klebsiella pneumoniae*[94;98] and *Klebsiella oxytoca*[118;119] noted.

The transmission route in these cases is thought to be due to water splash back from drains, with water flowing directly into the drain amplifying this.[115] This was demonstrated in a study by Starlander & Melhus,[94] which highlighted the spread of contaminated drain water by injecting dye into a sink drain. When the tap was run for 5 seconds, the drain contents and dye were visibly dispersed onto the sink and rim. Therefore demonstrating that contaminated drain water is likely to be aerosolized and as a result cause environmental contamination and also prevent adequate hand hygiene.[94] Similarly, a simulation using Green Fluorescent Protein (GFP) – expressing *E. coli* seeded

into the p-trap of sink drains found that biofilm extended up to the drain to the sink strainer resulting in droplet dispersal during tap operation (<30 inches).[140]

3.3.5 Wash Rooms and Hydrotherapy Rooms

Patient wash rooms and hydrotherapy rooms have been implicated in waterborne outbreaks within healthcare facilities. Shower heads used for patient cleansing have been implicated in several studies, colonized with NTM, *A. baumannii*, *P. aeruginosa* and *S. aureus.*[2;5;39;40;78;86;104;122] Reports within burns units have documented that shower heads are one of several environmental reservoirs within patient washing facilities and hydrotherapy rooms, with other sources including sinks,[104] showering platforms,[104] bathing stretchers,[122] or patient trolleys.[5] Additionally an adult burns hydrotherapy room was found to harbour *P. aeruginosa* in floor traps, shower trolleys and shower drains, which not only resulted in infection in adult burns patients but in a paediatric burns patient who visited the hydrotherapy room.[33] Other fixtures and fittings within shower rooms which have been identified as potential sources during outbreaks includes shower drains,[5;18] shower traps,[95] and shower fittings.[131] A bath was also implicated in one outbreak, with the bath water becoming contaminated when the tub was filled.[38] This was due to contamination from the area between the strainer and drain which was 2.5 cm long, resulting in patient infections with *P. aeruginosa*.[38]

An unusual case of mucormycosis infection occurred in two paediatric patients within an oncology unit.[127] This was due to a leaking shower, which caused water damage to plaster in the shower room and linen store; this resulted in a source of infectious moulds, such as *Aspergillus* spp. and *Rhizomucor* spp., which infected the severely immunocompromised patients.[127]

3.3.6 Drinking Water and Ice Dispensers

Drinking water and ice dispensing machines have been identified as sources of infection. Contaminated water and ice have been found to cause infections with NTM and *P. fluorescens* in immunocompromised patients within bone marrow and stem cell units.[84;121] Additionally an undersink drinking water cooling unit, caused *S. maltophilia* infection within an ICU.[125] Although this system had a carbon filter there were multiple biofilms found in the flexible tube from the carbon filter to the chiller, and from the chiller to tap at the kitchen sink, with the carbon filter found to remove chlorine dioxide from water and accumulate organics allowing microbial multiplication.[125]

Additionally three pseudo-outbreaks were associated with ice machines, with two studies detailing patient colonization with *M. fortuitum* following consumption of contaminated ice.[80;87] Ice was implicated in the third pseudo-outbreak when it was used to cool syringes of saline solution used during bronchoscopy, and resulted in patient colonization with *L. pneumophila.*[54]

Decorative drinking water fountains have also been implicated in cases of legionnaires disease, with one case, associated with foam material above the fountain trough, causing infection in 8 visitors to a hospital.[71] The second case of infection involved two patients within a radiation oncology suite and was due to stagnation of water for 4 months within the pipes that supplied and re-circulated water to the fountain.[58] Another drinking fountain was implicated in an outbreak of *P. aeruginosa* amongst oncology patients in an ear, nose and throat department.[20]

3.3.7 Water-Based Equipment

In several cases the outbreak source was thought to be water based medical equipment such as: heart-lung machines and associated heater-cooler units used during cardiothoracic surgery contaminated with *Mycobacterium abscessus,*[85] *Mycobacterium wolinskyi,*[76] *and Mycobacterium chimaera;*[81] water baths contaminated with *P. aeruginosa* used to heat feeding bottles and blood transfusion products within NNUs;[6;45] humidifiers contaminated with *L. pneumophila* used for oxygen therapy and drug delivery in pnuemology and nephrology units;[133] air humidifiers contaminated with *L. pneumophila* used within NNUs[67] and a bone marrow transplant unit.[53]

3.3.8 Humidity and air conditioning

There is a small volume of weak evidence to link contamination of Heating, Ventilation and Air Conditioning (HVAC) systems (including 'chilled beams') to outbreaks in healthcare settings.

One report described three cases of bacteraemia and one intravascular graft infection in four adult patient receiving haemodialysis at the same facility. The causative organism was *Phialemonium* spp. and typing showed all for cases to have an identical strain closely related to *Phialemonium curvata.*[141] The outbreak strain was isolated from drip trays from the HVAC system supplying the ward. The authors state that this may have acted as a transient reservoir but that other lapses in practice such as suboptimal performance of skin antisepsis likely contributed.[141]

The second report described the investigation of eight cases of *Acinetobacter baumannii* blood stream infections neonates in hospital in Barbados.[142] Settle plates placed in the nursery were significantly more likely to grow *Acinetobacter* spp. than those at other hospital sites (8/9 vs. 0/5, p <0.005) suggesting that airborne dissemination played a role in this outbreak. It was found that some air conditioners on the unit didn't have properly functioning filters and that filters were not regularly cleaned or changed. Thick dust was also observed on the external surfaces of the grates and near cooling vents. Increased absolute humidity was also recorded at the time of the outbreak; the authors suggest that in these conditions condensation may build up in the air conditioning system leading to potential aerosol dissemination of any organisms present in the condensate.[142] A practice review identified several additional risk factors and the authors conclude that the outbreak was associated with the use of multi-use vials on multiple patients in the context of environmental contamination linked to air conditioners on the unit.[142]

A conference abstract was identified describing three cases of bacteraemia caused by *Elizabethkingia miracola*.[143] Samples from chilled beams were included in the investigation as well as samples from water outlets, however, these all tested negative. Strain typing found the three strains to be unrelated and so a point source was considered unlikely in this situation.

3.4 What control measures can be put in place to stop waterborne outbreaks?

Control strategies differed between the studies included in this rapid review and were generally composed of several elements including both standard and transmission based infection control precautions and specific measures used to target the environmental source of waterborne infection.

The replacement of fixtures and fittings[35;44;50;95;105;111] or installation of point of use filters (POU) filters was commonly required as a final measure to cease outbreaks.[25;27;41;85;92;129] Several studies carried out replacements with less complex structures to prevent water stagnation and biofilm formation, which included aerators without wire meshes,[107] easier to clean sinks and plumbing,[111] rimless toilets to prevent splashing,[34] siphons without grooves,[32] strainers with larger holes to prevent splashing,[118] sinks with deeper basins,[93] sinks without overflow drains,[51] automatic taps replaced with simpler manual taps,[3;35;44;88] taps with altered lengths,[16;26] and self disinfecting sink siphons.[16;116]

3.4.1 Infection Control Measures

Infection control precautions and hygiene practices were reinforced during water system related outbreaks. The transmission based precautions implemented include: cessation of admissions;[25;55] transfer of patients to other wards;[25;94;127] cohorting or isolation of patients colonized or infected;[6;7;10;12;15;25;42;101;102;105;119] contact precautions;[6;10;12;35;102;105;107;117;118;123;132] reinforcing hand hygiene awareness and compliance;[6;7;25;39;101;105;107;112;118;119;123;124;132] use of alcohol based hand-rub as part of hand hygiene procedures;[26;29;35;44;62;113;124] education of staff;[6;15;17;34;39;44;51;78;89;101;105;111;117] and enhanced cleaning and decontamination of the hospital environmental and environmental reservoirs.[9;25;34;44;76;96;97;102;117;119;127;131;132] Microbiological screening of patients[7;15;73;94;113;117;118] and the environment[15;36;70;73;74;82;94;96;102] was often implemented as a result of outbreaks and included monthly bacteriologic surveillance of water supplies in the affected clinical areas.

3.4.2 Water Distribution Systems

Water distribution systems were implicated in the colonization and/or infection of patients due to the provision of microbiologically contaminated water. Control measures related to water systems included the implementation of water restrictions,[53;62;74;84;105;123;132] with showering avoided or limited to prevent patient exposure to tap water.[28;55;74] In many cases patients were provided with bottled water for drinking,[20;62;74;84;91;121] and this was also used for care procedures.[14;60;123] Sterile water was used frequently for high-risk and immunocompromised patients during care activities such as bathing, oral care and nasogastric feeding.[12;22;25;29;40;57;74;92;112;113;124] Waterless care techniques were also implemented in several reports, with waterless oral care[103] and use of disposable sponges or wash cloths implemented.[12;17;128]

Decontamination of the water system and fixtures and fittings usually included superheating (heat-shock) and flushing (≥60°C),[52;61;63;66;73;133] hyperchlorination,[4;14;24;36;40;57;64;90;92] or both such measures.[24;53;55;56;62;132] However, in several studies these techniques were inadequate with further patient infections of positive environmental samples.[57;59;63;92] The subsequent measures were varied: one study repeated superheating and flushing using water at an increased temperature of 70°C; one study installed POU filters after chlorination failed;[92] another disconnected the hot water supply and used electric showers;[59] whilst in two others complete eradication of the outbreak organism failed even after installation of continuous chlorine units[57] or heat shock units.[66]

Other control measures for water distribution systems included: immediate shut down of water systems;[60] cleaning of water tanks and associated fittings;[25;56;75;82] removal or capping of dead legs;[71;74;120] monitoring and/or increasing chlorine to ensure adequate levels;[62;82;88;90;120] introduction

of continuous, in-line, chlorine dioxide dosing of the water systems;[24;55;57;60;74;74;129] increasing chloramine levels;[85] increasing temperature of water heaters;[52;56] increasing temperature of circulating hot water temperature;[25;61] testing of temperature and flow;[24] and engineering controls to improve flow rates, water delivery and system pressure and the initiation of regular maintenance and flushing plans.[26;56;75;82;85;120] Further control strategies included installation of heat shock units;[66;73] UV light systems,[63] silver-copper ionization systems,[56;72] in-line filters,[49;129] and a water loop producing microbiologically controlled water.[2]

3.4.3 Taps, Aerators and POU filters

When taps and aerators were identified as the environmental reservoir of outbreaks, several different control measures were put in place including: restricting the use of sinks;[9;103;112;124] removal of mineral deposits on taps and aerators;[24;42;74;114] cleaning, decontamination or sterilization of taps and aerators;[4;14;24;112;114] flushing of taps;[74;133] removal of aerators;[24;89;108] replacement of aerators[107;112;124;126] and taps;[3;16;26;34-36;44;51;88;96;103;113;114;123] and replacement or installation of mixing valves to ensure correct temperatures at water outlets.[103;113] Additionally regular flushing[26] and cleaning of taps[12;14;103] and detachable aerators;[14;48;107] was implemented.

During one outbreak it became clear that the outlet remained intermittently positive despite remedial work, a point-of-use filter was installed on the outlet, following which there was no further cases of transmission and no further positive water samples were obtained.[27] POU filters, including 0.2 µm/PALL filters, were frequently fitted to water outlets as an outbreak control measure, including sinks and shower heads, to protect patients from circulating pathogens.[1;2;23-25;27;30;36;41;48;50] Four intervention studies using POU filters, found that rates of patient colonization and infection significantly decreased following implementation.[1;30;48;50] In addition, faucet membrane filters were shown to be more effective at reducing bacterial numbers, under experimental conditions.[144]

However in one of these studies sampling of filtered water 7 and 14 days after installation recovered heterotrophic plate count (HPC) bacteria, although none of these were identified as the organisms which had previously caused patient colonization and infection.[1] The positive samples were thought to be due to retrograde contamination via water splashing from the basin or contamination through hands and clothes.[1] Another identified *P. aeruginosa* and HPC bacteria 2 weeks after POU filter installation, again linked to retrograde contamination.[100]

HPS guidance states that '*routine use of point-of-use filters is not recommended. Point-of-use filters are not a primary preventative measure, or a primary control measure. They may be considered if there is a recognised clinical incident and the role of water in the incident is yet to be identified. Therefore any new taps in NNUs and ICUs should be capable of including a point-of-use filter.*'[139] *'While the installation of point-of-use filters will maximise delivery of safe water supplies there is a danger that their inclusion will lead to a false sense of security and reduce the risk of compliance with primary prevention measures of flushing all frequently used outlets, hand hygiene and the safe discarding of potentially contaminated fluids.*'[139]

The Scottish Health Technical Memorandum (SHTM) 04-01 states that if POU filters are used these must be changed in accordance with the manufacturer's instructions (typically monthly).[145] Once in situ, outlets must not be used without the POU filter in place unless samples are being taken.[145]

3.4.4 Sinks (Basins, Drains and Siphons)

Similar control measures were enforced when sinks and associated plumbing were found to be the source of waterborne outbreaks. These measures included: decommissioning or removal of sinks, siphons and overflow holes;[44;98;118;120] removal of mineral deposits[24] and biofilms;[115] cleaning, disinfection, decontamination or sterilization of sinks,[9;24;95;97;119;120] siphons[8;33;95] and drainage pipes;[8-11;32;40;98;101;114] replacement of sinks,[21;32;34;42;51;93;94;98;103;105;111;119] siphons,[16;17;95;96;98;111;116] and drainage pipes[21;29;94;111;118] and implementation of regular cleaning and disinfection of sinks,[7;32;75;93;105] siphons[42;75;111] and drains.[21;34;115;117] Several studies improved sink hygiene practices by implementing dedicated clean sinks,[12;111] ensuring staff did not using patient sinks for bodily fluid disposal,[17;47;51;94] and storing patient care items away from the sink area.[34;108] Other measures included addition of shut-off valves in drains,[117] closing floor drains,[13] and fixing or replacing splash backs.[7]

3.4.5 Wash Rooms and Hydrotherapy Rooms

To help control outbreaks related to patient wash rooms, measures put in place included: cleaning and decontamination of showers and siphons;[95] replacement of shower heads and hoses;[14;74;75;78] removal of shower curtains and treatment of room as a wet rooms;[75] ensuring hoses hang straight to prevent stagnation;[78] and ensuring showers were run before use.[39;75;91] In one study, the control measure implemented was to use baths which had drains which sealed at the top, rather than a space between the strainer and the drain.[38] Additionally the use of hydrotherapy rooms was ceased in one study[122] whilst another used disinfectants within the hydrotherapy room to inactivate environmental pathogens.[33]

3.4.6 Drinking Water and Ice Dispensers

Water dispensers including drinking fountains and cooling units which acted as environmental reservoirs were generally removed from use within the healthcare facilities,[58;71;121;125] or replaced with units with terminal UV treatment.[20] In the case of ice machines consumption of ice and water from the machine was banned and replaced with bottled water,[84] with machines disconnected, cleaned and disinfected[80;87] and filters installed,[87;92] or machines completely removed from service.[80] In one study, ice machines were replaced with smaller models, reducing the potential for water stagnation and continuous drains were installed to allow for daily flushing.[84] In the case of ice baths used for medical syringes, immersing syringes of saline into ice was discontinued and replaced by a practice of immersing the bottle of saline in ice and drawing aliquots of saline from the bottle using sterile technique to avoid contact with the ice.[54]

3.4.7 Water-Based Equipment

In the case of heart-lung machines and associated heater-cooler units, this equipment was replaced and sterile or filtered water used for these new devices[76;81;85] with regular disinfection and drainage implemented.[76;85] Sterile waster was also used for humidified respiratory equipment,[133] whilst air humidifiers were no longer used.[53] In the case of contaminated water baths, these were either replaced with dry heating incubators[45] or refilled using sterilised water.[6]

3.4.8 Other Control Measures

Several other control measures were used during water associated outbreak in healthcare facilities. Firstly sterile water was used for cleaning of reusable patient equipment such as surgical[83] and respiratory equipment,[57;133] and to prepare antiseptic solutions.[106]

Control strategies for patient care during outbreaks included the removal of CVCs[75;106] or covering CVCs when bathing to prevent contact with non-sterile water.[78;79] Antibiotics were also prescribed for prophylaxis or treatment patients during outbreaks.[53;75;89;106;127]

In several cases, major renovation works were undertaken to stop outbreaks, such as renovations of patient rooms[10] and bathrooms,[129] and reconditioning of water systems.[61;70] Other significant measures included ward relocation[18] and, in one case, the complete rebuilding of the ward, due to the age of the water system.[22]

3.5 Disinfection of hospital water systems

In NHSScotland premises preventative measures to maintain water safety should be carried out as per SHTM 04-0.1[145] In addition, the Scottish guidance for controlling the risk of *P. aeruginosa* from water in NNUs, adult and paediatric ICUs makes recommendations on flushing water outlets an states that: '*all non-auto flushed taps in the NNU and ICU patient areas and areas where clinical procedures are prepared or performed are flushed daily, first thing in the morning, at the maximum flow rate that does not give rise to any splashing beyond the basin/sink, e.g. on the floors. The flushing should be for a period of 1 minute and recorded*.'[139] Furthermore, the control of Legionella bacteria in hot and cold water systems guidance from the Health and Safety Executive recommends weekly flushing for several minutes of showers and taps that are not in regular use.[146] However, the Scottish Pseudomonas guidance states that where outlets are flushed daily there is no additional requirement for weekly flushing to comply with Legionella guidance (unless risk assessment specifies a need for greater frequency).[139]

A review by Otter et al on the susceptibility of biofilms to disinfection described the difficulties in comparing the available literature due to heterogeneity in test conditions and organisms, however, it find that oxidizing e.g. chlorine based bleaching agents, hydrogen peroxide etc., tend to be more effective against biofilms than other disinfectants as they target multiple components of the biofilms and microbes within.[147]

A number of studies were identified which utilised chlorine dioxide systems within hospital settings, and use of these was found to reduce bacterial numbers.[148-150] A single study was identified that measured the efficacy of chlorine dioxide against Gram-negative bacilli;[149] it was found that ClO_2 disinfection led to significantly fewer colonies of Gram-negative bacilli in water samples, specifically *Pseudomonas* spp. and *Stenotrophomonas* spp. SHTM 04-01, part B states that chlorine dioxide may be considered as a chemical control measure and provides guidance on its appropriate use.[145] SHTM 04-01 also states that chlorine dioxide may produce disinfection by-products that are deleterious to neonates and renal dialysis patients which should be filtered out from the supply to these units.[145]

Several studies were identified that assessed the effectiveness and consequences of monochloramine disinfection of hospital water distribution systems.[151-156] Monochloramine is an

alternative to chlorine for drinking water disinfection and has been used for this purpose since the early 20th century;[157] however, its use in the UK is limited and no NHSScotland premises currently have on-site monochloramine disinfection systems, that we are aware of. Chloramines remain active for longer than chlorine and so will disinfect until the end of pipes, it also produces fewer disinfection by-products than chlorine, which can cause illness.[157] Chloraminated water is considered safe for humans provided provides levels of chloramines are within acceptable limits. Dialysis user may need to treat chloraminated water before use due to the large volumes of water used for dialysis. [157] It is known that non-fermentative Gram-negative Bacilli such as *Pseudomonas* spp., *Stenotrophomonas* spp., *Acinetobacter baumannii* etc. have intrinsic resistance to antimicrobials.[152] This is a result of both active resistance mechanisms such as efflux pumps as well as physical characteristics such as impermeable outer membranes.[152] These organisms have also been shown to resist water system disinfection with monochloramine.[153;155] Monochloramine disinfection has been shown to have a profound effect on the microbial ecology of hospital water systems, it has been suggested that treatment with monochloramine may select organisms that are resistant to disinfection.[151;154;156]

It has been suggested that when water systems are disinfected with the aim of reducing a particular species that the effect this treatment has on other microorganisms in the system is also be measured.[153]

4. Discussion

The identified outbreak literature highlighted that the most at risk patients are those in haematology/oncology, intensive care units or neonatal units i.e. the most immunocompromised/susceptible patients. Although the organisms identified in the literature ranged from Gram-negative and Gram-positive bacteria through to fungi and even viruses, the most common were Gram-negative organisms such as Legionella spp., Pseudomonas spp. and other non-fermentative heterotrophic Gram-negative bacteria that are commonly found in water. All parts of the water system are susceptible to contamination but in particular those areas with complex parts such as aerators, sensors (solenoid valves etc.) or where drainage is suboptimal due to design of sink traps, drainage pipes, sink components. While a point source of contamination from some part of the water system was apparent in the vast majority of identified studies, failures of infection control such as hand hygiene compliance, use of multi-dose vials, cluttered environments etc. were also identified and likely contributed to the spread of infection in many cases.

The control methods described within the included articles highlights the complexity of outbreaks associated with water systems and the requirement for multi-faceted approaches to ensure outbreak resolution, with limited evidence to support a particular strategy bundle. Assessment of the most frequently implemented control measures suggests that strategies should as a minimum include;

- Control of the microbiological quality of water at the point of use through thermal or chemical disinfection, flushing and consideration of point of use filters.

- Replacement of water system components that have been identified as reservoirs such as sensor taps, aerators etc. and careful examination of the water system for any components that could contribute to stagnation/poor drainage.
- A review of practice to minimise the risk of transfer of contaminated water to patients, this may include a short-term move to sterile water for specific procedures or patients.

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Appendix 1: search strategies

Database: Embase <1974 to 2018 June 26>, Ovid MEDLINE(R) ALL <1946 to June 26, 2018>, MIDIRS: Maternity and Infant Care

Search Strategy:

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1. exp *water/
2. water system*.mp.
3. (tap* OR faucet*).mp.
4. (basin* or sink*).mp.
5. drain*.mp.
6. shower*.mp.
7. outbreak*.mp.
8. exp disease outbreaks/
9. nosocomial infection*.mp.
10. waterborne infection*.mp.
11. hospital*.mp.
12. healthcare facility.mp.
13. healthcare setting*.mp.
14. 1 or 2 or 3 or 4 or 5 or 6
15. 7 or 8 or 9 or 10
16. 11 or 12 or 13
17. 14 and 15 and 16
18. limit 17 to English language
19. limit 18 to human
20. limit 19 to yr="1998-Current"
21. remove duplicates from 20

Database: Embase <1974 to 2018 June 26>, Ovid MEDLINE(R) ALL <1946 to June 26, 2018>, MIDIRS: Maternity and Infant Care

Search Strategy:

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1 air conditioning.mp. [mp=ti, ab, hw, tn, ot, dm, mf, dv, kw, fx, dq, nm, kf, px, rx, an, ui, sy] (27343)

2 chilled beam*.mp. [mp=ti, ab, hw, tn, ot, dm, mf, dv, kw, fx, dq, nm, kf, px, rx, an, ui, sy] (5)

3 HVAC.mp. [mp=ti, ab, hw, tn, ot, dm, mf, dv, kw, fx, dq, nm, kf, px, rx, an, ui, sy] (702)

4 1 or 2 or 3 (27564)

5 (outbreak* or infection*).mp. [mp=ti, ab, hw, tn, ot, dm, mf, dv, kw, fx, dq, nm, kf, px, rx, an, ui, sy] (4120768)

6 (healthcare or hospital*).mp. [mp=ti, ab, hw, tn, ot, dm, mf, dv, kw, fx, dq, nm, kf, px, rx, an, ui, sy] (4021514)

7 4 and 5 and 6 (1671)

8 (water or waterborne).mp. [mp=ti, ab, hw, tn, ot, dm, mf, dv, kw, fx, dq, nm, kf, px, rx, an, ui, sy] (1830352)

9 7 and 8 (177)

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Database: Embase <1974 to 2018 June 26>, Ovid MEDLINE(R) ALL <1946 to June 26, 2018>, MIDIRS: Maternity and Infant Care

Search Strategy:

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1 water system.mp. [mp=ti, ab, hw, tn, ot, dm, mf, dv, kw, fx, dq, nm, kf, px, rx, an, ui, sy] (6285)

2 plumbing.mp. [mp=ti, ab, hw, tn, ot, dm, mf, dv, kw, fx, dq, nm, kf, px, rx, an, ui, sy] (1614)

3 water supply.mp. [mp=ti, ab, hw, tn, ot, dm, mf, dv, kw, fx, dq, nm, kf, px, rx, an, ui, sy] (73100)

4 (tap* or faucet* or water outlet* or sink* or drain*).mp. [mp=ti, ab, hw, tn, ot, dm, mf, dv, kw, fx, dq, nm, kf, px, rx, an, ui, sy] (575875)

5 1 or 2 or 3 or 4 (647621)

6 disinfection.mp. [mp=ti, ab, hw, tn, ot, dm, mf, dv, kw, fx, dq, nm, kf, px, rx, an, ui, sy] (59275)

7 treatment.mp. [mp=ti, ab, hw, tn, ot, dm, mf, dv, kw, fx, dq, nm, kf, px, rx, an, ui, sy] (10391487)

8 decontamination.mp. [mp=ti, ab, hw, tn, ot, dm, mf, dv, kw, fx, dq, nm, kf, px, rx, an, ui, sy] (24857)

9 (heat shock or heat-shock).mp. [mp=ti, ab, hw, tn, ot, dm, mf, dv, kw, fx, dq, nm, kf, px, rx, an, ui, sy] (150696)

10 saniti?ation.mp. [mp=ti, ab, hw, tn, ot, dm, mf, dv, kw, fx, dq, nm, kf, px, rx, an, ui, sy] (1016)

11 6 or 7 or 8 or 9 or 10 (10570389)

12 overgrowth.mp. [mp=ti, ab, hw, tn, ot, dm, mf, dv, kw, fx, dq, nm, kf, px, rx, an, ui, sy] (27202)

13 (diversity or biodiversity or ecology or microbiome).mp. [mp=ti, ab, hw, tn, ot, dm, mf, dv, kw, fx, dq, nm, kf, px, rx, an, ui, sy] (588358)

14 12 or 13 (614658)

15 5 and 11 and 14 (1280)

16 (hospital or healthcare).mp. [mp=ti, ab, hw, tn, ot, dm, mf, dv, kw, fx, dq, nm, kf, px, rx, an, ui, sy] (3404469)

17 15 and 16 (129)

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Appendix 2: Organism summaries

Prior to undertaking a full rapid literature review of water associated outbreaks in healthcare settings, several smaller literature searches were carried out to describe the characteristics of organisms that had been isolated from either the water or patient samples at the Royal Hospital for Children wards 2a/2b. These are summarized here.

Cupriavidas pauculas

Cupriavidus species are Gram-negative, aerobic, non-spore-forming, motile bacilli.[158]

Various naming conventions have previously been associated with this organism (formerly known as *Ralstonia paucula*, *Wautersia paucula* and CDC group IVc-2)[158-160] There are numerous case reports of infections caused by *C. pauculus* within the published literature. Many of these occurred in Europe,[161-169] but to date, there have been no case reports of infection in Scotland, or the UK. *C. pauculus* and other *Cupriavidus* species are considered to be environmental organisms,[159;170] (although negative environmental screening when investigating incidents/outbreaks has occasionally been reported[171;172]). More specifically, water is known to be a potential source of infection, including drinking water.[159;173-175] Very limited information on the mode of transmission of the organism is available. Contact with the environment has been proposed as the primary mode of transmission.[170-172] Person-to-person spread has been considered, but has not been proven.[165]

The majority of case reports identified one affected patient therefore it may be most appropriate to considered these as 'incidents', rather than true outbreaks.[160-164;166;167;169;170;172;176-183] The majority of reports were associated with immunocompromised patients, or those with various co-morbidities, with or without known immunosupression. A significant number of reports were associated with neonates, or paediatric patients.[160;164;165;170;178;180-182] Water as a source was suspected in a number of reports,[160;160;172;173;179;180] but no source was determined in the majority of cases.

Stenotrophomonas maltophilia

Stenotrophomonas maltophilia is a non-lactose fermenting Gram-negative aerobic bacillus, previously known as *Xanthomonas maltophilia* and *Pseudomonas maltophilia.* The organism has been implicated in causing nosocomial outbreaks since the 1970's.[184]

The organism is found in a variety of environments, including water, sewage and soil. Specifically within healthcare settings, *S. maltophilia* has been isolated from various reservoirs including taps, humidifiers, nebulizers, and ventilation equipment.[184] In addition, the organism has been isolated from bottled water.[185] Although numerous outbreaks associated with this organism have been reported, the source and mode of transmission it often difficult to establish. Typically, direct or indirect contact with a contaminated healthcare environment/equipment has been reported. Human carriage has also been noted in a number of studies, and therefore gives rise to the potential for person-to-person transmission.[184] Biofilm formation on a variety of surfaces has been demonstrated.[186] As a specific example; an *S. maltophilia* biofilm was found to be formed within a

flexible tube running from a carbon filter to a chiller, which was connected to a tap in a kitchen sink, used to supply patients with drinking water.[125]

Under laboratory conditions, optimum temperature for growth is considered to be 37˚C, although environmental isolates tend to have a propensity for growth at lower temperatures (20-30˚C). The organism is also known to survive in temperatures as low as 4˚C for significant periods of time.[187] In addition, it has been indicated that biofilm formation is temperature dependent, with one study citing optimum biofilm formation at 32˚C (in comparison to 18 and 37°C).[188] There are numerous published case reports and outbreak studies describing nosocomial infection and/or colonisation. One of these referred to an outbreak which occurred in the UK.[125] The majority of studies were associated with immunocompromised patients,[189-193] or those with various co-morbidities, with or without known immunosupression.[113;124;125;194-197] Four of the identified studies were associated with neonates, or paediatric patients.[90;124;195;197] Various sources of infection were reported including taps/tap water[124-126;190;198] and related environments (wash-hand basins[195;196] and a shower outlet[189]), medical solutions.[191;199]

Pseudomonas spp.

Pseudomonas spp are known to form biofilms both within the environment and in patient infections (i.e. on implanted biomaterials).[200] *P. aeruginosa* is known to survive a range of temperatures; typically 4-42˚C, with optimum growth occurring at 37˚C.[201] Biofilm formation has been shown to be temperature dependent, with one experimental study citing optimum biofilm formation at 37˚C (in comparison to 28, 33 and 42°C).[136] Various sources of infection were reported including taps/tap water,[16;20;27;31;34;35;44;202;203] as well as wider wash-hand basin environments[7;10;28;202;204] including a soap dispenser.[205] In addition, a further study demonstrated isolation of *P. aeruginosa* from various water fittings in intensive care rooms, in the absence of a recognised outbreak.[206]

Appendix 6 Initial report on the findings of the NHS Greater Glasgow and Clyde: Queen Elizabeth University Hospital/Royal Hospital for Children water contamination incident and recommendations for NHS Scotland

Initial report on the findings of the NHS Greater Glasgow and Clyde: Queen Elizabeth University Hospital/Royal Hospital for Children water contamination incident and recommendations for NHS Scotland

Report prepared on behalf of

HPS/HFS by: Annette Rankin

Nurse Consultant Infection Control Health Protection Scotland

Title: NHS GGC potential water contamination Version: 1.0

Date: 31/05/2018

Status: Final

Contents

Executive summary

NHS Greater Glasgow and Clyde (NHSGGC) are currently investigating a potentially contaminated water system across the Queen Elizabeth University Hospital (QEUH) and Royal Hospital for Children (RHC) with possible linked cases of bloodstream infections associated with ward 2A RHC.

Ward 2A RHC is a haemato-oncology unit, also known as Schiehallion, and houses the National Bone Marrow Transplant Unit. In 2016 a patient within ward 2A RHC was identified as having a blood stream infection (BSI) as a result of *Cupriavidus pauculus*. NHSGGC investigations included water samples from outlets within the aseptic suite of the pharmacy department where the parenteral nutrition was made that the child had received. *Cupriavidus pauculus* was isolated from water samples taken from a tap on a wash hand basin within this area. The wash hand basin was subsequently removed as a result. A further single case of *Cupriavidus pauculus* was identified in September 2017 however no environmental or water sampling was undertaken at this time.

Between the period of 29th January and 3rd April 2018 7 cases of blood stream infections (3 different organisms) with potential links to water contamination were identified. As a result widespread testing of the water supply was undertaken across both hospital sites. This testing identified widespread contamination of the water system. Control measures implemented included sanitisation of the water supply to ward 2A, the use of point of use filters in wash hand basins and showers in ward 2A and other areas where patients were considered high risk. There have been no new linked cases identified since the implementation of the control measures and whilst the investigation remains ongoing the clinical incident has been declared over with a full debrief held on 15th May 2018.

NHSGGC requested support from HPS with this incident on 16th March 2018 and Scottish Government invoked the national support framework on 20th March 2018 which requires HPS to lead an investigation and provide board support. This report is an initial summary of the findings from this investigation. A detailed technical report will be produced for NHSGGC by 31st July 2018

Introduction

NHS Greater Glasgow and Clyde (NHSGGC) are currently investigating a potentially contaminated water system across the Queen Elizabeth University Hospital (QEUH) and Royal Hospital for Children (RHC) with possible linked cases of bloodstream infections associated with ward 2A RHC. NHSGGC requested support from HPS with this incident on 16th March 2018 and Scottish Government invoked the national support framework[1] on 20th March 2018 which requires HPS to lead an investigation and provide board support. This report is an initial summary of the findings from this investigation. A detailed technical report will be produced for NHSGGC by 31st July 2018.

Background

NHS Greater Glasgow and Clyde's (NHSGGC) Queen Elizabeth University hospital (QEUH) is a 1109 bedded hospital with 100% en suite single side rooms which was handed over to the Board on 26th January 2015 with patient migration commencing from 24th April 2015 until 7th June 2015. The adjoining Royal Hospital for Children (RHC) is a 256 bedded childrens hospital which was handed over to the Board on 26th January 2015 with migration of patients occurring between 10th and 14th June 2015. The QEUH and RHC were both fully occupied from 15th June 2015 There are a number of additional healthcare facilities in the surrounding grounds including the maternity unit, neurosurgical unit, elderly care unit and the national spinal injuries unit.

Ward 2A RHC is a haemato-oncology unit, also known as Shiehallion, and houses the National Bone Marrow Transplant Unit. In February 2016 a patient within ward 2A RHC was identified as having a bloodstream infection (BSI) as a result of *Cupriavidus pauculus*. NHSGGC investigations included water samples from outlets within the aseptic suite of the pharmacy department where the parenteral nutrition was made that the child had received. *Cupriavidus pauculus* was isolated from water samples taken from a tap on a wash hand basin within this area. The wash hand basin was subsequently removed as a result. A further single case of *Cupriavidus pauculus* was identified in September 2017 however no environmental or water sampling was undertaken at this time. Appendix 1 details all incidents reported to Health Protection Scotland under the Healthcare associated incident investigation tool[2] related to ward 2A since 1st January 2016.

On 29th January 2018 *Cupriavidus pauculus* was identified from a bloodstream infection (BSI) in a patient in ward 2A. A series of investigations were undertaken including water sampling from outlets within the ward area. On 21st February *Pseudomonas* was identified from a BSI and between 11th and 16th March 2018 4 cases of *Stenotrophomonas maltophilia* were identified from patients in ward 2A and 1 patient in Paediatric ICU. *Cupriavidus, Pseudomonas and Stenotrophomonas* (amongst other gram negative bacillus and fungi) were identified. This led to enhanced control measures being applied within ward 2A and an extensive investigation into the potentially contaminated water system across the QEUH and RHC. Testing of the organisms in this incident has not provided an exact link to the patient cases and the water system. Testing in an incident like this can be difficult and should only be used to include cases rather than exclude. To attain appropriate representation of the bacteria within the water would require significant sampling of each organism identified to ensure a representation of strains was identified. A timeline of the patients with infections included in this incident is detailed in Appendix 2. A further case of *Stenotrophomonas* bacteraemia presented on admission to 2A on 3rd April 2018. Due to previous ward contact before implementation of control measures this case was included.

This report is an overview report of this investigation due to the large volume of data and complexities associated with this incident. A second more detailed and technical report is currently being produced which will cover more technical details and will be issued to Scottish Government and NHS GGC by end of July 2018. The longer timescale for this report is as a result of this incident being an ongoing live situation and covers information from the design and commissioning of the hospitals to the current position. HPS worked with the support of Health Facilities Scotland (HFS) as the technical engineering experts to support this investigation and report production.

Organisms linked to cases of infection in this incident

Details on the 3 organisms (*Cupriavidas, Stenotrophomonas and Pseudomonas*) that are linked to patient cases in this current investigation are covered in appendix 3.

The role of biofilm

Biofilm is a group of microorganisms in which the cells adhere to each other and often to a surface. These cells then become embedded within a slimy substance and can be prevalent in natural, industrial and hospital settings. There is a multitude of information in the published literature which directly links biofillm production/biofilm producing organisms to water source related outbreaks. In addition, 3 recent review articles focussed on the role of water in healthcare associated infections, with specific mention of biofilm formation as a key mechanism for sustained contamination of water systems.[3-5] Biofilm formation has been described for *Cupriavidus* species and *Pseudomonas spp*, particularly in association with water systems. Biofilm formation with *Stenotrophomonas* on a variety of surfaces has also been demonstrated.[6] As a specific example; an *S maltophilia* biofilm was found to be formed within a flexible tube running from a carbon filter to a chiller, which was connected to a tap in a kitchen sink, used to supply patients with drinking water.[6]

Initial findings

HPS, HFS and NHS GGC initiated a detailed investigation into the contaminated water system within QEUH/RHC. This includes reviewing commission, installation and maintenance records provided by the contractor. This has proved challenging due to the archiving of data and the fact that there are very few members of the initial project team available who are technically qualified to retrieve data and provide verbal clarification.

Results from ongoing water testing are being reviewed on a weekly basis and would appear to confirm that there continues to be regressional seeding of contamination and supports the theory that a whole system remedial approach is required. In

addition to the 3 organisms associated with the clinical incident, numerous additional gram negative bacilli and fungal species have been identified from samples.

A technical and epidemiological report is currently being produced which will include details of this investigation. Initial preliminary findings have identified that prior to handover from the contractor there were a number of water samples taken that produced results with high level of total viable counts (TVCs). TVCs are indicators that there are hygiene issues within the water system and are quantified as a generic indicator for microbial contamination. Specific microorganisms which can be tested for include: Coliforms, *Escherichia coli (*including O157), *Pseudomonas aeruginosa, Salmonella spp*, *Campylobacter spp* and Environmental Mycobacteria. Testing for these is not conducted as standard within current guidance and typically occurs in response to a suspected or confirmed outbreak, or due to identification of a series of sequential cases.

Commissioning and design of the hospital system

As part of the normal water system commissioning water samples were obtained. Some samples yielded high TVCs. In response to the high levels of TVCs NHSGGC did not accept the handover of the hospital at this time sanitisation of the water supply was undertaken prior to handover, with some impact and a reduction in TVCs in most areas, however there are a number of reports which indicate that there may still have been a number of areas with higher than normally acceptable levels of TVCs however work is still ongoing with this.

Evidence has been requested from NHS GG&C in relation to the infection control sign off of results and the system at commissioning/handover. Work continues to locate appropriate documentation and will be discussed in the final report. Water was first placed on the Infection prevention and control (IPCT) risk register in 2018.

The design and construct of wash hand basins, showers and taps in this hospital were agreed with NHS GGC in line with the Scottish Health Technical Memorandum (SHTM) in place at the point the hospital was designed, this included the installation of taps with flow regulators. HFS and HPS were involved in this decision making process as was NHSGGC Infection Control team. The SHTM (SHTM 04-01)[7] was revised in 2015 and no longer supports the use of flow regulators in clinical wash hand basins.

Biofilm formation in flow straighteners has been identified in a previous published outbreak.[8] The manufacturers of the taps/flow regulators recommend regular removal of the flow straighteners for cleaning/decontamination. Any records relating to decontamination of the flow straighteners will be reviewed in the wider review being undertaken.

The taps in place across all clinical wash hand basins in the hospital are not compatible with silver hydrogen peroxide, a product used during commission stage to sanitise the water system in view of the high TVC results. It is unclear whether this has caused any degradation of the taps, however NHS GGC have sent taps removed from the installation for metallurgical testing. In addition a tap was deconstructed and examined for the presence of biofilm, in addition to microbiological sampling. The presence of high levels of gram negative bacteria and fungus in the water system suggests that temperature control required has not always been achieved. This will be reviewed as part of the wider review being undertaken. In line with the national guidance there is a water safety group (WSG), and local Sector/Hospital Water Safety Groups. The Board Water Safety Group is a sub group of the Board Infection Control Group .Water Safety is a standing agenda item for the infection Control Team Senior Managers Team meeting.

There is a flushing regime in place across both hospitals however it is unclear whether the flushing process is adequate and all outlets are being flushed, including little used outlets, water coolers, baths etc. Due to the size of the system this is extremely difficult to assess. The wider report will review this.

Current management of situation

Point of use filters

Point of use (POU) filters were installed as one of the main control measures initially in high risk areas (wash hand basins and showers) to ensure a safe water supply at the point of use. These filters have been installed across all areas within QEUH and RHC where there are likely to be immunocompromised patients or in identified clinically higher risk areas. POU filters require to be changed every 30 days and are a costly approach. However, in the interim until the water contamination can be addressed, is the only feasible approach to ensure safe delivery of water. A number of studies found that installation of point of use filters reduced either infection rates in associated healthcare settings[9; 10] or pathogen counts within tested water samples.[11]

Water treatment

It is well recognised that drinking water distribution systems contain a diverse range of microorganisms.[12-14] The presence of microorganisms is affected by various factors including; the disinfection processes employed, the location and age of the system as well as pipe material.[15]

There are a number of options to be explored for longer term water treatment and NHS GGC are preparing a feasibility report on the most appropriate solution: these options include

Chlorine dioxide

A number of studies were identified which utilised chlorine dioxide systems within hospital settings, and use of these was found to reduce bacterial numbers. [14;16;17]

Various advantages and limitations associated with use of chlorine dioxide are known, with the most relevant summarised below.[18;19]

Advantages: Known to be effective against a wide range of bacteria, viruses and some protozoa including Giardia.

Limitations: Production of disinfection by- products (DBP's). Although potential production of DBP's always needs to be considered, the efficacy of water disinfection should not be compromised in trying to eliminate these. [19]

UV light

A number of drinking-water treatment technologies are available which employ UV light radiation to inactivate microorganisms.[19]

As with chlorine dioxide, various advantages and limitations associated with use UV are known, with the most relevant summarised below. [18-20]

Advantages: Bacteria, fungi and protozoa (considered to be more effective at killing Cryptosporidium than chlorine dioxide) are readily inactivated at low UV doses, with higher doses required for virus inactivation. In addition, UV disinfection does not result in the formation of DBP's like chlorine dioxide.

Limitations: UV disinfection does not leave any residual compound in treated water and therefore does not offer protection against possible microbial re-growth in distribution pipe-work.

Thermal disinfection

Very limited information was identified in the published literature in relation to advantages and limitations of thermal disinfection.

One study found that heat shock treatment at 80C reduced Gram negative bacteria in a hospital water system but did not lead to complete eradication.21

A risk benefit analysis of each option will be undertaken as part of the wider report. An additional approach for sanitisation which will also be reviewed is copper silver ionisation.

Hypothesis

There are a number of workable hypotheses being explored; it is currently considered the most likely cause of the widespread contamination is a combination of hypothesis B and C

A: Ingress contamination

A small low level number of micro-organisms may have been present in the water supply at the point of entry. Lack of temperature or chemical control may have enabled biofilm formation. Due to the increasing biofilm throughout the system this may have allowed any subsequent micro-organisms present at point of entry an opportunity to flourish and cause widespread contamination of the system.

B: Regressional contamination

This may have occurred due to contamination occurring at the taps/outlets or flow straighteners and contamination has regressed backwards throughout the system causing widespread contamination. The widespread positive results and array of bacteria point to contaminated outlets at installation or contamination of high risk components in the tap from ingress as opposed to the patient contact route.

C: Contamination at installation/commissioning

Contamination may have occurred due to presence of contaminated pipework or outlets. Prior to handover the system required to be sanitised due to high TVC counts. It is unclear if a robust flushing regime was in place from installation to handover and from handover to occupancy to prevent contamination.

Summary

There have been no new reported cases since 3rd April 2018 and the clinical aspect of this incident has been closed. This will be reopened if any new cases are identified. Control measures are in place to mitigate the risk however further work to address the widespread contamination is required. HPS will continue to liaise with HFS and NHSGGC and co- ordinate and produce a detailed technical report for NHSGGC and Scottish government which will include the review of installation, commission and maintenance and the risk/benefits of remedial approaches such as water dosing and tap replacement. This report will be prepared by July 2018.

Recommendations:

- Point of use filters will continue to be in place in ward 2A and other areas identified by the IMT until the risk to patients from the current situation of water contamination has been minimised.

- HPS will continue to liaise with HFS and NHSGGC and co-ordinate a wider technical report by 31st July 2018

- HPS via the existing Infection Control Built environment programme will, in conjunction with HFS:

A. Prioritise water safety and undertake a review of NHS Scotland current approach to water safety

B. Review existing national and international guidance relating to water safety and consider robust requirements for building handover requirements in relation to the water systems.

C. Establish a risk based approach to water testing and any remedial action required, including roles and responsibilities.

Appendix 1 - NHSScotland Incident and Outbreak Summary Ward 2a RHC (January 2016- April 2018).

NHS Greater Glasgow and Clyde have reported a total of 10 outbreaks and incidents for the clinical setting paediatric haemato-oncology. Of the 10 incidents and outbreaks HIIAT assessed; 4 were Red, 2 were Amber and 4 were Green. The data is displayed in the tables below providing a breakdown of the outbreaks reported by annual period with exception of the current period to date for 2018 and HIIAT Green in 2016 following introduction of mandatory report (non Norovirus) from April. Comparative data for this setting within NHSScotland identified no reported incidents or outbreaks out with NHS Greater Glasgow and Clyde.

2018:

Table 1 NHS Greater Glasgow & Clyde, RHC haemato-oncology (ward 2A), HIIAT RED 2018 ± Total (1)			
Date reported	**Organism**	**Infection Category**	**Summary**
01/03/2018	*Pseudomonas aeruginosa* or *Cupriavidus pauculus*	BSI	**Current ongoing** incident following initial reporting water system contamination with Cupriavidus pauculus/ Pseudomonas aeruginosa within ward 2A (haemato-oncology ward) at the Royal Hospital for Sick Children following 2 confirmed cases, 1 with *Cupriavidus pauculus* bacteraemia, 1 with *Pseudomonas aeruginosa* bacteraemia resulting in invokement of the national framework by Scottish Government on 21/3/18.

Table 2 NHS Greater Glasgow & Clyde, RHC haemato-oncology (ward 2A), HIIAT AMBER 2018 ± Total (1)			
Date reported	**Organism**	**Infection Category**	**Summary**
10/04/2018	Astrovirus	Respiratory	12 patient cases identified with Astrovirus

2017:

Table 3 NHS Greater Glasgow & Clyde, RHC haemato-oncology (ward 2A), HIIAT GREEN 2017 ± Total (3)			
Date reported	**Organism**	**Infection Category**	**Summary**
03/03/2017	*Elizabethkingia miricola*	BSI	Three cases BSI infection since September 2016. Action plan - focus on the environment
03/03/2017	Mixed	BSI	IPCT and clinical team noted a general increase in the number of blood cultures over January and February
31/5/2017	Norovirus	GI	3 cases, 2 of which HAI (some cases amongst parents within the unit)

Table 4 NHS Greater Glasgow & Clyde, RHC haemato-oncology (ward 2A), HIIAT RED 2017 ± Total (3)			
Date reported	**Organism**	**Infection Category**	**Summary**
7/3/2017	*Aspergillus fumigatus*	Airborne	A higher than expected incidence of Aspergillus in this patient population since June 2016. Three patients met the case definition of probable Aspergillosis
13/04/2017	Rotavirus	GI	5 patient cases of VRE 3 of which have rotavirus. 2 staff members confirmed rotavirus
26/7/2017	Stenotrophomonas	BSI	Two patients with positive Stenotrophomonas bacteraemia within 8 days. Both cases considered to be HAI. Control measures in place

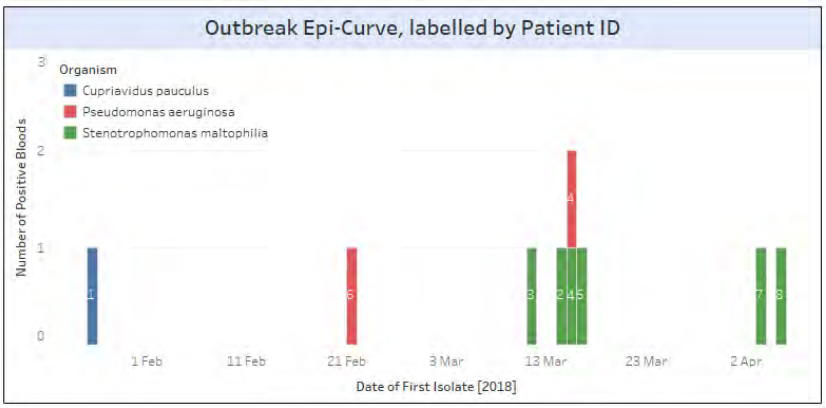
2016:

Table 5 NHS Greater Glasgow & Clyde, RHC haemato-oncology (ward 2A), HIIAT GREEN 2016- Total (1)			
Date reported	**Organism**	**Infection Category**	**Summary**
04/08/2016	Vancomycin Resistant *Enterococci*	GI	Increase in VRE

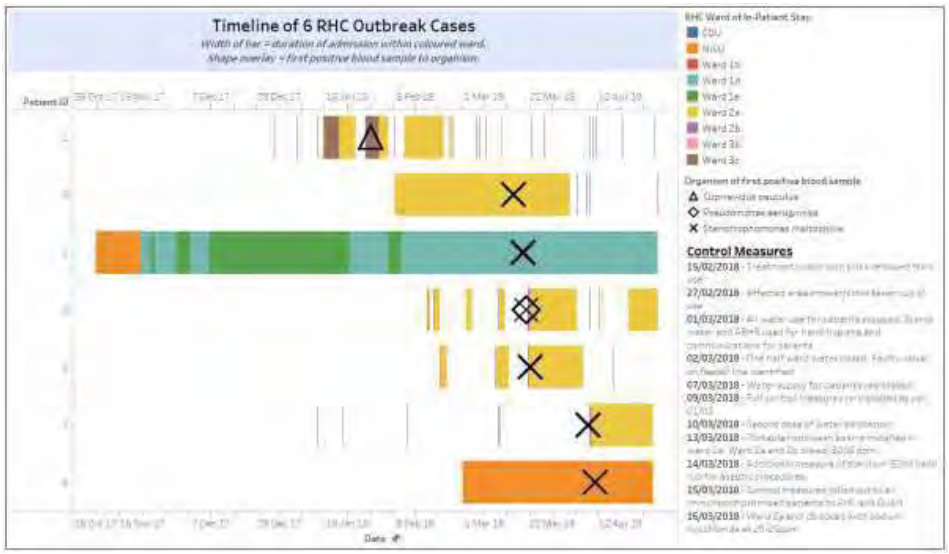
Table 6 NHS Greater Glasgow & Clyde, RHC haemato-oncology (ward 2A), HIIAT AMBER 2016- Total (1)			
Date reported to HPS	**Organism**	**Infection Category**	**Summary**

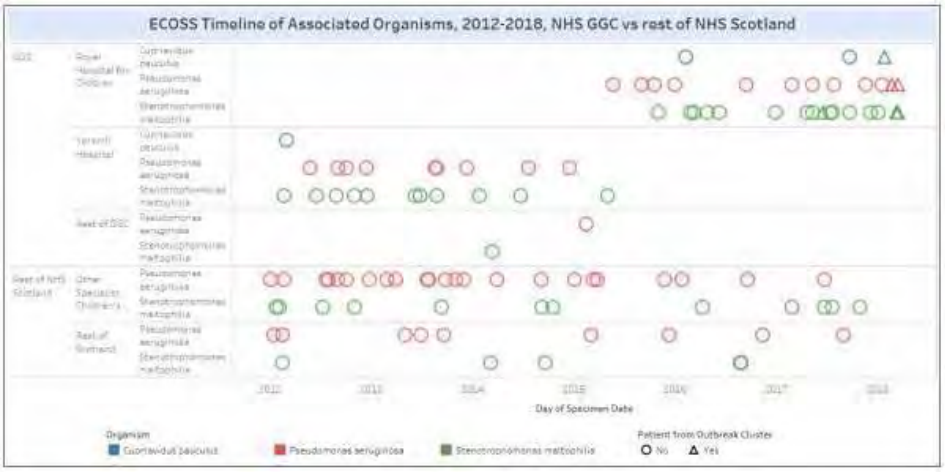
05/08/2016	Aspergillus	Respiratory	Two cases: one confirmed and one probable Neither giving cause for clinical concern specific to Aspergillus. Possible contributing environmental factors for cross transmission.

Appendix 2 Timeline of cases



The epi-curve demonstrates that only one case of *Cupriavidus pauculus* was reported from 26th January 2018, with the other associated cases being *Stenotrophomonas maltophilia* and/or *Pseudomonas aeruginosa* positive between 21st February 2018 and 5th April 2018.




ECOSS Timeline of Associated Organisms, 2012-2018, NHS GGC vs rest of NHS Scotland
Day of Specimen Date
Organism
Pseudomonas aeruginosa
Patient from Outbreak Cluster
No
Yes

Appendix 3 - *Cupriavidus, Stenotrophomonas, Pseudomonas*

Cupriavidus pauculus

1. Background

Cupriavidus species are Gram-negative, aerobic, non-spore-forming, motile bacilli.[22] Various naming conventions have previously been associated with this organism (formerly known as *Ralstonia paucula*, *Wautersia paucula* and CDC group IVc-2)[22-24]

a. Reservoir/s
C. pauculus and other *Cupriavidus* species are considered to be environmental organisms,[24;25] *(although negative environmental screening when investigating incidents/outbreaks has occasionally been reported26;27). More specifically, water is known to be a potential source of infection, including drinking water.24;28-30*

b. Mode/s of transmission
Very limited information on the mode of transmission of the organism is available. Contact with the environment has been proposed as the primary mode of transmission.[25-27] Person-to-person spread has been considered, but has not been proven.[31] In addition, other modes of transmission, including following a cat bite[32] have also been reported.

c. Biofilm formation
Biofilm formation has been described for *Cupriavidus* species, particularly in association with water systems.[26;30;33-35]

2. Summary of published incidents/outbreaks

There are numerous case reports of infections caused by *C. pauculus* within the published literature. Many of these occurred in Europe, [31;32;36-42] but to date, there have been no case reports of infection in Scotland, or the UK.

The majority of case reports identified one affected patient[23;25;27;32;36-38;40-50] therefore it may be most appropriate to considered these as 'incidents' rather than true outbreaks.

A number of the reports[23;31;38;43;44;47;49] considered infections to be nosocomial, although many of the patients had prolonged/intermittent hospital stays and it was therefore difficult to accurately establish healthcare versus community acquisition.

The majority of reports were associated with immunocompromised patients, [27;31;38;39;41-43;48;50] or those with various co-morbidities, with or without known immunosupression. [23;37;40;44;46;47]

A significant number of reports were associated with neonates, or paediatric patients. [23;25;31;36;44-46;48]

Various types of infections were described, the majority of reports described bacteraemia/septicaemia.[23;25;37;41-45;47;49;50] Other presentations included pneumonia,[36- 38;46] meningitis,[25] peritonitis,[40] and osteomyelitis/septic arthritis.[43] In addition, catheter associated infections were also reported.[27;42] A number of patient deathsoccurred, [37;44;46;48] but in most cases it was difficult to determine whether these were directly due to infection with the organism, or other factors associated with patient immunosupression /chronic disease.

Water as a source[23;27;29;43;44;47] was suspected in a number of reports, but no source was determined in the majority of cases.

In addition, two pseudo-outbreaks were reported, due likely environmental contamination by this organism of specimen swabs[29] and blood culture bottles.[26]

Stenotrophomonas maltophilia

1. Background

Stenotrophomonas maltophilia is a non-lactose fermenting Gram-negative aerobic bacillus, previously known as *Xanthomonas maltophilia* and *Pseudomonas maltophilia.*

The organism has been implicated in causing outbreaks since the 1970's.[51]

a. Reservoir/s

The organism is found in a variety of environments, including water, sewage and soil. Specifically within healthcare settings, *S. maltophilia* has been isolated from various reservoirs including taps, humidifiers, nebulizers, and ventilation equipment.[51] In addition, the organism has been isolated from bottled water.[52]

b. Mode/s of transmission

Although numerous outbreaks associated with this organism have been reported, the

source and mode of transmission it often difficult to establish. Typically, direct or indirect contact with a contaminated healthcare environment/equipment has been reported. Human carriage has also been noted in a number of studies, and therefore gives rise to the potential for person-to-person transmission.[51]

c. Biofilm formation

Biofilm formation on a variety of surfaces has been demonstrated.[6] As a specific example; an *S maltophilia* biofilm was found to be formed within a flexible tube running from a carbon filter to a chiller, which was connected to a tap in a kitchen sink, used to supply patients with drinking water.[53]

Under laboratory conditions, optimum temperature for growth is considered to be 37ÛC, although environmental isolates tend to have a propensity for growth at lower temperatures (20-30ÛC). The organism is also known to survive in temperatures as low as 4˚C for significant periods of time.[54] In addition, it has been indicated that biofilm formation is temperature dependent, with one study citing optimum biofilm formation at 32˚C (in comparison to 18 and 37°C).[55]

2. Summary of published incidents/outbreaks

There are numerous published case reports and outbreak studies describing nosocomial infection and/or colonisation. One of these referred to an outbreak which occurred in the UK.[53]

The majority of studies were associated with immunocompromised patients,[56-60] or those with various co-morbidities, with or without known immunosupression.[53;61-66]

25% (4 out of 16) of identified studies were associated with neonates, or paediatric patients.[62;64;66;67]

Various types of infections were described; predominantly bacteraemia/septicaemia.[56- 61;64;66;67] Other presentations included endopthalmitis,[68] as well as respiratory,[53;62;63;69] soft tissue[58] and catheter associated infections.[59] In addition, a number of studies described cases of both colonisation and infection[53;60;63;64] and one described colonisation alone.[70]

Various sources of infection were reported including taps/tap water[53;58;64;70;71] and related environments (wash-hand basins[62;65] and a shower outlet[60]), medical solutions, [56;68] and various medical equipment;[61;63;66;69;71-73] predominantly bronchoscopes (N.B all bronchoscope related outbreaks were found to be pseudo-outbreaks).

Limited information was provided on the mode of transmission but most studies considered this to be contact with the healthcare environment, relating to the sources described above. Two outbreaks stipulated that person-to-person transmission from colonised healthcare workers may have occurred.[66;67]

In addition, a number of reports described co-infections; primarily with other Gram negative organisms.[71-74]

Pseudomonas spp

Biofilm formation

Pseudomonas spp are known to form biofilms both within the environment and in patient infections (i.e. on implanted biomaterials).[75]

P. aeruginosa is known to survive a range of temperatures; typically 4-42° C, with optimum growth occurring at 37°C.[76] Biofilm formation has been shown to be temperature dependent, with one experimental study citing optimum biofilm formation at 37°C (in comparison to 28, 33 and 42°C).[3]

Further specific information in relation to biofilm formation associated with water sources can be found in '*Are biofilms associated with water source related transmission with healthcare settings?*' below.

Summary of published incidents/outbreaks

A multitude of nosocomial *Pseudomonas spp* outbreaks have been reported in the published literature. The summary below includes outbreaks occurring in the last 10 years only.

Outbreaks were reported internationally, with four of these occurring in the UK.[4;5;9;10]

The majority of studies were associated with immunocompromised patients, [56;77-89] or those with various co-morbidities, with or without known immunosupression.[4;9;10;90-118]

9% (7 out of 63) of identified studies were associated with neonates, or paediatric patients. [77;79;99;101;106;110;114] A recent systematic review outlines risk factors and environmental sources associated *with P. aeruginosa* outbreaks in neonatal intensive care settings.[119]

Various types of infections were described; predominantly bacteraemia/septicaemia.[11;56;78-81;83;85;88;89;94;98-101;107;109;113;114;118;120-122] Other presentations included endopthalmitis,[123-126] endocarditis[127] as well as respiratory,[10;69;78;80;89;96;105;109;112;113;118;128] surgical site[88;89;115;118;129] and urinary tract infections.[80;88;95;109;118;120;122;128;130;131] In addition, a number of studies described cases of both colonisation and infection. [78-81;93;94;97;99;104;110;111;114;116;128]

Various sources of infection were reported including bottled water,[91;99] taps/tap water, [5-77;82;97;101] as well as wider wash-hand basin environments [4;90;110;113;116] including a soap dispenser.[80] In addition, a further study demonstrated isolation of *P. aeruginosa* from various water fittings in intensive care rooms, in the absence of a recognised outbreak.[132] Outbreaks have also been associated with various medical solutions,[56;96;121;124;126;127] and medical equipment, including various types of endoscopes, [69;81;93;120;130;133] arthroscopic shavers,[129] a urodynamic transducer[122] and a transesophageal echocardiogram probe.[94]

Limited information was provided on the mode of transmission but most studies considered this to be contact with the healthcare environment, relating to the sources described above.

A number of outbreak reports stipulated that person-to-person transmission from colonised healthcare workers/patients may have occurred. [11;79;84;92;95;98;102;104;112;114]

The majority of outbreaks were associated with *P. aeruginosa* but other species were also reported including *P. putida* [56;100;93], *P. fulva*[93] and *P. fluorescens*.[107]

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Appendix 7 Supervisor Report

The following extracts are noted from the various Project Supervisor' (Capita Symonds) reports.

- Supervisors report number 12, dated March 2012

  Page 3 of 20 Executive Summary.

  In general terms we are satisfied that the installations are being installed to the correct standard, and are of a good quality. However we are concerned that there are a number of open ends being left on the main pipework installations. There is also some damage to the ductwork sections as they arrive on site.

  Page 8 of 20 item 4.3.7 Dual Carriageway to Renfrew Road

  We noted that pipework has been left with open ends. This can lead to debris and other material contaminating or restricting the operation of the systems. Brookfield provided *a short term fix all open ends sealed on site as of 30/03/12. The pipe in original photograph has final connection in place. Brookfield confirmed that in the long term Mercury supplier/sub-contractor are to ensure all pipe ends blanked are off prior to site delivery until final connection takes place. In this instance Supervisor s Communication General Matters / Other Instructions (CI 13.1) No 09 is now closed out.*

  Page 8 of 20 Item 4.3.8 Pipework

  Installation of hot, cold, heating, & chilled water pipework in the A&C hospital is now progressing and in general is being installed to a good standard. It was noted however that there are open ends being left on the pipework[97]*, and the contractor should be reminded that these need to be sealed, to prevent the ingress of moisture and subsequent corrosion that may develop.*

  Page 9 of 20 Item 4.3.10

  The thermal insulation installation to the pre-fabricated sections of pipework is being completed off site, before delivery. It should be confirmed with Brookfield that these pre-insulated sections of pipework have been pressure tested, prior to the insulation being fitted.

- Supervisors report number 14, May 2012

  Page 9 of 12 item 4.3.6 pipework

  Brookfield have confirmed that there will be no water in the sprinkler system at this stage the pressure test is pneumatic test and not hydraulic. Prior to commissioning a hydraulic test will be carried out prior to flushing and chemical

[97] Appendix 2 Item 7

clean and closed with inhibitor to stop rust. Supervisor s Communication General Matters / Other Instructions (CI 13.1) No 10 is closed out.

Installation of hot, cold, heating and chilled water and medical gas pipework in the A&C hospital is progressing at pace and in general is being installed to a good standard. The number of open ends seen has reduced to minimal levels. The contractor should be reminded that these need to be sealed, to prevent the ingress of moisture and subsequent corrosion that may develop.

Page 10 of 12

The thermal insulation installation to the pre-fabricated sections of pipework is being completed off site, before delivery. Brookfield has confirmed that these preinsulated sections of pipework have been pressure tested, prior to the insulation being fitted.

- Supervisors report number 19, October 2012

  Item 4.3.5 pipework

  Installation of hot, cold, heating, & chilled water pipework in the A&C hospital is progressing at pace and in general is being installed to a good standard. It was noted however that there are still some open ends being left on the pipework[98], although to a lesser degree than previously reported. The contractor should be reminded that these need to be sealed, to prevent the ingress of moisture and subsequent corrosion that may develop.

  We have identified locations where the dead legs on hot water pipe runs are excessive and greater than the specified distance of 3m. We are working with the Contractor to review and identify all areas and to ensure this is not repeated in the future installations. It is noted that the dead legs noted in area CCW-31 were closed out in item 76 of the Project Supervisors report and is dated 30th November 2012. No other areas are noted.

  We noted that Pipework was not capped on Level 2, Gridlines E1-F & 2.1-2.3, Level 2, Plantroom, Gridlines J-I1 & 1-1.1, Level 2, THE-208 Workstation 6x Persons and Level 1, Corridor, Gridlines G1-G & 4-5.1. Brookfield has confirmed that all ends capped off including facing module. MRI Quench pipe has been returned into the opening in the wall and this end is capped off. The other issues raised is work in progress, consequently Supervisor s Communication General Matters / Other Instructions (CI 13.1) No 59 is closed out

- Supervisors report number 24, March 2013

[98] Appendix 2 Item 8

4.3.5 pipework

Installation of hot, cold, heating, & chilled water pipework in the A&C hospital is progressing at pace and in general is being installed to a good standard. The contractor should be reminded that open ends on pipework should be sealed, to prevent the ingress of moisture and subsequent corrosion that may develop. More emphasis should be placed on this as work progresses at higher levels on site.

We are continuing to monitor all pipework installations to identify possible dead legs. The quality checking by Brookfield would appear to be identifying these before our inspections. Brookfield has confirmed that the maximum length prior to trimming back these pipes is cumulatively 2,890mm as shown in the photographs below Consequently pipework dead leg is no greater than 3 metres and Supervisor's Notification of Defect (CI 42.2) No 76 is closed out.

It should be noted that the version of SHTM 04-01 current during the design and installation stages of the contract advises in Paragraph 8.6 that for cold water systems *"All pipework should be insulated, except for any exposed final connections to sanitary appliances, and should be arranged to eliminate or minimise dead-legs."* For hot water systems paragraph 9.49 advises *"Generally, the downstream dead-leg should not exceed 2m, and the complete length of the spur without circulation should not exceed 3m".*

- Supervisors report number 25, April 2013

  Installation of hot, cold, heating, & chilled water pipework in the A&C hospital is progressing at pace and in general is being installed to a good standard.

  We are continuing to monitor all pipework installations to identify possible dead legs. The quality checking by Brookfield would appear to be identifying these before our inspections.

It should be noted from HSG 274 Part 2[99] that "*ensuring water cannot stagnate anywhere in the system by regular movement of water in all sections of the systems and by keeping pipe lengths as short as possible, and/or removing redundant pipework and dead-legs;" to prevent or control the risk of legionella".*

It should be further noted from SHTM 04-01 Part A that[100]

- *"All pipework should be insulated, except for any exposed final connections sanitary appliances, and should be arranged to eliminate or minimise dead-legs."*

It should be further noted from SHTM 04-01 Part E that[101]

[99] HSE HSG 274 Part 2, paragraph 23
[100] SHTM 04-01 Part A, paragraph 8.6
[101] SHTM 04-01 Part E, paragraph 3.18, note

- ***"Note:** Any pipes delivered unprotected or with open ends should be rejected." This equally applies to open ended unprotected pipe on-site, where the risk of contamination is the same as transportation/storage.*
- In addition the specification[102] makes it clear that pipework should be protected by caps to protect against dirt, rodents, frost and other inadvertent damage or consequences.

- Supervisors report number 26, May 2013

  4.3.5 Pipework.
  Installation of hot, cold, heating, & chilled water pipework in the A&C hospital is progressing and in general is being installed to a good standard. Some systems are undergoing chemical clean prior to testing. We have witnessed water tests for the chilled beam chilled water and heating pipework and results were acceptable.

It should be noted that during the course of the investigation the Contractor was asked[103]: - "once a system was chemically cleaned how was it left – i.e. purged with air or filled with water?

- The contractor response was "*None of the domestic water services were chemically cleaned only closed systems such as Low Temperature Hot Water and Chilled Water and in these instances system were flushed, chemically cleaned, flushed again before corrosion inhibitor added."*

- Supervisors report number 35 March 2014

  4.3.5 Pipework
  "Following a visit to site we raised our concerns that there are some locations where
  there is insufficient space for maintainable, replacement building services and plant
  as per the Employers Requirement Section 5.13 Facilities Management."

  and

  Level 3 / Zone H. Pipe Racks in area shown below have multiple levels of pipe work. We have asked Brookfield to confirm that future access will be available. Brookfield confirmed that access to the 3 areas identified will be accessible for FM in compliance with ER Section 5.13. The access arrangements for this item will be recorded as part of the Access Strategy Tracker which is currently being developed by Brookfield and
  Mercury. (See Supervisor's Communication General Matters /Other Instructions (Cl 13.1) No 126).
  We asked Brookfield to confirm that future access will be available to pipework on

[102] ZBP/TUV SUD ZBP-XX-XX-SP-520-307
[103] Email NHSGGC to HFS 3rd May 2018 "Queries regarding - Calibration certs, system cleaning, pipework storage"

Level 3 / Zone H and Level 2 Zone K. Brookfield confirmed that access to the areas
identified will be by an adapted MEWP 540x 540. This has been recorded on their
Access Strategy Tracker. Supervisor's Communication General Matters / Other Instructions (CI 13.1) No 126 is closed out.
And
Over the past few weeks there have been failures of crimped joints on Level 1 Area 1-533 and Level 0 Area 0-531. We have asked Brookfield to confirm if they propose to carry out a percentage quality inspection of the crimped joints to identify if it is operative error. Supervisor's Communication General Matters / Other Instructions (CI 13.1) No 202.

It should be noted that the "MAJOR PLANT AND EQUIPMENT REPLACEMENT STRATEGY[104]" within ZUTEC does not include reference to any pipe work access strategy. This document primarily deals with major plant replacement and access strategy. It is therefore unclear how pipe work would be replaced without major disruption to the hospital.

- Supervisors report 36 April 2014

  4.3.5 Pipework
  "Open unprotected ends are being monitored during our site inspections and there has been a marked improvement in all areas."

- Supervisors report 39 July 2014

  4.3.5 Pipework
  Installation of hot, cold, heating & chilled water pipework in the A&C Hospital and
  Children's Hospital is well in advance in all plantrooms and in general is being installed to a good standard which we are continuing to monitor. The DHWS and CW are being installed to a good standard with 2nd fix still to be completed. There is no water being discharged from the outlets at present.

- Supervisors report 40 August 2014

  4.3.5 Pipework
  Installation of hot, cold, heating & chilled water pipework in the A&C Hospital is well
  in advance in all plantrooms and in general is being installed to a good standard which we are continuing to monitor. The DHWS and CW are being installed to a good
  standard with 2nd fix still to be completed. We are aware that water supplied to

[104] ZDP MAJOR PLANT AND EQUIPMENT REPLACEMENT STRATEGY ZBP-XX-XX-DC-600-501 Rev 8 March 2014

pipework within the podium.

It should be noted that the pipe work has water present in advance of the water commissioning in November 2014. Supervisor's reports 41, 42 43 and 44 are identical with respect to the text noted above.

- Supervisors report number 43 November 2014

  3.2 Witness Testing and Commissioning
  We witnessed a number of tests during November which were satisfactory and these were as follows:
  ....
  (296) DHW systems in PR22 PU 103 / 104.
  (323) LTHW and CW water treatment tests.
  (324) Witnessing of sterilised outlets and tank inspection in Basement, and Levels 0, 1 & 2.

  4.3.5 Mechanical Services
  Installation of hot, cold, heating & chilled water pipework in the A&C Hospital is well in advance in all plantrooms and in general is being installed to a good standard which we are continuing to monitor. The DHWS and CW are being installed to a good standard with 2nd fix still to be completed. We are aware that water is now being supplied to pipework within the podium.

  This text indicates that water was being supplied to a partially complete system.

- It should be noted that at no time in the descriptions of the supervisor's reports are specific standards, specifications or guidance cross referenced for compliance (other than to note the systems are compliant). The terms "in general terms" and "a good standard" are quoted in the Supervisor's reports, but this is subjective and is not quality related.
- There is a consistent reporting of open-ended pipe throughout the supervisors reports examined and noted above. There is no evidence that the open-ended pipes were rejected or subject to any additional checks or cleaning measures. The open-ended pipes did not comply with the requirements of the specification[105], SHTM 04-01 or the various other guidance documents referenced.

[105] ZBP/TUV SUD Specification Common Mechanical Clauses ZBP-XX-XX-SP-520-307

Appendix 8 SBAR: Pseudomonas risk taps

Pseudomonas risk: Taps	
Situation	NHS Greater Glasgow and Clyde (GG&C) seeking advice from Health Protection Scotland (HPS) on the removal of flow straighteners from the taps procured for the new Southern General Hospital (SGH).
Background	The Horne Optitherm tap which incorporates flow straighteners, was procured for all clinical environments within the new SGH prior to the publication of UK and Scotland-wide pseudomonas guidance in June 2013[1, 2]. The HPS, Guidance for Neonatal Units (NNUs) and adult and paediatric ICUs, June 2013[1], states; *"Bio film can develop on flow straighteners and it is recommended that these are removed from taps."* This recommendation is also made within SHTM 04-01: part A Design, Installation and Testing, section 9.51, note 12[3]; suggesting that it should be applied universally in all clinical areas across the hospital.
Assessment	It is recognised that any alterations made to the taps may make the warranty of the devices invalid and therefore this assessment focuses on the: • Function of the flow straighteners as advised by Horne; and • Current guidance on minimising the risk of *Pseudomonas aeruginosa* infection from water. In assessing the HAI risks associated with flow straighteners HPS also sought the advice of Dr Jimmy Walker, Water System Microbiology and Decontamination Expert, Public Health England. In addition advice was sought from a Consultant Microbiologist from NHS Lothian and the Estates Department at NHS Forth Valley. Our response to Horne's statements on the function of flow straighteners is set

	out below: • Provide laminar flow: Agreed. Flow straighteners are there to provide laminar flow which reduces the dispersal of droplets from running water. • Regulate the flow rate: Agree in part. Some sites have issues with too much flow/pressure resulting in water droplets being disseminated from the wash hand station which can be an issue near medicine preparation areas or where medical equipment is being decontaminated. The fitting of flow control devices would have to be balanced with a risk of HAI issues (where too much flow is present) resulting in water droplets contaminating the surrounding area. • Retain water inside the tap: There is no evidence for this claim. Yes, bacteria will be present in the air as aerosols and in a hospital ward environment there will be dispersal of both aerosols and larger droplets which will tend to drop out and land on surfaces. As these larger droplets land on surface, the bacteria contained will tend to proliferate where the environment is moist and wet so it is not entirely convincing that water retention within a tap would prevent contamination. In considering water safety for healthcare premises, in particular minimising the risk of *Pseudomonas aeruginosa* infection from water, the removal of flow straighteners from taps in high risk units is one of a number of critical controls to be considered in the hospital water delivery system. The positioning of hand hygiene products around hand wash stations, water pressure, and flow rate are highlighted together with other considerations on pages 8 and 9 of the 2013 HPS guidance[1]. There are three options to tap installation in the SGH: 1. Instruct the contractor to install the procured taps in all clinical areas across the SGH. This would subsequently require NHS GG&C to commence a water sampling regimen to monitor for *Pseudomonas* in high risk units. 2. Instruct the contractor to install the: • Procured taps in all clinical areas across the hospital excluding high risk units; and • Procured taps without flow straighteners in high risk units. 3. Instruct the contractor to install: • The procured taps in all clinical areas across the hospital excluding high risk units; and • New compliant taps (without flow straighteners) in high risk units.
Recommendation	The HPS Guidance for NNUs, adult and paediatric ICUs in Scotland[1] is designed to m

	inimise the risk of infection with *Pseudomonas aeruginosa* – the risk however can never be eliminated. Based on the above assessment and the extant national guidance on water safety and potential infection risks to patients, particularly in high risk units[1, 2] HPS recommend NHS GG&C to progress with option 2 or 3.

References

1. Health Protection Scotland (HPS) 2013, Guidance for neonatal units (NNUs) (Levels 1, 2 & 3), adult and paediatric intensive care units (ICUs) in Scotland to minimise the risk of *Pseudomonas aeruginosa* infection from water http://www.hps.scot.nhs.uk/haiic/ic/guidelinedetail.aspx?id=54784

2. Scottish Executive Health Department, CEL (2013) 8, Water sources and potential infection risk to patients in high risk units – a revised guidance http://www.sehd.scot.nhs.uk/mels/CEL2013_08.pdf

3. Health Facilities Scotland (HFS) 2012, Scottish Health Memorandum 04-01: The control of *Legionella*, hygiene, 'safe' hat water, cold water and drinking water systems Part A: Design, installation and testing http://www.hfs.scot.nhs.uk/publications

SBAR Pseudomonas Risk: Taps Completed by Lisa Ritchie
Version 1 April 2014

References

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A report from the American Academy of Microbiology

FROM OUTSIDE to inside:

Environmental Microorganisms as Human Pathogens

AMERICAN SOCIETY FOR MICROBIOLOGY

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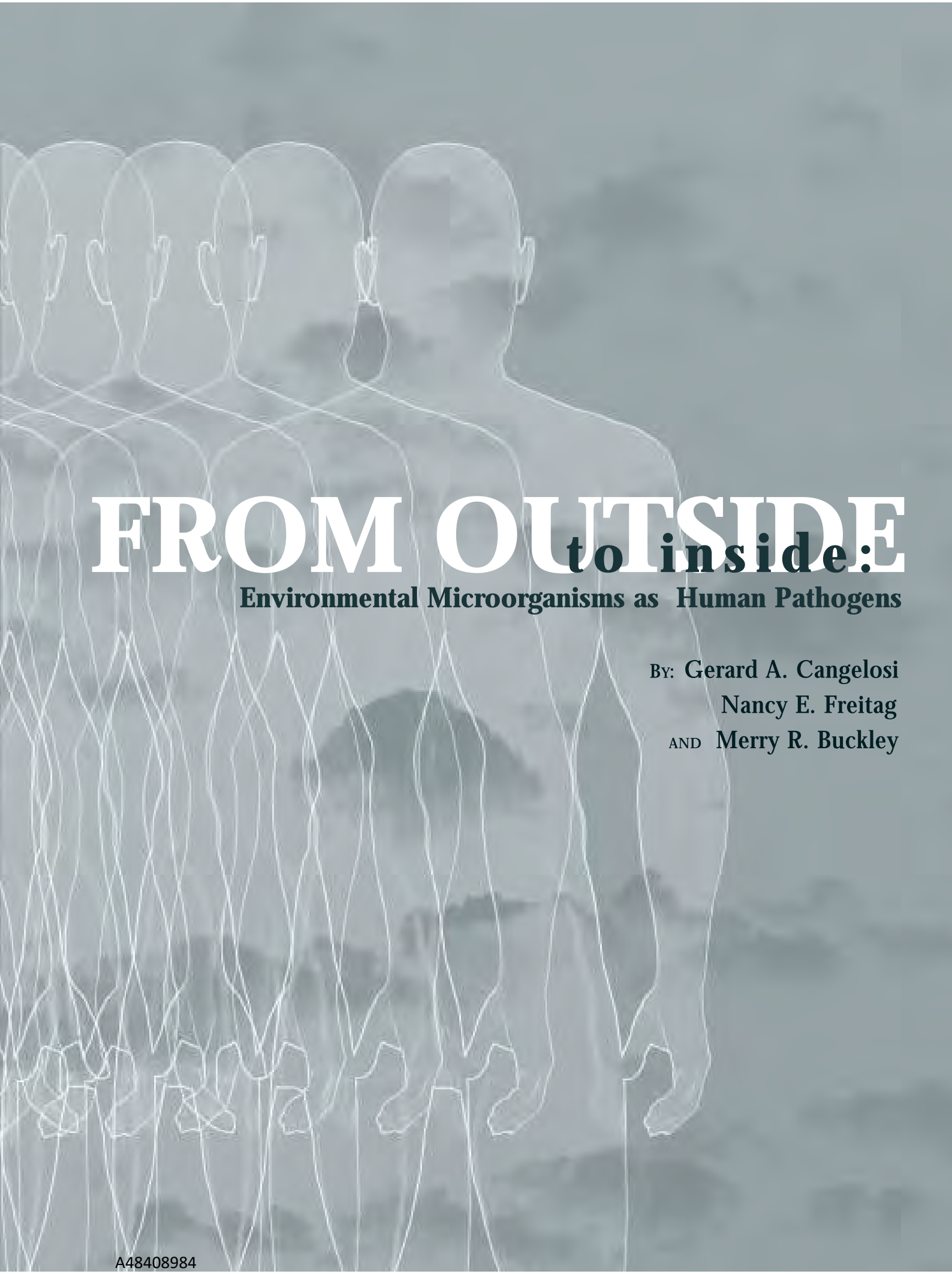

FROM OUTSIDE to inside:

Environmental Microorganisms as Human Pathogens

BY: Gerard A. Cangelosi
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Executive Summary

The American Academy of Microbiology convened a colloquium February 6-8, 2004, in Portland, Oregon, to discuss environmental pathogens and the current state of research on these organisms. Scientists with expertise in infectious diseases, food microbiology, bacteriology, molecular biology, microbial ecology, pathogenic mycology, and other areas in the microbiological sciences participated. Participants considered the knowledge gaps related to the incidence and epidemiology of environmental infectious diseases, dynamics of human pathogens in our surroundings, ways to alleviate environmental infectious diseases, research needs in the field, and education and communication issues. Recommendations were made for how to proceed on these fronts.

Environmental pathogens are defined as microorganisms that normally spend a substantial part of their lifecycle outside human hosts, but when introduced to humans cause disease with measurable frequency. They are borne in the water, soil, air, food, and other elements of our surroundings, and they affect almost every individual on the planet. Their adverse effects on human health and productivity cannot be controlled without first obtaining a thorough understanding of their environmental niches, their incidence, and the epidemiology of the diseases they cause. To achieve this understanding, surveillance of the environment to determine the numbers and distribution of environmental pathogens is needed, as is research into the microbial virulence and host factors that enable microbes to invade and damage human hosts.

The key difference between environmental pathogens and other human pathogens is their ability to survive and thrive outside the host. Their widespread occurrence in the environment makes them difficult to monitor and control. Inroads have been made to understand the persistence of these organisms in the environment, the reservoirs they inhabit, the ways they exchange virulence factors, and their diversity, but a great deal more research is needed. By grouping together phylogenetically diverse organisms under the umbrella of "environmental pathogens," it is hoped that the topic can gain the critical mass needed for sustained progress.

Colloquium participants examined other research needs for the field, including the diagnostic and environmental technologies that will be necessary for taking the next steps. It was agreed that because of the complex nature of studying organisms that can exist in the environment and in human hosts, work in this area is best carried out in an interdisciplinary fashion with coordinated input from medical, molecular, and environmental microbiologists, specialists in host responses, epidemiologists, ecologists, environmental engineers, and public health experts. The development of improved diagnostic techniques is critical for accurate assessment of health risks and potential human or animal population impact associated with environmental pathogens.

If the impacts of these diseases are to be effectively controlled, the techniques used to monitor and control infections by environmental pathogens—including interventions, exposure controls, drugs, and vaccines—require improvement. The processes surrounding drug and vaccine development must be tailored to the special problem of environmental pathogens, which often strike small numbers of individuals or individuals in less developed areas of the world and, therefore, offer less potential for drug development profit than more common diseases. A challenge exists, therefore, in meeting the need for targeted, specific interventions, including development of drugs and vaccines for infections by environmental agents, in the face of a lack of financial incentive for development of these tools.

Finally, because the impacts of environmental pathogens can be felt by almost every person on the planet, the public needs to be better informed of their presence and risks. In too many cases, dissemination of information is relegated to the popular media. Professional societies can play an important role in educating the public as to the quantifiable risk posed by environmental pathogens and in encouraging critical interactions between scientists to move the field forward.

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Introduction

In July 1976, over 4,000 World War II veterans from all over the United States converged on the Bellevue Stratford Hotel in Philadelphia for the bicentennial convention of the American Legion. A week after they arrived, several Legionnaires, as they are known, began to develop the same symptoms: chest pain, fever, lung congestion, and pneumonia. Influenza was ruled out. Public health officials, faced with mounting public anxiety, were forced to admit that the cause of the disease could not be identified. After months of investigation, the causative agent of the disease was found to be a common bacterium, later named *Legionella pneumophila,* often found in natural aquatic systems. Somehow, *L. pneumophila* had found its way into the air conditioning cooling towers at the Bellevue Stratford, enabling it to be spread as an aerosol throughout the hotel. A total of 221 hotel visitors eventually developed the disease, which was named for its first recognized victims. Today, Legionnaires' disease continues to strike between 8,000 and 18,000 people in the United States every year, usually in the summer and fall months. Also known as Legionellosis, the disease kills 5%-30% of those afflicted.

In the summer of 1999, a new disease arrived in United States. Victims suffered symptoms that ranged from mild flu-like symptoms to encephalitis, or swelling of the brain, a condition that is often fatal. The causative agent was identified as the West Nile Virus, a mosquito-borne pathogen endemic to Africa, the Middle East, and central and southern Europe. Just five years after the first U.S. cases were identified, West Nile Virus infections have been reported in all continental United States, except Oregon and Washington. In the 2003 mosquito season alone, 9,862 West Nile cases were reported to the Centers for Disease Control and Prevention. Over 260 of these individuals died as a result of their infections.

Every year, thousands of Americans develop a parasitic infection that can bring on diarrhea, stomach cramps, vomiting, and fever. The organism responsible, *Cryptosporidium parvum*, is a common parasite that resides in food, drinking water, and recreational waters. Chlorine-resistant strains of *Cryptosporidium* have been isolated from swimming pools with increasing frequency in recent years. Cryptosporidiosis is now considered one of the most common waterborne diseases in the U.S. and abroad.

These organisms have something in common. They are all environmental pathogens—organisms that normally spend a substantial part of their lifecycle outside human hosts, but when introduced to susceptible humans cause disease with measurable frequency. The world around us has a complex and dense content of microbes, including parasites, fungi, bacteria and viruses, and only a tiny fraction have been cataloged. Most cannot be grown in the laboratory today. The vast majority of these microbes are not capable of causing human disease, but the few microorganisms referred to as "environmental pathogens" pose significant threats to human health.

Virulence is the result of an evolved strategy for replication within a host that unavoidably causes pathology, e.g., because the preferred site for persistence or replication within the host is a "privileged" site, or because the evolved mechanisms for subverting or avoiding host defenses result in host damage. These replication strategies are rare among organisms that have not evolved in close contact with humans or closely-related hosts. However, a number of known human primary pathogens (those that commonly cause disease in normal hosts) and opportunistic pathogens (those that only cause disease in impaired hosts) exist primarily in the external environment, and there are reasons to believe that there are also currently-unrecognized pathogens that reside primarily in the external environment. These environmental pathogens cause disease in normal or immunocompromised humans when acquired from food, air, water, soil, living reservoirs, and vectors.

These threats to human health can only be assessed in a comprehensive multidisciplinary context in which ecology, epidemiology, and emerging areas in environmental engineering and microbiology are integrated. This combined approach can yield immediate and long-term health benefits by mitigating established environmental risks, identifying risky situations for disease emergence, and finding the causes of diseases of unknown etiology.

Environmental pathogens can be found in almost all the microbial phylogenetic groups, including bacteria, protists, and viruses (See Table 1).

Where Environmental Pathogens Are Found

Microbes surround us. They exist on almost every surface and in almost every liquid, and we interact with them continually. Environmental pathogens occur in a range of environments that, for practical purposes, can be divided into seven habitat types: water, food, soil, air, vectors, living reservoirs, and products of human activity.

- **Aquatic Environments:** Many environmental pathogens, including *Legionella pneumophila*, *Mycobacterium avium* complex (MAC), and *Vibrio cholera* thrive in aquatic environments. Environmental pathogens can exist in human drinking water supplies, recreational water (including fresh water, sea water, and even chlorinated systems), wastewater, air conditioning cooling towers, recirculating hot water systems, and other water systems.

- **Food:** Food can also serve as a habitat for environmental pathogens. Today, the picture of environmental pathogens in food is complicated by the global network of food supply and transportation. Changes in food harvesting, processing, handling, and livestock feeding practices can introduce new routes of infection and new pathogens to the food supply. Foodborne pathogens include *Listeria monocytogenes*, *Escherichia coli 0157:H7*, and *Campylobacter jejuni*.

- **Soil:** A number of human pathogens, including the common fungal pathogens *Histoplasma*, *Coccidioides*,

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and *Aspergillus fumigatus*, can spend part of their life-cycle in soil. Soil-borne pathogens can be affected by soil saturation, local geography, and by climatic and other environmental disturbances.

• **Air:** Pathogens in soil or other environments may also become airborne and can be found in indoor or outdoor air. Climatic events, like dust storms, can distribute airborne pathogens on a global scale.

• **Vectors:** Pathogen vectors are defined as organisms that play an active role in transmitting a pathogen. For human diseases, vectors are usually biting insects, including mosquitoes, fleas, and ticks, which can transmit West Nile Virus, plague, and Lyme disease, respectively. Vectors may also serve as reservoirs (see below). Various arthropod vectors (e.g., mites, sand flies, and mosquitoes) can transoverially transmit pathogens from one generation to the next so that the next generation is able to transmit at their initial blood feedings.

• **Living Reservoirs:** Living reservoirs are organisms in which a pathogen lives and multiplies without damaging the host. Reservoirs may include vectors, or may include organisms that do not actively participate in transmission of the disease to humans. Beavers, for example, can harbor the parasite *Giardia lamblia* without exhibiting signs of illness. Life in nonhuman

reservoirs may help some pathogens to maintain their abilities to infect humans.

• **Products of Human Activity:** Products of human activity, including dwellings and fomites (objects on which pathogens are deposited and transmitted to

Table 1: Examples of common environmental pathogens, the diseases they cause, and the major clinical signs of infection

	Pathogen	Disease	Clinical Signs*
Bacteria	*Vibrio cholerae*	Cholera	Diarrhea
	Vibrio parahaemolyticus	Gastroenteritis; wound infection; septicemia	Diarrhea, abdominal pain, nausea, vomiting, headache, fever
	Campylobacter species	Gastroenteritis	Diarrhea
	Mycobacterium avium complex (MAC)	Pulmonary, localized, or disseminated MAC	Lymphadenitis and tuberculosis-like diseas
	Coxsiella burnetti	Q-fever	Pneumonia
	Legionella species	Legionnaires' disease	Pneumonia
	Rickettsia typhi	Endemic typhus	Fever
	Bartonella henslei	Cat scratch disease	Swollen lymph nodes, fever
	Borrelia burgorferi	Lyme disease	Fever, rash, arthritis
	Listeria monocytogenes	Listeriosis	Gastroenteritis, meningitis, spontaneous abortions, neonatal sepsis
	Bacillus anthracis	Anthrax	Fever, respiratory illness
	Burkholderia cepacia		Pneumonia
Viruses	SARS virus	Severe Acute Respiratory Syndrome	Pneumonia
	Influenza viruses	Flu	Fever, cough, headache
	West Nile virus	West Nile fever, encephalitis	Fever, headache, altered mental status
	Hantavirus	Hantavirus pulmonary syndrome or Hemorrhagic fever	Cardiopulmonary or renal malfunction
Eukaryotes	*Histoplasma capsulatum*	Histoplasmosis	Pneumonia
	Coccidioides immitis/posadasii	Valley fever	Pneumonia, chest pain, fever, cough, malaise
	Cryptosporidium parvum	Cryptosporidiosis	Diarrhea
	Cryptococcus neoformans	Cryptococcosis	Meningitis, fever, headache

humans) can also be home to environmental pathogens.

In addition to the familiar suite of microbes with which we are confronted on a daily basis, altered human interactions with the environment can lead to exposure to new pathogens. For example, the organism responsible for Lyme disease, *Borellia burgdorferi*, has come into close proximity with human populations in recent decades as suburbanization of wild lands and increased deer populations has forced a closer-than-comfortable relationship between humans and deer. As a result, the deer ticks that spread Lyme disease are now familiar, even in city parks and backyards. The incidence of Lyme disease has now reached epidemic proportions in some regions. Other changes that have brought new microbes to our doorstep include advances in transportation, which have allowed the movement of people, products, foods, and microbes at an unprecedented pace. Global climate change also can be expected to change the landscape of environmental pathogens by altering surface water temperatures and destabilizing weather patterns.

Incidence and Epidemiology of Environmental Diseases

In studying diseases caused by environmental pathogens, scientists are sometimes forced to battle the notion that "what we don't know can't hurt us." Environmental pathogens, which strike many millions of people every year, certainly can hurt us, especially if we remain ignorant about their numbers and patterns of infection. Research into the incidence and epidemiology of environmental diseases is needed to understand the organisms and mechanisms that perpetuate disease and to better gauge the scope of the threat posed by environmental pathogens. These data, in turn, can be applied in risk assessments to develop appropriate responses for combating pathogens in the environment.

Surveillance

Surveillance is the key to understanding the incidence and epidemiology of environmental diseases. Accurate counts of the abundance of pathogens in natural environments and the number of cases of environmental disease are needed to enable researchers and public health officials to assess the true scope of the threat posed by these organisms. Surveillance must, therefore, include epidemiological surveillance (systematic collection of the number of cases of human or animal disease) and microbiological surveillance (determining the number of a given organism in the environment). A great deal of useful information can be assembled about a given environmental pathogen or disease from a combined approach of active and passive surveillance and point prevalence studies.

Microbiological surveillance for environmental pathogens should be targeted to specific environments at specific times. Targeting surveillance efforts appropriately requires knowledge of pathogen ecology and of the likely locations of human exposure. Environmental surveillance is needed not only for the known pathogens, but for the ranks of environmental pathogens we have yet to name and characterize. New tools may be required and existing tools improved to detect these organisms. Today, many of the methods available for detection are modifications of clinical procedures developed for other diseases and are not effective in detecting the low densities of pathogens found under most environmental conditions. Moreover, detection methods are needed that can deliver information about the virulence of targeted pathogens.

Methods for reporting and tracking of environmental infectious diseases (e.g., epidemiological surveillance) are in need of improvement. Disease reporting mechanisms in hospitals need to be enhanced to allow scientists and public health officials to track disease trends in real time. Many nations, including the United States, lack a single computerized system for tracking and collecting information on emerging outbreaks of environmental diseases. Such a system would enable the detection of spikes in the incidence of infectious disease and the detection of the emergence of particularly virulent strains. In the absence of a centralized tracking database, better use should be made of existing tools, such as PulseNet, Promed, and the Emerging

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Infections Network. In addition, regional centers are needed on the state level to serve as repositories of the records of all cases of infectious disease. These centers could report to the state or to the Centers for Disease Control and Prevention.

Other important points in surveillance of environmental diseases include monitoring spikes in infections abroad and tracking trends in the environmental diseases of animals, particularly livestock. Also, the emergence of new syndromes that lack an identifiable cause should be investigated thoroughly to determine whether a new infectious environmental agent may be involved.

Surveillance and Virulence Factors

The natural environment is rife with microorganisms, the vast majority of which pose no threat to human health. When conducting surveillance to determine the numbers and types of pathogens present in the environment, it is of paramount importance to distinguish harmless microbes from those that can make us sick. The fundamental difference between them is the expression of virulence factors—cellular products that enable a microbe to colonize or harm its host. Pathogens possess virulence factors; non-pathogens either do not possess them or they possess forms that are not active against humans. The types of virulence factors and their levels of expression can vary greatly between strains. Hence, with the right information in hand, virulence factors can be used to discriminate between human pathogens and non-pathogens and, in some cases, can identify the degree of virulence of pathogenic strains. This predictive strategy has been termed "Virulence Factor-Activity Relationships" (VFAR), similar to the Structure-Activity Relationships (SAR) used to predict the effects of chemical compounds in the environment.

The key virulence genes of environmental pathogens are rarely known. This information is vital to ensuring that the correct organism is targeted in environmental surveillance efforts and in efforts to quantify the risk associated with surveillance results. The dual use of genotyping and phenotyping tools is a feasible goal and could help to identify virulence factors. For example, if the virulence factors associated with a given disease were identified, cutting-edge tools like quantitative genomics could be used to determine the magnitude of the hazard in a specific environment. This approach, measuring the amount of a virulence-associated gene or gene product in the environment, offers an advantage over measuring the numbers of a given pathogen, since not all strains of an organism are equally virulent and a "false positive" identification would conclude that a weakly pathogenic strain poses a high level hazard.

The ability to measure virulence factors can be a powerful resource, since an understanding of the dynamics of the movement of virulence factors in the environment can provide insights into environmental disease in general. However, this tool must be applied with great caution. Many virulence factors are multi-functional, e.g., adhesion factors that may function in the colonization of living as well as non-living surfaces. Moreover, many virulence factors are present and expressed in animal pathogens that do not pose threats to humans. In the absence of information about specific virulence factors that are highly predictive of adverse effects on human health, strain genotyping methods could be applied to identify particular genotypes associated with disease.

Overall, better real-time methods are needed for enumerating the pathogens associated with key diseases. Also, tools are needed that can distinguish between the environmental species responsible for disease (for example, pathogens within fecal contaminants of water and food) from non-pathogenic microbes and can quantify pathogen numbers.

Bioterrorism

The question of intentional release occasionally arises when discussing environmental pathogens because of the relative ease with which some microbes could be employed to create a potential or real threat or even result in disease or death. Environmental pathogens can infect scores of individuals from a single source. They do not necessarily rely on infection by person-to-person contact or on engineered dispersal as is the case with other pathogens. Better information on environmental pathogens is needed to rapidly determine whether a given outbreak is the result of a natural occurrence or an intentional release and to allow public health and emergency officials to respond appropriately.

The fundamental information needed to investigate cases involving suspicious spikes in the incidence of an environmental disease is the baseline rate of infection. This information is not always available, and this limits the ability to investigate seemingly unusual numbers of illness.

The possibility of intentional introduction also makes it necessary to have a grasp of the genetic variability of natural populations of environmental pathogens. When infection rates rise, clinical isolates can be compared against known strains to determine whether the strain responsible for the outbreak can be matched with an environmental source. Such analysis can also identify unusual combinations of genes that might be the hallmark of a biologically engineered pathogen.

Culture Collections

Efforts to monitor the incidence and epidemiology of environmental diseases are greatly facilitated by the availability of strain collections. Among other advantages, the investigation of possible acts of bioterrorism involving environmental pathogens and the identification and tracking of new virulent isolates are facilitated by the comparison of new isolates with previously isolated strains.

Unfortunately, maintenance of strain collections is an expensive proposition. Some of the operating costs can be defrayed by streamlining the process of strain trans-

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port between laboratories. Currently, the regulations and required documentation pertaining to strain transport are time-consuming and expensive to fulfill. Reforming the collection and transport of strains between facilities could significantly aid efforts to fight disease. The biggest challenge, however, rests in the cataloging and maintenance of strain collections. A critical need could be met if relevant data pertaining to each bacterial strain within a collection could be catalogued and stored in a manner that facilitated data access and retrieval by a broad community of scientists and health care professionals. Ready access to available strains would significantly enhance the identification and comparison of new isolates with those previously identified.

Climate Change and Environmental Diseases

Climate affects environmental pathogens and diseases in a number of known and, probably, unknown ways. It is anticipated that global climate change will have an impact on these pathogens, creating new problems and diminishing old ones. In uncovering the effects of climate change, it will be necessary to continue to collect accurate disease surveillance data so that weather events can be linked to changes in incidence. Climatological data (precipitation, airborne particulates, surface water temperature, water pH and dissolved oxygen) and microbiological data (disease incidence and microbiological counts in environmental samples) will need to be assessed together to identify correlations.

Improving communication among researchers concerned with environmental pathogens and professionals in other fields will be helpful in uncovering the effects of climate change on environmental disease. The technologies used in remote biosensing, for example, could be adapted to tracking climate and diseases. This will require that the communication gap between biological scientists and engineers be bridged.

Predicting Outbreaks

Predicting outbreaks of environmental disease poses a major challenge to scientists and health workers. Retrospective analyses of data from recent outbreaks can be used to determine the conditions that preceded spikes in incidence, offering hints as to what might trigger the next outbreak. Such modeling efforts may make it possible to prevent outbreaks or at least to allow officials to prepare an appropriate public health response. Also, monitoring trends in human health across the globe can lend insights into the global dissemination of diseases and can allow public health officials to prepare for diseases that may be on the way.

Many recently identified human diseases (for example, Lyme disease) have been linked to animal reservoirs. Therefore, more aggressive tracking of zoonotic diseases may help to predict outbreaks of new diseases of humans.

The Lives of Human Pathogens in the Environment

The defining feature of environmental pathogens—their normal existence outside the human body—is precisely the trait that makes them difficult to study. Microscopic organisms can be difficult to identify in the environment and separating pathogenic organisms from nonpathogens is usually an extremely complicated task. However, the reservoirs of these pathogens, their persistence in these nonhuman habitats, their resistance to natural and man-made antibiotics, their virulence factors, and their existence in biofilms must all be understood in order to understand their biology and tackle the threats environmental diseases pose to people around the world. *In situ* studies, model organisms, and model systems may be useful tools for approaching these unknowns.

Reservoirs

Locating the environmental reservoir of a pathogen can be a difficult endeavor. However, identifying the source of a pathogen is the key to controlling infection rates. Identification of reservoirs requires multidisciplinary efforts involving epidemiologists, ecologists, Geographic Information Systems (GIS) specialists, microbiologists, and others.

Persistence

Unlike pathogens that are passed by person-to-person contact or by animal-to-person contact, environmental pathogens must find ways to survive, and possibly to reproduce, in the soil, water, air, and other materials that surround us. They accomplish this through dormancy and the formation of spores, cysts, biofilms, or alternative morphotypes. In some cases, they are part of the normal microbiota in soils and waters, where they grow and divide like any other predominantly environmental organism. Many techniques for survival serve a second purpose, in addition to the ability to cause disease in the host. For example, *Legionella pneumophila* replicates in the environment by colonizing the cells of aquatic amoebae, an ability that may allow the parasite to infiltrate the cells of human tissues. The mechanisms of environmental persistence are understudied and deserve more research attention.

Antibiotic Resistance

It has been said that the world is a dilute solution of antimicrobial agents. Many such compounds in the environment are produced naturally, most commonly by environmental microbes. All living things make substances to protect themselves from harmful microbes, and these substances exert constant selective pressure on microorganisms within their influence. Other antimicrobial agents in the environment originate from human sources, such as the agricultural use of antibiotics and the discharge of byproducts of antibiotic production. It is not surprising, therefore, that antibiotic resistance has been noted in a number of environmental pathogens that are unlikely to have developed this resistance through clinical exposure.

Some of the ways microbes have found to circumvent the effects of antibiotics in the environment may also confer resistance to antibiotics used in treating human infections. For example, in order to eliminate toxic agents inflicted on them by other organisms, microbes in the

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environment may over- express the genes that encode efflux pumps, a move that would also render many human-made antibiotics ineffective.

Antibiotic resistance could also be acquired through development of resistance to other substances, like metals, or by horizontal gene transfer between organisms. Horizontal transfer is especially troubling in cases where new resistances can be introduced to environmental pathogens from organisms that acquired resistance from human use of antibiotics. More work is needed to determine the extent of antibiotic resistance in environmental pathogen populations and to distinguish between intrinsic drug resistance acquired in natural environments and human-induced resistances acquired in clinical settings. New drug development is needed to control the human health effects of some intrinsically drug resistant environmental pathogens.

Virulence factors

Virulence factors, the abilities that pathogens use to invade or damage a host, are found in all pathogens, but how did they evolve in organisms that spend large parts of their lifecycles in the environment? As with the acquisition of antibiotic resistance, it is unlikely that a single answer to this question exists, but a number of hypotheses and relevant findings can be put forward for consideration.

Parallel selective pressures on pathogens in the environment and in human hosts may have facilitated the crossover of these organisms from the environment to the human body. The formation of biofilms by certain microbes, for example, is an ecological strategy that improves their persistence in certain habitats. This adaptation could help endow environmental microbes with virulence, since biofilm formation in the human lung and other tissues causes illness and often prevents attack by immune defenses.

Adaptations to living within a non-human host or vector may also confer virulence. *Legionella pneumophila*, for example, lives within the cells of microbial eukaryotes, an adaptation that may have enabled this organism to adapt to life within human macrophages. *Vibrio cholerae* colonize the surface of zooplankton copopods using bacterial factors that also contribute to colonization of the human intestine. Possible mechanisms leading to adaptations that promote virulence include gene reassortment, lateral transfer, and mutational drift. There is grave concern, for example, that co-infection of swine with strains of human and avian influenza will lead to viral gene reassortments that could result in new epidemic strains. A recent example of this is the emergence of avian influenza in many parts of the world.

Environmental microbes could also acquire virulence factors via horizontal transfer from pathogens in the environment. For example, type III secretion factors and certain bacterial toxins, like Shiga toxins are readily exchanged by horizontal transfer and may be changing hands among environmental microbes. Transfer of virulence factors can be mediated by phages and plasmids.

Characterizing the distribution and flow of the genetic material that enables virulence should be a research priority. Investigators should seek to evaluate the roles of environmental influences and human activities (including specific activities like animal husbandry) that may enhance the exchange of genetic material (and hence potential virulence determinants) within microbial populations. Other work should be aimed toward uncovering whether distinctions exist between environmental reservoirs of pathogens (where high densities of pathogens can be found) and reservoirs of virulence (where high densities of the genes that enable microbes to become pathogenic are found). Transmissible genetic material may be the key to making certain environmental organisms pathogenic. Understanding the movement of these genes in the environment may help in predicting the areas of greatest risk to human health.

Intraspecific Diversity

The designation "species" is difficult to apply to predominantly asexually-reproducing organisms like microbes; microbial strains identified as belonging to the same species can differ greatly from one another. In environmental pathogens, these differences can have critical consequences for virulence, transmissibility, environmental persistence, and patterns of environmental distribution. Research on environmental pathogens needs to address intraspecific diversity in order to understand the ecology of these diseases and to design and implement strategies for their control. Microbial surveys, databases, and sequence analysis are valuable tools in this effort. Currently, there is a need for targeted inventories of known pathogenic bacteria and their close relatives and for a renewed effort to survey viruses, fungi, and parasites in the environment.

Surveillance data should be appropriately housed in databases, including background information on the organisms present in specific habitats. This information can be analyzed to identify subpopulations of microbes associated with virulence. Sequence data from surveillance efforts can be used to determine whether increases in virulence are genetic or whether they are the result of environmental influences, such as an altered route of exposure. Once differences between more virulent and less virulent strains of the same species have been identified, efforts should be made to develop simplified laboratory methods for predicting the degree of virulence of unidentified strains.

Biofilms

In the environment, microbes, including environmental pathogens, often form assemblages known as biofilms. Biofilms likely play roles in ensuring the persistence of environmental pathogens, but little is currently known about the specific ways they benefit from these associations. Research is needed to uncover these details.

Biofilm formation can be modeled, albeit imperfectly, in the laboratory using microcosms. Naturally-occurring biofilms such as those in water pipes, on shower curtains, and on mechanical devices, can be analyzed by

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using a handful of available techniques. These include PCR-dependent methods, fluorescent in situ hybridization, and confocal microscopy. The role of biofilms in the antibiotic resistance of certain fungal pathogens, for example, could be studied in situ using biofilms on catheters or shower walls. *Legionella* biofilms are another suitable source of biofilms for study.

One difficulty in working with biofilms is the problem of collecting intact biofilm samples from the environment, as sampling often destroys the delicate structure of these films. More refined methods of biofilm collection are needed, as are methods for defining the microbial composition of biofilms.

Model Systems

Although it is wise to take a cautious approach in extrapolating findings from a model system to the wider world of pathogens in the environment, model systems have often illuminated key features of microbe physiology, adaptability, and virulence. Although no single system could represent the complexity of environmental pathogens, models can be useful for answering specific questions and for exploring potentially pathogenic mechanisms. Extensive study of selected systems has provided insights into other diseases of the same category. Studies of *Salmonella*, for example, have shed light on other zoonoses, while *V. cholerae* has served as a model for the ecology and epidemiology of other waterborne diseases.

Ideally, an infection is modeled in its natural host (defined as a host in which the pathogen can complete its development) as well as in the human host. *Legionella* species, for example, should be modeled in both amoebae and in human cells. There are advantages, however, in using host models that are amenable to genetic manipulation, such as the fruit fly *Drosophila melanogaster* or the nematode *Caenorhabditis elegans*, as these models facilitate the identification of host responses that may be important towards limiting infection. Where possible, model systems should represent the natural route of infection for that organism, as this can be an important determinant of virulence. The conditions under which virulence genes are expressed should be modeled as well. Highly virulent human isolates or strains that have caused large pandemics could be appropriate models for identifying the most dangerous genes and combinations of genes and identifying and studying virulence factors that may be common to other environmental pathogens.

Once an appropriate model system is developed and standardized for a given type of environmental pathogen, researchers and interested agencies should arrange for its use as a regional or national core resource. Such an arrangement would enable study of the system by many different researchers in a standardized way and would conserve money and resources.

E Mitigating Environmental Diseases

Although environmental pathogens have proven difficult to understand and prevent, science and public health have had some degree of success in combating the diseases these organisms cause. More and better interventions are needed, however, as are new methods to control exposure.

Strategies for Interventions

Interventions to reduce infections from environmental pathogens can tackle the problem from a number of different angles. Simple hygiene and cleanliness measures are often the first line of defense. Such basic practices as wearing protective clothing, improving sanitation and waste disposal, and proper food hygiene are essential for preventing infections. Even makeshift practices like filtering drinking water through clothing or fabric have been shown to be effective in resource-limited settings. This was illustrated by the recent demonstration that filtering drinking water through sari cloth effectively removed copepod-borne *Vibrio cholerae*, resulting in a measurable decrease in cholera in rural Bangladesh settings. Judicious handling and care of potentially infectious animals is another simple intervention.

More complex interventions can take on other strategies. One approach is to target the vectors of disease, for example, the insects that transmit pathogen to humans. Other interventions seek to destroy the specific habitats where infectious agents or their vectors flourish. Draining standing water to reduce mosquito populations is an example of this type of method. Avoiding exposure to the sources of infection, like reservoir species and suspected habitats, can also be extremely effective in reducing infections. However, the monetary and environmental costs of such measures must be weighed against the benefits, especially when considering relatively rare opportunistic infections.

Developing Interventions

The design and implementation of new interventions to combat environmental pathogens should be based on a careful assessment of risk. The foundation of such an assessment requires a hazard evaluation and exposure assessment of environmental pathogens. Dose-response analysis and risk characterization should also be determined in order to properly address risk, however it is not currently possible to address these two points for environmental pathogens. A risk assessment framework for most environmental pathogens has yet to be designed, but would prove highly valuable for the field.

In the absence of a framework with which to establish risk-based priorities for interventions, other criteria must be implemented. The first line of defense should be composed of relatively simple and inexpensive interventions that reduce the exposure of susceptible humans to environmental pathogens. These interventions should be consistent with the ecology of the organisms. Uncomplicated, proactive approaches are often much more effective than interventions that involve monitoring and response. For example, the prevalence of L. pneumoniae

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could be effectively reduced in many water systems by initiating a heating routine, a much simpler approach than water sampling, analysis, and treatment. If such straightforward methods fail to sufficiently protect human health, then the next set of interventions should be aimed toward reducing existing practices that encourage the proliferation of pathogens or encourage contact with the pathogens. For example, in certain cases agricultural practices could be altered to prevent the growth or spread of pathogens to nearby residents or consumers. . Alternatively, susceptible people could be encouraged to modify their behaviors and daily routines during times in which these agricultural practices are going on.

Once an intervention is devised and ready for implementation, surveillance needs to be carried out to determine the burden of disease before and after execution of the new measures.

Controlling Exposure

Controlling exposure to environmental pathogens can reduce infections under some conditions, and it may be the only line of defense available against pathogens such as viruses that do not lend themselves to antimicrobial therapy. However, the full consequences of exposure controls are not currently known and are impossible to predict. For example, natural exposure to environmental mycobacteria, some of which cause disease in susceptible people, is thought to impact the immune systems of susceptible and non-susceptible people alike. It is possible that such exposure confers some level of resistance to infection by the related professional human pathogen, *Mycobacterium tuberculosis*. Thus, wholesale exclusion of such organisms from human exposure could have favorable or unfavorable consequences on human health. More study is needed to adequately describe human responses to environmental microorganisms and their products, like endotoxins. Human responses such as immunity development and tolerance, the acquisition of specific and heterologous immunity, and the development of hypersensitivity and autoimmunity all need to be more fully characterized.

Efforts to control exposure can also have adverse effects on the environment. The use of ozone in disinfecting municipal effluent, for example, can break down dissolved organic materials into compounds that feed microbial blooms in receiving waters. In light of the unknowns about the effects of reducing exposure to environmental microbes, indiscriminate application of non-scientifically based control procedures is not acceptable.

New Drugs for Combating Environmental Pathogens

For many environmental infections, control at the level of exposure is not practical or cost effective, and antimicrobial therapy is the most feasible line of defense. Unfortunately, many existing antibiotics that are effective against well-known pathogens are less so against their environmental cousins. For example, drugs used to treat tuberculosis are not effective against environmental mycobacteria. New antibiotics targeted at treatment-refractory environmental pathogens are badly needed. In many cases, this will require new information about the basic biology of these organisms. Such information can be used to aim antibiotics at individual environmental microbes based on their unique properties.

Vaccines

There is considerable expense involved in developing vaccines; studies of efficacy and safety must be carried out in large populations of volunteers, requiring tremendous commitment of time and resources. Because of these costs, other routes of prevention, including exposure prevention and disease treatment, should be thoroughly explored first to lower the incidence of disease. However, certain criteria favor vaccine development as an effective strategy. These include:

- When risk analysis concludes that the incidence and severity of the disease are sufficiently taxing on human life and productivity to justify the investment, or
- When few or no treatment options are available for the disease, or
- When special subpopulations are at high risk from the disease and would benefit significantly from a vaccine.

If recovery from the disease confers immunity to an individual then vaccine success is likely. However, not all infections confer immunity. Those that do not may be difficult to control with vaccines unless improvements can be made.

Research opportunities exist in examining the role of innate immune responses to environmental pathogens. Understanding these phenomena could enable manipulation of innate immunity in an effort to combat infection without the aid of antibiotics or vaccines.

In light of the fact that many environmental pathogens appear to target individuals with weakened immune systems, a need exists for environmental disease vaccine strategies for immunocompromised populations. Lessons for this effort may be learned from experience in vaccinating HIV patients.

Problems in Developing Drugs and Vaccines for Environmental Pathogens

The current model for drug and vaccine development seeks to address the impacts of common diseases efficiently. In this system, diseases are recognized and defined by physicians, and the public health community defines their impact and the market to which drugs would be appropriate. In the United States the National Institutes of Health (NIH) as well as private industry funds needed research for discovering the drugs or vaccines to address these diseases, and industry follows up with drug and vaccine development, marketing, and distribution.

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This arrangement breaks down in the case of diseases that affect only a small number of people, as is true of many environmental diseases. Such diseases, which can occur at consistent, low rates in the population or in punctuated bursts, present a lower opportunity for profit than more common diseases, and this profit margin may not be sufficient to overcome the costs of seeing these products through safety testing and other required stages. Although modern research can and does provide meaningful drug candidates for environmental diseases, drug development does not proceed at a corresponding pace because of the costs involved. Moreover, the current form of the "orphan drug law", which offers financial incentives to companies that develop drugs for rare diseases, does not always bring needed drugs to market. As a result, environmental diseases often fall through the cracks in the system and may not be addressed with drug or vaccine development.

Solutions to the problem of getting drugs and vaccines for environmental diseases to market must be sought outside the usual routes of development. It may be desirable to involve smaller pharmaceutical and vaccine companies in developing remedies for environmental diseases, as these firms may have more rapid development paths and, in some cases, stronger motivation to carve out "niche" markets.

F Needs for Environmental Pathogen Research

Although the technologies and research available to date have brought us no small measure of success in understanding and combating environmental pathogens, new techniques and innovative research are needed to answer the challenges of the future.

Diagnostic and Environmental Technologies and Sensors

There are common needs inherent in detecting pathogens in clinical and environmental samples. Both endeavors require sensitive, specific, rapid, and simple tools for detecting pathogens and differentiating them from closely related species. Often, quantitative tools are also necessary to evaluate the threat posed by a given organism.

A number of polymerase chain reaction (PCR) based techniques have been developed to meet these needs in recent years, but difficulties can arise in their application and in the interpretation of results. For example, most PCR-based methods cannot provide an understanding of the viability of the organisms under scrutiny in environmental or clinical samples, and contamination by impurities or non-target nucleic acids can muddle testing results. Also, in dealing with environmental samples, it can be difficult to design specific probes for the target organism without complete knowledge of the background microbial population. In the absence of complete information, the probe and the PCR-based analysis may accidentally target avirulent strains of the organism. For this reason, detection of environmental pathogens should never rely on a single probe, and rarely on a single method. Hence, the current selection of PCR-based methods is not enough; more refined methods for detecting environmental pathogens are needed.

New technologies that should be developed or enhanced for exploring environmental pathogens and diseases include:

- Nucleic acid characterization, either by direct sequencing of DNA isolated from environmental sources or larger scale genomic analyses of cloned molecules
- High throughput flow cytometry
- Techniques for measuring the characteristics of single cells, including metabolic activity measurements,
- Real-time techniques to measure the viability, infectivity, and metabolic activity of environmental pathogens, and
- Technologies that employ microbial sentinels as biosensors of pathogen activity.

In addition to these technologies, there is a need to develop species-specific sensors to monitor known pathogens in the environment. Ideally, these sensors could be placed permanently in the environment of inter-

est, collecting real-time data sensitively and accurately and distinguishing between the signatures of pathogens and their close relatives. Toward this end, it may be cost effective to expand the mission and capabilities of the existing BioWatch sensor network, which is deployed to detect bioterror agents in 31 major cities of the United States. The benefits of this $60 million dollar-a-year network could be significantly enhanced if it was used to monitor naturally occurring infectious agents as well as man-made ones. Data gathered by this network could be integrated with climatological information and other environmental trends in large scale studies that could not be conducted in any other way.

Cultivation-independent methods and philosophies of investigation need to be adapted to the world of clinical microbiology. Hurdles to this transfer include the lengthy approval processes by clinical oversight bodies, difficulty fitting in new methods with on-line high throughput platforms in use, and convincing insurance companies to include new methods under health care coverage.

Although nucleic acid-based techniques and other new technologies offer a great deal of promise for the detection and identification of environmental pathogens, the need to cultivate some organisms must not be overlooked. Cultivation-dependent methods of study represent an important complement to non-cultural techniques as the availability of a living, growing pathogen is a prerequisite for answering many questions about virulence. The sophistication of cultivation techniques has increased considerably in recent years, but unfortunately many of these new approaches have yet to be introduced or accepted in routine clinical laboratories or reference labs. The continued improvement and dissemination of cultivation methods remains a critical need.

Getting Technologies to Market

In developing new technologies for the study of environmental pathogens, it will help to encourage feedback between developers and end-users. Such an effort would serve to inform continued development and adaptation of appropriate technologies. This will also require communication and collaboration between microbiologists and industrial technologists.

Interdisciplinary Research

Research on environmental pathogens and diseases requires the input of experts in multiple disciplines, including microbial ecology, genomics and bioinformatics, environmental sensor technologies, epidemiology, medicine, and other fields. Effectively addressing almost any single issue related to environmental pathogens requires the input of experts in multiple disciplines. These investigations also frequently require the assistance of theorists, database specialists, and data mining specialists. Consequently, all areas of investigation into environmental pathogens would benefit from using a multidisciplinary approach. Reservoir analysis, for example, in which the sources of pathogens in the environment are identified and described, requires the input of environmental and clinical microbiologists, ecologists, epidemiologists, engineers, and (depending on the reservoir) industrial hygienists. Similarly, investigations of outbreaks of environmental infections would benefit from the contributions of clinical and molecular microbiologists, physical chemists, water systems technicians, food purity technicians, air conditioning experts, epidemiologists, and analytical chemists.

Communications bridges are particularly needed to bring together two seemingly independent spheres of microbiology: pathogenesis specialists and environmental microbiologists. Fostering more meaningful interactions between these groups would do more than anything else to expand the state of knowledge of environmental pathogens. To further the goal of improved interactions, it may be advisable to arrange a meeting of 100 to 150 professionals to explore the ways environmental microbiology can be used to provide insights into environmental pathogens. Participants could include investigators interested in pathogenesis and environmental microbiology, investigators working with environmental pathogens, clinical microbiologists, and investigators with expertise in pathogen-rich environments. In the interest of garnering the contributions of many different types of investigators, the participants should represent a mix of senior investigators, postdoctoral researchers, and graduate students.

Long-term Effects of Environmental Diseases

The long-range impacts of environmental diseases on human health merit further investigation. The effects of infection may be shown to include impacts on mental health, immune function, and other parameters. The economic and social impacts of environmental disease should be researched as well.

Ecology of Environmental Pathogens

Although the human disease aspects of environmental pathogens are becoming better defined every year, the lives these organisms lead outside the human host remain much less clear. Research is needed to uncover how environmental pathogens survive, multiply, and evolve in the environment and how they are introduced to human hosts. These types of investigations can eventually shed light on the differences between pathogen gene expression, physiology, structure, morphology, and other activities in the environment and in the diseased host. This information has the potential to reshape our understanding of the spread of these pathogens, their evolutionary derivation, and the mechanisms by which they cause disease.

Targeted Environmental Inventories

A number of habitats where environmental pathogens are thought to thrive have yet to be thoroughly characterized with respect to the composition of their microbial communities. Targeted inventories of many environments are needed to understand the distribution and population dynamics of environmental pathogens. Particularly critical is the generation of viral inventories

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and determining the stability of different viral types in different habitats. Some locales where environmental inventories are needed include:

- Indoor habitats
- Drinking water (both optimized, ideal systems and real-world systems)
- Public buildings and construction materials
- Animals, and
- Biofilms with which humans come in contact.

Inventories are also needed of the endogenous microflora of human skin and mucosal surfaces, including the nose, mouth, and gastrointestinal tract. A two-pronged approach of broad surveys combined with targeted tracking of specific organisms would answer outstanding questions about how and when humans acquire new strains of commensals and potential pathogens and when pathogens cause disease and when they assimilate with the normal flora.

Diversity Surveillance

Questions of diversity are important to our understanding of endemicity, environmental monitoring results, and pathogen evolution. The natural diversity of many environmental pathogens is, at best, little understood Surveillance to better describe the diversity of environmental pathogens should be carried out to bridge these gaps in our knowledge. Such efforts could uncover the environmental determinants of endemicity, helping to identify the reasons why certain diseases and pathogens are localized to specific geographic areas and aiding in the public health battle against these illnesses. Appropriately sensitive methods for differentiating strains and methods that can resolve microbes at the sub-strain level should be applied in this effort.

Surveillance is also critically needed to identify the baseline or background incidence of environmental pathogens so that perceived perturbations and spikes in pathogen populations can be put into the context of their usual patterns of occurrence. Such surveillance can tackle targeted inventories of microbes or targeted habitats relevant to public health, such as watercourses.

Database Integration and Consolidation

Currently, most databases of information on microorganisms specialize in organisms from one habitat type: either the environment or the clinical setting. Moreover, these databases curate diverse types of information, ranging from molecular information to host and habitat figures. Because environmental pathogens bridge these two habitats, both the environment and human tissues, and because different types of key information for these organisms are only found in different databases, it has been difficult to successfully integrate the full information on a given environmental pathogen. It is recommended that clinical and environmental databases be integrated and that the information technology related to environmental pathogens be better coordinated. In the U.S., a national database should be established in which all these disparate pieces of information are consolidated to full advantage for research and for public health. These databases should include information on the emergence of diseases in the interest of developing predictive capabilities for the appearance of new environmental diseases. Smaller, organism-specific models for this type of enhanced database exist; the NSF and NIH are currently coordinating efforts to compile a database on the West Nile Virus, for example. Such database development would enable the development of new models for predicting the occurrence of known pathogens and the emergence of new threats to public health.

The Human Component of Environmental Disease

Research efforts are needed to better understand the interplay of human population dynamics and environmental pathogens. For example, what are the effects of increased population on disease incidence? What are the effects of movement to population centers? By answering these and other questions, scientists can empower public health officials with a better knowledge of how population density issues impact environmental disease.

Education and Communication Issues

Environmental pathogens affect the lives of almost every member of the public. From consumers of municipal drinking water to hikers in tick country to anyone outdoors during mosquito season, the vast majority of people face exposure or even infection by environmental pathogens many times in their lives. Steps need to be taken to convey the results of research on environmental pathogens and the diseases they cause to the public and to students. Professional societies can play a powerful role in this effort.

Communicating Research Results

Environmental diseases are pervasive while understanding of microbiological topics among nonscientists remains limited. There is a great need to educate the public and policy makers in the basics about pathogens in our environment. Communicating with the lay public is most easily carried out through print media and television. The public affairs boards of interested scientific societies may be most suited to promoting these messages in the media. In order to assure that this information is conveyed accurately and the risk of infection by opportunistic pathogens in the environment is not overstated, it is important to work with journalists with specialized training in microbiology

One captivating way to convey the results of research on environmental pathogens would be a series of announcements of "success stories" summarizing the achievement of milestones in research. These stories could be communicated via a website or possibly through a television program. Campaigns like this are not only an effective way to educate the public; they also serve to capture the imaginations of children and future researchers.

Since environmental pathogens have two homes, namely, the environment and human tissues, research into these organisms must bridge two traditional schools of learning in microbiology. The schools of environmental microbiology and clinical microbiology do not often find common ground, but in order to make progress and save lives, communication among professionals in these areas and others, including engineering, hydrology, soil science, etc., must be swift and complete. More interdisciplinary contact must be encouraged, possibly by including interdisciplinary sessions centered on environmental pathogen-related topics at national scientific meetings. It is expected that interest and participation in this research will grow, and will eventually warrant convening a specialized annual meeting. By considering these diverse organisms under the "environmental pathogens" umbrella, it should be possible to gain the critical mass needed to discuss and make progress on an appreciable list of shared issues.

Integrating Research and Education

Exposure to exciting research stimulates young people's desire to pursue training in that discipline. Students are drawn to fields that are perceived as pertinent, stimulating, and revolutionary. By exposing students to the results of cutting-edge work on environmental disease, researchers can encourage the next generation of scientists to focus their energies on this important public health issue. Some exposure at the primary and secondary levels of education may be warranted. Increased attention to environmental pathogens and disease in college courses and in clinical microbiology curricula in particular is strongly advised. Education regarding environmental pathogens is best conveyed in conjunction with a component on risk and cost-benefit analysis. It should also be connected with timely issues of environment and climate change, biodefense, human population growth, and refugee movement.

Professional Societies

Professional societies play many roles in education and outreach for science. In educating schoolchildren and the general public about environmental pathogens and disease, it is best to start with fundamental messages about microbial life in order to promote the public's understanding of microbiology. By sponsoring programs to educate high school teachers in microbiology and by providing opportunities for high school students to interact with microbiologists and to do basic microbiological work, professional societies can foster public awareness of microbes and of the risks posed by pathogens in the environment.

In advancing the cause of research, interdisciplinary meetings are one highly effective way of spurring a field forward. Professional societies can sponsor meetings to encourage interactions between scientists with expertise in microbiology and professionals in other fields, to develop common ground from which to tackle the interdisciplinary challenge of environmental pathogens.

In the interest of curbing outbreaks of environmental disease, societies can also sponsor training programs to tutor primary care physicians in the recognition of environmental infectious diseases and in the reporting of unusual occurrences of disease.

A48408984

Recommendations

1. The most critical factor limiting our understanding of environmental pathogens is information on the incidence of infections by these organisms, and on their occurrence in environmental samples. Therefore, the development and improvement of surveillance and reporting strategies should be a top priority. Effective monitoring of pathogens in the environment would allow researchers to understand the baseline incidence and persistence of pathogens in areas that are considered to be at risk for harboring these organisms. Existing tools, including the BioWatch infectious agent monitoring network and various infectious disease databases, could be leveraged to fill many of these needs in a cost effective fashion.

2. Multidisciplinary research is needed to predict the effects that changes in our environment, e.g. climate change, urbanization, and new agricultural practices, may have on the frequency of diseases caused by environmental pathogens.

3. The fields of medical and environmental microbiology need to be better integrated to stimulate the type of work that is required to combat environmental pathogens effectively. Positive measures to bring these fields together could include the establishment of interdisciplinary meetings and research funding opportunities. Professional societies and funding agencies that focus on individual aspects of the problem these organisms pose should collaborate to bring medical and environmental microbiologists together. New technologies for monitoring and cultivation of environmental pathogens are sorely needed. It is critical that, as these tools are developed, they be implemented in clinical as well as environmental settings, on the front lines of disease emergence.

4. Genetic and phenotypic virulence factors can be helpful in predicting the pathogenic capabilities of new organisms detected in the environment. However, this virulence factor-activity relationship (VFAR) approach must be used with considerable caution, because many microbial virulence factors are in fact multi-functional, and therefore not entirely predictive of risk to humans.

5. The adverse effects of environmental pathogens can be mitigated by reducing the frequency of exposure, or alternatively by reducing the effects of exposure through new vaccine and drug development. Control of exposure may be the most practical option for especially widespread and/or difficult-to-treat agents such as viruses and Borrelia, the causative agent of Lyme disease. Environmental infections that are relatively rare may best be combated at the level of antimicrobial therapy. New drugs may be needed for many environmental pathogens that are intrinsically resistant to existing antibiotics.

6. Catalogued culture collections of pathogen isolates greatly enhance efforts to identify, monitor, and characterize microbial pathogens. The development and maintenance of a multi-species environmental pathogen culture collection would be an expensive undertaking. However, it should be feasible to develop and maintain a general database of information that informs users of existing environmental pathogen collections that are available to the broad community of scientists and health care professionals. An integrated database of culture collections would not only help scientists locate strains of interest for research, but would also serve as a resource for the comparison of existing strains with new or emerging pathogens.

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NICE National Institute for Health and Care Excellence

NICE guideline

Healthcare-associated infections: prevention and control

Public health guideline
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Your responsibility

The recommendations in this guideline represent the view of NICE, arrived at after careful consideration of the evidence available. When exercising their judgement, professionals and practitioners are expected to take this guideline fully into account, alongside the individual needs, preferences and values of their patients or the people using their service. It is not mandatory to apply the recommendations, and the guideline does not override the responsibility to make decisions appropriate to the circumstances of the individual, in consultation with them and their families and carers or guardian.

All problems (adverse events) related to a medicine or medical device used for treatment or in a procedure should be reported to the Medicines and Healthcare products Regulatory Agency using the Yellow Card Scheme.

Local commissioners and providers of healthcare have a responsibility to enable the guideline to be applied when individual professionals and people using services wish to use it. They should do so in the context of local and national priorities for funding and developing services, and in light of their duties to have due regard to the need to eliminate unlawful discrimination, to advance equality of opportunity and to reduce health inequalities. Nothing in this guideline should be interpreted in a way that would be inconsistent with complying with those duties.

Commissioners and providers have a responsibility to promote an environmentally sustainable health and care system and should assess and reduce the environmental impact of implementing NICE recommendations wherever possible.

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This guideline is the basis of QS4, QS61, QS113 and QS49.

Overview

This quality improvement guide was produced by NICE, in partnership with Public Health England (PHE). Its aim is twofold: to reduce the risk of harm from healthcare-associated infections for patients, staff and visitors; and to reduce the costs associated with preventable infection.

The guide aims to improve the quality of care and practice over and above current standards as set out in the Department of Health's Health and Social Care Act 2008: Code of practice on the prevention and control of infections.

Who is it for?

- Board members working in (or with) hospitals
- Senior managers and others working elsewhere in the NHS
- Local authorities and the wider public, private, voluntary and community sectors

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Introduction

Following a referral from the Department of Health, NICE, in partnership with Public Health England (PHE), have developed this quality improvement guide. The guide offers advice on management or organisational actions to prevent and control healthcare-associated infections (HCAIs) in secondary care settings.

The guide is aimed at board members working in (or with) secondary care. It may also be of use to senior managers, those working elsewhere in the NHS, as well as those working in local authorities and the wider public, private, voluntary and community sectors.

In producing this guide, NICE and PHE have assumed that all secondary care settings are compliant with the current code of practice on preventing and controlling infections (Department of Health's Health and Social Care Act 2008: Code of practice on the prevention and control of infections).

The guide aims to help build on advice given in the code and elsewhere to improve the quality of care and practice in these areas over and above current standards. Taken together, the quality improvement statements contained in this guide describe excellence in care and practice to prevent and control HCAIs. Examples of evidence and other data to demonstrate progress against each statement are provided.

NICE and PHE recognise that a range of factors associated with infection prevention and control have the potential to impact on health inequalities (for example, in relation to age, ethnicity, gender and disability). However, the relative impact of different factors will vary for different organisations. NICE and PHE expect trusts and other secondary care organisations to consider local issues in relation to health inequalities when implementing this guide.

What is a healthcare-associated infection?

Healthcare-associated infections (HCAIs) can develop either as a direct result of healthcare interventions such as medical or surgical treatment, or from being in contact with a healthcare setting.

The term HCAI covers a wide range of infections. The most well known include those

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caused by meticillin-resistant *Staphylococcus aureus* (MRSA), meticillin-sensitive Staphylococcus aureus (MSSA), Clostridium difficile (C. difficile) and Escherichia coli (E. coli). HCAIs cover any infection contracted:

- as a direct result of treatment in, or contact with, a health or social care setting
- as a result of healthcare delivered in the community
- outside a healthcare setting (for example, in the community) and brought in by patients, staff or visitors and transmitted to others (for example, norovirus).

HCAIs pose a serious risk to patients, staff and visitors. They can incur significant costs for the NHS and cause significant morbidity to those infected. As a result, infection prevention and control is a key priority for the NHS (Department of Health's board to ward: How to embed a culture of HCAI prevention in acute trusts).

What action has been taken?

Following National Audit Office reports highlighting concerns about HCAIs, the Department of Health introduced a range of policies and measures designed to reduce rates of infection. (National Audit Office [2000] The management and control of hospital acquired infection in acute NHS trusts in England; National Audit Office [2004] Improving patient care by reducing the risk of hospital acquired infection: a progress report.)

For example, mandatory surveillance for meticillin-resistant *Staphylococcus aureus* (MRSA*)* was introduced in 2001. In 2004, a target was introduced to reduce MRSA bloodstream infections by 50% by 2008 in all NHS acute and foundation trusts. With the introduction of the Health Act in 2006, for the first time it became a legal requirement to have systems in place to minimise the risk of HCAIs (Department of Health's Health Act 2006: code of practice for the prevention and control of healthcare associated infections).

What action is needed now?

The 2009 National Audit Office report on reducing healthcare associated infections in hospitals in England identified four systemic issues that still needed to be tackled locally and nationally to reduce infection rates. It highlighted the need:

- for a culture of continuous improvement

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- for a whole-system approach, with clear structures, roles and responsibilities
- to ensure staff compliance with good infection control practice
- to monitor and record hospital prescriptions and the use of antibiotics.

What is this guide for?

This guide will help secondary care and other healthcare organisations improve the quality of care and practice, reduce the risk of harm from HCAIs to patients, staff and visitors and reduce the costs associated with preventable infection. The 11 quality improvement statements provide clear markers of excellence in infection prevention and control at a management or organisational level. Each statement is supported by examples of the type of evidence that could be used to prove the organisation has achieved excellence, and examples of what this would mean in practice on a day-to-day basis.

The aim is to help boards:

- assess current practice in relation to the prevention of HCAIs
- identify areas for quality improvement
- monitor progress
- provide leadership and support to infection prevention and control teams and other staff working to implement the guide.

The guide may also help inform investment decisions.

It will also give patients and the public information about the quality of care they can expect, and how secondary care organisations can improve patient safety and outcomes by improving quality in key areas.

How should the guide be used?

This guide is not mandatory. Rather, each quality improvement statement describes a level of excellence that could be achieved to prevent and control infections. Key areas of practice that underpin infection prevention and control, such as hand hygiene, antimicrobial stewardship and environmental cleanliness are included as measures and

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examples, where appropriate.

Organisations wishing to use the guide for quality assessment and improvement may choose a selection of the most appropriate measures for their setting as potential evidence of achievement. In organisations where, for example, tertiary care services are provided alongside secondary care, senior management should consider the applicability of each statement to their setting.

The examples of measures that could be taken may not be appropriate in all cases – and secondary care organisations may identify and use alternate measures as evidence of achievement, as necessary.

Performance in each statement area will depend upon healthcare professionals and other trust staff who have HCAI prevention and control – and public health, generally – as part of their remit.

Much of the information required to support the measures is already available and a range of other guidance can be used alongside this guide to assess and improve quality in secondary care settings. Overlaps between the statements and certain aspects of the code of practice are highlighted. In addition, where data routinely collated may help trusts monitor progress in an area covered by one of the statements, this is also highlighted.

How was the guide developed?

This guide was developed as a pilot project, based on processes and methods used by NICE to develop other types of guidance. A topic expert group was set up and led by an independent chair. It consisted of practitioners from the NHS, local authorities and the voluntary sector, as well as academics and patient and public representatives. The group worked with NICE and PHE to develop the guide.

The resulting quality improvement statements are based on recommendations from seven source guidance documents. They have been refined as a result of stakeholder consultation and committee discussion.

The following documents provide further information on the referral, scope, and methodology used as the basis for this guide:

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- Advice on the prevention and control of healthcare-associated infections: scope – this sets out the referral and scope for the work
- Quality improvement guide – prevention and control of healthcare-associated infections: topic briefing paper - this summarises the methods and process used to develop this guide and lists the source documents

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Quality improvement statement 1: Board-level leadership to prevent HCAIs

Statement

Trust boards demonstrate leadership in infection prevention and control to ensure a culture of continuous quality improvement and to minimise risk to patients.

What does this mean for people visiting, or receiving treatment in, hospitals?

People visiting, or receiving treatment in, hospitals can expect all trust staff – from board to ward level – to take responsibility, and be accountable for, continuous quality improvement in relation to infection prevention and control.

What does it mean for trust boards?

Boards are proactive in ensuring continuous quality improvement by leading on, and regularly monitoring compliance with, all relevant infection prevention and control objectives, policies and procedures.

Evidence of achievement

1. Evidence that the board is up-to-date with, and has a working knowledge and understanding of, infection prevention and control.

2. Evidence that the board has an agreed set of key performance indicators for infection prevention and control which includes compliance with antibiotic prescribing policy.

3. Evidence that the agreed key performance indicators are used by the board to monitor the trust's infection prevention and control performance.

4. Evidence that the trust's aims and objectives for infection prevention and control are

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included in the board's 'Balanced score card'.

5. Evidence that a board member has been assigned to lead on infection prevention and control.

6. Evidence of a board-approved infection prevention and control accountability framework. This includes evidence of specific responsibilities allocated to staff working in, or coming into contact with, clinical areas (reflected in their job descriptions and appraisals).

7. Evidence that a mechanism is in place to report regularly to board meetings on important infection risks and the control measures that have been implemented.

8. Evidence that the board has agreed an annual improvement programme on infection prevention and control which is linked to the business planning cycle and has identified actions and resources.

9. Evidence that the trust promotes a 'self-governance' culture for infection prevention and control. This includes evidence that all staff, from board to ward, are accountable and take ownership and responsibility for continuous quality improvement.

10. Evidence that the board is assured that monitoring mechanisms are in place in each clinical area, and that each area is accountable for compliance with relevant aspects of the code of practice.

11. Evidence of regular communication from the chief executive on the trust's expectation of patients, visitors and staff in relation to infection prevention and control.

12. Evidence that the director of infection prevention and control is involved in contract negotiations with commissioners on the key performance indicators for infection prevention and control.

13. Evidence that the board demonstrates to patients, the public, staff and itself that it is making continuous progress towards meeting all relevant statements in this guide.

14. Evidence of mechanisms to ensure transparent communication of all relevant surveillance outputs to staff and patients in line with duty of candour requirements.

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Practical examples

- Annual improvement plans include comparative data on progress towards relevant quality improvement statement goals, as well as in areas covered by other relevant guidance. (An example is NICE's guideline on surgical site infections: prevention and treatment.)
- Regular audit of board infection prevention and control accountability framework.
- Infection prevention and control features in the planned board development programme.
- Audit of infection prevention and control objectives within annual work programme.

Health and Social Care Act code of practice

Criterion 1: Guidance for compliance 1.1, 1.5

Criterion 6: Guidance for compliance 6.2

Relevant national indicators

None identified.

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Quality improvement statement 2: Be a learning organisation

Statement

Trusts use information from a range of sources to inform and drive continuous quality improvement to minimise risk from infection.

What does this mean for people visiting, or receiving treatment in, hospitals?

People visiting, or receiving treatment in, hospitals can expect the trust to learn from its own and other healthcare providers' experience, and to use this learning to improve the quality of care and practice in infection prevention and control.

What does it mean for trust boards?

Boards ensure mechanisms are in place for the trust to use a range of information, in addition to surveillance data, to minimise risk of infection to patients, staff and visitors. This includes information about both good and bad practice.

Evidence of achievement

1. Evidence that processes have been put in place to learn from experiences outside the organisation in relation to infection prevention and control. This includes evidence that learning is occurring on a continual basis.

2. Evidence of regular, systematic generation and sharing of learning from trust's own experiences of infection prevention and control – including good practice and adverse events. This includes evidence that learning is based on a range of intelligence sources and is used to inform, and feed into, clinical and risk management processes.

3. Evidence that mechanisms are in place to disseminate learning among relevant staff

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groups

4. Evidence that the trust promotes a culture of learning in relation to infection prevention and control, and ensures staff have time to participate in preventive learning activities.

5. Evidence that recommendations and actions identified as being needed following an incident, surveillance or learning activities have been implemented.

6. Evidence that the continuous quality improvement cycle is informed by conclusions from robust learning methodologies.

7. Evidence that the trust works with local health partners (including health protection units) to capture and learn lessons from the management of major infection outbreaks and other HCAI-related incidents.

8. Evidence that the trust promotes innovation to minimise harm from infection, for example by promoting research opportunities, practice development initiatives and action learning sets for staff.

Practical examples

- Local gap analyses performed on official reports and action plan developed to address identified gaps in local practice.
- Surveys of patient and staff experiences on infection prevention and control are fed into learning activities.
- A range of forums give staff the opportunity to learn from each others' experiences in relation to infection prevention and control.
- Audit of infection prevention activities undertaken across the trust as a result of learning from others.
- Audit of antimicrobial drug usage to check it complies with trust policy. Feedback given to relevant staff.
- Audit of hand-hygiene practices and feedback given to relevant staff.
- Feedback given to individual surgeons on wound infection rates.

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- Audit of appropriate isolation facility usage.

Health and Social Care Act code of practice

Criterion 1: Guidance for compliance 1.1, 1.3

Relevant national indicators

Quality improvement indicators include National Library of Quality Indicators:

- patient safety incident reporting (NHSOF)
- patient safety incident reporting (CCGOIS)
- severity of harm of patient safety incidents reported.

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Quality improvement statement 3: HCAI surveillance

Statement

Trusts have a surveillance system in place to routinely gather data and to carry out mandatory monitoring of HCAIs and other infections of local relevance to inform the local response to HCAIs.

What does this mean for people visiting, or receiving treatment in, hospitals?

People visiting, or receiving treatment in, hospitals can expect the trust to monitor infection levels across all service areas and use this information to adjust practice, where necessary. For example, they can expect the trust to close beds, or a ward to visitors, in response to an outbreak.

What does it mean for trust boards?

Boards ensure there is a fully resourced and flexible surveillance system to monitor infection levels in the trust. Outputs are shared across the organisation and used to drive continuous quality improvement.

Evidence of achievement

1. Evidence of an adequately resourced surveillance system with specific, locally defined objectives and priorities for preventing and managing HCAIs. The system should be able to detect organisms and infections and promptly register any abnormal trends.

2. Evidence of clearly defined responsibilities for the recording, analysis, interpretation and communication of surveillance outputs.

3. Evidence of arrangements for regular review of the surveillance programme to ensure it

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supports the trust's quality improvement targets for infection prevention.

4. Evidence of fit-for-purpose IT systems to support surveillance activity. This includes evidence of validation processes that ensure data accuracy and resources that can analyse and interpret surveillance data in meaningful ways.

5. Evidence of surveillance systems that allow data from multiple sources to be combined in real time (epidemiological, clinical, microbiological, surgical and pharmacy).

6. Evidence that surveillance systems capture surgical-site and post-discharge infections.

7. Evidence that trusts share relevant surveillance outputs and data with other local health and social care organisations to improve their infection prevention and control.

8. Evidence that systems are in place for timely recognition of incidents in different spaces (for example, wards, clinical teams, clinical areas, the whole trust). This includes evidence of regular time-series analyses of data.

9. Evidence that the trust reports all outbreaks, serious untoward incidents (SUIs) and any other significant HCAI-related risk and incident to the local health protection unit.

10. Evidence that surveillance data in key areas is regularly compared with other local and national data and, where appropriate, is available at clinical unit level.

11. Evidence of a process for surveillance outputs to feed into accountability frameworks, inform audit priorities and be used to set objectives for quality improvement programmes in relation to HCAI prevention.

12. Evidence of surveillance outputs being analysed alongside comparative data to ensure continual improvement.

13. Evidence of surveillance outputs being fed back to relevant staff and stakeholders, including patients, in an appropriate format to support preventive action.

14. Evidence that the trust has developed, and regularly reviews, a hospital-wide incident plan to investigate and manage major infection outbreaks and HCAI incidents. This includes evidence that high-level managerial and clinical mechanisms are in place for coordinating, communication (including with other agencies) and deploying adequate

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resources.

Practical examples

- Surveillance data (for example, on antimicrobial resistance) is routinely communicated to the board and to individual clinical units. This includes comparative data on performance within the trust over time and compared with other local or national data.
- Regular publication of outputs from the surveillance system, for example, on post-surgical infection rates and rates of compliance with recommendations on surgical prophylaxis.
- Analysis of trends from local and national surveillance data informs practice across the trust or setting. For example, it could be used to initiate a review of how prepared the trust is for an infection outbreak.
- Surveillance outputs are used to monitor progress against local quality improvement objectives.

Health and Social Care Act code of practice

Criterion 9: Guidance for compliance 9.3m, 9.3u

Relevant national indicators

Quality improvement indicators:

- Incidence of C.difficile: National Library of Quality Indicators: incidence of healthcare-associated infection - C. difficile infection (NHSOF) and incidence of healthcare-associated infection - C. difficile infection (CCGOIS)
- Incidence of MRSA bacteraemia: National Library of Quality Indicators: incidence of healthcare-associated infection - MRSA (NHSOF) and incidence of healthcare-associated infection - MRSA (CCGOIS)
- Surgical site infections: NICE Clinical Commissioning Group indicator: readmission rates for surgical site infections within 30 days of discharge from surgery.

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Quality improvement statement 4: Workforce capacity and capability

Statement

Trusts prioritise the need for a skilled, knowledgeable and healthy workforce that delivers continuous quality improvement to minimise the risk from infections. This includes support staff, volunteers, agency/locum staff and those employed by contractors.

What does this mean for patients and trust boards?

Patients can expect staff to have the necessary skills and knowledge to undertake infection prevention and control procedures in their area of work.

Boards ensure staff have the skills and training required for infection prevention and control.

Evidence of achievement

1. Evidence of local arrangements to ensure all staff working in clinical areas have an appraisal and development plan that includes discussion of infection prevention and control. This includes evidence that staff working in both clinical and non-clinical areas have clear objectives in relation to infection prevention and control which are linked to the trust's objectives.

2. Evidence that all staff working in clinical areas, including specialist link practitioners, have sufficient time to fulfil their responsibilities on (and objectives for) infection prevention and control.

3. Evidence that staff are provided with feedback on their performance in relation to infection prevention and control (for example, on hand hygiene or when prescribing antimicrobial drugs). This includes evidence that they are given support to fulfil this role.

4. Evidence of local arrangements to ensure all staff working in clinical areas complete

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infection prevention and control training within 1 week of commencing work.

5. Evidence of local arrangements to ensure infection prevention and control training and competencies are updated and checked at appropriate intervals.

6. Evidence that local workforce planning and workforce reviews explicitly consider, and are informed by, the trust's infection prevention and control strategy and local HCAI outcomes.

7. Evidence of local arrangements for an annual review of training resources to ensure consistency with the national evidence base and professional and occupational standards.

8. Evidence of local arrangements to ensure consultant medical staff from a range of specialities champion infection prevention control. This includes evidence that they are given protected time to achieve defined objectives in this role.

9. Evidence that all staff working in clinical areas are familiar with, and competent in applying, the trust's infection prevention and control policies and procedures.

10. Evidence of local arrangements to train all staff in the communication skills needed to discuss HCAIs with patients and the public.

11. Evidence that the trust has a proactive, accessible and user-sensitive occupational health service. This includes evidence of a high level of competence in all areas of healthcare infection prevention and control to ensure the welfare of healthcare workers (including short-term and agency workers). In addition, evidence is needed that the service puts an emphasis on preventing blood-borne viruses, tuberculosis, vaccine-preventable diseases and acute respiratory and gastrointestinal infections.

Practical examples

- An agreed performance indicator for the proportion of staff appraisals that include infection prevention and control. Performance against this indicator is checked on a regular basis.
- Monitoring of proportion of new staff who undergo pre-employment occupational health screening or assessment within a given timeframe.

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- Trust programme in place to review the immunisation status of staff and to ensure vaccines are offered, when necessary.
- Trust programme in place to review the skills, competence and capacity of the multi-disciplinary infection prevention and control team to ensure it is fit-for-purpose.
- A mechanism is in place to ensure the need to reduce HCAIs across the organisation is explicitly considered during workforce planning.
- Presence of an infection prevention and control 'link practitioner' or member of staff in every clinical and support unit (with protected time).
- Training needs-analysis is informed by the trust's infection prevention and control strategy and local HCAI outcomes and is reviewed annually.
- Staff education on the occupational health aspects of how to prevent and control healthcare infections is provided by occupational health service. (For example, this may include advice on the number of days staff should not work following an episode of sickness and diarrhoea.)
- Monitoring of the proportion of new staff undertaking mandatory infection prevention and control training within 1 week of commencing work.
- Presence of escalation procedures and processes for individuals who repeatedly do not fulfill their specified infection prevention and control responsibilities.
- Patient surveys of their experience of staff skills and knowledge in relation to infection prevention and control.
- Monitoring of the proportion of staff whose post-exposure prophylaxis (PEP) management to HIV is delayed.

Health and Social Care Act code of practice

Criterion 1: Guidance for compliance 1.1

Criterion 6: Guidance for compliance 6.2

Criterion 10: Guidance for compliance 10.1

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Relevant national indicators

None identified.

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Quality improvement statement 5: Environmental cleanliness

Statement

Trusts ensure standards of environmental cleanliness are maintained and improved beyond current national guidance.

What does this mean for: people visiting, or receiving treatment in, hospitals?

People visiting, or receiving treatment in, hospitals can expect secondary care settings to meet high standards of cleanliness, with each trust monitoring the condition of its premises to ensure levels exceed the minimum required standard.

What does it mean for trust boards?

Boards ensure policies, procedures and resources are in place to maintain and continuously raise the level of cleanliness across the trust.

Evidence of achievement

1. Evidence that the trust clearly sets out, and adheres to, a standard of cleanliness that is beyond current national guidance (for example, British Standards Institution PAS 5748 and/or National Patient Safety Agency specifications).

2. Evidence of clear and accessible local policies on cleaning and environmental decontamination. This includes evidence that they take into account the needs of different patient care areas and allow for flexibility in the deployment of resources. There should be evidence, for example, that individual staff understand their role and responsibilities.

3. Evidence of local arrangements for a risk-based, cleaning responsibility matrix and frequency schedule for each patient care area.

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4. Evidence of a local framework for monitoring of environmental cleanliness routinely and in an 'outbreak' situation. This includes evidence of a patient feedback system.

5. Evidence that the results of routine and outbreak monitoring are reviewed and cleaning arrangements updated, where appropriate

6. Evidence of local arrangements to ensure awareness of health and safety and environmental issues regarding the use of disinfectant preparations for decontamination purposes.

7. Evidence of regular, appropriate training and education of staff with responsibility for cleaning in the use of equipment, disinfection and decontamination.

8. Evidence that the trust incorporates patient feedback and involves patients and carers in its cleanliness monitoring programmes, with evidence that this impacts on standards.

Practical examples

- Mechanism is in place to ensure rapid response cleaning is initiated within appropriate timeframe.
- Clearly defined policy for cleaning and environmental decontamination (including roles, responsibilities and accountability).
- Trust collects visual and/or objective environmental monitoring data for different clinical areas. Visual and scientific methods are used for both routine and outbreak environmental assessment and the findings are used to inform improvements to the cleanliness programme.

Health and Social Care Act code of practice

Criterion 1: Guidance for compliance 1.1

Criterion 2: Guidance for compliance 2.1, 2.3, 2.4, 2.5, 2.6

Relevant national indicators

None identified.

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Quality improvement statement 6: Multi-agency working to reduce HCAIs

Statement

Trusts work proactively in multi-agency collaborations with other local health and social care providers to reduce risk from infection.

What does this mean for people visiting, or receiving treatment in, hospitals?

People visiting, or receiving treatment in, hospitals can expect the trust to be working collaboratively with other local health and social care providers to prevent and reduce harm from infection.

What does it mean for trust boards?

Boards are actively involved in local networks. They share governance structures, objectives and learning with other local health and social care providers to promote good practice among them.

Evidence of achievement

1. Evidence that a board member has been nominated as the trust's lead and representative for a multi-agency collaboration to prevent and manage HCAIs.

2. Evidence of support for, and participation in, joint working initiatives beyond mandatory or contractual requirements, to reduce HCAIs locally.

3. Evidence of an agreed policy for data sharing on HCAIs between local organisations.

4. Evidence of timely sharing of information risk assessments and strategic efforts to minimise harm from infection with other agencies.

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5. Evidence of a defined, shared and agreed governance structure with other local health and social care providers that includes clear lines of accountability.

6. Evidence of support for, and participation in, the development and implementation of a joint local strategy, policy and pathway on HCAIs between local health and social care providers.

7. Evidence of participation in the development of shared targets and joint working with other local health and social care providers to improve outcomes locally relating to HCAIs.

8. Evidence that the trust works collaboratively with the local health protection unit and other health partners to investigate and manage HCAI outbreaks and incidents. Evidence is particularly needed of collaboration to deal with incidents which may impact on the health of the wider community.

Practical examples

- Documented terms of reference for multi-agency collaboration to reduce HCAIs.
- Audit of outputs from collaboration disseminated to relevant trust committees (for example, clinical governance and policy development groups).
- Audits of outputs from relevant learning methodologies are shared with other local health and social care providers.

Health and Social Care Act code of practice

No relevant criteria identified.

Relevant national indicators

None identified.

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Quality improvement statement 7: Communication

Statement

Trusts ensure there is clear communication with all staff, patients and carers throughout the care pathway about HCAIs, infection risks and how to prevent HCAIs, to reduce harm from infection.

What does this mean for people visiting, or receiving treatment in, hospitals?

People visiting, or receiving treatment in, hospitals can expect to be provided with information on how to reduce the risks of an HCAI and to be given the opportunity to discuss HCAIs with staff.

Patients who have an HCAI can expect to be:

- notified of their infection
- told about the impact it will have on their care
- given relevant information about minimising the risk to others.

What does it mean for trust boards?

Boards ensure processes are in place to communicate relevant information about minimising the risk of (and from) HCAIs to patients, carers, visitors and staff. They also ensure staff have access to relevant patient information resources and up-to-date local surveillance information so they can communicate about HCAIs effectively.

Evidence of achievement

1. Evidence of mechanisms to ensure transparent communication of all relevant

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surveillance outputs to staff and patients.

2. Evidence that local health and social care services provide consistent patient and carer information on infection prevention and control.

3. Evidence that trust policies on infection prevention and control are available to, and used by, all staff.

4. Evidence that arrangements are in place to ensure providers in different settings can identify and communicate infection risks as the patient moves between services.

5. Evidence that patients, carers and visitors have access to up-to-date, accurate and easy to understand information about their own HCAI (if applicable) or HCAIs generally, in a suitable format. This includes evidence that they have access to information on the potential risk of infection and existing treatment and control measures.

6. Evidence that patients with an HCAI are informed of their infection and the implications for their care.

7. Evidence that staff are trained to (and can) communicate in an appropriate manner with patients and their carers about how to prevent, and reduce harm from, HCAIs.

8. Evidence of ongoing and timely dialogue with patients and carers throughout the trust's care pathway regarding the risk of HCAIs and how to prevent them.

Practical examples

- Audit of communications between different health and social care providers detailing any infections (for example, an audit of discharge summaries to GPs and admission letters from care homes).
- Audit of patient records for communication about HCAIs (for example, their MRSA status) throughout their hospital episode.
- Audit of patient records for communication about how to prevent HCAIs (for example, hand-hygiene procedures) throughout their hospital episode.
- Patient surveys on the trust's communication about HCAIs, and about their understanding of the risks.

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- Availability of easy to understand, standardised information on HCAIs for patients, carers and staff.
- Availability of standardised trust policies on infection prevention and control.
- Audit central venous catheter and indwelling catheter procedures to check they follow trust policies on infection prevention and control.
- Audit of antimicrobial stewardship programmes to ensure good prescribing practice (for example, appropriate use of prophylactic antibiotics in surgery).

Health and Social Care Act code of practice

Criterion 3: Guidance for compliance 3.1

Criterion 4: Guidance for compliance 4.1, 4.2

Relevant national indicators

None identified.

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Quality improvement statement 8: Admission, discharge and transfer

Statement

Trusts have a multi-agency patient admission, discharge and transfer policy which gives clear, relevant guidance to local health and social care providers on the critical steps to take to minimise harm from infection.

What does this mean for patients and trust boards?

Patients with an infection can expect relevant information about it to be shared between providers when they are admitted, transferred to, or discharged from a hospital to ensure seamless care.

Boards lead on the development of an agreed multi-agency admission, discharge and transfer policy. They ensure mechanisms are in place to support and monitor adherence to the policy.

Evidence of achievement

1. Evidence of an admission, discharge and transfer policy for patients with an infection that has been agreed by all agencies involved in the patient's care pathway, including local community and public health teams.

2. Evidence that the agreed policy includes a risk assessment on admission, and for all transfers, to determine the presence or risk of acquiring or transmitting infection.

3. Evidence of a procedure for documenting and sharing information about infections and their treatment. This includes evidence of information sharing to manage and support patients with an infection on an ongoing basis (including transfer and isolation arrangements for them) during admission, transfer and discharge.

4. Evidence of clear advice being given to patients on antimicrobial prescribing for their

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ongoing care.

5. Evidence of clear advice being given to patients on the management of medical devices for their ongoing care.

Practical examples

- Audit of adherence to relevant policy on admissions/transfers/discharges of patients with an HCAI.
- Reduction in the number of adverse events recorded as a result of discharge and transfer of a patient with an infection.

Health and Social Care Act code of practice

Criterion 1: Guidance for compliance 1.1, 1.9, 1.10

Relevant national indicators

None identified.

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Quality improvement statement 9: Patient and public involvement

Statement

Trusts use input from local patient and public experience for continuous quality improvement to minimise harm from HCAIs.

What does this mean for patients, the public and trust boards?

Patients and the public can expect the trust to provide opportunities for them to be involved with planning and decision-making on quality improvement activities to prevent and control infections.

Boards ensure the trust has mechanisms in place to seek patient and public views and involve them in decisions related to quality improvement for infection prevention and control.

Evidence of achievement

1. Evidence that a non-executive director or equivalent (for example, a trust governor) has been assigned to lead on patient and public involvement in infection prevention and control.

2. Evidence of a range of mechanisms to involve patients and the public in the trust's decision-making to ensure continuous quality improvement in infection prevention and control.

3. Evidence that a variety of information sources and participation methods are used to gain insight into patient experiences of infection prevention and control.

4. Evidence that patient and public involvement groups for infection prevention and control reflect local demographics.

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5. Evidence of mechanisms to ensure patient experiences of HCAIs are used to inform reviews or investigations (such as outbreak investigations and root-cause analysis). This includes evidence that they are used to provide patients and carers with feedback on the outcome.

6. Evidence that patients' and the general public's perspective and priorities on infection prevention and control are taken into account in the trust's quality improvement programme.

Practical examples

- Patient and public representation on relevant groups and committees.
- Audit of HCAI reviews and investigations that include comment from patients and the public.
- Meetings between trust lead and patient and public representatives to discuss infection prevention and control.

Health and Social Care Act code of practice

No relevant criteria identified.

Relevant national indicators

None identified.

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Quality improvement statement 10: Trust estate management

Statement

Trusts consider infection prevention and control when procuring, commissioning, planning, designing and completing new and refurbished hospital services and facilities (and during subsequent routine maintenance).

What does this mean for people visiting, or receiving treatment in, hospitals?

People visiting, or receiving treatment in, hospitals can expect hospitals, and other parts of the trust estate, to be built and maintained in such a way as to minimise the risk of infection.

What does it mean for trust boards?

Boards ensure the whole estate is managed and maintained to minimise risk from infection.

Evidence of achievement

1. Evidence of local arrangements for involving infection prevention and control teams in the planning, design, commissioning, completion and maintenance of services and facilities used by the trust.

2. Evidence of local procedures to ensure infection prevention and control is considered during the commissioning and handover of facilities.

3. Evidence of local procedures to ensure infection prevention and control is considered during the selection, commissioning and installation of equipment.

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4. Evidence of local arrangements (for example, a standard operating procedure) for involving the infection prevention and control team (or other appropriate expertise) in the development of estates policy.

5. Evidence of a planning process that 'designs out' potential infection risks and focuses on effective infection prevention.

6. Evidence of local arrangements to ensure estate management is considered and integrated into routine practice to reduce infection risk.

7. Evidence that estates and clinical staff, including temporary staff and subcontractors, receive annual training in infection prevention and control. This should include an assessment of their relevant competencies.

8. Evidence of mechanisms for consideration of current national estates policy and whether or not it should be incorporated into local practice.

Practical examples

- Record of adherence to the trust estates policy, including the infection prevention and control (IPC) team's involvement. This should include sign-off of documents at relevant stages of the building and maintenance process.
- Briefs and specifications outline the need to consider infection prevention and control when procuring, commissioning, planning, designing and completing new and refurbished services and facilities.
- Record of completed and due maintenance tasks, including an assessment of whether the infection prevention and control objectives have been achieved.
- Record of estates risk assessments that have considered infection prevention and control in areas of high HCAI risk (for example, in patient care areas and for facilities such as water-storage tanks).
- IPC team-approved written protocols for routine, planned preventive maintenance (PPM), remedial and interventional maintenance activity.
- Record of planned preventive, remedial and interventional maintenance works that adheres to IPC team-approved protocols.

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- Impact of planned preventive, remedial and interventional maintenance works in minimising the risk of infection to patients is regularly reviewed and considered.
- An appropriately competent person regularly reviews, verifies, confirms and signs off work delivered in accordance with infection-control protocols.
- IPC staff (or another recognised source of appropriate expertise) have allocated time and availability to review and advise on IPC issues during the initiation, planning, procurement, design and construction stages of projects.

Health and Social Care Act code of practice

Criterion 2: Guidance for compliance 2.1, 2.3

Relevant national indicators

None identified.

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Quality improvement statement 11: New technology and innovation

Statement

Trusts regularly review evidence-based assessments of new technology and other innovations to minimise harm from HCAIs and antimicrobial resistance (AMR).

What does this mean for people visiting, or receiving treatment in, hospitals?

People visiting, or receiving treatment in, hospitals can expect the trust to assess relevant new technologies and innovation to help improve the quality of care and practice to prevent, and reduce the harm from, infection.

What does it mean for trust boards?

Boards routinely identify technology needs relevant to HCAI prevention and control and assess the potential of new technologies and innovation to meet those needs. Where new technologies and methods are identified, they are evaluated and implemented, as appropriate.

Evidence of achievement

1. Evidence that a mechanism is in place to undertake a regular gap analysis of technology needs relevant to infection prevention and control.

2. Evidence that information on relevant new technologies and innovation is disseminated to directorates, along with guidance on evaluation and implementation.

3. Evidence of a mechanism to assess the evidence base underpinning technology and innovation in reducing HCAIs. This includes evidence that, where relevant, new technology, innovation and practice is incorporated into policies and procedures.

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4. Evidence of local arrangements to help individuals or clinical teams conduct relevant research (for example, translational research) to prevent or reduce the harm from HCAIs. This could include evidence that arrangements have been made with academic centres, or that trust-based preventive interventions have been assessed internally.

Practical examples

- Programme in place to consider current research activity and developments in HCAI innovation and technology.
- Mechanism is in place to support people who wish to conduct research into quality improvement methodology, behavioural sciences or other areas to improve the way HCAIs are prevented or controlled.
- Regular gap analyses carried out in relation to infection prevention and control.
- Relevant gaps in technology identified and communicated to appropriate research and funding bodies.

Health and Social Care Act code of practice

No relevant criteria identified.

Relevant national data indicators

None identified.

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Glossary

Accountability framework

The policies, procedures and lines of accountability for specific areas within an organisation.

Adverse event

An unplanned or unanticipated event involving actual (or potential) risk or harm to patients. In the context of this guide, this would be an infection occurring as a result of medical or surgical intervention or contact with a healthcare setting.

Continuous quality improvement (CQI)

Improving the provision of services and practice by using a range of audit and statistical tools to assess the current situation, identify areas for improvement and measure the results.

Hand hygiene

The use of soap or solution (non-antimicrobial or antimicrobial) and water, or a waterless antimicrobial agent, to remove transient or residual organisms from the hands.

Key performance indicators (KPIs)

Measures that provide an indication of performance in key areas.

Learning methodologies

Techniques and approaches that provide an opportunity to evaluate current practice, identify areas for improvement and disseminate the findings.

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Link practitioners

Local leaders and role models – either within a trust, or working in settings that link to that trust – promote the principles of safe, clean care or good prescribing practices during the day-to-day operation of their service. Link practitioners may have a clinical or lay background. An example of the former could be a nurse or pharmacist. An example of the latter could be a patient liaison officer.

Medical device

A product used to diagnose, treat or prevent disease or injury.

Planned preventive maintenance

The scheduling of planned maintenance to prevent damage, breakdown and functional failures.

Surveillance

Active monitoring of infection at patient, ward, trust or national level. This involves counting cases over time and recognising and controlling outbreaks and adverse trends. It also involves producing complete epidemiological records of infection outbreaks and adverse incidents which describe and summarise all cases.

Trust estates

All the buildings and grounds that fall under the management and control of the trust.

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Supporting documents

See supporting evidence for a full list of supporting documents for this guidance.

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Finding more information and committee details

To find NICE guidance on related topics, including guidance in development, see the NICE topic page on healthcare associated infections.

For full details of how this guide was developed, see the topic briefing paper and history of development process.

NICE has produced tools and resources to help you put this guide into practice. For general help and advice on putting our guidelines into practice, see resources to help you put NICE guidance into practice.

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Update information

Minor changes since publication

January 2023: We added transparent communication of surveillance outputs to the evidence of achievement section for quality improvement statement 1.

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Supporting organisations

This guideline is supported by:

- Association for Clinical Biochemistry and Laboratory Medicine
- British Infection Association
- C-diff Support
- Healthcare Infection Society
- Infection Prevention Society
- The Institute of Biomedical Science (IBMS)
- The Kidney Alliance
- MRSA Action UK
- National Association of LINks Members
- National Concern for Healthcare Infections
- NHS Institute for Innovation and Improvement
- Royal College of Pathologists
- Royal College of Physicians (RCP)
- Society for Acute Medicine (SAM)
- UK Clinical Pharmacy Association (UKCPA)

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Accreditation

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National Infection Prevention and Control Manual

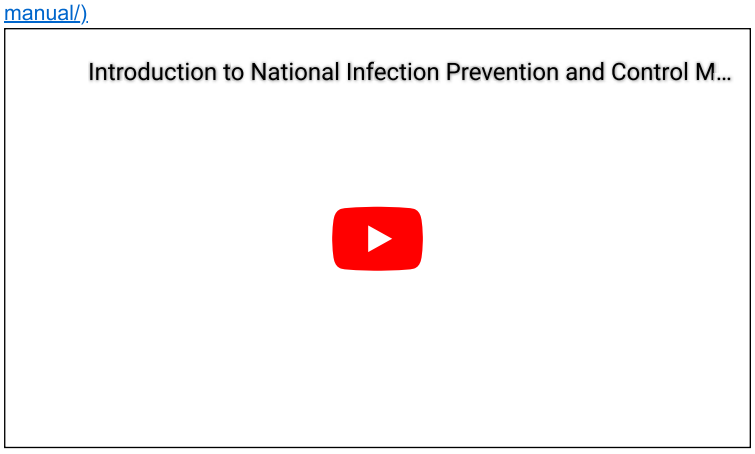
Introduction

The NHSScotland National Infection Prevention and Control Manual (NIPCM) was first published on 13 January 2012, by the Chief Nursing Officer (CNO (2012)1 (http://www.sehd.scot.nhs.uk/cmo/CNO(2012)01.pdf)), and updated on 17 May 2012 (CNO (2012)1 Update (http://www.sehd.scot.nhs.uk/cmo/CNO(2012)01update.pdf)).
The NIPCM provides IPC guidance to all those involved in care provision and is considered best practice across all health and care settings in Scotland.
The re-launch of the NIPCM by the CNO on 11 July 2022 emphasises the ongoing importance of application of Infection Prevention and Control (IPC) guidance within health and care settings across Scotland.

Video of Chief Nursing Officer re-launching the NIPCM

Find out more about the NIPCM

You can find out more about the NIPCM by watching the animation or going to the About the manual webpage. (/about-the-manual/)



Disclaimer

When an organisation, for example health and care setting, uses products or adopts practices that differ from those stated in this National Infection Prevention and Control Manual, that individual organisation is responsible for ensuring safe systems of work including the completion of a risk assessment approved through local governance procedures.

Responsibilities

Responsibilities for the content of this manual

ARHAI Scotland must ensure

- that the content of this manual remains evidence based or where evidence is lacking, content is based on consensus of expert opinion.

Stakeholders of the ARHAI Scotland programmes must ensure

- full participation in the working groups and oversight programmes including full engagement with the consultation process outlined in the Terms of Reference associated with each group

Responsibilities for the adoption and implementation of this manual

Organisations must ensure:

- the adoption and implementation of this manual in accordance with their existing local governance processes
- systems and resources are in place to facilitate implementation and compliance monitoring of infection prevention and control as specified in this manual in all care areas
    - compliance monitoring includes all staff (permanent, agency and where required external contractors)
- there is an organisational culture which promotes incident reporting and focuses on improving systemic failures that encourage safe infection prevention and control working practices including near misses

Managers of all services must ensure that staff:

- are aware of and have access to this manual
- have had instruction/education on infection prevention and control through attendance at events and/or completion of training (for example via NHS Education for Scotland (NES) and/or local board or organisation)
- have adequate support and resources available to enable them to implement, monitor and take corrective action to ensure compliance with this manual. If this cannot be implemented a robust risk assessment detailing deviations from the manual and appropriate mitigation measures must be undertaken and approved through local governance procedures.
- with health concerns (including pregnancy) or who have had an occupational exposure relating to the prevention and control of infection are timeously referred to the relevant agency, for example General Practitioner, Occupational Health or if required Accident and Emergency
- have undergone the required health checks or clearance (including those undertaking Exposure Prone Procedures (EPPs)
- include infection prevention and control as an objective in their Personal Development Plans (or equivalent)

Staff providing care must ensure that they:

- understand and apply the principles of infection prevention and control set out in this manual
- maintain competence, skills and knowledge in infection prevention and control through attendance at education events and/or completion of training, for example NHS Education for Scotland (NES) and/or local board or organisation
- communicate the infection prevention and control practices to be taken to appropriate colleagues, those being cared for, relatives and visitors without breaching confidentiality
- have up to date occupational immunisations/health checks/clearance requirements as appropriate
- report to line managers and document any deficits in knowledge, resources, equipment and facilities or incidents that may result in transmission of infection including near misses e.g sharps or PPE failures
- do not provide care while at risk of potentially transmitting infectious agents to others - if in any doubt they must consult with their line manager, Occupational Health Department, Infection Prevention and Control Team (IPCT) or Health Protection Team (HPT)
- contact HPT/IPCT if there is a suspected or actual HAI incident/outbreak

Infection Prevention and Control Teams (IPCTs) and Health Protection Teams (HPTs) must:

- engage with staff to develop systems and processes that lead to sustainable and reliable improvements in relation to the application of infection prevention and control practices
- provide expert advice on the application of infection prevention and control in all care settings and provide support to develop individual or organisational risk assessments where deviations from the NIPCM are necessary
- have epidemiological or surveillance systems capable of distinguishing patient case or cases requiring investigations and control
- complete documentation when an incident/outbreak or data exceedence is reported (IPCTs should ensure application of the HIIAT where applicable and report incidents and outbreaks using the ORT as outlined by the HIIAT).

Last updated: 4 October 2021

Chapter 1 - Standard Infection Control Precautions (SICPs)

Standard Infection Control Precautions (SICPs), covered in this chapter are to be **used by all staff, in all care settings, at all times, for all patients**[1] **whether infection is known to be present or not** to ensure the safety of those being cared for, staff and visitors in the care environment.
The Hierarchy of Controls (/appendices/appendix-20-hierarchy-of-controls/) should also be considered in controlling exposures to occupational hazards which include infection risks.

SICPs are the basic infection prevention and control measures necessary to reduce the risk of transmission of infectious agent from both recognised and unrecognised sources of infection.
Sources of (potential) infection include blood and other body fluids secretions or excretions (excluding sweat), non-intact skin or mucous membranes, any equipment or items in the care environment that could have become contaminated and even the environment itself if not cleaned and maintained appropriately.
The application of SICPs during care delivery is determined by an assessment of risk to and from individuals and includes the task, level of interaction and/or the anticipated level of exposure to blood and/or other body fluids.
To be effective in protecting against infection risks, SICPs must be applied continuously by all staff. The application of SICPs **during care delivery** must take account of;

- risk to and from the individual for whom care is being provided
- the task to be undertaken
- level of interaction
- the anticipated level of exposure to blood and/or other body

Doing so allows staff to safely apply each of the 10 SICPs by ensuring effective infection prevention and control is maintained.
SICPs implementation monitoring must also be ongoing to demonstrate safe practices and commitment to patient, staff and visitor safety.
Further information on using SICPs for Care at Home can be found on the NHS National Education Scotland (NES) website (https://learn.nes.nhs.scot/2482/infection-prevention-and-control-ipc-zone).

[1]**The use of the word 'Persons' can be used instead of 'Patient' when using this document in non-healthcare settings.**

Last updated: 28 August 2023

1.1 Patient Placement/Assessment for infection risk

Patients must be promptly assessed for infection risk on arrival at the care area (if possible, prior to accepting a patient from another care area) and should be continuously reviewed throughout their stay. This assessment should influence patient placement decisions in accordance with clinical/care need(s).

Patients who may present a particular cross-infection risk should be isolated on arrival and appropriate clinical samples and screening undertaken as per national protocols to establish the causative pathogen. This includes but is not limited to patients:

- With symptoms such as loose stools or diarrhoea, vomiting, fever or respiratory symptoms.
- With a known (laboratory confirmed) or suspected infectious pathogen for which appropriate duration of precautions as outlined in A-Z pathogens (/a-z-pathogens/) are not yet complete.
- Known or suspected to have been previously positive with a Multi-drug Resistant Organism (MDRO), for example MRSA, CPE.
- Who have been a close contact of a person who has been colonised or infected with CPE in the last 12 months.

- Who have been hospitalised outside Scotland in the last 12 months (including those who received dialysis).

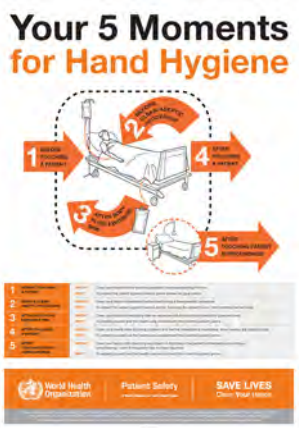
Resources
For assessment of infection risk see Section 2: Transmission Based Precautions. (/chapter-2-transmission-based-precautions-tbps/)
Further information can be found in the patient placement literature review (https://hpspubsrepo.blob.core.windows.net/hps-website/nss/2511/documents/1_sicp-tbp-patient-placement-v2.0.pdf).
Further information regarding general respiratory screening questions (/media/2147/2023-08-23-respiratory-screening-questions-aide.pdf) can be found within the resources section of the NIPCM.

1.2 Hand Hygiene

Please note that the term 'alcohol-based hand rub (ABHR)' has now been updated to 'hand rub'. A hand rub (alcohol or non-alcohol based) can be used if it meets the required standards. Please see further information in the hand hygiene products literature review (/web-resources-container/sicp-literature-review-hand-hygiene-products/).
Hand hygiene is considered an important practice in reducing the transmission of infectious agents which cause infections.
Hand washing sinks must only be used for hand hygiene and must not be used for the disposal of other liquids. (See Appendix 3 of Pseudomonas Guidance (/web-resources-container/guidance-for-neonatal-units-adult-and-paediatric-intensive-care-units-in-scotland-to-minimise-the-risk-of-pseudomonas-aeruginosa-infection-from-water/))
Before performing hand hygiene:

- expose forearms (bare below the elbows)
- remove all hand/wrist jewellery* including any embedded jewellery (a single, plain metal finger ring or ring dosimeter (radiation ring) is permitted but should be removed (or manipulated) during hand hygiene). Bracelets or bangles such as the Kara which are worn for religious reasons should be able to be pushed higher up the arm and secured in place to enable effective hand hygiene which includes the wrists
- ensure fingernails are clean, short and that artificial nails or nail products are not worn
- cover all cuts or abrasions with a waterproof dressing

Hand washing should be extended to the forearms if there has been exposure of forearms to blood and/or body fluids.
*For health and safety reasons, Scottish Ambulance Service Special Operations Response Teams (SORT) in high-risk situations require to wear a wristwatch.
To perform hand hygiene
Hand rubs must be available for staff as near to point of care as possible. Where this is not practical, personal hand rub dispensers should be used.
Application of sufficient volume of hand rub to cover all surfaces of the hands is important to ensure effective hand hygiene. Manufacturer's instruction should be followed for the volume of hand rub required to provide adequate coverage for the hands. In the absence of manufacturers instructions, volumes of approximately 3ml are recommended to ensure full coverage.
The World Health Organization's '5 moments for hand hygiene' should be used to highlight the key indications for hand hygiene. (/media/1445/who-5-moments-poster.pdf)



1. before touching a patient
2. before clean/aseptic procedures. If hand rub cannot be used, then antimicrobial liquid soap should be used
3. after body fluid exposure risk
4. after touching a patient
5. after touching a patient's immediate surroundings

Some additional examples of hand hygiene moments include but are not limited to:

- before handling medication
- before preparing food
- before donning (putting on) and after doffing (taking off) PPE
- after visiting the toilet
- between carrying out different care activities on the same patient
- (/media/1444/who-4-moments-residential-care.pdf)after cleaning and disinfection procedures
- after handling waste (/media/1444/who-4-moments-residential-care.pdf)

Download and print the 5 moments of hand hygiene poster (/media/1445/who-5-moments-poster.pdf).
Wash hands with non-antimicrobial liquid soap and water if:

- hands are visibly soiled or dirty
- hands are potentially contaminated with blood, other body fluids or excretions
- caring for patients with vomiting or diarrhoeal illnesses
- caring for a patient with a suspected or known gastro-intestinal infection, for example Norovirus or a spore forming organism such as *Clostridioides difficile*

Hands should be washed with warm/tepid water to mitigate the risk of dermatitis associated with repeated exposures to hot water and to maximise hand washing compliance. Compliance may be compromised where water is too hot or too cold. Hands should be dried thoroughly following hand washing using a soft, absorbent, disposable paper towel from a dispenser which is located close to

the sink but beyond the risk of splash contamination.
In all other circumstances use hand rub for routine hand hygiene during care.
Staff working in the community should carry a supply of hand rub to enable them to perform hand hygiene at the appropriate times.
Where staff are required to wash their hands in the service user's own home they should do so for at least 20 seconds using any hand soap available.
Staff should carry a supply of disposable paper towels for hand drying rather than using hand towels in the individual's own home.
Once hands have been thoroughly dried, hand rub should be used.
The use of antimicrobial hand wipes is only permitted where there is no access to running water. Staff must perform hand hygiene using hand rub immediately after using the hand wipes and perform hand hygiene with soap and water at the first available opportunity.

Resources

(The video above demonstrating Hand Washing and Drying Technique was produced by NHS Ayrshire and Arran)

For how to:

- wash hands see Appendix 1 (/appendices/appendix-1-how-to-hand-wash/)
- hand rub see Appendix 2 (/appendices/appendix-2-how-to-hand-rub/)

Hand hygiene posters and leaflets can be found at Wash Your Hands of Them Resources (http://www.washyourhandsofthem.com/home.aspx).
NSS supported WHO World Hand Hygiene Day 2023 (/resources/who-world-hand-hygiene-day-5-may-2023-accelerate-action-together-save-lives-clean-your-hands/) 'Accelerate action together'.

Skin care

- Hand rubs when used for hand hygiene should contain emollients in their formulation.
- Warm/tepid water should be used to reduce the risk of dermatitis. Hot water should be avoided.
- Pat hands dry thoroughly after hand washing using disposable paper towels. Avoid rubbing which may lead to skin irritation/damage.
- Use an emollient hand cream during work and when off duty. These should be applied all over the hands including between the fingers and the back of the hands.
- Do not use refillable dispensers or provide communal tubs of hand cream in the care setting.
- Staff with skin problems should seek advice from occupational health or their GP.
- Barrier creams should not be used in the workplace.

Surgical hand antisepsis

Surgical scrubbing/rubbing applies to persons undertaking surgical and some invasive procedures.
Perform surgical scrubbing/rubbing before donning sterile theatre garments or at other times, for example prior to insertion of central vascular access devices.
Surgical scrubbing using an antimicrobial surgical scrub product should be used for the first surgical hand antisepsis of the day. Or perform hand hygiene using water and a non-antimicrobial liquid soap prior to the first surgical antisepsis of the day, this can be carried out in an adjacent clinical area.
For surgical scrubbing

- Remove all hand/wrist jewellery.
- Nail brushes should not be used for surgical hand antisepsis.
- Nail picks (single-use) can be used if nails are visibly dirty.
- Soft, non-abrasive, sterile (single-use) sponges may be used to apply antimicrobial liquid soap to the skin if licensed for this purpose.
- Use an antimicrobial liquid soap licensed for surgical scrubbing or hand rub licensed for surgical rubbing (as specified on the product label).
- Hand rub can be used between surgical procedures if licensed for this use or between glove changes if hands are not visibly soiled.
- Skin should be blotted dry with sterile single-use towels.

Resources

- For surgical scrubbing technique see Appendix 3 (/appendices/appendix-3-surgical-scrubbing/).
- For surgical rubbing technique see Appendix 4 (/appendices/appendix-4-surgical-rubbing/).

Further information can be found in the **Hand Hygiene literature reviews**:

- Hand washing, hand rubbing and indications for hand hygiene (/web-resources-container/standard-infection-control-precautions-sicp-literature-review-hand-hygiene-hand-washing-hand-rubbing-and-indications-for-hand-hygiene/)
- Hand hygiene products (/web-resources-container/sicp-literature-review-hand-hygiene-products/)
- Skin care (/web-resources-container/sicp-literature-review-hand-hygiene-skin-care/)
- Surgical hand antisepsis in the clinical setting (/web-resources-container/literature-review-hand-hygiene-surgical-hand-antisepsis-in-the-clinical-setting/)

1.3 Respiratory and Cough Hygiene

Respiratory and cough hygiene is designed to minimise the risk of cross-transmission of respiratory illness (pathogens).

- Cover the nose and mouth with a disposable tissue when sneezing, coughing, wiping and blowing the nose. If a disposable tissue is not available use elbow to cover the nose and mouth when coughing or sneezing.
- Patients showing symptoms of respiratory illness should be encouraged to wear a surgical (TYPE II R FRSM) face mask where it is clinically safe and tolerated by the wearer.
- Dispose of used tissues and face masks promptly into a waste bin.
- In the absence of disposable tissues and hand hygiene facilities only, individuals should cough or sneeze into their elbow/sleeve.
- Wash hands with non-antimicrobial liquid soap and warm water after coughing, sneezing, using tissues, or after contact with respiratory secretions or objects contaminated by these secretions.
- Where there is no running water available or hand hygiene facilities are lacking, staff may use hand wipes followed by ABHR and should wash their hands at the first available opportunity.
- Keep contaminated hands away from the eyes nose and mouth.

Staff should promote respiratory and cough hygiene helping those who need assistance with this, for example elderly and children, providing patients with tissues, plastic bags for used tissues and hand hygiene facilities as necessary.

Resources

Further information can be found in the cough etiquette/respiratory hygiene literature review (/web-resources-container/sicp-literature-review-cough-etiquette/).

1.4 Personal Protective Equipment

Before undertaking any care task or procedure staff should assess any likely exposure to blood and/or body fluids and ensure PPE is worn that provides adequate protection against the risks associated with the procedure or task being undertaken.

All PPE should be:

- located close to the point of use
- stored to prevent contamination in a clean/dry area until required for use (expiry dates must be adhered to)
- single-use only items unless specified by the manufacturer
- changed immediately after each patient and/or following completion of a procedure or task
- disposed of after use into the correct waste stream i.e. healthcare waste or domestic waste

Reusable PPE items, for example non-disposable goggles/face shields/visors must have a decontamination schedule with responsibility assigned.

Resources

Further information on best practice for PPE use for SICPs can be found in Appendix 16 (/appendices/appendix-16-selection-of-personal-protective-equipment-ppe-by-healthcare-workers-hcws-during-the-provision-of-patient-care/).

Gloves must:

- be worn when exposure to blood, body fluids, (including but not limited to secretions and/or excretions), non-intact skin, lesions and/or vesicles, mucous membranes, hazardous drugs and chemicals, for example cleaning agents is anticipated/likely. (**Scottish National Blood Transfusion Service (SNBTS) adopt practices that differ from those stated in the National Infection Prevention and Control Manual)**;
    - Gloves are a single-use item and should be donned immediately prior to exposure risk and should be changed immediately after each use or upon completion of a task;
- never be worn inappropriately in situations such as to go between patients, move around a care area, work at IT workstations
- be changed if a perforation or puncture is suspected or identified
- be appropriate for use, fit for purpose and well-fitting
- not be worn as a substitute to hand hygiene.

Double gloving is only recommended during some Exposure Prone Procedures (EPPs) e.g. orthopaedic and gynaecological operations or when attending major trauma incidents and when caring for a patient with a suspected or known High Consequence Infectious disease. Double gloving is not necessary at any other time.

Resources

For appropriate glove use and selection see Appendix 5 (/appendices/appendix-5-gloves-use-and-selection/).

Further information can be found in the Gloves literature review (/web-resources-container/sicp-literature-review-personal-protective-equipment-ppe-gloves/).

Aprons must be:

- worn to protect uniform or clothes when contamination is anticipated/likely
- worn when in direct care contact with a patient or their immediate environment, for example providing toileting support or changing bed linen
- changed between patients and following completion of a procedure or task

Full body gowns/fluid repellent coveralls must be:

- worn when there is a risk of extensive splashing of blood and/or other body fluids, for example in the operating theatre
- worn when a disposable apron provides inadequate cover for the procedure/task being performed
- changed between patients and immediately after completion of a procedure or task

The choice of apron or gown is based on a risk assessment and anticipated level of body fluid exposure. Routine sessional use of gowns/aprons is not permitted.

Sterile surgical gowns must be:

- worn by all scrubbed members of the operating theatre surgical team
- worn for insertion of central venous catheters, insertion of peripherally inserted central catheters, insertion of pulmonary artery catheters and spinal, epidural and caudal procedures

Reusable gowns must:

- not be worn in the operating theatre environment or for aseptic surgical procedures
- be appropriately processed between uses based on manufacturer's instructions

If hand hygiene with soap and water is required, this should not be performed whilst wearing an apron/gown in line with a risk of apron/gown contamination; hand hygiene using ABHR is acceptable.

Resources

Further information can be found in the Aprons/Gowns literature review (/web-resources-container/sicp-and-tbp-literature-review-personal-protective-equipment-ppe-apronsgowns/).

Eye/face protection must:

- be worn if blood and/or body fluid contamination to the eyes/face is anticipated/likely and always during Aerosol Generating Procedures (/glossary/#Aerosol%20Generating Procedures (AGPs))
- be worn by all scrubbed members of the surgical team for all surgical procedures
- not be impeded by accessories such as piercings/false eyelashes
- not be touched when worn
- cover the full peri-orbital region and wrap around the sides of the face
- be removed or changed in accordance with manufacturer's instructions, if vision is compromised through contamination with blood or body fluids, if the integrity of the equipment is compromised, at the end of a clinical procedure/task and/or prior to leaving the dedicated clinical area.

Regular corrective spectacles and safety spectacles are not considered eye protection.

Resources

Further information can be found in the eye/face protection literature review (/web-resources-container/standard-infection-control-precautions-and-transmission-based-precautions-literature-review-personal-protective-equipment-ppe-eyeface-protection/).

Fluid Resistant Type IIR surgical face masks must be:

- worn by a patient known or suspected to be infected with a micro-organism spread by the droplet or airborne route when leaving their room or when moving between clinical areas including transfers by portering staff and ambulance services
- worn if splashing or spraying of blood, body fluids, secretions or excretions onto the respiratory mucosa (nose and mouth) is anticipated/likely. (As part of SICPs a full-face visor may be used as an alternative to fluid resistant Type IIR surgical face masks to protect against splash or spray)
- worn in combination with a full-face shield, integrated half face shield or goggles for AGPs on non-infectious patients

- worn to protect patients from the operator as a source of infection when performing invasive spinal procedures such as myelography, lumbar puncture and spinal anaesthesia, inserting a Central Vascular Catheter (CVC), performing intra-articular (joint) injections
- worn by all scrubbed members of the theatre surgical team for all surgical procedures
- worn by non-scrubbed members of the theatre surgical team if deemed necessary following a risk assessment of exposure to blood and/or body fluids
- well fitting and fit for purpose (fully covering the mouth and nose)
- removed or changed:
  - at the end of a procedure/task
  - if the integrity of the mask is breached, e.g. from moisture build-up after prolonged use or from gross contamination with blood or body fluids
  - in accordance with specific manufacturers' instructions

Transparent face masks

Transparent face masks may be used to aide communication with patients in some settings.

Transparent face masks must:

- meet the specification standards of the Transparent face mask technical specification (https://azuksappnpdsa01.blob.core.windows.net/datashare/Transparent-Mask-Specifications-December-2023.pdf)

and

- have been approved by the UK Transparent Mask review group for use within health and social care settings
- only be worn in areas where Fluid Resistant Type IIR surgical face masks are used as personal protective equipment.

Resources

Further information can be found in:

- aerosol generating procedures literature review (https://hpspubsrepo.blob.core.windows.net/hps-website/nss/2893/documents/1_tbp-lr-agp-v1.1.pdf)
- surgical face masks literature review (/web-resources-container/standard-infection-control-precautions-and-transmission-based-precautions-literature-review-surgical-face-masks/)
- section 2.4 (/chapter-2-transmission-based-precautions-tbps/) of the NIPCM
- appendix 11 (/appendices/appendix-11-aide-memoire-for-patient-placement-considerations-and-respiratory-protective-equipment-rpe-or-fluid-resistant-surgical-facemasks-frsms-for-infectious-agents/) of the NIPCM

Footwear must be:

- non-slip, impervious, clean and well maintained, and support and cover the entire foot to avoid contamination with blood or other body fluids or potential injury from sharps
- removed before leaving a care area where dedicated footwear is used, for example theatre. Employees must clean and decontaminate footwear upon removal and when visibly soiled with blood and/or body fluids following manufacturers recommended instructions for cleaning and disinfection
- dedicated for use in settings such as theatres and stored in a designated area when not in use

Footwear found to be defective should be repaired or replaced before further use.
Overshoes/shoe covers should not be used in the general health and care environment.

Resources

Further information can be found in the footwear literature review (/web-resources-container/sicp-literature-review-personal-protective-equipment-ppe-footwear/).

Headwear must be:

- worn in theatre settings/restricted and semi-restricted areas
- worn as PPE for procedures where splashing/spraying of body fluids is anticipated, and as source control when performing clean/aseptic procedures where risk of infection is deemed to be high
- well-fitting and completely cover the hair
- changed/disposed of at the end of a single clinical procedure/task or at the end of a theatre session (for sessional use): immediately if contaminated with blood and/or body fluids
- removed before leaving the theatre/clean room.

Resources

Further information can be found in the headwear literature review (/web-resources-container/standard-infection-control-precautions-sicp-literature-review-personal-protective-equipment-ppe-headwear/)

For the recommended method of putting on and removing PPE see video below and Appendix 6 (/appendices/appendix-6-putting-on-and-removing-ppe/).

COVID-19 - the correct order for donning, doffing and disposal of PPE for HCWs in a primary care setting

NHS National Services Scotland

06:12

The correct order for donning, doffing and disposal of PPE for healthcare workers (https://vimeo.com/393951705) from NHS National Services Scotland (https://vimeo.com/nationalservicesscotland) on Vimeo (https://vimeo.com).

PPE for visitors

PPE may be offered to visitors to protect them from acquiring a transmissible infection. If a visitor declines to wear PPE when it is offered then this should be respected and the visit must not be refused. PPE use by visitors cannot be enforced and there is no expectation that staff monitor PPE use amongst visitors. Below is the PPE which should be worn where it is appropriate to do so and when the visitor chooses to do so.

Visitors do not routinely require PPE unless they are providing direct care to the individual they are visiting.

The table below provides a guide to PPE for use by visitors if **delivering direct care.**

IPC Precaution	Gloves	Apron	Face covering/mask	Eye/Face Protection
Standard Infection Control Precautions (SICPs)	Not required*1	Not required*2	Where splash/spray to nose/mouth is anticipated during direct care	Not required*3
Transmission Based Precautions (TBPs)	Not required*1	Not required*2	If within 2 metres of service user with suspected or known respiratory infection	If within 2 metres of service user with suspected or known respiratory infection

*1 unless providing direct care which may expose the visitor to blood and/or body fluids i.e. toileting.
*2 unless providing care resulting in direct contact with the service user, their environment or blood and/or body fluid exposure i.e. toileting, bed bath.
*3 Unless providing direct care and splashing/spraying is anticipated

1.5 Safe Management of Care Equipment

Care equipment is easily contaminated with blood, other body fluids, secretions, excretions and infectious agents. Consequently it is easy to transfer infectious agents from communal care equipment during care delivery.
Care equipment is classified as either:

- **Single-use** – equipment which is used once on a single patient and then discarded. Must never be reused even on the same patient. The packaging carries the symbol below.

  - Needles and syringes are single use devices. They should never be used for more than one patient or reused to draw up additional medication.
  - Never administer medications from a single-dose vial or intravenous (IV) bag to multiple patients.
- **Single patient use** – equipment which can be reused on the same patient.
- **Reusable invasive equipment** - used once then decontaminated for example surgical instruments.
- **Reusable non-invasive equipment (often referred to as communal equipment)** - reused on more than one patient following decontamination between each use e.g. commode, patient transfer trolley.

Before using any sterile equipment check that:

- the packaging is intact
- there are no obvious signs of packaging contamination
- the expiry date remains valid

Decontamination of reusable non-invasive care equipment must be undertaken:

- between each use
- after blood and/or body fluid contamination
- at regular predefined intervals as part of an equipment cleaning protocol
- before inspection, servicing or repair

Adhere to manufacturers' guidance for use and decontamination of all care equipment.
All reusable non-invasive care equipment must be rinsed and dried following decontamination then stored clean and dry.
Decontamination protocols should include responsibility for, frequency of and method of environmental decontamination.
An equipment decontamination status certificate will be required if any item of equipment is being sent to a third-party, for example for inspection, servicing or repair.
Guidance may be required prior to procuring, trialling or lending any reusable non-invasive equipment.
Resources
Further information can be found in the management of care equipment literature review (/web-resources-container/sicp-and-tbp-literature-review-management-of-care-equipment/).
For how to decontaminate reusable non-invasive care equipment see Appendix 7 (/appendices/appendix-7-decontamination-of-reusable-non-invasive-care-equipment/).

1.6 Safe Management of Care Environment

It is the responsibility of the person in charge to ensure that the care environment is safe for practice (this includes environmental cleanliness/maintenance). The person in charge must **act** if this is deficient.
The care environment must be:

- visibly clean, free from non-essential items and equipment to facilitate effective cleaning
- well maintained and in a good state of repair

- routinely cleaned in accordance with the Health Facilities Scotland (HFS) National Cleaning Specification (https://www.nss.nhs.scot/publications/nhsscotland-national-cleaning-services-specification-shfn-01-02/):
  - a fresh solution of general-purpose neutral detergent in warm water is recommended for routine cleaning. This should be changed when dirty or at 15 minutes intervals or when changing tasks
  - routine disinfection of the environment is not recommended. However, 1,000ppm available chlorine should be used routinely on sanitary fittings

Staff groups should be aware of their environmental cleaning schedules and clear on their specific responsibilities.
Cleaning protocols should include responsibility for; frequency of; and method of environmental decontamination.
When an organisation adopts decontamination processes not recommended in the NIPCM the care organisation is responsible for governance of and completion of local risk assessment(s) to ensure safe systems of work.
Resources
Further information can be found in the routine cleaning of the environment in hospital setting literature review (/web-resources-container/sicp-literature-review-routine-cleaning-of-the-care-environment/).

1.7 Safe Management of Linen

Clean linen

- Should be stored in a clean, designated area, preferably an enclosed cupboard.
- If clean linen is not stored in a cupboard then the trolley used for storage must be designated for this purpose and completely covered with an impervious covering that is able to withstand decontamination.

Linen used during patient transfer

- Any linen used during patient transfer, for example blankets, should be categorised at the point of destination.

For all used linen (previously known as soiled linen)

- Ensure a laundry receptacle is available as close as possible to the point of use for immediate linen deposit.
- Do not:
  - rinse, shake or sort linen on removal from beds/trolleys
  - place used linen on the floor or any other surfaces, for example a locker/table top
  - re-handle used linen once bagged
  - overfill laundry receptacles
  - place inappropriate items in the laundry receptacle, for example used equipment/needles

For all infectious linen (this mainly applies to healthcare linen)
This is linen that has been used by a patient who is known or suspected to be infectious and/or linen that is contaminated with blood and/or other body fluids for example faeces.

- Place directly into a water-soluble/alginate bag and secure, then place into a plastic bag, for example clear bag, and secure before placing in a laundry receptacle. This applies also to any item(s) heavily soiled and unlikely to be fit for reuse.
- Used and infectious linen bags/receptacles must be tagged, for example ward/care area and date.
- Store all used/infectious linen in a designated, safe, lockable area whilst awaiting uplift. Uplift schedules must be acceptable to the care area and there should be no build-up of linen receptacles.

Local guidance regarding management of linen may be available.
All linen that is deemed unfit for re-use, for example torn or heavily contaminated, should be categorised at the point of use and returned to the laundry for disposal.
Resources
Further information can be found in the safe management of linen literature review (/web-resources-container/sicp-literature-review-safe-management-of-linen-in-the-hospital-setting/) and National Guidance for Safe Management of Linen in NHSScotland Health and Care Environments - For laundry services/distribution (https://www.nss.nhs.scot/publications/national-guidance-for-safe-management-of-linen-in-nhsscotland-health-and-care-environments-for-laundry-servicesdistribution-v22/).
Further information about linen bagging and tagging can be found in Appendix 8 (/appendices/appendix-8-management-of-linen-at-care-level/).
Scottish Government uniform, dress code and laundering policy (https://www.sehd.scot.nhs.uk/dl/DL(2018)04.pdf) is available.

1.8 Safe Management of Blood and Body Fluid Spillages

Spillages of blood and other body fluids may transmit blood borne viruses.

Spillages must be decontaminated immediately by staff trained to undertake this safely. Responsibilities for the decontamination of blood and body fluid spillages should be clear within each area/care setting.
If superabsorbent polymer gel granules for containment of bodily waste are used these should be used in line with national guidance. In Scotland refer to Safety Action Notice - SAN(SC)19/03 | National Services Scotland (nhs.scot) (https://eur01.safelinks.protection.outlook.com/?url=https%3A%2F%2Fwww.nss.nhs.scot%2Fpublications%2Fsafety-action-notice-san-sc-

1903%2F&data=05%7C01%7CCaroline.Creasey%40nhs.scot%7C7a077363eb78489abd9708dad6d1a43f%7C10efe0bda0304bca809cb5e67

Resources

For management of blood and body fluid spillages see Appendix 9 (/appendices/appendix-9-management-of-blood-and-body-fluid-spillages/).
Further information can be found in the management of blood and body fluid in health and social care settings literature review. (/web-resources-container/sicp-literature-review-management-of-blood-and-body-fluid-spillages-in-the-hospital-setting/)

1.9 Safe Disposal of Waste (including sharps)

Scottish Health Technical Note (SHTN) 3: NHSScotland Waste Management Guidance contains the regulatory waste management guidance for NHSScotland including waste classification, segregation, storage, packaging, transport, treatment and disposal.
The Health and Safety (Sharp Instruments in Healthcare) Regulations 2013 outline the regulatory requirements for employers and contractors in the healthcare sector in relation to the safe disposal of sharps.

Categories of waste

- **Healthcare (including clinical) waste** – is produced as a direct result of healthcare activities, for example soiled dressings, sharps.
- **Special (or hazardous) waste** – arises from the delivery of healthcare in both clinical and non-clinical settings. Special waste includes a range of controlled wastes, defined by legislation, which contain dangerous or hazardous substances for example chemicals, pharmaceuticals.
- **Domestic waste** – must be segregated at source into:
  - dry recyclates (glass, paper and plastics, metals, cardboard)
  - residual waste (any other domestic waste that cannot be recycled).

Waste streams

- **Black – trivial risk**
  - **Domestic waste or yellow and black stripes** (small quantities of hygiene waste).
  - Final disposal to landfill.
  - Clear/opaque receptacles may also be used for domestic waste at care area level.
- **Orange, light blue (laboratory) – low risk**
  - **Orange** - consists of items which are contaminated or likely to be contaminated with blood and/or body fluids including saliva. Final disposal following heat disinfection is to landfill.
  - **Light blue** – laboratory/microbiological waste that must be autoclaved before disposal via the orange stream.
- **Yellow– high risk**
  - Waste which poses ethical, highly infectious or contamination risks.
  - This includes anatomical and human tissue which is recognisable as body parts, medical devices and sharps waste boxes that have red, purple or blue lids.
  - Disposal is by specialist incineration.
- **Red – special waste**
  - Chemical waste.

For **care/residential homes** waste disposal may differ from the categories described above and guidance from local contractors will apply. Refer to SEPA guidance (http://www.sepa.org.uk/waste.aspx).

Safe waste disposal at care area level
Always dispose of waste:

- immediately and as close to the point of use as possible
- into the correct segregated colour coded UN 3291 approved waste bag (either orange/yellow for healthcare waste or black/clear/opaque for domestic) or container (sharps box)

Liquid waste, for example blood, must be rendered safe by adding a self-setting gel or compound before placing in an orange lidded leak-proof bin.
Waste bags must be no more than 3/4 full or more than 4 kgs in weight and use a ratchet tag/or tape (for healthcare waste bags only) using a 'swan neck' to close with the point of origin and date of closure clearly marked on the tape/tag.
Store all waste in a designated, safe, lockable area whilst awaiting uplift. Uplift schedules must be acceptable to the care area and there should be no build-up of waste receptacles.
Sharps boxes must:

- have a dedicated handle
- have a temporary closure mechanism, which must be employed when the box is not in use
- be labelled with date of assembly, point of origin and date of closure.
- be disposed of when the manufacturers' fill line is reached or following 3 months of assembly (whichever is first)

Local guidance regarding management of waste at care level may be available.
Resources
Further information can be found in the safe disposal of waste literature review. (/web-resources-container/sicp-literature-review-the-safe-disposal-of-waste/)

1.10 Occupational Safety: Prevention and Exposure Management (including sharps)

Exposure in relation to blood borne viruses (BBV) is the focus within this section and reflects the existing evidence base.
The Health and Safety (Sharp Instruments in Healthcare) Regulations 2013 outline the regulatory requirements for employers and contractors in the healthcare sector in relation to:

- arrangements for the safe use and disposal of sharps
- provision of information and training to employees
- investigations and actions required in response to work related sharps injuries

Sharps handling must be assessed, kept to a minimum and eliminated if possible with the use of approved safety devices.
Manufacturers' instructions for safe use and disposal must be followed.
Needles must not be re-sheathed/recapped.[4]
Always dispose of needles and syringes as 1 unit.
If a safety device is being used safety mechanisms must be deployed before disposal.
Occupational exposure
An occupational exposure is a percutaneous or mucocutaneous exposure to blood or other body fluids.
Occupational exposure risk can be reduced via application of other SICPs and TBPs outlined within the NIPCM.
Significant occupational exposure
A significant occupational exposure is a percutaneous or mucocutaneous exposure to blood or other body fluids from a source that is known, or found to be positive for a blood borne virus (BBV).
Examples of significant occupational exposures would be:

- a percutaneous injury, for example injuries from needles, instruments, bone fragments, or bites which break the skin
- exposure of broken skin, for example abrasions, cuts, eczema
- exposure of mucous membranes including the eye from splashing of blood or other high risk body fluids

There is a potential risk of transmission of a Blood Borne Virus (BBV) from a significant occupational exposure and staff must understand the actions they should take when a significant occupational exposure incident takes place. There is a legal requirement to report all sharps injuries and near misses to line managers/employers.
Additionally, employers are obligated to minimise or eliminate workplace risks where it is reasonably practicable. Immunisation against BBV should be available to all qualifying staff, and testing (and post exposure prophylaxis when applicable) offered after significant occupational exposure incidents.
Resources
For the management of an occupational exposure incidents see Appendix 10 (/appendices/appendix-10-management-of-occupational-exposure-incidents/)
Exposure prone procedures (EEPs)
Exposure prone procedures (EEPs) are invasive procedures where there is a risk that injury to the healthcare worker may result in the exposure of the patient's open tissues to the blood of the worker (bleed-back).
There are some exclusions for HCWs with known BBV infection when undertaking EPPs. The details of these and further information can be found in the occupational exposure management (including sharps) literature review (/web-resources-container/sicp-literature-review-occupational-exposure-management-including-sharps/).

[4] **A local risk assessment is required if re-sheathing is undertaken using a safe technique for example anaesthetic administration in dentistry.**

Chapter 2 - Transmission Based Precautions (TBPs)

SICPs may be insufficient to prevent cross transmission of specific infectious agents. Therefore, additional precautions, TBPs, are required to be used by staff when caring for patients with a known or suspected infection or colonisation.
Clinical judgement and decisions should be made by staff on the necessary precautions. This must be based on the:

- suspected or known infectious agent
- transmission route of the infectious agent
- care setting and procedures undertaken
- severity of the illness caused

TBPs are categorised by the route of transmission of infectious agents (some infectious agents can be transmitted by more than one route): Appendix 11 (/appendices/appendix-11-aide-memoire-for-patient-placement-considerations-and-respiratory-protective-equipment-rpe-or-fluid-resistant-surgical-facemasks-frsms-for-infectious-agents/) provides details of the type of precautions, optimal patient placement, isolation requirements and any respiratory precautions required. Application of TBPs may differ depending on the setting and the known or suspected infectious agent.
Please Note: The Transmission Based Precautions Literature Review is currently undergoing a full update with new research questions (available on request).

Contact precautions

Used to prevent and control infections that spread via direct contact with the patient or indirectly from the patient's immediate care environment (including care equipment). This is the most common route of cross-infection transmission.

Droplet precautions

Used to prevent and control infections spread over short distances (at least 3 feet or 1 metre) via droplets (greater than 5µm) from the respiratory tract of one individual directly onto a mucosal surface or conjunctivae of another individual. Droplets penetrate the respiratory system to above the alveolar level.

Airborne precautions

Used to prevent and control infections spread without necessarily having close patient contact via aerosols (less than or equal to 5µm) from the respiratory tract of one individual directly onto a mucosal surface or conjunctivae of another individual. Aerosols penetrate the respiratory system to the alveolar level.
Further information on Transmission Based Precautions can be found in the definitions of Transmission Based Precautions literature reviews. (/web-resources-container/tbp-literature-review-definitions-of-transmission-based-precautions/)

Last updated: 28 August 2023

2.1 Patient Placement/Assessment for Infection Risk

The potential for transmission of infection must be assessed at the patient's entry to the care area. If hospitalised or in a care home setting this should be continuously reviewed throughout the stay/period of care. The assessment should influence placement decisions in accordance with clinical/care need(s).
Patients who may present a cross-infection risk in any setting includes but is not limited to those:

- with symptoms such as loose stools or diarrhoea, vomiting, fever or respiratory symptoms.
- with a known (laboratory confirmed) or suspected infectious pathogen for which **appropriate** duration of precautions as outlined in A-Z of pathogens (/a-z-pathogens/) are not yet complete
- known or suspected to have been previously positive with a Multi-drug Resistant Organism (MDRO), for example MRSA, CPE
- who have been hospitalised (inpatient) outside Scotland in the last 12 months (including those who received dialysis)

Further information regarding general respiratory screening questions (/media/2147/2023-08-23-respiratory-screening-questions-aide.pdf) can be found within the resources section of the NIPCM.
Isolation facilities should be prioritised depending on the known/suspected infectious agent (refer to Aide Memoire - Appendix 11 (/appendices/appendix-11-aide-memoire-for-patient-placement-considerations-and-respiratory-protective-equipment-rpe-or-fluid-resistant-surgical-facemasks-frsms-for-infectious-agents/)). All patient placement decisions and assessment of infection risk (including isolation requirements) must be clearly documented in the patient notes.
When single-bed rooms are limited, patients who have conditions that facilitate the transmission of infection to other patients (e.g., draining wounds, stool incontinence, uncontained secretions) and those who are at increased risk of acquisition and adverse outcomes resulting from HAI (e.g., immunosuppression, open wounds, invasive devices, anticipated prolonged length of stay, total dependence on HCWs for activities of daily living) should be prioritised for placement in a single-bed room. Single-bed room prioritisation should be reviewed daily and the clinical judgement and expertise of the staff involved in a patient's management and the Infection Prevention and Control Team (IPCT) or Health Protection Team (HPT) should be sought particularly for the application of TBPs e.g. isolation prioritisation when single rooms are in short supply.

Hospital settings

- Patients who present a cross-infection risk should be isolated in a single room or for patients with a known or suspected pathogen spread by the airborne route, in a specialised negative pressure isolation facility where available.
- Isolation of infectious patients can be in specialised isolation facilities, single room isolation, cohorting of infectious patients where appropriate, ensuring that they are separated by at least 2 metres with the door closed.
- Signage should be used on doors/areas to communicate isolation requirements and prevent entry of unnecessary visitors and non-essential staff.

- Infectious patients should only be transferred to other departments if medically necessary. If the patient has an infectious agent transmitted by the airborne/droplet route, then if possible/tolerated the patient should wear a surgical face mask during transfer.
- Receiving department/hospital and transporting staff must be aware of the necessary precautions.

Cohorting in hospital settings
Cohorting of patients
Cohorting of patients should only be considered when single rooms are in short supply and should be undertaken in conjunction with the local IPCT.
Patients who should not be placed in multi bed cohorts:

- patients with **different** infectious pathogens/strains and patients with unknown infectious pathogens (laboratory confirmation still awaited)
- patients considered more vulnerable to infection
- patients with a known or suspected infectious pathogen spread by the droplet/airborne route who will undergo an AGP
- patients who are unlikely to comply with TBPs

Staff cohorting
Consider assigning a dedicated team of care staff to care for patients in isolation/cohort rooms/areas as an additional infection control measure during outbreaks/incidents. This can only be implemented through planning of staff rotas if there are sufficient levels of staff available to ensure consistency in staff allocation (so as not to have a negative impact on non-affected patients' care).
Before discontinuing isolation in hospital settings
Individual patient risk factors should be considered, for example there may be prolonged shedding of certain microorganisms in immunocompromised patients). Clinical and molecular tests to show the absence of microorganisms may be considered in the decision to discontinue isolation and can reduce isolation times. The clinical judgement and expertise of the staff involved in a patient's management and the Infection Prevention and Control Team (IPCT) or Health Protection Team (HPT) should be sought on decisions regarding isolation discontinuation.
Primary care/out-patient settings

- Patients attending these settings with suspected/known infection/colonisation should be prioritised for assessment/treatment, for example scheduled appointments at the start or end of the clinic session. Infectious patients should be separated from other patients whilst awaiting assessment and during care management wherever possible.
- If transfer from a primary care facility to hospital is required, the ambulance service should be informed of the infectious status of the patient.

Resources
Further information can be found in the patient placement literature review (https://hpspubsrepo.blob.core.windows.net/hps-website/nss/2511/documents/1_sicp-tbp-patient-placement-v1.0.pdf).

2.2 Safe Management of Patient Care Equipment in an Isolation Room/Cohort Area

- Use single-use items if possible.
- Reusable non-invasive care equipment should be dedicated to the isolation room/cohort area and decontaminated prior to use on another patient Section 1.5. Safe Management of Care Equipment (/chapter-1-standard-infection-control-precautions-sicps/#a1081)
- An increased frequency of decontamination should be considered for reusable non-invasive care equipment when used in isolation/cohort areas.

If an item cannot withstand chlorine releasing agents staff are advised to consult the manufacturer's instructions for a suitable alternative to use following or combined with detergent cleaning.
Resources
For how to decontaminate non-invasive reusable equipment see Appendix 7. (/appendices/appendix-7-decontamination-of-reusable-non-invasive-care-equipment/)
Note: Scottish Ambulance Service (SAS) and Scottish National Blood Transfusion Service adopt practices that differ from those stated in the National Infection Prevention and Control Manual.

2.3 Safe Management of the Care Environment

Routine environmental decontamination
Hospital/care home setting
Patient isolation/cohort rooms/area must be decontaminated **at least daily**, this may be increased on the advice of IPCTs/HPTs. These areas must be decontaminated using either:

- a combined detergent/disinfectant solution at a dilution of 1,000 parts per million available chlorine (ppm available chlorine (av.cl.)) or
- a general purpose neutral detergent in a solution of warm water followed by disinfection solution of 1,000ppm av.cl.

Manufacturers' guidance and recommended product "contact time" must be followed for all cleaning/disinfection solutions .
Increased frequency of decontamination/cleaning schedules should be incorporated into the environmental decontamination schedules for areas where there may be higher environmental contamination rates, for example

- toilets/commodes particularly if patients have diarrhoea
- “frequently touched” surfaces such as door/toilet handles and locker tops, over bed tables and bed rails

Patient rooms must be terminally cleaned following resolution of symptoms, discharge or transfer. This includes removal and laundering of all curtains and bed screens.
Vacated rooms should also be decontaminated following an AGP.

Primary care/out-patient settings

The extent of decontamination between patients will depend on the duration of the consultation/assessment, the patients presenting symptoms and any visible environmental contamination.
Equipment used for environmental decontamination must be either single-use or dedicated to the affected area then decontaminated or disposed of following use for example cloths, mop heads.

Terminal decontamination

Following patient transfer, discharge, or once the patient is no longer considered infectious.
Remove from the vacated isolation room/cohort area, all:

- healthcare waste and any other disposable items (bagged before removal from the room)
- bedding/bed screens/curtains and manage as infectious linen (bagged before removal from the room)
- reusable non-invasive care equipment (decontaminated in the room prior to removal) Appendix 7 (/appendices/appendix-7-decontamination-of-reusable-non-invasive-care-equipment/).

The room should be decontaminated using either:

- a combined detergent disinfectant solution at a dilution (1,000ppm av.cl.) or
- a general purpose neutral detergent clean in a solution of warm water followed by disinfection solution of 1,000ppm av.cl..

The room must be cleaned from the highest to lowest point and from the least to most contaminated point.
Manufacturers’ guidance and recommended product "contact time" must be followed for all cleaning/disinfection solutions .
Unless instructed otherwise by the IPCT there is no requirement for a terminal clean of an outpatient area or theatre recovery.
Note: Scottish Ambulance Service (SAS) and Scottish National Blood Transfusion Service adopt practices that differ from those stated in the National Infection Prevention and Control Manual.

When an organisation adopts practices that differ from those recommended/stated in the NIPCM with regards to cleaning agents, the individual organisation is fully responsible for ensuring safe systems of work, including the completion of local risk assessment(s) approved and documented through local governance procedures.

2.4 Personal Protective Equipment (PPE)

2.4.1 Surgical masks

A type IIR fluid resistant surgical mask should be worn when caring for a patient with a suspected/confirmed infectious agent spread by the droplet route.
Surgical masks worn by patients with suspected/confirmed infectious agents spread by the droplet or airborne routes, as a form of source control, should meet type II or IIR standards.

2.4.2 Eye/face protection

A face visor or goggles should be used in combination with a fluid resistant type IIR surgical mask when caring for symptomatic patients infected with droplet transmitted infectious agents.
A face visor or goggles should be used in combination with a fluid resistant FFP3 respirator when caring for symptomatic patients infected with an airborne transmitted infectious agent.
Eye/face protection should be worn

- by all of those in the room when potentially infectious AGPs are conducted
- for the care of patients with novel infectious agents including pandemic influenza

2.4.3 Aprons/Gowns

An apron should be worn when caring for patients known or suspected to be colonised/infected with antibiotic resistant bacteria including contact with the patient’s environment.
Plastic aprons should be used in health and social care settings for protection against contamination with blood and/or body fluids.
A fluid repellent gown should be used if excessive splashing or spraying is anticipated.
A full body fluid repellent gown should be worn when conducting AGPs on patients known or suspected to be infected with a respiratory infectious agent.

Resources

Further information can be found in the Aprons/Gowns literature review (/web-resources-container/standard-infection-control-precautions-sicp-literature-review-personal-protective-equipment-ppe-apronsgowns/).

2.4.4 Gloves

Gloves must:

- be worn when exposure to blood, body fluids, (including but not limited to secretions and/or excretions), non-intact skin, lesions and/or vesicles, mucous membranes, hazardous drugs and chemicals, e.g. cleaning agents is anticipated/likely;[2]
    - Gloves are a single-use item and should be donned immediately prior to exposure risk and should be changed immediately after each use or upon completion of a task;
- never be worn inappropriately in situations such as; to go between patients, move around a care area, work at IT workstations;

- be changed if a perforation or puncture is suspected or identified;
- be appropriate for use, fit for purpose and well-fitting;
- not be worn as a substitute to hand hygiene.

Double gloving is only recommended during some Exposure Prone Procedures (EPPs), for example orthopaedic and gynaecological operations, or when attending major trauma incidents and when caring for a patient with a suspected or known High Consequence Infectious disease. Double gloving is not necessary at any other time.

Resources

For appropriate glove use and selection see Appendix 5 (/appendices/appendix-5-gloves-use-and-selection/).
Further information can be found in the Gloves literature review (/web-resources-container/sicp-literature-review-personal-protective-equipment-ppe-gloves/).

2.4.5 RPE

PPE must still be used in accordance with SICPs when using Respiratory Protective Equipment. See Chapter 1.4 (/chapter-1-standard-infection-control-precautions-sicps/#a1080) for PPE use for SICPs.
Where it is not reasonably practicable to prevent exposure to a substance hazardous to health (as may be the case where healthcare workers are caring for patients with suspected or known airborne micro-organisms) the hazard must be adequately controlled by applying protection measures appropriate to the activity and consistent with the assessment of risk. If the hazard is unknown the clinical judgement and expertise of IPC/HP staff is crucial and the precautionary principle should apply.

Respiratory Protective Equipment (RPE), for instance FFP3 and facial protection, must be considered when:

- a patient is admitted with a known/suspected infectious agent/disease spread wholly by the airborne route
- carrying out aerosol generating procedures (AGPs) on patients with a known/suspected infectious agent spread wholly or partly by the airborne or droplet route

See Appendix 17 (/appendices/appendix-17-aerosol-generating-procedures-agps-and-post-agp-fallow-time-pagpft/) for the extant list of Aerosol Generating Procedures which require the application of airborne precautions. Appendix 17 also includes details of associated Post AGP Fallow times.

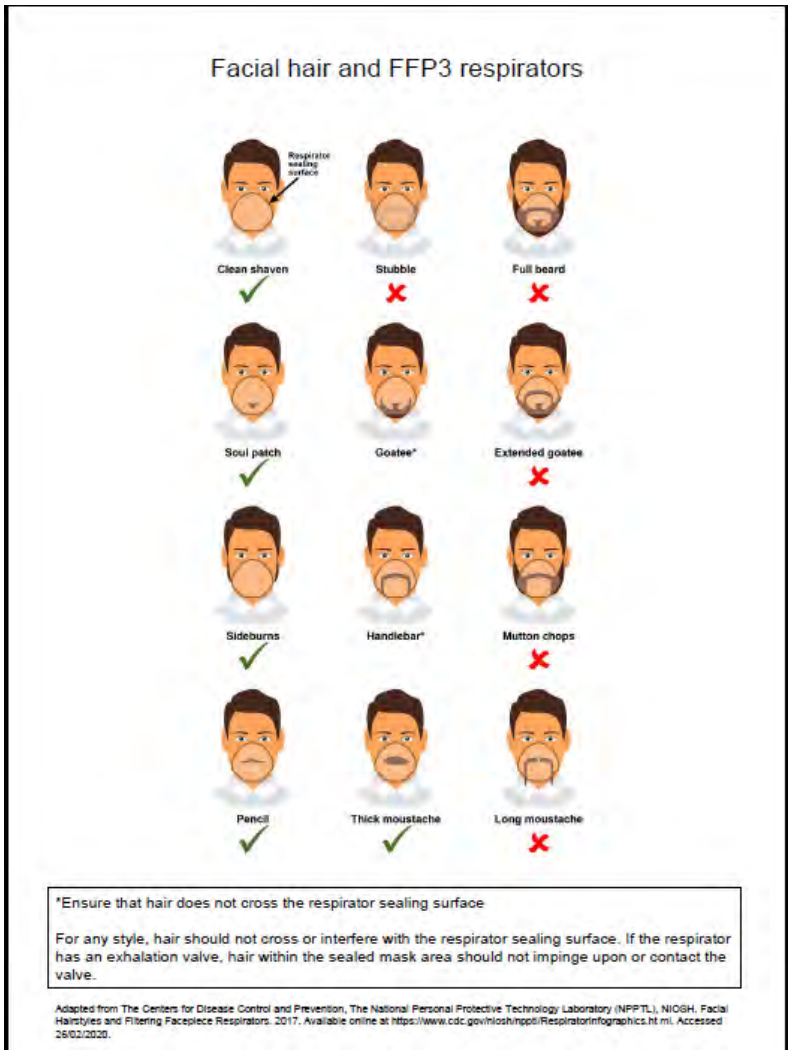
Filter Face Piece 3 (FFP3) Respirators

Where staff have concerns, they may choose to wear an FFP3 respirator rather than a fluid-resistant surgical mask (FRSM) when providing patient care, provided they are fit tested. This is a personal PPE risk assessment.
All tight fitting RPE (for instance FFP3) respirators must be:

- fit tested (by a competent fit test operator) on all healthcare staff who may be required to wear a respirator to ensure an adequate seal/fit according to the manufacturers' guidance
- fit checked (according to the manufacturers' guidance) every time a respirator is donned to ensure an adequate seal has been achieved. The poster below gives further information on compatibility of facial hair and FFP3 respirators and can be used when fit testing and fit checking
- single use (disposable) and fluid-resistant. Valved respirators may be shrouded or unshrouded. Respirators with unshrouded valves are not considered to be fluid-resistant and therefore should be worn with a full face shield if blood or body fluid splashing is anticipated
- non valved if a sterile procedure is being performed at the same time as an AGP requiring a respirator to be worn. An MHRA safety alert (https://www.cas.mhra.gov.uk/ViewandAcknowledgment/ViewAlert.aspx?AlertID=103169) can be viewed.
- compatible with other facial protection used, for instance protective eyewear, so that this does not interfere with the seal of the respiratory protection. Regular corrective spectacles are not considered adequate eye protection. If wearing a valved, non-shrouded FFP3 respirator a full face shield/visor must be worn
- always put on before entry into the patient room/area and prior to performing an aerosol generating procedure (AGP) and removed in an anteroom/lobby or in a safe area, for example outside the isolation/cohort room/area. All other PPE should be removed in the patient care area
- changed after each use. Other indications that a change in respirator is required include: if breathing becomes difficult, if the respirator becomes wet or moist, damaged or obviously contaminated with body fluids such as respiratory secretions.

Resources

Poster on compatibility of facial hair and FFP3 respirators can be used when fit testing and fit checking.



Further information regarding fitting and fit checking of respirators can be found on the Health and Safety Executive website. (http://www.hse.gov.uk/respiratory-protective-equipment/basics.htm)

National Priority Risk Categorisation for face fit testing with FFP3

The following risk categorisation is the minimum requirement for staff groups that require FFP3 fit testing. NHS boards can add to this for example where high-risk units are present. This categorisation is inclusive of out of hours services.

Level 1 – Preparedness for business as usual

Staff in clinical areas most likely to provide care to patients who present at healthcare facilities with an infectious pathogen spread by the airborne route; and/or undertake aerosol generating procedures. These are A&E, ICU, paediatrics, respiratory, infectious diseases, anaesthesia, theatres, Chest physiotherapists, Special Operations Response Team (Ambulance), A&E Ambulance Staff, Bronchoscopy Staff, Resuscitation teams, mortuary staff.

Level 2 – Preparedness in the event of emerging threat

Staff in clinical setting likely to provide care to patients admitted to hospital in the event of an emerging threat, for example Medical receiving, Surgical, Midwifery and Speciality wards, all other ambulance transport staff.

In the event of an 'Epidemic/Pandemic' Local Board Assessment as per their preparedness plans will apply.

The decision to wear an FFP3 respirator/hood should be based on clinical risk assessment, for example task being undertaken, the presenting symptoms, the infectious state of the patient, risk of acquisition and the availability of treatment.

Resources

For a list of organisms spread wholly or partly by the airborne (aerosol) or droplet routes see Appendix 11 (/appendices/appendix-11-aide-memoire-for-patient-placement-considerations-and-respiratory-protective-equipment-rpe-or-fluid-resistant-surgical-facemasks-frsms-for-infectious-agents/).

Further information can be found in the aerosol generating procedures literature review (/web-resources-container/tbp-literature-review-aerosol-generating-procedures/).

Powered respirator hoods

Powered respirator hoods are an alternative to FFP3 respirators for example when fit testing cannot be achieved.

Powered hoods must be:

- single use (disposable) and fluid resistant
- the filter must be enclosed with the exterior and the belt able to withstand disinfection with 10,000ppm av.cl.

FFP3 respirator or powered respirator hood

- may be considered for use by visitors if there has been no previous exposure to the infected person or infectious agent; **but**
- must never be worn by an infectious patient(s) due to the nature of the respirator filtration of incoming air not expelled air.

Work is currently underway by the UK Re-useable Decontamination Group examining the suitability of respirators for decontamination. This literature review will be updated to incorporate recommendations from this group when available. In the interim, ARHAI Scotland are unable to provide assurances on the efficacy of respirator decontamination methods and the use of re-useable respirators is not recommended.
Further information can be found in the Respiratory Protective Equipment (RPE) literature review (/web-resources-container/transmission-based-precautions-literature-review-respiratory-protective-equipment-rpe/) and the Personal Protective Equipment (PPE) for Infectious Diseases of High Consequence (IDHC) (/web-resources-container/literature-review-personal-protective-equipment-ppe-for-infectious-diseases-of-high-consequence-idhc/) literature review.
Frameworks to support the assessing and recording of staff competency in PPE for HCID are available in the resources section of the NIPCM (/resources/).

2.5 Infection Prevention and Control during care of the deceased

The principles of SICPs and TBPs continue to apply whilst deceased individuals remain in the care environment. This is due to the ongoing risk of infectious transmission via contact although the risk is usually lower than for living patients.
It is important that information on the infection status of the deceased is sought and communicated at each stage of handling.
Appropriate risk assessment must be carried out before performing activities that may increase the risk of transmission of infectious agents from deceased individuals (see literature review (/web-resources-container/tbp-literature-review-infection-prevention-and-control-during-care-of-the-deceased/) for further information on these activities).
Washing and/or dressing should not be carried out when the deceased is known or suspected to have been infected by any of the following key infectious agents: Hazard Group 4 organisms, anthrax, and rabies. For other HCIDs a local risk assessment should be undertaken to inform any decision making on washing and/or dressing of the deceased.
Viewing of the deceased should be avoided when the deceased is known or suspected to have been infected by Hazard Group 4 organisms, specifically those causing VHFs (including Ebola, Lassa etc.) and anthrax. For other HCIDs a local risk assessment should be undertaken to inform any decision making on viewing of the deceased.
See Appendix 12 Application of infection control precautions in the deceased (/appendices/appendix-12-application-of-infection-control-precautions-in-the-deceased/).
Staff should advise relatives of the appropriate precautions when viewing and/or having physical contact with the deceased including when this should be avoided.
Deceased individuals known or suspected to have a Hazard Group 4 infectious agent should be placed in a sealed double plastic body bag with absorbent material placed between each bag. The surface of the outer bag should then be disinfected with 1000 ppm av.cl before being placed in a robust sealed coffin.
Post-mortem examination should not be performed on a deceased individual known or suspected to have Hazard Group 4 infectious agents. See Appendix 12 Application of infection control precautions in the deceased (/appendices/appendix-12-application-of-infection-control-precautions-in-the-deceased/). Blood sampling can be undertaken in the mortuary by a competent person to confirm or exclude this diagnosis. Refer to Section 2.4 (/chapter-2-transmission-based-precautions-tbps/#a1091) for suitable PPE.
Post-mortem examination of deceased individuals known or suspected to have been infected by transmissible spongiform encephalopathies (TSE) causing agents should be carried out in such a way as to minimise contamination of the working environment. See Literature review (/web-resources-container/tbp-literature-review-infection-prevention-and-control-during-care-of-the-deceased/) for further information.

Chapter 3 - Healthcare Infection Incidents, Outbreaks and Data Exceedance

The purpose of this chapter is to support the early recognition of potential infection incidents and to guide IPCT/HPTs in the incident management process within care settings; (that is, NHSScotland, independent contractors providing NHS services and private providers of care).
This guidance is aligned to the Management of Public Health Incidents: Guidance on the Roles and Responsibilities of NHS led Incident Management Teams (https://publichealthscotland.scot/publications/management-of-public-health-incidents-guidance-on-the-roles-and-responsibilities-of-nhs-led-incident-management-teams/management-of-public-health-incidents-guidance-on-the-roles-and-responsibilities-of-nhs-led-incident-management-teams/)

Built environment incidents/outbreaks

ARHAI Scotland are currently working towards delivery of comprehensive evidence-based guidance which will form Chapter 4 of the National Infection Prevention and Control Manual (NIPCM) on the built environment and decontamination.
Two Aide-Memoires currently provide best practice recommendations to be implemented in the event of a healthcare water-associated or healthcare ventilation-associated infection incident/outbreak. These will ensure clinical staff, estates and facilities staff, and Infection Prevention and Control Teams (IPCT) have an understanding of the preventative measures required and the appropriate actions that should be taken.
Prevention and management of healthcare water-associated infection incidents/outbreaks (/web-resources-container/prevention-and-management-of-healthcare-water-associated-infection-incidentsoutbreaks/)
Prevention and management of healthcare ventilation-associated infection incidents/outbreaks (/web-resources-container/prevention-and-management-of-healthcare-ventilation-system-associated-infection-incidentsoutbreaks/)

3.1 Definitions of Healthcare Infection Incident, Outbreak and Data Exceedance

The terms ‘incident’ and ‘Incident Management Team’ (IMT) are used as generic terms to cover both incidents and outbreaks
A healthcare infection incident may be:

An exceptional infection episode

- a single case of rare infection that has severe outcomes for an individual AND has major implications for others (patients, staff and/or visitors), the organisation or wider public health for example, high consequence infectious disease (HCID) OR other rare infections such as XDR-TB, botulism, polio, rabies, or diphtheria.

See literature review for Infectious Diseases of High Consequence (IDHC (/web-resources-container/literature-review-personal-protective-equipment-ppe-for-infectious-diseases-of-high-consequence-idhc/))

A healthcare infection exposure incident

- Exposure of patients, staff, public to a possible infectious agent as a result of a healthcare system failure or a near miss e.g. ventilation, water or decontamination incidents.

A healthcare associated infection outbreak

- Two or more linked cases with the same infectious agent associated with the same healthcare setting over a specified time period.

or

- A higher-than-expected number of cases of HAI in a given healthcare area over a specified time period.

A healthcare infection data exceedance

- A greater than expected rate of infection compared with the usual background rate for the place and time where the incident has occurred.

A healthcare infection near miss incident

- An incident which had the potential to expose patients to an infectious agent but did not e.g. decontamination failure.

A healthcare infection incident should be suspected if there is:

- a single case of an infection for which there have previously been no cases in the facility (e.g. infection with a multidrug-resistant organism (MDRO) with unusual resistance patterns or a post-procedure infection with an unusual organism)

Resources

Further information can be found in the literature review Healthcare infection incidents and outbreaks in Scotland. (/web-resources-container/literature-review-healthcare-infection-incidents-and-outbreaks-in-scotland/)

3.2 Detection and recognition of a Healthcare Infection incident/outbreak or data exceedance

An early and effective response to an actual or potential healthcare incident, outbreak or data exceedance is crucial. The local Board IPCT and HPT should be aware of and refer to the national minimum list of alert organisms/conditions. See Appendix 13 (/appendices/appendix-13-nhsscotland-minimum-alert-organismcondition-list/).

Healthcare associated infection (HAI) Surveillance systems should be used to aid incident/outbreak detection using a combination of retrospective detection of cases alongside prospective enhanced surveillance in high-risk settings (ICU/PICU/NICU, oncology/haematology). A risk-based approach should be applied for other vulnerable groups e.g. cystic fibrosis, oncology and those undergoing renal dialysis.
Local surveillance/reporting systems should be used for recognition and detection of potential healthcare infection incidents/outbreaks within NHS boards. Systems should make use of 'triggers' to allow prompt detection of any variance from normal limits.
The Infection Prevention & Control Team (IPCT)/Health Protection Team (HPT) should utilise surgical site infection (SSI) surveillance systems to identify specific post-surgical healthcare infection incidents/outbreaks (in line with national SSI surveillance program (https://www.nss.nhs.scot/publications/surgical-site-infection-surveillance-protocol-and-resource-pack/) as a minimum).

3.2.1 Assessment

Following detection/recognition of an incident/outbreak a member of IPCT or HPT will:

- Undertake an initial assessment, utilising the **Healthcare Infection Incident Assessment Tool (HIIAT)** - Appendix 14 (/appendices/appendix-14-healthcare-infection-incident-assessment-tool-hiiat/), gather epidemiological data and clinical assessment information on the patient's condition as per:
  - Section 1.1 (/chapter-1-standard-infection-control-precautions-sicps/#a1068)
  - Section 2.1 (/chapter-2-transmission-based-precautions-tbps/#a1088)
- NHS boards are required to report all HIIAT assessed Green, Amber and Red reports to ARHAI Scotland through the electronic outbreak reporting tool (ORT). See section 3.2.3.
- NHS boards should monitor the ongoing impact of the incident by escalating and de-escalating as appropriate, using the HIIAT assessment tool. The HIIAT assessment should remain Amber or Red whilst there is ongoing risk of exposure, identification of new cases.

3.2.2 Investigation, management and communication

The IPCT/HPT will establish an IMT if required.

- In the NHS hospital setting the ICD will usually chair the IMT and lead the investigation of healthcare incidents. Where there are implications for the wider community e.g., TB or measles, or rare events such as CJD or a Hepatitis B/HIV look back, or where there is an actual or potential conflict of interest with the hospital service, the CPHM may chair the IMT. A draft agenda for the IMT (/web-resources-container/draft-agenda-for-incident-management-team/) is available.
- The membership of the IMT will vary depending on the nature of the incident.
- A healthcare infection incident investigation will usually consist of the following elements: an epidemiological investigation, a microbiological investigation and a specific investigation to identify how cases were exposed to the infectious agent (environmental investigation)
  - As part of the epidemiological investigation, a case definition(s) must be established by the IMT. A case definition should include the following: the people involved (for example, patients, staff), the symptoms/pathogen/infection (for example, with Group A Streptococci), the place (for example, care area(s) involved) and a limit of time (for example, between January and March year/date). The case definition(s) should be regularly reviewed and refined (if required) throughout the incident investigation as more information becomes available. A working hypothesis regarding the transmission route and source of the exposure must be formed based on initial investigation findings.
  - A microbiological investigation into the nature and characteristics of the implicated hazard /infective agent must be conducted.
  - Typing and whole genome sequencing can support outbreak and incident investigations. These services are available for some organisms and details of the services available should be discussed with your laboratory. Public Health Scotland continue to offer a SARS-CoV-2 whole genome sequencing service to support outbreak investigations and address important clinical and epidemiological questions.
  - An environmental investigation must be conducted if the findings of the epidemiological investigation suggest a common exposure to a potential environmental source/environmental reservoir.
  - Review of patient cases should consider any potential missed opportunities to isolate a patient, a delay in which may have resulted in onward transmission. Any learning should be widely communicated to all clinical staff in the board.
  - An infection prevention and control assessment to review the existing IPC practices must be conducted, so that areas for immediate improvement can be identified.
- The IMT should receive and discuss all information gathered and epidemiological outputs for example an epidemiological (epi) curve, a timeline and a ward map to:
  - determine whether additional case finding and control measures may be necessary
  - confirm that all incident control measures are being applied effectively and are sufficient
- Control measures must be directed at the source of the exposure and/or at affected persons in order to prevent secondary/further exposure to the agent. Control measures must be initiated within 24 hours of receiving the initial report and should be implemented based on relevant guidance (for example pathogen specific) and investigation findings of the nature of the outbreak.
- A follow-up period may be defined after an infection incident/outbreak has ended to ensure its termination, including assessment of any ongoing control measures and would be determined by the PAG/IMT.
- Identify any change(s) in the system: staffing, procedures/processing, equipment, suppliers. A step-by-step review of procedure(s). An outbreak checklist (/resources/outbreak-checklist/) is available.
- Identify and count all cases and/or persons exposed: This includes the total number of confirmed/probable/possible exposed cases. An incident/outbreak data collection tool (/web-resources-container/outbreakincident-data-collection-tool/) is available.

If staff screening is being considered as part of the investigation DL (2020)1 (https://www.sehd.scot.nhs.uk/dl/DL(2020)01.pdf) must be followed.

- HAI deaths, which pose an acute and serious public health risk, must be reported to the Procurator Fiscal, refer to SGHD/CMO(2018)11 (https://www.sehd.scot.nhs.uk/cmo/CMO(2018)11.pdf).
- The IMT must ensure affected patients, and where appropriate their next of kin, have been informed of any actual or potential harm as a result of the HAI. Duty of Candour must be considered at each IMT.
- All significant adverse event reviews involving a category 1 adverse event (events that may have contributed to or resulted in permanent harm, for example unexpected death) should also be reported.
- If no new cases arise and any remaining cases are considered to no longer pose a risk, the IMT should agree on actions prior to resumption of normal service.

3.2.3 Communications

- Following the PAG/IMT, the NHS Board is required to communicate all HIIAT Green, Amber and Red assessments with ARHAI Scotland, by completing the electronic Outbreak Reporting Tool (ORT) within 24 hours of HIIAT assessment.
- Exported MS Excel files must be emailed to ARHAI Scotland for processing – the “Export Data File for ARHAI” button within the ORT only saves the extract from the ORT into the folder. Extracted data files should be emailed to the ARHAI Scotland ICT mailbox (NSS.ARHAIinfectioncontrol@nhs.scot (mailto:nss.ARHAIinfectioncontrol@nhs.scot)).
- The Protocol for the Reporting of Healthcare Infection Incidents, Outbreaks and Data Exceedance in NHSScotland through the Outbreak Reporting Tool (ORT) (/media/2245/outbreak-reporting-tool-protocol-v14-final.pdf) is available in the resources section of the NIPCM.
- For incidents/outbreaks that are HIIAT assessed as Red, Amber or Green, frequency of updates are as follows:
    - HIIAT Red – review, update and submit a daily update.
    - HIIAT Amber– review, update and submit a twice weekly update.
    - HIIAT Green – review, update and submit a weekly update.
- The Healthcare Infection Incident and Outbreak Reporting Template (HIIORT) form is for any HIIAT Red, Amber or Green assessed incident/outbreaks. Incidents assessed as Red, Amber or Green, where ARHAI support is requested, will be reviewed for onward communication to Scottish Government Healthcare Associated Infection Policy Unit.
- Respiratory incidents/outbreaks associated with key respiratory pathogens (COVID-19, influenza and respiratory syncytial virus (RSV)), should be completed within the Respiratory Short Form. However, where IPC measures do not align with the outbreak checklist and NIPCM, or where ARHAI support is requested a full HIIORT form must be completed. The Outbreak Checklist (/resources/outbreak-checklist/) is available in the resources section of the NIPCM website.
- COVID-19 reporting should now align with reporting for other key respiratory pathogens (Influenza/RSV).
- Any adverse event related to equipment or medication must be reported as soon as possible (within one working day) to the Incident Reporting and Investigation Centre (IRIC) (https://www.nss.nhs.scot/health-facilities/incidents-and-alerts/report-an-incident/) and the escalation/de-escalation flowchart followed.

Closure of incident/outbreak with lessons learned

- Once the incident is declared over, and in addition to reporting via the electronic outbreak reporting tool (ORT), the IMT/NHS board should decide on the most appropriate format for a report. This is to communicate any lessons learned using the Hot Debrief Tool (https://eur01.safelinks.protection.outlook.com/?url=https%3A%2F%2Fwww.nipcm.hps.scot.nhs.uk%2Fweb-resources-container%2Fhot-debrief-template%2F&data=05%7C01%7Csofie.french2%40nhs.scot%7Caec1c9f1db1c44b33f4508db4c991216%7C10efe0bda0304bca809cb5e
Completion of this and submission to ARHAI Scotland is not mandatory, but for the purposes of sharing lessons learned across Scotland.

The IMT Chair, in discussion with the IMT, should determine whether further reporting on the incident and the incident management is required i.e. SBAR Report and full IMT report template are available in the resources section of the NIPCM website (/resources/).

Chapter 4 - Infection Control in the Built Environment and Decontamination

Introduction

Currently, chapter 4 exists as a repository for evidence reviews and tools relating to IPC in the built environment including delivery of appropriate decontamination within health and care settings and risk mitigation for water based pathogens.
Content going forward will be developed via the ARHAI Scotland Infection Control in the Built Environment and Decontamination (ICBED) programme informed by stakeholder engagement and requirements, learning from NHS Assurance programme and outbreaks and incidents.
Links to tools and guidance developed by ARHAI Scotland's Clinical Assurance Programme will also be included within chapter 4.
This chapter is in the early stages of development.

Bed spacing

Guidance consistently recognises that bed spacing requirements contribute towards the control of HAIs. All NHS boards and care providers should aim to meet the minimum bed spacing requirements laid out in the guidance below and in keeping with the date of design and construction of the building. This takes account of ergonomics within the clinical environment and not just healthcare associated infection (HAI) risk. Some other health and care settings may choose to adopt this guidance e.g. hospice settings.
Adult in-patient facilities designed post 2010 should achieve 3.6m (width) x 3.7m (depth) dimensions of SHPN 04-01, HBN 00-03 and SHFN 30. Width of 3.6m is measured from bed centre to bed centre. Since 2014, HBN 00-03's Figure 45 states a day treatment bay should achieve 2.45m width/centre-to-centre dimension.
Current NHS Scotland Guidance on bed spacing is listed below:

- Core guidance - General design for healthcare buildings (HBN 00-01) (https://www.nss.nhs.scot/publications/core-guidance-general-design-for-healthcare-buildings-hbn-00-01/)
- Core guidance - Clinical and clinical support spaces (HBN 00-03) (https://www.nss.nhs.scot/publications/core-guidance-clinical-and-clinical-support-spaces-hbn-00-03/)
- Critical care units (HBN 04-02) (https://www.nss.nhs.scot/publications/critical-care-units-hbn-04-02/)
- HAI-SCRIBE Manual information for project teams (SHFN 30 Part A) (https://www.nss.nhs.scot/media/1803/shfn-30-part-a-v40-oct-2014.pdf)
- HAI-SCRIBE Implementation strategy and assessment process (SHFN 30 Part B) (https://www.nss.nhs.scot/media/1804/shfn-30-part-b-v30-oct-2014.pdf)
- HAI-SCRIBE question sets and checklists (SHFN 30 Part C) (https://www.nss.nhs.scot/media/1802/shfn-30-part-c-v10-jan-2015.pdf)
- Adult in-patient facilities (SHPN 04-01) (https://www.nss.nhs.scot/publications/adult-in-patient-facilities-shpn-04-01-v1/)
- In-patient accommodation - supp 1 - Isolation facilities in acute settings (SHPN 4 sup 1) (https://www.nss.nhs.scot/publications/in-patient-accommodation-supplement-1-isolation-facilities-in-acute-settings-shpn-4-sup-1-v10/)

Publications

Work undertaken and published to date has been cited here for ease of reference and use at a clinical level.
Many of these publications were produced prior to development of chapter 4 and were published outwith the existing manual methodology.
Updates to publications will be made where required as part of the ARHAI programme work plans.
ARHAI Scotland will work with SG directorates responsible for these areas in planning to establish planned implementation.

Decontamination

Probes

- NHSScotland Guidance for decontamination of semi-critical ultrasound probes (https://www.nss.nhs.scot/publications/nhsscotland-guidance-for-decontamination-of-semi-critical-ultrasound-probes-semi-invasive-and-non-invasive-ultrasound-probes/)

Equipment and environment cleaning

- (https://www.hps.scot.nhs.uk/web-resources-container/roles-responsibilities-for-reusable-patient-care-equipment-and-environmental-decontamination/)NHSScotland Guidance for Decontamination and testing of Cardiac Heater Cooler Units (HCUs). v1.0 | National Services Scotland (https://www.nss.nhs.scot/publications/nhsscotland-guidance-for-decontamination-and-testing-of-cardiac-heater-cooler-units-hcus-v10/)

Alternative approaches to decontamination

- Literature Review and Practice Recommendations: Existing and emerging technologies used for decontamination of the healthcare environment

- Antimicrobial Copper Surfaces (https://www.nss.nhs.scot/publications/literature-review-and-practice-recommendations-existing-and-emerging-technologies-for-decontamination-of-the-health-and-care-environment-antimicrobial-copper-surfaces-v1/)
- Antimicrobial Copper and Silver Solutions (https://www.nss.nhs.scot/publications/literature-review-and-practice-recommendations-existing-and-emerging-technologies-for-decontamination-of-the-health-and-care-environment-antimicrobial-copper-and-silver-solutions-v10/)
- ATP Bioluminescence and Fluorescent Markers (v2.0, June 2023) (https://www.nss.nhs.scot/publications/literature-review-and-practice-recommendations-existing-and-emerging-technologies-for-decontamination-of-the-health-and-care-environment-atp-bioluminescence-and-fluorescent-markers-v1/)
- Chlorine Dioxide (https://www.nss.nhs.scot/publications/literature-review-and-practice-recommendations-existing-and-emerging-technologies-for-decontamination-of-the-health-and-care-environment-chlorine-dioxide-v10/)
- Electrolysed Water (https://www.nss.nhs.scot/publications/literature-review-and-practice-recommendations-existing-and-emerging-technologies-for-decontamination-of-the-health-and-care-environment-electrolysed-water-version-20/)
- HINS Light (https://www.nss.nhs.scot/publications/literature-review-and-practice-recommendations-existing-and-emerging-technologies-for-decontamination-of-the-health-and-care-environment-hins-light-v10/)
- Hydrogen Peroxide (https://www.nss.nhs.scot/publications/literature-review-and-practice-recommendations-existing-and-emerging-technologies-for-decontamination-of-the-health-and-care-environment-airborne-hydrogen-peroxide-v1-1/)
- Microfibre (https://www.nss.nhs.scot/publications/literature-review-and-practice-recommendations-existing-and-emerging-technologies-for-decontamination-of-the-health-and-care-environment-microfibre-version-20/)
- Ozone (https://www.nss.nhs.scot/publications/literature-review-and-practice-recommendations-existing-and-emerging-technologies-used-for-decontamination-of-the-healthcare-environment-ozone/)
- Steam (https://www.nss.nhs.scot/publications/existing-and-emerging-technologies-used-for-the-decontamination-of-the-healthcare-environment-steam-literature-review-and-practice-recommendations-version-30/)
- UV light (v2.0, November 2022) (https://www.nss.nhs.scot/publications/literature-review-and-practice-recommendations-existing-and-emerging-technologies-used-for-decontamination-of-the-healthcare-environment-ultraviolet-light-v11/)
- Wipes (v2.0, December 2022) (https://www.nss.nhs.scot/publications/literature-review-and-practice-recommendations-existing-and-emerging-technologies-used-for-decontamination-of-the-healthcare-environment-wipes-v10/)

Built environment

Water

- NHSScotland Guidance for the interpretation and clinical management of endoscopy rinse water (https://www.nss.nhs.scot/publications/nhsscotland-guidance-for-the-interpretation-and-clinical-management-of-endoscopy-final-rinse-water-v10/)
- Literature Review and Recommendations: Management of Dental Unit Waterlines (https://www.nss.nhs.scot/publications/literature-review-and-recommendations-management-of-dental-unit-waterlines-v20/)

Clinical Assurance

ARHAI Scotland's Clinical Assurance programme provides clinical and infection prevention and control (IPC) expertise to complement the work undertaken by the NHSScotland's Assure (NHSSA) assurance service (https://www.nss.nhs.scot/nhs-scotland-assure/assurance/about-nhs-scotland-assure/). More information about the programme and a list of tools and guidance (https://www.nss.nhs.scot/browse/antimicrobial-resistance-and-healthcare-associated-infection/clinical-assurance) developed is available.
Key Stage Assurance Reviews (KSAR) focus on ensuring infection prevention and control is a key consideration for healthcare construction projects. ARHAI Scotland have developed notes for NHS Board IPC Teams which aim to help navigate this process.

- Notes for Board IPC Teams document to navigate the KSAR process (/media/2145/2023-07-25-ksar-notes-for-board-ipc-teams-v10.pdf)

Below is an educational animation which focuses on clinical hand wash basins (CHWBs), their intended purpose, water associated infection risks, and what we all can do together to reduce this risk. The animation is supported by a poster for use beside CWHBs to locally promote good practice for health and care staff as well as the general public who may visit those settings.

- Animation: Good practice for clinical wash hand basins (https://learn.nes.nhs.scot/70353)
- Poster: Good practice for clinical wash hand basins (https://www.nss.nhs.scot/publications/clinical-wash-hand-basin-poster/)

Addendum for Infection Prevention and Control within Neonatal Settings (NNU)

The purpose of this addendum is to provide additional guidance to chapters 1,2 and 3 for NNUs.

4.1 Placement of neonates/assessment for infection risk

Undertake assessment for infection risk (/media/1453/2019-8-22-nnu-clinical-risk-assessment-v10-final.pdf) at the point of entry into the unit before placement of the neonate is decided. This assessment is the minimal microbiological testing required and any additional testing would be determined by the clinical presentation of the neonate. The potential for transmission of infection should be continuously reviewed throughout the stay/period and must be documented in the clinical notes.
Neonates who present as a cross infection risk include those who:

- have been transferred from another unit in Scotland with an ongoing incident/outbreak or
- were born outside Scotland
- have previously been positive with a Multidrug Resistant Organism (MDRO), or any alert organism or alert condition as found in Appendix 13 (/appendices/appendix-13-mandatory-nhsscotland-alert-organismcondition-list/).

From mothers who have:

- been hospitalised outside Scotland in the previous 12 months
- had no antenatal care
- been previously positive with a MDRO e.g. Meticillin Resistant Staphylococcus Aureus (MRSA) or Carbapenemase Producing Enterobacterales (CPE)

If a neonate is considered to be a cross infection risk then the clinical judgement of those involved in the management of the baby should assess the placement by prioritising the incubator/cot in a suitable area pending investigation i.e. place in a single room or cohort area/room with a wash hand basin.
Information/advice must be given to parents/carers of all neonates; particularly during outbreaks/incidents (/web-resources-container/healthcare-infections-in-neonatal-units-information-for-parents-and-guardians/)

4.2 Healthcare infection, incidents, outbreaks and data exceedance

In addition to the definitions in Chapter 3 (/chapter-3-healthcare-infection-incidents-outbreaks-and-data-exceedance/), in a neonatal unit investigation by IPCT is also required if:

- a single case of *Pseudomonas aeruginosa* is identified
- a single case of infection with an alert organism is identified
- two or more cases of colonisation with the same organism; linked in time and place are identified

Additionally, the local IPC team should consider the possibility of any onward transmission and potential for an incident/outbreak where there is:

- A single case of colonisation with an alert organism identified

Assigning a dedicated team to care for infected or colonised neonates may also be required. During outbreaks or incidents the ratio of staff to neonates may need to increase and it may be necessary to restrict admissions to the area. Prior to closing or restricting a neonatal unit, communication must be agreed across neonatal services and risk assessed.
Transfers to other units during incidents or outbreaks should be avoided, where possible; however this should take into consideration the clinical needs of neonates, and any practical or logistical issues for parents/carers.

4.3 Personal care of neonates

Due to the vulnerability of some neonates the use of tap water for personal care requires consideration and this is outlined in Guidance for neonatal units (NNUs) (levels 1, 2 & 3), adult and paediatric intensive care units (ICUs) in Scotland to minimise the risk of Pseudomonas aeruginosa infection from water (/web-resources-container/guidance-for-neonatal-units-adult-and-paediatric-intensive-care-units-in-scotland-to-minimise-the-risk-of-pseudomonas-aeruginosa-infection-from-water/). For example, an assessment should be made on the neonate's condition and whether tap water can be used or if an alternative, such as sterile water, is considered more appropriate.
In addition incubators/cots should not be placed near any water source where spraying or splashing may occur.
Further information for neonatal IPC management of healthcare incidents and outbreaks can be found in the supporting literature review (/web-resources-container/management-of-incidents-and-outbreaks-in-neonatal-units-nnus/).

Neonatal resources

Quality improvement tools provide short practice points which when followed correctly can help reduce HAIs and improve patient safety.
These quality improvement tools are based on scientific literature reviews and practice recommendations from ARHAI Scotland.

Materials including posters are available for the following procedures/situations:

- CVC insertion and maintenance quality improvement tools for neonates (/media/2095/2023-03-06-cvc-bundle-neonates-v10.docx)
- CVC insertion and maintenance poster for neonates (/media/2096/2023-03-06-cvc-neonatal-poster-final-v10.pdf)

Care Home Infection Prevention and Control Manual (CH IPCM)

When an organisation uses products or adopts practices that differ from those stated in this Care Home Infection Prevention and Control Manual, that individual organisation is responsible for ensuring safe systems of work including the completion of risk assessments approved through local governance procedures.

Use of this manual online is advised as printed versions are uncontrolled.The ARHAI Scotland Transmission Based Precautions (TBPs) literature review is currently ongoing and so the information may be subject to change.
Last updated: 28 August 2023

What is the Care Home Infection Prevention and Control Manual (CH IPCM)?

The Care Home Infection Prevention and Control Manual (CH IPCM), referred to as 'the manual' throughout, was first published in 2021. It is evidence-based and is intended to be used by all those involved in care home provision in Scotland.
The manual is context specific and has been co-produced with national and local stakeholders. The content of the manual is completely aligned to the evidence based National Infection Prevention and Control Manual (NIPCM) (/) which was first published in 2012, by the Chief Nursing Officer (CNO (2012)1 (http://www.sehd.scot.nhs.uk/cmo/CNO(2012)01.pdf)).
The manual currently contains

- Chapter 1 – Standard Infection Control Precautions (SICPs) (/infection-prevention-and-control-manual-for-older-people-and-adult-care-homes/#a2821)
- Chapter 2 – Transmission Based Precautions (TBPs) (/infection-prevention-and-control-manual-for-older-people-and-adult-care-homes/#a2926)

The manual is a practice guide for use in care homes. When used, it can help reduce the risk of infections and ensure the safety of residents, as well as staff and visitors in the care home environment. It is the Scottish Government expectation that care home settings apply guidance contained within this manual to achieve the aims.
The manual aims to:

- make it easy for staff to apply effective infection prevention and control (IPC) precautions
- help reduce the risk of infection
- reduce variation, promote standardisation, and optimise IPC practices throughout care home settings
- improve the application of staff knowledge and skills in IPC
- help align practice, monitoring, quality improvement and scrutiny

The manual should be adopted for all IPC practices and procedures within care home settings.
Is the manual based on scientific literature?
The recommendations for practice made in the manual are fully aligned to the NIPCM and are based on real-time reviews of the current scientific literature (for example Medical Journals) and best practice. Any major changes identified in the scientific literature may lead to a change being made to the content, and so, it is recommended that the online version is always accessed and used locally.
What's in the appendices?
The appendices (/appendices/) can be used as practical implementation of the manual and contain graphical representations (for example diagrams and charts) that can be used along with the contents of the manual.
Many of the appendices can be printed off as posters for local use throughout the care home.
Are there any other IPC materials that can be used?
There are links throughout the manual to additional resources and the resources page (https://www.nipcm.scot.nhs.uk/resources/) links to IPC campaign materials, education, training links and posters.
In addition you may find it useful to read the literature reviews and SBARs (/resources/literature-reviews/) for the manual.
How can I find out what the scientific and medical words mean?
A glossary (/glossary/) section has been provided.
Does the manual content work on mobile devices?
Yes, all content including appendices work on mobile devices for example laptops and smartphones.

Responsibilities for the CH IPCM

Responsibilities for content of the manual

ARHAI Scotland to ensure:

- that the content of this manual remains evidence based or where evidence is lacking, content is based on consensus of expert opinion

Stakeholders of ARHAI Scotland programme working groups to ensure:

- full participation in the working groups including full engagement with the consultation process outlined in the Terms of Reference associated with each working group

Responsibilities for the adoption and implementation of this manual

The manual should be used by:

- care home organisations
- care home staff including permanent, agency and where required external contractors
- health protection teams
- infection prevention and control teams
- professionals providing support
- individuals visiting the care home

Care home providers to ensure:

- the adoption and implementation of this manual in accordance with existing local governance processes
- that systems and resources are in place to facilitate implementation and compliance monitoring of IPC as specified in this manual in all care areas
    - compliance monitoring includes all staff (permanent, agency and where required external contractors)
- there is an organisational culture which promotes incident reporting and focuses on improving systemic failures that encourage safe IPC working practices including near misses
- there is a nominated lead with responsibility for IPC within the care home

Care home managers to ensure that all staff:

- are aware of and have access to this manual
- have completed appropriate IPC training relevant to their roles and that this is centrally recorded. Training may include resources developed by your organisation, your local NHS board, Health and Social Care Partnership, **NHS Education for Scotland (NES)** (https://learn.nes.nhs.scot/2482/infection-prevention-and-control-ipc-zone) (https://learn.nes.nhs.scot/2482/infection-prevention-and-control-ipc-zone) or the **Scottish Social Services Council (SSSC)** (https://www.sssc.uk.com/)
- have adequate support and resources available to enable them to implement, monitor and take corrective action to ensure full compliance with this manual
- implement a robust risk assessment including detailing any deviations from the manual and the local mitigation measures that were undertaken and post-approval documented via local governance procedures
- with health concerns (including pregnancy) or those who have had an occupational exposure relating to IPC are timeously referred to the relevant agency, for example general practitioner (GP or doctor), occupational health or if required accident and emergency
- have undergone the required health checks or clearance (including those undertaking exposure prone procedures (EPPs))
- include IPC as an objective in their personal development plans (or equivalent)

Care home staff providing care to:

- understand, adopt and implement the principles of IPC as set out in this manual
- maintain IPC competence, skills, and knowledge through completing appropriate training relevant to their role as directed by their line manager. IPC training, **NHS Education for Scotland (NES)** (https://learn.nes.nhs.scot/2482/infection-prevention-and-control-ipc-zone) (https://www.nes.scot.nhs.uk/) or the **Scottish Social Services Council (SSSC)** (https://www.sssc.uk.com/)
- communicate the IPC practices to be taken to appropriate colleagues, residents, relatives and visitors without breaching confidentiality
- have up to date occupational immunisations/health checks/clearance requirements as appropriate
- report to line managers and document any gaps in IPC knowledge, resources, equipment and facilities or incidents that may result in transmission of infection including near misses for example sharps or PPE failures
- do not provide care while at risk of potentially transmitting infectious agents to others - if in any doubt they should consult with their line manager, occupational health department, local infection prevention and control team (IPCT) or local health protection team (HPT)
- contact the local HPT/IPCT if there is a suspected or actual HAI incident/outbreak (/chapter-3-healthcare-infection-incidents-outbreaks-and-data-exceedance/)

Local infection prevention and control teams (IPCTs) and health protection teams (HPTs) to:

- engage with care home staff to develop systems and processes that lead to sustainable and reliable improvements in relation to the application of IPC practice
- provide expert advice on the application of IPC and provide support when requested to develop individual or organisational risk assessments where deviations from the manual are necessary
- have epidemiological or surveillance systems capable of distinguishing resident case or cases requiring investigations and control
- provide local support and advice (when necessary and/or requested) and complete documentation when an incident/outbreak or data exceedance is reported

Chain of infection

In order for infection to occur several things have to happen. This is often referred to as the chain of infection. The six links in the chain are:

1. **infectious agent** or the microorganism which can cause disease

2. **reservoir** or source of infection where the microorganism can live and thrive. This may be a person, an animal, any object in the general environment, food or water

3. **portal of exit** from the reservoir. This describes the way the microorganism leaves the reservoir. For example, in the case of a person with flu, this would include coughing and sneezing. In the case of someone with gastroenteritis microorganisms would be transmitted in the faeces or vomit

4. **mode of transmission.** This describes how microorganisms are transmitted from one person or place to another. This could be via someone's hands, on an object, through the air or bodily fluid contact

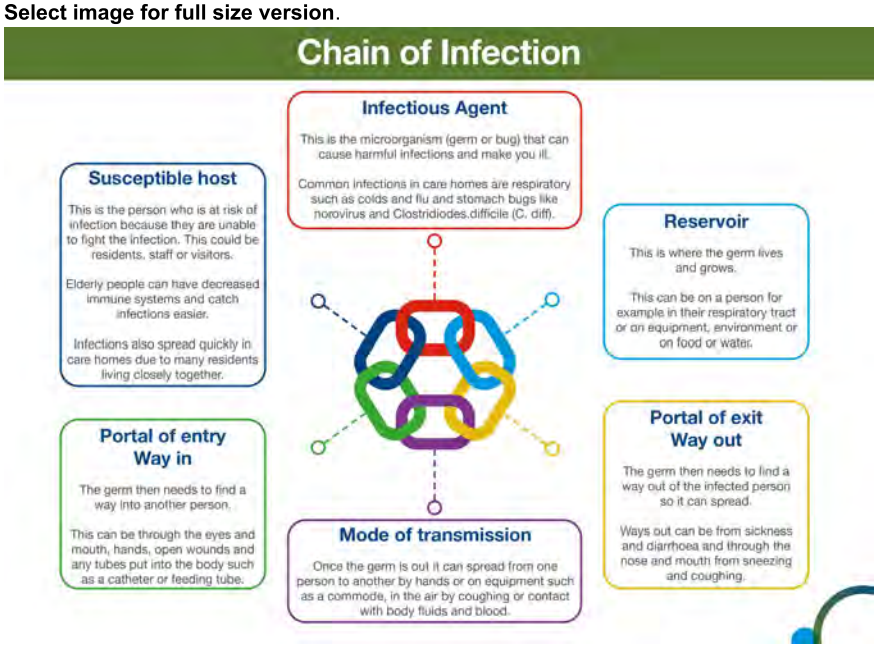
5. **portal of entry.** This is how the infection enters another individual. This could be landing on a mucous membrane, being breathed in, entering via a wound, or a tube such as a catheter.

6. **susceptible host.** This describes the person who is vulnerable to infection.

Infection can be prevented by breaking the chain of infection.

The chain of infection diagram illustrates and gives examples of actions that can be taken to break it. The overall aim of Standard Infection Control Precautions (SICPs) (/infection-prevention-and-control-manual-for-older-people-and-adult-care-homes/#a2821), is to break the chain of infection.

Select image for full size version.



(/media/1579/care_homes_chain_of_infection_graphic.jpg)

Use the NES SIPCEP Breaking the Chain of Infection (https://learn.nes.nhs.scot/3421/infection-prevention-and-control-ipc-zone/sipcep-foundation-layer/breaking-the-chain-of-infection) module to learn about breaking the chain of infection in care homes.

Reducing risk

The hierarchy of controls (HoC) (/appendices/appendix-18-hierarchy-of-controls/) is a system used to help prevent the transmission of infection. It details the most to least effective controls. You will note that PPE (/care-home-infection-prevention-and-control-manual-ch-ipcm/#a2884) is the last level of control in the hierarchy, used when all other controls have not reduced the risks sufficiently. To be effective, PPE must be used correctly which means putting it on and removing it correctly and safely (/care-home-infection-prevention-and-control-manual-ch-ipcm/#a2884).

See the Health and Safety Executive's (HSE) toolkit (https://www.hse.gov.uk/toolbox/index.htm) on management of risk when planning work: the right priorities for additional information.

The HoC principles can be broadly interpreted for care home settings and include:

- reducing hazards in the care home
- changing practice in the care home
- making the care home as safe as possible
- changing how we organise and work in the care home
- use of PPE

Examples of HoC principles

Here are some examples of how to apply the HoC principles in care home settings. These examples do not cover every situation where you might need to use HoC principles.

Reducing hazards in the care home

Measures such as vaccination, testing and isolation help to reduce the risk of infection. Not coming to work when ill, isolating while infectious and recognising and reporting infections promptly, all help to prevent infections spreading.

Changing practice in the care home

When faced with a particular risk, such as an outbreak, we may need to change what we do. This might include reducing communal activities, considering limiting visiting for a short period of time, or cleaning the care home environment more frequently. The local IPCT and/or HPT should always be contacted for advice and support in outbreak situations.

Making the care home as safe as possible

It is very unlikely that we will be able to change where we work but the care home setting should be made as safe as possible. You can reduce opportunities for pathogens to survive in the care home, ensuring fixtures and fittings are in good repair and can be easily cleaned and following water safety guidelines. Ventilation is also an effective measure to reduce the risk of some respiratory infections, by diluting and dispersing the pathogens which cause them. Consider opening windows and vents more than usual, even opening a small amount can be beneficial. Opening windows and doors may present security and safety issues and so a local risk assessment should always be undertaken.

Changing how we organise and work in the care home

Changing the way, we organise and work in the care home can also help reduce risk. This might include reducing the number of people in a space at any one time and minimising the movement of staff between different settings as well as using administrative controls. Administrative controls include local risk assessments, staff training, IPC audits, and providing clear signage and instructions throughout the care home.

Chapter 1: Standard Infection Control Precautions (SICPs)

The basic IPC measures that should be used in your care home are called **Standard Infection Control Precautions (SICPs).**

SICPs are used to reduce the risk of transmission of infectious agents from known and unknown sources of infection.

These should be used by **all staff, in all care settings, at all times, for all residents** whether infection is known to be present or not to ensure the safety of residents, staff and visitors in the care home.

SICPs should be part of everyday practice and applied **consistently** by everyone in the care home.

It is essential that optimal IPC measures are applied continuously as residents living in care homes are more vulnerable, therefore increasing their risk of acquiring infections which may then be serious and potentially life threatening. By applying optimum IPC precautions you will provide a safe environment and effective care.

There are 10 Standard Infection Control Precautions (SICPs)

1. resident placement/assessment for infection risk
2. hand hygiene
3. respiratory and cough hygiene
4. personal protective equipment
5. safe management of care equipment
6. safe management of care environment
7. safe management of linen
8. safe management of blood and body fluid spillage
9. safe disposal of waste
10. occupational safety: prevention and exposure management (including sharps)

1. Resident placement/assessment for infection risk

For residents being discharged from hospital to a care home/hospice the Public Health Scotland COVID-19 information and guidance for social, community and residential care settings (https://publichealthscotland.scot/publications/covid-19-information-and-guidance-for-social-community-and-residential-care-settings/covid-19-information-and-guidance-for-social-community-and-residential-care-settings-version-27/#section-1) should be followed.

Before a resident is admitted to the care home it is important to risk assess for infection as part of resident's care plan, an IPC admission assessment should be undertaken by staff.

If you suspect or are aware that a resident has an infection, then details should be confirmed for the correct IPC precautions to be put in place for the safety of the resident and others.

Obtaining infection details may include appropriate clinical samples and/or screening to establish the causative organism which may be on advice from your local GP, IPCT or HPT.

Residents who may present a cross-infection risk include those with:

- diarrhoea
- vomiting, being sick
- unexplained rash
- fever or temperature of 37.8 C or higher
- respiratory symptoms such as coughing and sneezing
- known to have been previously positive with a Multi-drug Resistant Organisms (MDRO), for example Meticillin Resistant *Staphylococcus aureus* (MRSA), Carbapenemase Producing Enterobacterales (CPE)

Further information regarding general respiratory screening questions (/media/2147/2023-08-23-respiratory-screening-questions-aide.pdf) can be found within the resources section of the NIPCM.

Note: If a resident requires isolation because of infection or in an outbreak situation, this should be individually risk assessed to ensure the safety and health and wellbeing needs of the resident. Isolation periods must be monitored on daily basis and be for the minimum period specified.

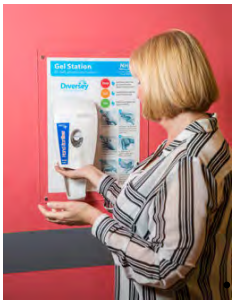
Resources

Appendix 11 (/appendices/appendix-11-best-practice-aide-memoire-for-optimal-patient-placement-and-respiratory-protective-equipment-rpe-for-infectious-agents-whilst-a-patient-is-in-hospital/) of the NIPCM gives you further information on the precautions required for different infections.

Read the **placement literature review** (/web-resources-container/patient-placement-isolation-and-cohorting-standard-infection-prevention-control-and-transmission-based-infection-control-precautions/) to understand the evidence base for resident placement.

2. Hand hygiene

Please note that the term 'alcohol-based hand rub (ABHR)' has now been updated to 'hand rub'. A hand rub (alcohol or non-alcohol based) can be used if it meets the required standards. Please see further information in the hand hygiene products literature review (/web-resources-container/sicp-literature-review-hand-hygiene-products/).



The most important thing you can do to prevent the spread of infection in a care home is to keep your hands clean. This is called **hand hygiene**.
Hand washing sinks should **only** be used for hand hygiene and should not be used for the disposal of other liquids (See Appendix 3 of Pseudomonas Guidance (https://www.nipcm.scot.nhs.uk/web-resources-container/guidance-for-neonatal-units-adult-and-paediatric-intensive-care-units-in-scotland-to-minimise-the-risk-of-pseudomonas-aeruginosa-infection-from-water/) for further information).

Before performing hand hygiene:

- expose forearms (known as bare below the elbows)
- remove all hand/wrist jewellery including any embedded jewellery (a single, plain metal finger ring or ring dosimeter (radiation ring) is permitted but should be removed (or manipulated) during hand hygiene). Bracelets or bangles such as the Kara which are worn for religious reasons should be able to be pushed higher up the arm and secured in place to enable effective hand hygiene which includes the wrists
- ensure fingernails are clean, short and that artificial nails or nail products are not worn
- cover all cuts or abrasions with a waterproof dressing

Hand washing should be extended to the forearms if there has been exposure of forearms to blood and/or body fluids.
To perform hand hygiene:

- hand rub should be available for staff as near to point of resident care as possible. Where this is not practical, personal hand rub dispensers should be used
- application of sufficient volume of hand rub to cover all surfaces of the hands is important to ensure effective hand hygiene
- manufacturer's instructions should be followed for the volume of hand rub required to provide adequate coverage for the hands. In the absence of manufacturer's instructions, volumes of approximately 3ml are recommended to ensure full coverage
- wall mounted or personal hand rub dispensers (cartridges/bottles) should not be refilled and should be replaced when empty or if outwith manufacturer expiry date

The World Health Organization's '4 moments for hand hygiene' should be used to highlight the key indications for hand hygiene:

1. before touching a resident
2. before clean/aseptic procedures. If hand rub cannot be used, then antimicrobial liquid soap should be used
3. after body fluid exposure risk
4. after touching a resident

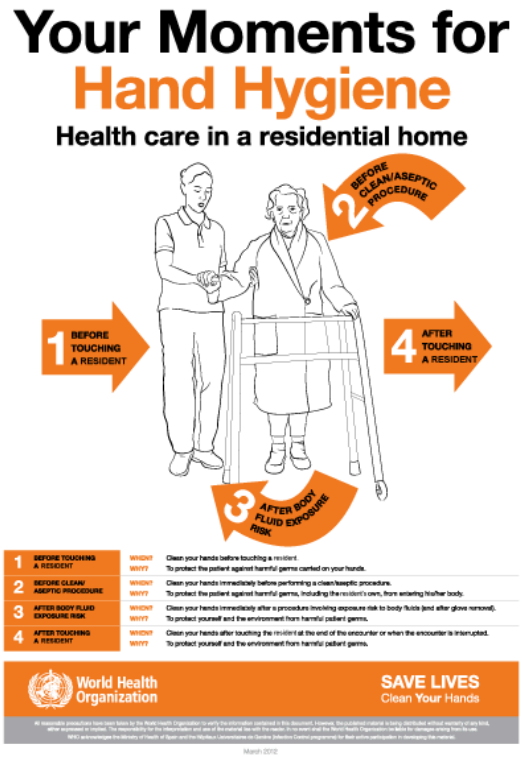
Some additional examples of hand hygiene moments include, but are not limited to:

- after touching a resident's immediate surroundings
- before handling medication
- before preparing food
- before donning (putting on) and after doffing (taking off) PPE
- after visiting the toilet
- before putting on and after removing PPE
- between carrying out different care activities on the same resident
- after cleaning and disinfection procedures
- after handling used linen
- after handling waste

It is important that residents are routinely encouraged to perform hand hygiene and given assistance if required.

The **four moments for hand hygiene poster** (/media/1444/who-4-moments-residential-care.pdf) can be used in your care home to show staff when hand hygiene should be done and the reasons why.

Select image for full size version.



(https://www.nipcm.scot.nhs.uk/media/1444/who-4-moments-residential-care.pdf)


Hands should be washed with liquid soap and water if/when:

- they are visibly soiled or dirty
- they are potentially contaminated with blood, other body fluids or excretions
- caring for a resident with vomiting or diarrhoeal illness
- caring for a resident with a suspected or known gastro-intestinal infection such as norovirus or a spore forming organism such as *Clostridioides difficile*

Note:
Hands should be washed with warm/tepid water to mitigate the risk of dermatitis associated with repeated exposures to hot water and to maximise hand washing compliance. Compliance may be compromised where water is too hot or too cold.
Hands should be dried thoroughly following hand washing using a soft, absorbent, disposable paper towel from a dispenser which is located close to the sink but beyond the risk of splash contamination.
The use of antimicrobial hand wipes is only permitted where there is no access to running water. Staff should perform hand hygiene using ABHR immediately after using the hand wipes and perform hand hygiene with soap and water at the first available opportunity.
In all other circumstances use hand rub for routine hand hygiene.

Skin care

- Hand rubs should contain emollients in their formulation.
- Pat hands dry after hand washing using disposable paper towels. Avoid rubbing which may lead to skin irritation/damage.
- Use an emollient hand cream during breaks and when off duty. These should be applied all over the hands including between the fingers and the back of the hands.
- Staff with skin problems should seek advice from the local occupational health department if available or their GP.
- Barrier creams should not be used in the workplace.

Do not use refillable containers or communal tubs of hand cream in the care home setting.

Resources

Read the hand hygiene literature reviews (/resources/literature-reviews/hand-hygiene/) to find out more about the evidence base for hand hygiene.

To make sure you clean your hands properly with soap and water you should follow the steps in the poster **'How to hand wash step by step images (/appendices/appendix-1-best-practice-how-to-hand-wash)'**. This poster can be printed off and displayed throughout the care home to ensure that all staff and visitors are aware of and practice this hand hygiene method when required in the care home.

Select image for full size version

(/appendices/appendix-1-best-practice-how-to-hand-wash)

To make sure you clean your hands properly with hand rub you should follow the steps in the poster **'How to hand rub step by step images** (/appendices/appendix-2-best-practice-how-to-hand-rub/)'. This poster can be printed off and displayed throughout the care home to ensure that all staff and visitors are aware of and practice this hand hygiene method when required in the care home.

Select image for full size version

(/appendices/appendix-2-best-practice-how-to-hand-rub/)

3. Respiratory and cough hygiene

Infections can spread by coughing and sneezing, therefore it is very important that respiratory and cough hygiene is used by everyone including staff, residents and visitors.
Any resident displaying symptoms of respiratory illness should be encouraged to wear a surgical (for instance TYPE IIR FRSM) face mask where it is clinically safe and can be tolerated by the wearer, especially in communal areas.

What you need for respiratory and cough hygiene• disposable tissues• waste bin and waste bags• hand hygiene products
If a resident has a cough, cold or other respiratory symptoms then they should be supported and encouraged to:

- cover their nose and mouth with a disposable tissue when sneezing, coughing, wiping and/or blowing the nose. If a disposable tissue is not available encourage the use of elbow/sleeve to cover the nose and mouth when coughing or sneezing
- put used tissues and face masks into a waste bin immediately after use
- wash their hands with soap and water after coughing, sneezing, using tissues, or after contact with respiratory secretions or objects contaminated by these secretions
- keep contaminated hands away from the eyes nose and mouth

Staff should:

- promote respiratory and cough hygiene and help residents who need assistance
- ensure that residents are provided with the necessary products for respiratory and cough hygiene including tissues, waste bag and hand hygiene products and make sure that products are in close vicinity for the resident to access
- use hand wipes followed by hand rub if there is no running water available or if hand hygiene facilities are out of reach then wash hands at the first available opportunity.

Read the **respiratory and cough hygiene literature review** (/web-resources-container/standard-infection-control-precautions-sicp-literature-review-cough-etiquetterespiratory-hygiene-in-the-hospital-setting/) to find out the evidence for respiratory and cough hygiene practice.

4. Personal Protective Equipment (PPE)

PPE products you might need in the care home:• gloves• aprons• masks• eye protection
PPE for visitors
Deciding which PPE to use

Before doing any procedure or task staff should risk assess any likely exposure to blood and/or body fluids and ensure PPE is worn that provides adequate protection against the risks associated with the procedure or task being undertaken.
All PPE should be:

- located close to the point of use
- stored in a clean and dry area to prevent contamination until needed for use
- within expiry dates
- single-use only items unless specified by the manufacturer
- changed immediately after individual use and/or following completion of a procedure or task
- disposed of after use into the correct waste stream, this means healthcare waste or domestic waste

Reusable PPE items, for example non-disposable goggles, face shields and visors, should have a decontamination schedule with responsibility assigned.

Read further information on best practice for PPE (/appendices/appendix-16-selection-of-personal-protective-equipment-ppe-by-healthcare-workers-hcws-during-the-provision-of-patient-care/) in Appendix 16.

Donning (putting on) personal protective equipment (PPE)
The order for putting on PPE is:

1. apron or gown
2. surgical mask
3. eye protection (where required)
4. gloves

Doffing (taking off) personal protective equipment (PPE)
It is important that PPE is removed in the correct order.
The order for taking off PPE is:

1. gloves
2. apron or gown
3. eye protection (if worn)
4. surgical mask

Note:
Always carry out hand hygiene immediately after taking off PPE.
All PPE should be removed before leaving the area and disposed of as healthcare waste

Resources
A video demonstrating the order for donning and doffing PPE (https://vimeo.com/393951705) is available.

COVID-19 - the correct order for donning, doffing and disposal of PPE for HCWs in a primary care setting

NHS National Services Scotland

06:12

The correct order for donning, doffing and disposal of PPE for healthcare workers (https://vimeo.com/393951705) from NHS National Services Scotland (https://vimeo.com/nationalservicesscotland) on Vimeo (https://vimeo.com).

A poster showing the order for putting on and removing PPE (/appendices/appendix-6-best-practice-putting-on-and-removing-ppe/) is available to print.

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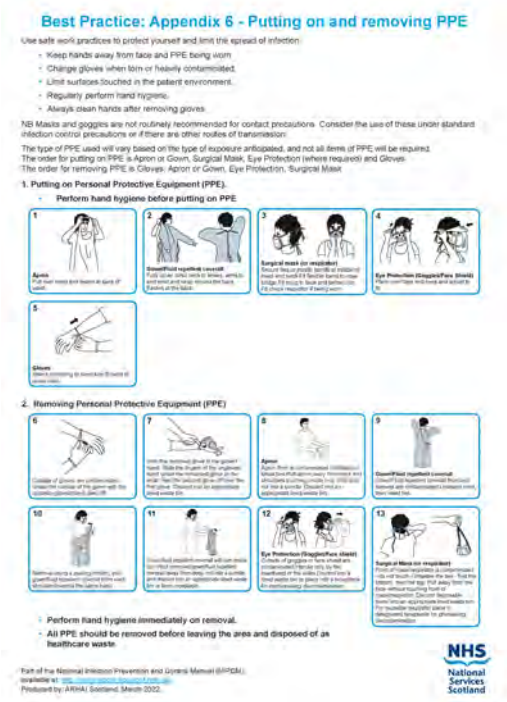
Best Practice: Appendix 6 - Putting on and removing PPE

Use safe work practices to protect yourself and limit the spread of infection:

- Keep hands away from face and PPE being worn
- Change gloves when torn or heavily contaminated.
- Limit surfaces touched in the patient environment.
- Regularly perform hand hygiene.
- Always clean hands after removing gloves.

NB Masks and goggles are not routinely recommended for contact precautions. Consider the use of these under standard infection control precautions or if there are other routes of transmission.

The type of PPE used will vary based on the type of exposure anticipated, and not all items of PPE will be required.
The order for putting on PPE is Apron or Gown, Surgical Mask, Eye Protection (where required) and Gloves.
The order for removing PPE is Gloves, Apron or Gown, Eye Protection, Surgical Mask.

1. Putting on Personal Protective Equipment (PPE).

- Perform hand hygiene before putting on PPE

2. Removing Personal Protective Equipment (PPE)

- Perform hand hygiene immediately on removal.
- All PPE should be removed before leaving the area and disposed of as healthcare waste.

NHS National Services Scotland

[(/media/1808/nipcm-appendix6-march_2022.pdf)](/media/1808/nipcm-appendix6-march_2022.pdf)

Gloves

Gloves should be:

- worn when it is likely or anticipated that you will be exposed to blood, body fluids (including but not limited to secretions and/or excretions), non-intact skin, mucous membranes, lesions and/or vesicles, hazardous drugs, and chemicals for example cleaning agents
- single-use and should be donned (put on) immediately prior to exposure risk and should be doffed (taken off) immediately after each use or upon completion of a task
- appropriate for use, fit for purpose and well-fitting. The glove selection chart (/appendices/appendix-5-best-practice-gloves-use-and-selection/) can help you select the correct gloves
- changed if damaged or a perforation or puncture is suspected

Note:

Using gloves reduces the risk of contamination but does not remove all risk.
Gloves should not be used instead of carrying out hand hygiene.
Gloves should not be worn inappropriately in situations such as to go between residents, move around a care area or whilst at workstations (on the telephone or computer).
Gloves should never be decontaminated or cleaned with hand rub or by washing with cleaning products.

Use the **glove selection chart** (/appendices/appendix-5-best-practice-gloves-use-and-selection/) to support you to select the correct glove type.

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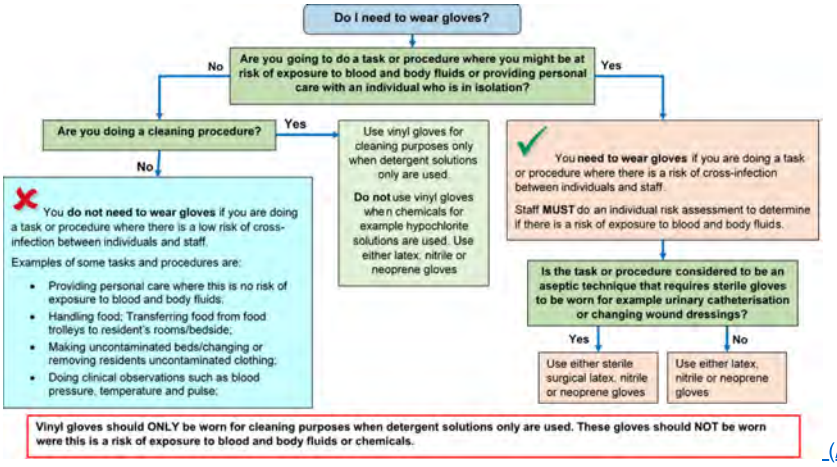

(/appendices/appendix-5-best-practice-gloves-use-and-selection/)

Aprons and gowns

Aprons should be:

- worn by care staff when there is a risk of clothing being contaminated with blood or other body fluids
- worn during direct care, for example oral hygiene, bed-making or when undertaking the decontamination of equipment
- changed between residents and following completion of a procedure or task

The choice of apron or gown is based on an individual risk assessment and anticipated level of blood/body fluid exposure. Routine sessional use of gowns/aprons is not permitted.

Eye/face protection

Eye/face protection (including full face visors) should:

- be worn if blood and/or body fluid contamination to the eyes/face is expected/likely and always during aerosol generating procedures (AGPs)

Note:

Eye/face protection (including visors) should not be touched when worn.
Facial accessories such as piercings or false eyelashes should not be worn when using eye/face protection.
Regular glasses or safety glasses are not considered eye protection.

Fluid Resistant Type IIR surgical face masks (FRSM)

Fluid Resistant Type IIR surgical face masks should be:

- worn if splashing or spraying of blood, body fluids, secretions or excretions onto the respiratory mucosa (nose and mouth) is expected/likely. (As part of SICPs a full-face visor may be used as an alternative to fluid resistant Type IIR surgical face masks to protect against splash or spray)
- well-fitting, fully covering the mouth and nose and fit for purpose. Manufacturer's instructions should be followed to ensure effective fit/protection
- removed or changed:
  - at the end of a procedure/task
  - if the mask is damaged or there is a build up from moisture after prolonged use or from gross contamination with blood or body fluids
  - following specific manufacturers' instructions

If you are using droplet precautions, you should always wear a Type IIR surgical face mask as well as the full-face visor (droplet precautions will be discussed further in Chapter 2 Transmission Based Precautions (/infection-prevention-and-control-manual-for-older-people-and-adult-care-homes/#a2926)).

Transparent face masks

Transparent face masks may be used to aid communication with residents where required.
Transparent face masks should:

- meet the specification standards of the Transparent face mask technical specification (https://azuksappnpdsa01.blob.core.windows.net/datashare/Transparent-Mask-Specifications-December-2023.pdf)

and

- have been approved for use within health and social care settings
- only be worn in areas where Fluid Resistant Type IIR surgical face masks are used as personal protective equipment

Resources

Read the aerosol generating procedures literature review (/web-resources-container/tbp-literature-review-aerosol-generating-procedures/)and surgical face masks literature review (/web-resources-container/standard-infection-control-precautions-and-transmission-based-precautions-literature-review-surgical-face-masks/) for further information regarding the evidence base.

(/appendices/appendix-11-best-practice-aide-memoire-for-optimal-patient-placement-and-respiratory-protective-equipment-rpe-for-infectious-agents-whilst-a-patient-is-in-hospital/)

See appendix 11 (/appendices/appendix-11-best-practice-aide-memoire-for-optimal-patient-placement-and-respiratory-protective-equipment-rpe-for-infectious-agents-whilst-a-patient-is-in-hospital/) for further information.

PPE for visitors

At times, PPE may be offered to visitors to protect them from acquiring a transmissible infection. If a visitor declines to wear PPE when it is offered then this should be respected, and the visitor should not be refused entry to the care home. PPE use by visitors cannot be enforced and there is no expectation that staff monitor PPE use amongst visitors. Below is the PPE which should be worn where it is appropriate to do so and when the visitor chooses to do so.
Visitors do not routinely require PPE unless they are providing direct care to residents they are visiting.
Table 1 is a guide to PPE for use by visitors if delivering direct care.

Table 1: PPE for use by visitors

IPC Precaution	Gloves	Apron/Gown	Face covering/mask	Eye/face protection
Standard Infection Control Precautions (SICPs)	Not required*1	Not required*2	Where splash/spray to nose/mouth is anticipated during direct care	Not required*3
Transmission Based Precautions (TBPs)	Not required*1	Not required*2	If within 2 metres of resident with suspected or known respiratory infection	If within 2 metres of resident with suspected or known respiratory infection

*1 Unless providing direct care which may expose the visitor to blood and/or body fluids, for instance toileting.

*2 Unless providing care resulting in direct contact with the resident, their environment or blood and/or body fluid exposure, for instance toileting, bed bath.
*3 Unless providing direct care and splashing/spraying is anticipated.

Read the PPE literature reviews (/resources/evidence-and-research/personal-protective-equipment-ppe/) to find out more information about the evidence base for PPE use.

5. Safe management of care equipment

Care equipment is easily contaminated with blood, other body fluids, secretions, excretions and infectious agents and this can spread infection.
Important words and what they mean**Routine cleaning** is regular cleaning which is carried out on a scheduled basis, not on an unplanned basis and not in response to an outbreak. For routine cleaning general purpose detergent and water solution or detergent impregnated wipes are sufficient.**Cleaning** is the removal of any dirt by use of an appropriate cleaning agent such as detergent.**Decontamination** is removing, or killing pathogens on an item or surface to make it safe for handling, re-use or disposal, by cleaning, disinfection and/or sterilisation.**Disinfectant** is a chemical used to reduce the number of infectious agents from an object or surface to a level that means they are not harmful to health.**Detergent** is a chemical cleansing agent that can dissolve oils and remove dirt.

If the resident has a known infection or the equipment is contaminated with blood or body fluids, then a disinfection agent needs to be used.
Note:
Do not use household bleach as the required dilution cannot be guaranteed.
Do not refill spray containers for cleaning products as there is a risk of contamination.
What you need for safe management of care equipment

- Cleaning/disinfectant products:
  - general purpose detergent and water solution/detergent impregnated wipes

    or
  - combined detergent/disinfectant solution at a dilution of 1,000 parts per million available chlorine (ppm available chlorine (av.cl.)

    or
  - a general purpose neutral detergent in a solution of warm water followed by disinfection solution of 1,000ppm av.cl.
- Paper towels/disposable cloths.

Types of equipment
There are three different types of care equipment that you will use in your care home and it is important that you know how to deal with each type.
You should follow manufacturers guidance for all equipment and products you use including those used for cleaning and decontamination.
Before using any **sterile equipment**, you should check that:

- the packaging is intact
- there are no obvious signs of packaging contamination
- the expiry date remains valid

1. Single-use - equipment which is used once on a single resident and then discarded.
Single-use equipment **must never be reused** even on the same resident. The packaging carries the symbol.

Note:

Needles and syringes are single-use devices. They should **never** be used for more than one resident or reused to draw up additional medication.
Never give medications from a single-dose vial or intravenous (IV) bag to multiple residents.

2. Single individual use – equipment which can be reused by same resident for example a sling and decontaminated following use as per manufacturers instructions.

3. Reusable non-invasive equipment (often referred to as 'communal equipment') – equipment which can be reused on more than one resident following decontamination between each use for example commode, moving and handling equipment or bath hoist.
Cleaning or decontaminating reusable non-invasive equipment

Residents should be given their own reusable (communal) non-invasive equipment where possible.
Reusable equipment should be checked frequently for cleanliness and signs of integrity. This will include mattresses and pillows which should be clean, have a waterproof covering which is in a good state of repair.
Pillows used on resident's beds may not require a waterproof cover if they are single resident use and are subject to regular checks/laundering. Resident pillows may require labelling where appropriate.
Reusable equipment should be cleaned or decontaminated:

- between individual use
- after blood and/or body fluid contamination
- as part of the regular scheduled cleaning schedules/process
- before inspection, servicing or repair

Staff should:

- follow the local cleaning protocol/schedule which should include responsibility for, frequency of and method of decontamination required
- use a general purpose detergent and water solution/detergent impregnated wipes

  or
  a combined detergent/disinfectant solution at a dilution of 1,000 parts per million available chlorine (ppm available chlorine (av.cl.)
  or
  a general purpose neutral detergent in a solution of warm water followed by disinfection solution of 1,000ppm av.cl;
- make up cleaning/disinfection solution following manufacturers guidance
- follow the manufacturer's contact time for the cleaning/disinfection solution
- rinse and dry reusable equipment then store it clean and dry

Note: When an organisation use products or adopts practices that differ from those stated in this manual, that individual organisation is responsible for ensuring safe systems of work including the completion of risk assessments approved through local governance procedures.
Resources

Read the **management of care equipment literature review** (http://www.nipcm.hps.scot.nhs.uk/web-resources-container/standard-infection-control-precautions-and-transmission-based-precautions-literature-review-management-of-care-equipment/) to find out more about why we do things this way for care equipment.

The **decontamination of non-invasive care equipment** (http://www.nipcm.hps.scot.nhs.uk/appendices/appendix-7-best-practice-decontamination-of-reusable-non-invasive-care-equipment/) poster can help staff decide how to clean equipment.

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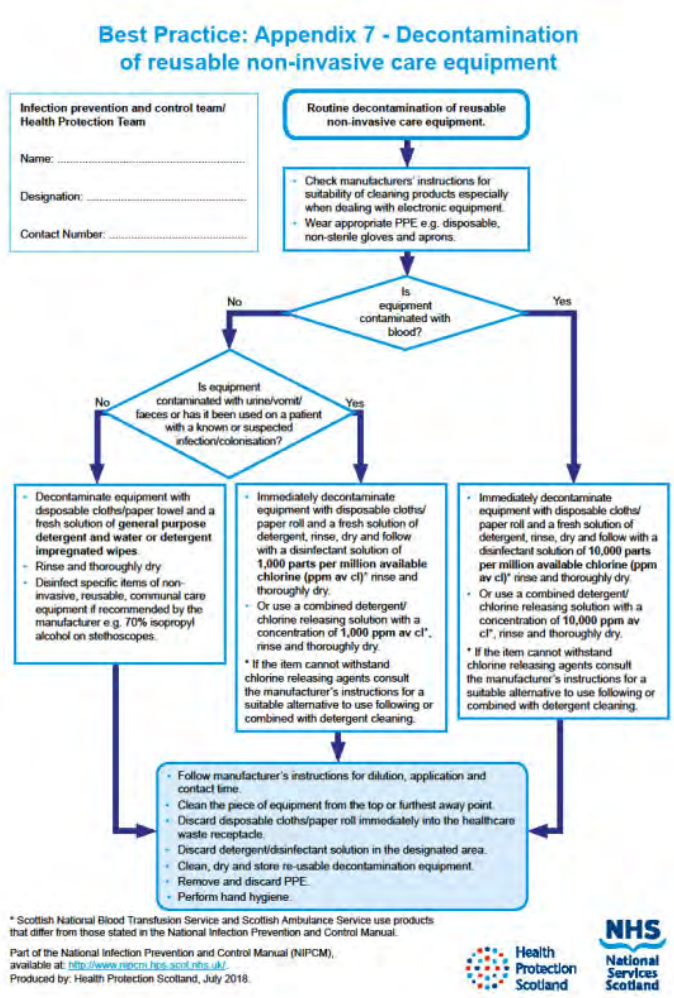


(http://www.nipcm.hps.scot.nhs.uk/appendices/appendix-7-best-practice-decontamination-of-reusable-non-invasive-care-equipment/)

6 - Safe management of the care environment

There are many areas in care homes that become easily contaminated with microorganisms (germs) for example door handles, toilets, waste bins, surfaces.
Furniture and floorings in a poor state of repair can have microorganisms (germs) in hidden cracks or crevices.
To reduce the spread of infection, the environment should be kept clean and dry and where possible clear from clutter and equipment.
Non-essential items should be stored and displayed in such a way as to aid effective cleaning
Keeping a high standard of environmental cleanliness is important in the care home as the residents are often elderly and vulnerable to infections.
The care home environment should be:

- visibly clean, free from non-essential items and equipment to help make cleaning effective
- well maintained and in a good state of repair
- routinely cleaned in accordance with the specified cleaning schedules:
  - a fresh solution of general purpose neutral detergent in warm water is recommended for routine cleaning. This should be changed when dirty or at 15 minutes' intervals or when changing tasks
  - routine disinfection of the environment is not recommended. However, 1,000 parts per million available chlorine (ppm available chlorine (av.cl.) should be used routinely on sanitary fittings

Staff should:

- report any issues with the environment cleanliness or maintenance to the person in charge to ensure that the care environment is safe. The person in charge should then act on problems reported to them
- be aware of the environmental cleaning schedules and clear on their specific responsibilities

Cleaning schedules should include:

- staff responsibilities
- cleaning frequencies

- cleaning methods

Managing cleaning services

Cleaning services should be managed in a systematic way, and staff responsible for cleaning should be appropriately trained to carry out the tasks they are responsible for.

The **care home manager** is responsible for managing the cleaning service which has a number of **essential** elements outlined in the cleaning services diagram.

Select the **Care Homes Cleaning Specification** (https://www.nss.nhs.scot/publications/safe-management-of-the-care-environment-shfn-01-05/) for full size version of cleaning services diagram.

Select the diagram for full size version

Cleaning Services

(https://www.nss.nhs.scot/publications/safe-management-of-the-care-environment-shfn-01-05/)

An effective service will include all of the elements above.

Care Homes Cleaning Specification

The **Care Homes Cleaning Specification** (https://www.nss.nhs.scot/publications/safe-management-of-the-care-environment-shfn-01-05/) provides a guide to planning cleaning services. It has tools to help with the planning and recording of cleaning activities and with the management activities marked with a * in the diagram above. These include:

- a structure to identify all spaces within a care home and plan appropriate cleaning tasks and frequencies
- a set of weekly and monthly **cleaning templates** to be assigned to each space within a care home. These can be used to develop a schedule and to provide a method for recording all cleaning activity

Table 2 provides an example of a cleaning schedule and record. These tools are examples and designed to support local practice, however care homes can use their own tools if preferred. If a local tool is used, it should reflect the standards set out in the Care Homes Cleaning Specification (https://www.nss.nhs.scot/publications/safe-management-of-the-care-environment-shfn-01-05/).

Table 2: Example cleaning schedule residents room

Cleaning Record A: Residents room and en-suite

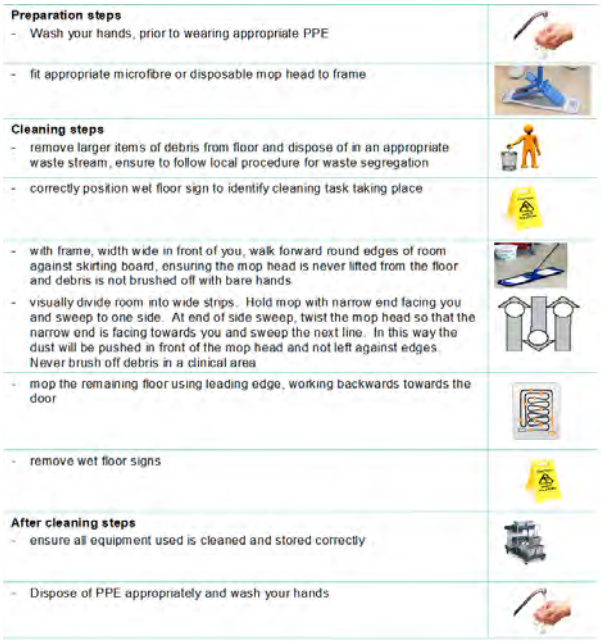
Room number: **Week Commencing:**

Task Group	Task Activity	Mon	Tues	Wed	Thurs	Fri	Sat	Sun
	Daily Tasks							
Toilet	Clean and check (clean once, check once)							
Toilet brush holder	Clean and check (clean once, check once)							
Soap and handtowels	Clean dispensers and replenish supplies							
Glass panels or mirror/ceramic wall tiles/wet wall	Check for marks and spot clean							
Sanitary fittings (wash-hand basin, sink, taps, fixtures)	Clean and check (clean once, check once)							
High level	Check for cleanliness, spot clean							
Furnishings	Remove debris							
	Damp clean							
Radiators	Check for marks and spot clean							
Low level	Check for cleanliness, spot clean							
Paintwork (walls and doors)	Check for marks and spot clean							
Refuse	Collect refuse and dispose							
	Check bin and spot clean							
	Replace liners							
Floors Hard/Soft	Remove debris							
	Dust control or suction clean							
	Damp mop							
	Check for spills, stains etc.							

	Weekly Tasks	
Glass panels or mirrors/ceramic wall tiles or wet wall	Clean	
High level surfaces	Clean ledges, pipes, directional signs	
Low level	Damp clean	
Telephone	Clean	
Window blinds	Suction clean	
Paintwork (walls and doors)	Remove marks	
Refuse	Clean holders and containers	
Floors Hard/Soft	Buff/burnish or scrub	
	Suction dry	
Less Frequent tasks*	Refer to yearly tasks record and note any activities undertaken	

- **Standard operating procedures (SOPs)** for all cleaning tasks. Each SOP outlines the correct equipment, safety considerations, method, and outcomes required for each task. Table 3 shows the important steps that must be taken during the cleaning of floors.

Table 3: Example cleaning SOP: Floors



- A **process for checking** the cleanliness of the care environment, to ensure standards are being maintained and to identify areas for improvement.

The tools within the Cleaning Specification should be used by the care home manager in the planning, training of staff, delivery, and checking of standards of the cleaning services they provide.
Manufacturer's instructions and recommended contact times should be adhered to.
Decontamination of soft furnishings
Decontamination of soft furnishings may require to be discussed with the local HPT/ICT. If the soft furnishing is heavily contaminated with blood or body fluids, it may have to be discarded. If it is safe to clean with standard detergent and disinfectant alone then follow appropriate procedure.
If the item cannot withstand chlorine releasing agents staff are advised to consult the manufacturer's instructions for a suitable alternative to use following or combined with detergent cleaning.

Note: When an organisation adopts decontamination processes not recommended in the CH IPCM the care organisation is responsible for governance of and completion of local risk assessment(s) to ensure safe systems of work.

Read the **routine cleaning of the care environment** (http://www.nipcm.hps.scot.nhs.uk/web-resources-container/standard-infection-control-and-transmission-based-precautions-literature-review-safe-management-of-the-care-environment/) literature review to find out more about why we do things this way for the care environment.

7 - Safe management of linen

Examples of linen you may have in the care home includes:

- bed linen (bed sheets, duvet, duvet covers, pillowcases)
- blankets
- curtains
- hoist slings
- towels
- resident clothing

There are three categories of linen:
Clean – Linen washed and ready for use
Used – All used linen in the care setting not contaminated by blood or body fluids
Infectious – All linen used by a person known or suspected to be infectious and/or linen that is contaminated with blood or body fluids for example faeces
Used or infectious linen may also be categorised as heat-labile: usually personal clothing where the clothing may be damaged (shrinking/stretching) by washing at a higher than recommended temperature than the label advises and therefore, cannot be subject to thermal disinfection. If such linen needs to be washed at a higher temperature for example if soiled or resident has a known infection they or their relatives need to be advised that the clothing may be damaged.
All clean, used and infectious linen should be handled with care and attention paid to the potential spread of infection. Appropriate temperatures for processing all used and infectious linen should be adhered to achieve thermal disinfection.
Clean linen

- Should be stored in a clean, allocated area. This should be an enclosed cupboard but a trolley could be used as long as it is

completely covered with a waterproof covering that is able to withstand cleaning.

Used linen
Staff should:

- put on disposable gloves and apron prior to handling used linen
- make sure that a laundry trolley or container is available as close as possible to the point of use for immediate linen deposit

Staff should **not**:

- rinse, shake or sort linen on removal from beds or trolleys
- place used linen on the floor or any other surfaces for example on a locker or tabletop
- re-handle used linen once bagged
- overfill laundry receptacles or trolleys
- place inappropriate items in the laundry receptacle for example used equipment/needles.

Infectious linen
Staff should**:**

- wear disposable gloves and apron before handling infectious linen
- put infectious linen directly into a water soluble laundry bag and secure before putting into a clear plastic bag and placing into a laundry receptacle/trolley

If using external laundry services both used and infectious linen bags/receptacles should follow local procedure and arrangements.
Store all used/infectious linen in a designated, safe, lockable area whilst awaiting uplift.
All linen that is deemed unfit for re-use, for example torn or heavily contaminated, should be categorised at the point of use and disposed of in the appropriate local healthcare waste stream.
Washing residents personal linen
Appendix 1 National Guidance for Safe Management of Linen in NHSScotland Health and Care Environments - For laundry services/distribution (https://www.nss.nhs.scot/publications/national-guidance-for-safe-management-of-linen-in-nhsscotland-health-and-care-environments-for-laundry-servicesdistribution-v22/) contains information that is particularly relevant and may be useful for residential care settings where domestic-type (household) washing machines may be in place for laundering resident's personal items and clothing.
Domestic-type washing machines are not typically programmed with the temperature settings required for thermal disinfection, therefore domestic-type machines may only be used for laundering personal items of clothing belonging to residents, such as those that are heat-labile.
Other types of used linen such as sheets should be reprocessed using a machine that is capable of a validated temperature disinfection stage.
If using a domestic type washing machine to launder resident's personal items:

- wash items using the highest temperature you can and following the washing instructions
- use your normal washing powder or detergent and follow the instructions on the correct amount to use
- tumble-dry (if possible) following the washing instructions
- iron according to washing instructions. If possible, use a hot steam iron.

It is considered best practise to launder a resident's personal items separately, that means not to mix items from multiple persons within a single load.
If visitors wish to take their relatives clothes home to be laundered, place laundry in an appropriate bag and provide them with a **washing clothes at home leaflet** (https://hpspubsrepo.blob.core.windows.net/hps-website/nss/2639/documents/1_washing-clothes-home-english.pdf).
If the residents clothing is very soiled or infectious, staff may recommend that the clothing is washed in the care home's laundry service if available, otherwise, the item should be disposed of in the appropriate healthcare waste stream following discussion with the resident or their relative(s).

Read the **safe management of linen** (http://www.nipcm.hps.scot.nhs.uk/web-resources-container/standard-infection-control-precautions-sicp-literature-review-safe-management-of-linen-in-the-hospital-setting/) literature review to find out more about why we do things this way when dealing with linen.

8 - Blood and body fluid spillages

Spillages of blood and other body fluids may transmit blood borne viruses.
Important words and what they meanA **blood borne virus** is a virus carried or transmitted by blood, for example Hepatitis B, Hepatitis C and HIV.**Body fluids** are fluids produced by the body such as urine, faeces, vomit or diarrhoea. These body fluids may also contain blood.

Blood and body fluid spillages must be decontaminated:

- immediately by staff trained to undertake this safely
- using body fluid spill kits/equipment available

Responsibilities for the decontamination of blood and body fluid spillages should be clear within each area/care setting.
Resources

Read the **management of blood and body fluid spillages** (http://www.nipcm.hps.scot.nhs.uk/web-resources-container/standard-infection-control-precautions-sicp-literature-review-management-of-blood-and-body-fluid-spillages-in-the-hospital-setting/) literature review to find out more about why we do things this way for blood and body fluid spillages.

Use the poster **management of blood and body fluids** (http://www.nipcm.hps.scot.nhs.uk/appendices/appendix-9-best-practice-management-of-blood-and-body-fluid-spillages/) to help you when you clean up blood and body fluid spillages.

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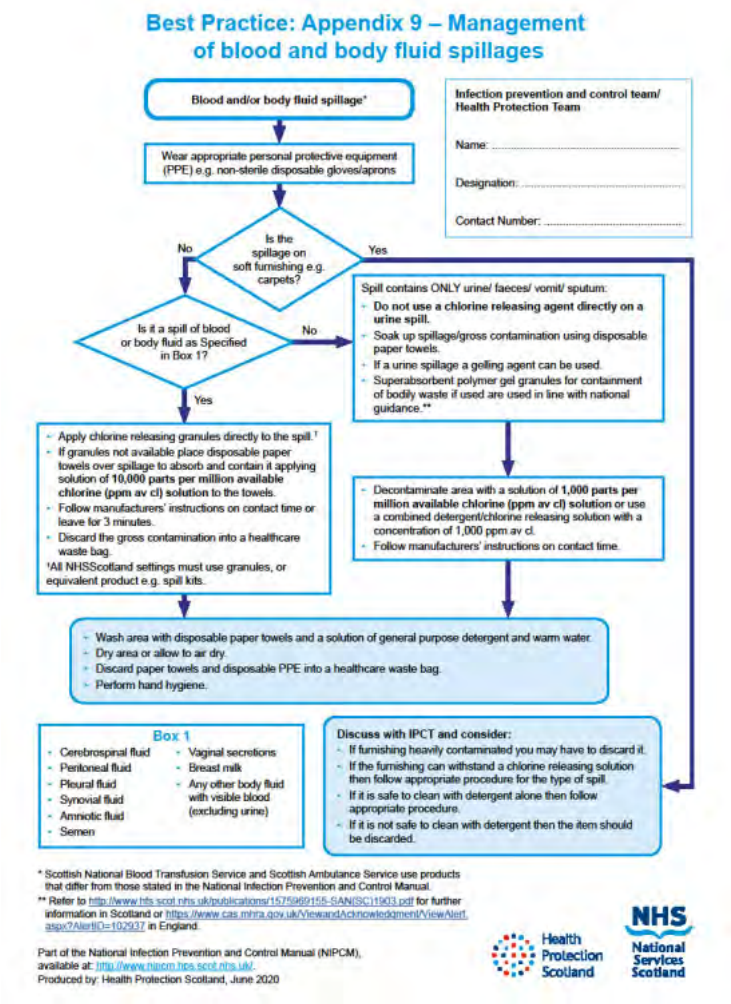

(http://www.nipcm.hps.scot.nhs.uk/appendices/appendix-9-best-practice-management-of-blood-and-body-fluid-spillages/)

9 - Safe disposal of waste (including sharps)

Different types of waste will be produced within care homes.
Some waste may be disposed of through the domestic waste route but other types of waste needs special handling and disposal for example sharps and waste from people who have or may have an infection.
Waste bags in care settings should be colour coded to denote the various categories of waste.
Local procedures and policies on waste disposal should be followed.

Segregation (separating) of waste

- **Healthcare (including clinical)** waste is produced as a direct result of healthcare activities for example soiled dressings, sharps
- **Special (hazardous**) waste arises from the delivery of healthcare in both clinical and non-clinical settings. Special waste includes a range of controlled wastes, defined by legislation, which contain dangerous or hazardous substances for example chemicals and pharmaceuticals
- **Domestic waste** – must be segregated at source into:
    - Dry materials that can be recycled (glass, paper and plastics, metals, cardboard)
    - Residual waste (any other domestic waste that cannot be recycled)

Care home waste disposal may differ from categories described and guidance from local contractors may apply.

Safe management of waste

Care home managers and staff should ensure:

- all waste is correctly segregated according to local regulations
- correct colour coded bags are being used according to local regulations
- there is a dedicated area for storage of clinical waste that is not accessible to residents or the public
- waste is stored in a designated, safe, lockable area whilst awaiting uplift. Uplift schedules should be acceptable to the care area and there should be no build-up of waste receptacles
- there is a schedule for emptying domestic waste bins at the end of the day and during the day if needed

All staff should:

- follow local schedules for emptying domestic waste bins
- always use appropriate personal protective equipment (PPE) (/care-home-infection-prevention-and-control-manual-ch-ipcm/#a2884)
- dispose of waste immediately as close as possible to where it was produced
- dispose of clinical waste into the correct UN 3291 approved waste bin or sharps container
- ensure that waste bins are never overfilled. Once the waste bin is three quarters full, tie waste bags up and put into the main waste bin
- use a 'swan neck' technique for closure of the bag and label with date and location as per local policy
    - a 'swan neck' is a way of closing bag by tying in a loop and securing with a zip tie or tape to make a handle
- clean waste bins regularly with a general purpose neutral detergent
- remove PPE and perform hand hygiene when you have finished handling waste

Read the **safe disposal of waste** (http://www.nipcm.hps.scot.nhs.uk/web-resources-container/standard-infection-control-precautions-literature-review-the-safe-disposal-of-waste/) literature review to find out more about why we do things this way when dealing with waste.

10. Occupational Safety: Prevention and Exposure Management (including sharps)

All care homes should have policies in place to ensure that staff are protected from occupational exposure to microorganisms (germs), particularly those that may be found in blood and body fluids.

Important words and what they mean Occupational exposure is exposure of staff to blood or body fluids in the course of their work.A **sharp** is a device or instrument such as needles, lancets and scalpels which are necessary for the exercise of specific healthcare activities and are able to cut, prick and/or have the potential to cause injury.**Safety device or safer sharp** is a medical sharps device which has been designed to incorporate a feature or mechanism that minimises and/or prevents the risk of accidental injury. Other terms include (but are not limited to) safety devices, safety-engineered devices and safer needle devices.
The **Health and Safety (Sharp Instruments in Healthcare) Regulations (2013)** (https://www.legislation.gov.uk/uksi/2013/645/made#:~:text=The%20Health%20and%20Safety%20%28Sharp%20Instruments%20in%20Healt outline the regulatory requirements for employers and contractors in the healthcare sector in relation to:

- arrangements for the safe use and disposal of sharps
- provision of information and training to employees
- investigations and actions required in response to work related sharps injuries

Safe management of sharps in the care home
Sharps handling must be assessed, kept to a minimum and eliminated if possible with the use of approved safety devices.
Sharps safety

- **Always** dispose of needles and syringes as a single unit immediately at the point of use.
- **Always** assemble and label sharps containers correctly as per manufacturers instructions.
- **Always** use the temporary closure mechanisms on sharps containers in between use.
- **Always** follow manufacturers' instructions for safe use and disposal.

- **Never** re-sheath used needles or lancets.
- **Never** store sharps containers on the floor.
- **Never** allow access of sharps containers to residents or the public.
- **Never** fill sharps containers more than three-quarters full.

Significant occupational exposure
A significant occupational exposure is when someone is injured at work from using sharps or exposed to risk from blood or body fluids which may then result in a blood borne virus (BBV) or other infection.
Examples of this would be:

- a percutaneous injury for example injuries from needles, instruments, bone fragments, or bites which break the skin
- exposure of broken skin for example abrasions, cuts, eczema
- exposure of mucous membranes including the eye from splashing of blood or other high risk body fluids

If you think or know you have had a significant occupational exposure you should:

- report this immediately to the designated person in your care home**, this is a legal requirement**
- follow the local agreed process for management of an occupational exposure incident and follow the management of occupational injuries flow chart

Resources

Read the **management of occupational exposure to Blood Borne Viruses (BBVs)** (http://www.nipcm.hps.scot.nhs.uk/web-resources-container/standard-infection-control-precautions-sicp-literature-review-occupational-exposure-management-including-sharps/) literature review to find out more about why we do things this way for occupational exposure.

The **management of occupational exposure incidents flowchart (http://www.nipcm.hps.scot.nhs.uk/appendices/appendix-10-best-practice-management-of-occupational-exposure-incidents/)** should be used within your care home so you know what to do for an occupational exposure.

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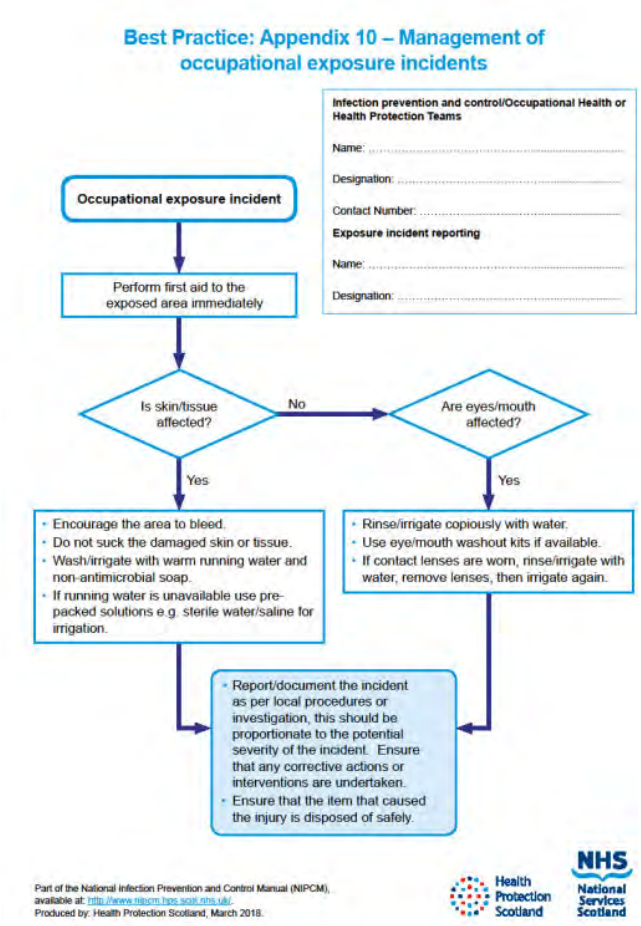


(http://www.nipcm.hps.scot.nhs.uk/appendices/appendix-10-best-practice-management-of-occupational-exposure-incidents/)

Transmission based precautions (TBPs)

In certain circumstances using standard infection control precautions (SICPs) won't be enough to stop an infection spreading and you will need to use some extra precautions. **These extra precautions are called Transmission Based Precautions or TBPs.** Clinical judgement and decisions should be made by staff to determine the necessary IPC precautions required (the local IPCT and/or the HPT should be contacted for advice and support where required).
Clinical judgement and decisions should be based on the:

- suspected or known infectious agent
- transmission route of the infectious agent
- care setting and procedures undertaken
- severity of the illness caused

When TBPs should be used

TBPs should be used if a resident has a suspected or known infection or colonisation.

Important words and what they meanColonisation is the presence of microorganisms on a body surface (such as the skin, mouth, intestines or airway) that does not cause disease in the person or signs of infection.
Infection transmission routes
Infections can be transmitted or spread by:

- **contact** with microorganisms (germs) on hands or from contaminated equipment or environment
- **droplet infection** by inhaling infectious droplets, for example flu or COVID-19
- **aerosol infection** which are inhaled or directly contaminate a mucosal surface or conjunctivae (eyes, nose, and mouth)

Different transmission routes need different TBPs
TBPs are categorised by the route of transmission of infectious agents (some infectious agents can be transmitted by more than one route). **Appendix 11** (https://www.nipcm.scot.nhs.uk/appendices/appendix-11-best-practice-aide-memoire-for-patient-placement-considerations-and-respiratory-protective-equipment-rpe-or-fluid-resistant-surgical-facemasks-frsms-for-infectious-agents/) provides details of the type of precautions, optimal resident placement, isolation requirements and any respiratory precautions required. Application of TBPs may differ depending on the setting and the known or suspected infectious agent.
Contact precautions are used to prevent infections that spread through direct contact with the resident or indirectly from the resident's immediate care environment and care equipment. This is the most common route of cross-infection transmission.
Droplet precautions are used to prevent and control infections spread over short distances (at least 3 feet or 1 metre) via small droplets from the respiratory tract of one individual directly onto the mucosal surface of another person's mouth or nose or eyes. Droplets penetrate the respiratory system to above the alveolar level.
Airborne precautions are used to prevent and control infections spread without necessarily having close contact via from the respiratory tract of one individual directly onto the surface of another person's mouth or nose or eyes. Aerosols penetrate the respiratory system to deep into the lung.
Different infections need different TBPs
You might have heard of some infections like norovirus, Meticillin-resistant *Staphylococcus aureus* (MRSA), *Clostridioides. difficile* (C.diff/CDI) and flu but there are lots of others.
You can find out more information about the infection the individual has and the precautions you should use in **Appendix 11** (http://www.nipcm.hps.scot.nhs.uk/appendices/appendix-11-best-practice-aide-memoire-for-optimal-patient-placement-and-respiratory-protective-equipment-rpe-for-infectious-agents-whilst-a-patient-is-in-hospital/) and/or **A-Z of pathogens** (http://www.nipcm.hps.scot.nhs.uk/a-z-pathogens/) in the NIPCM.
You can also contact your local IPCT or HPT for further advice if required.
Before using transmission based precautions you need to find out:

- what the suspected or known infection/colonisation is?
- how is it transmitted?
- how severe is the resident's illness?
- what is the care setting and required procedures?

There are different ways you can find out if a resident has an infection that needs TBPs to be put in place. You can get information about a resident's infection status from:

- their GP
- local health protection team
- local infection prevention and control team
- laboratory
- hospital or care homes staff from where the resident has been discharged or transferred

Local processes should be followed when obtaining this information.

Further information on transmission based precautions can be found in the definitions of (http://www.nipcm.hps.scot.nhs.uk/web-resources-container/transmission-based-precautions-literature-review-definitions-of-transmission-based-precautions/)Transmission Based Precautions literature review. (http://www.nipcm.hps.scot.nhs.uk/web-resources-container/transmission-based-precautions-literature-review-definitions-of-transmission-based-precautions/)

1. Resident placement/assessment for infection risk

All residents require to be regularly monitored for infection throughout their stay for the correct IPC precautions to be put in place to minimise the risk of infection being spread.
Residents may be an infection risk if they have:

- diarrhoea, vomiting, an unexplained rash, fever or respiratory symptoms
- a known (laboratory confirmed) or suspected infectious pathogen for which **appropriate** duration of precautions as outlined in A-Z of pathogens (https://www.nipcm.scot.nhs.uk/a-z-pathogens/)are not yet complete
- been previously positive with a Multi-drug Resistant Organism (MDRO) for example Meticillin-resistant Staphylococcus aureus (MRSA); Carbapenemase Producing Enterobacterales (CPE)*

*CPE should be considered if the resident meets **any** of the following criteria within the 12-month period before admission:

- been an inpatient in a hospital outside of Scotland
- received holiday dialysis outside of Scotland

- been a close contact of a person who has been colonised or infected with CPE.

See the CPE toolkit for non-acute settings (https://www.nss.nhs.scot/publications/toolkit-for-managing-carbapenemase-producing-enterobacteriaceae-cpe-in-scottish-non-acute-care-settings/) for further information and requirements.

Staff should do the following if any resident displays signs and/or symptoms of infection:

- obtain advice on the resident's clinical management from their GP and advice on appropriate IPC management from either the local HPT or IPCT
- make resident placement decisions based on advice received or sound judgement by clinical staff who are involved in the resident's management
- advise the ambulance service of the resident's infectious condition if transport to hospital is required

Residents should **not** be moved within the care home if they have signs and symptoms of infection unless essential.
Resident isolation requirements within the care home
Residents may require to be isolated in their own room because of a known or suspected infection. During this time it is important that:

- residents remain in their rooms whilst considered infectious and the door should remain closed. If it is not possible for safety reasons, for example the resident has dementia, an individual risk assessment should be done and any decisions or actions should be documented. The local HPT or IPCT should be contacted for advice
- suitable discrete signage is placed on the door advising others not to enter the room
- there should be as much consistency in staff allocation as possible to care for residents in isolation room areas as an additional IPC measure. This is known as 'staff cohorting'
- resident isolation requirements should remain under continuous review considering individual risk factors and the impact on the resident. The local HPT or IPCT should be contacted for advice in these circumstances

Note: If a resident requires isolation because of infection or in an outbreak situation, this should be individually risk assessed to ensure the safety and health and wellbeing needs of the resident. Isolation periods must be monitored on daily basis and be for the minimum period specified.

Read the **patient placement, isolation and cohorting** (http://www.nipcm.hps.scot.nhs.uk/web-resources-container/patient-placement-isolation-and-cohorting-standard-infection-prevention-control-and-transmission-based-infection-control-precautions/) literature review to find out more about why we do things this way for resident placement for TBPs.

2. Safe management of care equipment in an isolation room

Cleaning and decontamination of care equipment is essential to reduce the spread of infection when infection is confirmed/suspected.
When dealing with the equipment used in the resident's isolation room staff should:

- use single use or dedicated reusable care equipment, for example commodes, for the resident in isolation where possible
- clean and decontaminate all care equipment after each use as per Appendix 7 (/appendices/appendix-7-best-practice-decontamination-of-reusable-non-invasive-care-equipment/)

Read the **management of care equipment** (http://www.nipcm.hps.scot.nhs.uk/web-resources-container/standard-infection-control-precautions-and-transmission-based-precautions-literature-review-management-of-care-equipment/) literature review to find out more about why we do things this way for patient care equipment for TBPs.

3 - Safe management of the care environment

Isolation room cleaning
Staff should:

- clean and decontaminate the isolation room at least daily or more frequently if advised to do so. If you have been advised to clean more than daily this should be documented in the environmental cleaning schedule
- clean frequently touched surfaces like door handles, bed frames and bedside cabinets at least twice daily
- use correct cleaning products which are either:

  a combined detergent/disinfectant solution at a dilution of 1,000 parts per million available chlorine (ppm available chlorine (av.cl.));
  or
  a general purpose neutral detergent in a solution of warm water followed by disinfection solution of 1,000ppm av.cl.

- follow manufacturers guidance and instructions on how to use the product and what the recommended contact time is for the product to work. This may include rinsing off the disinfection solution to prevent damage to surfaces.

Do not **refill spray containers** for cleaning products as there is a risk of contamination.
Terminal clean

A **terminal clean** is carried out when the resident is no longer considered infectious and/or when the environment is cleaned/decontaminated to ensure it is safe for a new resident.
A terminal clean is carried out by:

- removing all healthcare waste and other disposable items from the room
- removing bedding, curtains (bagged before removal from the room) and then wash as infectious linen
- cleaning and decontaminating all reusable care equipment in the room (prior to removal from the room)

The room should then be decontaminated using either:

- a combined detergent disinfectant solution at a dilution (1,000ppm av.cl.) or
- a general purpose neutral detergent clean in a solution of warm water followed by disinfection solution of 1,000ppm av.cl.

The room should be cleaned from the highest to lowest point and from the least to most contaminated point.
Manufacturers' guidance and recommended product "contact time" should be followed for all cleaning/disinfection solutions.

(/appendices/appendix-7-best-practice-decontamination-of-reusable-non-invasive-care-equipment/) (/appendices/appendix-7-best-practice-decontamination-of-reusable-non-invasive-care-equipment/)Appendix 7 (/appendices/appendix-7-best-practice-decontamination-of-reusable-non-invasive-care-equipment/) is a poster flowchart for decontamination of reusable non-invasive care equipment that you may wish to print off and place in the care home.

Note: When an organisation use products or adopts practices that differ from those stated in this manual, that individual organisation is responsible for ensuring safe systems of work including the completion of risk assessments approved through local governance procedures.

4. Personal Protective Equipment (PPE): Respiratory Protective Equipment (RPE)

In addition to PPE used for Standard Infection Control Precautions, appendix 16 (http://www.nipcm.hps.scot.nhs.uk/appendices/appendix-16-best-practice-aide-memoire-for-levels-of-personal-protective-equipment-ppe-for-healthcare-workers-when-providing-patient-care/) of the NIPCM outlines what type of PPE and RPE you will need to wear for infections spread by different transmission routes.
AGPs (/care-home-infection-prevention-and-control-manual-ch-ipcm/#AGP)

Gloves

Gloves are a single-use item and should be donned immediately prior to exposure risk and should be doffed immediately after each use or upon completion of a task.
Gloves should:

- be worn when exposure to blood, body fluids, (including but not limited to secretions and/or excretions), non-intact skin, lesions and/or vesicles, mucous membranes, hazardous drugs, and chemicals for example cleaning agents, is anticipated/likely
- never be worn inappropriately in situations such as to go between residents, move around a care area, work at IT workstations
- be changed if a perforation or puncture is suspected or identified
- be appropriate for use, fit for purpose and well-fitting
- not be worn as a substitute to hand hygiene
- never be decontaminated with ABHR

Resources

For appropriate glove use and selection see the flowchart poster (https://www.nipcm.scot.nhs.uk/appendices/appendix-5-best-practice-gloves-use-and-selection/) which may be printed off and placed in the care home. (https://www.nipcm.scot.nhs.uk/appendices/appendix-5-best-practice-gloves-use-and-selection/)

Further information can be found in the Gloves literature review (https://www.nipcm.scot.nhs.uk/web-resources-container/sicp-literature-review-personal-protective-equipment-ppe-gloves/).

Aprons/gowns

An apron should be worn when caring for residents known or suspected to be colonised/infected with antibiotic resistant bacteria including contact with the resident's environment.
Plastic aprons should be used in care home settings for protection against contamination with blood and/or body fluids.
A fluid repellent gown should be used if excessive splashing or spraying is anticipated.
A full body fluid repellent gown should be worn when conducting AGPs on residents known or suspected to be infected with a respiratory infectious agent.

Further information can be found in the Aprons/Gowns literature review (https://www.nipcm.scot.nhs.uk/web-resources-container/standard-infection-control-precautions-sicp-literature-review-personal-protective-equipment-ppe-apronsgowns/).

Eye/face protection

A face visor or goggles should be used in combination with a fluid resistant Type IIR surgical mask when caring for symptomatic residents infected with droplet transmitted infectious agents.

A face visor or goggles should be used in combination with a fluid resistant FFP3 respirator when caring for symptomatic residents infected with an airborne transmitted infectious agent.
Eye/face protection should be worn:

- by all of those in the room if potentially infectious AGPs are conducted
- for the care of residents with novel infectious agents including pandemic influenza

Read Appendix 11 (/appendices/appendix-11-best-practice-aide-memoire-for-patient-placement-considerations-and-respiratory-protective-equipment-rpe-or-fluid-resistant-surgical-facemasks-frsms-for-infectious-agents/) for details of the type of precautions, optimal resident placement, isolation requirements and any respiratory precautions required.

Surgical masks

A Type IIR fluid resistant surgical mask (FRSM) should be worn when caring for a resident with a suspected/confirmed infectious agent spread by the droplet route.
FRSMs should be worn (where tolerated) by residents with suspected/confirmed infectious agents spread by the droplet or airborne routes, as a form of source control and should meet type II or IIR standards.

Read Appendix 11 (/appendices/appendix-11-best-practice-aide-memoire-for-patient-placement-considerations-and-respiratory-protective-equipment-rpe-or-fluid-resistant-surgical-facemasks-frsms-for-infectious-agents/) for details of the type of precautions, optimal resident placement, isolation requirements and any respiratory precautions required.

Respiratory Protective Equipment (RPE)

PPE should still be used in accordance with SICPs when using respiratory protective equipment (RPE). See Chapter 1.4 (/infection-prevention-and-control-manual-for-older-people-and-adult-care-homes/#a2884) for PPE use for SICPs.
The use of FFP3s is governed by health and safety regulations and they must be fit tested to the user to ensure the required protection is provided.
The Health and Safety Executive (HSE) provides information regarding fitting and fit checking of RPE (https://www.hse.gov.uk/respiratory-protective-equipment/basics.htm).
Respiratory Protective Equipment (RPE), for instance FFP3 and facial protection, should be considered when:

- a resident is admitted or develops a known/suspected infectious agent/disease spread wholly by the airborne route
- carrying out AGPs on residents with known/suspected infectious agent spread wholly or partly by the airborne or droplet route

FFP3 respirators

It is an HSE requirement that staff who need to wear an FFP3 respirator must be fit tested.
FFP3 respirators should **not** be worn by staff who are not trained in their use or who have not been fit tested.
All FFP3 respirators must be:

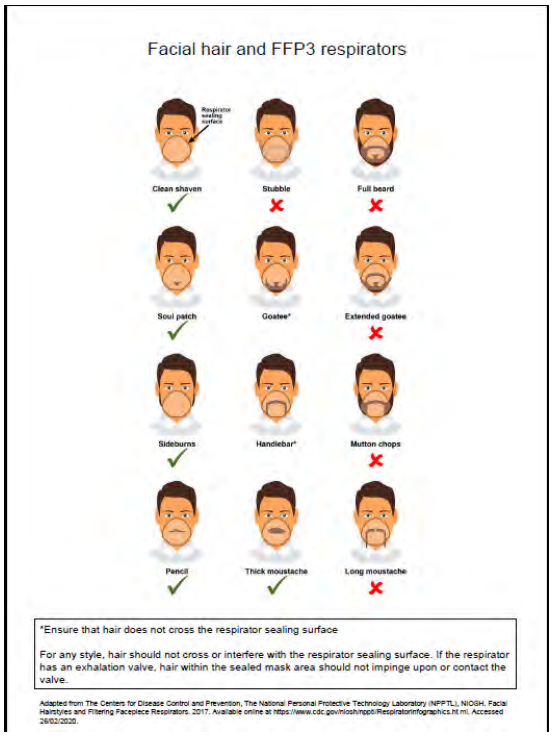
- fit tested (by a competent fit test operator) on all staff who may be required to wear a respirator to ensure an adequate seal/fit according to the manufacturers' guidance
- fit checked (according to the manufacturers' guidance) every time a respirator is donned to ensure an adequate seal has been achieved
- single-use (disposable) and fluid resistant
- compatible with other facial protection used such as protective eyewear so that this does not interfere with the seal of the respiratory protection. Regular corrective spectacles are not considered adequate eye protection
- put on before entry into the resident's room and removed in a safe area once outside the resident's room
- changed after each use

Signs that a change in respirator is required include:

- breathing becomes difficult
- the respirator is wet or moist
- the respirator is damaged
- the respirator is obviously contaminated with body fluids such as respiratory secretions

Resources

A poster (/media/1491/facial-hair-and-ffp3-respirators.png) containing information on compatibility of facial hair and FFP3 respirators can be used when fit testing and fit checking.



Further information regarding fitting and fit checking of respirators can be found from the Health and Safety Executive (http://www.hse.gov.uk/respiratory-protective-equipment/basics.htm)

Aerosol Generating Procedure (AGP)

An AGP is a medical procedure that can result in the release of airborne particles from the respiratory tract and is associated with an increased risk of transmission when treating someone who is suspected or known to be suffering from an infectious agent transmitted wholly or partly by the airborne or droplet route.

The most common AGPs undertaken in the Care Home Setting are Continuous Positive Airway Pressure Ventilation (CPAP) or Bi-level Positive Airway Pressure Ventilation (BiPAP) or tracheostomy procedures (insertion or removal) and open suctioning beyond the oro-pharynx.

The full list of medical procedures that have reported to be aerosol generating and are associated with an increased risk of respiratory transmission can be found in appendix 17 (/appendices/appendix-17-aerosol-generating-procedures-agps-and-post-agp-fallow-time-pagpft/).

A poster (/media/1898/2022-07-22-v4-ppe-when-undertaking-agps-poster.pdf) is also available on PPE when undertaking AGPs within health and social care settings.

Rooms should always be decontaminated following an AGP. Clearance of infectious particles after an AGP is dependent on the ventilation and air change within the room. In an isolation room with mechanical ventilation 10-12 air changes per hour (ACH) a minimum of 20 minutes is required; in a side room with 6 ACH this would be approximately one hour.

It is often difficult to calculate air changes in areas that have natural ventilation only, meaning no mechanical ventilation. Natural ventilation, particularly when reliant on open windows can vary depending on the climate. An air change rate in these circumstances has been agreed as 1-2 air changes/hour.

Rooms should always be decontaminated following the completion of an AGP. Regardless of the number of air changes, a period of 10 minutes should pass to allow larger droplets to settle before the room can be cleaned. Staff are required to wear the appropriate PPE until the fallow time (https://www.nipcm.scot.nhs.uk/appendices/appendix-17-aerosol-generating-procedures-agps-and-post-agp-fallow-time-pagpft/) has been met.

Resources

For further information on fallow times refer to Table 1 in Appendix 17 (https://www.nipcm.scot.nhs.uk/appendices/appendix-17-aerosol-generating-procedures-agps-and-post-agp-fallow-time-pagpft/).

Further information can be found in the literature reviews aerosol generating procedures, (/web-resources-container/tbp-literature-review-aerosol-generating-procedures/)Respiratory Protective Equipment (RPE) (https://www.nipcm.scot.nhs.uk/web-resources-container/transmission-based-precautions-literature-review-respiratory-protective-equipment-rpe/), Personal Protective Equipment (PPE) for Infectious Diseases of High Consequence (IDHC) (https://www.nipcm.scot.nhs.uk/web-resources-container/literature-review-personal-protective-equipment-ppe-for-infectious-diseases-of-high-consequence-idhc/)

Post AGP fallow time (PAGPFT)

Time is required after an AGP is performed to allow the aerosols still circulating to be removed/diluted. This is referred to as post AGP fallow time (PAGPFT) and is a function of the room ventilation air change rate.

The post aerosol generating procedure fallow time (PAGPFT) calculations are detailed in appendix 17 (/appendices/appendix-17-aerosol-generating-procedures-agps-and-post-agp-fallow-time-pagpft/). It is often difficult to calculate air changes in areas that have natural ventilation only.

If the area has zero air changes and no natural ventilation, then AGPs should not be undertaken in this area.

The duration of AGP is also required to calculate the PAGPFT and clinical staff are therefore reminded to note the start time of an AGP. It is presumed that the longer the AGP, the more aerosols are produced and therefore require a longer dilution time. During the PAGPFT staff should not enter this room without FFP3 masks. Other residents, other than the resident on which the AGP was undertaken, should not enter the room until the PAGPFT has elapsed and the surrounding area has been cleaned appropriately. As a minimum, regardless of air changes per hour (ACH), a period of 10 minutes should pass before rooms can be cleaned. This is to allow for the large droplets to settle. Staff should not enter rooms in which AGPs have been performed without airborne precautions for a minimum of 10 minutes from completion of AGP. Airborne precautions may also be required for a further extended period of time based on the duration of the AGP and the number of air changes. Cleaning can be carried out after 10 minutes regardless of the extended time for airborne PPE.
Contact your local HPT/IPCT if further advice is required.

Read the RPE (http://www.nipcm.hps.scot.nhs.uk/web-resources-container/transmission-based-precautions-literature-review-respiratory-protective-equipment-rpe/) literature review to find out more about why we do things this way for respiratory protective equipment.

Use of FFP3 respirators

- Where staff have concerns, they may choose to wear an FFP3 respirator rather than a fluid-resistant surgical mask (FRSM) when providing patient care, provided they are fit tested. This is a personal PPE risk assessment.

5. Infection prevention and control during care of the deceased

If a resident dies when in the care home SICPs and TBPs should still be applied. This is due to the ongoing risk of infectious transmission via contact although the risk is usually lower than for the living.
It is important that information on the infection status of the deceased is sought and communicated at each stage of handling and risk assessments performed.
Viewing, washing and/or dressing of the deceased see Appendix 12 - Application of infection prevention precautions in the deceased (http://www.nipcm.hps.scot.nhs.uk/appendices/appendix-12-mandatory-application-of-transmission-based-precautions-to-key-infections-in-the-deceased/) for guidance on the precautions required and what is permitted for certain types of infections. Staff should advise relatives of the appropriate precautions to be taken when viewing and/or having physical contact with the deceased, including when this should be avoided.

Read the **infection prevention and control during care of the deceased** (http://www.nipcm.hps.scot.nhs.uk/web-resources-container/transmission-based-precautions-literature-review-infection-prevention-and-control-during-care-of-the-deceased/) literature review to find out more about why we do things this way when dealing with the deceased.

Care home appendices

These appendices from the NIPCM can be used in care homes.
Appendix 1 - How to hand wash (/appendices/appendix-1-how-to-hand-wash/)
Appendix 2 - How to hand rub (/appendices/appendix-2-how-to-hand-rub/)
Appendix 5 - Glove use and selection (/appendices/appendix-5-gloves-use-and-selection/)
Appendix 6 - Putting on and removing PPE (/appendices/appendix-6-putting-on-and-removing-ppe/)
Appendix 7 - Decontamination of reusable care equipment (/appendices/appendix-7-decontamination-of-reusable-non-invasive-care-equipment/)
Appendix 8 - Management of linen at care level (/appendices/appendix-8-management-of-linen-at-care-level/)
Appendix 9 - Management of blood and body fluid spillages (/appendices/appendix-9-management-of-blood-and-body-fluid-spillages/)
Appendix 10 - Management of occupational exposure incidents (/appendices/appendix-10-management-of-occupational-exposure-incidents/)
Appendix 11 - Aide memoire for patient placement considerations and respiratory protective equipment (RPE) or fluid resistant surgical facemasks (FRSMs) for infectious agents (/appendices/appendix-11-aide-memoire-for-patient-placement-considerations-and-respiratory-protective-equipment-rpe-or-fluid-resistant-surgical-facemasks-frsms-for-infectious-agents/)
Appendix 12 - Application of infection control precautions in the deceased (/appendices/appendix-12-application-of-infection-control-precautions-in-the-deceased/)
Appendix 16 - Selection of personal protective equipment (PPE) by health and care workers (HCWs) during the provision of care (/appendices/appendix-16-selection-of-personal-protective-equipment-ppe-by-health-and-care-workers-hcws-during-the-provision-of-care/)
Appendix 18 - Hierarchy of controls (/appendices/appendix-18-hierarchy-of-controls/)

Care home resources

The resources section can be used as supporting tools for the Care Home Infection Prevention and Control Manual (CH IPCM).

- Aerosol Generating Procedures
  - Poster on PPE to wear when undertaking aerosol generating procedures (/resources/aerosol-generating-procedures-agps/)
- HAI Compendium (/resources/hai-compendium/)

- Hand hygiene
  - How to hand rub (/appendices/appendix-2-best-practice-how-to-hand-rub/)
  - How to hand wash (/appendices/appendix-1-best-practice-how-to-hand-wash/)
  - 4 moments for hand hygiene (/media/1444/who-4-moments-residential-care.pdf)
  - Washroom poster (/media/1472/germs-have-you-washed-your-hands-of-them.pdf)
  - Information leaflet (/resources/hand-hygiene-wash-your-hands-of-them/hand-hygiene-information-leaflets-for-the-public/) for the public
- Gastro-intestinal illness
  - Care home IPC resource for gastro-intestinal illness (/resources/care-home-ipc-resource-for-gastro-intestinal-illness/)
- Information leaflets.
  These leaflets are also available in different languages National Infection Prevention and Control Manual: Information Leaflets - language translations (scot.nhs.uk) (/resources/information-leaflets-language-translations/)
  - Clostridiodes difficile (CDI) - Information for people who are getting care, their visitors, and anyone else who is in a care setting (/media/1770/1_c-diff-information-leaflet-2020-03-26.pdf)
  - Group A Streptoccocal infection - information for patients (/media/1767/1_igas-english.pdf)
  - Healthcare associated infection (HAI) - Information for the public (/media/1769/1_hai-leaflet-easyread-english.pdf)
  - Vancomycin-resistant enterococci VRE - Information for patients (/media/1760/1_vre-patient-leaflet-final-190708.pdf)
  - Washing clothes at home - Information for people in hospitals or care homes and their relatives (/media/1758/1_washing-clothes-home-english.pdf)
- Respiratory hygiene
  - Catch it, bin it, kill it poster (/resources/respiratory-hygiene-catch-it-bin-it-kill-it/)
- Respiratory illness
  - Care home IPC resource for respiratory illness (/resources/care-home-ipc-resource-for-respiratory-illness/)
- Transmission Based Precautions
  - Airborne precautions poster (/media/1778/2022-1-13-tbp-ic-airborne-poster_jan22.pdf)
  - Contact precautions poster (/media/1779/2022-1-13-tbp-ic-contact-posters_jan22.pdf)
  - Droplet precautions poster (/media/1780/2022-1-13-tbp-ic-droplet-posters_jan22.pdf)
- World Hand Hygiene Day 5 May 2023 - Accelerate action together. SAVE LIVES clean your hands (/resources/who-world-hand-hygiene-day-5-may-2023-accelerate-action-together-save-lives-clean-your-hands/)

How to contact us

If you have any questions or feedback about the Care Home IPCM then you can contact us by email or telephone.
Email (https://www.nipcm.scot.nhs.uk/about/contact-us/)
Telephone: 0141 300 1175

COVID-19 NIPCM Archives

This page links to the following archived COVID-19 guidance that was in the NIPCM:

- Acute addendums
- Community addendums
- Care Home addendums
- Appendix 21 - COVID-19 Pandemic controls for Acute Settings including Scottish Ambulance Service
- Appendix 22 - Community Infection Prevention and Control COVID-19 Pandemic
- Appendix 21 - COVID-19 Pandemic controls for health and care settings
- Hospital Testing Tables

COVID-19 Acute Addendum Archives

Version	Date	Summary of changes
Version 1.0 (/media/2119/2020-10-27-covid-19-acute-addendum-v10.pdf)	**26/10/2020**	**First publication**
Version 1.1 (/media/2120/2020-10-28-covid-19-addendum-v11.pdf)	**28/10/2020**	**Update to section 5.7 'Safe Management of the Care Environment' to reflect detail of 2nd daily clean.** **Update to section 5.5 'Personal Protective Equipment' to be more explicit.**
Version 1.2 (/media/2122/2020-11-05-covid19-addendum-v12.pdf)	**06/11/2020**	**Update to align references to changing of facemasks between pathways.**
Version 1.3 (/media/2121/2020-11-20-covid-19-acute-addendum-v13.pdf)	**20/11/2020**	**New section on communications when transferring a suspected/confirmed case** **New section on car sharing** **New section on visiting** **Update to definition of recovered patient**
Version 1.4 (/media/2123/2020-12-09-covid-19-acute-addendum-v14.pdf)	**09/12/2020**	**New section on PPE requirements for delivery of vaccinations** **New section on outbreaks**
Version 1.5 (/media/2124/2020-12-14-covid-19-acute-addendum-v15.pdf)	**17/12/2020**	**New section on COVID-19 testing** **New section on Patients returning from weekend/day pass** **New section on Whole Genome Sequencing (WGS)** **Link to RCPCH paediatric guidance for pre-operative admission assessment and testing requirements** **New FRSM poster (ways to improve fit)**
Version 1.6 (/media/2125/2020-12-23-covid-19-acute-addendum-v16.pdf)	**23/12/2020**	**Update to 5.0.3 to reflect changes in stepdown guidance** **Inclusion of SG link to asymptomatic staff testing information** **New section on 5.1.1 Non-COVID patient transfers between different wards and hospitals**

Version	Date	Summary of changes
Version 1.7 (/media/2126/2021-02-09-covid19-acute-addendum-v17.pdf)	22/01/2021	Update to the COVID-19 testing section and associated testing table New section on guidance for the Discontinuation of Infection control precautions and discharging COVID-19 patients from hospital Update to PPE guidance specifically in relation to visors New section on the hierarchy of controls
Version 1.8 (/media/2127/2021-02-17-covid19-acute-addendum-v18.pdf)	18/02/2021	Update to resources and Rapid reviews content Additional wording added to definition of suspected case section to reflect wide variety of presenting symptoms Strengthening of triage question relating to travel history Additional paragraph in PPE section reinforcing need for visiting staff to seek clarity on patient pathway and PPE requirements prior to patient contact
Version 1.9 (/media/2128/2021-03-26-covid-19-acute-addendum-v19.pdf)	26/03/2021	Sessional PPE use no longer accepted beyond eye protection in the high risk pathway and FRSMs across all pathways. Update to stepdown requirement for inpatient table to recognise need for clinical assessment Useful tools section
Version 2.0 (/media/2129/2021-05-06-covid-19-acute-addendum-v20.pdf)	07/05/2021	Environmental risk assessment
Version 2.1 (/media/2130/2021-05-14-covid-19-acute-addendum-v21.pdf)	14/05/2021	Change to AGP list to remove upper airway suctioning during Upper GI Endoscopy and replace with suctioning beyond the oro-pharynx.
Version 2.2 (/media/2131/2021-05-18-covid-19-acute-addendum-v22.pdf)	18/05/2021	Update to COVID-19 testing table to reflect the need to test all contacts of confirmed cases.
Version 2.3 (/media/2132/2021-06-24-covid-19-acute-addendum-v23.pdf)	25/06/2021	Update to PPE table to emphasise Risk Assessment in low and medium risk pathway Addition of risk associated with valved respirators Change in controls for management of linen, waste and environmental cleaning from TBPs to SICPs within the Medium Risk pathway
Version 2.4 (/media/2133/2021-07-08-covid-19-acute-addendum-v24.pdf)	8/7/2021	5.2 COVID-19 testing. Update made to include 'or the first positive test, if asymptomatic or other symptoms, unless they develop new possible COVID-19 symptoms' regarding any patient who has previously tested positive for SARS-CoV-2 by PCR. 5.3.8 Update to table 2 - stepdown table for 'Patient discharging to a care facility including nursing homes and residential homes' 5.3.8 Inclusion of section on 'Patients discharged from hospital to a care home (non-COVID-19)
Version 2.5 (/media/2134/2021-07-16-covid-19-acute-addendum-v25.pdf)	19/7/2021	Update to Hierarchy of control including risk assessment algorithm Inclusion of a specific paragraph advising on the use of FFP3 masks
Version 2.6 (/media/2135/2021-08-30-covid-19-acute-addendum-v26.pdf)	30/8/2021	Update to physical distancing

Scottish COVID-19 Infection Prevention and Control Addendum for Community Health and Care Settings

Version	Date	Summary of changes
Version 1.0 (/media/2148/2021-01-07-covid-19-community-addendum-v10.pdf)	07/01/2021	First version
Version 1.1 (/media/2149/2021-01-25-covid-19-community-addendum-v11.pdf)	25/01/2021	Addition of section 7.2.5 'Discontinuing IPC control measures in community health and care settings for COVID-19 individuals (/scottish-covid-19-community-health-and-care-settings-infection-prevention-and-control-addendum/#7.2.5)'
Version 1.2 (/media/2150/2021-03-31-covid-19-community-addendum-v12.pdf)	31/03/2021	Health Centres included in list Additional paragraph added clarifying position when organisations adopts practices that differ from those in this national guidance. 7.1.2 Definition of suspected case; Additional information and links included 7.1.4 Triaging individuals. International travel isolation changed to reflect current guidance 7.2 Individual placement/Assessment of Infection Risk section updated. 7.2.3 Individuals returning from day or overnight stay, new section included. 7.2.4 Providing care at home; Title amended 7.2.6 Table 1 Stepdown requirements for community health and care settings amended. 7.5.1 Extended use of Face Masks for staff, visitors and outpatients; additional information with link to new FRSM poster (ways to improve fit) link included. 7.5.2 Table 2: PPE for direct patient/individual care determined by pathway; Eye/face protection updated to include coughing & sneezing in medium pathway. 7.5.7 Table 3: PPE for Aerosol Generating Procedures determined by category; additional information below table included on respirators. 7.5.10 New section on PPE for delivery of COVID-19 Vaccinations 7.7 Safe Management of the Care Environment; Additional detail provided where items cannot stand application of chlorine releasing agents. Also additional information if an organisation adopts practices that differ from those recommended/stated. 7.7.1 Cleaning practice points; Additional detail also included where items cannot stand application of chlorine releasing agents. Additional information if an organisation adopts practices that differ from those recommended/stated. 7.8 Safe management of linen amended to clarify linen categorisation where no outbreak. 7.10 Safe Disposal of waste (including sharps). Wording amended to provide clarity. 7.11.1 Vehicle sharing for all staff; title amended 7.12 New section on hierarchy of controls added. 7.1.6 Resources and tools section updated
Version 1.3 (/media/2151/2021-07-08-covid-19-community-addendum-v13.pdf)	08/07/2021	7.5.5 Change to AGP list to remove upper airway suctioning during Upper GI Endoscopy and replace with suctioning beyond the oro-pharynx. 7.5.7 Update to PPE table to emphasise Risk Assessment in medium risk pathway. Addition of risk associated with valved respirators 7.6 and 7.7 Change in controls for environmental and care equipment cleaning from TBPs to SICPs within the Medium Risk category. 7.8 and 7.10 Clarification on the safe management of linen and waste.
Version 1.4 (/media/2152/2021-08-25-covid-19-community-addendum-v14.pdf)	25/08/2021	Inclusion of dental services within the addendum Additional wording added to 'patient placement in primary care settings'

Version	Date	Summary of changes
Version 1.5 (/media/2153/2021-08-31-covid-19-community-addendum-v15.pdf)	31/08/2021	Update to physical distancing
Version 1.6 (/media/2154/2021-09-15-covid-19-community-addendum-v16.pdf)	15/09/2021	Update to physical distancing to include further information for visitors and residents within residential homes.

COVID-19 Care Home Addendum Archive

Version	Date	Summary of changes
Version 1.0 (/media/2168/2020-12-16-covid-19-ch-ipc-addendum-v10.pdf)	16/12/2020	First version
Version 1.1 (/media/2169/2021-01-25-covid-19-ch-ipc-addendum-v11.pdf)	25/01/2021	Inclusion of new section 6.2.4 'Discontinuing IPC precautions in care homes for residents who are COVID-19 positive (/scottish-covid-19-care-home-infection-prevention-and-control-addendum/#a2763)'

Version	Date	Summary of changes
Version 1.2 (/media/2170/2021-03-31-covid-19-ch-ipc-addendum-v12.pdf)	31/03/2021	6.1.2 Definition of suspected case; Additional information and links included. 6.1.3 Triaging of residents being admitted to a care home. International travel isolation changed to reflect current guidance 6.2 Resident Placement/Assessment of Infection Risk section updated. 6.2.4 Stepdown table renamed (Discontinuation of IPC) to be consistent with Acute Addendum. Discontinuing IPC precautions in care homes for residents who are COVID-19 positive information clarified. Residents discharged from hospital to care homes – additional information included to clarify 14 day isolation requirements. 6.2.4 Links have been removed that are no longer available. 6.2.5 Residents returning from overnight stay included 6.5 Additional information included on PPE & link to hierarchy of control. 6.5.1 New FRSM poster (ways to improve fit) link included 6.5.2 Face masks for residents, additional advice on wearing masks when moving around the care home 6.5.3 Table 2 PPE for direct resident care determined by risk category. Update to PPE guidance specifically in relation to visors. 6.5.4 PPE – Putting on (Donning) and Taking off (Doffing) further detailed information included 6.5.5 Aerosol Generating procedures (AGPs) Additional information added under table on requirements for respirators/fluid resistant requirement. 6.5.8 Additional section added on delivery of COVID-19 vaccinations. 6.7 Safe Management of the Care Environment. Additional detail provided where items cannot stand application of chlorine releasing agents. Also additional information if an organisation adopts practices that differ from those recommended/stated. 6.8 Wording amended to clarify linen categorisation where no outbreak. 6.10 Safe disposal of waste. Wording amended to provide clarity. 6.11.2 Engineering and Administration control measures added. 6.12 New section on hierarchy of controls 6.14 Visiting in care homes updated following publication of ‘Open with Care’ 6.16 Resources and Tools section updated. 6.17 Rapid reviews section added 6.18 Education resources added.

Version	Date	Summary of changes
Version 1.3 (/media/2171/2021-07-08-covid-19-ch-ipc-addendum-v13.pdf)	8 July 2021	6.1.3 Triaging of residents admitted to a care home updated with changes to testing and self-isolation 6.2.4 - Discontinuing IPC Precautions in Care Homes for residents who are COVID-19 positive Updated with clarification on self isolation in certain circumstances. Admission of individuals to the care home: section has been updated with changes to testing and self-isolation in certain circumstances. Table 1 Discontinuation of IPC Requirements for care homes (COVID-19 positive) Requirements on Admission of COVID-19 recovered residents from hospital: discharge updated. Residents/patients discharged from hospital to care homes (non-COVID-19) added to provide advice for self isolation requirements upon admission. 6.5.3 Update to PPE table to emphasise Risk Assessment in medium risk pathway 6.5.5 Addition of risk associated with valved respirators 6.6, 6.7 Change in controls for environmental and care equipment cleaning from TBPs to SICPs within the Medium Risk category. 6.8, 6.9 Clarification on the safe management of linen and waste. 6.11.2 Engineering and administration controls section deleted and incorporated into 6.12 Hierarchy of Controls 6.14 Visiting - amended to reflect the collection of guidance available.
Version 1.4 (/media/2172/2021-08-31-covid-19-ch-ipc-addendum-v14.pdf)	31/08/2021	Updates to physical distancing Inclusion of risk associated with powered air purifying respirator (PAPR) when undertaking a sterile procedure.

Respiratory Addendum archive

Version	Date	Summary of changes
Version 1.0 (/media/2210/2021-11-29-v10-winter-respiratory-ipc-guidance.pdf)	29/11/2021	Guidance launched
Version 1.1 (/media/2211/2021-12-13-v11-winter-respiratory-ipc-guidance.pdf)	13/12/2021	Update to 'Determining the IPC precautions required for AGPs'
Version 1.2 (/media/2212/2022-01-17-v12-winter-respiratory-ipc-guidance.pdf)	17/01/2022	Addition of advice for regular testing in critical care units where AGPs are regularly performed on the non respiratory pathway. Reduction of COVID-19 duration of precautions from 14 days to 10 days.

Version	Date	Summary of changes
Version 1.3 (/media/2213/2022-01-17-v13-winter-respiratory-ipc-guidance.pdf)	20/01/2022	Update to Non COVID-19 discharges (non respiratory pathway) from hospitals to care homes Addition of sections for primary care and care homes to reinforce and support assessment using the hierarchy of controls.
Version 1.4 (/media/2214/2022-02-03-v14-winter-respiratory-ipc-guidance.pdf)	03/02/2022	Additional information for visitors entering AGP zones.
Version 1.5 (/media/2215/2022-02-23-v15-winter-respiratory-ipc-guidance.pdf)	23/02/2022	Risk assessment for management of patient placement in long term residential community settings (section 5.8 and section 5.12.2) Update to hospital testing table
Version 1.6 (/media/2216/2022-04-02-v16-winter-respiratory-ipc-guidance.pdf)	01/04/2022	The following updates reflect changes to healthcare COVID-19 pandemic controls as outlined in DL (2022) 07 (https://www.sehd.scot.nhs.uk/dl/DL(2022)07.pdf) as follows; Changes to patient testing requirements including Hospital Testing Table Inclusion of the wider use of Rapid Diagnostic Testing (including POCT) or LFD testing Changes to management of contacts including inclusion of 28 day contact exemption Changes to respiratory screening questions Changes to testing requirement pre AGP on the non respiratory pathway Withdrawal of car sharing guidance Removal of physical distancing guidance Please note: the above changes within version 1.6 are not applicable in care homes, prisons and social community and residential care settings at the time of version update; Extant guidance remains in place for these settings.
Version 1.7 (/media/2217/2022-04-07-v17-winter-respiratory-ipc-guidance.pdf)	07/04/2022	Update to include definition of fully vaccinated Addition to physical distancing noting that services may choose to retain physical distancing where they deem it necessary
Version 1.8 (/media/2218/2022-04-27-v18-winter-respiratory-ipc-guidance.pdf)	27/04/2022	Addition of testing responsibilities at an organisational level and clarity of testing language Change to isolation advice for service users with COVID-19 Removal of vaccination as part of contact management.

Appendix 21 -COVID-19 Pandemic Controls for Acute NHS settings including Scottish Ambulance Service (SAS) Archive

Version	Date	Summary of changes
Version 1.0 (/media/2180/2022-05-10-v10-appendix-21-covid-19-pandemic.pdf)	**10/05/2022**	**First publication – Marks transition from Winter Respiratory Infection IPC Addendum back to NIPCM.**
Version 1.1 (/media/2187/2022-05-30-v11-appendix-21-covid-19-pandemic.pdf)	**30/05/2022**	**Reference to COVID-19 screening removed.**
Version 1.2 (/media/2181/2022-07-18-v12-appendix-21-covid-19-pandemic.pdf)	**13/07/2022**	**Addition of dental services and GPs to title.**
Version 1.3 (/media/2182/2022-07-28-appendix-21-v13.pdf)	**28/07/2022**	**Removal of GPs in title as now included in Appendix 22.**
Version 1.4 (/media/2183/2022-08-22-appendix-21-v14.pdf)	**22/08/ 2022**	**Changes made to testing requirements in line with DL 2022(29) issued on 22nd August 2022**
Version 1.5 (/media/2178/2022-09-16-appendix-21-v15.pdf)	**16/09/2022**	**Update following Directors Letter (2022)32 - pause in asymptomatic COVID-19 testing in health and social care**
Version 1.6 (/media/2184/2022-09-28-appendix-21-v16.pdf)	**28/09/2022**	**Removal of 'Primary Care Settings' from Table 2 – Respiratory Screening Questions**
Version 1.7 (/media/2185/2022-10-06-appendix-21-v17.pdf)	**06 /10/ 2022**	**Broken links replaced and update to COVID-19 testing requirements in line with Directors Letter (2022)32**
Version 1.8 (/media/2186/2022-11-18-appendix-21-v18.pdf)	**18/11/2022**	**Updated to reflect that the advice contained within the Scottish Government's DL(2022)10 remains extant.**

Appendix 22 - Community Infection Prevention and Control COVID-19 Pandemic Archive

Version	Date	Summary of changes
Version 1.0 (/media/2155/2022-07-18-appendix-22-v10.pdf)	**29/06/2022**	**First publication – Marks transition from Winter Respiratory Infection IPC Addendum to a Community COVID-19 Pandemic Appendix.**
Version 1.1 (/media/2156/2022-07-28-appendix-22-v11.pdf)	**28/07/2022**	**GP surgeries included in this this appendix and removed from Appendix 21 – COVID-19 acute settings**
Version 1.2 (/media/2157/2022-09-16-appendix-22-v12.pdf)	**16/09/2022**	**Content revised to reflect SG Extended Use of Facemasks Policy for ASC settings.**
Version 1.3 (/media/2158/2021-07-08-covid-19-community-addendum-v13.pdf)	**04/10/2022**	**Link added to revised content from SG clarifying use of facemasks in social care settings by healthcare staff**
Version 1.4 (/media/2159/2022-11-18-appendix-22-v14.pdf)	**18/11/2022**	**Updated to reflect that the advice contained within the Scottish Government's DL(2022)10 (https://www.sehd.scot.nhs.uk/dl/DL(2022)10.pdf) remains extant.**

Appendix 21 - COVID-19 Pandemic IPC Controls for Health and Social Care Settings Archive

Version	Date	Summary of changes
Version 1.0 (/media/2219/2023-03-20-appendix-21-v10-final.pdf)	**20/03/2023**	**New appendix which combines content from COVID-19 Appendix 21 for acute settings and Appendix 22 for community settings into a single pandemic appendix for health and social care settings.**
Version 2.0 (/media/2220/2023-05-12-appendix-21-v20.pdf)	**16/05/2023**	**Amendments to content made following Withdrawal of the Coronavirus (COVID-19): Extended Use of Face Masks and Face Coverings Guidance Across Health and Social Care Scottish Government DL (2023) 11. Renumbered as Appendix 19 on 2 June 2023 due to the archiving of outdated COVID-19 appendices.**

Hospital testing tables archive

Version	Date	Summary of changes
Version 1.0 (/media/2197/2020-12-23-v10-hospital-testing-table.pdf)	**23/12/2020**	**First version produced by Scottish Government**
Version 2.0 (/media/2206/2021-02-22-v20-hospital-testing-table.pdf)	**22/02/2021**	**ARHAI Scotland taking responsibility for producing table. Inclusion of frontpage and review of content undertaken.**
Version 2.1 (/media/2188/2021-05-18-hospital-testing-table-v21.pdf)	**18/05/2021**	**Update made to testing requirement 3 regarding emergency admissions and PCR/POCT testing. Update made to requirement 7 Transfer of a non COVID-19 patient to another hospital/NHS board about transferring patient while waiting for test results. Update to section Testing Contacts of confirmed COVID-19 cases.**
Version 2.2 (/media/2189/2021-09-03-hospital-testing-table-v22.pdf)	**06/09/2021**	**Updates to sections on staff testing. Reference to household member testing positive removed.**
Version 2.3 (/media/2208/2021-12-02-hospital-testing-table-v23.pdf)	**01/12/2021**	**Updated to be in line with the respiratory addendum.**
Version 2.4 (/media/2209/2021-12-02-hospital-testing-table-v24.pdf)	**02/12/2021**	**Update to frontpage reference to discharge to care homes to include for those still in the 14 day isolation period.**
Version 2.5 (/media/2191/2021-12-21-hospital-testing-table-v25.pdf)	**21/12/2021**	**Update to frontpage to include definition of admissions. Update to testing prior to an AGP to include further information on negative tests before an AGP.**
Version 2.6 (/media/2192/2022-02-23-hospital-testing-table-v26.pdf)	**23/02/2022**	**Addition of relevant policy letters or guidance relevant to each testing recommendation.**
Version 2.7 (/media/2193/2022-04-04-hospital-testing-table-v27.pdf)	**01/04/2022**	**Updates to reflect changes to healthcare COVID-19 pandemic controls outlined in DL (2022) 07 as follows** • Changes to testing requirements across all recommendations • Inclusion of wider point of care tests (POCTs) including lateral flow devices (LFDs) • Changes to testing requirement pre AGP on the non respiratory pathway • Removal of references to physical distancing

Version	Date	Summary of changes
Version 2.8 (/media/2194/2022-04-07-hospital-testing-table-v28.pdf)	07/04/2022	Clarity relating to COVID-19 testing terminology
Version 2.9 (/media/2195/2022-04-25-hospital-testing-table-v29.pdf)	25/04/2022	Additional clarifications relating to COVID-19 testing terminology
Version 2.10 (/media/2225/2022-05-30-hospital-testing-table-v210.pdf)	10/05/2022	Changes to reflect transition of Winter Respiratory IPC addendum to COVID-19 appendix
Version 2.11 (/media/2202/2022-08-22-hospital-testing-table-v211.pdf)	22/08/2022	Changes made to testing requirements in line with DL 2022(29) issued on 22nd August 2022
Version 2.12 (/media/2205/2022-09-16-hospital-testing-table-v212.pdf)	16/9/2022	Testing requirements updated with new paragraphs on symptomatic and asymptomatic testing. Addition of Appendix 1- List of PCR-based and non-PCR based tests in use in Scotland
Version 2.13 (/media/2204/2022-10-06-hospital-testing-table-v213.pdf)	06/10/2022	Update to duration of precautions to reference NIPCM and A-Z

References

Reference 1

The use of the word 'Persons' can be used instead of ‘Patient’ when using this document in non-healthcare settings.

Glossary

Abrasion
A graze. A minor wound in which the surface of the skin or a mucous membrane has been worn away by rubbing or scraping.

Acute care setting/Acute hospital
This is a unique, demanding and fast-paced environment designed to accommodate a wide variety of urgent, or emergent patient care needs.

Adverse event
An event that could have caused or did result in harm to people or groups of people.

Aerosol Generating Procedures (AGPs)
An AGP is a medical procedure that can result in the release of airborne particles from the respiratory tract when treating someone who is suspected or known to be suffering from an infectious agent transmitted wholly or partly by the airborne or droplet route.

Aerosols
See Airborne particles

Airborne (aerosol) transmission
The spread of infection from one person to another by airborne particles (aerosols) containing infectious agents.

Airborne particles (aerosols)
Very small particles (of respirable size) that may contain infectious agents. They can remain in the air for extended periods of time and can be carried over long distances by air currents. Aerosols can be released during aerosol generating procedures (AGPs).

Airborne precautions
A group of transmission-based precautions to prevent the spread of airborne pathogens.

Alcohol based hand rub (ABHR)
A gel, foam or liquid containing one or more types of alcohol that is rubbed into the hands to inactivate microorganisms and/or temporarily suppress their growth.

Alert organism
An organism that is identified as being potentially significant for infection prevention and control practices. Examples of alert organisms include *Meticillin Resistant Staphylococcus aureus (MRSA)*, *Clostridioides difficile* (C.diff) and *Group A Streptococcus*.

Alveolar
Refers to the alveoli which are the small air sacs in the lungs. Alveoli are located at the ends of the air passageways in the lungs, and are the site at which gas exchange takes place.

Anteroom
An area with a door from/to the outside corridor and a second door giving access to the patient area (where both doors will never be open at the same time).

Antimicrobial
An agent that kills microorganisms, or prevents them from growing.
Antimicrobials are grouped according to the microorganisms they act against, such as, antibiotics, antivirals, antifungals and antiparasitics.

Antimicrobial hand wipes

Hand wipes that are moistened with an antimicrobial solution/agent at a concentration sufficient to inactivate microorganisms and/or temporarily suppress their growth.

Antimicrobial resistance

The ability of a microorganism to resist the action of an antimicrobial drug/agent which previously could treat the infection caused by that microorganism.

Antisepsis

The process of preventing infection by inhibiting the growth and multiplication of infectious agents. This is usually achieved by application of a germicidal preparation known as an antiseptic.

Aseptic Technique

A healthcare procedure designed to minimise the risks of exposing the person being cared for to pathogenic micro-organisms during simple (e.g dressing wounds) and complex care procedures (e.g. surgical procedures).

Asymptomatic

Not showing any symptoms of disease but where an infection may be present.

Augmented Care

In the context of infection prevention and control, most care designated as augmented will be that where medical/nursing procedures render the patients susceptible to invasive disease from environmental and opportunistic pathogens. However, there is no fixed definition of ‘augmented care’.

Autoclave

Machine used for sterilising re-usable equipment using steam sterilisation. Re-usable equipment is exposed to steam at a required temperature, pressure, and time.

Bay

A partly enclosed area within a ward containing one bed (single bay) or multiple beds (multi-bed bay).

Blood Borne Viruses (BBV)

Viruses carried or transmitted by blood, for example Hepatitis B, Hepatitis C and HIV.

Body Fluids

Fluid produced by the body such as urine, faeces, vomit or diarrhoea.

British Standards (BS), European Standards (EN) and International Standards (ISO)

National standards specify the requirements for application in the particular country.

- BS denotes Britain's National Standards which are controlled by the British Standards Institute (BSI)
- EN denotes a Standard which is adopted by the European community and is controlled by the European Committee for Standardisation (CEN). Once a European Standard has been agreed it supersedes any existing national standard and becomes the new national standard. In Britain these Standards are then prefixed with BS EN
- ISO denotes a worldwide standard issued by the International Organisation for Standardisation. Once an International Standard has been adopted as a European Standard it supersedes the existing European standard. In Britain these Standards are then prefixed with BS EN ISO

Care setting

Includes but is not limited to general practice, dental and pharmacy (primary care), acute-care hospitals, emergency medical services, urgent-care centres and outpatient clinics (secondary care), specialist treatment centres (tertiary care), long-term care facilities such as nursing homes and skilled nursing facilities (community care), and care provided at home by professional healthcare providers (home care).

Care staff

Any person who cares for patients, including healthcare support workers and nurses.

Central Venous Catheter (CVC)

An intravenous catheter that is inserted directly into a large vein in the neck, chest or groin to give intravenous drugs, fluids and blood and to allow for quick medical tests.

Chlorine

A chemical that is used for disinfecting, fumigating and bleaching.

Cleaning
The removal of any dirt, body fluids (blood, vomit) etc by use of an appropriate cleaning agent such as detergent.

Clinical wash hand basin
A sink designated for hand washing in clinical areas.

Cohort area
A bay/ward in which a group of patients (cohort) with the same infection are placed. Cohorts are created based on clinical diagnosis, microbiological confirmation when available, epidemiology, and mode of transmission of the infectious agent.

Colonisation
The presence of microorganisms on a body surface (such as the skin, mouth, intestines or airway) that does not cause disease in the person or signs of infection.

Conjunctivae
Mucous membranes that cover the front of the eyes and the inside of the eyelids.

Contact dermatitis
The inflammation of the skin (epidermis and adjacent dermis) resulting from direct contact of a substance that could either be an irritant (irritant contact dermatitis) or allergen (allergic contact dermatitis) with the surface of the skin.

Contact precautions
Series of procedures/interventions used in addition to routine practices to prevent transmission of infectious agents that spread by direct or indirect contact.

Contact transmission
The spread of infectious agents from one person to another by contact. When spread occurs through skin-to-skin contact, this is called direct contact transmission. When spread occurs via a contaminated object, this is called indirect contact transmission.

Contaminated
The presence of an infectious agent on a body surface; also on or in clothes, bedding, surgical instruments or dressings, or other inanimate articles or substances including water and food.

Cough etiquette/respiratory hygiene
Source control measures intended to contain respiratory secretions in order to limit transmission of respiratory pathogens.

Cross-infection/Cross-transmission
Spread of infection from one person, object or place to another.

Decontamination
The process of removing, or killing pathogens on an item or surface to make it safe for handling, re-use or disposal, by cleaning, disinfection and/or sterilisation.

Detergent
A chemical cleansing agent that can dissolve oils and remove dirt.

Diarrhoea
Passing looser more frequent stools than is normal for the individual.

Direct contact transmission
Spread of infectious agents from one person to another by direct skin-to-skin contact.

Disinfectant
A chemical used to reduce the number of infectious agents from an object or surface to a level that means they are not harmful to health.

Disinfection

The treatment of surfaces/equipment using physical or chemical means, for example using a chemical disinfectant, to reduce the number of infectious agents from an object or surface to a level at which they are not harmful to health.

Doffing

To remove (an item of clothing or an item of PPE).

Domestic waste

Waste produced in the care setting that is similar to waste produced in the home.

Donning

To put on (an item of clothing or an item of PPE).

Droplet

A small drop of moisture, larger than airborne particle, that may contain infectious agents. Droplets can be released when a person talks, coughs or sneezes, and during some medical or patient care procedures such as open suctioning and cough induction by chest physiotherapy. It is thought that droplets can travel around 1 metre (3 feet).

Droplet Nuclei

Droplet nuclei are aerosols formed from the rapid evaporation/desiccation of larger droplet particles when expelled/exhaled from the respiratory tract.

Droplet transmission

The spread of infection from one person to another by droplets containing infectious agents.

Emollient

An agent used to soothe the skin and make it soft and supple.

Enhanced single room (with en-suite facilities and ventilated lobby)

See Isolation Suite/Room (/glossary/#I)

Enhanced single room (with en-suite facilities)

See Isolation Suite/Room (/glossary/#I)

En-suite facilities

En-suite facilities should contain a shower, WC and a general wash-hand basin.

En-suite single-bed room

A room with space for one patient with en-suite facilities.

Exceptional infection episode

A single case of an infection that has severe outcomes for an individual patient OR has major infection control/public health implications e.g. infectious diseases of high consequence such as extensively drug resistant tuberculosis (XDR-TB).

Excretions

Waste products produced by the body such as urine and faeces (bowel movements).

Exposure

The condition of being exposed to something that may have a harmful effect such as an infectious agent.

Exposure Prone Procedures (EPPs)

Certain medical and patient care procedures where there is a risk that injury to the healthcare worker may result in exposure of the patient’s open tissues to the healthcare worker’s blood e.g the healthcare worker’s gloved hands are in contact with sharp instruments, needle tips or sharp tissues inside a patient’s body.

Face covering

A term that applies collectively to items used to cover the nose and mouth. Also referred to as a face mask.
These should not be confused with items of PPE.

Fallow time
The period of time required for droplets and/or aerosols to settle and be removed from the air following a procedure. It is also known as settle time.

FFP3
Respiratory protection that is worn over the nose and mouth designed to protect the wearer from inhaling hazardous substances, including airborne particles (aerosols). FFP stands for filtering facepiece. There are three categories of FFP respirator: FFP1, FFP2 and FFP3. An FFP3 respirator or hood provides the highest level of protection, and is the only category of respirator legislated for use in UK healthcare settings.

Fit check/seal check
A fit check, otherwise known as a user seal check, is a simple and quick method of checking that a respirator has been donned correctly to form a tight seal around the face. Fit checks are not substitutes for, and should not be confused with, fit testing.

Fit Testing
A method to evaluate how well a tight-fitting respirator fits the wearer and seals adequately to their face. This process verifies the correct model, style, and size of respirator suitable for an individual.

Fluid resistant surgical mask (FRSM)
See surgical face mask (/glossary/#S)

Fluid-resistant
A term applied to fabrics that resist liquid penetration, often used interchangeably with 'fluid-repellent' when describing the properties of protective clothing or equipment.

Fomites
An inanimate substance or object that can transfer a pathogen to a host.

Germicide
An agent capable of destroying microorganisms, particularly organisms that are pathogenic.

GP
General practitioner (your family doctor).

Group 4 Infections
Definition taken from the HSE Approved list of biological agents www.hse.gov.uk/pubns/misc208.pdf (http://www.hse.gov.uk/pubns/misc208.pdf)
Group 4 infections cause severe human disease and are a serious hazard to employees; they are likely to spread to the community and there is usually no effective prophylaxis or treatment available.

Hand Hygiene
The process of decontaminating your hands using either alcohol based hand rub or liquid soap and water.

Hand rub
A gel, foam or liquid containing one or more types of active ingredient that is rubbed into the hands to inactivate microorganisms and/or temporarily suppress their growth. A hand rub should meet the required British/European Standards as defined in the hand products literature review.

Health Protection Team (HPT)
A team of healthcare professionals whose role it is to protect the health of the local population and limit the risk of them becoming exposed to infection and environmental dangers. Every NHS board has a HPT.

Healthcare Associated Infection (HAI)
Infections that occur as a result of medical care, or treatment, in any healthcare setting.

Healthcare associated infection outbreak
Two or more linked cases associated with the same infectious agent, within the same healthcare setting, over a specified time period; or a higher than expected number of cases in a given healthcare area over a specified time period.

Healthcare infection data exceedance

A greater than expected rate of infection compared with the usual background rate for the place and time where the incident has occurred.

Healthcare infection exposure incident

An exposure of patients, staff, or the public to a possible infectious agent, as a result of a healthcare system failure or near misses e.g. ventilation, water or a decontamination incident.

Healthcare Waste

Waste produced as a result of healthcare activities for example soiled dressings, sharps.

Hierarchy of controls

This is a systematic process which provides a consistent approach to minimizing or eliminating exposures to hazards in the workplace.

High Consequence Infectious Disease (HCID)

A High Consequence Infectious Disease (HCID) is defined according to the following criteria:

- causes acute infectious disease
- typically has a high case-fatality rate
- may not have effective prophylaxis or treatment
- difficult to recognise and detect quickly
- ability to spread in the community and within healthcare settings
- requires an enhanced individual, population, and system response for safe, efficient, and effective management

Previously referred to as an Infectious Diseases of High Consequence (IDHC).

Hospital infection incident assessment tool (HIIAT)

Used by the IPCT or HPT to assess every healthcare infection incident i.e. all outbreaks and incidents including decontamination incidents or near misses in any healthcare setting (that is the NHS, independent contractors providing NHS Services and private providers of healthcare).

Hygiene Waste

Waste that is produced from personal care. In care settings this includes feminine hygiene products, incontinence products and nappies, catheter and stoma bags. Hygiene waste may cause offence due to the presence of recognisable healthcare waste items or body fluids. It is usually assumed that hygiene waste is not hazardous or infectious.

Hypochlorite

A chlorine-based disinfectant such as bleach.

Immunisation

To provide immunity to a disease by giving a vaccination.

Immunocompromised patient/individual

Any person whose immune response is reduced or deficient, usually because they have a disease or are undergoing treatment. People who are immunocompromised are more vulnerable to infection.

Impervious

Cannot be penetrated by liquid.

Incident Management Team (IMT)

A multidisciplinary group with responsibility for investigating and managing an incident.

Incident/outbreak

An incident/outbreak may be:

- An **exceptional infection episode**, defined a single case of rare infection that has severe outcomes for an individual AND has major implications for others (patients, staff and/or visitors), the organisation or wider public health for example, high consequence infectious disease (HCID) OR other rare infections such as XDR-TB, botulism, polio, rabies, or diphtheria.
- A **healthcare infection exposure incident**, defined as exposure of patients, staff, public to a possible infectious agent as a result of a healthcare system failure or a near miss, for example ventilation, water or decontamination incidents.
- A **healthcare associated infection outbreak**, defined as two or more linked cases associated with the same infectious agent, within the same healthcare setting, over a specified time period, or a higher-than-expected number of cases in a given healthcare area over a specified time period.

- A **healthcare infection data exceedance**, defined as a greater than expected rate of infection compared with the usual background rate for the place and time where the incident has occurred.
- A **healthcare infection near miss incident**, which had the potential to expose patients to an infectious agent but did not, for example decontamination failure.

Indirect contact transmission

The spread of infectious agents from one person to another via a contaminated object.

Infection

Invasion of the body by a harmful organism or infectious agent such as a virus, parasite, bacterium or fungus.

Infection Prevention and Control Team (IPCT)

A multidisciplinary team responsible for preventing, investigating and managing an infection incident or outbreak.

Infectious agent

Any organism, such as a virus, parasite, bacterium or fungus, that is capable of causing an infection or infectious disease.

Infectious period

The time when an infectious agent may be transmitted directly or indirectly from an infected person to another person. Also known as “period of infectiousness” and “communicability”.

Inpatient

A patient is termed an inpatient when they occupy a staffed bed in a hospital and either remains overnight (whether intended or not), or is expected to remain overnight but is discharged earlier. An inpatient’s admission can be an emergency, an elective or as a transfer.

Invasive device

A device which penetrates the body, either through a body cavity or through the surface of the body. Central Venous Catheters (central line), Peripheral Arterial Lines and Urinary Catheters are examples of invasive devices.

Invasive procedure

A medical/healthcare procedure that penetrates or breaks the skin or enters a body cavity.

Isolation

Physically separating patients to prevent the spread of infection.

Isolation Suite/Room

An isolation room/suite consists of **enhanced** en-suite single bedrooms.
An en-suite single bedroom is defined as: consisting of a bed, locker/wardrobe, clinical wash-hand basin and en-suite shower, WC and wash-hand basin. (In new build, space for a social support zone for overnight stay and a clinical support zone is also provided).

- **Enhanced single room (with en-suite facilities),** also called isolation room, is the same as an en-suite single-bed room but with a ventilation system that prevents uncontrolled escape of infectious aerosols from the room to adjacent areas. It can also provide a degree of dilution of infectious aerosols in the room for the safety of staff and visitors. The room should have extract ventilation that exceeds its supply, such that gaps in its fabric leak inwards not outwards.

- **Enhanced single room (with en-suite facilities and ventilated lobby),** also called isolation suite**,** is the same as an **enhanced single room (with en-suite facilities)** but with a lobby having positive pressure ventilation.

J

No terms

K

No terms

Lateral Flow Device (LFD)

A test carried out using a small medical device that tests whether or not there is a particular substance, gene, etc. in a sample. For example, to identify those who have COVID-19 but are not presenting symptoms.

Long Term Care Facility (LTCF)
Long term care facilities provide a variety of services, both medical and personal care, to people who are unable to live independently.

Mechanical Ventilation
Mechanical ventilation brings fresh air into a building from outside via a controllable method. Basic systems consist of a fan and either collection (extraction) or distribution (supply) ductwork.

Microorganism (microbe)
Any living thing (organism) that is too small to be seen by the naked eye. Bacteria, viruses and some parasites are microorganisms.

Mode of transmission
The way that microorganisms spread from one person to another. The main modes or routes of transmission are airborne (aerosol) transmission, droplet transmission and contact transmission.

Mucocutaneous exposure
An incident in which the mucous membranes (e.g. mouth, nose, eyes) or non-intact skin have been contaminated with blood or other bodily fluids.

Mucous membranes/mucosa
The surfaces lining the cavities of the body that are exposed to the environment such as the lining of the mouth and nose.

Multi-bed room
A room that contains more than one bed.
The acceptable maximum number of beds in a multi-bed room is four. Multi-bed rooms require two clinical wash-hand basins and must have en-suite sanitary facilities. Ideally, an assisted shower room (with WC, shower and general wash-hand basin) and a separate semi-ambulant WC (with general wash-hand basin) both en-suite.

Negative pressure isolation room
A room which maintains permanent negative pressure. Air flow is from the outside adjacent space (for example corridor) into the room and then exhausted to the outside.
The room should be used to accommodate a patient known or suspected to be infected with a microorganism spread by the airborne route whilst the patient is considered infectious.

Non-intact skin
Skin that is broken for example by cuts, abrasions, dermatitis, chapped skin, eczema.

Non-intact skin exposure
An incident in which non-intact skin is exposed to blood or body fluids.

Non-sterile procedure
Care procedure that does not need to be undertaken in conditions that are free from bacteria or other microorganisms.

Nosocomial
An infection occurring in a patient during the process of care in a hospital or other health care facility, which was not present or incubating at the time of admission.

Novel
Scientifically, novel is used to refer to things of recent origin or introduction, such as a novel pathogen.

Occupational exposure
An occupational exposure is a percutaneous or mucocutaneous exposure to blood or other body fluids.

Organism
Any living thing that can grow and reproduce, such as a plant, animal, fungus or bacterium.

Outbreak
See incident/outbreak. (/glossary/#I)

Outpatient

An outpatient is a patient who attends a consultant or other medical/healthcare clinic or has an arranged meeting with a consultant or a senior member of their team out with a clinic session. Outpatient attendances involve treatment or assessment that only take a short time to complete. Outpatient attendances are categorised as new or return (follow-up).

Overcrowding

Within health and care settings, this is the state of being filled past capacity/comfort and therefore being burdened by excessive demands for services.

Pandemic

A disease outbreak that occurs over a wide geographical area (such as multiple countries and/or continents) and typically affects a significant proportion of the population.

Pathogen

Any disease-producing infectious agent.

Patient cohorting

Placing a group of two or more patients (a cohort) with the same infection/strain in the same bay/ward. Cohorts are created based on clinical diagnosis, microbiological confirmation, epidemiology, and mode of transmission.

PCR test

Highly accurate tests used to diagnose certain infectious diseases.

Percutaneous injury

An injury caused by a needle or sharp, instrument, bone fragment, human scratch or bite cutting or puncturing the skin.

Personal Protective Equipment (PPE)

Equipment a person wears to protect themselves from risks to their health or safety, including exposure to infections, for example disposable gloves and disposable aprons.

Physical Distancing

Keeping a distance from other people, in order to stop transmission of a disease to another person or other people.

Pre-symptomatic

The time period when someone has the infection but has not yet developed symptoms but does go on to develop symptoms later in the disease.

Primary Care setting

These provide the first point of contact in the healthcare system which includes general practice, dentistry, community pharmacies.

Problem Assessment Group (PAG)

A group that is convened by the Infection Prevention and Control Team (IPCT)/Health Protection Team (HPT) to assess a healthcare incident/outbreak/data exceedence and determine if further action is required.
The assessment and outcome may be:

- HIIAT Green - continue to monitor
- HIIAT Amber/Red - IMT required

Q

No pathogens

Recapping/Re-sheathing

To put a needle or other sharp object back into its plastic sheath or cap. Also known as ‘re-sheathing’.

Respiratory droplets

A small droplet >5 µm in diameter, such as a particle of moisture released from the mouth during coughing, sneezing, or speaking.

Respiratory Protective Equipment (RPE)

Respirators are devices that cover the nose and mouth and are designed to filter the air breathed in to protect the wearer from inhaling hazardous substances.
They provide respiratory protection from infectious agents transmissible by the airborne (aerosols) route. FPP3 respirators are recommended for use in UK health and care settings when exposure to aerosols is anticipated.

Safer sharp

A medical sharps device which has been designed to incorporate a feature or mechanism that minimises and/or prevents the risk of accidental injury. Other terms include (but are not limited to) safety devices, safety-engineered devices and safer needle devices.

Safer sharps device

Any device designed to reduce the risk of injury from needles. This may include needle-free devices or mechanisms on a needle, such as an automated resheathing device, that cover the needle immediately after use.

Sanitary fittings

All sinks and furniture in a bathroom, including a toilet, bath, shower.

Screening

Performing a test or enquiry to identify individuals at risk of a specific disorder or infection to warrant further investigation or direct preventive action.

Secondary care setting

Provided by health professionals who generally are not the first point of contact for a patient. These settings are usually hospitals but can also be community-based.

Secretions

Any body fluid that is produced by a cell or gland such as saliva or mucous, for a particular function in the organism or for excretion.

Segregated

Physically separating or isolating from other people.

Sepsis

A life-threatening condition that arises when the body's response to a severe complication of infection for example pneumonia (lung infection) injures its own tissues and organs. This can lead to multiple organ failure and death. Early recognition, treatment and management is key to successful patient outcomes.

Sharp

A 'sharp' is a device or instrument used in healthcare settings with sharp points or edges, such as needles, lancets and scalpels which have the potential to cause injury through cutting or puncturing the skin.

Sharps incident

A type of percutaneous injury caused by a sharp instrument or device which cuts or penetrates the skin.

Sharps injury

See percutaneous injury (/glossary/#P).

Significant occupational exposure

A percutaneous, mucocutaneous or non-intact skin (abrasions, cuts, eczema) exposure to blood or other body fluids from a source that is known (or later found to be) positive for a bloodborne virus infection.

Significant sharps incident

An incident which involves a used needle that has exposed, or may have exposed, the employee to blood/body fluids.

Single-bed room

A room with space for one patient and usually contains as a minimum: a bed; locker/wardrobe; clinical wash-hand basin.
Single-bed rooms should also have en-suite sanitary facilities comprising of a shower, WC and a general wash-hand basin.

Skin integrity

Skin being intact, and in an unimpaired condition.

Source control

This term encompasses all physical measures used to control the transmission of an infectious agent.

Spore

A reproductive cell produced by fungi and some types of bacteria under certain environmental conditions. Spores can survive for long periods of time and are very resistant to heat, drying and chemicals.

Staff cohorting

A dedicated team of healthcare staff who care for a cohort of patients, and do not care for any other patients.

Standard infection control precautions (SICPs)

These are a group of basic infection prevention and control practices that need to be adopted by all staff in health and care settings, irrespective of infectious status of patient.

Sterile

Free from live bacteria or other microorganisms.

Sterile procedure

Care procedure that is undertaken in conditions that are free from bacteria or other microorganisms.

Sterilisation

The procedure of making some object free of all germs, live bacteria or other microorganisms (usually by heat or chemical means).

Surgical face mask

A disposable fluid-resistant mask worn over the nose and mouth to protect the mucous membranes of the wearer’s nose and mouth from splashes and infectious droplets and to protect patients. When recommended for infection control purposes a 'surgical face mask' typically denotes a fluid-resistant (Type IIR) surgical mask.

Surgical hand antisepsis

Surgical scrubbing or surgical rubbing. More thorough than routine hand hygiene. In addition to the removal of visible soiling and transient bacteria, it prevents the growth of resident microbial skin flora before performing an invasive procedure.

Surgical rubbing

The process of surgical hand antisepsis using ABHR prior to performing a sterile or surgical procedure. An alternative to surgical scrubbing when hands are not visibly soiled.

Surgical scrubbing

The process of removing debris and sterilising hands prior to performing a sterile or surgical procedure.

Surgical site infection

This is an infection which occurs after the surgery at the site of the surgical incision due to introduction and multiplication of pathogens at the surgical site.

Swan-neck

Way of closing bag by twisting the top of the bag (must not be more than 2/3 full), looping the neck back on itself, holding the twist firmly, and placing a seal over the neck of the bag (such as with a tag).

Terminal decontamination

Cleaning/decontamination of the environment following transfer/discharge of a patient, or when they are no longer considered infectious, to ensure the environment is safe for the next patient or for the same patient on return.

Touch surfaces

These are surfaces that are frequently touched by different people throughout the day and are therefore more likely to be contaminated with bacteria or viruses for example doorknobs, tables, phones, which can then easily transfer to the user.

Transmission-based precautions (TBPs)

These are additional measures that are used in conjunction with SICPs when caring for patients with a known or suspected

infection or colonisation.

Vaccination
Treatment with a vaccine to produce immunity against a disease.

Vaccine
A suspension that is administered in order to stimulate the immune response of the body against an infectious agent.

Vascular access devices
Any medical instrument used to access a patient’s veins or arteries such as a Central Venous Catheter or Peripheral Vascular Catheter.

Ventilation
Ventilation is a means of removing and replacing the air in a space. In its simplest form this may be achieved by opening windows and doors.

Viral load
The viral load or viral burden is a numerical expression of the amount of virus present in biological fluids or environmental specimens.

Ward
An area forming a division of a care setting (or a suite of rooms) shared by patients who need a similar type of care.

X
No terms

Y
No terms

Z
No terms

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Prevention and management of healthcare water-associated infection incidents/outbreaks

HPS are aware of the limitations of current guidance in this area and are currently working towards delivery of comprehensive evidence-based guidance which will form Chapter 4 of the National Infection Prevention and Control Manual (NIPCM). In the interim, this **aide memoire** provides best practice recommendations to ensure clinical staff, estates and facilities staff, and Infection Prevention and Control Teams (IPCT) have an understanding of the preventative measures required and the appropriate actions that might be implemented in the event of a healthcare water-associated infection incident/outbreak. Evidence is derived from outbreak reports (Scottish and International), and the HPS Rapid Review of HAI outbreaks Associated with Healthcare Water Systems.

1. Infectious agents associated with incidents/outbreaks related to healthcare water

Table 1 includes the infectious agents which have been **identified in the literature**. ***NB this list is not intended for use as an alert organism list.*** The alert organisms list (Appendix 13 of the NIPCM) should be used in conjunction with local Board surveillance data i.e. a greater than expected rate of infection/colonisation compared with the usual background rate for that healthcare location, and local teams should consider if further investigation is required.

TABLE 1: Infectious agents associated with incidents/outbreaks related to healthcare water
(* denotes most frequently reported microorganisms).

Achromobacter spp.

Acinetobacter spp. (A.baumannii, A. junii, A. Ursingii)

Burkholderia spp.

Carbapenemase-producing *Enterobacteriaceae*

Chryseobacterium indologenes

Cupriavidus pauculus

Enterobacter cloacae

Fusarium spp.

Klebsiella spp. (K. pneumoniae, K. oxytoca)*

Nontuberculous mycobacteria (NTM)*

*Pseudomonas aeruginosa**

Rhizomucor spp.

Aspergillus spp.

Candida spp. (C. parapsilosis, C. metapsilosis)

Citrobacter freundii

Elizabethkingia meningoseptica

Exophiala jeanselmei

*Legionella pneumophila**

Pantoea agglomerans

Pseudomonas spp. (P. putida, P. fluorescens)

Serratia marcescens

Stenotrophomonas maltophilia

Staphylococcus aureus

NB – this list is not exhaustive and does not include unusual or rarely reported microorganisms such as atypical Mycobacterium.

2. Sources of water-associated infection incidents

The source of water-associated infection identified from the literature includes:

- **Contaminated water systems:** tanks and reservoirs, pipe work, faucets/taps, sinks, wash-hand sinks, sink traps, drains, showerheads, shower hoses, baths.
- **Contaminated water-based equipment:** haemodialysers, bronchoscopes, nebuliser chambers, water-based heater-cooler units, hydrotherapy pools, ice-makers, humidifier reservoirs, water dispensers.
- **Contaminated water-based products:** disinfectant/antiseptic solutions made with tap water, bottled water, medications.

3. Causes of contamination

- Inadequate **design and/or management** of water systems that allow water stagnation and the build up of sludge, sediment, scale, organic matter and rust, all of which favour microbial growth and/or biofilm formation within the system. Biofilms act as a reservoir for a multitude of infectious agents facilitating their survival within water systems, and provide protection from control measures such as heat and chlorine.
- Inadequate **cleaning/decontamination** protocols or poor compliance with adequate protocols for water systems and water-based equipment.
- Inappropriate **practices/behaviours** of healthcare staff, patients and visitors, that increase the risk of contamination, for example disposal of food/drinks, body fluids in clinical wash hand sinks, storage of patient toiletries on sinks, preparation of IV drugs within splash zone of water outlets.

4. Transmission routes for water-associated infection incidents/outbreaks

Transmission routes identified in the literature include:

- **Direct contact**
  - Ingestion/inhalation of contaminated water.
- **Indirect contact**
  - Hands of healthcare workers via contaminated water, or infectious agents from a colonised/infected patient.
  - Contaminated environment.
  - Contaminated equipment (i.e. surgical devices, nebuliser cups, suction apparatus for ventilated patients, diagnostic equipment (e.g. bronchoscopy, ERCP), aspiration tubes for neonates, patient feeding items including containers for nutrition solutions, tube feeding equipment and milk bottles).
  - Water-based equipment (heart-lung machines and associated heater-cooler units used during cardiac surgery, humidifiers within oxygen therapy and drug delivery equipment, as well as air humidifiers and carpet cleaners).
- **Aerosolisation**
  - Contaminated body fluids transferred through clinical procedures that produce aerosols (i.e. open suctioning or wound irrigation).
  - Contaminated water generated from the process of water splashing on to clinical wash hand basins, drains, sinks, baths, shower cubicles, and when flushing toilets.

- **Aspiration**
    - Contaminated drinking water in the airways which is a particular risk for patients with nasogastric tubes, stroke patients, those taking sedatives and narcotics and those with motor neurone disease.

5. High risk patient groups/settings

High risk patients are defined in the literature as those who are severely immunocompromised as a result of their disease, age or treatment. The healthcare settings most frequently reported in water-associated incidents/outbreaks, and therefore considered as **high risk settings**, include haematology and oncology units, bone marrow and stem cell transplant units, neonatal, paediatric and adult ICUs, and any other care areas where patients are severely immunocompromised through disease or treatment. Clinical judgement is required to assess individual patient risk for any patient not being managed in these high risk units. A local NHS board risk assessment should be undertaken to identify any additional healthcare settings where patients are extremely vulnerable to infection. This risk assessment should take account of surveillance data and any previous incidents in individual clinical settings.

6. Types of infection caused by water borne organisms

These include: bloodstream, respiratory (pneumonia, ventilator-associated pneumonia), skin and soft tissue (including insertion site infections around any invasive device), surgical site infection (endocarditis, wound infection), urinary tract infection (UTI) and disseminated disease.

7. Definitions of water-associated incidents/outbreaks (refer to Chapter 3 of the NIPCM)

- A **single** case of infection or two or more cases of colonisation with an alert organism (as per Appendix 13 of the NIPCM) in a **high risk setting/ patient** of which there is evidence of acquisition within that healthcare setting (i.e. occurring ≥48 hours after admission), will require investigation to exclude the possibility of linked cases (including historic), which could indicate an **outbreak,** or an ongoing contamination issue.
- In addition to this, the following scenarios may require further investigation depending on the clinical presentation and the infectious agent;
    - a single case of colonisation or infection **at any time** from point of stay in the **neonatal ICU**;
    - a single case of infection **in any setting** where the infection episode and/or causative infectious agent is very rare/novel or highly antibiotic-resistant.
- In all other situations, the trigger for further investigation would be two or more linked cases with the same infectious agent associated with the same healthcare setting over a specified time period.
- If further linked cases are identified, a more extensive investigation will be required to exclude all potential sources. If there is an indication of an association with water or water-related equipment, consideration should be given to conducting environmental sampling (including water testing).

8. Preventing an incident/outbreak

Water system maintenance:

- A Water Safety Plan (WSP) should be in place and reviewed by the Water Safety Group (WSG) on an annual basis and also when there are alterations, repairs, changes of use, building works, or critical incidents. The WSG in collaboration with unit staff should review all uses of water on the unit. For details regarding WSG roles and responsibilities, see SHTM04-01 Part B.
- Infrequently used water outlets should be removed if appropriate; a flushing regime should be instigated if it is not possible to remove the outlet.
- Measures to prevent water stagnation and biofilm formation may include (in addition to tap flushing) installation of easier to clean sinks and plumbing, rimless toilets to prevent splashing, and sinks with deeper basins. For further information on design see SHTM04-01 Part A.
- Staff should report any problems or concerns regarding the safety, maintenance, usage, and cleanliness of water outlets to the appropriate service e.g. estates and facilities department/ ancillary staff.
- High risk components such as flow straighteners and thermal mixing valves should be included in a decontamination and maintenance programme.
- To prevent splash back, water flowing from water outlets should not flow directly into drain holes but should impact on the basin offset from the drain hole. ***Please note that HPS/HFS are in the process of developing further guidance for drain cleaning/decontamination requirements.***

Water outlet flushing:

- For all high risk areas the frequency and duration of flushing will depend on the usage and water pressure of the individual outlet, and on a risk assessment of the local unit taking into account local surveillance data and patient risk. ***Please note that HPS/HFS are in the process of developing further guidance for outlet flushing requirements.***
- Outlet flushing should not cause splashing/spraying beyond the wash hand basin; if flushing creates splashing/spraying onto adjacent surfaces, the area should be cleaned/disinfected (as per NIPCM Chapter 1) to reduce the risk of contamination and slippages/falls.
- Daily outlet flushing should be scheduled to occur at a pre-agreed time that causes the least disruption to patient care and allows for cleaning/disinfection should there be any splashing onto adjacent surfaces. For example, flushing could be scheduled to take place at the time point immediately prior to scheduled domestic environmental cleaning in the care area.
- Responsibilities for outlet flushing will depend on the organisational structure specific to the healthcare setting and should be pre-agreed by the WSG.
- A record of all outlet flushing should be maintained; the standard operating procedure for this should be pre-agreed by the WSG.

Water testing:

- Routine water testing is not currently mandated in NHSScotland however it is recommended for *Pseudomonas aeruginosa (*as per the HPS Addendum - Pseudomonas aeruginosa routine water sampling in augmented care areas for NHSScotland) and compliance with the HSE Approved Code of Practice LG & HSG274 for Legionella water testing is required.
- If routine water testing is undertaken, a total viable count (TVC) is sufficient for organisms other than *Pseudomonas aeruginosa* and *Legionella*; typing to species level should be limited to incident/outbreak investigations and undertaken if there are clinical cases.

- The procedures to be followed for TVC sampling are set out in SHTM 04-01 Part C: TVC testing protocol.

Care activities:

- Severely immunocompromised patients should **not** consume/use ice from automatic ice-making machines.
- Aseptic procedures (i.e. preparation of IV drugs) should not be performed in areas where there are concurrent procedures generating splashes which could contaminate a sterile surface.
- Potentially contaminated fluids of small volumes (i.e. body fluids, ET condensate, baby washing water <50 mls) must not be discarded into clinical wash hand basins; fluids should be directly emptied into a healthcare waste bag. Alternatively these small volumes may be absorbed by cotton wool balls before disposal into a healthcare waste bag. Larger volumes (i.e. bed bath fluids) should be discarded into a sluice or sink not used for hand hygiene.
- All sink areas should be free from clutter i.e. toiletries, cosmetics and other personal sundries. Staff and patients should be educated on the correct use of wash hand sinks for hand hygiene purposes only; this should include a procedure for the removal of waste foods/drinks/liquids.

9. Checklist for managing an incident/outbreak

In conjunction with Chapter 3 of the NIPCM, the following actions should be considered. Please note that responsibilities may differ according to local policy.

Clinical staff
☐ Clinical cases have been isolated or cohorted if appropriate.
☐ Hand washing has been supplemented with alcohol based hand rub (ABHR).
☐ The provision of water-free care has been considered (waterless oral care, use of disposable sponges or wash cloths), use of detergent wipes for cleaning reusable patient equipment (*note that detergent wipes are not suitable for disinfection of reusable patient equipment),* and use of sterile water/boiled water for preparation of antiseptic solutions and drinking.
☐ Single use care equipment is in use wherever possible; other care equipment (*such as commodes, wash bowls, lifting equipment*) is dedicated to a single patient
☐ All reusable care equipment is decontaminated between each use using a cleaning agent with 1000 parts per million (ppm) available chlorine (av cl.) as per Appendix 7 of the NIPCM
IPCT
☐ A clinical risk assessment has been conducted for all patients within the area.
☐ A retrospective review of clinical cases/isolates has been conducted to identify any linked cases – this may require assessment of multiple units/areas.
☐ Environmental testing of the following components has been considered (*NB: water testing results are used to strengthen hypotheses, not to exclude links*). • Taps; • showers; • baths; • water-based equipment (haemodialysers, ice-makers, humidifier reservoirs); • drains; • points further back in the system (pre-outlet sampling). NB: In addition to obtaining TVCs from water samples, typing to species level must be conducted. The purpose of typing is to include causative agents, not exclude them; the occurrence of false negatives could result in ongoing transmission.
☐ Historical microbiological water test results have been reviewed (if available).
☐ The water system risk assessment/water safety plan has been reviewed with input from Estates and Facilities.

☐ Decontamination protocols for water-based equipment (e.g. water-based heater cooler units) have been reviewed.
☐ The severity of the incident has been assessed using the HIIAT and reported to HPS as per Chapter 3 of the NIPCM.
☐ HPS has been notified if there is an active ongoing clinical incident where the source is considered to potentially be tap water, regardless of HIIAT status.
☐ The situation has been communicated to all staff including clinical, domestic, estates and facilities, IPCT members, and the microbiology department.
Estates & Facilities
☐ Flushing regimens and process documentation for the clinical area(s) affected has been reviewed.
☐ If individual outlets have been temporarily taken out of service, daily flushing should be commenced (if not already in place) to prevent stagnation and exacerbation of the contamination.
☐ Environmental cleaning protocols for the clinical area(s) affected have been reviewed with input from IPCT and domestic services.
☐ An inspection of all point of use outlets has been conducted to identify any design flaws, faults, or signs of deterioration/contamination/colonisation/debris – this should include an assessment of water flow rate from outlets and corresponding impact points on basins/drains/shower trays to assess excess splash/spray.
Domestic services
☐ Staff have commenced **enhanced cleaning** of affected areas preferably at least twice daily *(use combined detergent/disinfectant containing 1,000 ppm av cl; include all hard surfaces, equipment, and frequently touched surfaces e.g. door handles, light switches, bed rails)*
☐ Compliance with procedures for cleaning hand wash stations has been checked (spray bottles must not be used).

10. Remedial actions

The incident management team (IMT) in conjunction with the WSG would make the decision to undertake the following remedial actions appropriate to the level of contamination:

- Decontamination of fixtures and fittings (i.e. sinks, drains, taps).
- Replacement of fixtures and fittings following a risk assessment to identify how far back in the system the contamination is (i.e. showerheads, taps, drains, aerators, as per SHTM04-01).
- The instalment of point of use (POU) filters if the source of infection has yet to be identified, as a short-term control measure only; the decision to install POU filters must be balanced against the potential detrimental effects on water pressure and the additional management/decontamination requirements for their ongoing use.
- Temporary installation of portable wash hand basins, following a risk assessment and supported by a maintenance/decontamination programme.
- Disinfection of the entire water system which may involve one or more of the following: shock superheating/pasteurisation (≥60°C), flushing, hyperchlorination, or silver hydrogen peroxide.
- Longer term control measures (if the system is identified as the source) which may include the use of chlorine dioxide, peracetic acid, copper silver ionisation, and Kemper waterproofing systems.

A Celebration of Women Writers

Notes on Nursing: What It Is, and What It Is Not.
By Florence Nightingale, 1820-1910.
New York: D. Appleton and Company, 346 & 348 Broadway, 1860. [First American Edition.]

[Title Page]

NOTES ON NURSING

WHAT IT IS, AND WHAT IT IS NOT.

BY

FLORENCE NIGHTINGALE.

NEW YORK:
D. APPLETON AND COMPANY,
346 & 348 BROADWAY.
1860.

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PREFACE.

THE following notes are by no means intended as a rule of thought by which nurses can teach themselves to nurse, still less as a manual to teach nurses to nurse. They are meant simply to give hints for thought to women who have personal charge of the health of others. Every woman, or at least almost every woman, in England has, at one time or another of her life, charge of the personal health of somebody, whether child or invalid,–in other words, every woman is a nurse. Every day sanitary knowledge, or the knowledge of nursing, or in other words, of how to put the constitution in such a state as that it will have no disease, or that it can recover from disease, takes a higher place. It is recognized as the knowledge which every one ought to have–distinct from medical knowledge, which only a profession can have. *[Page 4]*

If, then, every woman must at some time or other of her life, become a nurse, *i.e.*, have charge of somebody's health, how immense and how valuable would be the produce of her united experience if every woman would think how to nurse.

I do not pretend to teach her how, I ask her to teach herself, and for this purpose I venture to give her some hints.

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NOTES ON NURSING:

WHAT IT IS AND WHAT IT IS NOT.

Disease a reparative process.

SHALL we begin by taking it as a general principle–that all disease, at some period or other of its course, is more or less a reparative process, not necessarily accompanied with suffering: an effort of nature to remedy a process of poisoning or of decay, which has taken place weeks, months, sometimes years beforehand, unnoticed, the termination of the disease being then, while the antecedent process was going on, determined?

If we accept this as a general principle, we shall be immediately met with anecdotes and instances to prove the contrary. Just so if we were to take, as a principle–all the climates of the earth are meant to be made habitable for man, by the efforts of man–the objection would be immediately raised,–Will the top of Mount Blanc ever be made habitable? Our answer would be, it will be many thousands of years before we have reached the bottom of Mount Blanc in making the earth healthy. Wait till we have reached the bottom before we discuss the top.

Of the sufferings of disease, disease not always the cause.

In watching diseases, both in private houses and in public hospitals, the thing which strikes the experienced observer most forcibly is this, that the symptoms or the sufferings generally considered to be inevitable and incident to the disease are very often not symptoms of the disease at all, but of something quite different–of the want of fresh air, or of light, or of warmth, or of quiet, or of cleanliness, or of punctuality and care in the administration of diet, of each or of all of these. And this quite as much in private as in hospital nursing.

The reparative process which Nature has instituted and which we call disease, has been hindered by some want of knowledge or attention, in one or in all of these things, and pain, suffering, or interruption of the whole process sets in.

If a patient is cold, if a patient is feverish, if a patient is faint, if he is sick after taking food, if he has a bed-sore, it is generally the fault not of the disease, but of the nursing.

What nursing ought to do.

I use the word nursing for want of a better. It has been limited to signify little more than the administration of medicines and the application of poultices. It ought to signify the proper use of fresh air, light, warmth, cleanliness, quiet, and the proper selection and administration of diet–all at the least expense of vital power to the patient.

Nursing the sick little understood.

It has been said and written scores of time, that every woman makes a good nurse. I believe, on the contrary, that the very elements of nursing are all but unknown.

By this I do not mean that the nurse is always to blame. Bad sanitary, bad architectural, and bad administrative arrangements often make it impossible to nurse. But the art of nursing ought to include such arrangements as alone make what I understand by nursing, possible.

The art of nursing, as now practised, seems to be expressly constituted to unmake what God had made disease to be, viz.,a reparative process.

Nursing ought to assist the reparative process.

To recur to the first objection. If we are asked, Is such or such a disease a reparative process? Can such an illness be unaccompanied with suffering? Will any care prevent such a patient from suffering this or that?–I humbly say, I do not know. But when you have done away with all that pain and suffering, which in patients are the symptoms not of their disease, but of the absence of one or all of the above-mentioned essentials to the success of Nature's reparative processes, we shall then know what are the symptoms of and the sufferings inseparable from the disease.

Another and the commonest exclamation which will be instantly made is–Would you do nothing, then, in cholera, fever, &c.?–so deep-rooted and universal is the conviction that to give medicine is to be doing something,or rather everything; to give air, warmth, cleanliness, &c., is to do nothing. The reply is, that in these and many other similar diseases the exact value of particular remedies and modes of treatment is by no means ascertained, while there is universal experience as to the extreme importance of careful nursing in determining the issue of disease.

Nursing the well.

II. The very elements of what constitutes good nursing are as little understood for the well as for the sick. The same laws of health or of nursing, for they are in reality the same, obtain among the well as among the sick. The breaking of them produces only a less violent consequence among the former than among the latter,–and this sometimes, not always.

It is constantly objected,–"But how can I obtain this medical knowledge? I am not a doctor. I must leave this to doctors."

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Little understood.

Oh, mothers of families! You who say this, do you know that one in every seven infants in this civilized land of England perishes before it is one year old? That, in London, two in every five die before they are five years old? And, in the other great cities of England, nearly one out of two? * "The life duration of tender babies" (as some Saturn, turned analytical chemist, says) "is the most delicate test" of sanitary conditions. Is all this premature suffering and death necessary? Or did Nature intend mothers to be always accompanied by doctors? Or is it better to learn the piano-forte than to learn the laws which subserve the preservation of offspring?

Macaulay somewhere says, that it is extraordinary that, whereas the laws of motions of the heavenly bodies, far removed as they are from us, are perfectly well understood, the laws of the human mind, which are under our observation all day and every day, are no better understood than they were two thousand years ago.

But how much more extraordinary is it that, whereas what we might call the coxcombries of education–*e.g.*, the elements of astronomy–are now taught to every school-girl, neither mothers of families of any class, nor school-mistresses of any class, nor nurses of children, nor nurses of hospitals, are taught anything about those laws which God has assigned to the relations of our bodies with the world in which He has put them. In other words, the laws which make these bodies, into which He has put our minds, healthy or unhealthy organs of those minds, are all but unlearnt. Not but that these laws–the laws of life–are in a certain measure understood, but not even mothers think it worth their while to study them–to study how to give their children healthy existences. They call it medical or physiological knowledge, fit only for doctors.

Another objection.

We are constantly told,–"But the circumstances which govern our children's healths are beyond our control. What can we do with winds? There is the east wind. Most people can tell before they get up in the morning whether the wind is in the east."

To this one can answer with more certainty than to the former objections. Who is it who knows when the wind is in the east? Not the Highland drover, certainly, exposed to the east wind, but the young lady who is worn out with the want of exposure to fresh air, to sunlight, &c. Put the latter under as good sanitary circumstances as the former, and she too will not know when the wind is in the east.

I. VENTILATION AND WARMING.

First rule of nursing, to keep the air within as pure as the air without.

The very first canon of nursing, the first and the last thing upon which a nurse's attention must be fixed, the first essential to a patient, without which all the rest you can do for him is as nothing, with which I had almost said you may leave all the rest alone, is this: TO KEEP THE AIR HE BREATHES AS PURE AS THE EXTERNAL AIR, WITHOUT CHILLING HIM. Yet what is so little attended to? Even where it is thought of at all, the most extraordinary misconceptions reign about it. Even in admitting air into the patient's room or ward, few people ever think, where that air comes from. It may come from a corridor into which other wards are ventilated, from a hall, always unaired, always full of the fumes of gas, dinner, of various kinds of mustiness; from an underground kitchen, sink, washhouse, water-closet, or even, as I myself have had sorrowful experience, from open sewers, loaded with filth; and with this the patient's room or ward is aired, as it is called–poisoned, it should rather be said. Always air from the air without, and that, too, through those windows, through which the air comes freshest. From a closed court, especially if the wind do not blow that way, air may come as stagnant as any from a hall or corridor.

Again, a thing I have often seen both in private houses and institutions. A room remains uninhabited; the fire-place is carefully fastened up with a board; the windows are never opened; probably the shutters are kept always shut; perhaps some kind of stores are kept in the room; no breath of fresh air can by possibility enter into that room, nor any ray of sun. The air is stagnant, musty, and corrupt as it can by possibility be made. It is quite ripe to breed small-pox, scarlet-fever, diptheria, or anything else you please. *

Yet the nursery, ward, or sick room adjoining will positively be aired (?) by having the door opened into that room. Or children will be put into that room, without previous preparation, to sleep.

A short time ago a man walked into a back-kitchen in Queen square, and cut the throat of a poor consumptive creature, sitting by the fire. The murderer did not deny the act, but simply said, "It's all right." Of course he was mad.

But in our case, the extraordinary thing is that the victim says, "It's all right," and that we are not mad. Yet, although we "nose" the murderers, in the musty unaired unsunned room, the scarlet fever which is behind the door, or the fever and hospital gangrene which are stalking among the crowded beds of a hospital ward, we say, "It's all right."

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Without chill.

With a proper supply of windows, and a proper supply of fuel in open fire-places, fresh air is comparatively easy to secure when the patient or patients are in bed. Never be afraid of open windows then. People don't catch cold in bed. This is a popular fallacy. With proper bed-clothes and hot bottles, if necessary, you can always keep a patient warm in bed, and well ventilate him at the same time.

But a careless nurse, be her rank and education what it may, will stop up every cranny and keep a hot-house heat when her patient is in bed,–and, if he is able to get up, leave him comparatively unprotected. The time when people take cold (and there are many ways of taking cold, besides a cold in the nose,) is when they first get up after the two-fold exhaustion of dressing and of having had the skin relaxed by many hours, perhaps days, in bed, and thereby rendered more incapable of re-action. Then the same temperature which refreshes the patient in bed may destroy the patient just risen. And common sense will point out, that, while purity of air is essential, a temperature must be secured which shall not chill the patient. Otherwise the best that can be expected will be a feverish re-action.

To have the air within as pure as the air without, it is not necessary, as often appears to be thought, to make it as cold.

In the afternoon again, without care, the patient whose vital powers have then risen often finds the room as close and oppressive as he found it cold in the morning. Yet the nurse will be terrified, if a window is opened. *

Open windows.

I know an intelligent humane house surgeon who makes a practice of keeping the ward windows open. The physicians and surgeons invariably close them while going their rounds; and the house surgeon very properly as invariably opens them whenever the doctors have turned their backs.

In a little book on nursing, published a short time ago, we are told, that, "with proper care it is very seldom that the windows cannot be opened for a few minutes twice in the day to admit fresh air from without." I should think not; nor twice in the hour either. It only shows how little the subject has been considered.

What kind of warmth desirable.

Of all the methods of keeping patients warm the very worst certainly is to depend for heat on the breath and bodies of the sick. I have known a medical officer keep his ward windows hermetically closed. Thus exposing the sick to all the dangers of an infected atmosphere, because he was afraid that, by admitting fresh air, the temperature of the ward would be too much lowered. This is a destructive fallacy.

To attempt to keep a ward warm at the expense of making the sick repeatedly breathe their own hot, humid, putrescing atmosphere is a certain way to delay recovery or to destroy life.

Bedrooms most universally foul.

Do you ever go into the bed-rooms of any persons of any class, whether they contain one, two, or twenty people, whether they hold sick or well, at night, or before the windows are opened in the morning, and ever find the air anything but unwholesomely close and foul? And why should it be so? And of how much importance it is that it should not be so? During sleep, the human body, even when in health, is far more injured by the influence of foul air than when awake. Why can't you keep the air all night, then, as pure as the air without in the rooms you sleep in? But for this, you must have sufficient outlet for the impure air you make yourselves to go out; sufficient inlet for the pure air from without to come in. You must have open chimneys, open winows, or ventilators; no close curtains round your beds; no shutters or curtains to your windows, none of the contrivances by which you undermine your own health or destroy the chances of recovery of your sick. *

When warmth must be most carefully looked to.

A careful nurse will keep a constant watch over her sick especially weak, protracted, and collapsed cases, to guard against the effects of the loss of vital heat by the patient himself. In certain diseased states much less heat is produced than in health; and there is a constant tendency to the decline and ultimate extinction of the vital powers by the call made upon them to sustain the heat of the body. Cases where this occurs should be watched with the greatest care from hour to hour, I had almost said from minute to minute. The feet and legs should be examined by the hand from time to time, and wherever a tendency to chilling is discovered, hot bottles, hot bricks, or warm flannels, with some warm drink, should be made use of until the temperature is restored. The fire should be, if necessary, replenished. Patients are frequently lost in the latter stages of disease from want of attention to such simple precautions. The nurse may be trusting to the patient's diet, or his medicine, or to the occasional dose of stimulant which she is directed to give him, while the patient is all the while sinking from want of a little external warmth. Such cases happen at all times, even during the height of summer. This fatal chill is most apt to occur towards early morning at the period of the lowest temperature of the twenty four hours, and at the time when the effect of the preceding day's diets is exhausted.

Generally speaking, you may expect that weak patients will suffer cold much more in the morning than in the evening. The vital powers are much lower. If they are feverish at night, with burning hands and feet, they are almost sure to be chilly and shivering in the morning. But nurses are very fond of heating the footwarmer at night, and of neglecting it in the morning, when they are busy. I should reverse the matter.

All these things require common sense and care. Yet perhaps in no one single thing is so little common sense shown, in all ranks, as in nursing. *

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Cold air not ventilation, nor fresh air a method of chill.

The extraordinary confusion between cold and ventilation, even in the minds of well educated people, illustrates this. To make a room cold is by no means necessarily to ventilate it. Nor is it at all necessary, in order to ventilate a room, to chill it. Yet, if a nurse finds a room close, she will let out the fire, thereby making it closer, or she will open the door into a cold room, without a fire, or an open window in it, by way of improving the ventilation. The safest atmosphere of all for a patient is a good fire and an open window, excepting in extremes of temperature. (Yet no nurse can ever be made to understand this.) To ventilate a small room without draughts of course requires more care than to ventilate a large one.

Night air.

Another extraordinary fallacy is the dread of night air. What air can we breathe at night but night air? The choice is between pure night air from without and foul night air from within. Most people prefer the latter. An unaccountable choice. What will they say if it is proved to be true that fully one-half of all the disease we suffer from is occasioned by people sleeping with their windows shut? An open window most nights in the year can never hurt any one. This is not to say that light is not necessary for recovery. In great cities, night air is often the best and purest air to be had in the twenty-four hours. I could better understand in towns shutting the windows during the day than during the night, for the sake of the sick. The absence of smoke, the quiet, all tend to making night the best time for airing the patients. One of our highest medical authorities on Consumption and Climate has told me that the air in London is never so good as after ten o'clock at night.

Air from the outside. Open your windows, shut your doors.

Always air your room, then, from the outside air, if possible. Windows are made to open; doors are made to shut–a truth which seems extremely difficult of apprehension. I have seen a careful nurse airing her patient's room through the door, near to which were two gaslights, (each of which consumes as much air as eleven men,) a kitchen, a corridor, the composition of the atmosphere in which consisted of gas, paint, foul air, never changed, full of effluvia, including a current of sewer air from an ill-placed sink, ascending in a continual stream by a well-staircase, and discharging themselves constantly into the patient's room. The window of the said room, if opened, was all that was desirable to air it. Every room must be aired from without–every passage from without. But the fewer passages there are in a hospital the better.

Smoke.

If we are to preserve the air within as pure as the air without, it is needless to say that the chimney must not smoke. Almost all smoky chimneys can be cured–from the bottom, not from the top. Often it is only necessary to have an inlet for air to supply the fire, which is feeding itself, for want of this, from its own chimney. On the other hand, almost all chimneys can be made to smoke by a careless nurse, who lets the fire get low and then overwhelms it with coal; not, as we verily believe, in order to spare herself trouble, (for very rare is unkindness to the sick), but from not thinking what she is about.

Airing damp things in a patient's room.

In laying down the principle that the first object of the nurse must be to keep the air breathed by her patient as pure as the air without, it must not be forgotten that everything in the room which can give off effluvia, besides the patient, evaporates itself into his air. And it follows that there ought to be nothing in the room, excepting him, which can give off effluvia or moisture. Out of all damp towels, &c., which become dry in the room, the damp, of course, goes into the patient's air. Yet this "of course" seems as little thought of, as if it were an obsolete fiction. How very seldom you see a nurse who acknowledges by her practice that nothing at all ought to be aired in the patient's room, that nothing at all ought to be cooked at the patient's fire! Indeed the arrangements often make this rule impossible to observe.

If the nurse be a very careful one, she will, when the patient leaves his bed, but not his room, open the sheets wide, and throw the bed-clothes back, in order to air his bed. And she will spread the wet towels or flannels carefully out upon a horse, in order to dry them. Now either these bed-clothes and towels are not dried and aired, or they dry and air themselves into the patient's air. And whether the damp and effluvia do him most harm in his air or in his bed, I leave to you to determine, for I cannot.

Effluvia from excreta.

Even in health people cannot repeatedly breathe air in which they live with impunity, on account of its becoming charged with unwholesome matter from the lungs and skin. In disease where everything given off from the body is highly noxious and dangerous, not only must there be plenty of ventilation to carry off the effluvia, but everything which the patient passes must be instantly removed away, as being more noxious than even the emanations from the sick.

Of the fatal effects of the effluvia from the excreta it would seem unnecessary to speak, were they not so constantly neglected. Concealing the utensils behind the vallance to the bed seems all the precaution which is thought necessary for safety in private nursing. Did you but think for one moment of the atmosphere under that bed, the saturation of the under side of the mattress with the warm evaporations, you would be startled and frightened too!

Chamber utensils without lids.

The use of any chamber utensil *without a lid* * should be utterly abolished, whether among the sick or well. You can easily convince yourself of the necessity of this absolute rule, by taking one with a lid, and examining the under side of that lid. It will be found always covered, whenever the utensil is not empty, by condensed offensive moisture. Where does that go, when there is no lid?

Earthenware, or if there is any wood, highly polished and varnished wood, are the only materials fit for patients' utensils. The very lid of the old abominable close-stool is enough to breed a pestilence. It becomes

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saturated with offensive matter, which scouring is only wanted to bring out. I prefer an earthenware lid as being always cleaner. But there are various good new-fashioned arrangements.

Abolish slop-pails.

A slop pail should never be brought into a sick room. It should be a rule invariable, rather more important in the private house than elsewhere, that the utensil should be carried directly to the water-closet, emptied there, rinsed there, and brought back. There should always be water and a cock in every water-closet for rinsing. But even if there is not, you must carry water there to rinse with. I have actually seen, in the private sick room, the utensils emptied into the foot-pan, and put back unrinsed under the bed. I can hardly say which is most abominable, whether to do this or to rinse the utensil *in* the sick room. In the best hospitals it is now a rule that no slop pail shall ever be brought into the wards, but that the utensils shall be carried direct to be emptied and rinsed at the proper place. I would it were so in the private house.

Fumigations.

Let no one ever depend upon fumigations, "disinfectants," and the like, for purifying the air. The offensive thing, not its smell, must be removed. A celebrated medical lecturer began one day, "Fumigations, gentlemen, are of essential importance. They make such an abominable smell that they compel you to open the window." I wish all the disinfecting fluids invented made such an "abominable smell" that they forced you to admit fresh air. That would be a useful invention.

II.–HEALTH OF HOUSES. *

Health of houses. Five points essential.

There are five essential points in securing the health of houses:–

Pure air.
Pure water.
Efficient drainage.
Cleanliness.
Light.

Without these, no house can be healthy. And it will be unhealthy just in proportion as they are deficient.

Pure air.

1. To have pure air, your house be so constructed as that the outer atmosphere shall find its way with ease to every corner of it. House architects hardly ever consider this. The object in building a house is to obtain the largest interest for the money, not to save doctors' bills for the tenants. But, if tenants should ever become so wise as to refuse to occupy unhealthy constructed houses, and if Insurance Companies should ever come to understand their interest so thoroughly as to pay a Sanitary Surveyor to look after the houses where their clients live, speculative architects would speedily be brought to their senses. As it is, they build what pays best. And there are always people foolish enough to take the houses they build. And if in the course of time the families die off, as is so often the case, nobody ever thinks of blaming any but Providence * for the result. Ill-informed medical men aid in sustaining the delusion, by laying the blame on "current contagions." Badly constructed houses do for the healthy what badly constructed hospitals do for the sick. Once insure that the air in a house is stagnant, and sickness is certain to follow.

Pure water.

2. Pure water is more generally introduced into houses than it used to be, thanks to the exertions of the sanitary reformers. Within the last few years, a large part of London was in the daily habit of using water polluted by the drainage of its sewers and water closets. This has happily been remedied. But, in many parts of the country, well water of a very impure kind is used for domestic purposes. And when epidemic disease shows itself, persons using such water are almost sure to suffer.

Drainage.

3. It would be curious to ascertain by inspections, how many houses in London are really well drained. Many people would say, surely all or most of them. But many people have no idea in what good drainage consists. They think that a sewer in the street, and a pipe leading to it from the house is good drainage. All the while the sewer may be nothing but a laboratory from which epidemic disease and ill health is being distilled into the house. No house with any untrapped drain pipe communicating immediately with a sewer, whether it be from water closet, sink, or gully-grate, can ever be healthy. An untrapped sink may at any time spread fever or pyæmia among the inmates of a palace.

Sinks.

The ordinary oblong sink is an abomination. That great surface of stone, which is always left wet, is always exhaling into the air. I have known whole houses and hospitals smell of the sink. I have met just as strong a stream of sewer air coming up the back staircase of a grand London house from the sink, as I have ever met at Scutari; and I have seen the rooms in that house all ventilated by the open doors, and the passages all *un*ventilated by the closed windows, in order that as much of the sewer air as possible might be conducted into and retained in the bed-rooms. It is wonderful.

Another great evil in house construction is carrying drains underneath the house. Such drains are never safe. All house drains should begin and end outside the walls. Many people will readily admit, as a theory, the importance of these things. But how few are there who can intelligently trace disease in their households to such causes! Is it not a fact, that when scarlet fever, measles, or small-pox appear among the children, the very first thought which occurs is, "where" the children can have "caught" the disease? And the parents immediately run over in their minds all the families with whom they may have been. They never think of looking at home

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for the source of the mischief. If a neighbour's child is seized with small-pox, the first question which occurs is whether it had been vaccinated. No one would undervalue vaccination; but it becomes of doubtful benefit to society when it leads people to look abroad for the source of evils which exist at home.

Cleanliness.

4. Without cleanliness, within and without your house, ventilation is comparatively useless. In certain foul districts of London, poor people used to object to open their windows and doors because of the foul smells that came in. Rich people like to have their stables and dunghill near their houses. But does it ever occur to them that with many arrangements of this kind it would be safer to keep the windows shut than open? You cannot have the air of the house pure with dung-heaps under the windows. These are common all over London. And yet people are surprised that their children, brought up in large "well-aired" nurseries and bed-rooms suffer from children's epidemics. If they studied Nature's laws in the matter of children's health, they would not be so surprised.

There are other ways of having filth inside a house besides having dirt in heaps. Old papered walls of years' standing, dirty carpets, uncleansed furniture, are just as ready sources of impurity to the air as if there were a dung-heap in the basement. People are so unaccustomed from education and habits to consider how to make a home healthy, that they either never think of it at all, and take every disease as a matter of course, to be "resigned to" when it comes "as from the hand of Providence;" or if they ever entertain the idea of preserving the health of their households as a duty, they are very apt to commit all kinds of "negligences and ignorances" in performing it.

Light.

5. A dark house is always an unhealthy house, always an ill-aired house, always a dirty house. Want of light stops growth, and promotes scrofula, rickets, &c., among the children.

People lose their health in a dark house, and if they get ill they cannot get well again in it. More will be said about this farther on.

Three common errors in managing the health of houses.

Three out of many "negligences and ignorances" in managing the health of houses generally, I will here mention as specimens–1. That the female head in charge of any building does not think it necessary to visit every hole and corner of it every day. How can she expect those who are under her to be more careful to maintain her house in a healthy condition than she who is in charge of it?–2. That it is not considered essential to air, to sun, and to clean rooms while uninhabited; which is simply ignoring the first elementary notion of sanitary things, and laying the ground ready for all kinds of diseases.–3. That the window, and one window, is considered enough to air a room. Have you never observed that any room without a fire-place is always close? And, if you have a fire-place, would you cram it up not only with a chimney-board, but perhaps with a great wisp of brown paper, in the throat of the chimney–to prevent the soot from coming down, you say? If your chimney is foul, sweep it; but don't expect that you can ever air a room with only one aperture; don't suppose that to shut up a room is the way to keep it clean. It is the best way to foul the room and all that is in it. Don't imagine that if you, who are in charge, don't look to all these things yourself, those under you will be more careful than you are. It appears as if the part of a mistress now is to complain of her servants, and to accept their excuses–not to show them how there need be neither complaints made nor excuses.

Head in charge must see to House Hygiene, not do it herself.

But again, to look to all these things yourself does not mean to do them yourself. "I always open the windows," the head in charge often says. If you do it, it is by so much the better, certainly, than if it were not done at all. But can you not insure that it is done when not done by yourself? Can you insure that it is not undone when your back is turned? This is what being "in charge" means. And a very important meaning it is, too. The former only implies that just what you can do with your own hands is done. The latter that what ought to be done is always done.

Does God think of these things so seriously?

And now, you think these things trifles, or at least exaggerated. But what you "think" or what I "think" matters little. Let us see what God thinks of them. God always justifies His ways. While we are thinking, He has been teaching. I have known cases of hospital pyæmia quite as severe in handsome private houses as in any of the worst hospitals, and from the same cause, viz., foul air. Yet nobody learnt the lesson. Nobody learnt *anything* at all from it. They went on *thinking*–thinking that the sufferer had scratched his thumb, or that it was singular that "all the servants" had "whitlows," or that something was "much about this year; there is always sickness in our house." This is a favourite mode of thought–leading not to inquire what is the uniform cause of these general "whitlows," but to stifle all inquiry. In what sense is "sickness" being "always there," a justification of its being "there" at all?

How does He carry out His laws?
How does He teach His laws?

I will tell you what was the cause of this hospital pyæmia being in that large private house. It was that the sewer air from an ill-placed sink was carefully conducted into all the rooms by sedulously opening all the doors, and closing all the passage windows. It was that the slops were emptied into the foot pans!–it was that the utensils were never properly rinsed;–it was that the chamber crockery was rinsed with dirty water:–it was that the beds were never properly shaken, aired, picked to pieces, or changed. It was that the carpets and curtains were always musty;–it was that the furniture was always dusty;–it was that the papered walls were saturated with dirt;–it was that the floors were never cleaned;–it was that the uninhabited rooms were never sunned, or cleaned, or aired;–it was that the cupboards were always reservoirs of foul air;–it was that the windows were always tight shut up at night;–it was that no window was ever systematically opened even in the

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day, or that the right window was not opened. A person gasping for air might open a window for himself. But the servants were not taught to open the windows, to shut the doors; or they opened the windows upon a dank well between high walls, not upon the airier court; or they opened the room doors into the unaired halls and passages, by the way of airing the rooms. Now all this is not fancy, but fact. In that handsome house I have known in one summer three cases of hospital pyæmia, one of phlebitis, two of consumptive cough; all the *immediate* products of foul air. When, in temperate climates, a house is more unhealthy in summer than in winter, it is a certain sign of something wrong. Yet nobody learns the lesson. Yes, God always justifies His ways. He is teaching while you are not learning. This poor body loses his finger, that one loses his life. And all from the most easily preventible causes. *

The houses of the grandmothers and great grandmothers of this generation, at least the country houses, with front door and back door always standing open, winter and summer, and a thorough draught always blowing through–with all the scrubbing, and cleaning, and polishing, and scouring which used to go on, the grandmothers, and still more the great grandmothers, always out of doors and never with a bonnet on except to go to church, these things entirely account for the fact so often seen of a great grandmother, who was a tower of physical vigour descending into a grandmother perhaps a little less vigorous but still sound as a bell and healthy to the core, into a mother languid and confined to her carriage and house, and lastly into a daughter sickly and confined to her bed. For, remember, even with a general decrease of mortality you may often find a race thus degenerating and still oftener a family. You may see poor little feeble washed-out rags, children of a noble stock, suffering morally and physically, throughout their useless, degenerate lives, and yet people who are going to marry and to bring more such into the world, will consult nothing but their own convenience as to where they are to live, or how they are to live.

Don't make your sick-room into a ventilating shaft for the whole house.

With regard to the health of houses where there is a sick person, it often happens that the sick room is made a ventilating shaft for the rest of the house. For while the house is kept as close, unaired, and dirty as usual, the window of the sick room is kept a little open always, and the door occasionally. Now, there are certain sacrifices which a house with one sick person in it does make to that sick person: it ties up its knocker; it lays straw before it in the street. Why can't it keep itself thoroughly clean and unusually well aired, in deference to the sick person?

Infection.

We must not forget what, in ordinary language, is called "Infection;"*–a thing of which people are generally so afraid that they frequently follow the very practice in regard to it which they ought to avoid. Nothing used to be considered so infectious or contagious as small-pox; and people not very long ago used to cover up patients with heavy bed clothes, while they kept up large fires and shut the windows. Small-pox, of course, under this *regime*, is very "infectious." People are somewhat wiser now in their management of this disease. They have ventured to cover the patients lightly and to keep the windows open; and we hear much less of the "infection" of small-pox than we used to do. But do people in our days act with more wisdom on the subject of "infection" in fevers–scarlet fever, measles, &c.–than their forefathers did with small-pox? Does not the popular idea of "infection" involve that people should take greater care of themselves than of the patient? that, for instance, it is safer not to be too much with the patient, not to attend too much to his wants? Perhaps the best illustration of the utter absurdity of this view of duty in attending on "infectious" diseases is afforded by what was very recently the practice, if it is not so even now, in some of the European lazarets–in which the plague-patient used to be condemned to the horrors of filth, overcrowding, and want of ventilation, while the medical attendant was ordered to examine the patient's tongue through an opera-glass and to toss him a lancet to open his abscesses with?

True nursing ignores infection, except to prevent it. Cleanliness and fresh air from open windows, with unremitting attention to the patient, are the only defence a true nurse either asks or needs.

Wise and humane management of the patient is the best safeguard against infection.

Why must children have measles, &c.

There are not a few popular opinions, in regard to which it is useful at times to ask a question or two. For example, it is commonly thought that children must have what are commonly called "children's epidemics," "current contagions," &c., in other words, that they are born to have measles, hooping-cough, perhaps even scarlet fever, just as they are born to cut their teeth, if they live.

Now, do tell us, why must a child have measles?

Oh because, you say, we cannot keep it from infection–other children have measles–and it must take them–and it is safer that it should.

But why must other children have measles? And if they have, why must yours have them too?

If you believed in and observed the laws for preserving the health of houses which inculcate cleanliness, ventilation, white-washing, and other means, and which, by the way, *are laws*, as implicitly as you believe in the popular opinion, for it is nothing more than an opinion, that your child must have children's epidemics, don't you think that upon the whole your child would be more likely to escape altogether?

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III. PETTY MANAGEMENT.

Petty management.

All the results of good nursing, as detailed in these notes, may be spoiled or utterly negatived by one defect, viz.: in petty management, or in other words, by not knowing how to manage that what you do when you are there, shall be done when you are not there. The most devoted friend or nurse cannot be always *there.* Nor is it desirable that she should. And she may give up her health, all her other duties, and yet, for want of a little management, be not one-half so efficient as another who is not one-half so devoted, but who has this art of multiplying herself–that is to say, the patient of the first will not really be so well cared for, as the patient of the second.

It is as impossible in a book to teach a person in charge of sick how to *manage*, as it is to teach her how to nurse. Circumstances must vary with each different case. But it *is* possible to press upon her to think for herself: Now what does happen during my absence? I am obliged to be away on Tuesday. But fresh air, or punctuality is not less important to my patient on Tuesday than it was on Monday. Or: At 10 P.M. I am never with my patient; but quiet is of no less consequence to him at 10 than it was at 5 minutes to 10.

Curious as it may seem, this very obvious consideration occurs comparatively to few, or, if it does occur, it is only to cause the devoted friend or nurse to be absent fewer hours or fewer minutes from her patient–not to arrange so as that no minute and no hour shall be for her patient without the essentials of her nursing.

Illustrations of the want of it.

A very few instances will be sufficient, not as precepts, but as illustrations.

Strangers coming into the sick room.

A strange washerwoman, coming late at night for the "things," will burst in by mistake to the patient's sickroom, after he has fallen into his first doze, giving him a shock, the effects of which are irremediable, though he himself laughs at the cause, and probably never even mentions it. The nurse who is, and is quite right to be, at her supper, has not provided that the washerwoman shall not lose her way and go into the wrong room.

Sick room airing the whole house.

The patient's room may always have the window open. But the passage outside the patient's room, though provided with several large windows, may never have one open. Because it is not understood that the charge of the sick-room extends to the charge of the passage. And thus, as often happens, the nurse makes it her business to turn the patient's room into a ventilating shaft for the foul air of the whole house.

Uninhabited room fouling the whole house.

An uninhabited room, a newly-painted room, * an uncleaned closet or cupboard, may often become the reservoir of foul air for the whole house, because the person in charge never thinks of arranging that these places shall be always aired, always cleaned; she merely opens the window herself "when she goes in."

Delivery and non-delivery of letters and messages.

An agitating letter or message may be delivered, or an important letter or message *not* delivered; a visitor whom it was of consequence to see, may be refused, or one whom it was of still more consequence to *not* see may be admitted–because the person in charge has never asked herself this question, What is done when I am not there? *

At all events, one may safely say, a nurse cannot be with the patient, open the door, eat her meals, take a message, all at one and the same time. Nevertheless the person in charge never seems to look the impossibility in the face.

Add to this that the *attempting* this impossibility does more to increase the poor patient's hurry and nervousness than anything else.

Partial measures such as "being always in the way" yourself, increase instead, of saving, the patient's anxiety. Because they must be only partial.

It is never thought that the patient remembers these things if you do not. He has not only to think whether the visit or letter may arrive, but whether you will be in the way at the particular day and hour when it may arrive. So that your *partial* measures for "being in the way" yourself, only increase the necessity for his thought. Whereas, if you could but arrange that the thing should always be done whether you are there or not, he need never think at all about it.

For the above reasons, whatever a patient *can* do for himself, it is better, *i. e.* less anxiety, for him to do for himself, unless the person in charge has the spirit of management.

It is evidently much less exertion for a patient to answer a letter for himself by return of post, than to have four conversations, wait five days, have six anxieties before it is off his mind, before the person who has to answer it has done so.

Apprehension, uncertainty, waiting, expectation, fear of surprise, do a patient more harm than any exertion. Remember, he is face to face with his enemy all the time, internally wrestling with him, having long imaginary conversations with him. You are thinking of something else. "Rid him of his adversary quickly," is a first rule with the sick. *

For the same reasons, always tell a patient and tell him beforehand when you are going out and when you will be back, whether it is for a day, an hour, or ten minutes. You fancy perhaps that it is better for him if he

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does not find out your going at all, better for him if you do not make yourself "of too much importance" to him; or else you cannot bear to give him the pain or the anxiety of the temporary separation.

No such thing. You *ought* to go, we will suppose. Health or duty requires it. Then say so to the patient openly. If you go without his knowing it, and he finds it out, he never will feel secure again that the things which depend upon you will be done when you are away, and in nine cases out of ten he will be right. If you go out without telling him when you will be back, he can take no measures nor precautions as to the things which concern you both, or which you do for him.

What is the cause of half the accidents which happen?

If you look into the reports of trials or accidents, and especially of suicides, or into the medical history of fatal cases, it is almost incredible how often the whole thing turns upon something which has happened because "he," or still oftener "she," "was not there." But it is still more incredible how often, how almost always this is accepted as a sufficient reason, a justification; why, the very fact of the thing having happened is the proof of its not being a justification. The person in charge was quite right not to be "*there*," he was called away for quite sufficient reason, or he was away for a daily recurring and unavoidable cause; yet no provision was made to supply his absence. The fault was not in his "being away," but in there being no management to supplement his "being away." When the sun is under a total eclipse or during his nightly absence, we light candles. But it would seem as if it did not occur to us that we must also supplement the person in charge of sick or of children, whether under an occasional eclipse or during a regular absence.

In institutions where many lives would be lost and the effect of such want of management would be terrible and patent, there is less of it than in the private house. *

But in both, let whoever is in charge keep this simple question in her head (*not*, how can I always do this right thing myself, but) how can I provide for this right thing to be always done?

Then, when anything wrong has actually happened in consequence of her absence, which absence we will suppose to have been quite right, let her question still be (*not*, how can I provide against any more of such absences? which is neither possible nor desirable, but) how can I provide against anything wrong arising out of my absence?

What it is to be "in charge."

How few men, or even women, understand, either in great or in little things, what it is the being "in charge"–I mean, know how to carry out a "charge." From the most colossal calamities, down to the most trifling accidents, results are often traced (or rather *not* traced) to such want of some one "in charge" or of his knowing how to be "in charge." A short time ago the bursting of a funnel-casing on board the finest and strongest ship that ever was built, on her trial trip, destroyed several lives and put several hundreds in jeopardy–not from any undetected flaw in her new and untried works–but from a tap being closed which ought not to have been closed–from what every child knows would make its mother's tea-kettle burst. And this simply because no one seemed to know what it is to be "in charge," or *who* was in charge. Nay more, the jury at the inquest actually altogether ignored the same, and apparently considered the tap "in charge," for they gave as a verdict "accidental death."

This is the meaning of the word, on a large scale. On a much smaller scale, it happened, a short time ago, that an insane person burned herself slowly and intentionally to death, while in her doctor's charge and almost in her nurse's presence. Yet neither was considered "at all to blame." The very fact of the accident happening proves its own case. There is nothing more to be said. Either they did not know their business or they did not know how to perform it.

To be "in charge" is certainly not only to carry out the proper measures yourself but to see that every one else does so too; to see that no one either willfully or ignorantly thwarts or prevents such measures. It is neither to do everything yourself nor to appoint a number of people to each duty, but to ensure that each does that duty to which he is appointed. This is the meaning which must be attached to the word by (above all) those "in charge" of sick, whether of numbers or of individuals, (and indeed I think it is with individual sick that it is least understood. One sick person is often waited on by four with less precision, and is really less cared for than ten who are waited on by one; or at least than 40 who are waited on by 4; and all for want of this one person "in charge.")

It is often said that there are few good servants now; I say there are few good mistresses now. As the jury seems to have thought the tap was in charge of the ship's safety, so mistresses now seem to think the house is in charge of itself. They neither know how to give orders, nor how to teach their servants to obey orders–*i. e.*, to obey intelligently, which is the real meaning of all discipline.

Again, people who are in charge often seem to have a pride in feeling that they will be "missed," that no one can understand or carry on their arrangements, their system, books, accounts, &c., but themselves. It seems to me that the pride is rather in carrying on a system, in keeping stores, closets, books, accounts, &c., so that any body can understand and carry them on–so that, in case of absence or illness, one can deliver every thing up to others and know that all will go on as usual, and that one shall never be missed.

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Why hired nurses give so much trouble.

NOTE.–It is often complained, that professional nurses, brought into private families, in case of sickness, make themselves intolerable by "ordering about" the other servants, under plea of not neglecting the patient. Both things are true; the patient is often neglected, and the servants are often unfairly "put upon." But the fault is generally in the want of management of the head in charge. It is surely for her to arrange both that the nurse's place is, when necessary, supplemented, and that the patient is never neglected–things with a little management quite compatible, and indeed only attainable together. It is certainly not for the nurse to "order about" the servants.

IV. NOISE.

Unnecessary noise.

Unnecessary noise, or noise that creates an expectation in the mind, is that which hurts a patient. It is rarely the loudness of the noise, the effect upon the organ of the ear itself, which appears to affect the sick. How well a patient will generally bear, *e.g.*, the putting up of a scaffolding close to the house, when he cannot bear the talking, still less the whispering, especially if it be of a familiar voice, outside his door.

There are certain patients, no doubt, especially where there is slight concussion or other disturbance of the brain, who are affected by mere noise. But intermittent noise, or sudden and sharp noise, in these as in all other cases, affects far more than continuous noise–noise with jar far more than noise without. Of one thing you may be certain, that anything which wakes a patient suddenly out of his sleep will invariably put him into a state of greater excitement, do him more serious, aye, and lasting mischief, than any continuous noise, however loud.

Never let a patient be waked out of his first sleep.

Never to allow a patient to be waked, intentionally or accidentally, is a *sine qua non* of all good nursing. If he is roused out of his first sleep, he is almost certain to have no more sleep. It is a curious but quite intelligible fact that, if a patient is waked after a few hours' instead of a few minutes' sleep, he is much more likely to sleep again. Because pain, like irritability of brain, perpetuates and intensifies itself. If you have gained a respite of either in sleep you have gained more than the mere respite. Both the probability of recurrence and of the same intensity will be diminished; whereas both will be terribly increased by want of sleep. This is the reason why sleep is so all-important. This is the reason why a patient waked in the early part of his sleep loses not only his sleep, but his power to sleep. A healthy person who allows himself to sleep during the day will lose his sleep at night. But it is exactly the reverse with the sick generally; the more they sleep, the better will they be able to sleep.

Noise which excites expectation.

Whispered conversation in the room.

I have often been surprised at the thoughtlessness, (resulting in cruelty, quite unintentionally) of friends or of doctors who will hold a long conversation just in the room or passage adjoining to the room of the patient, who is either every moment expecting them to come in, or who has just seen them, and knows they are talking about him. If he is an amiable patient, he will try to occupy his attention elsewhere and not to listen–and this makes matters worse–for the strain upon his attention and the effort he makes are so great that it is well if he is not worse for hours after. If it is a whispered conversation in the same room, then it is absolutely cruel; for it is impossible that the patient's attention should not be involuntarily strained to hear. Walking on tip-toe, doing any thing in the room very slowly, are injurious, for exactly the same reasons. A firm light quick step, a steady quick hand are the desiderata; not the slow, lingering, shuffling foot, the timid, uncertain touch. Slowness is not gentleness, though it is often mistaken for such: quickness, lightness, and gentleness are quite compatible. Again, if friends and doctors did but watch, as nurses can and should watch, the features sharpening, the eyes growing almost wild, of fever patients who are listening for the entrance from the corridor of the persons whose voices they are hearing there, these would never run the risk again of creating such expectation, or irritation of mind.–Such unnecessary noise has undoubtedly induced or aggravated delirium in many cases. I have known such–in one case death ensued. It is but fair to say that this death was attributed to fright. It was the result of a long whispered conversation, within sight of the patient, about an impending operation; but any one who has known the more than stoicism, the cheerful coolness, with which the certainty of an operation will be accepted by any patient, capable of bearing an operation at all, if it is properly communicated to him, will hesitate to believe that it was mere fear which produced, as was averred, the fatal result in this instance. It was rather the uncertainty, the strained expectation as to what was to be decided upon.

Or just outside the door.

I need hardly say that the other common cause, namely, for a doctor or friend to leave the patient and communicate his opinion on the result of his visit to the friends just outside the patient's door, or in the adjoining room, after the visit, but within hearing or knowledge of the patient is, if possible, worst of all.

Noise of female dress.

It is, I think, alarming, peculiarly at this time, when the female ink-bottles are perpetually impressing upon us "woman's" "particular worth and general missionariness," to see that the dress of women is daily more and more unfitting them for any "mission," or usefulness at all. It is equally unfitted for all poetic and all domestic purposes. A man is now a more handy and far less objectionable being in a sick room than a woman. Compelled by her dress, every woman now either shuffles or waddles–only a man can cross the floor of a sickroom without shaking it! What is become of woman's light step?–the firm, light, quick step we have been asking for?

Unnecessary noise, then, is the most cruel absence of care which can be inflicted either on sick or well. For, in all these remarks, the sick are only mentioned as suffering in a greater proportion than the well from

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precisely the same causes.

Unnecesary (although slight) noise injures a sick person much more than necessary noise (of a much greater amount).

Patient's repulsion to nurses who rustle.

All doctrines about mysterious affinities and aversions will be found to resolve themselves very much, if not entirely, into presence or absence of care in these things.

A nurse who rustles (I am speaking of nurses professional and unprofessional) is the horror of a patient, though perhaps he does not know why.

The fidget of silk and of crinoline, the rattling of keys, the creaking of stays and of shoes, will do a patient more harm than all the medicines in the world will do him good.

The noiseless step of woman, the noiseless drapery of woman, are mere figures of speech in this day. Her skirts (and well if they do not throw down some piece of furniture) will at least brush against every article in the room as she moves. *

Again, one nurse cannot open the door without making everything rattle. Or she opens the door unnecessarily often, for want of remembering all the articles that might be brought in at once.

A good nurse will always make sure that no door or window in her patient's room shall rattle or creak; that no blind or curtain shall, by any change of wind through the open window be made to flap–especially will she be careful of all this before she leaves her patients for the night. If you wait till your patients tell you, or remind you of these things, where is the use of their having a nurse? There are more shy than exacting patients, in all classes; and many a patient passes a bad night, time after time, rather than remind his nurse every night of all the things she has forgotten.

If there are blinds to your windows, always take care to have them well up, when they are not being used. A little piece slipping down, and flapping with every draught, will distract a patient.

Hurry peculiarly hurtful to the sick.

All hurry or bustle is peculiarly painful to the sick. And when a patient has compulsory occupations to engage him, instead of having simply to amuse himself, it becomes doubly injurious. The friend who remains standing and fidgetting about while a patient is talking business to him, or the friend who sits and proses, the one from an idea of not letting the patient talk, the other from an idea of amusing him,–each is equally inconsiderate. Always sit down when a sick person is talking business to you, show no signs of hurry, give complete attention and full consideration if your advice is wanted, and go away the moment the subject is ended.

How to visit the sick and not hurt them.

Always sit within the patient's view, so that when you speak to him he has not painfully to turn his head round in order to look at you. Everybody involuntarily looks at the person speaking. If you make this act a wearisome one on the part of the patient you are doing him harm. So also if by continuing to stand you make him continuously raise his eyes to see you. Be as motionless as possible, and never gesticulate in speaking to the sick.

Never make a patient repeat a message or request, especially if it be some time after. Occupied patients are often accused of doing too much of their own business. They are instinctively right. How often you hear the person, charged with the request of giving the message or writing the letter, say half an hour afterwards to the patient, "Did you appoint 12 o'clock?" or, "What did you say was the address?" or ask perhaps some much more agitating question–thus causing the patient the effort of memory, or worse still, of decision, all over again. It is really less exertion to him to write his letters himself. This is the almost universal experience of occupied invalids.

This brings us to another caution. Never speak to an invalid from behind, nor from the door, nor from any distance from him, nor when he is doing anything.

The official politeness of servants in these things is so grateful to invalids, that many prefer, without knowing why, having none but servants about them.

These things are not fancy.

These things are not fancy. If we consider that, with sick as with well, every thought decomposes some nervous matter,–that decomposition as well as re-composition of nervous matter is always going on, and more quickly with the sick than with the well,–that, to obtrude abruptly another thought upon the brain while it is in the act of destroying nervous matter by thinking, is calling upon it to make a new exertion,–if we consider these things, which are facts, not fancies, we shall remember that we are doing positive injury by interrupting, by "startling a fanciful" person, as it is called. Alas! it is no fancy.

Interruption damaging to sick.

If the invalid is forced, by his avocations, to continue occupations requiring much thinking, the injury is doubly great. In feeding a patient suffering under delirium or stupor you may suffocate him, by giving him his

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food suddenly, but if you rub his lips gently with a spoon and thus attract his attention, he will swallow the food unconsciously, but with perfect safety. Thus it is with the brain. If you offer it a thought, especially one requiring a decision, abruptly, you do it a real not fanciful injury. Never speak to a sick person suddenly; but, at the same time, do not keep his expectation on the tiptoe.

And to well.

This rule, indeed, applies to the well quite as much as to the sick. I have never known persons who exposed themselves for years to constant interruption who did not muddle away their intellects by it at last. The process with them may be accomplished without pain. With the sick, pain gives warning of the injury.

Keeping a patient standing.

Do not meet or overtake a patient who is moving about in order to speak to him, or to give him any message or letter. You might just as well give him a box on the ear. I have seen a patient fall flat on the ground who was standing when his nurse came into the room. This was an accident which might have happened to the most careful nurse. But the other is done with intention. A patient in such a state is not going to the East Indies. If you would wait ten seconds, or walk ten yards further, any promenade he could make would be over. You do not know the effort it is to a patient to remain standing for even a quarter of a minute to listen to you. If I had not seen the thing done by the kindest nurses and friends, I should have thought this caution quite superfluous. *

Patients dread surprise.

Patients are often accused of being able to "do much more when nobody is by." It is quite true that they can. Unless nurses can be brought to attend to considerations of the kind of which we have given here but a few specimens, a very weak patient finds it really much less exertion to do things for himself than to ask for them. And he will, in order to do them, (very innocently and from instinct) calculate the time his nurse is likely to be absent, from a fear of her "coming in upon" him or speaking to him, just at the moment when he finds it quite as much as he can do to crawl from his bed to his chair, or from one room to another, or down stairs, or out of doors for a few minutes. Some extra call made upon his attention at that moment will quite upset him. In these cases you may be sure that a patient in the state we have described does not make such exertions more than once or twice a day, and probably much about the same hour every day. And it is hard, indeed, if nurse and friends cannot calculate so as to let him make them undisturbed. Remember, that many patients can walk who cannot stand or even sit up. Standing is, of all positions, the most trying to a weak patient.

Everything you do in a patient's room after he is "put up" for the night, increases tenfold the risk of his having a bad night. But, if you rouse him up after he has fallen asleep, you do not risk, you secure him a bad night.

One hint I would give to all who attend or visit the sick, to all who have to pronounce an opinion upon sickness or its progress. Come back and look at your patient *after* he has had an hour's animated conversation with you. It is the best test of his real state we know. But never pronounce upon him from merely seeing what he does, or how he looks, during such a conversation. Learn also carefully and exactly, if you can, how he passed the night after it.

Effects of over-exertion on sick.

People rarely, if ever, faint while making an exertion. It is after it is over. Indeed, almost every effect of over-exertion appears after, not during such exertion. It is the highest folly to judge of the sick, as is so often done, when you see them merely during a period of excitement. People have very often died of that which, it has been proclaimed at the time, has "done them no harm." *

Remember never to lean against, sit upon, or unnecessarily shake, or even touch the bed in which a patient lies. This is invariably a painful annoyance. If you shake the chair on which he sits, he has a point by which to steady himself, in his feet. But on a bed or sofa, he is entirely at your mercy, and he feels every jar you give him all through him.

Difference between real and fancy patients.

In all that we have said, both here and elsewhere, let it be distinctly understood that we are not speaking of hypochondriacs. To distinguish between real and fancied disease forms an important branch of the education of a nurse. To manage fancy patients forms an important branch of her duties. But the nursing which real and that which fancied patients require is of different, or rather of opposite, character. And the latter will not be spoken of here. Indeed, many of the symptoms which are here mentioned are those which distinguish real from fancied disease.

It is true that hypochondriacs very often do that behind a nurse's back which they would not do before her face. Many such I have had as patients who scarcely ate anything at their regular meals; but if you concealed food for them in a drawer, they would take it at night or in secret. But this is from quite a different motive. They do it from the wish to conceal. Whereas the real patient will often boast to his nurse or doctor, if these do not shake their heads at him, of how much he has done, or eaten, or walked. To return to real disease.

Conciseness necessary with sick.

Conciseness and decision are, above all things, necessary with the sick. Let your thought expressed to them be concisely and decidedly expressed. What doubt and hesitation there may be in your own mind must never be communicated to theirs, not even (I would rather say especially not) in little things. Let your doubt be to yourself, your decision to them. People who think outside their heads, the whole process of whose thought

appears, like Homer's, in the act of secretion, who tell everything that led them towards this conclusion and away from that, ought never to be with the sick.

Irresolution most painful to them.

Irresolution is what all patients most dread. Rather than meet this in others, they will collect all their data, and make up their minds for themselves. A change of mind in others, whether it is regarding an operation, or re-writing a letter, always injures the patient more than the being called upon to make up his mind to the most dreaded or difficult decision. Farther than this, in very many cases, the imagination in disease is far more active and vivid than it is in health. If you propose to the patient change of air to one place one hour, and to another the next, he has, in each case, immediately constituted himself in imagination the tenant of the place, gone over the whole premises in idea, and you have tired him as much by displacing his imagination, as if you had actually carried him over both places.

Above all, leave the sick room quickly and come into it quickly, not suddenly, not with a rush. But don't let the patient be wearily waiting for when you will be out of the room or when you will be in it. Conciseness and decision in your movements, as well as your words, are necessary in the sick room, as necessary as absence of hurry and bustle. To possess yourself entirely will ensure you from either failing–either loitering or hurrying.

What a patient must not have to see to.

If a patient has to see, not only to his own but also to his nurse's punctuality, or perseverance, or readiness, or calmness, to any or all of these things, he is far better without that nurse than with her–however valuable and handy her services may otherwise be to him, and however incapable he may be of rendering them to himself.

Reading aloud.

With regard to reading aloud in the sick room, my experience is, that when the sick are too ill to read to themselves, they can seldom bear to be read to. Children, eye-patients, and uneducated persons are exceptions, or where there is any mechanical difficulty in reading. People who like to be read to, have generally not much the matter with them; while in fevers, or where there is much irritability of brain, the effort of listening to reading aloud has often brought on delirium. I speak with great diffidence; because there is an almost universal impression that it is *sparing* the sick to read aloud to them. But two things are certain:–

Read aloud slowly, distinctly, and steadily to the sick.

(1.) If there is some matter which *must* be read to a sick person, do it slowly. People often think that the way to get it over with least fatigue to him is to get it over in least time. They gabble; they plunge and gallop through the reading. There never was a greater mistake. Houdin, the conjuror, says that the way to make a story seem short is to tell it slowly. So it is with reading to the sick. I have often heard a patient say to such a mistaken reader, "Don't read it to me; tell it me." * Unconsciously he is aware that this will regulate the plunging, the reading with unequal paces, slurring over one part, instead of leaving it out altogether, if it is unimportant, and mumbling another. If the reader lets his own attention wander, and then stops to read up to himself, or finds he has read the wrong bit, then it is all over with the poor patient's chance of not suffering. Very few people know how to read to the sick; very few read aloud as pleasantly even as they speak. In reading they sing, they hesitate, they stammer, they hurry, they mumble; when in speaking they do none of these things. Reading aloud to the sick ought always to be rather slow, and exceedingly distinct, but not mouthing–rather monotonous, but not sing song–rather loud but not noisy–and, above all, not too long. Be very sure of what your patient can bear.

Never read aloud by fits and starts to the sick.

(2.) The extraordinary habit of reading to oneself in a sick room, and reading aloud to the patient any bits which will amuse him or more often the reader, is unaccountably thoughtless. What *do* you think the patient is thinking of during your gaps of non-reading? Do you think that he amuses himself upon what you have read for precisely the time it pleases you to go on reading to yourself, and that his attention is ready for something else at precisely the time it pleases you to begin reading again? Whether the person thus read to be sick or well, whether he be doing nothing or doing something else while being thus read to, the self-absorption and want of observation of the person who does it, is equally difficult to understand–although very often the read*ee* is too amiable to say how much it hurts him.

People overhead.

One thing more:–From the flimsy manner in which most modern houses are built, where every step on the stairs, and along the floors, is felt all over the house; the higher the story, the greater the vibration. It is inconceivable how much the sick suffer by having anybody overhead. In the solidly built old houses, which, fortunately, most hospitals are, the noise and shaking is comparatively trifling. But it is a serious cause of suffering, in lightly built houses, and with the irritability peculiar to some diseases. Better far put such patients at the top of the house, even with the additional fatigue of stairs, if you cannot secure the room above them being untenanted; you may otherwise bring on a state of restlessness which no opium will subdue. Do not neglect the warning, when a patient tells you that he "Feels every step above him to cross his heart." Remember that every noise a patient cannot *see* partakes of the character of suddenness to him; and I am persuaded that patients with these peculiarly irritable nerves, are positively less injured by having persons in the same room with them than overhead, or separated by only a thin compartment. Any sacrifice to secure silence for these cases is worth while, because no air, however good, no attendance, however careful, will do anything for such cases without quiet.

NOTE.–The effect of music upon the sick has been scarcely at all noticed. In fact, its expensiveness, as it is now, makes any general application of it quite out of the question. I will only remark here, that wind instruments, including the human voice, and stringed instruments, capable of continuous sound, have generally

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a beneficent effect–while the piano-forte, with such instruments as have *no* continuity of sound, has just the reverse. The finest piano-forte playing will damage the sick, while an air, like "Home, sweet home," or "Assisa a piè d'un salice," on the most ordinary grinding organ, will sensibly soothe them–and this quite independent of association.

V. VARIETY.

Variety a means of recovery.

To any but an old nurse, or an old patient, the degree would be quite inconceivable to which the nerves of the sick suffer from seeing the same walls, the same ceiling, the same surroundings during a long confinement to one or two rooms.

The superior cheerfulness of persons suffering severe paroxysms of pain over that of persons suffering from nervous debility has often been remarked upon, and attributed to the enjoyment of the former of their intervals of respite. I incline to think that the majority of cheerful cases is to be found among those patients who are not confined to one room, whatever their suffering, and that the majority of depressed cases will be seen among those subjected to a long monotony of objects about them.

The nervous frame really suffers as much from this as the digestive organs from long monotony of diet, as *e.g.* the soldier from his twenty-one years' "boiled beef."

Colour and form means of recovery.

The effect in sickness of beautiful objects, of variety of objects, and especially of brilliancy of colour is hardly at all appreciated.

Such cravings are usually called the "fancies" of patients. And often doubtless patients have "fancies," as *e.g.* when they desire two contradictions. But much more often, their (so called) "fancies" are the most valuable indications of what is necessary for their recovery. And it would be well if nurses would watch these (so called) "fancies" closely.

I have seen, in fevers (and felt, when I was a fever patient myself), the most acute suffering produced from the patient (in a hut) not being able to see out of window, and the knots in the wood being the only view. I shall never forget the rapture of fever patients over a bunch of bright-coloured flowers. I remember (in my own case) a nosegay of wild flowers being sent me, and from that moment recovery becoming more rapid.

This is no fancy.

People say the effect is only on the mind. It is no such thing. The effect is on the body, too. Little as we know about the way in which we are affected by form, by colour, and light, we do know this, that they have an actual physical effect.

Variety of form and brilliancy of colour in the objects presented to patients are actual means of recovery.

But it must be *slow* variety, *e.g.,* if you shew a patient ten or twelve engravings successively, ten-to-one that he does not become cold and faint, or feverish, or even sick; but hang one up opposite him, one on each successive day, or week, or month, and he will revel in the variety.

Flowers.

The folly and ignorance which reign too often supreme over the sick-room, cannot be better exemplified than by this. While the nurse will leave the patient stewing in a corrupting atmosphere, the best ingredient of which is carbonic acid; she will deny him, on the plea of unhealthiness, a glass of cut-flowers, or a growing plant. Now, no one ever saw "overcrowding" by plants in a room or ward. And the carbonic acid they give off at nights would not poison a fly. Nay, in overcrowded rooms, they actually absorb carbonic acid and give off oxygen. Cut-flowers also decompose water and produce oxygen gas. It is true there are certain flowers, *e.g.,* lilies, the smell of which is said to depress the nervous system. These are easily known by the smell, and can be avoided.

Effect of body on mind.

Volumes are now written and spoken upon the effect of the mind upon the body. Much of it is true. But I wish a little more was thought of the effect of the body on the mind. You who believe yourselves overwhelmed with anxieties, but are able every day to walk up Regent-street, or out in the country, to take your meals with others in other rooms, &c., &c., you little know how much your anxieties are thereby lightened; you little know how intensified they become to those who can have no change; * how the very walls of their sick rooms seem hung with their cares; how the ghosts of their troubles haunt their beds; how impossible it is for them to escape from a pursuing thought without some help from variety.

A patient can just as much move his leg when it is fractured as change his thoughts when no external help from variety is given him. This is, indeed, one of the main sufferings of sickness; just as the fixed posture is one of the main sufferings of the broken limb.

Help the sick to vary their thoughts.

It is an ever recurring wonder to see educated people, who call themselves nurses, acting thus. They vary their own objects, their own employments, many times a day; and while nursing (!) some bed-ridden sufferer, they let him lie there staring at a dead wall, without any change of object to enable him to vary his thoughts;

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and it never even occurs to them, at least to move his bed so that he can look out of window. No, the bed is to be always left in the darkest, dullest, remotest, part of the room. *

I think it is a very common error among the well to think that "with a little more self-control" the sick might, if they chose, "dismiss painful thoughts" which "aggravate their disease," &c. Believe me, almost *any* sick person, who behaves decently well, exercises more self-control every moment of his day than you will ever know till you are sick yourself. Almost every step that crosses his room is painful to him; almost every thought that crosses his brain is painful to him: and if he can speak without being savage, and look without being unpleasant, he is exercising self-control.

Suppose you have been up all night, and instead of being allowed to have your cup of tea, you were to be told that you ought to "exercise self-control," what should you say? Now, the nerves of the sick are always in the state that yours are in after you have been up all night.

Supply to the sick the defect of manual labour.

We will suppose the diet of the sick to be cared for. Then, this state of nerves is most frequently to be relieved by care in affording them a pleasant view, a judicious variety as to flowers, * and pretty things. Light by itself will often relieve it. The craving for "the return of day," which the sick so constantly evince, is generally nothing but the desire for light, the remembrance of the relief which a variety of objects before the eye affords to the harassed sick mind.

Again, every man and every woman has some amount of manual employment, excepting a few fine ladies, who do not even dress themselves, and who are virtually in the same category, as to nerves, as the sick. Now, you can have no idea of the relief which manual labour is to you–of the degree to which the deprivation of manual employment increases the peculiar irritability from which many sick suffer.

A little needle-work, a little writing, a little cleaning, would be the greatest relief the sick could have, if they could do it; these *are* the greatest relief to you, though you do not know it. Reading, though it is often the only thing the sick can do, is not this relief. Bearing this in mind, bearing in mind that you have all these varieties of employment which the sick cannot have, bear also in mind to obtain for them all the varieties which they can enjoy.

I need hardly say that I am well aware that excess in needle-work, in writing, in any other continuous employment, will produce the same irritability that defect in manual employment (as one cause) produces in the sick.

VI. TAKING FOOD.

Want of attention to hours of taking food.

Every careful observer of the sick will agree in this that thousands of patients are annually starved in the midst of plenty, from want of attention to the ways which alone make it possible for them to take food. This want of attention is as remarkable in those who urge upon the sick to do what is quite impossible to them, as in the sick themselves who will not make the effort to do what is perfectly possible to them.

For instance, to the large majority of very weak patients it is quite impossible to take any solid food before 11 A.M., nor then, if their strength is still further exhausted by fasting till that hour. For weak patients have generally feverish nights and, in the morning, dry mouths; and, if they could eat with those dry mouths, it would be the worse for them. A spoonful of beef-tea, of arrowroot and wine, of egg flip, every hour, will give them the requisite nourishment, and prevent them from being too much exhausted to take at a later hour the solid food, which is necessary for their recovery. And every patient who can swallow at all can swallow these liquid things, if he chooses. But how often do we hear a mutton-chop, an egg, a bit of bacon, ordered to a patient for breakfast, to whom (as a moment's consideration would show us) it must be quite impossible to masticate such things at that hour.

Again, a nurse is ordered to give a patient a tea-cup full of some article of food every three hours. The patient's stomach rejects it. If so, try a table-spoon full every hour; if this will not do, a tea-spoon full every quarter of an hour.

I am bound to say, that I think more patients are lost by want of care and ingenuity in these momentous minutiæ in private nursing than in public hospitals. And I think there is more of the *entente cordiale* to assist one another's hands between the doctor and his head nurse in the latter institutions, than between the doctor and the patient's friends in the private house.

Life often hangs upon minutes in taking food.

If we did but know the consequences which may ensue, in very weak patients, from tem minutes' fasting or repletion (I call it repletion when they are obliged to let too small an interval elapse between taking food and some other exertion, owing to the nurse's unpunctuality), we should be more careful never to let this occur. In very weak patients there is often a nervous difficulty of swallowing, which is so much increased by any other call upon their strength that, unless they have their food punctually at the minute, which minute again must be arranged so as to fall in with no other minute's occupation, they can take nothing till the next respite occurs–so

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that an unpunctuality or delay of ten minutes may very well turn out to be one of two or three hours. And why is it not as easy to be punctual to a minute? Life often literally hangs upon these minutes.

In acute cases, where life or death is to be determined in a few hours, these matters are very generally attended to, especially in Hospitals; and the number of cases is large where the patient is, as it were, brought back to life by exceeding care on the part of the Doctor or Nurse, or both, in ordering and giving nourishment with minute selection and punctuality.

Patients starved to death in chronic cases.

But in chronic cases, lasting over months and years, where the fatal issue is often determined at last by mere protracted starvation, I had rather not enumerate the instances which I have known where a little ingenuity, and a great deal of perseverance, might, in all probability, have averted the result. The consulting the hours when the patient can take food, the observation of the times, often varying, when he is most faint, the altering seasons of taking food, in order to anticipate and prevent such times–all this, which requires observation, ingenuity, and perseverance (and these really constitute the good Nurse), might save more lives than we wot of.

Food never to be left by the patient's side.

To leave the patient's untasted food by his side, from meal to meal, in hopes that he will eat it in the interval is simply to prevent him from taking any food at all. I have known patients literally incapacitated from taking one article of food after another, by this piece of ignorance. Let the food come at the right time, and be taken away, eaten or uneaten, at the right time; but never let a patient have "something always standing" by him, if you don't wish to disgust him of everything.

On the other hand, I have known a patient's life saved (he was sinking for want of food) by the simple question, put to him by the doctor, "But is there no hour when you feel you could eat?" "Oh, yes," he said, "I could always take something at — o'clock and — o'clock." The thing was tried and succeeded. Patients very seldom, however, can tell this; it is for you to watch and find out.

Patient had better not see more food than his own.

A patient should, if possible, not see or smell either the food of others, or a greater amount of food than he himself can consume at one time, or even hear food talked about or see it in the raw state. I know of no exception to the above rule. The breaking of it always induces a greater or less incapacity of taking food.

In hospital wards it is of course impossible to observe all this; and in single wards, where a patient must be continuously and closely watched, it is frequently impossible to relieve the attendant, so that his or her own meals can be taken out of the ward. But it is not the less true that, in such cases, even where the patient is not himself aware of it, his possibility of taking food is limited by seeing the attendant eating meals under his observation. In some cases the sick are aware of it, and complain. A case where the patient was supposed to be insensible, but complained as soon as able to speak, is now present to my recollection.

Remember, however, that the extreme punctuality in well-ordered hospitals, the rule that nothing shall be done in the ward while the patients are having their meals, go far to counterbalance what unavoidable evil there is in having patients together. I have often seen the private nurse go on dusting or fidgeting about in a sick room all the while the patient is eating, or trying to eat.

That the more alone an invalid can be when taking food, the better, is unquestionable; and, even if he must be fed, the nurse should not allow him to talk, or talk to him, especially about food, while eating.

When a person is compelled, by the pressure of occupation, to continue his business while sick, it ought to be a rule WITHOUT ANY EXCEPTION WHATEVER, that no one shall bring business to him or talk to him while he is taking food, nor go on talking to him on interesting subjects up to the last moment before his meals, nor make an engagement with him immediately after, so that there be any hurry of mind while taking them.

Upon the observance of these rules, especially the first, often depends the patient's capability of taking food at all, or, if he is amiable and forces himself to take food, of deriving any nourishment from it.

You cannot be too careful as to quality in sick diet.

A nurse should never put before a patient milk that is sour, meat or soup that is turned, an egg that is bad, or vegetables underdone. Yet often I have seen these things brought in to the sick in a state perfectly perceptible to every nose or eye except the nurse's. It is here that the clever nurse appears; she will not bring in the peccant article, but, not to disappoint the patient, she will whip up something else in a few minutes. Remember that sick cookery should half do the work of your poor patient's weak digestion. But if you further impair it with your bad articles, I know not what is to become of him or of it.

If the nurse is an intelligent being, and not a mere carrier of diets to and from the patient, let her exercise her intelligence in these things. How often we have known a patient eat nothing at all in the day, because one meal was left untasted (at that time he was incapable of eating), at another the milk was sour, the third was spoiled by some other accident. And it never occurred to the nurse to extemporize some expedient,–it never occurred to her that as he had no solid food that day he might eat a bit of toast (say) with his tea in the evening, or he might have some meal an hour earlier. A patient who cannot touch his dinner at two, will often accept it gladly, if brought to him at seven. But somehow nurses never "think of these things." One would imagine they did not consider themselves bound to exercise their judgment; they leave it to the patient. Now I am quite sure that it is

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better for a patient rather to suffer these neglects than to try to teach his nurse to nurse him, if she does not know how. It ruffles him, and if he is ill he is in no condition to teach, especially upon himself. The above remarks apply much more to private nursing than to hospitals.

Nurse must have some rule of thought about her patient's diet.

I would say to the nurse, have a rule of thought about your patient's diet; consider, remember how much he has had, and how much he ought to have to-day. Generally, the only rule of the private patient's diet is what the nurse has to give. It is true she cannot give him what she has not got; but his stomach does not wait for her convenience, or even her necessity. * If it is used to having its stimulus at one hour to-day, and to-morrow it does not have it, because she has failed in getting it, he will suffer. She must be always exercising her ingenuity to supply defects, and to remedy accidents which will happen among the best contrivers, but from which the patient does not suffer the less, because "they cannot be helped."

Keep your patient's cup dry underneath.

One very minute caution,–take care not to spill into your patient's saucer, in other words, take care that the outside bottom rim of his cup shall be quite dry and clean; if, every time he lifts his cup to his lips, he has to carry the saucer with it, or else to drop the liquid upon, and to soil his sheet, or his bed-gown, or pillow, or if he is sitting up, his dress, you have no idea what a difference this minute want of care on your part makes to his comfort and even to his willingness for food.

VII. WHAT FOOD?

Common errors in diet.

I will mention one or two of the most common errors among women in charge of sick respecting sick diet. One is the belief that beef tea is the most nutritive of all articles. Now, just try and boil down a lb. of beef into beef tea, evaporate your beef tea, and see what is left of your beef. You will find that there is barely a teaspoonful of solid nourishment to half a pint of water in beef tea,–nevertheless there is a certain reparative quality in it, we do not know what, as there is in tea,–but it may safely be given in almost any inflammatory disease, and is as little to be depended upon with the healthy or convalescent where much nourishment is required. Again, it is an ever ready saw that an egg is equivalent to a lb. of meat,–whereas it is not at all so. Also, it is seldom noticed with how many patients, particularly of nervous or bilious temperament, eggs disagree. All puddings made with eggs, are distasteful to them in consequence. An egg, whipped up with wine, is often the only form in which they can take this kind of nourishment. Again, if the patient has attained to eating meat, it is supposed that to give him meat is the only thing needful for his recovery; whereas scorbutic sores have been actually known to appear among sick persons living in the midst of plenty in England, which could be traced to no other source that this, viz.: that the nurse, depending on meat alone, had allowed the patient to be without vegetables for a considerable time, these latter being so badly cooked that he always left them untouched. Arrowroot is another grand dependence of the nurse. As a vehicle for wine, and as a restorative quickly prepared, it is all very well. But it is nothing but starch and water. Flour is both more nutritive, and less liable to ferment, and is preferable wherever it can be used.

Beef tea.

Eggs.

Meat without vegetables.

Arrowroot.

Milk, butter, cream &c.

Again, milk and the preparations from milk, are a most important article of food for the sick. Butter is the lightest kind of animal fat, and though it wants the sugar and some of the other elements which there are in milk, yet it is most valuable both in itself and in enabling the patient to eat more bread. Flour, oats, groats, barley, and their kind, are, as we have already said, preferable in all their preparations to all the preparations of arrowroot, sago, tapioca, and their kind. Cream, in many long chronic diseases, is quite irreplaceable by any other article whatever. It seems to act in the same manner as beef tea, and to most it is much easier of digestion than milk. In fact, it seldom disagrees. Cheese is not usually digestible by the sick, but it is pure nourishment for repairing waste; and I have seen sick, and not a few either, whose craving for cheese shewed how much it was needed by them. *

But, if fresh milk is so valuable a food for the sick, the least change or sourness in it, makes it of all articles, perhaps, the most injurious; diarrhoea is a common result of fresh milk allowed to become at all sour. The nurse therefore ought to exercise her utmost care in this. In large institutions for the sick, even the poorest, the utmost care is exercised. Wenham Lake ice is used for this express purpose every summer, while the private patient, perhaps, never tastes a drop of milk that is not sour, all through the hot weather, so little does the private nurse understand the necessity of such care. Yet, if you consider that the only drop of real nourishment in your patient's tea is the drop of milk, and how much almost all English patients depend upon their tea, you will see the great importance of not depriving your patient of this drop of milk. Buttermilk, a totally different thing, is often very useful, especially in fevers.

Sweet things.

In laying down rules of diet, by the amounts of "solid nutriment" in different kinds of food, it is constantly lost sight of what the patient requires to repair his waste, what he can take and what he can't. You cannot diet a patient from a book, you cannot make up the human body as you would make up a prescription,–so many parts "carboniferous," so many parts "nitrogenous" will constitute a perfect diet for a patient. The nurse's observation here will materially assist the doctor–the patient's "fancies" will materially assist the nurse. For instance, sugar is one of the must nutritive of all articles, being pure carbon, and is particularly recommended in some books. But the vast majority of all patients in England, young and old, male and female, rich and poor, hospital and private, dislike sweet things,–and while I have never known a person take to sweets when he was ill who disliked them when he was well, I have known many fond of them when in health, who in sickness would leave off anything sweet, even to sugar in tea,–sweet puddings, sweet drinks, are their aversion; the furred

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tongue almost always likes what is sharp or pungent. Scorbutic patients are an exception, they often crave for sweetmeats and jams.

Jelly.

Jelly is another article of diet in great favor with nurses and friends of the sick; even if it could be eaten solid, it would not nourish, but it is simply the height of folly to take 1/8 oz. of gelatine and make it into a certain bulk by dissolving it in water and then to give it to the sick, as if the mere bulk represented nourishment. It is now known that jelly does not nourish, that it has a tendency to produce diarrhoea,–and to trust to it to repair the waste of a diseased constitution is simply to starve the sick under the guise of feeding them. If 100 spoonfuls of jelly were given in the course of the day, you would have given one spoonful of gelatine, which spoonful has no nutritive power whatever.

And, nevertheless, gelatine contains a large quantity of nitrogen, which is one of the most powerful elements in nutrition; on the other hand, beef tea may be chosen as an illustration of great nutrient power in sickness, coexisting with a very small amount of solid nitrogenous matter.

Beef tea.

Dr. Christison says that "every one will be struck with the readiness with which" certain classes of "patients will often take diluted meat juice or beef tea repeatedly, when they refuse all other kinds of food." This is particularly remarkable in "cases of gastric fever, in which," he says, "little or nothing else besides beef tea or diluted meat juices" has been taken for weeks or even months, "and yet a pint of beef tea contains scarcely 1/4 oz. of anything but water,"–the result is so striking that he asks what is its mode of action? "Not simply nutrient–1/4 oz. of the most nutritive material cannot nearly replace the daily wear and tear of the tissues in any circumstances. Possibly," he says, "it belongs to a new denomination of remedies."

It has been observed that a small quantity of beef tea added to other articles of nutrition augments their power out of all proportion to the additional amount of solid matter.

The reason why jelly should be innutritious and beef tea nutritious to the sick, is a secret yet undiscovered, but it clearly shows that careful observation of the sick is the only clue to the best dietary.

Observation, not chemistry, must decide sick diet.

Chemistry has as yet afforded little insight into the dieting of the sick. All that chemistry can tell us is the amount of "carboniferous" or "nitrogenous" elements discoverable in different dietetic articles. It has given us list of dietetic substances, arranged in the order of their richness in one or other of these principles; but that is all. In the great majority of cases, the stomach of the patient is guided by other principles of selection than merely the amount of carbon or nitrogen in the diet. No doubt, in this as in other things, nature has very definite rules for her guidance, but these rules can only be ascertained by the most careful observation at the bedside. She there teaches us that living chemistry, the chemistry of reparation, is something different from the chemistry of the laboratory. Organic chemistry is useful, as all knowledge is, when we come face to face with nature; but it by no means follows that we should learn in the laboratory any one of the reparative processes going on in disease.

Again, the nutritive power of milk and of the preparations from milk, is very much undervalued; there is nearly as much nourishment in half a pint of milk as there is in a quarter of a lb. of meat. But this is not the whole question or nearly the whole. The main question is what the patient's stomach can assimilate or derive nourishment from, and of this the patient's stomach is the sole judge. Chemistry cannot tell this. The patient's stomach must be its own chemist. The diet which will keep the healthy man healthy, will kill the sick one. The same beef which is the most nutritive of all meat and which nourishes the healthy man, is the least nourishing of all food to the sick man, whose half-dead stomach can *assimilate* no part of it, that is, make no food out of it. On a diet of beef tea healthy men on the other hand speedily lose their strength.

Home-made bread.

I have known patients live for many months without touching bread, because they could not eat baker's bread. These were mostly country patients, but not all. Homemade bread or brown bread is a most important article of diet for many patients. The use of aperients may be entirely superseded by it. Oat cake is another.

Sound observation has scarcely yet been brought to bear on sick diet.

To watch for the opinions, then, which the patient's stomach gives, rather than to read "analyses of foods," is the business of all those who have to settle what the patient is to eat–perhaps the most important thing to be provided for him after the air he is to breathe.

Now the medical man who sees the patient only once a day or even only once or twice a week, cannot possibly tell this without the assistance of the patient himself, or of those who are in constant observation on the patient. The utmost the medical man can tell is whether the patient is weaker or stronger at this visit than he was at the last visit. I should therefore say that incomparably the most important office of the nurse, after she has taken care of the patient's air, is to take care to observe the effect of his food, and report it to the medical attendant.

It is quite incalculable the good that would certainly come from such *sound* and close observation in this almost neglected branch of nursing, or the help it would give to the medical man.

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Tea and coffee.

A great deal too much against tea * is said by wise people, and a great deal too much of tea is given to the sick by foolish people. When you see the natural and almost universal craving in English sick for their "tea," you cannot but feel that nature knows what she is about. But a little tea or coffee restores them quite as much as a great deal, and a great deal of tea and especially of coffee impairs the little power of digestion they have. Yet a nurse, because she sees how one or two cups of tea or coffee restores her patient, thinks that three or four cups will do twice as much. This is not the case at all; it is however certain that there is nothing yet discovered which is a substitute to the English patient for his cup of tea; he can take it when he can take nothing else, and he often can't take anything else if he has it not. I should be very glad if any of the abusers of tea would point out what to give to an English patient after a sleepless night, instead of tea. If you give it at 5 or 6 o'clock in the morning, he may even sometimes fall asleep after it, and get perhaps his only two or three hours' sleep during the twenty-four. At the same time you never should give tea or coffee to the sick, as a rule, after 5 o'clock in the afternoon. Sleeplessness in the early night is from excitement generally and is increased by tea or coffee; sleeplessness which continues to the early morning is from exhaustion often, and is relieved by tea. The only English patients I have ever known refuse tea, have been typhus cases, and the first sign of their getting better was their craving again for tea. In general, the dry and dirty tongue always prefers tea to coffee, and will quite decline milk, unless with tea. Coffee is a better restorative than tea, but a greater impairer of the digestion. Let the patient's taste decide. You will say that, in cases of great thirst, the patient's craving decides that it will drink *a great deal* of tea, and that you cannot help it. But in these cases be sure that the patient requires diluents for quite other purposes than quenching the thirst; he wants a great deal of some drink, not only of tea, and the doctor will order what he is to have, barley water or lemonade, or soda water and milk, as the case may be.

Lehman, quoted by Dr. Christison, says that, among the well and active "the infusion of 1 oz. of roasted coffee daily will diminish the waste" going on in the body "by one-forth," and Dr. Christison adds that tea has the same property. Now this is actual experiment. Lehman weighs the man and finds the fact from his weight. It is not deduced from any "analysis" of food. All experience among the sick shows the same thing. *

Cocoa.

Cocoa is often recommended to the sick in lieu of tea or coffee. but independently of the fact that English sick very generally dislike cocoa, it has quite a different effect from tea or coffee. It is an oily starchy nut having no restorative power at all, but simply increasing fat. It is pure mockery of the sick, therefore, to call it a substitute for tea. For any renovating stimulus it has, you might just as well offer them chestnuts instead of tea.

Bulk.

An almost universal error among nurses is in the bulk of the food and especially the drinks they offer to their patients. Suppose a patient ordered 4 oz. brandy during the day, how is he to take this if you make it into four pints with diluting it? The same with tea and beef tea, with arrowroot, milk, &c. You have not increased the nourishment, you have not increased the renovating power of these articles, by increasing their bulk,–you have very likely diminished both by giving the patient's digestion more to do, and most likely of all, the patient will leave half of what he has been ordered to take, because he cannot swallow the bulk with which you have been pleased to invest it. It requires very nice observation and care (and meets with hardly any) to determine what will not be too thick or strong for the patient to take, while giving him no more than the bulk which he is able to swallow.

VIII. BED AND BEDDING.

Feverishness a symptom of bedding.

A few words upon bedsteads and bedding; and principally as regards patients who are entirely, or almost entirely, confined to bed.

Feverishness is generally supposed to be a symptom of fever–in nine cases out of ten it is a symptom of bedding. * The patient has had re-introduced into the body the emanations from himself which day after day and week after week saturate his unaired bedding. How can it be otherwise? Look at the ordinary bed in which a patient lies.

Uncleanliness of ordinary bedding.

If I were looking out for an example in order to show what *not* to do, I should take the specimen of an ordinary bed in a private house: a wooden bedstead, two or even three mattresses piled up to above the height of a table; a vallance attached to the frame–nothing but a miracle could ever thoroughly dry or air such a bed and bedding. The patient must inevitably alternate between cold damp after his bed is made, and warm damp before, both saturated with organic matter, * and this from the time the mattresses are put under him till the time they are picked to pieces, if this is ever done.

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Air your dirty sheets, not only your clean ones.

If you consider that an adult in health exhales by the lungs and skin in the twenty-four hours three pints at least of moisture, loaded with organic matter ready to enter into putrefaction; that in sickness the quantity is often greatly increased, the quality is always more noxious–just ask yourself next where does all this moisture go to? Chiefly into the bedding, because it cannot go anywhere else. And it stays there; because, except perhaps a weekly change of sheets, scarcely any other airing is attempted. A nurse will be careful to fidgetiness about airing the clean sheets from clean damp, but airing the dirty sheets from noxious damp will never even occur to her. Besides this, the most dangerous effluvia we know of are from the excreta of the sick–these are placed, at least temporarily, where they must throw their effluvia into the under side of the bed, and the space under the bed is never aired; it cannot be, with our arrangements. Must not such a bed be always saturated, and be always the means of re-introducing into the system of the unfortunate patient who lies in it, that excrementitious matter to eliminate which from the body nature had expressly appointed the disease?

My heart always sinks within me when I hear the good house-wife, of every class, say, "I assure you the bed has been well slept in," and I can only hope it is not true. What? is the bed already saturated with somebody else's damp before my patient comes to exhale in it his own damp? Has it not had a single chance to be aired? No, not one. "It has been slept in every night."

Iron spring bedsteads the best.

Comfort and cleanliness of *two* beds.

The only way of really nursing a real patient is to have an *iron* bedstead, with rheocline springs, which are permeable by the air up to the very mattress (no vallance, of course), the mattress to be a thin hair one; the bed to be not above 3 1/2 feet wide. If the patient be entirely confined to his bed, there should be *two* such bedsteads; each bed to be "made" with mattress, sheets, blankets, &c., complete–the patient to pass twelve hours in each bed; on no account to carry his sheets with him. The whole of the bedding to be hung up to air for each intermediate twelve hours. Of course there are many cases where this cannot be done at all–many more where only an approach to it can be made. I am indicating the ideal of nursing, and what I have actually had done. But about the kind of bedstead there can be no doubt, whether there be one or two provided.

Bed not to be too wide.

There is a prejudice in favour of a wide bed–I believe it to be a prejudice. All the refreshment of moving a patient from one side to the other of his bed is far more effectually secured by putting him into a fresh bed; and a patient who is really very ill does not stray far in bed. But it is said there is no room to put a tray down on a narrow bed. No good nurse will ever put a tray on a bed at all. If the patient can turn on his side, he will eat more comfortably from a bed-side table; and on no account whatever should a bed ever be higher than a sofa. Otherwise the patient feels himself "out of humanity's reach;" he can get at nothing for himself; he can move nothing for himself. If the patient cannot turn, a table over the bed is a better thing. I need hardly say that a patient's bed should never have its side against the wall. The nurse must be able to get easily to both sides of the bed, and to reach easily every part of the patient without stretching–a thing impossible if the bed be either too wide or too high.

Bed not to be too high.

When I see a patient in a room nine or ten feet high upon a bed between four and five feet high, with his head, when he is sitting up in bed, actually within two or three feet of the ceiling, I ask myself, is this expressly planned to produce that peculiarly distressing feeling common to the sick, viz., as if the walls and ceiling were closing in upon them, and they becoming sandwiches between floor and ceiling, which imagination is not, indeed, here so far from the truth? If, over and above this, the window stops short of the ceiling, then the patient's head may literally be raised above the stratum of fresh air, even when the window is open. Can human perversity any farther go, in unmaking the process of restoration which God has made? The fact is, that the heads of sleepers or of sick should never be higher than the throat of the chimney, which ensures their being in the current of best air. And we will not suppose it possible that you have closed your chimney with a chimney-board.

If a bed is higher than a sofa, the difference of the fatigue of getting in and out of bed will just make the difference, very often, to the patient (who can get in and out of bed at all) of being able to take a few minutes' exercise, either in the open air or in another room. It is so very odd that people never think of this, or of how many more times a patient who is in bed for the twenty-four hours is obliged to get in and out of bed than they are, who only, it is to be hoped, get into bed once and out of bed once during the twenty-four hours.

Nor in a dark place.

A patient's bed should always be in the lightest spot in the room; and he should be able to see out of the window.

Nor a four poster with curtains.

I need scarcely say that the old four-post bed with curtains is utterly inadmissible, whether for sick or well. Hospital bedsteads are in many respects very much less objectionable than private ones.

Scrofula often a result of disposition of bed clothes.

There is reason to believe that not a few of the apparently unaccountable cases of scrofula among children proceed from the habit of sleeping with the head under the bed clothes, and so inhaling air already breathed, which is farther contaminated by exhalations from the skin. Patients are sometimes given to a similar habit, and it often happens that the bed clothes are so disposed that the patient must necessarily breathe air more or less contaminated by exhalations from his skin. A good nurse will be careful to attend to this. It is an important part, so to speak, of ventilation.

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Bed sores.

It may be worth while to remark, that where there is any danger of bed-sores a blanket should never be placed *under* the patient. It retains damp and acts like a poultice.

Heavy and impervious bed clothes.

Never use anything but light Whitney blankets as bed covering for the sick. The heavy cotton impervious counterpane is bad, for the very reason that it keeps in the emanations from the sick person, while the blanket allows them to pass through. Weak patients are invariably distressed by a great weight of bed clothes, which often prevents their getting any sound sleep whatever.

NOTE–One word about pillows. Every weak patient, be his illness what it may, suffers more or less from difficulty in breathing. To take the weight of the body off the poor chest, which is hardly up to its work as it is, ought therefore to be the object of the nurse in arranging his pillows. Now what does she do and what are the consequences? She piles the pillows one-a-top of the other like a wall of bricks. The head is thrown upon the chest. And the shoulders are pushed forward, so as not to allow the lungs room to expand. The pillows, in fact, lean upon the patient, not the patient upon the pillows. It is impossible to give a rule for this, because it must vary with the figure of the patient. And tall patients suffer much more than short ones, because of the *drag* of the long limbs upon the waist. But the object is to support, with the pillows, the back *below* the breathing apparatus, to allow the shoulders room to fall back, and to support the head, without throwing it forward. The suffering of dying patients is immensely increased by neglect of these points. Any many an invalid, too weak to drag about his pillows himself, slips his book or anything at hand behind the lower part of his back to support it.

IX. LIGHT.

Light essential to both health and recovery.

It is the unqualified result of all my experience with the sick, that second only to their need of fresh air is their need of light; that, after a close room, what hurts them most is a dark room. And that it is not only light but direct sun-light they want. I had rather have the power of carrying my patient about after the sun, according to the aspect of the rooms, if circumstances permit, than let him linger in a room when the sun is off. People think the effect is upon the spirits only. This is by no means the case. The sun is not only a painter but a sculptor. You admit that he does the photograph. Without going into any scientific exposition we must admit that light has quite as real and tangible effects upon the human body. But this is not all. Who has not observed the purifying effect of light, and especially of direct sunlight, upon the air of a room? Here is an observation within everybody's experience. Go into a room where the shutters are always shut (in a sick room or a bedroom there should never be shutters shut), and though the room be uninhabited, though the air had never been polluted by the breathing of human beings, you will observe a close, musty smell of corrupt air, of air *i.e.* unpurified by the effect of the sun's rays. The mustiness of dark rooms and corners, indeed, is proverbial. The cheerfulness of a room, the usefulness of light in treating disease is all-important.

Aspect, view, and sunlight matters of first importance to the sick.

A very high authority in hospital construction has said that people do not enough consider the difference between wards and dormitories in planning their buildings. But I go farther, and say, that healthy people never remember the difference between *bed*-rooms and *sick*-rooms, in making arrangements for the sick. To a sleeper in health it does not signify what the view is from his bed. He ought never to be in it excepting when asleep, and at night. Aspect does not very much signify either (provided the sun reach his bed-room some time in every day, to purify the air), because he ought never to be in his bed-room except during the hours when there is no sun. But the case is exactly reversed with the sick, even should they be as many hours out of their beds as you are in yours, which probably they are not. Therefore, that they should be able, without raising themselves or turning in bed, to see out of window from their beds, to see sky and sun-light at least, if you can show them nothing else, I assert to be, if not of the very first importance for recovery, at least something very near it. And you should therefore look to the position of the beds of your sick one of the very first things. If they can see out of two windows instead of one, so much the better. Again, the morning sun and the mid-day sun–the hours when they are quite certain not to be up, are of more importance to them, if a choice must be made, than the afternoon sun. Perhaps you can take them out of bed in the afternoon and set them by the window, where they can see the sun. But the best rule is, if possible, to give them direct sunlight from the moment he rises till the moment he sets.

Another great difference between the *bed*-room and the *sick*-room is, that the *sleeper* has a very large balance of fresh air to begin with, when he begins the night, if his room has been open all day as it ought to be; the *sick* man has not, because all day he has been breathing the air in the same room, and dirtying it by the emanations from himself. Far more care is therefore necessary to keep up a constant change of air in the sick room.

It is hardly necessary to add that there are acute cases (particularly a few ophthalmic cases, and diseases where the eye is morbidly sensitive), where a subdued light is necessary. But a dark north room is inadmissible even for these. You can always moderate the light by blinds and curtains.

Heavy, thick, dark window or bed curtains should, however, hardly ever be used for any kind of sick in this country. A light white curtain at the head of the bed is, in general, all that is necessary, and a green blind to the window, to be drawn down only when necessary.

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Without sunlight, we degenerate body and mind.

One of the greatest observers of human things (not physiological), says, in another language, "Where there is sun there is thought." All physiology goes to confirm this. Where is the shady side of deep vallies, there is cretinism. Where are cellars and the unsunned sides of narrow streets, there is the degeneracy and weakliness of the human race–mind and body equally degenerating. Put the pale withering plant and human being into the sun, and, if not too far gone, each will recover health and spirit.

Almost all patients lie with their faces to the light.

It is a curious thing to observe how almost all patients lie with their faces turned to the light, exactly as plants always make their way towards the light; a patient will even complain that it gives him pain "lying on that side." "Then why *do* you lie on that side?" He does not know,–but we do. It is because it is the side towards the window. A fashionable physician has recently published in a government report that he always turns his patient's faces from the light. Yes, but nature is stronger than fashionable physicians, and depend upon it she turns the faces back and *towards* such light as she can get. Walk through the wards of a hospital, remember the bed sides of private patients you have seen, and count how many sick you ever saw lying with their faces towards the wall.

X. CLEANLINESS OF ROOMS AND WALLS.

Cleanliness of carpets and furniture.

It cannot be necessary to tell a nurse that she should be clean, or that she should keep her patient clean,–seeing that the greater part of nursing consists in preserving cleanliness. No ventilation can freshen a room or ward where the most scrupulous cleanliness is not observed. Unless the wind be blowing through the windows at the rate of twenty miles an hour, dusty carpets, dirty wainscots, musty curtains and furniture, will infallibly produce a close smell. I have lived in a large and expensively furnished London house, where the only constant inmate in two very lofty rooms, with opposite windows, was myself, and yet, owing to the above-mentioned dirty circumstances, no opening of windows could ever keep those rooms free from closeness; but the carpet and curtains having been turned out of the rooms altogether, they became instantly as fresh as could be wished. It is pure nonsense to say that in London a room cannot be kept clean. Many of our hospitals show the exact reverse.

Dust never removed now.

But no particle of dust is ever or can ever be removed or really got rid of by the present system of dusting. Dusting in these days means nothing but flapping the dust from one part of a room on to another with doors and windows closed. What you do it for I cannot think. You had much better leave the dust alone, if you are not going to take it away altogether. For from the time a room begins to be a room up to the time when it ceases to be one, no one atom of dust ever actually leaves its precincts. Tidying a room means nothing now but removing a thing from one place, which it has kept clean for itself, on to another and a dirtier one. * Flapping by way of cleaning is only admissible in the case of pictures, or anything made of paper. The only way I know to *remove* dust, the plague of all lovers of fresh air, is to wipe everything with a damp cloth. And all furniture ought to be so made as that it may be wiped with a damp cloth without injury to itself, and so polished as that it may be damped without injury to others. To dust, as it is now practised, truly means to distribute dust more equally over a room.

Floors.

As to floors, the only really clean floor I know is the Berlin *lackered* floor, which is wet rubbed and dry rubbed every morning to remove the dust. The French *parquet* is always more or less dusty, although infinitely superior in point of cleanliness and healthiness to our absorbent floor.

For a sick room, a carpet is perhaps the worst expedient which could by any possibility have been invented. If you must have a carpet, the only safety is to take it up two or three times a year, instead of once. A dirty carpet literally infects the room. And if you consider the enormous quantity of organic matter from the feet of people coming in, which must saturate it, this is by no means surprising.

Papered, plastered, oil-painted walls.

As for walls, the worst is the papered wall; the next worst is plaster. But the plaster can be redeemed by frequent lime-washing; the paper requires frequent renewing. A glazed paper gets rid of a good deal of the danger. But the ordinary bed-room paper is all that it ought *not* to be. *

The close connection between ventilation and cleanliness is shown in this. An ordinary light paper will last clean much longer if there is an Arnott's ventilator in the chimney than it otherwise would.

The best wall now extant is oil paint. From this you can wash the animal exuviæ.*

These are what make a room musty

Best kind of wall for a sick-room.

The best wall for a sick-room or ward that could be made is pure white non-absorbent cement or glass, or glazed tiles, if they were made sightly enough.

Air can be soiled just like water. If you blow into water you will soil it with the animal matter from your breath. So it is with air. Air is always soiled in a room where walls and carpets are saturated with animal exhalations.

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Want of cleanliness, then, in rooms and wards, which you have to guard against, may arise in three ways.

Dirty air from without.

1. Dirty air coming in from without, soiled by sewer emanations, the evaporation from dirty streets, smoke, bits of unburnt fuel, bits of straw, bits of horse dung.

Best kind of wall for a house.

If people would but cover the outside walls of their houses with plain or encaustic tiles, what an incalculable improvement would there be in light, cleanliness, dryness, warmth, and consequently economy. The play of a fire-engine would then effectually wash the outside of a house. This kind of *walling* would stand next to paving in improving the health of towns.

Dirty air from within.

2. Dirty air coming from within, from dust, which you often displace, but never remove. And this recalls what ought to be a *sine qua non.* Have as few ledges in your room or ward as possible. And under no pretence have any ledge whatever out of sight. Dust accumulates there, and will never be wiped off. This is a certain way to soil the air. Besides this, the animal exhalations from your inmates saturate your furniture. And if you never clean your furniture properly, how can your rooms or wards be anything but musty? Ventilate as you please, the rooms will never be sweet. Besides this, there is a constant *degradation,* as it is called, taking place from everything except polished or glazed articles–*E.g.*, in colouring certain green papers arsenic is used. Now in the very dust even, which is lying about in rooms hung with this kind of green paper, arsenic has been distinctly detected. You see your dust is anything but harmless; yet you will let such dust lie about your ledges for months, your rooms for ever.

Again, the fire fills the room with coal-dust.

Dirty air from the carpet.

3. Dirty air coming from the carpet. Above all, take care of the carpets, that the animal dirt left there by the feet of visitors does not stay there. Floors, unless the grain is filled up and polished, are just as bad. The smell from the floor of a school-room or ward, when any moisture brings out the organic matter by which it is saturated, might alone be enough to warn us of the mischief that is going on.

Remedies.

The outer air, then, can only be kept clean by sanitary improvements, and by consuming smoke. The expense in soap, which this single improvement would save, is quite incalculable.

The inside air can only be kept clean by excessive care in the ways mentioned above–to rid the walls, carpets, furniture, ledges, &c., of the organic matter and dust–dust consisting greatly of this organic matter–with which they become saturated, and which is what really makes the room musty.

Without cleanliness, you cannot have all the effect of ventilation; without ventilation, you can have no thorough cleanliness.

Very few people, be they of what class they may, have any idea of the exquisite cleanliness required in the sick-room. For much of what I have said applies less to the hospital than to the private sick-room. The smoky chimney, the dusty furniture, the utensils emptied but once a day, often keep the air of the sick constantly dirty in the best private houses.

The well have a curious habit of forgetting that what is to them but a trifling inconvenience, to be patiently "put up" with, is to the sick a source of suffering, delaying recovery, if not actually hastening death. The well are scarcely ever more than eight hours, at most, in the same room. Some change they can always make, if only for a few minutes. Even during the supposed eight hours, they can change their posture or their position in the room. But the sick man who never leaves his bed, who cannot change by any movement of his own his air, or his light, or his warmth; who cannot obtain quiet, or get out of the smoke, or the smell, or the dust; he is really poisoned or depressed by what is to you the merest trifle.

"What can't be cured must be endured," is the very worst and most dangerous maxim for a nurse which ever was made. Patience and resignation in her are but other words for carelessness or indifference–contemptible, if in regard to herself; culpable, if in regard to her sick.

XI. PERSONAL CLEANLINESS.

Poisoning by the skin.

In almost all diseases, the function of the skin is, more or less, disordered; and in many most important diseases nature relieves herself almost entirely by the skin. This is particularly the case with children. But the execretion, which comes from the skin, is left there, unless removed by washing or by the clothes. Every nurse should keep this fact constantly in mind,–for, if she allow her sick to remain unwashed, or their clothing to remain on them after being saturated with perspiration or other execretion, she is interfering injuriously with the natural processes of health just as effectually as if she were to give the patient a dose of slow poison by the mouth. Poisoning by the skin is no less certain than poisoning by the mouth–only it is slower in its operation.

Ventilation and skin-cleanliness equally essential.

The amount of relief and comfort experienced by sick after the skin has been carefully washed and dried, is one of the commonest observations made at a sick bed. But it must not be forgotten that the comfort and relief

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so obtained are not all. They are, in fact, nothing more than a sign that the vital powers have been relieved by removing something that was oppressing them. The nurse, therefore, must never put off attending to the personal cleanliness of her patient under the plea that all that is to be gained is a little relief, which can be quite as well given later.

In all well-regulated hospitals this ought to be be, and generally is, attended to. But it is very generally neglected with private sick.

Just as it is necessary to renew the air round a sick person frequently, to carry off morbid effluvia from the lungs and skin, by maintaining free ventilation, so is it necessary to keep the pores of the skin free from all obstructing excretions. The object, both of ventilation and of skin-cleanliness, is pretty much the same,–to wit, removing noxious matter from the system as rapidly as possible.

Care should be taken in all these operations of sponging, washing, and cleansing the skin, not to expose too great a surface at once, so as to check the perspiration, which would renew the evil in another form.

The various ways of washing the sick need not here be specified,–the less so as the doctors ought to say which is to be used.

In several forms of diarrhoea, dysentery, &c., where the skin is hard and harsh, the relief afforded by washing with a great deal of soft soap is incalculable. In other cases, sponging with tepid soap and water, then with tepid water and drying with a hot towel will be ordered.

Every nurse ought to be careful to wash her hands very frequently during the day. If her face too, so much the better.

One word as to cleanliness merely as cleanliness.

Steaming and rubbing the skin.

Compare the dirtiness of the water in which you have washed when it is cold without soap, cold with soap, hot with soap. You will find the first has hardly removed any dirt at all, the second a little more, the third a great deal more. But hold your hand over a cup of hot water for a minute or two, and then, by merely rubbing with the finger, you will bring off flakes of dirt or dirty skin. After a vapour bath you may peel your whole self clean in this way. What I mean is, that by simply washing or sponging with water you do not really clean your skin. Take a rough towel, dip one corner in very hot water,–if a little spirit be added to it it will be more effectual,–and then rub as if you were rubbing the towel into your skin with your fingers. The black flakes which will come off will convince you that you were not clean before, however much soap and water you have used. These flakes are what require removing. And you can really keep yourself cleaner with a tumbler of hot water and a rough towel and rubbing, than with a whole apparatus of bath and soap and sponge, without rubbing. It is quite nonsense to say that anybody need be dirty. Patients have been kept as clean by these means on a long voyage, when a basin full of water could not be afforded, and when they could not be moved out of their berths, as if all the appurtenances of home had been at hand.

Washing, however, with a large quantity of water has quite other effects than those of mere cleanliness. The skin absorbs the water and becomes softer and more perspirable. To wash with soap and soft water is, therefore, desirable from other points of view than that of cleanliness.

XII. CHATTERING HOPES AND ADVICES.

Advising the sick.

The sick man to his advisers.

"My advisers! Their name is legion. * * * Somehow or other, it seems a provision of the universal destinies, that every man, woman, and child should consider him, her, or itself privileged especially to advise me. Why? That is precisely what I want to know." And this is what I have to say to them. I have been advised to go to every place extant in and out of England–to take every kind of exercise by every kind of cart, carriage–yes, and even swing (!) and dumb-bell (!) in existence; to imbibe every different kind of stimulus that ever has been invented. And this when those *best* fitted to know, viz., medical men, after long and close attendance, had declared any journey out of the question, had prohibited any kind of motion whatever, had closely laid down the diet and drink. What would my advisers say, were they the medical attendants, and I the patient left their advice, and took the casual adviser's? But the singularity in Legion's mind is this: it never occurs to him that everybody else is doing the same thing, and that I the patient *must* perforce say, in sheer self-defence, like Rosalind, "I could not do with all."

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"Chattering Hopes" may seem an odd heading. But I really believe there is scarcely a greater worry which invalids have to endure than the incurable hopes of their friends. There is no one practice against which I can speak more strongly from actual personal experience, wide and long, of its effects during sickness observed both upon others and upon myself. I would appeal most seriously to all friends, visitors, and attendants of the sick to leave off this practice of attempting to "cheer" the sick by making light of their danger and by exaggerating their probabilities of recovery.

Chattering hopes the bane of the sick.

Far more now than formerly does the medical attendant tell the truth to the sick who are really desirous to hear it about their own state.

How intense is the folly, then, to say the least of it, of the friend, be he even a medical man, who thinks that his opinion, given after a cursory observation, will weigh with the patient, against the opinion of the medical attendant, given, perhaps, after years of observation, after using every help to diagnosis afforded by the stethoscope, the examination of pulse, tongue, &c.; and certainly after much more observation than the friend can possibly have had.

Supposing the patient to be possessed of common sense,–how can the "favourable" opinion, if it is to be called an opinion at all, of the casual visitor "cheer" him,–when different from that of the experienced attendant? Unquestionably the latter may, and often does, turn out to be wrong. But which is most likely to be wrong?

The fact is, that the patient * is not "cheered" at all by these well-meaning, most tiresome friends. On the contrary, he is depressed and wearied. If, on the one hand, he exerts himself to tell each successive member of this too numerous conspiracy, whose name is legion, why he does not think as they do,–in what respect he is worse,–what symptoms exist that they know nothing of,–he is fatigued instead of "cheered," and his attention is fixed upon himself. In general, patients who are really ill, do not want to talk about themselves. Hypochondriacs do, but again I say we are not on the subject of hypochondriacs.

Patient does not want to talk of himself.

If, on the other hand, and which is much more frequently the case, the patient says nothing, but the Shakespearian "Oh!" "Ah!" "Go to!" and "In good sooth!" in order to escape from the conversation about himself the sooner, he is depressed by want of sympathy. He feels isolated in the midst of friends. He feels what a convenience it would be, if there were any single person to whom he could speak simply and openly, without pulling the string upon himself of this shower-bath of silly hopes and encouragements; to whom he could express his wishes and directions without that person persisting in saying, "I hope that it will please God yet to give you twenty years," or, "You have a long life of activity before you." How often we see at the end of biographies of cases recorded in medical papers, "after a long illness A. died rather suddenly," or, "unexpectedly both to himself and to others." "Unexpectedly" to others, perhaps, who did not see, because they did not look; but by no means "unexpectedly to himself," as I feel entitled to believe, both from the internal evidence in such stories, and from watching similar cases; there was every reason to expect that A. would die, and he knew it; but he found it useless to insist upon his own knowledge to his friends.

Absurd consolations put forth for the benefit of the sick.

In these remarks I am alluding neither to acute cases which terminate rapidly nor to "nervous" cases.

By the first much interest in their own danger is very rarely felt. In writings of fiction, whether novels or biographies, these death-beds are generally depicted as almost seraphic in lucidity of intelligence. Sadly large has been my experience in death-beds, and I can only say that I have seldom or never seen such. Indifference, excepting with regard to bodily suffering, or to some duty the dying man desires to perform, is the far more usual state.

The "nervous case," on the other hand, delights in figuring to himself and others a fictitious danger.

But the long chronic case, who knows too well himself, and who has been told by his physician that he will never enter active life again, who feels that every month he has to give up something he could do the month before–oh! spare such sufferers your chattering hopes. You do not know how you worry and weary them. Such real sufferers cannot bear to talk of themselves, still less to hope for what they cannot at all expect.

So also as to all the advice showered so profusely upon such sick, to leave off some occupation, to try some other doctor, some other house, climate, pill, powder, or specific; I say nothing of the inconsistency–for these advisers are sure to be the same persons who exhorted the sick man not to believe his own doctor's prognostics, because "doctors are always mistaken," but to believe some other doctor, because "this doctor is always right." Sure also are these advisers to be the persons to bring the sick man fresh occupation, while exhorting him to leave his own.

Wonderful presumption of the advisers of the sick.

Wonderful is the face with which friends, lay and medical, will come in and worry the patient with recommendations to do something or other, having just as little knowledge as to its being feasible, or even safe for him, as if they were to recommend a man to take exercise, not knowing he had broken his leg. What would the friend say, if *he* were the medical attendant, and if the patient, because some *other* friend had come in,

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because somebody, anybody, nobody, had recommended something, anything, nothing, were to disregard *his* orders, and take that other body's recommendation? But people never think of this.

Advisers the same now as two hundred years ago.

A celebrated historical personage has related the commonplaces which, when on the eve of executing a remarkable resolution, were showered in nearly the same words by every one around successively for a period of six months. To these the personage states that it was found least trouble always to reply the same thing, viz., that it could not be supposed that such a resolution had been taken without sufficient previous consideration. To patients enduring every day for years from every friend or acquaintance, either by letter or *viva voce*, some torment of this kind, I would suggest the same answer. It would indeed be spared, if such friends and acquaintances would but consider for one moment, that it is probable the patient has heard such advice at least fifty times before, and that, had it been practicable, it would have been practised long ago. But of such consideration there appears to be no chance. Strange, though true, that people should be just the same in these things as they were a few hundred years ago!

To me these commonplaces, leaving their smear upon the cheerful, single-hearted, constant devotion to duty, which is so often seen in the decline of such sufferers, recall the slimy trail left by the snail on the sunny southern garden-wall loaded with fruit.

Mockery of the advice given to sick.

No mockery in the world is so hollow as the advice showered upon the sick. It is of no use for the sick to say anything, for what the adviser wants is, *not* to know the truth about the state of the patient, but to turn whatever the sick may say to the support of his own argument, set forth, it must be repeated, without any inquiry whatever into the patient's real condition. "But it would be impertinent or indecent in me to make such an inquiry," says the adviser. True; and how much more impertinent is it to give your advice when you can know nothing about the truth, and admit you could not inquire into it.

To nurses I say–these are the visitors who do your patient harm. When you hear him told:–1. That he has nothing the matter with him, and that he wants cheering. 2. That he is committing suicide, and that he wants preventing. 3. That he is the tool of somebody who makes use of him for a purpose. 4. That he will listen to nobody, but is obstinately bent upon his own way; and 5. That he ought to be called to a sense of duty, and is flying in the face of Providence;–then know that your patient is receiving all the injury that he can receive from a visitor.

How little the real sufferings of illness are known or understood. How little does any one in good health fancy him or even *her*self into the life of a sick person.

Means of giving pleasure to the sick.

Do, you who are about the sick or who visit the sick, try and give them pleasure, remember to tell them what will do so. How often in such visits the sick person has to do the whole conversation, exerting his own imagination and memory, while you would take the visitor, absorbed in his own anxieties, making no effort of memory or imagination, for the sick person. "Oh! my dear, I have so much to think of, I really quite forgot to tell him that; besides, I thought he would know it," says the visitor to another friend. How could "he know it?" Depend upon it, the people who say this are really those who have little "to think of." There are many burthened with business who always manage to keep a pigeon-hole in their minds, full of things to tell the "invalid."

I do not say, don't tell him your anxieties–I believe it is good for him and good for you too; but if you tell him what is anxious, surely you can remember to tell him what is pleasant too.

A sick person does so enjoy hearing good news:–for instance, of a love and courtship, while in progress to a good ending. If you tell him only when the marriage takes place, he loses half the pleasure, which God knows he has little enough of; and ten to one but you have told him of some love-making with a bad ending.

A sick person also intensely enjoys hearing of any *material* good, any positive, or practical success of the right. He has so much of books and fiction, of principles, and precepts, and theories; do, instead of advising him with advice he has heard at least fifty times before, tell him of one benevolent act which has really succeeded practically,–it is like a day's health to him. *

You have no idea what the craving of sick with undiminished power of thinking, but little power of doing, is to hear of good practical action, when they can no longer partake in it.

Do observe these things with the sick. Do remember how their life is to them disappointed and incomplete. You see them lying there with miserable disappointments, from which they can have no escape but death, and you can't remember to tell them of what would give them so much pleasure, or at least an hour's variety.

They don't want you to be lachrymose and whining with them, they like you to be fresh and active and interested, but they cannot bear absence of mind, and they are so tired of the advice and preaching they receive from everybody, no matter whom it is, they see.

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There is no better society than babies and sick people for one another. Of course you must manage this so that neither shall suffer from it, which is perfectly possible. If you think the "air of the sick room" bad for the baby, why it is bad for the invalid too, and, therefore, you will of course correct it for both. It freshens up a sick person's whole mental atmosphere to see "the baby." And a very young child, if unspoiled, will generally adapt itself wonderfully to the ways of a sick person, if the time they spend together is not too long.

If you knew how unreasonably sick people suffer from reasonable causes of distress, you would take more pains about all these things. An infant laid upon the sick bed will do the sick person, thus suffering, more good than all your logic. A piece of good news will do the same. Perhaps you are afraid of "disturbing" him. You say there is no comfort for his present cause of affliction. It is perfectly reasonable. The distinction is this, if he is obliged to act, do not "disturb" him with another subject of thought just yet; help him to do what he wants to do; but, if he *has* done this, or if nothing *can* be done, then "disturb" him by all means. You will relieve, more effectually, unreasonable suffering from reasonable causes by telling him "the news," showing him "the baby," or giving him something new to think of or to look at than by all the logic in the world.

It has been very justly said that the sick are like children in this, that there is no *proportion* in events to them. Now it is your business as their visitor to restore this right proportion for them–to show them what the rest of the world is doing. How can they find it out otherwise? You will find them far more open to conviction than children in this. And you will find that their unreasonable intensity of suffering from unkindness, from want of sympathy,&c., will disappear with their freshened interest in the big world's events. But then you must be able to give them real interests, not gossip.

Two classes of patients peculiar to this generation.

NOTE.–There are two classes of patients which are unfortunately becoming more common every day, especially among women of the richer orders, to whom all these remarks are preeminently inapplicable. 1. Those who make health an excuse for doing nothing, and at the same time allege that the being able to do nothing is their only grief. 2. Those who have brought upon themselves ill-health by over pursuit of amusement, which they and their friends have most unhappily called intellectual activity. I scarcely know a greater injury that can be inflicted than the advice too often given to the first class to "vegetate"–or than the admiration too often bestowed on the latter class for "pluck."

XIII. OBSERVATION OF THE SICK.

What is the use of the question, Is he better?

There is no more silly or universal question scarcely asked than this,"Is he better?" Ask it of the medical attendant, if you please. But of whom else, if you wish for a real answer to your question, would you ask? Certainly not of the casual visitor; certainly not of the nurse, while the nurse's observation is so little exercised as it is now. What you want are facts, not opinion–for who can have any opinion of any value as to whether the patient is better or worse, excepting the constant medical attendant, or the really observing nurse?

The most important practical lesson that can be given to nurses is to teach them what to observe–how to observe–what symptoms indicate improvement–what the reverse–which are of importance–which are of none–which are the evidence of neglect–and of what kind of neglect.

All this is what ought to make part, and an essential part, of the training of every nurse. At present how few there are, either professional or unprofessional, who really know at all whether any sick person they may be with is better or worse.

The vagueness and looseness of the information one receives in answer to that much abused question, "Is he better?" would be ludicrous, if it were not painful. The only sensible answer (in the present state of knowledge about sickness) would be "How can I know? I cannot tell how he was when I was not with him."

I can record but a very few specimens of the answers * which I have heard made by friends and nurses, and accepted by physicians and surgeons at the very bed-side of the patient, who could have contradicted every word, but did not–sometimes from amiability, often from shyness, oftenest from languor!

"How often have the bowels acted, nurse?" "Once, sir." This generally means that the utensil has been emptied once, it having been used perhaps seven or eight times.

"Do you think the patient is much weaker than he was six weeks ago?" "Oh no, sir; you know it is very long since he has been up and dressed, and he can get across the room now." This means that the nurse has not observed that whereas six weeks ago he sat up and occupied himself in bed, he now lies still doing nothing; that, although he can "get across the room," he cannot stand for five seconds.

Another patient who is eating well, recovering steadily, although slowly, from fever, but cannot walk or stand, is represented to the doctor as making no progress at all.

Leading questions useless or misleading.

Questions, too, as asked now (but too generally) of or about patients, would obtain no information at all about them, even if the person asked of had every information to give. The question is generally a leading

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question; and it is singular that people never think what must be the answer to this question before they ask it: for instances, "Has he had a good night?" Now, one patient will think he has a bad night if he has not slept ten hours without waking. Another does not think he has a bad night if he has had intervals of dosing occasionally. The same answer has actually been given as regarded two patients–one who had been entirely sleepless for five times twenty-four hours, and died of it, and another who had not slept the sleep of a regular night, without waking. Why cannot the question be asked, How many hours' sleep has — had? and at what hours of the night? * "I have never closed my eyes all night," an answer as frequently made when the speaker has had several hours' sleep as when he has had none, would then be less often said. Lies, intentional and unintentional, are much seldomer told in answer to precise than to leading questions. Another frequent error is to inquire whether one cause remains, and not whether the effect which may be produced by a great many different causes, *not* inquired after, remains. As when it is asked, whether there was noise in the street last night; and if there were not, the patient is reported, without more ado, to have had a good night. Patients are completely taken aback by these kinds of leading questions, and give only the exact amount of information asked for, even when they know it to be completely misleading. The shyness of patients is seldom allowed for.

How few there are who, by five or six pointed questions, can elicit the whole case, and get accurately to know and to be able to report *where* the patient is.

Means of obtaining inaccurate information.

I knew a very clever physician, of large dispensary and hospital practice, who invariably began his examination of each patient with "Put your finger where you be bad." That man would never waste his time with collecting inaccurate information from nurse or patient. Leading questions always collect inaccurate information.

At a recent celebrated trial, the following leading question was put successively to nine distinguished medical men. "Can you attribute these symptoms to anything else but poison?" And out of the nine, eight answered "No!" without any qualification whatever. It appeared, upon cross-examination:–1. That none of them had ever seen a case of the kind of poisoning supposed. 2. That none of them had ever seen a case of the kind of disease to which the death, if not to poison, was attributable. 3. That none of them were even aware of the main fact of the disease and condition to which the death was attributable.

Surely nothing stronger can be adduced to prove what use leading questions are of, and what they lead to.

I had rather not say how many instances I have known, where, owing to this system of leading questions, the patient has died, and the attendants have been actually unaware of the principal feature of the case.

As to food patient takes or does not take.

It is useless to go through all the particulars, besides sleep, in which people have a peculiar talent for gleaning inaccurate information. As to food, for instance, I often think that most common question, How is your appetite? can only be put because the questioner believes the questioned has really nothing the matter with him, which is very often the case. But where there is, the remark holds good which has been made about sleep. The *same* answer will often be made as regards a patient who cannot take two ounces of solid food per diem, and a patient who does not enjoy five meals a day as much as usual.

Again, the question, How is your appetite? is often put when How is your digestion? is the question meant. No doubt the two things depend on one another. But they are quite different. Many a patient can eat, if you can only "tempt his appetite." The fault lies in your not having got him the thing that he fancies. But many another patient does not care between grapes and turnips–everything is equally distasteful to him. He would try to eat anything which would do him good; but every thing "makes him worse." The fault here generally lies in the cooking. It is not his "appetite" which requires "tempting," it is his digestion which requires sparing. And good sick cookery will save the digestion half its work.

There may be four different causes, any one of which will produce the same result, viz., the patient slowly starving to death from want of nutrition:

Defect in cooking;
Defect in choice of diet;
Defect in choice of hours for taking diet;
Defect of appetite in patient.

Yet all these are generally comprehended in the one sweeping assertion that the patient has "no appetite."

Surely many lives might be saved by drawing a closer distinction; for the remedies are as diverse as the causes. The remedy for the first is to cook better; for the second, to choose other articles of diet; for the third, to watch for the hours when the patient is in want of food; for the fourth, to show him what he likes, and sometimes unexpectedly. But no one of these remedies will do for any other of the defects not corresponding with it.

I cannot too often repeat that patients are generally either too languid to observe these things, or too shy to speak about them; nor is it well that they should be made to observe them, it fixes their attention upon

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themselves.

Again, I say, what *is* the nurse or friend there for except to take note of these things, instead of the patient doing so? *

As to diarrhoea.

Again, the question is sometimes put, Is there diarrhoea? And the answer will be the same, whether it is just merging into cholera, whether it is a trifling degree brought on by some trifling indiscretion, which will cease the moment the cause is removed, or whether there is no diarrhoea at all, but simply relaxed bowels.

It is useless to multiply instances of this kind. As long as observation is so little cultivated as it is now, I do believe that it is better for the physician *not* to see the friends of the patient at all. They will oftener mislead him than not. And as often by making the patient out worse as better than he really is.

In the case of infants, *everything* must depend upon the accurate observation of the nurse or mother who has to report. And how seldom is this condition of accuracy fulfilled.

Means of cultivating sound and ready observation.

A celebrated man, though celebrated only for foolish things, has told us that one of his main objects in the education of his son, was to give him a ready habit of accurate observation, a certainty of perception, and that for this purpose one of his means was a month's course as follows:–he took the boy rapidly past a toy-shop; the father and son then described to each other as many of the objects as they could, which they had seen in passing the windows, noting them down with pencil and paper, and returning afterwards to verify their own accuracy. The boy always succeeded best, *e.g.*, if the father described 30 objects, the boy did 40, and scarcely ever made a mistake.

I have often thought how wise a piece of education this would be for much higher objects; and in our calling of nurses the thing itself is essential. For it may safely be said, not that the habit of ready and correct observation will by itself make us useful nurses, but that without it we shall be useless with all our devotion.

I have known a nurse in charge of a set of wards, who not only carried in her head all the little varieties in the diets which each patient was allowed to fix for himself, but also exactly what each patient had taken during each day. I have known another nurse in charge of one single patient, who took away his meals day after day all but untouched, and never knew it.

If you find it helps you to note down such things on a bit of paper, in pencil, by all means do so. I think it more often lames than strengthens the memory and observation. But if you cannot get the habit of observation one way or other, you had better give up the being a nurse, for it is not your calling, however kind and anxious you may be.

Surely you can learn at least to judge with the eye how much an oz. of solid food is, how much an oz. of liquid. You will find this helps your observation and memory very much, you will then say to yourself, "A. took about an oz. of his meat to day;" "B. took three times in 24 hours about 1/4 pint of beef tea; "instead of saying "B. has taken nothing all day," or "I gave A. his dinner as usual."

Sound and ready observation essential in a nurse.

I have known several of our real old-fashioned hospital "sisters," who could, as accurately as a measuring glass, measure out all their patients' wine and medicine by the eye, and never be wrong. I do not recommend this, one must be very sure of one's self to do it. I only mention it, because if a nurse can by practice measure medicine by the eye, surely she is no nurse who cannot measure by the eye about how much food (in oz.) her patient has taken. * In hospitals those who cut up the diets give with sufficient accuracy, to each patient, his 12 oz. or his 6 oz. of meat without weighing. Yet a nurse will often have patients loathing all food and incapable of any will to get well, who just tumble over the contents of the plate or dip the spoon in the cup to deceive the nurse, and she will take it away without ever seeing that there is just the same quantity of food as when she brought it, and she will tell the doctor, too, that the patient has eaten all his diets as usual, when all she ought to have meant is that she has taken away his diets as usual.

Now what kind of a nurse is this?

Difference of excitable and *accumulative* temperaments.

I would call attention to something else, in which nurses frequently fail in observation. There is a well-marked distinction between the excitable and what I will call the *accumulative* temperament in patients. One will blaze up at once, under any shock or anxiety, and sleep very comfortably after it; another will seem quite calm and even torpid, under the same shock, and people say, "He hardly felt it at all," yet you will find him some time after slowly sinking. The same remark applies to the action of narcotics, of aperients, which, in the one, take effect directly, in the other not perhaps for twenty-four hours. A journey, a visit, an unwonted exertion, will affect the one immediately, but he recovers after it; the other bears it very well at the time, apparently, and dies or is prostrated for life by it. People often say how difficult the excitable temperament is to manage. I say how difficult is the *accumulative*temperament. With the first you have an out-break which you could anticipate, and it is all over. With the second you never know where you are–you never know when the consequences are over. And it requires your closest observation to know what *are* the consequences of what–

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for the consequent by no means follows immediately upon the antecedent–and coarse observation is utterly at fault.

Superstition the fruit of bad observation.

Almost all superstitions are owing to bad observation, to the *post hoc, ergo propter hoc;* and bad observers are almost all superstitious. Farmers used to attribute disease among cattle to witchcraft; weddings have been attributed to seeing one magpie, deaths to seeing three; and I have heard the most highly educated now-a-days draw consequences for the sick closely resembling these.

Physiognomy of disease little shewn by the face.

Another remark: although there is unquestionably a physiognomy of disease as well as of health; of all parts of the body, the face is perhaps the one which tells the least to the common observer or the casual visitor. Because, of all parts of the body, it is the one most exposed to other influences, besides health. And people never, or scarcely ever, observe enough to know how to distinguish between the effect of exposure, of robust health, of a tender skin, of a tendency to congestion, of suffusion, flushing, or many other things. Again, the face is often the last to shew emaciation. I should say that the hand was a much surer test than the face, both as to flesh, colour, circulation, &c., &c. It is true that there are *some* diseases which are only betrayed at all by something in the face, *e.g.*, the eye or the tongue, as great irritability of brain by the appearance of the pupil of the eye. But we are talking of casual, not minute, observation. And few minute observers will hesitate to say that far more untruth than truth is conveyed by the oft repeated words, He *looks* well, or ill, or better or worse.

Wonderful is the way in which people will go upon the slightest observation, or often upon no observation at all, or upon some *saw* which the world's experience, if it had any, would have pronounced utterly false long ago.

I have known patients dying of sheer pain, exhaustion, and want of sleep, from one of the most lingering and painful diseases known, preserve, till within a few days of death, not only the healthy colour of the cheek, but the mottled appearance of a robust child. And scores of times have I heard these unfortunate creatures assailed with, "I am glad to see you looking so well." "I see no reason why you should not live till ninety years of age." "Why don't you take a little more exercise and amusement," with all the other commonplaces with which we are so familiar.

There is, unquestionably, a physiognomy of disease. Let the nurse learn it.

The experienced nurse can always tell that a person has taken a narcotic the night before by the patchiness of the colour about the face, when the re-action of depression has set in; that very colour which the inexperienced will point to as a proof of health.

There is, again, a faintness, which does not betray itself by the colour at all, or in which the patient becomes brown instead of white. There is a faintness of another kind which, it is true, can always be seen by the paleness.

But the nurse seldom distinguishes. She will talk to the patient who is too faint to move, without the least scruple, unless he is pale and unless, luckily for him, the muscles of the throat are affected and he loses his voice.

Yet these two faintnesses are perfectly distinguishable, by the mere countenance of the patient.

Peculiarities of patients.

Again, the nurse must distinguish between the idiosyncracies of patients. One likes to suffer out all his suffering alone, to be as little looked after as possible. Another likes to be perpetually made much of and pitied, and to have some one always by him. Both these peculiarities might be observed and indulged much more than they are. For quite as often does it happen that a busy attendance is forced upon the first patient, who wishes for nothing but to be "let alone," as that the second is left to think himself neglected.

Nurse must observe for herself increase of patient's weakness, patient will not tell her.

Again, I think that few things press so heavily on one suffering from long and incurable illness, as the necessity of recording in words from time to time, for the information of the nurse, who will not otherwise see, that he cannot do this or that, which he could do a month or a year ago. What is a nurse there for if she cannot observe these things for herself? Yet I have known–and known too among those–and *chiefly* among those–whom money and position put in possession of everything which money and position could give–I have known, I say, more accidents (fatal, slowly or rapidly) arising from this want of observation among nurses than from almost anything else. Because a patient could get out of a warm-bath alone a month ago–because a patient could walk as far as his bell a week ago, the nurse concludes that he can do so now. She has never observed the change; and the patient is lost from being left in a helpless state of exhaustion, till some one accidentally comes in. And this not from any unexpected apoplectic, paralytic, or fainting fit (though even these could be expected far more, at least, than they are now, if we did but *observe*). No, from the unexpected, or to be expected, inevitable, visible, calculable, uninterrupted increase of weakness, which none need fail to observe.

Accidents arising from the nurse's want of observation.

Again, a patient not usually confined to bed, is compelled by an attack of diarrhoea, vomiting, or other accident, to keep his bed for a few days; he gets up for the first time, and the nurse lets him go into another

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room, without coming in, a few minutes afterwards, to look after him. It never occurs to her that he is quite certain to be faint, or cold, or to want something. She says, as her excuse, Oh, he does not like to be fidgetted after. Yes, he said so some weeks ago; but he never said he did not like to be "fidgetted after," when he is in the state he is in now; and if he did, you ought to make some excuse to go in to him. More patients have been lost in this way than is at all generally known, viz., from relapses brought on by being left for an hour or two faint, or cold, or hungry, after getting up for the first time.

Is the faculty of observing on the decline?

Yet it appears that scarcely any improvement in the faculty of observing is being made. Vast has been the increase of knowledge in pathology–that science which teaches us the final change produced by disease on the human frame–scarce any in the art of observing the signs of the change while in progress. Or, rather, is it not to be feared that observation, as an essential part of medicine, has been declining?

Which of us has not heard fifty times, from one or another, a nurse, or a friend of the sick, aye, and a medical friend too, the following remark:–"So A is worse, or B is dead. I saw him the day before; I thought him so much better; there certainly was no appearance from which one could have expected so sudden (?) a change." I have never heard any one say, though one would think it the more natural thing, "There *must* have been *some* appearance, which I should have seen if I had but looked; let me try and remember what there was, that I may observe another time." No, this is not what people say. They boldly assert that there was nothing to observe, not that their observation was at fault.

Let people who have to observe sickness and death look back and try to register in their observation the appearances which have preceded relapse, attack, or death, and not assert that there were none, or that there were not the *right* ones.*

Observation of general conditions.

A want of the habit of observing conditions and an inveterate habit of taking averages are each of them often equally misleading.

Men whose profession like that of medical men leads them to observe only, or chiefly, palpable and permanent organic changes are often just as wrong in their opinion of the result as those who do not observe at all. For instance, there is a broken leg; the surgeon has only to look at it once to know; it will not be different if he sees it in the morning to what it would have been had he seen it in the evening. And in whatever conditions the patient is, or is likely to be, there will still be the broken leg, until it is set. The same with many organic diseases. An experienced physician has but to feel the pulse once, and he knows that there is aneurism which will kill some time or other.

But with the great majority of cases, there is nothing of the kind; and the power of forming any correct opinion as to the result must entirely depend upon an enquiry into all the conditions in which the patient lives. In a complicated state of society in large towns, death, as every one of great experience knows, is far less often produced by any one organic disease than by some illness, after many other diseases, producing just the sum of exhaustion necessary for death. There is nothing so absurd, nothing so misleading as the verdict one so often hears: So-and-so has no organic disease,–there is no reason why he should not live to extreme old age; sometimes the clause is added, sometimes not: Provided he has quiet, good food, good air, &c., &c., &c.: the verdict is repeated by ignorant people *without* the latter clause; or there is no possibility of the conditions of the latter clause being obtained; and this, the *only* essential part of the whole, is made of no effect. I have heard a physician, deservedly eminent, assure the friends of a patient of his recovery. Why? Because he had now prescribed a course, every detail of which the patient had followed for years. And because he had forbidden a course which the patient could not by any possibility alter. *

Undoubtedly a person of no scientific knowledge whatever but of observation and experience in these kinds of conditions, will be able to arrive at a much truer guess as to the probable duration of life of members of a family or inmates of a house, than the most scientific physician to whom the same persons are brought to have their pulse felt; no enquiry being made into their conditions.

In Life Insurance and such like societies, were they instead of having the person examined by the medical man, to have the houses, conditions, ways of life, of these persons examined, at how much truer results would they arrive! W. Smith appears a fine hale man, but it might be known that the next cholera epidemic he runs a bad chance. Mr. and Mrs. J. are a strong healthy couple, but it might be known that they live in such a house, in such a part of London, so near the river that they will kill four-fifths of their children; which of the children will be the ones to survive might also be known.

"Average rate of mortality" tells us only that so many per cent. will die. Observation must tell us *which* in the hundred they will be who will die.

Averages again seduce us away from minute observation. "Average mortalities" merely tell that so many per cent. die in this town and so many in that, per annum. But whether A or B will be among these, the "average rate" of course does not tell. We know, say, that from 22 to 24 per 1,000 will die in London next year. But minute enquiries into conditions enable us to know that in such a district, nay, in such a street,–or even on one side of that street, in such a particular house, or even on one floor of that particular house, will be the excess of mortality, that is, the person will die who ought not to have died before old age.

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Now, would it not very materially alter the opinion of whoever were endeavouring to form one, if he knew that from that floor, of that house, of that street the man came.

Much more precise might be our observations even than this, and much more correct our conclusions.

It is well known that the same names may be seen constantly recurring on workhouse books for generations. That is, the persons were born and brought up, and will be born and brought up, generation after generation, in the conditions which make paupers. Death and disease are like the workhouse, they take from the same family, the same house, or in other words, the same conditions. Why will we not observe what they are?

The close observer may safely predict that such a family, whether its members marry or not, will become extinct; that such another will degenerate morally and physically. But who learns the lesson? On the contrary, it may be well known that the children die in such a house at the rate of 8 out of 10; one would think that nothing more need be said; for how could Providence speak more distinctly? yet nobody listens, the family goes on living there till it dies out, and then some other family takes it. Neither would they listen "if one rose from the dead."

What observation is for.

In dwelling upon the vital importance of *sound* observation, it must never be lost sight of what observation is for. It is not for the sake of piling up miscellaneous information or curious facts, but for the sake of saving life and increasing health and comfort. The caution may seem useless, but it is quite surprising how many men (some women do it too), practically behave as if the scientific end were the only one in view, or as if the sick body were but a reservoir for stowing medicines into, and the surgical disease only a curious case the sufferer has made for the attendant's special information. This is really no exaggeration. You think, if you suspected your patient was being poisoned, say, by a copper kettle, you would instantly, as you ought, cut off all possible connection between him and the suspected source of injury, without regard to the fact that a curious mine of observation is thereby lost. But it is not everybody who does so, and it has actually been made a question of medical ethics, what should the medical man do if he suspected poisoning? The answer seems a very simple one,–insist on a confidential nurse being placed with the patient, or give up the case.

What a confidential nurse should be.

And remember every nurse should be one who is to be depended upon, in other words, capable of being a "confidential" nurse. She does not know how soon she may find herself placed in such a situation; she must be no gossip, no vain talker; she should never answer questions about her sick except to those who have a right to ask them; she must, I need not say, be strictly sober and honest; but more than this, she must be a religious and devoted woman; she must have a respect for her own calling, because God's precious gift of life is often literally placed in her hands; she must be a sound, and close, and quick observer; and she must be a woman of delicate and decent feeling.

Observation is for practical purposes.

To return to the question of what observation is for:–It would really seem as if some had considered it as its own end, as if detection, not cure, was their business; nay more, in a recent celebrated trial, three medical men, according to their own account, suspected poison, prescribed for dysentery, and left the patient to the poisoner. This is an extreme case. But in a small way, the same manner of acting falls under the cognizance of us all. How often the attendants of a case have stated that they knew perfectly well that the patient could not get well in such an air, in such a room, or under such circumstances, yet have gone on dosing him with medicine, and making no effort to remove the poison from him, or him from the poison which they knew was killing him; nay, more, have sometimes not so much as mentioned their conviction in the right quarter–that is, to the only person who could act in the matter.

CONCLUSION.

Sanitary nursing as essential in surgical as in medical cases, but not to supercede surgical nursing.

The whole of the preceding remarks apply even more to children and to puerperal woman than to patients in general. They also apply to the nursing of surgical, quite as much as to that of medical cases. Indeed, if it be possible, cases of external injury require such care even more than sick. In surgical wards, one duty of every nurse certainly is *prevention.* Fever, or hospital gangrene, or pyoemia, or purulent discharge of some kind may else supervene. Has she a case of compound fracture, of amputation, or of erysipelas, it may depend very much on how she looks upon the things enumerated in these notes, whether one or other of these hospital diseases attacks her patient or not. If she allows her ward to become filled with the peculiar close foetid smell, so apt to be produced among surgical cases, especially where there is great suppuration and discharge, she may see a vigorous patient in the prime of life gradually sink and die where, according to all human probability, he ought to have recovered. The surgical nurse must ever be on the watch, ever on her guard, against the want of cleanliness, foul air, want of light, and of warmth.

Nevertheless let no one think that because *sanitary* nursing is the subject of these notes, therefore, what may be called the handicraft of nursing is to be undervalued. A patient may be left to bleed to death in a sanitary palace. Another who cannot move himself may die of bed-sores, because the nurse does not know how to change and clean him, while he has every requisite of air, light, and quiet. But nursing, as a handicraft, has not been treated of here for three reasons: 1. That these notes do not pretend to be a manual for nursing, any more than for cooking for the sick; 2. That the writer, who has herself seen more of what may be called surgical nursing, *i.e.* practical manual nursing, than, perhaps, any one in Europe, honestly believes that it is impossible

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to learn it from any book, and that it can only be thoroughly learnt in the wards of a hospital; and she also honestly believes that the perfection of surgical nursing may be seen practised by the old-fashioned "Sister" of a London hospital, as it can be seen nowhere else in Europe. 3. While thousands die of foul air, &c., who have this surgical nursing to perfection, the converse is comparatively rare.

Children: their greater susceptibility to the same things.

To revert to children. They are much more susceptible than grown people to all noxious influences. They are affected by the same things, but much more quickly and seriously, viz., by want of fresh air, of proper warmth, want of cleanliness in house, clothes, bedding, or body, by startling noises, improper food, or want of punctuality, by dulness and by want of light, by too much or too little covering in bed, or when up, by want of the spirit of management generally in those in charge of them. One can, therefore, only press the importance, as being yet greater in the case of children, greatest in the case of sick children, of attending to these things.

That which, however, above all, is known to injure children seriously is foul air, and most seriously at night. Keeping the rooms where they sleep tight shut up, is destruction to them. And, if the child's breathing be disordered by disease, a few hours only of such foul air may endanger its life, even where no inconvenience is felt by grown-up persons in the same room.

The following passages, taken out of an excellent "Lecture on Sudden Death in Infancy and Childhood," just published, show the vital importance of careful nursing of children. "In the great majority of instances, when death suddenly befalls the infant or young child, it is an *accident;* it is not a necessary result of any disease from which it is suffering."

It may be here added, that it would be very desirable to know how often death is, with adults, "not a necessary, inevitable result of any disease." Omit the word "sudden;" (for *sudden* death is comparatively rare in middle age;) and the sentence is almost equally true for all ages.

The following causes of "accidental" death in sick children are enumerated:–"Sudden noises, which startle–a rapid change of temperature, which chills the surface, though only for a moment–a rude awakening from sleep–or even an over-hasty, or an overfull meal"–"any sudden impression on the nervous system–any hasty alteration of posture–in short, any cause whatever by which the respiratory process may be disturbed."

It may again be added, that, with very weak adult patients, these causes are also (not often "suddenly fatal," it is true, but) very much oftener than is at all generally known, irreparable in their consequences.

Both for children and for adults, both for sick and for well (although more certainly in the case of sick children than in any others), I would here again repeat, the most frequent and fatal cause of all is sleeping, for even a few hours, much more for weeks and months, in foul air, a condition which, more than any other condition, disturbs the respiratory process, and tends to produce "accidental" death in disease.

I need hardly here repeat the warning against any confusion of ideas between cold and fresh air. You may chill a patient fatally without giving him fresh air at all. And you can quite well, nay, much better, give him fresh air without chilling him. This is the test of a good nurse.

In cases of long recurring faintnesses from disease, for instance, especially disease which affects the organs of breathing, fresh air to the lungs, warmth to the surface, and often (as soon as the patient can swallow) hot drink, these are the right remedies and the only ones. Yet, oftener than not, you see the nurse or mother just reversing this; shutting up every cranny through which fresh air can enter, and leaving the body cold, or perhaps throwing a greater weight of clothes upon it, when already it is generating too little heat.

"Breathing carefully, anxiously, as though respiration were a function which required all the attention for its performance," is cited as a not unusual state in children, and as one calling for care in all the things enumerated above. That breathing becomes an almost voluntary act, even in grown up patients who are very weak, must often have been remarked.

"Disease having interfered with the perfect accomplishment of the respiratory function, some sudden demand for its complete exercise, issues in the sudden stand-still of the whole machinery," is given as one process:–"life goes out for want of nervous power to keep the vital functions in activity," is given as another, by which "accidental" death is most often brought to pass in infancy.

Also in middle age, both these processes may be seen ending in death, although generally not suddenly. And I have seen, even in middle age, the "*sudden* stand-still" here mentioned, and from the same causes.

Summary.

To sum up:–the answer to two of the commonest objections urged, one by women themselves, the other by men, against the desirableness of sanitary knowledge for women *plus* a caution, comprises the whole argument for the art of nursing.

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Reckless amateur physicking by women. Real knowledge of the laws of health alone can check this.

(1.) It is often said by men, that it is unwise to teach women anything about these laws of health, because they will take to physicking,–that there is a great deal too much of amateur physicking as it is, which is indeed true. One eminent physician told me that he had known more calomel given, both at a pinch and for a continuance, by mothers, governesses, and nurses, to children than he had ever heard of a physician prescribing in all his experience. Another says, that women's only idea in medicine is calomel and aperients. This is undeniably too often the case. There is nothing ever seen in any professional practice like the reckless physicking by amateur females. * But this is just what the really experienced and observing nurse does *not* do; she neither physics herself nor others. And to cultivate in things pertaining to health observation and experience in women who are mothers, governesses or nurses, is just the way to do away with amateur physicking, and if the doctors did but know it, to make the nurses obedient to them,–helps to them instead of hindrances. Such education in women would indeed diminish the doctor's work–but no one really believes that doctors wish that there should be more illness, in order to have more work.

What pathology teaches. What observation alone teaches. What medicine does. What nature alone does.

(2). It is often said by women, that they cannot know anything of the laws of health, or what to do to preserve their children's health, because they can know nothing of "Pathology," or cannot "dissect,"–a confusion of ideas which it is hard to attempt to disentangle. Pathology teaches the harm that disease has done. But it teaches nothing more. We know nothing of the principle of health, the positive of which pathology is the negative, except from observation and experience. And nothing but observation and experience will teach us the ways to maintain or to bring back the state of health. It is often thought that medicine is the curative process. It is no such thing; medicine is the surgery of functions, as surgery proper is that of limbs and organs. Neither can do anything but remove obstructions; neither can cure; nature alone cures. Surgery removes the bullet out of the limb, which is an obstruction to cure, but nature heals the wound. So it is with medicine; the function of an organ becomes obstructed; medicine, so far as we know, assists nature to remove the obstruction, but does nothing more. And what nursing has to do in either case, is to put the patient in the best condition for nature to act upon him. Generally, just the contrary is done. You think fresh air, and quiet and cleanliness extravagant, perhaps dangerous, luxuries, which should be given to the patient only when quite convenient, and medicine the *sine qua non*, the panacea. If I have succeeded in any measure in dispelling this illusion, and in showing what true nursing is, and what it is not, my object will have been answered.

Now for the caution:–

(3.) It seems a commonly received idea among men and even among women themselves that it requires nothing but a disappointment in love, the want of an object, a general disgust, or incapacity for other things, to turn a woman into a good nurse.

This reminds one of the parish where a stupid old man was set to be schoolmaster because he was "past keeping the pigs."

Apply the above receipt for making a good nurse to making a good servant. And the receipt will be found to fail.

Yet popular novelists of recent days have invented ladies disappointed in love or fresh out of the drawing-room turning into the war-hospitals to find their wounded lovers, and when found, forthwith abandoning their sick-ward for their lover, as might be expected. Yet in the estimation of the authors, these ladies were none the worse for that, but on the contrary were heroines of nursing.

What cruel mistakes are sometimes made by benevolent men and women in matters of business about which they can know nothing and think they know a great deal.

The everyday management of a large ward, let alone of a hospital–the knowing what are the laws of life and death for men, and what the laws of health for wards–(and wards are healthy or unhealthy, mainly according to the knowledge or ignorance of the nurse)–are not these matters of sufficient importance and difficulty to require learning by experience and careful inquiry, just as much as any other art? They do not come by inspiration to the lady disappointed in love, nor to the poor workhouse drudge hard up for a livelihood.

And terrible is the injury which has followed to the sick from such wild notions!

In this respect (any why is it so?), in Roman Catholic countries, both writers and workers are, in theory at least, far before ours. They would never think of such a beginning for a good working Superior or Sister of Charity. And many a Superior has refused to admit a *Postulant* who appeared to have no better "vocation" or reasons for offering herself than these.

It is true *we* make "no vows." But is a "vow" necessary to convince us that the true spirit for learning any art, most especially an art of charity, aright, is not a disgust to everything or something else? Do we really place the love of our kind (and of nursing, as one branch of it) so low as this? What would the Mère Angélique of Port Royal, what would our own Mrs. Fry have said to this?

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NOTE.–I would earnestly ask my sisters to keep clear of both the jargons now current everywhere (for they *are* equally jargons); of the jargon, namely, about the "rights" of women, which urges women to do all that men do, including the medical and other professions, merely because men do it, and without regard to whether this *is* the best that women can do; and of the jargon which urges women to do nothing that men do, merely because they are women, and should be "recalled to a sense of their duty as women," and because "this is women's work," and "that is men's," and "these are things which women should not do," which is all assertion, and nothing more. Surely woman should bring the best she has, *whatever* that is, to the work of God's world, without attending to either of these cries. For what are they, both of them, the one *just* as much as the other, but listening to the "what people will say," to opinion, to the "voices from without?" And as a wise man has said, no one has ever done anything great or useful by listening to the voices from without.

You do not want the effect of your good things to be, "How wonderful for a *woman!*" nor would you be deterred from good things by hearing it said, "Yes, but she ought not to have done this, because it is not suitable for a woman." But you want to do the thing that is good, whether it is "suitable for a woman" or not.

It does not make a thing good, that it is remarkable that a woman should have been able to do it. Neither does it make a thing bad, which would have been good had a man done it, that it has been done by a woman.

Oh, leave these jargons, and go your way straight to God's work, in simplicity and singleness of heart.

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APPENDIX.

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TABLE A.
GREAT BRITAIN.
AGES.

NURSES.	All Ages.	Under 5 Years.	5-	10-	15-	20-	25-	30-	35-	40-	45-	50-	55-	60-	65-	70-	75-	80-	85 and Upwards
Nurse (not Domestic Servant)	25,466	...	...	...	...	624	817	1,118	1,359	2,223	2,748	3,982	3,456	3,825	2,542	1,568	746	311	147
Nurse (Domestic Servant)	39,139	...	508	7,259	10,355	6,537	4,174	2,495	1,681	1,468	1,206	1,196	833	712	369	204	101	25	16

TABLE B.
AGED 20 YEARS, AND UPWARDS.

[*Editor's Note: Table has been rotated so that contents are displayed vertically rather than horizontally, for easier display in HTML.*]

NURSES.	Nurse (Not Domestic Servant)	Nurse (Domestic Servant)
Great Britain and Islands in the British Seas.	25,466	21,017
England and Wales.	23,751	18,945
Scotland.	1,543	1,922
Islands in the British Seas.	172	150
1st Division. London.	7,807	5,061
2nd Division. South Eastern.	2,878	2,514
3rd Division. South Midland.	2,286	1,252
4th Division. Eastern Counties.	2,408	959
5th Division. South Western Counties.	3,055	1,737
6th Division. West Midland Counties.	1,225	2,283
7th Division. North Midland Counties.	1,003	957
8th Division. North Western Counties.	970	2,135

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9th Division. Yorkshire.	1,074	1,023
10th Division. Northern Counties.	402	410
11th Division. Monmouth and Wales.	343	614

NOTE AS TO THE NUMBER OF WOMEN EMPLOYED AS NURSES IN GREAT BRITAIN.

25,466 were returned, at the census of 1851, as nurses by profession, 39,139 nurses in domestic service, * and 2,822 midwives. The numbers of different ages are shown in table A, and in table B their distribution over Great Britain.

To increase the efficiency of this class, and to make as many of them as possible the disciples of the true doctrines of health, would be a great national work.

For there the material exists, and will be used for nursing, whether the real "conclusion of the matter" be to nurse or to poison the sick. A man, who stands perhaps at the head of our medical profession, once said to me, I send a nurse into a private family to nurse the sick, but I know that it is only to do them harm.

Now a nurse means any person in charge of the personal health of another. And, in the preceding notes, the term *nurse* is used indiscriminately for amateur and professional nurses. For, besides nurses of the sick and nurses of children, the numbers of whom are here given, there are friends or relations who take temporary charge of a sick person, there are mothers of families. It appears as if these unprofessional nurses were just as much in want of knowledge of the laws of health as professional ones.

Then there are the schoolmistresses of all national and other schools throughout the kingdom. How many of children's epidemics originate in these! Then the proportion of girls in these schools, who become mothers or members among the 64,600 nurses recorded above, or schoolmistresses in their turn. If the laws of health, as far as regards fresh air, cleanliness, light, &c., were taught to these, would this not prevent some children being killed, some evil being perpetuated? On women we must depend, first and last, for personal and household hygiene–for preventing the race from degenerating in as far as these things are concerned. Would not the true way of infusing the art of preserving its own health into the human race be to teach the female part of it in schools and hospitals, both by practical teaching and by simple experiments, in as far as these illustrate what may be called the theory of it?

NOTES.

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Curious deductions from an excessive death rate.

* Upon this fact the most wonderful deductions have been strung. For a long time an announcement something like the following has been going the round of the papers:–"More than 25,000 children die every year in London under 10 years of age; therefore we want a Children's Hospital." This spring there was a prospectus issued, and divers other means taken to this effect:–"There is a great want of sanitary knowledge in women; therefore we want a Women's Hospital." Now, both the above facts are too sadly true. But what is the deduction? The causes of the enormous child mortality are perfectly well known; they are chiefly want of cleanliness, want of ventilation, want of whitewashing; in one word, defective *household* hygiene. The remedies are just as well known; and among them is certainly not the establishment of a Child's Hospital. This may be a want; just as there may be a want of hospital room for adults. But the Registrar-General would certainly never think of giving us as a cause for the high rate of child mortality in (say) Liverpool that there was not sufficient hospital room for children; nor would he urge upon us, as a remedy, to found an hospital for them.

Again, women, and the best women, are wofully deficient in sanitary knowledge; although it is to women that we must look, first and last, for its application, as far as *household* hygiene is concerned. But who would ever think of citing the institution of a Women's Hospital as the way to cure this want?

We have it, indeed, upon very high authority that there is some fear lest hospitals, as they have been *hitherto*, may not have generally increased, rather than diminished, the rate of mortality–especially of child mortality.

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Why are uninhabited rooms shut up?

* The common idea as to uninhabited rooms, is that they may safely be left with doors, windows, shutters, and chimney-board, all closed–hermetically sealed if possible–to keep out the dust, it is said; and that no harm will happen if the room is but opened a short hour before the inmates are put in. I have often been asked the question for uninhabited rooms.–But when ought the windows to be opened? The answer is–When ought they to be shut?

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* It is very desirable that the windows in a sick room should be such that the patient shall, if he can move about, be able to open and shut them easily himself. In fact, the sick room is very seldom kept aired if this is not the case–so very few people have any perception of what is a healthy atmosphere for the sick. The sick man often says, "This room where I spend 22 hours out of the 24, is fresher than the other where I spend only 2. Because here I can manage the windows myself." And it is true.

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* Dr Angus Smith's air test, if it could be made of simpler application, would be invaluable to use in every sleeping and sick room. Just as without the use of a thermometer no nurse should ever put a patient into a bath, so should no nurse, or mother, or superintendent, be without the air test in any ward, nursery, or sleeping-room. If the main function of a nurse is to maintain the air within the room as fresh as the air without, without lowering the temperature, then she should always be provided with a thermometer which indicates the temperature, with an air test which indicates the organic matter of the air. But to be used, the latter must be made as simple a little instrument as the former, and both should be self-registering. The senses of nurses and mothers become so dulled to foul air, that they are perfectly unconscious of what an atmosphere they have let their children, patients, or charges, sleep in. But if the tell-tale air test were to exhibit in the morning, both to nurses and patients, and to the superior officer going round, what the atmosphere has been during the night, I question if any greater security could be afforded against a recurrence of the misdemeanor.

An air-test of essential consequence.

And oh, the crowded national school! where so many children's epidemics have their origin, what a tale its air-test would tell! We should have parents saying, and saying rightly, "I will not send my child to that school, the air-test stands at 'Horrid.'" And the dormitories of our great boarding schools! Scarlet fever would be no more ascribed to contagion, but to its right cause, the air-test standing at "Foul."

We should hear no longer of "Mysterious Dispensations," and of "Plague and Pestilence," being "in God's hands," when, so far as we know, He has put them into our own. The little air-test would both betray the cause of these "mysterious pestilences," and call upon us to remedy it.

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* With private sick, I think, but certainly with hospital sick, the nurse should never be satisfied as to the freshness of their atmosphere, unless she can feel the air gently moving over her face, when still.

But it is often observed that the nurses who make the greatest outcry against open windows, are those who take the least pains to prevent dangerous draughts. The door of the patients' room or ward *must* sometimes stand open to allow of persons passing in and out, or heavy things being carried in and out. The careful nurse will keep the door shut while she shuts the windows, and then, and not before, set the door open, so that a patient may not be left sitting up in bed, perhaps in a profuse perspiration, directly in the draught between the open door and window. Neither, of course, should a patient, while being washed or in any way exposed, remain in the draught of an open window or door.

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* But never, never should the possession of this indispensable lid confirm you in the abominable practice of letting the chamber utensil remain in a patient's room unemptied, except once in the 24 hours, *i.e.*, when the bed is made. Yes, impossible as it may appear, I have known the best and most attentive nurses guilty of this; aye, and have known, too, a patient afflicted with severe diarrhoea for ten days, and the nurse (a very good one) not know of it, because the chamber utensil (one with a lid) was emptied only once in 24 hours, and that by the housemaid who came in and made the patient's bed every evening. As well might you have a sewer under the room, or think that in a water-closet the plug need be pulled up but once a day. Also take care that your *lid*, as well as your utensil, be always thoroughly rinsed.

If a nurse declines to do these kinds of things for her patient, "because it is not her business," I should say that nursing was not her calling. I have seen surgical "sisters," women whose hands were worth to them two or three guineas a-week, down upon their knees scouring a room or hut, because they thought it otherwise not fit for their patients to go into. I am far from wishing nurses to scour. It is a waste of power. But I do say that these women had the true nurse-calling–the good of their sick first, and second only the consideration what it was their "place" to do–and that women who wait for the housemaid to do this, or for the charwoman to do that, when their patients are suffering, have not the *making* of a nurse in them.

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* The health of carriages, especially close carriages, is not of sufficient universal importance to mention here, otherwise than cursorily. Children, who are always the most delicate test of sanitary conditions, generally cannot enter a close carriage without being sick–and very lucky for them that it is so. A close carriage, with the horse-hair cushions and linings always saturated with organic matter, if to this be added the windows up, is one of the most unhealthy of human receptacles. The idea of taking an *airing* in it is something preposterous. Dr. Angus Smith has shown that a crowded railway carriage, which goes at the rate of 30 miles an hour, is as

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unwholesome as the strong smell of a sewer, or as a back yard in one of the most unhealthy courts off one of the most unhealthy streets in Manchester.

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* God lays down certain physical laws. Upon His carrying out such laws depends our responsibility (that much abused word), for how could we have any responsibility for actions, the results of which we could not foresee–which would be the case if the carrying out of His laws were not certain. Yet we seem to be continually expecting that He will work a miracle–*i.e.*, break His own laws expressly to relieve us of responsibility.

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Servants rooms.

* I must say a word about servants' bed-rooms. From the way they are built, but oftener from the way they are kept, and from no intelligent inspection whatever being exercised over them, they are almost invariably dens of foul air, and the "servants' health" suffers in an "unaccountable" (?) way, even in the country. For I am by no means speaking only of London houses, where too often servants are put to live under the ground and over the roof. But in a country "*mansion*," which was really a "mansion," (not after the fashion of advertisements,) I have known three maids who slept in the same room ill of scarlet fever. "How catching it is," was of course the remark. One look at the room, one smell of the room, was quite enough. It was no longer "unaccountable." The room was not a small one; it was up stairs, and it had two large windows–but nearly every one of the neglects enumerated above was there.

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Diseases are not individuals arranged in classes, like cats and dogs, but conditions growing out of one another.

* Is it not living in a continual mistake to look upon diseases, as we do now, as separate entities, which *must* exist, like cats and dogs? instead of looking upon them as conditions, like a dirty and a clean condition, and just as much under our own control; or rather as the reactions of kindly nature, against the conditions in which we have placed ourselves.

I was brought up, both by scientific men and ignorant women, distinctly to believe that small-pox, for instance, was a thing of which there was once a first specimen in the world, which went on propagating itself, in a perpetual chain of descent, just as much as that there was a first dog, (or a first pair of dogs,) and that small-pox would not begin itself any more than a new dog would begin without there having been a parent dog.

Since then I have seen with my eyes and smelt with my nose small-pox growing up in first specimens, either in close rooms, or in overcrowded wards, where it could not by any possibility have been "caught," but must have begun.

Nay, more, I have seen diseases begin, grow up, and pass into one another. Now, dogs do not pass into cats.

I have seen, for instance, with a little overcrowding, continued fever grow up; and with a little more, typhoid fever; and with a little more, typhus, and all in the same ward or hut.

Would it not be far better, truer, and more practical, if we looked upon disease in this light?

For disease, as all experiences hows, are adjectives, not noun substantives.

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Lingering smell of paint a want of care.

* That excellent paper, the *Builder*, mentions the lingering of the smell of paint for a month about a house as a proof of want of ventilation. Certainly–and, where there are ample windows to open, and these are never opened to get rid of the smell of paint, it is a proof of want of management in using the means of ventilation. Of course the smell will then remain for months. Why should it go?

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Why let your patient ever be surprised?

* Why should you let your patient ever be surprised, except by thieves? I do not know. In England, people do not come down the chimney, or through the window, unless they are thieves. They come in by the door, and somebody must open the door to them. The "somebody" charged with opening the door is one of two, three, or at most four persons. Why cannot these, at most, four persons be put in charge as to what is to be done when there is a ring at the door-bell?

The sentry at a post is changed much oftener than any servant at a private house or institution can possibly be. But what should we think of such an excuse as this: that the enemy had entered such a post because A and not B had been on guard? Yet I have constantly heard such an excuse made in the private house or institution, and accepted: viz., that such a person had been "let in" or *not* "let in," and such a parcel had been wrongly delivered or lost because A and not B had opened the door!

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* There are many physical operations where *coeteris paribus* the danger is in a direct ratio to the time the operation lasts: and *coeteris paribus* the operator's success will be in direct ratio to his quickness. Now there are many mental operations where exactly the same rule holds good with the sick; *coeteris paribus* their capability of bearing such operations depends directly on the quickness, *without hurry*, with which they can be got through.

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Petty management better understood in institutions than in private houses.

* So true is this that I could mention two cases of women of very high position, both of whom died in the same way of the consequences of a surgical operation. And in both cases, I was told by the highest authority that the fatal result would not have happened in a London hospital.

What institutions are the exception?

But, as far as regards the art of petty management in hospitals, all the military hospitals I know must be excluded. Upon my own experience I stand, and I solemnly declare that I have seen or known of fatal accidents, such as suicides in *delirium tremens*, bleedings to death, dying patients dragged out of bed by drunken Medical Staff Corps men, and many other things less patent and striking, which would not have happened in London civil hospitals nursed by women. The medical officers should be absolved from all blame in these accidents. How can a medical officer mount guard all day and all night over a patient (say) in *delirium tremens?* The fault lies in there being no organized system of attendance. Were a trustworthy *man* in charge of each ward, or set of wards, not as office clerk, but as head nurse, (and head nurse the best hospital serjeant, or ward master, is not now and cannot be, from default of the proper regulations,) the thing would not, in all probability, have happened. But were a trustworthy *woman* in charge of the ward, or set of wards, the thing would not, in all certainty, have happened. In other words, it does not happen where a trustworthy woman is really in charge. And, in these remarks, I by no means refer only to exceptional times of great emergency in war hospitals, but also, and quite as much, to the ordinary run of military hospitals at home, in time of peace; or to a time in war when our army was actually more healthy than at home in peace, and the pressure on our hospitals consequently much less.

Nursing in Regimental Hospitals.

It is often said that, in regimental hospitals, patients ought to "nurse each other," because the number of sick altogether being, say, but thirty, and out of these one only perhaps being seriously ill, and the other twenty-nine having little the matter with them, and nothing to do, they should be set to nurse the one; also, that soldiers are so trained to obey, that they will be the most obedient, and therefore the best of nurses, add to which they are always kind to their comrades.

Now, have those who say this, considered that, in order to obey, you must know *how* to obey, and that these soldiers certainly do not know how to obey in nursing. I have seen these "kind" fellows (and how kind they are no one knows so well as myself) move a comrade so that, in one case at least, the man died in the act. I have seen the comrades' "kindness" produce abundance of spirits, to be drunk in secret. Let no one understand by this that female nurses ought to, or could be introduced in regimental hospitals. It would be most undesirable, even were it not impossible. But the head nurseship of a hospital serjeant is the more essential, the more important, the more inexperienced the nurses. Undoubtedly, a London hospital "sister" does sometimes set relays of patients to watch a critical case; but, undoubtedly also, always under her own superintendence; and she is called to whenever there is something to be done, and she knows how to do it. The patients are not left to do it of their own unassisted genius, however "kind" and willing they may be.

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Burning of the crinolines.

* Fortunate it is if her skirts do not catch fire–and if the nurse does not give herself up a sacrifice together with her patient, to be burnt in her own petticoats. I wish the Registrar-General would tell us the exact number of deaths by burning occasioned by this absurd and hideous custom. But if people will be stupid, let them take measures to protect themselves from their own stupidity–measures which every chemist knows, such as putting alum into starch, which prevents starched articles of dress from blazing up.

Indecency of the crinolines.

I wish, too, that people who wear crinoline could see the indecency of their own dress as other people see it. A respectable elderly woman stooping forward, invested in crinoline, exposes quite as much of her own person to the patient lying in the room as any opera dancer does on the stage. But no one will ever tell her this unpleasant truth.

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Never speak to a patient in the act of moving.

* It is absolutely essential that a nurse should lay this down as a positive rule to herself, never to speak to any patient who is standing or moving, as long as she exercises so little observation as not to know when a patient cannot bear it. I am satisfied that many of the accidents which happen from feeble patients tumbling down stairs, fainting after getting up, &c., happen solely from the nurse popping out of a door to speak to the patient just at that moment; or from his fearing that she will do so. And that if the patient were even left to himself, till he can sit down, such accidents would much seldomer occur. If the nurse accompanies the patient, let her not call upon him to speak. It is incredible that nurses cannot picture to themselves the strain upon the heart, the lungs, and the brain, which the act of moving is to any feeble patient.

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Careless observation of the results of careless visits.

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* As an old experienced nurse, I do most earnestly deprecate all such careless words. I have know patients delirious all night, after seeing a visitor who called them "better," thought they "only wanted a little amusement," and who came again, saying, "I hope you were not the worse for my visit," neither waiting for an answer, nor even looking at the case. No real patient will ever say, "Yes, but I was a great deal the worse."

It is not, however, either death or delirium of which, in these cases, there is most danger to the patient. Unperceived consequences are far more likely to ensue. *You* will have impunity–the poor patient will *not*. That is, the patient will suffer, although neither he nor the inflictor of the injury will attribute it to its real cause. It will not be directly traceable, except by a very careful observant nurse. The patient will often not even mention what has done him most harm.

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* Sick children, if not too shy to speak, will always express this wish. They invariable prefer a story to be *told* to them, rather than read to them.

The sick would rather be told a thing than have it read to them.

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* It is a matter of painful wonder to the sick themselves, how much painful ideas predominate over pleasurable ones in their impressions; they reason with themselves; they think themselves ungrateful; it is all of no use. The fact is, that these painful impressions are far better dismissed by a real laugh, if you can excite one by books or conversation, than by any direct reasoning; or if the patient is too weak to laugh, some impression from nature is what he wants. I have mentioned the cruelty of letting him stare at a dead wall. In many diseases, especially in convalescence from fever, that wall will appear to make all sorts of faces at him; now flowers never do this. Form, colour, will free your patient from his painful ideas better than any argument.

Sick suffer to excess from mental as well as bodily pain.

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* I remember a case in point. A man received an injury to the spine, from an accident, which after a long confinement ended in death. He was a workman–had not in his composition a single grain of what is called "enthusiasm for nature"–but he was desperate to "see once more out of window." His nurse actually got him on her back, and managed to perch him up at the window for an instant, "to see out." The consequence to the poor nurse was a serious illness, which nearly proved fatal. The man never knew it; but a great many other people did. Yet the consequence in none of their minds, so far as I know, was the conviction that the craving for variety in the starving eye, is just as desperate as that of food in the starving stomach, and tempts the famishing creature in either case to steal for its satisfaction. No other word will express it but "desperation." And it sets the seal of ignorance and stupidity just as much on the governors and attendants of the sick if they do not provide the sick-bed with a "view" of some kind, as if they did not provide the hospital with a kitchen.

Desperate desire in the sick to "see out of the window."

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* No one who has watched the sick can doubt the fact, that some feel stimulus from looking at scarlet flowers, exhaustion from looking at deep blue, &c.

Physical effect of colour.

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* Why, because the nurse has not got some food to-day which the patient takes, can the patient wait four hours for food to-day, who could not wait two hours yesterday? Yet this is the only logic one generally hears. On the other hand, the other logic, viz., of the nurse giving a patient a thing because she *has* got it, is equally fatal. If she happens to have fresh jelly, or fresh fruit, she will frequently give it to the patient half an hour after his dinner, or at his dinner, when he cannot possibly eat that and the broth too–or worse still, leave it by his bed-side till he is so sickened with the sight of it, that he cannot eat it at all.

Nurse must have some rule of time about the patient's diet.

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* In the diseases produced by bad food, such as scorbutic dysentery and diarrhoea, the patient's stomach often craves for and digests things, some of which certainly would be laid down in no dietary that ever was invented for sick, and especially not for such sick. These are fruit, pickles, jams, gingerbread, fat of ham or bacon, suet, cheese, butter, milk. These cases I have seen not by ones, nor by tens, but by hundreds. And the patient's stomach was right and the book was wrong. The articles craved for, in these cases, might have been principally arranged under the two heads of fat and vegetable acids.

Intelligent cravings of particular sick for particular articles of diet.

There is often a marked difference between men and women in this matter of sick feeding. Women's digestion is generally slower.

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* It is made a frequent recommendation to persons about to incur great exhaustion, either from the nature of the service, or from their being not in a state fit for it, to eat a piece of bread before they go. I wish the recommenders would themselves try the experiment of substituting a piece of bread for a cup of tea or coffee, or beef-tea, as a refresher. They would find it a very poor comfort. When soldiers have to set out fasting on fatiguing duty, when nurses have to go fasting in to their patients, it is a hot restorative they want, and ought to have, before they go, not a cold bit of bread. And dreadful have been the consequences of neglecting this. If they can take a bit of bread *with* the hot cup of tea, so much the better, but not *instead* of it. The fact that there is more nourishment in bread than in almost anything else, has probably induced the mistake. That it is a fatal

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mistake, there is no doubt. It seems, though very little is known on the subject, that what "assimilates" itself directly, and with the least trouble of digestion with the human body, is the best for the above circumstances. Bread requires two or three processes of assimilation, before it becomes like the human body.

The almost universal testimony of English men and women who have undergone great fatigue, such as riding long journeys without stopping, or sitting up for several nights in succession, is that they could do it best upon an occasional cup of tea–and nothing else.

Let experience, not theory, decide upon this as upon all other things.

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* In making coffee, it is absolutely necessary to buy it in the berry and grind it at home. Otherwise you may reckon upon its containing a certain amount of chicory, *at least.* This is not a question of the taste, or of the wholesomeness of chicory. It is that chicory has nothing at all of the properties for which you give coffee. And therefore you may as well not give it.

Again, all laundresses, mistresses of dairy-farms, head nurses, (I speak of the good old sort only–women who unite a good deal of hard manual labour with the head-work necessary for arranging the day's business, so that none of it shall tread upon the heels of something else,) set great value, I have observed, upon having a high-priced tea. This is called extravagant. But these women are "extravagant" in nothing else. And they are right in this. Real tea-leaf tea alone contains the restorative they want; which is not to be found in sloe-leaf tea.

The mistresses of houses, who cannot even go over their own house once a day, are incapable of judging for these women. For they are incapable themselves, to all appearance, of the spirit of arrangement (no small task) necessary for managing a large ward or dairy.

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* I once told a "very good nurse" that the way in which her patient's room was kept was quite enough to account for his sleeplessness; and she answered quite good-humouredly she was not at all surprised at it–as if the state of the room were, like the state of the weather, entirely out of her power. Now in what sense was this woman to be called a "nurse?"

Nurses often do not think the sick room any business of theirs, but only the sick.

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* For the same reason if, after washing a patient, you must put the same night-dress on him again, always give it a preliminary warm at the fire. The night-gown he has worn must be, to a certain extent, damp. It has now got cold from having been off him for a few minutes. The fire will dry and at the same time air it. This is much more important than with clean things.

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* If you like to clean your furniture by laying out your clean clothes upon your dirty chairs or sofa, this is one way certainly of doing it. Having witnessed the morning process called "tidying the room" for many years, and with ever-increasing astonishment, I can describe what it is. From the chairs, tables, or sofa, upon which the *"things"* have lain during the night, and which are therefore comparatively clean from dust or blacks, the poor "things" having "caught" it, they are removed to other chairs, tables, sofas, upon which you could write your name with your finger in the dust or blacks. The *other* side of the "things" is therefore now evenly dirtied or dusted. The housemaid then flaps everything, or some things, not out of her reach, with a thing called a duster–the dust flies up, then re-settles more equally than it lay before the operation. The room has now been "put to rights."

How a room is *dusted.*

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* I am sure that a person who has accustomed her senses to compare atmospheres proper and improper, for the sick and for children, could tell, blindfold, the difference of the air in old painted and in old papered rooms, *coeteris paribus.* The latter will always be dusty, even with all the windows open.

Atmosphere in painted and papered rooms quite distinguishable.

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* If you like to wipe your dirty door, or some portion of your dirty wall, by hanging up your clean gown or shawl against it on a peg, this is one way certainly, and the most usual way, and generally the only way of cleaning either door or wall in a bed room!

How to keep your wall clean at the expense of your clothes.

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* There are, of course, cases, as in first confinements, when an assurance from the doctor or experienced nurse to the frightened suffering woman that there is nothing unusual in her case, that she has nothing to fear but a few hours' pain, may cheer her most effectually. This is advice of quite another order. It is the advice of experience to utter inexperience. But the advice we have been referring to is the advice of inexperience to bitter experience; and, in general, amounts to nothing more than this, that *you* think *I* shall recover from consumption because somebody knows somebody somewhere who has recovered from fever.

Absurd statistical comparisons made in common conversations by the most sensible people for the benefit of the sick.

I have heard a doctor condemned whose patient did not, alas! recover, because another doctor's patient of a *different* sex, of a *different* age, recovered from a *different* disease, in a *different* place. Yes, this is really true. If people who make these comparisons did but know (only they do not care to know), the care and preciseness with which such comparisons require to be made, (and are made,) in order to be of any value whatever, they would spare their tongues. In comparing the deaths of one hospital with those of another, any statistics are justly considered absolutely valueless which do not give the age, the sexes, and the diseases of all the cases. It does not seem necessary to mention this. It does not seem necessary to say that there can be no comparison between old men with dropsies and young women with consumptions. Yet the cleverest men and the cleverest women are often heard making such comparisons, ignoring entirely sex, age, disease, place–in fact, *all* the conditions essential to the question. It is merest *gossip.*

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* A small pet animal is often an excellent companion for the sick, for long chronic cases especially. A pet bird in a cage is sometimes the only pleasure of an invalid confined for years to the same room. If he can feed and clean the animal himself, he ought always to be encouraged to do so.

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* It is a much more difficult thing to speak the truth than people commonly imagine. There is the want of observation *simple*, and the want of observation *compound*, compounded, that is, with the imaginative faculty. Both may equally intend to speak the truth. The information of the first is simply defective. That of the second is much more dangerous. The first gives, in answer to a question asked about a thing that has been before his eyes perhaps for years, information exceedingly imperfect, or says, he does not know. He has never observed. And people simply think him stupid.

The second has observed just as little, but imagination immediately steps in, and he describes the whole thing from imagination merely, being perfectly convinced all the while that he has seen or heard it; or he will repeat a whole conversation, as if it were information which had been addressed to him; whereas it is merely what he has himself said to somebody else. This is the commonest of all. These people do not even observe that they have *not* observed, nor remember that they have forgotten.

Courts of justice seem to think that anybody can speak "the whole truth, and nothing but the truth," if he does but intend it. It requires many faculties combined of observation and memory to speak "the whole truth," and to say "nothing but the truth."

"I knows I fibs dreadful; but believe me, Miss, I never finds out I have fibbed until they tells me so," was a remark actually made. It is also one of much more extended application that most people have the least idea of.

Concurrence of testimony, which is so often adduced as final proof, may prove nothing more, as is well known to those accustomed to deal with the unobservant imaginative, than that one person has told his story a great many times.

I have heard thirteen persons "concur" in declaring that a fourteenth, who had never left his bed, went to a distant chapel every morning at seven o'clock.

I have heard persons in perfect good faith declare, that a man came to dine every day at the house where they lived, who had never dined there once; that a person had never taken the sacrament, by whose side they had twice at least knelt at Communion; that but one meal a day came out of a hospital kitchen, which for six weeks they had seen provide from three to five and six meals a day. Such instances might be multiplied *ad infinitum* if necessary.

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* This is important, because on this depends what the remedy will be. If a patient sleeps two or three hours early in the night, and then does not sleep again at all, ten to one it is not a narcotic he wants, but food or stimulus, or perhaps only warmth. If, on the other hand, he is restless and awake all night, and is drowsy in the morning, he probably wants sedatives, either quiet, coolness, or medicine, a lighter diet, or all four. Now the doctor should be told this, or how can he judge what to give?

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* It is commonly supposed that the nurse is there to spare the patient from making physical exertion for himself–I would rather say that she ought to be there to spare him from taking thought for himself. And I am quite sure, that if the patient were spared all thought for himself, and *not* spared all physical exertion, he would be infinitely the gainer. The reverse is generally the case in the private house. In the hospital it is the relief from all anxiety, afforded by the rules of a well-regulated institution, which has often such a beneficial effect upon the patient.

More important to spare the patient thought than physical exertion.

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English women have great capacity of, but little practice in close observation.

* It may be too broad an assertion, and it certainly sounds like a paradox. But I think that in no country are women to be found so deficient in ready and sound observation as in England, while peculiarly capable of being trained to it. The French or Irish woman is too quick of perception to be so sound an observer–the Teuton is too slow to be so ready an observer as the English woman might be. Yet English women lay themselves open to the charge so often made against them by men, viz., that they are not to be trusted in handicrafts to which their strength is quite equal, for want of a practised and steady observation. In countries where women (with average intelligence certainly not superior to that of English women) are employed, *e.g.*, in dispensing, men responsible for what these women do (not theorizing about man's and woman's "missions,") have stated that they preferred the service of women to that of men, as being more exact, more careful, and incurring fewer mistakes of inadvertence.

Now certainly English women are peculiarly capable of attaining to this.

I remember when a child, hearing the story of an accident, related by some one who sent two girls to fetch a "bottle of salvolatile from her room;" "Mary could not stir," she said, "Fanny ran and fetched a bottle that was not salvolatile, and that was not in my room."

Now this sort of thing pursues every one through life. A woman is asked to fetch a large new bound red book, lying on the table by the window, and she fetches five small old boarded brown books lying on the shelf by the fire. And this, though she has "put that room to rights" every day for a month perhaps, and must have observed the books every day, lying in the same places, for a month, if she had any observation.

Habitual observation is the more necessary, when any sudden call arises. If "Fanny" had observed "the bottle of salvolatile" in "the aunt's room," every day she was there, she would more probably have found it when it was suddenly wanted.

There are two causes for these mistakes of inadvertence. 1. A want of ready attention; only a part of the request is heard at all. 2. A want of the habit of observation.

To a nurse I would add, take care that you always put the same things in the same places; you don't know how suddenly you may be called on some day to find something, and may not be able to remember in your haste where you yourself had put it, if your memory is not in the habit of seeing the thing there always.

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Approach of death, paleness by no means an invariable effect, as we find in novels.

* It falls to few ever to have had the opportunity of observing the different aspects which the human face puts on at the sudden approach of certain forms of death by violence; and as it is a knowledge of little use, I only mention it here as being the most startling example of what I mean. In the nervous temperament the face becomes pale (this is the only *recognised* effect); in the sanguine temperament purple; in the bilious yellow, or every manner of colour in patches. Now, it is generally supposed that paleness is the one indication of almost any violent change in the human being, whether from terror, disease, or anything else. There can be no more false observation. Granted, it is the one recognised livery, as I have said *–de rigueur* in novels, but nowhere else.

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* I have known two cases, the one of a man who intentionally and repeatedly displaced a dislocation, and was kept and petted by all the surgeons; the other of one who was pronounced to have nothing the matter with him, there being no organic change perceptible, but who died within the week. In both these cases, it was the nurse who, by accurately pointing out what she had accurately observed, to the doctors, saved the one case from persevering in a fraud, the other from being discharged when actually in a dying state.

I will even go further and say, that in diseases which have their origin in the feeble or irregular action of some function, and not in organic change, it is quite an accident if the doctor who sees the case only once a day, and generally at the same time, can form any but a negative idea of its real condition. In the middle of the day, when such a patient has been refreshed by light and air, by his tea, his beef-tea, and his brandy, by hot bottles to his feet, by being washed and by clean linen, you can scarcely believe that he is the same person as lay with a rapid fluttering pulse, with puffed eye-lids, with short breath, cold limbs, and unsteady hands, this morning. Now what is a nurse to do in such a case? Not cry, "Lord, bless you, sir, why you'd have thought he were a dying all night." This may be true, but it is not the way to impress with the truth a doctor, more capable of forming a judgment from the facts, if he did but know them, than you are. What he wants is not your opinion, however respectfully given, but your facts. In all diseases it is important, but in diseases which do not run a distinct and fixed course, it is not only important, it is essential that the facts the nurse alone can observe, should be accurately observed, and accurately reported to the doctor.

I must direct the nurse's attention to the extreme variation there is not unfrequently in the pulse of such patients during the day. A very common case is this: Between 3 and 4 A. M., the pulse become quick, perhaps 130, and so thready it is not like a pulse at all, but like a string vibrating just underneath the skin. After this the

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patient gets no more sleep. About mid-day the pulse has come down to 80; and though feeble and compressible, is a very respectable pulse. At night, if the patient has had a day of excitement, it is almost imperceptible. But, if the patient has had a good day, it is stronger and steadier, and not quicker than at mid-day. This is a common history of a common pulse; and others, equally varying during the day, might be given. Now, in inflammation, which may almost always be detected by the pulse, in typhoid fever, which is accompanied by the low pulse that nothing will raise, there is no such great variation. And doctors and nurses become accustomed not to look for it. The doctor indeed cannot. But the variation is in itself an important feature.

Cases like the above often "go off rather suddenly," as it is called, from some trifling ailment of a few days, which just makes up the sum of exhaustion necessary to produce death. And everybody cries, Who would have thought it? except the observing nurse, if there is one, who had always expected the exhaustion to come, from which there would be no rally, because she knew the patient had no capital in strength on which to draw, if he failed for a few days to make his barely daily income in sleep and nutrition.

I have often seen really good nurses distressed, because they could not impress the doctor with the real danger of their patient; and quite provoked because the patient "would look" either "so much better" or "so much worse" than he really is "when the doctor was there." The distress is very legitimate, but it generally arises from the nurse not having the power of laying clearly and shortly before the doctor the facts from which she derives her opinion, or from the doctor being hasty and inexperienced, and not capable of eliciting them. A man who really cares for his patients, will soon learn to ask for and appreciate the information of a nurse, who is at once a careful observer and a clear reporter.

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Danger of physicking by amateur females.

* I have known many ladies who, having once obtained a "blue pill" prescription from a physician, gave and took it as a common aperient two or three times a week–with what effect may be supposed. In one case I happened to be the person to inform the physician of it, who substituted for the prescription a comparatively harmless aperient pill. The lady came to me and complained that it "did not suit her half so well."

If women will take or give physic, by far the safest plan is to send for "the doctor" every time–for I have known ladies who both gave and took physic, who would not take the pains to learn the names of the commonest medicines, and confounded, *e.g.*, colocynth with colchinum. This *is* playing with sharp-edged tools "with a vengeance."

There are excellent women who will write to London to their physician that there is much sickness in their neighbourhood in the country, and ask for some prescription from him, which they used to like themselves, and then give it to all their friends and to all their poorer neighbours who will take it. Now, instead of giving medicine, of which you cannot possibly know the exact and proper application, nor all its consequences, would it not be better if you were to persuade and help your poorer neighbours to remove the dung-hill from before the door, to put in a window which opens, or an Arnott's ventilator, or to cleanse and limewash the cottages? Of these things the benefits are sure. The benefits of inexperienced administration of medicines are by no means sure.

Homoeopathy has introduced one essential amelioration in the practice of physic by amateur females; for its rules are excellent, its physicking comparatively harmless–the "globule" is the one grain of folly which appears to be necessary to make any good thing acceptable. Let then women, if they will give medicine, give homoeopathic medicine. It won't do any harm.

An almost universal error among women is the supposition that everybody *must* have the bowels opened once in every twenty-four hours, or must fly immediately to aperients. The reverse is the conclusion of experience.

This is a doctor's subject, and I will not enter more into it; but will simply repeat, do not go on taking or giving to your children your abominable "courses of aperients," without calling in the doctor.

It is very seldom indeed, that by choosing your diet, you cannot regulate your own bowels; and every woman may watch herself to know what kind of diet will do this; I have known deficiency of meat produce constipation, quite as often as deficiency of vegetables; baker's bread much oftener than either. Home made brown bread will oftener cure it than anything else.

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* A curious fact will be shown by Table A, viz., that 18,122 out of 39,139, or nearly one-half of all the nurses, in domestic service, are between 5 and 20 years of age.

About This Edition

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Infection Control and the Built Environment: No Easy Answers

April 21, 2014 - Brooke Schmidt

By Susan Carr

For more than 160 years, healthcare providers have understood that aspects of the built or physical environment of hospitals may deter healing or cause patients to develop new health problems, including infections, even as they seek help for existing illness and injuries.

Driven by conditions she observed while caring for soldiers during the Crimean War, Florence Nightingale exhorted nurses to make providing clean, healthy environments their first priority:

> *The very first canon of nursing, the first and the last thing upon which a nurse's attention must be fixed, the first essential to a patient, without which all the rest you can do for him is as nothing, with which I had almost said you may leave all the rest alone, is this: TO KEEP THE AIR HE BREATHES AS PURE AS THE EXTERNAL AIR, WITHOUT CHILLING HIM (1860).*

Poor sanitation affected the health of all populations—sick and well—at the time. Although Nightingale did not make the direct connection between pathogens and infection that we understand today, the effect of her crusade to improve living conditions inside and outside hospitals was visionary at the time.

Noskin and Peterson (2001) point out that Semmelweis, known best for making the connection in 1847 between new infections in patients and providers with unclean hands, also identified a more generalized danger of being in the hospital compared with being cared for at home. When Semmelweis realized that women giving birth in one hospital unit, where medical students often assisted with deliveries immediately after performing autopsies, had higher rates of infection than other units, he also recognized that women who gave birth at home had even lower rates of infection than mothers in the safest units in the hospital. Semmelweis knew that providers must wash their hands regularly to protect patients from infection, and that it simply is best to avoid being in the hospital, where there is likelihood of acquiring additional health problems.

Private, single-patient rooms are becoming common in U.S. hospitals, but this is not a new idea in facility design. In JAMA in 1920, Asa Bacon, superintendent of Presbyterian Hospital in Chicago, called for private rooms for all hospital patients, not just for the wealthy, to speed their recovery (Noskin & Peterson, 2001). Bacon recognized then, as we do now, that patients housed together in close proximity were more likely to share their infections and diseases.

The Effects of the Built Environment

Despite dramatic advances in medicine, disinfection techniques, environmental systems, construction methods and materials, the built environment of modern hospitals still presents the risk of what we now call

hospital-associated infections (HAIs) and other preventable adverse events. Beyond the fact that hospitals harbor organisms that may cause illness, the design of buildings and furnishings pose other hazards and may even impede efforts to control the transmission of disease and infection.

Although pathogens may be transmitted through air and water, most infection control efforts in hospitals focus on transmission through contact with surfaces: furniture; fabrics; walls; fixtures; devices; and, of course, human hands. Infection control focuses on environmental cleaning and disinfection, with new materials, cleaning products, and disinfection techniques being developed to perform more effectively and, in some cases, even to disinfect themselves. Having the most effective cleaning strategy is, however, not enough. Nor does investment in sinks and hand-sanitizer dispensers guarantee that clinicians will comply with hand hygiene policies. As is true with most improvement efforts, effective infection control requires commitment and collaboration throughout the ranks of professional and service workers, a pervasive and supportive safety culture, and a built environment that supports improvement efforts and best practices.

AHRQ Report

Although the effects of the built environment on health and healing were recognized long ago, the healthcare industry is still developing an understanding of how to use design effectively to promote infection control and patient safety in general. To understand the effects of the built environment specifically on HAIs, the Agency for Healthcare Research and Quality (AHRQ) recently sponsored a study to evaluate the evidence supporting best practices and the experience of experts in a variety of fields.

Published as a supplement to *HERD: Health Environments Research & Design Journal*, AHRQ's report, *Understanding the Role of Facility Design in the Acquisition and Prevention of Healthcare-Associated Infections* (Hamilton & Stichler, 2013), is available for free download from the publisher (www.herdjournal.com).

Carolyn Clancy, MD, director of AHRQ when the report was written, explains in the introduction that two kinds of science are necessary for preventing HAIs: 1) traditional infection control science—eradicating or reducing the incidence of infection and treating those that occur and 2) human factors and behavioral science—helping healthcare workers employ infection control science effectively and making sure that the environment makes that work easier rather than harder to accomplish (Hamilton & Stichler, 2013).

For the report, a multidisciplinary team of researchers from AHRQ, RTI International, Emory University, and the Georgia Institute of Technology reviewed current literature to learn how the design of hospital environments affects the transmission of infectious organisms by air, water, and contact. Working with experts in library science, researchers chose more than 1,000 articles in various disciplines, which were narrowed down to more than 780 for further review, and more than 200 for final review. The materials came from the "gray" literature—such as technical reports, conference proceedings, and government publications—as well as peer-reviewed journals. Overall, researchers found that clear evidence for best practices in using design to combat HAIs is lacking:

> *There are, however, few rigorous studies demonstrating the link between design and a subsequent reduction in HAIs. As a result, the field largely remains an idiosyncratic patchwork of best practices and inferential steps from lab or epidemiological research (Hamilton & Stichler, 2013, p. 14).*

Evidence, Guidelines, and Experience

Lack of definitive evidence related to patient outcomes, however, does not mean that improvement efforts are performed without guidance. There are aspects of facility design that clearly improve infection control. To reduce the incidence of HAIs, for example, the use of single occupancy inpatient rooms and convenient placement of hand hygiene equipment—sinks and dispensers—are recommended, intuitively compelling, supported with research, and guided by regulation.

In recommended guidelines for the "hospital of the future," The Joint Commission pointed out that single rooms offer better privacy and comfort for patients, space for their visitors, and further stated that "single-patient rooms may have the single most important impact on patient safety" among other improvements to the built environment (2008, p. 34–35). Single-patient rooms were also number one on the Institute for Healthcare Improvement's 2009 list of design priorities for hospitals engaged in new construction or major renovation (p. 7). In addition to decreased opportunity for patient-to-patient germ transfer, IHI claims that providers caring for patients in single rooms are more likely to wash their hands between patients, perhaps prompted by the obvious passage in and out of separate rooms. Detsky and Etchells (2008) cited similar advantages in "Single-Patient Rooms for Safe Patient-Centered Hospitals," published in JAMA in August 2008. The Facility Guidelines Institute, a non-profit organization that publishes Guidelines for Design and Construction of Health Care Facilities, designated single-patient rooms as a "minimum standard" for hospitals in the 2010 edition of the guidelines.

The use of single-occupancy rooms is, however, not a simple solution for HAIs and illustrates how advances in patient care and the built environment may pose new challenges. In addition to infection prevention efforts, recent attention to patient preferences and comfort—patient-centeredness and satisfaction—have influenced the move toward single-occupancy hospital rooms. For all their advantages, these newly designed patient rooms are harder to clean. Hospitals are providing better accommodations for friends and family members, with more space, open visiting hours, and sometimes upholstered furniture or recliners that allow overnight visits, all of which complicate cleaning strategies. Computer terminals with touchscreens for patient and provider use, likewise, improve patient care and require additional cleaning. While mounting hand-sanitizer dispensers in each room improves usage, they present more surfaces—especially the dispenser's operable bar or button—in need of regular cleaning. All of these items complicate and prolong the process of cleaning and disinfecting the room after discharge as well as on a daily basis.

In addition to a literature review, researchers working on the AHRQ-sponsored report (2013) performed small-group interviews with interdisciplinary teams of experts, including professionals in infection

control, facility design, and hospital and medical administration. An infection preventionist interviewed for the AHRQ report commented,

> *Thinking back to 1975 when all we had was an overhead table, bedside table, and an IV pole, it was easy to turn over a room. Now, we have a hugely complex environment with frequent patient-to-surface contact—adequate cleaning on a daily basis is becoming insurmountable (Hamilton & Stichler, 2013, p. 35).*

There should be no turning back on these efforts to improve the patient experience. It is important, however, to recognize that infection prevention in this environment requires increased collaboration, resources, time, and support.

Advances in Materials and Processes

Copper, now being used in new ways in healthcare for its continuous antimicrobial characteristics, and disinfection techniques such as ultraviolet germicidal irradiation (UVGI) and hydrogen peroxide vapor (HPV), may help make these newly complex environments easier to manage. As with any new process or technology, however, these solutions come with caveats. AHRQ researchers found that copper has proven anti-microbial qualities, but there is no research that shows its use reduces infections in patients (Hamilton & Stichler, 2013). It is also not yet known how the anti-microbial activity will hold up to intensive, repeated cleaning over time.

There is much interest in the use of UVGI for disinfecting rooms at turnover. Its limitations are that it is "not 100% effective against all pathogens (Hamilton & Stichler, 2013, p. 39)," is effective only when the light beam makes direct contact with surfaces, and it requires everyone to leave the space being disinfected for an extended period. While UVGI, like copper, offers advantages for infection control programs over some older processes, it has not been shown to reduce rates of infection in patients, and its long-term effect on devices and room furnishings is unknown. Hospitals are also exploring the use of HPV for disinfecting patient rooms at turnover. Similar to UVGI, it requires a vacated room for a certain period of time, but it reaches areas that UVGI cannot reach and leaves only water as a residue, which is an improvement over other products used for disinfection.

More research is needed before the full effects and best practices for use of these new tools will be fully understood. In addition to new research, observation, training, and follow-up are needed for effective implementation of these and other new materials and processes.

Evidence-Based?

The idea of "evidence-based design" is appealing, but AHRQ and others have found limited evidence to link features of the built environment directly to patient outcomes, including hospital-associated infections. Referring to interviews performed for the study, AHRQ reports:

The experts were supportive of the concept of evidence-based design but expressed concerns regarding its definitions and inconsistent standards of evidence. The terminology that these experts preferred was "evidence-influenced design." The need for additional evidence addressing cost, return on investment, and, most importantly, efficacy in reducing infections was a

recurring topic discussed in the interviews (Hamilton & Stichler, 2013, p. 132-133).

Recognizing the complexity of infection prevention and the built environment, the report also calls for increased cooperation among design experts, health professionals including infection preventionists, executives, and facility mangers. In addition to using evidence and guidelines, experience across many disciplines will provide the best guidance possible for reducing HAIs.

In the end, the built environment is but one element of the healthcare system that must be accounted for in safety and quality improvement. As with other patient safety efforts, reduction of HAIs can only be accomplished with collaboration and a commitment to support front-line caregivers with effective training, technology, leadership, and resources.

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This SOP applies to all staff employed by NHS Greater Glasgow & Clyde and locum staff on fixed term contracts and volunteer staff.

SOP Objective

To minimise the risk of healthcare associated infection (HAI) from the environment.

KEY CHANGES FROM THE PREVIOUS VERSION OF THIS SOP

- Updated wording in **procedure** section

Document Control Summary

Approved by and date	Board Infection Control Committee .....
Date of Publication	
Developed by	Infection Control Policy Sub-Group 0141 201 0326
Related Documents	National Infection Prevention and Control Manual NHSGGC Decontamination Policy NHSGGC Standard Precautions Policy NHSGGC Hand Hygiene Policy NHSGGC SOP Cleaning of Near Patient Equipment. NHS Scotland National Cleaning Services Specification
Distribution/Availability	NHSGGC Infection Prevention and Control Manual and the Internet www.nhsggc.org.uk/infectionpreventionandcontrol
Implications of Race Equality and other diversity duties for this document	This policy must be implemented fairly and without prejudice whether on the grounds of ethnicity, gender, sexual orientation, religion, belief, disability or age.
Lead Manager	Board Infection Control Manager
Responsible Director	Board Medical Director

Aim	To minimise the risk of healthcare associated infection (HAI) from the environment.
Statement	Patients with certain alert organisms / conditions to be nursed in isolation to prevent the spread of the infection to other patients and staff. This is known as **source isolation**. In some situations if more than one patient is affected, during an outbreak of vomiting and diarrhoea for example, the restrictions may apply to a whole ward or part of a ward.
Communication	The ward / area will notify the domestic staff when twice daily cleaning is required. An isolation notice will be displayed at the entrance to a single isolation room.
Requirements	The Domestic Supervisor / Team Leader will ensure domestic staff have the necessary equipment and that staff working in the area are fully trained on the correct procedures. • Disposable or launderable mop (yellow) head • Appropriately colour coded re-usable items, e.g. bucket and / or small bucket and bowl • Dust control mop (disposable cover) • Single-use cloths • Single-use scourer • Non-sterile single-use gloves • Yellow single-use apron • Clinical waste bag (orange) • Chlorine based detergent (1000ppm) Where possible it is intended that individual cleaning equipment should be used per isolation room unless there are two or more in an individual bay, then the same isolation equipment may be used. Personal Protective Equipment (PPE, i.e. gloves, aprons) must be changed between each room / area. All re-usable equipment must be cleaned with chlorine based detergent. If multiple isolation rooms are being cleaned, the solution must be changed between rooms or after 15 minutes, whichever comes first. Cloths used in sanitary areas must be discarded immediately after use and

	a fresh cloth must be used for the general area. There should be a minimum of 4 hours between cleans.
Procedure	Nursing staff are responsible for cleaning any medical equipment within the room as well as mattresses and patient call buzzer. **NB: please see SOP Cleaning of Near Patient Equipment** **Prior to entering a room / area**: Report to the nurse in charge to ensure that it is convenient for cleaning to start and to receive any special instruction. The number of domestic staff cleaning isolation rooms / areas must be kept to a minimum. • Collect any equipment and materials required for cleaning inside the room / area as stated above. • Carry out hand hygiene using alcohol hand gel or liquid soap and water. • Put on a disposable yellow plastic apron and disposable gloves (check with the nurse in charge if any other protective clothing is required). • Make up solution of chlorine based detergent (1000ppm). **Procedure within isolation area:** **The door to the room must remain closed until the following procedure has been completed. PPE should be removed and hand hygiene carried out when leaving the room / area.** • Explain to the patient what you are going to do in the room. • Check room / area if there is any visible contamination with blood / body fluids inform nursing staff to decontaminate the area with chlorine based detergent (10,000ppm) before commencing cleaning. • Gather large items of rubbish including locker bag and bin liners and place in a clinical waste bag (orange). • Clinical waste bags should be sealed in accordance with the NHSGGC Waste Policy. • Damp dust all horizontal surfaces with a chlorine based detergent (1000ppm) first.

Procedure (cont/ …)	**NB: please see SOP Cleaning of Near Patient Equipment** • Replace waste bags. Cont/… • If there is a hand wash basin or en suite facilities ensure hand wash basin, shower, tiles, all fixtures and fittings, toilet seat and toilet bowl are thoroughly cleaned using a chlorine based detergent (1000ppm). Always clean the toilet last and dispose of cloth immediately into clinical waste bag. Toilets may be pre-cleaned using a sanitiser. • Dry mop the floor working from furthest point towards the door. The floor should then be damp mopped using dedicated equipment and a solution of chlorine based detergent (1,000ppm available chlorine). Mops used in isolation rooms should be disposed of or laundered after use. • **No buffing should take place in the room.** • Once clean is complete, the mop head should be bagged for laundering. • Staff should then take the mop handle and bucket straight to DSR while still wearing PPE. • Dispose of water, decontaminate equipment and return to the room. • Dispose of PPE, seal waste and **WASH HANDS using liquid soap and water.** • Replenish supplies (e.g. paper towels, soap) within the room. **NB: crockery and cutlery** – **No special requirements.** Crockery and cutlery used by patients in isolation can be returned with the meal trolley for processing in a dishwasher or double sink and bactericidal detergent.
After Care	• Storage of equipment should be in accordance with local infection prevention control advice. • Where mop heads are laundered this should be done as per local guidance / policy. • Inform the nurse in charge that the clean has been completed. If unable to complete clean of isolation room, inform the nurse in charge and ensure exception report is completed.

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HEALTHCARE ASSOCIATED INFECTIONS (G BEARMAN AND D MORGAN, SECTION EDITORS)

Hospital Water and Opportunities for Infection Prevention

Brooke K. Decker · Tara N. Palmore

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Abstract Nosocomial waterborne pathogens may reach patients through several modes of transmission. Colonization of healthcare facility waterworks can occur in the proximal infrastructure, in the distal water outlets, or both. Infections with waterborne organisms such as *Legionella*, mycobacteria, *Pseudomonas*, and others cause significant morbidity and mortality, particularly in immunocompromised patients. Hospitals should have prospective water safety plans that include preventive measures, as prevention is preferable to remediation of contaminated hospital water distribution systems. Whole-genome sequencing may provide more informative epidemiologic data to link patient infections with hospital water isolates.

Keywords Nosocomial · Waterborne · Legionella

Introduction

Hospital water safety is a major priority and constant challenge for healthcare epidemiologists, safety officers, engineers, and administrators. Waterborne infections incur significant morbidity and mortality, and some are preventable. As with other healthcare-associated infections, occurrence of nosocomial waterborne infections erodes public confidence in healthcare facilities. Pathogens such as *Legionella* and nontuberculous mycobacteria can colonize the deep infrastructure or outlets of hospital water distribution systems, while other Gram-negative bacteria and molds tend to adhere to biofilms at or near the distal points of use. In this review, we discuss frequent routes of transmission, categories of waterborne organisms, considerations for prevention and management of waterborne transmission to patients, and future directions in investigation of waterborne outbreaks.

This article is part of the Topical Collection on *Healthcare Associated Infections*

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Routes of Transmission of Waterborne Pathogens

Waterborne infections can occur from proximal (central pipes) or distal (points of use) contamination of the hospital water supply. Municipal and hospital tap water are not expected to be free of pathogens, but municipal water undergoes routine microbiological surveillance to assure safe levels of important community pathogens such as coliform bacteria. Although contaminated municipal water can cause outbreaks that affect immunocompromised patients in healthcare settings [1], contamination of hospital water usually occurs within the infrastructure of the healthcare facility [2]. Bacteria that would not sicken most users of potable water in the community may infect hospitalized patients because of underlying conditions, immunosuppression, and the presence of invasive devices. Waterborne pathogens can be transmitted to patients in a number of ways. Following are examples of the diverse modes of transmission:

- Direct aerosol transmission from water to patients: aerosol from a shower or room humidifier [3, 4] or cooling tower [5], aspiration while drinking water;
- Indirect transmission from fomites that had contact with contaminated water: bath supplies and linens [6]; inappropriate use of nonsterile water for tasks that warrant higher measures of caution, such as oral/tracheostomy care of ventilated patents [7•, 8] and rinsing of respiratory therapy or endoscopic equipment in tap water [9, 10];

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- Exposure of implanted devices to water (e.g., bathing with a central venous catheter improperly covered) [11, 12];
- Transmission on the hands of healthcare personnel: failure to perform hand hygiene after contact with a contaminated environment or patients colonized with waterborne organisms [8]; hand washing with contaminated water [13]; splashback from contaminated sink drains [14].

All of the above defects or practices represent opportunities for prevention through hospital policies, education and monitoring of healthcare personnel practices, and proper cleaning and maintenance of equipment. The precise route of transmission is often unknown, even when infections can be linked to a water source [15].

Biofilms of water distribution systems and points of use have long been recognized as a rich environment for growth of *Legionella,* mycobacteria, *Pseudomonas*, and other waterborne organisms. Eliminating biofilms and their pathogenic residents is a major challenge, as organisms dwelling in these environments may be especially impervious to disinfectants [16, 17]. Biofilms occur in the pipes and the points of use of the water distribution system. Stagnation promotes the ideal conditions for biofilm formation. Guidelines for hospital construction recommend against water pipe formations (such as dead legs and long, horizontal runs [18, 19]) and practices (such as intermittent water usage leading to low flow) that contribute to stagnation. Older facilities may have predated these recommendations, and convoluted pipe architecture may render their structures more vulnerable to water system colonization with *Legionella*, mycobacteria, and others. Cooling towers have been implicated in multiple nosocomial outbreaks, including a recent case reported from a hospital in Japan [5]. Water can also stagnate at the points of use; colonization of fixtures such as electronic eye faucets [20–23], aerators, sink drainage pipes [19], ice machines, decorative fountains [18, 24], and others, has been reported, and sometimes implicated in nosocomial transmission.

Studies of hospital water contamination and some waterborne infections have shown an increase in culture positivity during the summer and early fall. A series of 1,154 cases of Legionnaire's disease, occurring over 16 years in the United States Military Health System, revealed a seasonal predominance favoring the fall and summer months. Over half of cases occurred between June and October, with July and September having the highest and March the lowest prevalence [25]. Others have shown similar results [26]. Other hospital-acquired Gram-negative infections have also been shown to vary seasonally and correlate with humidity [27]. This seasonality of water contamination levels and disease may confound uncontrolled studies or retrospective comparisons between outbreaks and interventions occurring at different times of the year.

Role of the Host

Most waterborne pathogens that cause opportunistic infections in hospital patients do so in a small proportion of patients. Although many more may be exposed to contaminated water, nosocomial infections with *Legionella*, other Gram-negative bacteria, mycobacteria, and molds usually occur in patients who have specific host characteristics—which may differ from the host characteristics that predispose to community-acquired infection because of the concentration of vulnerable patients in healthcare facilities. For example, risk factors for community-acquired Legionnaire's disease include male sex, age over 60, history of tobacco use, chronic underlying lung disease, and diabetes. Risk factors for infection among hospitalized patients who are exposed to *Legionella* include stem cell or organ transplantation, chronic comorbid conditions, and receipt of immunosuppressive therapies [18, 28–31]. Healthy hosts (including healthcare personnel) who are exposed to *Legionella* in aqueous aerosols may develop Pontiac fever, which is a self-limited hypersensitivity reaction to the bacteria, or may seroconvert without symptoms [32, 33]. Hospitalized patients who develop infections with Gram-negative nonfermentering bacteria, such as *Sphingomonas, Achromobacter, Stenotrophomonas, Burkholderia,* and *Acinetobacter* spp., often have endotracheal tubes, central venous catheters, or other implanted devices that allow the bacteria to circumvent the body's physiological barriers.

Legionnaire's Disease

Legionnaire's disease, a potentially lethal pneumonia caused by members of the genus *Legionella*, is an important nosocomial infection. *Legionella pneumophila*, the species responsible for the vast majority of infections, is one of the most dreaded waterborne pathogens. Although most Legionnaire's disease is acquired in the community, approximately 10 % of cases are thought to result from hospital water exposure. As described above, the most immunologically vulnerable patients in the hospital, as well as those with advanced age and chronic lung disease, are at the greatest risk for nosocomial Legionnaire's disease. The mortality rate of nosocomial Legionnaire's disease is approximately 32 %, more than fourfold higher than that of community-acquired infection, likely because of the underlying comorbidities of hospitalized patients [34].

Legionella grow within free-living amoebae, which are hardy and tolerate a wide range of temperatures and other environmental conditions [35, 36]. *Legionella* replicate between 20 and 50 °C, with fastest growth as temperatures

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approach 40 °C—when most bacteria are killed but *Legionella* continue to thrive within amoebae. Temperatures above 60 ° C are highly effective at suppressing (but not eradicating) *Legionella* and do so within minutes. However, heat flushing that provides effective bacterial suppression may also pose safety risks to building occupants.

There are significant geographic variations in the epidemiology of *Legionella* spp. While the infection is common throughout the developed world, different *Legionella* species and serogroups may predominate among countries and continents. Whereas most Legionnaire's disease in Australia is attributed to *L. longbeachae*, most cases of Legionnaire's disease in the USA is caused by *L. pneumophila* serogroup 1, with a minority of infections attributed to other species of *Legionella* and other subtypes of *L. pneumophila.* In the USA, infection with other species and serogroups may be under-recognized because of the diagnostic bias of the *Legionella* urine antigen, which detects only *L. pneumophila* serogroup 1 and accounts for 97 % of *Legionella* tests performed in the USA [37]. *Legionella* PCR and culturing on buffered charcoal yeast extract (BCYE) are means of detecting species other than *L. pneumophila.*

Prevention of hospital-acquired legionellosis requires a multidisciplinary approach involving healthcare epidemiologists and hospital safety officers, facilities architects, and maintenance engineers, as well as clinicians and the microbiology laboratory. Construction of new hospitals or hospital wings should incorporate published guidance that aims to minimize the structural features of water distribution systems that promote growth of *Legionella* [38, 39]. Healthcare epidemiologists must conduct close surveillance for possible cases of nosocomial *Legionella* infection; a single hospital-acquired case should generate an urgent investigation to identify nosocomial sources and preempt further transmission [40].

Microbiology laboratories should have prompt *Legionella* testing available, and clinicians should be reminded to order diagnostic testing for Legionnaire's disease in patients who have compatible clinical syndromes. Testing for suspected *Legionella* need not stop with a negative urine antigen, as that test rules out only one serogroup of one species of *Legionella.* In our hospital, all bronchoalveolar lavage fluid is tested for *Legionella* by both *L. pneumophila* PCR and *Legionella* culture in order to detect rapidly the most likely species and to avoid missing less common species of *Legonella*.

Other Gram-Negative Bacteria

Waterborne Gram-negative bacteria (other than *Legionella)* that have been reported in recent years to infect hospitalized patients tend to be multidrug resistant. The pathogens may be introduced to the water supply via colonized patients and then spread within the environment or to points of water use through the routes of transmission described above.

Although the role of the environment is unclear in many types of nosocomial outbreaks, sink drains have been repeatedly implicated in reports of transmissions of Gram-negative bacteria, including *Pseudomonas* [13, 14], *Klebsiella* spp. [19, 41, 42], and others. Sink aerators [43], drains [23, 44], and more distal drainage sites [19] may become colonized with waterborne human pathogens that enter via hand hygiene of patients or healthcare personnel, rinsing of patient care equipment, or pouring of patient material down the drains. The bacteria may then become incorporated into the existing (and expected) biofilm in these areas that are proximal to patients but distal to the water distribution system [2]. Splashback from sink drains, documented in one clever study using dye [14], may be responsible for the transmission of sinkbound pathogens to patients directly or indirectly on equipment rinsed in or stored near the sink, or on the recently washed hands of healthcare providers [8]. The attribution of an outbreak to sink drain contamination has usually been based on similar genotypic pattern and the termination of the outbreak following remediation of the contaminated sink drain [14, 19, 23]. This set of circumstantial evidence can be convincing but does not definitively demonstrate the drain's responsibility.

Sink biofilm contamination with multidrug-resistant bacteria has proven challenging to remediate, as evidenced by the struggles of Kotsanas et al., Vergara-Lopez et al., and others, to eradicate multidrug-resistant organisms from sink drains [19, 23]. Reflux of more distal contamination may contribute to the tenacity of the outbreak strains in the sink drain. In one prolonged ICU-based outbreak of metallo-β-lactamase-producing *K. oxytoca* in a Spanish hospital, a contaminated sink drain was eventually removed in an attempt to end the outbreak. The intervention reduced the rate of new cases but did not end the outbreak. Further investigation revealed that the outbreak organism could be cultured from a horizontal wastewater pipe in the ICU, and elimination of that drainage system was associated with termination of the outbreak [19].

Because of the difficulty in achieving enduring disinfection of hospital sinks, preventing transmission from sink drains via optimizing sink design (slow flow of water, faucet far above the drain, and location of the sink away from patient and patient care equipment) may be worth the investment of resources [14].

It behooves the healthcare epidemiology team to keep an open mind regarding patients' less common direct or indirect exposures to water. Several reports have documented transmission of *Aeromonas* spp. to patients via leeches (kept in tanks that were inadequately cleaned) [45]. As might be expected, some *A. hydrophila* isolates have been resistant to the antibiotics that are used as prophylaxis against infection [46, 47]. Proper cleaning and maintenance of leech tanks would seem to provide enduring value in preventing leech-associated infections.

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Nontuberculous Mycobacteria

Hospital water has been linked to nosocomial outbreaks and pseudo-outbreaks of nontuberculous mycobacteria of diverse species, some more pathogenic than others. Unlike Gram-negative bacteria, which characteristically colonize the distal components of the water distribution system, mycobacteria often colonize both the proximal and distal components of a building's water infrastructure [2, 7•, 48, 49]. Once they colonize a water distribution system, it is very difficult to suppress their growth using means that are effective for *Legionella* and other waterborne organisms [7•].

Species belonging to *Mycobacterium avium* complex, the most frequent nontuberculous mycobacterial causes of community-acquired infection, have been isolated from potable water in the community [50] and in hospitals [51, 52]. Other mycobacterial species that are not generally pathogens in the community (e.g., *M. mucogenicum* and *M. smegmatis*) may cause opportunistic infections—particularly central venous catheter-related bacteremia—in highly immunocompromised, hospitalized patients. A recent outbreak of rapidly growing mycobacteria reported among stem cell transplant recipients at a children's hospital was traced to ice machines and the potable water supply [53]. Pseudo-outbreaks of mycobacteria traced to water contamination of respiratory specimens have also been reported, leading to avoidable antibiotic exposure in some of the affected patients [7•, 49, 54, 55].

Molds

Studies have shown contamination of hospital water outlets with molds that are potentially pathogenic to immunocompromised patients [56–60]. Species such as *Aspergillus* and *Fusarium* cause opportunistic sinopulmonary infections in neutropenic patients as well as stem cell and organ transplant recipients. They are usually thought to derive from inhalation of airborne fungal spores, but their presence in cultures of showerheads and faucets raises the possibility that they could be transmitted from these points of water use [56–60].

Prevention and Control of Water System Colonization

Proximal Water Management

The water system of a hospital may not inspire much consideration until a problem occurs. Published guidelines recommend that each healthcare facility develop prospectively and follow a comprehensive water management program [38, 39]. This plan should include a risk assessment that identifies all water treatment systems at play, all points of water use that pose potential hazards, and control strategies to mitigate any hazards. Krageschmidt et al. describe in detail such a program in a complex healthcare system [61•].

Actions that help prevent *Legionella* contamination of hospital water distribution systems include avoiding water temperatures between 20 and 50 °C, avoiding areas of water stagnation and low flow that promote biofilm growth, avoiding plumbing components that provide nutrients and hospitable environments for *Legionella* (such as rubber hoses), and managing the accumulation of sediment and scale that can nourish and harbor *Legionella*.

Many disinfection systems are now available for use in hospital water distribution systems, each with optimal operational levels and limits. Several of these modalities have been reviewed by Lin et al. [62]. A growing body of evidence supports the effectiveness of monochloramine over other modalities of *Legionella* control; chloramination is used widely in municipal water systems, but there are insufficient data on its supplemental use in hospitals. Marchesi et al. monitored *Legionella* contamination of water in three hospital buildings (two occupied by patients) for three years, comparing *Legionella* counts with the use of chlorine dioxide, monochloramine, and control [63]. Both modalities reduced levels of *Legionella* below those in the control building, but monochloramine was significantly more effective [63]. Monochloramine may have a greater effect than other disinfectants on bacteria associated with biofilm [64].

Regardless of the methodology used, monitoring is critical. In addition to monitoring levels of any added disinfectant, a facility may need to test levels of relevant breakdown products [65]. Close monitoring of levels is crucial, but not sufficient, and the presence of adequate biocide parameters does not guarantee that water is safe. Outbreaks have occurred when systems were operating within recommended guidelines. Copper-silver levels were measured at goal levels in a recent outbreak of *Legionella* in a Pittsburgh area hospital [66], and a functioning ozone system and bromide filter were in place prior to an outbreak of *Legionella* associated with a decorative fountain in a hospital [18]. Some studies have noted the persistence of *Legionella* tolerant to disinfectants [67–69].

The decision to switch treatment modality to ameliorate overgrowth of one pathogen may have unintended consequences on growth of other potential pathogens. Casini et al. describe the successful reduction in *Legionella* growth after switching from chlorine to monochloramine, although the switch was associated with increased detection of mycobacteria [68]. In an ICU-based outbreak of metallo-β-lactamase-producing *K. oxytoca* in Spain, each wave of the outbreak terminated after annual hyperchlorination was performed for *Legionella* prevention; the *K. oxytoca* in wastewater pipe biofilms was presumably suppressed following the intervention and recrudesced each time several months later [19]. Due to the limitations of our current water treatment strategies, it is critical for the infection prevention team to maintain a high level of suspicion, even in the setting of what appears to be optimal disinfection.

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The literature and published guidelines on the prevention of nosocomial *Legionella* infection reflect varying levels of conservatism with respect to primary prevention. The Centers for Disease Control and Prevention recommend close clinical surveillance for *Legionella* infection and a low threshold for investigation when a suspected nosocomial case occurs and suggest prospective sampling and testing of water on wards that house stem cell or organ transplant patients [40]. Guidelines in much of Europe recommend prospective, regular sampling and testing of water in a range of buildings, including hospitals.

Water disinfection systems are often implemented urgently to avoid or ameliorate a catastrophe. There is a great need for long-term, methodologically rigorous studies to move the field forward and answer clinical questions with data rather than expert opinion whenever possible.

Distal Water Management

Many reports implicate colonization of point-of-use water sources in outbreaks of all categories of pathogens discussed above. Nosocomial infections associated with showers [70], ice machines [53, 71, 72], decorative fountains [18, 24], steam towel warmers [6], and dental water lines [73–76] have all been reported. Management of these contaminated fixtures ranges from attempted cleaning and disinfection to outright removal or replacement. Reporting bias in the literature may favor publications that describe the eventual success of measures to suppress or eradicate contamination at water outlets. There is no one method, including removal and replacement, that has proven successful in all cases. In the case of equipment that serves as a water outlet, such as ice machines, regular cleaning and maintenance are critical to avoid contamination that can overwhelm bandaid measures such as inline filtration [7•].

In addition to preventing proximal colonization of water systems and obligatory removal of colonized hardware, point-of-use filtration may serve as a final barrier and safety measure in some settings. The Centers for Disease Control and Prevention suggest such filters in patient care units that serve transplant recipients. One liver transplant unit within a 1,600-bed hospital with no internal disinfection system succeeded in eliminating cold-water colony counts of *Legionella*, mycobacteria, and filamentous fungi by installing faucet filters, while control sources without filters continued to grow these organisms. Interestingly, over time, the heterotrophic plate count increased, suggesting splashback from the sink drain or breakthrough contamination of the filters [26]. Williams et al. noted similar findings after they installed point-of-use filters in a select handful of faucets in a skilled nursing facility that had experienced an outbreak/pseudo-outbreak of rapidly growing mycobacteria [7•]. In that setting, faucet filters prevented mycobacterial (but not heterotrophic plate count bacteria) contamination of patient water; an inline filter failed to prevent contamination of the ice machine with either mycobacteria or heterotrophic plate count bacteria in a setting of low water use and low free chlorine levels [7•]. Point-of-use filters may be a useful approach in a strategic set of faucets, but are not a practical solution for an entire hospital, as they must be changed frequently. However, they can be considered as a last-resort safety measure to lower the exposure risk for the most vulnerable patients.

In some settings, avoidance of water may be an appropriate interim intervention—particularly when highly vulnerable patients are at risk and the water contamination cannot be solved promptly. In the aforementioned cluster of mycobacterial infections and colonization among pediatric stem cell transplant recipients, a switch to bottled water and a two-minute flush of all showers preceding use by this patient population ended the outbreak [53].

Future Research

Finding on a water fixture the same genus and species of organism that is responsible for a healthcare-associated infection is merely suggestive of an environmental role in transmission to the patient. Genotypic confirmation of this association, and, when possible, the use of more granular technology such as whole-genome sequencing, can further elucidate the direction, timing, and likelihood of intermediate steps involved in transmission.

Most outbreak reports, including those described in this review, utilized limited molecular strain typing methods to link potential sources to patient isolates. Time-honored techniques such as pulsed field gel electrophoresis and repetitive element PCR (REP-PCR) have narrow ability to detect genotypic differences among isolates. In the past 4 years, the use of whole-genome microbial sequencing to document and describe outbreaks both within [41, 77] and outside [78, 79] healthcare settings has accelerated rapidly. Whole-genome sequencing provides the high resolution needed to make connections among patient isolates and water or other environmental isolates and to detect the minute variations that occur with chronic colonization of a water distribution system [80, 81]. In combination with epidemiologic meta-data, whole-genome microbial sequencing and techniques based on that technology such as pan-PCR [82] promise increasingly to replace speculation about the dynamics of transmission of waterborne pathogens. Healthcare epidemiologists may be able to act on these data to target more effectively their preventive measures and outbreak control interventions to interrupt the transmission of waterborne pathogens to patients.

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Conclusion

Microbial contamination of a healthcare facility water supply is better prevented than remediated. Many waterborne infections are preventable with adherence to optimal healthcare hygiene practices. Hospitals must have prospective water management program that are updated regularly. Even if that program includes properly monitored, supplemental disinfection of the water distribution system, healthcare epidemiologists and clinicians must be vigilant to the possibility of breakthrough contamination and infections, which tend to occur first among the most immunocompromised or critically ill patients. Whole-genome microbial sequencing has the potential to provide a higher level of actionable epidemiologic data in assessing transmission of waterborne pathogens. Facilities can consider the limited use of extra measures such as point-of-use filters as a last line of protection for the most vulnerable patients.

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Compliance with Ethics Guidelines

Conflict of Interest Tara Palmore and Brooke Decker have no conflicts of interest.

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Outbreak of nosocomial urinary tract infections due to *Pseudomonas aeruginosa* in a paediatric surgical unit associated with tap-water contamination

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Summary: An outbreak of 14 cases of urinary tract infections by *Pseudomonas aeruginosa*, including six symptomatic infections, occurred from September to November 1994 in a paediatric surgical unit. During the outbreak, urine samples from patients and multiple samples from the environment of patients were tested for the presence of *P. aeruginosa*. Bacterial isolates were studied by pulsed-field gel electrophoresis. Genotypic analysis showed that most of the isolates from children were different. Multiple *P. aeruginosa* isolates were also found in the tap water, as the only putative source of contamination. Two of these isolates were identified in two infected patients, indicating possible direct contamination of patients via tap water and this was related to the distal colonization of faucets. Bacteria were eradicated from tap water by replacement of taps. The cluster of cases of *P. aeruginosa* urinary infection was, therefore, related to multiple contaminations through tap water. These results illustrate an unexpected risk of nosocomial infection and emphasizes the importance of checking tap water to prevent bacterial contamination through handwashing in contaminated water.

Keywords: *Pseudomonas aeruginosa*; urinary infection; tap water.

Introduction

Pseudomonas aeruginosa is an opportunistic pathogen frequently responsible for hospital-acquired infections.[1–4] This Gram-negative bacterium is widespread in the environment, often isolated from soil, water and plants.[2] The epidemiology of *P. aeruginosa* reflects its predilection for moist environments. It colonizes humans at moist sites such as the perineum, axilla and ear.[2] Hospital-acquired outbreaks have often been traced to specific reservoirs, including antiseptics, respiratory equipment and sinks.[5–7] Patient-to-patient transmission via the hands of hospital staff or by other means is often assumed but difficult to prove.[2,8]

Urinary tract infections by *P. aeruginosa* are usually hospital-acquired and often iatrogenic.[9]

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They may be related to urinary tract catheterization,[10] instrumentation or surgery, including renal transplantation.[11–13] *P. aeruginosa* is the third most common nosocomial urinary tract pathogen after *Escherichia coli* and Enterococci, and is responsible for almost 11% of all hospital-acquired urinary infections.[14] *P. aeruginosa* usually affects the urinary tract through ascending infection and adheres strongly to bladder uroepithelium.[15] Prevention of nosocomial infections is based on the use of a closed, sterile drainage system and on the continuing education of the staff about careful handwashing, before and after handling of the patient's catheter. Here, we report an outbreak of nosocomial urinary tract infections associated with contamination of tap water in a paediatric surgical unit. This illustrates an unexpected risk of nosocomial transmission through handwashing.

Materials and methods

The paediatric surgical ward

The paediatric surgical ward of our hospital comprises 59 beds located on the two highest levels of a six-floor building. The fifth and sixth floors are reserved for children aged zero to three years (fifth floor) and four to 15 years (sixth floor). The operating room is located on the ground floor. Host patients come directly to the unit from their homes but more serious cases are transferred to the intensive care unit, which is located on the third floor. On the sixth floor, all rooms are equipped with a hand-basin and a baby bath-tub. The fifth floor is equipped only with individual hand-basins.

Bacteriological methods

Fifty millilitres of tap water were collected into sterile flasks after running the tap for a few seconds. Samples were filtered through 0.45 μm mesh filters, then incubated at 41°C for 48 h on cetrimide agar medium (Diagnostics Pasteur, Marnes-La-Coquette, France). Urine samples were cultured at 37°C on a CPS medium (bioMérieux, Marcy-l'Etoile, France). *P. aeruginosa* isolates were identified by positive oxidase reaction, colony morphology, pyocyanin production, motility, growth at 41°C and the API 20 NE system (bioMérieux). O-serotyping of isolates was performed by slide agglutination using antisera from Diagnostics Pasteur. Isolates agglutinated by more than one typing serum were designated non-typeable. Antimicrobial susceptibility testing was carried out on Muëller–Hinton agar (bioMérieux) with a disk diffusion technique using 10 antibiotics (ticarcillin, ceftazidim, aztreonam, fosfomycin, ciprofloxacin, piperacillin, tobramycin, amikacin, cefsulodin, imipenem).

Pulsed-field gel electrophoresis (PFGE)

P. aeruginosa strains were compared by PFGE, using a modified version of the method of Boukadida *et al.*[16] DNA was incubated overnight with 20 UI *Spe*I (New England Biolabs, Inc, Beverly, Mass) and fragments were separated on a 1% agarose gel by PGFE with a CHEF mapper DRII apparatus (Bio-Rad Laboratories, Richmond, USA) for 24 h at 14°C and 6 V/cm. The control strains used in this work were: ATCC 27853 and one unrelated wild-type isolate n° 147589 cultured from the sputum of an adult hospitalized in another building of the hospital.

Results

Outbreak of urinary infection by P. aeruginosa *in the paediatric surgical unit*

From September to November 1994, 503 children were admitted to the paediatric surgical ward of our hospital. *P. aeruginosa* was isolated from the urine samples of 14 children during this period (14/503: 2·8%). In the same period of the previous year, only three children (3/564: 0·5%) were asymptomatically infected by *P. aeruginosa* as detected by urine samples ($P = 0{\cdot}003$). Urinary infection by *P. aeruginosa* was associated with clinical symptoms (fever, dysuria, leucocyturia) in six of the 14 patients, the other patients being asymptomatic. Urine

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cultures from the six patients with symptoms yielded more than 10^5 bacterial/mL. Five of these six patients were under the age of two, the other was 12 years old. Infection occurred in a mean period of four days after admission and three days after surgery. Eleven of the 14 patients had a urinary catheter (Table I). Five of the six symptomatic patients underwent kidney surgery. All patients rapidly recovered with specific antibiotic treatment.

Characterization of P. aeruginosa *isolates*

Twenty-two isolates of *P. aeruginosa* were collected from the urine samples of 14 patients. For each isolate, a phenotypic and genotypic analysis was performed by O-serotyping, antibiotic susceptibility tests and PFGE-restriction patterns. Six and two isolates belonged to serotype O6 and serotype O10, respectively. The other isolates were non-typeable (Table I). When isolates were repeatedly collected from a given patient, they always proved to be a single strain with the same phenotype and genotype. Genotype analysis by PFGE showed that there were 13 different restriction patterns in the 14 isolates from patients (Figure 1), without correlation between PFGE pattern and serotype or antibiotic pattern (Table I). These results suggest that patients were infected via various sources of contamination. Two isolates (patients 13 and 14) were identical, suggesting possible cross-contamination or a common source of infection.

Bacteriological investigation of the ward environment

A complete bacteriological investigation on the ward environment was performed during the outbreak. The water supplies of the entire building were sampled, as were all possible environmental reservoirs of *P. aeruginosa* (antiseptic solutions, aerosol supplies, vaseline, syphons, sinks, surface of taps and showers before the first use each morning). The collection pipes of the building were also examined. Three hundred and fifty-three samples were thus obtained from 257 sites, including repeated samples from taps. The results are summarized in Table II. Thirty-three *P. aeruginosa* isolates were cultured from repeated samples of 21 of the 118 taps tested (18%), from the surgical unit (fifth and sixth floors). Water samples tested negative in the operating room and on the other floors, except the intensive care unit (third floor) where four of 26 samples of tap water were positive. Four samples from the main water pipes entering the building failed to yield *P. aeruginosa* but in the surgical ward, the species was isolated from six of 10 basin trap samples and from seven of 98 samples taken from showers and anti-splash tap-nozzles. No *P. aeruginosa* was isolated from the six samples taken from aerosol pipes, the three samples from vaseline and the 18 samples from various surfaces (Table II). Genotypic analysis by PFGE was performed on 18 of the 21 isolates obtained from tap water that tested positive in the surgical unit (data not shown). We found 15 different PFGE-restriction patterns, illustrating the genetic diversity of the environmental strains. One serotype O6 isolate was collected from two contiguous rooms on the sixth floor and this isolate was genotypically identical to that recovered from patient 9 who was hospitalized in one of these rooms. In addition, the profile of a serotypically non-typeable strain isolated from the water of the fifth floor bathroom was identical to the profile of the two identical strains isolated from patients 13 and 14 (Figure 1).

Prevention and control of contamination

During the outbreak, strict hygiene measures were enforced, including urinary tract nursing with sterile water. Environmental decontamination was also set up. This included disinfection of basin traps and anti-splash devices, followed by two trials of chlorine decontamination of the entire water supply of the building. In spite of these measures, three of 118 water supplies still tested positive for *P. aeruginosa*, suggesting a distal origin of the contamination. All taps were then removed from the unit, allowing a complete eradication of bacteria from the water. The same measures were undertaken within the intensive care unit.

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Table I *Characteristics of the 14 patients with urinary tract colonization by* Pseudomonas aeruginosa

Case No	Age*	Floor	Date of hospitalization (1994)	Date of surgical intervention	Clinical symptoms	Urinary catheter	Isolation date (1994)	Serotype†	Antibiotic susceptibility‡	PFGE restriction pattern
1	1 y	5	17 Nov	17 Nov	Yes	Yes	21–22 Nov	NT	S	A
2	1 y	6	12 Sept	13 Sept	No	Yes	13 Sept	NT	R to Fos	B
3	1 y	6	5 Oct	6 Oct	Yes	Yes	11, 13, 14 Oct	O6	R to Fos	C
4	9 y	5	21 Sept	14 Oct	No	Yes	23 Sept 15, 16 Nov	O6	R to Fos	D
5	1 y	6	23 Sept	23 Sept	Yes	No	27Sept	O6	R to Fos	E
6	3 y	5	17 Oct	18 Oct	No	No	18 Oct	O10	R to Fos	F
7	1 y	6	24 Oct	25 Oct	Yes	Yes	29 Oct	NT	R to Tic, Pip, Azt, Cefs, Caz	G
8	2 m	6	13 Sept	14 Sept	No	Yes	20, 22 Sept	O6	R to Fos	H
9	2 m	6	7 Nov	8 Nov	No	Yes	14 Nov 16, 19 Nov	O6	S	I
10	12 y	5	22 Sept	23 Sept	Yes	No	27 Sept	NT	R to Fos	J
11	7 m	6	15 Nov	17 Nov	No	Yes	25 Nov	O6	R to Fos	K
12	2 y	5	11 Oct	12 Oct	Yes	Yes	17 Oct	NT	R to Fos	L
13	9 y	5	28 Sept	29 Sept	No	Yes	7 Nov	O10	R to Tic, Pip, Amk, Tob, Cefs, Fos	M
14	1 y	5	15 Nov	15 Nov	No	Yes	22 Nov	NT	R to Tic, Pip, Amk, Tob, Cefs, Fos	M

* y = years; m = months.

† NT = non-typeable.

‡ S: susceptibility to all antibiotics tested; R: resistance; Fos: fosfomycin; Tic: ticarcillin; Pip: piperacellin; Azt: aztreonam; Cefs: cefsulodin; Caz: ceftazidime; Amk: amikacin; Tob: tobramycin.

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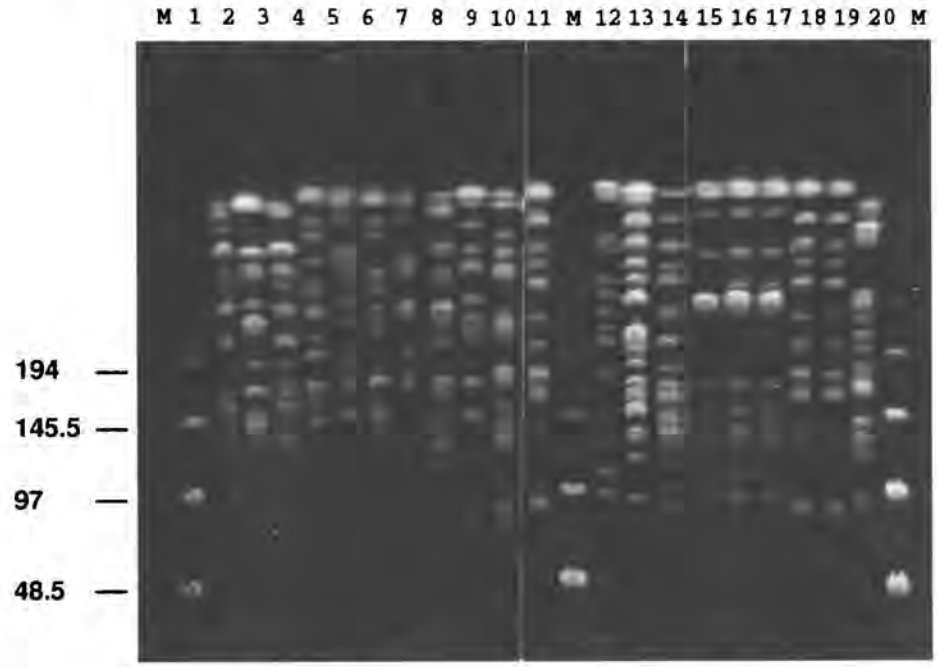

Figure 1 PFGE restriction profiles of clinical and environmental isolates of *P. aeruginosa*. Chromosomal DNA was digested with *Spe*I. M = bacteriophage λ DNA ladder (bp). Lanes: 1, strain ATCC 27853; 2, control unrelated wild isolate n° 147589; 3–16, strains from patients 1–14 (cf. Table 1); 17, *P. aeruginosa* O6 isolated from tap water of the bathroom on the 5th floor; 18 and 19, *P. aeruginosa* O6 isolates from the tap water of two rooms on the 6th floor; 20, non-typeable *P. aeruginosa* isolate from a room on the 6th floor.

Table II *Bacteriological investigation of the environment of patients*

			Isolation of *P. aeruginosa*	
Sources	No. samples	No. sites	No. isolates	No. sites
Tap water	214	118	33	21
Water network	4	4	0	0
Basin traps	10	10	6	6
Anti-splash tap nozzles and showers	98	98	7	7
Miscellaneous*	27	27	0	0
Total	353	257	46	34

* Antiseptic solutions, aerosols, vaseline, syphons, sinks, surfaces of taps and showers.

After the outbreak was brought under control, several guidelines were proposed for daily decontamination of taps and basin traps with chlorine, and a monthly bacteriological survey of all the water supplies of the unit. Introduction of these measures was followed by a marked decrease in urinary tract infections involving *P. aeruginosa* in the unit. Since 1994, tap water has been found to be sporadically contaminated at low level: each time taps were immediately removed and cleaned, and no subsequent contamination was recorded.

Discussion

We report in this work a cluster of 14 cases of nosocomial urinary tract infections by *P.*

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aeruginosa, including six symptomatic infections, in children hospitalized in a surgical unit. By genotypic analysis with PFGE, we found that the isolates were highly heterogeneous, except in two cases where cross-contamination or a common source of contamination was possible. These results suggest that infection of children might have resulted from exogeneous sources of contamination. An in-depth investigation of the ward environment involving 353 samples from 257 different sites showed that the only source of contamination was tap water. Indeed, 21 of 118 taps (18%) in the surgical unit were contaminated by *P. aeruginosa*, all other samples testing negative. Genotypic analysis showed that these isolates were also highly heterogeneous. The isolates of two patients displayed the same PFGE patterns as those found for the isolates from the tap water in the rooms where they were hospitalized or in the bathroom of the same floor. These results strongly suggest that the outbreak of *P. aeruginosa* infections was due to contamination via tap water. Removing all 10-year-old taps and reinforcement of hygiene measures resulted in the complete eradication of water contamination and in a marked decrease in *P. aeruginosa* urinary tract infections.

Urinary infections are a frequent complication of surgical procedures involving the urinary tract. These infections are related to nursing procedures in the days following the operation, rather than to the surgical procedure itself.[17] Bacterial colonization is also facilitated by urinary tract malformations and indwelling urinary devices.[9,18] Most of the infections reported here affected recently operated children with urinary catheters, so daily nursing procedures using contaminated tap water probably caused urinary infections, despite the use of antiseptic solutions. *P. aeruginosa* may have been transmitted directly, for example during bath, or indirectly, via handling by the nursing team after they had washed their hands with contaminated tap water.

P. aeruginosa has often been reported as the causative pathogen in outbreaks of urinary tract infections,[17,19] but tap water has rarely been reported as a source of contamination. To our knowledge, only one outbreak of *P. aeruginosa* in a burns unit, involving five cases of septicaemia, has been related to tap water contamination.[20] *P. aeruginosa* contamination was restricted to showers and tubing permanently connected to tap water, and the outbreak stopped after disinfection.[20] In this outbreak, it is likely that anti-splash tap nozzles and shower pommels heads may have constituted a reservoir, presumably via biofilm formation, as these devices permanently contain stagnant water at room temperature, favouring bacterial survival. The inner part of 10-year-old taps were never disinfected. This outbreak emphasizes that tap water may be an important, often underestimated, source of contamination for hospital patients and suggests that the use of sterile water for nursing procedures may be beneficial.

Acknowledgements

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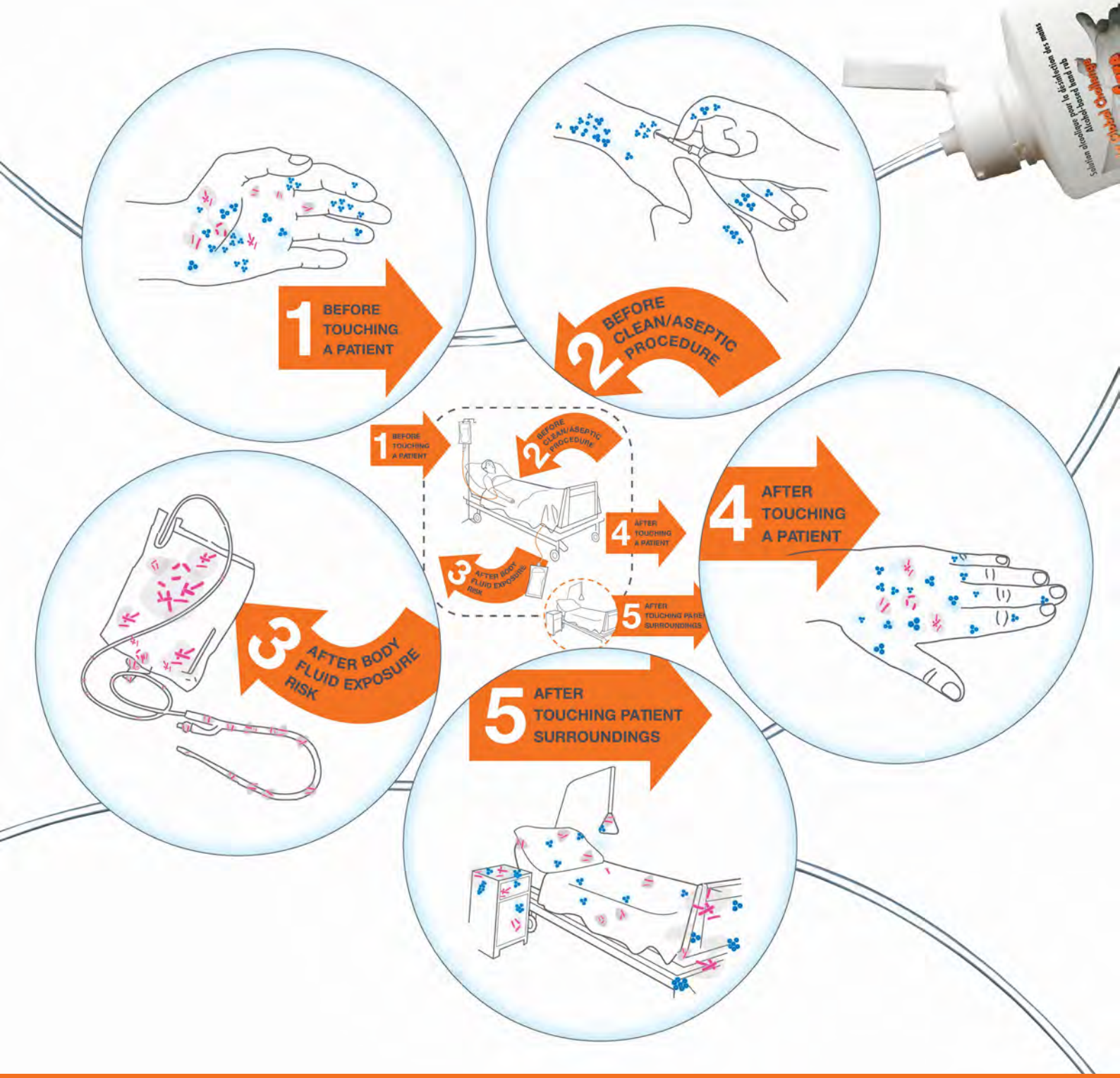

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INFECTION CONTROL AND HOSPITAL EPIDEMIOLOGY JANUARY 2009, VOL. 30, NO. 1

ORIGINAL ARTICLE

Outbreak of Multidrug-Resistant *Pseudomonas aeruginosa* Colonization and Infection Secondary to Imperfect Intensive Care Unit Room Design

Susy Hota, MD; Zahir Hirji, MHSc; Karen Stockton, MHSc; Camille Lemieux, MD, LLB; Helen Dedier, MLT; Gideon Wolfaardt, PhD; Michael A. Gardam, MD, MSc

BACKGROUND. *Pseudomonas aeruginosa* has been increasingly recognized for its ability to cause significant hospital-associated outbreaks, particularly since the emergence of multidrug-resistant strains. Biofilm formation allows the pathogen to persist in environmental reservoirs. Thus, multiple hospital room design elements, including sink placement and design, can impact nosocomial transmission of *P. aeruginosa* and other pathogens.

METHODS. From December 2004 through March 2006, 36 patients exposed to the intensive care unit or transplant units of a tertiary care hospital were infected with a multidrug-resistant strain of *P. aeruginosa*. All phenotypically similar isolates were examined for genetic relatedness by means of pulsed-field gel electrophoresis. Clinical characteristics of the affected patients were collected, and a detailed epidemiological and environmental investigation of potential sources was carried out.

RESULTS. Seventeen of the infected patients died within 3 months; for 12 (71%) of these patients, infection with the outbreak organism contributed to or directly caused death. The source of the outbreak was traced to hand hygiene sink drains, where biofilms containing viable organisms were found. Testing by use of a commercial fluorescent marker demonstrated that when the sink was used for handwashing, drain contents splashed at least 1 meter from the sink. Various attempts were made to disinfect the drains, but it was only when the sinks were renovated to prevent splashing onto surrounding areas that the outbreak was terminated.

CONCLUSION. This report highlights the importance of biofilms and of sink and patient room design in the propagation of an outbreak and suggests some strategies to reduce the risks associated with hospital sinks.

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An important goal in hospital design is to create a safe environment for the delivery of patient care. While much attention is typically directed toward the potential dispersion of environmental organisms, such as *Aspergillus* and *Legionella* species, during construction activities, other pathogens, such as *Pseudomonas* and *Serratia* species, may also pose an ongoing hazard once the facility is operational. By advising on aspects of room design, patient placement, and plumbing facilities, infection control consultation can ensure that the risks of hospital-acquired infections are minimized.

Pseudomonas aeruginosa has been increasingly recognized for its ability to cause significant hospital-associated outbreaks of infection, particularly since the emergence of multidrug-resistant strains. Outbreaks of multidrug-resistant *P. aeruginosa* colonization or infection have been reported on urology wards, a burn unit, hematology/oncology units, and adult and neonatal critical care units.[1-8] Various medical devices and environmental reservoirs have been implicated in these outbreaks, including antiseptic solutions and lotions; endoscopy equipment; ventilator apparatus; and mouth swabs.[9-13] These sources can easily be eliminated once identified. A greater challenge exists if the source of an outbreak involves permanent components of the hospital physical plant, such as plumbing fixtures.

We describe an outbreak of multidrug-resistant *P. aeruginosa* infection that resulted from colonization of hand hygiene sink drains in a recently constructed tertiary care medical/surgical intensive care unit (MSICU), transplant stepdown unit, and transplant ward. This report highlights the key role of sink design and inpatient room design in causing such an outbreak, and it outlines effective strategies to manage outbreaks of this nature. We also emphasize the challenges that surround early outbreak recognition in a complex medical care facility.

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METHODS

Outbreak Overview

The outbreak occurred from December 2004 through March 2006 and involved 3 hospital areas: the MSICU, the solid organ transplant stepdown unit, and the solid organ transplant ward. The outbreak strain of *P. aeruginosa* was phenotypically determined to be resistant to all antipseudomonal antibiotics (ie, ceftazidime, imipenem, ciprofloxacin, piperacillin-tazobactam, and gentamicin), except for variable sensitivity to amikacin.

Epidemiologic Investigation

Possible outbreak-affected patients were defined as patients admitted to the affected area during the outbreak period who were colonized or infected with *Pseudomonas* isolates that matched the outbreak phenotype. An epidemiologic investigation was carried out to search for potential case-case links or case–common environmental source links. Demographic and clinical information for affected patients was collected by means of retrospective review of electronic medical records and the laboratory information system. Environmental screening for the outbreak strain was performed on 8 occasions in the outbreak areas.

Microbiologic Evaluation of Clinical and Environmental Isolates

All specimens collected for culture and sensitivity testing were tested for antimicrobial susceptibilities, according to standard protocols.[14] The routine panel of antimicrobials tested by means of the VITEK automated instrument (bioMérieux) included ceftazidime, ciprofloxacin, gentamicin, tobramycin, piperacillin-tazobactam, amikacin, and imipenem. Additional testing of susceptibility to meropenem and colistin was performed using the E-test (AB Biodisk). No standard guidelines for interpretation of E-test susceptibility of *P. aeruginosa* to colistin are available; an isolate with an E-test minimum inhibitory concentration of no more than 4 ug/mL was considered susceptible, in keeping with published recommendations.[15]

Molecular Characterization

The initial determination of whether an isolate belonged to the outbreak strain was made on the basis of the antimicrobial resistance phenotype; pulsed-field gel electrophoresis (PFGE) was then used to determine genetic relatedness. Isolates were digested using the restriction enzyme *Spe*I, with a protocol run time of 20 hours and switch times of 5.35 seconds (Bio-Rad CHEF Mapper; Bio-Rad). Bionumerics software (Applied Maths) was used to determine phylogenetic relatedness, as the criteria previously developed by Tenover et al.[16] were found to be too discriminatory.

Biofilm Testing

Drain plugs from 3 sink traps were carefully rinsed with sterile water to remove nonattached cells, stained with the Live/Dead BacLight kit (Molecular Probes), and examined in a fully hydrated state using confocal laser scanning microscopy. Whole sink traps were also removed, sealed with trapped water left inside, and stored at room temperature for up to 6 weeks. Replicate sections of the traps were cut off at intervals of 2 weeks; at each interval, one-half of the samples were directly stained with BacLight and examined with confocal laser scanning microscopy, and the other half were flooded with a tryptic soy broth (diluted to a concentration of 1%) and incubated for 24 hours at room temperature to determine the persistence and viability of biofilm microcolonies.

Hand Hygiene Sink Evaluation

To determine whether sink drain contents were being dispersed onto surfaces outside of the drain itself, an emulsification of a commercially available fluorescent marker (Glow Germ) was injected deep into the drain cover of a MSICU hand hygiene sink. The faucet was then turned on and the water run for 15 seconds, while handwashing took place. With light eliminated from the room and all surfaces of the room covered with black paper, the area surrounding the sink was examined for evidence of fluorescent residue by use of a long-wave ultraviolet light source. In order to ensure that nonspecific fluorescence was absent, a pretest using the same protocol but without the fluorescent marker was performed.

Outbreak Control Measures

The following outbreak control measures were attempted: the use of contact precautions (wearing of gowns and gloves by healthcare workers and single room isolation of the patient) for all colonized or infected cases; staff education; enhanced environmental cleaning; disinfection of hand hygiene sink drains; closure of hand hygiene sinks; and renovation of hand hygiene sinks to prevent splashing of drain contents.

Setting

The Toronto General Hospital is part of the University Health Network and is located in Toronto, Ontario, Canada. It is a 400-bed tertiary care center and solid organ transplantation referral center for central and eastern Canada, performing over 400 transplants per year (lung, renal, liver, heart, and multivisceral). The MSICU consists of 22 single rooms and 1 semiprivate room; the percentage of beds occupied by transplant recipients is approximately 40%. Adjacent to the MSICU is a transplant stepdown unit, with 8 single beds, for patients who are transitioning from the MSICU to the transplant ward or vice versa. The transplant ward is located 3 floors directly below the MSICU and contains 39 beds (in 17 single and 11 semiprivate rooms).

A typical MSICU room layout is shown in Figure 1*A*. The

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dedicated hand hygiene sink is approximately 1.3 meters from the head of the bed, and it is directly adjacent to the medication and sterile dressing preparatory area (Figure 1*B*). The sink is a wall-mounted, hands-free model with a shallow stainless steel bowl. The water spout was designed to flow water directly into the sink drain, without hitting the sides of the bowl (Figure 1*C*).

RESULTS

Patient Characteristics

The epidemiologic curve for the preoutbreak, outbreak, and postoutbreak periods is shown in Figure 2. From December 2004 to July 2006, there were 36 patients identified as infected or colonized with the outbreak strain of *P. aeruginosa.* Table 1 outlines the characteristics of affected patients and types of infections.

Two-thirds of affected patients (24 of 36) were considered infected with the outbreak strain, and 17 (47.2%) of the total cohort died. An independent chart review of all deaths in infected patients revealed that infection with the outbreak strain caused death in 5 (29.4%) and contributed to death in 7 (41.2%).

Twenty-one (58.3%) of affected patients were identified while in the MSICU, 5 (13.9%) in the transplant stepdown unit, 4 (11.1%) on the transplant ward, and 6 (16.7%) elsewhere in the hospital building. Of note, all of the patients identified elsewhere in the building had prior exposure to the MSICU, transplant stepdown unit, or transplant ward within the outbreak period. Thirty-four (94.4%) of affected patients

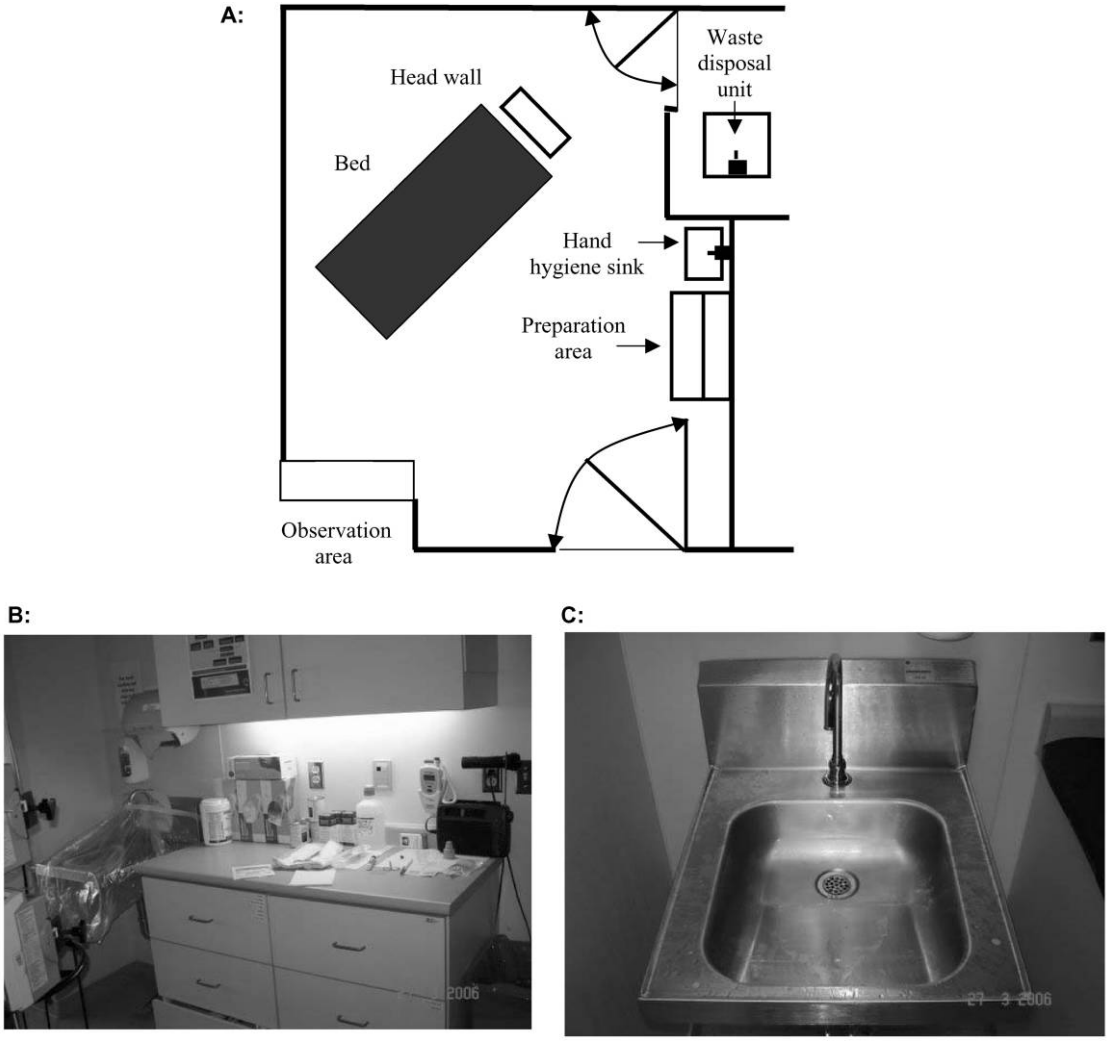

FIGURE 1. Three images from the medical surgical intensive care unit. *Panel A,* typical room layout; *panel B,* counter used for sterile procedures and medication preparation, in relation to sink; *panel C,* close-up of hand hygiene sink; note shallow bowl and gooseneck faucet.

were considered immunocompromised (by receipt of transplant, by malignancy, or by other cause).

Environmental Testing

A total of 288 environmental specimens were collected and analyzed for the presence of the outbreak strain; 28 specimens yielded positive results (Table 2). No multiuse equipment was found to be contaminated. Of all sources of environmental specimens, hand hygiene sink drains accounted for the highest proportions of positive culture results (11 of 65 sink drain specimens from the MSICU were positive for the outbreak strain, as were 10 of 59 sink drain specimens from the transplant stepdown unit and 5 of 89 sink drain specimens from the transplant ward). Many drains were found to be intermittently colonized. None of 39 specimens of source water tested yielded growth of *Pseudomonas* species. Two external plumbing fixtures were found to be positive (1 showerhead in the MSICU and 1 spout in the transplant stepdown unit).

Molecular Characterization

PFGE banding patterns for clinical and environmental isolates are presented in Figure 3. Two types, designated 1 and 16, were deemed sufficiently genetically related to be considered involved in the outbreak. The majority of clinical isolates were of PFGE type 1.

Biofilm Testing

Confocal laser scanning microscopy confirmed the presence of confluent biofilms, some areas more than 100 μm thick, in the samples analyzed (Figure 4). Viable multidrug-resistant *P. aeruginosa* isolates phenotypically consistent with the outbreak strain were recovered from these samples. Starvation experiments, in which the intact biofilms were kept for up to 6 weeks before addition of a dilute nutrient solution, showed that the biofilms rapidly responded: the relative abundance of viable cells in the biofilms more than doubled within 24 hours after nutrient addition.

Hand Hygiene Sink Evaluation

Tests using the fluorescent marker revealed that splashes originating from the drains of hand hygiene sinks were visible under fluorescence at least 1 m from the sink. We assume that microparticles not visible through fluorescence traveled further than 1 m. Most of the surfaces of adjacent medication and sterile dressing preparation areas were within the 1-m range.

Sink and Room Design Interventions

Disinfection of the hand hygiene sinks that yielded the outbreak strain was attempted on 2 separate occasions, as follows (Figure 2): a 7% accelerated hydrogen peroxide gel was

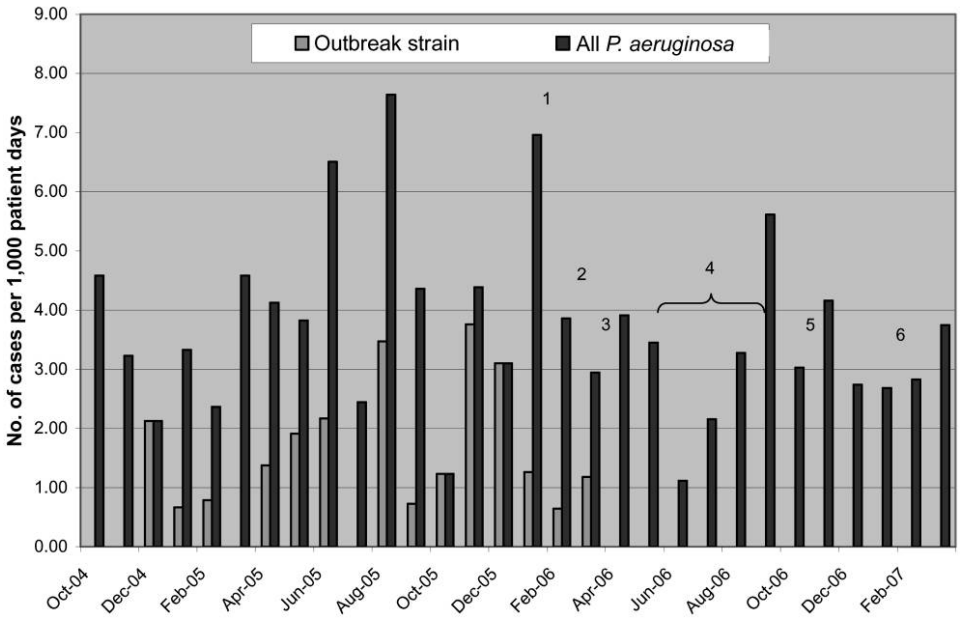

FIGURE 2. Epidemiologic curve showing the rate of colonization or infection with any strain of *Pseudomonas aeruginosa* and with the multidrug-resistant outbreak strain in the medical/surgical intensive care unit (MSICU) and transplant units, in relation to various sink and room design interventions. 1, sinks disinfected on 2 occasions, and sinks closed in MSICU and stepdown unit; 2, sinks opened in MSICU and transplant stepdown unit, and sinks in the 3 outbreak units closed and cleaned; 3, all sinks in outbreak units closed; 4, sinks renovated; 5, sinks opened in MSICU and transplant stepdown unit; 6, sinks opened in transplant ward.

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TABLE 1. Characteristics of Cases in Outbreak of Multidrug-Resistant *Pseudomonas aeruginosa* Colonization and Infection Affecting 36 Patients

Variable	Value
Patient characteristic	
Age, years	
Mean ± SD	53.4 ± 14.3
Mean (range)	53.4 (19–80)
Male sex	19 (55.6)
Location of patient at recovery of first positive specimen	
MSICU	21 (58.3)
Transplant stepdown unit	5 (13.9)
Transplant ward	4 (11.1)
Other	6 (16.7)
Type of specimen yielding first positive result	
Sputum	17 (47.2)
Urine	7 (19.4)
Blood	5 (13.9)
Other[a]	7 (19.4)
Effect of pathogen on patient	
Colonization	12 (33.3)
Infection	24 (66.7)
Immunocompromised status	
Yes	
Due to solid organ transplant	21 (58.3)
Due to other immunosuppression	9 (25.0)
Due to cancer	4 (11.1)
No	2 (5.6)
Type of solid organ transplant received, no. (% of all transplants)	
Liver	8 (38.1)
Kidney	3 (14.3)
Lung	6 (28.6)
Heart	2 (9.5)
Multivisceral[b]	2 (9.5)
Underwent surgery prior to recovery of first positive specimen	17 (47.2)
Underwent invasive procedure prior to recovery of first positive specimen[c]	14 (38.9)
Death within 3 months of first positive specimen	17 (47.2)
Relation of multidrug-resistant *P. aeruginosa* infection to death	
Infection directly caused death	5 (29.4)
Infection contributed to death	7 (41.2)
Infection was unrelated to death	5 (29.4)
Duration of exposure to outbreak unit for all case patients, mean ± SD, days	34.2 ± 23.8
Isolate characteristic	
Resistant to amikacin	19 (52.8)
Susceptible to amikacin	17 (47.2)

NOTE. Data are no. (%) of patients, unless otherwise indicated. MSICU, medical surgical intensive care unit; SD, standard deviation.

[a] Percutaneous transhepatic cholangiography drain, wound, or catheter tip.

[b] One patient received a liver and lung transplant; 1 received a liver and short bowel transplant.

[c] Cystoscopy, endoscopy, bronchoscopy, tracheostomy, or chest tube insertion.

poured into sink drains and left for 5 minutes; sink surfaces, including the interior of faucet spouts, were exposed to a 1 : 16 dilution of the same product for 5 minutes. We submerged gooseneck faucets, drain strainers, and tap covers in 250 cc accelerated hydrogen peroxide 7% solution (diluted 1 : 16) for 5 minutes; wiped bowls with accelerated hydrogen peroxide 0.05% wipes; and closed MSICU and transplant stepdown unit patient room sinks. While sinks were closed, 2 additional attempts were made at cleaning drains of sinks with accelerated hydrogen peroxide 7% solution (diluted 1 : 16) gel product. Although postintervention cultures were sterile, several hand hygiene sinks became recolonized over time, and disinfection had no lasting impact on eradication of the outbreak strain. On the other hand, a decision to close

TABLE 2. Proportion (%) of Environmental Specimens Found Positive for the Outbreak Strain of *Pseudomonas aeruginosa,* by Hospital Unit

	Outbreak units				
Source of specimen	MSICU	Stepdown unit	Transplant unit	All 3	Other unit[a]
Sink taps and shower heads	1/27 (3.7)	1/16 (6.3)	0/10 (0.0)	2/53 (3.8)	…
Sink drains	11/65 (16.9)	10/59 (16.9)	5/89 (5.6)	26/213 (12.2)	…
Equipment[b]	0/16 (0.0)	0/4 (0.0)	0/2 (0.0)	0/22 (0.0)	0/5 (0.0)
Source water	…	…	…	0/19 (0.0)	0/20 (0.0)

NOTE. MSICU, medical/surgical intensive care unit.

[a] Cardiovascular intensive care unit or medical, surgical, or nephrology wards.

[b] Respiratory equipment, crash cart components, intravenous monitors, patient-lifting equipment, Pyxis medication-dispensing machine, multiple use fluid dispensers, ice machine, ultrasound gel, scissor hooks, and temperature probe.

all hand hygiene sinks in the outbreak areas corresponded with an immediate halt to identification of new cases. While closed, the sinks were renovated, as follows: traps were replaced; new faucet spouts were installed that did not flow directly into the drain, thereby minimizing splashback; water flow pressure was decreased; a barrier was installed between the sinks and adjacent preparatory areas (Figure 5); and patient care materials were moved move than 1 m from sinks. During this period, portable hand hygiene sinks and alcohol-based hand gel were used. After the sink modifications were complete, the fluorescent marker test for splash of drain contents was repeated on 1 intensive care unit sink; it revealed no splash onto the adjacent counter or patient bed.

DISCUSSION

We report a large outbreak of colonization and infection with multidrug-resistant *P. aeruginosa* that resulted in significant

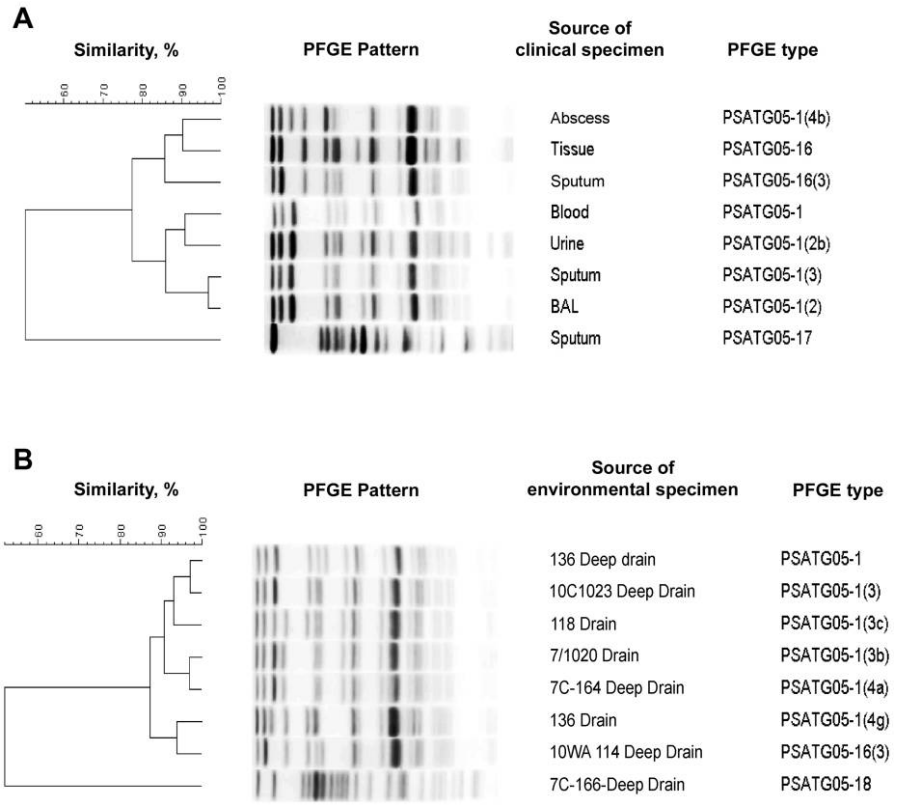

FIGURE 3. Banding patterns determined by pulsed-field gel electrophoresis (PFGE) and a dendrogram showing the genetic relatedness of isolates of multidrug-resistant *Pseudomonas aeruginosa* recovered from different patients and environmental sites. *Panel A,* clinical isolates; *panel B,* environmental isolates. BAL, bronchoalveolar lavage.

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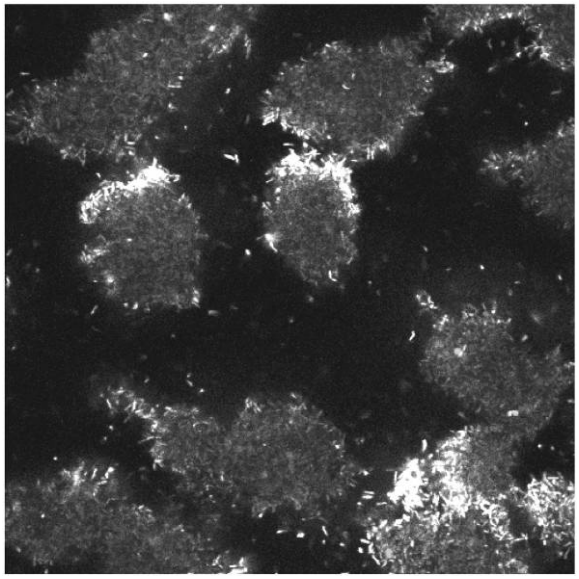

FIGURE 4. Confocal laser scanning micrograph showing biofilms containing microcolonies of the outbreak strain of *Pseudomonas aeruginosa*. Distance of optical thin section from attachment surface, 30 μm; original magnification, × 750.

morbidity and mortality in an immunocompromised population: 36 patients acquired the organism during an 18-month period, two-thirds of whom developed invasive infections. Of the 36 affected patients, 17 (47%) died, and 12 (71%) of these deaths were directly related either to the infection or to a subsequent complication. This high attributable mortality may be a reflection of the immunocompromised nature of the patient population, as well as the multidrug resistance and possible enhanced virulence of the outbreak strain.

This outbreak originated in hand hygiene sink drains. In conformity with current American Institute of Architects guidelines,[17] the MSICU was designed to have 1 hand hygiene sink installed per room; however, the outbreak investigation demonstrated that both the sink design and location were less than ideal. Sinks were situated sufficiently close to an area where sterile procedures and medication preparation were performed to presumably allow contamination of that area through the splash of drain contents. This risk was significantly reduced through the installation of splash barriers. The close proximity of the sink to the patient bed, while appropriate for point-of-care hand hygiene, likely enabled direct patient contamination. We assume that smaller, less visible particles traveled far further than the 1 m we were able to visualize using fluorescence.

We identified several issues with sink design on the affected units. Gooseneck faucets are a popular choice for hospital hand hygiene sinks because the faucet spout, when positioned the standard 10 inches (25.4 cm) above the bowl,[18] is high enough to minimize inadvertent touching of the bowl by utensils or hands. In our MSICU, the spout was fixed to flow water directly into the sink drain. In combination with high water pressure and a very shallow sink bowl, this created a means by which *Pseudomonas* biofilms within the drains could be disrupted, thereby transferring the viable organism to surrounding surfaces or, potentially, to the hands of healthcare workers.

Others have reported taps and drains as sources of outbreaks of *P. aeruginosa* colonization and infection.[1-4,6,7,19-25] These reports have been based on the sequential isolation of phenotypically or genotypically related strains from both sinks and clinical specimens, as in the present study.[19-22] *P. aeruginosa* was generally impossible to eradicate using disinfection techniques alone, and replacement of sinks or sink and/or plumbing components was emphasized as a means to eliminate the organism.[1-4,21,23] One group of investigators was able to successfully control an outbreak of infection with

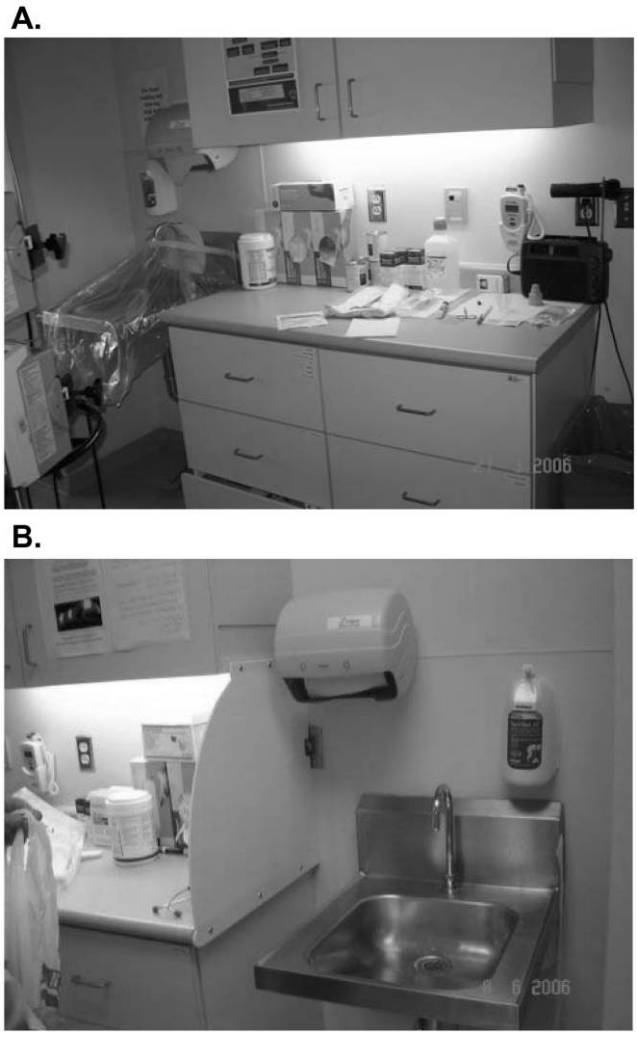

FIGURE 5. Sink and counter design in the medical/surgical intensive care unit where the outbreak occurred. *Panel A,* before renovation; *panel B,* after renovation.

multidrug-resistant *P. aeruginosa* by implementing pasteurization of water taps rather than the replacement of components[5]; however, tap colonization was only a late source of the organism in the outbreak (other sources were found earlier on environmental screening) and, thus, presumably had less opportunity to disseminate extensively. Also, environmental and clinical surveillance ended less than 2 months after the tap contamination was identified, so no long-term follow-up information was available.

In the present study, we visually demonstrated the probable mechanism of transfer of the outbreak organism to patients by means of the fluorescent marker testing. We also aborted the outbreak through simple sink and room design modifications to prevent splashing, without actually eradicating the organism or moving the sinks. We based this approach on the concept that biofilms are resistant to traditional disinfectant methods[26,27] and may, in fact, be more widespread than can be documented through visualization. The drains in our outbreak areas were proven to contain biofilms that tested positive for *P. aeruginosa*. These biofilms typically consist of a variety of microbial species that may protect pathogens from antimicrobials. Furthermore, our results showed the resilience and survival potential of biofilms under prolonged conditions of no water flow, which strongly suggest that biofilms can play an important role in recontamination or seeding. Replacing sinks and exposed piping would not eradicate biofilm that is more distal within the plumbing system; presumably this biofilm would simply recolonize new plumbing over time.

Identification of the outbreak was challenging on several levels. The background prevalence of patients colonized or infected with other multidrug-resistant *P. aeruginosa* strains made the cluster of outbreak cases less apparent. The continuous flow of patients between the 3 affected units, and the fact that many of these patients were close contacts of one another, made it challenging to determine the mechanism of acquisition of the outbreak strain.

A further delay resulted from difficulty in determining the relatedness of strains. Although the antibiogram pattern of the outbreak strain was relatively unique, it would occasionally change; similar antibiogram unpredictability of related strains of *P. aeruginosa* has been previously reported.[6,28] This made it challenging to identify possible cases requiring further investigation and PFGE typing; therefore, caution should be exercised in the use of phenotypic measures to determine relatedness. In addition, PFGE patterns frequently changed over time for both patient and environmental isolates; *P. aeruginosa* is known to mutate frequently, and isolates that would traditionally be considered genetically unrelated[16] may actually be from the same original clone.[28] Indeed, it was only after performing PFGE on many clinical and environmental isolates that we were able to identify 2 related families (types 1 and 16) of organisms that were in keeping with the clinical epidemiology of the outbreak.

Our renovations were successful in preventing the reemergence of infections with the outbreak strain. Follow-up environmental screening more than 1 year after the termination of the outbreak has shown that the organism persists in many drains in the outbreak area (data not shown); however, only 1 new infection has been identified on the previous outbreak units, in a patient at high risk, with large open wounds requiring extensive dressing changes.

In conclusion, our experience has demonstrated that, in addition to ensuring adequate numbers of hand hygiene sinks, sink placement and sink design are crucially important elements in the design of hospital rooms. This point becomes especially important in critical care areas, such as intensive care units.

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Potential for aerosolization of *Clostridium difficile* after flushing toilets: the role of toilet lids in reducing environmental contamination risk

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SUMMARY

Background: Toilet facilities in healthcare settings vary widely, but patient toilets are commonly shared and do not have lids. When a toilet is flushed without the lid closed, aerosol production may lead to surface contamination within the toilet environment.
Aim: To substantiate the risks of airborne dissemination of *C. difficile* following flushing a toilet, in particular when lids are not fitted.
Methods: We performed *in-situ* testing, using faecal suspensions of *C. difficile* to simulate the bacterial burden found during disease, to measure *C. difficile* aerosolization. We also measured the extent of splashing occurring during flushing of two different toilet types commonly used in hospitals.
Findings: *C. difficile* was recoverable from air sampled at heights up to 25 cm above the toilet seat. The highest numbers of *C. difficile* were recovered from air sampled immediately following flushing, and then declined 8-fold after 60 min and a further 3-fold after 90 min. Surface contamination with *C. difficile* occurred within 90 min after flushing, demonstrating that relatively large droplets are released which then contaminate the immediate environment. The mean numbers of droplets emitted upon flushing by the lidless toilets in clinical areas were 15–47, depending on design. *C. difficile* aerosolization and surrounding environmental contamination occur when a lidless toilet is flushed.
Conclusion: Lidless conventional toilets increase the risk of *C. difficile* environmental contamination, and we suggest that their use is discouraged, particularly in settings where CDI is common.
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Introduction

Control measures to limit *Clostridium difficile* transmission in healthcare environments include barrier methods, isolation of infected patients and compliance with hand hygiene measures to minimize the risk of the dissemination of *C. difficile* spores.[1] Additionally, adherence to environmental cleaning and disinfection policies, including surfaces and equipment, have been shown to be important in reducing spore contamination and *C. difficile* infection (CDI) rates.[2,3] Recent work has demonstrated the potential for airborne dissemination of *C. difficile* spores, especially from patients with recent onset diarrhoea, and has suggested that this may contribute to widespread environmental contamination.[4,5] Despite implementation of these control measures, hospitals continue to

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experience CDI case clusters, prompting a search for additional ways to reduce environmental contamination.

Toilet facilities in healthcare settings vary widely, but patient toilets are commonly shared and do not have lids. When a toilet is flushed without the lid closed, aerosol production may lead to surface contamination within the toilet environment.[6–10] There are no data to substantiate the risks of airborne dissemination and environmental contamination by *C. difficile* following toilet flushing, in particular when lids are not fitted.

Methods

Toilet used for seeding experiments

The toilet room is in the Microbiology Department of Leeds Teaching Hospitals NHS Trust (LTHT), measures 8 m^2, contains two toilet cubicles (only one of which was used in the study), and was closed for normal use throughout the study. The toilet was a standard wash-down design (Armitage Shanks, Rugeley, UK) with a seat lid. Lidless or lidded versions of the same model are installed throughout patient, staff and public areas in LTHT. Before experiments, all inside and outside surfaces of the toilet were thoroughly cleaned/disinfected with Chlor-clean (1000 ppm of free available chlorine; Guest Medical, Edenbridge, UK), and then neutralized with sodium thiosulphate (VWR, Lutterworth, UK) to remove any residual chlorine. The toilet was then flushed four times to remove any traces of cleaning products. This procedure was also carried out to decontaminate the toilet between experiments. The floor and walls of the toilet cubicle used were also cleaned with Chlor-clean.

Preparation of faecal suspension

Human faeces were collected from five healthy elderly volunteers (>65 years) with no history of antimicrobial use in the two months before donation. The samples were confirmed as *C. difficile* culture-negative and then pooled to produce 100 g of faeces. Pooled faeces were emulsified in 1 L pre-reduced phosphate-buffered saline, stomached and coarse-filtered through sterile muslin to give a smooth faecal suspension and divided into 200 mL aliquots.

Preparation of C. difficile spores and inoculation of faecal suspension

Ten fresh blood agar plates were inoculated with *C. difficile* strain P24 (UK epidemic strain, polymerase chain reaction ribotype 001) and incubated anaerobically for 10 days. All growth was removed and resuspended in 1 mL sterile saline. An equal volume of absolute ethanol was added and the suspension was left for 1 h at room temperature to kill vegetative bacteria. Suspensions were centrifuged at 3000 *g* for 15 min and the pellet resuspended in 1 mL sterile water. Spore suspensions were enumerated on *C. difficile* selective agar and stored at 4 °C until use. Immediately before testing an aliquot of spore suspension was added to a 200 mL aliquot of faecal suspension to give a final spore concentration of 10^7 cfu/mL. Bacterial *C. difficile* counts were measured by serial dilution and culture on selective agar.

Air sampling

Air was collected using an AirTrace Environmental portable sampler (microbial contamination control) (Biotrace International plc, Bridgend, UK) via a 2 m Tygon tube (Saint-Gobain, Courbevoie, France). The end of the tube was clamped at one of three heights above the toilet bowl: toilet seat height, 10 cm above the seat and handle height (25 cm). As air enters the air sampler (28.3 L/min) it is forced through a fine slit (44 × 0.152 mm) at a velocity of 70 m/s thereby causing particulate matter (minimum size 0.4 μM) to impact on a *C. difficile* selective agar plate. The plate rotated constantly, and thus after culture the location of the colonies represents the time of recovery from the air (e.g. relative to toilet flushing). Plates were transported to the laboratory and incubated anaerobically (37 °C for 48 h). After each test the machine was cleaned externally and internally with a sporicidal disinfectant (Trigene, Medichem International, Sevenoaks, UK) and run on a purge cycle.

Environmental testing

For each test, six *C. difficile* selective agar settle plates were placed around the toilet: top of the cistern, on the right- and left-hand side of the toilet seat (located on top of the lid for lid-closed tests) and three on the floor (15 cm in front of the toilet, on the left- and right-hand sides of the toilet). Plates were sited before flushing and remained in place throughout the 90 min testing time. Following testing, plates were transported to the laboratory and incubated as above.

Organization of testing

Experiments were performed to determine the extent of contamination of the air and environment following toilet flushing. Replicate experiments were performed to determine the magnitude of aerosol dissemination following flushing, with the lid open and closed, and with the air sampling tube at different heights. For each test the inoculated faecal suspension was poured into the toilet bowl and applied to the porcelain sides above the water line in order to mimic the effect of diarrhoea in the bowl. The air sampler was switched on and the toilet was flushed. To confirm the baseline microbiological status of the toilet and environment, six settle plates were placed in the room 24 h before testing began. Control tests were carried out before each series of tests and involved using sterile water instead of inoculated faecal suspension.

In-situ measurement of droplet emission

Separate experiments were carried out to determine the extent of droplet emission associated with toilet flushing. These included the toilet used in seeding experiments, and a further 10 different toilets in clinical areas of LTHT. One hundred millilitres of natural food colouring was added to the toilet bowl, and a sheet of cling film was stretched over the top of the toilet seat prior to toilet flushing. After flushing, the sheet of cling film was removed, placed on to a sheet of filter paper and transferred droplets were counted.

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Results

Experiments to determine the extent of C. difficile contamination from lidless and lidded toilet following flushing.

Initial tests were carried out to determine the extent of *C. difficile* aerosolization following toilet flushing. In order to maximize the recovery of aerosolized *C. difficile*, the end of the air sampling tube was clamped in the centre of the toilet seat at the level of the toilet seat. The mean air count ($N = 4$ experiments) of *C. difficile* immediately following a flush was 36 cfu, the majority of which were recovered during the first 5 min; the air counts declined to 8 cfu after 60 min and 3 cfu after 90 min. *C. difficile* was not recovered from air in the control experiments where water was added to the bowl and the toilet flushed. With the toilet seat lid open, tests demonstrated that *C. difficile* could be recovered following a single flush with the end of the air sampling tube at seat level (12-fold greater counts than when lidded), but also at heights of 10 cm and 25 cm (Table I).

Environmental contamination of surfaces surrounding the toilet

With the lid closed, no *C. difficile* was recovered on the settle plates on any surface. By contrast, with the lid open, *C. difficile* was recovered on the settle plates at all locations ($N = 6$ experiments; mean 1–3 cfu per plate) except for the floor on the left-hand side. Similar counts were obtained in replicate experiments; in each case no *C. difficile* was recovered from the floor on the left-hand side, presumably reflecting the hydrodynamics of the toilet flush.

In-situ measurement of droplet emission

Upon flushing, droplets of varying size were ejected to the height of the seat in all toilets tested (Table II) (Figure 1). The mean number of droplets (11) emitted by the (Microbiology Department) toilet used for in-situ testing experiments was similar (15) to that observed for other toilets of the same style in the hospital (Figure 1a). Droplet counts for rimless toilets in the hospital were higher (mean 47) (Figure 1b).

Table I
Comparison of recovery of *Clostridium difficile* from the air with the toilet seat open and closed ($N = 2$)

Sample time	Mean cfu *C. difficile* detected in air samples 0–90 min after each flush					
	Control tests (water only added)	Toilet lid closed		Toilet lid open		
		10 cm above	Seat height	25 cm above	10 cm above	Seat height
0–30 min	0	4	3	7	6	35
30–60 min	0	1	7	4	0	3
60–90 min	0	0	0	1	0	0

Table II
Number of droplets ejected from toilets following a single flush

Location	Toilet style	Usage	No. of droplets[a]
Microbiology department	A	Staff	8
Microbiology department	A	Staff	13
Hospital ward	A	Staff	12
Hospital ward	A	Patient	7
Hospital ward	A	Patient	14
Hospital ward	A	Patient	16
Hospital ward	A	Patient	26
Hospital ward	B	Patient	55
Hospital ward	B	Patient	43
Hospital ward	B	Patient	61
Hospital ward	B	Patient	46
Hospital ward	B	Patient	29

Toilet style A, standard wash-down design; toilet style B, rimless pan with a raised seat.
[a] Represents the number of droplets of toilet bowl water collected on to cling film placed over the bowl at the toilet seat height following a single flush.

Discussion

Our study is the first to investigate the effect of a lid closure on the aerosolization and deposition of *C. difficile* associated with toilet flushing. Earlier studies investigated the aerosolization of microbes with considerably less survival potential than *C. difficile*. Using a domestic toilet seeded with *Serratia marcescens*, Darlow and Bale reported that bacteria carrying droplets produced by flushing a toilet remained airborne for up to 12 min, before settling on surfaces throughout a bathroom.[11] Later studies used coliform bacteria in domestic and hospital toilets and demonstrated aerolization and deposition of bacteria carrying particles on adjacent surfaces.[6,7] Gerba *et al.* showed that large numbers of *E. coli* or MS-2 phage remained in the bowl after flushing with the lid open due to the adsorption of organisms to the porcelain surfaces of the bowl; even continual flushing could not remove the bacteria.[8] Barker and Bloomfield carried out toilet seeding experiments using *Salmonella enteritidis* and were able to isolate the organism from the air using an air sampler following flushing with the lid open.[10]

Newsom concluded from a series of in-situ tests that the potential for environmental contamination by faecal bacteria associated with flushing of hospital toilets was low, based on the concentration of bacteria in faeces required to generate aerosolization in relation to those present during disease. However, neither anaerobes nor spore-forming bacteria were examined, as the study predated the first reports of human CDI. Notably, there was a 100-fold variation in the magnitude of airborne bacteria released when toilets were flushed, depending on which bacterial species was examined. Crucially, the faecal concentration of *C. difficile* can vary markedly in CDI, and explosive diarrhoea is not uncommon. Louie *et al.* reported that mean *C. difficile* faecal counts in 30 CDI cases were 7.0 $\log_{10} \pm 2.4$ per g (95% CI: 6.0–7.9).[12]

We simulated an episode of *C. difficile* diarrhoea when there is likely to be heavy contamination of both the internal toilet bowl and water. We used an inoculum of *C. difficile* spores representative of the average bacterial load present in

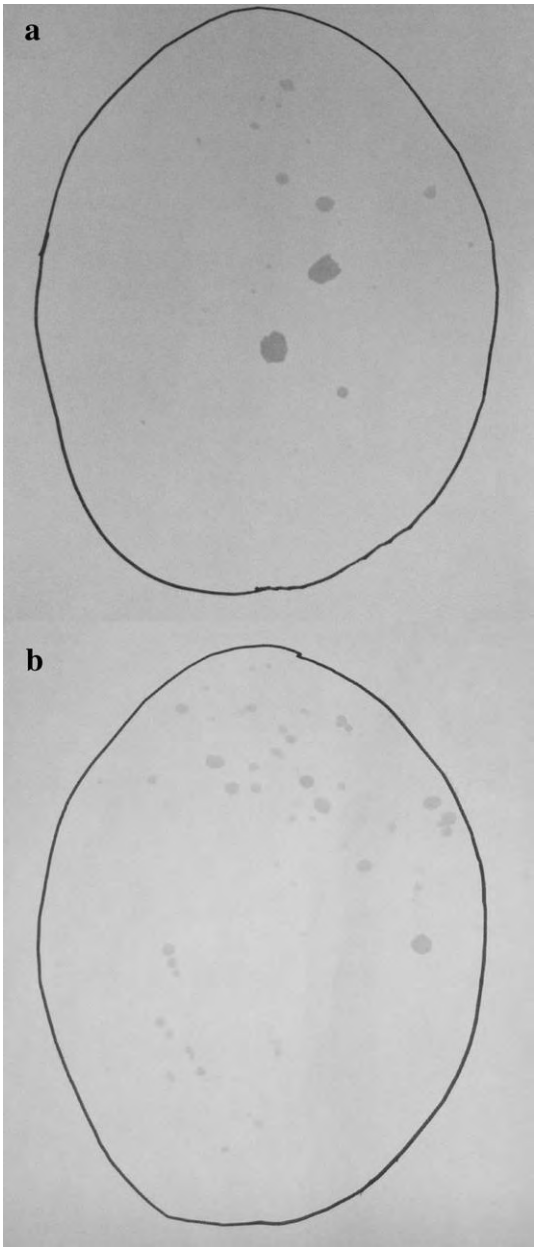

Figure 1. Filter paper impression to show droplets ejected during flushing on to cling film placed across a standard wash-down design toilet (a) and rimless pan with raised seat toilet (b).

CDI.[12] The highest levels of *C. difficile* were recovered immediately following flushing, and then declined 8-fold after 60 min and a further 3-fold after 90 min. The highest bacterial counts were detected from air sampled at the height of the toilet seat; however, it was still possible to recover *C. difficile* at heights of 10 cm and 25 cm above the toilet seat, demonstrating that water turbulence created during flushing can force droplets out of the toilet bowl and into the air. Closing the toilet seat lid markedly reduced the number of *C. difficile* recovered from air after flushing; there was a 10-fold reduction in recovered bacteria from air sampled at seat level. Low numbers of *C. difficile* were still recovered following flushing with the lid closed, suggesting that organisms were still aerosolized, most likely being forced out through gaps between the top of the toilet bowl and seat, and between the lid and the seat (15 and 10 mm, respectively).

C. difficile was recovered on settle plates placed on the floor, cistern and toilet seat during the 90 min after flushing, demonstrating that relatively large droplets are released and that these then contaminate the immediate environment. We confirmed the production of droplets upon flushing by visual inspection of cling film placed over toilets, which is consistent with other reports.[8–11] Closing the toilet seat lid was shown to prevent such large droplet aerosolization, as *C. difficile* was not recovered on any settle plates under such conditions. We have recently demonstrated that *C. difficile* aerosolization occurs commonly in patients with CDI, especially early in disease. We found that *C. difficile* spore-bearing particles fall ~1 m in 15 min.[13] This suggests that the majority of the *C. difficile* recovered on the settle plates in the present study was due to relatively quick deposition of *C. difficile* spores following flushing. Thus, surfaces can become rapidly seeded with *C. difficile* after toilet flushing (without a closed lid). Importantly, the resilient nature of spores means that only very frequent cleaning could be expected to remove such environmental contamination, especially in the context of repeated toilet use.

There are some limitations to the present study. We investigated only one toilet in detail and thus only one design. We believe that the toilet was correctly functioning, and note that there is no routine servicing of toilets, remedial work instead being dependent on fault reporting. Toilet bowl contents were rinsed away as expected, droplet measurements were consistent with the same design of toilets in clinical areas, and thus ostensibly the toilet used for seeding experiments was functioning 'normally'. The toilet model investigated was a standard wash-down design, which is present in many patient areas of the hospital. Some newer hospital areas have alternative designs. National Health Service guidance (SHTM 64 Sanitary Assemblies; www.spaceforhealth.nhs.uk) recommends installation of toilets with a hospital pattern rimless pan and a raised seat and that are water saving (Health Facilities, Note 30; www.spaceforhealth.nhs.uk). Actually, our assessment of toilets in clinical areas showed that such models produced more droplets than the standard wash-down design. It is not known whether the findings from this study would be applicable to newer toilet styles, such as those that use less water. The toilet area used was not ventilated (no extractor fan and the window was closed) and it is possible that such options would help to remove airborne bacteria. However, as the particle deposition occurred rapidly following flushing, it is doubtful that a high proportion of such droplets would be effectively removed by toilet ventilation, which is designed primarily to remove odours.

The majority of toilets installed in hospital patient areas are not fitted with lids, as is also the case in many public areas. The reasoning used is that lids may be a source of bacteria, are not desirable to touch, and may therefore not be used. It has also been suggested that lids may make it harder to clean toilets, as they are another surface to decontaminate. However, discussion with cleaning staff suggests that the latter is not a major issue, and a method is in place to clean lidded toilets. Our findings have implications for infection prevention and control practices, notably in hospital environments where lidless toilets are present and are likely to be used by patients, including those with infective and non-infective diarrhoea. Shared toilets are commonplace within a hospital environment and our data suggest that lidless toilets could be a vehicle for *C. difficile*

contamination and thus transmission of bacteria. Although patients with known CDI should use either a dedicated toilet or commode, this may not happen early in the course of symptoms, and because patients may prefer to use shared toilets in preference to a commode. Other patients may also excrete high numbers of *C. difficile* (asymptomatic carriers, especially those with diarrhoea due to other causes) and may be an inadvertent source of toilet environment contamination. We speculate that such contamination could permit transmission of *C. difficile* from asymptomatic carriers, and thus explain some CDI cases where no apparent linked CDI cases are found.[14,15]

The scope for environmental seeding associated with toilet flushing highlights the imperative for hand washing after toilet use, and frequent cleaning to remove contamination. Toilets with improved design that do not create aerosols are desirable. Our results demonstrate that if lids are fitted to current models they will very likely become contaminated upon flushing. It is already known that *C. difficile* may spread markedly in hospitals. Lidless conventional toilets increase the risk of *C. difficile* environmental contamination, and thus we suggest that their use is discouraged, particularly in settings where CDI is common.

Conflict of interest statement
None declared.

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Multidrug-resistant *Pseudomonas aeruginosa* outbreaks in two hospitals: association with contaminated hospital waste-water systems

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SUMMARY

Background: Multidrug-resistant *Pseudomonas aeruginosa* (MDR-P) expressing VIM-metallo-beta-lactamase is an emerging infection control problem. The source of many such infections is unclear, though there are reports of hospital outbreaks of *P. aeruginosa* related to environmental contamination, including tap water.

Aim: We describe two outbreaks of MDR-P, sensitive only to colistin, in order to highlight the potential for hospital waste-water systems to harbour this organism.

Methods: The outbreaks were investigated by a combination of descriptive epidemiology, inspection and microbiological sampling of the environment, and molecular strain typing.

Findings: The outbreaks occurred in two English hospitals; each involved a distinct genotype of MDR-P. One outbreak was hospital-wide, involving 85 patients, and the other was limited to four cases in one specialized medical unit. Extensive environmental sampling in each outbreak yielded MDR-P only from the waste-water systems. Inspection of the environment and estates records revealed many factors that may have contributed to contamination of clinical areas, including faulty sink, shower and toilet design, clean items stored near sluices, and frequent blockages and leaks from waste pipes. Blockages were due to paper towels, patient wipes, or improper use of bedpan macerators. Control measures included replacing sinks and toilets with easier-to-clean models less prone to splashback, educating staff to reduce blockages and inappropriate storage, reviewing cleaning protocols, and reducing shower flow rates to reduce flooding. These measures were followed by significant reductions in cases.

Conclusion: The outbreaks highlight the potential of hospital waste systems to act as a reservoir of MDR-P and other nosocomial pathogens.

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Introduction

Multidrug-resistant *Pseudomonas aeruginosa* (MDR-P), sometimes expressing VIM metallo-beta-lactamase (*bla*VIM) and sensitive only to colistin, is increasingly being recognized

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as a serious problem in hospitals in the UK and elsewhere.[1] A recent HPA report noted that 73 British hospitals had reported cases of *bla*VIM MDR-P.[2] Though the report did not indicate how many of these hospitals had experienced outbreaks, nor the sources of these infections, there have been reports of pseudomonas (including MDR-P) in association with hospital tap water, including some high-profile outbreaks.[3,4] However, any wet or moist environment may harbour pseudomonas, and it is important that other possible sources are not overlooked.[5]

We report two hospital outbreaks of MDR-P, where the hospital waste pipe system was the likely reservoir and source of infection. The outbreaks occurred in large university teaching hospitals in the south of England — one in London ('outbreak 1'), and one on the south coast ('outbreak 2'). Outbreak 1 was hospital-wide, outbreak 2 affected just one specialist medical unit.

Methods

Both outbreaks were investigated by a combination of descriptive epidemiological methods, environmental inspection and microbiological sampling in order to ascertain possible sources and reservoirs of the organism. Cases were defined as patients from whom *P. aeruginosa* resistant to all antibiotics tested except colistin was isolated in any microbiological sample. Antibiotics tested included carbapenems (imipenem and/or meropenem), ceftazidime, gentamicin, amikacin, piperacillin–tazobactam, ciprofloxacin, aztreonam and colistin.

Isolates obtained from routine diagnostic samples were phenotypically identified using biochemical testing. Non-lactose-fermenting oxidase-positive Gram-negative rods were confirmed as *P. aeruginosa* using routine methods (API, bioMérieux, France). Sensitivity testing was performed using BSAC disc diffusion methodology. Molecular typing by serotyping, pulsed-field gel electrophoresis (PFGE) and variable nucleotide tandem repeat (VNTR) analysis was carried out in the Health Protection Agency Laboratory for Healthcare Associated Infection (LHCAI), Colindale, London.

In outbreak 1, cases were mapped according to ward and dates of admission and discharge, in order to identify clustering and overlap between cases. When a new case was identified on a ward, screening swabs were taken to identify further carriers. Swabs were taken from the groin, axilla, oropharynx and perineum, and inoculated on a CLED agar plate (Oxoid, Basingstoke, UK). Any colony growing around a 10 μg gentamicin disc (Oxoid) was fully identified and had further antibiotic susceptibility testing. A second case on the same ward within a month was categorized as overlapping. A questionnaire was applied to cases in order to identify possible sources or risks that could be explored further with a case–control study. Environmental inspections and microbiological sampling were carried out on wards whenever cases or clusters of cases occurred. Sampling was focused around the affected patients; when clusters of cases occurred on a ward, sampling was extended to the whole ward. Particular attention was given to swabbing wet surfaces such as taps and tap handles, sink drain traps ('U-bends'), shower heads and drains, ward sluices and toilets, as well as common patient areas, such as bed spaces or tables. Samples were inoculated on CLED agar (Oxoid) with a 10 μg gentamicin disc, as above. In addition, during and after clusters of cases on the intensive care unit and haematology unit, all water outlets on affected wards ($N = 51$ on the haematology unit, and $N = 9$ on the intensive care unit) had 300 mL samples taken and sent for formal analysis by a commercial testing company (Alcontrol Laboratories, Hawarden, UK). Samples were collected between 09:00 and 11:00, and transported in a container containing sodium thiosulphate. Samples were filtered and cultured on pseudomonas agar containing potassium sulphate and magnesium chloride to enhance pigment production, and cetryl trimethylammonium bromide and nalidixic acid as selective agents. Water samples that yielded *P. aeruginosa* were sent to the clinical laboratory for full identification and sensitivity testing.

In outbreak 2, as there were fewer cases on a single ward over a shorter time, investigations focused on questioning the patients and staff, followed by environmental screening of likely sources as identified during this questioning.

Results

Epidemiology

Outbreak 1 comprised 85 identified cases from 2005 to 2011. The epidemic curve is shown in Figures 1 and 2. The cases peaked in 2008, and most were in the main hospital wing: 31 cases were on the general intensive care unit, seven were on the haematology unit, and 27 were found on a wide number of other wards in that wing. The remaining 20 cases were either in other hospital wings (12) or in outpatients who had previously been on a hospital ward (Figure 1). Most cases (78/85) were first identified more than 48 h after admission. Of those that were detected at the time of admission, all had previously been inpatients in recent months; there were no cases where the acquisition of the bacterium was unequivocally in the community. In all, cases were identified in or associated with 21 different inpatient wards. The pattern of infection was one of sporadic cases or small clusters (no more than four cases in a calendar month), with long infection-free intervals (Figure 2). The mean interval between consecutive cases was 25.4 days, ranging from 0 to 130 days. Only 25/85 cases (29%) overlapped, suggesting that person-to-person spread did not play a major role in the outbreak.

A hypothesis-generating questionnaire (applied to 24 cases and 24 control patients on the intensive care unit) did not identify any common links or exposures that could be explored further with a case–control study.

Outbreak 2 comprised four cases of MDR-P infection occurring in neutropenic inpatients on a haematology ward between April 2009 and June 2010. The ward consisted of six single rooms with en-suite wet rooms.

Clinical features and outcome

The cases in outbreak 1 varied by site of infection, severity and outcome. The overall case fatality rate was 34/85 (40%). However, the case fatality rate was 14/18 (78%) in patients who had bacteraemia. Haematology patients were more likely to be bacteraemic (6/7 cases), and all the bacteraemic haematology patients died.

The cases in outbreak 2 were all bacteraemic, with two admitted to intensive care. One patient developed orchitis resulting in orchidectomy. There were no deaths directly attributable to MDR-P infection in outbreak 2.

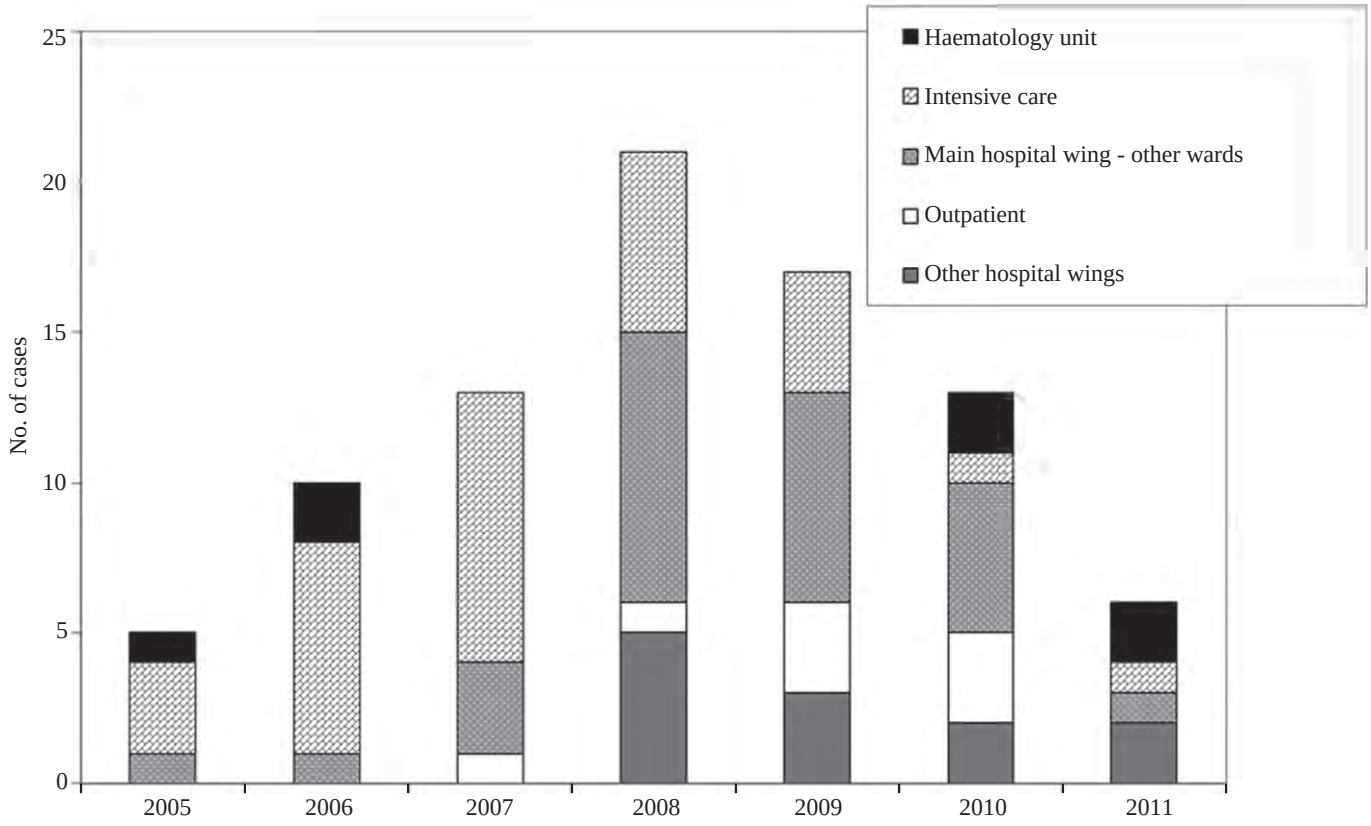

Figure 1. Outbreak 1: cases of multidrug-resistant *Pseudomonas aeruginosa* for each year 2005—2011, broken down by location within the hospital.

Microbiology

Most isolates from outbreak 1 (74/85), and all the isolates from outbreak 2, were sent to the Health Protection Agency Laboratory for Healthcare Associated Infections for molecular typing. The results indicated that each outbreak was caused by a different genetic type of *P. aeruginosa*. Both strains expressed VIM-2 carbapenemase. Each strain was unique to its hospital.

Environmental investigations

The cases in outbreak 1 — in particular the clusters in the intensive care and haematology units — were subject to extensive environmental inspection and investigation. Inspections revealed occasional suboptimal hygiene practices, in addition to examples of poor handbasin design (where the water was directed directly into the outlet, allowing splashback from the sink drain trap), and poor design and usage of sluice facilities (with excessive splashing, and inappropriate storage of clean items). Inspection of the plant room directly above the haematology unit also revealed evidence of a previous waste pipe leak which could possibly have led to contamination of clinical areas.

Multiple samples of hot and cold tap water from outlets were negative for MDR-P. Waste outlets (sink and shower plugholes, sluices, toilet pans and cisterns, macerators) were also sampled extensively — most samples were negative, but a small number of waste outlets on the intensive care and haematology units yielded the outbreak strain of MDR-P. As these results raised the possibility that the waste pipe system was a reservoir of the organism, a sewage leak in the X-ray department was sampled early in 2011 (at a time when there were no known cases on the wards); this also yielded the outbreak strain of MDR-P. This hypothesis was further explored when the main hospital sewer was tested for MDR-P by means of a Moore swab.[6] The swab was left in the sewer for 48 h, and then inoculated in a selective broth containing vancomycin and meropenem. The swab yielded MDR-P, although at the time of testing, there had been no known clinical case of MDR-P for several months. Records showed that from 2005 to 2010 there had been a mean of 391 notifications of blocked sinks, toilets or sluices in the hospital each year. Anecdotal reports suggested that most of these blockages were due to paper towels or patient wipes.

Of the four cases in outbreak 2, three had been housed in the same single room. Questioning staff and patients revealed longstanding concerns about slow drainage of water from the showers, frequent foul smells emanating from the shower drains and recurring problems with blocked sewage pipes leading to backflow of dirty water into toilets and showers. These problems were attributed to blockage caused by inappropriate disposal of paper towels down toilets. Environmental inspection revealed a failure to clean the shower drains, with large quantities of hair and slime found beneath the lid covering the trap. The design of the toilets was found to impede cleaning with the flush water flowing in a closed

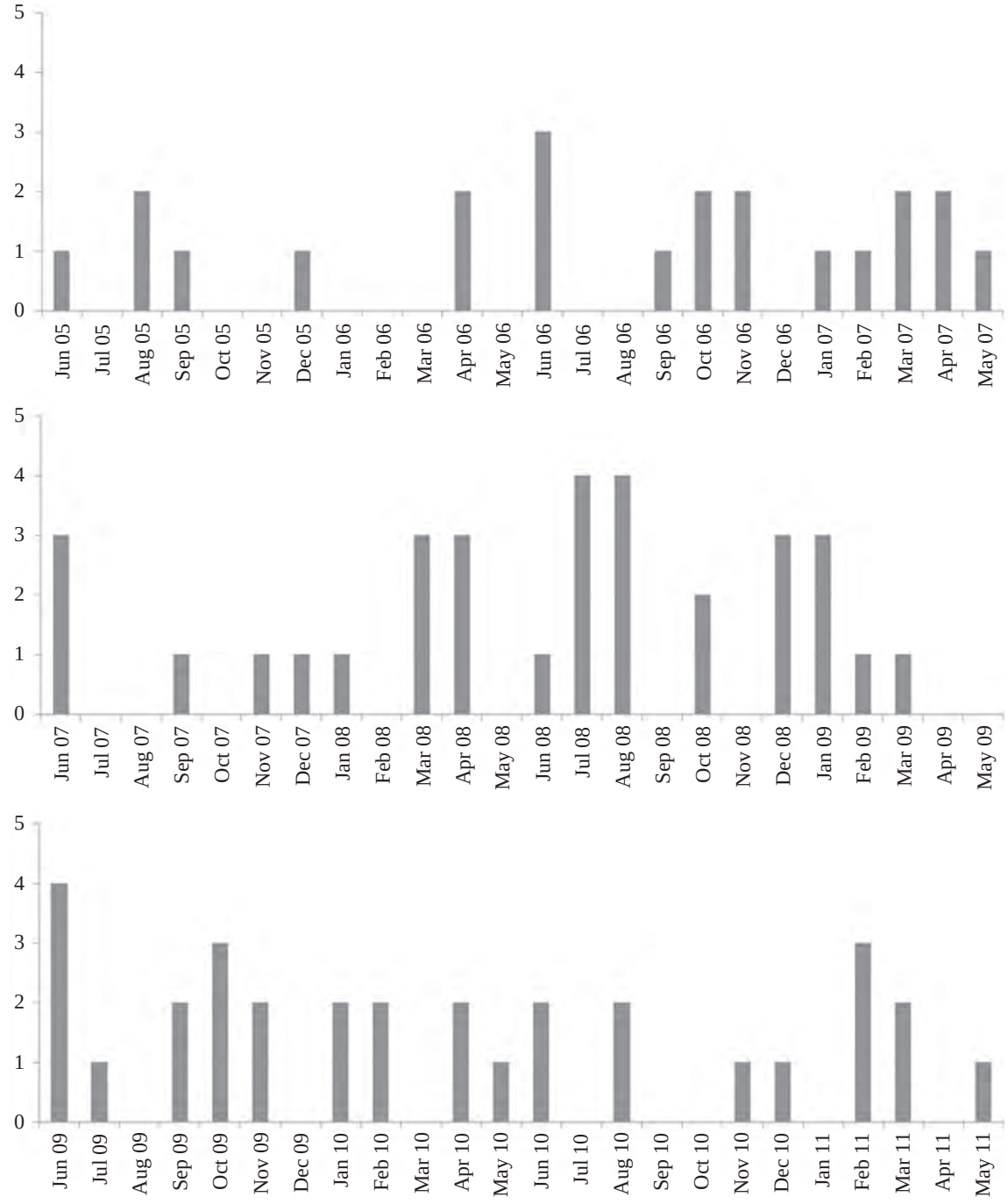

Figure 2. Outbreak 1: epidemic curve, showing cases of multidrug-resistant *Pseudomonas aeruginosa* each calendar month from 2005 to 2011.

channel within the rim. No other environmental concerns were identified. Cleaning procedures were observed and found to be satisfactory. The hands of staff were inspected and no cases of onychomycosis or other finger nail issues were found.

Environmental samples yielded growth of the outbreak strain from shower drains, toilet bowls and toilet brushes. Incoming waters for drinking, hand washing and showering were negative. Pseudomonas was not isolated from cleaning equipment, soaps and skin antiseptic preparations.

Detailed investigation of the causes of sewage blockages took place. Blockages were found to be partly due to paper towels and clinical wipes down toilets, confirming reports of inappropriate disposal of these items. In addition, macerator use was found to be defective with macerators being overloaded, switched off mid-cycle and challenged with indestructible items such as mop heads and clothing. The blockages were compounded by the presence of a 'T-junction' on the main waste pipe, although the plans for the building had mandated a gradual curve.

Control measures

Outbreak 1

Because of the scale and duration of the outbreak, and initial uncertainty concerning the source, many interventions were implemented over time in an effort to reduce cases. These included enhanced cleaning and decontamination measures, and refurbishment/replacement of taps, sinks, toilets and sluice areas where these were identified as suboptimal. After the recognition in 2011 that the waste pipe system was the likely reservoir of infection, measures were targeted at reducing back-contamination of clinical areas. These included avoidance of inappropriate storage of clean items in sluice areas; education of staff to reduce the number of waste pipe blockages, switching paper towels to a more degradable type, upgrading handwash basins to models with integral back outlets, and introduction of rimless toilet pans.[7] It was decided not to institute a programme of regular environmental screening for the organism, as it was felt that the waste water system was likely to remain colonized indefinitely with this organism, and the control measures were intended to reduce contamination of clinical areas, rather than eliminate this colonization. Since May 2011 there has only been one case of the outbreak strain of MDR-P identified.

Outbreak 2

Although it remained possible that colonized patients were contaminating their environment rather than vice versa, the association of infected patients with reports of sewage floods led the outbreak control team to re-plumb the main wastepipe, replace toilet bowls with an easily cleaned design, reduce incoming shower water pressure, re-educate staff, patients and visitors on the safe disposal of sanitary items, add shower drain cleaning to the cleaner's routine duties and order the weekly disposal of toilet brushes. Since these measures were introduced there has been a marked decrease in foul odours and blockages and to date there have been no further cases of MDR-P infection on the unit.

Discussion

These outbreaks, though very different in scale, illustrate both the emerging threat posed by *P. aeruginosa* producing metallo-beta-lactamase[8] — particularly concerning as the isolates are frequently susceptible only to colistin — and also the danger of pseudomonas infection from hospital waste systems. Initially, in outbreak 1, the likely reservoir was unidentified, and it was thought that the isolates from waste outlets might indicate transfer from patients, rather than vice-versa. However, on reflection, the weight of evidence favours the waste system being the actual source of infection: MDR-P was not isolated from any other environmental samples; some environmental MDR-P isolates were recovered when there were no clinical cases present; blockage data suggest the frequent potential for waste-water organisms to contaminate clinical areas; the pattern of infection (with 21 wards affected, yet with long intervals without any cases, and with only 29% of cases overlapping) suggests a widespread environmental reservoir. Finally, the biology of pseudomonas means that it is liable to colonize any moist environment, and waste outlets in sinks and showers have been implicated in previous hospital outbreaks, though recent concern in the UK at least is focused more on the risk from hospital tap water.[4,9—13]

Both outbreaks serve as a reminder of the importance of hospital design and engineering in controlling and preventing infection, a factor that is probably under-appreciated by many clinical staff.[14] Hospital waste systems will be heavily colonized by bacteria, and given the antibiotic selection pressure in hospitals, it is unsurprising that many of these bacteria have been shown to express various mechanisms of antibiotic resistance.[15—17] The factors which reduce the chance of these organisms spreading back to clinical areas include regular flushing of sinks/toilets/sluices, cleaning of the accessible parts of outlets to reduce scale and biofilm, and a free-flowing system that can rapidly carry away waste water. Sink traps help prevent pests and vermin gaining access to clinical areas, but they will also act as a reservoir of bacteria. As observed in these outbreaks, several factors can lead to back-contamination. Poorly designed sinks, with water flowing directly into the plughole, will lead to splashback from the U-bend, and have been previously implicated in MDR-P outbreaks.[18] Contamination of the environment with pathogenic bacteria also occurs when toilets and sluices are flushed.[19] This should be self-evident, but given the lack of storage space on many hospital wards, it is possible that this risk will be overlooked from time to time, and clean items stored in sluice areas. Toilet bowls with rims and dual flushing outlets are harder to clean, and thus pose a greater infection risk. Shower trays with inadequate drainage (which is more likely if the outlets are not cleaned regularly, or if the showers deliver too much water) will lead to pooling in the shower tray: this is likely to be a mixture of tap and stagnant shower-trap water. Any waste pipe leak will inevitably lead to contamination of nearby areas. Similarly, blockages of waste-pipe systems will lead to backflow upstream, and flooding of outlets. The frequency of blockage reports was a surprise to the investigators in outbreak 1. Reports from both hospitals suggested that the most common cause of blockages was incorrect disposal (into toilets) of paper towels and patient wipes. Patient wipes were particularly problematic as they were less degradable. Blocked bedpan macerators were also identified as a common cause of blockages in outbreak 2. Design factors of the waste system itself may play a part — for example sharp angles and long horizontal runs in the piping will be prone to blockage, as noted in outbreak 2.[14]

Finally, it is worth noting that these outbreaks were recognized because of the highly unusual antibiotic resistance pattern of the organisms. Hospital waste systems could also be the source of many cases of infection with different bacteria, as a result of the factors described above. However, unless the organisms are distinctive in some way, such as being multiply resistant, or several cases with the same species linked in time or place, it is likely that the source of many such infections will remain unrecognized.

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Conflict of interest statement
None declared.

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Water Review Meeting – Draft meeting Note

Tuesday 18th September 2018 at 8 a.m. in Corporate Directors Room JB Russell House

Present	
Jonathan Best (JB)	Director – Acute Services
Jim Leiper (JL)	Lead Project Manager
Tom Walsh (TW)	Infection Control Manager
Mary Anne Kane (MAK)	Interim Director of PPFM
Jane Grant (JG)	Chief Executive
Jennifer Armstrong (JA)	Medical Director
Grant Archibald (GA)	Chief Officer (Acute)
In Attendance	
Allyson Hirst (AH)	Admin Support to – Interim Director of PPFM

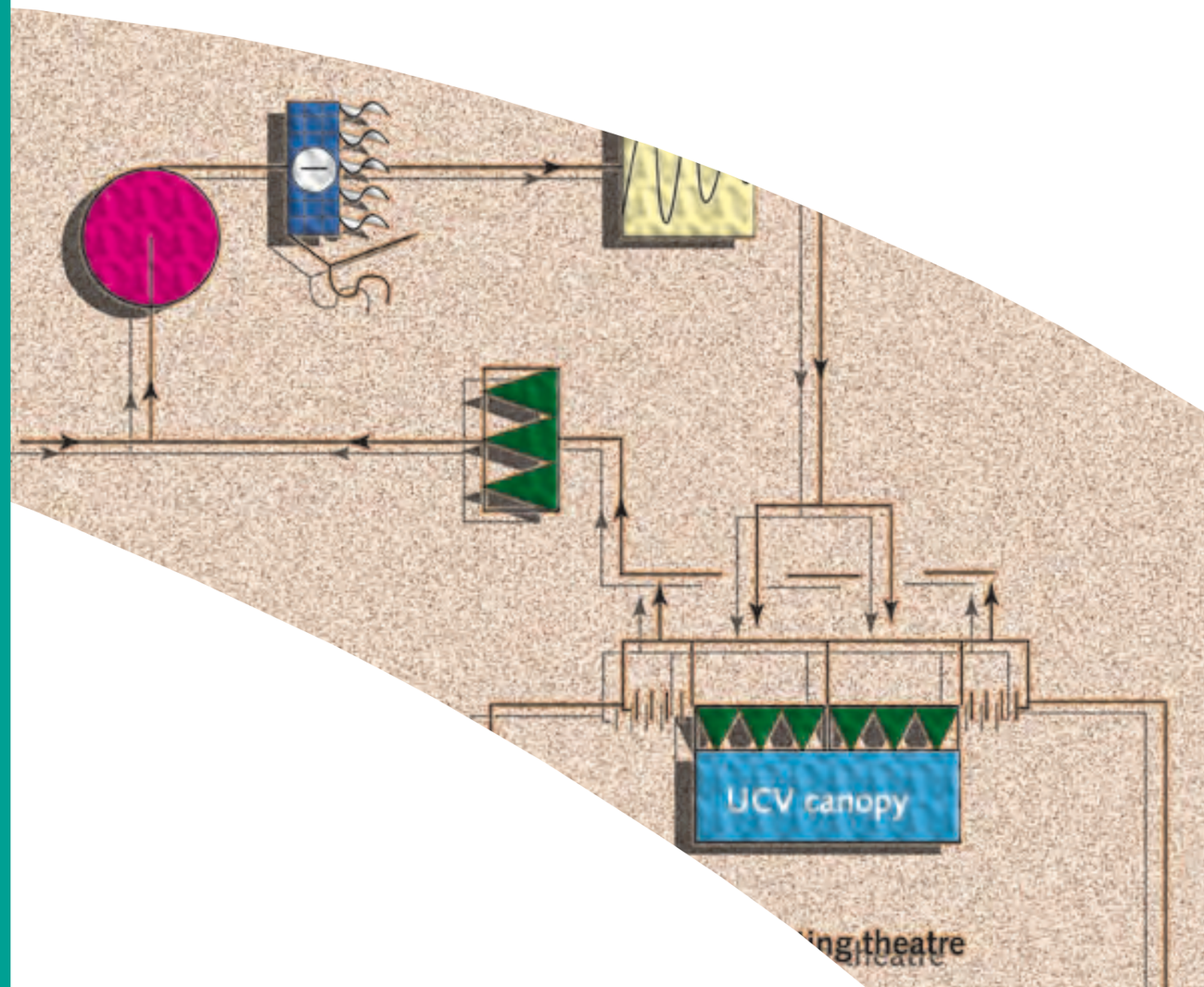
	Discussion	**Action**
	Legionella	
	• JA relayed a telephone conversation she had with Teresa Inkster on the recent findings of legionella at QEUH. It was noted that Legionella screening had been implemented after routine monitoring had identified an increase in the temperature of the incoming water supply from Scottish Water. It was noted that there are many strains of Legionella. The LP1 strain of the microorganism does give cause for concern if it is shown to be present. With the work carried out by Estates as part of their normal response protocols in the last few weeks it was noted that the counts were now reduced. An alert was sent to clinicians. The only areas that appeared to have been affected were floors 5, 7 and 9 of QEUH • MAK noted that during routine testing it was noted that the temperature of the incoming water had risen. As part of the SHTM protocol Scottish Water were contacted. The response from Scottish Water was if the temperature was below 25^{c}C then it was of no concern to them as this was within their normal supply standards and they would take no action. As part of our routine protocols, testing was carried out in various areas and the remedial protocol was put into action. Further testing shown that the counts were reduced to acceptable levels or nil. Since 9th September there has been no further reports of contamination. JG noted her concerns that she had not been informed of this matter and how sensitive this issue is at this time. MAK noted that normal protocols were followed and the issue was not raised to a higher management level because the counts of samples were less than 1000and the remedial action had successfully and appropriately managed the situation. JA noted that clinicians are routinely informed when any Legionella is found so that they are aware and will then check for a very specific pneumonia that can occur when Legionella is present. • JL supported the action that had taken place as quick, robust action would mitigate the risk and that we need to be quite clear on the detail of the issued communications. He noted that counts now reporting seemed to be reasonable and noted that post flushing had reported negative results or very low counts • It was noted that there is an importance in the information given to staff about actions that could encourage the growth of microorganisms in the water system, particularly as it was found that two sinks in the Maternity block had been put out of action. Because of this action by the Clinical Staff, it effectively made the sinks, 'little used outlets' and the stagnant water in the system, created by the sinks not being used, had the potential to encourage proliferation. Staff should be aware of how to report faults in order that these can be dealt with appropriately without increasing the level of risk. • It was noted that Legionella was a naturally occurring in the environment and commonly found in a water systems and that the actions being taken within the Board are as per national guidance and protocols but concern was expressed that there were messages around the system to start testing patients when it was not necessary. I was agreed that awareness and vigilance were important in these circumstances – clear message to staff is required • MAK noted that out Authorising Engineer has stated that elevated temperatures in incoming water supplies are commonly apparent in many hospitals all over the country at this time of	

	the year but he was satisfied that we have implemented satisfactory protocols appropriately. • TW noted that this was not an unusual situation as we can instigate this protocol around 6-7 times per year across the Board • The group agreed that TW should write up a clarifying statement with input from ICT and technical input	**TW**
	Decant of 2A/2B and 4B	
	• It was agreed that due to the bio film being found in some sink areas within this ward and the patient demographic it would be appropriate to decant this patient group to another area in order to carry out investigatory works and get to the bottom of this problem • In order to progress this several discussions need to take place including : – Clarification of the incoming patients and their medical needs – Work to ensure the minimum number of moves with approval from Infection Control and clinical staff on what is best for the patient – Risk Assessment on the ward – mixing adults with children – Updating patients, parents and families on the moves and reasons behind this – Making ready the wards in Gartnavel should they be required and determine what if any patients to be moved to this – Communications with staff – Risk Assessment of the ward environment the children will be moved to, to ensure as far as practicable, that the area is safer for the Children on the balance of risk and to establish a base line that would allow future comparison if required. – Review of play and education provision availability in the new location – Preparation of the ward prior to the move including – deep cleans, toilets, sinks, drains and showers – documentation to evidence the level of cleans taking place – Understanding if there is further bacteremia how this will be handled and what protocols to be followed – Clarification from IMT that they are content with the proposals and the final option of the decant location being offered – Note all reasonings and decisions being made. TW to maintain his record of actions and information – Write up of planning and what the acceptable measure would be for moving patients back to RHC • JG noted that there should be as little delay as possible in progressing this and where possible planned meetings pulled forward and works progressed	**TW**
	Communication	
	• Prepare statements for staff, patients and parents. Ensure that the message is consistent, true and relayed appropriately • KHill and Corporate Comms working on a press release	**Corporate Comms/ KH**
	Date and Time of Next Meeting	
	25th September 2018 at 8am in MAKs office of by telephone conference call	**All**

Department of Health

Heating and ventilation systems
Health Technical Memorandum 03-01: Specialised ventilation for healthcare premises

Part A: Design and validation



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Heating and ventilation systems
Health Technical Memorandum 03-01: Specialised ventilation for healthcare premises

Part A: Design and validation

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Preface

About Health Technical Memoranda

Engineering Health Technical Memoranda (HTMs) give comprehensive advice and guidance on the design, installation and operation of specialised building and engineering technology used in the delivery of healthcare.

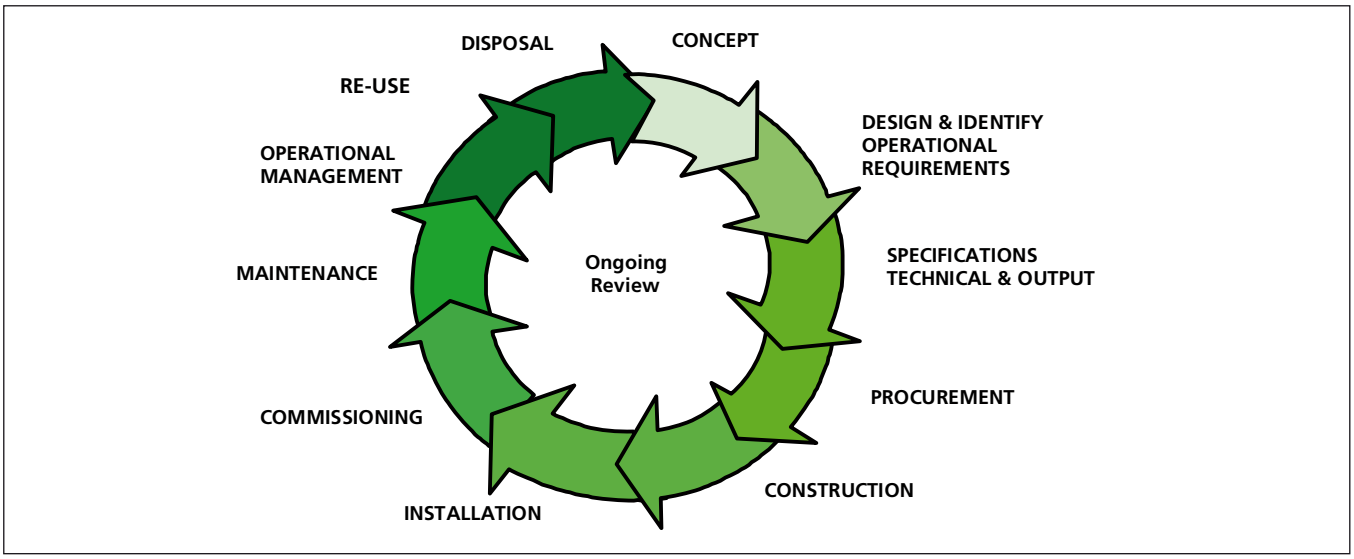
The focus of Health Technical Memorandum guidance remains on healthcare-specific elements of standards, policies and up-to-date established best practice. They are applicable to new and existing sites, and are for use at various stages during the whole building lifecycle.

main source of specific healthcare-related guidance for estates and facilities professionals.

The core suite of nine subject areas provides access to guidance which:

- is more streamlined and accessible;
- encapsulates the latest standards and best practice in healthcare engineering;
- provides a structured reference for healthcare engineering.

Figure 1 Healthcare building life-cycle



Healthcare providers have a duty of care to ensure that appropriate engineering governance arrangements are in place and are managed effectively. The Engineering Health Technical Memorandum series provides best practice engineering standards and policy to enable management of this duty of care.

It is not the intention within this suite of documents to unnecessarily repeat international or European standards, industry standards or UK Government legislation. Where appropriate, these will be referenced.

Healthcare-specific technical engineering guidance is a vital tool in the safe and efficient operation of healthcare facilities. Health Technical Memorandum guidance is the

Structure of the Health Technical Memorandum suite

The series of engineering-specific guidance contains a suite of nine core subjects:

Health Technical Memorandum 00
: Policies and principles (applicable to all Health Technical Memoranda in this series)

Health Technical Memorandum 01
: Decontamination

Health Technical Memorandum 02
: Medical gases

Health Technical Memorandum 03
Heating and ventilation systems

Health Technical Memorandum 04
Water systems

Health Technical Memorandum 05
Fire safety

Health Technical Memorandum 06
Electrical services

Health Technical Memorandum 07
Environment and sustainability

Health Technical Memorandum 08
Specialist services

Some subject areas may be further developed into topics shown as -01, -02 etc and further referenced into Parts A, B etc.

Example: Health Technical Memorandum 06-02 Part A will represent:

Electrical Services – Electrical safety guidance for low voltage systems

In a similar way Health Technical Memorandum 07-02 will simply represent:

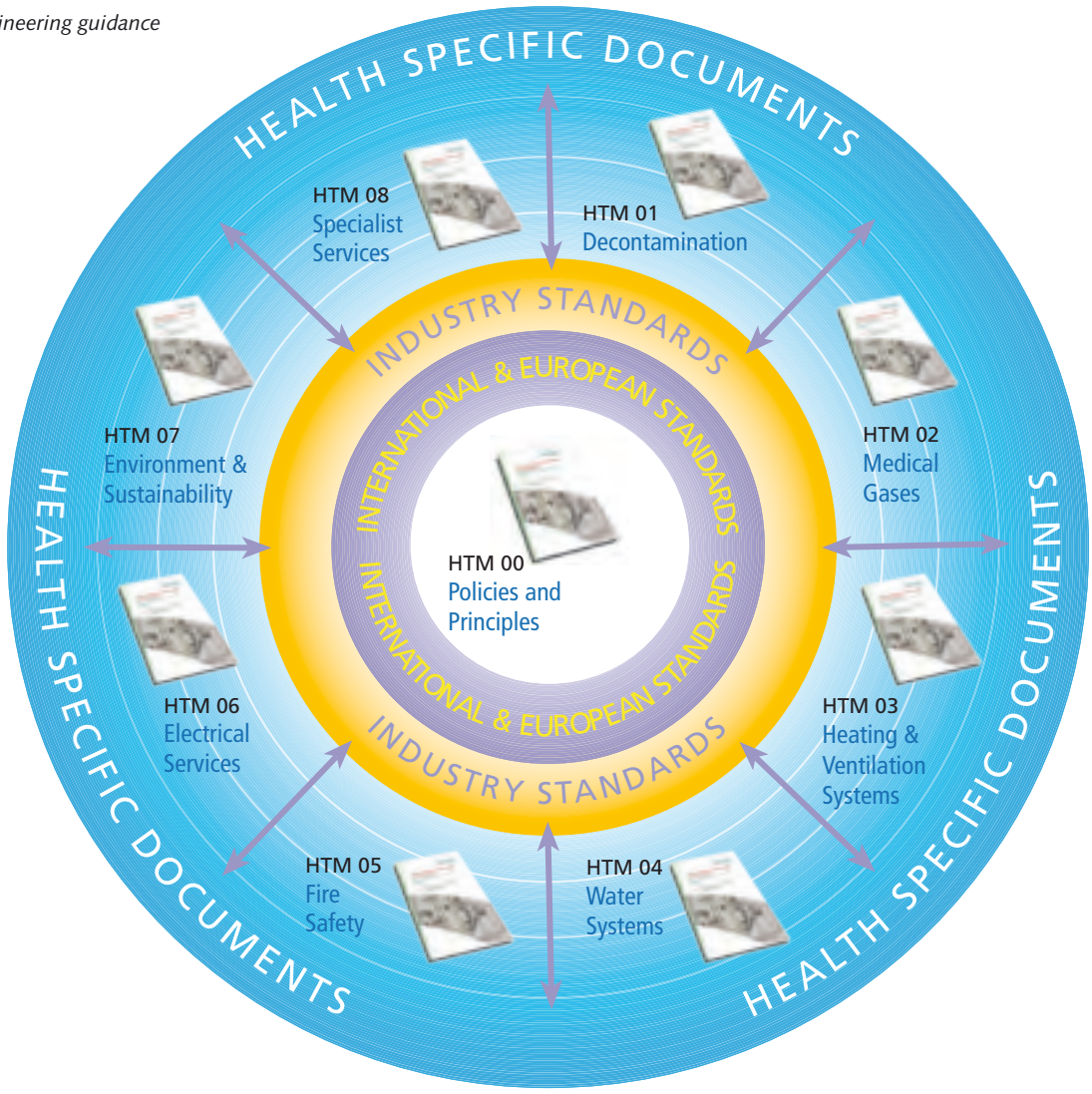
Environment and Sustainability – EnCO_2de.

All Health Technical Memoranda are supported by the initial document Health Technical Memorandum 00 which embraces the management and operational policies from previous documents and explores risk management issues.

Some variation in style and structure is reflected by the topic and approach of the different review working groups.

DH Estates and Facilities Division wishes to acknowledge the contribution made by professional bodies, engineering consultants, healthcare specialists and NHS staff who have contributed to the review.

Figure 2 Engineering guidance



Executive summary

Preamble

Health Technical Memorandum 03-01 – 'Specialised ventilation in healthcare premises' is published in two parts: Part A deals with the design and installation of ventilation systems; Part B covers operational management.

The document gives comprehensive advice and guidance on the legal requirements, design implications, maintenance and operation of specialised ventilation in all types of healthcare premises.

The guidance contained in this Health Technical Memorandum applies to new installations and major refurbishments of existing installations.

Health Technical Memorandum 03-01 supersedes all previous versions of Health Technical Memorandum 2025 – 'Ventilation in healthcare premises'.

Who should use this guidance?

This document is aimed at healthcare management, design engineers, estates managers and operations managers.

Main changes from Health Technical Memorandum 2025

This Health Technical Memorandum has been revised to reflect the current guidance on theatre suite layout and room sizes given in Health Building Note 26, Volume 1 – 'Facilities for surgical procedures', including the recommended air-change rates.

Other key issues

- It addresses the issues relating to patient comfort and the prevention and control of healthcare-associated infections. Specialised ventilation systems play a central role in these important areas.
- It looks at the methods of controlling the casual exposure of staff to anaesthetic substances.
- It outlines the design and acceptance testing of general and ultra-clean ventilation (UCV) systems.
- It sets out the minimum requirements for the design of air-handling units with regard to the control of *Legionella* and safe access for routine inspection and maintenance.

Acknowledgements

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Department of Health

Welsh Health Estates

NHS in Scotland

Health & Social Services, Northern Ireland

Health Protection Agency (HPA)

Building Research Establishment (BRE)

Building Services Research and Information Association (BSRIA)

University of Leeds

CIBSE Healthcare Group

IMechE/ASHRAE

IHEEM

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Couch Perry Wilkes consultancy

DSSR consultancy

Howorth Airtech

Medical Air Technology/Thermo Electric

BPG Medical

Admeco/Trumpf Medical Systems

Volkes SPX

Weiss Klimatechnik

Sound Research Laboratories

NHS Security Management Service

Pennine Acute NHS Trust

Hospital Infection Society (HIS)

Central Sterilising Club

HEVAC – Air-handling Unit Manufactures Group

Contents

1 Introduction

Preamble

1.1 Health Technical Memorandum 03-01 – 'Specialised ventilation in healthcare premises' is published in two parts: Part A deals with the design and installation of ventilation systems; Part B covers operational management.

1.2 The document gives comprehensive advice and guidance to healthcare management, design engineers, estates managers and operations managers on the legal requirements, design implications, maintenance and operation of specialised ventilation in all types of healthcare premises.

1.3 The guidance contained in this Health Technical Memorandum applies to new installations and major refurbishments of existing installations.

1.4 Health Technical Memorandum 03-01 supersedes all previous versions of Health Technical Memorandum 2025 – 'Ventilation in healthcare premises'.

Ventilation in healthcare premises

1.5 Ventilation is used extensively in all types of healthcare premises to provide a safe and comfortable environment for patients and staff. More specialised ventilation is provided in primary patient treatment areas such as operating departments, critical care areas and isolation units.

1.6 It is also installed to ensure compliance with quality assurance of processed items in pharmacy and sterile services departments, and to protect staff from harmful organisms and toxic substances (for example in laboratories).

1.7 The sophistication of ventilation in healthcare premises is increasing. Patients and staff have a right to expect that it will be designed, installed, operated and maintained to standards that will enable it to fulfil its desired functions reliably and safely.

Reasons for ventilation

The Building Regulations require that all enclosed workspaces be ventilated by either natural or mechanical means. The following are some of the factors that determine the ventilation requirements of a workspace:

- human habitation (minimum fresh-air requirement);
- the activities of the department, that is, extraction of odours, aerosols, gases, vapours, fumes and dust – some of which may be toxic, infectious, corrosive, flammable, or otherwise hazardous (see the Control of Substances Hazardous to Health (COSHH) Regulations);
- dilution and control of airborne pathogenic material;
- thermal comfort;
- the removal of heat generated by equipment (for example catering, wash-up, sterilizing areas, electrical switchrooms, and some laboratory areas);
- the reduction of the effects of solar heat gains;
- the reduction of excessive moisture levels to prevent condensation (for example hydrotherapy pools);
- combustion requirements for fuel burning appliances;
- "make-up supply air" where local exhaust ventilation (LEV) etc is installed.

Mechanical ventilation systems are expensive in terms of capital and running costs, and planning solutions should be sought which take advantage of natural ventilation, provided the above criteria are met.

Ventilation – application examples

Requirement	Reason	Application
Statutory	Health and Safety at Work etc Act	Operating departments
	COSHH Regulations	Laboratories
	Local exhaust ventilation (LEV)	Pharmacies
		Areas containing identified biological or chemical hazards
		Areas containing oxygen-displacing gases
		Enclosed workspaces
		Workshops
Functional	Comfort	Situations where the quality of the environment for staff and patients is critical to their general performance and well-being
Clinical	Reduction of surgical site infection	Ultra-clean operating suites, conventional operating suites and treatment rooms used for all types of surgical procedures
		Obstetrics and maternity procedures
	Source and protective isolation	Isolation units for patients who present a biological, chemical or radiation hazard to others
		Isolation units for patients with a reduced immune system

Statutory requirements

Increased health risks to patients will occur if ventilation systems do not achieve and maintain the required standards. The link between surgical site infection and theatre air quality has been well established. Plants serving a conventional operating department, for instance, will be required to ensure the separation of areas within the suite by maintaining a specific direction of air flow between rooms, even when doors are opened. They will also maintain the selected operating department's environmental conditions regardless of changes in outside air conditions or activities within the space.

In addition, ultra-clean ventilation systems (which are designed to provide a zone around the patient that is effectively free of bacteria-carrying airborne particles while the operation is in progress) have been shown to significantly reduce surgical site infection in patients undergoing large joint replacement surgery. Their use for other forms of surgery may well be indicated.

Health and Safety at Work etc Act 1974

1.8 The Health and Safety at Work etc Act 1974 is the core legislation that applies to ventilation installations. As these installations are intended to prevent contamination, closely control the environment, dilute contaminants or contain hazards, their very presence indicates that potential risks to health have been identified.

COSHH

1.9 The Control of Substances Hazardous to Health (COSHH) Regulations 2002 place upon management an obligation to ensure that suitable measures are in place to protect their staff and others affected by the work activity. These methods may include both safe systems of work and the provision of a specialised ventilation system. In laboratories the requirements are often met by the provision of fume cupboards and microbiological safety cabinets.

1.10 The requirements to provide ventilation, implicit under the Health and Safety at Work etc Act 1974 and COSHH, have been made explicit by the Management of Health and Safety at Work Regulations 1999, the Workplace (Health, Safety and Welfare) Regulations 1992 and the Provision and Use of Work Equipment Regulations 1998, all issued as a result of European Directives.

1.11 Where specialised ventilation plant is provided as part of the protection measures, there is a statutory requirement that it be correctly designed, installed,

commissioned, operated and maintained. The local exhaust ventilation (LEV) section of COSHH requires that the plant be inspected and tested at least every 14 months by a competent person and that management maintain comprehensive records of its performance, repair and maintenance.

1.12 Certain substances have workplace exposure limits (WELs) set out in the Health and Safety Executive's (2005) Guidance Note EH40 – 'Workplace exposure limits: containing the list of workplace exposure limits for use with the Control of Substances Hazardous to Health Regulations 2002 (as amended)'. If specialised ventilation systems are provided in order to achieve these standards, they will be subject to the COSHH Regulations as above.

Fire regulations

1.13 The fire regulations require that, if ventilation ductwork penetrates the compartment or subcompartment of a building, it should be designed and installed so as to contain the spread of fire (see Health Technical Memorandum 05-02 – 'Guidance in support of functional provisions for healthcare premises' for further guidance).

Plants installed in units manufacturing medicinal products

1.14 Plants installed in units manufacturing medicinal products to the standards set out in the current European guide to good manufacturing practice (http://ec.europa.eu/enterprise/pharmaceuticals/eudralex/homev4.htm) may also be subject to particular legislation with regard to their operation in addition to that mentioned above.

1.15 Records should be kept of equipment design and commissioning information. The Health and Safety Executive, Medicines Inspectorate and other interested bodies have a statutory right to inspect them at any time. All records should be kept for at least five years.

Plants installed in laboratories

1.16 Specialised ventilation plants installed in laboratories dealing with research, development or testing, whether involving drugs, animals or genetically modified organisms, may be subject to particular legislation with regard to their operation in addition to that mentioned above. Further information is given by the Health & Safety Commission's Health Services Advisory Committee in:

- 'Safe working and the prevention of infection in clinical laboratories and similar facilities';
- 'The management, design and operation of microbiological containment laboratories'.

Note

If the ventilation plant has been installed to dilute or contain harmful substances (the definition of which now includes microorganisms), its failure may expose people to unacceptable levels of hazard. Proven failures can give rise to a civil suit against the designers and operators by the individuals who have been affected. This would be in addition to the actions brought as a result of breaching the statutory requirements.

Codes of practice and other guidance

1.17 All ventilation systems should conform to the principles set out in the Health and Safety Commission's Approved Code of Practice and guidance document 'Legionnaires' disease: the control of *Legionella* bacteria in water systems' (commonly known as L8), and Health Technical Memorandum 04-01 – 'The control of *Legionella*, hygiene, "safe" hot water, cold water and drinking water systems'.

1.18 The Department of Health publication 'The Health Act 2006: code of practice for the prevention and control of healthcare associated infections' is a code of practice that has been brought out to help NHS bodies to plan and implement how they can prevent and control healthcare-associated infections. It sets out criteria by which managers of NHS organisations are to ensure that patients are cared for in a clean environment and where the risk of healthcare-associated infections is kept as low as possible. Specialised ventilation systems often play a central role in achieving this objective.

This document deals with the healthcare-specific aspects of ventilation. Basic information on the design, installation, commissioning and testing of ventilation systems is contained in documents produced by the following (see the References section):

- the Chartered Institute of Building Services Engineers (CIBSE);

- International and British Standards (ISO and BS EN);
- the Building Services Research and Information Association (BSRIA);
- trade associations such as the Heating and Ventilating Contractors' Association (HVCA).

Design and validation process

1.19 It is essential, when undertaking the design of a specialised ventilation system, that the project be considered as a whole. The process model set out in Table 1 should ensure that all relevant factors are considered.

Table 1 Design and validation process model

Step	Question	Design statement and information required	Comment
1	Why is the system required?	Healthcare applications Statutory elements Non-healthcare applications	
2	What is the required system performance?	Room air-flow pattern Air-change rate Differential pressures Air quality Room air-condition Noise limits	
3	What are the constraints on the distribution system?	Ducts: Location, size, materials Dampers, access, insulation Fire considerations Room terminals	
4	What are the minimum requirements for the air-handling units (AHUs)?	Intake/discharge positions Legionella, health and safety Access, fire, electrical safety Leaks, insulation, cleanliness Filtration, drainage	
5	What control functions are required?	User control requirements Estates control functions Energy management Environmental conditions Control sequence logic Run, set-back, Off philosophy	
6	How will the system performance be validated?	Validation methodology Instruments used Design information required: • design air-flow rates • design air velocities • pressure differentials • noise levels • air quality • installation standard	
7	The system will only be acceptable to the client if at the time of validation it is considered fit for purpose and will only require routine maintenance in order to remain so for its projected life.		
8	Handover to client[1]	Basic design information Commissioning results Validation report	

Note: 1. When new ventilation systems are accepted for use, full information as to their designed mode of operation together with recommended maintenance procedures should be provided as part of the handover procedure

Ventilation – terms in use

1.20 The terms "ventilation" and "air-conditioning" are often used interchangeably to describe the same equipment. A general explanation of the terms is given below.

Ventilation

1.21 Ventilation is a means of removing and replacing the air in a space. In its simplest form this may be achieved by opening windows and doors.

1.22 Mechanical ventilation systems provide a more controllable method. Basic systems consist of a fan and collection or distribution ductwork; more complex systems may include the ability to heat and filter the air passing through them.

1.23 Ventilating equipment may be required in order to remove smells, dilute contaminants and ensure that a supply of fresh air enters a space.

Air-conditioning

1.24 Air-conditioning is the ability to heat, cool, dehumidify and filter air. For full air-conditioning, humidification may also be provided. This means that the climate within a space being supplied by an air-conditioning plant can be maintained at a specific level regardless of changes in outside air conditions or the activities within the space. Air-conditioning equipment may be required in order to provide close control of "comfort conditions" within a space.

Specialised ventilation

1.25 In healthcare premises, certain activities will necessitate the provision of ventilation equipment with additional special features in order to achieve and maintain specific conditions. These may be needed in order to assist with the treatment of patients or maintain the health and safety of staff. The precise reason for providing specialised ventilation will depend upon the intended application. The list below indicates some of the more typical reasons:

a. to remove, contain or dilute specific contaminants and fumes;

b. to ensure the isolation of one space from another;

c. to preserve a desired air-flow path from a clean to a less clean area;

d. to provide control of the cleanliness of a space;

e. to provide close control of temperature;

f. to provide close control of humidity.

1.26 The following departments will usually have specialised ventilation requirements, either for a single room or throughout a suite of rooms:

a. operating department;

b. laser surgery unit;

c. operative imaging unit;

d. intensive treatment unit;

e. infectious diseases isolation unit;

f. wards housing immunocompromised patients;

g. manufacturing pharmacy;

h. specialised imaging, X-ray and scanning unit;

j. pathology containment laboratories;

k. mortuary and dissection suite;

m. research laboratories;

n. sterile services department;

p. emerging treatment technologies, including gene therapy and stem cell units.

1.27 Ventilation may be provided in a wide variety of ways. These will include:

- extensive purpose-built air-handling units housed in their own plantrooms;
- proprietary "packaged" systems often sited outside on a roof; or
- wall-mounted electric fans located at the point of use.

1.28 A fixed volume of air may be supplied, often expressed in terms of the resulting number of air changes per hour (ac/h), within the space being ventilated. Alternatively the volume of air supplied may be varied in order to maintain a specific pressure relationship between the area supplied and other surrounding areas. In some situations a combination of both methods may be adopted.

1.29 Modern plants should be fitted with the means to recover energy from the extract air without causing contamination of the incoming supply air.

1.30 Ultra-clean systems use the same basic plant and equipment as standard air-conditioning systems, but are in addition fitted with a terminal device that supplies the air in a unidirectional manner to the working area. Their standard of filtration will

be capable of delivering air with a very low particle count to the space that they serve.

Local exhaust ventilation

1.31 Local exhaust ventilation (LEV) is a term used to describe systems installed to prevent hazardous substances from entering the general atmosphere of the room in which they are being used. Their primary function is to protect staff from the effects of their work activity.

1.32 Simple LEV systems comprise a receptor or capture hood, extract ductwork and a fan. These are used to contain industrial types of hazard such as fumes from welding processes, gas discharges from standby battery banks and dust from woodworking machinery.

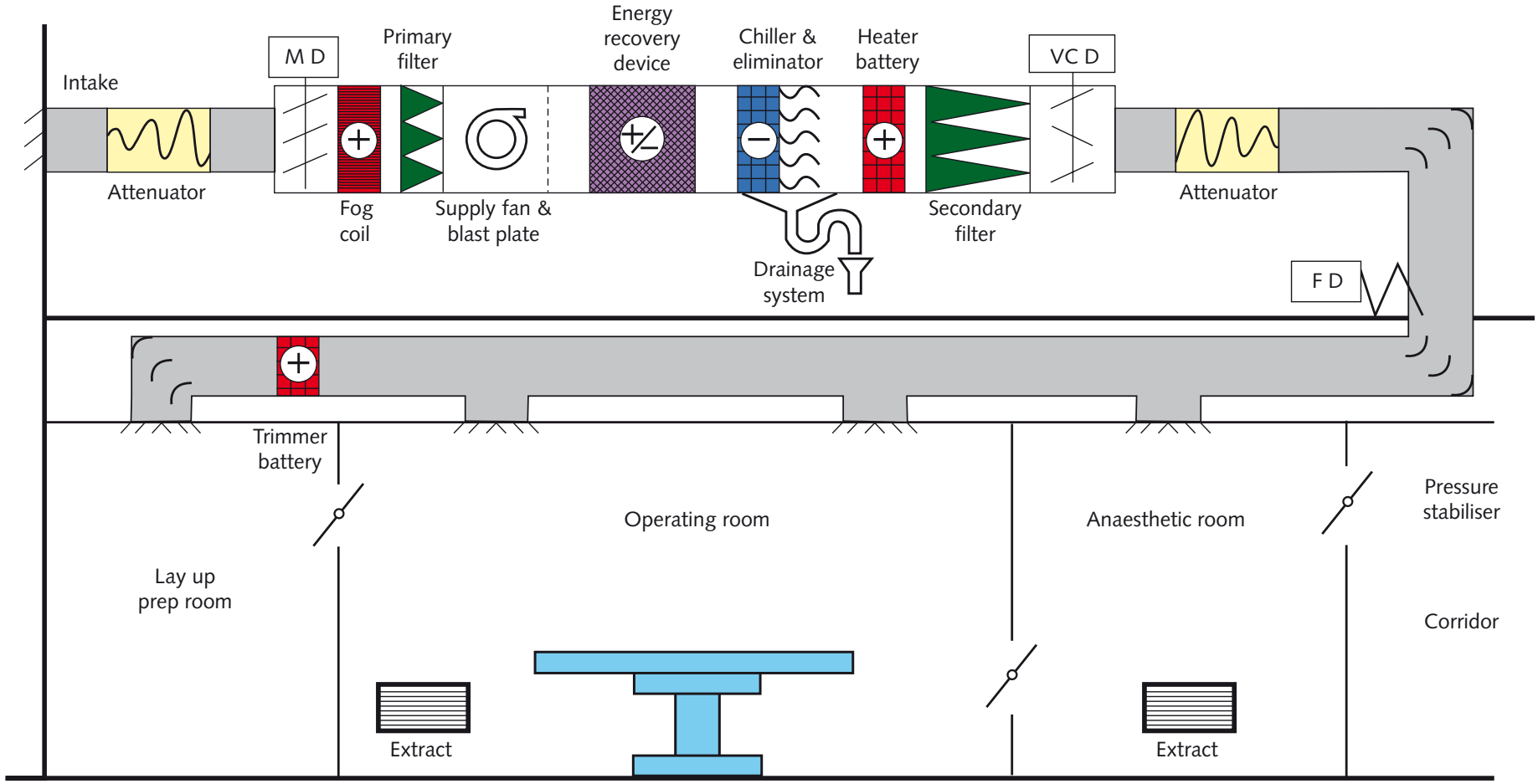
1.33 The vapour given off when large quantities of chemicals are decanted into ready-use containers and fumes from X-ray film processing units are examples of chemical hazards often controlled by LEV systems.

1.34 In laboratories, pharmaceutical manufacturing facilities and operating suites, LEV systems usually take the form of semi-open-fronted cabinets within which the hazardous substance is manipulated. These cabinets either have their own filtered air supply or are fed with air from the room. The air extracted from the cabinet is passed through a high-efficiency filter before being discharged either to the atmosphere or back into the room. Microbiological safety cabinets, laboratory fume cupboards, cytotoxic drug cabinets and fixed or mobile disinfection enclosures are all examples of this type of facility.

1.35 Mortuaries and dissection suites may have LEV systems incorporated within the dissection table, specimen bench and bone saw.

1.36 The layout of a typical plant that conforms to the regulations for healthcare applications is shown in Figure 1. For an explanation of the equipment used in the diagram, see Appendix 1.

Figure 1 Example of a typical operating theatre ventilation system



2 Provision of ventilation in healthcare buildings

2.1 Planning constraints caused by a building's shape and/or the functional relationships of specific areas will invariably result in some measure of deep planning, thus reducing the opportunity for natural ventilation.

2.2 However, ventilation costs can be minimised by ensuring that, where practicable, core areas are reserved for those rooms that need to have mechanical ventilation. Examples are:

- sanitary facilities, dirty utilities and those rooms where clinical or functional requirements have specific environmental needs; and
- those rooms where – for reasons of privacy, absence of solar gain etc – windowless accommodation is acceptable.

2.3 Other spaces appropriate to core areas are those which have only transient occupation and therefore require little or no mechanical ventilation (for example circulation and storage areas).

Natural ventilation

2.4 Natural ventilation is usually created by the effects of wind pressure. It will also occur if there is a temperature difference between the inside and the outside of a building. The "thermo-convective" effect frequently predominates when the wind speed is low, and will be enhanced if there is a difference in height between inlet and outlet openings.

2.5 Ventilation induced by wind pressures can induce high air-change rates through a building, provided air is allowed to move freely within the space from the windward to the leeward side. However, in most healthcare applications, internal subdivisions will restrict or prevent this effect.

2.6 It is almost impossible to maintain consistent flow rates and ensure that minimum ventilation rates will be achieved at all times. However, this variability is normally acceptable in such areas as office accommodation, staff areas, library/seminar rooms and dining rooms, where opening windows (of a design that facilitates natural ventilation) should be provided.

Note

If natural ventilation is "single-sided", it will usually only be effective for a three-metre depth within the space. Beyond that it will need to be supplemented by mixed-mode or forced ventilation.

2.7 Current guidance restricts the opening of windows for safety reasons; also, as many designs are top-hung, their ability to permit natural ventilation is limited. It may therefore be necessary to provide dedicated ventilation openings in the fabric of the building to allow a sufficient natural flow of air into and out of the space.

2.8 In all cases, excessive heat gain, indoor air-quality requirements or external noise may limit or preclude the use of natural ventilation.

2.9 Detailed guidance on natural ventilation can be found in CIBSE's (2005) Applications Manual AM10 – 'Natural ventilation in non-domestic buildings'.

Extract ventilation systems

2.10 Extract ventilation is required in sanitary facilities, dirty utilities and rooms where odorous but non-toxic fumes are likely; this is to ensure air movement into the space. A single fan/motor unit should be provided to meet this need. There is no healthcare requirement to provide a separate foul/dirty extract system.

2.11 WCs should have an extract rate as set out in Approved Document F of the Building Regulations. Where WCs are located in shower and bathroom spaces, the ventilation required for the WC will normally be adequate for the whole space.

Supply-only ventilation

2.12 Mechanical supply ventilation is required in areas where it is important to maintain a positive

pressure in order to prevent the ingress of less clean air (for example in units caring for immuno-compromised patients, aseptic suites in pharmacies, packing rooms in sterile services departments, operating theatres and theatre preparation rooms; air-change rates are given in Appendix 2).

Supply and extract ventilation

2.13 Mechanical supply and extract ventilation should be provided in rooms where there is a need to control room pressure in relation to adjacent spaces. Critical care areas, isolation suites and treatment areas are typical applications.

Comfort cooling

2.14 Cooling is very expensive in terms of energy costs and should be provided only where necessary to maintain a comfortable environment for staff and patient, or to ensure satisfactory operation of equipment. The imaging department in particular may require cooling to offset the equipment load.

2.15 Calculations and thermal modelling should be undertaken to ensure that, during the summertime, internal temperatures in patient areas do not exceed 28°C (dry bulb) for more than 50 hours per year.

2.16 Certain non-patient areas may also require cooling (for example laboratories and other areas that are subject to high heat gains from equipment).

2.17 Where deep planning of other continuously occupied spaces (for example offices) is unavoidable, there will also be occasions when acceptable levels of comfort can only be maintained by cooling.

2.18 Refrigeration plant should be of sufficient capacity to offset heat gains and maintain areas at a temperature that does not exceed the external design shade temperatures by more than about 3 K, taking into account the level of design risk for the application.

Air-conditioning

2.19 Owing to capital and running costs, full air-conditioning should be used only in essential areas. These include operating departments, critical care areas, manufacturing pharmacies and areas with particularly sensitive equipment.

Specialised ventilation

2.20 Owing to the nature and extent of activities carried out in healthcare buildings, there will be a need for a wide range of specialised ventilation systems. Information on systems for individual departments is given in Chapter 7.

Local exhaust ventilation

2.21 Wherever the escape of chemicals, toxic fumes, biological materials or quantities of dust into the general area would present a hazard to the occupants, LEV must be provided. This is a statutory requirement under COSHH.

Ventilation for general areas

2.22 Appendix 2 provides recommended air-change rates, temperatures and pressures for general areas requiring mechanical ventilation in healthcare buildings.

Acceptable methods

Use of natural ventilation

2.23 The airtightness of new buildings has improved to the point that infiltration through building leakage can no longer be relied upon to provide sufficient air flow. Attention must therefore be given to the provision of purpose-made ventilation openings to achieve the necessary flow rates. The air entering the openings may need to be controlled by motorised dampers linked to temperature and/or occupancy sensors in the ventilated space.

2.24 Internal partitions, fire compartment walls and closed doorways can often impede the flow path; when this happens, the process will be more dependent on single-sided ventilation. Nevertheless, even with this degree of compartmentation, acceptable ventilation may still be achieved without window openings, which would prejudice safety, security or comfort.

2.25 Some types of window (for example vertical sliding) can enhance single-sided air change by temperature difference, and these will improve the overall rate of natural ventilation in protected or sheltered areas where the effect of wind pressure is likely to be minimal.

2.26 Natural cross-flow ventilation is able to give reasonable air distribution for a distance of up to 6 metres inwards from the external facade, provided

that reasonably clear air paths are maintained. Beyond this distance – in areas where clear air paths cannot be maintained and in areas where high minimum air-change rates are specified – mechanical ventilation should be provided.

2.27 Further information can be found in Health Technical Memorandum 55 – 'Windows', BS 5925 and CIBSE's (2005) Applications Manual AM10 – 'Natural ventilation in non-domestic buildings'.

Mixed mode ventilation

2.28 Mixed mode ventilation is an assisted form of natural ventilation. Fans are fitted in purpose-made damper-controlled ventilation openings. Alternatively, a separate draw- or blow-through ventilation unit may be installed. In both cases the dampers and fans are controlled by temperature and occupancy sensors to ensure a minimum air-flow rate while taking advantage of natural ventilation effects when present.

2.29 Where natural or mixed mode ventilation is adopted with complex air paths, the designer should produce an air-flow diagram in order to ensure correct provision of air-transfer devices. CIBSE's (2000) Applications Manual AM13 – 'Mixed mode ventilation' gives guidance.

Mechanical extract ventilation

2.30 General extract systems can vary in complexity from a single wall-mounted fan to a ducted air system with dual extract fans.

2.31 Replacement air either is provided by a central supply system or enters the building through gaps in the structure or purpose-made openings. Unless special precautions are taken, the latter may result in an unacceptable level of draughts occurring in winter, and possible risk of unacceptable levels of noise transmission.

2.32 If individual systems are used, the ventilation can be operated intermittently, provided it continues to run for at least 15 minutes after the room is vacated (as with light-switch-operated fans in individual toilets).

2.33 If general exhaust systems are used, filtered and tempered replacement air should be provided via a central supply plant to adjoining lobbies or corridors, to prevent the risk of discomfort caused by the ingress of cold air. Fire compartmentation requirements must be maintained.

2.34 Information on specialised extract systems is given in Chapter 7.

Mechanical supply systems

2.35 Where mechanical supply systems are required, the fresh air should be tempered and filtered before being delivered to the space in order to avoid discomfort.

2.36 The air should be heated using a constant or variable temperature source, but generally only to the space air temperature. In most instances, the low pressure hot water (LPHW) heating system should offset any fabric loss so that set-back room temperatures can be maintained during unoccupied periods without the need for the ventilation system to operate.

Balanced ventilation

2.37 A balanced ventilation system is a combination of both a supply and an extract system of equal volume; either a single space or a whole building may be considered to be balanced.

2.38 A balanced system is necessary in instances where it is essential to maintain consistent air movement within an area (for example treatment rooms).

Cascade ventilation

2.39 In operating departments, it is normal practice to supply air to the operating room and allow it to flow through less clean areas – corridors, utility rooms etc (from where it is eventually extracted).

Recirculation systems

2.40 Air recirculation systems are normally used in HEPA-filtered clean rooms where the extract air is significantly cleaner than the outside supply and where odour levels are not significant.

2.41 Recirculation is also routinely used in the canopy section of ultra-clean operating theatre ventilation systems.

2.42 Where the designer is considering the installation of an air recirculation system, due account must be taken of:

a. minimum fresh-air-supply volume required by the Building Regulations Part F – Non-domestic Buildings;

b. prevention of contamination of supply air from vitiated air in extract systems;

c. prevention of stratification occurring within plenum chambers and mixing boxes, which may result in freezing of downstream coils;

d. ensuring sufficient velocities through control dampers (ideally 5–6 m/s) to provide suitable authority and good shut-off;

e. modulating control of mixing to provide optimum on-plant conditions;

f. use of "free cooling" by cycling the dampers to minimum fresh air when the enthalpy of the outside air is greater than that of the extract air under conditions when cooling is required.

Chilled beams

2.43 The use of chilled beams for the provision of heating, cooling and ventilation is increasingly common in healthcare premises.

2.44 Active chilled beams providing tempered, filtered air to the room can provide effective local control of environmental conditions.

2.45 Care should be taken in positioning chilled beams to ensure that cold draughts are avoided, particularly when used in the cooling mode. The control settings should ensure that the external elements of the beam are always above dew-point. Manufacturers of these devices are able to provide specific advice on the siting and design limits of their equipment.

2.46 Chilled beam units should be easily accessible for cleaning and maintenance.

Split comfort air-conditioners

2.47 Split comfort air-conditioners, room conditioners or cassette units are used increasingly where there is a small local requirement for cooling for operational purposes. They can provide an effective economic solution to cooling needs where a central refrigeration system is not practicable.

2.48 A fresh-air make-up system to the standard required by the Building Regulations Part F – Non-domestic Buildings must be provided.

2.49 Split units may be used for single applications or as multiple linked units that can independently provide either heating or cooling – all served by a single outdoor unit. These systems help to maintain a more precise temperature control across multiple rooms, with maximum energy efficiency.

2.50 Whether single or multiple systems are used, it is essential that the designer give due consideration to the source of electrical supply, location of the heat rejection unit, environmental effects to the refrigerant used and drainage provision for the cooling-coil condensate.

2.51 Recirculated room air affects indoor air quality and may increase the risk of healthcare-associated infection (HCAI). Split units should therefore not be used in critical care areas.

2.52 The units should be easily accessible for cleaning and maintenance.

Dilution ventilation and clean air-flow paths

2.53 Dilution ventilation has been used to control levels of hazardous substances in a space. This approach in itself is no longer considered acceptable. COSHH requires that known hazardous substances should be substituted for safe alternatives. If this is not possible, they should be controlled at source by using a closed system (such as an anaesthetic gas scavenging unit) or a protective enclosure (such as a fume cupboard). A good level of background ventilation will assist in diluting any casual release of the substance.

2.54 The exposure of staff to casual spillages of substances such as medical gases in anaesthetic rooms should in the first instance be dealt with by establishing a clean air-flow path. Air should be supplied at high level and extracted at low level directly behind the anaesthetic equipment position. The philosophy of establishing a clean air-flow path – from the air-supply point, to the staff, on to the patient, and out via a low-level extract – would also apply in recovery rooms and birthing rooms. A suitable air-change rate will provide background dilution ventilation as an additional safeguard. This approach ensures that "all reasonable steps are taken to prevent or control exposure (of staff) to the hazardous substance" as required by COSHH.

2.55 In operating theatres, patients will be on a closed breathing circuit in a room with a high air-change rate. Under these circumstances, the dilution effect would be considered sufficient to control any casual exposure to anaesthetic gases.

Mechanical ventilation systems

System selection

2.56 Natural ventilation is always the preferred solution for a space, provided that the quantity and quality of air required, and consistency of control to suit the requirements of the space, are achievable. If this is not the case, a mechanical ventilation system will be required.

Choice of central/local plant

2.57 Mechanical ventilation is expensive to operate – it should therefore be used only when the space being served requires ventilation. In addition, loads on air-conditioning plant are rarely constant owing to changes in solar gain, occupancy, the use of heat-generating equipment and lights. Therefore control of the supply-air temperature is critical.

2.58 If the ventilation loads throughout a department or building are in phase, or are not significant, a central plant with single zone control can be adopted. However, this is rarely the case, so the condition or quantity of supply air to different areas or zones of the building must be varied accordingly. This can be achieved by either providing individual plants to each zone or providing separate controls for each zone such as provided by a variable air volume (VAV) system. Where there is a high density of rooms with similar ventilation requirements in an area of a building or department, it is usually economical to combine them into a central system.

2.59 In large buildings, a choice between a single distribution system and multiple smaller systems may arise. Large distribution systems and their plant can have the advantage of lower operating costs, but require more space for vertical shafts. In general, very long runs of ducting should be avoided to prevent undue heat losses or gains, excessive leakage, and difficulties in balancing during commissioning. As the pressure losses in the long runs will be greater and a higher initial static pressure will be required, this will lead to a more expensive class of ductwork.

2.60 Multiple smaller distribution systems may be more expensive in capital and operating costs but they avoid long runs, large ducts and vertical shafts, and this may reduce overall building costs. They also provide a more robust service, as the failure of an individual system does not prevent the use of the rest of the building.

Zoning of the building

2.61 The efficiency and effectiveness of any ventilation or air-conditioning installation depends largely on the zoning and control of the installation. The factors to consider when determining the zoning of a ventilation system for a building or department are:

a. periods of occupancy;

b. fresh-air/ventilation requirements;

c. smoke control.

2.62 Where the ventilation system is not merely tempering the air, but also providing the heating and/or cooling requirements, the following additional factors will need to be considered:

a. internal or peripheral location;

b. orientation of windows;

c. variation in internal loads;

d. level of control required.

2.63 For single-zone plant in staff areas, local control (with a run-on-timer if required) is recommended, as the system can be turned off when the space is not in use, thus saving both thermal and electrical energy. Most supply and extract systems, conversely, are required to operate continuously while the department is occupied; thus some form of time or use control is necessary.

2.64 The control of individual plant items is covered in Chapter 4, with examples of typical control strategies in Chapter 5. For control of particular specialised ventilation and air-conditioning systems, see Chapter 7.

2.65 On rare occasions a duplicate standby air-handling plant may be justified. If installed, it must be provided with a gas-tight damper at its junction with the supply distribution duct so that no back-flow can occur. Standby plants can become sources of contamination if warm moist air is allowed to dwell within them. Their design and control system must ensure that this cannot happen.

3 Assessment of service requirement

Selection of design criteria

External design conditions

3.1 The most accurate data that is available for the summer and winter conditions at the site should be used. The Met Office can supply data for the United Kingdom (www.metoffice.gov.uk).

3.2 Healthcare ventilation systems will normally be "full fresh air".

3.3 Local adjustments, such as for height above sea level, exposure factor or other climate peculiarities, should be made as appropriate.

Internal design conditions

3.4 The design conditions selected within patient areas must strike a balance between the comfort requirements of staff and patients, who often have very different levels of clothing and activity.

3.5 Recommendations for the dry resultant temperature and humidity of individual spaces are shown on Activity DataBase A-sheets. Appendix 2 gives a summary.

Minimum fresh-air requirements

3.6 The dilution of body odours is the critical factor in determining ventilation requirements. Where natural ventilation or full fresh-air systems are used, all ventilation air will be fresh.

3.7 Where odour dilution is the overriding factor, it is recommended that 10 litres per second per person should be taken as the minimum ventilation rate.

3.8 In non-standard applications such as laboratories, aseptic suites, operating departments etc, the particular requirements for each area should be considered independently in order to determine the overriding minimum requirement for ventilation.

Limiting supply air conditions

3.9 For most applications in healthcare buildings, it is the temperature differential between the supply and room air, rather than the actual temperature of the supply air, which is the critical factor. The maximum recommended supply-to-room-air temperature differential is:

- summer cooling: –7 K
- winter heating: +10 K.

3.10 In areas that have high heat gains from equipment (for example critical care areas), the summer cooling temperature differential limit given above may result in excessive air-change rates. A differential of up to –10 K is acceptable in these circumstances, providing the supply-air diffusers are of a type that provide good mixing.

3.11 If a humidifier is fitted, it is necessary to keep supply-air humidity below 70% during winter in order to minimise the risk of condensation on cold surfaces.

Air purity

3.12 In healthcare premises, the standard of filtration will depend on the activities within the occupied spaces. With the exception of specialist areas (for example manufacturing pharmacies), aerobiological requirements are not stringent, and filtration is only required to:

a. maintain hygienic conditions for the health and welfare of occupants, or for processes such as food preparation;

b. protect finishes, fabrics and furnishings in order to reduce redecoration costs;

c. protect equipment either within the supply air system (that is, to prevent blocking of coils), or in the space itself to prevent dust build-up.

3.13 Given that almost all viable particles originate from the occupants of a space and not from the incoming air, dilution is the more important factor aerobiologically. Therefore, for general areas a G4 filter is suitable. More critical areas will require an F7 filter. High-efficiency particulate air (HEPA)

filters are required only in ultra-clean systems (information on filter grades is given in Chapter 4).

Humidity control requirements

3.14 Providing humidification is expensive in terms of plant, running costs and maintenance, and therefore its use should be restricted to where it is necessary for physiological or operational reasons.

3.15 Humidification was originally required for some healthcare applications (for example operating theatres) in order to control the risk associated with the use of flammable anaesthetic gases. The use of such gases has now ceased. Humidification is therefore no longer required unless there is a very specific application requirement.

Noise levels

3.16 Noise will be generated by fans, ductwork fittings, dampers and grilles. The specified maximum noise level will depend on the activities within the occupied spaces.

3.17 Attention must be given to the reduction of tonal components. High tonal components from air diffusers etc can seriously disturb concentration over longer periods even when the overall noise level is low. Broadband noise causes less annoyance.

3.18 Attenuation should be incorporated into the ductwork system or plant arrangement as necessary to reduce noise from fans and plant items in order to achieve acceptable limits within rooms at the design air flows.

3.19 The designer must also consider noise escaping to the external environment, and this must not be unacceptable to occupants of adjacent areas or buildings.

3.20 The overall noise levels should not exceed the values given in Health Technical Memorandum 08-01 – 'Acoustics'.

3.21 Plant noise is subject to the Control of Noise at Work Regulations 2005 and should not exceed 80 dB(A) within a plantroom. It should be reduced to lower levels where the plant is near to departments sensitive to noise.

Calculation of building loads

Air infiltration

3.22 CIBSE's (2006) Guide A – 'Environmental design' provides information and formulae for the calculation of air infiltration. Pressure testing enables the true infiltration rate to be established. In all cases the requirements of the appropriate section of the Building Regulations Part L2 must be met.

Summertime temperatures

3.23 The calculation method for determining the summertime temperature is described in CIBSE's Guide A. It is very important to select the time of day and time of year of peak loadings for the calculations. These will be dependent on the building orientation and proportion of solar to total heat gain. In establishing design values, the design risk – having regard to the function and occupancy of the building – should be considered.

3.24 Calculations and thermal modelling should be undertaken to see whether, during the summertime, internal temperatures in patient areas will exceed 28ºC dry bulb for more than 50 hours per year. It can generally be assumed that for a naturally ventilated building, the internal temperature will be approximately 3 K above the external shade temperature. For a building with simple mechanical ventilation, the internal temperature can never be less than the external shade temperature and will invariably be higher. The relationship between preferred indoor temperatures and mean outside temperature is discussed in CIBSE's Guide A.

3.25 Where calculations indicate that internal temperatures will exceed the selected design for a period that exceeds the building design risk, methods of reducing temperature rise should be implemented. Options include:

- reducing solar and casual gains;
- the use of chilled beams or ceilings;
- increasing ventilation rates; or
- providing mechanical cooling.

3.26 In some situations it may be possible to alter the thermal mass of the structure to "move" the peak temperature event time so that it occurs outside of the occupancy period.

Peak heating load

3.27 Peak heating local calculations are necessary on all mechanical supply systems to establish the size of heater-batteries and subsequently the central plant.

3.28 Where ventilation systems provide tempered air to spaces that have supplementary LPHW to offset the building fabric losses, the plant's heating load should be based on the design values of the external winter temperature and internal air temperature, and the calculated total air volume (including a suitable allowance for leakage).

3.29 Where the ventilation system is the only means of heating a space, an increase in load equivalent to the calculated fabric heat losses from the space should be added to the ventilation load. A check of supply temperature difference should be made. If it exceeds 10 K, the ventilation supply volume should be increased to suit.

Condensation risk

3.30 A check should be made to ensure that the selected air condition will not lead to surface condensation on low-temperature elements of the ventilated space.

3.31 Where there are local sources of moisture that would require excessive levels of ventilation to avoid condensation, the designer should consider the capture and removal of moisture at the source of the evaporation via an exhaust hood or similar device.

3.32 In intermittently heated buildings, it is necessary to consider the condensation risk at night set-back conditions as well as during normal operation. Calculation methods for this assessment are given in CIBSE's Guide A.

Peak cooling load

3.33 In addition to the base data of air-flow rates and temperatures, when calculating cooling loads, the designer must take into account:

a. solar cooling loads;

b. surface conduction cooling loads;

c. internal gain cooling loads;

d. cooling loads due to high-level humidity control;

e. method of control of internal conditions;

f. fluctuations in internal temperatures.

3.34 When the peak internal loads have been assessed and a suitable allowance made for non-coincidence, the supply temperature can be calculated.

3.35 Once the lowest required supply temperature of the air-handling unit (AHU) has been established, and an allowance made for temperature rise through the fan and ductwork (usually 1 K for low-pressure systems), the off-plant enthalpy can be established from a psychrometric chart or table.

3.36 The cooling loads for all plants on the chilled water system should be calculated at each of the individual peak times in order to accurately establish the required (diversified) capacity of the chiller.

Annual energy consumption

3.37 Annual energy consumptions of heating-only ventilation systems are simple to calculate, based on supply-to-external air temperature rise, and frequency of occurrence of external temperature data (see CIBSE's Guide A).

3.38 Minimum air volumes are usually fixed by the room loads or fresh-air requirements; however, the designer may increase air flow to some rooms or zones in order to balance loads (as detailed in paragraphs 3.42–3.71).

3.39 The method of zoning and control can significantly influence energy consumption.

3.40 The concept of load and plant operation charts is outlined in CIBSE's Guide A. The method requires the designer to establish the minimum and maximum loads on all zones across the range of external temperatures between winter and summer design conditions. Once the load chart is complete, the plant chart converts the loads to supply temperatures, which are then superimposed on external air temperatures.

3.41 When all temperatures for all zones are plotted on the plant operation chart, set-points and resetting schedules can be established. From this information, the outputs of individual heaters, coolers and humidifiers can be established at any given external temperature. When those loads are computed against annual frequency of occurrence of external temperatures (as given in CIBSE's Guide A), the annual energy consumption of individual elements, and thus the air-conditioning system, can be established.

Calculation of plant requirements

Air-supply volumes

3.42 The minimum air supply volume for a room is determined by the greater of the following three criteria:

a. the minimum fresh-air requirement;

b. the minimum supply volume for the room load as determined by the maximum heating or cooling supply temperature differential;

c. the desired air-change rate.

Plant sizing

3.43 Once the design air flow has been established, the cross-sectional area of the AHU can be calculated based on a maximum coil face velocity of 2.0 m/s.

3.44 In order to establish the length of the AHU, it will be necessary to refer to manufacturers' literature, ensuring all necessary access panels and components are included as detailed in Chapter 4.

3.45 The fan duty should be calculated by adding the resistances of all elements that contribute to the pressure drop of the index circuit.

3.46 The main elements that must be considered are:

a. inlet or discharge louvres;

b. plant entry and discharge;

c. attenuators;

d. components within the AHU;

e. duct-mounted heaters and filters (including a dust allowance);

f. ductwork distribution;

g. ductwork fittings including: fire dampers, volume control dampers, bends and sets, tees, changes of section;

h. air terminal device;

j. discharge velocity.

3.47 Where packaged AHUs are installed, the fan pressure drop is usually quoted as external plant resistance, and thus the designer does not need to calculate the resistances of individual plant items. The designer should, however, ensure that an allowance has been made for "dirty filter" conditions, and confirm whether the fan pressure quoted is fan total or static pressure.

3.48 Resistances of ductwork and fittings may be obtained from CIBSE's Guide A; however, the designer should exercise some care when using tabulated pressure loss information for fittings that are relatively close together.

3.49 Upon completion of the resistance calculation exercise, the designer should make allowances for calculation and construction tolerances as indicated in Table 2.

Table 2 Typical fan volume and pressure margins

Criteria	Low-pressure systems	Medium/high-pressure systems
Volume flow rate margin for leaking and balancing requirements	+5%	+5%
Total pressure loss margin: a. for increase in volume flow rate (above)	+5%	+5%
b. for uncertainties in calculation	+5%	+10%
Combined total pressure loss margin	+10%	+15%

Plantroom size and location

3.50 The ventilation plant and associated equipment should be positioned to give maximum reduction of noise and vibration transmitted to sensitive departments; and at the same time, achieve an economic solution for the distribution of services.

3.51 It is not recommended that noise and vibration generating plant be housed either directly above or below sensitive areas (for example operating or anaesthetic rooms) unless there is no alternative, in which case additional care and attention must be given to the control measures.

3.52 The plant must also be located so that it is remote from possible sources of contamination, heat gains and adverse weather conditions. The design should ensure that wind speed and direction have a minimal effect on plant throughput.

3.53 Safe access to and around plant is essential to facilitate inspection, routine maintenance, repair and plant replacement.

Provision of primary services

3.54 Where more than one air-handling plant requires cooling, remote central cooling plants with piped chilled water are preferred. In the case of a single

plant, a multi-stage direct expansion cooling coil with refrigerant piped from an adjacent compressor/condensing plant could be considered. If this option is selected, a refrigerant gas detector mounted in the base of the duct and an alarm system audible to the end-user will also need to be provided (as dictated by the COSHH Regulations).

3.55 Clean, dry steam is preferred for humidification, provided that the boiler water treatment does not render the steam unusable for direct humidification.

3.56 If a suitable supply of steam cannot be obtained from the steam main, a steam generator should be provided locally, or a self-generating humidifier installed. The location of a local steam generator is critical if condensate is to drain back into it.

Inlet and discharge sizing and location

3.57 Air intakes and discharge points should preferably be located at high level, to minimise the risks of noise nuisance to surrounding buildings, contamination and vandalism.

3.58 Intakes and discharges should be designed and located so that wind speed and direction have a minimal effect on the plant throughput.

3.59 Helicopter landing pads in the vicinity of ventilation intakes and discharges can result in large short-term pressure changes. This can cause pressure surges in supply systems and reverse air flows in extracts. Exhaust fumes from the helicopter may also be drawn into intakes.

3.60 Intake points should be situated away from cooling towers, boiler flues, vents from oil storage tanks, fume cupboards and other discharges of contaminated air, vapours and gases, and places where vehicle exhaust gases may be drawn in.

3.61 Where intakes have necessarily to be sited at or near ground level, the area around them should be paved or concreted to prevent soil or vegetation being drawn in. They should also be caged or located within a compound to prevent rubbish being left in the vicinity. The likely proximity of vehicle exhausts should be taken into account when determining the protected area around the intake.

3.62 The discharge from a general extract system must be located so that vitiated air cannot be drawn back into the supply-air intake or any other fresh-air inlet. Ideally, the extract discharge will be located on a different face of the building from the supply intake(s). In any event, there must be a minimum separation of 4 m between them, with the discharge mounted at a higher level than the intake.

3.63 Discharges from LEV systems should preferably be vertical and usually not less than 3 m above roof level. They should not be fitted with a cowl that could cause the discharge to be deflected downwards.

3.64 Each intake and discharge point should be fitted with corrosion-resistant weatherproof louvres or cowls to protect the system from driving rain (BS EN 13030, Class B).

3.65 It is recommended that louvres be sized based on a maximum face velocity of 2 m/s in order to prevent excessive noise generation and pressure loss.

3.66 The inside of the louvres should be fitted with a mesh of not less than 6 mm and not more than 12 mm to prevent leaves being drawn in and infestation by vermin.

3.67 The duct behind a louvre should be self-draining. If this is not practicable, it should be tanked and provided with a drainage system.

3.68 Cleaning access must be provided either from the outside via hinged louvres or by access doors in the plenum behind the louvre. Where a common plenum is provided, cleaning access should be via a walk-in door.

Heat-rejection devices

3.69 The design conditions given in Chapter 2 make no allowance for the elevated temperatures that can occur on the roof of buildings. Refrigeration condensers and cooling towers should, if practicable, be shaded from direct solar radiation, or the design should be adjusted to take account of the gain.

3.70 Air-cooled condensers should be the first choice for heat rejection from any refrigeration plant.

3.71 Evaporative cooling systems should not be used in healthcare premises unless limitations of space mean that they are the only way that the cooling load can be met. If they are used, guidance on preventing and controlling legionellae must be closely followed (see Health Technical Memorandum 04-01 – 'The control of *Legionella*, hygiene, "safe" hot water, cold water and drinking water systems'; and the Health and Safety Commission's Approved Code of Practice and guidance document 'Legionnaires' disease: the control of *Legionella* bacteria in water systems' (commonly known as L8)).

4 Air-handling unit design and specification guidance

General requirements

Location and access

4.1 AHUs should be located in an accessible area secured from unauthorised entry. Siting units in ceiling voids above occupied spaces is not appropriate.

4.2 Units located on roofs should have a safe means of access together with suitable precautions to prevent personnel or equipment falling or being blown off during maintenance activities.

4.3 Units located at ground level should be secured within a compound to prevent unauthorised access. Measures should be taken to exclude vehicles from the vicinity to ensure that exhaust fumes will not be drawn into intakes.

4.4 Units may have a working life of 25 to 30 years. It can be anticipated that over this period there will be a need to access every element within the unit for deep cleaning. It is also quite possible that the main fan and individual heater and chiller batteries will need replacement. Suitably positioned service connection joints and adequate spacing should permit these items to be withdrawn without the need to dismantle other installed plant or equipment. Batteries that are significantly wider than 1 m should be split to permit withdrawal from both sides.

4.5 It is essential that AHUs are positioned so that all parts are easily and safely accessible for routine inspection and service. If a unit is located against a wall or backs onto another unit, access to all parts must be available from the front. Units greater than 1 m wide should preferably have access from both sides or have access doors large enough to permit the full and safe entry of maintenance personnel.

4.6 The area around the unit should be tanked to prevent water penetration to adjacent areas, and should be adequately drained.

4.7 Fire precautions should be incorporated in accordance with Firecode (the Health Technical Memorandum 05 series). See also Chapter 3.

4.8 Combustion equipment must not be located in a fire compartment that houses air-handling equipment.

Technical requirements

4.9 The basic technical requirements of the whole of the ventilation system should meet the relevant clauses of Model Engineering Specification C04 – 'Mechanical ventilation and air-conditioning systems'. This document contains a menu of clauses that cover a wide range of applications, so it is important to select only those that are relevant to the specific application.

Note

At the time of writing, Model Engineering Specification C04 was due for revision in order to bring it into line with the revised standards set out in this Health Technical Memorandum. Where conflicts in specification arise, the Health Technical Memorandum takes precedence.

4.10 It is essential that the main plant/ductwork is located far enough from the floor to permit the correct installation of drainage systems for cooling coils, humidifiers and heat-recovery systems. Easy access for maintenance of drainage systems and their associated pipework must be provided.

4.11 Organic materials or substances that can support the growth of microorganisms must not be used in the construction of the plant or its distribution system. The Water Regulations Advisory Scheme's (WRAS) (2005) 'Water Fittings and Materials Directory' lists suitable materials for sealants and gaskets.

4.12 The plant and its distribution system must not contain any material or substance that could cause or support combustion.

4.13 Plants should have a high standard of airtightness. The double-skin method of construction with insulation sandwiched between two metal faces is recommended. The panels may be available in a variety of colours at no additional cost. This can aid identification by colour-coding of units in a plantroom (for example green for general ventilation; blue for theatres; red for laboratories and isolation facilities; grey for extract etc).

4.14 The inside of the plant should be as smooth as possible. Channels, rolled angles or formed sections that could trap or hold moisture should be kept to a minimum. If stiffeners are required, they should be fitted externally. If internal bracing has to be fitted, it must be of a design that will not trap or hold moisture.

4.15 Air flow across air treatment components such as filters, heat exchangers and humidifiers will be influenced by the pattern of the approaching air stream. If unsatisfactory conditions are created, the performance of the component will be reduced.

4.16 Access to items that require routine service such as filters, fog coils and chiller batteries should be via hinged doors. The doors should be large enough (for example 500 mm minimum) to allow easy access. Items requiring infrequent access, such as attenuators, may be via bolted-on, lift-off panels. All doors and panels should be close-fitting and without leaks.

4.17 Care should be taken during installation to ensure that electrical and mechanical services are not installed in positions that will reduce or impede access.

4.18 It can be difficult to turn off AHUs in order to inspect filters and drainage trays. Viewing ports and internal illumination will therefore facilitate routine patrol inspection of such items. Viewing ports should be at a convenient height. In double-stacked units, placing the viewing ports at the bottom of the access doors of the upper unit will remove the need to use temporary ladders or steps when carrying out patrol inspections.

4.19 Internal illumination should be provided by fittings to at least IP55 rating. Fittings should be positioned so that they provide both illumination for inspection and task lighting. All lights in a unit should be operated by a single switch.

4.20 Access to AHUs and items in the distribution system such as filters or heater/chiller batteries should be via fixed ladders and platforms or pulpit-style movable steps. The installation of distribution ductwork and other electrical or mechanical services should provide sufficient clearance to allow the pulpit steps to be easily wheeled into position.

AHU drainage system

4.21 All items of plant that could produce moisture must be provided with a drainage system. The system will comprise a drainage tray, glass trap, air break and associated drainage pipework.

4.22 The drainage tray should be constructed of a corrosion-resistant material – stainless steel is preferred – and be so arranged that it will completely drain. To prevent "pooling", it is essential that the drain connection should not have an up-stand and that a slope of approximately 1 in 20 in all directions should be incorporated to the drain outlet position. The tray must be completely accessible or, for smaller units, easily removable for inspection and cleaning.

Removable drainage tray

4.23 Each drainage tray should be provided with its own drain trap. The drain trap should be of the clear (borosilicate) glass type. This permits the colour of the water seal to be observed, thus giving an early indication of corrosion, biological activity or contamination within the duct. The trap should have a means for filling and incorporate couplings to facilitate removal for cleaning. It should be located in an easily visible position where it will not be subject to casual knocks. The pipework

connecting it to the drainage tray should have a continuous fall of not less than 1 in 20.

4.24 Traps fitted to plant located outside or in unheated plantrooms may need to be trace-heated in winter. The trace-heating must not raise the temperature of water in the trap above 5ºC.

4.25 Water from each trap must discharge via a clear air gap of at least 15 mm above the unrestricted spill-over level of either an open tundish connected to a foul drainage stack by way of a second trap, or a floor gully (or channel). A support should be provided to ensure that the air gap cannot be reduced. More than one drain trap may discharge into the tundish providing each has its own air break.

4.26 Drainage pipework may be thermoplastic, copper or stainless steel. Glass should not be used. The pipework should be a minimum diameter of 22 mm and have a fall of at least 1 in 60 in the direction of flow. It should be well supported and located so as not to inhibit access to the AHU.

Layout of AHU

4.27 The AHU should be arranged so that most items are under positive pressure. Any item of plant requiring a drain should be on the positive pressure side of the fan. A recommended layout is given in Figure 1.

4.28 A separate extract unit will generally be required for the area served by each supply unit.

4.29 An energy recovery system will normally be fitted between the supply and extract units.

Provision of dampers

4.30 Fire- or smoke-actuated dampers should be provided at the locations required by Health Technical Memorandum 05-02 – 'Guidance in support of functional provisions for healthcare premises' (see also paragraph 5(c) in Appendix 1 and paragraph 6.21).

4.31 Motorised low-leakage shut-off dampers should be located immediately behind the intake and discharge of each supply and extract system respectively. They should be of the opposed-blade type, opening through a full 90 degrees, and must close automatically in the event of power failure or plant shut-down to prevent any reversal of the system air flow.

4.32 The quality of motorised dampers is critical. They should:

- be rigid;
- have square connections fitted with end and edge seals of a flexible material; and
- have minimal play in linkages.

The leakage on shut-off should be less than 2%.

4.33 A manually operated isolating damper should be installed between the main AHU and its distribution system to enable the unit to be isolated when cleaning is in progress.

4.34 Some systems will require the fitting of a main volume control damper so that the design air-flow rate can be set at commissioning. The damper should be lockable in any position. If it will also be used for plant isolation, it should be capable of being reset to give the design air flow without the need for remeasurement.

4.35 Internal plant-isolating dampers are not required. Neither is the provision of fittings for shut-off plates between items within a unit.

Vibration

4.36 Vibration from a remote plantroom can be transmitted by the structure of the building, may be regenerated and may sometimes be magnified many times. Units should be selected to have the minimum vibration generation and to be installed on suitable anti-vibration mounts. Pipe and ductwork should incorporate anti-vibration couplings, preferably in two planes at right angles, as close to the vibration source as possible. Consideration should be given to the use of anti-vibration pipe hangers and supports.

Sequence of components

4.37 The following arrangement of plant components is typical, although in many instances not all elements will be required:

a. fresh-air intake;

b. motorised isolation/smoke damper;

c. frost/fog coil;

d. prefilter;

e. energy-recovery device;

f. attenuator (these may be located in the intake and discharge duct if they are of a suitable type – see also paragraph 4.166);

g. fan;

h. blast plate;

j. attenuator (see (f));

k. chiller battery;

m. eliminator;

n. heater-battery;

p. humidifier;

q. final filter;

r. manual isolation/volume control damper.

4.38 There may be instances where this arrangement is not appropriate, and the plant arrangement should be planned accordingly.

Fans

General requirements

4.39 The fan should be selected for efficiency and minimum noise level, but the overriding factor should be the selection of a fan characteristic such that the air quantity is not greatly affected by system pressure changes due to filters becoming dirty or due to external wind effects.

Acceptable types

4.40 Fans can be of the axial, centrifugal, cross-flow, mixed-flow or propeller type, depending on the requirements of the system.

4.41 Where used, centrifugal fans should preferably be of the backward-blade type. Alternatively, where noise levels are more critical and pressure requirements are lower, forward-curved blade fans are acceptable. For high-power applications, aerofoil-blade fans are appropriate.

4.42 In all cases the fan power performance requirements of the Building Regulations Part L2 must be met.

Selection

4.43 Generally, large ventilation systems will use centrifugal fans due to their efficiency, non-overloading characteristics and developed pressures.

4.44 Axial flow or propeller fans are generally only used in local through-the-wall systems or systems with very low-pressure requirements.

4.45 Cross-flow fans have very low operating efficiencies, and thus their use is restricted to applications such as fan-coil units.

Location and connection

4.46 Fans are normally positioned to “blow through” the central plant so that the cooling coil and humidifier drains will be under positive pressure.

4.47 The fan performance figures given by manufacturers in their catalogue data are based on tests carried out under ideal conditions, which include long uniform ducts on the fan inlet/outlet. These standard test connections are unlikely to occur in practice; the designer should therefore ensure as far as is practical that the fan performance will not be significantly de-rated by the system. This objective can be approached by ensuring that the fan inlet flow conditions comprise uniform axial flow velocities with low levels of turbulence.

4.48 Where the outlet duct is larger than the fan discharge connections, there should be a gradual transition, with a following section of straight duct having a length equivalent to three duct diameters.

4.49 The design of the fan inlet connection must be carefully considered to avoid swirl in the air stream. When the air spins in the same direction as the impeller, the performance and power consumption of the fan are reduced. When the air spins in the opposite direction to the impeller, power consumption and noise will increase with hardly any pressure increase. Air-stream swirl is usually induced by large variations across the fan’s inlet eye, caused by the air passing round a tight bend immediately before the eye.

4.50 Where a centrifugal fan is located with a free inlet, the clear distance between the suction opening and the nearest wall should be not less than half the diameter of the inlet. If two fans with free inlets are positioned within the same chamber, their adjacent suction openings should be at least one (inlet) diameter apart.

4.51 Airtight flexible joints should be provided at the fan’s inlet and outlet connections. They should be equal in cross-section to the points of connection, and be neither longer than 200 mm nor shorter than 100 mm.

4.52 For centrifugal fans, a diffuser screen/blast plate should be fitted immediately downstream of their discharge.

Supply fan drive arrangements

4.53 Where the fan drive is via a motor-driven belt and pulley, it should be external to the air stream. This arrangement has the following advantages:

a. the fire risk is reduced;

b. the drive is visible, so it is simple to check that the belt is still there;

c. particles shed from the drive belt are outside of the air stream;

d. if the belt slips, the "burning rubber smell" is not transmitted down into occupied areas of the premises;

e. noise generated by the motor and drive will not be transmitted along the ductwork;

f. waste heat is excluded from the system;

g. the drive may be through a V-belt or toothed belt and pulley. The latter has the advantage of eliminating belt squeal on start-up and has a longer service life. It is particularly suitable where the fan's drive motor is fitted with a soft start.

4.54 The drive train should be easily visible without the need to remove access covers. Protecting the drive train with a mesh guard is the preferred option. For weatherproof units designed to be located outside, the fan drive will be external to the duct, but enclosed. It should be easily visible through a viewing port with internal illumination and be accessible via a lockable hinged door.

4.55 For direct-coupled fan and motor units, the motor may be within the air stream, provided the motor windings are protected from over-temperature by a thermister and lockout relay.

4.56 For induction-drive "plug" motor arrangements (where the motor is fitted within the fan and is integral to it) and in-line axial fans with a pod motor, the fan/motor combination may be within the air stream, provided the motor windings are protected from over-temperature by a thermister and lockout relay.

Extract fan drive arrangements

4.57 Where the fan drive is via a motor-driven belt-and-pulley arrangement, it should be located external to the air stream.

4.58 The fan drive and motor may be located inside the duct within the air stream, provided the motor windings are protected from over-temperature by a thermister and lockout. The drive train should be easily visible through a viewing port, have internal illumination, and be accessible via a lockable hinged door.

4.59 Where the system air is explosive, aggressive or has a high moisture content, the extract fan motor must be located outside the air stream. This is generally achieved with axial fans by using a bifurcated unit.

Control

4.60 Fans in healthcare applications are generally either single- or two-speed. Where there is a requirement for two-speed operation, this is generally via a local user control (for example in a hood-extract system to provide a boost facility) or via a time schedule for energy saving during unoccupied periods.

4.61 Normally, only a single motor is required with a standby motor available for fitting as necessary, or fitted, but not belted. Twin, run and standby motors – with the standby being jockeyed around – are not required.

4.62 Where there is a specified requirement for standby fans, the system should incorporate an automatic changeover facility activated via an air-flow sensor. Fault indication should be provided.

4.63 In terms of start-up and operation, fans are increasingly becoming computer-controlled. Inverter-drive, variable-speed and soft-start systems are becoming a standard approach. Most healthcare applications require known amounts of air to be delivered while the system is in use. Constant-volume systems that deliver specified air-change rates are therefore the norm. Duct- or room-pressure-controlled, variable-speed systems have a very limited application in healthcare.

4.64 It is necessary to ensure that – should the computer control system or its software develop a fault – the fan can be switched to a direct-start, fixed-speed manual operation. This is particularly important for critical care systems serving operating suites, high-dependency care units of any type, isolation

facilities, laboratories and pharmaceutical production suites. Off-site software support is not a substitute for the ability of on-site staff to override automatic controls and keep the system operating in an emergency. Under these circumstances, actions that may shorten the life of the plant are considered of secondary importance to that of preserving the health and safety of patients and staff.

Heater-batteries

General requirements

4.65 Fog/frost heating coils are installed to protect the downstream filters from low-temperature, high-humidity intake air conditions. As they handle unfiltered air, they should be constructed of plain tubing without fins and be as near to the outside as possible to minimise condensation during cold weather. Access for cleaning will need to be provided to both sides of the coil.

4.66 Where steam coils are used for a fog/frost battery, they may be constructed using spiral-finned copper tube. As they will be prone to fouling, the tube layout and spacing should permit easy access for regular cleaning.

4.67 Main and branch heater-batteries should be constructed of solid-drawn copper-tube coils with copper fins, generally connected in parallel.

4.68 Where there is a wet heating system in the areas served, the main heater-battery should be sized for the ventilation requirements only, and not for the fabric loss.

4.69 Access for cleaning must be provided to both sides of all fog coils and heater-batteries.

Acceptable types

4.70 Electric, water or steam heater-batteries may be considered; however, electric heater-batteries are expensive to operate and, where there are alternatives, their use should be restricted to low-power use (for example trimming control).

4.71 Where steam-supplied heater-batteries are used, their control, venting and trapping systems should be designed so that a vacuum cannot occur within the coil. The condensate drainage arrangements should not allow pressure to build in the main, resulting in a back-up of condensate in the coil.

Location

4.72 Where possible, wet-trimmer heater-batteries should be located in plant areas.

4.73 Where it is necessary to locate auxiliary heater-batteries in false ceilings, consideration should be given to the use of electric heaters. If this is not practicable, a catch tray should be installed under both the battery and the control-valve assembly to protect the ceiling from leaks. A moisture sensor and alarm should be fitted in the tray. In any event, to facilitate maintenance access, auxiliary wet heater-batteries should be located above corridors or other non-critical areas and not above patient-occupied spaces.

4.74 Auxiliary fan-coil units should not be installed in the ceiling above an occupied space. They should be accessible for routine maintenance and cleaning without the need to cause significant disruption to the operation of the department that they serve.

Control

4.75 LPHW fog/frost coils should be controlled by an off-coil temperature sensor operating a motorised valve to provide a minimum plant "on temperature" of between 2ºC and 5ºC. The off-coil temperature of the frost coil is generally sensed by a serpentine thermostat downstream of the coil or upstream of the next plant item. This thermostat will shut the fan down if any part of the air stream is below the minimum set-point.

4.76 Steam-supplied fog/frost coils should be fitted with an on/off control operated by a temperature sensor mounted upstream of the battery. These are normally set to fully open the control valve when the outside temperature drops to +1ºC. This will ensure that there is no standing condensate in the base of the coil.

4.77 The main heater-battery should be controlled in the same manner under the dictates of either an off-coil temperature sensor or a room temperature sensor, depending on the plant configuration and method of control. Trimmer heater-batteries are generally controlled by one or more averaging temperature sensors within the room or rooms in the zone.

4.78 Heater-battery control valves should automatically close on system shut-down or fan failure. The control system should then automatically set to provide frost protection.

Cooling coils

General requirements

4.79 Cooling coils will need to be periodically cleaned or decontaminated. They must have good access both up- and downstream. Hinged access doors with viewing ports and illumination inside the duct should be provided both sides of the coil.

4.80 An eliminator will be required downstream of all cooling coils. The eliminator may take the form of an extension of the coil fins or be a separate device. If a separate device, it should be removable as a unit to permit cleaning of the coil face.

4.81 All cooling coils must be fitted with their own independent drainage system as specified above. A baffle or similar device must be provided in the drain tray to prevent air bypassing the coil. The tray should be large enough to capture the moisture from the eliminator, bends and headers.

4.82 Where coils are greater than 1 m high, intermediate drain trays are needed.

Selection

4.83 Cooling coils supplied with chilled water are the preferred option. For small loads or where chilled water is not available, direct expansion coils may be used.

4.84 Care must be taken to minimise electrolytic action resulting from condensation on the air side. Coils constructed from copper tubes with copper fins extended on the downstream side in the form of an eliminator, and electro-tinned after manufacture, are preferred. Aluminium fins should only be used if vinyl-coated.

4.85 All parts of the coil and its associated ductwork in contact with moisture must be manufactured from corrosion-resistant materials. Pressed-steel coil headers, even if treated, have been shown to be prone to corrosion over time and should not be used. Steel mounting frames and casings present similar problems, so stainless steel is preferred.

Location

4.86 Cooling coils in AHUs should be located upstream of the final filter.

4.87 Auxiliary fan-coil units should not be installed in the ceiling above an occupied space. They should be accessible for routine maintenance and cleaning without the need to cause significant disruption to the operation of the department that they serve. The drainage of such items is often problematic. If a suitable fall in the drain line cannot be achieved, a pump-out system must be provided.

4.88 Where any cooling coil has to be located above a ceiling, an external catch tray should be installed under the unit and its control valve assembly to protect the ceiling from leaks. A moisture sensor and alarm should be fitted in the catch tray. To facilitate maintenance access, coils should be located above corridors or other non-critical areas, but not above patient-occupied spaces.

Control

4.89 There are three basic methods of control for cooling coils:

a. **Temperature control.** A room or duct temperature sensor controls the cooling coil and heater-battery in sequence to maintain the desired room temperature. This is used where close control of room humidity is not required. If a suite of rooms is served by the same unit, the control sensor may be located in a common extract duct to achieve an "average" condition.

b. **Temperature and humidity control.** Room temperature and humidity sensors control the cooling coil, heater-battery and humidifier in sequence. The room temperature and humidity are kept within an acceptable range, with temperature taking precedence over humidity. It is usual to interlock the cooling coil and humidifier so that they cannot be on together.

c. **Full temperature and humidity control.** Room temperature and humidity sensors control the heater-battery, humidifier, cooling coil and a re-heater-battery in sequence to maintain a specific room condition regardless of the room load. This is very expensive in energy and can rarely be justified. In healthcare it is only likely to be considered for specialised research facilities.

4.90 It is usual to isolate the cooling coil upon selection of set-back operation. In addition, on system shut-down, low air flow or fan failure, the cooling coil must be isolated.

Humidifiers

Design need

4.91 Humidification was originally required for some healthcare applications in order to control the risk associated with the use of flammable anaesthetic gases. The use of such gases has now ceased. Humidification is therefore no longer required unless there is a very specific application requirement.

4.92 Operating-theatre AHUs do not generally require humidifiers, but provision for their retrofitting in terms of space provision and a capped drainage system should be provided.

4.93 Where humidification is required, it will be subject to the specific requirements set out below. These are intended to ensure that the unit will operate safely and not become a source of contamination.

General requirements

4.94 The most important requirement for a humidifier is to create complete mixing of the steam with the air. The manufacturers' instructions should be closely followed regarding minimum distances, which should be allowed before bends or other components. This is particularly important with respect to a filter mounted downstream. If it becomes saturated by the humidifier, organisms can grow through the filter and be released into the duct. These may then be carried on the air stream into an occupied space.

4.95 The section of ductwork containing the humidifier may need to be periodically cleaned. Hinged access doors with viewing ports and internal illumination should be provided. A label warning that the device emits live steam and should be isolated prior to opening should be affixed to the access door.

4.96 All parts of the humidifier and its associated ductwork in contact with moisture must be manufactured from corrosion-resistant materials; stainless steel is preferred.

4.97 The electrodes of self-generating electrode-boiler humidifiers should be stainless steel.

4.98 All humidifiers must be fitted with their own independent drainage systems as detailed above.

4.99 For self- and locally-generated steam humidifiers, the cleanliness of the water supply is essential for their safe operation. The water supply should be derived from a potable source. Chemical treatments must not be added to the water supply to humidifier units.

4.100 If the quality of the water supply to a self-generating humidifier unit cannot be assured, an ultraviolet (UV) system to control microbiological growth could be installed. However, given the limitations of UV systems, this will require high-quality water filtration to ensure the effective exposure of organisms to the UV irradiation. As with all water-treatment systems, the unit should be of proven efficacy and incorporate UV monitors so that any loss of transmission can be detected.

4.101 Provision should be made for draining down supply pipework and break tanks serving self-generating humidifiers during the seasons when they are not required in service. Isolation of the water supply should be at its junction with the "running" main to prevent the creation of a dead-leg. All parts of the system should be capable of being cleaned and/or disinfected as necessary.

Acceptable types

4.102 Only steam-injection manifold-type humidifiers are suitable for use within air-conditioning systems in healthcare facilities. Water-curtain, spray or mist humidifiers of any type should not be used.

4.103 Steam may be derived from the central steam supply provided that it does not contain any treatment carry-over, or may be generated locally either within or adjacent to the humidifier.

4.104 The introduction of steam should be by an appliance specifically designed to discharge dry steam into the air-conditioning system without objectionable noise or carry-over of moisture.

4.105 During the design stage, consideration should be given to the proposed methods for the regular cleansing of the humidifier(s) and their components.

Selection

4.106 The number and length of steam-injection manifolds to be used is dependent on various factors such as duct cross-sectional area, air velocity, dry-bulb temperature and manifold design. Guidance from the manufacturer should be closely followed.

4.107 A mains steam humidifier can be noisy and will be difficult to control if it is operated at an excessive steam pressure. It should be sized for an operating pressure of approximately 1 bar. The pipework

supplying it should be provided with a dirt pocket, pressure-reducing valve and steam trap installed as close as practicable to the humidifier so that the steam condition at entry is as dry as possible. A temperature switch on the condensate line (or equivalent design provision by the humidifier manufacturer) should be incorporated to prevent "spitting" on start-up.

4.108 Most operational problems with mains steam humidifiers arise because of back-pressure in the condensate discharge line, which will result in flooding into the duct. Unless the condensate from the device can be discharged and collected at atmospheric pressure, it should be discharged directly to drain.

4.109 Some steam generators incorporate a heated tank that requires regular cleaning and descaling. The design must allow the steam-supply manifold to be physically isolated from the air duct in order to prevent contamination of the air stream by cleaning agents while this is taking place.

Location

4.110 Careful siting of the humidifier lance is required to prevent the steam impinging onto the side(s) of the duct, condensing and generating excess moisture.

Control

4.111 Accurate humidity control can only be provided on single-zone systems or multi-zone systems with zonal humidifiers. In the former, humidity sensors control the humidifier for low-level humidity control and override the temperature controls to open the cooling-coil valve for high-level humidity control.

4.112 Multi-zone systems are more usually controlled by a minimum humidity sensor located in the supply duct(s) following the last heater-battery.

4.113 Overriding controls separate from the normal plant humidistat should be installed. Their purpose is to prevent excessive condensation in the conditioned space when starting up. A time delay should be incorporated into the humidifier control system such that the humidifier does not start until 30 minutes after the ventilation/plant start-up. In addition, a high-limit humidistat should be installed to limit the output of the humidifier so that the saturation in the duct does not exceed 70%. This humidistat is to control the added moisture; it is not necessary to install a dehumidifier to reduce the humidity of the incoming air if it already exceeds 70%. The humidifier control system should ensure that the humidifier is switched off when the fan is not running.

4.114 It is usual to isolate the humidifier upon selection of set-back operation. In addition, on system shut-down, low air flow or fan failure, the humidifier should be isolated.

4.115 If a water-supplied local steam generator is unused for a period exceeding 48 hours, it must automatically self-drain (that is, all water content must drain out – including that contained in the supply pipework – all the way back to the running main) and remain empty.

Filtration

General requirements

4.116 The purpose of filtration is to reduce the level of airborne contamination in an air stream. It is generally carried out in stages.

4.117 Filters must be securely housed and sealed in well-fitting frames that minimise air bypass. Air bypass significantly reduces filtration efficiency: the higher the filter grade, the greater the effect. Mounting frames should be designed so that the air flow pushes the filter into its housing to help minimise air bypass. Mounting frames that withdraw so that the filter can be changed without having to reach into the unit are preferred.

4.118 Neither the filter media nor any material used in the construction of the filters should be capable of sustaining combustion. The filter media should be such that particles of it do not detach and become carried away by the air flow.

4.119 Filters need to be readily accessible for replacement; therefore, a hinged access door should be provided. The upstream side of the filter should be visible for inspection through a viewing port with internal illumination.

4.120 All filters should be provided with a means of visually checking the differential pressure across them. Direct-reading dial-type gauges marked with clean and dirty sectors are preferred.

4.121 A complete spare set of filters must be provided to the client at handover.

Definition of filter terms

4.122 Particulate air filters are divided into four categories:

a. general ventilation filters graded G1 to G4;

b. fine filters graded F5 to F9;

c. HEPA filters graded H10 to H14;

d. ultra-low particulate air filters (ULPA) graded U15 to U17.

4.123 General filters are graded in terms of their "synthetic dust weight arrestance". This represents the percentage of a test dust captured by a filter. "Arrestance" provides a good indication of a filter's ability to remove the larger, heavier particles found in outdoor air. These are of a size to block finned batteries and large enough to settle out in the air distribution system (see Table 3).

Table 3 General filters

BS EN 779 grade (Eurovent grade)	% Arrestance	Notes and typical healthcare applications
G1 (EU1)	<65	Metal-mesh grease filter
G2 (EU2)	65 to <80	Coarse primary filter
G3 (EU3)	80 to <90	Primary air intake; Return air; Energy-recovery device protection
G4 (EU4)	>90	General-purpose tempered air supply

4.124 Fine filters are graded in terms of their "atmospheric dust spot efficiency". This is a measure of the filter's ability to remove the very fine staining particles found in outdoor air. It will indicate how "visibly" clean a filter will keep a ventilated space. The staining particles are approximately the same size as most common bacteria so it is also a rough measure of the filters' ability to remove them (see Table 4).

Table 4 Fine filters

BS EN 779 grade (Eurovent grade)	% Efficiency	Notes and typical healthcare applications
F5 (EU5)	40 to <60	General-purpose panel/bag filter
F6 (EU6)	60 to <80	Basic grade bag filter
F7 (EU7)	80 to <90	Medium grade bag or pleated paper Conventional operating theatre supply air
F8 (EU8)	90 to <95	High grade bag or pleated paper
F9 (EU9)	>95	Basic HEPA filter – level 8 clean rooms

4.125 High-efficiency filters (HEPA and ULPA) are graded in terms of their ability to capture their "most penetrating particle size" (MPPS).

4.126 High-efficiency filters self-select the particle that they are least able to trap, hence the MPPS. They are then tested against that size of particle.

4.127 These filters are designed to provide very high-efficiency filtration of particles in the sub-micron size range (see Table 5).

Table 5 High efficiency (HEPA) filters

BS EN 1822 grade (Eurovent grade)	% Efficiency at most penetrating particle size (MPPS)	Notes and typical healthcare applications
H10 (EU10)	85	Ultra-clean theatre terminal
H11 (EU11)	95	
H12 (EU12)	99.5	
H13 (EU13)	99.95	
H14 (EU14)	99.995	Pharmacy aseptic suite Category 3 room extract
U15–U17	–	Not generally used in healthcare

Selection

Primary filters

4.128 All filters should be of the dry type.

4.129 Panel filters are cheap and disposable with relatively low dust-holding capacity. They are generally used as prefilters to eliminate large particles which would otherwise clog or cause damage to the fan and finned heating and cooling batteries. Stainless steel frames that hold disposable pre-cut filter pads are more economic, create less waste and are therefore the preferred option.

4.130 General ventilation supply plant should incorporate primary air filters of grade G3, sized for a maximum face velocity of 2 m/s. Additional coarse prefilters may be justified where the intake air is exceptionally polluted. They are sometimes fitted as a temporary measure when building work is being carried out in the vicinity of the air intake.

Secondary filters

4.131 Where a higher standard of filtration is required, secondary bag or pleated-paper panel filters can be used. Rigid frame filters incorporating pleated-paper elements are preferred over bag filters for critical care applications such as operating theatres.

4.132 In urban or other areas of high atmospheric pollution, a higher standard of filtration may be justified to reduce the level of staining to internal finishes.

Extract air filters

4.133 Extract filtration will generally only be required where heat-recovery devices are installed. There are a very limited number of specialised applications (microbiological safety cabinets and similar LEV systems) where contaminated air is required to be filtered prior to discharge to atmosphere. If it is safe for staff to work in a room without wearing respiratory protective equipment, it is safe to discharge the room air to atmosphere without filtration.

Return-air filters

4.134 Return-air filters are used to reduce the load on HEPA filters in recirculating applications such as ultra-clean operating suite ventilation canopies and pharmacy aseptic suites.

High-efficiency filters – HEPA and ULPA

4.135 HEPA filters are expensive. Therefore, their use should be kept to a minimum. Applications requiring HEPA filters include the air supply to aseptic suites in manufacturing pharmacies and the discharges from microbiological safety cabinets.

4.136 If used, HEPA filters should be of the replaceable-panel type with leak-proof seals. They should be installed in a manner that permits on-site validation of the filter and its housing. This may involve the release of a dispersed oil particle (DOP) challenge smoke through an injection point upstream of the filter plus measurement of the DOP penetration across the downstream face. Alternatively, a particle-counting method may be used.

4.137 HEPA filters are sometimes fitted in extract systems to capture hazardous substances or organisms. Design provision must be made for the subsequent safe handling of contaminated filters by maintenance staff. This may be achieved by:

- sealing the hazardous substance into the filter before it is removed;
- providing a system to fumigate the filter to kill any organisms;
- housing it in a ”safe change” unit that permits the filter to be ejected into a bag and sealed without staff having to come into direct contact with it.

4.138 In view of the costs and problems associated with placing HEPA filters in extracts, it is recommended that a full risk assessment be carried out at the design stage. This should include defining the need for HEPA filters in an extract; validation of its performance at installation; the method of safely changing a contaminated filter; and its subsequent disposal.

4.139 ULPA filters are very expensive and are designed to remove particles below a size that are either surgically or aerobiologically significant. There would have to be exceptional circumstances in order to justify their use in healthcare ventilation systems.

Activated carbon filters

4.140 Activated carbon filters are able to remove gases and vapours from the air stream and are graded according to the range of substances they can

remove. They are not normally fitted in air-conditioning supply systems.

4.141 They are occasionally fitted retrospectively because the main air intake has been poorly sited and is drawing in traffic fumes. Where used, they must be protected by a particulate air filter.

4.142 Activated carbon filters are more commonly used in specialised fume-extraction systems when the location of the discharge means that dilution cannot be relied upon to disperse noxious fumes.

Location

4.143 The primary filter should be positioned on the inlet side of the supply fan, downstream of the frost coil. The secondary filter, when fitted, should be on the positive-pressure side of the fan. This will prevent air being drawn into the system after the filter and capture any particles shed by items of equipment within the AHU.

4.144 The filter installation must be arranged to provide easy access to filter media for cleaning, removal or replacement, with side or front withdrawal as required.

Control

4.145 Differential-pressure transducers should be provided to remotely monitor and alarm on excessive filter pressure drop. In critical care areas, dirty-filter indication lights should be provided at the point of use.

Energy recovery

General requirements

4.146 Energy recovery must be fitted to all healthcare ventilation systems. It may be omitted only where it would clearly be uneconomic (for example to a single WC extract system).

4.147 For systems in healthcare premises, a plate heat exchanger or "run-around coil" system is suitable. Thermal wheels may be used providing they are fitted with a purge sector. The small amounts of air leakage across these devices are not considered significant. Other systems such as heat pumps or heat pipes are also suitable. Selection should be based on the relative locations of the supply and extract units, ease of maintenance and practicality. Cleaning access will be required to both sides of any energy-recovery device.

4.148 The following are the minimum energy transfer efficiencies required for devices handling equal air volumes:

- run-around coil – 45%;
- plate heat exchanger – 50%;
- thermal wheel – 65%;
- any other energy-recovery device – 50%.

4.149 If a plate heat exchanger is chosen, the plates should be constructed of metal. An internal bypass is not always required but, if fitted, plastic should not be used for the internal dampers and drive gears.

4.150 Whichever energy-recovery device is chosen, the extract side will need to be protected by a G3 filter and provided with a drainage system (as described above) to remove condensate.

Location

4.151 Energy-recovery devices should be located downstream of the fog coil and prefilter, prior to the cooling coil or main heater-battery on the supply side. If heat pipes are selected, it may be possible to use them to replace the fog coil.

Control

4.152 It is essential to consider the control of both the energy-recovery device and the fog/frost coil when assessing the economics of recovery, as all energy provided by the frost coil will directly reduce the heat exchange of the recovery device. To this end, the off-coil setting of the frost coil should be the minimum possible to protect the primary filter (for example +2ºC).

4.153 The control of the energy-recovery device should be fully integrated with that of the main plant to ensure maximum economic benefit.

4.154 Plate heat exchangers and heat pipes can be self-controlling in the sense that energy will transfer across the device from the extract to the supply at winter design values and from the intake to the extract discharge at summer design values, thus obviating the need for a bypass and sophisticated control system.

Attenuation

General requirements

4.155 Noise is generated in an air distribution system by the fan, plant items and air flow. The ductwork is a very effective transmitter of this noise; hence, there is generally a need to limit the noise transmission to meet the requirements of the building. This normally involves the provision of sound attenuation treatment as part of the overall ductwork system design.

4.156 A thorough assessment of the design should be made to assess the noise impact. This should take into account the following primary factors:

- fan- and plant-noise generation;
- air-flow-generated noise in ductwork fittings and dampers;
- noise generated at grilles, diffusers and other terminals;
- noise break-in and break-out of ductwork;
- cross-talk and similar interference;
- the noise limitations for the building and surrounding areas;
- external noise generation.

4.157 A method of assessment of these factors and the sound attenuation requirements of ductwork systems is given in CIBSE's Guide B.

4.158 The fan is usually the main source of system noise. The sound power that it generates varies as the square of the fan pressure, and thus to limit the fan noise level the system resistance should be kept as low as economically possible. As a general rule, the selected fan should operate close to its point of maximum efficiency to minimise its noise generation. Where there is disturbance to the air flow at the fan inlet, the manufacturer's stated fan noise levels should be increased by up to 5 dB(A). More precise guidance on this aspect may be available from the manufacturers.

4.159 Fans radiate noise through both the inlet and outlet connections, and it may be necessary to provide attenuation to limit the noise from both of these connections. It is always preferable and more economic to control noise and vibration at source, or as close to source as possible. It should be noted that attenuators offer a resistance to air flow. The resistance must be included in the fan and ductwork calculations.

4.160 Provided care is taken in the design and construction of low-pressure systems to avoid significant noise generation in the ductwork, attenuation should only be needed to absorb fan noise.

4.161 Noise break-out from all equipment housed in the plantroom must be taken into consideration if control is to be satisfactory. Any ductwork within the plantroom after the silencer should be acoustically insulated to prevent noise break-in.

4.162 There is no complete means of control over external noise generation from sources such as road traffic, aircraft, factory and community noise. Consideration must be given to this at the design and planning stage.

Acceptable types and location

4.163 The noise levels produced by ventilation and other plant should be reduced by either lining the inside of the duct with sound-absorbing material or fitting bespoke attenuator units.

4.164 In supply systems, sound-absorbing material should not be applied to the inside surface of a duct system downstream of the final filter, owing to the risk of mechanical damage and the subsequent dispersal of the media into the ventilation system.

4.165 In supply and extract systems, sound-absorbing material should not be applied to the inside of a duct within 1 m of a fire damper. The material should be non-particle-shedding and fire-resistant (see Health Technical Memorandum 05-02). Where sound-absorbing material is applied in a section of duct that will be routinely exposed during maintenance activities, it should be protected from mechanical damage.

4.166 Bespoke attenuator units with a sound-absorbing in-fill suitable for the quality of air being handled and protected by a perforated sheet metal casing are the preferred option for critical systems. Absorption of moisture, dirt and corrosive substances into the "in-fill" and the release of fibrous particles into the air stream should be prevented by the use of a membrane. The membrane material should have a declared service life of at least 25 years. If these conditions can be met, the attenuator may be located in the supply ductwork downstream of the final filter. When so located, cleaning access should be provided at both ends of the attenuator unit.

5 Air distribution system

Air distribution arrangements

Ductwork distribution systems

5.1 Ductwork systems for ventilating and air-conditioning applications are referred to by their velocity or pressure category, that is, as low, medium or high velocity (or pressure) systems. HVCA limits are up to:

- 10 m/s or 1000 Pa in the case of conventional low-pressure systems;
- 20 m/s or 1750 Pa in the case of conventional medium-pressure systems; and
- 40 m/s or 3250 Pa in the case of high-pressure systems.

Note

High-pressure systems are disappearing because of the constraints of the Building Regulations, but existing systems may sometimes need to be altered or extended.

5.2 For normal applications in healthcare buildings, low-velocity systems are recommended; the use of higher velocities than those recommended may not be economical. Future trends are for even lower optimum duct velocities; however, velocities below 2 m/s are unlikely to be justified.

5.3 The site will often dictate the main routing of ductwork systems but, in general, the design should seek to make the layout as symmetrical as possible; that is, the pressure loss in each branch should be as nearly equal as possible. This will aid regulation and may reduce the number and variety of duct fittings that are needed.

5.4 Main distribution ductwork should not be routed above sleeping areas. Where there is no alternative route, additional acoustic insulation is required.

5.5 Where auxiliary air-conditioning units, fans, filters or trimming devices are installed in the distribution system, they must be independently supported and fitted with a suitable drainage system, where appropriate. If they are a source of vibration, they should be linked to the distribution ductwork via flexible connections.

5.6 The fan of an LEV system provided under the COSHH Regulations should be located outside the building so that all ductwork within the building is under negative pressure. Where the fan has to be within the building, it should be located as close as practicable to the outside, with an absolute minimum run of discharge ductwork within the building. This discharge ductwork will be under positive pressure, so it must not be penetrated by test holes or inspection hatches.

Ductwork materials and construction

5.7 The choice of duct material should take account of the nature of the air or gas being conveyed and the environment in which the duct will be placed.

5.8 Galvanised-sheet-steel ductwork is the most suitable and economical choice for normal ventilating and air-conditioning applications. Its inherent mechanical strength renders it resistant to casual damage both during the construction phase and throughout its service life when mechanical and electrical services around it are altered. It also readily withstands the impacts sustained when rotary equipment is used to clean it internally.

5.9 In instances where moisture levels and/or corrosive elements in the air being conveyed are very high, aluminium, stainless steel, PVC or GRP (glass-reinforced plastic) ducts should be used. Stainless or black steel are the only suitable materials for high-temperature ductwork.

5.10 In inherently wet areas, such as the base of fresh-air inlet ducts and some extract systems, the ductwork may require draining to prevent a build-up of standing water. The layout of the drains should be as specified in Chapter 4.

5.11 Where builders' work ducts or plenum chambers are used, these may be constructed of various materials. However, all such ducts must be

rendered and sealed to prevent dust-shedding. A greater allowance may need to be made for leakage.

5.12 Galvanised, black and stainless steel ductwork should be manufactured and installed to the current HVCA specification for sheet metal ductwork DW144, but excluding the use of bolt-through supports.

5.13 GRP and PVC ductwork should be manufactured and installed to the current HVCA specification for plastic ductwork DW154.

5.14 Flexible ductwork is unsuitable for air distribution in healthcare applications. It should only be used to make the final connection to a terminal (see paragraphs 5.53–5.54).

5.15 Where phenolic-board ductwork is considered, care should be taken to ensure that it is fabricated to a quality standard and installed strictly in accordance with the manufacturers' instructions. Its pressure rating and degree of support should be suitable for the application, and the duct should be fitted with mechanical protection where required.

5.16 The inside of the ductwork should be free from structural projections and as smooth as possible. Flanged gasketed joints between sections are preferred.

Fire aspects, damper types and locations

5.17 It is essential that all relevant fire aspects of ducting systems are agreed with the fire officer before the design is finalised.

5.18 Ductwork must be fire-stopped where it penetrates fire compartment walls, floors and enclosures, cavity barriers and subcompartment walls or enclosures, and must be provided with weatherproof collars where roofs or external walls are penetrated.

5.19 Fusible-link and automatically controlled fire dampers should be provided at the locations required by Health Technical Memorandum 05-02. The fire-damper mounting frame must be securely attached to the building fabric. Where a fire damper is not mounted directly in a fire compartment wall, it must be correctly supported and the ductwork between it and the firewall must possess the same fire rating as the firewall that it penetrates. The fire-rated portion of ductwork must not be penetrated by test holes or inspection hatches.

5.20 An access hatch should be provided adjacent to each fire damper so that its correct operation can be directly observed. The hatch must be suitably sized to permit inspection, testing and maintenance.

5.21 Smoke-diverting dampers must be provided on recirculation air systems to automatically divert any smoke-contaminated return air to the outside of the building in the event of a fire. It should be arranged such that the normal open smoke-diverting damper on the return-air branch to the input unit closes and all the return air is exhausted through the extract fan. Guidance is available in Health Technical Memorandum 05-02 and BS 5588-9.

Duct sections

5.22 Ducting is generally available in rectangular, circular and flat oval sections, although other sections may be manufactured for particular situations.

5.23 Rectangular ducting is most common on low-pressure systems for the following reasons:

- it can be readily adapted to fit into the space available;
- fittings are cheaper than those for circular or flat oval ductwork;
- it can be readily joined to such component items as heating and cooling coils, and filters.

5.24 When sizing ductwork, the designer should take into account:

- installation and operating costs;
- space limitations imposed by the structure and other services;
- operating noise levels;
- requirements of regulation at the commissioning stage.

5.25 For overall economy and performance, the aspect ratio should be as close to 1:1 as possible, since high aspect ratios increase the pressure loss, heat gains or losses and overall cost (for example, changing the aspect ratio from 1:1 to 1:4 can typically increase the installed cost of the ductwork by 40% and add 25% to the heat gains or losses).

5.26 Circular ducting is preferable for high-pressure systems and for systems operating at high negative pressures. In the latter case, additional stiffening rings may be necessary. Machine-formed spirally-

wound ducting and a standard range of pressed and fabricated fittings can sometimes make circular ducting more economical, particularly in low-pressure systems having a relatively low proportion of fittings.

5.27 Flat oval ducting provides an alternative to circular ducting, principally where there is a limitation on one of the dimensions in the space available for the duct run.

5.28 Other sections may be used, such as triangular sections to pass through roof trusses. Such sections present difficulties in the provision of fittings and connections to standard plant items, and are likely to be more expensive than traditional sections.

Standard ductwork fittings

5.29 All fittings should conform to current HVCA specification DW144. Wherever possible, long radius bends, large radius main branches, sub-branches with angles no greater than 45 degrees, and long-taper transformations should be used.

5.30 Fittings should be arranged with vanes in sub-branches connected directly to grilles and diffusers, and turning vanes in square bends (when used). When vanes are used, additional cleaning access will be required.

5.31 The number of duct fittings should be kept to a minimum, and there should be a conscious attempt to achieve some standardisation of types and sizes. Increasing the number and variety of fittings in a system can markedly increase its overall cost.

5.32 Bad design in relation to air flow can lead to vibrating flat duct surfaces, increases in duct-generated noise and pressure loss, unpredictable behaviour in branch fittings and terminals, and adverse effects on the performance of installed plant items (such as trimmer batteries).

Branches

5.33 There are many designs of branch and junction in use. The important features are that the flow should be divided (or combined) with the minimum interference and disturbance. Changes in duct sizes should not be made at the branch but at a short distance downstream (or upstream). A good dividing-branch design cannot be effective if the flow entering the branch is not uniform across the section.

Changes of section

5.34 The expansion of a duct section should be formed with sides having a total included angle of no more than 30 degrees, and preferably less than 20 degrees. If the angle of expansion is greater, the flow is not likely to remain attached to the walls of the duct, and large eddies will be formed with flow reversal at the walls. This leads not only to a high-pressure loss, but also to non-uniform velocity pattern at the outlet. Where there is insufficient space for a gentle expansion and a greater angle is necessary, internal splitters should be used.

5.35 A contraction in a duct section is less critical, but the total included angle of the taper should not exceed 40 degrees (or 20 degrees where the contraction is made on one side of the duct only).

5.36 The most economical way to change the section of a rectangular duct is to restrict the change of duct size to one side only. If the calculated reduction or increase to the side dimension is 50 mm or less, it is usually not economical to change the size at the position. The minimum size of a rectangular duct should be 150 mm × 100 mm.

Other fittings

5.37 Fittings that have abrupt changes in direction and sharp edges should be avoided, as this will increase turbulence, thus increasing pressure loss and causing noise generation. If the fitting leads to the flow preferentially attaching to one side of the outlet, a significant length of straight downstream duct is necessary before the next branch or fitting; this length should be greater than five equivalent diameters.

Thermal insulation

5.38 Thermal insulation is applied to ductwork to reduce heat exchange and to prevent condensation.

5.39 In a duct system, the air-temperature changes can be significant, especially when passing through untreated space, and these have the effect of reducing the heating or cooling capacity of the air and of increasing the energy input to the system. The heat transmission to and from the surrounding space can be reduced by effective insulation of the ducts.

5.40 Condensation can arise in ductwork systems conveying cooled air and, apart from creating conditions conducive to corrosion of ductwork, condensation affects the heat and vapour-resisting

properties of insulating materials themselves, which may induce further condensation.

5.41 In normal circumstances, the insulation thickness for heat resistance is sufficient to prevent surface condensation, but in extreme conditions the insulation thickness for vapour resistance may be greater than that for heat resistance. When cold ducts pass through areas that have a high dew-point, carefully selected vapour barriers should be applied externally to the insulation.

Noise generation within the ductwork

5.42 Noise is generated in ductwork at sharp edges, and by tie rods, damper blades, duct obstructions and sharp bends. This air-flow-generated noise becomes an important factor if it is about the same or greater level than the upstream noise level. (Air-flow-generated noise is often referred to as "regenerated noise".)

5.43 The noise level generated by the air flow in ductwork is very sensitive to the velocity. The sound power of this noise is approximately proportional to the sixth power of the velocity; that is, a doubling of the duct velocity will increase the sound power by a factor of 64. The duct velocities should therefore be kept as low as possible. In general, duct fittings that have lower pressure-loss factors in similar flow conditions will generate less noise.

5.44 Ductwork serving quiet areas should not be routed through noisy areas, where noise break-in can occur and increase the noise level in the ductwork.

5.45 Grille register and louvre noise should be kept to a minimum by selecting types that:

- have low noise-producing characteristics; and
- are without high tonal noise.

They should be fitted with acoustically-treated external inlet and outlet louvres.

5.46 Cross-talk attenuators may be necessary where noise intrusion between adjacent spaces can arise and where confidentiality is required. They will normally be of the "through-the-ceiling, up-and-over" type, and may include a fire damper if required.

Volume control damper locations

5.47 Manually-operated balancing dampers are needed generally:

a. in the main duct downstream of the fan;

b. in branches of zone ducts;

c. in sub-branch ducts serving four or more terminals;

d. at terminals not covered by (c) above.

5.48 Dampers integral with terminals should only be used for final trimming of air volumes; otherwise noise and air distribution problems may ensue.

5.49 Dampers in rectangular ducts should be single-bladed when the longer side is up to 450 mm, but be of the opposed-blade multi-leaf type when above this size. In circular ducts, iris-type dampers are recommended. Dampers must be accessible, and incorporate a position indicator and means of locking in the commissioned position. Dampers should be located as far away as possible from adjacent branches or plant items.

Cleaning and access door locations

5.50 Cleaning and access doors are required to facilitate access to plant items and ductwork components for inspection, maintenance, cleaning and replacement. They must be of sufficient size to permit safe access for the required functions. Consideration should also be given to the number of doors to be provided.

5.51 Recommended locations for access doors are given in current HVCA specification DW144. They are generally provided to give access to:

- every regulating damper;
- every fire and motorised damper;
- filters (to facilitate filter withdrawal);
- both sides of cooling/heating coils;
- humidifiers;
- fans; and
- motors and impellers.

5.52 Care should be taken when siting cleaning and access doors to ensure that no other services to be installed will prevent reasonable access.

Flexible ducting

5.53 Flexible ductwork may be used for final connections to grilles and diffusers, provided it is constructed to meet the fire precautions recommended in BS 8313. It must not pass through fire compartment or subcompartment enclosures, or through cavity barriers.

5.54 Flexible ducting will cause a significant frictional loss and may be difficult to clean without damage. It should never be used in lieu of a bend. Where installed, it should take the most direct route and be as short as possible, never exceeding 1 m in length.

Diffuser and grille selection and sizing

5.55 The effectiveness of all ventilation and air-conditioning systems depends on the methods by which air is introduced to, and vitiated air is removed from, the space. The usual results of poor air-terminal selection and/or positioning are:

- draughts;
- stagnation;
- poor air quality;
- large temperature gradients; and
- excessive noise.

5.56 Air can be supplied to a space in a number of ways, although any device can be broadly placed into one of two categories:

a. that producing a diffused supply; or

b. that producing a perpendicular jet.

Diffusers may be radial or linear, and normally utilise the Coanda effect (that is, adhesion of the air stream to an adjacent surface) to reduce the risk of excessive room-air movement. A perpendicular jet is formed by discharging air through grilles, louvres or nozzles, which are generally adjustable.

5.57 Supply air terminals can be incorporated into any room surface (for example floors, walls (high or low level) and desktop).

5.58 As they operate on the jet principle, the use of side-wall and linear grilles is restricted to areas where air-change rates are fewer than ten per hour. Perforated rectangular diffusers can provide acceptable conditions within the occupied zone at up to 15 air changes per hour. In areas where a higher air-change rate is required, square or circular ceiling-mounted diffusers should be used.

5.59 The performance of supply air-terminal devices is based on three criteria:

a. **throw** – defined as perpendicular or parallel distance from the terminal to the point at which the air velocity is 0.5 m/s isovel;

b. **spread** – defined as the width of the 0.5 m/s isovel; and

c. **drop** – defined as the vertical distance from the centre line of the terminal to the bottom edge of the 0.25 m/s isovel.

5.60 It is necessary to consider each of these parameters in both summer and winter conditions to ensure satisfactory operation of the air-terminal device, as warm jets behave very differently from cold jets.

5.61 A warm jet tends to rise until it attaches itself to a horizontal surface, while a cold jet falls. Care must be taken to ensure that this does not lead to unacceptable temperature gradients in winter, or excessive air velocities in the occupied zone in summer.

5.62 In order to ensure satisfactory air movement within a space, it is necessary to consider interaction between air movement from adjacent terminals and ceiling-mounted fixtures (light fittings etc), as well as interaction between air movement and room surfaces.

5.63 If the supply and extract terminals are too close, short-circuiting may occur; if they are too far apart, stagnant zones may be formed. Where two opposing air streams meet, the individual velocities must not be greater than 0.25 m/s.

5.64 Supply and extract grilles and diffusers should be fitted with opposed-blade dampers for fine balancing purposes.

5.65 Further guidance on the selection of grilles and diffusers is given in CIBSE's Guide B.

5.66 In operating theatres, supply terminals must be able to produce a down-flow movement of air in the operating zone, 1 m above floor level. The following supply terminals are acceptable:

- ceiling-mounted diffusers with fixed directional vanes that provide a downward turbulent air flow are the preferred option;
- plenum boxes fitted with perforated screens that produce a parallel downward flow;
- linear ceiling-mounted diffusers that provide a downward air curtain around the operating zone (additional supply terminals may be located within the area bounded by the linear diffusers to provide ventilation within the air-curtained zone).

5.67 Nozzles or jets of any type are not acceptable in an operating theatre. Side-wall-mounted linear

diffusers that utilise the Coanda effect to send air across the ceiling and "drop" it into the operating zone are not suitable.

Transfer grille – size and location

5.68 Air-transfer grilles in walls, partitions or doors form an integral part of the building's air distribution system. Modern doorsets have very low leakage rates, so cannot be relied upon to permit even quite small air flows. Failure to make adequate provision for air to move from room to room will result in excessive pressure differentials and "door whistle".

5.69 Transfer grilles are required in locations where there is a significant imbalance between the supply and extract rates in a room. They will relieve any pressure differential that may affect the operation of the spaces and/or the ventilation system, and permit air flow in a known direction.

5.70 Care needs to be taken to ensure that the positioning of transfer grilles does not interfere with the fire or smoke integrity of the building. In general, air-transfer grilles should not be installed within fire-resisting boundaries, although if this is unavoidable, they should be fitted with fire or smoke dampers.

5.71 Where installed, transfer grilles should be of the non-vision type and sized for a maximum face velocity of 1.5 m/s.

5.72 In photographic darkrooms, lightproof transfer grilles are recommended.

5.73 Cross-talk attenuators may be necessary where noise intrusion between adjacent spaces can arise and where confidentiality is required (see also paragraphs 5.42–5.46).

Pressure stabilisers – size and location

5.74 Pressure stabilisers are required in lieu of air-transfer grilles in areas where it is necessary to maintain pressure differentials between adjacent rooms to prevent reversal of air flows (for example in operating suites, isolation facilities and clean rooms (see also Chapter 7)).

5.75 Fire precautions for pressure stabilisers are the same as for transfer grilles. For sizing criteria, see Chapter 7.

5.76 Pressure stabilisers should be of the balanced-blade type, with the facility to make fine adjustments to the pressure setting. They should be silent in operation and give a seal as tight as practicable when closed. The materials of construction and method of assembly should allow for cleaning and disinfection.

5.77 Pressure stabilisers should be installed in a visible location so that their operation can be readily observed.

5.78 Cross-talk attenuators may be necessary where noise intrusion between adjacent spaces can arise and where confidentiality is required. In these cases, the pressure stabiliser and cross-talk attenuator should be mounted in a short length of ductwork within the ceiling void.

5.79 Pressure stabilisers may need to be fitted with a stand-off baffle on their discharge side to prevent a sight line in situations where a laser will be used. Baffles may also be required to preserve privacy or to prevent discharge air causing draughts or disturbing the air-distribution pattern in an adjoining room. They are also useful in low-level locations to prevent the air-flow path being obstructed by portable equipment.

Pressure stabiliser with stand-off cage

6 Automatic controls

6.1 Various options for control of single and multi-zone air-conditioning systems are given in CIBSE Guide B.

General requirements

6.2 The basic requirements for an automatic control system are as follows:

- facilities to start, set-back and stop the plant;
- facilities to control the volumetric air flow;
- facilities to control the system or room pressure;
- temperature control and indication;
- humidity control and indication;
- devices to monitor and indicate the plant's operating state;
- alarms to indicate plant failure, low air flow and filter state.

6.3 The control functions provided will depend on the purpose of the ventilation system.

6.4 There will also be a need to determine the control strategy in the event of a fire either within the zone being served or within an adjoining zone.

6.5 Designers should consider whether it is necessary for the supply and extract fans to be interlocked – either so that the supply fan will not operate unless air flow is established within the extract system, or vice-versa depending on the required pressures within the rooms being served.

6.6 The sequence switching of units in order to prevent transient reverse air flows will be particularly important in laboratories and pharmacies that contain fume cupboards, safety cabinets and other LEV systems.

6.7 Alarms should be provided to show "filter fault" and "low air flow". The "filter fault" alarm should be initiated by a predetermined increase of pressure differentials across the filter. The "low air flow" alarm should be initiated when the supply-air quantity falls to 80% of the design value.

Objectives of the control system

6.8 The primary objective of a ventilation or air-conditioning plant control system is to keep the space served within the required environmental control limits, at the appropriate times – regardless of external conditions or internal loads – and with the minimum energy consumption.

6.9 Control of most systems will be via a building management system (BMS). This will enable the operating conditions and control tolerances to be set and monitored. Often, it is not possible to accurately predict building load variation at the design stage. Information provided by monitoring the operation of the plant via a BMS will enable optimum set-points to be established and energy consumption reduced. The BMS may also be set to log the actual energy consumed by the system together with that recovered by the energy-recovery device. This will provide a useful check on overall operating efficiency and provide evidence that energy targets are being achieved.

6.10 A BMS incorporating self-adaptive control algorithms that automatically adjust the set-point to suit the usage and load is preferred. The provision of movement sensors within the controlled space in order to determine the actual occupancy will facilitate this process.

6.11 The failure of specialised ventilation systems can have grave consequences for the delivery of healthcare. Control systems should therefore be simple, robust and reliable.

6.12 Computer-software-driven control systems are becoming the norm in building services. However, healthcare ventilation systems need to be available for operation outside of normal working periods when software support is not available. Should the software fail, it will be left to site staff, who may have little knowledge of the control algorithms, to restart the ventilation system. It is therefore essential to ensure that a simple means of restarting critical systems in the event of a software failure is provided (see also paragraphs 4.62–4.63).

Location of controls

6.13 Whether within the plant, duct or room, sensors should be located to provide accurate measurement of the condition of the air being monitored.

6.14 Sensors and control items such as control valves should be located close to the element being sensed or plant item being controlled in order to minimise time lags within the system, which may create over-shoot of conditions beyond the design envelope and result in additional energy consumption.

6.15 There are practical advantages in locating all control valves for an AHU in a bank (at a convenient height) at one end of the unit. (This should not result in an additional control lag.)

6.16 Some applications require intermittent mechanical ventilation, frequently at a high air-change rate (for example in bathrooms and treatment rooms). Local controls to facilitate this mode of operation should be placed in a prominent position to encourage economical use.

6.17 Local controls that enable the user to select more than one mode of operation should be clearly labelled to identify the particular mode selected. Where the system allows different room pressures to be selected, a direct-reading pressure gauge should be fitted within the eye line of the users to provide an independent confirmation of the resultant mode of operation. A clear description of the selectable modes of operation should be mounted adjacent to the control switch.

Fire aspects

6.18 A fire control panel should be mounted at the entrance of the area that the ventilation serves. Access to the panel should be restricted to the fire officer and include independent on/off controls and an indication of the supply and extract systems.

6.19 In certain critical care areas, it is preferable to maintain the supply ventilation in case of a fire within the area. For example, in an operating department, while undergoing surgery, the patient cannot always be easily moved without significant risk. In the event of a fire in a staff or support area of the department, or adjoining zone, the continued supply of air to a theatre will maintain it at a positive pressure and protect the patient and staff from the effects of smoke. This will allow time for the patient to be stabilised so that he/she can be safely evacuated if necessary.

6.20 In all critical care areas, the ventilation system should continue to operate unless smoke starts to enter the AHU. A notice should be affixed to the fire control panel stressing the need to liaise with departmental staff before switching off fan units.

6.21 All supply AHUs should have a smoke sensor mounted in the main supply duct immediately downstream of the AHU. In the event of a fire in the AHU or smoke being drawn into the system from an outside source, it should cause the supply-air fire damper to close and shut down the AHU.

Time switching

6.22 Facilities to start, set-back and stop the plant should be provided in the plantroom. Remote start and set-back control and indication, if required, should be provided at a manned staff location (for example at the reception or staff base).

6.23 Many ventilation systems may be completely shut down when the area served is not in active use (for example operating theatres). Alternatively, where there is a need to maintain a background condition, the ventilation output can be reduced by "setting back" the system. This will significantly reduce energy consumption and extend the life of filters and other system components.

Start-up control

6.24 The plant's start control should contain a control logic that will start the plant in the sequence set out in the algorithms in Figures 2–5.

Set-back control

6.25 Where variable-speed controls are installed, the set-back facility for each plant should depress the control temperature to around 15°C; exclude any humidification and cooling from the system; and reduce the supply and extract air volumes to around 50%. The extract fan can also be turned off as long as the desired direction of air movement from clean to less clean will be maintained.

Use control

6.26 The installation of movement detectors allows for "use control" of ventilation systems. A simple control logic that reduces the system to a "set-back" condition if there has been no movement detected in the space for, say, 30 minutes and that switches the system "off" if no movement is detected for one hour is recommended for many applications,

Figure 2 Typical plant control algorithm – normal start-up sequence

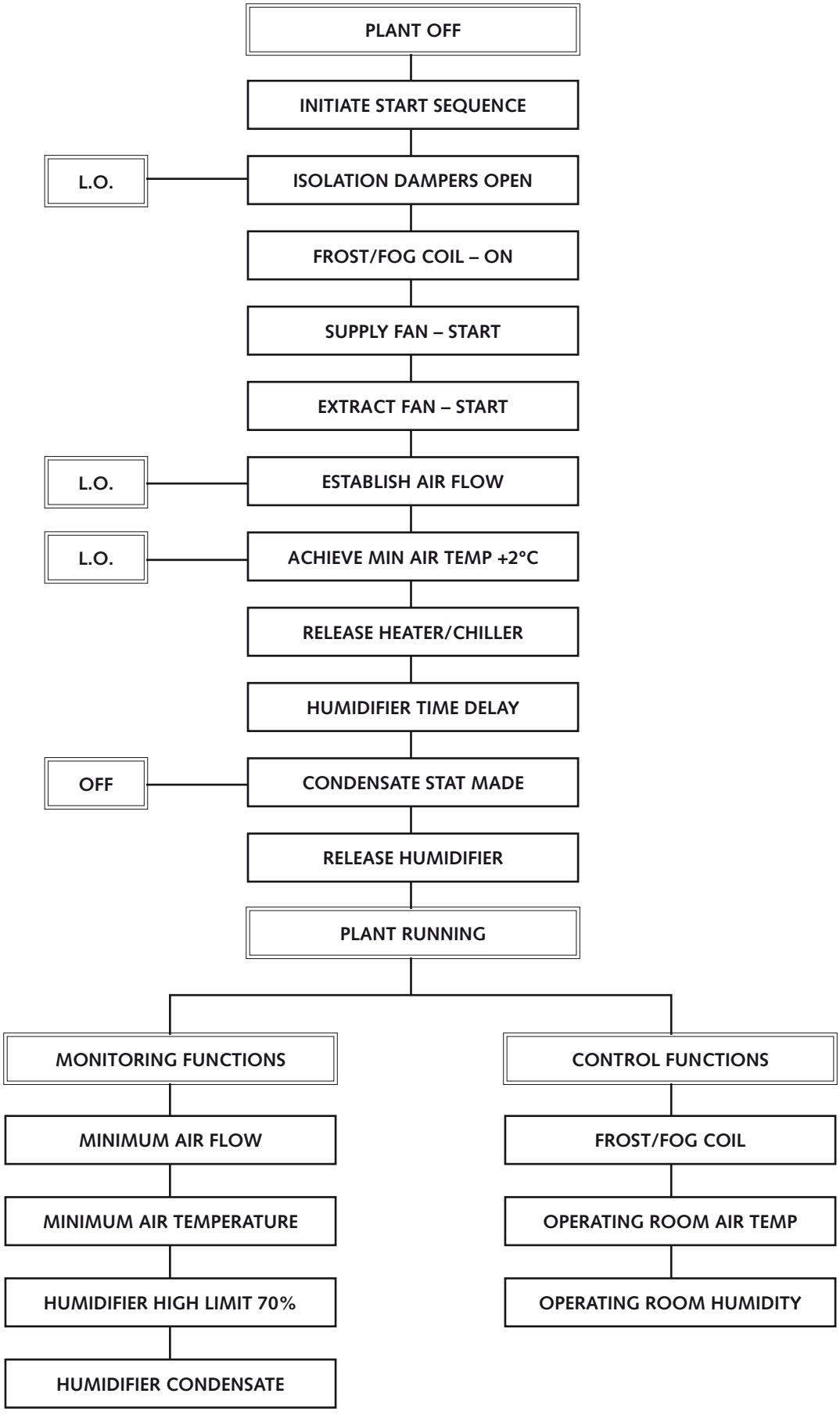


Figure 3 Plant control algorithm – normal shut-down sequence

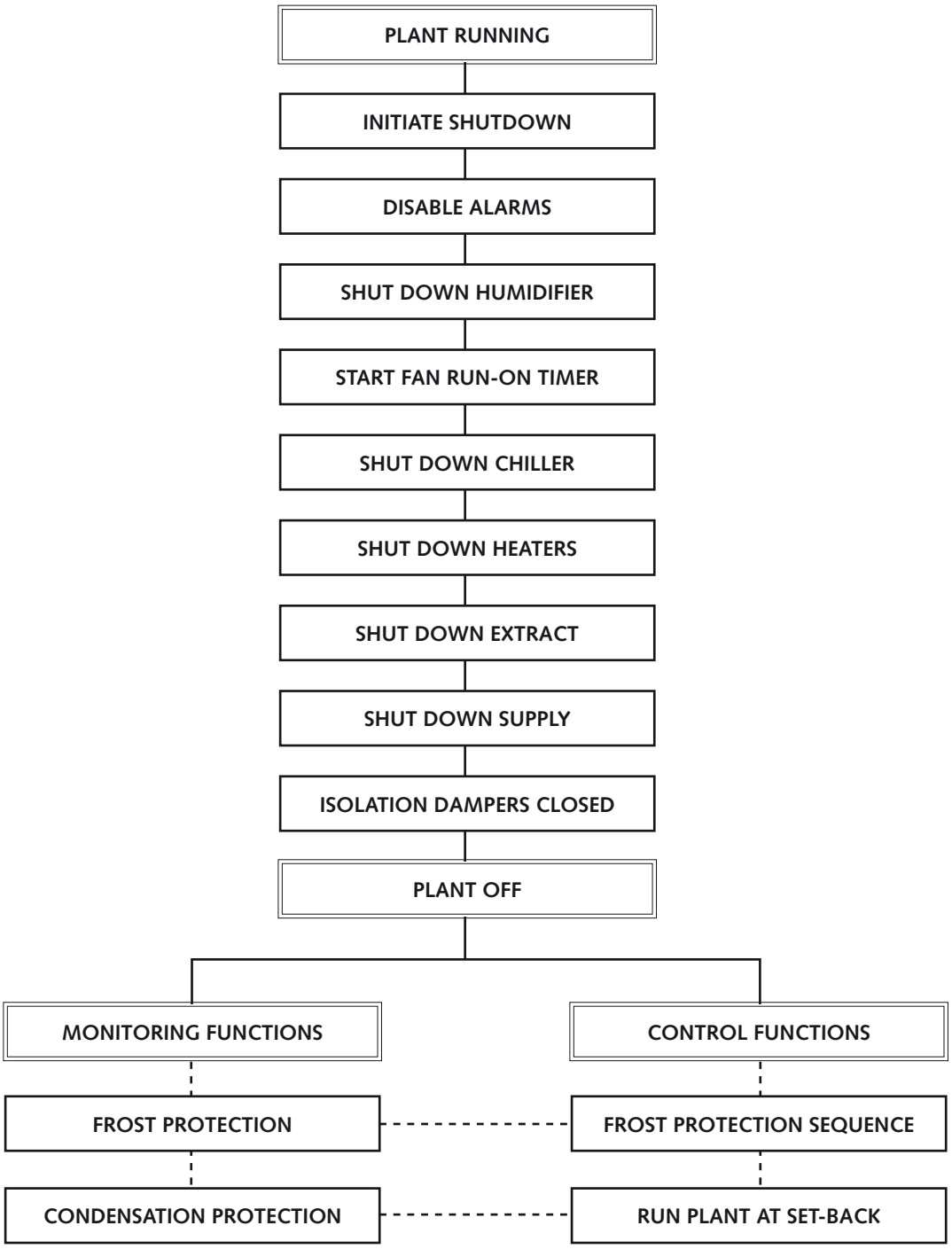


Figure 4 Plant control algorithm – set-back sequence

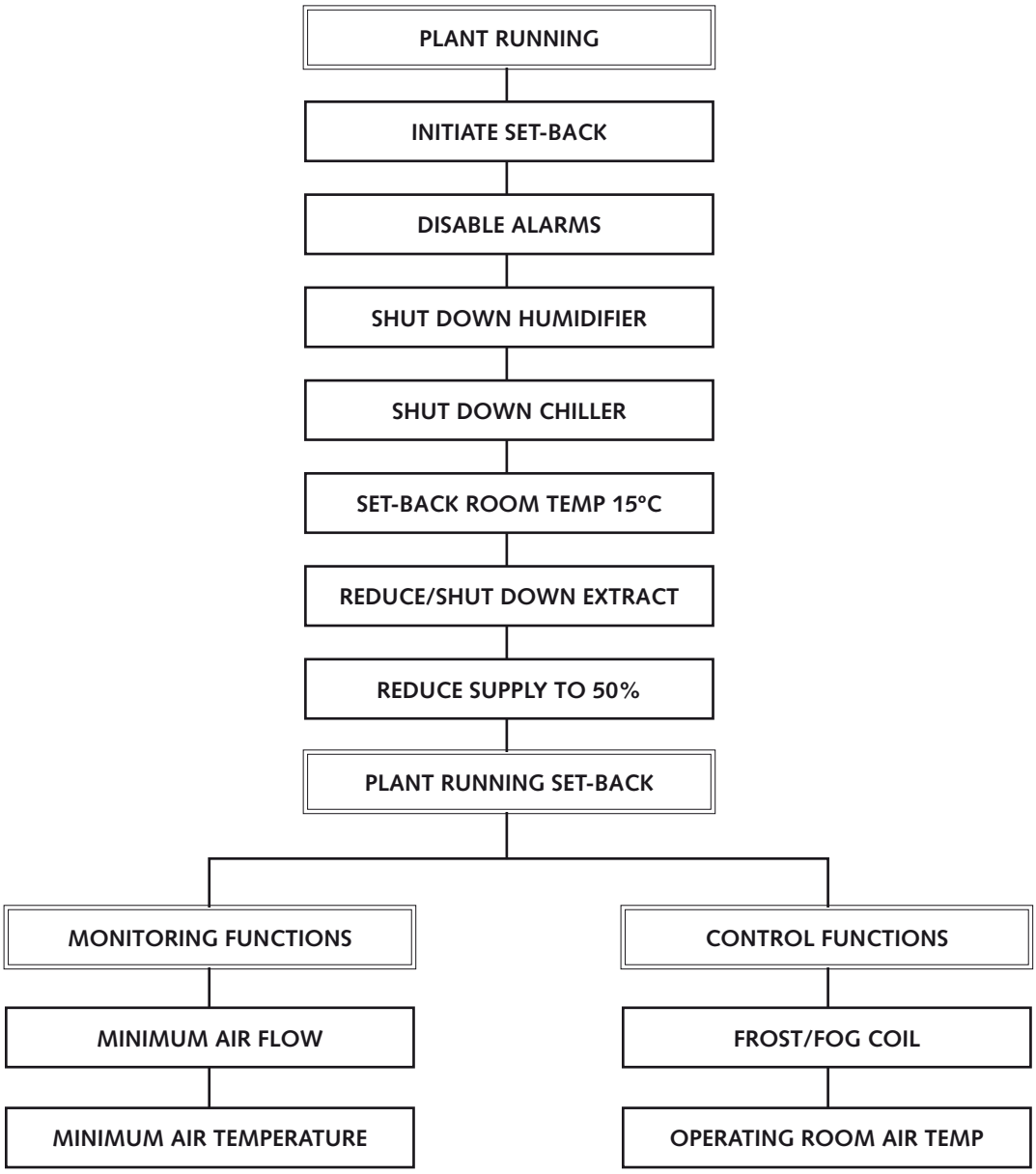
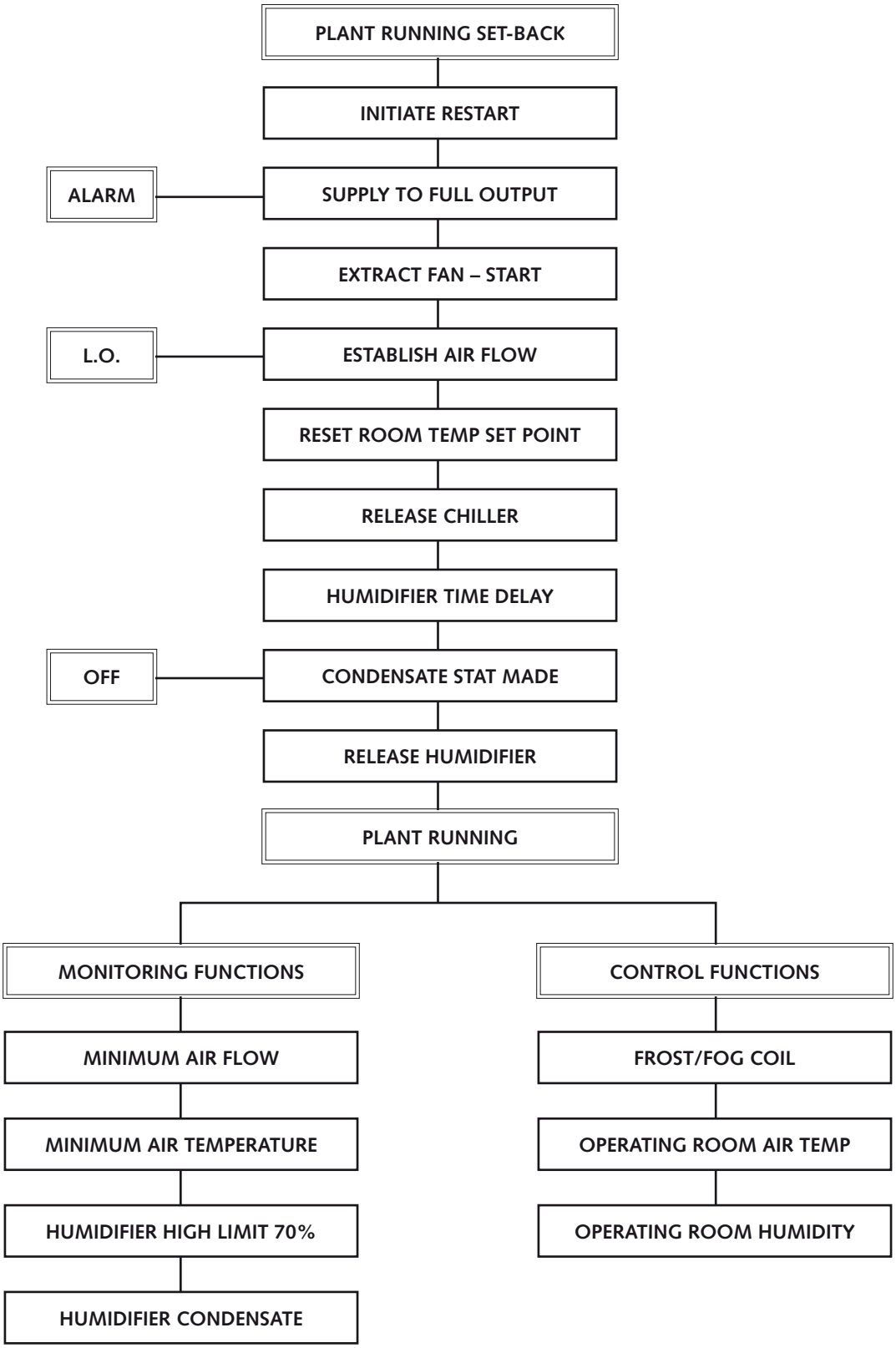


Figure 5 Plant control algorithm – restart from set-back



including operating suites (see paragraphs 7.31–7.90).

6.27 A variation on this can be provided by linking ventilation controls to the lighting. For example, in an operating theatre, the system may be off outside of working hours, could run at set-back when the general lighting is switched on, and increase to full speed when the operating lamp is switched on. As with movement detection, a 30-minute run-on should be provided at each stage when the lights are turned off.

6.28 Either of the above control strategies may be refined by linking to the BMS to provide a control logic related to normal working hours and associated "real-time" movement within the zone being controlled. This should result in significant energy savings.

Environmental control

Temperature control methods and application

General

6.29 All control valves must fail-safe, that is, close in the event of power or air-flow failure, with the exception of the fog/frost battery control valve, which should open upon power or air-flow failure.

6.30 Control valves should be located in an accessible position. Isolation valves should be provided to enable the control valve to be removed for service without the need to drain-down the system.

6.31 Care should be taken to ensure that the installation of control valves and their associated pipework do not obstruct access to the AHU inspection doors and hatches.

Room temperature control

6.32 The limits for room temperature set-point are generally between 16ºC and 25ºC depending on the particular application, and in some specialised instances (for example operating departments) are adjustable within a predetermined range by the user.

6.33 The selection of temperature set-point for each room or zone may be by a control facility in the room/zone or be carried out remotely at the control panel or BMS. Where the control device is mounted within the room/zone and is adjustable by the user, it should be marked either "raise" and "lower" or "+" and "–". It should control within a specified temperature range to suit the user requirement with a control tolerance of ±1 K. All other control set-points should be selectable either on the control panel or at the BMS interface.

6.34 Where local control is provided, an indication of temperature will be required locally or at a staff base (if appropriate) using an analogue or digital indicator. The indicator should be large enough to be read from the normal working position (for example at the operating table in a theatre). This may be mounted in a supervisory control panel, with the signal repeated on the main system control panel or BMS. It is important that this indicator displays the actual measured temperature and not the selected temperature.

Frost coil control

6.35 Steam-supplied fog/frost batteries must be operated as on/off devices with their sensor mounted upstream of the battery. This will give "open loop" control. A set-point of +1ºC is recommended.

6.36 LPHW-supplied frost batteries should be controlled using the proportional mode. Their sensor should be located downstream of the battery to give "closed loop" control. A set-point of between 2ºC and 5ºC is recommended.

6.37 If the temperature downstream of the frost battery, as sensed by a serpentine thermostat, falls below the required set-point over any part of the coil, the plant must automatically shut down in order to prevent damage to the other batteries. The serpentine thermostat must not be in direct contact with the coil.

Off-plant control

6.38 The control logic must prevent the chiller and pre-heater being on at the same time.

Humidity control methods and application

6.39 In order to prevent excessive condensation when starting up from a total plant shut-down, a time delay should be incorporated into the control system such that the humidifier does not start until 30 minutes after the ventilation plant starts up.

6.40 Irrespective of the method of control, a high-limit humidistat should be installed to ensure that when the humidifier operates, the condition of the air in the duct does not exceed 70% saturated, particularly during plant start-up.

6.41 With certain types of steam humidifier, it may be necessary to install a thermostat in the condensate line from the humidifier's steam supply, to ensure that the steam at the control valve is as dry as possible before it is injected into the air supply.

6.42 The humidifier and cooling-coil control must be interlocked so that they cannot be on at the same time.

6.43 The humidifier control system should ensure that it is switched off with the fan. It is preferable to design the control system so that the humidifier is isolated for an adequate time before the fan is turned off so as to purge humid air from the system.

6.44 All control valves must fail-safe (that is, close in the event of power failure), and the humidifier must be interlocked with the low air-flow switch.

Multi-zone control methods and application.

6.45 Close control of all air-conditioning parameters may be difficult to achieve with multi-zone systems, since each zone will in theory require a reheater and humidifier to give total control of humidity, if that is what is required. In reality, such close control is rarely required. It is therefore usual with multi-zone systems to provide control of zonal temperature only, with humidity control, where fitted, being based on average conditions within all zones, or minimum conditions within one zone.

6.46 Where there is a requirement for close control of air-conditioning parameters in a number of zones (for example an operating department), separate plants should be provided for each zone in order to avoid the need for expensive over-cooling and reheating of individual zones.

6.47 The control of most multi-zone systems within healthcare premises is based on off-coil control within the central plant, with trimmer heater-batteries on individual zones.

Alarms and indication

6.48 Supply and extract systems should include indicator lamps on the control panels to confirm the operational status of each system. Where the usage is on a regular daily pattern, time control with a user-operated, timed manual override should be provided.

6.49 Where a system is provided for a particular space, the indicator should be in, or immediately adjacent to, that space, and local controls should be provided with labels clearly defining their function (for example isolation suites).

6.50 The "plant failure" and "low air flow" alarm should be initiated by a paddle switch or other device located in the main air-supply duct. This should operate when the air quantity fails to reach or falls to around 80% of the design value and will give indication of fan failure, closed damper, left-open access door, or any other eventuality that could cause a reduction of air quantity. Monitoring the current drawn by the fan motor is not a substitute for a sensing device that is directly affected by the air flow.

6.51 The "filter fault alarm" should be initiated by a predetermined increase of pressure differential across the filters, thereby indicating a dirty filter.

6.52 Direct-reading gauges or manometers should be installed across filters to give maintenance staff an indication of their condition.

6.53 Visual indication should be provided at a manned staff location (for example the reception or staff base), on the main control panel and on the BMS to show "plant failure" and "low air flow".

7 Specialised ventilation systems

7.1 This section contains design information for a range of healthcare ventilation applications.

7.2 The following departments will require a degree of specialised ventilation:

a. Operating departments:
   (i) treatment rooms;
   (ii) endoscopy, day-case and minimum invasive suites;
   (iii) cardiology and operative imaging suites;
   (iv) conventional operating theatres;
   (v) ultra-clean ventilation (UCV) operating theatres;
   (vi) barn theatres;
   (vii) recovery and ancillary areas.

b. Obstetrics:
   (i) maternity theatres;
   (ii) birthing rooms.

c. Critical areas and high dependency units of any type.

d. Isolation facilities:
   (i) infectious diseases units;
   (ii) bone marrow and other transplant units;
   (iii) chemotherapy and oncology units.

e. Sterile services departments:
   (i) wash rooms;
   (ii) inspection and packing rooms;
   (iii) storage rooms.

f. Pharmacy departments:
   (i) aseptic suites;
   (ii) extemporaneous preparation areas;
   (iii) radio pharmacies.

g. Pathology departments:
   (i) laboratories;
   (ii) Category 3 and 4 rooms.

h. Mortuary and post-mortem rooms:
   (i) mortuaries;
   (ii) post-mortem rooms;
   (iii) specimen stores.

j. Hydrotherapy units.

k. Burns units:
   (i) burns theatres;
   (ii) treatment rooms;
   (iii) isolation rooms;
   (iv) tissue banks.

m. Emerging specialties:
   (i) gene therapy units;
   (ii) stem-cell laboratories.

n. Infrastructure:
   (i) plantrooms housing combustion equipment;
   (ii) welding facilities;
   (iii) woodworking workshops;
   (iv) electric-vehicle charging areas.

7.3 Design information for many of these applications is given in this chapter and also in Appendix 2.

General information

7.4 The section on operating theatre suites is the most extensive and contains much information that is common to other applications. Where no specific guidance is given, the principles set out below should be followed:

a. The foregoing sections of the document contain general information on healthcare-specific

aspects of ventilation system design and specification.

b. A set of standard solutions for the design of general operating theatre suites to conform to past and new standards is given in paragraphs 7.31–7.90, and those for UCV theatres in paragraphs 7.91–7.147.

c. The CIBSE guides A and B contain basic information on ventilation design, which can be applied to most applications.

d. Where a British or European standard exists that is specific to the application (for example a clean room), it should be used as the basis of the design requirement.

e. Air should always move from clean to less clean areas. A hierarchy of room cleanliness is given in Appendix 3.

f. Differential pressure will prevent contamination between areas when doors are closed. Information on air leakage through closed doors and hatches for a range of differential pressures is given in Appendix 4.

g. The flow of air will prevent contamination between areas when doors are open. Information on air leakage through open doors and hatches for a range of differential pressures is given in Appendix 6.

h. If anaesthetic gases are used, 15 air changes per hour will be required.

j. A methodology for calculating a design solution for a non-standard suite of operating rooms is given in Appendix 8. This may be adapted as necessary to suit other less complex applications where air is required to cascade from clean to less clean areas.

7.5 The supply of air to a room has four main functions:

a. to dilute airborne contamination;

b. to control air movement such that the transfer of airborne contaminants from less clean to cleaner areas is minimised;

c. to control the temperature and, if necessary, the humidity of the space;

d. to assist the removal of, and dilute, waste gases where used.

7.6 Because of the complexities of controlling air-movement patterns, much design effort will be required for this aspect. It is important that the design makes the best possible use of the air available, as excessive supply air flows for the control of air movement should not be used. The amount of air supplied will be determined by the number of doors and desired air-change rate.

7.7 Airborne contaminants may enter a room via the following routes:

a. through the supply air;

b. shed directly by the room occupants;

c. as a result of work activities;

d. transferred from adjacent spaces.

7.8 Particles entering with the supply air can be controlled by the selection of suitable filter grades.

7.9 Particles shed directly by the room occupants can be controlled by:

a. restricting access to essential persons only;

b. the choice of the occupants' clothing;

c. the room's air-change rate.

7.10 Particles arising as a result of the work activity can be controlled by:

a. enclosing, semi-enclosing, or otherwise, the work-based source;

b. the room air-change rate.

7.11 The transfer of particles from adjacent spaces can be controlled by:

a. differential pressure;

b. clean air-flow paths.

7.12 Air-change rates are given in Appendix 2. These figures have been found to give sufficient dilution of airborne contaminants, provided the mixing of room air is reasonably uniform.

7.13 Downward-displacement turbulent air distribution is generally preferred. The supply and extract diffusers should be positioned to ensure that all parts of the room are actively ventilated and that, where necessary, staff will be in a clean air-flow path (see Chapter 5 for additional guidance on supply terminals).

7.14 Horizontal-flow room-air distribution with or without a Coanda effect can be a source of draughts and difficult to set up correctly. Its use should be confined to non-critical areas.

Air-movement control

7.15 The design of the system should seek to minimise the movement of contaminated air from less clean to cleaner areas. Transfer grilles enable air to pass in either direction between rooms of equal class and pressure. Pressure stabilisers operate in one direction only; they allow excess air to be directed to the area desired and assist in maintaining room-pressure differentials. When closed, they prevent significant reverse air flow.

7.16 The relative locations of supply and extract terminals and their design air-volume rates will determine the basic air flow between adjacent spaces. Transfer grilles and pressure stabilisers will permit and control the flow of air between spaces, ensuring a flow from the clean to less clean areas. Failure to provide such devices will lead to uncontrolled air flows when personnel move between rooms. It may also result in doors being held partially open by air pressure.

Temperature and humidity control

7.17 To achieve the required room conditions, supply flow rates are calculated conventionally, taking account of all heat and moisture gains and losses, and of maximum permissible temperature differences between the room and supply air. In most applications, the base heating load will be provided by a heating system. In critical systems, the room or suite being considered will be within the heated building envelope so the ventilation will be sized to suit the casual gains or losses.

7.18 Temperature differences of up to 10 K for winter heating and 7 K for summer cooling should not be exceeded (see paragraph 3.10).

7.19 It is acceptable for supply-air humidity to swing uncontrolled between 35% and 70% saturation.

Removal and dilution of waste anaesthetic gases

7.20 Anaesthetic gases are subject to workplace exposure limits. Waste anaesthetic gases must be contained and removed by a suitable gas-scavenging system. Some leakage from anaesthetic equipment and the patient's breathing circuit will occur with all systems, particularly during connection and disconnection, and from the interface with the patient. The air-movement scheme should ensure that this leakage is diluted and removed from the room. Anaesthetic agents are heavier than air; therefore, placing the supply terminal at high level with an extract at low level, adjacent to the anaesthetic-gas terminal units, will ensure that staff are in a clean air-flow path.

7.21 In birthing rooms, the use of anaesthetic gas is controlled on demand by the patient. This may result in significant leakage that – in order to reduce staff exposure – will need to be controlled by establishing a clean air-flow path. A supply at high level at the foot-end of the bed with extract at low level at the head-end will provide such a path.

Fire aspects

7.22 When considering the overall air-flow movement, careful thought needs to be given to the operation of the ventilation system, to limit smoke spread in the event of a fire.

Door protection

7.23 Air should flow from the cleaner to the less clean areas as shown in Appendix 3. There are several factors that affect the likelihood of reverse air flow through doorways:

- when a person passes through a doorway, both the passage of the person and the movement of the door flap cause a transfer of air between the areas separated by the door;
- when a door is left open, there is a transfer of air between the two areas separated by the doorway. This is caused by air turbulence, but is greatly increased by any temperature differential between the areas (a 1.4 m wide doorway may allow the transfer of 0.19 m^3/s of air in each direction when there is no temperature difference, but when the temperature differential increases to 2 K, the volume transferred may increase to 0.24 m^3/s).

7.24 In order to reduce the likelihood of contamination of a clean area by reverse air flow from a less clean area, two methods of door protection are used:

a. closed door protection – a pressure differential is created across a closed door so that any air leakage is from the clean to the less clean area. Appendix 4 gives details of closed-door leakage rates for a range of differential pressures;

b. open door protection – the pressure differential drops (see Appendix 6) and is effectively replaced by a flow of air through the doorway from the clean to the less clean area. The flow of air needs to be sufficiently large to ensure that significant reverse air flow cannot occur, and

will be related to the relative cleanliness of the areas being considered. Appendix 5 gives air-flow rates for open-door protection related to door/opening size and classification of the adjoining areas.

7.25 Pressure stabilisers enable the room's differential pressure to be set when the doors are shut, thus providing closed-door protection. When a door is opened, the stabilisers will close, forcing air to be directed through the doorway, thus providing open-door protection.

7.26 The recommended air-flow rates to achieve this are given in Appendix 4. Provided that the dilution criteria in Appendix 2 are met, the occasional small back-flows created (when two doors are opened simultaneously or when there is a high temperature difference across an open door) will have little effect on the overall air cleanliness of the affected room.

7.27 In applications where it is critical to maintain a specific air flow and/or pressure regime (for example isolation rooms), all windows in the zone should be locked shut or sealed. Trickle vents, if fitted, should also be sealed.

Systems design

7.28 The design of the ventilation system for an area depends on the overall configuration of the department. Where the department is served by more than one AHU, the control of the units may need to be interlocked so that reverse air-flow patterns do not occur.

7.29 Dual-duct high-velocity systems have advantages, but are noisy, costly, and may give rise to unacceptable values of humidity. Single-duct, low-velocity/pressure systems are preferred.

7.30 Extract grilles should be sited and balanced to promote air movement in the desired direction.

Operating department ventilation systems

7.31 The information given in this section relates to general operating suites. It is also applicable to other types of theatre suite such as maternity, burns, cardiac etc. The standard values given may need to be adjusted to reflect non-standard room sizes, pressure regimes and air-change rates.

7.32 A method of obtaining a design solution for non-standard theatres is given in Appendix 8. Additional information for UCV theatres is given in paragraphs 7.91–7.147.

General

7.33 The supply of air to an operating room has four main functions:

a. to dilute airborne contamination;

b. to control air movement within the suite such that the transfer of airborne contaminants from less clean to cleaner areas is minimised;

c. to control the temperature and, if necessary, the humidity of the space;

d. to assist the removal of, and dilute, waste anaesthetic gases.

7.34 Because of the complexities of controlling air-movement patterns, much design effort will be required for this aspect. It is important that the design makes the best possible use of the air available, as excessive supply air flows for the control of air movement should not be used. The amount of air supplied to the operating room will be determined by the number of doors and desired air-change rate.

7.35 The detailed considerations upon which the supply air-flow rate is based are as follows.

Dilution of airborne bacterial contaminants

7.36 Airborne contaminants may enter an operating room via the following routes:

a. through the supply air;

b. shed by operating staff;

c. through surgical activities;

d. transferred from adjacent spaces.

7.37 Supply flow rates for the main rooms of the operating suite are given in Appendix 7. For the other areas where room sizes and activities vary from site to site, air-change rates are given in Appendix 2. These figures have been found to give sufficient dilution of airborne bacterial contaminants, provided the mixing of room air is reasonably uniform.

7.38 Downward-displacement air distribution is preferred, and may be either turbulent or parallel downward flow. For turbulent flow, supply-air diffusers should be positioned either in the centre of each quadrant of the ceiling or along a line between the centres of each quadrant. This should

ensure that all parts of the room are actively ventilated and that there will be adequate air movement at the operating table. Parallel downward flow is provided by a perforated plenum terminal centred above the operating table (see Chapter 5 for additional guidance on supply terminals).

7.39 Suspended, articulated pendants in theatres require significant structural steelwork in the ceiling void to cater for the loads imposed by the resulting bending moments. It is important to ensure that the void is deep enough to accommodate both the steelwork and the ventilation ducts. However, the location of the steelwork must not prevent a suitable layout of the ventilation ductwork and the appropriate positioning of supply air terminals – the correct ventilation of an operating theatre plays a significant role in controlling healthcare-associated infections and should not therefore be compromised by the need to facilitate the movement of equipment.

7.40 Horizontal-flow distribution with or without a Coanda effect can be difficult to set up correctly and is unlikely to be as effective in theatre applications. It should not be used in new installations; however, space constraints may force its retention or replacement when refurbishing existing installations. Where fitted, the supply grilles will require a means of directional adjustment.

7.45 For general operating theatres, the air supply is filtered in the AHU. Terminal or HEPA filters are not generally required.

Control of air movement within the suite

7.46 The design of the system should seek to minimise the movement of contaminated air from less clean to cleaner areas. Transfer grilles enable air to pass in either direction between rooms of equal class and pressure. Pressure stabilisers operate in one direction only; they allow excess air to be directed to the area desired and assist in maintaining room-pressure differentials.

7.47 The relative locations of supply and extract terminals and their design air-volume rates will determine the basic air flow between adjacent spaces. Transfer grilles and pressure stabilisers will permit and control the flow of air between spaces, ensuring a flow from the clean to less clean areas of the suite. Failure to provide such devices will lead to uncontrolled air flows when personnel move between rooms and doors are held partially open by air pressure.

Temperature and humidity control

7.48 Supply flow rates to achieve the required room conditions are calculated conventionally, taking account of all heat and moisture gains and losses, and of maximum permissible temperature differences between the room and supply air. In most applications the base heating load will be provided by a heating system, or the room being considered will be within the heated building envelope.

7.49 Temperature differences of up to 10 K for winter heating and 7 K for summer cooling must not be exceeded.

7.50 It is acceptable for the humidity to swing uncontrolled between 35% and 60% saturation.

Removal and dilution of waste anaesthetic gases

7.51 Anaesthetic gases are subject to workplace exposure limits. The air-movement scheme should ensure that staff are in a clean air-flow path (see paragraphs 7.20–7.21).

7.52 Air extracted from operating suites should not be recirculated, as it may contain malodorous contaminants; however, an energy-recovery system must be fitted in the extract in order to reduce the plant's energy consumption (see paragraphs 4.146–4.154).

Fire aspects

7.53 When considering overall air-flow movement, careful thought needs to be given to the operation of the ventilation system in order to limit smoke spread in the event of a fire. However, this is a highly staffed department with a low fire risk/load status, and these factors need to be recognised when developing the fire strategy. It is considered satisfactory to treat the complete operating department as a single fire compartment providing there are at least two exits from it. Over-compartmentalisation can lead to difficulties in establishing clean air-flow paths and room-air dilution rates, which in turn may lead to an increased risk of healthcare-associated infections. Staff areas within the department should be treated as a subcompartment (see paragraphs 6.19–6.21).

Door protection

7.54 Air should flow from the cleaner to the less clean areas as shown in Appendix 3. The factors that affect the likelihood of a reverse air flow through doorways are discussed in paragraphs 7.24–7.26.

7.55 It is not possible to design an air-movement scheme, within the restraints of the amount of air available, that will protect the operating room when two doors are simultaneously opened. The design process that has been used considers that each door is opened in turn and ensures that the direction and rate of air flow through any open doorway is sufficient to prevent any serious back-flow of air to a cleaner area.

7.56 Provided that the air-change rates in Appendix 2 are met, dilution will be sufficient to ensure that the occasional small back-flows created (when two doors are opened simultaneously or when there is a high temperature difference across an open door) will have little effect on the overall air cleanliness of the affected room.

7.57 The following general points should be taken into consideration during the design of operating suites:

- Number of exits – the fewer the number of rooms (and therefore doorways) leading from the operating room, the better, as traffic is reduced and less complicated air-movement control schemes are required.
- Scrub and hand-wash facilities – these may be a part of the operating room, often in a bay. The bay would count as a part of the operating room volume and should have a low-level active or passive extract to remove the moisture-laden air. Should a separate room be required for the scrub area, a door between the scrub-up room and the operating room is an inconvenience to scrubbed staff, and could be replaced by an opening that is wider than a normal single doorway. In this case, the scrub would not be considered a part of the operating room volume.
- If a shared scrub is provided for a pair of theatres, it should have an active extract to ensure that air flow is always into it from either theatre.
- If an alcohol scrub regime is employed, individual theatre scrubs may not be required and would be replaced by a common departmental pre-/post-operation scrub position in the corridor. This would require local extract to prevent a build-up of moisture.
- Preparation room "sterile pack store" (SPS) – if it is intended to lay-up instruments in the operating room, the preparation room will simply be used as a sterile pack store. The nominal room pressure can therefore be the same as that of the operating room and the air flow between the two rooms in either direction. Air supplied to the preparation room may be directed into the operating room either through a door-mounted transfer grille, or if no door is fitted, through the opening. Alternatively, stock ready-use sterile items can be located in a bay within the theatre. In this case a portion of the total theatre supply air should be provided in the bay to ensure it is actively ventilated.
- Preparation room "lay-up" – when the preparation room is used as an instrument "lay-up" room, it should be regarded as being of greater cleanliness than the operating room, and the design should minimise the transfer of air from the operating room to the preparation room. Air supplied to the room may be directed to the operating room through a pressure stabiliser, taking care not to compromise the air-flow pattern in the operating room. The air may also be directed into a corridor.
- Shared preparation rooms – if the preparation room is to be shared between two theatres, it should be at a higher pressure (35 Pa) than either of the theatres – even if it is only to be used as a sterile pack store. The doors to the theatres should be interlocked to prevent them both being open at the same time, and the stabilisers should be positioned to discharge into the corridor.
- Service corridor – if materials to be disposed of are placed in impervious material for transportation, it is not necessary to have a separate corridor for this purpose. However, a service corridor has many operational advantages in terms of the flow of materials through the theatre suite. It also permits routine service and maintenance access without compromising the use of adjacent theatre suites.

Standard air-movement control schemes

7.58 In previous versions of this guidance, standard air-movement control schemes were given that provided a range of design solutions to typical

operating-suite layouts. These were satisfactory design solutions for "standard" sized rooms within the suite, but were never intended to be universal for any sized room or suite. Health Building Note 26 – 'Facilities for surgical procedures' increased the recommended size of the operating room from approximately 35 m^2 to 55 m^2. Ancillary room sizes and air-change rates also increased. This meant that the original standard solutions were no longer appropriate for new-build installations.

7.59 Because of the resulting increase in the volume of air supplied to the theatre, provision needs to be made to either actively remove it or allow it to passively escape through pressure stabilisers. The increase in room size has also made the number and position of air-supply terminals critical to the effective ventilation of the room.

7.60 Four new standard solutions have been developed to reflect the current guidance on theatre suite layout and room sizes given in Health Building Note 26, as well as the general increase in air-change rates.

7.61 The most commonly used original standard solutions have been revised and updated. They have been retained in this guidance, as they will remain applicable to older theatre suites that are being refurbished to their original performance standards or are being converted from conventional to UCV theatres. They will also be applicable in existing operating departments where space constraints do not permit a complete upgrade to the latest standard of performance or where a pre-built "shell" is being fitted out.

7.62 It is important to recognise that in any situation where a non-standard room size or theatre suite layout is being considered, the designer must return to first principles when developing a solution. Examples of non-standard configurations are:

- cardiac theatres that typically have an operating room 50% larger than a normal theatre, a perfusion laboratory and no anaesthetic room;
- operating departments served by a central instrument lay-up preparation area rather than individual preparation rooms;
- balanced-flow theatres for infectious cases.

7.63 Appendix 8 contains a methodology for assisting the designer to arrive at a suitable solution.

7.64 The new and revised standard design solutions are as follows:

1 Typical conventional theatre – room sizes as Health Building Note 26.

2 Typical UCV theatre – room sizes as Health Building Note 26.

3 Health Building Note 26 illustrated conventional theatre.

4 Health Building Note 26 illustrated theatre with UCV terminal fitted.

5 Pre-2006 conventional theatre, single corridor (Health Technical Memorandum 2025; 1b).

6 Pre-2006 UCV theatre, single corridor (Health Technical Memorandum 2025; 1a).

7 Pre-2006 conventional theatre, two corridors (Health Technical Memorandum 2025; 5b).

8 Pre-2006 UCV theatre, two corridors (Health Technical Memorandum 2025; 5a).

7.65 Details of these standard solutions are given in Appendix 7, which contains diagrams showing the relationship of rooms and the various doors and transfer devices between them, **but these should not be regarded as architectural layouts**. The schemes have been developed using the calculation procedure described in Appendix 8. Important features of the solutions are:

- Zone trimmer heaters – a trimmer heater-battery is advocated when calculations indicate that the temperature differential between rooms may be greater than 2 K. Generally this will only be the case in the preparation room when designated as a lay-up, although they are sometimes required for anaesthetic rooms.
- The preparation room (sterile pack store)/operating room interface – these rooms are deemed to be of equal cleanliness, and thus a transfer grille is required between them, or the door can be replaced with an opening wider than a standard door.
- Preparation room (lay-up)/operating room interface – pressure stabilisers are recommended here to provide an air path when doors are closed, while preventing back-flow when a door is opened elsewhere.
- Operating room/anaesthetic room interface – pressure stabilisers, or in some cases carefully sized transfer grilles, are recommended here and also between the anaesthetic room and corridor. The amount of air being passed through the

anaesthetic room should not be so great as to cause an unacceptable draught.

- Operating room/clean and service corridors interface – pressure stabilisers combined with low-level active or passive extracts appropriately spaced to ensure air movement in all parts of the operating room.
- Operating room/scrub room interface – an opening is provided between these rooms. The flow of air through the opening provides protection and gives bacterial dilution within the scrub room; the air is then exhausted to the corridor via a pressure stabiliser.

7.66 Mechanical supply or extract ventilation is not normally provided in the scrub room; thus, when a door is opened elsewhere in the suite, the stabiliser will close, allowing the air to be redirected in order to help protect the doorway. If the scrub is a bay within the theatre or if its configuration is liable to cause (in air-movement terms) "dead areas", a combination of a suitably positioned pressure stabiliser and/or active extract should be provided to ensure air movement and to prevent a local build-up of moisture.

7.67 Any other scheme may be used and the standard solutions applied if the following conditions are met:

- room relationships in air network terms are as shown in the plans;
- door-gap measurements approximate to those given in Health Technical Memorandum 58 – 'Internal doorsets' (but see also Appendix 4);
- casual heat gains are accounted for;
- a trimmer battery is installed in the air-supply system to the preparation room;
- leakage through the structure is kept to a minimum.

7.68 It is recommended that every effort should be made to adopt one of the schemes described above.

Air terminals and air distribution within rooms

7.69 The selection and sighting of air diffusers is critical in establishing an efficient pattern of mixing. To this end, the diffusers selected must be fit for purpose. Diffuser designs that provide a downward-displacement turbulent air flow are the preferred option, for example:

a. ceiling-mounted circular "air-master"-style diffusers; and

b. square "four-way-blow" diffusers; or

c. similar designs to those in (a) and (b) (see paragraph 5.68).

7.70 Plenum-type laminar-flow-style diffusers with a footprint that encompasses the operating site are acceptable but may be prone to buoyancy effects as a result of temperature difference. Manufacturers' type-test data should be consulted to ensure that the terminal will achieve the required performance envelope. Note that these are not true laminar-flow systems in the strict sense of the word, but produce downward-displacement parallel-flow air distribution.

7.71 The diffuser equipment chosen should not cause "dumping", and it should provide a velocity 1 m above floor level at the operating position of between 0.2 m/s and 0.3 m/s.

7.72 In the operating room, the supply air terminals must be at high level and should all be adjustable for rate of flow, as well as being easily cleaned and silent in operation.

7.73 In order to ensure that all parts of the operating room are actively ventilated, there should be an air-out path on each face or in each corner of the theatre. This may be provided by a pressure stabiliser, transfer grille, or active or passive extract terminal. A minimum of three, but preferably four, air-out paths – approximately equally spaced – should be provided.

Automatic control

7.74 The automatic control of ventilation in operating suites needs to be simple and robust. Over-reliance on complex room pressure and flow relationships linked to automatic fan speed control are unnecessary and in the long term have been shown to be unreliable. Complex software algorithms that can only be accessed and interpreted by off-site specialists should not be used. Whichever control strategy is chosen, it is important that on-site staff have the facility to override the control system and keep the ventilation operating at least until the surgical procedure is complete (see also paragraph 6.12).

7.75 Theatre air-conditioning control sensors should be actively ventilated. They would typically be located in a sampling duct mounted in the surgeon's panel

and be accessible for cleaning and the removal of fluff and lint.

7.76 Wall-mounted passive-temperature and humidity sensors are not recommended.

7.77 Controls should be provided to enable operating department ventilation plants to be closed down when the operating suites are unoccupied (see also paragraphs 6.26–6.28).

7.78 When in the "off" mode, the control system should ensure that the ventilation plant is automatically reinstated if the space temperature falls below 15°C.

7.79 The theatre's control panel should include:

- plant status indication;
- clearly-readable temperature and humidity gauges; and
- a means of adjusting the set-point for temperature (see paragraphs 6.32–6.34).

The theatre's ventilation-plant status indication should also be located at the staff control base.

7.80 Where it is considered necessary to fit a humidifier, it should be selected to humidify to 40% saturation at 20°C during external winter design conditions. The cooling coil should be able to remove sufficient moisture so that 60% saturation at 20°C is not exceeded during external summer design conditions.

7.81 Each operating suite should be served by an independent supply and extract plant.

Ventilation of operating department ancillary areas

General

7.82 There are advantages in providing mechanical ventilation to all areas of the department. Maintaining operating-suite air-flow patterns is simpler; grilles and diffusers can be sited to eliminate condensation on windows. Where radiators or embedded wall or ceiling panels are installed, they should be confined to the corridors and staff-only areas of the department.

Ventilation requirements

7.83 Appendix 3 gives guidance on the operating department areas in descending order of cleanliness, and this should be considered in the overall design of the department ventilation systems. The specified flow rates of air through doors given in Appendix 5 for the operating suite are not necessary for other areas of the department; however, air-flow directions must be maintained from the clean to the less clean areas.

7.84 All windows in the department should be double-glazed and hermetically-sealed in order to ensure that the desired air-flow pattern is maintained under all external environmental conditions and to avoid infestation. Trickle vents, if fitted, should be sealed.

Systems design

7.85 The design of the ventilation system for ancillary rooms depends on the overall configuration of the department. The ancillary rooms' plant may need to be interlocked to the theatre suite's plants so that reverse air-flow patterns do not occur.

7.86 Extract grilles should be sited and balanced to promote air movement along the clean and access corridors towards the reception/transfer areas. This should not affect the air distribution in the operating suite(s).

Reception

7.87 The aim in these areas is to provide comfortable conditions, having regard to the movement-control requirements of the department as a whole. The number of air changes will depend on the particular design.

Sterile pack bulk store

7.88 The store needs to be maintained at a positive pressure in order to preserve the cleanliness of the outside of the packs; six air changes are recommended.

Recovery

7.89 The air-change rate in the recovery room will be rather higher than that needed merely to provide clean, comfortable conditions, as it is necessary to control the level of anaesthetic gas pollution; 15 air changes are recommended, with a balanced air flow.

7.90 The supply air terminals should be ceiling-mounted above the foot-end of the bed. Extract should be at low level (bed height or below) behind the bedhead or in the corners. This will establish a clean air-flow path so that all reasonable steps are taken to reduce the risk of staff inhaling anaesthetic gases exhaled by recovering patients.

Ultra-clean ventilation systems

General requirements

7.91 The design philosophy of a conventionally ventilated operating suite is based on the need to dilute contaminants and control both the condition and movement of air in an operating suite. Ultra-clean ventilation (UCV) is a means of significantly increasing the dilution effect by providing a large volume of clean filtered air to the zone in which an operation is performed and sterile items are exposed. Air is discharged above the operating zone and, while not truly laminar, its downward displacement purges the clean zone of any contaminants and particles generated within it. The air flow in and around the clean zone also serves to prevent particles originating outside the zone from entering. The resulting reduction in contaminants has been shown to significantly reduce post-operative sepsis following certain orthopaedic procedures.

7.92 The number of bacteria that are present in the air at the wound site and exposed surgical items is dependent on the operating team, their procedural discipline, choice of clothing and the type of UCV system. Ultra-clean air is defined as that containing not more than 10 CFU/m^3.

7.93 UCV systems are very successful in reducing contaminants at the wound site, so it is often considered that there is no need for complex air-movement control schemes in the rest of the suite. However, when designing the ventilation scheme, it should be noted that the users may switch the UCV terminal to set-back when non-orthopaedic surgery is taking place. This is because the high air-flow rate can cause increased moisture evaporation of exposed tissue, which may be detrimental to the surgical outcome. In recognition of this, the ventilation scheme should be capable of providing operating conditions to at least a conventional theatre standard throughout the suite with the UCV in set-back mode. It should also be remembered that suitable levels of ventilation will always be required in the peripheral rooms.

7.94 UCV systems can be designed and built from first principles; or a range of bespoke modular units of varying shapes and sizes are available, each manufacturer having a slightly different approach to UCV design. Some systems are fitted with partial or full walls to delineate the clean zone and direct a laminar or exponential downflow of air within it. Other designs utilise slotted linear supply terminals to produce an air curtain around the clean zone together with laminar-flow diffusers to provide a downward-displacement supply within it. **Notwithstanding any variation in the design philosophy, all UCV systems will be required to completely achieve the performance standards set out in Chapter 8.**

7.95 As with conventional theatres, each UCV operating suite should have its own dedicated AHU to the standard set out in Chapter 4.

7.96 To ensure operational flexibility and permit routine maintenance, AHUs should not be shared between suites.

7.97 In retrofit installations, site conditions may preclude individual AHUs for each suite. In these circumstances, an AHU may be shared between not more than two operating suites, providing each suite has its own control of temperature.

7.98 An accessible air-flow measurement test-point should be provided in the branch supply duct to each theatre so that the primary air volume to each UCV canopy can be determined.

7.99 In addition, the branch supply and extract should be capable of being physically isolated and the main air-flow rate reduced so that either suite can be taken out of use without detriment to operating conditions in the other.

7.100 An inherent feature of a UCV system is its large air flow, so it is essential to recirculate the air supplied to the operating theatre and/or to recover its energy in order to optimise operating costs.

7.101 The primary fresh-air volume supplied to a UCV suite will be the same as in a conventional suite, and it should be dispersed to the rooms in the suite in the same manner. This is an important aspect of the design. Requests by UCV suppliers for increased primary air-supply volumes should be resisted.

7.102 Laying-up in the clean zone is preferable for infection control reasons. Where a preparation room/sterile pack store is provided, a transfer grille should be installed in the preparation room/theatre door.

7.103 If the preparation room is intended to be used for laying-up instruments, a pressure stabiliser will be required between the preparation room and theatre. It should be fitted with a stand-off baffle

to prevent air transfer disturbing the ultra-clean air-flow distribution.

7.104 Separate scrub-up or disposal facilities are not necessary for air cleanliness, although operational policy may prefer such a provision. However, a separate anaesthetic room should be provided.

7.105 There is no aerobiological reason why two or more UCV systems should not be installed in a common area as long as adequate spacing is provided. This type of arrangement is known as a "barn theatre" and requires special design considerations and operational discipline.

7.106 The relative positions of the UCV units, temperature control range and location of doors and openings to other areas will all significantly affect the air flow at the operating positions.

Types of UCV system

Remote plant systems

7.107 In a remote plant system, all air-conditioning equipment is located outside of the operating room, except for the unidirectional air-flow terminal, terminal filter, air diffuser and the return-air grilles (see Figure 6).

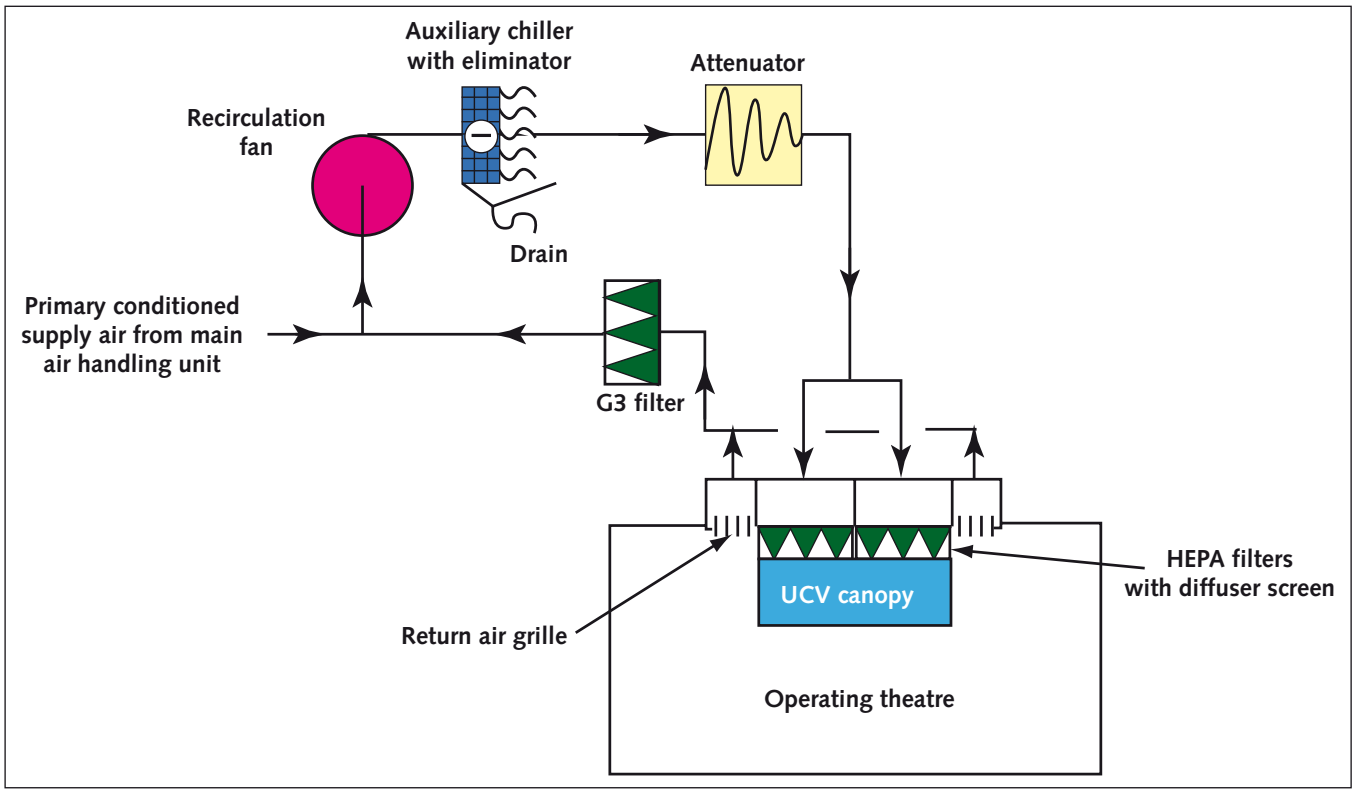
7.108 This arrangement is the preferred option for new installations as it has the following advantages:

- recirculation fans are located outside the theatre, thus reducing noise. Multiple recirculation fans can be replaced by a single fan unit with its drive out of the air stream;
- casual heat gains from recirculation fan(s), canopy lights, equipment and people within the theatre can be removed by a chiller battery in the return air stream. This will prevent heat build-up in the theatre;
- return-air filters can be changed without needing access to the theatre, making routine maintenance more feasible;
- the opportunity exists to locate HEPA filters in the primary supply duct rather than the theatre terminal. This will reduce the number of filters required and allow them to be changed without entering the theatre.

Modular systems

7.109 Modular systems are frequently used in retrofit applications. Vertical or horizontal units are available.

Figure 6 UCV theatre with remote air recirculation



7.110 Vertical-flow modular units comprise a ceiling-mounted air-terminal module containing return-air filters, return-air fans, final filter and air diffuser. Primary air is supplied by a remote air-conditioning unit at the volume and to the standard required for a conventional operating suite (see Figure 7).

7.111 Horizontal- or cross-flow modular units comprise a wall-mounted air-terminal module standing vertically to produce a horizontal flow of air and containing final filter/diffuser, return-air filters and fans. The module may incorporate a full air-conditioning unit or be supplied with fresh air from a separate primary air-conditioning system.

Vertical-flow UCV systems

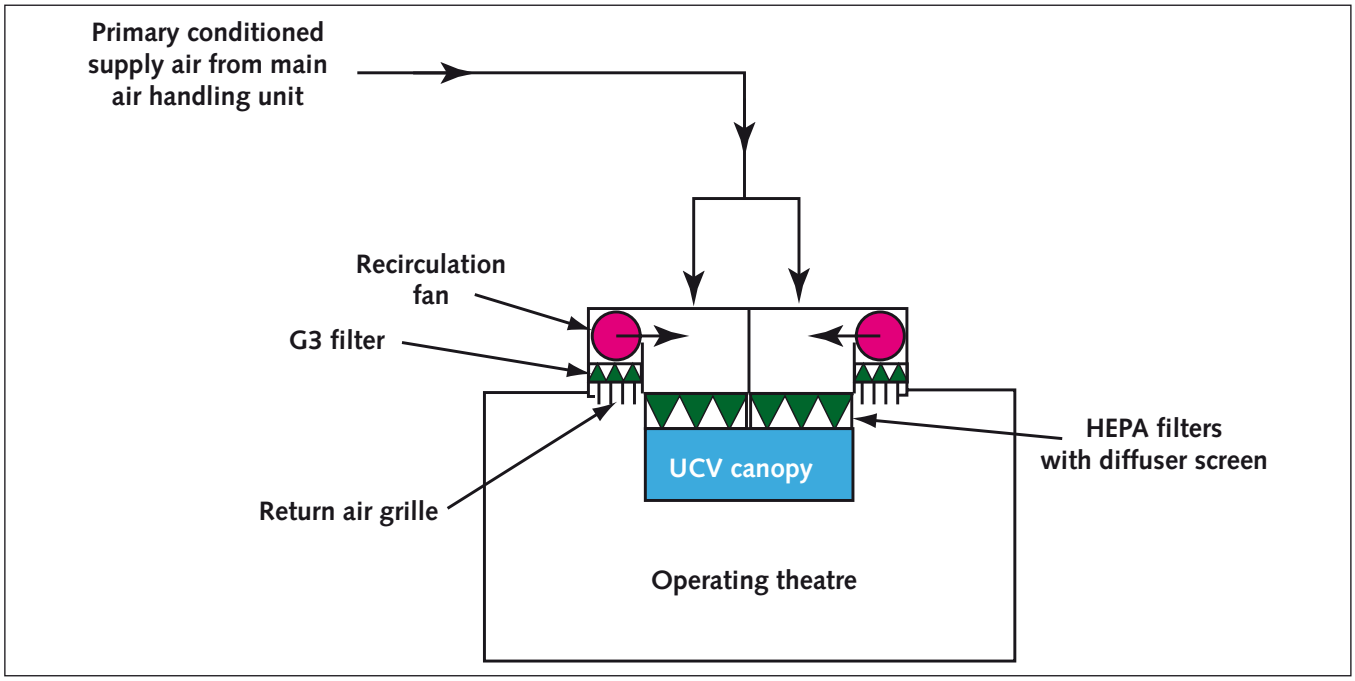
7.112 Vertical-flow systems have a superior performance and are more effective at reducing infection risks. Air-curtain or partial-wall systems are acceptable, but are known to be more susceptible to problems arising from performance deterioration, poor operating-team discipline and high occupancy rates than is the case with full-wall systems. A full wall is considered to be any wall terminating not more than 1 m above the finished floor level.

7.113 Because of the large volume of air being moved in a relatively small space, the siting of the return-air grilles can cause short-circuiting of the air discharged through the UCV terminal. If the return-air grilles are positioned at high level, partial walls should be provided to control short-circuiting. For a 2.8 m × 2.8 m terminal, the partial walls should be not less than 1 m from the operating room walls. The clearance should be increased proportionally for larger terminals (that is, 1.15 m for 3.2 m × 3.2 m units; and 1.25 m for 3.5 m × 3.5 m units). In all cases, the side walls should terminate at 2 m above floor level.

7.114 Siting the return-air grilles around the periphery of the theatre at low level will eliminate short-circuiting, remove the need for partial walls and give an improved air-flow path. In any event, there should be an air-out path on each face or in each corner of the theatre. These may be provided by combination of pressure stabilisers and passive or active low-level extract grilles. Failure to provide air-out paths on all faces of the theatre may result in the surplus air causing entrainment into the clean zone.

7.115 Vertical systems should have a clean zone large enough to encompass the operating site and all of the instrument trays likely to be needed for the surgical procedures to be undertaken. Ophthalmic and minor hand surgery would typically require a 1.4 m circular or rectangular terminal. For major orthopaedic procedures, a minimum size of 2.8 m × 2.8 m will be required. This is the area projected on the floor under the supply air terminal within the partial walls, full walls or air curtain. Any air outside this zone cannot be guaranteed to be ultra-

Figure 7 UCV theatre with modular system



clean although – given the dilution factor – the level of microbiological contamination will be much lower than the general level in a conventional operating room. The use of lines or a coloured area on the floor delineating the extent of the clean zone will assist staff and is therefore essential.

7.116 When upgrading an existing conventional theatre to an ultra-clean standard, the only solution may be the installation of a modular system. In these units, the heat gains from the return-air fans and terminal lights may warrant the inclusion of supplementary cooling within the module. However, issues of cooling-coil drainage, condensate removal and maintenance access within the space constraints of the module may make this option impracticable. The additional cooling load should then be accommodated by conditioning the primary air to compensate.

7.117 If an existing AHU is to be retained, it may require modification to ensure that it achieves the minimum standards set out in Chapter 4. The fan may need re-rating to accommodate the change in system resistance. The cooling coil may also need to be upgraded to cater for the increased load resulting from the return-air fans and terminal lights. Failure to make adequate provision for this may make the theatre unusable during prolonged warm spells.

7.118 A factor affecting air-flow pattern is the supply-air and room-air temperature difference. When the supply-air temperature is significantly above room temperature, buoyancy effects will reduce the volume of air reaching the operating zone. If it is anticipated at design stage that this will be a regular occurrence, a system incorporating full walls should be used. Demountable extensions that convert a partial wall to a full-wall unit are available.

7.119 Convection up-currents from the surgical team and operating lamp tend to counter the movement of clean air towards the operating site; hence, the air velocity reaching the operating level is critical. The minimum velocity given in paragraphs 7.120–7.121 has been selected to take account of these factors and is greater than the theoretical minimum value.

7.120 For all vertical UCV systems, the design discharge velocities will be as follows:

Air velocity 2 m above floor level:

- partial-wall system = 0.38 m/s average;
- full-wall system = 0.30 m/s average.

7.121 In order to ensure that the terminal quadrants are in balance, the average air velocity for each quadrant should not exceed ±6% of the measured average velocity for the terminal.

Air velocity 1 m above floor level:

- all systems = 0.2 m/s minimum within the operating zone.

7.122 Chapter 8 gives details of the method of measurement.

7.123 Variable-speed recirculation fans with differential-pressure control may be the most suitable solution for maintaining consistent performance and energy saving.

Horizontal UCV systems

7.124 Horizontal UCV air-flow systems have been shown to be less effective than vertical systems and are not the preferred solution. There may be occasions, however, where architectural, engineering, economic or workload considerations prevent the installation of a vertical-flow system and only a horizontal-flow system can be installed.

7.125 Horizontal- or cross-flow modular units comprise a wall-mounted air terminal standing vertically to produce a horizontal flow of air across the operating field. The terminal module contains the final filters, air diffuser, return-air grilles, filters and fans. The module may incorporate a full air-conditioning unit or be supplied with fresh air from a separate primary air-conditioning system. In the latter case, the return-air fan power may warrant the inclusion of a supplementary cooling coil within the module.

7.126 The system should have side-wall panels at least 2.4 m apart. The panels may fold to facilitate cleaning of the theatre. The minimum height of the terminal should be 2.1 m, and a deflector at the top of the filter/diffuser will be acceptable as an alternative to a full roof. These dimensions reflect currently available equipment and may impose operational constraints in addition to a lower level of performance common to these systems.

Note

In horizontal-flow systems, personnel working between the filter and surgical wound will disperse bacteria that are more likely to contaminate exposed surgical instruments and enter the wound. This may be minimised by the use of improved clothing and operating procedure to reduce dispersion of bacteria. The use of lines on the floor delineating the extent of the clean zone and hatching or colour-coding the "no-entry" zone between the air diffuser and patient will serve to prompt staff and are therefore essential.

7.127 The air discharge velocity as measured 1 m from the diffuser face should have a mean value of 0.4 m/s. Chapter 8 gives details of the method of measurement.

Filters

7.128 The main plant's primary and secondary filters should be to the standards and in the location set out in Chapter 4.

7.129 Terminal filters should be provided within the air-flow terminal or in the air supply to it. HEPA filters grade H10 (as specified in BS EN 1822) should be installed. There is no aerobiological benefit in fitting filters of a higher grade than this, although for practical reasons most UCV manufacturers recommend the fitting of H12-grade filters.

7.130 In some modular UCV units, the terminal filter is used as a pressure equaliser to balance air flow; filters of a higher grade with a greater pressure drop may be recommended by manufacturers. The increased resistance may affect the velocity of air reaching the operating level, and there will be penalties in terms of installed fan power and higher noise levels.

7.131 The final filters should be installed in a leak-proof housing in a manner that allows the terminal unit, filters and their seals to be validated. A challenge test should be carried out during commissioning to prove the effectiveness of the complete installation.

7.132 Where UCV units are constructed in sections, a means of measuring the pressure drop across the terminal filters in each section should be provided. The pressure test-points should be located outside of the partial wall, capped to prevent air leakage and accessible within the theatre without the need to open the unit's inspection panels. Alternatively, direct-reading pressure gauges should be fitted.

7.133 The UCV system will require a return-air filter to capture the relatively coarse particles that would otherwise significantly reduce the life of the final filter. This should be at least a G3 grade to BS EN 779. In remote recirculation systems, there may be advantages in fitting a higher grade return-air filter as it will reduce the load on the terminal HEPA filters and extend their life.

Noise level

7.134 If sound-attenuating material is used to line any portion of the inside of the UCV unit, it should be non-particle-shedding and fire-resistant (see Health Technical Memorandum 05-02).

7.135 The maximum noise level in an operating room fitted with a UCV terminal of any type should not exceed 50 NR. Chapter 8 gives details of the method of measurement.

Lighting and operating lights

7.136 CIBSE lighting guide LG2 and BS EN 12464-1 give detailed information on lighting requirements. Operating luminaires should comply with the photometric requirements detailed in relevant sections of BS EN 60601.

7.137 The position of the UCV light fittings and style of partial walls, where fitted, should neither adversely disturb the air flow nor result in significant spatial variations in illuminance levels.

7.138 In vertical units, specialised task lighting should be provided by toroidal, cruciform or small multiple dome-shaped luminaires, as they have good aerodynamic properties. The ideal luminaire will have a minimal effect on the air flow regardless of where it is positioned. Large-diameter saucer-shaped luminaires should not be used in vertical-flow systems as they will occlude the air flow in the critical central zone. It is important to consider the suitability of existing luminaires when retrofitting UCV systems.

7.139 In vertical UCV installations, a minimum of 2.75 m from floor to underside of the diffuser is required to allow for supporting mechanisms and lamp articulation. When upgrading existing systems, this dimension may not be achievable; however, when parked, the lowest point of the central light stem, luminaire and articulation arms should never be less than 2 m above floor level.

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7.140 The traditional means of light support is a central column that passes through the UCV terminal and is rigidly fixed to the building structure. The position of the support therefore prevents air being supplied at the centre of the terminal. Separate supports displaced from the centre of the clean zone would lead to improved air flow.

Note

This approach was advocated in the 1994 version of this guidance but at the time of writing, no UK manufacturer has chosen to adopt this solution.

7.141 In horizontal units, the size or shape of the specialised task luminaire has little effect on the air-flow pattern.

Controls and instrumentation

7.142 The functions of the supply AHU and extract ventilation should be continuously monitored by a BMS control unit. The controls and instrumentation for the main plant are set out in Chapter 6.

7.143 UCV systems will additionally require:

- a set-back facility that can reduce the air supplied through the UCV terminal to a volume that equates to an amount not less than 25 air changes per hour of the operating room's gross volume whilst still leaving the supply AHU operating at full speed;
- a facility to turn off the entire system, the supply AHU and the UCV terminal (an emergency stop is not required);
- a read-out sufficiently large to be clearly visible from the operating table that shows the temperature of the air being supplied by the UCV terminal;
- a read-out sufficiently large to be clearly visible from the operating table that shows the relative humidity of the air being supplied by the UCV terminal;
- a red indicator light that will illuminate when either the supply AHU or the UCV terminal fails; either or both are switched off or the AHU and UCV terminal are at set-back;
- an amber indicator light that will illuminate when the UCV terminal is at set-back and the supply AHU is running;
- a green indicator light that will illuminate when both the supply AHU and UCV terminal are operating at full speed;
- a blue indicator light that will illuminate when the UCV terminal's HEPA-filter resistance causes the air delivered to fall below 80% of the design flow rate.

See Table 6.

7.144 The switching devices and indicators should be incorporated in the surgeon's panel and their functions clearly labelled. In retrofit installations, an auxiliary panel for the UCV may be the most practical option. If fitted, it should be mounted adjacent to the surgeon's panel and their control functions interlocked as necessary.

7.145 When a system is designed to have partial walls with full-wall extensions, a volume control facility may be incorporated to allow the system to be run with reduced velocity when the demountable full walls are in place. It is the responsibility of the user to ensure correct operation of the system. To assist

Table 6 Indicator-light logic table

AHU	UVC terminal	Indicator light	Comment
Off or Fault	Off or Fault	Red	Ventilation not operating at a suitable level to commence surgical procedures
Off or Fault	On (set-back)		
Off or Fault	On (full speed)		
On (set-back)	Off or Fault		
On (full speed)	Off or Fault		
On (set-back)	On (set-back)		
On (full speed)	On (set-back)	Amber	Ventilation provided to at least conventional theatre standard
On (full speed)	On (full speed)	Green	Full UCV standard conditions
–	–	Blue	HEPA-filter resistance causing low air flow

the user, an explanatory notice should be included on the theatre's control panel.

7.146 A direct-reading gauge should be fitted in the theatre to show a representative pressure drop across the final filters. If the UCV control box is located out of the theatre and has a means of manually adjusting the return-air fan speed, it should also be fitted with a direct-reading differential-pressure gauge. The means of adjusting the return-air fan speed should be lockable to prevent casual adjustment. The direct-reading gauges should be fitted with a means of indicating the correct operating pressure range.

7.147 The UCV-unit manufacturer's control box should be located in an accessible position, preferably in the operating department adjacent to the operating theatre that it serves. A service corridor, if provided, is an ideal location. The control box should be clearly labelled with the identity of the operating theatre that it serves.

Extract systems

7.148 Extracts may be provided for a variety of reasons including:

- simple odour control (for example in a WC or mortuary);
- to receive and remove moisture-laden air (for example in a kitchen);
- as part of a combined supply/extract balanced system (for example in an operating suite);
- to capture a hazardous substance at source (for example a safety cabinet).

7.149 Devices that use an inflow of air to control exposure of staff to hazardous substances are classified as LEV systems under the COSHH Regulations.

7.150 An LEV system may comprise a self-contained unit incorporating its own carbon filter such as a simple bench-top fume cupboard. Alternatively, it may be a complete ventilation system comprising a make-up air supply, multiple-exhaust-protected workstations, branch and central extract ductwork, duplex extract fans and a high-level discharge terminal. It may also incorporate a special filtration system appropriate to the hazardous substance being controlled. Such systems could be required for workshops containing woodworking machinery or large centralised pathology laboratories housing multiple safety cabinets, cut-up benches, fume cupboards and specimen stores.

7.151 Typical LEV systems found in healthcare premises include:

- microbiological safety cabinets and Category 3 containment rooms;
- fume cupboards and plate-staining equipment;
- welding-fume extracts;
- woodworking-machinery dust collectors;
- battery-charging bay extracts;
- powered plaster and bone saws;
- pharmaceutical preparation cabinets and tablet machines;
- dissection benches, cut-up benches and some specimen stores;
- isolation facilities for medium- and high-risk infectious diseases;
- dental furnaces, grinders and polishers.

7.152 General design information and guidance for LEV systems is produced by the Health and Safety Executive (HSE) as HS(G)37. Information on the design and installation of microbiological safety cabinets is given in BS5726 and that for fume cupboards is given in BS EN 14175. Their recommendations should be closely followed.

7.153 LEV systems are statutory items that are subject to an independent inspection and test at least every 14 months.

Hood extract systems

Special requirements

7.154 Extract canopies are required over steam-and-heat-emitting appliances, for example sterilizers, and catering and washing equipment.

7.155 Perimeter-drain gulleys and corrosion-proof grease eliminators should be provided on kitchen hoods.

Typical arrangements

7.156 An air-flow velocity of 0.25 m/s to 0.5 m/s is suitable to collect and remove evaporation of steam and cooking vapours. Excessive velocities are wasteful of power and generate noise.

7.157 The lowest edge of the canopy should be 2 m above finished floor level, with a minimum of

300 mm overhang beyond the edge of the equipment on all sides.

7.158 A compact arrangement of equipment (but with access for maintenance) will minimise the canopy area and hence reduce the air volume necessary to achieve the optimum capture velocity.

7.159 Hoods required for the control of heat gain and vapours may be connected to the general extract system when it is convenient to do so, but where non-corrosive ductwork materials are necessary, a separate discharge is preferred.

7.160 Lighting and internal divider plates are often included in the perimeter of large canopies; however, built-in shelving systems are not recommended as they interfere with the air flow and constitute a maintenance problem.

Control of hood extracts

7.161 Provided that it does not interfere with the operation of the department when not in use, the ventilation system for the hood extract and any associated supply make-up can be shut down. To this end, local or automatic-use control should be provided.

Bench extract systems

Special requirements

7.162 Bench extract ventilation is required in departments such as pathology and mortuary where activities involve the release of malodorous fumes or hazardous substances. Where hazardous substances are being controlled, the system should be designated an LEV.

7.163 Processes that produce hazardous vapours, fumes, dusts or vapours should be enclosed or semi-enclosed in a suitable cabinet or exhaust-protected workstation.

Typical arrangements

7.164 Each ventilated position will usually be accommodated in a continuous run of benching, which should not be more than 650 mm from front to rear and which should be provided with a continuous upstand at the rear. Each position should have a 1200 mm × 150 mm linear extract grille mounted on a purpose-designed plenum box (incorporating guide vanes as necessary), with its face flush with the upstand. The bottom of the grille should be as close as practicable to the level of the working surface (usually 75 mm above, to allow for cleaning). The minimum velocity across any part of the grille should be 1 m/s. The grille should be readily demountable to allow for cleaning.

Control of bench extract systems

7.165 Provided that it does not interfere with the operation of the department when not in use, the ventilation system for the bench extract and any associated make-up supply can be shut down. However, a run-on timer with a minimum setting of 30 minutes must be provided. To this end, local or automatic-use control should be provided.

Safety cabinet and fume-cupboard extract systems

7.166 Safety cabinets and fume cupboards are devices that use an inflow of air to control exposure of staff to hazardous substances. The units, their exhaust systems, filters, fans and discharge terminals are all classified as local exhaust ventilation (LEV) systems under the COSHH Regulations. The make-up air system to a room that contains an LEV system should also be considered as an essential part of the system and be included in the LEV classification.

7.167 Information on the design and installation of microbiological safety cabinets is given in BS5726 and that for fume cupboards is given in BS EN 14175. Their recommendations should be closely followed. The Advisory Committee on Dangerous Pathogens (ACDP) publishes 'The Management, Design and Operation of Microbiological Containment Laboratories' covering the general environment in which they are used and operational considerations.

Special requirements

7.168 The supply-air system should not distort the unidirectional and stable air pattern required for fume cupboards and microbiological safety cabinets. In general, supply-air ceiling diffusers should not discharge directly towards fume cupboards or safety cabinets, unless the terminal velocity is such that the air-flow pattern of the cabinet is unaffected. The design should ensure that high air-change rates and/or the opening and closing of doors do not have any adverse effect on the performance of safety cabinets or fume cupboards. A damped door-closure mechanism may help.

7.169 In order to safeguard the user, all safety cabinets and fume cupboards must be fitted with a clear indication that they are operating correctly. Direct-reading gauges or falling-ball indicators are preferred (in addition to electronic pressure indicators). The system should be set to audibly alarm if the face velocity falls below the minimum safe operating level.

Arrangements for safety cabinet installations

7.170 A Class 1 microbiological safety cabinet must be specified for routine work involving Group 3 pathogens. It should be housed in a Category 3 containment room. Information on containment rooms is issued by ACDP in 'The Management, Design and Operation of Microbiological Containment Laboratories'.

7.171 Siting and installation of microbiological safety cabinets are of particular importance because:

- protection afforded to the operator by the cabinet depends on a specific and stable unidirectional air flow through the open front;
- protection to the environment by the cabinet depends on HEPA filters. The exhaust air should never be considered as totally free from microbiological hazard.

7.172 Extract air from a microbiological safety cabinet is HEPA-filtered prior to discharge to the outside. The extract ductwork should as far as practicable be kept under negative pressure while inside the building.

7.173 Current standards permit the installation of microbiological safety cabinets with integral fans, provided that the extract ductwork can be kept short (that is, less than 2 m); such an installation, however, is likely to be noisy and is not recommended for use in new buildings.

7.174 The discharge from the cabinet should be fitted with a back-draught damper. In multiple installations where several cabinets discharge into a common extract and discharge duct, it must be possible to isolate each cabinet from the system when not in use.

7.175 Roof-level discharge, wherever practicable, is preferred since it removes much of the uncertainty over air re-entering the building through ventilation inlets and/or windows. In such an installation, the extract fan should be situated separately from the cabinet and close to the discharge outlet, to maintain the duct within the building under negative pressure. The discharge point on a flat roof should be through a 3 m high terminal. This is required to safeguard staff who may need to periodically access the roof for maintenance. This requirement will also be applicable to fume-cupboard discharges.

7.176 Where this is impracticable, discharge into the room via a double HEPA filter has been accepted; the preferred method, however, is to discharge above the roof line as above.

Arrangements for fume-cupboard installations

7.177 The primary factors which contribute to the effective performance of fume cupboards include:

- an adequate volume of supply air;
- an effective exhaust system to promote the safe dispersal of waste products to atmosphere.

7.178 The air velocities through sash openings must be sufficient to prevent hazardous materials from entering the laboratory while avoiding excess flow rates that interfere with the investigation process. The design velocity must be maintained irrespective of whether the sash opening is varied or whether doors or windows are open or closed. Variable air volume (VAV) cupboards are available, which will offer a reduction in energy costs.

7.179 The possibility of a fire or explosion which may not be contained by a fume cupboard must always be considered. A fume cupboard should not, therefore, be sited in a position where exit to an escape route will necessitate passing directly in front of it.

7.180 Fume-cupboard fans should be installed as near as possible to the termination of the duct, thus maintaining the maximum amount of ductwork at negative pressure.

7.181 Where there are adjacent buildings with opening windows, or where down-draughts occur, it may be necessary to increase the height of discharge ducts in order to achieve adequate dispersal. In complex locations, air-flow modelling or wind-tunnel tests may be required to determine the optimum height of the stack (see also paragraph 7.174).

7.182 Fume cupboards for certain processes must have separate extract systems; however, if permissible, individual fume-cupboard exhaust systems may discharge via non-returning dampers into a single

collection duct rather than having a large number of separate stacks. The collection duct should:

- have a large cross-sectional area to minimise its effect on individual exhaust systems;
- be open to atmosphere upstream of the first connection; and
- be designed to discharge a total air volume at least equal to the combined individual extract systems.

7.183 Individual fume-cupboard extract systems, discharging either directly to atmosphere or into a collection duct, do not require duplex fans. However, a collection duct designed to provide dispersal of effluent from a number of individual extracts should have duplex fans with automatic change-over.

7.184 Some fumes are particularly corrosive, so the choice of material for the ductwork and type of extract fan fitted should reflect the nature of the fume being conveyed.

Control of extract systems

7.185 It is desirable to provide local control of safety cabinets in order to maximise the life of the HEPA filter and to permit the sealing of the cabinet and room for fumigation if spillage occurs.

7.186 To cope with the risk of an accident or spillage outside safety cabinets, a panic button should be provided to switch off the supply to that area and to discharge all extracted air to atmosphere.

7.187 In pathology departments, it is necessary to have one or more microbiological safety cabinets and one or more fume cupboards available for use at all times, including weekends; therefore, local overriding controls for all these items and any associated ventilation plant will be necessary.

Plantroom ventilation

General requirements

7.188 Plantrooms need to be ventilated to maintain acceptable temperatures for satisfactory operation of the plant and controls, and for maintenance activities. In the case of plantrooms housing combustion equipment, a secondary function of the ventilation is to provide make-up air for the combustion process.

7.189 The air required should be introduced into the space through inlets positioned to minimise the discomfort to occupants. It should be ensured that they are not blocked, closed deliberately (except in the case of fire shutters if required) nor rendered inoperative by prevailing winds.

Typical LEV discharge stacks

7.190 Plantroom ventilation air should not be used for any other purposes, such as make-up air for extract. Where the plantroom contains combustion equipment, the appliance pressure must not fall below the outside air pressure.

7.191 Specialised healthcare air-handling equipment must not be located in a fire compartment that houses combustion equipment.

7.192 Statutory regulations for plantroom ventilation are contained in the Building Regulations Part J, and further guidance in given in the CIBSE Guides A and B.

7.193 Plant noise is subject to the Control of Noise at Work Regulations 2005 and should not exceed 80 dB(A) within a plantroom. It should be reduced to lower levels where the plant is near to departments sensitive to noise.

Assessment of ventilation levels

7.194 Ventilation requirements must take into account all heat sources within a plantroom and, where there are large glazing areas, solar gains. The ventilation rate should limit the maximum temperature within the plantroom to 32°C.

7.195 As the level of equipment operating during mid-season and summer is often lower than winter conditions, and the cooling effect of the outside air is reduced, it is necessary to calculate the minimum volume for each season of operation, and the inlet and outlet grilles or fan sizes should be chosen to cater for the largest seasonal air volume.

7.196 Replacement air should not be drawn through pipe trenches or fuel service ducts. Where metal ducts penetrate walls and floors, effective sealing should be provided to confine the ventilation to the boiler room and to meet fire protection requirements. Penetration of fire-barrier walls by ventilation ducts should be avoided if possible.

7.197 Fire dampers in plantroom ventilation ducts should be electrically interlocked with the boiler plant.

7.198 Care must be taken to prevent any noise generated in the plantroom emerging from natural or mechanical ventilation openings to the detriment of the surrounding environment. Particular care is necessary with mechanical flue draughts and fan-diluted flue systems.

7.199 Information on required air volumes in contained in the CIBSE Guides A and B.

7.200 Where combustion plant is installed, the high-level (outlet) openings should be sized to cater for the total ventilating air quantity, and the low-level (supply) openings sized to cater for the total combined ventilating and combustion air quantity.

Choice of ventilation system

7.201 Ventilation air may be introduced and exhausted by either natural or mechanical means or a combination of both; however, where possible, natural systems are preferred.

7.202 Generally, small installations at or above ground level should have their combustion and ventilation air provided by natural means, employing both high- and low-level openings.

7.203 Basement, internal and large installations at or above ground level will usually require a combination of natural and mechanical ventilation. If the air-flow rate is difficult, both supply and extract may require mechanical means.

7.204 Whether natural or mechanical, the system should be designed to avoid both horizontal and vertical temperature gradients. Both inlet and outlet openings should be placed on opposite or adjacent sides of the building to reduce the effect of wind forces.

7.205 Where mechanical air supply is employed, electrical interlocks with the boiler plant should be provided to prevent damage in the event of failure of the supply fan(s) once the air volume is established.

7.206 The necessary free opening areas for a naturally ventilated plantroom may be calculated using the method in the CIBSE Guides A and B.

7.207 A combined natural and mechanical ventilation system should allow for natural extract at high level, to take advantage of convective forces in the room, with mechanical supply at low level. The high-level natural ventilators should be sized to cope with the total quantity of ventilation air, as above.

7.208 To prevent leakage of flue gases and to ensure that the flue draught is not impeded at any time, air pressure in the boiler room must not exceed the prevailing outside pressure. Therefore, the fan duty should exceed the calculated total combined combustion and ventilation air quantity by at least 25%. Fan-powered inlets should be arranged to flow outside air into the space at a point where cross-ventilation will ensure pick-up of heat without causing discomfort to occupiers.

7.209 Where it is impractical to provide sufficient natural ventilation to remove the heat emitted by the plant, both mechanical supply and extract will be required.

7.210 The high-level extract should be sized to cater for the total ventilating air quantity, and the low-level supply should exceed the total combined combustion and ventilating air quantity by at least 25%, as above.

Ventilation of hydrotherapy suites

General requirements

7.211 In a hydrotherapy suite, heat recovery should be via a heat pump.

7.212 The quantity of supply air should be calculated as 25 L/s per square metre of wetted surface, with the wetted surface taken as 110% of the pool water surface area.

7.213 A recirculation plant is recommended with fresh air make-up to the standard required by the Building Regulations Part F – Non-domestic Buildings. In practice this may need to be increased to control condensation.

7.214 As far as practicable, recirculated pool air should be provided to the ancillary changing and recovery accommodation, with the only extract from the toilets, laundry/utility room and pool hall.

7.215 Supply air to the pool hall should be introduced at high level and directed towards the perimeter to mitigate condensation, with extract air taken from directly over the pool.

Control of hydrotherapy pool installations

7.216 The supply and extract fans should be interlocked so that the supply fan does not operate until flow is established within the extract system.

7.217 Time-clock control should be provided, with a local override switch to extend the normal operating period as required.

7.218 Night set-back temperature (in the range of 21–25°C) and high humidity control (in the range of 60–75% sat) should be provided to override the time-clock in order to prevent condensation. The exact set-points should be ascertained post-installation.

7.219 A remote indication panel should be provided in the pool hall, giving a visual display of the pool water and pool air temperature.

8 Validation of specialised ventilation systems

Definitions

Commissioning. Commissioning is the process of advancing a system from physical completion to an operating condition. It will normally be carried out by specialist commissioning contractors working in conjunction with equipment suppliers. Commissioning will normally be the responsibility of the main contractor.

Validation. A process of proving that the system is fit for purpose and achieves the operating performance originally specified. It will normally be a condition of contract that "The system will be acceptable to the client if at the time of validation it is considered fit for purpose and will only require routine maintenance in order to remain so for its projected life."

Commissioning is often subdivided into sections (for example AHU, automatic controls, air-side balance, building fabric and fittings). Each section may be commissioned by its specialist installer, and they are often accepted in isolation. Validation differs from commissioning in that its purpose is to look at the complete installation from air intake to extract discharge and assess its fitness for purpose as a whole. This involves examining the fabric of the building being served by the system as well as inspecting the ventilation equipment fitted and measuring the actual ventilation performance.

It is unlikely that "in-house" staff will possess the knowledge or equipment necessary to validate critical ventilation systems such as those serving operating suites, pharmacy clean rooms and local exhaust ventilation systems. Validation of these systems should therefore be carried out by a suitably qualified Authorised Person appointed by the client.

It is anticipated that training and certification in the validation of specialised healthcare ventilation systems for Authorised Persons will become available during the life of this Health Technical Memorandum.

Commissioning

8.1 Commissioning is an essential process for ventilation systems. It is therefore important that adequate provision for the process be made at the design stage of the project. Procedures for commissioning air-handling systems are given in CIBSE Commissioning Codes and BSRIA Application Guide Set COMPAK 1.

8.2 The duct-sizing procedure should take into account the requirements of system balancing, and the position and number of regulating dampers included in the design should be sufficient for this purpose.

Location of dampers and test holes

8.3 Balancing/commissioning dampers should be installed in each branch of the distribution ductwork.

8.4 Test holes for the measurement of air-flow should be provided at carefully selected points in main and all branch ducts. The number and spacing of holes are given in the BSRIA Application Guide Set COMPAK 1. Their positions must be identified at the design stage.

8.5 The test positions need to be accessible for commissioning to take place. They may also be required for subsequent annual verification of the system performance, so they should be capped to prevent air leakage but not covered by permanent lagging.

8.6 The measurement point should be in a straight length of duct as far away as possible from any upstream bends, dampers or other elements that could cause disturbance to the air flow. The actual location should be:

a. at least 1.5 duct diameters upstream of sources of turbulence (such as dampers and bends);

b. if (a) is not possible, ten duct diameters downstream of dampers, bends or tees, and five

duct diameters downstream of eccentric reducers;

c. where there is enough space round the duct to insert the Pitot tube and to take readings;

d. where the duct has a constant cross-sectional area.

8.7 Test holes for measuring total air-flow from a fan should be located either four duct diameters upstream or ten duct diameters downstream of the fan. Provision should also be made for ascertaining the direction and measuring the speed of rotation.

Commissioning personnel

8.8 It is unlikely that one particular individual will have all of the required commissioning skills; a commissioning team is therefore usually needed. The objective of commissioning is to ensure that the necessary performance and safety requirements are met.

8.9 During the commissioning process, a great deal of information will be generated, which will form an invaluable future source of reference about the plant. It is essential to ensure that it is collected together in the form of a commissioning manual and handed over to the client on completion of the contract together with the as-fitted drawings. The information should be both in hard copy and electronic format.

8.10 In order to be successful, the commissioning process must start before practical completion, as many parts of the system will become progressively less accessible. The correct installation of those parts will need to be witnessed, and leak-rate tests carried out as construction proceeds. Failure to establish responsibility for commissioning early enough will delay the completion of the project or lead to unsatisfactory plant performance.

Commissioning brief

8.11 The commissioning team will require a detailed brief from the system designer. This should include:

- a user brief comprising a description of the installation and its intended mode of operation;
- the precise design requirements with regard to the scheme of air movement, room static pressures, supply and extract air-flow rates and acceptable tolerances;
- full details of the design conditions, both inside and out, for winter and summer together with the control strategy;
- the equipment manufacturer's type-test data, commissioning, operation and maintenance recommendations;
- drawings showing the layout of the system, positions of air-flow measurement test-points, dampers, regulating devices and filters within the duct runs, together with sizes of ducts and terminal fittings. It will save time if these drawings are annotated with the design volumes and static pressures required at each branch and outlet point (see Table 7 for information to be included on schematic drawings);
- wiring diagrams for all electrical equipment associated with the air-handling systems including motor control circuit details and any interlocking and safety devices such as emergency-stop buttons adjacent to the item of plant.

8.12 CIBSE's Commissioning Code A – 'Air distribution systems' provides full guidance on the information that will be required by the commissioning team.

8.13 The designer should include in the contract documents instructions on verifying the accuracy of test instruments, which should be supported by reference to relevant calibration certificates.

8.14 On completion, the system should be operated by the contractor as a whole and subject to performance tests in accordance with the contract requirements. For critical systems, these should include independent validation of the system performance on behalf of the client.

8.15 The commissioning process should be carried out in the order in which it appears in this guidance document; that is, the static checks and visual inspections should be followed by the dynamic and performance tests (as outlined in this chapter) and finally the handover procedures.

8.16 Prior to dynamic commissioning, it is essential that builders' work in the area served by the system is complete, all rubbish and dust is removed, Institute of Plumbing service (IPS) panels are in position and ceiling tiles are in place and clipped. Floors should be mopped, and visible dust removed from all other surfaces.

8.17 Once the system is shown to meet the design intent, the handover documentation should be

Table 7 Information to be provided on schematic drawings

Items in system	Information to be provided
Fans	Fan total pressure Volume flow rate at high and low speed Maximum motor current
Plant items	Type and identification numbers from equipment schedules Fluid and air-volume flow rates Fluid and air-side pressure losses Dry-bulb temperatures Wet-bulb temperatures Humidity
Dampers, including motorised and fire dampers	Identification numbers from equipment schedules Location Identification number Volume flow rate
Main and branch ducts	Dimensions Volume flow rates and velocities Identification numbers from equipment schedules
Terminal	Location Identification number Grille or diffuser factor Volume flow rate and neck velocity Operating static pressure
Test holes and access panels	Location Identification number
Controllers	Set-points

Notes: Fan total pressure is the difference between the total pressure (static pressure + velocity pressure) at the fan outlet and the total pressure at the fan inlet.
Where volume flow rates are variable, maximum and minimum values should be provided.

completed. In the event of performance not being acceptable, the matter should be dealt with in accordance with the contract arrangements.

Pre-commissioning checks

8.18 The pre-commissioning checks consist of visual inspection, manual operation of equipment, static measurements and functional tests of individual components. They should be carried out prior to setting the system to work and undertaking the dynamic commissioning process set out in paragraphs 8.29–8.42.

Standard of installation

8.19 During the installation of the system, the following must be witnessed by either the client or his representative:

- that the plant and installations have been provided and installed in accordance with the design specification and drawings;
- that only approved sealants have been used in the installation;
- that all components function correctly;
- that the satisfactory sealing of access doors and viewing ports have been carried out;
- that air-pressure tests and air-leakage tests on ventilation ducting have been carried out in accordance with the methods set out in the HVCA's (1998) 'DW/143 – A practical guide to ductwork leakage testing'. It is usual to carry out these tests a section at a time as the ductwork is installed and before its insulation is applied. The results must be recorded in the commissioning manual;
- that gaps around doors and hatches are as specified in the design;
- that the correct operation of pressure stabilisers, and control, isolating and non-return dampers have been checked and installed in the correct orientation for air flow;

- that test holes have been provided in their specified locations and are sealed with suitable grommets;
- that control dampers are secured and their quadrants fitted correctly;
- that any interlocks are operative and in accordance with specification;
- that the electric circuits are completed, tested and energised;
- that electric motors have been checked for correct direction of rotation at both full speed and set-back;
- that cooling and heating media are available at correct temperatures and pressures, and in specified quantities;
- that the air-conditioning plant's components and controls function correctly;
- that the air-conditioning plant's interlocks and safety controls function correctly;
- that the plant is physically complete, insulation is applied, and all ducts and pipework are identified as specified;
- that the building housing the ventilation plant is generally in a fit condition for commissioning and performance tests to commence – that is, windows, doors, partitions etc are completed, surfaces sealed and their final finish applied;
- that the areas containing the ventilation plant and those being served by it are clean;
- that access to all parts of the system is safe and satisfactory.

Cleanliness of installation

8.20 During installation it must be established that ductwork is being installed to the "advanced level" as defined in the HVCA's (2005) 'TR/19 – Guide to good practice: internal cleanliness of ventilation systems'. This specifically includes ensuring that ductwork sections arrive on site and are stored with their open ends sealed and that open ends remain sealed during installation to prevent the ingress of builders' dust.

8.21 Should any doubt exist as to whether the guidance has been observed, the ducts must be cleaned internally to restore them to this standard before being taken into use.

8.22 Builders' work ducts of brick or concrete must be surface-sealed to prevent the release of dust before being taken into use.

8.23 The area around the supply-air intake must be free of vegetation, waste, rubbish, builders' debris or any other possible source of contamination.

Certification of equipment

8.24 The following test certificates should be assembled by the commissioning team and be available for inspection at any time during the contract period. They will form part of the handover information and should be placed in the commissioning manual:

- type-test performance certificates for fans;
- pressure-test certificates for:
  - heater-batteries;
  - cooling coils;
  - humidifiers (if appropriate);
- type-test certificates for attenuators;
- type-test certificates for primary and secondary filters;
- individual test certificates for HEPA filters.

Equipment tests

8.25 Prior to setting the system to work, the checks in paragraphs 8.26–8.28 should be witnessed, and proving tests should be carried out as detailed.

Filters

8.26 The quality of filter housing and, in particular, seals is a critical factor in maintaining the efficacy of the filtration system by ensuring that air does not bypass the filter panels. Therefore, the following checks should be made:

- filter seals should be fitted and in good condition;
- filters should be installed correctly with respect to air flow;
- bag filters should be installed so that the bags are vertical and their pockets free;
- HEPA filters should be installed in a sealed housing and their seals tested to DIN 1946 if specified;

- all filters should be checked to ensure they are free of visible damage;
- the differential-pressure indicators should be checked for accuracy and to see that they are marked with the initial and final filter resistance.

Drainage arrangements

8.27 The drain should conform in all respects to the guidance given in this Health Technical Memorandum. In addition, the following must be proved:

- that the drain tray is easily removable;
- that a clear trap is fitted and is easily removable;
- that the drain has a clear air gap of at least 15 mm;
- that the pipework and trap are supported so that the air break cannot be reduced;
- that the drain system from each drain tray is independent up to the air break;
- that the operation of the drainage system is proved by introducing water into the duct at the drain tray and observing that it completely drains out. This check is to be repeated both at normal speed and set-back once the fans have been commissioned. At this time, the clear trap can be marked to indicate the normal water level with the fan running.

Fire dampers

8.28 The following must be witnessed, and proving tests should be carried out as detailed:

- the operation of all fire dampers;
- access provided to enable the dampers to be visually inspected and/or re-set should be sufficient for the purpose;
- indication should be provided of the dampers' position (open/tripped);
- indication of the fire dampers' location should be provided both on the ductwork and at a visible point on the building fabric if the ductwork is concealed.

Dynamic commissioning

Air-handling and distribution system

8.29 The fan drive, direction of rotation, speed and current drawn should be set in accordance with manufacturers' instructions.

8.30 After the installation has been checked to ensure that it is in a satisfactory and safe condition for start-up, it should be set to work and regulated to enable the plant to meet its design specification. The proportional balancing method described in CIBSE's Commissioning Code A should be followed. The air-flow rates must be set within the tolerances laid down in the design brief. This will normally be the design air-flow rate +10% –0%, that is, the measured value must at least achieve the design but must not exceed it by more than 10%.

8.31 When combined supply and extract systems are to be balanced and the area that they serve is to be at or above atmospheric pressure, the supply should be balanced first with the extract fan switched off, and then the extract balanced with the supply fan(s) on.

8.32 For combined systems where the area that they serve is to be below atmospheric pressure, the extract should be balanced first with the supply fan switched off and then the supply balanced with the extract fan on.

8.33 On completion of the balance, all volume air flows in supply and extract ducts and from grilles and diffusers must be measured and recorded. The true air-change rate can then be calculated from the data obtained.

8.34 The main supply and extract duct-volume control dampers should be locked and their position marked.

8.35 All grille and diffuser volume-control registers should be locked to prevent alteration and their final position marked.

Room-air distribution

8.36 Pressure-relief dampers and pressure stabilisers should be set to achieve the specified room's static pressures and should be locked. The grille's direction-control vanes and diffuser cones must be set to give the specified air-movement pattern. Visualisation techniques may need to be employed in order to prove that the required air-flow pattern is being achieved. This may be a particular

requirement when commissioning LEV systems or rooms that contain them.

Air-conditioning plant

8.37 The specified flow rate and/or pressure drops must be set for all heater-batteries, cooling coils and humidifiers. The methods described in CIBSE's Commissioning Codes W and R should be followed. On completion, their regulating devices must be locked to prevent alteration.

Control system

8.38 The control system should not be commissioned until both the air distribution system and air-conditioning equipment have been commissioned.

8.39 Because of the specialised nature of control systems and the fact that each manufacturer's system will contain its own specific components and settings, the commissioning should be completed by the supplier and contractor before being witnessed by a representative of the client.

8.40 The location of all control and monitoring sensors should be checked and their accuracy proved.

8.41 The control system's ability to carry out its specified functions must be proved. In this respect it is essential that control indication lights on the panel or mimic on the BMS actually relate to the running of a specific fan or movement of a damper.

8.42 If the plant is provided with a user's control panel in addition to the one located in the plantroom, the operation of both must be proved. This will typically apply to operating departments and laboratory systems.

Specific performance standards

Air movement

8.43 The performance of the system should be measured and compared with information provided by the designer.

Plant capacity and control

8.44 When setting to work and proving the design, both the contractor responsible for the air-handling plant and the control specialist should attend the site together and jointly commission the system.

8.45 If any doubt exists as to the capacity of the installed system, its ability to achieve the specified internal design conditions with the plant operating at external winter and summer design conditions must be proved. Artificial loads will be required in order to simulate the internal gains/losses and the external design conditions.

8.46 On completion of the plant's performance test, recording thermo-hygrographs should be placed in each room/area served by the plant and also the supply-air duct upstream of the fog/frost coil. The plant should be run for 24 hours with all doors closed. During this period, the inside conditions must stay within the tolerances specified. Alternatively the BMS may be used to obtain the information required.

Noise levels – general

8.47 The commissioning noise level is that measured with a sound-level meter in the unoccupied room, taking account of the external noise together with the noise generated by the ventilation system. Appendix 2 gives a summary for many applications. Full details and design information are contained in Health Technical Memorandum 08-01 – 'Acoustics'.

8.48 The noise levels apply at the maximum velocity for which the system is designed to operate. Acoustic commissioning tests should be carried out with all plant and machinery running normally and achieving the design conditions of air flow, temperature and humidity.

8.49 An industrial-grade Type 2 sound-level meter fitted with a muff will normally be sufficient to check the noise level. Its accuracy should be checked using a calibrated sound source before use.

8.50 The noise-level readings should be taken at typical normal listening positions 1.5 m above floor level and at least 1 m from any surface, and not on any line of symmetry. In critical care areas, the noise should be measured near to the centre of the room and near to the centre of each quarter. The mean of the five readings should then be calculated.

8.51 In the event of a contractual deficiency, a Type 1 precision-grade sound-level meter should be used, and the noise level determined by the procedure given in Health Technical Memorandum 08-01.

Filter challenge

General ventilation filters

8.52 In-situ performance tests will not normally be required for primary and secondary filters and

their housings. However, filters should be visually inspected for grade, tears, orientation and fit within their housings. Filters should be clean and a replacement set should be available. Bag filters should be installed so that their bags are vertical, and spaced so that air can move through them freely. Any filter found to be wet should be replaced and the cause investigated.

HEPA filters (for exhaust protective enclosures and laboratories)

8.53 Pathogenic material may be discharged through damaged or badly installed HEPA terminal filters. The complete installation must be tested using the method set out in BS EN: 14644 'Method of Testing for the Determination of Filter Installation Leaks'.

8.54 The challenge tests may be carried out using either of the following techniques:

- use DOP to provide the challenge and a photometer to detect leaks;
- use a discrete particle counter (DPC) to detect leaks. (In order to obtain a sufficient challenge, it may be necessary to temporarily remove the supply AHU's secondary filters.)

8.55 In both cases, the upstream challenge should be measured. A measurement of particle penetration through a representative section of the HEPA-filter media is then taken and used as the reference background level. These two readings enable the range of the detecting instrument to be set.

8.56 A challenge aerosol of inert particles of the type produced by a DOP generator should be introduced into the air, upstream of the HEPA filter. The downstream face of the filter, its mounting seal and housing would then be scanned for leakage using a photometer. A leak should be deemed to have occurred if a steady and repeatable reading on the photometer at any point exceeds 0.01% of the upstream reading.

8.57 Alternatively, a DPC may be used. For the DPC method, the filter face is sampled at several points to establish the smallest non-penetrating particle size. This will directly relate to the grade of filter under test. The filter face, its seal and housing are then scanned, and if a significant number of particles at or above this size are detected, there is deemed to be a leak at or near the test position.

8.58 Should the HEPA filter fail this test, it must be replaced. Should the filter mounting seal or housing fail this test, it may be repaired and the test repeated.

Bacteriological sampling

General ventilation systems

8.59 Bacteriological sampling will not normally be required for either general or local exhaust ventilation (LEV) systems unless otherwise specified.

Conventional operating rooms

8.60 Before commencing bacteriological testing, the room and its ventilation system should have achieved a steady state condition (see also paragraph 8.75).

8.61 The level of airborne bacteria introduced by the supply air should be checked by closing all doors and leaving the operating room empty with the ventilation system running for 15 minutes. An active air sampler set to take at least a 1 m^3 sample and mounted in the centre of the room approximately 1 m above floor level should then be activated remotely. Aerobic cultures on non-selective media should not exceed ten bacterial and/or fungal colony forming units per cubic metre (CFU/m^3).

8.62 The results should be examined to establish the broad category of organisms present. A high preponderance of fungal organisms may be an indication of inadequate filtration for the particular installation. Precise guidance is inappropriate and will depend on local circumstances.

8.63 A check of airborne bacteria should be carried out during a surgical operation. Unless there are unusually high numbers of personnel or extensive activity in the room, the number of airborne bacterial and/or fungal CFU averaged over any five-minute period would be unlikely to exceed 180 per m^3.

The Hospital Infection Society has issued guidance on the microbiological testing of operating theatres (www.his.org.uk/_db/_documents/OTIC-final.pdf).

Information on the additional validation testing of UCV operating suites is given in paragraphs 8.66–8.164.

Ventilation system commissioning/validation report

8.64 Following commissioning and/or validation, a full report detailing the findings should be produced. The system will only be acceptable to the client if at the time of validation it is considered fit for purpose and will only require routine maintenance in order to remain so for its projected life.

8.65 The report should conclude with a clear statement as to whether the ventilation system achieved or did not achieve the required standard. A copy of the report should be lodged with the following groups:

- the user department;
- infection control (where required);
- estates and facilities.

Validation of UCV operating suites

General

8.66 Commissioning of a UCV terminal will normally be carried out by its supplier. Commissioning of the AHU, fire dampers, distribution ductwork and control systems may be undertaken by different teams. It is therefore important to recognise that the UCV terminal is only one element of the specialised ventilation system serving the operating suite, and it cannot be accepted in isolation.

8.67 In order to ensure that the complete system operates correctly, it will be necessary to validate the system as a whole from the air intake through to the extract discharge.

8.68 It is unlikely that in-house staff will possess the knowledge or equipment necessary to undertake this process. Therefore, a suitably qualified Authorised Person appointed by the client should carry out the validation of ultra-clean operating theatre ventilation systems.

Note

It is anticipated that training in the validation of specialised healthcare ventilation systems for Authorised Persons will become available during the life of this Health Technical Memorandum.

8.69 The following regime of inspection and testing should be applied to the validation of new installations designed to provide ultra-clean conditions in an operating suite. The test regime has been devised to ensure that the system, as installed, fully achieves the design requirement for these systems as set out in paragraphs 7.91–7.147.

Basic requirement

8.70 The operating suite to be validated should be physically complete with final finishes applied. All ventilation systems serving it should be operating correctly and delivering their design air-flow rates.

8.71 In order to avoid preloading the UCV terminal's recirculation ducts and HEPA filters, the operating suite should be free of any obvious dust and at least "builders clean" before the recirculation fans are set to work (see also paragraph 8.16).

8.72 The validation procedure for a conventional theatre suite should have been satisfactorily completed to the standard set out in this chapter prior to attempting to validate the UCV unit. In particular:

- the supply AHU will have achieved the minimum standard;
- the operation of all fire dampers will have been proved;
- the supply and extract air-flow rates as measured in ducts and at room terminals will achieve their design values +10% –0% (see paragraph 8.30);
- the room's differential pressures will be correct.

8.73 Evidence of the satisfactory achievement of the foregoing standards should be available for inspection and independently measured as necessary prior to validating the UCV unit.

UCV unit validation procedure

8.74 Tests to validate the suitability and performance of an ultra-clean operating suite should be undertaken in the order that they appear in Table 8. Should an item fail to meet the required standard, it should be rectified and successfully retested before passing on to the next test.

Table 8 Summary of test regime

1. Challenge tests to ensure that: • the UCV terminal unit is correctly assembled and sealed so that no air will bypass the filters; • the terminal filters are correctly sealed in their housings; • the terminal filters are of the same grade, of uniform quality and undamaged.
2. Air velocity measurements to ensure that: • a sufficient quantity of air is being delivered by the terminal; • the terminal quadrants are in balance; • the air flow has sufficient velocity to reach the working plane.
3. An entrainment test to ensure that contaminants arising outside of the UCV terminal footprint are not drawn into it.
4. Visualisation techniques to gain an understanding of the overall system performance.
5. Noise measurement to ensure that working conditions are satisfactory.
6. Control system checks to ensure that the system operates as specified.
7. Biological monitoring to determine how effective the system is in use.

Test and measuring conditions

8.75 While validating the UCV terminal, the conditions in the operating room should be stable and within the given ranges:

- temperature: 19–23°C dry bulb;
- humidity: 30–65% relative humidity.

Test and measuring equipment

8.76 Any test or measuring equipment used should have a certificate to prove that it has been validated within the previous 12 months at a calibration facility using traceable national standards.

8.77 In the case of a noise meter, its "matched sound source" should have a certificate to prove that it has been validated within the previous 12 months at a calibration facility using traceable national standards. The noise meter should be calibrated to the sound source on each occasion that it is used.

Test grid – vertical units

8.78 A test grid should be constructed on the floor within the ultra-clean terminal footprint as projected by the inside dimensions of the side walls or boundary air curtain. A suitably marked test sheet will provide a consistent standard of test grid.

8.79 The test grid should comprise test squares of 280 mm each side.

8.80 The test grid should be aligned along the centre lines of the terminal footprint with its centre under the centre point of the terminal.

8.81 Any test square with 80% or more of its area within the UCV footprint should be used as a test position.

8.82 An inner zone should be designated that is not less than 36% of the total footprint. It should be made up of a number of test squares distributed symmetrically about the terminal footprint's centre-line. Regardless of the shape of the terminal footprint, the inner zone should comprise a minimum grid of 6 × 6 test squares.

8.83 Unless specified otherwise, a test position should be in the geometric centre of a test square.

8.84 Test position 1 should be the leftmost test square in the row nearest to the operating room wall that houses the surgeon's panel.

8.85 Figure 8 shows a grid for a 2.8 m × 2.8 m terminal.

Test grid – horizontal units

8.86 A line of test positions should be marked on the floor 1 m in front of the face of the UCV terminal.

8.87 A test position should be marked in the centre of the line. Additional test positions should be marked at 280 mm intervals along the line either side of the centre position, up to the full face width of the unit.

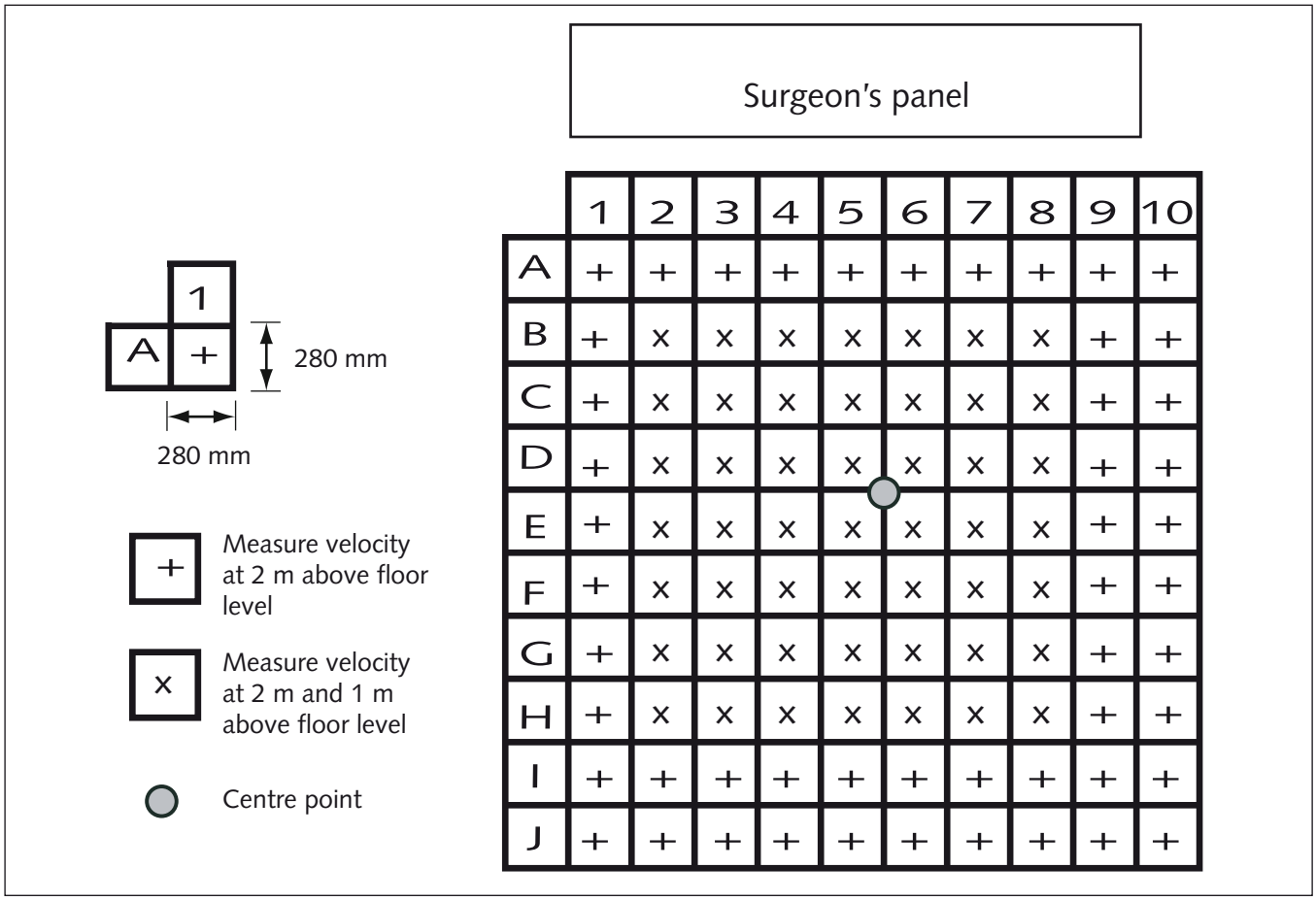
UCV terminal challenge tests (vertical and horizontal systems)

8.88 The diffuser screen fitted below the face of the terminal HEPA filters should be lowered or removed while the challenge tests are being carried out.

8.89 The installed HEPA filters should be checked to ensure that their grades accord with the design specification and that their performance has been certified by the manufacturer.

8.90 The challenge tests may be carried out using either of the following techniques:

Figure 8 Example of a test grid for a 2.8 m x 2.8 m UCV terminal



- use DOP to provide the challenge and a photometer to detect leaks;
- use a DPC to detect leaks. (In order to obtain a sufficient challenge, it may be necessary to temporarily remove the supply AHU's secondary filters.)

8.91 In both cases, the upstream challenge should be measured. A measurement of particle penetration through a representative section of the HEPA-filter media is then taken and used as the reference background level. These two readings enable the range of the detecting instrument to be set.

8.92 For the DOP test, this should be set as the reference level, and a leak will be declared significant if penetration greater than 0.01% of the range is detected (see paragraph 8.56 for details).

8.93 For the DPC method, the filter face is scanned to establish the smallest non-penetrating particle size. If significant particles at or above this size are detected when subsequent scans are made, there is deemed to be a leak at or near the test position (see paragraph 8.57 for details).

UCV terminal unit clean zone leak test

8.94 This test will confirm that there is no unfiltered air bypassing the HEPA filter.

8.95 The joints and service penetration points under the UCV terminal within its side walls or boundary air curtain should be scanned to prove that there are no leaks.

8.96 A leak is defined as a significant rise above the background level.

Terminal HEPA filter seal leak test

8.97 This test will confirm that there is no unfiltered air bypassing the HEPA filter's seal.

8.98 Each HEPA filter's seal should be scanned to prove that there are no leaks.

8.99 A leak is defined as a significant rise above the background level.

Terminal HEPA filter media leak test

8.100 This test will confirm that the HEPA filters have not sustained damaged while being installed.

8.101 The face of each HEPA filter should be scanned to prove that there are no leaks.

8.102 A leak is defined as a significant rise above the background level.

Vertical UCV terminal air velocity tests

Test set-up

a. The terminal face diffuser screen should be in place for these tests.

b. Take spot readings to establish that the room is within the specified temperature and humidity test conditions.

c. Set out the test grid as described in paragraphs 8.78–8.85.

d. Swing the operating lamp arms and any other stem arms so that they align to present the least resistance to air flow, are perpendicular to the front edge of the test sheet, and face the back edge. Any lamp and equipment heads should as far as practicable be outside of the UCV terminal footprint.

Test instrument

8.103 The measuring instrument should be a hot-wire anemometer with a digital read-out. The instrument resolution should be at least 0.01 m/s, have a tolerance of ±0.015 m/s or 3% of the reading, and be calibrated down to 0.15 m/s or lower. An alternative instrument may be used, providing it is of no lesser specification.

Test method

8.104 The instrument should be mounted on a test stand and set to record a mean reading over a ten-second sample interval.

8.105 It is recommended that a printer be linked to the test instrument so that readings are recorded automatically. Alternatively they could be downloaded to a computer or data logger at the end of the test.

8.106 The test stand should be positioned at each test point in turn and the reading taken when the instrument has stabilised.

8.107 When taking a reading, the test person should not stand within the same quadrant as the test instrument.

8.108 Readings are to be taken at the test positions – with the instrument probe facing the wall that houses the surgeon's panel – commencing at the first test position. Readings are taken either working along the row from left to right and back, or for all test positions in one quadrant at a time.

8.109 When all the test positions under one half of the terminal have been covered, readings of temperature and humidity are taken at the specified height in the centre of the terminal. The read-outs on the surgeon's panel should be recorded at the same time.

8.110 Having completed one half of the test grid, the operating lamp arms and any other stem arms should be swung round through 180 degrees and the test stand reversed so that the wall that houses the surgeon's panel is behind the test person. Readings are recommenced starting at the right of the test row and working from right to left or a quadrant at a time, as above.

UCV high level discharge velocity test

8.111 Measurements of air velocity are to be taken at every test position 2 m above floor level, and the results averaged.

8.112 The average of the total readings taken is to be not less than:

- 0.38 m/s for a partial-wall system;
- 0.30 m/s for a full-wall system.

8.113 The average air velocity for each quadrant should not exceed ±6% of the measured average velocity for the terminal.

UCV low level air velocity test

8.114 Measurements of air velocity are to be taken at each of the inner zone test positions 1 m above floor level.

8.115 The measured velocity at every test position in the inner (operating) zone should be not less than 0.2 m/s.

Horizontal UCV terminal air velocity test

Test set-up

a. Set out the line of test positions as described previously.

b. Swing the operating lamp arms and any other stem arms so that they align to present the least

resistance to air flow and are perpendicular to the line of test positions.

Test instrument

8.116 See paragraph 8.103.

Test method

8.117 The instrument should be mounted on a test stand and set to record a mean reading over a ten-second sample interval.

8.118 It is recommended that a printer be linked to the test instrument so that readings are recorded automatically. Alternatively, they could be downloaded to a computer or data logger at the end of the test.

8.119 The test stand should be positioned on each test point in turn and the reading taken when the instrument has stabilised.

8.120 When taking readings, the test person should stand well downstream of the instrument.

8.121 Readings are to be taken at the test positions – with the instrument probe facing the UCV terminal – commencing at the first test position on the left and working along the row from left to right at the specified height.

8.122 The instrument should be reset to the next specified height and the test repeated, and so on.

8.123 Readings of temperature and humidity should be taken at the specified height in the centre of the terminal. The read-outs on the surgeon's panel should be recorded at the same time.

UCV discharge velocity test

8.124 Measurements of air velocity are to be taken at all test positions at 1 m, 1.5 m and 2 m above floor level.

8.125 The average of the total readings taken should be no less than 0.4 m/s.

UCV entrainment test (vertical systems only)

Rationale for the entrainment test

8.126 The performance of UCV systems may be compromised by room air being drawn into the ultra-clean air flow, a phenomenon known as "entrainment". Significant levels of entrainment could lead to microbial contamination of items left exposed on instrument trolleys laid out beneath the canopy.

8.127 UCV systems having permanently fitted full side walls do not need to be tested, as the side walls physically prevent entrainment.

Principle of the test

8.128 A source of particles is produced outside of the UCV terminal and is used to challenge the system. A detector is placed within the ultra-clean air flow and used to determine the percentage penetration of the test particles at predefined locations under the UCV terminal footprint. The source and detector are moved in tandem around the UCV canopy and pairs of readings taken, from which the percentage penetration at specified locations is calculated. The degree of penetration should be below specified maximum limits if entrainment is to be declared not significant.

8.129 The entrainment test may be carried out using either of the following techniques:

- use DOPs to provide the challenge source at the specified release position and a photometer to measure the entrainment; or
- duct non-HEPA-filtered air to the specified release position and use a DPC to measure the entrainment.

Test set-up

a. The terminal face diffuser screen should be in place for these tests.

b. The test should be performed without any equipment in place beneath or closely adjacent to the UCV terminal.

c. Theatre lights should be moved to a central position beneath the terminal and raised to 2 m above floor level so as not to interfere with the peripheral air flows.

d. Take spot readings at the centre of the canopy, 1 m from floor level, to establish that the room is within the specified temperature and humidity test conditions.

e. Set out the test grid as described previously.

f. For either of the entrainment tests mentioned in paragraphs 8.131–8.132, a measurement of particle penetration through a representative section of the HEPA-filter media is to be taken and used as the reference background level.

Test equipment

a. Challenge source, measuring instrument and detector head

8.130 The challenge and detector equipment should be chosen so that:

- the tracer particles are mainly within the size range 0.3–5 µm and thus capable of remaining airborne for a substantial time;
- the particles used should not be able to penetrate the terminal filters in sufficient numbers to cause a background count that is more than 0.1% of the challenge count;
- the choice of particle and detector will enable a minimum of a three-logarithm (1000-fold) range of counts to be recorded between the highest (that is, source) and lowest (that is, background) readings expected. (A concentration of approximately 10^5 particles per cubic metre of source air has been shown to be adequate.)

b. Challenge source – DOP

8.131 The DOP generator should be able to produce a cloud of test particles in the form of a visible smoke. The test smoke should be delivered via an aperture so that it flows vertically downward from the lowermost edge of the partial wall, on the outside of the UCV canopy.

Note

To prevent undue contamination of the theatre and filters with deposits of oil, DOP should only be released for the minimum amount of time necessary to complete the test.

c. Challenge source – natural particles

8.132 The source unit should be a fan/blower or other method that takes non-HEPA-filtered air and expels it via a delivery head at the specified release position to provide the particle challenge. The challenge air should be delivered vertically downwards from the lowermost edge of the partial wall, on the outside of the UCV canopy, parallel to the air flow coming from the diffusers. The challenge air velocity should be the same as the measured average velocity at 2 m for the terminal under test.

Note

The use of DOP for testing is gradually being phased out and replaced by a natural challenge measured with a DPC. At the time of writing research is under way to more precisely define a challenge source unit for natural particles. It is anticipated that such a unit, together with a matching test methodology, will become available during the life of this Health Technical Memorandum.

The detector

8.133 This may be a photometer or a DPC. It is recommended that a printer be linked to the test instrument so that readings are recorded automatically. The instrument should be capable of sampling a minimum of 28.3 L of air (1 ft^3) per minute and, in the case of the DPC, provide readings for particle size ranges from 0.3 µm to 5 µm and greater. The instrument should be compliant with the requirements of BS EN ISO 14644-1. An alternative instrument may be used providing it is of no lesser specification.

Test positions and orientation of source and detector

8.134 The test positions should be at the centre of each test square, as defined for the velocity test.

8.135 For rectangular UCV terminals, measurements of penetration are to be taken at the four corner test squares of the test grid and at intermediate positions along the line of test squares between the corners. The number of intermediate test positions should be as equally spaced as possible around the periphery, with no fewer than three and no more than five complete test squares between test positions.

8.136 A further series of measurements are to be obtained around the periphery of the inner zone. Measurements of penetration are to be taken at the four corner test squares of the inner zone of the test grid and, if necessary, at intermediate positions along the line of test squares between the corners as equally spaced as possible, with no fewer than three and no more than five complete test squares between test positions.

8.137 A single measurement should be taken at the geometric centre of the UCV terminal footprint. The centre measurement should be taken with the

detector head mounted vertically upwards, 1 m above floor level.

8.138 The centre of the challenge particle source should be aligned with the centre of the designated test square, with its longer edge against the outer edge of the partial wall and delivering the challenge from the lower edge of the partial wall. The air containing challenge particles is directed vertically downwards from the lower edge of the partial wall, in a plane parallel to the partial wall. Where there is physical interference due to obstructions such as gas pendants, the source should be moved to the next available non-obstructed test-square location nearest to the stipulated sampling position. The detector should then also be moved to remain opposite the source.

8.139 In the case of non-rectangular terminals, an interpretation of the above strategy should be adopted that will yield a no less searching examination of the unit's ability to control entrainment.

Test method

8.140 The sampling head of the detector instrument is mounted on a test stand with its sampling orifice facing outwards horizontally from the centre of the UCV canopy, 1 m above floor level. The sampling head should be orientated at right-angles to the partial wall when sampling along the sides of the test grid, but should be set to bisect the angle when measuring at the corner test positions.

8.141 The test will commence at the first test position, this being designated the leftmost corner of the test grid when facing the wall housing the surgeon's panel. The penetration should also be measured at the corresponding test point on the inner zone commencing at the corner nearest to the first test position. When these tests have been completed, the source and detector equipment should be moved to the next test positions, working around the test grid in a clockwise direction.

8.142 The test stand should be positioned on each test point in turn and a pair of readings (challenge, then penetration) taken when the instrument has stabilised. The detector should be set to take a reading over a 15-second sample interval.

8.143 When taking a reading, the test person should stand within the UCV terminal footprint but not in the same quadrant as the detector head.

Analysis and interpretation

8.144 The following standard is to be achieved:

- at each test position in the outer zone, penetration is to be no greater than 10% of the challenge;
- at each test position in the inner zone, penetration is to be no greater than 1% of the challenge;
- at the centre test position, penetration is to be no greater than 0.1% of the challenge.

8.145 If a result is close to, or above, the given limits, a further reading must be obtained using a longer time base (one minute), and the penetration must not exceed the given limit.

Note

The entrainment test is based on the research of Whyte et al (1974) and Whyte et al (1983).

UCV visualisation

8.146 The use of smoke to gain an understanding of the overall performance of the system may prove useful at this stage in the validation process but cannot be relied on to produce a contractually definitive measure of performance.

UCV noise level

8.147 An industrial-grade Type 2 sound-level meter fitted with a muff should be used to check the noise level. The instrument should be calibrated using a matched sound source prior to each set of readings.

Vertical systems

8.148 The noise level readings should be taken at typical normal listening positions 1.5 m above floor level and at least 1 m from any surface and not on any line of symmetry. Measurements should be taken approximately under the centre of each quadrant of the UCV terminal and the four readings averaged.

Horizontal systems

8.149 The noise-level readings are to be taken at typical normal listening position 1.5 m above floor level on the test line. The width of the unit should be divided in two and a measurement taken in the

centre of each half but avoiding any line of symmetry. The two readings should be averaged.

8.150 Measurements should also be taken in each room of the suite.

8.151 In the event of a contractual deficiency, a Type 1 precision-grade sound-level meter should be used in accordance with Health Technical Memorandum 08-01.

8.152 For vertical or horizontal systems, the noise level should not exceed:

- 50 NR [55 dB(A)] – for UCV operating rooms and spaces without doors that open directly onto it (for example the scrub);
- 40 NR [45 dB(A)] – for all other peripheral rooms of the suite.

UCV control system checks

Temperature

8.153 The readings of temperature taken under or in front of the UCV unit should be within ±1 K of each other and the read-out on the surgeon's panel.

Humidity

8.154 The readings of humidity taken under or in front of the UCV unit should be within ±5% of each other and the read-out on the surgeon's panel.

Direct-reading differential-pressure gauges

8.155 The accuracy of the indicated reading of these gauges should be checked by measuring the actual differential pressure across the terminal filter(s).

Control functions

8.156 The operation of all control functions provided on the surgeon's panel should be proved for conformity with the design specification.

8.157 If an auxiliary panel has been fitted, its interlocking with the control functions of the main surgeon's panel must be proved to conform to the design specification.

Panel indicator lights

8.158 The panel indicator lights should illuminate as appropriate when the control functions are selected or warning levels are reached.

BMS interface

8.159 The operation, monitoring and alarm functions must be proved to conform to those set out in the design specification.

UCV theatre microbiological tests

8.160 There is little value in performing microbiological sampling in a new theatre supplied with ultra-clean ventilation. The foregoing filter challenge tests, air velocity measurements and entrainment test should have proved that the system operates satisfactorily and achieves the contracted level of performance. The HEPA filters will remove bacteria-sized particles from the air supplied through the UCV terminal. Therefore there will be an insignificant number of bacterial and/or fungal CFU present until the theatre is actually used.

8.161 Once the theatre has been taken into use, microbial sampling during a surgical procedure should help to confirm the satisfactory performance of the system and discipline of the users. Before commencing bacteriological testing, the room and its ventilation system should have achieved a steady state condition (see also paragraph 8.75).

8.162 The installation should be tested during surgical procedure at intervals between the time of first incision and final closure of the wound. On average, air sampled within 300 mm of the wound should not contain more than 10 CFU/m^3.

The Hospital Infection Society has issued guidance on the microbiological testing of UCV operating theatres (www.his.org.uk/_db/_documents/OTIC-final.pdf).

UCV validation report

8.163 Following validation, a full report detailing the findings should be produced. The report should conclude with a clear statement as to whether the UCV theatre suite achieved or did not achieve the standard set out above.

8.164 A copy of the report should be lodged with the following groups:

- operating department;
- infection control;
- estates and facilities.

Appendix 1 – Use and function of typical equipment used in ventilation systems

A1.1 Typical equipment used in ventilation systems is listed below together with a brief description of both function and use.

General

A1.2 The equipment built into the ventilation system and its ductwork should be of a type that will neither cause nor sustain combustion.

A1.3 No materials that could sustain biological activity should be used in the construction or assembly of the system.

Air intake

A1.4 An uncontaminated air supply to the system is essential. In order to achieve this, the air intake should be positioned so that air discharged from extract systems or other sources of dubious quality cannot be drawn in. Exhaust fumes from vehicles can present particular problems. The area surrounding the intake will need to be kept clean and free of vegetation and waste material in order to reduce the possibility of biohazards or fire. The intake itself should be protected by a louvre and mesh screen to prevent rainwater, vermin and leaves etc entering the system.

Damper

A1.5 Several types of damper may be fitted:

a. automatic dampers fitted immediately behind the air intake and extract louvres. They will automatically close when the system is shut down in order to prevent an uncontrolled circulation of air;

b. balance dampers are fitted into each branch of the air distribution ductwork system so that the design air-flow rate can be set during the commissioning process;

c. where ductwork passes through a fire compartment wall, ceiling or floor, a fire and/or smoke damper may be required;

d. plant-isolating dampers are fitted so that the main plant can be isolated from its air distribution duct system. They are manually operated, and enable cleaning and maintenance of the air-conditioning equipment to be carried out.

Ducting

A1.6 Ducting is the means by which air is conveyed from the intake to its point of use. It is usually constructed of galvanised steel and will normally be insulated to reduce noise and conserve energy. Ducts can also be formed in concrete, brickwork, stainless steel or plastic, and may be rigid or flexible.

Fan

A1.7 A fan is a series of rotating blades that move the air in the direction required. Fans are usually powered by electric motors either directly connected to them or driven through belts and pulleys. A fan may be arranged to either force air into or draw air from a ductwork system.

Attenuator/silencer

A1.8 An attenuator is a device that will contain and absorb the noise emitted by a fan. It may be required to reduce disturbance caused by noise breaking out through the air intake and also noise transmitted along the ductwork to the conditioned space.

Filter

A1.9 A filter consists of a labyrinth of fibrous material contained in a frame. It is designed to capture and hold particles being carried in the air stream. Because of the size range and number of particles that exist in air, no filter can remove them all. The purpose of filtration is to reduce their number and size range to an acceptable level. Filters of progressively higher grades are fitted through the ventilation system:

- primary filters (coarse) are designed to collect the larger particles and are intended to keep the air-handling plant clean;
- secondary filters (fine) remove the staining particles from air and keep the ventilated space visibly clean;
- high efficiency particulate air filters (HEPA/absolute) remove virtually all particles from air. These may be required in order to reduce contamination in the working area either biologically or in terms of particle count.

A1.10 Filters may be fitted to extract systems to protect energy-recovery devices. They are also fitted to remove biological, radiation or chemical hazards. They are often contained in a "safe change" facility in order to protect those carrying out maintenance.

A1.11 Activated carbon filters will reduce odours in extracted or recirculated air.

Heater coil/battery

A1.12 A heater coil/battery is a series of coils with or without fins through which steam or hot water is circulated. Heat is given up to the air passing over the battery, thus increasing its temperature. Heating is usually carried out in stages, the final battery being controlled by the end-user. Small batteries may be electric.

Humidifier

A1.13 A humidifier is a device for increasing the humidity of air by adding moisture. For ventilation in healthcare premises, this is normally achieved by releasing clean steam into an air-supply duct. The steam should be completely absorbed into the air, increasing its humidity. The level of humidity may be preset or controlled by the end-user.

Chiller battery/cooling coil

A1.14 A chiller battery/cooling coil is a series of finned coils mounted in the air-supply duct. Either chilled water or refrigerant is circulated through the coils, causing heat to be removed from the air. This will reduce its temperature and may also condense moisture out of the air. As free moisture in a duct can be a source of contamination, the coil will be fitted with an eliminator and drainage system.

Eliminator

A1.15 An eliminator is a device for catching and removing water droplets from an air stream. It may form part of a cooling coil or be a separate device.

Drainage system

A1.16 The drainage system is a means of removing water from ductwork and disposing of it safely. Typically it will consist of a tray mounted in the duct to catch moisture, a glass water-seal trap, continuously falling drainage pipework and an air break in the drain run to prevent waste water returning and contaminating the duct.

Access doors and observation ports

A1.17 Access doors and observation ports are doors and removable panels that provide access for routine maintenance and cleaning. The doors should be fitted with glazed ports, and suitable lighting should be provided so that the condition and correct operation of devices such as cooling coils, humidifiers and filters can be easily observed without needing to switch off the plant.

Energy recovery

A1.18 Modern plants are fitted with the means to recover energy from the extract air without causing contamination of the incoming supply air. These devices will be fitted with a drainage system and may incorporate an eliminator. Several types of energy-recovery system are available.

A1.19 Precise definitions of ventilation and air conditioning terms are given in CIBSE Guide B.

Typical plant

A1.20 The layout of a typical plant that conforms to the requirements for healthcare applications is shown in Figure 1 in Chapter 1 of this document. It contains most of the equipment described above.

Appendix 2 – Recommended air-change rates

Application	Ventilation	AC/hr	Pressure (Pascals)	Supply filter	Noise (NR)	Temp (°C)	Comments (for further information see Chapter 6)
General ward	S/N	6	–	G4	30	**18–28**	
Communal ward toilet	E	6	–ve	–	40	–	
Single room	S/E/N	6	0 or –ve	G4	30	**18–28**	
Single room WC	E	3	–ve	–	40	–	
Clean utility	S	6	+ve	G4	40	**18–28**	
Dirty utility	E	6	–ve	–	40	–	
Ward isolation room	–	–	–	–	–	–	See Health Building Note 04-01 (Supplement 1)
Infectious diseases isolation room	E	10	–5	G4	30	**18–28**	Extract filtration may be required
Neutropeanic patient ward	S	10	+10	H12	30	**18–28**	
Critical care areas	S	10	+10	F7	30	*18–25*	Isolation room may be –ve pressure
Birthing room	S & E	15	–ve	G4	40	*18–25*	Provide clean air-flow path
SCBU	S	6	+ve	F7	30	*18–25*	Isolation room may be –ve pressure
Preparation room (lay-up)	S	>25	35	F7	40	*18–25*	
Preparation room/bay (sterile pack store)	S	10	25	F7	40*	*18–25*	*50 NR if a bay in a UCV theatre
Operating theatre	S	25	25	F7	40	*18–25*	
UCV operating theatre	S	25*	25	H10 or greater	50	*18–25*	*Fresh-air rate; excludes recirculation
Anaesthetic room	S & E	15	>10	F7	40	*18–25*	Provide clean air-flow path
Theatre sluice/dirty utility	E	>20	–5	–	40	–	
Recovery room	S & E	15	0	F7	35	*18–25*	Provide clean air-flow path
Catheterisation room	S	15	+ve	F7	40	*18–22*	
Endoscopy room	S	15	+ve	F7	40	*18–25*	
Endoscopy cleaning	E	>10	–ve	–	40	–	
Day-case theatre	S	15	+ve	F7	40	*18–25*	
Treatment room	S	10	+ve	F7	35	*18–25*	
Pharmacy aseptic suite	S	20	#	H14	–	*18–22*	# See EGGMP (Orange guide) [a]
Category 3 or 4 containment room	#	>20	#	H14*	–	*18–22*	# See ACDP guide; *Filter in extract
Post-mortem room	S & E	S = 10 E = 12	–ve	G4	35	**18–22**	Provide clean air-flow path
Specimen store	E	–	–ve	–	–	–	Fan accessible from outside of store

Notes: **18–22**°C indicates the range over which the temperature may float.
18–22°C indicates the range over which the temperature should be capable of being controlled.
S = suppy
E = extract
N = natural ventilation
a – European guidelines on good manufacturing practice published by the Medicines and Healthcare products Regulatory Agency (MHRA)

Appendix 3 – Hierarchy of cleanliness

			Air-flow rate for bacterial contaminant dilution	
Class	**Room**	**Nominal pressure (Pa)[a]**	**Flow in or supply (m^3/s)**	**Flow out or extract (m^3/s)**
Sterile	Preparation room		See standard schemes in Appendix 7 for recommended design values	
	(a) lay-up	35		
	(b) sterile pack store	25		
	Operating room	25		
	Scrub bay[b]	25		
Clean	Sterile pack bulk store	+ve	6 AC/h	–
	Anaesthetic room[c]	14[c]	The greater of 15 AC/hr or 0.15	The greater of 15 AC/hr or 0.15
	Scrub room	14	–	0.10
Transitional	Recovery room	3	15 AC/hr[d]	15 AC/hr[d]
	Clean corridor	0	(See note e)	7 AC/hr
	General access corridor	0	(See note e)	7 AC/hr
	Changing rooms	3	7 AC/hr	7 AC/hr
	Plaster room	3	7 AC/hr	7 AC/hr
Dirty	Service corridor	0	–	(See note f)
	Disposal room	–5 or 0	–	0.41 or 0.10

Notes:

a. Nominal room pressures are given to facilitate setting up of pressure-relief dampers, the calculation process, and the sizing of transfer devices. In practice, the resultant pressures are not critical, provided the desired air-flow rates and movement are achieved.

b. An open or semi-open bay is considered to be part of the operating room; provided air movement is satisfactory, no specific extract is required. However, if the layout means that air movement is poor, a local extract may be required to control local condensation on the building surfaces, which can result in mould growth.

c. For design purposes, anaesthetic should be assumed to be at 14 Pa. When commissioning, 10 Pa is considered suitable.

d. 15 AC/hr is considered necessary for the control of anaesthetic gas pollution.

e. Supply air-flow rate necessary to make up 7 AC/hr after taking into account secondary air from cleaner areas.

f. No dilution requirement. Temperature control requirements only.

Appendix 4 – Leakage flows in m^3/s through closed door gaps

Type	Pressure difference (Pa)						
	5	10	15	20	25	30	40
Single door	0.03	0.05	0.06	0.06	0.07	0.07	0.08
Double door	0.04	0.08	0.10	0.11	0.12	0.13	0.14
High permanent length of 3 mm gap	0.004	0.008	0.010	0.011	0.012	0.012	0.013

Designers' notes:

The door gaps assumed are 4 mm along the bottom, 3 mm at the top and sides, and 2 mm between double leaves.

If doors are fitted with cold smoke seals, these will significantly reduce the door leakage rate when new and undamaged. It is therefore recommended that provision for the design leakage be factored into the size of the appropriate transfer grille or pressure stabiliser. Failure to do this will result in air-gap whistles and doors being held partially open by air pressure.

Factory-assembled door-sets with a steel frame and pre-hung leaves are becoming common. There is effectively no leakage across these doors when closed. Therefore, when this type of door assembly is fitted, the door leakage can be ignored and the design air flow into the room reduced accordingly. The design air flow would then become that required either (i) for open door protection (Appendix 5), or (ii) to achieve the specified air-change rate – whichever is the greater.

Appendix 5 – Recommended air-flow rates in m^3/s through a doorway between rooms of different cleanliness to control cross-contamination

Room class		Dirty	Transitional	Clean	Sterile
Sterile	Hatch	0.3	0.24	0.18	
	Single door	0.47	0.39	0.28	0 or 0.28[a]
	Double door	0.95	0.75	0.57	0 or 0.57[a]
Clean	Single door	0.39	0.28	0 or 0.28[a]	
	Double door	0.75	0.57	0 or 0.57[a]	
Transitional	Single door	0.28	0 or 0.28[a]		
	Double door	0.57	0 or 0.57[a]		
Dirty	Single door	0	Open single door = 0.80 m × 2.01 m high		
	Double door	0	Open double door = 1.80 m × 2.01 m high		

Designers' notes:

The degree of protection required at an open doorway between rooms is dependent on the degree of difference in cleanliness between them.

Flow rate required between rooms within the same class tends to zero as class reduces.

a. If two rooms are of equal cleanliness, no flow is required (in practice there will be an interchange in either direction) and the design of the air movement will assume zero air flow. In certain cases, however, interchange is not permitted, and a protection air flow of 0.28 is assumed in the design – for example in the case of a preparation room used as a "lay up"

Appendix 6 – Typical approximate pressures in an operating suite when a given door is open

		Typical approximate effect on other rooms	
Door open between	**Typical approximate resultant pressure in these rooms (Pa)**	**Room**	**Pressure (Pa)**
Operating room and corridor or Scrub bay and corridor	0	Anaesthetic Preparation – lay-up Disposal Preparation – sterile pack store	0 12 –6 5
Operating room and anaesthetic room (or other series room with double doors)	17	Preparation – lay-up Disposal Preparation – sterile pack store	26 –9 22
Operating room and disposal room or Operating room and preparation room	25	No change	
Anaesthetic room and corridor (or other series room with double doors)	0	Preparation – lay-up Disposal Operating room Preparation – sterile pack store	30 –6 20 25
Preparation room and corridor or Disposal room and corridor	0	No change	
Disposal room and outer corridor	0	No change	

Notes:

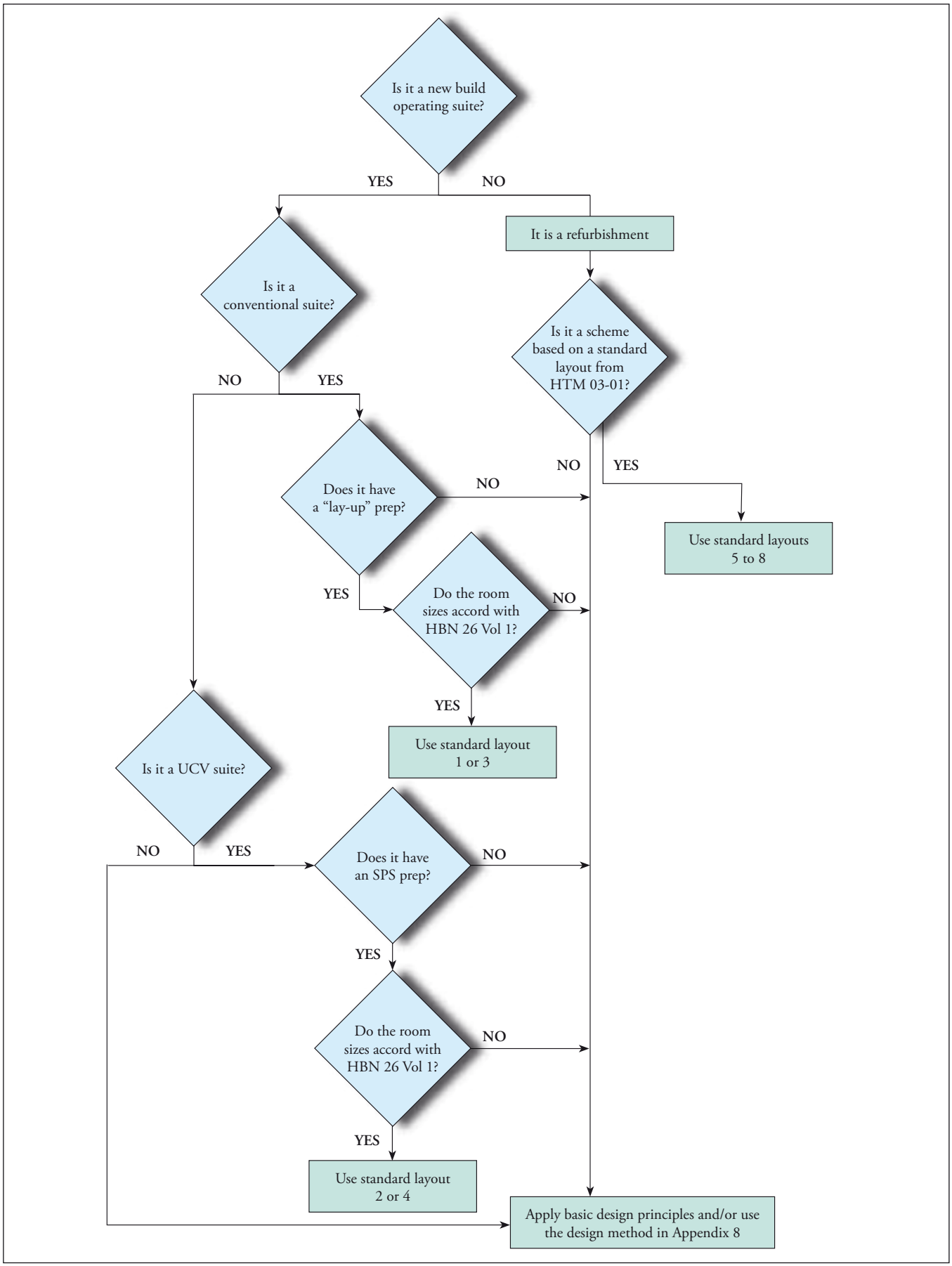
The room differential pressure protects against reverse flows when the door is closed.

The flow of air through a doorway protects against reverse air flow when the door is open.

Pressure stabilisers control flow and ensure a known air-flow path between rooms when doors are closed, and also reduce back-flow between rooms when doors to other rooms are open

Appendix 7 – Operating suite standard design solutions

Operating suite design logic



Standard layout 1 – Suitable for a typical conventional theatre suite

Room	Size (m^3)‡	Air-change rate (AC/hr)	Nominal pressure (Pa)	Flow rate (m^3/s)
Theatre	165	25	25	1.15
Anaesthetic	57	15	>10	0.24
Lay-up-prep	36	>25	35	0.28**
Scrub	*	–	25	–

Notes:

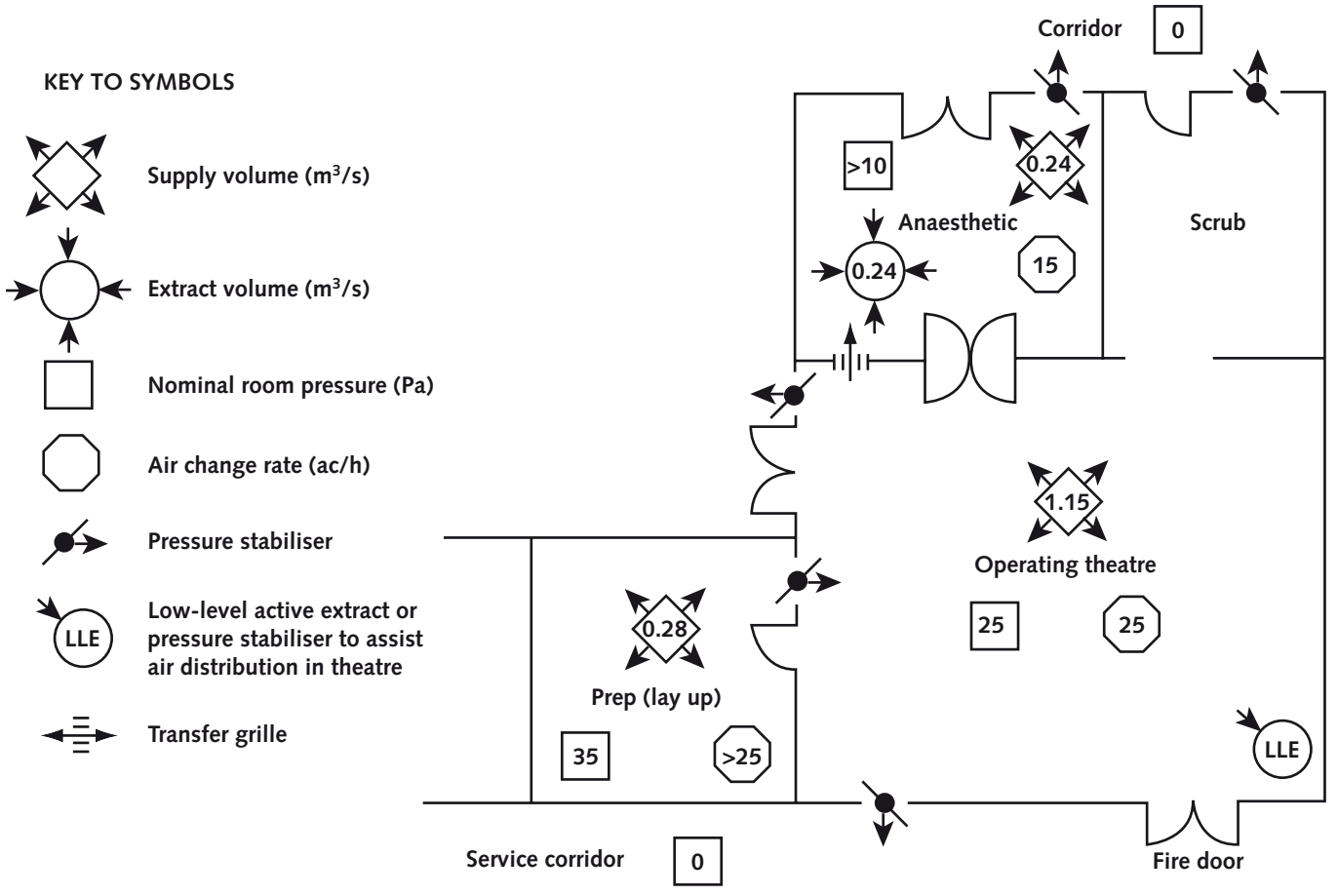
‡ Derived from Health Building Note 26.

* This is a separate scrub and is not considered as being part of the theatre volume.

** Interchange is not permitted between the theatre and lay-up prep; therefore, as in Appendix 5, an air-flow protection of 0.28 m^3/s is required as a minimum (but see also the "designers' notes" in Appendix 4).

The volume of air to be extracted from the theatre should be determined by subtracting the air flow required for door protection at the key door from the total air entering the space. The balance should be equally divided between the passive or active extract locations.

The extracts within the theatre may be either passive and fitted with pressure stabilisers, or active and connected to the extract system. They should where possible be located at low level and positioned to promote the ventilation of all areas of the space



Standard layout 2 – suitable for a typical UCV theatre suite

Room	Size (m^3)‡	Air-change rate (AC/hr)	Nominal pressure (Pa)	Flow rate (m^3/s)
Theatre	165	25	25	1.15**
Anaesthetic	57	15	>10	0.24
Sterile pack store prep	36	10	25	0.10
Scrub	*	–	25	–

Notes:

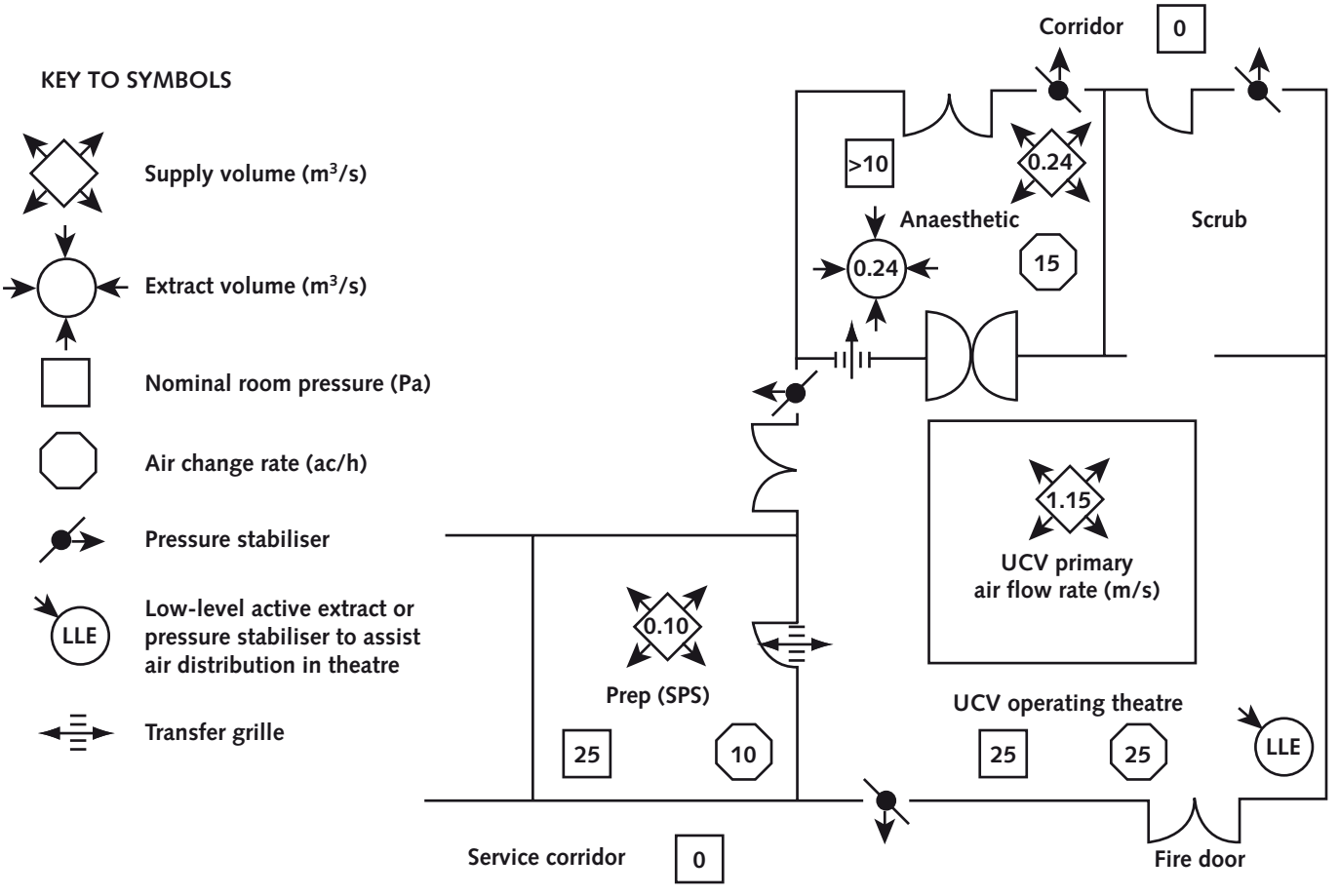
‡ Derived from Health Building Note 26

* This is a separate scrub and is not considered as being part of theatre volume.

** Primary fresh-air volume only.

The volume of air to be extracted from the theatre should be determined by subtracting the air flow required for door protection at the key door from the total air entering the space. The balance should be equally divided between the passive or active extract locations.

The extracts within the theatre may be either passive and fitted with pressure stabilisers, or active and connected to the extract system. They should be located at low level and positioned to promote the ventilation of all areas of the space



Standard layout 3 – suitable for a typical conventional theatre suite

Room	Size (m^3)‡	Air-change rate (AC/hr)	Nominal pressure (Pa)	Flow rate (m^3/s)
Theatre	165	25	25	1.15
Anaesthetic	57	15	>10	0.24
Lay-up prep	36	>25	35	0.34**
Scrub	*	–	25	–
Dirty utility	36	–	–5	0.41

Notes:

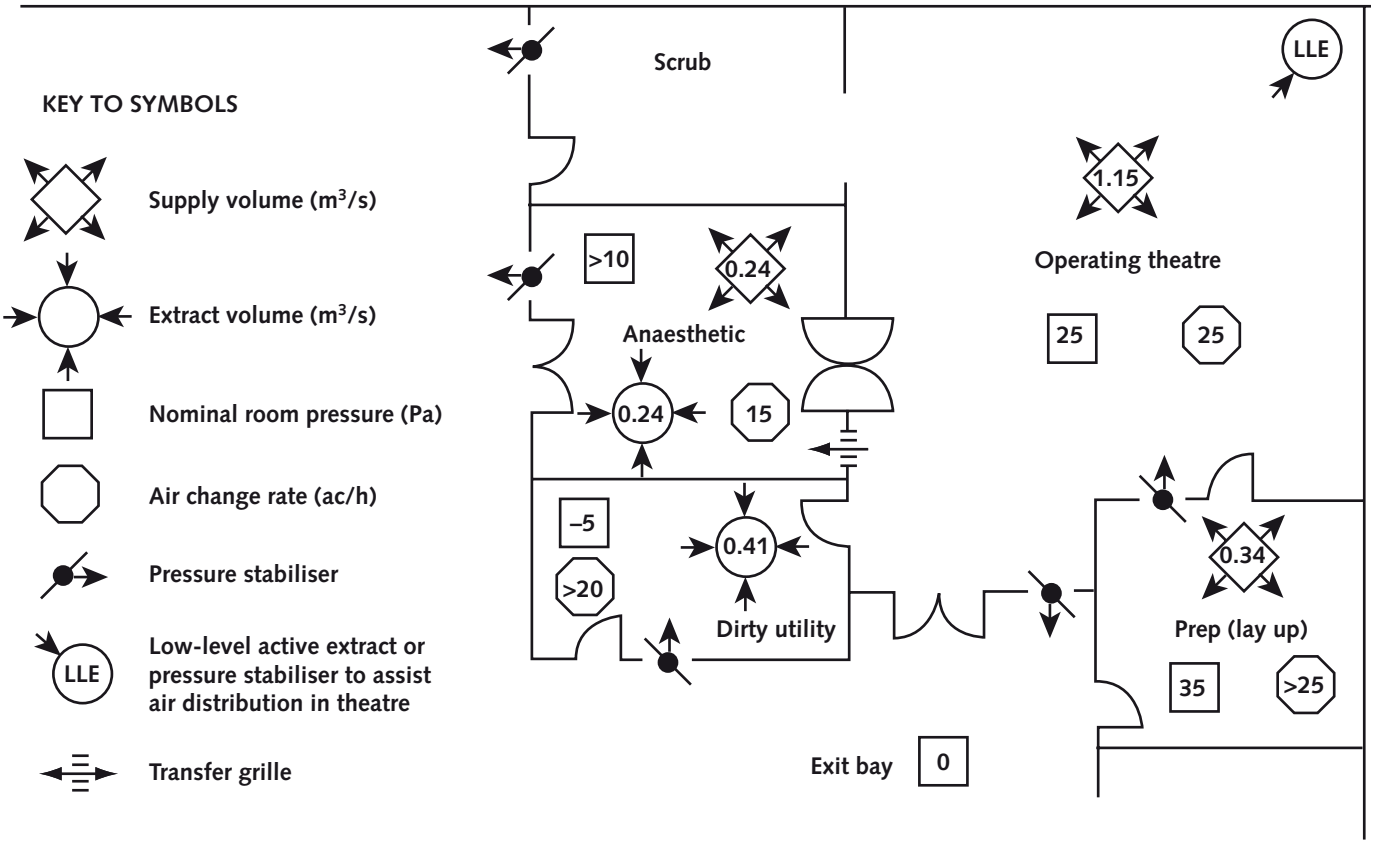
‡ Derived from Health Building Note 26

* This is a separate scrub and is not considered as being part of the theatre volume.

** Interchange is not permitted between the theatre and lay-up prep; therefore, as in Appendix 5, an air-flow protection of 0.28 + 0.06 closed-door air flow is required as a minimum (but see also the "designers' notes" in Appendix 4).

The volume of air to be extracted from the theatre should be determined by subtracting the air flow required for protection at the key door from the total air entering the space. The balance should be equally divided between the passive or active extract locations.

The extracts within the theatre may be either passive and fitted with pressure stabilisers, or active and connected to the extract system. They should be located at low level and positioned to promote the ventilation of all areas of the space



Standard layout 4 – suitable for a typical UCV theatre suite

Room	Size (m^3)‡	Air-change rate (AC/hr)	Nominal pressure (Pa)	Flow rate (m^3/s)
Theatre	165	25	25	1.15**
Anaesthetic	57	15	>10	0.24
Sterile pack store prep	36	10	25	0.10
Scrub	*	–	25	–
Dirty utility	36	–	–5	0.41

Notes:

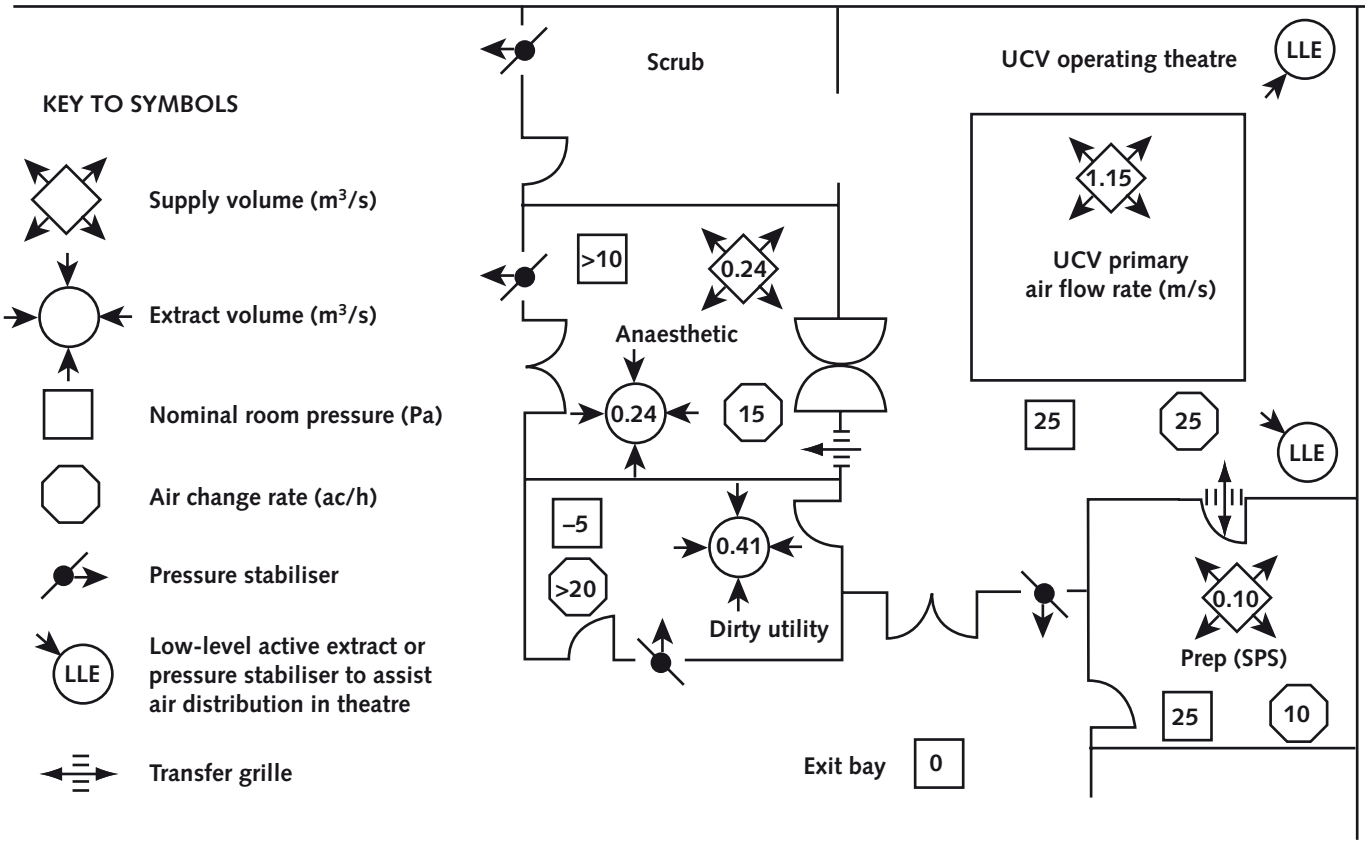
‡ Derived from Health Building Note 26

* This is a separate scrub and is not considered as being part of the theatre volume.

** Primary fresh-air volume only.

The volume of air to be extracted from the theatre should be determined by subtracting the air flow required for protection at the key door from the total air entering the theatre space. The balance should be equally divided between the passive or active extract locations.

The extracts within the theatre may be either passive and fitted with pressure stabilisers, or active and connected to the extract system. They should be located at low level and positioned to promote the ventilation of all areas of the space



Standard layout 5 (Health Technical Memorandum 2025 existing standard plan "1b") – typical layout for a conventional theatre suite

Note

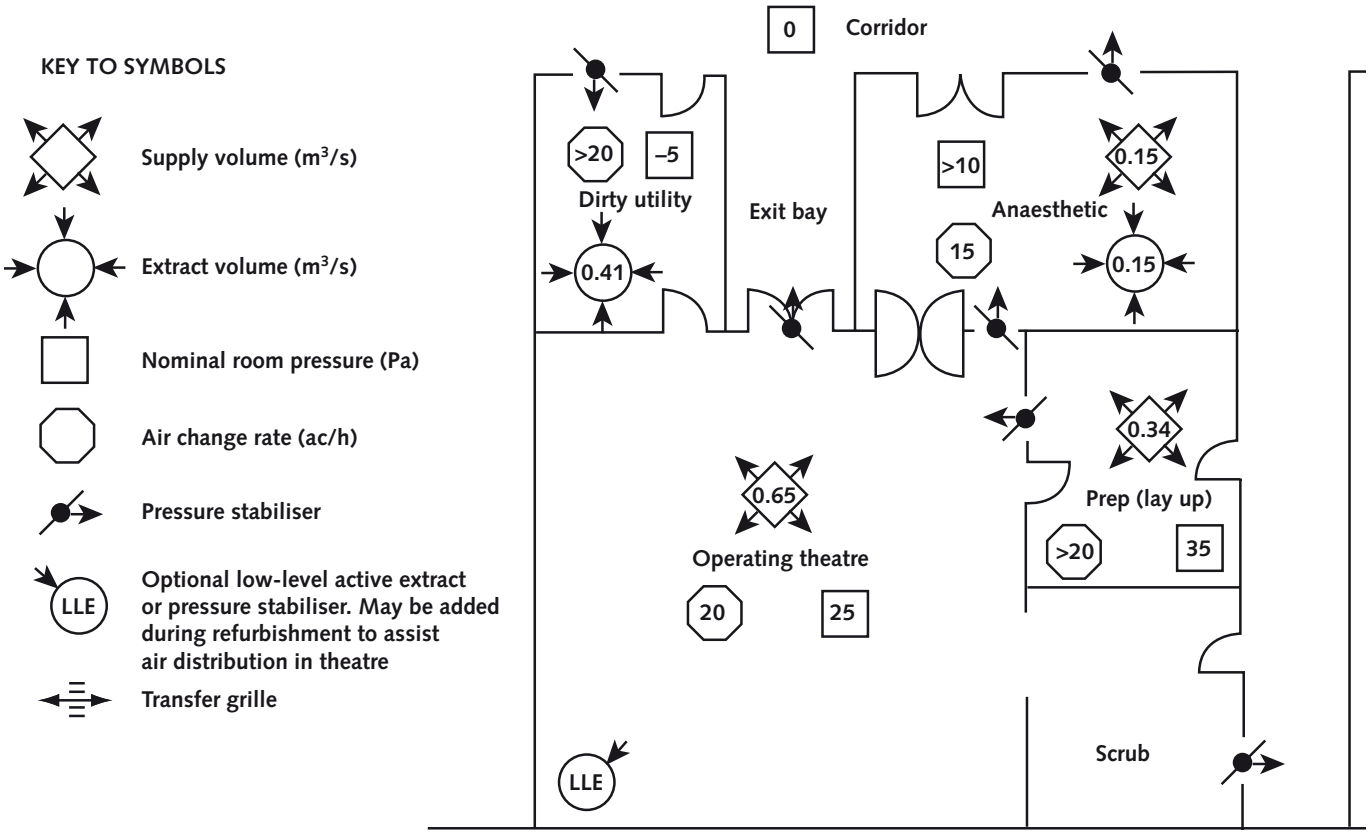
This layout and data is for historical purposes only. The information is to be used for the evaluation of existing systems, the fitting out of existing shell schemes or rebalancing following ventilation system cleaning.

Room	Size	Air-change rate (AC/hr)	Nominal pressure (Pa)	Flow rate (m^3/s)
Theatre	**Existing theatre suite to be measured on site**	20	25	0.65
Anaesthetic		15	>10	0.15
Lay-up prep		–	35	0.34*
Scrub		–	25	–
Disposal		–	–5	0.41

Notes:

* See the "designers' notes" in Appendices 4 and 5.

The disposal layout detailed will remain the same should a hatch be utilised instead of a door onto the outer corridor



Standard layout 6 (Health Technical Memorandum 2025 existing standard plan "1a") – typical layout for a UCV theatre suite

Note

This layout and data is for historical purposes only. The information is to be used for the evaluation of existing systems, the fitting out of existing shell schemes or rebalancing following ventilation system cleaning.

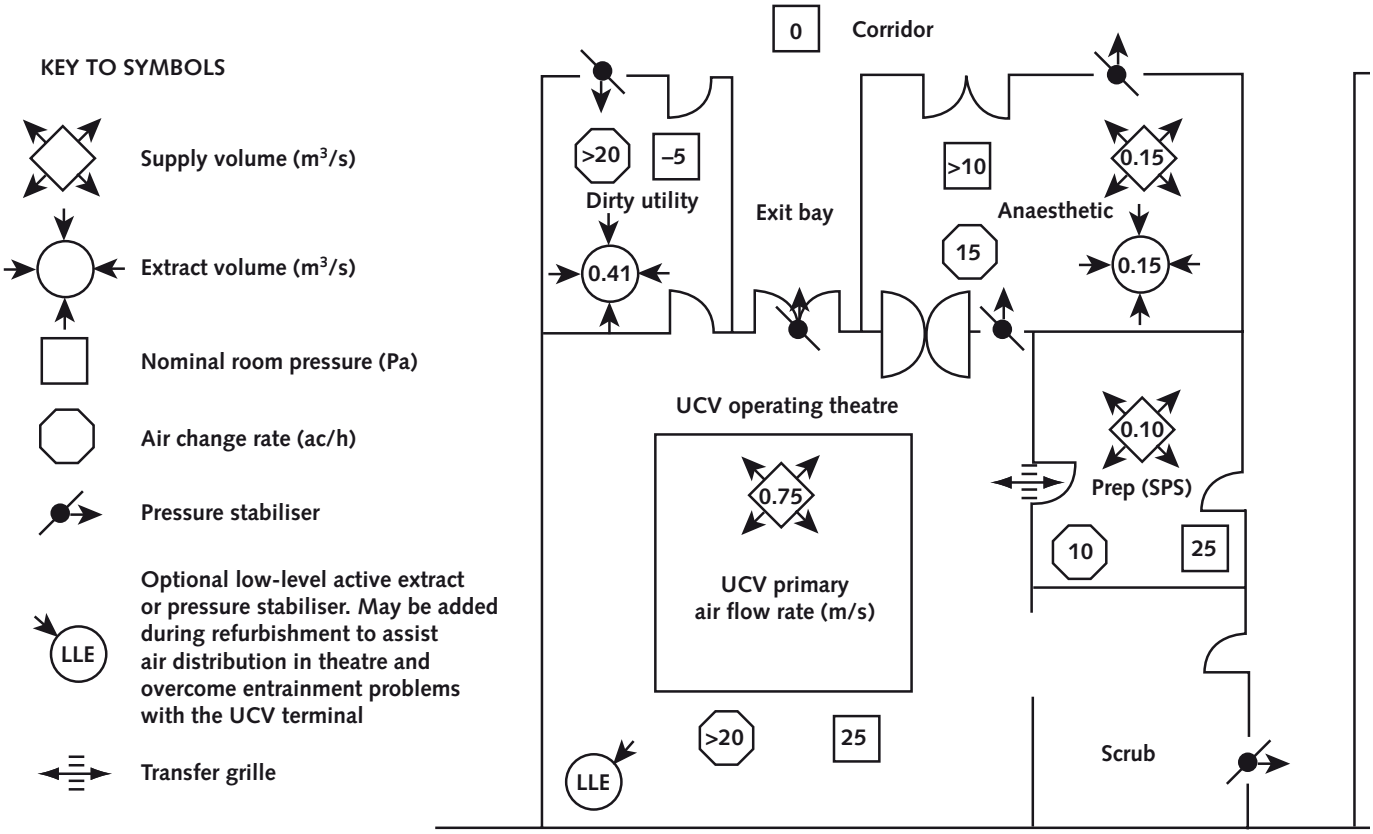
If difficulties are experienced with entrainment around the periphery of the UCV, adding a low-level active or passive extract in the location indicated will usually resolve the problem.

Room	Size	Air-change rate (AC/hr)	Nominal pressure (Pa)	Flow rate (m^3/s)
Theatre	**Existing theatre suite to be measured on site**	20	25	0.75*
Anaesthetic		15	>10	0.15
Sterile pack store prep		10	25	0.1
Scrub		–	25	–
Disposal		–	–5	0.41

Notes:

* Primary fresh-air-flow volume

The disposal layout detailed will remain the same should a hatch be utilised instead of a door onto the outer corridor



Standard layout 7 (Health Technical Memorandum 2025 existing standard plan "5b") – typical layout for a conventional theatre suite

Note

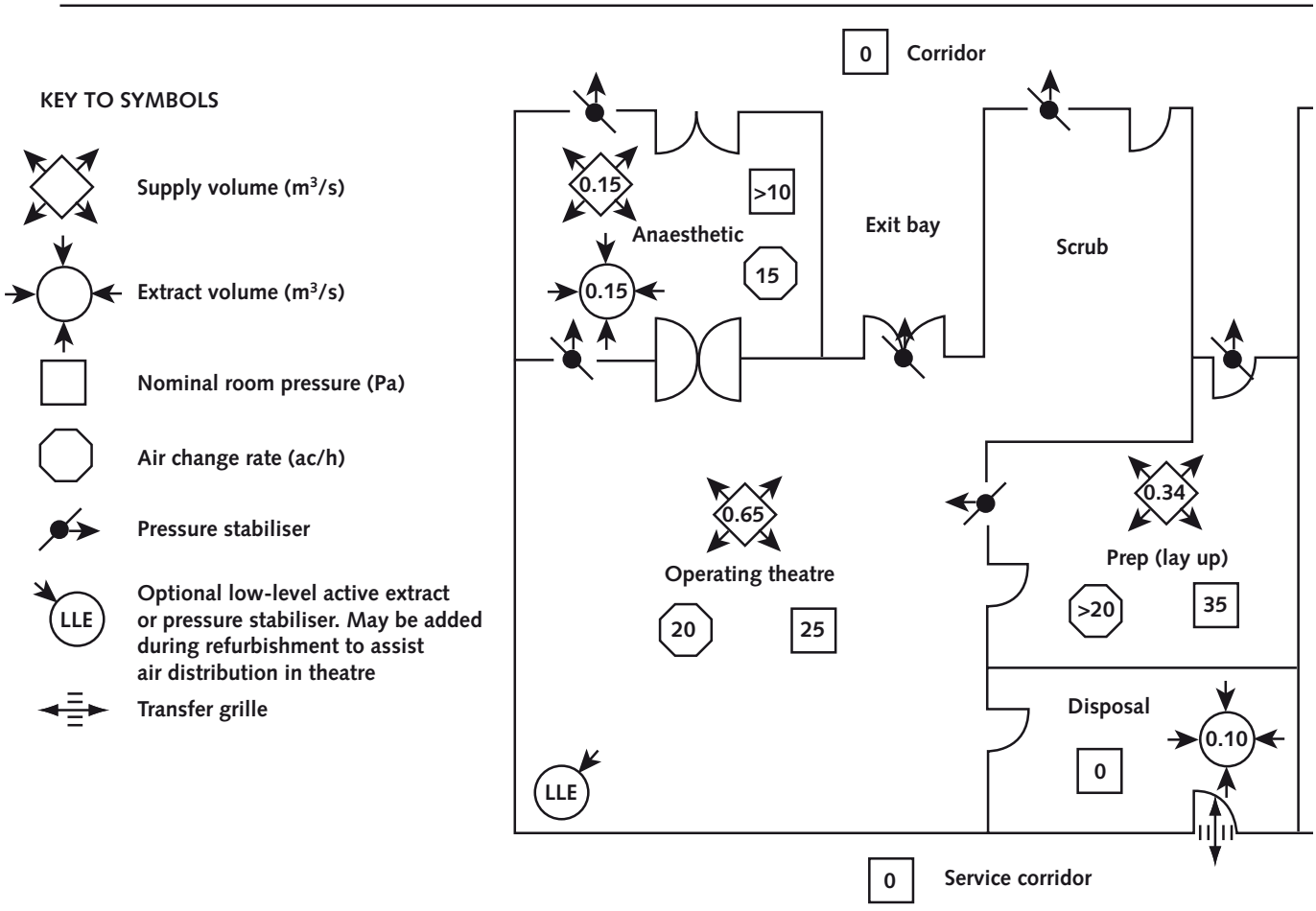
This layout and data is for historical purposes only. The information is to be used for the evaluation of existing systems, the fitting out of existing shell schemes or rebalancing following ventilation system cleaning.

Room	Size	Air-change rate (AC/hr)	Nominal pressure (Pa)	Flow rate (m^3/s)
Theatre	**Existing theatre suite to be measured on site**	20	25	0.65
Anaesthetic		15	>10	0.15
Lay-up prep		>20	35	0.34*
Scrub		–	25	–
Disposal		–	0	0.1

Notes:

* See the "designers' notes" in Appendices 4 and 5.

The disposal layout detailed will remain the same should a hatch be utilised instead of a door onto the outer corridor. Alternatively the disposal room could be omitted and replaced with a disposal hatch between the theatre and corridor



Standard layout 8 (Health Technical Memorandum 2025 existing standard plan "5a") – typical layout for a UCV theatre suite

Note

This layout and data is for historical purposes only. The information is to be used for the evaluation of existing systems, the fitting out of existing shell schemes or rebalancing following ventilation system cleaning.

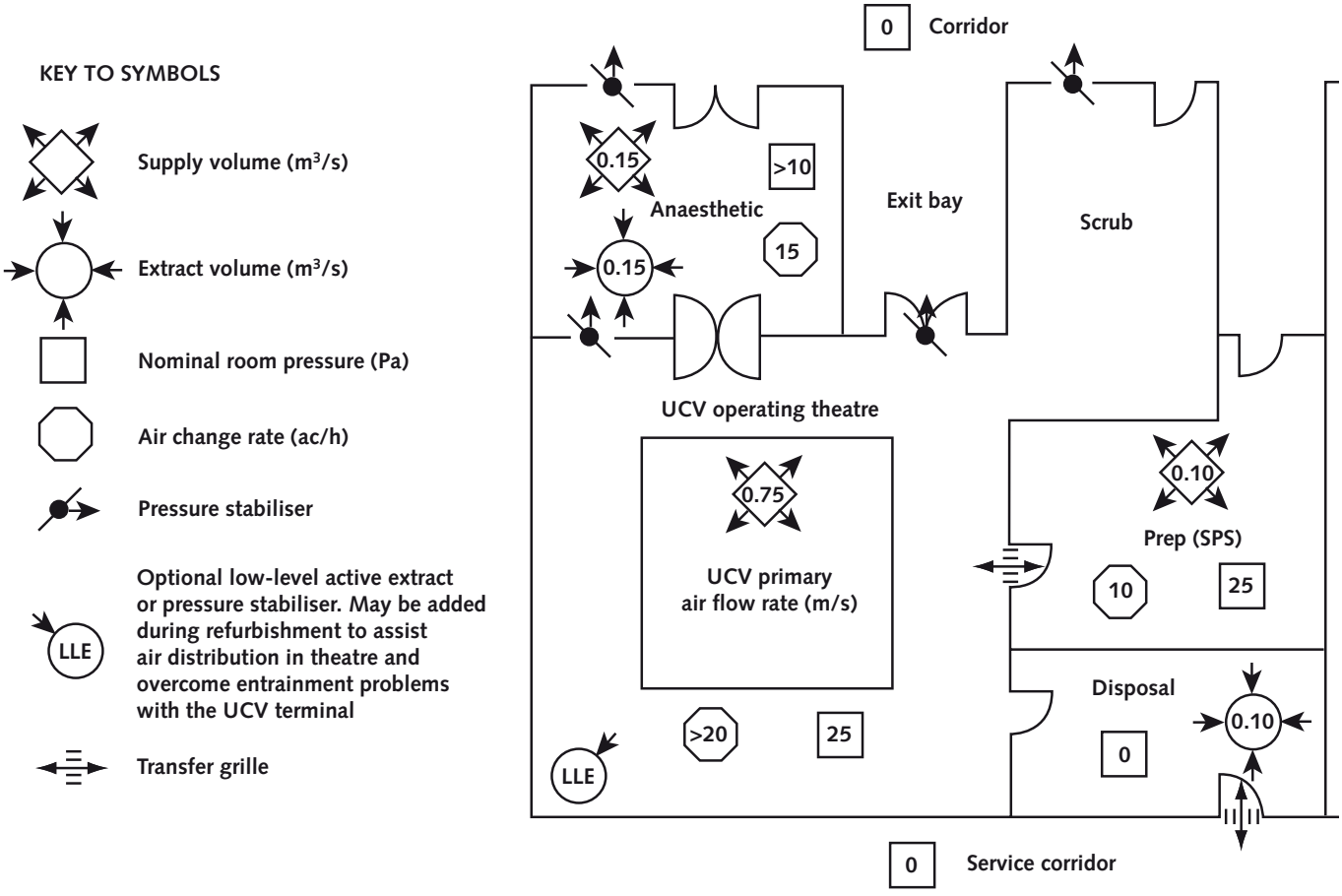
If difficulties are experienced with entrainment around the periphery of the UCV, adding a low-level active or passive extract in the location indicated will usually resolve the problem.

Room	Size	Air-change rate (AC/hr)	Nominal pressure (Pa)	Flow rate (m^3/s)
Theatre	**Existing theatre suite to be measured on site**	20	25	0.75*
Anaesthetic		15	>10	0.15
Sterile pack store prep		10	25	0.1
Scrub		–	25	–
Disposal		–	0	0.1

Notes:

* Primary fresh-air-flow volume only

The disposal layout detailed will remain the same should a hatch be utilised instead of a door onto the outer corridor. Alternatively the disposal room could be omitted and replaced with a disposal hatch between the theatre and corridor



Appendix 8 – Design of air-movement control schemes for operating theatres

General

A8.1 Standard operating suite design solutions are given in paragraphs 7.31–7.90 and Appendix 7. If these standard solutions cannot be used, the following procedure should be adopted, which will result in an acceptable design. Note that the method employed can equally be used to provide a design solution to a ventilated suite of rooms for any application.

A8.2 The method is concerned with the calculation of air-flow rates to ensure that correct air movement occurs between rooms when any one door is open. Under most circumstances, the air quantities required for air-movement control will approximate to those for either temperature control or bacterial contaminant dilution. This flow rate is sufficient to control the effects of any slight reverse flows occurring when a door is opened.

A8.3 The progression through the design procedure is shown in the air-flow design procedure chart (Figure A3) and is supported by worksheets WS1 to WS7 described in paragraph A8.4. It is recommended that a plan of the suite and an air-flow network be made (Figure A2) to collate all information. Flow rates, air-transfer devices etc should be entered as required. The remainder of this Appendix may be treated as reference data to assist in the various steps. The following symbols are used:

S_S – supply air-flow rate for summer temperature control;

S_W – supply air-flow rate for winter temperature control;

S_D – supply air-flow rate for dilution of bacterial contaminants;

S_L – supply air-flow rate for heat loss;

S_G – supply air-flow rate for heat gain;

E_D – extract air-flow rate for dilution of bacterial contaminants;

S_F – final supply air-flow rates

E_F – final extract flow rates;

S_{AMC} – air-supply flow rate for air-movement control;

E_{AMC} – air-extract flow for air-movement control;

L_{OUT} – leakage air-flow rate outward;

L_{IN} – leakage air-flow rate inward;

Σ_{OUT} – total air-flow rate outward;

Σ_{IN} – total air-flow rate inward.

A8.4 To simplify the procedure, standard worksheets (WS1 to WS7) have been devised. For each operating suite, a set is required comprising one each of WS1, WS3, WS5, WS6a, WS6b and WS7, one WS4 for each corridor and one WS2 to cover each peripheral room. WS2 has five versions:

- WS2a single flow,
- WS2b parallel/series multi-flow,
- WS2c parallel multi-flow or series multi-flow (unbalanced);
- WS2d series multi-flow (balanced); and
- WS2e bay (semi-open).

Peripheral room type

A8.5 The rooms in the operating suite other than the operating room and corridor are referred to as peripheral rooms. Peripheral rooms have been classified according to the flows in and out. These room classifications are defined in paragraphs A8.6–A8.11.

Single flow

A8.6 This is a room with only one door and a net surplus of supply or extract air.

Parallel multi-flow

A8.7 This is a room with two or more doors through each of which the air flows either outwards (high pressure) or inwards (low pressure) (for example the Prep (lay-up) in standard layout 5 in Appendix 7).

Parallel/series multi-flow

A8.8 This is a room having a net surplus of supply or extract and with two or more doors. One or more doors will be to an area of equal cleanliness and need not be protected; hence, the flow may vary between inwards and outwards, the remaining door being to an area of greater or lesser cleanliness (for example the Prep (SPS) in standard layout 6 in Appendix 7).

Series multi-flow (unbalanced)

A8.9 This is a room having a net surplus of supply or extract and with two or more doors. Air flows inwards through one or more doors and outwards through one or more doors.

Series multi-flow (balanced)

A8.10 This is a room as in paragraph A8.9 above, but having either no mechanical ventilation or no net surplus of supply or extract (for example an anaesthetic room).

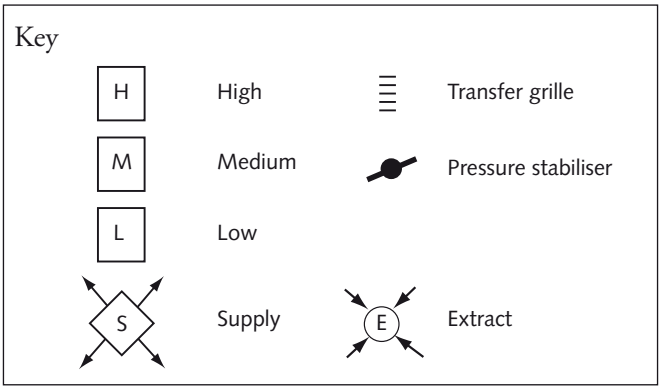
Bay

A8.11 A room which has a permanent opening to the operating room may be considered as a bay off the latter (for example a scrub). Two categories exist:

- open bay – the opening is larger than a normal single door opening. The bay may be considered as part of the main room;
- semi-open bay – the opening is no larger than a normal single door opening. In this case it is possible to protect the bay from the main room by provision of air supply or extract in the bay, or by passing air to or from another area.

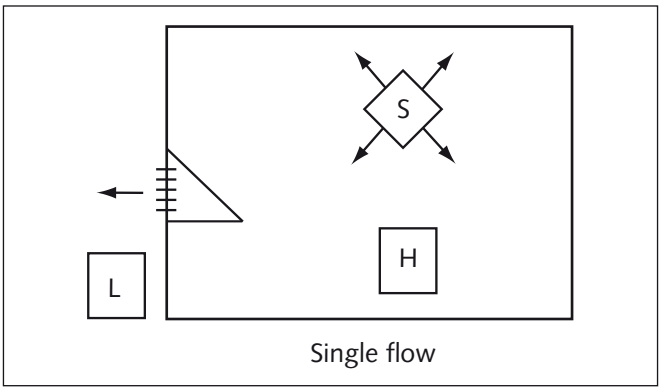
Air-movement control in peripheral rooms

A8.12 For the design of air-movement control, two types of air-transfer device are considered. These are transfer grilles and pressure stabilisers. Each has a particular field of application within the design, as described in paragraphs A8.34–A8.43. Air movement is controlled in each of the different room types described in paragraphs A8.13–A8.31.



Single flow rooms

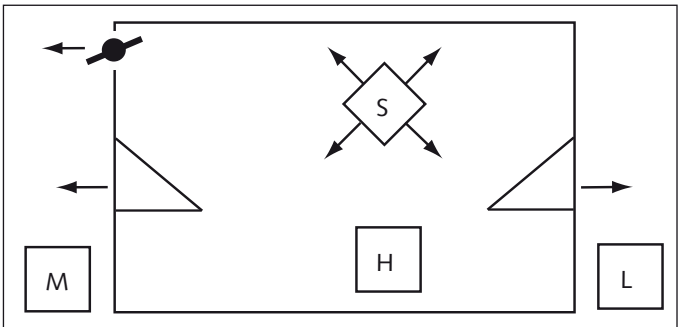
A8.13 An appropriately-sized transfer grille should be located in or adjacent to the door of each single flow room to relieve the pressure differences across the door when closed.



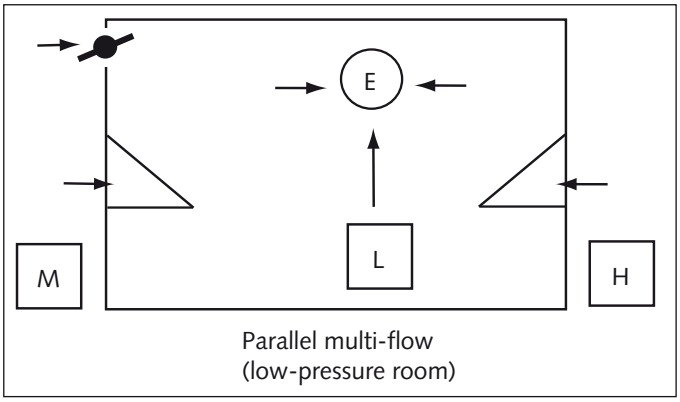
Single flow

Parallel multi-flow rooms

A8.14 The pressure difference across the closed doors must be relieved, but transfer grilles are not appropriate where two doors lead to areas of different pressures, because reverse flow could occur when the other door is open. For this reason, pressure stabilisers are used.



Parallel multi-flow
(high-pressure room)



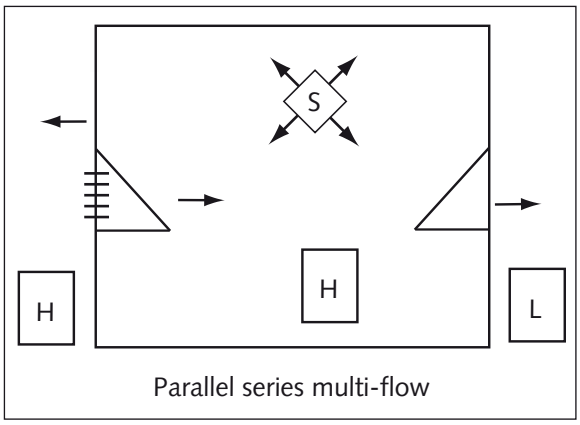
Parallel multi-flow
(low-pressure room)

A8.15 These rooms will be either high-pressure or low-pressure with respect to the adjacent areas (see preparation lay-up room and disposal room, respectively, in standard layout 5 of Appendix 7). The pressure-relief damper is always situated between the room and area, which results in the smaller differential pressure to ensure best use of air.

A8.16 Just as reverse flow can occur if transfer grilles are used, it can similarly occur via door gaps when the other door is opened. It is not possible to avoid this, except by using air locks, but due to the low flow rates and short durations involved, this is not considered to be of importance.

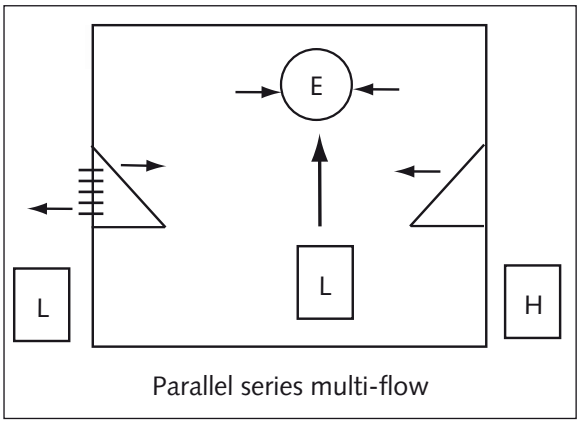
Parallel-series multi-flow rooms

A8.17 These rooms are similar to those in paragraph A8.14 above, but because the room is of equal cleanliness to one of the adjacent rooms, the nominal pressures will be equal and air may flow through the adjoining doorway in either direction (for example the Prep (SPS) in standard layout 6 of Appendix 7).



Parallel series multi-flow

A8.18 Where the nominal room pressure equals that of the higher-pressure adjacent room, the best use of air is by supplying air required for bacterial dilution only and allowing this to exhaust via a transfer grille to the area of equal cleanliness. The doorway to the lower pressure area is protected by the combination of the supply air and the air that will flow inwards through the transfer grille from the area of equal cleanliness.

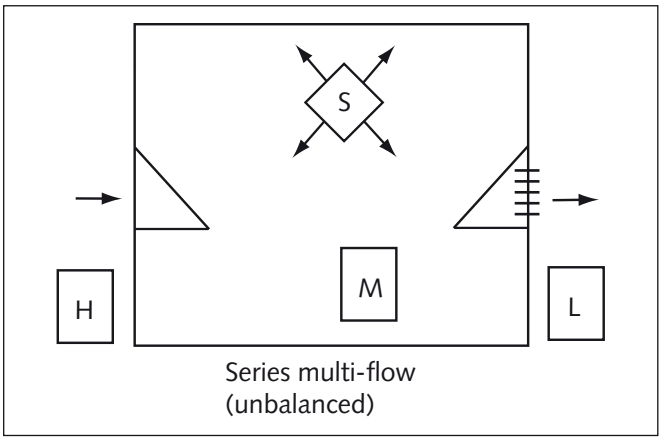


Parallel series multi-flow

A8.19 Conversely, where the nominal pressure equals that of the lower-pressure adjacent room, extract ventilation and a transfer grille to the lower pressure adjacent room should be provided (for example the disposal room in standard layout 8 of Appendix 7).

Series multi-flow (unbalanced)

A8.20 These rooms are somewhat similar to those in paragraph A8.15 above, but because the pressure lies between that of the rooms on either side, the back-flow problem does not exist.



Series multi-flow
(unbalanced)

A8.21 Where the room has a net surplus of mechanical supply air, a transfer grille should be located in or adjacent to the door through which air flows outwards, and the mechanical supply flow rate to the room should be chosen to give protection when this door is open.

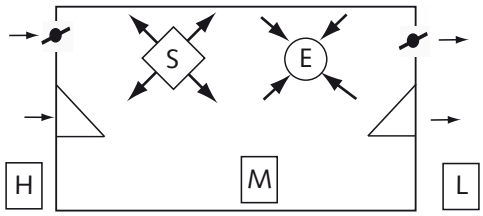
A8.22 Where the room has a net surplus of mechanical extract air, a transfer grille should be located adjacent to the door through which the air flows

inwards, and the mechanical extract flow rate to the room should be chosen to give protection when this door is open.

A8.23 The grille must be sized for the protection requirement of the opposing door when open. When the room on the high-pressure side depressurises, there is a possibility of back-flow through gaps around the door, but this problem may be ignored.

Series multi-flow (balanced)

A8.24 In these rooms, a transfer device adjacent to each doorway is required in order to provide a flow path for the air required to protect the opposing door when opened.



Series multi-flow (balanced)

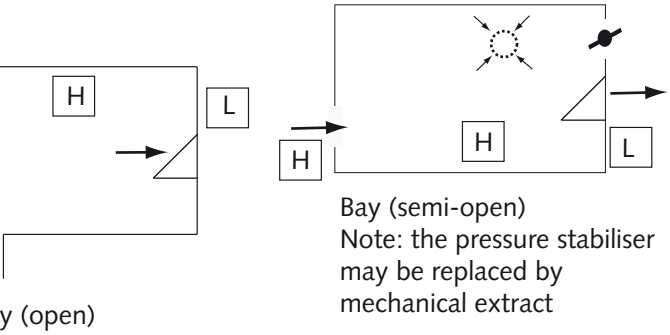
A8.25 These transfer devices will normally be pressure stabilisers, although transfer grilles may be used where a large amount of excess air is to be exhausted from the operating room when all doors are closed (for example anaesthetic rooms).

A8.26 The calculation procedure is to assume that pressure stabilisers are being used; then – if there is sufficient excess air – change to transfer grilles as described in paragraph A8.50.

Bay

Open bay

A8.27 A bay of the open type (for example scrub-up) is considered to be part of the operating room. Provided air movement is satisfactory, no specific extract is required.



Bay (open)

Bay (semi-open)
Note: the pressure stabiliser may be replaced by mechanical extract

Semi-open bay

A8.28 In a bay of the semi-open type, protection of one area from the other is possible (for example scrub-up).

A8.29 As stated previously, the need for protection between operating room and scrub-room is not very great. Better use of air can therefore be achieved in this case by installing a pressure stabiliser between the scrub-room and clean corridor. This will allow a flow of air through the scrub-room at all times, except when a door is opened elsewhere in the suite. The pressure stabiliser will then close and the air will be diverted to the other door. When it is considered necessary to protect the scrub-room at all times, either a transfer grille to the corridor or mechanical extract in the scrub-room should be provided.

Operating room

A8.30 Once the peripheral rooms have been considered, the operating room requirements may then be decided and the supply flow rate required for air-movement control calculated. This flow rate should be such that, with any one door open, the correct air movement directions are maintained. There will be one door in the suite that will require the largest supply flow rate to the operating room for protection when open. This is called the "key door" and is discussed separately in paragraph A8.33. Use of this concept avoids repetitive calculations for each door in turn. Having established the required supply flow rate, a relief route must be provided to the clean corridor for any excess air when the doors are closed. This would be via transfer grilles or pressure stabilisers through a series-flow room or via pressure stabilisers to the clean corridor directly.

Corridors

A8.31 All surplus air from the suite, except that lost through structure leakage and any passing to the outer corridor, will arrive in the patient/staff corridor. Should this air be insufficient to achieve the required air-change rate (see Appendix 3), some additional air supply should be provided. (The air balance should take account of structural leakage.)

Door opening

A8.32 Whereas the resulting pressures are dependent on ductwork layout, room relationships and characteristics of the fan, the generalisations shown in Appendix 6 can be used to estimate the change in room pressure when a door is opened.

A8.33 The "key door" will be the open double door which leaves the operating room at the highest pressure, and/or requires the largest air flow. This should be determined using the procedure in worksheet WS3.

Transfer grilles

A8.34 These may be used to limit the pressure differences across the closed door of a single-flow room or, in some instances, for protection of a series-flow or parallel-series-flow room. They allow air flow in both directions and may not be suitable for all applications.

A8.35 The free area of a grille is calculated from the following equation:

$$A = \frac{Q}{0.84\sqrt{\Delta P}}$$

where:

A is free area (m^2)

Q is flow rate (m^3/s)

P is pressure difference (Pa).

A8.36 The flow through a grille at a different pressure may be found from the following equation:

$$Q_2 = Q_1\sqrt{\frac{\Delta P_1}{\Delta P_2}}$$

where:

Q_1 and P_1 are original flow and differential pressure

Q_2 and P_2 are new flow and differential pressure.

A8.37 The transfer grille may be replaced by carefully proportioned door undercuts of the equivalent free area.

A8.38 The function of the transfer grille is to provide a means of air-flow control by which the volume and pressure loss can be established. If a grille is used, it should have an easily removable core to facilitate cleaning.

Pressure-relief dampers

A8.39 The functions of a pressure-relief damper are now carried out by pressure stabilisers. Accordingly, all mention of them has been removed from this document.

Pressure stabilisers

A8.40 Pressure stabilisers can be adjusted to hold the pressure constant over a wide range of flow rates. They are used where requirements exist for accurate room-pressure control or rapid shut-off on pressure fall.

A8.41 The installation of a grille or baffle in association with a stabiliser will alter the operating characteristics. It is recommended that a location be chosen to avoid the need for visual screening, for example, at high level. The location should be chosen to minimise the likelihood of damage.

A8.42 The stabilisers used should be virtually silent in operation, adjustable on site, maintenance-free and of a type which cannot be wrongly inserted. They should not be used in external walls or where the pressure difference is less than 5 Pa. The required size of a pressure stabiliser is dependent on the design pressure difference across it and flow rate through it. The manufacturer should provide data relating pressure difference to mean velocity (or flow rate per unit area). From this, the required area can be calculated and then rounded-up to the nearest size manufactured or nearest combination of smaller sizes.

A8.43 It is sometimes possible to arrange for a pressure stabiliser to perform two tasks. In an anaesthetic room, for example, the two pressure stabilisers may be made to pass the open door protection air, and also control the operating and anaesthetic room pressures with the door closed. To achieve this, the stabilisers are sized for the flow rate required with one of the doors open, but the pressure setting is

adjusted to be the value required with the doors closed. This is shown in Figure A1.

Door leakage flows

A8.44 For an air-movement control scheme to work satisfactorily, it is essential that the estimates of door-gap leakage made at the design stage are closely related to those which are achieved in practice. The calculation of gap-flows is complicated by the fact that such flows generally fall into the transition region between laminar and turbulent flow and hence do not follow the normal flow equations. The gaps assumed are 4 mm along the bottom, 3 mm at the top and sides, and 2 mm between double leaves. Doors should not have wider gaps than these. Tighter gaps would result in lower flow-rate requirements and hence lower fan power, but care should be taken to ensure that all doors in the suite have similar gap dimensions. It may be possible to ignore the door leakage and so reduce the air-flow requirement (see the "designers' notes" in Appendix 4).

Room temperature estimation

A8.45 The air-flow rate required to prevent back-flow through an open door is dependent on the temperature difference across the door. The design figures shown in Appendix 6 are based on the temperature differences that will normally occur in practice, assuming heat gains and losses in accordance with Appendix 4.

A8.46 At step 11 of the air-flow design process, the temperature differences across the doors of all rooms classed as "sterile" are calculated. Worksheet WS6 is recommended for the calculations, using the following criteria:

a. assume that the operating room is being controlled at 20°C and calculate the incoming air-supply temperature as shown on worksheet WS6;

b. the calculation should be repeated for both summer and winter conditions, with an operation in progress;

c. assume all doors are closed;

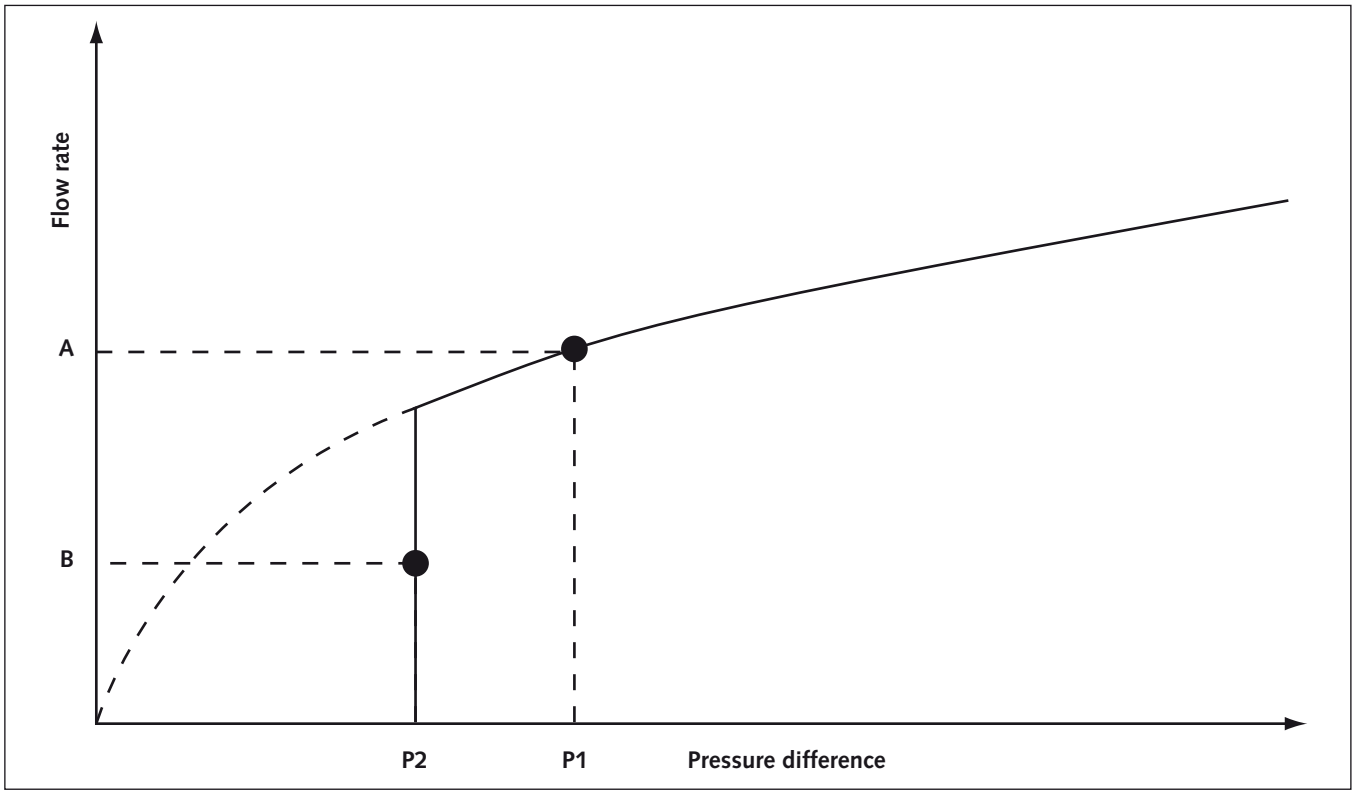
d. use the room supply flow rates from WS1;

e. use the inward air flows through air-transfer devices and closed door leakages from WS2a to WS2E;

f. the formula used in worksheet WS6 is as follows:

$$T = \frac{(t_1Q_1 + t_2Q_2 + \ldots + t_nQ_n) + 0.828H}{(Q_1 + Q_2 + \ldots Q_n)}$$

Figure A1 Pressure stabilisers performing two tasks



where:

Q = flow rate from source (m^3/s)

t = the temperature of source (°C)

H = the room heat gain (kW).

A8.47 If the evaluated temperature differences between rooms do not exceed 2°C, the solution is satisfactory; otherwise proceed as follows:

(i) check the assumption on which the heat gains are based;

(ii) take steps to reduce the heat gains;

(iii) if the door is to a corridor, the flow through the open door will be larger than the value given in Appendix 6. Calculate on WS3, assuming it is the "key door" with door-flow unknown, and the supply as known;

(iv) if the door leads to a room with mechanical supply, install a trimmer heater in the supply to the room controlled by either a differential thermostat or a thermostat slaved to the operating room thermostat to ensure that T is minimised;

(v) if the door leads to a room with no mechanical supply, increase the door protection flow as follows:

$$Q_{new} = Q_{old}\left[\frac{\Delta T + 1}{2}\right]$$

A8.48 These options should be considered in this order, and (i), (ii) and (iii) should be investigated thoroughly before proceeding to (iv) or (v). The mechanical supply may need to be increased in order to achieve the desired air-change rates.

Relief of excess air from operating room when all doors are closed

A8.49 As the mechanical supply to the operating room is sized to provide an appropriate flow outward through any door which is opened, it follows that when all doors are closed, there will be more air supplied to the operating room than can exit from it via leaks etc. This "excess" air can be relieved by either of the two methods described in paragraphs A8.50–8.54.

By transfer devices via the anaesthetic room

A8.50 For door protection, the transfer devices in the anaesthetic room are typically designed to pass 0.47 m^3/s at a differential pressure of 14 Pa. When the doors are closed, the differential pressure will change to 11 Pa between theatre and anaesthetic room, and 14 Pa between anaesthetic room and corridor; the volume of air passed by the transfer devices will be modified as shown in the following formula:

$$Q = Q_1\left(\frac{\Delta P_1}{\Delta P_2}\right)^{1/2}$$

$$= 0.47\left(\frac{11}{14}\right)^{1/2}$$

$$= 0.42\ m^3/s$$

where:

Q = "excess" air to be vented with doors closed

Q_1 = air flow required for door protection through transfer device

ΔP_1 = nominal differential pressure with door to operating room closed and door to corridor closed

ΔP_2 = nominal differential pressure between either the anaesthetic room and corridor when the operating room door is open, or the anaesthetic room and operating room when the corridor is open. This differential pressure is used when selecting size of both devices.

A8.51 If the "excess" air is less than 0.42 m^3/s, a pressure stabiliser is required to ensure that the correct protection air-flow is available to pass through the door.

A8.52 If the "excess" air is greater than 0.42 m^3/s, a transfer grille is acceptable because at all times the air-flow will exceed the flow required for door protection.

By pressure stabilisers to the corridor

A8.53 If it is undesirable to pass operating room air through the anaesthetic room, it may be passed directly to a corridor via a separate pressure stabiliser.

A8.54 If there is sufficient "excess" air, the transfer grille solution at paragraph A8.52 should be adopted, as it provides the simplest solution and, once set up, will require no further maintenance. With less excess air, it is recommended that the air be passed through the anaesthetic room via the pressure stabilisers as at paragraph A8.51, thus keeping the number of pressure stabilisers to a minimum. Both these solutions increase the air-change rate in the anaesthetic room, but care should be taken to avoid passing excessive amounts through that would cause discomfort to the occupants.

Figure A2 An example of an air-flow network

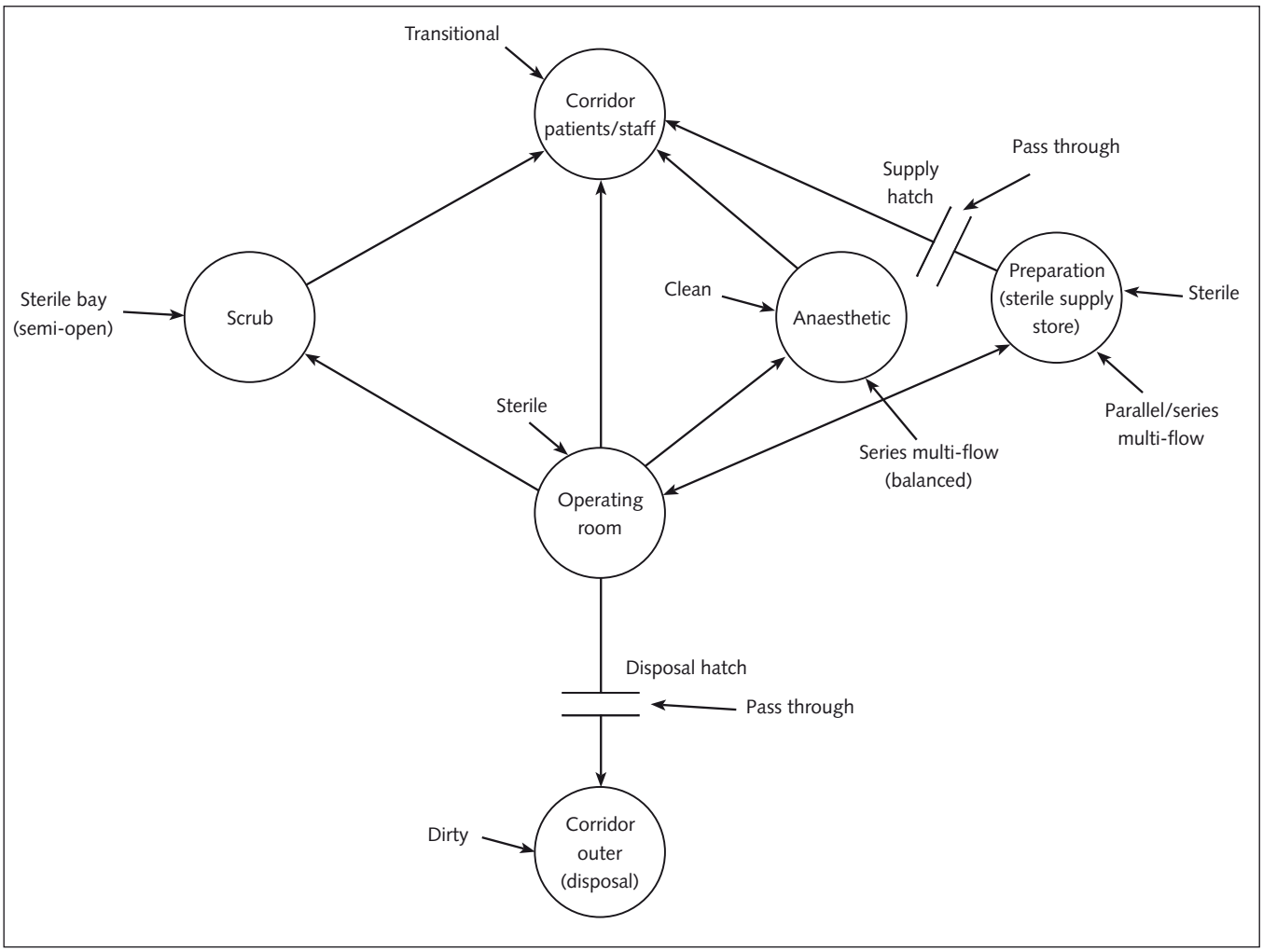


Figure A3 Air-flow design procedures

Step	Description	Worksheet
1	Show nominal room pressures and air flow directions on the plan of the theatre suite and WS1	WS1
2	Enter heat/loss/gain data and calculate supply air flow rates for temperature control only. Categorise room types, eg sterile, clean etc	WS1
3	Enter air flows required for bacterial contamination control or air change rate, whichever is the greater; add supply and extract volumes (S_D, E_D) on the plan	WS1
4	Define peripheral room types, see paragraphs A8.5–A8.11, and select appropriate worksheets	Select from WS2a to WS2e
5	Locate air transfer devices, enter details on worksheets and locate on the plan and Figure A2	Selected worksheets from WS2a to WS2e
6	For each peripheral room, determine air flows through doors when open and calculate mechanical supply or extract and transfer device flows	as above
7	Select "Key Door" and calculate air supply for operating room	WS3
	Does this door produce solution with greatest flow? — NO → (return to step 7)	
	YES ↓	
8	Transfer to WS1 and select final rate S_F and E_F	WS1, WS3
9	Make provision for relief of excess air with doors closed	Selected worksheets and WS3
10	Calculate supply and extract flow rates for corridor(s)	WS4, WS5
11	Calculate room temperatures (all doors closed) and ΔT's	WS6a and WS6b
	Do any ΔT's across doors to sterile rooms exceed 1.0°C? — YES → Rectify as in paragraph A8.47	
	NO ↓	
12	Make summary of flows	WS6a and WS6b
13	Size transfer devices, size ductwork, central plant etc	WS7
14	Design ductwork layout, control plant etc	–

Calculation sheet for flow rates			**Worksheet WS1** **Reference:**			
Room name						
1. Summer temperature control Heat gain	kW					
2. Acceptable Δt	°C					
3. Air flow rate (S_G) $= \frac{\text{Gain}}{\Delta t \times 1.2}$	m^3/s					
4. Winter temperature control Heat loss	kW					
5. Acceptable Δt	°C					
6. Air flow rate (S_L) $= \frac{\text{Loss}}{\Delta t \times 1.2}$	m^3/s					
7. Dilution of bacterial contaminants Air flow rate	m^3/s					
S_D or E_D						
8. Desired air change rate	AC/hr					
$\frac{\text{AC/hr} \times \text{room volume } (m^3)}{3600}$	m^3/s					
9. Maximum of S_G, S_L, S_D or E_D or air change rate from step 8	m^3/s					
10. Air movement control Air flow rate for air movement control S_{AMC} or E_{AMC} (from WS2, WS3 or WS4)	S m^3/s					
	E m^3/s					
11. Final supply flow rate (S_F)	m^3/s					
12. Final extract	m^3/s					
13. Total supply		m^3/s				
14. Total extract		m^3/s				

Surveyor (AP(V)/CP(V)) ..... Date .....

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Air movement control **Peripheral room ..... type, single flow**	**Worksheet WS2a** **Reference:**
	Nominal pressure: **Pa**

Consider door to ..... open

			Air flow, m^3/s		
	Pa	Δt	Out	In	Remarks
Flow required through doorway to give protection					
Total					

S_{AMC} $(\Sigma_{OUT} - \Sigma_{IN})$ ☐ m^3/s

or

E_{AMC} $(\Sigma_{IN} - \Sigma_{OUT})$ ☐ m^3/s

Transfer S_{AMC} or E_{AMC} to WS1

Consider door to ..... closed

	Pa	Δt	Out	In	Remarks
Closed door leakage					
Total					

Return S_F and E_F to WS1 ☐ ☐

Flow through transfer grille outward $(S_F - E_F - L_{OUT})$ ☐

or

Flow through transfer grille inward $(E_F - S_F - L_{IN})$ ☐

Surveyor (AP(V)/CP(V)) ..... Date .....

Air movement control **Peripheral room ..... type, parallel/series multi-flow**	**Worksheet WS2b** **Reference:** **Nominal pressure:** **Pa**

Door from this room to ..... (room of equal cleanliness) is not to be protected.
A transfer grille is located in, or adjacent to, this door

Consider other door to ..... open.

Room pressure now becomes [ ] or [ ] or [ ] Pa (see Appendix 6)

			Air flow, m^3/s		
			Out	In	Remarks
Flow required through doorway to give protection					
At above pressures leaks through closed doors	Pa	ΔP			
Mechanical supply or extract (S_F/E_F)					
		Total			

X ($\Sigma_{OUT} - \Sigma_{IN}$) [ ] or Y ($\Sigma_{IN} - \Sigma_{OUT}$) [ ]

Transfer grille required
from high-pressure zone Flow = X
or [ ] at [ ] ΔPa
to low-pressure zone Flow = Y
Size of transfer grille (free area) A1 [ ]

Consider doors and hatch closed – room presssure becomes [ ] Pa (nominal)

Closed door leakage from Appendix 4 (assuming no transfer grille)	Pa	ΔP	Out	In	Remarks
Mechanical supply or extract					
		Total			

Air flow required through transfer grille = IN – OUT = Z' [ ]
or OUT – IN = Z'' [ ]

Transfer grille required flow Z' or Z'' [ ] @ [ ] ΔP

Size of transfer grille (free area) A2 = [ ]

Select larger of A1 or A2 [ ]

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Air movement control **Peripheral room ..... type, parallel multi-flow high/low or series multi-flow (unbalanced)**	**Worksheet WS2c** **Reference:** **Nominal pressure:** **Pa**

Consider door from this room to ..... open.

Room pressure now becomes [ ] or [ ] or [ ] Pa (see Appendix 6)

			Air flow, m^3/s		
			Out	In	Remarks
Flow required through open doorway to give protection					
At above pressures leaks through closed doors are:	Pa	ΔP			
Total					

S_1 ($\Sigma_{OUT} - \Sigma_{IN}$) [ ] or E_1 ($\Sigma_{IN} - \Sigma_{OUT}$) [ ]

Consider door from this room to ..... open.

Room pressure now becomes [ ] or [ ] or [ ] Pa

			Out	In	Remarks
Flow required through open doorway to give protection					
At above pressures leaks through closed doors are:	Pa	ΔP			
Total					

S_2 ($\Sigma_{OUT} - \Sigma_{IN}$) [ ] or E_2 ($\Sigma_{IN} - \Sigma_{OUT}$) [ ]

Consider doors closed. Closed doors leakage from Appendix 4

Door to:	Pa	ΔP	Out	In	Remarks
Total					

Return S_F and E_F from WS1 [ ]

Flow through transfer device outward ($S_F - L_{OUT}$) [ ] to .....

or

Flow through transfer device inward ($E_F - L_{IN}$) [ ] from .....

Transfer grille [ ] Pressure relief damper [ ]

Surveyor (AP(V)/CP(V)) ..... Date .....

Air movement control **Peripheral room ..... type, series multi-flow (balanced)**	**Worksheet WS2d** **Reference:** **Nominal pressure:** **Pa**

Note: In this type of room the supply and extract air flow rates are equal and take no part in the air movement control (AMC)

First, open door to higher pressure area.

Room pressure then becomes [ ] or [ ] or [ ] Pa (see Appendix 6)

			Air flow, m^3/s		
			Out	In	Remarks
Flow required through open doorway to give protection. See Appendix 6					
At above pressures leaks through closed doors are:	Pa	ΔP			
Total					

Q_1 ($\Sigma_{IN} - \Sigma_{OUT}$) [ ] (+ve inwards)

Next, open door to lower pressure area.

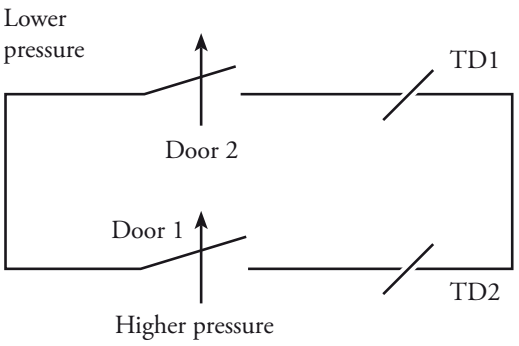
Room pressure then becomes [ ] or [ ] or [ ] Pa

			Out	In	Remarks
Flow required through open doorway to give protection					
At above pressures leaks through closed doors are:	Pa	ΔP			
Total					

Q_2 ($\Sigma_{OUT} - \Sigma_{IN}$) (+ve outwards)

Flow through transfer device (TD1) to protect door 1 = $Q1$ [ ] at resultant ΔP .....

Flow through transfer device (TD2) to protect door 2 = $Q2$ [ ] at resultant ΔP .....



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Surveyor (AP(V)/CP(V)) ..... Date .....

Air movement control **Peripheral room ..... type bay (semi-open)**			**Worksheet WS2e** **Reference:** **Nominal pressure:** **Pa**		
Note: If the room is of the open bay type (ie opening is larger than normal single doorway), the room should be considered part of the main room. No air movement control considerations need then be made, and this sheet can be discarded. Supply and/or extract flow will be based on air distribution considerations.					
Consider permanent opening					
			Air flow, m^3/s		
			Out	In	Remarks
Flow required through opening to give protection					
Leaks through closed doors to:	Pa	ΔP			
		Total			
E_{AMC} [ ] or flow outward through transfer device ($\Sigma_{IN} - \Sigma_{OUT}$) [ ]					
Transfer S_{AMC} or E_{AMC} to WS1					
Transfer device – transfer grille [ ] – pressure stabiliser [ ]					
Size select transfer device for flow rate [ ] @ ΔP [ ]					
Note: A door from the bay is considered with the peripheral room to which it leads or, if it leads to the corridor, it is considered with the main room					

Surveyor (AP(V)/CP(V)) ..... Date .....

Air movement control **Operating room**	**Worksheet WS3** **Reference:** **Nominal pressure:** **Pa**

Note: To avoid considering each door open in turn, the "key door" concept is introduced. This is the door which requires the greatest mechanical flow when open. See paragraph A8.33

Select "key door" (see above).

Consider this door open – room pressure now becomes [ ] Pa (see Appendix 6)

See Appendix 7 for room pressures

			Air flow, m^3/s		
			Out	In	Remarks
Flow required through doorway to give protection					
Air flow "out" or "in" via doors, transfer devices etc	Pa	ΔP			
Mechanical extract					
Total					

S_{AMC} ($\Sigma_{OUT} - \Sigma_{IN}$) [ ] transfer S_{AMC} to WS1

Consider all doors closed.

Return S_F from WS1 [ ] Room pressure now [ ] Pa (nominal)

Air flow "out" or "in" via door leakage, transfer devices etc	Pa	ΔP	Out	In	Remarks
Mechanical extract and supply					
Total					

Flow ($\Sigma_{IN} - \Sigma_{OUT}$) through transfer device [ ] @ ΔP [ ] to .....

For final selection of transfer device see paragraphs A8.50–A8.54

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Surveyor (AP(V)/CP(V)) ..... Date .....

Air movement control **Corridor**			**Worksheet WS4** **Reference:**		
			Nominal pressure:		**Pa**
Consider all doors closed					
			Air flow, m^3/s		
			Out	In	Remarks
Flow required through doorway to give protection					
Leaks through closed doors, transfer devices, permanent openings etc	Pa	ΔP			
Total flow inwards (S_1)					
Add mechanical input (S_2) if necessary to increase S_1 to give 7 AC/hr					
Total flow outwards and inwards					
$S_{AMC} = (\Sigma_{OUT} - \Sigma_{IN} + S_2)$ [ ] Transfer to WS5					
or $E_{AMC} = (\Sigma_{IN} - \Sigma_{OUT} + S_2)$ [ ] Transfer to WS5					

Note: this sheet to be used for each individual operating theatre suite (or pair of suites if they share a preparation room)

Surveyor (AP(V)/CP(V)) ..... Date .....

Air movement control	**Worksheet WS5** **Reference:**	
Summary of air supply and extract for an operating suite		
Air flow to corridor	All doors closed	Anaesthetic (key door open)
	m^3/s	m^3/s
From preparation		
From operating room		
From scrub		
From anaesthetic		
Total (a)		
Air flow to corridor From disposal		
From other source		
Total (b)		
Other room supplies ..... Total (c)		
Total air supply (a) + (b) + (c)		
Consider corridor ventilation (see Appendix 3) and calculate air volume required, based on 7 AC/hr (see Note 1)		
		m^3/s
Air flow required to ventilate corridor		
Air flow required to ventilate service corridor (see Note 2)		
If the air flow from the operating suite (a) and (b) is greater than the calculated required volume, no further supply air is necessary		
		m^3/s
Additional air to ventilate corridor		
Additional air to ventilate service corridor (see Note 2)		
Air extract The size of the extract plant should be of the order of 10% below the supply to assist in maintaining the department under positive pressure relative to the outside departments		
		m^3/s
Extract plant = Supply less leakage		
Less 10% of supply		
Total extract (see Note 3)		

Notes: 1. In the case of a multi-theatre operating department, the air balance for the corridor should be considered as a separate exercise, taking into account the final dispersal of excess air.
2. Omit these if only one corridor in operating suite.
3. The extract volume includes 0.24 m^3/s from the anaesthetic room for a balanced condition

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Surveyor (AP(V)/CP(V)) ..... Date .....

Room temperature – summer	**Worksheet WS6a** **Reference:**

Find summer supply temperature $T_{SS} = 20 - 0.828\frac{H(\text{O/R})}{Q(\text{O/R})}$ = T_{SS} ____ °C

Note: the temperature of a space may be calculated from

$$T = \frac{t_1Q_1 + t_2Q_2 + \ldots\ldots\ldots + t_nQ_n + (0.828H)}{Q_1 + Q_2 + \ldots Q_n}$$

Where t_1 is temperature of source 1 (°C)
Q_1 is flow from source 1 when all doors are closed (m^3/s)
H is heat gain in space (kW)

Room	Heat gain kWh	Supply		Flows inwards										Temperature °C T
		Q	T_{SS}	From		From		From		From		From		
				Q	t	Q	t	Q	t	Q	t	Q	t	

Check doors to sterile areas

Door between	Calculated room ΔT (°C)	Maximum ΔT permitted	Remarks

Surveyor (AP(V)/CP(V)) ..... Date .....

Room temperature – winter	**Worksheet WS6b** **Reference:**

Find winter supply temperature $T_{SW} = 20 - \dfrac{0.828H(\text{O/R})}{Q(\text{O/R})}$ = T_{SW} ____ °C

Note: the temperature of a space may be calculated from

$$T = \frac{t_1Q_1 + t_2Q_2 + \ldots\ldots\ldots + t_nQ_n + (0.828H)}{Q_1 + Q_2 + \ldots Q_n}$$

Where t_1 is temperature of source 1 (°C)
Q_1 is flow from source 1 when all doors are closed (m^3/s)
H is heat gain in space (kW)

Room	Heat gain kWh	Supply		Flows inwards										Temperature °C T
		Q	T_{SW}	From		From		From		From		From		
				Q	t	Q	t	Q	t	Q	t	Q	t	

Check doors to sterile areas

Door between	Calculated room ΔT (°C)	Maximum ΔT permitted	Remarks

Surveyor (AP(V)/CP(V)) ..... Date .....

Transfer grilles, pressure relief dampers and pressure stabilisers	**Worksheet WS7** **Reference:**

Transfer grilles – see paragraphs A8.34–A8.38

No	Location	Pressure difference Pa	Flow rate m^3/s	Free area m^2	Model	Resultant Δp Pa	Remarks

Pressure relief dampers – see paragraph A8.39

No	Location	Pressure difference Pa	Flow rate m^3/s	Free area m^2	Pressure setting Pa	Remarks

Pressure stabilisers – see paragraphs A8.40–A8.43

Note: where a stabiliser is acting both as series room door protection and operating pressure control, "pressure difference" and "flow rate" are from WS2d; "pressure setting" is from WS3

No	Location	Pressure difference Pa	Flow rate m^3/s	Free area m^2	Pressure setting Pa	Remarks

Surveyor (AP(V)/CP(V)) ..... Date .....

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DH Department of Health

Heating and ventilation systems

Health Technical Memorandum 03-01: Specialised ventilation for healthcare premises

Part B: Operational management and performance verification

DH INFORMATION READER BOX

Policy	**Estates**
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Document Purpose	Best practice guidance		
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Preface

About Health Technical Memoranda

Engineering Health Technical Memoranda (HTMs) give comprehensive advice and guidance on the design, installation and operation of specialised building and engineering technology used in the delivery of healthcare.

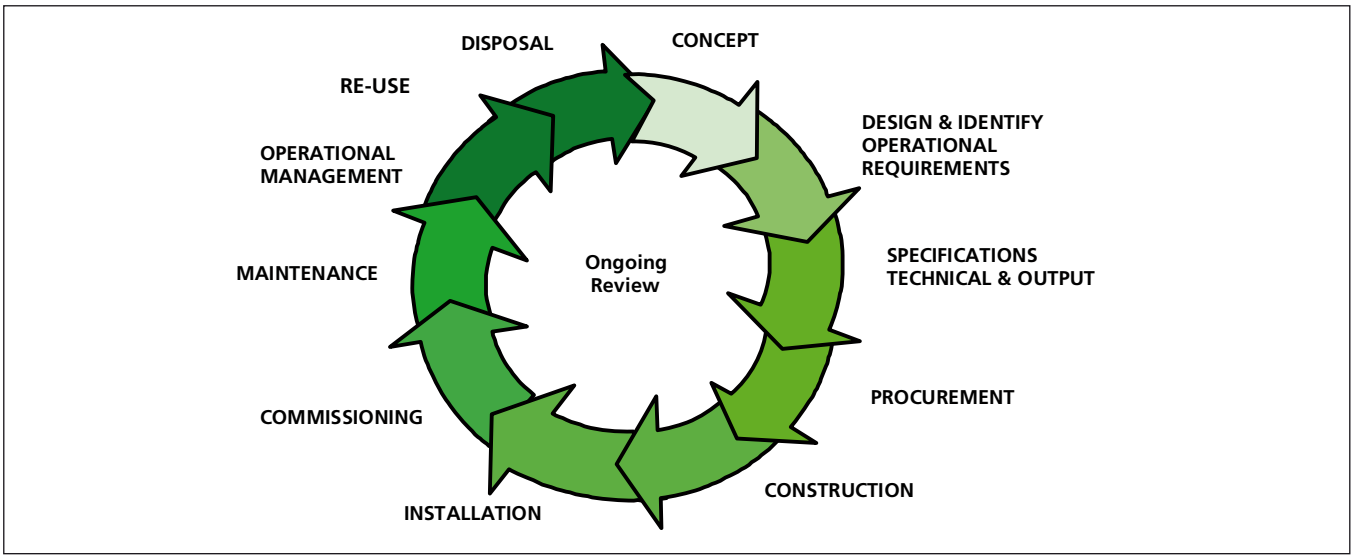
The focus of Health Technical Memorandum guidance remains on healthcare-specific elements of standards, policies and up-to-date established best practice. They are applicable to new and existing sites, and are for use at various stages during the whole building lifecycle.

main source of specific healthcare-related guidance for estates and facilities professionals.

The core suite of nine subject areas provides access to guidance which:

- is more streamlined and accessible;
- encapsulates the latest standards and best practice in healthcare engineering;
- provides a structured reference for healthcare engineering.

Figure 1 Healthcare building life-cycle



Healthcare providers have a duty of care to ensure that appropriate engineering governance arrangements are in place and are managed effectively. The Engineering Health Technical Memorandum series provides best practice engineering standards and policy to enable management of this duty of care.

It is not the intention within this suite of documents to unnecessarily repeat international or European standards, industry standards or UK Government legislation. Where appropriate, these will be referenced.

Healthcare-specific technical engineering guidance is a vital tool in the safe and efficient operation of healthcare facilities. Health Technical Memorandum guidance is the

Structure of the Health Technical Memorandum suite

The series of engineering-specific guidance contains a suite of nine core subjects:

Health Technical Memorandum 00
: Policies and principles (applicable to all Health Technical Memoranda in this series)

Health Technical Memorandum 01
: Decontamination

Health Technical Memorandum 02
: Medical gases

Health Technical Memorandum 03
Heating and ventilation systems

Health Technical Memorandum 04
Water systems

Health Technical Memorandum 05
Fire safety

Health Technical Memorandum 06
Electrical services

Health Technical Memorandum 07
Environment and sustainability

Health Technical Memorandum 08
Specialist services

Some subject areas may be further developed into topics shown as -01, -02 etc and further referenced into Parts A, B etc.

Example: Health Technical Memorandum 06-02 Part A will represent:

Electrical Services – Electrical safety guidance for low voltage systems

In a similar way Health Technical Memorandum 07-02 will simply represent:

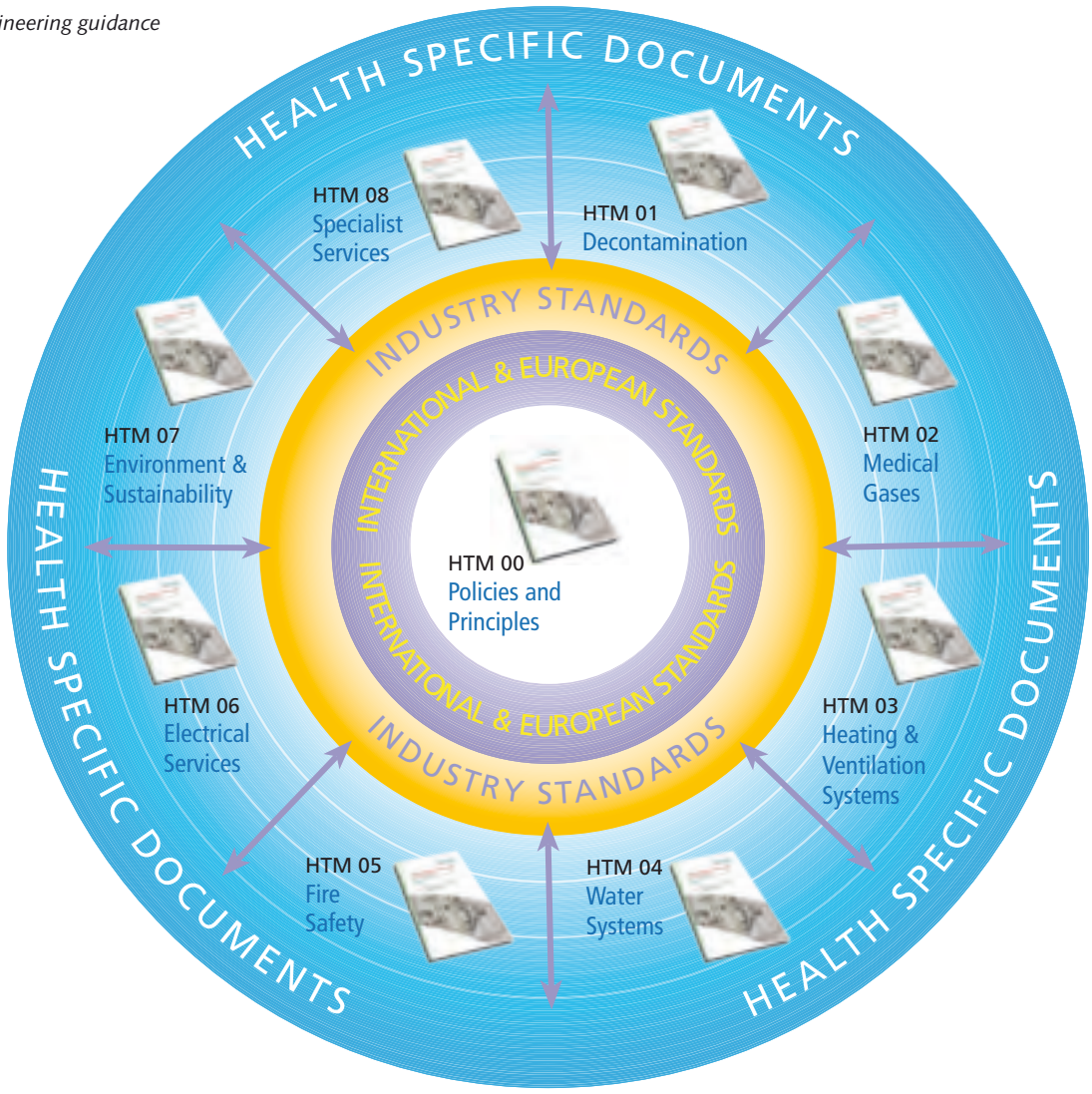
Environment and Sustainability – EnCO_2de.

All Health Technical Memoranda are supported by the initial document Health Technical Memorandum 00 which embraces the management and operational policies from previous documents and explores risk management issues.

Some variation in style and structure is reflected by the topic and approach of the different review working groups.

DH Estates and Facilities Division wishes to acknowledge the contribution made by professional bodies, engineering consultants, healthcare specialists and NHS staff who have contributed to the review.

Figure 2 Engineering guidance



Executive summary

Preamble

Health Technical Memorandum 03-01 – 'Specialised ventilation in healthcare premises' is published in two parts: Part A deals with the design and installation of ventilation systems; Part B covers operational management.

The document gives comprehensive advice and guidance on the legal requirements, design implications, maintenance and operation of specialised ventilation in all types of healthcare premises.

The guidance contained in this Health Technical Memorandum applies to new installations and major refurbishments of existing installations.

Health Technical Memorandum 03-01 supersedes all previous versions of Health Technical Memorandum 2025 – 'Ventilation in healthcare premises'.

Who should use this guidance?

This document is aimed at healthcare management, estates managers and operations managers.

Main recommendations

- All ventilation plant should meet a minimum requirement in terms of the control of *Legionella* and safe access for inspection and maintenance.
- All ventilation plant should be inspected annually.
- The performance of all critical ventilation systems (such as those servicing operating suites) should be verified annually.

Contents

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Welsh Health Estates

NHS in Scotland

Health & Social Services, Northern Ireland

Health Protection Agency (HPA)

Building Research Establishment (BRE)

Building Services Research and Information Association (BSRIA)

University of Leeds

CIBSE Healthcare Group

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Medical Air Technology/Thermo Electric

BPG Medical

Admeco/Trumpf Medical Systems

Volkes SPX

Weiss Klimatechnik

Sound Research Laboratories

NHS Security Management Service

Pennine Acute NHS Trust

Hospital Infection Society (HIS)

Central Sterilising Club

HEVAC – Air-handling Unit Manufactures Group

1 Introduction

Preamble

1.1 Health Technical Memorandum 03-01 – 'Specialised ventilation in healthcare premises' is published in two parts: Part A deals with the design and installation of ventilation systems; Part B covers operational management.

1.2 The document gives comprehensive advice and guidance to healthcare management, design engineers, estates managers and operations managers on the legal requirements, design implications, maintenance and operation of specialised ventilation in all types of healthcare premises.

1.3 The guidance contained in this Health Technical Memorandum applies to new installations and major refurbishments of existing installations.

1.4 Health Technical Memorandum 03-01 supersedes all previous versions of Health Technical Memorandum 2025 – 'Ventilation in healthcare premises'.

Ventilation in healthcare premises

1.5 Ventilation is used extensively in all types of healthcare premises to provide a safe and comfortable environment for patients and staff. More specialised ventilation is provided in areas such as operating departments, critical care areas and isolation facilities for primary patient treatment.

1.6 It is also installed:

- to ensure compliance with the quality assurance requirements of items processed in pharmacies and sterile services departments;
- to protect staff from harmful organisms and toxic substances (for example in laboratories).

Statutory requirements

Increased health risks to patients will occur if ventilation systems do not achieve and maintain the required standards. The link between surgical site infection and theatre air quality has been well established.

If the ventilation plant has been installed to dilute or contain harmful substances, its failure may expose people to unacceptable levels of contamination. Proven breaches of the statutory requirements can result in prosecution and may also give rise to a civil suit against the operators.

Health and Safety at Work etc Act 1974

1.7 The Health and Safety at Work etc Act 1974 is the core legislation that applies to ventilation installations. As these installations are intended to prevent contamination, closely control the environment, dilute contaminants or contain hazards, their very presence indicates that potential risks to health have been identified.

COSHH

1.8 The Control of Substances Hazardous to Health (COSHH) Regulations 2002 place upon management an obligation to ensure that suitable measures are in place to protect their staff and others affected by the work activity. These methods may include both safe systems of work and the provision of a specialised ventilation system. In laboratories the requirements are often met by the provision of fume cupboards and microbiological safety cabinets.

1.9 Where specialised ventilation plant is provided as part of the protection measures, there is a statutory requirement that it be correctly designed, installed, commissioned, operated and maintained. The local exhaust ventilation (LEV) section of COSHH requires that the system be examined and tested at least every 14 months by a competent person and

that management maintain comprehensive records of its performance, repair and maintenance.

1.10 Certain substances have workplace exposure limits (WELs) set out in the Health and Safety Executive's (2005) Guidance Note EH40 – 'Workplace exposure limits: containing the list of workplace exposure limits for use with the Control of Substances Hazardous to Health Regulations 2002 (as amended)'. If specialised ventilation systems are provided in order to achieve these standards, they will be subject to the COSHH Regulations as above.

Fire regulations

1.11 The fire regulations require that, if ventilation ductwork penetrates the fabric of a building, it should be designed and installed so as to contain the spread of fire (see Health Technical Memorandum 05-02 – 'Guidance in support of functional provisions for healthcare premises' for further guidance).

1.12 It is management's responsibility to ensure that the standards applied during the design and installation are not reduced during the subsequent operation and maintenance of the equipment.

Plants installed in units manufacturing medicinal products

1.13 Plants installed in units manufacturing medicinal products to the standards set out in the current European guide to good manufacturing practice (http://ec.europa.eu/enterprise/pharmaceuticals/eudralex/homev4.htm) may also be subject to particular legislation with regard to their operation and maintenance.

1.14 There are specific requirements under the Medicines Act 1968 to maintain accurate records of plant performance, room conditions and maintenance events. Such records would need to be preserved for up to 35 years as part of a quality assurance audit trail.

Plants installed in laboratories

1.15 Specialised ventilation plants installed in laboratories dealing with research, development or testing, whether involving drugs, animals or genetically modified organisms, may be subject to particular legislation with regard to their operation in addition to that mentioned above.

Codes of practice and guidance

1.16 All ventilation systems should conform to the principles set out in the Health and Safety Commission's Approved Code of Practice and guidance document 'Legionnaires' disease: the control of *Legionella* bacteria in water systems' (commonly known as L8), and Health Technical Memorandum 04-01 – 'The control of *Legionella*, hygiene, "safe" hot water, cold water and drinking water systems'.

1.17 The Department of Health publication 'The Health Act 2006: code of practice for the prevention and control of healthcare associated infections' is a code of practice that has been brought out to help NHS bodies to plan and implement how they can prevent and control healthcare-associated infections. It sets out criteria by which managers of NHS organisations are to ensure that patients are cared for in a clean environment and where the risk of healthcare-associated infections is kept as low as possible. Specialised ventilation systems often play a central role in achieving this objective.

Management responsibilities – general

1.18 It is a management responsibility to ensure that inspection, service and maintenance activities are carried out safely without hazard to staff, patients or members of the public.

1.19 Those required to monitor and/or maintain ventilation equipment will need to show that they are competent to do so (see Chapter 2).

1.20 Maintenance procedures should be reviewed periodically to ensure that they remain appropriate.

System information

1.21 When new ventilation systems are accepted for use, full information as to their designed mode of operation together with recommended maintenance procedures should be provided as part of the handover procedure.

1.22 In many existing systems, original design and commissioning information will not be available. It will therefore be necessary to determine a suitable level of system performance based on the function, purpose and age of the installation.

1.23 Part A of this Health Technical Memorandum gives design parameters for new installations.

1.24 Chapter 3 of this document sets out the minimum standards for all air-handling units (AHUs) and their air distribution systems.

1.25 Ventilation system records and logbooks should be kept of the commissioning information, operational management routine, monitoring and maintenance. The Health and Safety Executive and other interested bodies have a statutory right to inspect them at any time. All records should be kept for at least five years.

1.26 In the event of a reportable incident connected with ventilation equipment or the area that it serves, all records and plant logbooks will need to be collected as evidence.

1.27 A set of specimen maintenance checklists is given in Appendix 1.

Frequency of inspections and verifications

1.28 All ventilation systems should be subject to, at least, a simple visual inspection annually.

1.29 Ventilation systems serving critical care areas should be inspected quarterly and their performance measured and verified annually. The quarterly inspection should be a simple visual check; the annual verification will be a more detailed inspection of the system together with the measurement of its actual performance.

1.30 The LEV section of the COSHH regulations contains a statutory requirement that systems installed to contain or control hazardous substances be examined and tested at least every 14 months by a competent person.

1.31 Regular tests, at intervals agreed with the local fire prevention officer, will need to be carried out in order to demonstrate the continuing efficiency of the fire detection and containment systems. These may be in addition to the inspections detailed above. Records of these tests should be kept.

2 Functional responsibilities

Management responsibilities

2.1 Clear lines of managerial responsibility should be in place so that no doubt exists as to who is responsible for the safe operation and maintenance of the equipment.

2.2 A periodic review of management systems should take place in order to ensure that the agreed standards are being maintained.

2.3 Those required to inspect, verify or maintain ventilation equipment will need to show that they are competent to do so. As a minimum they should have sufficient knowledge of its correct operation to be able to recognise faults.

2.4 It is anticipated that training in the validation and verification of specialised healthcare ventilation systems for Authorised Persons and Competent Persons will become available during the life of this Health Technical Memorandum.

Designated staff functions

2.5 A person intending to fulfil any of the staff functions specified below should be able to prove that they possess sufficient skills, knowledge and experience to be able to safely perform the designated tasks.

Management

2.6 Management is defined as the owner, occupier, employer, general manager, chief executive or other person who is ultimately accountable for the safe operation of premises.

Designated Person

2.7 This person provides the essential senior management link between the organisation and professional support. The Designated Person should also provide an informed position at board level.

Authorising Engineer (Ventilation) (AE(V))

2.8 The AE(V) is defined as a person designated by Management to provide independent auditing and advice on ventilation systems and to review and witness documentation on validation.

Authorised Person (Ventilation) (AP(V))

2.9 The AP(V) will be an individual possessing adequate technical knowledge and having received appropriate training, appointed in writing by the Designated Person (in conjunction with the advice provided by the AE(V)), who is responsible for the practical implementation and operation of Management's safety policy and procedures relating to the engineering aspects of ventilation systems.

Competent Person (Ventilation) (CP(V))

2.10 The CP(V) is defined as a person designated by Management to carry out maintenance, validation and periodic testing of ventilation systems.

Infection Control Officer

2.11 The Infection Control Officer (or consultant microbiologist if not the same person) is the person nominated by management to advise on monitoring the infection control policy and microbiological performance of the systems.

2.12 Major policy decisions should be made through an infection control committee. The infection control committee should include representatives of the user department and estates and facilities or their nominated representative (that is, the Authorised Person).

Plant Operator

2.13 The Plant Operator is any person who operates a ventilation installation.

User

2.14 The User is the person responsible for the management of the unit in which the ventilation

system is installed (for example head of department, operating theatre manager, head of laboratory, production pharmacist, head of research or other responsible person).

Contractor

2.15 The Contractor is the person or organisation responsible for the supply of the ventilation equipment, its installation, commissioning or validation. This person may be a representative of a specialist ventilation organisation or a member of the general manager/chief executive's staff.

Records

2.16 A record should be kept of those appointed to carry out the functions listed above. The record should clearly state the extent of the postholder's duties and responsibilities, and to whom they are to report.

2.17 Substitute or replacement staff should be designated in order to cover for sickness, holidays and staff transfers.

Training

2.18 Routine inspection and maintenance procedures can cause risks to the health of staff carrying out the work and those receiving air from the plant. All those involved should be made aware of the risks, and safe systems of work should be agreed. Suitable safety equipment should be provided as necessary, and training in its use should be given.

2.19 Any training given should be recorded, together with the date of delivery and topics covered.

2.20 Training in the use of safety equipment and a safe system of work will need to be repeated periodically in order to cater for changes in staff.

Specific health and safety aspects

2.21 Staff engaged in the service and maintenance of extract ventilation systems from pathology departments, mortuaries, laboratories, source-protected isolation facilities and other areas containing a chemical, biological or radiation hazard may be particularly at risk. In these cases, the risk should be identified and assessed.

2.22 The means by which the system can be rendered safe to work on should be determined, and a permit-to-work on the system implemented.

2.23 Training in the exact procedures should be given to all staff involved.

2.24 Some healthcare facilities may contain specialised units that are subject to access restrictions (for example pharmacy aseptic suites). Estates or contract staff requiring access may need additional training or to be accompanied when entering the unit.

See also the following guidance published by the Health and Safety Commission's Health Services Advisory Committee:

a. 'Safe working and the prevention of infection in clinical laboratories and similar facilities';

b. 'The management, design and operation of microbiological containment laboratories';

c. 'Safe working and prevention of infection in the mortuary and post-mortem room'.

3 Ventilation systems – minimum requirements

General requirements

3.1 All ventilation systems should be inspected annually to ensure conformity with minimum requirements, which are designed to:

a. ensure safe access when carrying out routine service and maintenance activities;

b. prevent or control risks associated with *Legionella* and other potential hazardous organisms;

c. check that the system remains fit for purpose.

3.2 Every effort should be made to ensure that all AHUs achieve the minimum requirement set out below.

Location and access

3.3 AHUs should be secured from unauthorised access.

3.4 Units located on roofs should have a safe and permanent means of access. Suitable precautions must be in place to prevent personnel or equipment from falling during maintenance activities.

3.5 Units located outside at ground level should be secured within a compound to prevent unauthorised access. Vehicles should be excluded from the vicinity to ensure that exhaust fumes will not be drawn into intakes.

3.6 All parts of the AHU should be easily and safely accessible for routine inspection and service.

3.7 The area around an AHU within a building should be tanked to prevent water penetration to adjacent areas, and should be adequately drained.

3.8 Fire precautions should be in accordance with Firecode.

3.9 Combustion equipment must not be located in a fire compartment that houses air-handling equipment.

3.10 Plantrooms that house AHUs should not be used for general storage. Care should be taken to ensure that combustible material is not kept in the plantroom.

Basic requirements

3.11 The plant must not contain any material or substance that could support the growth of microorganisms.

3.12 The plant must not contain any material or substance that could cause or support combustion.

3.13 Access to items that require routine service, such as filters, fog coils and chiller batteries, should be via hinged doors.

3.14 Items requiring infrequent access such as attenuators may be via clipped or bolted-on lift-off panels.

3.15 All doors and panels should be close-fitting and without leaks.

3.16 Every effort should be made to ensure that access is via fixed ladders and platforms or pulpit-style movable steps.

3.17 Electrical and mechanical services should not restrict or impede access to those parts of the AHU that require inspection.

3.18 Viewing ports and internal illumination should be fitted in order to inspect filters and drainage trays.

3.19 Internal illumination should be provided by fittings to at least IP55 rating. Fittings should be positioned so that they provide both illumination for inspection and task lighting.

3.20 A single switch should operate all of the lights in a unit.

AHU intakes and discharges

3.21 Intake and discharge points should not be situated where they will cause vitiated air to be drawn into a system (see paragraphs 3.57–3.68 in Part A, which give detailed information). In existing systems, it may be necessary to extend the intake or discharge point to a suitable position.

3.22 Each intake and discharge point should be fitted with corrosion-resistant weatherproof louvres or cowls to protect the system from driving rain. The inside of the louvres should be fitted with a mesh of not less than 6 mm and not more than 12 mm to prevent infestation by vermin and prevent leaves being drawn in.

3.23 The duct behind a louvre should be self-draining. If this is not practicable, it should be tanked and provided with a drainage system. Cleaning access must be provided either from the outside via hinged louvres or by access doors in the plenum behind the louvre. Where a common plenum is provided, cleaning access should be via a walk-in door.

AHU drainage system

3.24 All items of plant that could produce moisture must be provided with a drainage system. The system will comprise a drip-tray, glass trap, air break and associated drainage pipework.

3.25 Some existing units may not have been mounted far enough above the floor to permit the correct installation of a drainage system. If the AHU cannot be raised to an adequate height, an alternative arrangement (such as a pump-out system) must be provided.

3.26 The drip-tray should be constructed of a corrosion-resistant material (stainless steel is preferred) and be so arranged that it will completely drain. To prevent "pooling", it is essential that the drain connection should not have an up-stand and that a slope of approximately 1 in 20 in all directions should be incorporated to the drain outlet position. The tray must be completely accessible or, for smaller units, easily removable for inspection and cleaning.

3.27 Each drip-tray should be provided with its own drain trap. The drain trap should be of the clear (borosilicate) glass type. This permits the colour of the water seal to be observed, thus giving an early indication of corrosion, biological activity or contamination within the duct (see Table 3).

3.28 The trap should have a means for filling and should incorporate couplings to facilitate removal for cleaning. It should be located in an easily visible position where it will not be subject to casual knocks. The pipework connecting it to the drainage tray should have a continuous fall of not less than 1 in 20.

3.29 Traps fitted to plant located outside or in unheated plantrooms may need to be trace-heated in winter. The trace heating should be checked for operation and must not raise the temperature of water in the trap above 5°C.

3.30 Water from each trap must discharge via a clear air gap of at least 15 mm above the unrestricted spill-over level of either an open tundish connected to a drainage stack via a second trap, or a floor gully (or channel). A support should be provided to ensure that the air gap cannot be reduced. More than one drain trap may discharge into the tundish, providing each has its own air break.

3.31 Drainage pipework may be thermoplastic, copper or stainless steel. Glass should not be used. The pipework should be a minimum diameter of 22 mm and have a fall of at least 1 in 60 in the direction of flow. It should be well supported, and located so as not to inhibit access to the AHU.

Dampers

3.32 AHUs serving critical areas and those areas that are shut down out of hours should be fitted with motorised low-leak shut-off dampers located immediately behind the intake and discharge of each supply and extract system.

Fan drives

3.33 Fan-drive trains, whether supply or extract, should be easily visible without the need to remove access covers. Protecting the drive train with a mesh guard is the preferred option. For weatherproof units designed to be located outside, the fan drive should be enclosed. It should be easily visible through a viewing port with internal illumination and be accessed via a lockable, hinged door.

3.34 The motor windings of induction-drive "plug" motor arrangements and in-line axial fans having a pod motor within the air stream must be protected from over-temperature by a thermistor and lock-out relay.

3.35 It is necessary to ensure that – should the computer control system or its software develop a fault – the fan can be switched to a direct start with fixed speed and manual operation. This is particularly important for critical care systems serving operating suites, high dependency care units of any type, isolation facilities, laboratories and pharmaceutical production suites.

Heater-batteries

3.36 Access for cleaning must be provided to both sides of all fog coils and heater-batteries.

3.37 Where auxiliary wet heater-batteries are located in false ceilings, they should be fitted with a catch tray and leak alarm. The catch tray should be installed under both the battery and the control valve assembly to protect the ceiling from leaks. A moisture sensor and alarm should be fitted in the tray.

Cooling coils

3.38 All cooling coils – whether with the AHU or with a branch duct – must be fitted with their own independent drainage system as specified above. A baffle or similar device must be provided in the drip-tray to prevent air bypassing the coil, and the tray should be large enough to capture the moisture from the eliminator, bends and headers.

3.39 The cooling-coil control valve should close upon selection of low speed, system shut-down, low air flow or fan failure.

3.40 Where auxiliary wet-cooling coils are located in false ceilings, they should be fitted with a catch tray and leak alarm. The catch tray should be installed under both the battery and the control valve assembly to protect the ceiling from leaks. A moisture sensor and alarm should be fitted in the tray.

Humidifiers

3.41 Humidifiers are not generally required. Where they are fitted, but have been out of use for a significant period of time, they should be removed. All associated pipework should also be removed back to its junction with the running main.

3.42 Where humidifiers are fitted and their use is still required, they should fully conform to the installation standard set out in Chapter 4 of Part A.

3.43 The section of ductwork containing the humidifier may need to be periodically decontaminated. Hinged access doors with viewing ports and internal illumination should be provided.

3.44 All humidifiers must be fitted with their own independent drainage system as detailed above.

3.45 Only steam-injection humidifiers, whether mains fed or locally generated, are suitable for use in air-conditioning systems within healthcare facilities. Water humidifiers, if fitted, should be removed.

3.46 Self- and locally-generated steam humidifiers must be supplied with potable water. The installation should be capable of being isolated, drained and cleaned. Chapter 4 in Part A of this Health Technical Memorandum gives further details.

3.47 Some steam generators are of a type that requires regular cleaning and descaling. The installation should enable them to be physically isolated from the air duct in order to prevent contamination of the air supply by cleaning agents.

3.48 The humidifier control system should fully conform to the standard set out in Chapters 4 and 6 of Part A.

Filtration

3.49 Filters must be securely housed and sealed in well-fitting frames that minimise air bypass. Air bypass significantly reduces filter efficiency; the higher the filter grade, the greater the effect. Mounting frames should be designed so that the air flow pushes the filter into its housing to help minimise air bypass.

3.50 All filters should be of the dry type. Panel filters are generally used as prefilters and should be positioned on the inlet side of the supply fan, downstream of the frost coil. Where required, secondary filters (these will be bags or pleated paper) should be on the positive-pressure side of the fan.

3.51 The filter installation should provide easy access to filter media for cleaning, removal or replacement; therefore, a hinged access door should be provided. The upstream side of the filter should be visible for inspection through a viewing port with internal illumination.

3.52 All filters should be provided with a means of checking the differential pressure across them. Direct-reading dial-type gauges marked with clean and dirty sectors are preferred.

High-efficiency filters – HEPA and ULPA

3.53 Where fitted, HEPA filters should be of the replaceable-panel type with leak-proof seals. Their installation should permit the validation of the filter and its housing.

3.54 HEPA filters are sometimes used in extract systems for the containment of hazardous substances or

organisms. They may be fitted with prefilters to extend their service life.

3.55 When used for the containment of hazardous substances, the installation should incorporate design provision for the subsequent safe removal and handling of contaminated filters by maintenance staff.

Energy recovery

3.56 Energy recovery, where fitted, will require cleaning access to both sides of the device.

3.57 Whichever type of energy recovery device is fitted, the extract side should be protected by a G3 filter and provided with a drainage system to remove condensate.

3.58 The heat-recovery device should be controlled in sequence with the main heater-battery, and may need to incorporate a control to prevent the transfer of unwanted heat when the air-on condition rises above the plant's required set-point.

Attenuation

3.59 Cleaning access should be provided at both ends of any attenuator unit.

Identification and labelling

3.60 All supply and extract ventilation systems should be clearly labelled. The label should identify both the AHU and the area that it serves. The lettering should be at least 50 mm high and be mounted in an easily visible place near the fan of the unit. Any subsystems and the principal branch ducts should be similarly labelled.

3.61 The direction of air flow should be clearly marked on all main and branch ducts.

3.62 All air-flow test-points should be clearly identified, and the size of the duct given.

Pressure stabilisers

3.63 Pressure stabilisers should be unobstructed and silent in operation.

4 Annual inspection and verification requirements

Ventilation systems inspection

4.1 All ventilation systems should be subject to at least a simple visual inspection annually.

4.2 The purpose of the inspection is to establish that:

a. the system is still required;

b. the AHU conforms to the minimum standard (see Chapter 3);

c. the fire containment has not been breached;

d. the general condition of the system is adequate for purpose;

e. the system overall is operating in a satisfactory manner.

4.3 It is recommended that a simple check sheet be used to record the result of the inspection. Examples are given in Appendices 1 and 2.

Critical ventilation systems

4.4 All critical ventilation systems should be inspected quarterly and verified at least annually. In some circumstances the verification may need to be carried out more frequently.

4.5 The quarterly inspection should be as detailed in paragraphs 4.1–4.3.

4.6 The purpose of the annual verification will be to additionally ensure that the system:

a. achieves minimum standards specific to the application;

b. is operating to an acceptable performance level;

c. remains fit for purpose.

Definition of a critical system

4.7 Ventilation systems serving the following are considered critical:

a. operating theatres of any type, including rooms used for interventional investigations (for example catheter laboratories);

b. patient isolation facility of any type;

c. critical care, intensive treatment or high-dependency unit;

d. neonatal unit;

e. Category 3 or 4 laboratory or room;

f. pharmacy aseptic suite;

g. inspection and packing room in a sterile services department;

h. MRI, CAT and other types of emerging imaging technologies that require particularly stable environmental conditions to remain within calibration;

j. any system classified as an LEV system under the COSHH Regulations;

k. any other system that clearly meets the definition.

4.8 The loss of service from such a system would seriously degrade the ability of the premises to deliver optimal healthcare.

Annual verification

4.9 The annual verification is intended to establish that:

a. the system is still required;

b. the AHU conforms to the minimum standard (see Chapter 3);

c. the fire containment has not been breached;

d. the general condition of the ventilation system is adequate;

e. the fabric of the area served is satisfactory;

f. the system performance is adequate with respect to the functional requirement – this will require:

(i) a full measure of the supply and extract air-flow rates;

(ii) the calculation of room air-change rates if applicable;

(iii) the measurement of room differential pressures if applicable;

(iv) the measurement of room noise levels;

(v) air-quality checks if appropriate;

(vi) a check on the control functions.

4.10 An assessment should then be made as to whether the system overall is fit for purpose and operating in a satisfactory manner.

Fabric of the area served

4.11 The building elements in the room or rooms served by a critical ventilation system should also be suitable for the function. As an example, in a suite of rooms comprising an operating theatre complex, the following elements should be checked:

a. the ceiling should be complete and, if tiled, all tiles should be clipped down and sealed;

b. the walls and floors should be free from significant construction and finish defects;

c. windows and their trickle vents should be sealed and locked shut;

d. the doors should close completely and the door closers should be correctly adjusted to hold them against the room pressure;

e. all service penetrations and access panels should be sealed to prevent uncontrolled air flow between rooms and service voids;

f. steps should have been taken (if necessary) to prevent portable equipment and stock items from obstructing low-level supply, transfer or extract air-flow paths.

4.12 Failure to achieve a suitable standard will render even the most sophisticated ventilation system ineffective.

4.13 All fire dampers should be tested as part of the annual verification.

4.14 LEV systems will be subject to an examination and test by a competent person at least every 14 months.

4.15 Table 1 provides a model for the verification of critical ventilation systems.

Critical ventilation systems – verification standards

4.16 Unless otherwise specified below, the ventilation system should achieve not less than 75% of the design air-change rate given in Appendix 2 of Part A, or its original design parameters.

4.17 The pressure regime should achieve not less than 75% of the design value given in Appendix 2 of Part A, or its original design parameters; and the pressure gradient relationships with regards to surrounding areas must be maintained.

4.18 The sound levels given in Table 2 are maximum permissible levels and should not be exceeded. Measurements should be made using at least a Type 2 sound meter fitted with a muff. Its accuracy should be checked using a calibration sound source before use.

Vertical ultra-clean operating theatres

4.19 The following additional measurements should be taken:

- **the average air velocity at the 2 m level under the canopy:** it should achieve a minimum average of 0.38 m/s for a partial wall system and 0.3 m/s for a full wall system;
- **the air velocity within the inner zone at the 1 m level:** every reading should achieve a minimum velocity of 0.2 m/s.

4.20 The air velocity measurements are to be taken using the equipment, test grid and method set out in Chapter 8 of Part A.

Note

There is no requirement to carry out filter scanning or entrainment tests at the annual verification unless the HEPA filters or recirculating air fans are changed, or the system is in some other significant way disturbed or altered. Changing the filters in the AHU or recirculating air filters does not constitute a significant disturbance to the ultra-clean ventilation (UCV) unit.

4.21 Should the UCV terminal fail to achieve a suitable standard, resulting in the need to disturb or replace the HEPA filters or recirculating air fans, the unit should be revalidated using the procedure given in Chapter 8 of Part A.

Table 1 Operational management and routine verification process model

Step	Question	Information/standard required	Comment
1	Is the system still required?	Why was it installed?	Is that function still required?
2	Does the AHU achieve the minimum standard?	• Health and safety aspects • Intake/discharge positions • Inspection access • *Legionella* control and drainage • Fire and electrical safety • Leaks, cleanliness and insulation • Filtration	Inspect to ascertain compliance with minimum standards set out in Chapter 3 of Health Technical Memorandum 03-01 (Part B)
3	Is the air distribution system satisfactory?	• Access • Fire dampers • Cleanliness • Insulation • Identification • Room terminals • Pressure stabilisers	Inspect to ascertain continued fitness for purpose
4	Does the measured system performance still accord with the design intent and achieve a minimum acceptable standard?	• Design air velocities • Design air-flow rates • Room air-change rates • Pressure differentials • Noise levels • Air quality	Establish the design values Measure the system output to verify its performance
5	Does the control system function correctly?	• Desired environmental conditions • Control sequence logic • Run; set-back; off philosophy	Establish the design requirement Inspect/test to verify performance
6	Having regard to the foregoing, is the system "fit for purpose" and will it only require routine maintenance in order to remain so until the next scheduled verification?		Yes or No!
7	What routine service and maintenance will be required for the system to remain fit for purpose and function correctly until the next scheduled verification?	• Filter changes • System cleaning • Performance indication • Performance monitoring • Performance measurement	Decide inspection frequency and maintenance schedule

Table 2 Maximum sound levels (service noise only)

Location	Design sound level (NR)	Measured sound level (dB(A))
Ultra-clean operating room	50	55
Conventional operating room	40	45
All other non-specified rooms	40	45
Corridors	40	45
Recovery room	35	40
Ward areas; sleeping areas	30	35

Note: Health Technical Memorandum 08-01 gives detailed guidance on acoustics and the measurement of sound

Horizontal ultra-clean operating theatres

4.22 The following additional measurements should be taken:

- **the discharge velocity test at 1 m, 1.5 m and 2 m in front of the terminal:** the average velocity should be not less than 0.4 m/s.

4.23 The measurements are to be taken using the equipment, test grid and method set out in Chapter 8 of Part A.

Note

There is no requirement to carry out filter scanning at the annual verification unless the HEPA filters or recirculating air fans are changed; or the system is in some other significant way disturbed or altered. Changing the filters in the AHU or recirculating air filters does not constitute a significant disturbance to the UCV unit.

4.24 Should the UCV terminal fail to achieve a suitable standard, resulting in the need to disturb or replace the HEPA filters or recirculating air fans, the unit should be revalidated using the procedure given in Chapter 8 of Part A.

Category 3 and 4 laboratories and rooms

4.25 These areas should conform to the requirements of current information published by the Advisory Committee on Dangerous Pathogens and the Health and Safety Executive:

- 'The management, design and operation of microbiological containment laboratories';
- 'Biological agents: managing the risks in laboratories and healthcare premises'; and
- 'Biological agents: the principles, design and operation of Containment Level 4 facilities'.

Pharmacy aseptic suites

4.26 Pharmacy aseptic suites should conform to the requirements of the European guide to good manufacturing practice (http://ec.europa.eu/enterprise/pharmaceuticals/eudralex/homev4.htm) and the requirements of the Medicine Inspectorate if a licensed manufacturing unit.

Sterile services department – inspection and packing rooms

4.27 Inspection and packing rooms should conform to the requirements of BS EN ISO 14644 and any additional requirements for the processing of medical devices, if applicable (see also Health Building Note 13 – 'Sterile services department').

LEV systems

4.28 LEV systems should conform to the Health and Safety Executive's 'The maintenance, examination and testing of local exhaust ventilation'.

Critical system verification failure

4.29 Should a critical system be unable to achieve the standard set out above, it should be taken out of service. If healthcare provision needs prevent the system being taken out of service, the senior manager of the user department should be informed in writing that the system performance is suboptimal. A copy of the notice should be sent to the infection control committee.

4.30 If a critical system is refurbished in order to bring it to a suitable standard, it should be subject to the full validation procedure set out in Chapter 8 of Part A or other application-specific guidance as appropriate.

5 Inspection and maintenance

General

5.1 Inspection and maintenance activities should be assessed to ensure that they do not create a hazard for those who undertake the work or for those who could be affected by it.

5.2 The degree and frequency of maintenance should relate to the function of the system, its location, its general condition and the consequence of failure.

5.3 Specimen inspection and maintenance checklists are given in the Appendices.

Inspection and maintenance of critical systems

5.4 The loss of service of these systems would seriously degrade the ability of the premises to deliver optimal healthcare. In order to ensure reliable service provision, it is essential to inspect, verify and maintain these systems at appropriate intervals.

5.5 For many of these systems a permit-to-work will need to be completed to ensure that taking the ventilation system out of service does not compromise the activities of the user department. In any event, it will be necessary to liaise with the user department when switching the system off to carry out routine inspection and maintenance.

AHU drainage

5.6 AHU drainage systems comprise a drainage tray, glass trap, connecting pipework and an air break. The system should be inspected to ensure that it is clean and operating correctly. The cleanliness of the drainage tray and colour of the water in the trap will give an indication of a fault condition (see Table 3).

Filter changing

5.7 Dirty supply air filters may pose a general dust hazard when being changed.

Table 3 Colour of water in glass trap

Colour of water	Probable cause and comment
Normal	Satisfactory
Green	Copper corrosion of pipework Possible leak in battery tubing
White	Aluminium corrosion of battery fins
Black	General dirt Filter faulty allowing air bypass System is overdue for a thorough clean Urgent action required
Brown/red	Iron corrosion (rust) within the duct May indicate a specific *Legionella* hazard Immediate action required
Bubbly/slimy	Microbiological activity within the duct May indicate a specific *Legionella* hazard Immediate action required

5.8 Dirty extract-and-return air filters may pose an increased level of hazard. This will relate to the particular contamination within the air that they have filtered. Filters handling extract air from general areas are unlikely to present a significantly greater hazard than that posed by dirty supply air filters.

5.9 Care should be taken to protect staff from inhaling the dust. If there is a need to enter the duct when changing filters, a dust mask should be worn.

5.10 Dirty filters should be carefully removed and placed in the box that contained the replacement filters or in a plastic bag. On completion of the work, the dirty filters should be removed from the plantroom and disposed of appropriately.

5.11 The duct in the area of the filter housing should be carefully vacuumed before fitting the replacement filters. This will prevent particles (that is, those that are shed when the dirty filters are disturbed) being blown into the system downstream.

5.12 It is important to ensure that replacement filters are fitted the right way round. Most panel filters are manufactured with a membrane or wire support mesh on their downstream side. Alternatively they

may be colour-coded. The manufacturer's instructions regarding fitting should be followed.

5.13 Bag filters should be fitted with the pockets vertical. Care should be taken to remove any transit tapes and to ensure that the individual pockets are separate and free to inflate.

Changing extract filters containing hazardous substances

5.14 Filters handling extract air from an LEV system will obviously present a hazard and should be subject to a safe system of work.

5.15 Filters used in an extract system for the containment of hazardous substances or organisms should incorporate design provision for their safe removal when so contaminated. This may be achieved by:

a. sealing the hazardous substance into the filter before it is removed;

b. a system to fumigate the filter to kill any organisms;

c. housing it in a "safe change" unit that permits the filter to be ejected into a bag and sealed without staff having to come into direct contact with it.

5.16 The method chosen should reflect the nature of the hazard.

5.17 Filters fitted to remove hazardous substances from extract air are classed as hazardous waste and should be handled and disposed of accordingly.

Ventilation system cleaning

5.18 The intake section of a ventilation system should be vacuumed-out as necessary to remove visible particles.

5.19 AHUs should be vacuumed-out and/or washed down internally as necessary to remove obvious dust and dirt.

5.20 Chiller batteries, humidifier units, energy-recovery batteries or plates and their drainage systems should be washed down with hot water annually to remove visible contamination.

5.21 Supply air distribution ductwork conveys air that has been filtered. It will require internal cleaning only when it becomes contaminated with visible dirt. The frequency of cleaning will depend on the age of the system and grade of the AHU final filter but will typically be in excess of ten years. There is no requirement to clean ductwork annually. A rapid build-up of visible dirt within a supply duct is an indication of a failure of the filtration or its housing.

5.22 Extract air systems handle unfiltered air. They should be cleaned as frequently as necessary in order to maintain their operating efficiency. Room extract terminals, particularly those sited at low level in critical care areas, will need regular cleaning.

5.23 On completion of cleaning, the ductwork should not be "fogged" with chemicals. This treatment has no lasting biocidal effect and is responsible for initiating the breakdown of the galvanised coating of ductwork. This will result in accelerated corrosion of the inside of the duct, with the products of corrosion being shed into the air stream. It will also significantly shorten service life.

5.24 Following duct cleaning, all service hatches should be checked to ensure that they have been correctly replaced and do not leak.

5.25 Duct-cleaning equipment that uses rotating brushes or a vacuum unit can easily damage flexible sections of ductwork. On completion of cleaning, all flexible duct sections should be checked for rips and tears. The straps that secure them to rigid duct sections and air terminals should also be checked to ensure that there is no air leakage.

Chilled beams

5.26 The efficiency of these units will rapidly decline if they become blocked with fluff/lint. They should be inspected every six months and cleaned as appropriate.

Split and cassette air-conditioning units

5.27 These units incorporate internal recirculation air filters and a drainage system to remove condensate from the cooling coil. The systems should be inspected and cleaned every three months.

Portable room air-conditioning units

5.28 Portable units are sometimes kept in-store or hired-in to cope with temporary local situations giving rise to excessive temperatures. They typically incorporate internal recirculation air filters and a drainage system to remove condensate from the

cooling coil. The infection control team must be consulted before these types of unit are deployed.

5.29 The units should be inspected and thoroughly cleaned before being taken into use. Units that are to be used in areas containing immunocompromised patients will, unless new, need to be fumigated before use.

5.30 All portable units should be inspected and cleaned every week that they remain in use.

5.31 Units that have been used in isolation rooms or areas containing infective patients will need to be fumigated before being used in other locations, or returned to store or to the hirer.

5.32 Units employing an internal water reservoir and wick to promote evaporative cooling must not be used in healthcare premises.

Self-contained mobile filter and/or ultraviolet (UV) light units

5.33 The efficacy of these units is directly related to their cleanliness. In this respect, the manufacturer's instructions regarding service/maintenance and lamp and filter replacement should be closely followed.

5.34 Units that have been used in isolation rooms or areas containing infective patients will need to be fumigated before being used in other locations, or returned to store.

5.35 Filters fitted to remove hazardous substances from the recirculated room air are classed as hazardous waste and should be handled and disposed of accordingly (see also Health Technical Memorandum 07-01 – 'Safe management of healthcare waste').

Inspection and maintenance records

5.36 Records of inspection and maintenance activities should be kept for at least five years.

Appendix 1 – Annual inspection of critical ventilation systems – AHU and plantroom equipment

Definition of terms used on survey form

General condition

End of useful life
This should be clear from the condition of the AHU and its associated services and plant. The main indicators will be: • extensive internal and/or external corrosion of the AHU casing; • failure of filter housings to prevent air bypass; • general corrosion of heater and cooling battery fins, attenuator surfaces etc; • significant failure to meet minimum standards; • associated plant services and control elements in a poor condition or not able to fulfil their purpose; • AHU aged 20 years or more.
Action: Urgent replacement indicated.

Poor
Should be fairly apparent but would include an assessment of the degree of corrosion; cleanliness of coils and batteries; quality of filter mountings and their ability to prevent air bypass; fan and drive train condition; the control system elements' ability to fulfil their function; condition of the access doors and inspection covers. The age of the AHU is generally less important.
Action: Extensive refurbishment or programmed replacement indicated.

Average
Some faults but generally free of significant corrosion, clean internally and conforming to minimum standards.
Action: Faults capable of correction at next maintenance period.

Good
Conforming to the minimum standards, obviously cared for and subject to routine maintenance.
Action: Routine maintenance will preserve standard of the equipment.

Compliance with minimum standards (questions 2 to 23, 32 and 33)

Poor
More than three answers are negative.
Action: Management action required by estates/facilities department.

Average
No more than three answers are negative.
Action: Maintenance action required.

Good
No answers are negative, full compliance.
Action: None.

Maintenance quality (questions 5, 12, 26 to 31 and 34 to 40)

Poor
More than three answers are negative.
Action: Management action required by estates/facilities department.

Average
No more than three answers are negative.
Action: Maintenance action required.

Good
No answers are negative.
Action: None.

Annual inspection of critical ventilation systems – AHU and plantroom equipment

Hospital

Plantroom

Air-handling unit **Age of unit**

Area served by unit

Date of survey **Name**

General condition: **End useful life** **Poor** **Average** **Good**

Compliance with minimum standards (Questions 2 to 23; 32 and 33) **Poor** **Average** **Good**

Maintenance quality (Questions 5, 12, 26 to 31, 34 to 40) **Poor** **Average** **Good**

No	Survey question	Yes	No	Comments
1	Plant running?			
2	Is the unit and its associated plant secure from unauthorised access?			
3	Is the unit safely accessible for inspection and maintenance?			
4	Is the air intake positioned to avoid short circuiting with extract or foul air from other sources such as gas scavenging outlets?			
5	Are all inspection lights operating?			
6	Are motorised dampers fitted to the intake and discharge?			
7	Are fan motor(s) outside of the air stream?			
8	Is the fan drive train visible without removing covers?			
9	Is the cooling coil located on the discharge side of the fan?			
10	Is an energy-recovery system fitted (state type)?			
11	Are condensate drainage systems fitted to all energy recovery systems, cooling coils and humidifiers in accordance with Chapter 3 of Health Technical Memorandum 03-01, Part B?			

No	Survey question	Yes	No	Comments
12	Are drainage traps clean and filled with water? (see Table 3 in Health Technical Memorandum 03-01, Part B)			
13	Is the drain trap air break at least 15 mm?			
14	If a humidifier is fitted, state the type	–		
15	Is the humidifier capable of operation?			
16	Is there space to safely change the filters?			
17	Are there test holes in the principal ducts?			
18	Are the test holes capped?			
19	What is the general condition of the exterior of the AHU?	–		
20	Are the principal ducts lagged?			
21	What is the general condition of the associated control valves and pipework?	–		
22	Is the pipework adequately lagged?			
23	Is the system clearly labelled?			
24	Record prefilter differential pressure	–		
25	Record main filter differential pressure	–		
	Switch plant off. Fit padlock to isolator			
26	Did the motorised dampers close on plant shut-down?			
27	Is the vermin/insect screen clean?			
28	Is the intake section including the fog coil clean?			
29	Are the prefilters correctly fitted with no air bypass?			
30	Are all drive belts correctly aligned and tensioned?			
31	Is the cooling-coil matrix clean?			
32	Are all drip-trays fully accessible or capable of being removed for cleaning and have a fall to drain?			
33	Are the drainage trays stainless?			
34	Are the drainage trays clean?			
35	Are there any signs of water ponding in the AHU?			

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No	Survey question	Yes	No	Comments
36	Is the matrix clean for each heater-battery?			
37	Have the main filters been correctly fitted with no air bypass?			
38	Is AHU and its associated main ductwork clean internally?			
	Energise plant			
39	Did unit restart satisfactorily?			
	Test automatic fan-motor change-over, if fitted			
40	Did automatic change-over operate satisfactorily?			

Additional comments

(For example: air leaks from access doors; control valves leaking or passing; general cleanliness of the area around the unit; or any other items of concern.)

Competent Person/Authorised Person .....

Appendix 2 – Operating suite annual verification

Definition of terms used on survey form

Assessment of compliance with Health Building Note 26 and Health Technical Memorandum 03-01 (all questions relevant to the type of theatre)

Poor
Air volumes and hence air-change rate is less than 75% of the design; room pressure differentials do not ensure a flow from clean to less clean areas; supply or extract air diffusers are not clean; pressure stabilisers not clean and/or not operating correctly; significant faults or failures of indicators on surgeon's panel; visible faults in the fabric of the suite; doors unable to close completely; general air of neglect.
Action: Urgent management action required.

Average
Air volumes and room pressure differentials approximate to the original design values; supply air diffusers clean but extracts visibly fouled; most pressure stabilisers clean and operating correctly; some of the indicators on the surgeons panel not working; minor faults in the fabric and décor of the suite.
Action: Maintenance action required.

Good
Better than average.
Action: None.

Maintenance quality (all questions relevant to the type of theatre)

Poor
More than three answers are negative.
Action: Management action required by estates/facilities department.

Average
No more than three answers are negative.
Action: Maintenance action required.

Good
No answers are negative.
Action: None.

Annual verification of theatre ventilation systems
Theatre suite information

Hospital

Theatre name/no. **Type of Theatre**

Date of survey **AHU location & ID**

Name

Compliance with HBN & HTM **Poor** **Average** **Good**

Maintenance quality **Poor** **Average** **Good**

No	Survey question	Yes	No	Comments
1	Has the annual verification of the AHU been carried out?			
2	Are windows hermetically sealed?			
3	Are the ceilings in the theatre and prep room complete and sealed?			
4	Are there any significant faults in the fabric of the rooms in the suite?			
5	Are room light fittings correctly sealed?			
6	Do all doors close completely and hold against the room pressure?			
7	Are the pressure stabilisers operating correctly and silently?			
8	Are all supply and extract air terminals and pressure stabilisers visibly clean?			
9	Measure and record the operating room temperature	–		
10	Does this accord with that displayed on the surgeon's panel?			
11	Measure and record the operating room relative humidity	–		
12	Does this accord with that displayed on the surgeon's panel?			
13	Measure and record the supply and extract air flow in the principle ducts	–		
14	Measure and record the air flow at all supply and extract terminals	–		
15	Does the derived air-change rate achieve at least 75% of the design?			
16	For UCV units, also measure and record the air velocities within the canopy using the method set out in Chapter 8 of Health Technical Memorandum 03-01 (Part A)	–		

No	Survey question	Yes	No	Comments
17	Do the air velocities achieve the standard appropriate for the type of canopy?			
18	Measure and record the room differential pressures	–		
19	Do the room differential pressures ensure a flow of air from the clean to the less clean areas?			
20	Measure and record the noise levels in the principal rooms of the suite	–		
21	Do the noise levels fall below the limits set out in Table 2 of Health Technical Memorandum 03-01, Part B?			
22	Check the operation of all ventilation control functions represented on the surgeon's panel.	–		
23	Do the indicators accurately represent the operational state of the ventilation system(s)?			
24	For UCV systems: is the UCV and AHU interlocked to ensure that the AHU runs at full speed when the UCV is at operating speed or at set-back? (see Table 6 in Health Technical Memorandum 03-01, Part A)			
25	With the UCV running at set-back, does the system maintain the standard of a conventional operating room?			
26	For all theatres: with the system running at set-back, does it maintain a flow of air from the clean to the less clean areas?			

Additional comments

(For example: the general décor; are the suite and its ventilation systems suitable for their designated functions?)

Competent Person/Authorised Person .....

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Guidance on ventilation revised and updated

Speaking in the 'System Governance' stream on the first day of last October's IHEEM Healthcare Estates 2021 conference, consulting engineer, Malcolm Thomas, the main author of the 2021 version of HTM 03-01, *Specialist Ventilation for Healthcare Premises*, published last June, explained the background to, and aims behind, the HTM's revision, and highlighted some of the major changes that those responsible for ventilation plant in hospitals and other healthcare facilities need to be aware of. *HEJ* editor, Jonathan Baillie, reports.

Malcolm Thomas was the lead author for both editions (published in 2007 and last year) of HTM 03-01, and also of the ventilation-related HTM 2025 that preceded them. Also the lead author of the engineering section of several HBNs, he has worked in the healthcare sector for over 40 years – both within and outside the NHS. He is President of the Specialised Ventilation for Healthcare Society, and a visiting lecturer at the University of Leeds. Welcoming attendees to his presentation, he explained that as the lead author of HTM 03-01 (2021), he would explain some of the main thinking behind it, and set out the reasons for a number of key changes in the 'rewritten version'. He began: "As some background to where the HTMs and other guidance on ventilation originated, back in 1972 Dr Owen Lidwell led a Joint Working Party on ventilation and operating suites, and this was the foundation of all the guidance that has emerged since. Many people have asked me," he continued," why we bother with material that is 'so old'? The reason is that when this work was done, it was very evident what worked well in practice, and what didn't, in a way that's no longer nearly so clear. When you have significant infection rates in operating theatres, it's quite easy to see whether – if you change the colour of the paintwork – it makes any difference. Conversely, with very small infection rates – which fortunately we have now – it's very difficult to know whether changing the surgeons' gowns, the air change rate, or the colour of the walls, or putting carpet in, makes any significant difference. We're talking about low percentage changes. We're in a situation now where people think changes will improve things, but they don't actually know, and it's hard to prove what is a good or a bad thing. Back when Owen Lidwell did this work, it was relatively easy, there were step-changes, and he was able to conduct a number of trials."

Malcolm Thomas, the main author of the HTM 03-01 (2021), *Specialist Ventilation for Healthcare Premises*, published last June.

Comparative trials

Malcolm Thomas explained that in one, Owen Lidwell and his team took a particular acute hospital, and identified two operating theatres as theatres 'A' and 'B', with had two surgical teams – also named 'A' and 'B', staffing them. He elaborated: "They picked out patients at random, drawing lots to decide which theatre they were operated in. They could thus see which team and which patients fared better under certain circumstances, and thus demonstrate changes in the outcomes in infection rate terms." From this work, and drawing on theatres with low infection rates and good patient outcomes, Owen Lidwell and his team were able to determine the optimal airflow and temperature, and consider elements such as the impact of different gowning procedures. This in turn enabled them to draw some conclusions.

"The conclusions they drew have stood the test of time," said Malcolm Thomas. Following Owen Lidwell's work, the Department of Health and Social Security – as it was then – set up a working group, and codified the ventilation of operating departments in a document called DV4, specifying what was required for the theatre, and what worked and what didn't, 'taking Lidwell's work forward'.

Request to update guidance

"When I came on board," Malcolm Thomas explained, "I was asked to update DV4, but soon after I'd finished doing this, I was told it was now going to be an HTM, and HTM 2025 was duly published in 1994. Some years later I was asked if I could I take that forward again, and HTM 03-01, *Specialised ventilation healthcare*, was published in 2007. It was delayed by SARS, and avian flu, just as the Coronavirus outbreak delayed the publication of the current version of HTM 03-01. So, all of these iterations are based on some good solid work many years ago. I've been working in this area for some time, and it's very evident that these earlier learnings have stood the test of time. Where we have encountered problems, it's generally been clear that the guidance wasn't followed."

Historical reasons for not following guidance

Among the historical reasons for failure to follow established guidance, the speaker explained, had been changing procedures in both operating suites, and other 'spaces' in healthcare facilities, while on occasions people 'had not perhaps been as careful as they should have been' –

> **We're in a situation now where people think changes will improve things, but they don't actually know, and it's hard to prove what is a good or a bad thing**

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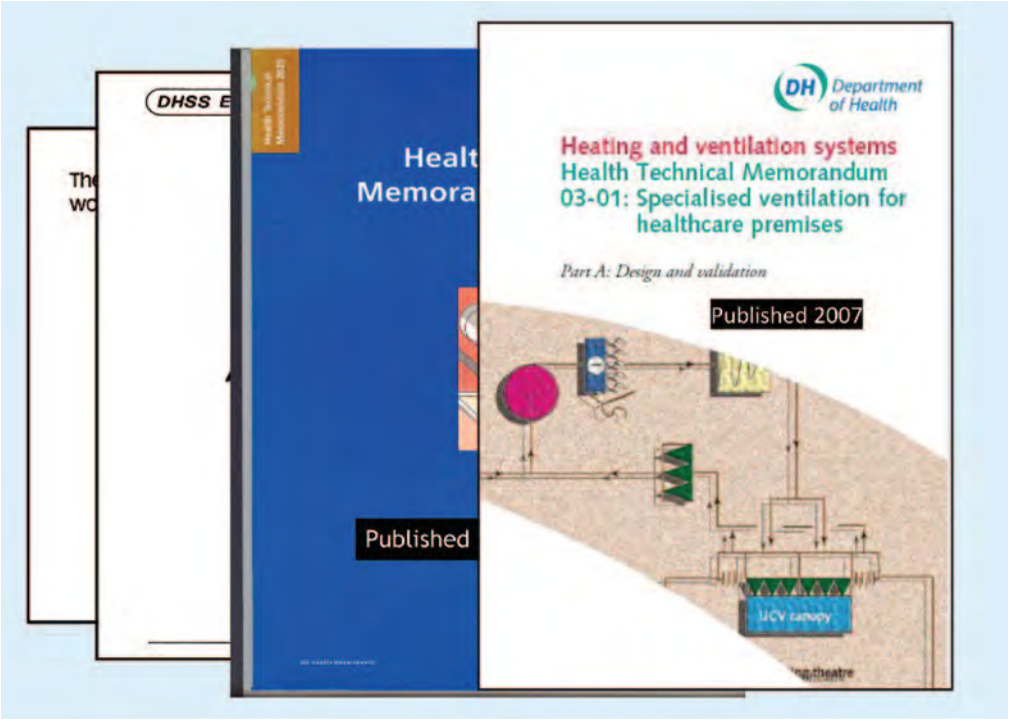
leading to 'something going wrong with the ventilation'. Malcolm Thomas said: "Put the people right, and – if I can put it like that – we'll get the ventilation right. There's a good pedigree, a good history, and we can have some confidence in past learnings and guidance. It isn't just people's opinion; it's what works."
'Backing this up, he added, was 'a fair amount of ongoing research by Department of Health, the NHS, and private companies', with the findings taken on board when HTMs were revised and updated. He said: "So, in these guidance documents we try to avoid just featuring people's opinion of what works and what doesn't, and instead coming down to some facts. History appears to show that this is a correct way of doing it."

Do we need the HTM guidance?

'Back in 2017/18', he explained, when it was decided to look at revising HTM 03-01, one of the questions asked had been: 'Do we need it?' He explained: "We have, in fact, been trying to reduce the amount of guidance issued, because at one point there were something like 400 different pieces of guidance, and it's almost impossible to keep that sort of volume of guidance up to date." Over the years there had thus been some 'pruning', together with a 'focus on what is different about ventilation in healthcare'. The speaker said: "What matters to us is, for example, whether CIBSE guidance on ventilation is adequate. If so, that's great, but if not, do we need to do more than CIBSE is suggesting, or perhaps less in some cases? Things that CIBSE would allow may not be what we want to do. They may not be appropriate in a hospital or other healthcare setting. So," he said, "having decided we did indeed need HTM 03-01, we questioned whether it needed updating, and, having determined that it did, began looking at how." This resulted in a 'scoping exercise' which ran for over a year with wide-ranging consultation, to look at what was in the documents, whether the HTM could just be given 'a dust down' and a little updating, or whether indeed some fundamental changes were needed He said: "That led to the move to produce a new document, in two parts, with part A on design and installation for those putting in something new, and Part B about how you manage an existing healthcare ventilation system."

A 'complete re-write' required

He continued: "It was decided that Part A needed to be completely rewritten, it having become clear from the scoping exercise that in existing form it assumed that designers knew what the healthcare industry needed." "Interestingly," he added, "back when I authored the HTM for the first time, I was told: 'Well, you can't put that sort of thing in, Malcolm. People who do these things already know what they're doing.' On the contrary though, it became very evident – and particularly with the PFI process – that a lot of people designing hospitals and hospital systems in fact had no idea what their customer wanted."



The latest iteration of HTM 03-01 – on which Malcolm Thomas primarily focused – followed several previous guidance documents on healthcare ventilation.

Historical context

Here Malcolm Thomas showed slides of Owen Lidwell's report, followed by DV4, then HTM 2025, and then HTM 03-01, both in 2007 form and in the latest iteration. Referring to HTM 03-01 (2021), he said: "It was decided that we should produce the latest HTM 03-01 in two parts – it was clear that Part A needed to have more of an explanation, not just of what we wanted, but why – so that people understood the importance of things. We thus changed the title, the Concept, the Design, Specification, Installation, and Acceptance Testing – the whole process. We tended in the PFI days to say: 'Give us a new hospital, and give me the key when it's finished', and clearly that wasn't a good idea. While we have some very good hospitals, constructed and built and working well, some were much less successful than they should have been. Part A of the 2021 HTM 03-01 thus refers both to all new installations, and to refurbishments and changes in use of existing installations. I would stress that it's not retrospective; you don't have to rip everything out and re-start. However, if you're in the middle of the project, and you find that the new HTM would suit you better, then providing everybody else agrees, and you've addressed any cost implications, there's no reason why you can't move over to the new standard." This, Malcolm Thomas said, applied even where a project team was working to guidance set out in the 'old' HTM."

Part B of the new HTM

He continued: "Part B is about the management, operation, maintenance, and routine testing, of existing healthcare systems. It's much as it was, but there are some additional changes. The thing to remember with Part B is that it applies to all installations; it doesn't matter how old."
He continued: "I'm often told a hospital installation dates from the time of HTM 2025, and that's why it doesn't conform. However, the minimum standards have been there ever since that HTM was published; in fact they were introduced because of the Stafford outbreak and Legionnaires' disease in 1986, and were in the Big White Book, for which I wrote a section on standards for ventilation plant." These had – he said – been carried forward in every HTM since.

Moving to the 'major themes' in HTM 03-01 Part A, he said: " One thing we have had to focus on particularly is supporting the Government's zero carbon policy – so there's quite a push in terms of energy use, and how we go about things to support this objective."

Also considered in compiling the new guidance, Malcolm Thomas explained, had been the EcoDesign Directive and regulations, which he pointed out were 'legal requirements'; he was surprised many equipment manufacturers still viewed them as 'options'.

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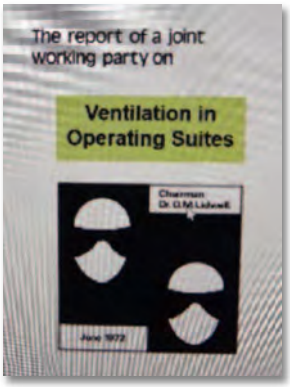
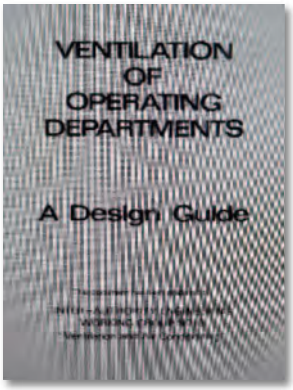
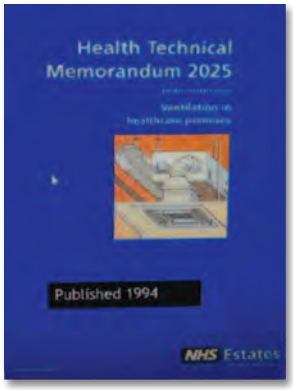






Left: In 1972 Dr Owen Lidwell led a Joint Working Party on ventilation and operating suites, which was to be 'the foundation of all the guidance that has emerged since'. Centre: Following Owen Lidwell's work, the Department of Health and Social Security – as it was then – set up a working group and codified the ventilation of operating departments in a document called DV4. Right: On 'coming on board' with official ventilation guidance, Malcolm Thomas was asked to update DV4, but soon after doing so, he was told it was now to be an HTM, and HTM 2025 was duly published in 1994.

Taking advantage of new technology

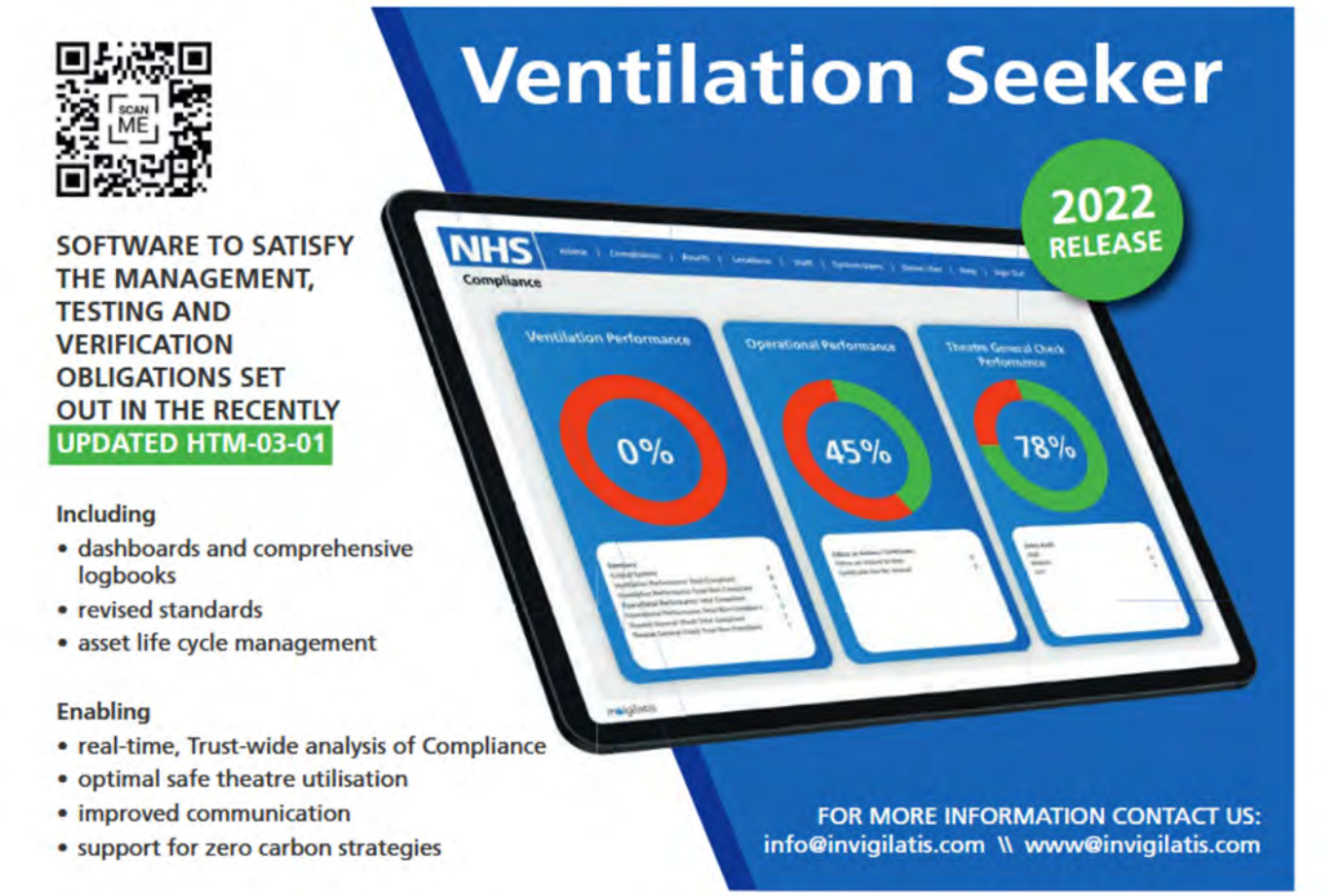
He continued: "On carbon reduction, we changed quite a few things to try to get maximum benefit from new technology and reduced energy use – fans being a good example." He elaborated: "Those of us who grew up with belt-drive fans know we were stuck with a particular fan speed, regardless of whether it was optimal, and with specific outputs; there wasn't much you could easily do about either.

"Nowadays, we have a whole range of more efficient fans, and more coming along; control technology has moved on – we can be more accurate in how much air comes down the system, and we don't need to build in such a big margin to allow for system deterioration over time. We've striven to take advantage of all this in the new HTM." Malcolm Thomas explained that the authors had also striven to provide background information to assist the understanding of client needs.

He expanded: "So, you will find, scattered throughout, little blue boxes with little aide-memoires, which highlight why the preceding paragraph is important, particularly in a healthcare setting. They are very sound ideas, so please don't depart from them."

A clarification of design parameters

The new HTM also incorporated 'a clarification of design parameters'. "There's been problems in the past with what standards we actually want," he explained. "We've now got much more of a clarification of design parameters." In terms of 'the new elements', the HTM's authors had put in the user requirements, listed under 'surgical', 'medical', 'mental health', 'palliative care', 'and so on'. He said: "We have thus sought to answer the questions: 'What does the user want, and why have we provided ventilation?', 'What's it for?', 'Is it for infection control, comfort, or to remove odours?' What's it about?' Again, it is about trying to clarify for the designers exactly what is important, and what you can do some adjustment on." He continued: "We've also introduced the concept of the Ventilation Safety Group, mirroring what we already have with the Water Safety Group, i.e. a group of Trust stakeholders made up of people from Estates, Finance, and Infection Control, and other key



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personnel, all of whom have an input, and make some decisions on the ventilation systems and their operation."

Derogations

In circumstances where somebody wanted to derogate in future, they would now need to take the matter to the Ventilation Safety Group, which must agree and sign up to the derogation. He added: "The Group must also record what the derogation was, why it was agreed, and who agreed it. It thus takes away this 'Mr Jones said it was OK'-type approach. Notice too," he said, "that somebody from Finance is involved, because some of these things have ongoing financial commitments. For example, some of the ways of installing ventilation plant mean they need more regular cleaning over time, with a financial implication ongoing for the system's lifetime, so it's essential that the Finance people are involved and recognise that if you go down that path, there needs to be provision to undertake the maintenance correctly over a period of perhaps 20 years."

Guidance on refurbishments

Malcolm Thomas explained that while the new ventilation HTM covers refurbishments and change, the old one didn't. He and his counterparts had encountered 'a lot of problems' with people refurbishing theatres, where they had 'completely gutted' an existing such facility, installed new ceilings, plastered the walls, put in new doors, a new floor, new operating tables, lamps, 'and everything', but kept a 30-year old ventilation plant. He said: "This is like buying a new car, but taking the engine out of the old one because that will save you a bit of money." He continued: "The ventilation plants are not as expensive as an operating table; you wouldn't dream of using a 30-year-old operating table, so why consider using 30-year-old ventilation plant? We should surely be taking advantage of new technology. We want new plant with good controls, not old plant 'mashed up to save a couple of bob'. That's an important aspect which is clearly spelt out.

Natural ventilation where possible

"We have also suggested various ventilation strategies; we would like natural ventilation where practical. Such ventilation can, however, 'be tricky in the case of hospitals', Malcolm Thomas acknowledged. As he put it: "You're relying on the wind blowing, and blowing in the right direction, not too much and not too little, so it's not easy, particularly in a hospital." However," he added, "mixed mode ventilation, taking advantage of natural ventilation while it's there, and then supporting it with a fan that will come on when it's needed, and perhaps some supplementary heating etc, can be one potential solution."

Natural ventilation wasn't 'just about opening a window'. The speaker elaborated: "It's about having ventilation openings, which may be supported with some ductwork attached, with a means of adjusting the ventilation rate when the natural ventilation is available, and taking advantage of it when it is." Where full ventilation, 'which costs money', was selected, the question arose about whether it needed to run 24 hours a day, seven days a week, 52 weeks a year. He said: "The answer, in most cases, is 'no'. If there's nobody there, you can turn it off – a really good energy-efficient way of doing it. This is not new; it was in EnCO_2de for many years."

Unnecessary plant operation

Noting that people still left theatre ventilation running '24/7' to keep the rooms sterile, which was 'absolutely not required', Malcolm Thomas explained that he and the co-authors of HTM 03-01 (2021) had expanded the 'Operating theatres' section 'quite significantly'. He said: "We've, for example, changed the parameters for air change rates to reflect what we can do to take advantage of the latest technology. We don't need to have as much slack in the systems as previously. So, the advice is much more appropriate for today, although still in line with what Owen Lidwell found worked, and history has subsequently proven right." Some of the 'old information' for where older theatres were still in use had been retained, but the new HTM 03-01 also incorporated 'a whole new set of information'.

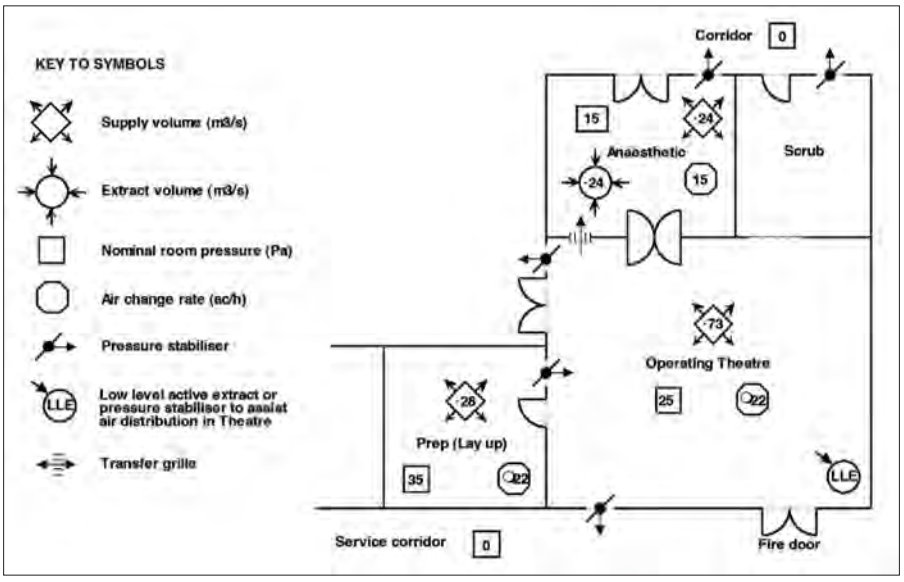
Installation guidance

Malcolm Thomas told attendees: "In a new 'Installation standards' section, we've spelt out some of the things that cause us numerous problems – including guidance on very simple things, which cost no money to do, but if not done right cost an awful lot of time and effort. So, for instance, with a basic thing like balancing damper handles, why install them at the top of the damper? When the ceiling is up, you then can't reach them. Air doesn't know where the handle is, but putting the handle on the bottom of a damper costs no more installation-wise, but means that when you come to balance, or subsequently re-balance, the system, you can reach the handle without killing yourself."

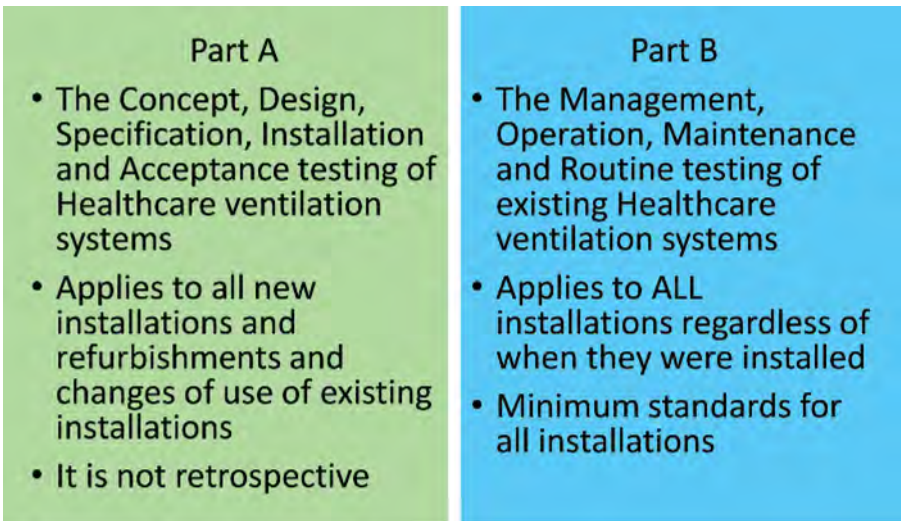
Turning to another key topic in the new HTM – 'Acceptance testing and validation', Malcolm Thomas explained that 'validation is a process of accepting the whole job, the whole project', so in the theatre, wasn't 'just about how much air goes in, but rather about where the air comes from: what the air-conditioning and air-handling unit is like, what the ductwork is like, and what the fabric of the theatre is like'. The speaker stressed that it was 'very different from commissioning', and entailed looking more holistically at 'Does it work, and can we at the end of the validation say it is safe to operate?'

Appendices expanded

The authors had also expanded the appendices 'to cover some of these things'. Here he showed a diagram of 'an example of one of new standard schemes, and the amount of air in the theatre'. He said: "The air change rate has changed, and above this, if you look in the appendices, there's a whole range of information that's much more definitive compared with what we has before. So, there are four schemes – single-corridor and two-corridor schemes for standard theatres and ultraclean, and another four



A ventilation diagram for a standard operating theatre taken from HTM 03-01 (2021).



Malcolm Thomas urged all those with a professional interest in, or responsibility for, healthcare, to read and familiarise themselves both Parts A and B of the new HTM 03-01 – 'including the appendices and the accompanying explanations'.

historical schemes for those of you with older, smaller, theatres."

The authors of the new HTM had also created quite a lot of application-specific guidance – for instance dividing up applications into 'Treatment and Procedure Facilities', 'Airborne Protective Facilities', 'Airborne Isolation Facilities', 'Maternity Facilities', 'Pharmacy Facilities', 'Sterile Services Facilities', and 'Extract systems and local exhaust ventilation'. Malcolm Thomas said: "We have presented that information in terms of tables." Here, by way of example, he showed a slide of an 'Airborne Isolation Facilities' table, covering Isolation rooms, Categories 2 and 3. He explained: "If you want to know what the categories are, look at the bibliography in the index at the back of the HTM, and it's all explained." Down the side of the table were the areas or zones being discussed, with the next column highlighting the reasons and purpose of the ventilation, and the next 'some typical design factors to help make it easier for people to understand what's required'.

Part B

Turning to Part B and its 'major themes', Malcolm Thomas said that, in writing it, the authors had sought to 'clarify things', 'plug up the holes', and 'explain more clearly what we require'. So," he continued, "there is a legal requirement to keep records and information on ventilation systems, but many hospitals don't, so they have broken the law."
In fact, he explained, Part B now includes a requirement for an inventory with a uniform system of identification. He said: "Go round some hospitals and they have 10 air-handling units all called 'Air-handling unit number 1' in 10 different plantrooms, so we obviously need to be a lot clearer. Part B thus suggests that each ventilation plant has a unique number, corresponding to all the information about it, what it is, the spaces it serves, all the parameters and information about the equipment, the system performance over the years, and when we should 'scrap it'. Then," he continued, "we archive that information with its number plate, and put a new number plate on the new plant. We thus have an auditable trail. Generally, when you go around hospitals, a lot of information about systems is in people's heads, so when they leave it goes with them." This, Malcolm Thomas argued, was not only 'not conducive to running an efficient system', but was also dangerous.

Phased replacement

Part B of the 2021 HTM also discusses 'mid-life refurbishment', and phased plant replacement. The speaker explained: "We suggest that after 10 years, the air-handling unit should be taken out of use, cleaned, examined, and any corrosion treated, fitted with new controls, updated to get the best from the technology available, and then put back into use. After 20 years, plant should be replaced. If you don't start thinking about this when you put the plant in the equipment doesn't get replaced, and you then find 30-40-year-old plant still in use in the NHS. We want to take the best, get the most efficient systems, and take advantage of the latest technology; not cling to the older things."

The Ventilation Safety Group

Malcolm Thomas explained that the Ventilation Safety Group had a key role here in getting a phased replacement programme going. He said: "With a brand new hospital, there may be 50 ventilation plants installed, all of the same age; you'll have a mountain to climb to replace them all at the 20-year period, so you need to try to split that up somehow, and start looking at the critical ones maybe slightly earlier."

At any time they needed specialist guidance or help, NHS healthcare engineering teams could, of course, call on an Authorised Engineer (Ventilation) – 'people with independent knowledge, totally independent of the Trust/Health Board', and thus 'there to tell you the truth'. He said: "You may not like what your AE (V) says about your ventilation, but they are there to tell you it like it is, so please listen to them. Similarly," he added, "they should be involved in the process of providing plant to advise on what goes in. The reason I say this is – and I've been a hospital engineer – is that your knowledge here will be limited, and it's very easy to be bamboozled by an outside design team into accepting something they think is alright. It may be that what's being proposed is a great solution, but, conversely, it could be that it won't benefit you long term. Authorised Engineers are there to help with those decisions."

Observing standards

Nearing the end of his presentation, Malcolm Thomas said: "There are minimum standards for all plants – as I said at the beginning – and they should certainly be observed. They are there because there are legal requirements about access, cleanliness, and the efficiency of the plant, listed in both Parts A and B; most of the major pieces of legislation that affect and handling ventilation systems, in a hospital or anywhere else. In a hospital, we also have the Medicine Act, and the Health Act, which impose a duty of care on us for our patients and what we do in healthcare settings." These, the speaker said, 'sat alongside' other legislation such as the Health & Safety At Work etc, the COSHH Regulations, '*et al*'.

Lastly, Malcolm Thomas explained, Part B of HTM 03-01 (2021) included a section on 'Verification'. He said: "This requires you to ensure, every year, that the critical systems in your hospitals are still safe to use. They may be getting slightly older, but the things that matter within your ventilation system must still be working correctly, and then there is the annual routine inspection and maintenance. All the standards on these areas have been there for a considerable time, but need to be adhered to."

He added: "So, to conclude, the HTM has been entirely revised, with many changes, and I would encourage all those with a professional interest in, or responsibility for, healthcare ventilation, to read and familiarise themselves with both Parts A and B, including the appendices and the accompanying explanations." With this, he closed his presentation, and invited questions. hej

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Scottish Health Technical Memorandum 2025

(Part 2 of 4)

Design considerations

Ventilation in healthcare premises

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1. Introduction

General

1.1 Ventilation is used extensively in healthcare premises for primary patient treatment, eg. in operating departments, intensive treatment units and isolation suites. It is also installed to ensure compliance with quality assurance of manufactured items in pharmacy and sterile supply departments and to protect staff from harmful organisms and toxic substances, for example in laboratories.

1.2 This edition of SHTM 2025; *Ventilation in healthcare premises,* is published in four separate parts. It is equally applicable to both new and existing sites. It gives comprehensive advice and guidance to healthcare management, design engineers, estates' managers and operations managers on the legal requirements, design implications, maintenance and operation of specialist ventilation in all types of healthcare premises.

1.3 Current statutory legislation requires both "management" and "staff" to be aware of their collective responsibilities.

1.4 "Ventilation" is provided in healthcare premises for the comfort of the occupants of buildings. More specialised ventilation will also provide comfort but its prime function will be to closely control the environment and air movement in the space that it serves in order to contain, control and reduce hazards to patients and staff from airborne contaminants.

1.5 Ventilation systems in themselves present little danger to patients or staff; however, they do possess the ability to transmit hazards arising from other sources to large numbers of people. The danger may not become apparent until many patients and staff have been affected.

1.6 The sophistication of ventilation systems in healthcare premises is increasing. Patients and staff have a right to expect that the systems will be designed, installed, operated and maintained to standards that will enable them to fulfil their desired functions reliably and safely.

Definitions

1.7 **Air distribution** – the transportation of air to or from the treated space or spaces, generally by means of ducts.

Air diffusion – distribution of the air in a treated space, by means of air terminal devices, in a manner so as to meet certain specified conditions, such as air change rate, pressure, cleanliness, temperature humidity, air velocity and noise level.

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Supply air – the air flow entering the treated space.

Exhaust air – the air flow leaving the treated space.

Exhaust may be implemented by one or more of the following methods:

a. extraction: exhaust in such a manner that the air is discharged into the atmosphere;
b. relief: exhaust in such a manner that the air is allowed to escape from the treated space if the pressure in that space rises above a specified level;
c. re-circulation: exhaust in which the air is returned to the air treatment system;
d. transfer: exhaust in which air passes from the treated space to another treated space.

Dampers – components inserted into air ducts or used in conjunction with air terminal devices, which when activated permit modification of the air resistance of the system and consequently a change complete shut-off; or control of the air flow rate.

Dampers can be:

a. multiple-leaf - comprising a number of opposed or parallel blades;
b. single-leaf dampers - commonly called splitter dampers, having two or more slotted slides;
c. butterfly dampers - with two flaps in a "V" arrangement;
d. iris dampers - with inter-leaving vanes.

Fire dampers – components which are installed in an air distribution system between two fire separating compartments and are designed to prevent propagation of fire and/or smoke. They are maintained open until activated by fire or smoke detection.

Sound attenuators/silencers – components which are inserted into the air distribution system and designed to reduce noise being propagated along the ducts.

Air terminal device – a device located in an opening provided at the end of the duct to ensure a predetermined motion of air in the occupied space.

Supply air diffuser – a supply air terminal device through which air enters a treated space. It usually consists of one or more deflecting blades, which produce a reduction of the air velocity to a suitable level in the occupied zone; a given direction of throw; and efficient mixing of the supply air with the air in the treated space. May be of the fixed or adjustable type.

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Exhaust grille – an air terminal device with multiple passages for the air, through which air leaves the treated space. May be of the fixed or adjustable type.

Slot diffuser – a diffuser with one or several slots with an aspect ratio of 10:1 or more for each slot.

Register – a combined grille and damper assembly.

Nozzle – an air terminal device designed to generate a low energy loss and thus produce a maximum throw by minimum entrainment.

Nominal Size – of an air terminal device is the nominal value of the dimensions of the opening required to mount the air terminal device in.

Effective area – of an air terminal device is the smallest net area used by the air stream in passing through the air terminal device.

Envelope – the geometrical surface of the points in an air jet.

Throw – for a supply air terminal device, is the maximum distance between the centre of the core and the extremity of the terminal velocity envelope.

Induction – process by which the primary air entrains secondary air into motion in the room.

Induction ratio – ratio of the combined primary and secondary air flow rate to the primary air flow rate.

Spread – for a supply air terminal device, is the maximum width of the terminal velocity envelope.

Drop – for a supply air terminal device, is the vertical distance between the extremity of the terminal velocity envelope and the air terminal location plane.

Coanda effect – also called ceiling or wall effect, is the tendency of an air stream to follow a plane when the stream is in contact with the plane. This effect increases throw and reduces drop.

Isovel – a free jet of given momentum which then gives an established velocity profile.

Velocity pressure – pressure inherent in a moving air stream due to its velocity, expressed in Pa (N/m^2).

Static Pressure – pressure. inside the duct which is available to overcome the frictional resistance.

Total pressure – sum of the velocity and static pressures.

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2. Provision of ventilation in healthcare buildings

General requirements

Reasons for ventilation

2.1 Ventilation is essential in all occupied premises. This may be provided by either natural or mechanical means. The following factors determine the ventilation requirements of a department or area:

a. human habitation (fresh air requirements);

b. the activities of the department, that is, extraction of odours, aerosols, gases, vapours, fumes and dust - some of which may be toxic, infectious, corrosive, flammable, or otherwise hazardous (see Control of Substances Hazardous to Health (COSHH) Regulations);

c. dilution and control of airborne pathogenic material;

d. thermal comfort;

e. the removal of heat generated by equipment (for example in catering wash-up and sterilizing areas and in some laboratory areas);

f. the reduction of the effects of solar heat gains;

g. the reduction of excessive moisture levels to prevent condensation (for example, Hydrotherapy pools);

h. combustion requirements for fuel burning appliances (see BS 6798, BS 5410 and BS 5440);

i. “make up supply air” where local exhaust ventilation (LEV), etc. is installed.

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Influences on building layout

2.2 Mechanical ventilation systems are expensive in terms of capital and running costs, and planning solutions should be sought which take advantage of natural ventilation.

NOTE: There is a statutory requirement to mechanically ventilate all enclosed work spaces.

2.3 It is acknowledged that planning constraints imposed by the building shape and/or functional relationships of specific areas will invariably result in some measure of deep planning thus minimising the opportunity for natural ventilation. However, ventilation costs can be minimised by ensuring that wherever practicable, core areas are reserved for rooms that require mechanical ventilation irrespective of their internal or peripheral location. Examples are sanitary facilities, dirty utilities and those rooms where clinical

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or functional requirements have specific environmental needs; and where for reasons of privacy, absence of solar gain, etc, windowless accommodation is acceptable. Other spaces appropriate to core areas are those which have only transient occupation and therefore require little or no mechanical ventilation, for example circulation and storage areas, consistent with the requirements of the Building Standards (Scotland) Regulations.

Natural ventilation

2.4 Natural ventilation is usually created by the effects of wind pressure. It will also occur to some extent if there is a temperature difference between the inside and the outside of the building. The thermo-convective effect frequently predominates when the wind speed is low and will be enhanced if there is a difference in height between inlet and outlet openings. Ventilation induced by wind pressures can induce high air change rates through a building, provided air is allowed to move freely within the space from the windward to the leeward side.

2.5 As the motivating influences of natural ventilation are variable, it is almost impossible to maintain consistent flow rates and thereby ensure that minimum ventilation rates will be achieved at all times. This variability normally is acceptable for general areas including office accommodation, general wards, staff rooms, library/seminar rooms, dining rooms and similar areas, which should be naturally ventilated, that is, provided with opening windows.

2.6 In some cases, however, heat gain or external noise may preclude natural ventilation.

General extract ventilation systems

2.7 A general extract system will be required in rooms where odorous, but non-toxic fumes are likely, in order to ensure air movement into the space. Examples are therapy kitchens and beverage preparation rooms. A single fan/motor unit should be provided to meet this need.

Foul extract ventilation systems

2.8 A separate extract system will be required for sanitary facilities, lavage areas and dirty utilities, using dual motor/fan extract units with automatic change-over facilities to ensure that these rooms are maintained at negative pressure while the unit is in use.

2.9 Lavatories and dirty utilities should have an extract rate of 10 air changes/hour. Where WCs are located in bathroom spaces, the ventilation required for the WC will usually be adequate for the whole space.

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Supply only ventilation

2.10 Mechanical supply ventilation should be provided in areas where it is important to maintain a positive pressure in a room, to prevent the ingress of less clean air, for example in clean utilities, or operating departments.

Supply and extract ventilation

2.11 Mechanical supply and extract ventilation should be provided in rooms where it is desirable to maintain the room at a neutral pressure at all times, such as treatment areas and plaster rooms.

Comfort cooling

2.12 Cooling is very expensive in terms of energy costs, and should be provided only where necessary to maintain a comfortable environment for staff and patient, or to ensure satisfactory operation of equipment.

2.13 Summertime temperature calculations using the method mentioned in paragraph 3.40, should be completed for all areas where there is a risk of excessive temperatures. Generally, air cooling should be provided where these calculations show that, without excessive levels of ventilation, internal temperatures are likely to rise more than about 3 K below external shade temperatures. In these circumstances, cooling should commence when the space temperature reaches 23°C. Typical areas which may require cooling are some laboratories, central wash-up, and similar areas which are subject to high equipment heat gains. Where deep planning of other continuously occupied spaces, for example offices, is unavoidable, there will also be occasions when acceptable levels of comfort can only be maintained by air cooling. Planning solutions of this type, however, will be exceptional; and no provision for cooling plant will generally have been included in the Departmental Cost Allowance (DCA).

2.14 Refrigeration plant should be of sufficient capacity to offset heat gains and maintain areas at a temperature 3°K below external shade temperature.

Air-conditioning

2.15 Air-conditioning is only required in a very small number of areas within healthcare buildings; and due to the capital and running cost implications, its inclusion should be kept to a minimum.

2.16 Areas whose functions do warrant the installation of full air-conditioning, include operating departments, intensive therapy units, manufacturing pharmacies, sterile supplies departments, kitchens and areas with sensitive equipment where the environment needs to be maintained within specified limits to prevent equipment failure.

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Specialist ventilation

2.17 Due to the nature and extent of activities carried out in healthcare buildings, there are needs for a wide range of specialist ventilation systems. These types of system which are generally required in individual departments and typical arrangement are given in Chapter 6.

2.18 The activities within some departments will require the provision of local exhaust ventilation (LEV). This is a statutory requirement under COSHH wherever the escape of chemicals, toxic fumes, biological material or quantities of dust into the general area would present a hazard to the occupants.

Air scrubbing

2.19 Air scrubbing is the process by which air is recirculated through a filter in order to maintain airborne contamination at an acceptable level. An example of this is laminar flow cabinets.

Ventilation for general areas

2.20 Table 2.1 provides recommended air change rates, temperatures and pressures for general areas which require mechanical ventilation in healthcare buildings.

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Table 2.1: Typical internal design conditions

(Refer to Activity Database for specific details)

Room description	Temperature °C		Nominal room pressure with respect to surroundings	Ventilation type and rate		
	Summer (if cooling)	Winter		Supply ac/h	General extract ac/h	Foul extract ac/h
All departments						
WCs	–	20°C	-ve	–	–	10
Bathroom/ Shower	–	22°C	-ve	–	–	6
Laboratories	Ambient -3°K	18°C	-ve	To suit Room Loads		–
Treatment	25°C	22°C	0	10	10	–
Staff change	–	21°C	+ve	5	–	–
Coffee lounge	–	20°C	-ve	–	3	–
Beverage room	–	21°C	[illegible]	–	5	–
Dirty utility	–	18°C	-ve	–	–	10
Clean utility	–	18°C	+ve	6	–	–

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Acceptable methods

Use of natural ventilation

2.21 With the trend towards better sealed buildings, infiltration through building leakage has significantly reduced; and more attention is now given to the provision of purpose-made ventilation openings to achieve the necessary flow rates.

2.22 However, internal partitions, fire compartment walls and closed doorways can often impede the flow path, and when this happens, the process will be more dependent on single-sided ventilation. Nevertheless, even with this degree of compartmentation acceptable ventilation may still be achieved without window openings which would prejudice safety, security or comfort.

2.23 Some types of window, for example vertical sliding, can enhance single-sided air change by temperature difference, and these will improve the overall rate of natural ventilation in protected or sheltered areas where the effect of wind pressure is likely to be minimal.

2.24 It is generally considered that cross-flow ventilation is able to give reasonable air distribution for a distance of up to 6 metres inwards from the external facade, provided that reasonably clear air paths are maintained. Beyond this distance in areas where clear air paths cannot be maintained

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and in areas where high minimum air change rates are specified, mechanical ventilation should be provided. Section 2.3 of HTM 55: *Windows*, BS 5295 and CIBSE Symposium: Natural Ventilation by Design (2/12/80)' provide further information.

2.25 Where natural ventilation is adopted with complex air paths, the designer should produce an air flow diagram in order to ensure correct provision of air transfer devices.

Mechanical extract ventilation

2.26 Both foul and general extract systems can vary in complexity from a single wall-mounted fan for each facility, to a ducted air distribution system with dual extract fans.

2.27 Replacement air is either provided by a central supply system (as described below), or enters the building through gaps in the structure or purpose-made openings. Unless special precautions are taken, the latter may result in an unacceptable level of draughts occurring in winter and possible risk of unacceptable levels of noise transmission.

2.28 If individual systems are used, the ventilation can be operated intermittently, provided it continues to run for at least 15 or 20 minutes after the room is vacated, as with light switch-operated fans in individual toilets.

2.29 If general exhaust systems are used, it is recommended that filtered and tempered replacement air is provided via a central supply plant to adjoining lobbies or corridors, to prevent the risk of discomfort caused by the ingress of cold air. Fire compartmentation requirements must be maintained.

2.30 Information on specialist extract systems is given in Chapter 6.

Mechanical supply systems

2.31 Where mechanical supply systems are required, the fresh air should be tempered and filtered before being delivered to the space, to avoid discomfort.

2.32 The air should be heated using a constant rather than variable temperature source, but generally only to the space air temperature. In most instances, the low pressure hot water heating (LPHW) should offset any fabric loss, so that set-back room temperatures can be maintained during unoccupied periods without the need for the ventilation system to operate.

Balanced ventilation

2.33 Balanced ventilation systems are merely a combination of a supply and extract system of equal volume; and either a single space or a whole building may be considered to be balanced. A balanced system is necessary in instances where it is essential to maintain consistent air movement within an area, for example, treatment rooms.

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Cascade ventilation

2.34 In operating departments it is normal practice to supply air to the operating room, and allow it to pass through to less clean areas - corridors, utility rooms etc from whence it is exhausted.

Recirculation systems

2.35 Due to the nature of the use of mechanical ventilation systems within healthcare buildings, there are few opportunities for the application of recirculation air systems.

2.36 Where the designer is considering the installation of a recirculation air system, due account must be taken of:

a. minimum fresh air supply volumes;

b. prevention of contamination of supply air from vitiated air in extract systems;

c. prevention of stratification occurring within mixing boxes which may result in freezing of downstream coils;

d. ensuring sufficient velocities through control dampers (ideally 5–6 m/s) to provide suitable authority; and good shut-off;

e. modulating control of mixing to provide optimum on-plant conditions;

f. use of “free cooling” by cycling the dampers to minimum fresh air when the enthalpy of the outside air is above that of the extract air under conditions when cooling is required.

Split comfort air-conditioners

2.37 Split comfort air-conditioners, room conditioning or cassette units are used increasingly where there is a small (up to 15 kW) local requirement for cooling for operational purposes.

2.38 Until recently, the application of these units was restricted to single room but recent technological advances have led to the development of systems which allow multiple indoor units to independently provide either heating or cooling served by a single outdoor unit. These systems enable good temperature control of a number of rooms with maximum energy efficiency.

2.39 Split comfort air conditioners can often provide an effective economic solution to cooling needs, where a central refrigeration system is not practicable.

2.40 Whether single or multiple systems are used, it is essential that the designer gives due consideration to the provision of maintenance, the source of electrical supply and the environmental effects of the refrigerant used.

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Dilution ventilation

2.41 Dilution ventilation may be appropriate under COSHH in certain circumstances, provided that the threshold limit values (TLV) are capable of being maintained without excessive air change rates. In addition, the source and distribution of the contaminants within the space must be reasonably uniform. In cases where substances are highly toxic or where the rate of evolution is high, it is preferable to use local exhaust ventilation systems. These tend to give greater control of the substance and minimise the overall ventilation needs. Certain substances are regarded as too highly toxic for "ventilation control" and require devices such as "glove-boxes".

Mechanical ventilation systems

System selection

2.42 Natural ventilation is always the preferred solution for a space, provided that the quantity and quality of air required, and the consistency of control of ventilation to suit the requirements of the space, are achievable with this method. If this is not the case, a mechanical ventilation system will be required.

Choice of central/local plant

2.43 Mechanical ventilation is expensive to operate, and as such, should be controlled to operate when the space being served requires to be ventilated. In addition, loads on air conditioning plant are rarely constant owing to changes in solar gain, occupancy and use of heat-generating equipment and lights, therefore control of temperature is critical.

2.44 If the variation of loads throughout a department or building are in phase, or are not significant, a central plant with single zone control can be adopted. However, this is rarely the case, and elsewhere, the condition or quantity of supply air to different areas or zones of the building must be varied accordingly. This can be done by providing either individual plants to each zone, or separate zone terminal control. Where there is a high density of rooms with similar ventilation requirements in an area of a building or department, it is usually economical to combine them into a central system.

2.45 In large buildings, a choice between a single distribution system and multiple smaller systems may arise. Large distribution systems and their plant can have the advantage of lower operating costs, but require more space for vertical shafts. In general, very long runs of ducting should be avoided to prevent undue heat losses or gains, excessive leakage, and difficulties in balancing during commissioning. As the pressure losses in the long runs will be greater and a higher initial static pressure will be required, this will lead to a more expensive class of ductwork. Multiple smaller distribution systems may be more expensive in capital and operating costs but they avoid long

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runs, large ducts and vertical shafts, and this may reduce overall building costs.

Zoning of the building

2.46 The efficiency and effectiveness of any ventilation or air-conditioning installation depends largely on the zoning and control of the installation. The factors to consider when determining the zoning of a ventilation system for a building or department are:

a. periods of occupancy;

b. fresh air/ventilation requirements;

c. smoke control.

2.47 Where the ventilation system is not merely tempering the air, but also providing the heating and/or cooling requirements, the following additional factors will need to be considered:

a. internal or peripheral location;

b. orientation of windows;

c. variation in internal loads;

d. level of control required.

Methods of control

2.48 The method of control selected for a ventilation system is governed to a large extent by the complexity of the system installed. The options available range from an electrical spur, to a building management system (BMS). Further information on BMS is contained in SHTM 2005; *Building Management Systems*.

2.49 For single zone plant in staff areas, local control (with a run-on timer if required) is recommended, as this can be turned off when the space is not in use, thus saving both thermal and electrical energy. Most supply and extract systems, conversely, are required to operate continuously while the department is in use, thus some form of time control is necessary.

2.50 For most ventilation applications in healthcare buildings, the supply system is only required to temper the air, hence the supply temperature of the plant can either be maintained at a constant level, or controlled by a room sensor in an internal zone or return air duct (if applicable).

2.51 The control of individual plant items is covered in Chapter 4, with examples of typical control strategies in Chapter 5. For control of particular specialist ventilation and air-conditioning systems refer to Chapter 6 of this document.

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Specific requirements for hospital departments

2.52 Specific requirements for individual spaces and departments are included in the Scottish Hospital Planning Notes (SHPN), Health Building Notes (HBN) and Activity Data Base (ADB) A-Sheets.

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3. Assessment of service requirements

Selection of design criteria

External design conditions

3.1 The most accurate data that is available for the summer and winter conditions at the site should be used.

3.2 As virtually all healthcare ventilation systems are “full fresh air” without recirculation, the majority of the load on the air-handling plant is in treating the incoming air. The plant therefore responds closely to the enthalpy of the outside air and is not influenced to a great extent by other factors.

3.3 To improve design accuracy the figures advocated herein (Table 3.1) are based on long-term frequency distribution of ambient enthalpy (Legg and Robertson, 1976). The use of simultaneous occurrences of wet and dry bulb temperatures (enthalpy) avoids errors associated with choosing values from two independent frequency distributions.

Table 3.1: Outside design values

	Summer			Winter	
Location	Design enthalpy	Associated temperature		Design enthalpy	Associated saturated temperature
	kj/kg	DB °C	WB sling °C	kj/kg	°C
Kinloss	53	19 – 26	18.8	-5	-9.0
Glasgow	55	20 – 28	19.2	-4	-8.5
Stornoway	51	18 – 23	18.0	-1	-6.5
Edinburgh	54	20 – 26	19.0	-6	-10.0

The “design enthalpies” are values which are exceeded for 10 hours/year (0.11%).

The “associated temperature” values give the ranges of temperature which occur in association with the “design enthalpy” values. The higher value would be used for the calculation of fabric gains and for sizing air-cooled condensers, while the lower value is relevant to the design of cooling coils.

3.4 The enthalpy figures are also chosen such that they will be exceeded (higher in summer, lower in winter) for only 10 hours in the average year. This is a more accurate requirement than the CIBSE recommendation for ordinary buildings.

3.5 For each summer design enthalpy, the possible range of temperature (dry bulb) is quoted. All figures quoted are “air” temperatures and enthalpies, and therefore pertain to areas shaded from the sun. Items of equipment located in direct sunlight, particularly when adjacent to sunlit surfaces, will be

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subjected to higher temperatures. Air-cooled refrigeration condensers are particularly vulnerable.

3.6 Local adjustments such as for height above sea level, or other climate peculiarities, should be made as appropriate.

3.7 For summertime temperature and cooling load calculations, the effect of orientation and the properties of building materials affect the sol-air temperature, and effective time; details must be obtained before calculations are undertaken.

Internal design conditions

3.8 A person's feeling of comfort depends on a complex combination of air temperature, radiant temperature, air movement, and humidity, together with personal factors such as clothing and activity. The non-personal factors have been combined to produce a comfort index referred to as "Resultant temperature".

3.9 The choice of a suitable resultant temperature for system design resolves itself into choosing that temperature which should give optimum comfort for the occupants concerned, taking into account their clothing and level of activity. It must be remembered, however, that unless mechanical cooling is installed the internal air temperature can never be less than the external shade temperature.

3.10 Studies have shown that the majority of people will be neither warm nor cool in winter in rooms with still air (that is, the air velocity in the occupied zone is < 0.1 m/s) when the resultant temperature is between 19 and 23°C, and that levels of dissatisfaction do not increase when the temperature varies by within ± 1.5 K of the selected value.

3.11 It has also been found that there is a relationship between preferred indoor temperatures and mean outside temperature. Figure A1.2 in the CIBSE Guide indicates this relationship.

3.12 The design conditions selected within patient areas must strike a balance between the comfort requirements of staff and patients, who often have very different levels of clothing and activity. In areas such as operating departments, the comfort of the surgeon is of prime importance whereas in ward areas, the patient requirements are the overriding factor.

3.13 The effect of relative humidity on thermal comfort is less well defined than that of temperature. For most applications, the comfort range is between 40% and 70%, in order to minimise the build-up of static electricity; and allow for evaporation of perspiration.

3.14 Recommendations for the resultant temperatures and humidities of individual spaces are shown on activity data A-Sheets, but generally acceptable figures are given in Table 3.2.

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Table 3.2: Internal conditions for design of plant

Season	Inside design conditions		Control range
	Dry bulb temp °C	% sat	
Winter heating	22	40(nominal) +5% -0%	15 to 25°C
Summer cooling	20	60(nominal) +0% -5%	15 to 25°C
Manual selection control	15 to 25°C max range obtainable at non-extreme external conditions only	50% sat minimum for using flammable anaesthetics +5% -0%	

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Minimum fresh air requirements

3.15 For most applications involving human occupancy, the dilution of body odours is the critical factor in determining ventilation requirements; and where natural ventilation or full fresh-air systems are used, all ventilation air will be fresh.

3.16 Where odour dilution is the overriding factor, it is recommended that 8 litres/second/person should be taken as the minimum ventilation rate; however, this rises to 12 litres/second/person for rooms with heavy smoking (CIBSE Table B2.2).

3.17 In non-standard applications such as laboratories or operating departments, the particular requirements for each area should be considered independently in order to determine the overriding minimum requirement for ventilation.

Limiting supply air conditions

3.18 Where the ventilation system is used to maintain conditions within the space or pressure differentials between spaces, this requirement may exceed that for provision of fresh air. In these instances, recirculation systems can be used (if appropriate) in order to reduce the energy consumption of the system.

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3.19 For most applications in healthcare buildings, it is the temperature differential between the supply and room air, rather than the actual temperature of the supply air which is the critical factor. The maximum recommended supply-to-room air temperature differential is:

summer cooling: -7K

winter heating: +10K

3.20 It is also necessary to maintain supply air humidity below 70% in order to minimise risks associated with condensation.

Air purity

3.21 In healthcare premises, the standard of filtration will depend on the activities within the occupied spaces. With the exception of special areas, (for example manufacturing pharmacies), the requirement for aerobiological needs is not stringent, and filtration is only required to:

a. maintain hygienic conditions for the health and welfare of occupants, or for processes such as food preparation;
b. protect finishes, fabrics and furnishings, to reduce redecoration costs;
c. protect equipment either within the supply air system that is, to prevent blocking of coils, or in the space itself to prevent dust collection.

In these instances, an arrestance of 80% to 90% is acceptable, requiring an EU3 grade filter.

Humidity control requirements

3.22 Providing humidification is expensive in terms of plant, running costs and maintenance, and therefore its use should be restricted to where it is necessary for physiological or operational reasons.

3.23 The comfort band for humidity is wide; current practice recommends that it should be kept between 40% and 60% saturation.

3.24 Below 40% saturation, there is a tendency to feel dryness in the eyes, nose and throat, while static electricity increases, and organisms spore, making them more difficult to kill by means of surface disinfectants.

3.25 At humidity levels above 70%, there is increased risk of surface condensation and mould growth, and organisms are more likely to multiply.

Maximum noise levels

3.26 Noise will be generated in an air distribution system by the fan, ductwork fittings, dampers and grilles. Again, the specified maximum noise level will depend on the activities within the occupied spaces.

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3.27 The overall noise level should be to levels set down in SHTM 2045; *Acoustics*, although general requirements are given in Table 3.3.

3.28 Attenuation should be incorporated into the ductwork system or plant arrangement as necessary to reduce noise from fans and plant items in order to achieve the acceptable limits within the rooms at the design air flows.

3.29 Plant noise should not be greater that 85 dBA within the plantroom from the fans, coolers, heaters, humidifiers etc, when starting up or running; and should be reduced to lower noise levels where the plant is near to departments sensitive to noise.

3.30 Attention must be given to the reduction of tonal components. High tonal components from air diffusers etc, can seriously disturb concentration over longer periods even when the overall noise level is low. Broadband noise causes less annoyance.

3.31 The values recommended in Table 3.3 are for the total noise environment of space. In general, there will be noise transmitted into the space and noise generated within the space. The designer requires knowledge of the total hospital layout and operational policies to assign acceptance magnitudes to all the possible noise sources, in order to arrive at the correct rating.

Table 3.3: Interior noise leve

Room	Overall noise level L_{10} dB(A)	Ventilation plant commissioning – dB(A)	Ventilation plant design – dB(A)
Operating room(ultra-clean)	See 6.96	-	-
Operating room (conventiona	50	45	40
Anaesthetic	50	45	40
Preparation	50	45	40
Scrub-up	50	45	40
Ward areas	35	30	30
Sanitary facilities	45	40	35
Industrial areas	50	45	40
Circulation areas	50	45	40

3.32 In Table 3.3 the overall noise level takes account of all internal and external noise sources. The commissioning noise level is the level measured with a sound level meter in the unoccupied room, taking account of the external noise together with the noise generated by the ventilation system. When occupied and in use, this commissioning level will constitute a continuous background noise which will allow the overall noise level to be achieved. The ventilation plant design noise level is that generated by the plant alone with no other noise source being considered. The levels suggested make

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recognised allowance for the ingress of environmental noise which must be considered in the overall design, that is, in specifying the attenuation of walls, partitions, ceilings, etc.

3.33 The recommended criterion is measured as the “A” weighted sound pressure level expressed in decibels, which should not be exceeded for more than 10% of the time.

3.34 The designer must also consider noise escaping to the external environment and this must not be unacceptable to occupants of adjacent buildings.

Calculation of building loads

Air infiltration

3.35 Air infiltration occurs due to a complex combination of wind pressures and thermal effects operating on a building, and is governed by the size and number of openings in the building envelope and the complexity of internal air paths.

3.36 Table A4.4 in the CIBSE Guide provides formulae for calculation of ventilation for a simple building; however, in general buildings where it is necessary to accurately calculate infiltration rates, solutions can only be obtained by computer modelling.

3.37 CIBSE Tables A4.12 and A4.13 give empirical values for typical buildings in normal use in winter. For non-standard applications, the infiltration chart (Figure A4.3) with the appropriate correction factors should be referred to.

3.38 When calculating thermal loads due to infiltration, based on Table A4.12, the following should be noted:

a. infiltration allowances may be halved during unoccupied periods;

b. where the majority of rooms have only single-sided ventilation, the load on the central plant will be roughly half the total of individual room loads;

c. if the ratio of openable doors and windows exceeds 25% on one wall only, the tabulated infiltration rate should be increased by 25%;

d. if the ratio of openable doors and windows exceeds 25% on two or more walls, the tabulated infiltration rate should be increased by 50%;

e. on severely exposed sites, the tabulated infiltration rates should be increased by 50%;

f. on sheltered sites, the tabulated infiltration rates should be reduced by 33%;

g. in rooms with mechanical supply systems, half the tabulated value should be used for calculations of room loads, to ensure that room temperatures can be maintained when the ventilation system is not operating.

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Summertime temperatures

3.39 Summertime temperature calculations should be carried out for all rooms where the possibility of local solar or other heat gains may cause the temperature within an uncooled area to rise to an unacceptable level for the equipment and/or procedures to be carried out.

3.40 The calculation method for determining the summertime temperature is described in section A8 of the CIBSE Guide; however, it is very important to select the time of day and time of year of peak loadings for the calculations, which are dependent upon the orientation and proportion of solar to total heat gain.

3.41 Where calculations indicate that internal temperatures frequently approach external shade temperatures by less than 3 K, methods of reducing temperature rise should be investigated. Options include increasing ventilation rates, reducing gains, or providing mechanical cooling.

Peak heating load

3.42 Peak heating load calculations are necessary on all mechanical supply systems to establish the size of heater batteries and subsequently the central plant.

3.43 Where ventilation systems provide tempered air to spaces which have supplementary LPHW to offset the building fabric losses, the plant heating load should be calculated based on the external winter design temperature (selected from Table 3.1), the internal air temperature (given in activity data sheets, or selected from CIBSE Table A1.3), and the calculated total air volume (including a suitable allowance for leakage).

3.44 Where the ventilation system is the only means of heating a space, an increase in load equivalent to the calculated fabric heat losses from the space should be added to the ventilation load. A check of supply temperature difference should be made. If it exceeds 10°K the ventilation supply volume should be increased.

3.45 If there are multiple heater batteries within a ventilation system, the size of each battery will be determined by the desired temperature rise across it.

Peak cooling load

3.46 Peak cooling load calculations are far more complex than heating load calculations.

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3.47 In addition to the base data of air flow rates and temperatures, when calculating cooling loads, the engineer must take into account:

a. solar cooling loads;
b. surface conduction cooling loads;
c. internal gain cooling loads;
d. cooling loads due to high-level humidity control;
e. method of control of internal conditions;
f. fluctuations in internal temperatures.

3.48 When the peak internal loads have been assessed and a suitable allowance made for non-coincidence, the supply temperature may be calculated.

3.49 Once the lowest required supply temperature of the air handling unit has been established, and an allowance made for temperature rise through the fan and ductwork (usually 1 K for low pressure systems), the off-plant enthalpy can be established from a psychrometric chart or table.

3.50 The cooling load is calculated from the difference between the internal and external design enthalpies and total air flow.

3.51 The cooling loads for all plants on the chilled water system should be calculated at each of the individual peak times in order to accurately establish the required (diversified) capacity of the chiller.

3.52 Due to the complexity of the calculations and the necessity to perform multiple calculations, cooling load calculations computer modelling may be helpful.

3.53 There is, however, a manual calculation procedure detailed in section A5 of the CIBSE Guide and a simplified approximate procedure detailed in Section A9.

Annual energy consumption

3.54 Annual energy consumptions of simple heating-only ventilation systems are simple to calculate, based on supply-to-external air temperature rise, and frequency of occurrence of external temperature data (CIBSE Table A2.8).

3.55 Air-conditioning systems are expensive to operate in terms of energy costs, when compared with standard heating systems.

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3.56 The energy consumption of an air-handling unit is dependent upon:

a. external conditions;

b. internal control bands;

c. volume of air flow;

d. method of zoning and control.

3.57 Minimum air volumes are usually fixed by the room loads or fresh air requirements; however, the designer may increase air flow to some rooms or zones in order to balance loads, as detailed in paragraphs 3.70–3.71.

3.58 The method of zoning and control can significantly influence energy consumption.

3.59 The nature of air-conditioning operation, that is cooling and reheating for humidity or zonal temperature control, makes prediction of energy consumption very complex. It is imperative that these calculations are performed to ensure optimum energy efficiency.

3.60 Computer modelling is the preferred method; however, a manual method is available, for example load and plant operation charts.

3.61 The concept of load and plant operation charts is outlined in CIBSE Guide section B3. The method requires the designer to establish the minimum and maximum loads on all zones across the range of external temperatures between winter and summer design conditions. Once the load chart is complete, the plant chart converts the loads to supply temperatures, which are then superimposed on external air temperatures.

3.62 Humidity levels are plotted based on a mean condition line of dew-point temperatures, and the required supply dew-point temperature.

3.63 When all temperatures for all zones are plotted on the plant operation chart, set points and resetting schedules can be established. From this information, the outputs of individual heaters, coolers and humidifiers can be established at any given external temperature. When those loads are computed against annual frequency of occurrence of external temperatures as given in CIBSE Table A2.8, the annual energy consumption of individual elements, and thus the air-conditioning system, can be established.

Assessment of condensation risk

3.64 Condensation of water vapour occurs whenever a surface temperature falls below the ambient dew-point temperature.

3.65 The prediction of surface condensation on building elements such as walls, windows and roofs can therefore be obtained by comparing the room dew-point and surface temperatures.

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3.66 To undertake calculations on the risks of surface condensation, it is necessary to estimate the vapour pressure or moisture content of air within the building. This will largely be determined by the sources of moisture evaporation within the building, that is combustion of gas and other hydrocarbons; cooking, washing, bathing and other processes involving open vessels of hot water; and perspiration and respiration of building occupants.

3.67 In order to prevent surface condensation occurring, it is necessary to provide sufficient ventilation to maintain the maximum ambient dew-point temperature below the lowest surface temperature, the coldest surface usually being the glazing.

3.68 Where this would require excessive ventilation levels, the designer should consider removal of the moisture at the source of the evaporation via an exhaust hood or similar device.

3.69 In intermittently heated buildings, it is necessary to consider the condensation risk at night set-back conditions as well as during normal operation. Calculation methods for this assessment are given in section A10 of the CIBSE Guide.

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Calculation of plant requirements

Air supply volumes

3.70 The minimum air supply volume for a room is determined by the greatest of the three criteria, viz.:

a. minimum fresh air requirements (paragraphs 3.15–3.17); and

b. minimum supply volume for room loads for heating or cooling maximum supply temperature differential (paragraphs 3.18–3.20);

c. specific supply air volumes for dilution ventilation.

NOTE: However, the air supply volume to individual rooms is often in excess of the minimum volume in order to enable a number of rooms to be supplied at the same temperature, that is, air volumes are increased to balance the zonal load in terms of energy per unit of supply air volume ($W/m^3/s$).

3.71 Multi-zone systems often do not have terminal cooling coils, and thus it is often necessary to balance the plant load in terms of cooling energy per unit of supply air volume ($W/m^3/s$) in order to prevent excessive overcooling and reheating occurring continuously on lightly loaded zones.

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Plant sizing

3.72 Once the air flow has been established as described above, the cross-sectional area of the air-handling unit can be calculated based on a maximum coil face velocity of 2.5 m/s.

3.73 In order to establish the length of the air-handling unit, it will be necessary to refer to manufacturers' literature, ensuring all necessary access panels and components are included as detailed in Chapter 4.

3.74 The fan duty should be calculated by adding the resistances of all elements which contribute to the pressure drop of the index circuit.

3.75 The main elements which must be considered are:

a. inlet or discharge louvres;
b. plant entry and discharge;
c. attenuators;
d. components within the air-handling unit;
e. duct-mounted heaters and filters (including a dust allowance);
f. ductwork distribution;
g. ductwork fittings, including: fire dampers, volume control dampers, bends and sets, tees, changes of section;
h. air terminal device;
i. discharge velocity.

3.76 The pressure drops of louvres, grilles, external filters and attenuators may be obtained from the selected manufacturers' literature.

3.77 Where packaged air-handling units are installed, the fan pressure drop is usually quoted as external plant resistance, and thus the designer does not need to calculate the resistances of individual plant items. The designer should, however, ensure that an allowance has been made for filter clogging; and confirm whether the fan pressure quoted is fan total or static pressure.

3.78 Resistances of ductwork and fittings may be obtained from the CIBSE Guide, section C4; however, the designer should exercise some care when using tabulated pressure loss information for fittings which are relatively close together.

3.79 Upon completion of the resistance calculation exercise, the designer should make allowances for calculation and construction tolerances as indicated in Table 3.4.

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Table 3.4: Typical fan volume and pressure margins

Criteria	Low pressure systems	Medium/high pressure systems
Volume flow rate margin for leaking and balancing requirements	+10%	+5%
Total pressure loss margin		
a. for increase in volume flow rate (above)	+10%	+5%
b. for uncertainties in calculations	+10%	+10%
Combined total pressure loss margin	+20%	+15%

Plantroom size and location

3.80 The ventilation plant and associated equipment should be positioned to give maximum reduction of noise and vibration transmitted to sensitive departments, and, at the same time, achieve an economic solution for the distribution of services.

3.81 It is not recommended that noise and vibration generating plant be housed either directly above or below sensitive areas (for example, operating or anaesthetic rooms) unless there is no alternative, in which case additional care and attention must be given to the control measures.

3.82 The plant must also be located so that it is remote from possible sources of contamination, heat gains and adverse weather conditions. The design should ensure that wind speed and direction have a minimal effect on plant throughput.

3.83 Access to and around plant is essential to facilitate inspection, routine maintenance, repair and plant replacement.

Provision of primary services

3.84 Where more than one air-handling plant requires cooling, remote central cooling plants with piped chilled water are preferred. In the case of a single plant, a multi-stage direct expansion cooling coil with refrigerant piped from an adjacent compressor/condensing plant could be considered. If this option is selected, a refrigerant gas detector mounted in the base of the duct and an alarm system audible to the end-user will also need to be provided (COSHH regulations).

3.85 Clean dry steam is preferred for humidification, provided that the boiler water treatment does not render the steam unusable for direct humidification.

3.86 When boiler steam is used, a warning notice regarding water treatment must be prominently displayed in the boilerhouse stating that the steam is to be used for humidification in the hospital air-conditioning plant; and that only approved additives must be used. Boiler treatments that comply with the

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Federal Drug Administration (FDA) Regulations 21: Part 173.310 and also **exclude volatiles** are considered suitable.

3.87 If a suitable supply of steam cannot be obtained from the steam main, a steam generator should be provided locally, or a self-generating humidifier installed. The location of a local steam generator is critical if condensate is to drain back into it.

NOTE: Reference should be made to SHTM 2031; *Clean steam for sterilization*.

Discharge and inlet sizing and location

3.88 Air intakes and discharge points are generally located at high level, to minimise the risks of noise nuisance to surrounding buildings, contamination and vandalism.

3.89 Each intake and discharge point should be protected from weather by louvres, a cowl, or a similar device.

3.90 Louvres should be sized based on a maximum face velocity of 2 m/s in order to prevent excessive noise generation and pressure loss.

3.91 Any space behind or under louvres or cowls should be tanked and drained if there is a possibility of moisture penetration. The layout of the drains should be in accordance with paragraphs 4.8 to 4.18.

3.92 Intake points should be situated away from cooling towers, boiler flues, vents from oil storage tanks, fume cupboards and other discharges of contaminated air, vapours and gases, and places where vehicle exhaust gases may be drawn in.

3.93 The discharge from an extract system must be located so that vitiated air cannot be drawn back into the supply air intake or any other fresh-air inlet. Ideally, the extract discharge will be located on a different face of the building from the supply intake(s). Where this is not practicable, there must be a minimum separation of 4 metres between them, with the discharge mounted at a higher level than the intake, or 10 metres separation with no requirement on relative positioning.

3.94 The discharge should be designed and located so that wind speed and direction have a minimal effect on the plant throughput; and should be fitted with corrosion-resistant weatherproof louvres to protect the system from driving rain, with mesh screens of not less than 6 mm and not more than 12 mm to prevent infestation. If possible, the inlet duct should slope back towards its intake, so that it is self-draining. If this is not practicable, it should be provided with a drainage system the layout of which should be in accordance with paragraphs 4.8 to 4.18.

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Heat rejection devices

3.95 The design conditions given in Chapter 2 make no allowance for the elevated temperatures that can occur on the roof of buildings. Refrigeration condensers and cooling towers should, if practicable, be shaded from direct solar radiation, or the design adjusted to take account of the gain.

3.96 Air-cooled condensers must always be the first choice for heat rejection from any refrigeration plant. Evaporative cooling systems must not be used in healthcare premises unless limitations of space mean that they are the only way that the cooling load can be met. If they are used, the guidance set out in SHTM 2040; *The control of legionnellae in healthcare premises - a code of practice* must be closely followed.

Air distribution arrangements

Ductwork distribution systems

3.97 Ductwork systems for ventilating and air-conditioning applications are referred to by their velocity or pressure category, that is, as low, medium or high velocity or pressure systems. HVCA limits are up to 10 m/s or 1000 Pa; 20 m/s or 1750 Pa; and 40 m/s or 3250 Pa in the case of conventional low, medium and high pressure systems respectively. High pressure systems are more expensive to install and because of their greater input power requirements, are increasingly more expensive to run.

3.98 For normal applications in healthcare buildings, low velocity systems are recommended; and the use of higher velocities than those recommended is not likely to be economical. Future trends are likely to be towards even lower optimum duct velocities; however, velocities lower than 2.5 m/s are unlikely to be justified.

3.99 The site will often dictate the main routing of ductwork systems, but in general the design should seek to make the layout as symmetrical as possible; that is, the pressure loss in each branch should be as nearly equal as possible. This will aid regulation and may reduce the number and variety of duct fittings that are needed.

Ductwork materials and construction

3.100 The choice of material to be used for the formation of a duct should take account of the nature of the air or gas being conveyed through the duct, the environment in which the duct will be placed, and the cost of the installation.

3.101 Galvanised sheet steel is generally suitable and most economical for normal ventilating and air-conditioning applications.

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3.102 In instances where moisture levels and/or corrosive elements in the air being conveyed are very high, aluminium, stainless steel, PVC or GRP ducts should be used. Stainless or black steel are, however, the only suitable materials for high temperature ductwork.

3.103 Where builders' work ducts are used, these may be constructed of various materials; however, brickwork ducts must be rendered, and a greater allowance made for leakage.

3.104 Galvanised, black and stainless steel ductwork should be manufactured and installed to DW/142 - HVCA specification for sheet metal ductwork, but excluding the use of bolt-through supports.

3.105 GRP and PVC ductwork should be manufactured and installed to DW/151 – HVCA specification for plastic ductwork.

3.106 The inside of the ductwork should be free from structural projections and as smooth as possible. Flanged, gasketed joints are preferred.

3.107 Ductwork must be fire-stopped where it penetrates fire compartment walls, floors and enclosures, cavity barriers and sub-compartment walls or enclosures, and provided with weatherproof collars where roofs or external walls are penetrated.

3.108 In inherently wet areas, such as the base of fresh air inlet ducts, the ductwork may require draining to avoid any formation of water with the layout of any drains as specified for paragraphs 4.8 to 4.13.

Duct sections

3.109 Ducting is generally available in rectangular, circular and flat oval sections, although other sections may be made for special situations.

3.110 Rectangular ducting is most common on low pressure systems, for the following reasons:

a. it can readily be adapted to fit into the space available;

b. fittings are cheaper than those for circular or flat oval ductwork;

c. it can readily be joined to such component items as heating and cooling coils, and filters.

3.111 When sizing ductwork, the designer should take into account:

a. both installation and operating costs;

b. space limitations imposed by the structure and other services;

c. operating noise levels;

d. requirements of regulation at the commissioning stage.

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3.112 For overall economy and performance, the aspect ratio should be close to 1:1, since high aspect ratios increase the pressure loss, heat gains or losses and overall cost (for example, changing the aspect ratio from 1:1 to 1:4 can typically increase the installed cost of the ductwork by 40% and add 25% to the heat gains or losses).

3.113 Rectangular ducting should not be the first choice for high pressure systems, and should be avoided in systems operating at high negative pressures, because the strengthening of the flat sides and the sealing requirements necessary to make rectangular ducts suitable for these high pressures are costly.

3.114 Circular ducting is preferable for high pressure systems and for systems operating at high negative pressures. In the case of the latter, additional stiffening rings may be necessary. Machine-formed spirally-wound ducting and a standard range of pressed and fabricated fittings can sometimes make circular ducting more economical, particularly in low pressure systems having a relatively low proportion of fittings.

3.115 Flat oval ducting provides an alternative to circular ducting, principally where there is a limitation on one of the dimensions in the space available for the duct run.

3.116 Other sections may be used, such as triangular sections to pass through roof trusses. Such sections present difficulties in the provision of fittings, and connections to standard traditional sections plant items, and are likely to be more expensive than traditional sections.

3.117 Builder's work ducts and intake chambers should be surface treated and sealed to prevent dust particles being picked up by the airstream.

3.118 Flexible ductwork can be used for final connections to grilles and diffusers, provided it is constructed to meet the fire precautions recommended in BS 8313: 1997/BS 5588-9: 1999. That is the length of flexible ductwork branches is not greater than 3.7 metres and does not pass through fire compartment walls, floors or enclosures of sub-compartment walls or enclosures, or through cavity barriers.

Standard ductwork fittings

3.119 All fittings should conform to HVCA DW/142. Wherever possible, long radius bends, large radius main branches, not more than 45° angle sub-branches and long taper transformations shall be used.

3.120 Fittings should be arranged with vanes in sub-branches connected directly to grilles and diffusers, and turning vanes in square bends (when used).

3.121 The number of duct fittings should be kept to a minimum and there should be a conscious attempt to achieve some standardisation of types and sizes. Increasing the number and variety of fittings in a system can markedly raise its overall cost.

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3.122 Bad design in relation to air flow can lead to vibration of flat duct surfaces, increases duct-generated noise and pressure loss, unpredictable behaviour in branch fittings and terminals, and adverse effects on the performance of installed plant items, such as dehumidifying coils.

Branches

3.123 There are many designs of branches and junctions in use. The important features are that the flow should be divided (or combined) with the minimum interference and disturbance. Changes in duct sizes should not be made at the branch but a short distance downstream (or upstream). A good dividing branch design cannot be effective if the flow entering the branch is not uniform across the section.

Changes of section

3.124 The expansion of a duct section should be formed with sides having a total included angle of no more than 30º, and preferably less than 20º. If the angle of expansion is greater, the flow is not likely to remain attached to the walls of the duct and large eddies will be formed with flow reversal at the walls. This leads not only to a high pressure loss, but also to a non-uniform velocity pattern at the outlet. Where there is insufficient space for a gentle expansion and a greater angle is necessary, internal splitters should be used.

3.125 A contraction in a duct section is less critical, but the total included angle of the taper should not exceed 40° or 60° where the contraction is made on one side of the duct only.

3.126 The most economical way to change the section of a rectangular duct is to restrict the change of duct size to one side only. If the calculated reduction or increase to the side dimension is 50 mm or less, it is usually not economical to change the size at that position. The minimum size of a rectangular duct should usually be 150 mm x 100 mm.

Other fittings

3.127 As a general rule, fittings should avoid abrupt changes in direction and sharp edges which cause the flow to separate and form eddies, thus limiting pressure loss and noise generation. If the fitting leads to the flow preferentially attaching to one side of the outlet, then a significant length of straight downstream duct is necessary before the next branch or fitting; this length should be greater than five equivalent diameters.

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Noise generation within the ductwork

3.128 Noise is generated in ductwork at sharp edges, by tie rods, damper blades, duct obstructions and sharp bends, etc. This air flow-generated noise becomes an important factor if it is about the same or greater level than the upstream noise level. Air flow-generated noise is often referred to as re-generated noise.

3.129 The noise level generated by air flow in ductwork is very sensitive to the velocity. The sound power of this noise is approximately proportional to the sixth power of the velocity; that is, a doubling of the duct velocity will increase the sound power by a factor of 64 (or about 18 dB). The duct velocities should therefore be kept as low as possible. In general, duct fittings which have lower pressure loss factors in similar flow conditions will generate less noise.

3.130 Ductwork serving quiet areas should not be routed through noisy areas, where noise break-in can occur and increase the noise level in the ductwork.

3.131 Grille register and louvre noise should be kept to the minimum by selecting types having low noise-producing characteristics, without high tonal noise; and should be fitted with acoustically treated external inlet and outlet louvres.

Volume control damper locations

3.132 Manually operated dampers are needed generally:

a. in the main duct downstream of the fan for volume control and isolating;

b. in branches of zone ducts for balancing;

c. in sub-branch ducts serving four or more terminals for balancing;

d. at terminals not covered by (c) above for balancing.

3.133 Dampers integral with terminals should only be used for final trimming of air volumes, or noise and air distribution problems may ensue.

3.134 Dampers in rectangular ducts should be single-bladed up to 450 mm longer side and opposed-blade multi-leaf type above this size. In circular ducts, iris-type dampers are recommended, provided there is enough space round the duct for the damper housing. Dampers must be accessible and have a quadrant plate with locking screw. Dampers should be located as far away as possible from adjacent branches or plant items.

Fire damper types and locations

3.135 Smoke-diverting dampers must be provided on recirculation air systems to automatically divert any smoke-contaminated return air to the outside of the building in the event of a fire; and arranged so that the normally open smoke-diverting damper on the return air branch to the input unit closes and all the return air is exhausted through the extract fan.

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NOTE: Further guidance is available in NHS in Scotland Firecode, BS 5588: Part 9 1999 'Fire precautions in the design, construction and use of buildings: Code of practice for ventilation and air-conditioning ductwork' and The Building Standards (Scotland) Regulations.

3.136 Electrically actuated, fire detection linked fire and/or smoke dampers should be of the "slow" closing type to avoid possible damage to ductwork which can result with instantaneous closure of dampers.

3.137 It is essential that all relevant fire aspects of ducting systems are agreed with the fire officer before the design is finalised.

Access door locations

3.138 Access doors are required to facilitate access to plant items and ductwork components for inspection, maintenance, cleaning and replacement, and must be of sufficient size to permit access for the required functions.

3.139 Recommended locations for access doors are given in HVCA DW/142, and are generally provided to give access to:

a. every regulating/control/balancing damper;
b. every fire and motorised damper;
c. filter (to facilitate filter withdrawal);
d. both sides of cooling/heating coils;
e. humidifiers;
f. fans and to provide access to motors and impellers.

3.140 Care should be taken when siting access doors to ensure that no other services to be installed will prevent reasonable access.

Diffuser and grille selection and sizing

3.141 The effectiveness of all ventilation and air-conditioning systems depends on the methods by which air is introduced to, and vitiated air is removed from, the space. The usual results of poor air terminal selection and/or positioning are draughts, stagnation, poor air quality, large temperature gradients and excessive noise.

3.142 Air can be supplied to a space in a number of ways, although any device can be broadly placed into one of two categories: that producing a diffused supply, or that producing a perpendicular jet. Diffusers may be radial or linear, and normally utilise the Coanda effect to reduce the risk of excessive room air movement. A perpendicular jet is formed by discharging air though grilles, louvres or nozzles, which are generally adjustable.

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3.143 Air flow patterns produced by both types of terminal are dependent to a large extent on the presence of the Coanda effect (i.e. adhesion of the air stream to an adjacent surface).

3.144 Supply air terminals can be incorporated into any room surface, for example floors, walls (high or low level), desk top, etc.

3.145 As they operate on the jet principle, the use of side wall and linear grilles is restricted to areas where air change rates are low, that is, less than 10 per hour. Linear perforated or rectangular diffusers can provide acceptable conditions within the occupied zone at up to 15 air changes per hour. In areas where a higher air change rate is required, circular diffusers should be used.

3.146 The performance of supply air terminal devices is provided, based on three criteria: throw, spread and drop. Throw is defined as perpendicular or parallel distance from the terminal to the point at which the air velocity is 0.5 m/s isovel. Spread is defined as the width of the 0.5 m/s isovel; and drop is defined as the vertical distance from the centre line of the terminal to the bottom edge of the 0.25 m/s isovel.

3.147 It is necessary to consider each of these parameters in both summer and winter conditions to ensure satisfactory operation of the air terminal device, as warm jets behave very differently from cold jets.

3.148 A warm jet tends to rise until it attaches itself to a horizontal surface, while a cold jet falls. Care must be taken to ensure that this does not lead to unacceptable temperature gradients in winter, or excessive air velocities in the occupied zone in summer.

3.149 In order to ensure satisfactory air movement within a space, it is necessary to consider interaction between air movement from adjacent terminals, and ceiling mounted fixtures (light fittings, etc), as well as interaction between air movement and room surfaces. In this context great care must be taken in siting supply grilles in areas where patients, and staff be immobile for extended periods, to avoid them being exposed to draughts eg. nurse stations, bedded areas, dialysis stations, blood donating couches.

3.150 If the supply and extract terminals are too close, short circulating may occur, while if they are too far apart, stagnant zones may be formed. Where two opposing air streams meet, the individual velocities must not be greater than 0.25 m/s.

3.151 Supply and extract grilles and diffusers should be fitted with opposed-blade dampers for fine balancing purposes.

3.152 Further guidance on the selection of grilles and diffusers is given in Section B3 of the CIBSE Guide.

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Transfer grilles size and location

3.153 Transfer grilles are required in locations where there is a significant imbalance between the supply and extract rates in a room, to relieve any pressure differentials which may affect the operation of the spaces and/or the ventilation system. Minor air flows can be catered for by leakage around doors and frequent opening.

3.154 While air transfer grilles in walls, partitions or doors, etc are not strictly part of the ventilation system, they form essential components of the building's air distribution.

3.155 Care needs to be taken to ensure that the positioning of transfer grilles does not interfere with the fire or smoke integrity of the building. In general, the air transfer grilles should not be installed within fire-resisting boundaries, although if this is unavoidable, these should be fitted with fire or smoke dampers.

3.156 Where installed, transfer grilles should be of the non-vision type, sized for a maximum face velocity of 1.5 m/s.

Pressure relief damper size and location

3.157 Pressure relief dampers are required in lieu of air transfer grilles in areas where it is necessary to maintain pressure differentials between adjacent rooms to prevent reversal of air flows (for example in operating theatre suites and clean rooms).

3.158 Fire precautions for pressure relief dampers are the same as transfer grilles (see paragraphs 3.135–3.137); and for sizing criteria, refer to Chapter 6 (operating departments).

3.159 Where installed, pressure relief flaps should be of the balanced blade type, with fine adjustment of relief pressure settings; and should give a seal as tight as practicable when closed.

Thermal insulation

3.160 Thermal insulation is applied to ductwork to reduce heat exchange, and to prevent condensation.

3.161 In a duct system, the air temperature changes can be significant, especially when passing though untreated space, and these have the effect of reducing the heating or cooling capacity of the air and of increasing the energy input to the system. The heat transmission to and from the surrounding space can be reduced by effective insulation of the ducts.

3.162 Condensation can arise in ductwork systems conveying cooled air and, apart from creating conditions conducive to corrosion of ductwork, condensation affects the heat and vapour-resisting properties of insulating materials themselves and this induces further condensation.

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3.163 In normal circumstances, the insulation thickness for heat resistance is sufficient to prevent surface condensation, but in extreme conditions the insulation thickness for vapour resistance may be greater than that for heat resistance. When cold ducts pass through areas of high dew-point, carefully selected vapour barriers should be applied externally to the insulation.

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4. Plant equipment selection

General requirements

Air-handling unit construction

4.1 The basic technical requirements of the whole of the ventilation system should meet the requirements of Model Engineering Specification C04: *Mechanical ventilation and air-conditioning systems*; and fire precautions should be incorporated in accordance with NHS in Scotland Firecode.

4.2 Guidance is available in SHTM 81, BS 5588: Part 9 and the Building Standards (Scotland) Regulations.

4.3 The plants should have a high standard of air-tightness. The double-skin method of construction with insulation sandwiched between two metal faces is recommended.

4.4 The inside of the plant should be as smooth as possible with no channels, rolled angles or formed sections that could trap or hold moisture. If stiffeners are required, they should be fitted externally. Internal bracing may be fitted provided it is of a design that will not trap or hold moisture.

4.5 Access must be provided adjacent to filters, cooling and heating coils, heat recovery devices, attenuators and humidifiers to facilitate easy cleaning and maintenance (see individual plant items).

4.6 Air flow across air treatment components such as filters, heat exchangers and humidifiers will be influenced by the pattern of the approaching airstream; and if unsatisfactory conditions are created, the performance of the component will be reduced.

4.7 The height of the air-handling unit (AHU) must provide sufficient ground clearance to enable the installation of a drainage system as described below.

AHU drainage system

4.8 All items of plant that could produce moisture must be provided with a drainage system.

4.9 The drip-tray should be constructed of a corrosion-resistant material and be so arranged that it will completely drain. To prevent “pooling”, it is essential that the drain connection should not have an up-stand; and that a slope of approximately 1 in 20 in all directions should be incorporated to the drain outlet position. The tray must be easily removable for inspection and maintenance.

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4.10 The trap need not be directly under the drainage tray, provided that the pipework connecting the two has a continuous fall. Each trap should be of the clear (borosilicate) glass type to show (visibly) the integrity of the water seal, and should be provided with a means for filling. A permanent marker on each trap should be provided to indicate the water seal level when the system fan is running at its design duty. Each installation should incorporate quick-release couplings to facilitate removal of the traps for cleaning.

4.11 Traps fitted to plant located outside or in unheated plantrooms may need to be trace heated in winter. The trace-heating must not raise the temperature of water heated in the trap above 5°C.

4.12 Pipework from each trap outlet should be thermoplastic, copper or stainless steel tube. Stainless steel could be particularly useful in situations requiring mechanical strength (glass is not necessary). The pipework should be a minimum diameter of 22 mm and have a minimum fall of 1 in 60 in the direction of flow and be well supported.

4.13 Water from each trap must discharge via a type AA air gap, as specified in BS 6281 :Part 1, above the unrestricted spill-over level of either an open tundish connected to a drainage stack via a second trap, or a floor gully (or channel).

Layout of plants

4.14 The plant must be arranged so that the majority of items are under positive pressure. It is preferable that any item of plant requiring a drain be on the positive pressure side of the fan. A recommended layout is given in schematic form in Figure 4.1.

4.15 Flexible joints should be provided at fan inlet and outlet connections; should be equal in cross-section to the points of connection; and should not be longer than 200 mm or shorter than 100 mm.

4.16 Separate extract plant will generally be required for the area served by each supply plant. If applicable, energy recovery equipment should be fitted and provision made for the fitting of a grade EU2 panel filter to protect it.

Provision of dampers

4.17 Motorised non-return dampers should be located immediately behind the intake and discharge of each supply and extract system respectively. They should be of the opposed blade type, opening through a full 90°; and must close automatically in the event of power failure or plant shutdown to prevent any reversal of air flow.

4.18 The quality of motorised dampers is critical. They should be rigid, with square connections fitted with end and edge seals of a flexible material and with minimal play in linkages. The leakage on shut-off should be less than 2%.

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4.19 A manually operated isolating damper should be installed between the main plant and its distribution system, to enable the plant to be isolated when cleaning is in progress.

4.20 A main volume control damper should be provided in the main plant, to set the design flow rate during commissioning. The damper must be capable of being locked in any position. If it is intended to use it for plant isolation also, it must be capable of being reset to give the design air flow without the need for re-measurement.

Health and safety aspects

4.21 It is essential that the main plant ductwork is located far enough from the floor to permit the correct installation of drainage systems for cooling coils, humidifiers and heat recovery systems. Easy access for maintenance of drainage systems and their associated pipework must be provided. Further guidance is available in SHTM 2023; *Access and accommodation for engineering services.*

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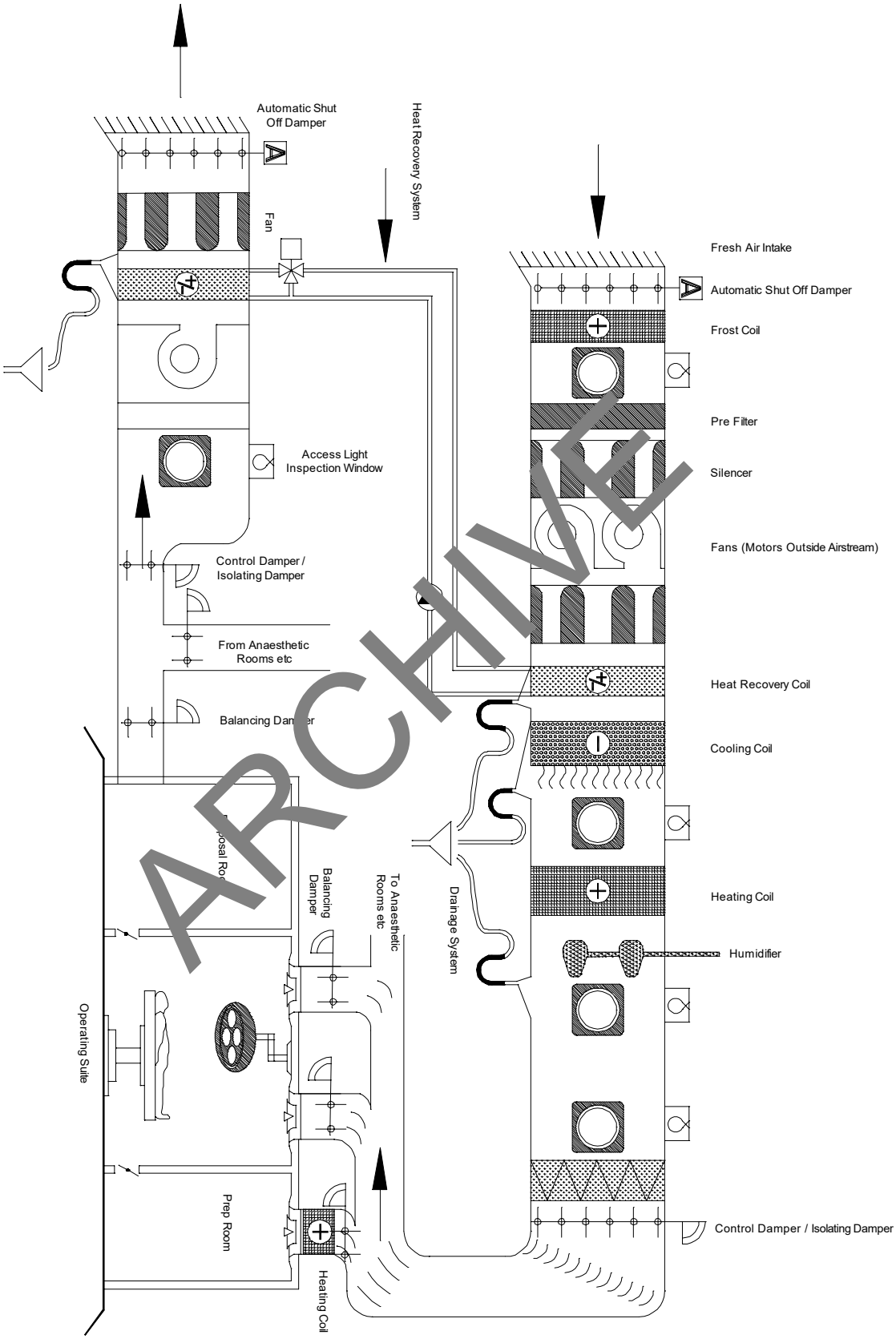
Figure 4.1: Typical operating suite ventilation system



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4.22 Organic materials or substances that can support the growth of micro-organisms must not be used in the construction of the plant or its distribution system. The water fittings and materials directory lists suitable materials for sealants and gaskets.

4.23 The plant and its distribution system must not contain any material or substance that could cause or support combustion.

Vibration

4.24 Vibration from a remote plantroom can be transmitted by the structure of the building, may be regenerated and may sometimes be magnified many times. Plant should be selected to have the minimum vibration generation and should be installed on suitable anti-vibration mounts. Pipe and ductwork should incorporate anti-vibration couplings, preferably in two planes at right angles, as close to the vibration source as possible. Consideration should also be given to anti-vibration pipe hangers and supports.

Sequence of components

4.25 Generally, the following arrangement of plant components should be used, although in many instances not all components are required:

a. fresh air inlet;
b. automatic shut-off damper;
c. frost coil;
d. pre-filter;
e. silencer;
f. fan;
g. heat recovery coil;
h. cooler coil;
i. heater coil;
j. silencer;
k. humidifier;
l. final filter;
m. control/isolation damper.

There may, however, be instances where this arrangement is not appropriate; and the plant arrangement should be planned accordingly.

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Fans

General requirements

4.26 The fan should be selected for good efficiency and minimum noise level, but the overriding factor should be the selection of a fan characteristic such that the air quantity is not greatly affected by system pressure changes due to filters becoming dirty or external wind effects.

Acceptable types

4.27 Fans can be of the axial, centrifugal, cross flow, mixed flow or propeller type, depending upon the requirements of the system.

4.28 Where used, centrifugal fans should preferably be of the backward blade type, and give an efficiency of not less than 78%. Alternatively, where noise levels are more critical and pressure requirements are lower, forward curved blade fans are acceptable. For high power applications, aerofoil blade fans may be appropriate.

NOTE: Forward curved centrifugal fans can overload if allowed to handle more air than they are designed for.

Selection

4.29 Generally, large ventilation systems will always use centrifugal fans owing to their efficiency, non-overloading characteristics, and developed pressures.

4.30 Alternatively, it may be appropriate to use mixed flow fans in high pressure systems.

4.31 Axial flow or propeller fans are generally only used in local through-the-wall systems, or systems with low pressure requirements.

4.32 Cross-flow fans have very low operating efficiencies, and thus their use is restricted to applications such as fan coil units.

Fan location and connection

4.33 Fans can be positioned to either “blow through” or “draw through” the central plant.

4.34 Blow through units are preferred particularly in areas having clinical requirements, their advantages (which outweigh any disadvantages) are:

a. any air leakage from the plant will be outwards ensuring no plant room air is drawn into the plant;

b. the plant component drains will be under positive pressure.

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4.35 The fan performance figures given by manufacturers in their catalogue data are based on tests carried out under ideal conditions, which include long uniform ducts on the fan inlet/outlet. These standard test connections are unlikely to occur in practice. The designer should therefore ensure as far as is practical that the fan performance will not be significantly de-rated by the system. This objective can be approached by ensuring that the fan inlet flow conditions comprise uniform axial flow velocities with low levels of turbulence.

4.36 Where the outlet duct is larger than the fan discharge connection, there should be a gradual transition, with a following section of straight duct having a length equivalent to three duct diameters.

4.37 The design of the fan inlet connection must be carefully considered to avoid swirl in the airstream. When the air spins in the same direction as the impeller, the performance and power consumption of the fan are reduced. When the air spins in the opposite direction to the impeller the power consumption and noise will increase with hardly any pressure increase. Airstream swirl is usually induced by large variations across the fan inlet eye caused by the air passing round a tight bend immediately before the eye.

4.38 For any condition in which a centrifugal fan is located with a free inlet, the clear distance between the suction opening and the nearest wall should be not less than the diameter of the inlet. If two fans with free inlets are positioned within the same chamber, their adjacent suction openings should be at least 1.5 diameters apart.

Control

4.39 Fans in healthcare applications are generally either single or two-speed. Where there is a requirement for two-speed operation, this is generally via a local user control (for example in a hood extract system to provide a boost facility) or via a time schedule for energy saving during unoccupied periods.

4.40 Where two-speed operation is required, twin supply fans may be preferred, as they allow greater flexibility of plant control and avoid the need for spare motors to be provided. If single-speed fans are selected, speed reduction will be required to reduce the flow rate by 50% during set-back as detailed elsewhere.

4.41 Where there is a requirement for stand-by fans, (for example in foul extract systems), the system should incorporate an automatic changeover facility activated via an air flow sensor, and fault indication should be provided.

Requirements for particular applications

4.42 Where the system air is explosive, aggressive, or has a high moisture content, the extract fan motor should be located outside the air stream. This is generally achieved with axial fans by using a bifurcated unit.

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Heater batteries/heater coils

General requirements

4.43 Fog/frost heating coils should not be protected by filters. They should therefore be constructed in plain tubing without fins and be as near to the outside as possible to minimise condensation during cold weather. Access for cleaning must be provided.

4.44 Finned tube coils should be constructed of solid drawn copper pipe, generally connected in parallel, with aluminium fins. In instances where the atmosphere is particularly corrosive, copper fins should be used.

4.45 Where there is a wet heating system in the areas served, the main heater battery should be sized for the ventilation requirements only, not for the fabric loss.

Acceptable types

4.46 Electric, water or steam heater batteries may be considered; however, electric heater batteries are expensive to operate and where there are alternatives, their use should be restricted to low power use, for example, trimming control.

4.47 If steam supplied heater batteries are used, their venting, trapping and condensate systems must be designed so that a vacuum cannot occur within the coil and nor will the condensate back up due to excessive back-pressure in the condensate main.

Location

4.48 The standard arrangement of heater batteries in air-handling units is given in Chapter 3.

4.49 Where possible, wet trimmer heater batteries should be located in plant areas.

4.50 Where it is necessary to locate heater batteries in false ceilings etc, consideration should be given to the use of electric heaters. If this is not practicable, drip-trays should be installed under both the battery and the control valve assembly to protect the ceiling.

Control

4.51 Water heater batteries should be connected to a constant temperature heating circuit. Fog/frost coils should be controlled by an off-coil temperature sensor operating a two or three-port motorised valve to provide a minimum plant “on temperature” of between 2°C and 5°C. The off-coil temperature of the frost coil is generally sensed by a serpentine thermostat laid across the downstream face of the coil or upstream of the next plant item. This

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thermostat will shut the fan down if any part of the air stream is below the minimum set-point.

4.52 The main heater battery should be controlled in the same manner under the dictates of either an off-coil temperature sensor, or a room temperature sensor, depending on the plant configuration and method of control. Trimmer heater batteries are generally controlled by one or more averaging temperature sensors within the room or rooms served by the zone.

4.53 Various options for control of single and multi-zone air-conditioning systems are given in section B3 of the CIBSE guide.

4.54 It is usual to open the pre-heater, and close other heater batteries on system shutdown or fan failure.

Cooling coils

General requirements

4.55 Eliminator plates are required to be fitted downstream of the coil if face velocities exceed 2.25 m/s.

4.56 Cooling coils will need to be periodically decontaminated. The downstream access door should be glazed and have a low-voltage weatherproof light fitting provided for maintenance purposes. The light fitting should be mounted so that its bulb can be changed from outside the duct.

Acceptable types

4.57 All cooling coils must be fitted with their own independent drainage system. A baffle or similar device must be provided in the drip tray to prevent air bypassing the coil and the tray should be large enough to capture the moisture from the bends and headers.

4.58 Where coils are greater than 1 m high, intermediate drip-trays are required.

Selection

4.59 Care must be taken in selection to minimise electrolytic action resulting from condensation on the air side. Coils constructed from copper tubes with copper fins extended on the downstream side in the form of an eliminator, and electro-tinned after manufacture are preferred. All parts of the coil and its associated ductwork in contact with moisture must be manufactured from corrosion-resistant materials. Stainless steel, GRP or plastic finishes are preferred.

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Location

4.60 Micro-organisms which multiply in moisture cannot be avoided when the coil is dehumidifying, but the risk of infection will be reduced by locating the final filter downstream of the coils.

4.61 The standard arrangement of cooling coils in air-handling units is given in Chapter 3.

Control

4.62 The method of controlling cooling coils (and the subsequent heating coil when dehumidifying) will depend upon the relative requirements of the areas being supplied with air.

4.63 Unless these areas have similar temperatures and relative humidity requirements, accurate control can be achieved only by zoning with cooling coil/reheat coil assemblies being allocated to each zone having similar requirements or by providing separate plant for each zone having similar requirements. here is limited scope for compensation by overprovision of air, which is wasteful particularly in non-recirculating systems, and may compromise other control requirements.

4.64 Where close control of each zone is required their respective cooling coil/heater coil assemblies should respond to humidity and temperature sensors located in the areas being supplied or in the extract ductwork serving these areas. The sensors can be configured to “average” temperature and/or humidity, or can be positioned to sense the conditions in the most critical area of the zone, thus providing close control in this area with a looser control in the other areas of the zone.

4.65 On systems with two speed operating, it is usual to isolate the cooling coil upon selection of low speed. In addition, on system shutdown, low air flow or fan failure, the cooling coil must be isolated.

Humidifiers

General requirements

4.66 The most important requirement for a humidifier is to create complete mixing of the steam with the air; and the manufacturers’ instructions should be followed regarding minimum distances which should be allowed before bends or other components.

4.67 The number and length of steam injection manifolds to be used is dependent on various factors such as duct cross-section area, air velocity, air dry bulb temperature and manifold design.

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4.68 Adequately sized glazed access doors and low-voltage swimming-pool type weatherproof bulkhead light fittings are essential for maintenance purposes. The light fittings should be mounted so that their bulbs can be changed from outside the duct.

4.69 All parts of the humidifier and its associated ductwork in contact with moisture must be manufactured from corrosion-resistant materials. Stainless steel, GRP or plastic finishes are preferred.

4.70 The cleanliness of the water supply serving the local steam raising humidifying plant is essential for the safe operation of humidifiers. Provision should be made for draining down supply pipework and break tanks for periodic disinfection and for periods when they are not required in service.

4.71 The addition of treatment chemicals for continuous control of water quality for humidifier/air handling units should be avoided. Consideration could be given to installing a UV system to control microbiological growth. Given the limitations of UV systems, however, this will require filtration to high quality to ensure the effectiveness of exposure of organisms to the UV irradiation. As with all water treatment systems the unit should be of proven efficacy and incorporate UV monitors so that any loss of transmission can be detected.

4.72 All humidifiers must be fitted with their own independent drainage system as detailed in paragraphs 4.8–4.13.

Acceptable types

4.73 Steam injection manifold-type humidifiers are considered suitable for use in health building air conditioning systems.

4.74 Steam may be derived from the central steam supply, or generated locally either within or adjacent to the humidifier.

4.75 The introduction of steam should be by an appliance specially designed to discharge dry steam into the air-conditioning system without objectionable noise or carry-over of moisture.

4.76 During the design stage, consideration should be given to the proposed methods for the regular cleansing of the humidifier(s) and their components.

4.77 Ultrasonic humidifiers are available. The action of ultrasonic frequencies should not be considered an effective method for control of micro-organisms. The supply of water to the humidifier should be free from viable bacteria. The humidifier reservoir is accessible to micro-organisms, including legionellae, carried by the incoming air, and the water temperature in the humidifier during operation may be such as to encourage growth of these bacteria; biofilms may form. These units are capable of producing aerosols that may transmit legionellae.

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Selection

4.78 A mains steam humidifier can be noisy, and will be difficult to control if it is operated at an excessive steam pressure. It should be sized for an operating pressure of approximately 1 bar; and the pipework supplying it should be provided with a dirt pocket, pressure reducing valve and steam trap installed as close as practicable to the humidifier, so that the steam condition at entry is as dry as possible. A temperature switch on the condensate line (or equivalent design provision by the humidifier manufacturer) should be incorporated to prevent “spitting” on start-up.

4.79 Most operational problems with mains steam humidifiers arise because of back-pressure in the condensate discharge line. Unless the condensate from the device can be discharged and collected at atmospheric pressure, it should be discharged directly to drain.

4.80 A local steam generator, where used, must be fed with potable quality water. Additional water treatment to the standard set out above may be required. If the humidifier is unused for a period exceeding 48 hours, it must automatically drain its water content, including that contained in the supply pipework, right back to the running main, and leave itself empty.

4.81 Some generators are of a type that requires regular cleaning and descaling. The design must allow for them to be installed such that they can be physically isolated from the air duct in order to prevent contamination of the supply by cleaning agents while this is taking place.

Location

4.82 Careful siting of the humidifier lance is required to prevent the steam impinging onto the side(s) of the duct, condensing and generating excess moisture.

4.83 It is essential to position the humidifier upstream of the final attenuator, with at least 1 metre unobstructed air flow downstream.

Control

4.84 When in humidifying mode, accurate control of humidity can be provided only on single zone systems or multi-zone systems with zonal humidifiers , particularly where there are large disparities in the humidification requirements for the zones.

These humidifiers respond to humidity sensors situated in the zones being supplied or in the extract ducts from these zones.

4.85 Multi-zone systems supplied via a common humidifier may be satisfactory where the humidification requirements do not differ greatly and they can all be held in the satisfactory range of 40% to 60% RH.

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Such systems can be controlled by averaging sensors positioned in the zones r in the extract ductwork serving these zones. Alternatively, control can be effected by positioning a humidity sensor in the common supply ductwork following final heater battery to control the humidity in the zone having the greatest demand at a minimal level.

4.86 Overriding controls separate from the normal humidification should be installed. Their purpose being to:

a. prevent excessive condensation when starting up by incorporating a time delay into the humidifier control system such that the humidifier is held off for a period of 30 minutes after ventilation plant start-up;

b. override the normal control to ensure that the humidifier induced saturation does not exceed 70% RH.

Filtration

General requirements

4.87 The purpose of filtration is to reduce the level of airborne contamination entering a building, and is generally carried out in one or two stages.

4.88 General ventilation supply plant should incorporate air filters of grade EU3, minimum and generally in accordance with table 4.2, sized for a maximum face velocity of 2.5 m/s. Coarse pre-filters may be justified where the intake air is exceptionally polluted. Extract filtration will only be required where heat recovery devices are installed, or contaminated air is required to be filtered prior to discharge to atmosphere.

4.89 In urban or other areas of high atmospheric pollution, a higher standard of filtration may be justified to reduce the level of staining to internal finishes.

4.90 Filters must be securely housed and sealed in well-fitting frames, readily accessible for replacement, and must be provided with a differential pressure indicator.

4.91 Neither the filter media, nor any material used in the construction of the filters, should be capable of sustaining combustion; and the filter media should be such that particles of the media do not detach and become carried away by the air flow.

4.92 A complete spare set of filters is required to be provided by the contractor at handover.

Acceptable types

4.93 A grading system based on arrestance and efficiency has been introduced by Eurovent (the European Committee of the Manufacturers of Air Handling Equipment) and is shown in Table 4.1.

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4.94 "Arrestance" is a measure of the total weight of synthetic dust captured by a filter. The weight of dust caught is expressed as a percentage of the total weight of dust entering the filter. "Arrestance" provides a good indication of a filter's ability to remove the larger, heavier particles found in outdoor air. It is used, primarily, as a measure of the performance of the lower grade filters, as indicated in Table 4.1.

4.95 Efficiency of a filter is measured as the percentage of microscopic particles removed from the air stream by the filter, and is used to grade high-performance filters, as indicated in Table 4.1.

Table 4.1: Eurovent filter grades

Filter grade	Arrestance (A)	Efficiency (E) %
1	A<65	
2	65<A<80	
3	80<A<90	
4	A>90	
5		40<E<60
6		60<E<80
7		80<E<90
8		90<E<95
9		E<95

4.96 All filters should be of the dry type. Panel filters are cheap and disposable with relatively low dust-holding capacity, and are generally used as pre-filters to eliminate large particles which would otherwise clog or cause damage to the fan and coils.

4.97 Where a higher standard of filtration is required, secondary bag filters should generally be used.

NOTE: Most filter companies no longer supply automatic roll-type filter housings, although they are continuing to supply replacement filters for existing installations.

4.98 Where installed as pre-filters, automatic roll type fabric filters should be of the dry type (grade EU2), be operated automatically by an electric motor under the dictates of a pressure differential switch, and include a visual indication of the end of the roll. All filters develop a higher resistance to air flow with the build-up of dirt, and this governs the effective life of the filter. Filters should therefore be selected for optimum dust holding capacity, however, this may often only be finally determined from the plant history.

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Selection

4.99 Some general guidance on the application of the various grades of filter is given in Table 4.2:

Table 4.2: Filter applications

Grade	Application
2/3	Pre – filter and filters for a system serving areas not requiring any great degree of cleanliness, such as toilet supply systems and light industrial applications.
4	For application as main filters where low to moderate cleanliness is required.
5	Main filters for general applications where decor protection is not critical. Suitable for paint spray installations.
6	As 5, but with added decor protection. Intermediate filter to extend life of a HEPA main filter.
7	As 5, but for use where protection of décor is particularly important. Typically operating rooms.
8	High protection from dust staining suitable for computer room and other areas containing electronic equipment.
9	For high quality filtration but where HEPA filters are not justified, for example, Class 3 clean room applications.

4.100 In addition to the nine grades of filter already described, there is another classification known as High Efficiency Particulate Air (HEPA) filters, sometimes known as absolute filters. They are designed to provide very high-efficiency filtration of tiny particles in the sub-micron size range.

4.101 HEPA filters are expensive and their use should be kept to a minimum. Where used, HEPA filters should be of the replaceable panel type with air-proof seals. Areas requiring HEPA filters include ultra-clean ventilation (UCV) suites and manufacturing pharmacies.

Location

4.102 The primary filter will be positioned on the inlet side of the fan, downstream from the frost coil. It is essential, however, that when fitted, the secondary filter is on the positive side of the fan to prevent air being drawn into the system after the filter, and after any item of equipment which could shed particles.

4.103 The filter installation must be arranged to provide easy access to filter media for cleaning, removal or replacement, with side or front withdrawal as required.

Control

4.104 Differential pressure transducers should be provided to monitor and alarm on excessive filter pressure drop.

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Heat recovery

General requirements

4.105 Where recirculation of air is not permitted for operational reasons, there is a significant risk of discharging large quantities of useful energy in extract air. Heat recovery must be considered in all ventilation system design, to assess the useful value of energy discharged in relation to the cost of recovery of such heat. For most systems in healthcare premises, either a “run-around” system of heat exchangers, a thermal wheel or a plate type unit may be appropriate.

4.106 A full economic assessment of the benefits and costs of heat recovery should be carried out prior to inclusion of heat recovery in a ventilation system.

4.107 Where a local comparable heat demand can be supplied economically by thermal reclamation, heat recovery equipment should be installed. Where extracted air has a high moisture level, the cooling effect on the extract air may require drains for condensate and access for cleaning heat exchangers. Selection should be based on efficiency, maintenance requirements and the practical reliability of the preferred system. Run-around coils offer ease of installation in either new or existing plantrooms and, like plate heat exchangers, require little maintenance.

4.108 Where heat recovery devices are installed, they should be protected on the extract air side by a grade EU2 filter to prevent clogging, fitted in accordance with the requirements of paragraphs 4.87–4.101. This subject is covered in ‘Energy Efficiency: Heat recovery from ventilation systems’.

Location

4.109 Heat recovery devices should be installed with an upstream filter on the extract side, and prior to the cooling coil or main heater battery on the supply side.

Control

4.110 It is essential to consider the control of both the heat recovery device and the fog/frost coil when assessing the economics of heat recovery, as all energy provided by the frost coil will directly reduce the heat exchange of the heat recovery device. To this end, the off-coil setting of the frost coil should be the minimum possible to protect the primary filter (around 2°C).

4.111 The heat recovery device should be controlled in sequence with the main heater battery, and should incorporate a control to prevent the transfer of unwanted heat when the air-on condition rises above the required plant set-point.

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4.112 In instances where the plant is cooling the air, it may be possible to remove heat from the supply air at high ambient conditions under the dictates of enthalpy comparators in the intake and discharge ducts.

Attenuation

General requirements

4.113 Noise will be generated in an air distribution system by the fan, plant items, and air flow. The ductwork is a very effective transmitter of this noise, hence there is generally a need to limit the noise transmission to meet the requirements of the building. This normally involves the provision of sound attenuation treatment as part of the overall ductwork system design.

4.114 A thorough assessment of the design should be made to assess the noise problem and sound treatment requirements and this should take into account the following primary factors:

a. fan and plant noise generation;
b. air flow generated noise in ductwork fittings and dampers;
c. noise generated at grilles, diffusers and other terminals;
d. noise break-in and break-out of ductwork;
e. cross-talk and similar interference;
f. the noise limitations for the building and surrounding areas;
g. external noise generation.

4.115 A method of assessment of these factors and the sound attenuation requirements of ductwork systems is given in section B12 of the CIBSE Guide.

4.116 The fan is usually the main source of system noise. The sound power that it generates varies as the square of the fan pressure, and thus to limit the fan noise level the system resistance should be kept as low as economically possible. As a general rule the selected fan should operate close to its point of maximum efficiency to minimise its noise generation. Where there is disturbance to the air flow at the fan inlet, the manufacturer's stated fan noise levels should be increased by up to 5 dB. More precise guidance on this aspect may be available from fan manufacturers.

4.117 Noise break-out from all equipment housed in the plantroom must be taken into consideration if control is to be satisfactory. Any ductwork within the plantroom after the silencer should be acoustically insulated to prevent noise break-in.

4.118 There is no complete means of control over external noise generation from such as road traffic, aircraft, factory and community noise. Consideration must be given to this at the design planning stage.

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4.119 The Scottish Hospital Planning Note 4; *In-patient accommodation* and SHTM 2045; *Acoustics* should be consulted for detailed guidance.

Acceptable types

4.120 The noise levels produced by ventilation and other plant should be reduced by using duct silencers. These reduce fan noise generated within the duct systems and also control noise break-out to the atmosphere. It should be noted that duct silencers offer a resistance to air flow. The resistance must be included in the fan and ductwork calculations.

4.121 The construction of the sound-absorbing in-fill should be suitable for the quality of air being handled. The duct silencer acoustic in-fill should be protected by a perforated sheet metal casing. Absorption of moisture, dirt and corrosive substances into the “in-fill” and the release of fibrous particles into the airstream should be prevented by the use of a plastic membrane.

Selection

4.122 Provided care is taken in the design and construction of low pressure systems to avoid significant noise generation in the ductwork, attenuation should only be needed to absorb fan noise.

4.123 Cross-talk attenuators may be necessary where noise intrusion between adjacent spaces can arise and where individual room confidentiality is required.

Location

4.124 It is always preferable to control noise and vibration at source, or as close to source as possible. This may be achieved in the equipment specification and selection at the design stage and usually results in a lower cost than corrective measures.

4.125 Fans radiate noise through both the inlet and outlet connections and it may be necessary to provide attenuators to limit the noise from both of these connections.

4.126 Attenuation or other sound-absorbing material should not be applied to the inside surface of the duct system after the final filter, owing to the risk of mechanical damage and the subsequent dispersal of the media into the ventilation system.

4.127 In addition, attenuators should be located so that sound insulation is not nearer to a fire damper than one metre.

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Requirements for particular applications

4.128 Rooms in operating departments typically have hard surfaces for hygienic reasons. This makes the room acoustically very live, that is, the reverberation times will be long. Due account must be taken of both the direct noise and the reverberant (diffuse) noise from any source in the room.

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5. Automatic control

General requirements

Requirements for automatic control

5.1 The basic requirements for an automatic control system are as follows:

a. facilities to start, set-back and stop the plant;

b. temperature control and indication;

c. humidity control and indication;

d. alarms to indicate plant failure, low air flow, and filter state.

5.2 The designer should consider whether it is necessary for the supply and extract fans to be interlocked, either so that the supply fan will not operate unless air flow is established within the extract system, or vice-versa depending on required pressures within rooms being served.

5.3 This will be particularly important in laboratory and pharmacy areas that also contain fume cupboards, safety cabinets and LEV systems.

5.4 Alarms should be provided to show "filter fault" and "low air flow". The "filter fault" alarm should in initiated by a predetermined increase of pressure differentials across the filter. The "low air flow" alarm should be initiated when the supply air quantity falls to 80% of the design value.

Objectives of control system

5.5 The primary object of a ventilation or air-conditioning plant control system is to maintain the space served within the required environmental control bands, at the appropriate times, regardless of external conditions or internal loads.

5.6 It is the task of the designer to select a control system to achieve the above with minimum energy consumption.

Selection of control system

5.7 Air-conditioning plants are both complex to control and expensive in terms of energy costs. This makes them ideal for microprocessor or intelligent control.

5.8 With developments in building management systems (BMS), it is often cost-effective to provide intelligent controls in lieu of conventional analogue controls for air-conditioning plants, whether or not there is a general site BMS system.

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5.9 Often, it is not possible to accurately predict building load variation at the design stage, and thus optimum set points cannot be assessed. Information provided by monitoring the operation of the plant via a BMS system will enable optimum set points to be established and energy consumptions reduced.

NOTE: Further information is available in SHTM 2005; *Building management systems*.

Location of controls

5.10 Whether within the plant, duct or room, sensors should be located to provide accurate measurement of the condition of the air being monitored.

5.11 Sensors and control items such as control valves should be located close to the element being sensed or plant item being controlled, in order to minimise time lags within the system which may create over-shoot of conditions beyond the design envelope and result in additional energy consumption.

5.12 Specific activities will require continuous or intermittent mechanical ventilation, and where the latter occurs, frequently at a high air change rate, for example in bathrooms and treatment rooms, sufficient prominence in position and type should be given to the local control of this facility to encourage economical use.

Time switching

Requirements for time switching

5.13 Facilities to start, set-back and stop the plant should be provided in the plantroom. Remote start and set-back control and indication, if required, should be provided at a manned staff location, for example at the reception or staff base.

5.14 Where two speed controls are installed, the set-back facility for each plant should depress the control temperature to around 15°C; exclude any humidification and cooling from the system; and reduce the supply and extract air volumes by around 50%. Provided any desired direction of air movement from clean to less clean can be maintained, it may be possible to turn the associated extract fan off during set-back.

Methods of time switching

Start-up control

5.15 The plant start control should contain a control logic that will start the plant in the sequence set out in the algorithms in Tables 5.1 and 5.2.

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Set-back control

5.16 If a two-speed fan or twin supply fans are used, the volume can be reduced to 50%, and the control temperature set point depressed to around 15°C when spaces are in the set-back position.

5.17 The chosen method will depend on the likely usage and economic advantages of the system. Provision should be made to lock out the alarms when on set-back and to interlock the extract fan, humidifiers, cooling coils, main and trimmer heaters with the fan so that they cannot operate when the air system is off. See also the control algorithms in Tables 5.3 and 5.4.

5.18 The fire control panel should have restricted access for the fire officer and include independent on/off control and indication of the supply and extract.

Environmental control

Temperature control methods and applications

General

5.19 All control valves must fail safe, that is, close in the event of power or air flow failure, with the exception of the frost/frost battery control valve, which should open upon power or air flow failure.

5.20 A suggested arrangement for controlling heating and cooling batteries is shown in Figures 5.1 and 5.2. Complete plant control algorithms showing their interrelationship with the rest of the control system are shown in Tables 5.1 to 5.4.

Room temperature control

5.21 The limits for room temperature set point are generally between 16°C and 25°C depending on the particular application; and in some specialised instances (for example operating departments) are selectable by the user.

5.22 The selection of temperature set point for each room or zone may be by a control facility in the room or zone, or remotely at the control panel or BMS system. The control device should be marked “raise” and “lower”, and should control within the specified air temperature range with a tolerance of ± 1 K. All other control set points must be selectable in the plantroom and the BMS system (where installed).

5.23 Where local control is provided, an indication of temperature will be required locally, or at a staff base (if appropriate), using an analogue or digital indicator. This may be mounted in a supervisory control panel, with the signal repeated in the plantroom or on the BMS system.

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Frost coil control

5.24 Steam supplied fog/frost batteries must be operated as on/off devices with their sensor mounted upstream of the battery. This will give “open loop” control; a set point of + 1°C is recommended. This arrangement however, reduces the efficiency of any heat recovery system.

5.25 Low pressure hot water (LPHW) supplied frost batteries should be controlled using the Proportional mode. Their sensor should be located downstream of the battery to give “closed loop” control. A set point of 2–5°C is recommended.

5.26 If the temperature downstream of the frost battery, as sensed by a serpentine thermostat, falls below the required set point over any part of the coil, the plant must automatically shut down in order to prevent damage to the other batteries.

Off-plant control

5.27 The control logic must prevent the chiller and pre-heater being on at the same time. It should also never be possible for the chiller and humidifier to be on at the same time.

Humidity control methods and application

5.28 In order to prevent excessive condensation when starting up from a total plant shut-down, a time delay should be incorporated into the control system such that the humidifier does not start until 30 minutes after the ventilation/plant start-up.

5.29 Irrespective of the method of control, a high-limit humidistat should be installed to ensure that the condition of the air in the duct does not exceed 70% sat, particularly during plant start-up.

5.30 With certain types of steam humidifiers, it may be necessary to install a thermostat in the condensate line from the humidifier’s steam supply, to ensure that the steam at the control valve is as dry as possible before it is injected into the air supply.

5.31 The humidifier and cooling coil control must be interlocked so that they cannot be on at the same time.

5.32 The humidifier control system should ensure that it is switched off with the fan. It is preferable to design the control system so that the humidifier is isolated for an adequate time before the fan is turned off so as to purge humid air from the system.

5.33 All control valves must fail safe, that is, close in the event of power failure, and the humidifier must be interlocked with the low air flow switch.

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5.34 Suggested humidifiers plant control algorithms showing their interrelationship with the rest of the control system are shown in Figures 5.1 and 5.2 and Tables 5.1 to 5.4.

Multi-zone control methods and application

5.35 Control of all air-conditioning parameters is difficult to achieve with multi-zone systems, since each zone requires reheater and humidifier to give total control of humidity (assuming reheat for each zone).

5.36 It is therefore usual with multi-zone systems to provide control of zonal temperature only, with humidity control based on average conditions within all zones, or minimum conditions within one zone.

5.37 Where there is a requirement for control of air-conditioning parameters in a number of areas, consideration should be given to providing separate plants for each area in order to avoid the need for expensive over-cooling and reheating of individual areas or zones.

5.38 Most multi-zone systems within healthcare premises are controlled based on off-coil control within the central plant, with terminal heater batteries on individual zones.

Alarms and indication

5.39 Supply and extract systems should include indicator lamps on plant room control panels to confirm the operational status of each system. Where the usage is on a regular daily pattern, a time switch control with manual over-rider for a limited period should be considered.

5.40 Where a system is provided for a particular space, the indicator should be in or immediately adjacent to that space and local controls should be provided with labels clearly defining their function.

5.41 The “plant failure” and “low air flow” alarm should be initiated by a paddle switch or other device located in the main air supply duct. This should operate when the air quantity fails to reach or falls to around 80% of the design value and will give indication of fan failure, damper closed, access door left open, or any other eventuality that could cause a reduction of air quantity.

5.42 The “filter fault alarm” should be initiated by a predetermined increase of pressure differential across the filters, thereby indicating a dirty filter.

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5.43 Visual indication should be provided at a manned staff location, for example the reception or staff base, and in the plantroom to show “plant failure”, low air flow and “filter fault”.

NOTE: Inclined gauge manometers must be installed across filters to give maintenance staff a direct indication of their condition.

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Figure 5.1: Control System

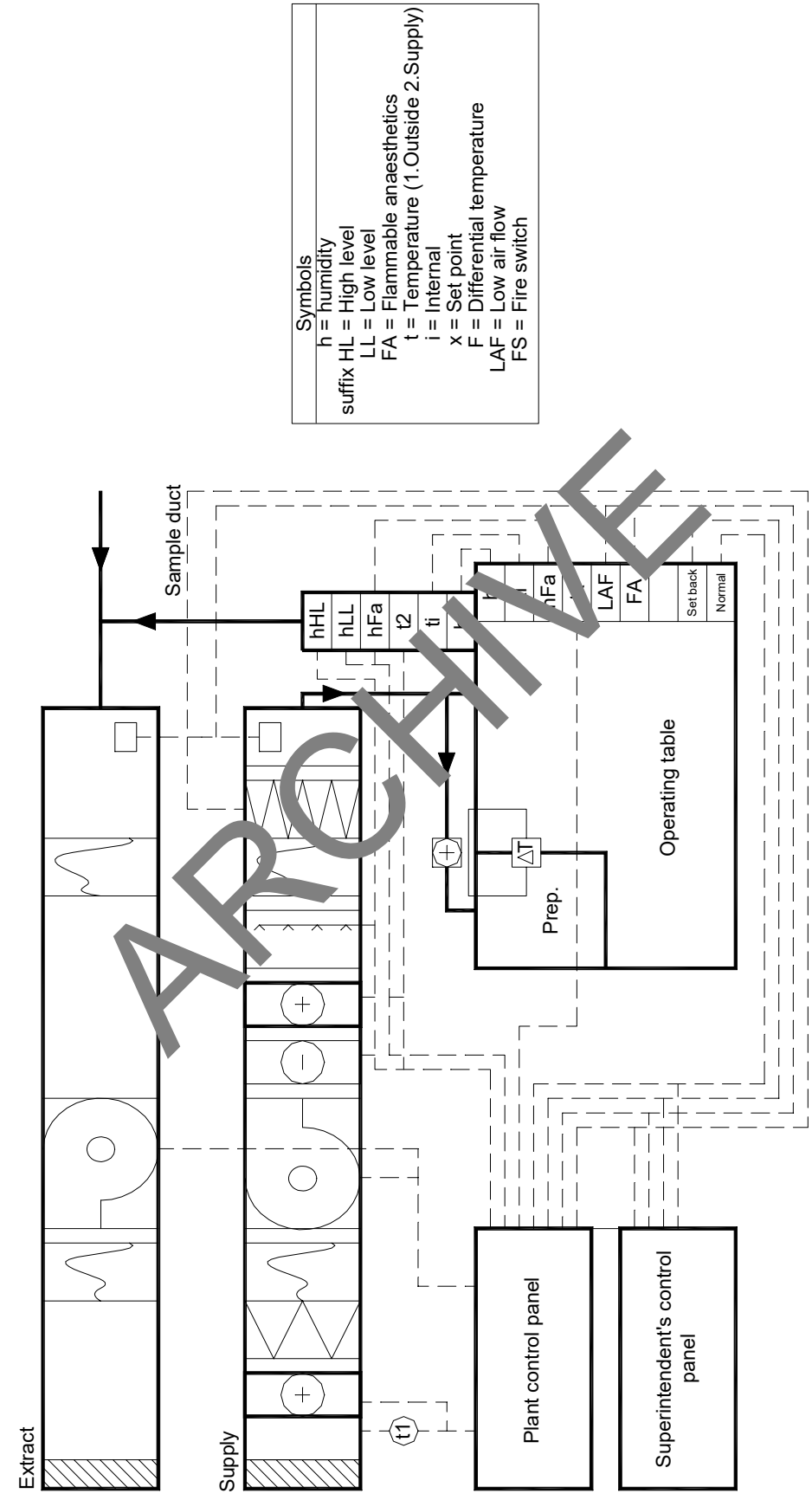

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Figure 5.2: Plant control algorithm – normal shut-down sequence

System	Control	Set point	Control status	Operation
Frost coil	t_1	5°C	t_1<5°C	
Cooling coil	t_2	t_x	t_2>t_x	
Cooling coil	h_{HL}	60 $^{+0}_{-5}$ sat.	h_{HL}>60%	
Heating coil	t_2	t_x	t_2<t_x	
Humidifier	h_{LL}	40 $^{+5}_{-0}$ sat.	h_{LL}<40%	
Humidifier	h_{FA}	50 $^{+5}_{-0}$ sat.	h_{FA}<50%	Flammable anaesthetics
Prep.heater	ΔT	0°C	± 1°C	
Set back see 6.10	t_2	15°C	50% air vol. cooling/hum-off	Op room
Fire switch	FS		Manual fan selection	Plant room Op dept
Plant	On/Off	-		Plant room Op dept
Indication temp		ti		Op room
Indication %sat		hi		Op room
Flow alarm		% flow	alarm > 80%	
Filter alarm				Replace filter

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Table 5.1: Typical plant control algorithm – normal start-up sequence

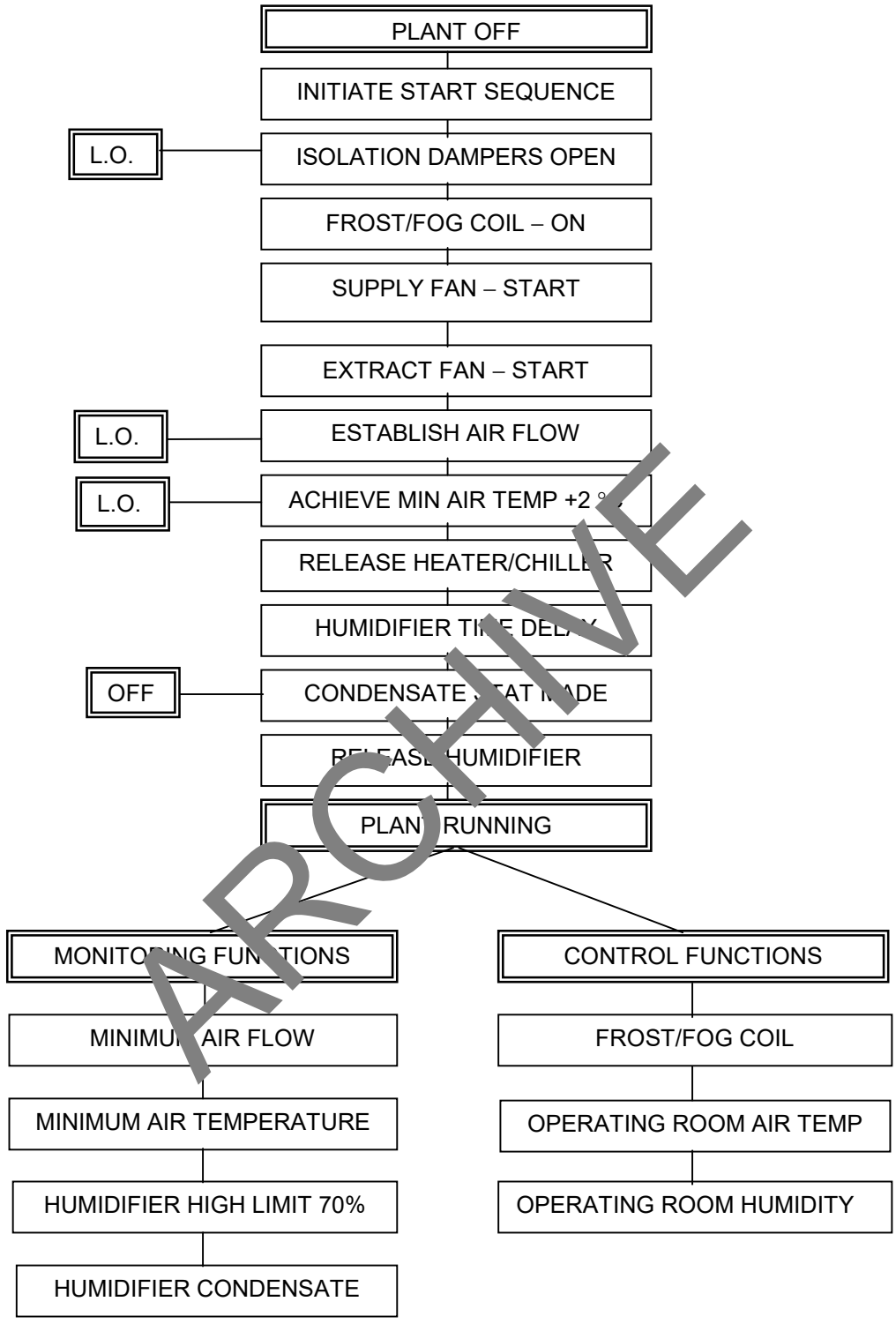

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Table 5.2: Plant control algorithm – normal shut-down sequence

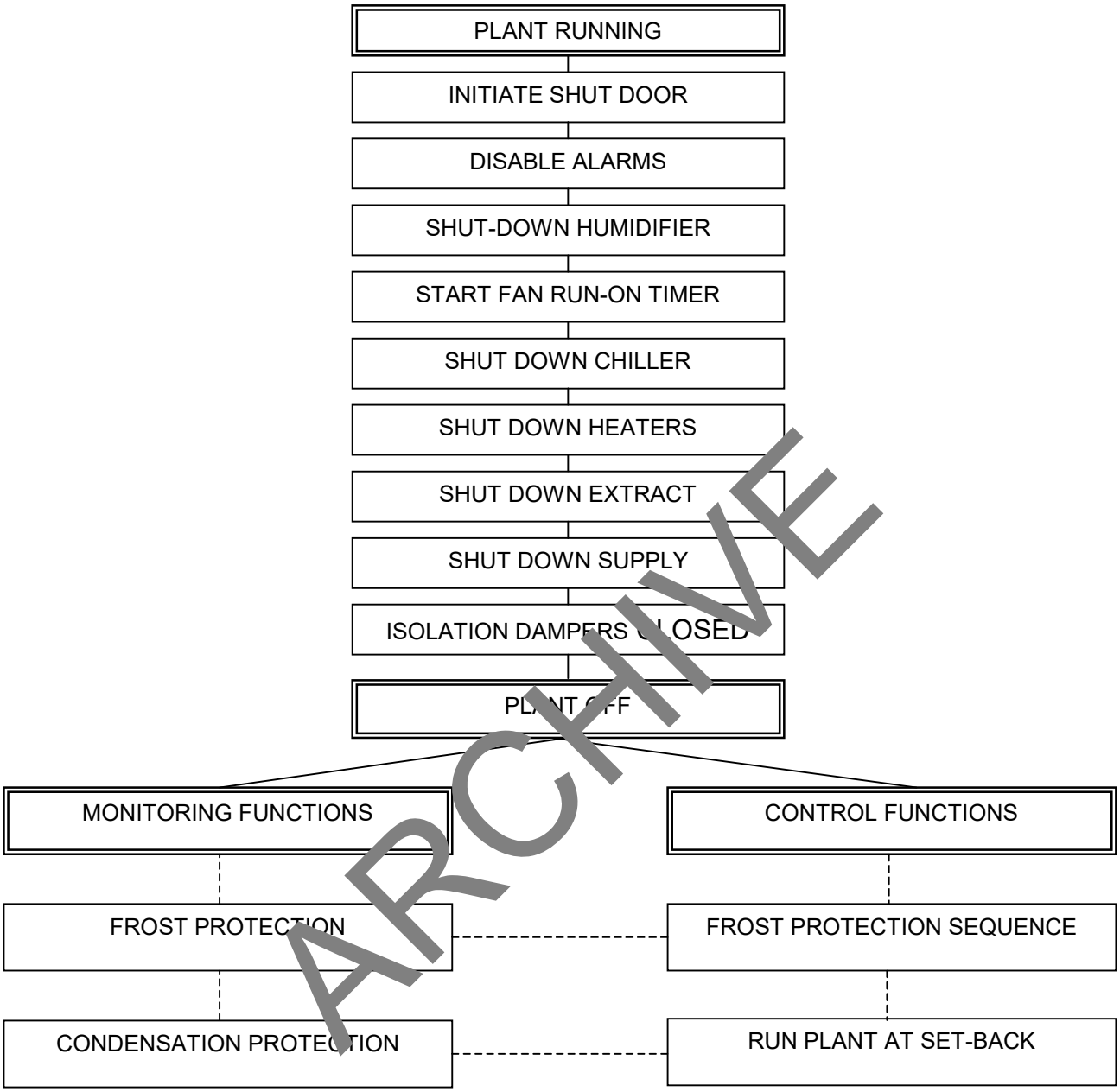

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Table 5.3: Plant control algorithm – set-back sequence

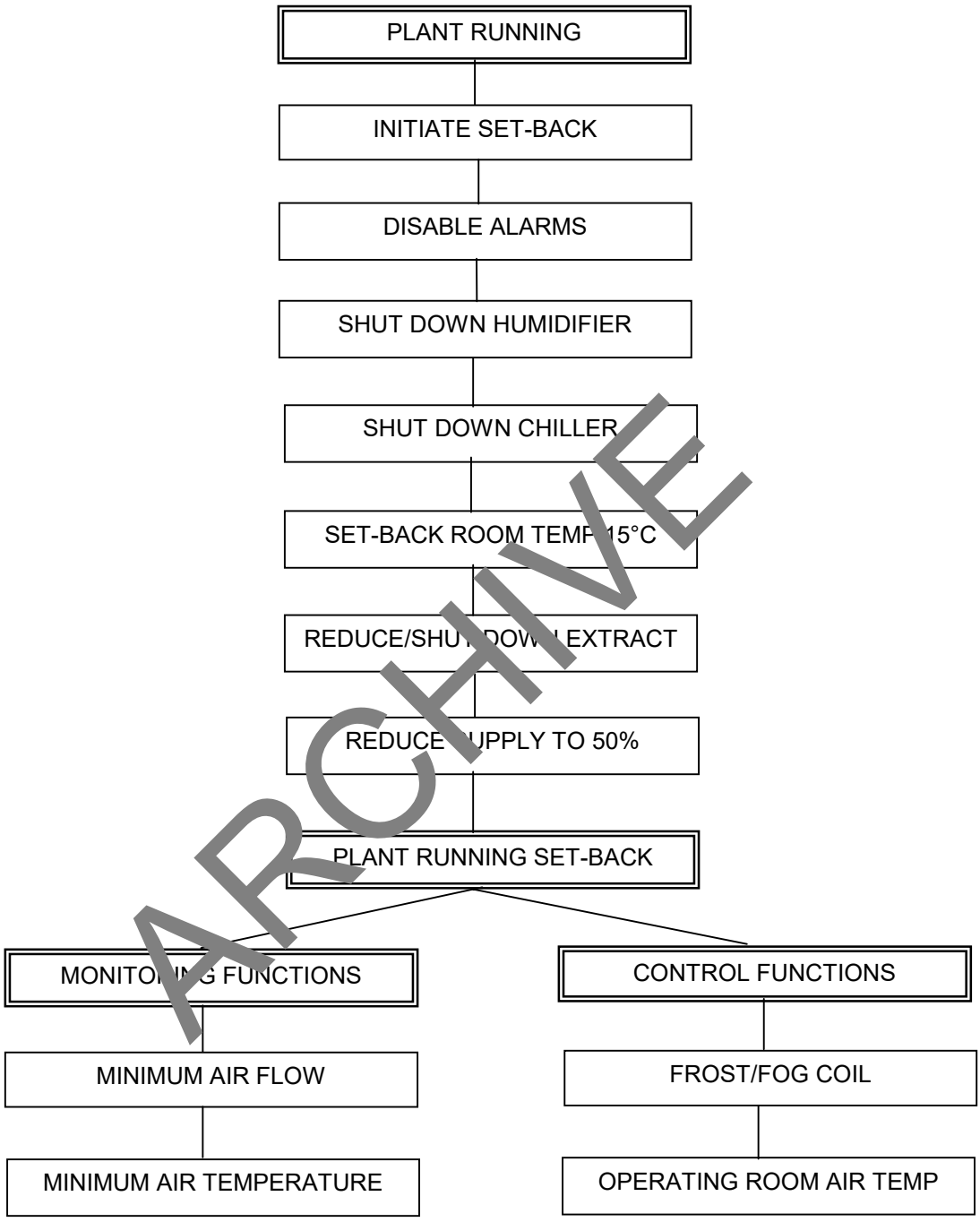

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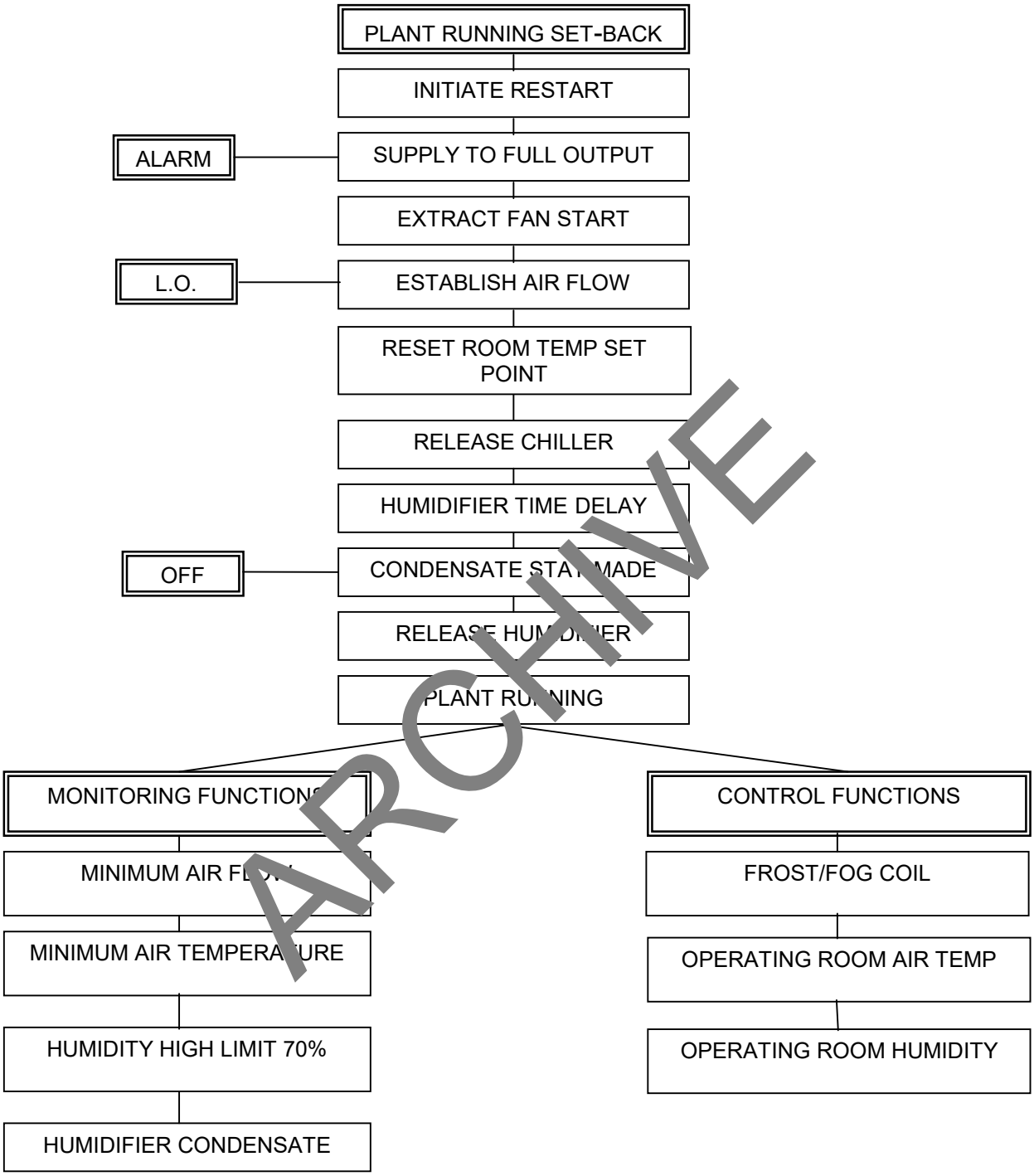
Table 5.4: Plant control algorithm – restart from set-back



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6. Special ventilation systems

Operating departments

Special requirements

6.1 The supply of air to an operating room has four main functions:

a. to control the temperature and humidity of the space;

b. to assist the removal of and dilute waste anaesthetic gases;

c. to dilute airborne bacterial contamination;

d. to control air movement within the suite such that the transfer of airborne bacteria from less clean to cleaner areas is minimised.

6.2 Functions (a), (b) and (c) are important and must be achieved in full, but it is not essential to achieve perfect air movement control (d), provided that bacterial dilution is adequate.

6.3 Terminal or HEPA filters are not generally required.

6.4 Because of the complexities of controlling air movement patterns, much design effort will be required for this aspect. It is important that the design makes the best possible use of the air available, as excessive supply air flows for the control of air movement should not be used. The maximum air supplied to the operating room should be 1.0 m^3/sec; and this air should be distributed evenly within the space, usually via ceiling diffusers.

6.5 The detailed considerations upon which the supply air flow rate is based are as follows.

Temperature and humidity control

6.6 Supply flow rates to achieve the required room conditions, are calculated conventionally, taking account of all heat and moisture gains and losses, and of maximum permissible temperature differences between the room and supply air.

6.7 Temperature differences of up to 10 K for winter heating and 7 K for summer cooling must not be exceeded.

Removal and dilution of waste anaesthetic gases

6.8 Waste anaesthetic gas must be contained and removed by a suitable gas scavenging system. Some leakage from the anaesthetic equipment and the patient's breathing circuit will occur with all systems, during connection and disconnection; and from the interface with the patient. The air movement

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scheme should ensure that this leakage is diluted and removed from the theatre suite.

6.9 Air extracted from operating suites should not be recirculated, as it may contain these contaminants; however, an energy recovery system should be fitted in the extract in order to reduce the plant energy consumption.

6.10 It is acceptable for the humidity to swing uncontrolled between 40% and 60% saturation. In the unlikely event of flammable anaesthetic gases being used, a minimum of 50% humidity must be maintained within the operating room. The set point for the humidity control would therefore be set at 55% ± 5%.

NOTE: If it is decided that no flammable anaesthetic gases are to be used, neither this nor the antistatic floor need be provided. In this case, a notice that the theatre suite is not suitable for the use of flammable anaesthetic gases must be prominently fixed at the entrance.

Dilution of airborne bacterial contaminants

6.11 Supply flow rates for the main rooms of the operating suite are given in Table 6.6. For the other areas where room sizes and activities vary from site to site, air change rates are given in Table 6.1. These figures have been found to give sufficient dilution of airborne bacterial contaminants, provided the mixing of room air is reasonably uniform.

Air movement control

6.12 The design of the system should seek to minimise the movement of contaminated air from dirty to clean to cleaner areas. Transfer grilles or suitably dimensioned door undercuts enable air to pass in either direction between rooms of equal class and pressure. Pressure relief dampers and pressure stabilisers operate in one direction only, allow excess air to be directed to the area desired, and assist in maintaining room pressure differentials.

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Table 6.1: Hierarchy of cleanliness and recommended air flow rates for dilution of airborne bacterial contaminants

Class	Room	Nominal pressure Pa (A)	Air flow rate for bacterial contaminant dilution	
			Flow in or supply m^3/s	Flow out or extract m^3/s
Sterile	Preparation room			
	(a) lay-up	35	See Table 6.5 for recommended schedules and specific values	
	(b) sterile pack store	25±5		
	Operating room	25		
	Scrub bay/(B)	25		
Clean	Central sterile pack store	14	0.10	-
	Anaesthetic room	14	0.15	0.15
	Scrub room	1[illegible]	-	0.10
Transitional	Recovery room	[illegible]	1[illegible] ac/h(C)	15 ac/h(C)
	Clean corridor	3[illegible]	(D)	7 ac/h
	General access corridor	[illegible]	(D)	7 ac/h
	Changing rooms	3	7 ac/h	7 ac/h
	Plaster room	3	7 ac/h	7 ac/h
Dirty	Disposal corrido[illegible]	0	-	(E)
	Disposal roo[illegible]	-5 or 0	-	0.10

Notes:

A. Nominal room pressures are given to facilitate setting up of pressure relief dampers, the calculation process and the sizing of transfer devices. The resultant pressures are not critical provided the desired air movement is achieved.

B. An open or semi-open bay is considered to be part of the operating room, and provided air movement is satisfactory, no specific extract is required.

C. 15 ac/h is considered necessary for the control of anaesthetic gas pollution.

D. Supply air flow rate necessary to make up 7 ac/h after taking into account secondary air from cleaner areas.

E. No dilution requirement. Temperature control requirements only.

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Maintenance of room pressures

6.13 When considering the overall air flow movement, careful thought needs to be given to the operation of the ventilation system, to limit smoke spread in the event of a fire. However, this is a highly staffed department with a low fire risk/load status and these factors need to be recognised when developing the fire strategy.

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Table 6.2: Typical pressures in an operating suite when a given door is open

Door open between	Resultant pressure in these rooms	Effect on other rooms	
		Room	Pressure (Pa)
Operating room or corridor		Anaesthetic	3
or	3 Pa	Preparation – lay up	18
Scrub bay and corridor		Disposal	-12
		Preparation – sterile pack store	8
Operating room and anaesthetic		Preparation – lay up	30
room (or other series room	17 Pa	Disposal	-9
with double doors)		Preparation – sterile pack store	22
Operating room and disposal room			
or	25 Pa	No change	
Operating room and preparation room			
Anaesthetic room and corridor		Preparation – lay up	30
(or other series room with	3 Pa	Disposal	-9
double doors)		Operating room	17
		Preparation room – sterile pack store	22
Preparation room - corridor	3 Pa	No change	
Disposal room – corridor			
Disposal room – other corridor	0	No change	

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6.14 Air should flow from the cleaner to the less clean areas as shown in Table 6.1. This is fairly easy to achieve by creating room pressure differentials if the doors are closed, but once a door is open, the pressure differentials are much more difficult to maintain (see Table 6.2). This difficulty is caused by the following:

a. when a person passes through a doorway, both the passage of the person and the movement of the door flap cause a transfer of air between the areas separated by the door;

b. when a door is left open there is a transfer of air between the two areas separated by the doorway. This is caused by air turbulence, but is greatly increased by any temperature differential between the areas (a 1.4 m wide doorway may allow the transfer of 0.19 m^3/s of air in each direction when there is no temperature difference, but when the temperature differential increases to say 2 K, the volume transferred may increase to 0.24 m^3/s).

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6.15 To minimise the air flow between areas of different orders of cleanliness, air movement control schemes must be designed to ensure that excess air flows through the doorway from the clean to the less clean area.

6.16 It is not possible to design an air movement scheme, within the restraints of the amount of air available, that will protect the operating room when two doors are simultaneously opened. The design process used here considers that each door is opened in turn and ensures that the direction and rate of air flow through any open doorway is sufficient to prevent any serious back-flow of air to a cleaner area.

Table 6.3: Recommended air flow rates in m^3/s through a doorway between rooms of different cleanliness to control cross-contamination

Room class		Dirty	Transitional	Clean	Sterile
Sterile	Hatch	0.3	0.24	0.18	
	Single door	0.47	0.39	0.28	0 or 0.28 (C)
	Double door	0.95	0.75	0.57	0 or 0.57 (C)
Clean	Single door	0.39	0.28	0 or 0.28 (C)	
	Double door	0.75	0.57	0 or 0.57 (C)	
Transitional	Single door	0.28	0 or 0.28 (C)		
	Double door	0.57	0 or 0.57 (C)		
Dirty	Single door	0	Open single door = 0.80m x 2.01 m high		
	Double door	0	Open double door = 1.80m x 2.01 m high		

Notes:

A. The degree of protection required at an open doorway between rooms is dependent upon the degree of difference in cleanliness between them.

B. Flow rate required between rooms within the same class tends to zero as class reduces.

C. If two rooms are of equal cleanliness, no flow is required (in practice there will be an interchange in either direction) and the design of the air movement will assume zero air flow. In certain cases, however, interchange is not permitted and a protection air flow of 0.28 is assumed in the design, for example in the case of a preparation room used as a "lay up".

6.17 The recommended air flow rates to achieve this are given in Table 6.3. Provided that the dilution criteria in Table 6.1 are met, the occasional small back-flows created (when two doors are opened simultaneously; or when there is a high temperature difference across an open door) will have little effect on the overall air cleanliness of the affected room.

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Notes on the layout of operating suites

6.18 The following general points should be taken into consideration during the design of operating suites:

a. number of exits – the fewer the number of rooms (and therefore doorways) leading from the operating room the better, as traffic is reduced and less complicated air movement control schemes are required;

b. scrub and hand-wash facilities – these may be a part of the operating room, often in a bay.

Should a separate room be required for the scrub area, a door between the scrub-up room and the operating room is an inconvenience to scrubbed staff, and could be replaced by an opening. This opening should be larger than a normal single doorway;

c. lay-up room – if it is intended to "lay up" instruments in the operating room, the preparation room is then used simply as a sterile pack store. The nominal room pressure can therefore be the same as that of the operating room and the air flow between the two rooms in either direction. Air supplied to the preparation room may be directed into the operating room, thus reducing the required quantity of air supplied directly to the operating room, and consequently the total volume required for the necessary air movement control;

d. preparation room – when the preparation room is used as an instrument "lay-up" room in the traditional way, it should be regarded as being of greater cleanliness than the operating room, and the design should minimise the transfer of air from the operating room to the preparation room;

e. dirty corridor – if materials to be disposed of are placed in impervious material for transportation, it is not necessary to have a separate corridor for this purpose.

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Standard air movement control schemes

6.19 Air movement control schemes have been developed for several possible operating suite layouts as follows:

Plan 1a – single corridor with sterile pack store;

1b – single corridor with lay-up;

2a – linked corridor with sterile pack store;

2b – linked corridor with lay-up;

3 – linked corridor with external scrub and sterile pack store;

4 – two corridors, with sterile pack store and disposal hatch;

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5a – two corridor with sterile pack store;

5b – two corridor with lay-up.

6.20 These appear in diagrammatic form in Figure 6.1, which shows the relationships of rooms and the various doors and transfer devices between them, and should not be regarded as architectural layouts. The schemes have been developed using the calculation procedure described in Appendix 1 of this SHTM. Important features of the solutions are:

a. zonal trimmer heaters – a trimmer heater battery is advocated when calculations indicate that the temperature differential between rooms may be greater than 2 K. Generally this will only be the case in the preparation room;

b. the preparation room (sterile pack store)/operating room interface – these rooms are deemed to be of equal cleanliness, and thus a transfer grille is required between these rooms;

c. preparation (lay-up)/disposal room interface – pressure relief dampers are recommended here to provide an airpath when doors are closed, while preventing back-flow when a door is opened elsewhere;

d. operating room/anaesthetic room interface – pressure stabilisers, or in some cases carefully sized transfer grilles or door undercuts, are recommended here, and between the anaesthetic room and corridor, and between the operating room and corridor;

e. operating room/scrub room interface – an opening is provided between these rooms. The flow of air through the opening provides protection, and gives bacterial direction within the scrub room; the air is then exhausted to the corridor via a pressure stabiliser.

No mechanical supply or extract ventilation is provided in the scrub room, and thus when a door is opened elsewhere in the suite, the stabiliser will close, allowing the air to be re-directed to help protect the doorway.

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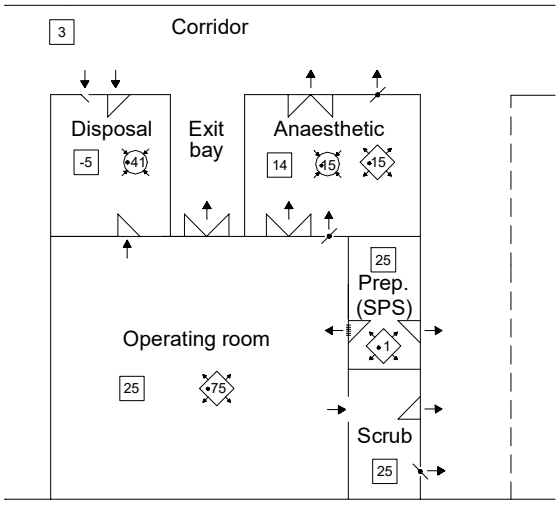
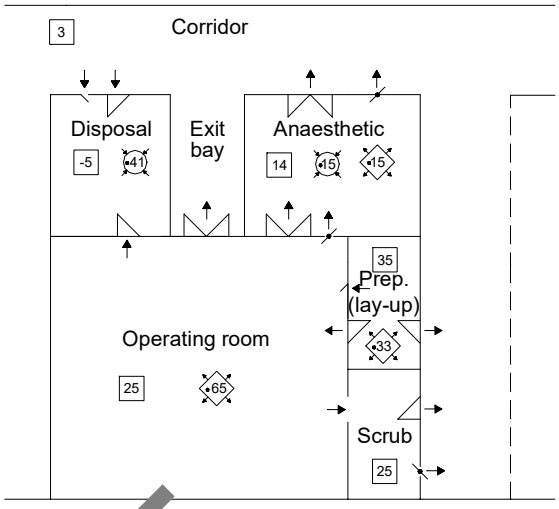
Figure 6.1(a): Eight suggested air movement control systems



Plan 1a
Single corridor with sterile pack store



Plan 1
Single corridor with lay-up

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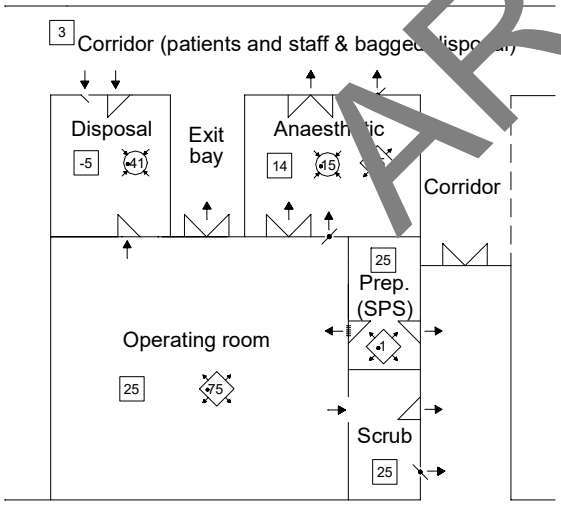
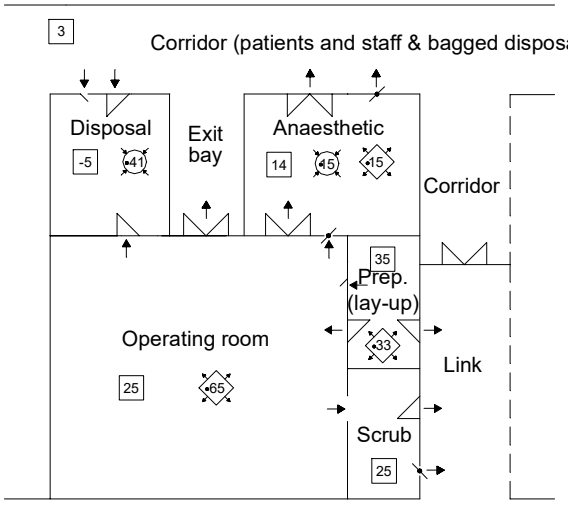
Supply m³/s	Desired air flo	Door mounted transfer grille
Nominal pressure Pa	Door (double)	Pressure relief damper
Extract m³/s	Door (single)	Pressure stabilizer



Plan 2a
Linked corridor with sterile pack store



Plan 2b
Linked corridor with lay-up

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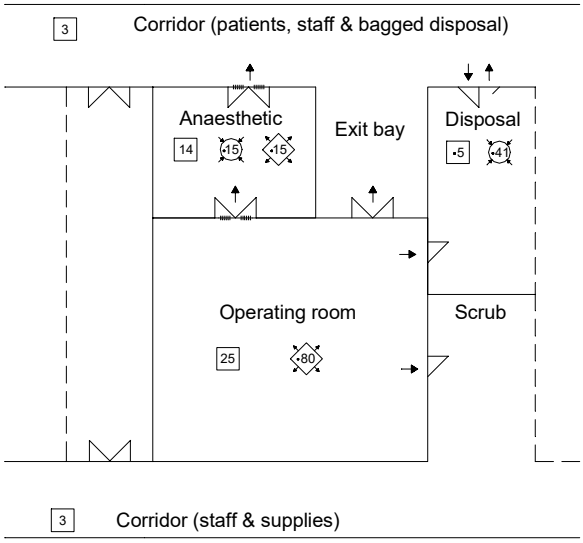
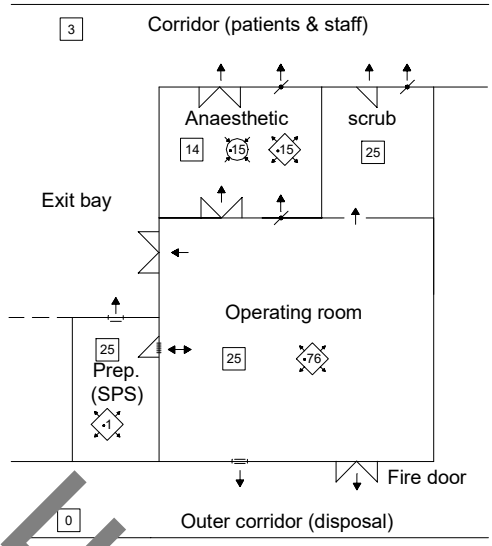
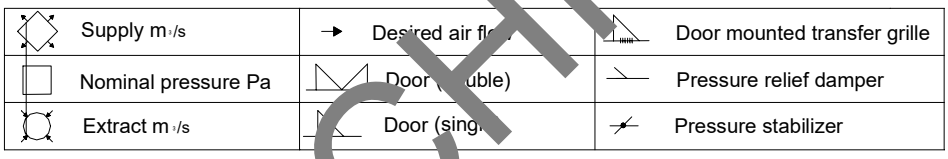
Figure 6.1 (b)

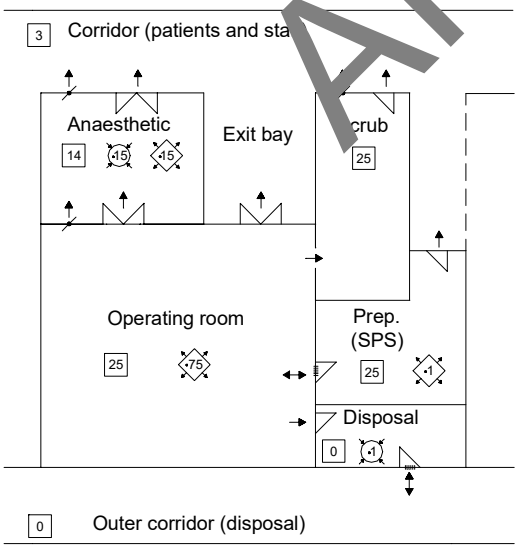


Plan 3
Linked corridor with external scrub and remote sterile pack store

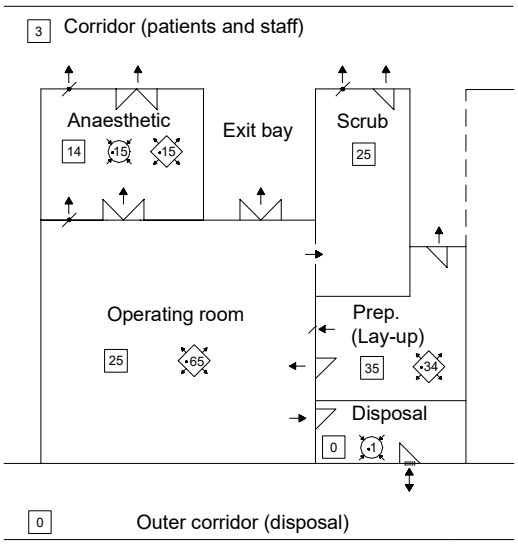


Plan 4
Two corridor sterile pack store with disposal hatch





Plan 5a
Conventional two corridor with sterile pack store



Plan 5b
Conventional two corridor with lay up

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6.21 Any other scheme may be used and the standard solutions applied, if the following conditions are met:

a. room layouts in air network terms are as shown in the plans in Figure 6.1;

b. door gaps approximate to those given in Component Data Base (4 mm along bottom, 3 mm along top and sides, 2 mm between double leaves), see Table 6.4;

c. heat gains are similar to those given in Table 6.5;

d. a trimmer battery is installed in the air supply system to the preparation room;

e. leakage through the structure is kept to a minimum.

A complete specification is given in Table 6.6.

Table 6.4: Leakage flows in m^3/s through closed door gaps

Type	Pressure difference – Pa						
	5	10	15	20	25	30	40
Single door (CDB size 2.4.3.2.6.)	.03	.05	.06	.08	.07	.07	.08
Double door (CDB)	.04	.08	.10	.11	.12	.13	.14
High permanent length of 3mm gap	.004	.008	.010	.011	.012	.012	.013

Note: CDB = Component Data Base - see paragraph 6.21.

6.22 It is recommended that every effort should be made to adopt one of the schemes described earlier. Provided it is possible to comply with the specification given in Table 6.6, the entire design may adopted; otherwise, the manual design procedure should be followed.

Air distribution within rooms

6.23 The method of introducing air into the operating room is of little bacteriological significance at the recommended rates of flow. The velocity working zone should be between 0.1 m/s and 0.3 m/s and diffuser equipment should be selected to avoid “dumping”.

6.24 In the operating room, the air terminals must be at high level, and should all be adjustable for rate of flow as well as being easily cleaned and silent in operation. Supply terminals will require means of directional adjustment.

6.25 Large supply diffusers, for example “ultra-clean” style diffusers, are particularly prone to buoyancy effects as a result of temperature difference (see paragraphs 6.48–6.83). Unless the manufacturer of a proprietary system of this type is able to provide type test data of the performance envelope, the installation of these devices is not recommended.

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Automatic control

6.26 Each operating room should have a sampling extract duct for the air-conditioning control sensors. This should be positioned at normal working height (1.8 m above fixed floor level (AFFL)) and be accessible for cleaning and removal of fluff and lint.

Table 6.5: Heat gains and losses assumed in standard solutions

Room	Item	Typical heat gain (Watts) Summer (S)	Winter (W)
Operating	8 people at 150 W/p (a)	1,200	1,200
	Lights – general	750	750
	Lights – operating	1,000	1,000
	Fabric	250	-750
	Equipment (b)	1,000	1,000
	Nett gain	4,200	3,200
Preparation	1 person at 150 W/p	150	150
	Lights – general	140	140
	Fabric	60	-160
	Equipment	0	0
	Nett gain	350	130
Scrub	0 people (during operation)	0	0
	Lights – general	180	180
	Fabric	70	-140
	Equipment	0	0
	Nett gain	250	40
Anaesthetic	3 people at 150 W/p	450	450
	Lights – general	300	300
	Fabric	150	-280
	Equipment	100	100
	Nett gain	1,000	570
Disposal	0 people (during operation)	0	0
	Lights – general	150	150
	Fabric	50	-150
	Equipment	0	0
	Nett gain	200	0

Notes:

a. typical maximum;

b. includes full patient monitoring, video monitors, diathermy, etc. To be taken into account for selecting the cooling plant.

6.27 This duct should run from the sampling point and either connect into the general extract ductwork system, or be provided with its own fan, built into the operating theatre surgeons' panel.

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6.28 Where one supply and extract plant serves two operating rooms, the sensors should be located in the common extract duct at a point where there is a representative sample of air from both rooms.

6.29 The individual control sensors should be removable to prevent damage during cleaning. Wall-mounted sensors, thermostats and humidistats are not recommended.

6.30 Controls should be provided in the air-handling plantroom to enable operating department ventilation plants to be closed down when the operating suites are unoccupied.

6.31 When in the “off” mode, the control system should ensure that the ventilation plant is automatically reinstated if the space temperature falls below 15°C. Theatre ventilation plant control and its status indication for run and stop should also be located at the staff control base.

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Table 6.6: Air movement control specification for standard plans – (a) supply and extract flow rates

Item		Specification		Plan							
	Room	Nominal pressure (Pa)	Flow rate (m^3/s)	1a	1b	2a	2b	3	4	5a	5b
	Operating room (OR)	25	0.75 S	*		*				*	
			0.65 S		*		*				*
			0.80 S					*			
			0.76 S						*		
Air supply (S) and Extract (E) flow rates and nominal room pressures	Anaesthetic room (AN)	14	0.15 S	*	*	*	*	*	*	*	*
			0.15 E	*	*	*	*	*	*	*	*
	Sterile pack store (SPS)	25±5	0.10 S	*		*			*	*	
	Instrument lay-up (LU)	35	0.34 S		*		*				*
	Scrub bay (SC)	25	0.00 S		*	*	*	*	*	*	*
			0.00 E								
	Disposal (DI)	-5	0.1 E	*	*	*	*	*			
		0±5	0.10 E							*	*
	Clean corridor (CC)	3	7 ac/h	*	*	*	*	*	*	*	*
	Outer corridor (DC)	0							*	*	*
	Total supply to the suite		1.00 m^3/s	*		*				*	
			1.14		*		*				*
			0.95					*			
			1.01						*		

NOTES: S – Supply
E – Extract
ac/h – Air changes per hour

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6.32 The theatre control panel should also include plant status indication; temperature and humidity indicating gauges and means of adjusting the set point for temperature and humidity. The panel should also include the air sampling terminal.

6.33 The humidity within the operating department should be kept within the range 40% to 60%. Provision should be made for raising the minimum level to 50% in the unlikely event that flammable anaesthetics are to be used. The humidifier should be selected to humidify to 50% saturation at 20°C during the design winter outside conditions, and the cooling coil should be able to remove sufficient moisture so that 60% saturation at 20°C is not exceeded during the design summer outside conditions.

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Plant arrangement

6.34 Cost analysis has shown that there can be economic advantages in serving each operating suite with independent supply and extract plant. There are also operating and thermodynamic advantages to be gained from this arrangement.

Table 6.6: Air movement control specification for standard plans – (b) transfer devices

Item	Specification			Plan							
	Location and flow direction	Flow rate (m^3/s)	Pressure (Pa)	1a	1b	2a	2b	3	4	5a	5b
Transfer grilles (Door mounted) or Door undercut	OR→AN & AN→CC	0.53 (c)	14					*			
	OR↔SPS	0.23	22			*				*	
		0.03	5						*		
	DC↔DI	0.40	25							*	*
Pressure relief dampers (Wall mounted)	LU→OR	0.22	1[illegible]		*		*				*
	CC→DI	0.29	[illegible]	*	*	*	*	*			
	SC→CC	0.22	[illegible]	*	*	*	*		*	*	*
Pressure stabilisers (wall mounted)	OR→AN & AN→CC	0.47	4 (a)	*	*	*	*	d	*	*	*
		[illegible]	22	*		*			*	*	
	OR→CC (B)	[illegible].35	22		*		*				*
		0.45	22					*			

Notes:

a. If excess OR air is to be routed via AN, the pressure setting of AN stabilisers is to be 11 Pa, and OR→CC stabiliser is then not required.

b. For use when excess OR air is to be passed directly to CC.

c. Plan 3 only; use transfer grilles only when excess OR air is to be routed via AN (see note (d)).

d. Plan 3 only; use pressure stabilisers only when excess OR air is to be passed directly to CC (see notes (b) and (c)).

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Table 6.6: Air movement control specification for standard plans – (c) open door air flows

Item	Specification			Plan							
	Location and flow direction	Size	Flow rate (m^3/s)	1a	1b	2a	2b	3	4	5a	5b
Design flow rate through open doors. Note: In many cases the actual flow will be greater than this.	LU→OR	Single	0.28		*		*				*
	OR↔SPS	Single	0	*		*			*	*	
	OR→DI	Single	0.47	*	*	*	*				
	OR→DI	Single	0.60							*	*
	OR→SC	(a)	0.28	*	*	*	*		*	*	*
	OR→CC	Single	0.39					*			
	OR→CC	Double	0.75	*	*	*	*	*	*	*	*
	OR→AN	Double	0.57		*	*	*	*	*	*	*
	AN→CC	Double	0.57	*			*	*	*	*	*
	LU→CC	Single	0.[illegible]		*		*				*
	SPS→CC	Single	0.39			*				*	
	SC→CC	Single	0.39	*	*	*	*		*	*	*
	DC↔DI	Single	0							*	*
	CC→DI	Single	0.28	*	*	*	*				
	OR→DC	Double	0 (b)						*		
	OR→DC	Hatch	0 (c)						*		
	SPS→DC	Hatch	0.20						*		
Trimmer heater	LU supply				*		*				*
	SC supply			*		*			*	*	

Notes: a. Single opening - no door
b. = Fire door
c. = Air lock

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6.35 As a general rule, if a theatre is out of use, but having to be supplied with air from a common plant for more than 25% of the time, a separate plant will be preferred. In any event, it is recommended that a plant or common plant components be limited to supplying two operating suites.

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Ventilation of ancillary areas

General

6.36 In order to maintain air flow patterns in the operating suite, it is recommended that the whole department should be mechanically ventilated, and that the plant be sized to cope with all heat losses, thereby making separate radiator or convector systems unnecessary. The grilles and diffusers should be located to eliminate condensation on windows and provide even air distribution. The use of ceiling heating and embedded heating panels is not recommended.

Ventilation requirements

6.37 Table 6.6(a) gives guidance on the operating department areas in descending order of cleanliness, and this should be considered in the overall design of the department ventilation systems. The specified flow rates of air through doors given in Table 6.6(c) for the operating suite are not necessary for other areas of the department, however, the air flow directions must be maintained from the clean to the less clean areas.

6.38 All windows in the department should be double glazed and hermetically sealed in order to ensure that the desired air flow pattern is maintained under all external environmental conditions and to avoid infestation.

Systems design

6.39 The design of the ventilation system for the ancillary rooms depends on the overall configuration of the department. The ancillary room plants may need to be interlocked to the theatre suite plant so that reverse air flow patterns do not occur.

6.40 Generally, the most satisfactory solution is to have a number of plants. Spare motors should be provided, but apart from this, no provision for standby plant can normally be justified.

6.41 If a standby plant is required, it must be provided with a gas-tight damper at its junction with the supply distribution duct, so that no back-flow can occur. Standby plants can become sources of contamination if warm moist air is allowed to stand in them. Their design must ensure that this cannot happen.

6.42 Dual-duct high velocity systems have advantages, but are noisy, costly and may give rise to unacceptable values of humidity; thus, single-duct, low velocity/pressure systems are preferred.

6.43 Extract grilles should be sited and balanced to promote air movement along the clean and access corridors towards the reception/transfer areas. This should not affect the air distribution in the operating suite.

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Sterilizing and disinfecting unit

6.44 Because of high heat gains within this department, it is possible that ventilation in excess of 7 air changes per hour may be necessary. Sterilizers, steam and condensate piping, valves etc. must be carefully and efficiently lagged and the plant space adequately ventilated.

Reception

6.45 The aim in these areas is to provide comfortable conditions having regard to the movement control requirements of the department as a whole. The number of air changes will depend on the design, but 7 per hour should give acceptable conditions.

Recovery

6.46 The air change rate in the recovery room will be rather higher than that needed merely to provide clean, comfortable conditions, as it is necessary to control the level of anaesthetic gas pollution; 15 air changes are recommended, with a balanced air flow.

6.47 Where possible, the supply air terminals should be ceiling-mounted above the recovery bed positions (carefully sized and designed to cause no draught nuisance) so that anaesthetic gas exhaled by recovering patients will be immediately diluted.

Ultra-clean ventilation systems

Special requirements

6.48 Ultra-clean ventilation (UCV) systems installed in operating rooms can reduce the joint sepsis rate after total joint replacement surgery to approximately half that found in a conventionally-ventilated operating room. Clothing designed to reduce airborne bacteria dispersion (total body exhaust gowns) when used in UCV systems, was shown to reduce the sepsis rate by half again. The bacteria counts at the wound site associated with these results are approximately $10/m^3$ and $1/m^3$ respectively. A minimum standard for the UCV has been suggested where the average count at the wound should not exceed 10 bacteria carrying particles/m^3 (BCP/m^3). However, it is also suggested that to ensure minimal or no contamination of the wound from the air, an airborne concentration of no more than 1 BCP/m^3 would be required.

6.49 Investigations have shown that different designs of UCV systems give different airborne bacteriological concentrations.

6.50 Many design issues such as the merits of vertical or horizontal flow systems, the use of partial or full walls, the choice of special operating room, etc. are not discussed in depth. Systems designed and commissioned in accordance with this guidance can provide a significant benefit to patients.

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Design considerations

6.51 The design philosophy of a conventionally ventilated operating suite is based on the need to dilute contaminants and control both the condition and movement of air in the suite.

6.52 The general objective of an ultra-clean ventilation (UCV) system is to provide clean filtered air in the zone in which the operation is to be performed; and sterile instruments and drapes are exposed. This is achieved by means of a uni-directional discharge of air from an air filter bank or diffuser over the sterile field of the operation. Generally, vertical flow systems provide a more effective solution than horizontal flow systems.

6.53 Some factors which are important when designing operating departments with conventional ventilation systems are not relevant when an UCV system is to be installed. UCV systems are so efficient in preventing airborne bacteria reaching the sterile zone, and in reducing the bacterial concentrations in the remainder of the operating room, that there is no need for complex air movement control schemes; and except for the preparation room, there is no need for high air supply volumes to adjacent areas.

6.54 There are several factors to be considered when designing a UCV system:

a. convection up-current from the surgical team, the operating lamp and buoyany effects tend to counter the movement of clean air towards the wound, hence the discharge velocity is critical;

b. the size of the operating zone has to be large enough to encompass the operating site and instruments; consequently, a large area of air diffusion is required (typically 7.8 m^2);

c. the high discharge air velocities and large area of air distribution continue to produce a high discharge air volume, and thus, recirculation of a considerable proportion of this volume is essential to minimise operating costs.

6.55 Because of the size of the uni-directional flow terminal and the large volume of air being moved in a relatively small space, the siting of the return air grilles can cause short-circuiting of the air discharge. Partial walls must be provided to control short-circuiting.

6.56 Return air grilles can be positioned at high level adjacent to the “partial wall”, but the partial wall must be not less than one metre from the operating room wall.

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6.57 A further factor affecting the air flow pattern is the supply/room air temperature difference. The supply air temperature should not exceed the general room temperature. If the supply air temperature is above room temperature, buoyancy effects reduce the volume of air reaching the operating zone. In such cases only systems with full walls should be used as, if the temperature difference is greater than 1 K, it will prevent air reaching the operating site. A full wall is considered to apply to any wall terminating not more than one metre above the finished floor level.

6.58 The term “laminar flow” is generally misused when discussing UCV systems. Commercial systems are available which provide a true laminar flow from the terminal (Reynolds No <2000), but this “laminar flow” will be destroyed due to the disturbance caused by the operating light and personnel. Most systems produce the uni-directional non-laminar flow from the terminal.

6.59 The air movement in the operating room as a whole will ultimately depend on:

a. the discharge velocity, velocity profile;
b. the provision of full or partial walls;
c. the location of the extract grilles;
d. the supply/room air temperature difference.

Operating department design consideration

6.60 A UCV system will usually be designed to provide the air-conditioning to an individual operating suite and will include primary, secondary and terminal filtration and diffusion of air, heating, cooling, humidification, attenuation controls and instrumentation to the standards set out for a conventional operating suite will also be included as part of the installation.

6.61 Separate scrub-up and disposal facilities are not necessary for air cleanliness where a UCV system is installed, although operational policy may prefer such a provision. A separate anaesthetic room should however be provided. The preparation room/sterile store can be shared where the workload permits. When a sterile store is provided, laying up in the clean zone is preferable bacteriologically.

6.62 There is no aerobiological reason why two or more UCV systems should not be installed in a common area as long as adequate spacing is provided, but this will require special design considerations and operational discipline.

Selection of UCV system

6.63 The types of UCV systems available are as follows.

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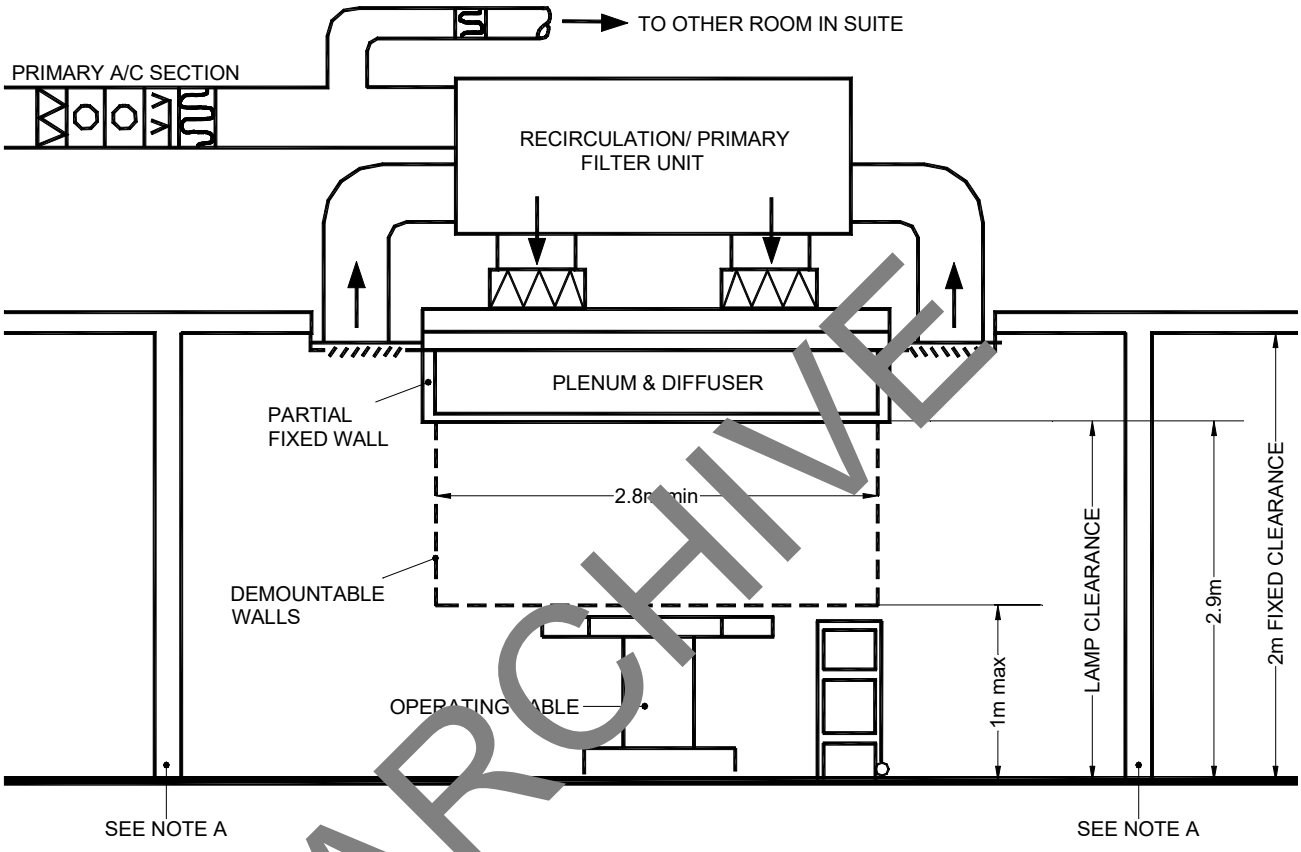
Remote plant systems

6.64 In a remote plant system, all the air-conditioning equipment is located outside the operating room, except for the uni-directional air flow terminal, the terminal filter, and the return air grilles/filter (see Figure 6.2).

Figure 6.2: Typical remote plant UCV system



Note: Final filters may form part of plenum chamber

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Modular systems

6.65 Horizontal flow systems are typically of the modular type, and can be:

a. vertical flow - comprising a recirculating air module containing final filter and terminal.

   Return air filters and fans may be incorporated into a false ceiling to improve headroom.

   These do not include primary “fresh air” conditioning equipment within the module. The module must be connected to the primary air-conditioning system (see Figures 6.3 and 6.4).

b. horizontal or cross flow – comprising a recirculating air module standing vertically to produce a horizontal flow of air, and containing final filter/diffuser, return air filters and fans.

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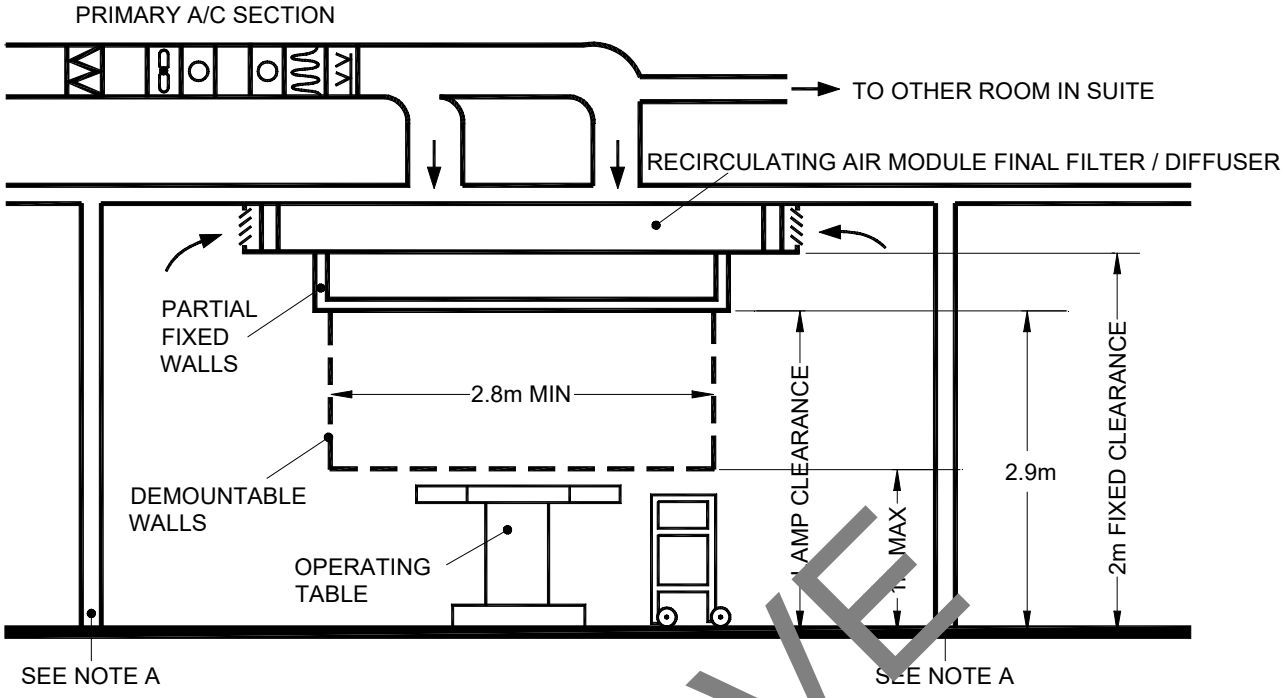
Figure 6.3: Typical commercial modular system



Note: Make-up air volume escapes to peripheral area via doors, etc.

The system must have side walls which may fold to facilitate cleaning of the theatre. A deflector at the top of the filter/diffuser will be acceptable as an alternative to a full roof.

Regardless of which of the above systems is preferred, the recirculation fan power may necessitate the inclusion of supplementary cooling coils within the module. These should be designed to the same criteria as the main plant. To avoid problems with the removal of moisture from the cooling battery, it is preferable to effect cooling by means of the primary supply system.

6.66 The number of bacteria at the wound site depends on the operating team, their discipline and the type of UCV system and choice of clothing. Table 6.7 indicates the typical range of values for bacteria carrying particles per cubic metre of air (BCP/m^3) which can be expected at the wound site, and shows the combination of clothing and system selection required. The maximum recommended standard is 10 BCP/m^3. The installed system will be required to meet the performance standard set out in Part 3, 'Validation and verification', of this SHTM.

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Table 6.7: Typical performance of UCV systems for different types of clothing – BCP counts expressed as an average over a number of operations

Types of clothing	Horizontal flow system with wall	Vertical flow system
Conventional cotton clothing	>10 BCP/m^3	>1:<10BCP/m^3
Clothing designed to minimise the dispersion of bacteria	>1:<20 BCP/m^3	<1 BCP/m^3

6.67 Horizontal flow systems have been shown to be three to volume eight times less effective than vertical flow systems, and clothing designed to minimise dispersal of bacteria is up to 20 times more effective than conventional cotton clothing.

6.68 It should be the objective when designing a UCV system to achieve levels of less than 10 BCP/m^3 when conventional cotton clothing is used, so that the use of occlusive clothing or body exhaust systems result in counts of less than 1 BCP/m^3.

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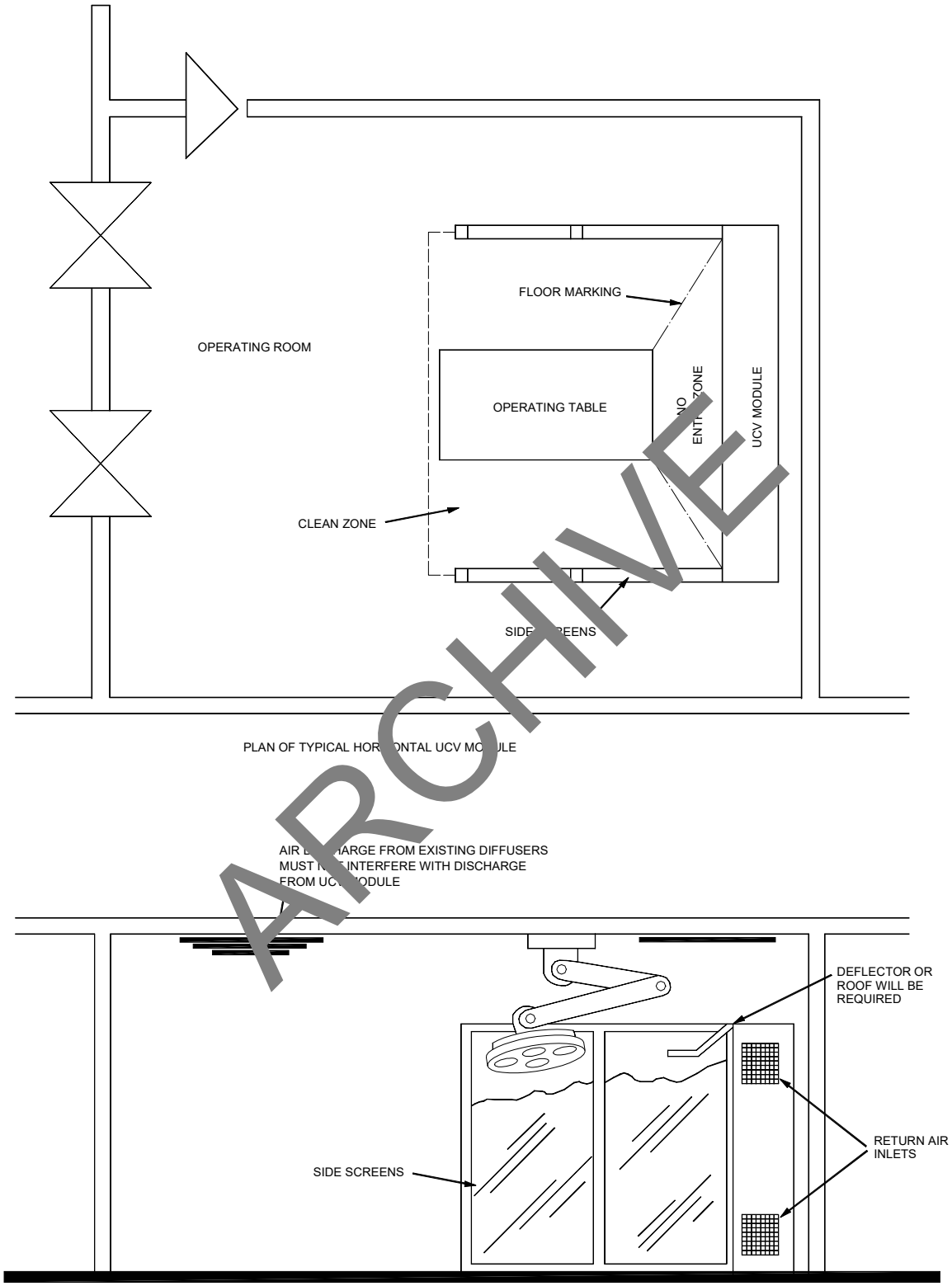
Figure 6.4: Typical horizontal UCV modular system



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Performance of UCV system

6.69 Systems incorporating partial walls only are acceptable, but are known to be more susceptible to problems arising from poor operating team discipline, occupancy, and design parameters than is the case with full walls.

Choice of system

6.70 Vertical flow systems have a superior performance and are preferred. Remote systems will ensure that noise levels are minimal and provide the fewest restraints within the room. In addition, the handling point equipment can be maintained from outside the operating suite.

6.71 In an existing operating department, the only solution may be the installation of a modular system. The existing primary conditioning plant may require modification to ensure that the standards recommended are achieved.

6.72 Horizontal air flow systems are less effective and are not the preferred solution. There may be occasions, however, where architectural, engineering, economic or workload considerations prevent the installation of vertical flow systems, and only a horizontal flow system can be installed.

6.73 In the horizontal flow systems, personnel working between the filter and surgical wound will disperse bacteria which is more likely to enter the wound. This may be minimised by the use of improved clothing and operating procedure to reduce dispersion of bacteria.

6.74 The use of lines on the floor delineating the extent of the clean zone in all systems, and the "protected" zone in horizontal systems will assist staff and are therefore recommended (see Figures 6.4 and 6.5).

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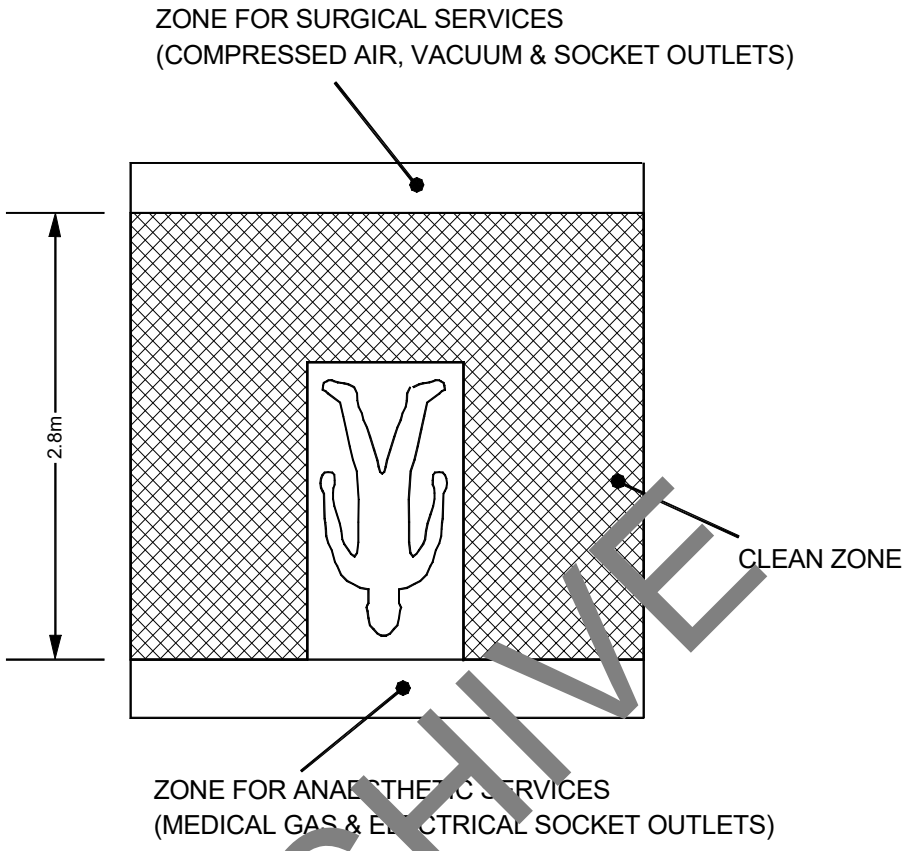
Figure 6.5: Plan of vertical flow supply



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Design requirements

General

6.75 Vertical flow systems are preferred; they should have a minimum area of 2.8 m x 2.8 m. This is the area projected on a plan of the supply air terminal within the partial or full walls, with a clearance to the underside of the fixed partial wall of 2 m from finished floor level (FFL). Any air outside this zone should not be considered as ultra-clean although the level of microbiological contamination will be much lower than the general level in a conventional operating room. The system should have either fixed partial walls with demountable full-wall extensions, or fixed full walls down to at least 1 m above FFL.

6.76 Horizontal flow systems should have a minimum distance between the side wall panels of 2.4 m. The minimum height of the terminal should be 2.1 m. These dimensions reflect currently available equipment and may impose operational constraints in addition to a lower level of performance common in these systems.

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Air movement scheme

6.77 There is no strict requirement when using a UCV system to have an air movement control system, except in the preparation room.

6.78 The inherent feature of a UCV system is its large air flow and it is essential to recirculate air to optimise energy savings.

6.79 The fresh air volume should be dispersed via the disposal room and other doors or openings from the operating room as required. The anaesthetic room can have balanced ventilation; this may be achieved by use of door grilles, under-cuts or other means.

6.80 If preparation rooms are intended to be used for “laying -up” they should have balance ventilation to avoid air transfers interfering with the ultra-clean air zone perimeter.

Discharge air velocities

6.81 To ensure that sufficient air reaches the operating plane, the discharge velocity is crucial. A number of factors either singly or collectively tend to prevent this:

a. uncontrolled short-circuiting;
b. heat emission from the operating lamp;
c. buoyancy effects difference; resulting from the supply/room air temperature
d. up-current generated by personnel;
e. the movement of staff within the zone.

6.82 The minimum discharge velocity is selected to take account of these factors and is greater than the theoretical minimum value.

6.83 At the suggested minimum discharge velocity, insufficient air will reach the working zone if the supply air temperature is greater than the room air temperature.

6.84 The minimum velocity of the discharged air as measured 2 metres above the FFL should be as shown in Table 6.8.

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Table 6.8: Minimum discharge velocities

Vertical flow systems (velocity measured 2m from FFL)		Horizontal flow systems
Full walls terminated not more than 1m above FFL (these walls may be demountable extensions of the fixed partial wall)	Fixed Partial Walls terminated 2m above FFL	Measured 1m from filter/diffuser face
0.3m/s	0.38m/s average	0.40m/s

6.85 The minimum discharge velocity measured 1 m above FFL, for vertical flow systems should be 0.2 m/s.

6.86 Variable speed fans with differential pressure control may be the most suitable solution for maintaining consistent performance and energy saving (see also paragraphs 4.26–4.42).

6.87 Some UCV systems are designed to have a variable velocity over the working zone, the velocity decreasing from the centre towards the edge of the terminal. In such systems, the total air volume should be the same as uniform velocity systems of the same size and should otherwise satisfy the requirements of this guidance document.

6.88 When a system is designed to have partial walls with full wall extensions, a volume control facility may be incorporated to allow the system to be run with reduced velocity when the demountable full-walls are in place. It would be the responsibility of the user to ensure correct operation of the system, but to assist the user, a warning notice should be included on the control panel.

Filters

6.89 The main plant primary and secondary filters should be to the standards and in the location set out in paragraphs 4.87–4.104.

6.90 Terminal filters must be provided within or on the air supply to the uni-directional air flow terminal. High efficiency particulate air (HEPA) filters with a penetration of not greater than 5% when measured against BS 3928 (Eurovent Grade EU9) will be required.

6.91 In some systems, the terminal filter is used as a pressure equaliser to balance air flow and filters of greater pressure drop with a lower penetration may be required. This is acceptable, but there will be penalties in terms of the installed fan power and higher operating noise levels.

6.92 The final filters must be installed in a leak proof housing in a manner which ensures that the filter and its seal can be verified. A DOP test will be carried out during commissioning to prove the effectiveness of the complete installation; the design must allow access for the introduction of the DOP at least 2 metres upstream of the terminal filter. Some manufacturers can

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provide HEPA filter housings that enable a DIN 1946 housing seal leakage test to be carried out. These have the advantage that the test can easily be repeated using simple, non-specialist equipment as part of the systems monitoring procedures.

6.93 An EU3 grade recirculation/return air filter is required to capture relatively coarse particles which could otherwise significantly reduce the life of the final filter. Some manufacturers of filters believe that these are not necessary, as the larger particles will form a layer on the upstream face of the HEPA filter, thus increasing both its efficiency and capacity.

6.94 The design of the system must ensure that all terminal filters are easily accessible for monitoring and maintenance. An access point at least 2 m upstream of the terminal filter for the DOP test and a means of monitoring the pressure drop across all filters must be provided.

Controls and instrumentation

6.95 The controls and instrumentation for the main plant are set out in Chapter 5. UCV systems will additionally require:

a. a set-back facility to reduce the main supply air volume to 0.35 m^3/s by fan control, or (depending upon the operational policy) isolate the ventilation plant;

b. dirty terminal filter indication and alarm;

c. for modular systems, a means of selecting and indicating module running/set-back/off. Low air flow indication fan(s) failure indication;

d. a “system purging” run-on timer (minimum 5 minutes) linked to the plant start-up/restart from set-back control.

Noise levels

6.96 The total noise level for a remote plant system within the operating room should be no greater than L_{10} 50 dBA. For modular systems, whether vertical or horizontal flow, the maximum noise level should not be more than L_{10} 55 dBA.

6.97 The noise levels apply at the maximum velocity for which the system is designed to operate (see Table 3.3).

Air terminal

6.98 Vertical flow systems must either be designed to support the operating luminaire system, which typically should have a lowest point not less than 2 m above finished floor level (FFL), or allow the luminaire system to be fixed to the structural soffit of the room.

6.99 The plenum chamber and any ductwork downstream of the terminal filter must be clean and of high pressure (Class D) construction (see Figures 6.6 and 6.7).

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Lighting

6.100 The general lighting in the theatre should give at least 500 lux at the working plane, and be as uniform as possible. Systems incorporating lighting within the terminal should be considered.

6.101 Specialised task lighting should be provided by thyroidal, cruciform or small multiple dome-shaped luminaires when vertical air flows are employed, as they have good aerodynamic properties. The larger (typically 1 m diameter) saucer-shaped luminaires supported from a central pillar will occlude the air flow in the critical central zone, and are not recommended for vertical flow systems, but may be used for horizontal systems where the lamp shape has little influence on the air flow.

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Figure 6.6: Methods of filter installation

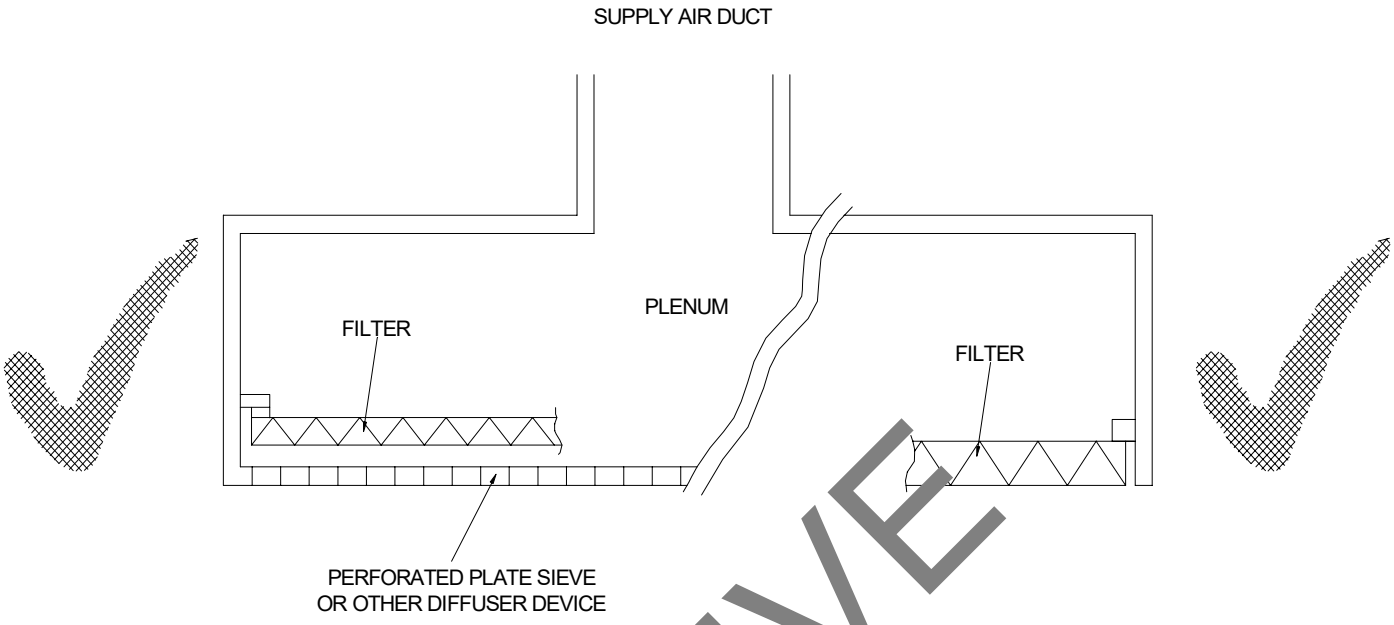
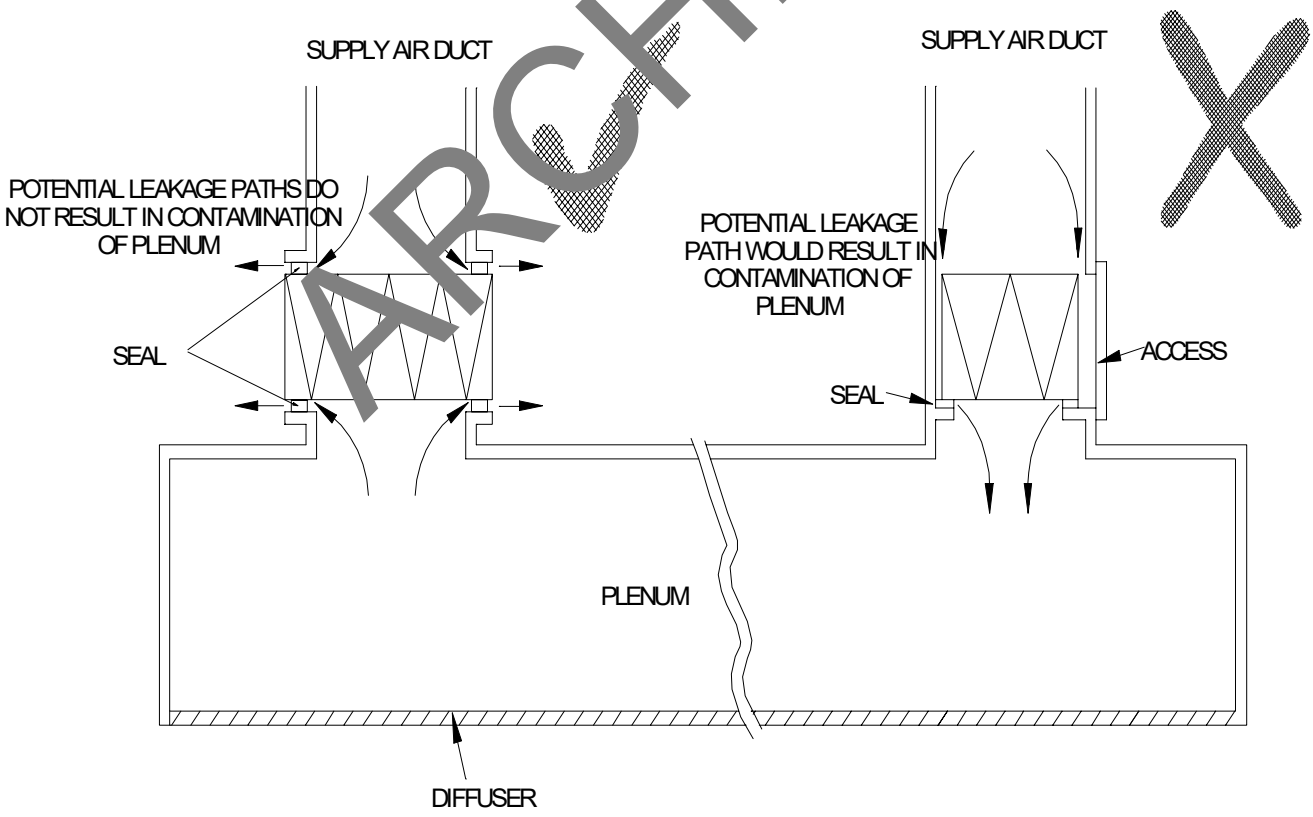


Figure 6.7: Methods of filter installation



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6.102 Orthopaedic surgery normally requires a broad beam of light from the task lighting theatre luminaire. To achieve the best photometric results allowing the surgeon maximum flexibility of the luminaire, a minimum of 2.75 m from floor to underside of the diffuser of the UCV system is required to allow for supporting mechanisms.

6.103 New designs of operating luminaires should comply with the photometric requirements detailed in relevant sections of BS 4533 and be mounted such that there is a clearance of 1 m between the underside of the luminaire and the operating table top.

NOTE: The traditional means of light support is a central column rigidly fixed to the building structure. Separate supports displaced from the centre of the clean zone would lead to improved air flow, but as yet no manufacturer has adopted this solution .

Hood extract systems

Special requirements

6.104 Extract canopies will be required over steam- and heat-emitting appliances, for example sterilizers, catering and washing equipment; and for the extraction of toxic fumes over benches used for mixing, sifting and blending procedures.

6.105 Perimeter drain gulleys and corrosion-proof grease eliminators should be provided on kitchen hoods.

Typical arrangements

6.106 The air flow rate must be sufficient to ensure an adequate capture velocity in the vicinity of the process; typical values are as follows:

a. evaporation of steam and like vapours 0.25 m/s to 0.5 m/s;

b. chemical and solvent releases 1.0 m/s;

c. vapour or gases 5 m/s to 6 m/s;

d. light dusts 7 m/s to 10.0 m/s;

Excessive velocities will be wasteful of power and generate noise.

6.107 The lowest edge of the canopy should be 2 m above finished floor level, with a minimum of 300 mm overhang beyond the edge of the equipment on all sides.

6.108 A compact arrangement of equipment (but with access for maintenance) will minimise the canopy area, and hence reduce the air volume necessary to achieve the optimum capture velocity.

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6.109 Hoods required for the control of heat gain and vapours may be connected to the general extract system when it is convenient to do so, but where non-corrosive ductwork materials are necessary, a separate discharge is preferred.

6.110 Lighting and internal divider plates are often required to be built into the perimeter of large canopies; however, built-in shelving systems are not recommended, as they interfere with the air flow, and constitute a maintenance problem.

Control of hood extracts

6.111 Provided that it does not interfere with the operation of the department when not in use, the ventilation system for the hood extract and any associated supply can be shut down. To this end, local control should be provided.

Bench extract systems

Special requirements

6.112 Bench extract ventilation is required in departments such as pathology and mortuary, where activities involve the release of malodorous or toxic fumes which should not be inhaled.

Typical arrangements

6.113 Each ventilated position will usually be accommodated in a continuous run of benching, which should not be more than 650 mm from front to rear and which should be provided with a continuous upstand at the rear. Each position should have a 1200 mm x 150 mm linear extract grille mounted on a purpose-designed plenum box (incorporating guide vanes as necessary), with its face flush with the upstand. The bottom of the grille should be as close as practicable to the level of the working surface (usually 75 mm above, to allow for cleaning). The minimum velocity across any part of the grille should be 1m/s. The grille should be readily demountable to allow for cleaning.

Control of bench extract systems

6.114 Provided that it does not interfere with the operation of the department when not in use, the ventilation system for the bench extract and any associated supply can be shut down. However, a run-on timer with a minimum setting of 30 minutes must be provided. To this end, local control should be provided.

6.115 Glutaraldehyde mobile cabinets and work stations development are continuing to take place in the design of system using glutaraldehyde, generally used for the disinfection of scopes. These include totally enclosed processing machines to fume cupboard type of installation. Technical requirements and guidance is being developed and will be published when completed.

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Safety cabinet and fume cupboard extract systems

Special requirements

6.116 The supply air system should not distort the uni-directional and stable air pattern required for fume cupboards and microbiological safety cabinets. In general, supply air ceiling diffusers should not discharge directly towards fume cupboards or safety cabinets, unless the terminal velocity is such that the air flow pattern of the cabinet is unaffected. The design should ensure that high air change rates, and/or the opening and closing of doors do not have any adverse effect on the performance of safety cabinets or fume cupboards. A damped door closure mechanism may help.

Arrangements for safety cabinet installations

6.117 The manufacture and installation of microbiological safety cabinets must be in accordance with BS EN 12469: 2000 and the *Code of practice for the prevention of infection in clinical laboratories and post-mortem rooms*. Further information on the selection and installation of these cabinets is contained in Health Equipment Information No 86. A Class 1 microbiological safety cabinet must be specified for routine work involving Group 3 pathogens.

6.118 Siting and installation of microbiological safety cabinets are of particular importance because:

a. the protection afforded to the operator by the cabinet depends on a specific and stable uni-directional air flow through the open front;

b. the protection afforded to the environment by the cabinet depends on the high efficiency particulate air (HEPA) filters. The exhaust air should never be considered as totally free from microbiological hazard.

6.119 Due to the HEPA filters, the discharge from safety cabinets is relatively “clean”. Discharge to outside provides additional safeguards by dilution of any penetrating materials in the event of filter failure. In view of the hazard involved, it is usually preferable to provide short discharge ducts to atmosphere, through a wall or window or through the roof.

6.120 Where this is impracticable, discharge into the room via a double HEPA filter has been accepted; the preferred method however is to discharge above the roofline as per the standard for fume cupboard discharges.

6.121 BS EN 12469 permits the installation of microbiological safety cabinets with integral fans, provided that the extract ductwork can be kept short (that is, less than 2 m); such an installation, however, is likely to be noisy and is not recommended for use in new buildings.

6.122 Roof-level discharge, wherever practicable, is preferred provided that this does not result in extensive and complicated extract ducts, since it removes much of the uncertainty over air re-entering the building through ventilation

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inlets and/or windows. In such an installation, the extract fan should be situated separate from the cabinet and close to the discharge outlet, to maintain the duct under negative pressure.

Laminar flow cabinets

6.123 Vertical laminar flow cabinets (BS EN 12469 Class II) will be required for certain procedures (for example media preparation). They operate by drawing air from the laboratory and discharging filtered air uni-directionally over the work space.

6.124 They protect the media from contamination, but protection of the operator depends on the design of the cabinet and subsequent maintenance.

6.125 Limitations on the use of Class II cabinets are given in 'Categorisation of pathogens according to hazard and categories of containment', Appendix A.

Arrangements for fume cupboard installations

6.126 The primary factors which contribute to the effective performance of fume cupboards include:

a. an adequate volume of supply air;

b. an effective exhaust system to promote the safe dispersal of waste products to atmosphere

6.127 The air velocities through sash openings must be sufficient to prevent hazardous materials from entering the laboratory while avoiding excess flow rates that interfere with the investigation process. Average face velocities should be between 0.5 and 1.0 m/s, with a minimum at any point within 20% of the average, the upper end of the range being applicable to the containment of materials of high toxicity. The design velocity must be maintained irrespective of whether the sash opening is varied, or whether doors or windows are open or closed.

6.128 The possibility of a fire or explosion which may not be contained by a fume cupboard must always be considered. A fume cupboard should not, therefore, be sited in a position where exit to an escape route will necessitate passing directly in front of it.

6.129 Fume cupboard fans should be installed as near as possible to the termination of the duct, thus maintaining the maximum amount of ductwork at negative pressure.

6.130 Where there are adjacent buildings with opening windows, or where downdraughts occur, it may be necessary to increase the height of discharge ducts in order to achieve adequate dispersal. In complex locations, air flow modelling or wind tunnel tests may be required to determine the optimum height of the stack.

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6.131 Fume cupboards for certain processes must have separate extract systems; however, where appropriate, individual fume cupboard exhaust systems may discharge via non-return dampers into a single collection duct rather than having a large number of separate stacks. The collection duct should have a large cross-sectional area to minimise its effect on the individual exhaust systems; be open to atmosphere upstream of the first connection; and be designed to discharge a total air volume at least equal to the combined individual extract systems.

6.132 Individual fume cupboard extract systems, discharging either directly to atmosphere or into a collection duct, do not require duplex fans. However, a collection duct designed to provide dispersal of effluent from a number of individual extracts, should have duplex fans with automatic change-over.

6.133 Further detailed guidance concerning the selection and installation of fume cupboards is contained in Health Equipment Information No 86 and BS 7258 ‘Laboratory fume cupboards’ published in 1990.

Control of extract systems

6.134 It is desirable to provide local control of safety cabinets in order to maximise the life of the HEPA filter, and to permit the sealing of the cabinet and room for fumigation if spillage occurs.

6.135 To cope with the risk of an accident or spillage outside safety cabinets, a “panic button” should be provided to switch off the supply to that area; and discharge all extracted air to atmosphere.

6.136 In pathology departments, it will be necessary to have one or more microbiological safety cabinets and one or more fume cupboards available for use at all times, including weekends. Therefore, local overriding controls for all these items and any associated ventilation plant will be necessary.

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Plantroom ventilation

General requirements

6.137 Plantrooms are required to be ventilated in order to maintain acceptable temperatures for satisfactory operation of the plant and controls, and for maintenance activities. In the case of plantrooms containing combustion equipment, a secondary function of the ventilation air is to provide make-up air for the combustion process.

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6.138 The air required for these purposes should be introduced into the space through inlets positioned to minimise the discomfort to occupants; they should be unlikely to be blocked, closed deliberately (except in the case of fire shutters if required), or rendered inoperative by prevailing winds.

6.139 Plantroom ventilation air should not be used for any other purposes, such as make-up air for extract; and where the plantroom contains combustion equipment, the appliance pressure must not fall below the outside air pressure.

6.140 Statutory regulations for plantroom ventilation are contained in the Building (Scotland) Regulations, and further guidance in Section B13 of the CIBSE Guide.

Assessment of ventilation levels

6.141 Ventilation requirements must take into account all heat sources within a plantroom, and where there are large glazing areas, solar gains. The ventilation rate should limit the maximum temperature within the plantroom to 32°C.

6.142 As the level of equipment operating during mid-season and summer is often lower than the winter condition, and the cooling effect of the outside air is reduced, it is necessary to calculate the minimum volume for each season of operation, and the inlet and outlet grilles or fan sizes should be chosen to cater for the largest seasonal air volume.

6.143 Replacement air should not be drawn through pipe trenches or fuel service ducts. Where metal ducts penetrate walls and floors, effective sealing should be provided to confine the ventilation to the boiler room and to meet fire protection requirements. Penetration of fire barrier walls by ventilation ducts should be avoided if possible.

6.144 Fire dampers in ventilation ducts should be electrically interlocked with the boiler plant.

6.145 Care must be taken to prevent any noise generated in the boiler room emerging from natural or mechanical ventilation openings to the detriment of the surrounding environment. Particular care is necessary with mechanical flue draughts and fan-diluted flue systems.

6.146 Information on required air volumes is contained in section B13 of the CIBSE Guide.

6.147 Where combustion plant is installed, the high-level (outlet) openings should be sized to cater for the total ventilating air quantity; and the low-level (supply) openings sized to cater for the total combined ventilating and combustion air quantity.

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Choice of ventilation system

6.148 The ventilation air may be introduced and exhausted by either natural or mechanical means or a combination of both; however, where possible, natural systems are preferred.

6.149 Generally, small installations at or above ground level should have their combustion and ventilation air provided by natural means, employing both high and low-level openings.

6.150 Basement, internal and large installations at or above ground level will usually require a combination of natural and mechanical ventilation. If the air flow route is difficult, both supply and extract may require mechanical means.

6.151 Whether natural or mechanical, the system should be designed to avoid both horizontal and vertical temperature gradients. Both inlet and outlet openings should be placed on opposite or adjacent sides of the building to reduce the effect of wind forces.

6.152 Where mechanical air supply is employed, electrical interlocks with the boiler plant should be provided to prevent damage in the event of failure of the supply fan(s) once the air volume is established.

6.153 The necessary free opening areas for a naturally ventilated plantroom may be calculated using either the method in A4 of the CIBSE Guide, or the table in Section B13.

6.154 A combined natural and mechanical ventilation system should allow for natural extract at high level, to take advantage of convective forces in the room, with mechanical supply at low level. The high level natural ventilators should be sized to cope with the total quantity of ventilation air, as above.

6.155 To prevent leakage of flue gases and to ensure that the flue draught is not impeded at any time, the air pressure in the boiler room must not exceed the prevailing outside pressure. Therefore, the fan duty should exceed the calculated total combined combustion and ventilation air quantity by at least 25%. Fan-powered inlets should be arranged to flow outside air into the space at a point where cross-ventilation will ensure pick-up of heat without causing discomfort to the occupants.

6.156 Where it is impractical to provide sufficient natural ventilation to remove the heat emitted by the plant, both mechanical supply and extract will be required.

6.157 The high-level extract should be sized to cater for the total ventilating air quantity and the low-level supply should exceed the total combined combustion and ventilating air quantity by at least 25%, as above.

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Ventilation of hydrotherapy suites

Special requirements

6.158 The Departmental Cost Allowance for a hydrotherapy suite includes for heat recovery via a heat pump system.

Arrangements for hydrotherapy pool installations

6.159 The quantity of supply air should be calculated as 25 litres/sec/m^2 wetted surface, with the wetted surface taken as 110% of the pool water surface area.

6.160 A recirculation plant is recommended, with a minimum of 20% fresh air.

6.161 As far as practicable, recirculated pool air should be provided to the ancillary changing and recovery accommodation, with the only extract from the toilets, laundry/utility room and pool hall.

6.162 Supply air to the pool hall should be introduced at high level and directed towards the perimeter to mitigate condensation, with extract air taken from directly over the pool.

Control of hydrotherapy pool installations

6.163 The supply and extract fans should be interlocked so that the supply fan does not operate until flow is established within the extract system.

6.164 Time-clock control should be provided, with a local override switch to extend the normal operating period as required.

6.165 Night set-back temperature (in the range of 21–25°C) and high humidity control (in the range of 60–75% sat) should be provided to override the time-clock in order to prevent condensation. The exact set points should be ascertained post-installation.

6.166 A remote indication panel should be provided in the pool hall, giving a visual display of the pool water and pool air temperature.

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7. Commissioning

General

7.1 Commissioning is an essential process for ductwork systems, and if the needs of on-site regulation are not foreseen and provided for in the design stage, balancing the system within accepted limits may never be possible. Procedures for commissioning air-handling systems are given in CIBSE Commissioning Code A and in BSRIA Application Guide 1/75. Part 3 of this SHTM, 'Validation and verification', sets out commissioning procedures.

7.2 The duct sizing procedure should take into account the requirements of system balancing, and the position and number of regulating dampers included in the design should be sufficient for this purpose.

Location of dampers and test holes

7.3 Balancing/commissioning dampers will be required in each branch of the distribution ductwork.

7.4 Test holes for the measurement of air flow will be required at carefully selected points in main and all branch ducts. Their positions must be identified at the design stage. The test positions should be located in a straight length of duct, so that accurate measurement can be made, and generally in the following positions:

a. on both sides of the fans and heating and cooling coils (for pressure drop measurements);

b. in the main ducts;

c. in all branches;

d. in centrifugal fan drive guards, opposite the end of the fan spindle, for speed measurements.

7.5 The number and spacing of holes at a particular location are given in BSRIA Application Guide 1/75.

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7.6 The actual location for the measurement point should be chosen:

a. at least 1.5 duct diameters upstream of sources of turbulence such as dampers and bends;

b. if this is not possible, 10 diameters downstream of dampers, bends or tees, and 5 diameters downstream of eccentric reducers;

c. where there is enough space round the duct to insert the pitot tube and take readings;

d. where the duct has a constant cross-sectional area.

7.7 Test holes for measuring total air flow from a fan should be located either 4 diameters upstream, or 10 diameters downstream of the fan.

Information to be provided

7.8 It is essential that the designer should pass on his intentions fully to the commissioning engineer by indicating which parts of the system are high, medium and low pressure, and by providing:

a. relevant parts of the specification;

b. schematic drawings indicating data listed in Table 7.1;

c. equipment schedules;

d. controller and regulator schedule;

e. fan performance curves;

f. wiring diagrams for electrical equipment, including interlock details.

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Table 7.1: Information to be provided on schematic drawings

Item of system	Information to be provided
Fans	Fan total pressure Volume flow rates Motor current
Plant items	Type and identification numbers from equipment schedules Volume flow rates Pressure losses Dry bulb temperatures Wet bulb temperatures Humidity
Dampers, including motorised and fire dampers	Identification numbers from equipment schedules Location Volume flow rates Location
Main and branch ducts	Dimensions Volume flow rate and velocities Identification numbers from equipment schedules
Terminals	Location Dimensions Volume flow rates and velocities Operating pressures
Test holes and access panels	Location
Controllers	Set points

Notes:

1. Fan total pressure is the difference between the total pressure (static pressure + velocity pressure) at the fan outlet and the total pressure at the fan inlet.
2. Where volume flow rates are variable, maximum and minimum values should be provided.

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Appendix 1

Design of air movement control schemes for operating suites

General

1.1 The standard plans are given in paragraph 6.1. If these standard solutions cannot be used, the following procedure should be adopted, which will result in an acceptable design.

1.2 The method is concerned with the calculation of air flow rates, to ensure that correct air movement occurs between rooms when any one door is open. Under most circumstances the air quantities required for air movement control will approximate to those for either temperature control or bacterial contaminant dilution and the air flow rate to the operating department will not exceed 1 m^3/sec. This flow rate is sufficient to control the effects of any slight reverse flows occurring when a door is opened.

1.3 The progression through the design procedure is shown in the Air flow design procedure chart, Figure A1, and is supported by the worksheets WS1 to WS7 described below. It is recommended that a plan of the suite and an air flow network be made to collate all information. Flow rates, air transfer devices, etc are entered as required. The remainder of this Appendix may be treated as reference data to assist in the various steps. The following symbols are used:

a. S_S – supply air flow rate for summer temperature control;

b. S_W – supply air flow rate for winter temperature control;

c. S_D – supply air flow rate for dilution of bacterial contaminants;

d. E_D – extract air flow rate for dilution of bacterial contaminants;

e. S_F – final supply air flow rates;

f. E_F – final extract flow rates;

g. S_{AMC} – air supply flow rate for air movement control;

h. E_{AMC} – air extract flow for air movement control.

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1.4 To simplify the procedure standard worksheets WS1 to WS7 have been devised. For each operating suite a set is required comprising one each of WS1, WS3, WS5, WS6 (a), WS6 (b) and WS7, one WS4 for each corridor and one of WS2 to cover each peripheral room. WS2 has five versions, WS2a single flow, WS2b parallel/series multi-flow, WS2c parallel multi-flow or series multi-flow (unbalanced), WS2d series multi-flow (balanced) and WS2e Bay (semi-open).

Peripheral room types

1.5 The rooms in the operating suite other than the operating room and corridor are referred to as peripheral rooms. Peripheral rooms have been classified according to the flows in and out. These room classifications are under the headings below.

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Figure A1: Air flow design procedures

Step	Description	Worksheet
1	Show nominal room pressures and air flow directions on the plan (fig C1) and WS1.	WS1
2	Enter heat/loss/gain data and calculate supply air flow rates for temperature control only. Categorise room types, e.g. sterile, clean, etc.	WS1
3	Enter air flows required for bacterial contamination control, add supply and extract volumes (Sd, Ed) on plan (fig C1).	WS1
4	Define peripheral room types, see clauses B2 and B3 and select appropriate worksheets.	Select from WS2a to WS2e.
5	Locate air transfer devices, enter details on worksheets and locate on figures C1 and C2.	Selected worksheets from WS2a-WS2e.
6	For each peripheral room determine air flows through doors when open and calculate mechanical supply or extract air transfer device flows.	as above
7	Select 'Key Door' and calculate air supply for operating room.	WS3
	Does this door provide solution with greatest flow → NO (return to 7)	
	YES	
8	Transfer to WS1 and select final rate S_F and E_F.	WS1, WS3
	Does S_F to OR exceed 1.0 m^3/s → YES: Reduce S_F to 1.0 m^3/s Correct WS1.	
	NO	
9	Make provision for relief of excess air with doors closed.	Selected worksheets & WS3.
10	Calculate supply and extract flow rates for corridors.	WS4, WS5
11	Calculate room temperatures (all doors closed) and ∈Ts.	WS6a and WS6b
	Do any ∈Ts across doors to sterile rooms exceed 1.0°K → YES: Rectify as in clause B9.	
	NO	
12	Make summary of flows.	WS6a and WS6b
13	Size transfer devices, size ductwork, central planet, etc.	WS7
14	Design ductwork layout, control plant, etc.	–

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Single flow

1.6 This is a room with only one door and a nett surplus of supply or extract air

Parallel multi-flow

1.7 This is a room with two or more doors through each of which the air flows either outwards (high pressure) or inwards (low pressure) (for example lay-up plan 1b).

Parallel/series multi-flow

1.8 This is a room having a nett surplus of supply or extract and with two or more doors. One or more doors will be to an area of equal cleanliness and need not be protected, hence the flow may vary between inwards and outwards, the remaining door being to an area of greater or lesser cleanliness (for example a sterile pack store plan 7a).

Series multi-flow (unbalanced)

1.9 This is a room having a nett surplus of supply or extract and with two or more doors. Air flows inwards through one or more doors and outwards through one or more doors.

Series multi-flow (balanced)

1.10 This is a room as in paragraph 1.9 above but having either no mechanical ventilation or no nett surplus of supply or extract (for example an anaesthetic room).

Bay

1.11 A room which has a permanent opening to the operating room may be considered as a bay off the latter (for example a scrub). Two categories exist:

a. open bay - the opening is larger than a normal single door opening. The bay may be considered as part of the main room;

b. semi-open bay - the opening is no larger than a normal single door opening. In this case it is possible to protect the bay from the main room by provision of air supply or extract in the bay, or by passing air to or from another area.

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Calculation sheet for Flow rates			**Worksheet WS1** Reference:			
Room Name						
Summer temperature control Heat gain	kW					
2. Acceptable Δt	°C					
3. Air flow rate (S_G) $= \frac{\text{Gain}}{\Delta t \times 1.2}$	m^3/s					
4.Winter temperature control Heat loss	kW					
5. Acceptable Δt	°C					
6. Air flow rate (S_L) $= \frac{\text{Loss}}{\Delta t \times 1.2}$	m^3/s					
7. Dilution of bacterial contaminants Air flow rate	m^3/s					
S_D or E_D						
8. Maximum of S_G, S_L, S_D or E_D	m^3/s					
9. Air movement control Air flow rate for air movement control S_{AMC} or E_{AMC}	S m^3/s					
(From WS2, WS3 or WS4)	E m^3/s					
10. Final supply flow rate (S_F)	m^3/s					
11. Final extract	m^3/s					
12. Total supply		m^3/s				
13. Total extract		m^3/s				

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Air Movement Control **Peripheral room……type , single flow**	**Worksheet WS2a** Reference: Nominal pressure: Pa

Consider door to …… open.

			Air flow, m^3/s		
	Pa	∈t	Out	In	Remarks
Flow required through doorway to give protection.					
Structural leakage					
Total					

S_{AMC} $(\Sigma_{OUT} - \Sigma_{IN})$ _____ m^3/s

or

E_{AMC} $(\Sigma_{IN} - \Sigma_{OUT})$ _____ m^3/s

Transfer S_{AMC} or E_{AMC} to WS1.

Consider door to …… closed.

	Pa	∈t	Out	In	Remarks
Closed door leakage					
Structural leakage					
Total					

Return S_F and E_F to WS1. _____ _____

Flow through transfer grille outward (S_F - E_F - L_{OUT}) _____

or

Flow through transfer grille inward (E_F - S_F- L_{IN}) _____

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Air Movement Control **Peripheral room……type, parallel/series multi-flow**	**Worksheet WS2b** Reference
	Nominal pressure: Pa

Door from this room to …… (room of equal cleanliness) is not to be protected.

A transfer grille is located in, or adjacent to, this door.

Consider other door to……open.

Room pressure now becomes [25] or [3] or [ ] Pa (See table 6.2)

			Air flow, m^3/s		
			Out	In	Remarks
Flow required through open doorway to give protection					
At above air pressure leaks through closed doors	Pa	∈ P			
Mechanical supply/extract S_F/E_F					
		Total			

$X(\Sigma_{OUT} - \Sigma_{IN})$ [ ] or $Y(\Sigma_{IN} - \Sigma_{OUT})$ [ ]

Transfer grille required

From high pressure zone Flow = X

or [ ] at [ ] ∈ Pa

To low pressure zone Flow = Y

Size of transfer grille (free area) A1 [ ]

Consider doors and hatches closed – Room pressure becomes [ ] Pa. (nominal)

Closed door leakage from table 6.4 (assuming no transfer grille)	Pa	∈ P	Out	In	Remarks
Mechanical supply extract					
Structural leakage					
Total					

Air flow required through transfer grille = IN – OUT = Z' [ ]

or OUT – IN = Z'' [ ]

Transfer grille required for flow Z' or Z'' [ ] @ [ ] ∈ P

Size of transfer grille (free area) A2 = [ ]

Select larger of A1 or A2. [ ]

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Air Movement Control **Peripheral room……..…type, parallel/series multi-flow, high/low or series multi-flow (unbalanced)**	**Worksheet WS2c** Reference: Nominal pressure: Pa

Consider door from this room to ……open.

Room pressure now becomes [25] or [3] or [ ] Pa (See table 6.2)

			Air flow m^3/s		
			Out	In	Remarks
Flow required through open doorway to give protection					
At above pressure leaks through closed doors are:-	Pa	∈P			
Structural leaks					
		Total			

S_1 (Σ_{OUT} !Σ_{IN}) [ ] or E_1 (Σ_{IN} !Σ_{OUT}) [ ]

Consider door from this room to ……open.

Room pressure now becomes [ ] or [ ] or [ ] Pa

			Out	In	Remarks
Flow required through open doorway to give protection					
At above pressures leaks through closed doors are:-	Pa	∈P			
Structural leaks					
		Total			

S_2 (Σ_{OUT} !Σ_{IN}) [ ] or E_2 (Σ_{IN} !Σ_{OUT}) [ ]

Consider doors closed

Closed doors leakage from table 6.4.

Door to:	Pa	∈P	Out	In	Remarks
Structural leaks					
	Total				

Return S_F and E_F from WS1. [ ]

Flow through transfer device outward (S_F – L_{OUT}) [ ] to ……..

or

Flow through transfer device inward (E_F – L_{IN}) [ ] from ……

Transfer grille [ ] Pressure relief damper [ ]

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Air Movement Control **Peripheral room……type series multi-flow (balanced)**	**Worksheet WS2d** Reference: Nominal pressure: Pa

Note:- In this type of room the supply and extract air flow rates are equal and take no part in the air movement control (AMC).

Firstly open door to higher pressure areas.

Room pressure then becomes [25] or [17] or [ ] Pa (See table 6.2)

			Air flow m^3/s		
			Out	In	Remarks
Flow required through open doorway to give protection See table 6.2					
At above air pressure leaks through closed doors are:-	Pa	∈P			
Structural leakage					
		Total			

Q_1 (Σ_{IN} !Σ_{OUT}) [ ] (+ ve inwards)

Next, open door to lower pressure area

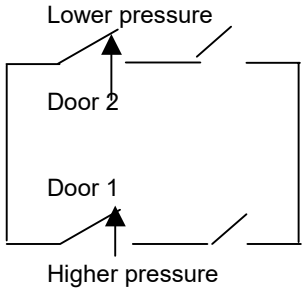
Room pressure then becomes [ ] or [ ] or [ ] Pa.

			Out	In	Remarks
Flow required through open doorway to give protection					
At above pressures leaks through closed doors are:-	Pa	∈P			
Structural leakage					
Total					

Q_2 (Σ_{OUT} !Σ_{IN}) [ ] (+ ve outwards)

Flow through transfer device (TD1) to protect door 1 = Q_1 [ ] at resultant ∈P……

Flow through transfer device (TD2) to protect door 2 = Q_2 [ ] at resultant ∈P……



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Air Movement Control **Peripheral room……..type bay (semi-open)**	**Worksheet WS2e** References:

Note:- If the room is of the open bay type (i.e. opening is larger than normal single doorway) the room should be considered as part of the main room. No air movement control considerations need to be made, and this sheet can be discarded. Supply and/or extract flow will be based on air distribution considerations.

Consider permanent opening

			Air flow, m^3/s		
			Out	In	Remarks
Flow required through opening to give protection					
Leaks through closed doors to:	Pa	Δp			
Structural leakage					

E_{AMC} [ ] or flow outward through transfer device. (Σ_{IN} !Σ_{OUT}) [ ]

Transfer S_{AMC} or E_{AMC} to WS1.

Transfer device – transfer grille [ ]

pressure stabilizer [ ]

Size select transfer device for flow rate [ ] @ ∈p [ ]

Note:-A door from the bay is considered with the peripheral room to which it leads or if it leads to the corridor it is considered with the main room.

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Air Movement Control Operating room	**Worksheet WS3** **Reference:** **Nominal pressure:** **Pa**

Note:- To avoid considering each door in turn the “key door” concept is introduced. This is the door which requires the greatest mechanical flow when open. See guidance clause B5.2.

Select “key door” (see above).
Consider this door open – room pressure now becomes [ ] Pa (see table 6.2)
See B.3 for room pressures.

			Air flow m^3/s		
			Out	In	Remarks
Flow required through doorway to give protection.					
Air flow “out” or “in” via doors transfer devices, etc.	Pa	∈p			
Structural leakage					
Mechanical extract					
		Total			

S_{AMC} (Σ_{OUT}!Σ_{IN}) [ ] transfer S_{AMC} to WS1

Consider all doors closed.
Return S_F from WS [ ] Room pressure now [ ] Pa. (nominal)

Air flow ‘out’ or ‘in’ via closed door leakage transfer devices, etc.	Pa	∈p	Out	In	Remarks
Structural leakage					
Mechanical extract & supply					
		Total			

Flow (Σ_{IN} !Σ_{OUT})through transfer device [ ] @ ΔP [ ] to ……..

For final selection of transfer device see B7.

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Air Movement Control Corridor	**Worksheet WS4** **Reference:**
	Nominal pressure: Pa

Consider all doors closed.

			Air flow m^3/s		
			Out	In	Remarks
Flow required through doorway to give protection.					
Leaks though closed doors, transfer devices, permanent openings, etc.	Pa	ΔP			
Total flow inwards (SI)					
Add mechanical input (S_2) if necessary to increase SI to give 7 A/C per hour.					
Total flow outwards = inwards.					
$S_{AMC} = (\Sigma_{OUT} - \Sigma_{IN} + S_2)$			Transfer to WS5.		
or $E_{AMC} = (\Sigma_{IN} - \Sigma_{OUT} + S_2)$			Transfer to WS5.		

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Air Movement Control	**Worksheet WS5** Reference:……
Summary of air supply and extract for an operating suite	

Air flow to corridor	All doors closed	Anaesthetic (key door open)
	m^3/sec	m^3/sec
From preparation		
From operating room		
From scrub		
From anaesthetic		
Total (a)		
Air flow to corridor From disposal		
From other source		
Total (b)		
Structural leakage total (c)		
Other room supplies……Total (d)		
Total air supply a + b + c + d		

Consider corridor ventilation (see table 6.1) and calculate air volume required, based on 7 A/C per hour.

	m^3/sec
Air flow required to ventilate corridor	
Air flow required to ventilate corridor	

If the air flow from the operating suite (a) and (b) is greater than the calculated required volume, no further supply air is necessary.

	m^3/sec
Additional air to ventilate corridor	
Additional air to ventilate corridor	

Air extract

The size of the exact plant should be sized in the order of 10% below the supply to assist in maintaining the department under positive pressure relative to the outside departments.

	m^3/sec
Extract plant = 90% of supply less leakage	
extract plant	
Total extract	

Note: The exact volume includes 0.15 m^3/sec from the anaesthetic room for a balanced condition.

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Room temperature - Summer

Worksheet WS6a
Reference:

Find summer supply temperatures $t_{(s)} = 20 - 0.828 \times \frac{H(O/R)}{Q(O/R)}$ = Tss °C

Note: The temperature of a space may be calculated from

$$T = \frac{t_1 Q_1 + t_2 Q_2 + \ldots\ldots\ldots + t_n Q_n + (0.828H)}{\Sigma Q}$$

Where t_1 is temperature of source 1 (°C)
Q_1 is flow from source 1 when all doors are closed (m^3/s)
H is heat gain in space kW

Room	Heat gain kW H	Supply Q	Supply t_s	Flows inwards From Q	From t	From Q	From t	From Q	From t	From Q	From t	From Q	From t	Temperature °C T

Check door to sterile areas

Door between	Calculated room Δt (K)	Maximum Δt permitted	Remarks

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Room temperature - Winter

Worksheet WS6b
References:

Find winter supply temperatures $t_{(s)} = 22 - 0.828 \times \frac{H(O/R)}{Q(O/R)}$ [ ] [ ] [ ]

°C

Note: The temperature of a space may be calculated from

$$T = \frac{t_1 Q_1 + t_2 Q_2 + \ldots\ldots\ldots + t_n Q_n + (0.828H)}{\sum Q}$$

Where t_1 is temperature of source 1 (°C)
Q_1 is flow from source 1 when all doors are closed (m^3/s)
H is heat gain in space kW

Room	Nett heat loss kW H	Supply Q	Supply t_s	Flows inward From.. Q	From.. t	From.. Q	From.. t	From.. Q	From.. t	From.. Q	From.. t	Temperature °C T

Door between	Calculated room Δt (°K)	Maximum Δt permitted	Remarks

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Transfer grilles, pressure relief dampers and pressure stabilizers

Worksheet WS7

Reference:

Transfer grilles – see clause B.5

No	Location	Pressure difference Pa	Flow rate m^3/s	Free area m^2	Model	Resultant Δp Pa	Remarks

Pressure relief dampers – see clause B.6

No	Location	Pressure difference Pa	Flow rate m^3/s	Free area	Pressure setting Pa	Remarks

Pressure stabilizers – see clause B.7

Note: Where a stabilizer is acting both as a series room door protection and operating pressure control, 'pressure difference' and 'flow rate' are from WS2d 'pressure setting' is from WS3.

No	Location	Pressure difference Pa	Flow rate m^3/s	Free area	Pressure setting Pa	Remarks

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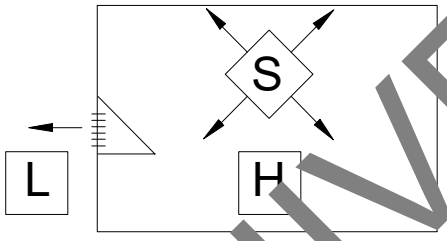
Air movement control in peripheral rooms

1.12 For the design of air movement control, three types of air transfer device are considered. These are transfer grilles, pressure relief dampers and pressure stabilisers. Each has a particular field of application within the design as described in paragraphs 1.32–1.39. Air movement is controlled in each of the different room types below.

Single flow rooms

1.13 An appropriately sized transfer grille should be located in or adjacent to the door of each single flow room to relieve the pressure difference across the door when closed.



SINGLE FLOW

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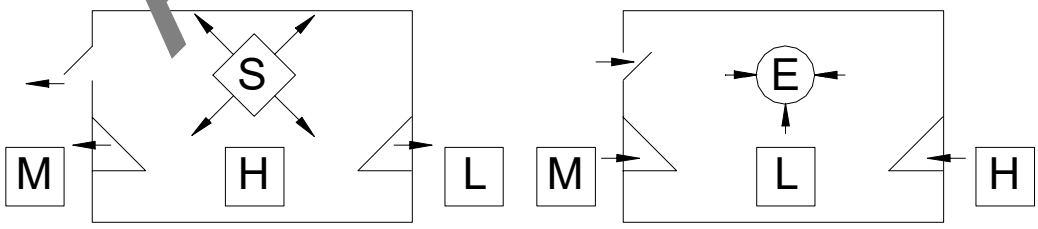
Parallel multi-flow room

1.14 The pressure difference across the closed doors must be relieved but transfer grilles are not appropriate where two doors lead to areas of different pressures, because reverse flow could occur when the other door is open. For this reason, pressure relief dampers are used.



PARALLEL MULTI FLOW
(HIGH PRESSURE ROOM)

PARALLEL MULTI FLOW
(LOW PRESSURE ROOM)

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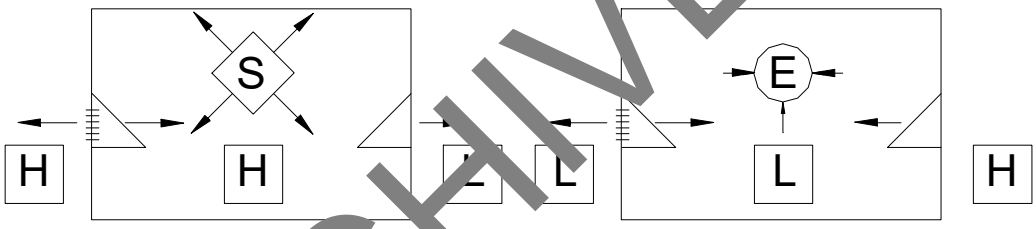
1.15 These rooms will be either high pressure or low pressure with respect to the adjacent areas. See preparation lay-up room in Plan 1b and disposal room in Plan 1b respectively. The pressure relief damper is always situated between the room and area, which results in the smaller differential pressure to ensure best use of air.

1.16 Just as reverse flow can occur if transfer grilles are used, it can similarly occur via door gaps when the other door is opened. It is not possible to avoid this, except by using air locks, but due to the low flow-rates and short durations involved, this is not considered to be of importance.

Parallel-series multi-flow rooms

1.17 These rooms are similar to those in paragraph 1.14 above, but because the room is of equal cleanliness to one of the adjacent rooms the nominal pressures will be equal and air may flow through the adjoining doorway in either direction for example, the prep-sterile pack store in Plan 1a.



PARALLEL SERIES MULTI FLOW PARALLEL SERIES MULTI FLOW

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1.18 Where the nominal room pressure equals that of the higher pressure adjacent room, the best use of air is by supplying air required for bacterial dilution only and allowing this to exhaust via a transfer grille to the area of equal cleanliness. The doorway to the lower pressure area is protected by the combination of the supply air and the air which will flow inwards through the transfer grille from the area of equal cleanliness.

1.19 Conversely, where the nominal pressure equals that of the lower pressure adjacent room, extract ventilation and a transfer grille to the lower pressure adjacent room should be provided for example, the disposal room in Plan 5a.

Series multi-flow (unbalanced)

1.20 These rooms are somewhat similar to those in paragraph 1.15 above, but because the pressure lies between that of the rooms on either side, the back-flow problem does not exist.

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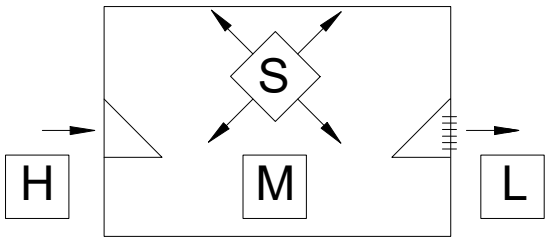
1.21 Where the room has a nett surplus of mechanical supply air, a transfer grille should be located in or adjacent to the door through which air flows outwards and the mechanical supply flow rate to the room should be chosen to give protection when this door is open.



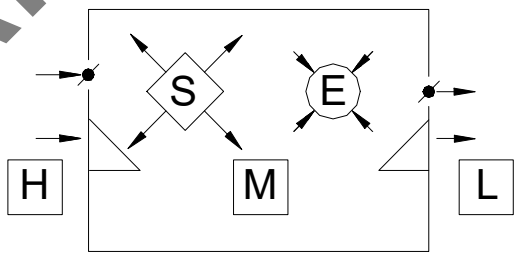
SERIES MULTI-FLOW
(UNBALANCED)

1.22 Where the room has a nett surplus of mechanical extract air, a transfer grille should be located adjacent to the door through which the air flows inwards and the mechanical extract flow rate to the room should be chosen to give protection when this door is open.

1.23 The grille must be sized for the protection requirement of the opposing door when open. When the room on the high pressure side is depressurised there is a possibility of back-flow through gaps around the door, but this problem may be ignored.

Series multi-flow (balanced)

1.24 In these rooms a transfer device is required adjacent to each doorway to provide a flow path for the air required to protect the opposing door when opened.



SERIES MULTI FLOW (BALANCED)

1.25 These transfer devices will normally be pressure stabilisers although transfer grilles may be used where a large amount of excess air is to be exhausted from the operating room when all doors are closed, for example, anaesthetic rooms.

1.26 The calculation procedure is to assume that pressure stabilisers are used and then if there is sufficient excess air, change to transfer grilles as described in paragraphs 1.43 to 1.44.

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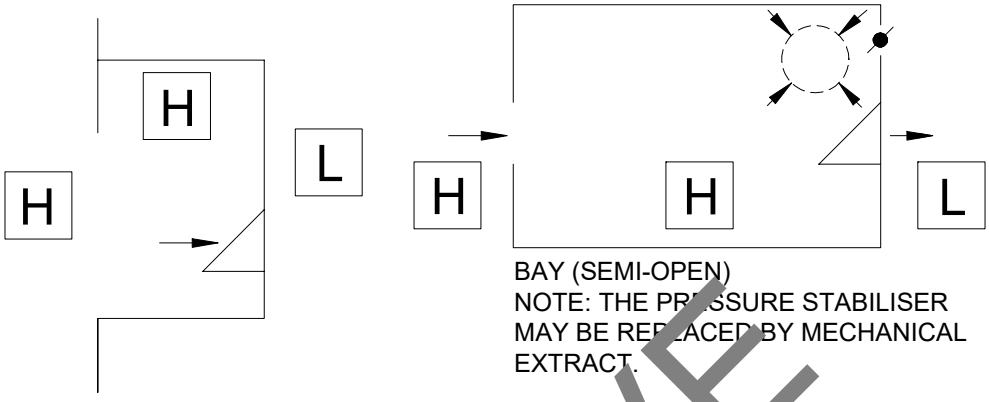
Bay

1.27

a. Open bay - a bay of the open type (for example, scrub-up) is considered to be part of the operating room and provided air movement is satisfactory no specific extract is required.



b. Semi-open bay - in a bay of the semi-open type, protection of one area from the other is possible (for example, scrub-up).

As stated in paragraph 6.2, the need for protection between operating room and scrub-room is not very great. Better use of air can therefore be achieved in this case by installing a pressure stabiliser between the scrub-room and clean corridor. This will allow a flow of air through the scrub-room at all times, except when a door is opened elsewhere in the suite. The pressure stabiliser will then close and the air will be diverted to the other door. When it is considered necessary to protect the scrub-room at all times, either a transfer grille to the corridor or mechanical extract in the scrub-room, should be provided.

Operating room

1.28 Once the peripheral rooms have been considered, the operating room requirements may then be decided and the supply flow-rate required for air movement control calculated. This flow-rate should be such that with any one door open the correct air movement directions are maintained. There will be one door in the suite which will require the largest supply flow rate to the operating room for protection when open. This is called the “key door” and is discussed separately in paragraph 1.32 below. Use of this concept avoids repetitive calculations for each door in turn. Having established the required supply flow-rate, a relief route must be provided to the clean corridor for any excess air when the doors are closed. This could be via transfer grilles or pressure stabilisers through a series flow room or via pressure stabilisers to the clean corridor directly.

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Corridors

1.29 All the surplus air from the suite except that lost through structure leakage and any passing to the outer corridor will arrive in the patient/staff corridor. Should this air be insufficient to achieve the required air change rate (see Table 6.1), then some additional air supply should be provided. (The air balance should take account of structural leakage.)

Door opening

1.30 Whereas the resulting pressures are dependent upon the ductwork layout, the room relationships and the characteristics of the fan, the generalisations shown in Table 6.2 can be used to estimate the change in room pressure when a door is opened.

1.31 The "key door" will be the open double door which leaves the operating room at the highest pressure, and/or requires the largest air flow. This will normally be the door to the anaesthetic room, but other doors should be checked using the procedure in Worksheet WS3.

Transfer grilles

1.32 These may be used to limit the pressure differences across the closed door of a single flow room or, in some instances, for protection of a series-flow or parallel-series flow room. They allow air flow in both directions and may not be suitable for all applications.

1.33 The free area of a grille is calculated from:

$$A = \frac{Q}{0.84\sqrt{\Delta P}}$$

where: A is free area (m^2)
Q is flow rate (m^3/s)
ΔP is pressure difference (Pa)

The flow through a grille at a different pressure may be found from:

$$Q1 = Q2\sqrt{\frac{\Delta P_2}{\Delta P_1}}$$

where: Q_1 and ΔP_1 are original flow and differential pressure
Q_2 and ΔP_2 are new flow and differential pressure.

The transfer grille may be replaced by carefully proportioned door undercuts of the equivalent free area.

1.34 The function of the transfer grille is to provide a means of air flow control by which the volume and pressure loss can be established. Any method which achieves this, for example carefully prepared door undercuts or a simple

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framed opening is satisfactory. If a grille is used, it should have an easily removable core to facilitate cleaning.

Key to figures (see paragraph 1.13 to 1.27)

H M L High, medium or low pressure

All other symbols as per key to Figure 6.1

Pressure relief dampers

1.35 Pressure relief dampers have an approximately linear flow/differential pressure characteristic, but do not have the steep characteristic of the pressure stabiliser (see Figure B1). They are therefore not suitable for accurately controlling pressure to a pre-set level, but may be used to control air volume, allowing excess air to vent when not required to protect an open doorway. The damper may then be sized to give the desired room pressure at the known flow-rate.

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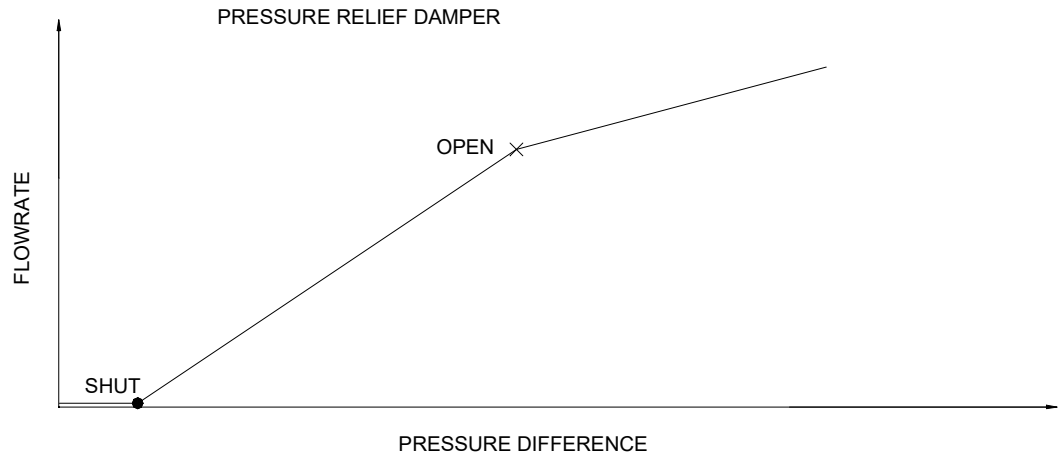
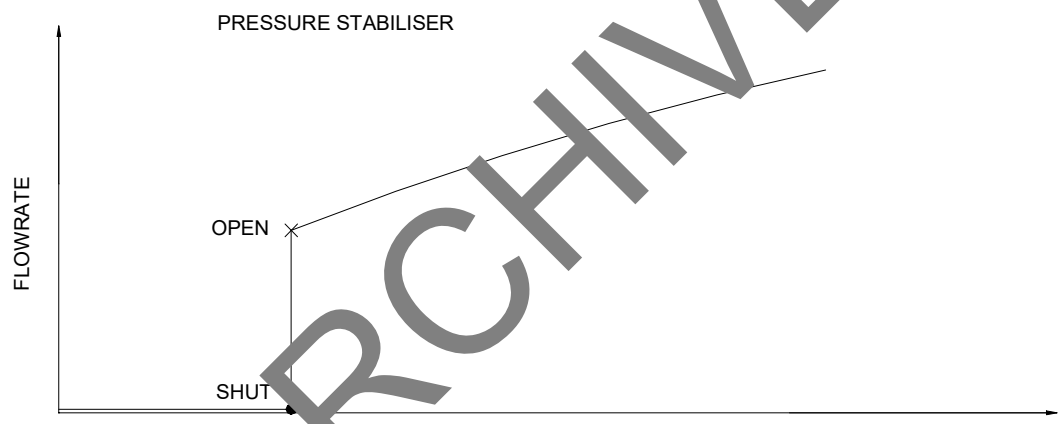
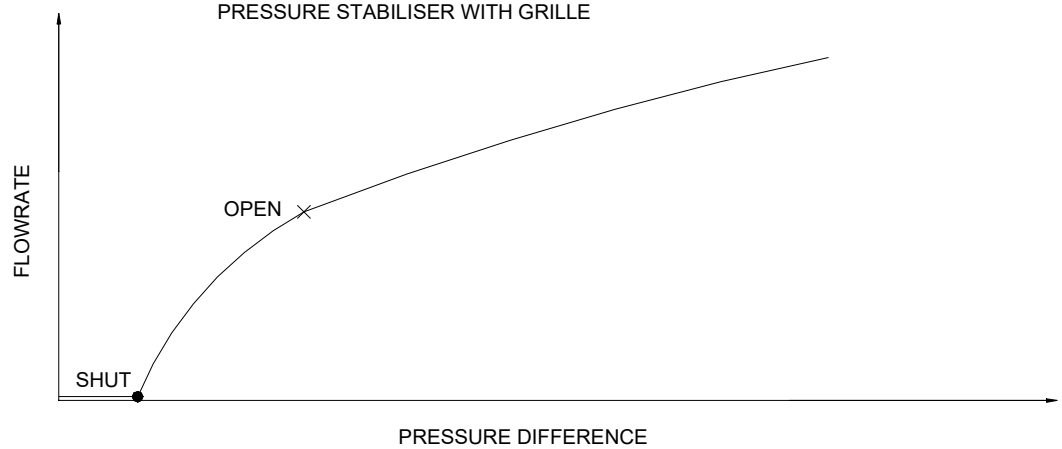
Figure B1: Typical flow rate / pressure characteristics







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Pressure stabilisers

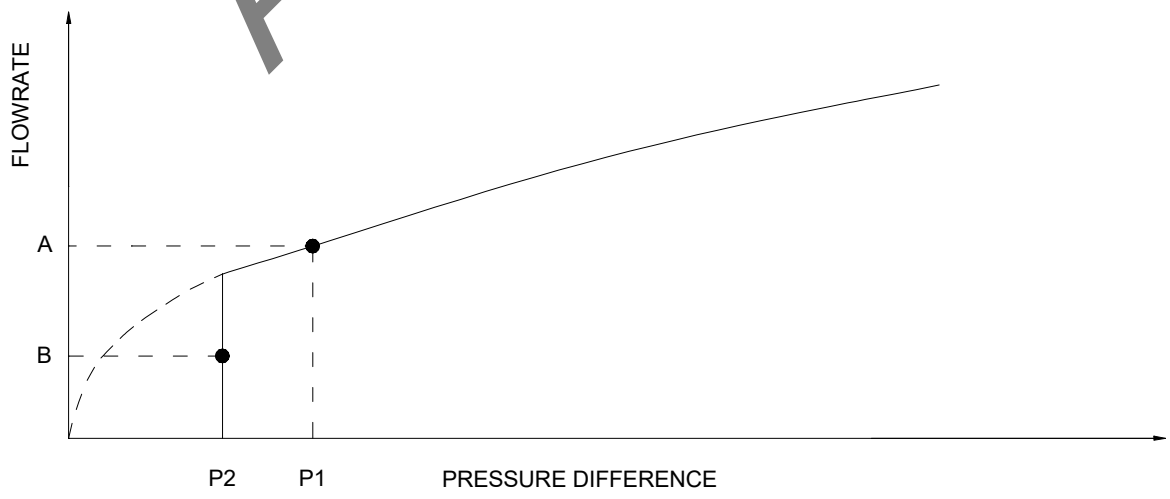
1.36 Pressure stabilisers (Figure B1) have a steep flow-rate differential pressure characteristic. They, therefore, hold the pressure constant over a wide range of flow-rates. They are useful where requirements exist for accurate room pressure control or rapid shut-off on pressure fall.

1.37 Because the installation of a grille in association with a stabiliser will seriously alter the operating characteristics, it is recommended that a location be chosen to avoid the need for visual screening for example, at high level. The location should be chosen to minimise the likelihood of damage.

1.38 The stabilisers used should be virtually silent in operation, adjustable on site, maintenance free, and of a type which cannot be wrongly inserted. They should not be used in external walls or where the pressure difference is less than 1OPa. The required size of a pressure stabiliser is dependent on the design pressure difference across it and flow-rate through it. The manufacturer should provide data relating pressure difference to mean velocity (or flow-rate per unit area). From this the required area can be calculated and then rounded-up to the nearest size manufactured or nearest combination of smaller sizes.

It is sometimes possible to arrange for a pressure stabiliser to perform two tasks. In an anaesthetic room for example, the two pressure stabilisers may be made to pass the open door protection air, and also control the operating and anaesthetic room pressures with the door closed. To achieve this the stabilisers are sized for the flow-rate required with one of the doors open, but the pressure setting is adjusted to be the value required with the doors closed. This is shown in Figure B2:

Figure B2 Pressure stabilisers performing two tasks



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Note: The size of the unit is chosen to give (as nearly as possible) the door protection flow A against the pressure difference P1. The stabiliser will be fully open and acting as an orifice.

The pressure setting of the stabiliser is adjusted to P2 to control the closed door room pressures (P2) by passing flow B.

Door leakage flows

1.40 For an air movement control scheme to work satisfactorily it is essential that the estimates of door gap leakage made at the design stage are closely related to those which are achieved in practice. The calculation of gap-flows is complicated by the fact that such flows generally fall into the transition region between laminar and turbulent flow and hence do not follow the normal flow equations. Leakage flows have been calculated for doors installed to the specification in the CDB (Component Data Base). The gaps assumed are 4 mm along the bottom, 3 mm at the top and sides and 2 mm between double leaves. Doors should not have wider gaps than these Tighter gaps would result in lower flow-rate requirements and hence lower fan power, but care should be taken to ensure that all doors in the suite have similar gap dimensions.

Room temperature estimation

1.41 The air flow-rate required to prevent backflow through an open door is dependent on the temperature difference across the door. The design figures shown in Table 6.2 are based upon the temperature differences which will normally occur in practice, assuming heat gains and losses in accordance with Table 6.4.

1.42 At step 11 of the airflow design process the temperature differences across the doors of all rooms classed as “sterile” are calculated. Worksheet WS6 is recommended for the calculations, using the following criteria:

a. assume that the operating room is being controlled at 20°C and calculate the incoming air supply temperature as shown on Worksheet WS6;

b. the calculation should be repeated for both summer and winter conditions, with an operation in progress;

c. assume all doors are closed;

d. use the room supply flow-rates from WS1;

e. use the inward air flows through air transfer devices and closed door leakages from WS2a to WS2e;

f. the formulae used in Worksheet WS6 is as follows:

$$T = \frac{(Q_1 t_1 + Q_1 t_2 + \ldots\ldots + Q_n t_n) + 0.828H}{(Q_1 + Q_2 + \ldots Q_n)}$$

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where Q_1 is flow rate from Source 1(m^3/s)

t_1 is the temperature of Source 1 (°C)

H is room heat gain kW.

If the evaluated temperature differences between rooms do not exceed 2°C the solution is satisfactory, otherwise proceed as follows:

(i) check the assumption on which the heat gains are based;

(ii) take steps to reduce the heat gains;

(iii) if the door is to a corridor, the flow through the open door will be larger than the value given in Table 6.2. Calculate on WS3 assuming it is the "key door" with door-flow unknown, and the supply as known;

(iv) if the door leads to a room with mechanical supply, install a trimmer heater in the supply to the room controlled by either a differential thermostat or a thermostat slaved to the operating room thermostat to ensure that δt is minimised;

(v) if the door leads to a room with no mechanical supply, increase the door protection flow as follows:

$$Q_{new} = Q_{old} \, x \, \frac{\Delta t + 1}{2}$$

These options should be considered in this order and (i), (ii) and (iii) should be investigated thoroughly before proceeding to (iv) or (v). The mechanical supply should be increased in exceptional circumstances only and in no case should the supply flow-rate to the operating room exceed 1.0 m^3/s.

Relief of excess air from operating room when all doors are closed

1.43 As the mechanical supply to the operating room is sized to provide an appropriate flow outward through any door which is opened, it follows that when all doors are closed there will be more air supplied to the operating room than can exit from it via leaks etc. This "excess" air can be relieved by either of the two methods following.

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By transfer devices via the anaesthetic room

1.44 For door protection the transfer devices in the anaesthetic room are typically designed to pass 0.47 m^3/sec at a differential pressure of 14Pa. When the doors are closed the differential pressure will change to 11Pa and the volume of air passed by the transfer devices will be modified as shown in the following formula:

$$Q = Q_1 \sqrt{\frac{\Delta P_1}{\Delta P_2}}$$

$$= 0.47 \, x \sqrt{\frac{11}{14}}$$

$$= 0.42 \ m^3/sec$$

Q = "excess" air to be vented with doors closed.

Q_1 = air flow required for door protection through transfer device.

ΔP_1= nominal differential pressure with door to operating room and door to corridor closed.

ΔP_2= nominal differential pressure between, either the anaesthetic room and corridor when the operating room door is open or the anaesthetic room and operating room when the corridor door is open. This differential pressure is used when selecting size of both devices.

a. If the "excess" air is less than 0.42 m^3/sec, a pressure stabiliser is required to ensure that the correct protection air flow is available to pass through the door.

b. If the "excess" air is greater than 0.42 m^3/sec, a transfer grille will be acceptable because at all times the air flow will exceed the flow required for door protection.

By pressure stabilisers to the corridor.

1.45 If it is undesirable to pass operating room air through the anaesthetic room, it may be passed directly to a corridor via a separate pressure stabiliser.

1.46 If there is sufficient "excess" air, the transfer grille solution at 1(b) above should be adopted, as it provides the simplest solution and once set up, will require no further maintenance. With less "excess" air it is recommended that the air be passed through the anaesthetic room via the pressure stabilisers as at 1(a) above, thus keeping the number of pressure stabilisers to a minimum. Both these solutions increase the air change rate in the anaesthetic room.

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Figure C1: Plan of operating suite – Two corridor with sterile pack store and disposal hatch

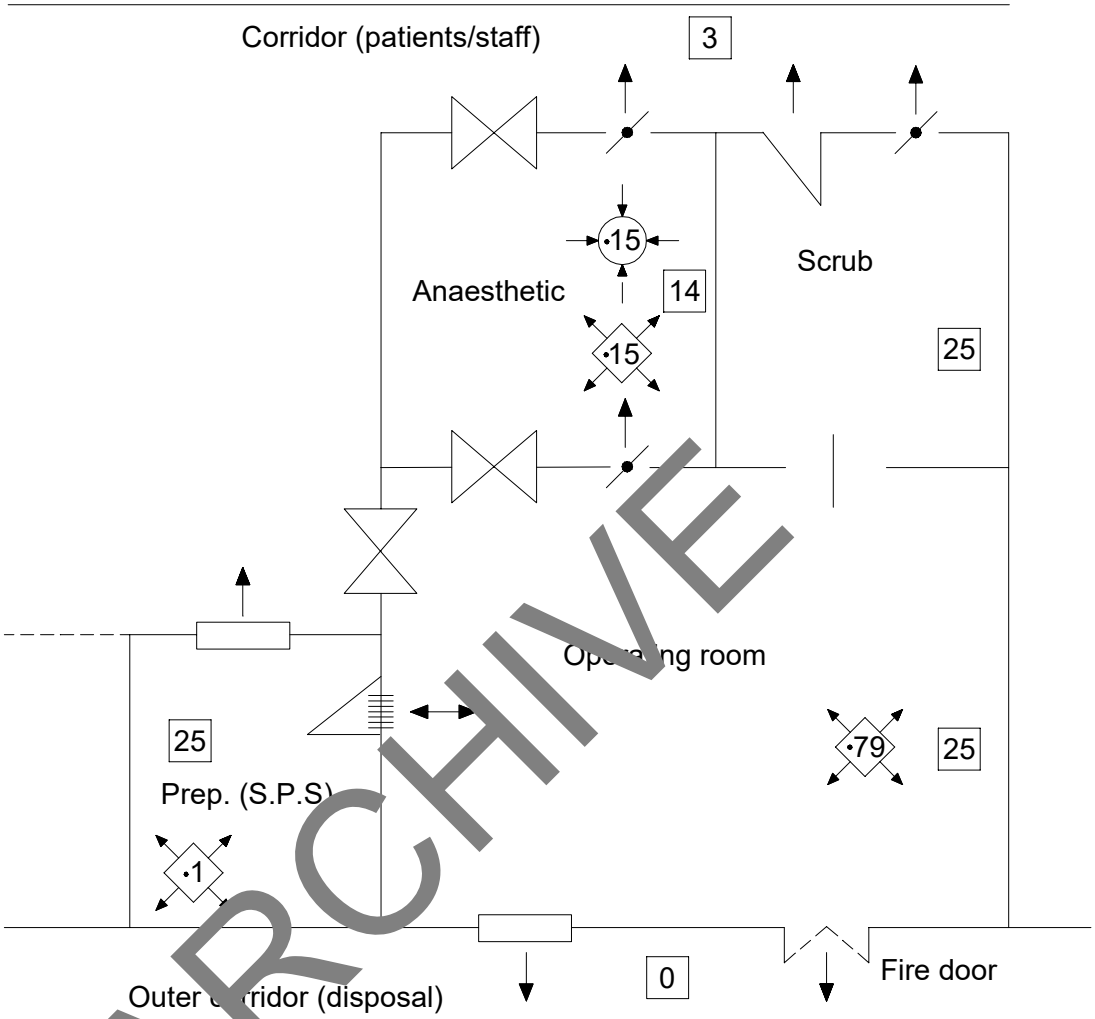

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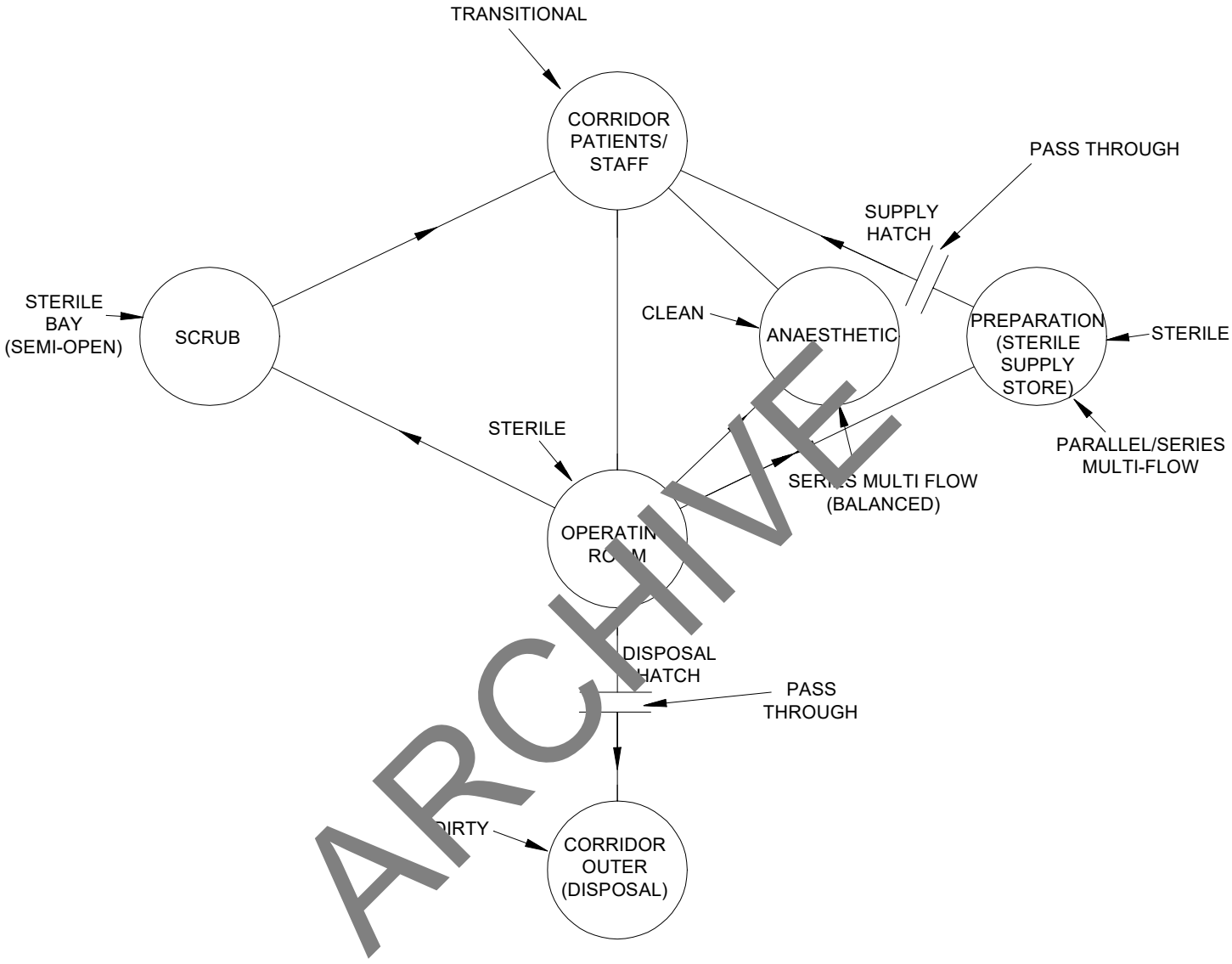
Figure C2: Air flow network



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Appendix 2: Abbreviations

ac/h	Air change per hour
AHU	Air handling unit
AN	Anaesthetic (room)
BCP/m^3	Bacteria carrying particles/cubic metre
BMS	Building Management System
BS	British Standard
BSRIA	British Services Research and Information Association
°C	Degrees Celsius
CC	Clean corridor
CIBSE	Chartered Institute of Building Services Engineers
COSHH	Control of Substances Hazardous to Health
CP	Code of practice
dB(A)	Decibel
DC	Dirty corridor
DI	Disposal (room)
DOP	Dispersed oil particles
EU	European Union
GRP	Glass reinforced plastic
HEPA	High Efficiency Particle
HMSO	Her Majesty's Stationery Office
HTM	Health Technical Memorandum
HVCA	Heating and Ventilating Contractors Association
K	Kelvin
kJ/kg	kilojoule per kilogram
kN	kilonewton
LEV	Local exhaust ventilation
LPHW	Low pressure hot water
LU	Laundry (room)
m^2	Square metres
mm	millimetres
m/s	metres per second
m^3/s	Cubic metres per second
NHS	National Health Service
OR	Operating room
Pa	Pascal
PVC	Polyvinylchloride
RH	Relative humidity
Sat	Saturated
SC	Scrub bay
sec	second
SHPN	Scottish Health Planning Note
SHTM	Scottish Health Technical Memorandum
SI	Statutory Instrument
S.P.S.	Sterile pack store
T	Temperature
t	temperature

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UCV	Ultra clean ventilation
UV	Ultra violet
WC	Water closet
W/m^3/s	Watts per cubic metre per second
W/p	Watts per person
WRc	Water Research centre
WS	Work sheet
Δ	Temperature, pressure etc. difference
+ve	Positive
-ve	Negative

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References

NOTE:
Where there is a requirement to address a listed reference, care should be taken to ensure that all amendments following the date of issue are included.

Publication ID	*Title*	*Publisher*	*Date*	*Notes*
Acts and Regulations				
	Building (Scotland) Act	HMSO	1959	
	Clean Air Act	HMSO	1993	
	Electricity Act	HMSO	1989	
	Health and Safety at Work etc Act	HMSO	1974	
	Registered Establishments (Scotland) Act	HMSO	1998	
	Water (Scotland) Act	HMSO	1980	
SI 2179 & 187	The Building Standards (Scotland) Regulations (as amended)	HMSO	1990	
	Building Standards (Scotland) Regulations: Technical Standards Guidance	HMSO	1998	
SI 1460	Chemicals (Hazard Information and Packaging for Supply) Regulations (CHIP2)	HMSO	1997	
SI 3140	Construction (Design and Management) Regulations	HMSO	1994	
SI 437	Control of Substances Hazardous to Health Regulations (COSHH)	HMSO	1999	
SI 1057	Electricity Supply Regulations (as amended)	HMSO	1988 (amd 1994)	
SI 635	Electricity at Work Regulations	HMSO	1989	
SI 2372	Electromagnetic Compatibility Regulations (as amended)	HMSO	1992	
SI 2451	Gas Safety (Installation and Use) Regulations	HMSO	1998	
SI 2792	Health and Safety (Display Screen Equipment) Regulations	HMSO	1992	
SI 917	Health & Safety (First Aid) Regulations	HMSO	1981	
SI 682	Health & Safety (Information for Employees) Regulations	HMSO	1989	

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Publication ID	*Title*	*Publisher*	*Date*	*Notes*
SI 1380	Health and Safety (Training for Employment) Regulations	HMSO	1990	
SI 341	Health and Safety (Safety Signs and Signals) Regulations	HMSO	1996	
SI 2307	Lifting Operations and Lifting Equipment Regulations 1998 (LOLER)	HMSO	1998	
SI 2793	Manual Handling Operations Regulations	HMSO	1992	
SI 3242	Management of Health and Safety at Work Regulations	HMSO	1999	
SI 1790	Noise at Work Regulations	HMSO	1989	
SI 3139	Personal Protective Equipment (EC Directive) Regulations (as amended)	HMSO	1992	
SI 2966	Personal Protective Equipment at Work (PPE) Regulations	HMSO	1992	
SI 128	Pressure Systems Safety Regulations (PSSR)	HMSO	2000	
SI 2306	Provision and Use of Work Equipment Regulations (PUWER)	HMSO	1998	
SI 3163	Reporting of Injuries, Diseases and Dangerous Occurrences Regulations (RIDDOR)	HMSO	1995	
SI 3004	Workplace (Health, Safety and Welfare) Regulation	HMSO	1992	
British Standards				
BS 848	**Part 1:** Fans for general purpose performance testing using standardized airways	BSI Standards	1997	
BS 1710	**Specification for identification of pipelines and services**	BSI Standards	1984	
BS 3928	**Method for sodium flame test for air filters (other than for air supply to I.C. engines and compressors)**	BSI Standards	1969	
BS 4533	**Luminaires. Particular requirements. (Relevant parts)**	BSI Standards		
BS 4718	**Methods of tests for silencers in air distribution systems**	BSI Standards	1971	
BS 4979	**Methods for aerodynamic testing of constant and variable dual or single duct boxes**	BSI Standards	1986	
BS 5295	**Environmental cleanliness in enclosed spaces** **Parts 1 & 2**	BSI Standards	1989	

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Publication ID	*Title*	*Publisher*	*Date*	*Notes*
BS 5410	**Code of practice for oil firing. Installations of 44kW and above capacity for space heating, hot water and steam supply purposes** **Part 2**	BSI Standards	1978	
BS 5440	**Installation of flues and ventilation for gas appliances**	BSI Standards	1990	
BS 5588	**Fire precautions in the design, construction and use of buildings** **Part 9:** Code of practice for ventilation and air-conditioning ductwork	BSI Standards	1999	
BS 5720	**Code of practice for mechanical ventilation and air-conditioning in buildings**	BSI Standards	1979	
BS 5726	**Microbiological Safety Cabinets** **Part 1:** Specification for design construction and performance	BSI Standards	1992	
BS 5726	**Microbiological safety cabinets.** **Part 4:** Recommendation for selection, use and maintenance	BSI Standards	1992	
BS 6281	**Devices without moving parts for the prevention of contamination of water by backflow** **Part 1:** Specification for type A gaps for inlet or feed pipes.	BSI Standards	1992	
BS 6798	**Specification for installation of gas-fired boilers of rated input not exceeding 70 kW net**	BSI Standards	2000	
BS 7258	**Laboratory Fume Cupboards** **Parts 1 & 2**	BSI Standards	1994	
BS 7258	**Laboratory fume cupboards.** **Part 3:** Recommendations for selection, use and maintenance	BSI Standards	1994	
BS 8313	**Code of practice for accommodation of building services in ducts**	BSI Standards	1997	
BS EN 255	**Air conditioners liquid chilling packages and heat pumps with electrically driven compressors**	BSI Standards	1997	
BS EN 12469	**Biotechnology. Performance Criteria for microbiological safety cabinets**	BSI Standards	2000	
BS EN 60651	**Specification for sound level meters**	BSI Standards	1994	

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Publication ID	*Title*	*Publisher*	*Date*	*Notes*
PO 6609	**Insitu aerosol testing of HEPA filtration- an explanatory supplement to BS 5295 Part 1**	BSI Standards	1996	
Scottish Health Technical Guidance				
SHTM 2005	Building management systems	P&EFEx	2001	CD-ROM
SHTM 2007	Electrical services supply and distribution	P&EFEx	2001	CD-ROM
SHTM 2011	Emergency electrical services	P&EFEx	2001	CD-ROM
SHTM 2020	Electrical safety code for low voltage systems (Escode – LV)	P&EFEx	2001	CD-ROM
SHTM 2023	Access and accommodation for engineering services	P&EFEx	2001	CD-ROM
SHTM 2040	Control of legionellae in healthcare premises – a code of practice	P&EFEx	2001	CD-ROM
SHTM 2045	Acoustics	P&EFEx	2001	CD-ROM
SHPN 1	Health service building in Scotland	HMSO	1991	
SHPN 2	Hospital briefing and operational policy	HMSO	1993	
SHTN 1	Post commissioning documentation for health buildings in Scotland	HMSO	1993	
SHTN 4	General Purpose Estates and Facilities Model Safety Permit-to-Work System	EEF	1997	
	NHS in Scotland – PROCODE	P&EFEx	2001	Version 1.1
NHS in Scotland fireco				
SHTM 81	Fire precautions in new hospitals	P&EFEx	1999	CD-ROM
SHTM 82	Alarm and detection systems	P&EFEx	1999	CD-ROM
SHTM 83	Fire safety in healthcare premises: general fire precautions	P&EFEx	1999	CD-ROM
SHTM 84	Fire safety in NHS residential care properties	P&EFEx	1999	CD-ROM
SHTM 85	Fire precautions in existing hospitals	P&EFEx	1999	CD-ROM
SHTM 86	Fire risk assessment in hospitals	P&EFEx	1999	CD-ROM
SHTM 87	Textiles and furniture	P&EFEx	1999	CD-ROM
SFPN 3	Escape bed lifts	P&EFEx	1999	CD-ROM
SFPN 4	Hospital main kitchens	P&EFEx	1999	CD-ROM
SFPN 5	Commercial enterprises on hospital premises	P&EFEx	1999	CD-ROM
SFPN 6	Arson prevention and control in NHS healthcare premises	P&EFEx	1999	CD-ROM
SFPN 7	Fire precautions in patient hotels	P&EFEx	1999	CD-ROM

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Publication ID	*Title*	*Publisher*	*Date*	*Notes*
SFPN 10	Laboratories on hospital premises	P&EFEx	1999	CD-ROM
Health and Safety Publications				
EH 40	HSE Occupational Exposure limits	HSE	Annual	
MES	Model Engineering Specifications	NHS Estates	1997	As required
Miscellaneous References				
	Buffalo Forge Co. Fan Engineering	Buffalo Forge Co. Woods		
	CIBSE Guides and Commissioning Codes, A, W and R	CIBSE	1986	
	HVCA: Specification for sheet metal ductwork	HVCA		
DW/143	Ductwork leakage testing			
DW/TM2	Cleanliness of new ductwork			
CM0101	HVCA: Standard maintenance specification for mechanical services in buildings: CM0101 Volume 1 Heating and Pipework Services Volume 2 Ventilating and Air Conditioning Volume 3 Control, energy and building management systems Volume 4 Ancillaries, plumbing and sewerage Volume 5 Electrics in buildings	HVCA		
	Model Water Byelaws: Dept of the Environment	HMSO	1986	
	Water Supplies Byelaws Guide	WRC		

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Scottish Health Technical Memorandum 03-01 (Interim Version – Additional guidance related to COVID 19 to be added in an update in 2022)

Specialised ventilation for healthcare premises
Part A: The concept, design, specification, installation and acceptance testing of healthcare ventilation systems

February 2022
Interim Version 3.0

Contents

Executive Summary

Scottish Health Technical Memorandum 03-01 – 'Specialised ventilation in healthcare premises' is published in two parts:

Part A: The concept, design, specification, installation and acceptance testing of healthcare ventilation systems.

Part B: The management, operation, maintenance and routine testing of existing healthcare ventilation systems.

The documents give comprehensive advice and guidance on the legal requirements, design implications, maintenance and operation of specialised ventilation in healthcare premises providing acute care. The use of these premises is very intense, the occupancy level high and the patients may be particularly susceptible to airborne infection risks. Their condition may also require close control of the environment.

The ventilation of non-healthcare facilities within the hospital curtilage should be designed to suit the application and specific guidance relating to the activity should be followed, for example pharmacy, central decontamination unit, etc. However, as they are on the hospital site, the means of providing ventilation should not adversely impact upon the hospital (for example, evaporative cooling towers should not be installed, sound levels should be appropriate and if the facility is within or attached to an area accessed by patients, their needs and the risk of airborne contamination should be considered).

In other types of healthcare facility that are outside of the hospital curtilage, for example GP practices, health centres, minor injuries units, dental, ophthalmic and podiatry clinics, mental health facilities, respite and long stay care homes and hospices, a risk assessment of the nature of the treatment being delivered, condition of the patients and intensity of use needs to be undertaken by those responsible for the facility in order to determine the extent to which this guidance will be applicable.

The guidance contained in Part A of this Scottish Health Technical Memorandum applies to new installations and major refurbishments of existing installations and should be considered as the standard to be achieved.

The guidance contained in Part B of this Scottish Health Technical Memorandum applies to all ventilation systems installed in healthcare premises irrespective of the age of the installation and should be considered as the standard to be achieved.

Scottish Health Technical Memorandum 03-01 (2022) supersedes all previous versions of Scottish Health Technical Memorandum 03-01 – 'Specialised ventilation in healthcare premises' (2014). It also supersedes SHTM 2025 (1994) and DV4 (1983).

Who should use this guidance?

This document is aimed at specifiers, designers, suppliers, installers, estates and facilities managers and operations. Elements of the document will also be relevant to

managers concerned with the day-to-day management of healthcare facilities and senior healthcare management.

Main changes since the 2014 edition

- design information for specific healthcare applications has been revised and information on the reason for ventilation given. For example, endoscopy rooms may now be either negative (to contain and remove odours and manage airborne risks to staff) or positive pressure (to maintain a higher level of cleanliness where it is intended to puncture body membranes with the endoscope). These endoscopy-specific risks (i.e. waste anaesthetic gases and pathogenic material (for example, multi-drug- resistant tuberculosis) discharged by the patient during the procedure being undertaken) were identified prior to the SARS-CoV-2 pandemic. As with other elements in Part A, the application of this change is not retrospective but applies to new installations and major refurbishments (see Preamble above);
- the client's needs and legal requirements are more clearly explained;
- this edition of Scottish Health Technical Memorandum 03-01 introduces the concept of the Ventilation Safety Group in healthcare organisations (similar to the Water Safety Group in Scottish Health Technical Memorandum 04-01 and the Electrical Safety Group in Scottish Health Technical Memorandum 06-01). This is a multidisciplinary group whose remit will be to assess all aspects of ventilation safety and resilience required for the safe development and operation of healthcare premises;
- the SHTM introduces a standard method of identifying and labelling ventilation systems and the creation of an inventory of installed systems;
- the issues of resilience and diversity are addressed;
- guidance is provided on refurbishments or when changing the use of an existing installation;
- guidance is given on lifecycle and the updating of mid-life plant;
- design information for specific healthcare application has been extensively revised;
- issues around rooms where anaesthetic agents are used are addressed;
- airflow rates are more tailored to the applications to take advantage of new fan and control technology and so reduce energy consumption;
- revised air quality and filter standards are given;
- new and emerging technologies are catered for;
- advice is given on installation standards and the appointment of an independent validator;
- more detailed information is given on the commissioning process;
- validation acceptance standards and methodology has been completely revised;
- routine inspection and maintenance guidance has been revised and updated.

Net Zero Carbon

Scottish Health Technical Memorandum 03-01 supports UK legislation to bring all greenhouse gas emissions to net zero by 2045, and promotes sustainable methods of ventilation in healthcare facilities.

SHTM's core principle is that the default method of ventilation should as far as possible be natural ventilation followed by mixed mode (natural with mechanical ventilation), with mechanical ventilation being the last option.

The energy consumption of ventilation systems should be further minimised by specifying solutions with the lowest lifecycle environmental cost. The basic objective of energy-saving strategies in this SHTM is to provide the required ventilation service using the minimum energy. To this end, Scottish Health Technical Memorandum 03-01 recommends switching a system "off" when not required to be the most energy-efficient policy. If the system is needed to maintain a minimum background condition, reducing its output by "setting back" to the minimum necessary to achieve and maintain the desired condition is the next best option.

Fans represent an enormous potential for energy savings to reduce carbon emissions, as they are among the largest single users of energy (they use approximately 40% of all electricity in ventilation systems). The European Regulation 1253/2014, implementing the Energy-related Products (ErP) Directive, has significantly reduced the power to drive fans. Accordingly, Scottish Health Technical Memorandum 03-01 recommends using electronically commutated fans, as these have been proven to be the most energy-efficient, while also advising that belt-driven fans should no longer be installed.

There have been many legislative changes aimed at reducing energy consumption and technical advances that have increased operational efficiency. This revised SHTM incorporates those changes and has amended many of the design parameters for healthcare ventilation. Designs that are simply repeated from previous installations designed to superseded standards and guidance will not meet the revised energy or operational standards and will not produce a compliant result.

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1. Introduction

The needs of the building occupants

1.1 Ventilation is used extensively in all types of healthcare premises to provide a safe and comfortable environment for patients and staff and control odours. More specialised ventilation is provided to help reduce airborne infection risks in areas such as operating departments, critical care facilities, isolation rooms and primary patient treatment areas.

1.2 The Health and Social Care Act places a duty of care on healthcare providers. Increased health risks to patients will occur if ventilation systems do not achieve and maintain the required standards. The link between surgical site infection and theatre air quality has been well established. If the ventilation plant has been installed to dilute or contain harmful substances, its failure may expose people to unacceptable levels of risk. Proven breaches of the statutory requirements can result in prosecution and may also give rise to a civil suit against the operators.

The building environment

1.3. Healthcare buildings are visited and used by large numbers of people. Many will be unwell or anxious so a well-ventilated environment with a fresh feel and an absence of noxious odours is essential.

1.4 Ventilation may also be installed:

- to ensure compliance with highly regulated quality assurance requirements of items processed in pharmacies and central decontamination units;
- to protect staff from airborne microorganisms and toxic substances (for example, in laboratories and anaesthetic rooms);
- to contain the spread of smoke between fire compartments as part of the fire strategy.

1.5 Healthcare buildings are continuously occupied, intensively used and because of the specialised nature of the facilities it may be extremely difficult to provide the service elsewhere if the ventilation fails. In order to ensure continuity of service, ventilation systems should be designed and installed so that they can be quickly and easily maintained. The resilience of the proposed system in the event of service outage should also be considered.

1.6 The ventilation of healthcare facilities consumes a significant portion of their energy load, so wherever possible natural ventilation is the preferred option. Where mechanical ventilation is used, sustainable design concepts allied to good-quality installation and the provision of controls that maintain the desired environment when the facility is in use will result in the minimum energy input for the maximum benefit.

Airborne risks to staff

1.7 Most healthcare staff are no more at risk from airborne hazards when at their workplace than they are when not in a healthcare environment; however, certain groups as detailed below may be exposed to a variety of airborne contaminants.

- staff who administer anaesthetic agents or who work in areas where they are routinely used will be at risk of casual exposure to these agents;
- staff who routinely work in areas where they may come into close contact with patients who have respiratory symptoms will be at risk of exposure to the microorganisms causing the symptoms;
- staff who routinely work in areas where they may come into close contact with patients that have skin lesions, an infectious disease or a dermatological condition will be at risk of exposure to the microorganisms causing the condition;
- staff who routinely process pathology specimens;
- staff who decant, mix and/or process chemicals used as reagents for the setting or processing of pathology specimens;
- staff who harvest organs, tissues and specimens at a post-mortem;
- staff who handle drugs or the components of drugs;
- staff who pre-clean used scopes, surgical instruments and equipment prior to decontamination;
- staff who may be routinely exposed to airborne hazards listed in EH40 issued under the Control of Substances Hazardous to Health Regulations (COSHH) (for example, woodworking dust, welding fumes, chemical vapours).

1.8 A well-designed ventilation system can mitigate the airborne risks to staff. It should:

- supply sufficient unvitiated air to dilute the possible contaminants;
- have air terminals located to efficiently scour the ventilated space;
- move the air from the clean to the less clean space and/or out of the building;
- supply the air at high level and remove it at low level so that the breathing zone of staff is in a clean airflow path.

1.9 Adoption of these principles will be sufficient to control the general risk to the staff identified above in their particular working environment. More specific airborne hazards should be captured at source and removed by local exhaust ventilation (LEV) systems provided under the COSHH Regulations (see paragraphs 3.3–3.5).

Airborne risks to patients

1.10 In general terms an environment that is satisfactory for staff will be satisfactory for patients. There are, however, exceptions as below:

- intensive treatment units of any type;
- haematology/oncology units;

- transplant units and units treating patients that have had their immune system compromised;
- bone marrow transplant units (BMT);
- burns units;
- cystic fibrosis units;
- operating theatres.

Patients being treated in these areas will need an environment supplied with good-quality filtered air and that is maintained at a positive pressure with respect to surrounding areas

Note: Patients who are particularly at risk from airborne microorganisms will normally be placed in an isolation room or suite that is maintained at a positive pressure. Patients who have a condition that could be transmitted to others are normally placed in a negative pressure isolation suite. When the patient's exact condition is unknown they may be placed in a neutral pressure (PPVL) isolation suite (see Health Building Note 04-01 Supplement 1 – 'Isolation facilities for infectious patients in acute settings for detailed guidance).

1.11 A more general airborne risk will result from poorly designed and constructed air handling units (AHUs) that allow water to stagnate inside; they can then become a source of microorganisms such as Legionella. If their intake is badly sited or housekeeping in the area is poor, fungal spores such as aspergillus can be drawn in. The ventilation system will then become a means of spreading these microorganisms and fungal spores around the healthcare building.

1.12 All ventilation systems should conform to the principles set out in the Health and Safety Executive's (HSE) Approved Code of Practice and guidance document HSG274 'Legionnaires' disease: the control of Legionella bacteria in water systems' and Scottish Health Technical Memorandum 04-01 – 'Safe water in healthcare premises'.

Specialist equipment environment

1.13 Imaging and other non-invasive scanning equipment will require stable environmental conditions to stay within calibration and provide accurate repeatable results. Health Building Note 06-01 and Health Building Note 10 (2021) give detailed guidance and the equipment manufacturers should be consulted.

Note: Health Building Note 26 – 'Facilities for surgical procedures' (2004) and Health Building Note 10-02 – 'Facilities for day surgery units' (2007) are under revision at the time of writing and will become Health Building Note 10-01 once updated.

Health Building Note 06-01 (2001) on diagnostic imaging and interventional radiology is also under revision at the time of writing.

Medicinal products environment

1.14 Pharmacists are required to ensure that any manufacture or preparation activities involving medicinal products undertaken in their units conform with the requirements of the Medicine Act. Processes must be carried out in a suitable facility usually termed an aseptic preparation facility. The quality of air supply and design of the ventilation cascade are essential to ensure a suitable environment for the activities undertaken.

Fire and smoke control fundamentals

1.15 Scottish Health Technical Memorandums 81 to 87 (including sub-parts) are the base documents for fire aspects. When designing a ventilation system, a fire and smoke control strategy should be developed that is relevant to the site and its function. The fire and smoke strategy should take account of the planned activity within the area, the type of patient present, staff-to- patient ratio and treatment being delivered (see also Chapters 5 and 7).

1.16 When ventilation systems are originally designed, they will conform to an agreed fire strategy. This will determine the compartmentation, provision of fire-rated ductwork, fitting of sprinklers, the siting of fire and smoke dampers and an agreed control action for the ventilation in the event of a fire. The agreed fire and smoke control strategy must be clearly set out as part of the design specification.

1.17 The fire regulations require that, if ventilation ductwork penetrates the fabric of a building, it should be designed and installed to contain the spread of fire (see Health Technical Memorandum 05-02 – 'Guidance in support of functional provisions for healthcare premises' for further guidance).

1.18 If a ventilation system is upgraded or altered to suit a change of use, it will be necessary to reassess the fire strategy.

1.19 It is management's responsibility to ensure that the fire strategy applied during the design and installation of a system is not reduced during the subsequent operation and maintenance of the equipment.

1.20 The number and location of fire and smoke dampers can be problematic. Fire- rated ductwork within fire zones will reduce the need for fire and smoke dampers. It will eliminate the need to provide access for routine damper testing and the infection control problems associate with reversed airflow paths resulting from damper failures and nuisance tripping (see also Chapter 7 for ventilation control in the event of fire).

Note: In developing a fire and smoke containment strategy the design of ventilation for infection control cannot be ignored. Over-compartmentation and poorly chosen fire lines can prevent air moving from clean to less clean areas and thus increase the infection risk. This can be a particular problem in operating departments where the desire to create a protected escape route can be at odds with the need to cascade air through a suite of rooms and out into a corridor in order to control the airborne infection risk.

2. The User Requirements

2.1 Patient treatment falls into four basic categories:

- surgical procedures – physical interventions to diagnose, repair, remove or rebuild damaged or infected tissue;
- medical care – the administering of drugs or various forms of practical, non-invasive treatment to diagnose, cure or reduce the severity of an infection or condition;
- mental health – the use of counselling, often in conjunction with drugs, to control or alleviate abnormal behavioural or false perception issues in patients;
- palliative care – treatment to temporarily or partially relieve or mitigate long-term conditions;

In all cases a patient may require treatment in one or more of the categories as either an in-patient or an out-patient.

Surgical procedures

2.2 It is thought that up to 25% of infections that occur as a result of a surgical intervention are caused by the airborne route. The source of these infections are predominantly as a result of airborne microorganisms, typically skin scales, liberated during the surgical procedure becoming airborne and landing in the wound or on surgical instruments. These then become a means of inoculating the patient with the contaminant. There are five possible routes that may result in airborne infections:

- skin scales liberated by the surgical team during the procedure;
- organic material liberated from the patient as a result of the procedure;
- microorganisms remaining from a previous use of the space becoming airborne;
- airborne microorganisms liberated outside of the space entering during the procedure;
- microorganisms in the supply air from a ventilation system that has been contaminated with biological material.

2.3 The level of airborne organic material present or biological burden (bioburden) is typically defined in terms of the number of colony forming units (cfus) present at the wound site during the procedure. It will be dependent on:

- the number of persons present;
- the completeness and effectiveness of their gowning;
- the duration of the procedure;
- the type of procedure;
- the use of air-driven power tools;
- the extent to which a patient contributes to the bioburden in the space;

- the general cleanliness of the space;
- the discipline of the surgical team;
- the measures that have been taken to prevent or control contaminants from outside sources entering the space;
- the quality and volume of the incoming supply air;
- the efficiency of the incoming air to “scour” the space;
- the means of removing contaminated air from the space.

2.4 Good surgical discipline, effective patient preparation, the cleanliness of the space and control of the entry and exit of personnel during the procedure will all contribute to reducing the bioburden present.

2.5 A well-designed ventilation scheme that provides a suitable quality of air and efficiently scours the space will further reduce the bioburden. If the ventilation maintains the space at a positive pressure to adjoining areas, the risk of contaminants originating outside of the space entering will be reduced.

2.6 In addition to controlling the bioburden, the ventilation should provide comfortable conditions for the staff and patient.

2.7 The ventilation system should also control the risks to staff from anaesthetic agents and other hazardous fumes and emissions typically found in surgical facilities (see paragraphs 1.10–1.12).

2.8 Minor procedures may be carried out in a treatment room or at the bedside so surgical procedures are not exclusive to the operating department. (See Humphreys et al (2012) for further guidance on facilities for minor surgical procedures and minimal access interventions).

Medical care

2.9 In general the main requirement will be to ensure that staff and patients are kept in comfortable conditions.

2.10 There are specific instances where staff can be at risk of contracting an illness by the airborne route from a patient. This is the case in infectious disease units where the ventilation will be designed to maintain the unit and individual patient rooms at negative pressure relative to adjacent areas. This will protect persons outside of the unit from infection by the airborne route but not staff entering and working in the unit, who may need to take additional precautions to protect themselves.

2.11 The opposite problem occurs when patients are neutropenic, that is, they have a reduced or extremely low resistance to infection. They are then at risk of infection by the airborne route from other persons such as staff and visitors. This will be the case in cancer/oncology units, critical care areas, and bone marrow and general transplant units. The ventilation in these areas will need a higher air quality and be set to maintain a positive pressure to adjacent areas.

Mental health

2.12 Any specific patient needs should be assessed and addressed. The main requirement will be to ensure that staff and patients are kept in comfortable conditions (see comments on other types of healthcare facility in the Executive Summary).

2.13 The fire risk may be considered more likely and additional steps may need to be taken to control it.

Palliative care

2.14 The main requirement is to ensure that staff and patients are kept in comfortable conditions. Temperature control may be more stringent for patients with long-term and/or end of life conditions (see the Executive Summary for further information).

2.15 Difficulties with evacuating patients in the event of fire may need to be considered.

Diagnostic and support services

Imaging and Interventional imaging

2.16 There are major advances in diagnosis and minimally invasive treatment involving imaging. It may be necessary during these invasive or non-invasive procedures to provide sedation or general anaesthesia to help with anxiety or pain. This may involve the use of inhaled anaesthetic agents and/or nitrous oxide (N2O). Staff working in these areas may be exposed to these anaesthetic agents when they are administered or subsequently when they are exhaled as the patient is recovered.

2.17 A similar situation occurs in maternity units, where a mixture of nitrous oxide and oxygen (N2O/O2) (Entonox) is used as an inhaled analgesic.

2.18 In both of the above cases ventilation should be designed to provide a clean airflow path and dilute any casual spillages of the gas. This approach will help control the casual exposure of staff to the anaesthetic agent (see paragraphs 3.3–3.5).

Post-mortem and pathology

2.19 Staff who harvest organs and specimens at a post-mortem and place them into preservative solutions may be exposed to the microorganisms present and fumes from the preservative.

2.20 Staff who section organs and prepare specimens for analysis may be exposed to the microorganisms present and the chemicals used for staining and fixing the specimens.

2.21 In both of the above situations local exhaust ventilation (LEV) in the form of downflow benches, safety cabinets and fume cupboards need to be provided to control the risk.

Pharmacy

2.22 Exposure to the active ingredients of drugs represents a hazard to pharmacy staff who are involved in their production. These activities are carried out in an aseptic

preparation facility to ensure that the drugs themselves are not contaminated. The actual production typically takes place inside an isolator so that there is a physical barrier between the hazard and the operator.

2.23 Alcohol sprays are used and staff exposure may be controlled by the provision of downflow LEV systems to remove the hazard.

2.24 Comfortable conditions are essential for staff working in preparation facilities as they need to be fully gowned, and entry and exit is restrictive.

Decontamination facilities

2.25 Staff may be exposed to airborne biological material and chemicals when handling and processing used scopes, surgical instruments and equipment as part of the decontamination process. The ventilation should provide a clean airflow path to control staff exposure. The quality, quantity and flow pattern of the air are also critical to the protection of the decontaminated items.

Estates and facilities

2.26 Staff may be engaged in welding, soldering, machining wood or paint- spraying. They may also decant chemicals in quantity (for example, for boiler treatment or hydrotherapy-pool dosage). LEV systems are routinely used to control the hazards arising.

3. Legal Requirements – Applicable Legislation

Health and Safety at Work etc. Act

3.1 The Health and Safety at Work etc. Act 1974 is the core legislation that applies to ventilation installations. As these installations are intended to prevent contamination, closely control the environment, dilute contaminants or contain hazards, their very presence indicates that potential risks to health have been identified.

3.2 The Act places a duty of care on ALL to provide and maintain a safe workplace. This includes designers and suppliers of goods or services. Those trading as competent designers or suppliers are therefore liable to provide outcomes that meet the client's needs and are without hazard to staff, patients and others who may be affected by the work activity.

Control of Substances Hazardous to Health Regulations

3.3 The Control of Substances Hazardous to Health (COSHH) Regulations 2002 place upon management an obligation to ensure that control measures are in place to protect their staff and others affected by the work activity. These methods may include both safe systems of work and the provision of a specialised ventilation system. In laboratories the requirements are often met by the provision of fume cupboards and microbiological safety cabinets.

3.4 Where specialised ventilation plant is provided as part of the control measures, there is a statutory requirement that it be correctly designed, installed, commissioned, operated and maintained. The local exhaust ventilation (LEV) section of COSHH requires that the system be examined and tested at least every 14 months by a competent person (P601 certified) and that management maintain comprehensive records of its performance, repair and maintenance.

3.5 Certain substances have workplace exposure limits (WELs) as set out in the Health and Safety Executive's (2005) Guidance Note EH40 – 'Workplace exposure limits'. This contains the list of workplace exposure limits for use with the Control of Substances Hazardous to Health Regulations 2002 (as amended). If specialised ventilation systems are provided in order to achieve these standards, they will be subject to the COSHH Regulations.

Workplace (Health, Safety and Welfare) Regulations

3.6 These state that:

- all enclosed workplaces must be ventilated by natural or artificial means;
- any plant provided under this legislation must include an effective device to give an audible or visual warning of plant failure where necessary for health and safety;
- the Regulations require that ventilation systems are maintained in an efficient state, in efficient working order and in good repair.

The Building Regulations

3.7 Approved documents L and F:

- apply to domestic and non-domestic buildings;
- clarify satisfactory methods of providing ventilation and give ventilation rates;
- set minimum standards for:
  - the protection of the supply position;
  - precautions against *Legionella;*
  - the purity of recirculated air;
  - access for service and maintenance;
  - documentation and proof of performance;
  - energy performance.

Health and Social Care Act 2008 (Regulated Activities)

Regulations 2014

3.8 Regulation 12(2)(h) of the Act decrees that registered providers must assess the risk of, and prevent, detect and control the spread of, infections, including those that are healthcare associated.

3.9 Appropriate standards of cleanliness and hygiene should be maintained in premises used for the regulated activity. DH (2015) issued 'The Health and Social Care Act 2008 Code of Practice on the prevention and control of infections and related guidance' (the HCAI Code of Practice), which contains statutory guidance about compliance with regulation 12(2)(h).

3.10 Regulation 15 of the Act states that:

All premises and equipment used by the service provider must be:

- clean;
- secure;
- suitable for the purpose for which they are being used;
- properly used;
- properly maintained; and
- appropriately located for the purpose for which they are being used.

The registered person must, in relation to such premises and equipment, maintain standards of hygiene appropriate for the purposes for which they are being used.

Note: The "registered person" means, in respect of a regulated activity, the person who is the service provider or a registered manager in respect of that activity. A "service provider" means a person registered with the CQC under Chapter 2 of Part 1 of the Health and Social Care Act 2008 as a service provider in respect of that regulated activity.

The Medicines Act 1968 and Human Medicines Regulations 2012

3.11 Pharmacy aseptic preparation facilities should conform to the requirements of EudralLex – Volume 4 – Good Manufacturing Practice (GMP) guidelines or equivalent UK legislation, and the requirements of the UK Medicines Inspectorate (MHRA) if a licensed manufacturing unit.

3.12 There are specific requirements under the Medicines Act 1968 to maintain accurate records of plant performance, room conditions and maintenance events. Such records would need to be preserved for up to 25 years as part of a quality assurance audit trail.

3.13 Specialised ventilation plant installed in laboratories dealing with research, development or testing, whether involving drugs, animals or genetically modified microorganisms, may be subject to legislation regarding their operation in addition to that mentioned above.

Indoor air quality (IAQ)

3.14 There is increasing awareness that IAQ has an important impact on health and well-being. The World Health Organization and the Royal College of Paediatrics and Child Health (2020) have produced papers on the importance of IAQ, and the National Institute for Health and Care Excellence (NICE) (2020) has issued guidelines for domestic environments. Indoor and outdoor sources of contaminants are important contributors to IAQ, and designers of ventilation systems should consider both. The Department for Environment, Food and Rural Affairs (Defra) gives data for outdoor air quality by postcode for the UK. This enables designers to choose suitable filter grades by location and application (see the Specialised Ventilation for Healthcare Society's (2018) SVHSoc.02 – 'Change in air filter test and classification standards' for further information).

Other relevant standards and sources of guidance

3.15 The Chartered Institution of Building Services Engineers (CIBSE) Guides and associated published documents (TMs) are the principal source of general ventilation specification and design guidance.

3.16 ISO 14644 and ISO 17141 provide basic information on cleanrooms used in pharmacy preparation facilities and inspection, assembly and packing (IAP) rooms for the processing of medical devices in central decontamination units.

3.17 BS EN 15780 applies to both new and existing ventilation and air-conditioning systems and specifies the assessment criteria of cleanliness and cleaning procedures of these systems.

3.18 HSG 258 issued by the Health & Safety Executive provides guidance on the design of local exhaust ventilation (LEV) systems.

3.19 Other relevant guidance is listed in the References.

3.20 The Board and their supply chain must ensure that the competence of all parties is considered at the point of their introduction and on an ongoing basis. The philosophies that are included in the HSE leaflet INDG368 (current revision), "Using Contractors" should be adopted. In addition, the outputs from the "Setting the Bar" report should be adopted as they are introduced through legislation. Evidence that the recommendations of "Setting the Bar" are being implemented in advance of the legislation would be considered to be good practice, particularly for high risk buildings. BSI Flex 8670 “Built environment. Core criteria for building safety in competence frameworks. Code of practice” should also form part of the project planning.

Note: In all cases the most recent version of any legislation, regulation, standard or guidance document should be consulted.

4. The Design and Specification Process

Project brief

4.1 The ventilation aspects of a contract will normally form part of a wider project to provide, upgrade or replace a healthcare facility. It is important that the ventilation designer closely liaises with the architect, as the layout of the facility and the adjacency of spaces within it will have a major impact on the ability of the ventilation system to achieve the client's requirements. All new major projects are required to use building information modelling (BIM) in order to ensure a coordinated design and provide information for the subsequent operation and possible future development of the facility.

4.2 The Building Services Research and Information Association (BSRIA) has produced an approach to project delivery known as "Soft landings" (BSRIA, 2018). It aims to ensure that the client's success criterion is kept in focus during the inception and briefing, design, construction, pre-handover, initial aftercare and extended aftercare phases of a project. It is strongly recommended that the client and project contractor adopt this approach.

Basis of design

4.3 This SHTM assumes that designers will be familiar with current CIBSE guidance and will use it as the basis for specifying and designing ventilation systems. However, the actual guidance contained in this SHTM may differ from the CIBSE guidance due to healthcare-specific issues and will take precedence over the CIBSE guidance where there are conflicts.

Note: Scottish Health Technical Memorandum 03- 01 Parts A and B need to be read and considered in their entirety when specifying and designing ventilation systems to ensure that the end result will comply with the client's needs.

Ventilation Safety Group (VSG)

4.4 The management of the ventilation systems of a healthcare provider should be overseen by a Ventilation Safety Group (VSG). The VSG should have clearly defined roles and responsibilities, be part of a healthcare organisation's governance structure and report to the "Designated Person" at Board level. It should be led and chaired by a person who has appropriate management responsibility, knowledge, competence and experience (for example, the Designated Person). (See Chapter 2 in Part B of Health Technical Memorandum 03-01 for further information.)

4.5 The VSG should be a multidisciplinary group and should typically comprise:

- an Authorising Engineer/independent adviser for ventilation (AE(V));
- an Infection Prevention and Control person;
- the Authorised Person(s) for ventilation services (AP(V));
- estates (operations and projects) staff;

- clinicians and specialist departments (for example, theatres, critical care areas, pharmacy, medical microbiology, nursing, decontamination);
- personnel from the finance department with accountability for capital and revenue evaluation;
- other stakeholders as appropriate;
- coopted expertise (for example, ventilation designers, consultants and suppliers).

4.6 The VSG remit should be to assess all aspects of ventilation safety and resilience required for the safe development and operation of healthcare premises. It should inform the following areas:

- the design process for new healthcare premises;
- the design process for modifications to existing premises;
- the commissioning and validation process;
- operational management and maintenance;
- annual verification and performance testing;
- prioritising the plant replacement programme;
- decommissioning and removal of redundant equipment.

Note: Where estates and facilities provider services are part of a contract (including PFI), it is essential that these providers participate fully in all those aspects of estate and facilities management that can affect patients. This includes responding to specific requests from the VSG, which may be in addition to relevant guidance and documentation.

4.7 It is important that decisions affecting the resilience, safety and integrity of the ventilation systems and associated equipment are not taken without the agreement of the VSG. The VSG should ensure that appropriate expertise and competence is available when making such decisions.

4.8 Whenever significant building work is undertaken; the VSG should consider its effects on the existing ventilation system air intakes. These may need to be protected from airborne dust during construction by the fitting of temporary additional filtration. There will also be a need to identify any risks to construction personnel who may be working in the vicinity of extract air discharges.

4.9 When construction or alteration work is undertaken inside an occupied building, its effects on the occupiers should be considered. The VSG should be consulted, and they may require that the area be sealed off from the occupied parts of the building and that a temporary extract be provided to maintain the worksite at a negative pressure to prevent the spread of dust into the rest of the building.

Derogations and alternative design strategies

4.10 Any derogations or alternative design strategies from this guidance should be subject to the scrutiny and agreement in writing by the VSG. The reason for the derogation or alternative design strategy and limits to its application should be recorded.

4.11 Designers proposing a derogation or alternative design strategy should be able to supply a body of evidence that their proposal will provide a degree of safety no less than if the guidance in this document had been followed.

Definition of clinical areas and critical systems

4.12 Healthcare ventilation may serve clinical or non-clinical areas of the estate:

- clinical areas are defined as spaces within the building where surgical or medical treatment is administered to patients. This includes patient bedrooms;
- non-clinical areas are defined as spaces where patients may be present but are not under direct treatment. It also includes staff and healthcare services areas.

4.13 Certain clinical and non-clinical areas within a healthcare establishment are considered critical to its ability to provide healthcare. Typically, ventilation systems serving the following are considered critical:

- operating suites of any type including rooms used for image-guided surgical procedures and their recovery areas;
- airborne isolation facilities, both source and protective;
- critical care areas and neonatal units;
- invasive treatment, endoscopy and bronchoscopy rooms;
- containment level 3 laboratory;
- pharmacy aseptic preparation facility;
- inspection, assembly and packing (IAP) room in a central decontamination unit;
- MRI, CAT and other types of emerging imaging technologies that require particularly stable environmental conditions to remain within calibration;
- any system classified as an LEV system under the COSHH Regulations;
- any other system that clearly meets the definition that “a loss of service from such a system would seriously degrade the ability of the premises to deliver optimal healthcare”.

Note: If any doubt exists about whether a system falls within this definition, the VSG should be consulted regarding the risk to patient safety and business continuity.

Resilience and diversity

4.14 When planning the ventilation of healthcare facilities, it is important at the outset to consider how the service will be delivered if the installed ventilation system fails or the area served has to close due to the effects of fire, flood or an outbreak of

infection. The loss of power, primary heating or cooling medium, or an integrated control system can cause the loss of ventilation to an area, so subsystem resilience is an important consideration.

4.15 Resilience in critical healthcare areas can be provided by splitting the ventilation load between two or more AHUs and/or employing a design that allows two or more AHUs to feed a common plenum with isolation dampers on individual branches to each critical zone. (Note that it is not proposed that duplicate back-up units be provided.) As an example, a large critical care area (CCA) level 2 or 3 could be split into two sections with an AHU for each. A small CCA cannot easily be split, so a decant area with a suitable level of ventilation should be pre-designated.

4.16 Diversity can be achieved by having several facilities each served by its own AHU. As an example, in an operating department, if each theatre suite is fed from its own dedicated AHU, the loss of one suite, while inconvenient, will not shut the department. The same scenario applies to isolation rooms if several of them are each independently ventilated (see Health Building Note 04-01 for further information).

Note: Providing twin ventilation fans in an AHU delays the time at which the system needs to be completely shut down in the event of a fan failure. It does not in itself provide resilience in terms of delivering healthcare (see Chapter 9 for further guidance).

New build facilities

4.17 New build healthcare facilities must be fully compliant with the requirements of all legislation in force at a date agreed when signing the contract. They should comply with the guidance contained in the current SHTM unless a derogation has been agreed with the VSG (see paragraphs 4.10 and 4.11).

Assessment of service requirements: selection of design criteria

External design conditions

4.18 The most accurate data that is available for the summer and winter conditions at the site should be used. The Meteorological Office supplies data for the United Kingdom; data is also available from CIBSE and other sources. It is essential that the designer agrees with the client as to which source of data is used and the design risk associated with the chosen external design conditions.

Note: It is essential to design to future climate projection to ensure design temperatures are maintained even in the event of prolonged heatwave conditions. CIBSE (2014) publishes design summer year weather files morphed to reflect future climate change.

4.19 Local adjustments for height above sea level, exposure factor, or other local climate peculiarities should be made as appropriate.

Internal design conditions

4.20 The design conditions selected within patient areas should strike a balance between the comfort requirements of staff and patients, who often have very different levels of clothing and activity.

4.21 Recommendations for the operative temperature and humidity of individual spaces are given in Activity Data A-Sheets (see Chapter 8 for specific requirements). Particular departmental requirements are given in the respective SHPN/HBN and room data sheets. However, the determination of the room environment must be driven by the patient cohort plus the range of procedures envisaged for that room.

Minimum fresh air requirements

4.22 In general areas and wards within healthcare premises, odour control is the main reason for providing ventilation. In the absence of other guidance, 10 L/s/person should be taken as the minimum ventilation requirement. Healthcare ventilation systems will normally be “full fresh air” either by natural, mixed mode or mechanical means, with energy recovery from the extracted air.

4.23 In non-clinical areas recirculated air systems may be considered. At least 20% of the recirculated air should be fresh. Additional filtration will be required to remove airborne particulate contamination and, if necessary, odours. This will affect running and maintenance costs and, given the high ErP rating of heat recovery devices, it will be necessary to prove that recirculating the air will be more energy- efficient overall.

Note: Ultra clean ventilated (UCV) operating theatres use air recirculation. The fresh air requirements of this specific application are given in Chapters 8 and 9.

4.24 Smoking is generally not permitted in healthcare premises, so no allowance need be made. Reference should be made to local national policy guidance.

4.25 In treatment and support areas the overriding requirement may be due to airborne infection control, hazard containment, the stability of specialist equipment or relate to a specific department’s function. Each case should be considered independently in order to determine the overriding minimum requirement for ventilation (see Chapter 8 for specific guidance).

Limiting supply air conditions

4.26 For most applications in healthcare buildings, it is the temperature differential between the supply and room air, rather than the actual temperature of the supply air, which is the critical factor. The maximum recommended supply-to-room air temperature differential is:

- summer cooling: 7 K
- winter heating: 10 K

4.27 Room air humidity should be kept below 70% in order to minimise risks associated with condensation and mould growth. There is no lower limit in unoccupied spaces.

4.28 Some types of diagnostic imaging technologies require close control of both temperature and humidity as well as the rate of change of conditions to ensure clarity of the image and accuracy of the data generated. The manufacturer’s guidance should be followed.

Air purity

4.29 In healthcare premises, the standard of filtration will depend on the activities within the occupied spaces. Except for special areas (for example, manufacturing pharmacies), the requirement for aerobiological needs is not stringent and filtration is only required to:

- maintain hygienic conditions for the health and welfare of occupants, or for processes such as centralised food preparation facilities;
- protect finishes, fabrics and furnishings – to reduce redecoration costs;
- protect equipment either within the supply air system – to prevent blocking of coils – or in the space itself to prevent dust accumulation

4.30 Given that almost all viable particles will originate from the occupants of a space and not from the incoming air, dilution is the more important factor aerobiologically. Therefore, for general areas an ISO ePM 2.5 ≥55% filter may be suitable. More critical areas would require an ISO ePM1 ≥50% filter. Efficiency or high-efficiency (EPA or HEPA) filters will only normally be required in ultra-clean systems, designated “cleanrooms” (see Chapter 9 for specific information) or for some immune-suppressed patient areas

4.31 In some inner-city areas the local airborne particulate level may be particularly high. In those special cases filters to ISO ePM1 ≥50% may be required to achieve the required indoor air quality. (See Defra’s website and the Specialised Ventilation for Healthcare Society’s (2018) SVHSoc.02 – ‘Change in air filter test and classification standards’.)

Humidity control requirements

4.32 Close control of humidification was originally required for some healthcare applications (for example, operating theatres) in order to control the risk associated with the use of flammable anaesthetic gases. The use of such gases has now ceased.

4.33 Providing humidification is expensive in terms of plant, running costs and maintenance, and therefore its use should be restricted to where it is necessary for physiological or operational reasons (see Chapter 8 and associated SHPNs/HBNs).

4.34 In general terms the humidity within an occupied building or space will naturally float between 30% and 70% RH (relative humidity). Humidity should not be allowed to rise above 70% at any time but there is no need to maintain a background minimum level when the building or space is unoccupied.

Maximum noise levels

4.35 Noise will be generated in an air distribution system by the fan, ductwork fittings, dampers and grilles. The specified maximum noise level will depend on the activities within the occupied spaces.

4.36 Attenuation should be incorporated into the ductwork system or plant arrangement as necessary to reduce noise from fans and plant items in order to achieve the acceptable limits within the rooms at the design airflows.

4.37 Plant room noise level from fans when starting up or running should not be greater than 80 dB(A), and should be reduced where the plant is near to departments sensitive to noise.

4.38 Attention should be given to the reduction of tonal components. High tonal components from air diffusers etc. can seriously disturb concentration over longer periods even when the overall noise level is low. Broadband noise causes less annoyance.

4.39 The values recommended in Table 1 are for the total noise environment of space. In general, there will be noise transmitted into the space and noise generated within the space. The designer requires knowledge of the total hospital layout and operational policies, to assign acceptance magnitudes to all the possible noise sources, in order to arrive at the correct rating.

4.40 In Table 1 the overall noise level takes account of all internal and external noise sources. The noise level is the level measured with a sound-level meter in the unoccupied room, taking account of the external noise together with the noise generated by the ventilation system. The ventilation plant design noise level is that generated by the plant alone with no other noise source being considered. The levels suggested make recognised allowance for the ingress of environmental noise which will have to be considered in the overall design, that is, in specifying the attenuation of walls, partitions, ceilings, etc.

Table 1: Interior Noise Level

Area	Room: overall noise level – dB(A)	Ventilation design value – dB(A)
Operating department all rooms including preparation, anaesthetic, scrub and utility, interventional and diagnostic imaging departments – all rooms	48	Operating department all rooms including preparation, anaesthetic, scrub and utility, interventional and diagnostic imaging departments – all rooms
UCV operating theatre and adjacent open- plan scrub only	53	–
Treatment rooms Consulting rooms Sleeping areas/rooms Recovery rooms	35	Treatment rooms Consulting rooms Sleeping areas/rooms Recovery rooms
Sanitary facilities	45	40
Aseptic preparation facility	45	40
Industrial areas	50	45
Circulation waiting areas	50	45
Plantrooms	85	80

4.41 The recommended criterion is measured as the “A” weighted sound pressure level expressed in decibels, which should not be exceeded for more than 10% of the time. See Scottish Health Technical Memorandum 08-01 – ‘Acoustics’ for further information.

4.42 The designer should also consider noise escaping to the external environment and this should not be unacceptable to occupants of adjacent buildings.

Calculation of building loads

Air infiltration

4.43 Air infiltration occurs due to a complex combination of wind pressure, thermal effects, location relative to other features and the construction standard of the building. The infiltration rate is governed by the size and number of doors and other openings in the building envelope and the complexity of internal air paths.

4.44 CIBSE guide TM52 provides information and formulae for the calculation of air infiltration in buildings. In all cases the requirements of the appropriate section of the current Building Regulations Part L (airtightness minimum requirements) must be met.

Summertime temperatures

4.45 To prevent overheating and avoid the future need for portable room air- conditioners, thermal modelling should be undertaken to ensure that internal temperatures in all areas do not exceed CIBSE Guide A guidance. Thermal modelling should be carried out whether the space is ventilated by natural, mixed mode or mechanical means. The modelling should be undertaken by a competent software user and take into account not only absolute values but also the time component.

4.46 Where thermal modelling indicates internal temperatures will exceed the recommended levels defined in CIBSE Guide A, additional measures should be explored to achieve compliance such as reducing solar and casual gains, improving building fabric performance, etc.

Peak heating load

4.47 Peak heating local calculations are necessary on all mechanical supply systems to establish the size of heater-batteries and subsequently the central plant. Note that with the introduction of the requirement to fit energy recovery set out in EU 1253, the heater-battery size will be reduced. If the energy-recovery value is ignored, the heater-battery and its control valve will be oversized and the system when put to use will be unstable and liable to hunt.

4.48 Where ventilation systems provide tempered air to spaces which have supplementary low pressure hot water (LPHW) to offset the building fabric losses, the AHU heating load should be calculated based on the external winter design temperature, the design internal air temperature, and the calculated total air volume (including a suitable allowance for leakage).

4.49 Where the ventilation system is the only means of heating a space, an increase in load equivalent to the calculated fabric heat losses from the space should be added to the ventilation load. A check of supply temperature difference should be made. If it exceeds that recommended in paragraph 4.26 the ventilation supply volume should be increased to suit.

Peak cooling load

4.50 In addition to the base data of airflow rates and temperatures, when calculating cooling loads, the designer should take into account:

- solar cooling loads;

- surface conduction cooling loads;
- internal gain cooling loads;
- air infiltration cooling loads;
- cooling loads due to high limit humidity control;
- method of control of internal conditions;
- fluctuations in internal temperatures.

Allowances must be made for all medical equipment in every space. Where the final item has not yet been selected, a unit that is reflective of the needs must be agreed with the stakeholders. A record must be included in the design documentation as to the unit which has been included in the design and the impact on all MEP systems of this unit. The stakeholders must have access to this data to ensure the compatibility of equipment and MEP systems can be checked against final medical equipment selections.

4.51 When the peak internal loads have been assessed and a suitable allowance made for non-coincidence, the supply temperature can be calculated.

4.52 Once the lowest required supply temperature of the air handling unit has been established, and an allowance made for temperature rise through the fan and ductwork (usually 1 K for low pressure systems), the off-plant enthalpy can be established from a psychrometric chart or table.

4.53 The cooling loads for all plant on the chilled water system should be calculated at each of the individual peak times in order to accurately establish the required (diversified) capacity of the chiller.

Note: Note that as with heating, the introduction of the requirement to fit energy recovery set out in EU 1253 means that the cooling-coil size will be reduced. If the energy-recovery value is ignored, the cooling coil and its control valve will be oversized and the system when put to use will be unstable and liable to hunt.

Annual energy consumption

4.54 The annual energy consumption of simple heating-only ventilation systems is simple to calculate, based on supply to external air temperature rise, and frequency of occurrence of external temperature data (see CIBSE Guide A).

4.55 Minimum air volumes are usually fixed by the room loads or fresh air requirements; however, the designer may increase airflow to some rooms or zones in order to balance loads, as detailed in paragraphs 4.63–4.68

4.56 The method of zoning and control can significantly influence energy consumption.

4.57 The nature of air-conditioning operation, that is, cooling and reheating for humidity or zonal temperature control, makes prediction of energy consumption very complex. It is imperative that these calculations are performed to ensure optimum energy efficiency.

4.58 The concept of load and plant operation charts is outlined in the CIBSE Guide TM52. The method requires the designer to establish the minimum and maximum loads on

all zones across the range of external temperatures between winter and summer design conditions. The total coil loads can be calculated taking account of the external air temperature and humidity plus the supply air conditions.

4.59 When all temperatures/enthalpies for all zones are plotted on the plant operation chart, set points and resetting schedules can be established. From this information, the outputs of individual heaters, coolers and humidifiers can be established at any given external condition. When those loads are computed against annual frequency of occurrence of external conditions as given in CIBSE Guide TM52, the annual energy consumption of individual elements, and thus the air-conditioning system, can be established.

4.60 In order to prevent surface condensation occurring, it is necessary to provide enough ventilation to maintain the maximum and ambient dew-point temperature below the lowest surface temperature, the coldest usually being the glazing.

4.61 Where this would require excessive ventilation levels, the designer should consider removal of the moisture at the source of the evaporation via an exhaust hood or similar device.

4.62 In intermittently heated buildings, it is necessary to consider the condensation risk at night set-back conditions as well as during normal operation. Calculation methods for this assessment are given in CIBSE Guide A.

Calculation of plant requirements

Air supply volumes

4.63 The minimum air supply volume for a room is determined by the greatest of:

- the minimum fresh air requirement;
- the air required to achieve the room differential pressure and provide open door protection at the key door;
- the minimum supply volume for the room load as determined by the maximum heating or cooling supply temperature differential;
- the desired air-change rate;
- the make-up air for a local extract (for example, cooker hood or LEV system).

Plant sizing

4.64 Once the design airflow has been established, the cross-sectional area of the air-handling unit can be calculated based on values given in Commission Regulation EU 1253/2014.

4.65 The fan duty should be calculated by adding the resistances of all elements that contribute to the pressure drop of the index circuit.

4.66 In order to establish the length of the AHU, it will be necessary to refer to manufacturers' literature, ensuring all necessary access panels and components are included as detailed in Chapter 9.

4.67 The designer should ensure that an allowance has been made for “dirty filter” conditions and confirm whether the fan pressure quoted is the total or static pressure.

4.68 Upon completion of the resistance calculation exercise, the designer should make allowances for calculation and construction tolerances as indicated below:

Total pressure loss margin:

- for leakage and balancing requirement =+5%
- for uncertainties in calculation = +5%

Combined total pressure loss margin =+10%.

Note: All installed ductwork whether new or reused should be subject to a leakage test on site prior to the application of any insulation. The leakage test should be to BESA DW144 but with a permissible leakage rate of not greater than 3%.

Refurbishment of existing facilities and fitting out shell schemes

4.69 When refurbishing existing facilities or fitting out “shell” schemes, every effort should be made to achieve full compliance with this SHTM and current Scottish Health Planning Notes (SHPNs). It is important that use of the space is revisited at this stage. Patient cohort, forms of treatment and all other stakeholder requirements must be compared to the capabilities of any existing system/plant and adjustments made to suit.

4.70 The physical constraints of the building may mean that some derogation in terms of layout and room dimensions are unavoidable, but it is vital that the infection control aspects, clean airflow paths, cascade of air from clean to less clean areas and fire and smoke requirements are not compromised and that the complete facility will be fit for purpose. The VSG should be consulted and agree in writing to any derogations.

4.71 A new AHU fully compliant with current standards will normally be required. The existing AHU should only be retained if it is not more than 10 years old and is (or can be made) fully compliant with current standards.

Note: The application of the ErP regulations may mean that new plant could be physically larger than that previously installed. If the replacement plant cannot be accommodated in the existing plant space, the plantroom may need to be expanded or a new plant space created. It may be that reconsidering how the ventilation load is determined, whether it can be shared, which type of AHU configuration will fulfill the design need, etc., will provide a satisfactory solution rather than just specifying like-for-like replacement plant.

4.72 The most commonly used original standard operating theatre design solutions from previous versions of this HTM have been revised and updated (see Appendix 7). They have been retained in this guidance as they will remain applicable to older theatre suites that are being refurbished within their original footprint. They may also be applicable where a pre-built “shell” is being fitted out.

Change of use of existing facilities

4.73 When a change of use of existing facilities is contemplated, the ventilation requirement should be completely revised to suit the new use (see paragraphs 4.63 and 4.69). All requirements must be agreed with the Ventilation Safety Group.

4.74 A new AHU fully compliant with current standards will normally be required. The existing AHU should only be retained if it is not more than 10 years old and is (or can be made) fully compliant with current standards.

4.75 If the ventilation load is to be increased or reduced and the existing system is retained, its output should be adjusted to suit. This will necessitate a recalculation of the heater and cooler loads and resizing of the control valves to match the new loads. It may also necessitate a change in fan size. Failure to carry out this exercise will carry an energy penalty and loss of control function.

4.76 The area/zone fire strategy should be reassessed to suit the new layout and purpose.

Computer-aided design (CAD) and building information modelling (BIM)

4.77 The design of new ventilation systems should be created using a CAD package, and the information generated should be incorporated into the BIM for the project. The client should have access to the BIM model as the project progresses; it will be transferred over to the client on completion (see paragraph 13.28 onwards)

5. Ventilation Strategies

5.1 In order to reduce energy costs and provide a more sustainable healthcare estate and support the declared zero- carbon target, ventilation selection should be as follows:

- first choice – natural ventilation;
- second choice – mixed mode ventilation;
- final option – mechanical ventilation.

Natural ventilation

5.2 Natural ventilation is usually created by the effects of wind pressure. It will also occur if there is a temperature difference between the inside and the outside of a building. The “thermo-convective” effect frequently predominates when the wind speed is low, and will be enhanced if there is a difference in height between inlet and outlet openings.

5.3 Ventilation induced by wind pressures can induce high air-change rates through a building, provided air is allowed to move freely within the space from the windward to the leeward side. However, in most healthcare applications, internal subdivisions will restrict or prevent this effect.

5.4 Current guidance restricts the opening of windows for safety reasons; also, as many designs are top-hung, their ability to permit natural ventilation is limited. Some types of window (for example, vertical sliding) can enhance single-sided air change by temperature difference, and these will improve the overall rate of natural ventilation in protected or sheltered areas where the effect of wind pressure is likely to be minimal.

5.5 Current healthcare building design philosophy suggests that windows are provided to allow light into and a view out of a healthcare building. Ventilation should be provided by purpose-made openings with appropriate consideration for thermal comfort and air quality. The airflow may need to be controlled by motorised dampers linked to temperature and/or occupancy sensors in the ventilated space.

Note: Natural cross-flow ventilation can provide reasonable air distribution for a distance of up to 6 m inwards from the external facade, provided that reasonably clear air paths are maintained. Beyond this distance – in areas where clear air paths cannot be maintained and in areas where high minimum air-change rates are specified – mechanical ventilation should be provided.

If natural ventilation is single-sided, it will usually only be effective for a 3 m depth within the space. Beyond that it should be supplemented by mixed- mode or mechanical ventilation.

5.6 With natural ventilation, it is almost impossible to maintain consistent flow rates and ensure that minimum ventilation rates will be achieved at all times. However, this variability is normally acceptable in non-clinical spaces such as office accommodation, staff areas, library/seminar rooms and dining rooms, and some

clinical areas such as level 0 and 1 care spaces and waiting and consulting rooms where risk of airborne infections is likely to be low. The design must still aim to achieve agreed limits for room temperatures and, for clinical areas, achieve the desired room air change rate with “thermo-convective” effect (at peak room temperature coincident with summer external design temperature). Where it is essential to achieve a minimum ventilation rate at all times, mixed mode or mechanical methods will be needed.

5.7 Constraints caused by a building’s shape and/or the functional relationships of specific areas will inevitably result in some measure of deep planning, thus reducing the opportunity for natural ventilation.

5.8 In all cases, for natural ventilation to be effective it will be necessary to take steps to reduce any solar gain to a minimum. Outdoor air-quality, excessive heat gain, indoor air-quality requirements or external noise are all factors that may limit or preclude the use of natural ventilation.

5.9 Further information can be found in Health Building Note 00-10 Part D – ‘Windows’, BS 5925 and CIBSE’s Applications Manual AM10 – ‘Natural ventilation in non-domestic buildings’.

Mixed mode ventilation

5.10 Mixed mode ventilation is an assisted form of natural ventilation. Fans are fitted in purpose-made damper-controlled ventilation openings. Alternatively, a separate draw- or blow-through ventilation unit may be installed. In both cases the dampers and fans are controlled by temperature and occupancy sensors to ensure a minimum airflow rate while taking advantage of natural ventilation effects when present.

5.11 Where natural or mixed mode ventilation is adopted with complex air paths, the designer should produce an airflow diagram in order to ensure correct provision of air-transfer devices. CIBSE’s Applications Manual AM13 – ‘Mixed mode ventilation’ gives guidance. Modelling of the airflows under a range of conditions should be undertaken to establish the airflow paths.

Mechanical ventilation

Central versus local plant

5.12 Mechanical ventilation is expensive so it should only be provided when the space being served requires close control of its environmental conditions.

5.13 If the ventilation loads throughout a department or building are in phase, or are not significant, a central plant with single zone control may be adopted. However, this is rarely the case, so the condition or quantity of supply air to different areas or zones of the building will be varied accordingly. This may be achieved by either providing individual plant to each zone or providing separate controls for each zone such as provided by a variable air volume (VAV) system. Where there is a high density of rooms with similar ventilation requirements in an area of a building or department, it is usually economical to combine them into a central system; however, the operational resilience should be considered.

5.14 In large buildings, a choice between a small number of large ventilation systems located in centralised plant areas, or a larger number of smaller locally distributed systems, may arise

5.15 Large distribution systems and their plant can have the advantage of lower capital costs, but because they operate to a fixed supply condition, reheating or cooling may be locally required which will reduce energy efficiency. The distribution system will require more space for vertical shafts. In general, very long runs of ducting should be avoided to prevent undue heat losses or gains, excessive leakage and difficulties in balancing during commissioning. As the pressure losses in the long runs will be greater and a higher initial static pressure will be required, this may lead to a more expensive class of ductwork.

5.16 Decentralised AHUs feeding multiple smaller distribution systems may be more expensive in capital costs but as they avoid long runs, large ducts and vertical shafts, this may reduce overall costs. They can provide a more robust service, as the failure of an individual system does not prevent the use of the rest of the building. Future refurbishment or replacement of AHUs is also simpler. See also Chapters 4 and 9.

Horizontal and vertical AHUs

5.17 AHUs may be configured as horizontal or linear units that are single or double-stacked in the case of combined supply and extract units. They may also be configured more compactly as vertical or cabinet-style units. Selection will be dependent on the plant space available and where the unit is to be located. Whichever style is selected, good access for service and maintenance is essential. See legal requirements in paragraphs 3.6 and 3.10.

Chilled beams

5.18 Active chilled beams can provide an energy-efficient means of controlling environmental conditions. They are, however, subject to increased maintenance requirements due to the need for regular cleaning if they are to remain working efficiently. Access for this will not pose problems in non-clinical and office areas, but in clinical areas and patient bedrooms, routine access will be a major problem in an operational hospital.

5.19 Chilled beams should not be installed in clinical areas without the agreement in writing of the VSG.

Note: Patient bedrooms are classed as clinical areas as treatment is often delivered at the bedside rather than in a designated treatment room.

5.20 Where chilled beams are installed in non-clinical areas, they should be positioned to ensure that cold draughts are avoided.

5.21 In order to avoid condensation on the beam coils and the potential for mould growth, the temperature of the secondary chilled water circuit needs to be kept above dew-point (usually 15ºC). With active beams the supply air may, under some outside air conditions, need to be dehumidified. Manufacturers of these devices can provide specific advice on the design limits and siting of their equipment.

5.22 Where chilled beams are installed in rooms with opening windows, the window should be fitted with a switch to automatically turn off the beam when the window is open. To avoid condensation, chilled beams should not be installed in entry lobbies that directly connect to the outdoors.

5.23 Active and passive chilled beams require regular cleaning if they are to remain efficient. They should be of a design that allows full access to the beam coils for cleaning and be positioned where they will be accessible for maintenance and not installed above fixed items of equipment.

5.24 There is no benefit in installing chilled beams if the resources to keep them in efficient working order over their entire life cycle will not be available. The maintenance aspects of using chilled beams should be discussed and the decision to use them agreed in writing with the client.

Note: Maintenance access to chilled beams will require the use of pulpit steps or wheel-around access equipment. The use of such equipment in a working hospital is very restricted.

Stand-alone air-conditioners

5.25 Stand-alone air conditioners include fan coil units, split-comfort air-conditioners, room conditioners and cassette units. All of these devices recirculate air which affects indoor air quality and may increase the risk of healthcare-associated infections (HAIs). Therefore, they should not be installed in clinical areas.

Note: Patient bedrooms are classed as clinical areas as treatment is often delivered at the bedside rather than in a designated treatment room.

5.26 Stand-alone air conditioners may be installed in suitable non-clinical areas, but they should be positioned to ensure that cold draughts are avoided. The control settings should ensure that the external elements of the units are always above dew-point. Manufacturers of these devices can provide specific advice on the siting and design limits of their equipment.

5.27 Stand-alone air-conditioners recirculate air, therefore, a primary fresh air supply of at least 20% of the room air-change rate, or that required by the Building Regulations, or 10 L/s/person − whichever is the greatest − should be provided.

5.28 Whether single or multiple systems are used, it is essential that the designer give due consideration to the source of electrical supply, location of the heat rejection unit, environmental effects and flammability of the refrigerant used, and drainage provision for the cooling-coil condensate.

5.29 Stand-alone air conditioners require regular cleaning if they are to remain efficient and not become a source of airborne bio-hazards. If they incorporate an open water drainage system, they must be risk assessed under L8/HSG274 as part of the Legionella assessment (see the Health & Safety Executive's (HSE) Approved Code of Practice and guidance document HSG274 'Legionnaires' disease: the control of Legionella bacteria in water systems'). They should be easily accessible for maintenance and should not be installed above fixed items of equipment which would make access difficult.

Notes: Maintenance access to stand-alone air-conditioners will require the use of pulpit steps or wheel-around access equipment. The use of such equipment in a working hospital is very restricted.

Traditional refrigerants are being phased down because of their effects on the environment and are becoming ever more expensive. Their replacements at the time of writing have a degree of flammability. Both these factors pose serious consideration as to whether stand-alone air-conditioners are suitable devices to choose. In scanning and control equipment rooms, the use of chilled racks, shelves and embedded panels supplied with water above dew- point would be a more suitable option.

Where the refrigerant pipework is located must be checked against the need to restrict risk. This may necessitate the need for refrigerant gas monitoring. The requirement must be checked during the design (refer to BS EN 378, using the relevant current edition for the application).

System selection

5.30 Natural ventilation is always the preferred solution for a space, provided that the quantity and quality of air required, and consistency of control to suit the requirements of the space, are achievable. This should also take account of the guidance from the WHO (Natural Ventilation for Infection Control in Health-Care Settings). If this is not the case, mixed mode or a mechanical ventilation system will be required.

5.31 Ventilation costs can be minimised by ensuring that, where practicable, core areas are reserved for those rooms that need to have mechanical ventilation. Examples are:

- sanitary facilities, dirty utilities and those rooms where clinical or
- functional requirements have specific environmental needs; and
- those rooms where – for reasons of privacy, absence of solar gain, etc. – windowless accommodation is acceptable.
- Other spaces appropriate to core areas are those which have only transient occupation and therefore require little or no mechanical ventilation (for example, circulation and storage areas).

Zoning of the building

5.32 The efficiency and effectiveness of any ventilation or air-conditioning installation depends largely on the zoning and control of the installation. The factors to consider when determining the zoning of a ventilation system for a building or department are:

- periods of occupancy;
- the service delivery resilience;
- fresh-air/ventilation requirements;
- the fire and smoke control strategy for the area.

5.33 Where the ventilation system is not merely tempering the air, but also providing the heating and/or cooling requirements (air-conditioning) the following additional factors should be considered:

- internal or peripheral location;
- orientation of windows;
- variation of internal loads;
- level of control required.

5.34 For single-zone plant in staff areas, local control (with a run-on-timer if required) is recommended, as the system can be turned off when the space is not in use, thus saving both thermal and electrical energy. Most clinical-zone supply and extract systems, conversely, are required to operate continuously while the department is occupied; thus some form of time or use control is necessary.

5.35 The control of individual plant items is covered in Chapter 9, with examples of typical control strategies in Chapters 6 and 7. For control parameters of particular critical ventilation and air-conditioning systems, see Chapter 8.

5.36 On rare occasions a duplicate standby air-handling plant may be justified. If installed, it should be provided with a gas-tight damper (see BS EN 1751) at its junction with the supply distribution duct so that no back-flow can occur. Standby plant can become sources of contamination if warm, moist air is allowed to dwell within them. Their design and control system should ensure that this cannot happen.

Note: The presence of duplicate plant should be reflected in the fire strategy.

Fire and smoke control

5.37 Within a designated departmental fire zone, the total mechanical supply and extract ventilation volumes should be approximately equal so that in the event of a fire, smoke is neither drawn into nor blown out of the zone. Note that individual sub-zones within the departmental zone may be positively or negatively pressured to suit the clinical need (for example, isolation rooms, operating theatres).

Note: In atria, stairwells and designated escape routes, dedicated smoke clearance fans may be installed to keep evacuation routes clear in the event of a fire. These together with their associated smoke dampers do not form part of the building's general ventilation system and their operation will be automatically initiated by the building's fire detection system and/or manually controlled by fire service personnel (see Health Technical Memorandum 05 Firecode).

Air-conditioning

5.38 Air-conditioning is the facility to filter, heat, cool, dehumidify and if required humidify the supply air to maintain an internal condition regardless of changes in the external conditions or internal load. It is expensive in plant and energy.

5.39 Due to capital and running costs, air-conditioning should only be used in essential areas. These include operating departments, critical care areas, manufacturing pharmacies and areas with particularly sensitive equipment. Information on system performance requirements for individual departments is given in Chapter 8.

Local exhaust ventilation

5.40 There is a statutory requirement under the COSHH regulations to prevent or control the escape of chemicals, toxic fumes, biological materials or quantities of dust into the general environment. For airborne hazards to people, control may be by the provision of an LEV system designed to the standard set out in HSG 258.

Ventilation for general areas

5.41 Chapter 8 and Appendix 2 provide recommended air-change rates, temperatures and pressures for general areas requiring mechanical ventilation in healthcare buildings.

Mechanical extract ventilation

5.42 General extract systems can vary in complexity from a single wall-mounted fan to a central ducted air system with dual extract fans.

5.43 Replacement air is provided by either a central supply system or enters the building through gaps in the structure or purpose- made openings. The design should ensure that the latter does not result in an unacceptable level of draughts occurring in winter.

5.44 If individual systems are used, the ventilation can be operated intermittently, provided it continues to run for at least 15 minutes after the room is vacated (as with light-switch-operated fans in individual toilets).

5.45 If general exhaust systems are used, filtered and tempered replacement air should be provided to adjoining lobbies or corridors, to prevent the risk of discomfort caused by the ingress of cold air. Fire compartmentation requirements should be maintained.

5.46 Information on specialised extract systems is given in Chapters 8 and 9.

Mechanical tempered-air-supply systems

5.47 Where mechanical supply systems are required, the fresh air should be tempered and filtered before being delivered to the space in order to avoid discomfort.

5.48 The majority of space air temperature heating load will be provided by the energy-recovery device with the balance from a constant or variable temperature battery. In most instances, the low pressure hot water (LPHW) heating system should offset any fabric loss so that set-back room temperatures can be maintained during unoccupied periods without the need for the ventilation system to operate.

Balanced ventilation

5.49 A balanced ventilation system is a combination of both a supply and an extract system of equal volume; either a single space or a whole building may be considered to be balanced.

5.50 A balanced system is necessary in instances where it is essential to maintain consistent air movement within an area (for example, recovery rooms).

Cascade ventilation

5.51 In operating departments, it is normal practice to supply air to the operating theatre and allow it to flow through less clean areas – corridors, utility rooms, etc (from where

it is eventually extracted). Pharmacy aseptic preparation facilities, maternity delivery rooms and treatment rooms are similar.

5.52 In negative pressure facilities it will be necessary to provide make-up air in order to promote the correct pressure cascade from the clean to the less clean (for example, supply in an outer area – to lobby to patient's room – to toilet extract). Infectious diseases units and bronchoscopy rooms are similar.

Recirculation systems

5.53 Air recirculation systems are normally used in HEPA-filtered cleanrooms where the return air is significantly cleaner than the outside supply and where odour levels are not significant.

5.54 Recirculation is also routinely used in the canopy section of ultra-clean operating theatre ventilation systems (UCV). The recirculated air is EPA filtered to ensure that biological contaminants released by the surgical team are not discharged back into the clean zone.

5.55 Recirculation may also be used for swimming and hydrotherapy pool ventilation.

5.56 Where the designer is considering the installation of an air recirculation system, due account should be taken of:

- a 20% minimum fresh air supply volume or that required by the Building Regulations or 10 L/s/person, whichever is the greatest;
- prevention of supply air contamination from vitiated return air;
- prevention of stratification occurring within plenum chambers and mixing boxes, which may result in freezing of downstream coils;
- ensuring sufficient velocities through automatic control dampers (ideally 5–6 m/s) where fitted, to provide suitable authority and good shut-off;
- modulating control of mixing to provide optimum on-plant conditions;
- the use of "free cooling" by cycling the dampers to minimum fresh air when the enthalpy of the outside air is greater than that of the extract air under conditions when cooling is required.

Note: Recirculating air can create particular problems when its ductwork breaches fire compartmentation. Designers should ensure that the system complies with the fire strategy in all modes of operation.

Dilution ventilation and clean airflow paths

5.57 In the past dilution ventilation has been used as the sole means of controlling levels of airborne hazardous substances in a space. This approach in itself is no longer considered acceptable. COSHH requires that airborne hazardous substances should be controlled at source by using a closed system (such as an anaesthetic gas scavenging unit) or a protective enclosure (such as a fume cupboard). A good level of background ventilation will assist in diluting any casual release of the substance.

5.58 In anaesthetic rooms, the casual exposure of staff to leakage or spillage when administering anaesthetic agents should be dealt with by establishing a clean airflow

path. Air should be supplied at high level above or behind the area where the staff will typically stand and extracted at low level directly behind the anaesthetic equipment position (see Figure A25 and photographs in Appendix 9).

5.59 The philosophy of establishing a clean airflow path – from the air-supply point, past the breathing zone of the staff, on to the patient or other source of airborne hazard, and out via a low-level extract – would also apply in recovery rooms, birthing rooms, bronchoscopy rooms, laboratories and post-mortem rooms. A suitable air-change rate (see Chapter 8) will provide background dilution ventilation as an additional safeguard. This approach ensures that regarding the ventilation aspects, “all reasonable steps are taken to prevent or control exposure (of staff) to the hazardous substance” as required by COSHH.

Note: In these areas the supply air should be 100% fresh and not recirculated.

5.60 In operating theatres, patients will be on a closed breathing circuit in a room with a high air-change rate. Under these circumstances, the dilution effect would be considered sufficient to control any casual exposure of staff to anaesthetic gases.

Displacement ventilation

5.61 Displacement ventilation introduces air at low level and removes it at high level. It uses the natural thermal buoyancy resulting from heat gain to achieve air movement throughout a space with minimal or no energy input. Displacement ventilation can be natural, mixed mode or mechanical with the supply untreated, tempered or fully conditioned depending on the application.

5.62 Displacement ventilation can be very energy-efficient and works well in applications that have significant casual heat gains from solar effects, people or equipment. Typical applications in a healthcare setting would be the ventilation of atria, central dining rooms, main kitchens, hydrotherapy pools, computer server rooms, lecture theatres and open- plan waiting or office areas. It is also applicable to non-interventional imaging and scanning suites where there are significant equipment-generated casual gains but no aerobiological infection risks.

5.63 Supply terminals will be located at low level, usually in the form of large perforated plate style diffusers mounted vertically. The supply air terminal face velocity is low so that it does not create draughts. It is essential that they are located in several positions so that they can ventilate the entire space. Care should be taken to ensure that fixed or movable equipment and devices cannot obstruct them. Extract will be at high level through vents or by a ducted extract system. The ventilation rate may be controlled by temperature or CO2 sensor-initiated motorised dampers with or without fan assistance at the extract points. The supply air volume is then slaved to match.

6. Energy Control Strategies

6.1 The operation of ventilation systems should be monitored through a building management system (BMS). The basic objective should be to provide the necessary service utilising the minimum energy. To this end, switching a system “Off” when not required is the most energy-efficient policy.

6.2 If the system is needed to maintain a minimum background condition, reducing its output by “Setting back”, to the minimum necessary to achieve and maintain the desired condition, is the next best option.

Note on “Set back”:

In previous times when fan motors only had two speeds, turning the system

to “Set back” meant switching to the lower fan speed. With modern fans the speed is widely variable so “Set back” is not a fixed fan speed but rather a

control strategy that reduces the system output in order to maintain a desired minimum condition. This may be related to the air velocity at a fixed point,

air-change rate, pressure differential, temperature, humidity or a combination of these parameters. Providing a dew- point sensor in an internal space that brings the system on to “Set back” is a simple way of maintaining a minimum condition.

6.3 The system should only run at full output when needed to achieve and maintain the defined “in-use” operating condition

6.4 Care should be taken when specifying plant to discover the true “in-use operating condition”. Overstating the condition will lead to oversized plant, unstable control and excessive energy consumption.

6.5 The design and selection of set points for an AHU and associated extract system will have a significant impact on the overall energy consumption and efficiency of the system as a whole (see Chapter 9 for detailed information).

Timed control

6.6 Switch the AHU “On” and “Off” at fixed times using a time clock or BMS programme. The AHU needs to come on early enough in the morning to bring the space up to temperature by the normal start time.

6.7 As above but with an “Optimum start” control that uses the outside temperature to determine the start time. In the winter, the lower the outside temperature, the earlier the AHU starts. In summer, the higher the outside temperature above that desired, the earlier the AHU starts.

6.8 As above but link the AHU to a temperature sensor in the space. If out of hours the temperature inside drops to the dew-point, typically 16ºC in winter, or rises above 25ºC in summer, the AHU will start and run at “Set back” (see definition in the Note after paragraph 6.2).

6.9 Any combination of the above or any other appropriate and applicable method that uses the least energy to maintain the specified condition is valid. Various options for the control of single- and multi-zone air-conditioning systems are given in CIBSE Guides F and H.

Occupancy control – user triggered

6.10 The ventilation system output should be linked to occupancy detectors. These may take the form of movement, CO2, passive infrared (PIR) or other sensing technologies that can detect that the area served is in use and switch the system “On” or “Off” and/or adjust the ventilation output to suit the actual load.

6.11 In intermittently used spaces such as operating suites, movement sensors (for example, PIR or similar) should be installed in the space with a “double knock” program so that if movement is detected twice within 10 minutes the AHU will switch “On” to full speed. If no movement is detected for 30 minutes, the AHU switches “Off”. Double-knock detection prevents the system from switching on in situations where a person has briefly entered a space when it is not in use.

6.12 The above may be combined so that if there is no movement for 15 minutes, the AHU switches to “Set back” (see definition in the Note after paragraph 6.2) during the working day and “Off” outside of normal hours.

Note: In Ultra Clean Ventilated (UCV) operating theatres the UCV terminal should be linked to the AHU control so that when the AHU goes to “Set back” the UCV also goes to “Set back”, and if the AHU goes “Off”, the UCV terminal fans also switch “Off”. There is no aerobiological benefit in keeping the UCV terminal fans running when the theatre is not in use, it results in wasted energy.

6.13 An alternative strategy in operating suites is to link the AHU control to the lighting. If the theatre general lights are switched “On” the AHU switches “On” in “Set back” mode. If the main operating lamp is then switched “On” the AHU goes to “Full speed”. If all the lights are out the AHU goes “Off”.

Note: There are occasions when this approach may need to be used with caution; for example, if a type of surgical procedure requires the operating or general lights to be “Off” during a part of the operation, an override timer or plant extension switch will be needed. The operating department manager and VSG should be consulted for approval before adopting this strategy.

User control

6.14 Some applications require intermittent mechanical ventilation, frequently at a high air-change rate (for example, in certain types of treatment room for odour control). Local controls to facilitate this mode of operation if required should be placed in a prominent position to encourage economical use. Specifying timers that shut the system down after a suitable operating period and need to be reset manually will reduce energy waste.

6.15 Local controls that enable the user to select more than one mode of operation should be clearly labelled to identify the particular mode selected.

6.16 Where the system allows different room pressures to be selected, a direct- reading pressure gauge should be fitted within the eye line of the users, 1.5 m above floor level, adjacent to the selector control unit to provide an independent confirmation of the resultant mode of operation. A permanent notice giving a clear description of the selectable modes of operation should be mounted adjacent to the control unit.

7. Environmental Control

7.1 The primary objective of a ventilation control system is to keep the space served within the required environmental control limits, at the appropriate times – regardless of external conditions or internal loads – and with the minimum energy consumption.

7.2 The building heating load will normally be met by a wet heating system with ventilation provided to suit the activities within it. The control of the heating system will normally be compensated to the outside air temperature. Control of the ventilation will usually be via a building management system (BMS) with “outstations” in individual plantrooms and/ or for individual AHUs.

7.3 A BMS incorporating self-adaptive control algorithms that automatically adjust the set-point to suit the usage and load is preferred. This will enable the operating conditions and control tolerances to be set and monitored. It is often not possible to accurately predict building load variation at the design stage. Information provided by monitoring the operation of the plant via a BMS will enable optimum set-points to be established and energy consumption reduced.

7.4 The BMS may also be set to log the actual energy consumed by the system together with that recovered by the energy- recovery device. This will provide a useful check on overall operating efficiency and provide evidence that energy targets are being achieved. The provision of movement sensors within the controlled space in order to determine the actual occupancy will facilitate this process.

7.5 The failure of ventilation systems serving critical areas can have grave consequences for the delivery of healthcare. Control systems should therefore be simple, robust and reliable.

7.6 Computer-software-driven control systems are now the norm in building services. However, healthcare ventilation systems need to be available for operation outside of normal working periods when software support is not available. Should the software fail, it will be left to site staff, who may have little knowledge of the control algorithms, to restart the ventilation system. It is therefore essential to ensure that a simple means of restarting critical systems in the event of a software failure is provided (see also Chapter 9).

7.7 Where BMS use “outstations” to control plant, the “outstation” should be independently able to control the plant if the BMS link is lost.

Location of controls

7.8 Whether within the plant, duct or room, sensors should be located to provide accurate measurement of the condition of the air being monitored.

7.9 Sensors and control items such as control valves should be located close to the element being sensed or plant item being controlled in order to minimise time lags within the system. These may create over- shoot of conditions beyond the design envelope and result in additional energy consumption.

7.10 Where there is a requirement for close control of air-conditioning parameters in a number of zones (for example, an operating department), separate plant should be

provided for each zone in order to avoid the need for expensive over-cooling and reheating of individual zones. The control of most multi-zone systems within healthcare premises is based on off-coil control within the central plant, with trimmer heater-batteries on individual zones.

Note: In modern buildings the cooling load is often significantly greater than the heating load and may exist all year round. Whenever possible, the design should take advantage of free cooling when available.

7.11 Facilities to start, set back and stop the plant should be provided in the plantroom. Remote start and set-back control and indication, if required, should be provided at a manned staff location (for example at the reception or staff base).

7.12 Many ventilation systems may be completely shut down when the area served is not in active use (for example, operating suites). Alternatively, where there is a need to maintain a background condition, the ventilation output may be reduced by "setting back" the system (see paragraph 6.2 and associated Note). This will significantly reduce energy consumption and extend the life of filters and other system components

Multi-zone control methods and application

7.13 Close control of all air-conditioning parameters may be difficult to achieve with multi-zone systems, since each zone will in theory require a reheater and humidifier to give total control of humidity, if that is what is required. In reality, such close control is rarely required. It is therefore usual with multi-zone systems to provide control of zonal temperature only, with humidity control, where fitted, being based on average conditions within all zones, or a minimum condition within one zone.

7.14 Designers should consider whether it is necessary for the supply and extract fans to be interlocked – either so that the supply fan will not operate unless airflow is established within the extract system, or vice-versa depending on the required pressures within the rooms being served (see also Chapter 8).

7.15 The sequence switching of units in order to prevent transient reverse airflows will be particularly important in laboratories and pharmacies that contain fume cupboards, safety cabinets and other LEV systems.

Fire aspects

7.16 The control strategy for ventilation systems in the event of a fire should be set out in an agreed fire and smoke control strategy for the site (see Chapter 1).

7.17 All supply AHUs should have a smoke sensor linked to the fire control panel and mounted in the main supply duct immediately downstream of the AHU. In the event of a fire in the AHU or smoke being drawn into the system from an outside source, it should cause the AHU to shut down and the main supply-air damper and system fire damper(s) to close.

7.18 In critical areas a ventilation control panel should be mounted at the main entrance of the area that the ventilation serves (see Health Technical Memorandum 05-02 for more detailed guidance). Access to the panel should be restricted to the fire officer and appointed site AP(V). It should include independent on/off controls and an

indication of the status of the supply and extract systems. A notice should be affixed to the control panel stressing the need to liaise with departmental staff before switching off fan units

Note: In certain critical care areas, it is preferable to maintain the supply ventilation in case of a fire within the area. For example, in an operating department, while undergoing surgery, the patient cannot always be easily moved without significant risk. In the event of a fire in a staff or support area of the department, or adjoining zone, the continued supply of air to a theatre will maintain it at a positive pressure and protect the patient and staff from the effects of smoke. This will allow time for the patient to be stabilised so that they can be safely evacuated if necessary.

User requirements

Room temperature control

7.19 The limits for room temperature set- point are generally between 18ºC and 22ºC depending on the particular application. In some specialised applications (for example, operating departments), the user may require a wider range of adjustment (see Chapter 8).

7.20 The selection of temperature set-point for each room or zone may be by a control facility in the room/zone or be carried out remotely at the control panel or BMS. Where the control device is mounted within the room/zone and is adjustable by the user, it should be marked either “raise” and “lower” or “+” and “–”. It should control within a specified temperature range to suit the user requirement with a control tolerance of ±1 K. All other control set- points should be selectable either on the control panel or at the BMS interface.

7.21 Where local control is provided, an indication of temperature will be required locally or at a staff base (if appropriate) using an analogue or digital indicator. The indicator should be large enough to be read from the normal working position (for example at the operating table in a theatre). This may be mounted in a supervisory control panel, with the signal repeated on the main system control panel or BMS. It is important that this indicator displays the actual measured temperature and not the selected temperature.

Alarms and indication

7.22 Supply and extract systems should include indicator lamps on the control panels to confirm the operational status of each system. Where the usage is on a regular daily pattern, time control with a user-operated, timed manual override should be provided.

7.23 Where a system is provided for a particular space, the indicator should be in, or immediately adjacent to, that space, and local controls should be provided with permanent labels clearly defining their function (for example isolation suites).

7.24 If room differential pressure gauges are required, they should be mounted directly adjacent to the entry door of the room to which they apply at a height of 1.5 m above floor level so that they are in the eye line of staff entering the room. If a mechanical gauge is fitted, it should have a green sector to indicate the acceptable normal

pressure range. If electronic, it should have a permanent label affixed underneath it giving the normal acceptable pressure range.

Note: For specific departmental control parameters, see Chapter 8. For plant controls see Chapter 9.

Maintaining balanced air flow rates

Consideration must be given to the method of maintaining the correct proportional balance throughout a system when in use. This becomes particularly important where duct or terminal mounted filters are to be used. As the filters soil, the pressure and flow balance of the system would change unless control measures are included to enable automatic compensation/adjustment (e.g. constant volume boxes, variable speed drives).

8. Specific Healthcare Department Requirements

General considerations

8.1 The foregoing chapters of this document contain general information on healthcare aspects of ventilation system design and specification. This chapter gives information relating to the specific design requirements for a range of healthcare applications.

8.2 The following departments will require a degree of ventilation appropriate to their function.

- the operating department;
- treatment rooms, endoscopy and minimally invasive suites;
- critical care area – levels 2 and 3;
- diagnostic and interventional imaging and cardiology suites;
- obstetrics/maternity;
- infectious diseases unit and isolation facilities;
- bone marrow and other transplant units;
- chemotherapy and oncology units;
- the pharmacy department;
- the pathology department, mortuary and post-mortem suite;
- central decontamination units;
- burns unit;
- cystic fibrosis unit;
- tissue bank, gene therapy and emerging treatment specialties;
- physiotherapy and hydrotherapy;
- estates infrastructure.

Design information for many of these applications is given below, in Appendix 2 or the relevant SHPN/HBN.

8.3 It is not possible to give definitive guidance for every healthcare ventilation application; however, the section on operating theatres contains much information that is common to other applications. Where no specific guidance is given, the principles set out below should be followed:

- the CIBSE guides and technical manuals contain basic information on ventilation design that can be applied to most applications;
- where a British or European standard exists that is specific to the application (for example, a cleanroom), it should be used as the basis of the design requirement;

- air should always move from clean to less clean areas. A hierarchy of room cleanliness is given in Appendix 3;
- differential pressure will prevent contamination between areas when doors are closed. Information on air leakage through gaps around closed doors and hatches for a range of differential pressures is given in Appendix 4;
- the flow of air will prevent contamination between areas of different cleanliness when doors are open. Information on airflow through open doors and hatches is given in Appendix 5;
- a methodology for calculating a design solution for a non-standard operating suite in terms of its room sizes, layout or number of people present is given in Appendix 8. This may be adapted as necessary to suit other less complex applications where air is required to cascade through rooms from clean to less clean areas.

Note: In all cases it is essential that the design solution adopted will ensure adequate scouring of the space being ventilated. The selected airflow rates, relative position of supply terminals, extract terminals, air transfer devices and pressure stabilisers will all have a bearing on the effectiveness of the room ventilation.

8.4 There are four routes by which airborne contaminants may appear in a room:

- shed directly by the room occupants;
- arising as a result of the work activities;
- transferred from adjacent spaces;
- through the supply air.

Particles shed directly by the room occupants can be controlled by:

- restricting access to essential persons only;
- the choice of the occupants' clothing;
- the room air-change rate.

Particles arising as a result of the work activity can be controlled by:

- enclosing, semi-enclosing or otherwise controlling the work-based source;
- the room air-change rate.

The transfer of particles from adjacent spaces can be controlled by:

- a differential pressure between spaces when doors are shut;
- airflow paths flowing from clean to less clean spaces when doors are open.

Particles entering with the supply air can be controlled by the selection of a suitable filter.

When designing ventilation for a healthcare application, the sources of airborne contamination, their degree of hazard to patients and/or staff and the ability of ventilation to control them should be taken into account. For any particular healthcare

application, the ventilation safety group (VSG) should be able to give advice on any specific risks to patients and staff.

8.5 The supply of air to a room has the following main functions:

- to dilute airborne contamination;
- to control air movement within such that the ingress or discharge of airborne contaminants from or to adjacent areas is minimised;
- to control the temperature and, if necessary, the humidity of the space;
- to aid the removal of and dilute fumes, odours and waste gases.

8.6 The supply air volume flow rate for any particular application will be that required to:

- achieve the application's recommended air-change rate;
- provide closed and/or open-door protection;
- achieve comfort or application-specific room conditions;
- replace (make up) that removed by an installed extract system;
- meet the fresh air requirement relating to the number of people anticipated to be present;
- achieve the minimum fresh air requirement if air is recirculated.

Whichever is the greatest amount.

Note: Air-change rates are given in Appendix 2. These figures have been found to give enough dilution of airborne contaminants, provided the mixing of room air is reasonably uniform. Closed and open door protection volumes are given in Appendices 4 and 5. Fresh air requirement is at least 10 L/s/person. Minimum fresh air volume if recirculated is 20%, whichever is the greater.

8.7 Natural and/or mixed mode ventilation should be used wherever possible. Where mechanical ventilation is chosen, a downward displacement turbulent air distribution is generally preferred, though displacement ventilation may be used if appropriate.

8.8 The supply and extract terminals should be positioned to ensure that all parts of the room are actively ventilated and that where necessary the staff will be in a clean airflow path. Extract and air-out paths via door gaps, transfer grilles, pressure stabilisers and low-level active extract should be evenly distributed to encourage efficient scouring of the room. (See paragraphs 8.37–8.40 and 9.161–9.172 for additional guidance on location and types of terminal.)

8.9 Horizontal flow room air distribution with or without a coanda effect (see paragraph 9.162) can be a source of draughts and difficult to set up correctly. Its use should be confined to non-critical areas or situations where ceiling-mounted diffusers could be obstructed by movable equipment support tracks (for example, in imaging rooms). Alternatively, a displacement ventilation scheme may be considered.

Temperature and humidity control

8.10 Supply flow rates to achieve the required room conditions are calculated conventionally, taking account of all heat and moisture gains and losses, and of maximum permissible temperature differences between the room and supply air. In most applications the base heating load will be provided by a heating system. In critical systems the room or suite being considered will be within the heated building envelope so the ventilation will be sized to suit the casual gains or losses.

8.11 Temperature differences between supply and room air of up to 10 K for winter heating and 7 K for summer cooling should not be exceeded.

8.12 Room air humidity should be kept below 70% in order to minimise risks associated with condensation and mould growth. There is generally no lower limit in unoccupied spaces; however, see application-specific guidance.

Ventilation where anaesthetic agents are present

8.13 During treatment, anaesthetic gas or anaesthetic agents may be delivered to the respiratory tract of a patient either directly or using a carrier gas. Anaesthetic gases and agents are subject to workplace exposure limits and while beneficial to the patient are harmful to staff. Waste anaesthetic gas should be contained and removed by a suitable anaesthetic gas scavenging system (AGSS). Some leakage from the anaesthetic equipment and the patient's breathing circuit will occur with all systems, particularly during connection and disconnection and from the interface with the patient. In recovery areas the patient will exhale the anaesthetic agent directly into the room air. The room ventilation scheme should ensure that any leakage or exhaled anaesthetic agents are diluted and removed.

Note: Staff tend to be standing and patients lying down when anaesthetic agents are delivered; also anaesthetic agents are slightly heavier than air, so locating the supply terminal at high level behind where staff normally stand, with an extract at low level adjacent to the source (for example, the anaesthetic gas terminal units), will ensure that staff are in a clean airflow path.

8.14 The design primary air supply to an operating suite anaesthetic room that is equipped with a N2O terminal or in which an anaesthetic agent is delivered to the respiratory tract of a patient using a carrier gas, or an operating department recovery room, should be 15 ac/h.

8.15 In delivery rooms the intake of anaesthetic gas is controlled on demand by the patient, who will then exhale directly into the room air. Locating the supply air at high level at the foot end of the bed with extract at low level at the head end will establish a clean airflow path and reduce the casual exposure of staff to the waste gas.

8.16 The primary air supply to any other room that is equipped with a N2O or N2O/O2 (Entonox) terminal or in which an anaesthetic agent is delivered to the respiratory tract of a patient using a carrier gas or in which the patient is subsequently recovered, where the anaesthetic is employed for the purpose of pain relief or sedation but not full anaesthesia, should be 15 ac/h. However, subject to risk assessment, consideration may be given to reducing this to no less than 10 ac/h, only where use of the anaesthetic gas release into the space will be both very infrequent and in very small quantities.

Note: Staff employed in operating suite anaesthetic rooms and an operating department recovery room will potentially be exposed to anaesthetic agents for the duration of their working day. In other areas (for example, maternity, imaging, treatment rooms), anaesthetic agents are only used for pain control and/or sedation. The strength, quantity and frequency of use may be significantly less, hence the the option to carry out a risk assessment.

Door protection

8.17 Air should flow from the cleaner to the less clean areas as shown in Appendix 3 and Figure A23 in Appendix 8. There are several factors that affect the likelihood of a reverse airflow through doorways:

- when a person passes through a doorway, both the passage of the person and the movement of the door flap cause a transfer of air between the areas separated by the door;
- when a door is left open, there is a transfer of air between the two areas separated by the doorway. This is caused by air turbulence, but is greatly increased by any temperature differential between the areas (a 1.4 m wide doorway may allow the transfer of 0.19 m3/s of air in each direction when there is no temperature difference, but when the temperature differential increases to say 2 K, the volume transferred may increase to 0.24 m3/s). This may be a problem if for example the heat gain from a fluid warming cabinet is not allowed for.

8.18 In order to reduce the likelihood of contamination of a clean area by a reverse airflow from a less clean area two methods of door protection are used:

- closed door protection – a pressure differential is created across a closed door so that any air leakage is from the clean to the less clean area. Appendix 4 gives details of closed door leakage rates for a range of differential pressures;
- open door protection – the pressure differential drops when a door is opened (see Appendix 6) and is effectively replaced by a flow of air through the doorway from the clean to the less clean area. The flow of air needs to be sufficiently large to ensure that significant reverse airflow cannot occur and will be related to the relative cleanliness of the areas being considered. Appendix 5 gives airflow rates for open-door protection related to door/opening size and the classification of the adjoining area.

8.19 Pressure stabilisers enable the room differential pressure to be set when the doors are shut, thus providing closed-door protection. When a door is opened, the stabilisers will close, forcing air to be directed through the doorway, thus providing open-door protection. Provided that the dilution criteria in Appendix 3 are met, the occasional small back-flows created (when two doors are opened simultaneously; or when there is a high temperature difference across an open door) will have little effect on the overall air cleanliness of the affected room.

8.20 In applications where it is critical to maintain a specific airflow and/or pressure regime, for example isolation rooms, all windows in the zone should be locked shut or sealed. Trickle vents, if fitted, should also be sealed.

8.21 The design of the ventilation system for an area depends on the overall configuration of the department. Where the department is served by more than one AHU the

control of the units may need to be interlocked so that reverse airflow patterns do not occur.

8.22 Extract grilles should be sited and balanced to promote air movement in the desired direction.

8.23 Transfer grilles enable air to pass in either direction between rooms of equal class and pressure. Pressure stabilisers operate in one direction only; they allow excess air to be directed to the area desired and assist in maintaining room pressure differentials.

8.24 The relative locations of supply and extract terminals and their design air volume rates will determine the basic airflow between adjacent spaces. Transfer grilles and pressure stabilisers will permit and control the flow of air between spaces, ensuring a flow from the clean to less clean areas of the suite. Failure to provide such devices will lead to uncontrolled airflows when personnel move between rooms and doors being held partially open by air pressure.

Air handling unit

8.25 AHUs should be to the standard set out in Chapter 9. The extent of the system served by an individual AHU should reflect the operational need and required resilience of the application.

Fire aspects

8.26 When considering the overall airflow movement, careful thought needs to be given to the operation of the ventilation system to limit smoke spread in the event of a fire.

Operating department

General

8.27 An operating department will consist of one or more operating suites, a recovery area, sterile pack and equipment stores, entry/exit/service corridors, office, staff changing and support facilities. Each operating suite will typically comprise a preparation room, operating theatre, anaesthetic room, scrub area and a utility room. In order to ensure satisfactory conditions and the correct movement of air, the entire department will usually be mechanically ventilated.

8.28 The information given in this section relates to conventional operating suites used for general surgery. It will be applicable to other types of operating suite such as maternity whose layout and dimensions conform to the principles of Health Building Note 26 (see Note below). Additional information for UCV theatres is given in paragraphs 8.75 onwards.

Note: Health Building Note 26 − ‘Facilities for surgical procedures’ (2004) and Health Building Note 10-02 − ‘Facilities for day surgery units’ (2007) are under revision and will be replaced by a single document: Health Building Note 10-01. It will provide guidance on the planning and design of infrastructure for in- patient and day-patient surgical services in the UK.

8.29 For other types of operating suite, the standard values may need to be adjusted to reflect non-standard room sizes, pressure regimes and air-change rates. A method of obtaining a design solution for non- standard theatres from first principles is given in Appendix 8 (see also paragraph 8.3 and accompanying Note).

Standard air movement control schemes

8.30 In all previous versions of this guidance, standard air-movement control schemes were given that provided a range of design solutions for typical operating- suite layouts. Improvements in the technology of ventilation control systems coupled with the ability to accurately sense and control real-time fan output has enabled operating-suite ventilation parameters to be tightened. These now more accurately meet the airborne- infection-control requirement (see the Lidwell Report). The previous standard design solutions have therefore been fully revised to take advantage of the technological advances and benefit from the reduced energy consumption and plant size they allow.

8.31 A new set of standard operating suite design solutions extensively amended to conform to the guidance contained in this edition of Scottish Health Technical Memorandum 03-01 are given in Appendix 7. They contain diagrams that show the relationship of rooms and the various doors and transfer devices between them but should not be regarded as architectural layouts. The schemes have been developed using the methodology described in Appendix 8.

These design solutions should be used for new projects and when refurbishing or upgrading existing operating suites.

8.32 Any other scheme may be used, and the standard solutions applied, if the following conditions are met:

- room relationships in air network terms are as shown in the plans;
- room sizes and shapes approximate to those given in Health Building Note 26 (under revision at the time of writing and to become Health Building Note 10-01);
- door gaps approximate to those given in the designer’s notes in Appendix 4;
- casual heat gains are accounted for;
- a trimmer battery is installed in the air supply to the anaesthetic room and lay-up prep room;
- leakage through the structure is kept to a minimum. Note that theatre suites will be subject to an air permeability test at first-fix and final validation (see Chapters 10 and 12).

It is recommended that every effort should be made to adopt one of the schemes described above.

Ventilation design requirement

8.33 The need for ventilation of the individual rooms and areas within the operating department will be as follows:

- Preparation room – to protect sterile packs and instruments from pre-contamination;

- operating theatre – to control the airborne infection risk, remove airborne contaminants and prevent the ingress of airborne contaminants from adjacent areas;
- anaesthetic room – to protect staff from casual exposure to anaesthetic agents and maintain a suitable environment for patients;
- scrub – to remove aerosolised microbiological contamination and moisture released when staff scrub- up;
- utility (also known as sluice or disposal) – to contain any airborne hazards arising from the initial processing of biological material, contaminated instruments and general waste and prevent it entering the operating theatre or adjacent spaces;
- entry/exit/service corridors – to remove vitiated air cascading from the operating suite(s);
- sterile pack/ Layup Prep and equipment stores – to prevent airborne contamination of the packs and equipment;
- staff changing, shower and toilet facilities – odour control and moisture removal;
- staff rest room – moisture and odour control;
- office and general areas – comfort conditions;
- recovery – to protect staff from casual exposure to exhaled anaesthetic agents and maintain a suitable environment for patients.

The ventilation requirement for each space will be met by the desired air-change rate, room pressure differential, relative position of the room supply and extract, comfort requirement or a combination of all elements.

8.34 **Preparation room – sterile pack store (SPS)** - The preparation room is used simply as a store; sterile packs are set out on trolleys but not opened. They are then transferred to the operating theatre and opened as required. The nominal room pressure can therefore be the same as that of the operating theatre and the air allowed flow between the rooms in either direction. Air supplied to the preparation room should be directed into the operating theatre either through a door-mounted transfer grille or if no door is fitted, through the opening. It should not flow via a pressure stabiliser or transfer grille into the corridor.

8.35 **Preparation room "lay up"** – When the preparation room is used as an instrument "lay up" room (that is, sterile packs are opened and their contents exposed ready for transfer to the operating theatre), it should be regarded as being of greater cleanliness than the operating theatre. The preparation room should be at 10 Pa above the operating theatre to minimise the transfer of air and prevent pre-contamination of the instruments. The design air supply volume should relate to the door protection factors (for example, open door to theatre and closed door or hatch to corridor, where provided) and result in not less than 22 ac/h. Air should discharge into the operating theatre through a pressure stabiliser fitted with a stand-off baffle plate on the theatre side (see photograph). It should not flow via a pressure stabiliser or transfer grille into the corridor. The volume of supply air being discharged through the pressure stabiliser may be used to offset the volume of supply air to the operating theatre.

Where the unpacking of the instruments involves not only the removal of the protective packing but also the opening of the sterile barrier, the supply air to the room must be delivered via a terminal HEPA filter (H12 grade). The system must include constant volume and variable speed controls to ensure that the air flow rates remain constant as the HEPA filter soils. In this case it is also necessary to design a specific air flow regime to enhance the cleanliness of the environment. The supply air must be delivered from the ceiling in a manner which directs that air down into the zone where the sterile barriers are to be removed. Air will then be relieved from the room at low level with an air pressure stabiliser into the theatre.

8.36 **Operating theatre** – The supply of air to an operating theatre has four main functions:

- to dilute airborne microbial contamination – this will arise from the surgical activity and microbiological material shed by staff;
- to aid the removal of and dilute fumes, odours and waste anaesthetic agents;
- to control air movement so that the airborne contaminants from other less clean areas do not enter;
- to control the temperature and if necessary, the humidity of the room.

Design notes

- an air-change rate of 22 ac/h will control (a) and (b) above. When calculating the air volume required to achieve the air-change rate, the physical volume of the operating theatre will be based on whether the scrub does or does not form part of it. See Note to paragraph 8.46 for further information;
- the room to corridor differential pressure and amount of air required to give door protection will control (c). Door protection is calculated on the basis that during use, only one door or a single leaf of a double door will be open transiently, and all the rest will be closed. The designated “open” door will be the worst case (for example, typically that between the operating theatre and utility). The volume of supply air can be calculated from the flow rates for open and closed door protection given in Appendices 4 and 5. The smaller the number of rooms (and therefore doorways) leading from the operating theatre the better, as traffic is reduced, and a less complicated air movement control scheme is required;
- the supply air volume to control (d) temperature and humidity conditions can be calculated conventionally, taking account of all heat and moisture gains and losses resulting from equipment, lighting and number of occupants. Supply to room air temperature differences of up to 10 K for winter heating and 7 K for summer cooling should not be exceeded. Room humidity should not exceed 70% saturation.

The design supply air volume for an operating theatre will be whichever of the above calculations yields the greater figure.

In the case of an operating suite with a “lay up” preparation room, the actual air volume supplied by the operating theatre terminals will be the design air volume determined above minus that entering via the preparation room pressure stabiliser.

Note: In the majority of operating theatres the air-change rate will be the dominant factor; however, for small operating theatres the door protection factor may dominate.

8.37 The supply and extract terminals should be positioned to ensure that all parts of the operating theatre are actively ventilated. The ceiling should be divided into four quadrants and a supply terminal positioned at the centre of each quadrant and along the lines that join them as necessary to ensure that all parts of the room are equally supplied. In a large theatre, additional terminals around the centre point may be necessary to promote efficient scouring and achieve satisfactory air movement at the operating table level. This will help create in ventilation terms a well-mixed space and ensure good dilution of any airborne contaminants. Extract and air-out paths via door gaps, transfer grilles, pressure stabilisers and low-level active extract should be evenly distributed to encourage efficient scouring of the room. A minimum of three and preferably fourair-out paths, approximately equally spaced, should be provided.

Note: In order to ensure correct air distribution, it is essential that the supply terminal locations are not displaced by light fittings or ceiling-mounted pendants and articulated booms. Ideally the supply terminals should alternate with light fittings along the quadrant lines described above.

8.38 Supply terminals should be ceiling- mounted circular “air master” style, square “four-way blow” or perforated plate style that produce a downward displacement, turbulent airflow (see paragraph 9.170 onwards). Multi-section plenum-style perforated-flow diffusers with a footprint that encompasses the operating site are acceptable but may be prone to buoyancy effects as a result of temperature difference. Manufacturers’ type test data should be consulted to ensure that the terminal will achieve the required performance envelope. Note that these are not true laminar flow systems in the strict sense of the word but produce a downward displacement parallel flow style of air distribution.

Note: Where an operating theatre requires a higher than normal air-change rate (for example, cranial surgery, which may specify 35 ac/h), the volume of supply air means that four-way blow diffusers would be noisy and probably cause unacceptable draughts. A UCV terminal would deliver too much air, which could result in exposed tissue drying out during the procedure. A multi-section, plenum-style perforated flow diffuser with a footprint that encompasses the operating site would be the most suitable option.

8.39 The diffuser equipment chosen should not cause “dumping” and provide an air velocity 1 m above floor level at the operating position of between 0.2 m/s and 0.3 m/s.

8.40 Horizontal flow distribution should not be used in new installations; however, space constraints may force its retention when refurbishing existing installations. Where fitted, the supply grilles will require a means of directional adjustment that is lockable in position to prevent casual alteration in future when being cleaned.

8.41 Anaesthetic room – Anaesthetic gas or anaesthetic agents will be delivered to the respiratory tract of a patient either directly or using a carrier gas. Anaesthetic gases and agents are subject to workplace exposure limits and while beneficial to the patient are harmful to staff. Some leakage from the anaesthetic equipment and the

patient's breathing circuit will occur with all systems, particularly during connection and disconnection, and from the interface with the patient. The room ventilation scheme should ensure that any leakage is diluted and removed, and that staff are in a clean airflow path. Locating the supply terminal on the ceiling in a position behind where the anaesthetist will normally stand, and the extract terminal at low level adjacent to the medical gas pipeline terminals, will encourage a clean airflow path past the breathing zone of the anaesthetist, thus reducing their casual exposure to airborne anaesthetic agents (see information in Appendix 9).

8.42 An operating theatre suite anaesthetic room that is equipped with a N2O terminal or in which an anaesthetic agent is delivered to the respiratory tract of a patient using a carrier gas should have a design primary supply and extract flow rate to achieve 15 ac/h.

8.43 In order to maintain the core temperature of patients being anaesthetised, a trimmer heater-battery should be provided in the anaesthetic room supply. It is also important that the location of pressure stabilisers and transfer grilles does not cause draughts across the patient.

8.44 The anaesthetic room will be at an intermediate pressure between the operating theatre and corridor.

8.45 **Scrub** – This may be a separate room or a bay within the operating theatre. If the scrub is a separate room, a door between the scrub and operating theatre is an inconvenience to scrubbed staff and may be replaced by an opening that is larger than a normal single doorway. If a door is fitted between the scrub and operating theatre is should have a transfer grille in its lower half. In either case there should be an active extract at low level under the end of the scrub trough most remote from the operating theatre, or a low-level pressure stabiliser that discharges onto a corridor at the end of the scrub room most remote from the operating theatre (see figure 1). If the scrub has an outside wall and/or is particularly large, additional extract terminals may be required to ensure air movement throughout the entire space and prevent surface condensation and mould growth.

Figure 1 Scrub room with extract under trough

8.46 Where the scrub is a trough on the wall or in an open bay within the operating theatre, it should have low-level extract under it.

Note: If the Scrub is in effect a separate room that is open (no door) to the operating theatre and it has a low-level pressure stabiliser discharging onto a corridor or an active low-level extract at its far end, so that air has to travel through the scrub to leave the operating theatre, the volume of the scrub will not be counted as being a part of the operating theatre room volume.

If the scrub is a trough on the wall or in an open bay within the operating theatre, the volume of space it occupies will be considered part of the operating theatre room volume for the purpose of calculating the operating theatre air supply.

8.47 **Utility (sluice or disposal)** – The room is kept at negative pressure with respect to the operating theatre so that contaminants contained in the surgical waste do not re-enter the operating theatre. A utility opening onto a clean corridor is considered to pose a greater risk than one opening onto a service corridor and so has a greater differential pressure. A utility may be shared between two operating theatres or be centralised to serve a group of operating suites.

8.48 **Entry/exit corridor** – Air cascading from the operating suite should be removed in the adjacent corridors. Note that though design flows may be calculated, the actual extract airflows may need to be adjusted at commissioning in order to achieve the design room differential pressures.

8.49 **Service corridor** – If materials to be disposed of are placed in impervious material for transportation, it is not necessary to have a separate corridor for this purpose. However, a service corridor has many operational advantages in terms of the flow of materials through the operating suite. It provides a heated envelope around the operating suite, thus obviating the need to run the theatre ventilation out of hours to maintain its temperature above dew-point, so significantly reducing energy consumption. Lastly it permits access for routine service and maintenance, and the eventual refurbishment of an operating suite without compromising the use of adjacent suites.

8.50 **Sterile pack store** – The central operating department sterile pack and prosthesis store should be supplied with 6 ac/h and be at a positive pressure to their corridor. It is important to coordinate the position of the supply air terminals with any racking so that the terminals are accessible for annual airflow measurement with a balometer.

8.51 **Equipment store(s)** – Supply air ventilation only to keep them at positive pressure to the corridor.

8.52 **Staff changing, shower and toilet facilities** – ventilation as per building regulations and for moisture control.

8.53 **Staff rest room** – Ventilation for kitchen area and general comfort.

8.54 **Office and general areas** – Ventilation as per building regulations and comfort.

8.55 **Recovery room** – Anaesthetic agents will be exhaled by patients while recovering; they are subject to workplace exposure limits and are harmful to staff. Anaesthetic gas scavenging systems (AGSS) will be provided but the room ventilation scheme should ensure that any leakage is diluted and removed.

8.56 The supply air terminals should be ceiling-mounted above the foot end of the recovery bed positions. Extract should be at low (bed height or below) level behind the bedhead positions or in the corners of the bed bay. This will establish a clean airflow path so that staff do not inhale anaesthetic agents exhaled by recovering patients (see the COSHH Regulations).

8.57 In an operating department recovery room, the design primary air supply will be 15 ac/h with a balanced airflow.

General notes

8.58 Supply flow rates for the main rooms of the operating suite are given in Appendix 7. For the other areas where room sizes and activities vary from site to site, air-change rates are given in Appendix 2 and Tables 2–7 in this chapter. These figures have been found to give enough dilution of airborne microbial contaminants, provided the mixing of room air is reasonably uniform.

8.59 For conventionally ventilated operating theatres, the primary air supply would be filtered in the AHU. Terminal filters, EPA or HEPA, are not required.

8.60 Air extracted from operating suites should not be recirculated as it may contain malodorous contaminants.

Note: Where thermal wheels are used for energy recovery, the small leakage across them from extract to supply should not cause odour problems and is not considered aerobiologically significant. In any event, all the air supplied will pass through the final filter.

Operating suite pressure regime

8.61 When designing the ventilation scheme the room pressure differentials given in Appendix 7 should be used. However, when the suite is balanced and commissioned these values are not to be taken as immutable but rather as desired orders of magnitude. What is important is the direction of airflow between rooms when doors are closed. Specifying doors of a laboratory standard that close and sit against a seal or have drop seals on their bottom edge is not necessary and will be counterproductive of the aim to allow air to flow from clean to less clean areas.

Note: Fire officers often require that doors are fitted with cold smoke seals as standard. These will significantly reduce the door- leakage rate and increase the differential pressure when new and undamaged. It is therefore recommended that provision for the design door leakage be factored into the sizing of the appropriate transfer grille or pressure stabiliser.

Temperature and humidity control and indication

8.62 In an operating theatre the temperature should be adjustable within the range 18ºC to 25ºC by the staff at the theatre control panel. The ventilation system should be capable of maintaining an internal temperature of 20ºC at summer outside design and 22ºC at winter outside design in all but the most extreme outside conditions. There may be instances where these temperatures may not be appropriate (for example, children and patients with a low body mass). The internal design temperatures should then be discussed with the VSG and agreed in writing.

8.63 Theatre temperature and humidity control sensors should be actively ventilated. They would typically be located in a sampling extract duct mounted in or adjacent to the theatre control panel, positioned at normal working height (1.5 m above finished floor level). Alternatively, they may be mounted in one of the operating theatre's low-level extract ducts. Whichever location is chosen they should be accessible for cleaning, and removable for periodic calibration and replacement.

8.64 Passive wall-mounted temperature and humidity sensors are not recommended.

8.65 Controls should be provided to enable operating department ventilation plant to be closed down when the operating suites are unoccupied (see also Chapter 9).

8.66 When in the "off" mode, to provide dewpoint protection the control system should switch the ventilation "on" to "Set back" if the space temperature falls below 16ºC.

8.67 All operating theatres and rooms where surgical interventions are carried out should have a control panel mounted on a wall with its screen centre at 1.5 m high and in the direct line of sight of staff standing at the normal operating position. The theatre control panel should include plant status indication, clearly readable temperature and humidity indicating gauges, and a means of adjusting the set point for temperature. Theatre ventilation plant status indication should also belocated at the operating department staff control base (see the Specialised Ventilation for Healthcare Society's (2017) SVHSoc.01 – 'Operating theatres: energy control strategies and the surgeon's panel' for further details).

8.68 The following indicators should be incorporated in the theatre control panel and their functions clearly labelled.

- a readout sufficiently large (25 mm) to be clearly visible from the operating table that shows the temperature of the air in the theatre;
- a readout sufficiently large (25 mm) to be clearly visible from the operating table that shows the relative humidity of the air in the theatre;
- a red indicator light that will illuminate when either the supply AHU fails or is switched off or is in "Set back" (legend: "Theatre not to be used in this condition");
- a green indicator light that will illuminate when the supply AHU is operating at full speed (legend: "Conventional theatre mode").

Note: In touch-screen panels, the red indicator should be a band across the screen with the statement "Theatre ventilation not operational. Do not use". The green indicator may be moving arrows representing airflow with the legend "Ventilation operational".

8.69 The humidity within the operating department when in use should fall within the range 35% to 60%. Where it is considered necessary to fit a humidifier, it should be selected to humidify to 40% saturation at 22ºC during the design winter outside conditions. The cooling coil should be able to remove sufficient moisture so that 60% saturation at 20ºC is not exceeded during the design summer outside conditions.

Note: When not in use the humidity may be allowed to fall below 35% but should not be allowed to rise above 70%.

8.70 The automatic control of ventilation in operating suites needs to be simple and robust. Over-reliance on complex room pressure and flow relationships linked to automatic fan speed control are unnecessary and in the long term have been shown to be unreliable. Complex software algorithms that can only be accessed and interpreted by off-site specialists should not be used. Whichever control strategy is chosen, it is important that on-site staff have the facility to override the control system and keep the ventilation operating at least until the surgical procedure is complete (see also Chapter 9).

Operating suite air handling unit

8.71 Each conventional operating theatre suite should have its own dedicated AHU to the standard set out in Chapter 9. To ensure operational flexibility and permit routine maintenance, an air handling unit should not be shared between suites.

8.72 In retrofit installations, site conditions may preclude individual AHUs for each suite. In these circumstances, subject to VSG approval, an AHU may be shared between not more than two operating suites providing each suite has its own control of temperature. An accessible airflow measurement test point should be provided in the supply branch duct to each theatre suite so that the primary air volume to each can be determined. In addition, the branch supply and extract should be capable of being physically isolated and the main airflow rate reduced so that either suite can be taken out of use without detriment to operating conditions in the other.

Note: An AHU provided under paragraph 8.72 may be shared between two conventional operating suites, but not between a conventional and a UCV suite

8.73 The AHU supply and extract fans should be interlocked so that the supply starts up first and shuts down last, thus preventing reverse airflows. If the extract plant fails when the theatre is in use, it may continue to be used but a warning should show on the BMS and theatre control panel. If the supply fails when the theatre is in use the extract should shut down to prevent reverse airflows and an alarm should sound and show on the theatre control panel.

Fire aspects

8.74 When considering the overall airflow movement, careful thought needs to be given to the operation of the ventilation system to limit smoke spread in the event of a fire. However, this is a highly staffed department with a low fire risk/load status and these factors need to be recognised when developing the fire strategy. Operating departments typically comprise a series of linked rooms with multiple exits. Over-compartmentation can lead to difficulties in establishing clean airflow paths and room air dilution rates. This will lead to an increased risk of healthcare- acquired infections. Staff areas within the department should be treated as a subcompartment.

Ultra-clean ventilation system

General requirements

8.75 The design philosophy of a conventionally ventilated operating suite is based on the need to dilute contaminants and control both the condition and movement of air in an operating suite. Ultra-clean ventilation (UCV) is a means of significantly increasing

the dilution effect by providing a large volume of clean filtered air to the zone in which an operation is performed, and sterile items are exposed. Air is discharged above the operating zone and while not truly laminar, its downward displacement purges the clean zone of contaminants and particles generated by the activities within it. The airflow in and around the clean zone also serves to prevent particles originating outside the zone from entering it. The resulting reduction in contaminants has been shown to significantly reduce post- operative sepsis following certain orthopaedic procedures.

Note: The number of microorganisms that are present in the air at the wound site and exposed surgical items is dependent on the operating team, their procedural discipline, choice of clothing and the type of UCV system. Ultra-clean air is defined as that containing not more than 10 colony forming units per cubic metre of air (10 cfu/m3) present at the wound site during a surgical procedure. In practice levels of only 1 cfu/m3 are often attained.

8.76 UCV systems are very successful in reducing contaminants at the wound site so it is often considered that there is no need for complex air movement control schemes in the rest of the suite. However, when designing the ventilation scheme, it should be noted that the users may switch the UCV terminal to “low speed” when non-orthopaedic surgery is taking place. This is because the high airflow rates can cause increased moisture evaporation of exposed tissue which may be detrimental to the surgical outcome. In recognition of this, the ventilation scheme should be capable of providing operating conditions to at least a “conventional” theatre standard throughout the suite with the UCV in “low speed” mode. It should also be remembered that suitable levels of ventilation will always be required in the peripheral rooms.

8.77 UCV systems can be designed and built from first principles or a range of bespoke modular units of varying shapes and sizes are available, with each manufacturer having a slightly different approach to UCV design. Notwithstanding any variation in their design philosophy, all UCV systems will be required to completely achieve the performance standard set out in Chapter 12.

8.78 As with conventional theatres, each UCV operating suite should have its own dedicated AHU to the standard set out in Chapter 9. To ensure operational flexibility and permit routine maintenance, an AHU should not be shared between suites.

8.79 In retrofit installations, site conditions may preclude individual AHUs for each suite. In these circumstances, subject to VSG approval, an AHU may be shared between not more than two UCV operating suites providing each suite has its own control of temperature. An accessible airflow measurement test point should be provided in the supply branch duct to each theatre so that the primary air volume to each UCV canopy can be determined. In addition, the branch supply and extract should be capable of being physically isolated and the main airflow rate reduced so that either suite can be taken out of use without detriment to operating conditions in the other.

Note: An AHU provided under paragraph 8.79 may be shared between two UCV operating suites, but not between a conventional and a UCV suite.

8.80 An inherent feature of a UCV system is its large airflow so it is essential to recirculate the air supplied to the operating theatre and/or to recover its energy in order to optimise operating costs.

8.81 The primary fresh air volume supplied to a UCV operating suite will be the same as for a conventional suite and it should be dispersed to the rooms in the suite in the same manner. The UCV canopy will typically incorporate recirculation fans. In order to prevent these fans “robbing” the air supply to the rooms, the primary air supply to the UCV theatre suite should be split into two ducts each with a volume control damper, one duct to feed the UCV canopy and the other for the anaesthetic and preparation rooms (which will be subdivided to accommodate heater batteries before they serve their respective room).

8.82 “Laying up” instruments in the clean zone is preferable microbiologically and considered best practice by the Royal College of Orthopaedic Surgeons, so an SPS preparation room should be provided. A transfer grille will be needed in the door between the theatre and preparation room.

8.83 If the client requires a “lay up” preparation room, a pressure stabiliser will be required between the preparation room and theatre. It should be fitted with a baffle on the theatre side to prevent air transfer interfering with the airflow distribution under the UCV canopy (see figure 2). Where space planning permits, consideration may be given to a location of the lay up preparation room in which the air pressure stabiliser discharges from it into the theatre at a point beyond the end of the canopy.

Figure 2 Pressure stabiliser fitted in preparation “lay up” room with stand-off baffle in theatre

8.84 Separate scrub-up or disposal facilities are not necessary for air cleanliness, although operational policy may prefer such a provision. A separate anaesthetic room should however be provided.

Types of UCV system

Remote plant systems

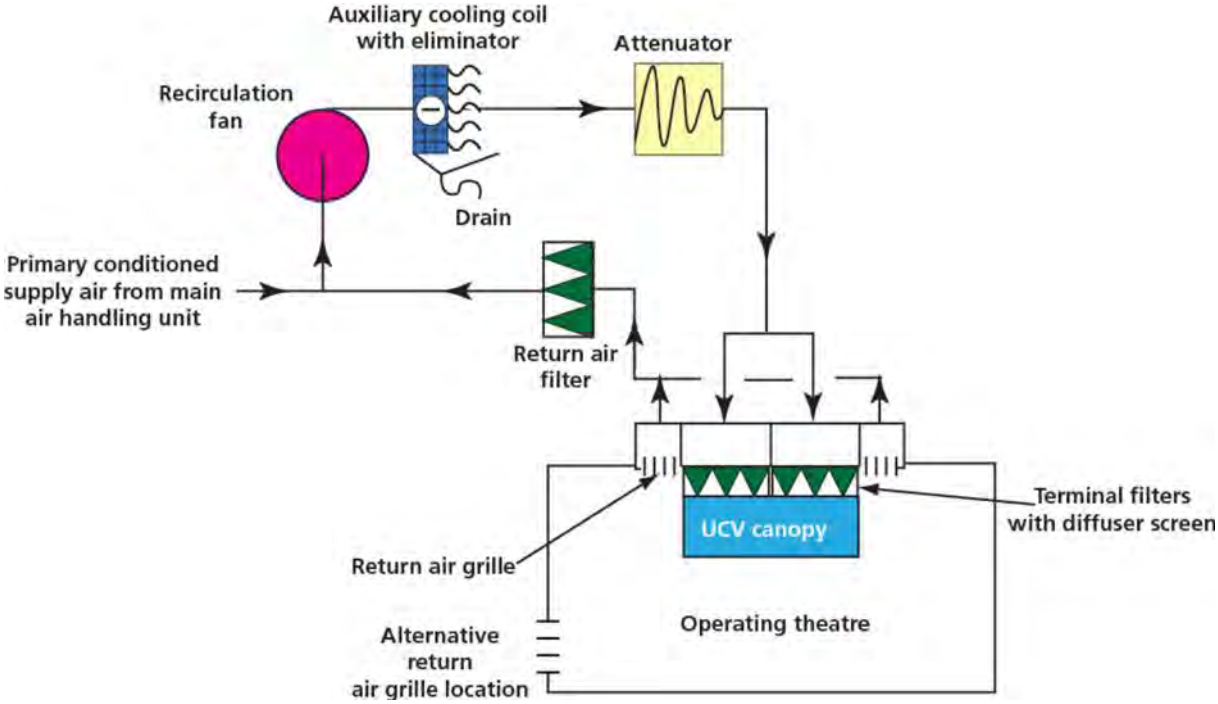
8.85 In a remote plant system, all the air- conditioning equipment is located outside of the operating theatre, except for the unidirectional airflow terminal, terminal filter, air diffuser and the return air grilles (see Figure 3).

8.86 This arrangement has the following advantages:

- the recirculation fans are out of the theatre, thus reducing noise. Multiple recirculation fans may be replaced by a single fan unit.
- casual heat gains from recirculation fan(s), canopy lights, equipment and people within the theatre can be removed by a cooling coil in the return air stream. This will prevent heat build-up in the theatre.

- the return air filters can be changed without needing access to the theatre, making routine maintenance more feasible.
- the opportunity exists to locate the EPA filter in the primary supply duct rather than the theatre terminal. This will reduce the number of filters required and allow them to be changed without entering the theatre.

Figure 3 Remote plant UCV systems



Modular systems

8.87 Vertical-flow modular units comprise a ceiling-mounted canopy containing return air filters, final filter and air diffuser. Primary air is supplied by a remote air- conditioning unit at the volume and to the standard required for a conventional operating suite. The UCV-canopy return-air fans may be within the unit or mounted independently of it in the ceiling void or wall space (see Figure 4).

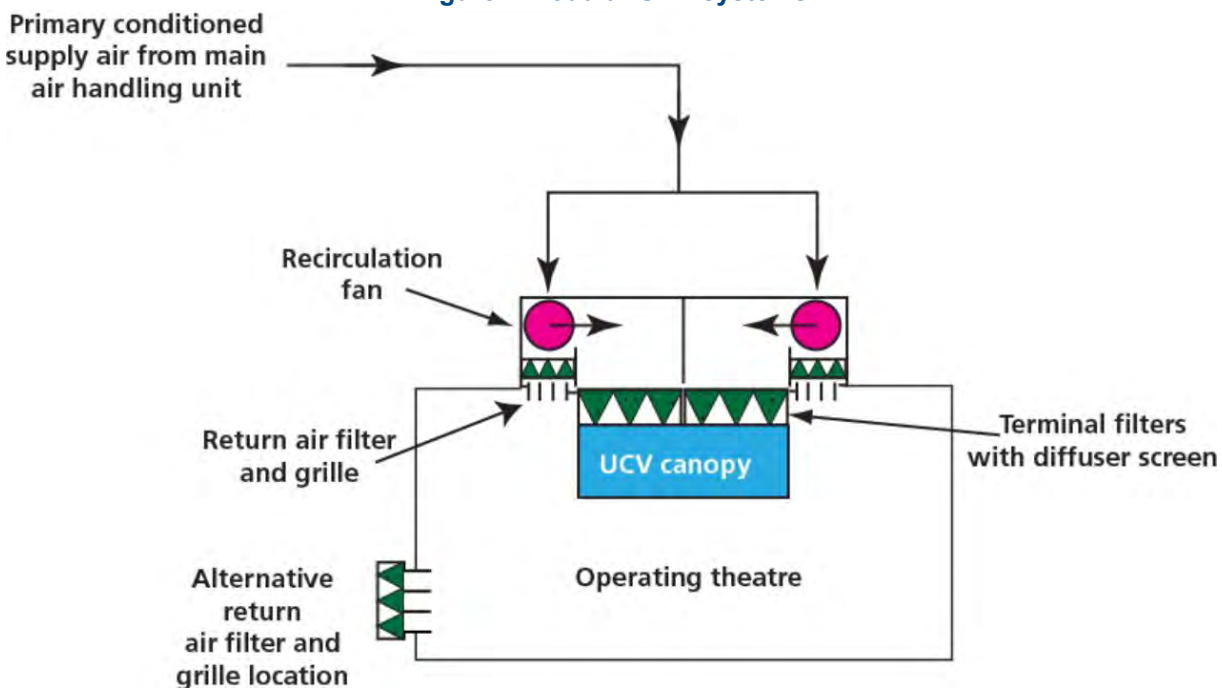
8.88 Modular units have the following advantages:

- as they are produced in a modular form, installation is generally more straightforward;
- they can be used to upgrade an existing conventional operating suite to a UCV suite without the need to change the AHU;
- all the UCV elements are in one place, making maintenance simpler.

8.89 UCV systems can be designed and built from first principles, or a range of bespoke modular units of varying shapes and sizes are available, with each manufacturer having a slightly different approach to UCV design. Whichever system is used, in order for the UCV terminal to produce the desired airflow within its footprint without entraining non-filtered air, the physical outside edge of the UCV canopy unit should not be less than 1 m from the operating theatre wall.

Notwithstanding any variation in their design philosophy, all UCV systems will be required to completely achieve the performance standard set out in Chapter 12.

Figure 4 Modular UCV systems



Vertical flow UCV systems

8.90 Vertical flow systems are effective at reducing infection risks (Lidwell et al., 1982). Some systems have no walls and use auxiliary fans to create an air curtain around the clean zone. Partial wall systems have side screens that terminate 2 m above floor level and full wall UCV have side screens that terminate 1 m above floor level.

8.91 Full wall systems provide a physical barrier between the operating team and other theatre occupants and guide the air down to the operating table level. They can therefore work at a lower air velocity.

8.92 Siting the return air grilles around the periphery of the theatre at low level will help control short-circuiting and give an improved airflow path. In any event there should be an “air out” path on each face or in each corner of the theatre. These may be provided by combination of pressure stabilisers and passive or active low-level extract grilles. Failure to provide “air out” paths on all faces of the theatre may result in the surplus air causing entrainment into the clean zone.

8.93 Vertical systems should have a clean zone large enough to encompass the operating site and all instrument trays likely to be needed for the procedures to be undertaken. Where the surgical site is small, a 1.4 m circular or rectangular terminal may be provided. For major orthopaedic procedures, a minimum size of 2.8 m × 2.8 m will be required. This is the area projected on the floor under the supply air terminal within the full walls, partial walls or air curtain. Any air outside this zone cannot be guaranteed to be ultra-clean although given the dilution factor, the level of microbiological contamination will be much lower than the general level in a conventional operating theatre. Having a contrasting coloured area on the floor delineating the extent of the “clean zone” will assist staff and is therefore essential.

Note: The entire “clean zone” footprint of the UCV canopy will be designated by a contrasting coloured inlay in the floor covering. A line marked on, or cut into, the floor covering is not sufficient and will not be accepted at validation.

8.94 When upgrading an existing conventional theatre to an ultra-clean standard the only solution may be the installation of a modular system. In these units, the heat gains from the return air fans may warrant the inclusion of supplementary cooling within the module. However, issues of cooling-coil drainage, condensate removal and maintenance access within the space constraints of the module may make this option impracticable. The additional cooling load should then be catered for by conditioning the primary air to compensate.

8.95 If an existing AHU is to be retained, it may require modification to ensure that it achieves the standards set out in Chapter 9 of this document (see also paragraph 4.73). The fan may need re-rating to accommodate the change in system resistance. The cooling coil may also need to be upgraded to cater for the increased load resulting from the return air fans and terminal lights. Failure to make adequate provision for this may make the theatre unusable during prolonged warm spells.

8.96 A factor affecting the airflow pattern is the supply/room air temperature difference. When the supply air temperature is significantly above room temperature, buoyancy effects will reduce the volume of air reaching the operating zone. This can occur at start-up in a large theatre where the temperature when not in use has dropped below 18ºC. If it is anticipated at design stage that this will be a regular occurrence, a system incorporating full walls should be used. Demountable extensions that convert a partial wall to a full wall unit are available.

8.97 Convection up-currents from the surgical team and operating lamp tend to counter the movement of clean air towards the operating site, hence the air velocity reaching the operating level is critical. The minimum velocity given below has been selected to take account of these factors and is greater than the theoretical minimum value. For all vertical UCV systems the design discharge velocities will be as follows:

- air velocity 2 m above floor level:
  - no side wall system = 0.38 m/s average;
  - partial wall system = 0.38 m/s average;
  - full wall system = 0.30 m/s average.
- air velocity 1 m above floor level:
  - all systems = 0.2 m/s minimum within the inner operating zone.

Chapter 12 gives details of the method of measurement.

8.98 Variable speed recirculation fans with differential pressure control may be the most suitable solution for maintaining consistent performance and energy saving. The recirculation fans should be accessible for replacement without the need to disturb the fabric of the operating suite.

UCV filters

8.99 The AHU primary and secondary filters should be to the standards and in the location set out in Chapter 9.

8.100 Terminal filters should be provided within the UCV canopy or in the air supply to it. Efficiency particulate air (EPA) filters grade E10 as specified in BS EN 1822 will be required as a minimum. There is no aerobiological benefit in fitting filters of a higher grade than this.

8.101 In some modular UCV units their manufacturers state that the terminal filter is used as a pressure equaliser to balance airflow so a grade higher than E10 is fitted. The increased resistance may affect the velocity of air reaching the operating level and there will be penalties in terms of installed fan power, energy consumption and higher noise levels.

8.102 The final filters should be installed in a leak-proof housing in a manner which allows the terminal unit, filters and their seals to be validated. The UCV canopy and its terminal filters will be scanned with a light scattering airborne particle counter (LSAPC) during validation to prove the effectiveness of the complete installation.

8.103 Where UCV units are constructed in sections, a means of measuring the pressure drop across the terminal filters in each section should be provided. The pressure test points should be located outside of the partial wall, capped to prevent air leakage and accessible within the theatre without the need to open the unit inspection panels. Alternatively, direct-reading non- electronic pressure gauges (of the minihelic type) may be fitted.

8.104 The UCV system will require a return air filter to capture the relatively coarse particles which would otherwise significantly reduce the life of the final filter. This should be at least an ISO 16890 Coarse 60%. In remote recirculation systems there may be advantages in fitting a higher- grade return air filter as it will reduce the load on the terminal EPA filters and extend their life.

Noise level

8.105 If sound-attenuating material is used to line any portion of the inside of the UCV unit it should be non-particle shedding and non-combustible.

8.106 The maximum noise level in an operating theatre fitted with a UCV terminal of any type should not exceed 53 dB(A). Chapter 12 gives details of the method of measurement.

Lighting and operating lights

8.107 The position of the UCV light fittings and style of partial walls, where fitted, should neither adversely disturb the airflow nor result in significant spatial variations in illuminance levels.

8.108 In vertical units, specialised task lighting should be provided by toroidal, cruciform or small multiple dome-shaped luminaires as they have good aerodynamic properties. The ideal luminaire will have a minimal effect on the airflow regardless of where it is positioned. Large diameter saucer-shaped luminaires should not be used in vertical

flow systems as they will occlude the airflow in the critical central zone. It is important to consider the suitability of existing luminaires when retrofitting UCV systems.

8.109 In vertical UCV installations the distance between the UCV canopy diffuser screen and the floor should be between 2.75 m and 3 m. This will allow space for the operating lamps and their articulation arms, and ensure that air at the correct velocity arrives at the operating level. When parked the lowest point of the central light stem, luminaire, monitor, camera, their associated articulation arms and any other ceiling-hung equipment should never be less than 2 m above floor level.

Note: The traditional means of light support is a central column that passes through the UCV canopy and is rigidly fixed to the building structure. The position of the support therefore prevents air being supplied at the centre of the canopy. Separate supports displaced from the centre of the clean zone would lead to improved airflow. This approach was advocated in the 1994 version of this guidance but at the time of writing no UK manufacturer has chosen to adopt this solution. Alternatively, equipping the operating team with battery- powered headset lamps may remove the need for traditional operating lamps and their supports.

Controls and instrumentation

8.110 The functions of the supply AHU and extract ventilation should be continuously monitored by a BMS control unit and interlocked with the UCV terminal control and monitoring functions. The room temperature sensor should be located in the re-circulated air return path. The controls and instrumentation for the main plant are set out in Chapter 9.

8.111 UCV systems will additionally require a low speed facility that can reduce the air supplied through the UCV canopy to a volume that equates to not less than 22 ac/h of the operating theatre gross volume or that required for door protection, whichever is greater, whilst still leaving the supply AHU operating at full speed. In this operational mode the theatre may be used as a conventional operating suite. A means of switching between conventional and UCV mode will be provided on the theatre control panel and its function clearly labelled (see the Specialised Ventilation for Healthcare Society's (2017) SVHSoc.01 – 'Operating theatres: energy control strategies and the surgeon's panel' for further details).

Note: UCV theatre ventilation may be completely switched off when the theatre is not in use, but the room temperature should not be allowed to drop below 18ºC (see paragraph 8.96). The AHU and UCV control should be interlocked so that when the AHU goes to "Set back" the UCV also goes to "Set back", and if the AHU goes "Off", the UCV terminal fans also switch "Off".

There is no aerobiological benefit in keeping the UCV terminal fans running when the theatre is not in use, it results in wasted energy.

8.112 The following indicators should be incorporated in the theatre control panel and their functions clearly labelled. In retrofit installations, an auxiliary panel for the UCV may be the most practical option. If fitted it should be mounted adjacent to the theatre panel and their control functions interlocked.

- A readout sufficiently large (25 mm) to be clearly visible from the operating table that shows the temperature of the air at the UCV canopy.
- A readout sufficiently large (25 mm) to be clearly visible from the operating table that shows the relative humidity of the air at the UCV canopy.
- A red indicator light that will illuminate when either the supply AHU or the UCV canopy fails, or either or both are switched off or the AHU is in “Set back” (legend: “Theatre not to be used in this condition”).
- An amber indicator light that will illuminate when the UCV canopy is at low speed and the supply AHU is running at full speed (legend: “Conventional theatre mode”).
- A green indicator light that will illuminate when both the supply AHU and UCV canopy are operating at full speed (legend: “UCV theatre mode”).
- A blue indicator light that will illuminate when the UCV canopy airflow, as detected by a differential pressure sensor, falls below 80% of the design flow rate (legend: “UCV requires service”).

Note: In touch screen panels the red indicator should be a band across the screen with the statement “Theatre ventilation not operational. Do not use” The amber indicator may be moving arrows representing airflow with the legend “Conventional Theatre mode”. The green indicator may be moving arrows representing airflow with the legend “UCV Theatre mode”. The blue indicator may be a band across the UCV terminal mimic stating “UCV requires servicing”.

8.113 When a system is designed to have partial walls with full wall extensions, a volume control facility may be incorporated to allow the system to be run with reduced velocity when the demountable full walls are in place. It would be the responsibility of the user to ensure correct operation of the system. To assist the user, an explanatory notice should be included on the theatre control panel.

8.114 The UCV unit manufacturer’s control box should be located in an accessible position preferably in the operating department adjacent to the operating theatre that it serves. A service corridor, if provided, is an ideal location. The control box should be clearly labelled with the identity of the operating theatre that it serves.

Barn and semi-barn theatres

8.115 There is no aerobiological reason why two or more UCV systems should not be installed in a common area if adequate spacing is provided. These are known as barn theatres and require special design considerations and operational discipline. The relative positions of the UCV units, temperature control range and location of doors and openings to other areas will all significantly affect the airflow at the operating positions.

8.116 A barn theatre has two or more operating positions each ventilated by a UCV canopy all in one open operating theatre. There may be a common scrub trough, SPS preparation room and shared utility, all of which reduce the facility’s footprint. For reasons of privacy and dignity, there is usually a separate anaesthetic room for each operating position. The operating positions may be separated by glass screens to

prevent bone fragments being propelled from one position to another when high-pressure air-driven surgical tools are being used.

8.117 A semi-barn theatre is very similar but would have a full-height dividing wall between the operating positions. The wall will not extend across the full width of the room, only its middle section. This creates a degree of physical separation between the operating positions but allows staff to walk from one to another around the ends of the dividing wall.

8.118 It is important that the physical layout and ventilation strategy of the barn or semi-barn are in harmony if the installation is to work successfully. The following points should be resolved with the architect and VSG when considering the design:

- in order to reduce the risk of pre- contamination, surgical instruments should not have to pass one operating position in order to get to the one that they are destined for;
- staff having scrubbed should not have to pass one operating position in order to get to the one that they are destined for;
- waste material being cleared from an operating position should not pass another when being removed from the operating theatre;
- the operating positions and their UCV canopies should be placed in line and not staggered or offset, otherwise their airflow patterns will interfere with each other;
- while barns and semi-barns have, from the staffing and space utilisation point of view, many advantages, they can create problems with temperature control and energy efficiency. It is not advisable to shut their ventilation off at night or weekends as if the operating theatre temperature drops it can take a considerable time for the ventilation to achieve the required air velocity at the operating position (paragraph 8.96). Because the barn is a large open space, when it becomes cold the warm air supplied by the UCV canopies tends to rise and stratification occurs. As a result, although from the user's point of view the ventilation appears to be running, the air being delivered does not actually have enough velocity to reach the operating table;
- access for service, maintenance and future upgrades or refurbishment will be restricted as this can only be carried out when none of the operating positions is in use.

8.119 Ventilation of each UCV canopy and associated anaesthetic room will be by a dedicated AHU; ventilation of the shared spaces and perhaps recovery area would either be shared between the operating position AHUs or provided by a separate AHU.

Hybrid theatres

8.120 A designation given to operating theatres that contain scanning equipment on a robotic arm. Major surgical procedures are carried out and the patient is scanned as necessary during the procedure. The scanning equipment may be floor-mounted or ceiling-hung and there will be one or more large monitors, a variety of screens and the medical gas terminal units all ceiling-hung on articulated pendants. The number of pendants and their supporting steelwork can reduce the space available to install

ventilation ductwork and compromise the location of the supply air terminals. Liaison with the architects at an early stage in the project design is essential to ensure a satisfactory ventilation solution.

8.121 Hybrid theatres tend to be significantly larger than conventional theatres and may have a radiation protected control room and an equipment room to house the servers for the scanning equipment and its robotic arm in addition to the standard operating suite of rooms. The ventilation load will therefore be larger and standard solutions should be adapted to suit or the designer will need to return to first principles (see Appendix 8).

8.122 Because of the increased airflow requirement, the AHU will be larger than for a standard conventional operating suite.

8.123 In all other respects the ventilation design and theatre control panel will be as for a conventional operating suite as above.

Neutral pressure theatres for infectious patients

8.124 The client may have a requirement for an operating suite for surgery on infectious patients. This may be a dedicated neutral-pressure operating suite or a standard operating suite that is designed to be easily convertible to a neutral-pressure suite. If airborne microorganisms liberated from a patient during a surgical procedure are allowed to cascade out into the adjacent corridors, they could infect other patients or the staff in the operating department.

8.125 The room provision and layout will be as for a conventional operating suite with the following variation to the ventilation scheme:

- the operating theatre will have a balanced supply and extract so that it is at the same pressure as the corridor;
- air should not cascade from the theatre to the surrounding rooms, so pressure stabilisers and/or transfer grilles should not be fitted. In the case of a convertible operating suite, permanently fitted hinge-down blanking plates with clamps should;
- be provided to close the pressure stabiliser/transfer grille openings when required;
- the preparation room may be dispensed with to avoid having stock that could become pre-contaminated. Sterile packs, instruments and consumables would be delivered to the theatre on a case by case basis. If a preparation room is required, it should be maintained at 10 Pa to both the theatre and corridor;
- the anaesthetic room should have a supply in excess of extract so that is maintained at 10 Pa above both the corridor and the theatre. There should be a pressure stabiliser between the anaesthetic room and the corridor but no transfer device between the anaesthetic room and the theatre;
- the scrub should have an active extract as for a conventional operating suite but no pressure stabiliser between it and the corridor;
- the utility should be at negative pressure of not less than –5 Pa to the theatre and its corridor;

- the corridor extract will be sized to cater for the air leakage from the preparation and anaesthetic rooms.

Overall, the ventilation scheme should ensure that all air supplied to the operating theatre is removed in the theatre. The theatre should be neutral (at the same pressure) to the corridor so that when the theatre exit door is open there is effectively no interchange of air between them. When the preparation or anaesthetic doors are opened, air flows from them into the theatre and not the other way.

8.126 The theatre control panel, automatic control strategy and air handling unit will be as for a conventional operating suite.

Interventional imaging suites

8.127 Interventional imaging refers to rooms in which surgical interventions are carried out guided by imaging equipment. The risk of infection by the airborne route is low as the surgical site is small, and sterile instruments tend to be unwrapped immediately before use. Anaesthetic gas or agents are used for pain relief or sedation Patients requiring full anaesthesia will normally be treated in a hybrid or conventional operating suite. The VSG should advise on the likely scope of use.

8.128 An interventional image suite may simply be a room containing the imaging equipment, an adjoining radiation protected control room or bay for staff and an equipment room for the imaging server. Support rooms for patient changing, sit recovery, toilets and a utility may also be needed.

8.129 Ventilation of the imaging room would be 10 ac/h with the room at a positive pressure to the corridor. Ceiling- mounted steelwork to support the imaging equipment may reduce the space available to install ventilation ductwork and compromise the supply terminal locations. This may mean that sidewall linear terminals are the only viable option. If fitted, their discharge velocity should not cause draughts and the direction vanes should be fixed or capable of being locked to prevent alteration during routine cleaning. Alternatively, a displacement ventilation scheme may be considered.

8.130 A full “theatre style” control panel is not required, but a green light to show the ventilation is operational and a red one to show it is not should be provided.

8.131 Radiation shielding and warning notices may be required to ductwork where it penetrates ceilings, walls or floors to plantrooms or adjacent spaces to which staff may need access.

Other application-specific design guidance

Application: Bronchoscopy, Endoscopy, Dental and General treatment facilities

Table 2: Treatment and procedure facilities

Area/zone	Reason for ventilation	Typical design factors
Bronchoscopy procedure room	Control of exposure of staff to airborne pathogenic material discharged by the patient e.g. multi-drug-resistant tuberculosis (MDR-TB) during the procedure being undertaken. (COSHH Regs) Control of exposure of staff to waste anaesthetic agents when used. (COSHH Regs)	Establish a clean airflow path – Supply terminal at high level at foot end of patient's chair/couch and extract terminal at patient's head level behind the chair/couch. Design parameters Air change: 15 per hour Pressure regime: Where patient membranes are breached and the procedure would present an infection risk to the patient, the pressure should be +10 Pa to the corridor. In Bronchoscopy and all other Endoscopy procedure rooms –5 Pa to corridor shall be established. (NOTE The decision as to the preferred pressure regime for each room must be made at design stage. They must not be designed and set up as switchable pressure rooms) Noise level: 40 d(B)A Temp range: 20 to 25ºC must maintain any selected set point in the range via BMS Humidity: Floating; max 70%RH Air quality: BS EN 16798 - SUP2 Extract discharge – Discharge in safe position away from people or open windows. If no suitable position available treat the discharge in the same way as a LEV with a discharge stack at a minimum of 3 m above the roof line.
Endoscopic procedure room	As above and odour control	
Dental treatment room	Control of exposure of staff to airborne pathogenic material discharged by the patient during the procedure being undertaken. (COSHH Regs) Control of exposure of staff to waste anaesthetic agents when used. (COSHH Regs)	Establish a clean airflow path – Supply terminal at high level and extract terminal at low level near patient's chair/ couch. Design parameters Air change: 10 per hour Pressure regime: Neutral to corridor Noise level: 40 d(B)A Temp range: 20 to 25ºC must maintain any selected set point in the range via BMS Humidity: Floating; max 70%RH Air quality: BS EN 16798 - SUP2
Emergency department resuscitation room	As above	
General treatment room	Comfort conditions only	

All of the above rooms are suitable for aerosol-generating procedures (AGPs)

Applications: Level 2 and 3 critical care areas, bone marrow transplant (BMT), oncology, organ and tissue transplant units

Table 3: Airborne protective facilities

Area/zone	Reason for ventilation	Typical design factors
Note: Level 2 & 3 Critical care areas should be treated identically in terms of service provision as their only difference is the staff- to-patient ratio.		
Level 2 or 3 critical care individual room	Protection of patients from airborne organisms and fungal spores	Supply only in patient's room and cascade air out via door undercut, transfer grille or pressure stabiliser through rooms of a lower classification. Design parameters Air change: ≥10 per hour Pressure regime: +10 Pa to general area Noise level: 35 d(B)A Temp range: 20 to 25ºC must maintain any selected set point in the range via BMS Humidity; Floating; max 60%RH Final filter; BS EN 1822 – EPA10
Level 2 or 3 critical care open bays	As above	
Bone Marrow Transplant (BMT) unit	Protection of patients from airborne organisms and fungal spores Note: Patient(s) will have a very poor immune system (neutropenia) so will be particularly vulnerable to infection by the airborne route.	Supply only in room and cascade air out via door undercut, transfer grilles or pressure stabilisers through rooms of a lower classification. Design parameters Air change: ≥10 per hour Pressure regime: +15 Pa to corridor Noise level: 35 d(B)A Temp range: 20 to 25ºC must maintain any selected set point in the range via BMS Humidity: Floating; max 60%RH Final filter: BS EN 1822 – EPA12
Haematology/Oncology ward	As for BMT	
Organ and Tissue Transplant unit	As for BMT	

Applications: Isolation rooms category 2 & 3, Infectious disease units, Containment level 3 rooms

Table 4: Airborne isolation facilities

Area/zone	Reason for ventilation	Typical design factors
Category 2 isolation room	Protection of staff and all other building occupants from airborne organisms dispersed by a patient with an infectious disease. See Scottish Health Planning Note 4 Supplement 1	Extract only in patient's room and en-suite. Supply air from corridor passing into room via door undercut, transfer grille or pressure stabiliser. Alternatively the patient's room may have a supply and extract provided they are interlocked to ensure that the room is always at –ve pressure with regard to the corridor. Design parameters: Air change: ≥10 per hour Pressure regime: –5 Pa to general area Noise level: 35 d(B)A Temp range: 20 to 25ºC must maintain any selected set point in the range via BMS Humidity: Floating; max 60%RH Air quality: BS EN 16798 – SUP2
Category 3 isolation room		

Area/zone	Reason for ventilation	Typical design factors
Positive pressure ventilated lobby (PPVL) isolation room Universal isolation facility	Protection of building occupants from patients who may be infected and protection of patients who may be immunocompromised and protection for patients with both conditions. See Scottish Health Planning Note 4 Supplement 1	Supply in lobby flowing through a pressure stabiliser to patient's room and on via a door undercut or transfer grille to an extract in the en-suite. Design parameters: Bedroom air change: ≥10 per hour Lobby pressure: +10 Pa to corridor Bedroom pressure: Neutral En-suite pressure: –ve Comfort parameters as above Air quality: BS EN 16798 – SUP2 With facility to fit BS EN 1822 – EPA12
Containment level 3 laboratory	Protection of occupants in adjoining spaces from airborne bio-hazards	For design details see the Medical Research Council's "Standards for containment level 3 facilities"
Category 4 facility	Design advice will be provided by the client	

Application: Obstetrics theatre, delivery rooms, nursery, neonatal intensive care and special care baby units

Table 5: Maternity facilities

Area/zone	Reason for ventilation	Typical design factors
Obstetrics theatre	Protection of patients from airborne organisms and fungal spores. Control of exposure of staff to waste anaesthetic agents (COSHH Regs)	Ventilation design parameters as for a conventional operating suite. System should normally be at "set back" with a minimum temperature of 18ºC and be able to attain full operating conditions within 5 minutes of triggering the system
Delivery room	Control of exposure of staff to waste anaesthetic agents. (COSHH Regs)	Establish a clean airflow path – Supply terminal at high level at foot end of bed and extract terminal at low level at head end of bed. Design parameters: Air change: 15 per hour Pressure regime: Neutral to corridor Noise level: 35 d(B)A Temp range: 20 to 25ºC must maintain any selected set point in the range via local control Humidity: Floating – max 70%RH Air quality: BS EN 16798 – SUP2
Delivery room with birthing pool	As for standard delivery room above	
Specials delivery room	As for standard delivery room above	
Nursery	Comfort conditions only	
Neonatal intensive care unit or special baby care unit (SCBU)	Protection of neonates from airborne organisms and fungal spores. Neonates are kept in incubators but may be removed for feeding, changing etc. so local temperature control and ensuring a draught-free environment is essential.	Standard supply and extract Design parameters: Air change: 10 per hour Pressure regime: +5 Pa to corridor Noise level: 45 d(B)A Temp range: 20 to 28ºC must maintain any selected set point in the range via local control Humidity: Floating – max 70%RH Air quality: BS EN 16798 – SUP1 (Filter grade depends on ODA category – see the Specialised Ventilation for Healthcare Society's (2018) SVHSoc.02)
N.B. This is a critical healthcare facility and consideration should be given to system resilience and/or how suitable alternative accommodation may be provided in the event of a ventilation system failure.		

Applications: pharmacy aseptic suite, gene therapy, radiopharmacy, support rooms

Table 6: Pharmacy facilities

Area/zone	Reason for ventilation	Typical design factors
Aseptic suite Cleanroom	Protection of product during and after processing. Protection of the wider environment from cytotoxic agents and antibiotics. EUGGMP standards (European Commission, 2011) apply and the Medicine Act if the facility is licensed. Control of exposure by the airborne route to staff of substances during and after processing products. (COSHH Regs). Note: While this application is a critical facility, it is usual to have a plan in place to decant to another site in the event of a ventilation system failure	Supply only in cleanroom and cascade air out via pressure stabilisers through rooms of a lower classification or where there are multiple cleanrooms, a balanced supply and stable cascade out. Thimble extract may be provided for class 3 safety cabinets depending on the location of room within the building. Note: Advice from the client's lead pharmacist should be sought prior to engaging in detailed design. Design parameters: Air change: ≥20 per hour Pressure regime: +15 Pa between unclassified rooms and +10 Pa between classified rooms Noise level: 45 d(B)A Temp range: 20–24ºC must maintain any selected set point in the range via BMS Humidity: Floating – max 60%RH Final filter: BS EN 1822 – HEPA14
Gene therapy cleanroom	As above, plus protection of the wider environment from product	As per cleanroom above plus negative-pressure access lobby and controlled exhaust
Radiopharmacy cleanroom	As for standard cleanroom with additional requirements of the Ionising Radiation (Medical Exposure) Regulations	As per cleanroom above
Non-sterile stores and support rooms	Comfort conditions only	

Application: decontamination facilities

Table 7: Decontamination unit

Facility	Applicable Standards
Central Decontamination Unit	These are highly regulated production facilities dictated by:- Planning note - Scottish Health Planning Note 13 Part 1: 2010 Decontamination Facilities: Central Decontamination Unit. HFS, 2011 Mandated by compliance document - Requirements for Compliant Central Decontamination Units Version 2 – GUID 5014, HFS 2019 Equipment manufacturer's design and installation instructions
Local Decontamination Unit	These are highly regulated production facilities dictated by:- Planning note - Scottish Health Planning Note 13 Part 2 Decontamination Facilities: Local Decontamination Units, HFS 2008 Mandated by two compliance documents - Compliant Dental Local Decontamination Units in Scotland Version 2 – GUID 5005, HFS 2019 and Provision of Compliant Podiatry Instruments – GUID 5007 Version 3.0, HFS 2020. Equipment manufacturer's design and installation instructions

Facility	Applicable Standards
Endoscope Decontamination Unit	These are highly regulated production facilities dictated by:- Planning note - Scottish Health Planning Note 13. Part 3 – Decontamination Facilities: Endoscope Decontamination Units, HFS 2010 Mandated by compliance document - Requirements for Compliant Endoscope Decontamination Units, v2 – GUID 5013 HFS 2014 Equipment manufacturer's design and installation instructions

Hydrotherapy: general requirements

8.132 In a hydrotherapy suite, heat recovery should be via a heat pump.

8.133 In general, the quantity of supply air should be calculated as 25 L/s/m2 wetted surface, with the wetted surface taken as 110% of the pool water surface area. (See the Swimming Pool and Allied Trades Association (SPATA) for detailed guidance.)

8.134 A recirculation plant is recommended, with fresh air make-up to the standard required by the Building Regulations Part F – Non-domestic Buildings. In practice this may need to be increased to control condensation.

8.135 As far as practicable, recirculated pool air should be provided to the ancillary changing and recovery accommodation, with the only extract from the toilets, laundry/utility room and pool hall.

8.136 Supply air to the pool hall should be introduced at high level and directed towards the perimeter to mitigate condensation, with extract air taken from directly over the pool.

8.137 The ceiling void above the pool may need to be ventilated to prevent condensation.

Control of hydrotherapy pool installations

8.138 The supply and extract fans should be interlocked so that the supply fan does not operate until flow is established within the extract system.

8.139 Time-clock control should be provided, with a local override switch to extend the normal operating period as required.

8.140 Night set-back temperature (in the range of 21–25ºC) and high humidity control (in the range of 60–75% sat) should be provided to override the time clock in order to prevent condensation. The exact set points should be ascertained post- installation.

8.141 A remote indication panel should be provided in the pool hall, giving a visual display of the pool water and pool air temperature.

Extract systems

LEV systems

8.142 Devices that use an inflow of air to control exposure of staff to hazardous substances are classified as local exhaust ventilation (LEV) systems under the COSHH

Regulations. Note that the supply or make- up air to a room containing an LEV system may itself be considered to be a part of the LEV system.

8.143 An LEV system may comprise a self- contained unit incorporating its own carbon filter such as a simple bench-top fume cupboard. Alternatively, it may be a complete "ventilation system" comprising a make-up air supply, multiple exhaust protected workstations, branch and central extract ductwork, duplex extract fans and a high-level discharge terminal. It may also incorporate a special filtration system appropriate to the hazardous substance being controlled. Such systems could be required for workshops containing woodworking machinery or large centralised pathology laboratories housing multiple safety cabinets, cut-up benches, fume cupboards and specimen stores.

8.144 It is important to recognise at the design stage whether an extract is being provided for comfort, to remove odours or as an LEV system. Typical LEV systems in healthcare include:

- microbiological safety cabinets and containment level 3 rooms;
- fume cupboards;
- welding fume extracts;
- woodworking-machinery duct collectors;
- lead-acid battery charging-bay extracts;
- powered plaster and bone saws;
- pharmaceutical preparation cabinets and tablet machines;
- dissection benches, cut-up tables and some specimen stores;
- medium- and high-risk infectious diseases isolation facilities;
- dental furnaces, grinders and polishers.

Note: Post-mortem tables may incorporate downflow peripheral ventilation but unless otherwise specified by the equipment supplier, their ventilation is only provided to control odours.

8.145 Information on the design of ductwork, fan and discharge stack arrangements will be applicable to all types of LEV system and is given in Chapter 9.

8.146 LEV systems are statutory items that will be subject to an independent examination and test at least every 14 months by a competent person holding an in-date P601 certificate.

Note: For AGSS, see Scottish Health Technical Memorandum 02-01.

Bench extract systems

8.147 Bench extract ventilation is required in departments such as pathology and mortuary, where activities involve the release of malodorous or toxic fumes which should not be inhaled. They may also be required in central decontamination units and wash-rooms within endoscope reprocessing units to remove airborne biological material liberated when the used items are given a preliminary clean.

8.148 In all cases bench extract systems that create an airflow from the front to the rear are preferred over those that rely on a downflow of air through a perforated surface, as the airflow is easily obstructed when in use.

Typical arrangements

8.149 Each ventilated position will usually be accommodated in a continuous run of benching, which should not be more than 650 mm from front to rear and which should be provided with a continuous upstand at the rear. Each position should have a 1200 mm × 150 mm linear extract grille mounted on a purpose-designed plenum box (incorporating guide vanes as necessary), with its face flush with the upstand. The bottom of the grille should be as close as practicable to the level of the working surface (usually 75 mm above, to allow for cleaning). The minimum velocity across any part of the grille should be 1 m/s. The grille should be readily demountable to allow for cleaning.

Control of bench extract systems

8.150 Provided that it does not interfere with the operation of the department when not in use, the ventilation system for the bench extract and any associated supply may be shut down. However, a run-on timer with a minimum setting of 30 minutes should be provided. To this end, local control should be provided.

8.151 Processes that produce hazardous vapours, fumes, dusts or noxious vapours should be enclosed or semi-enclosed in a suitable cabinet or exhaust-protected workstation (LEV).

Microbiological safety cabinets and fume cupboards

8.152 Safety cabinets and fume cupboards are devices that have an inflow of air to control exposure of staff to hazardous substances. The units and their exhaust systems, filters, fans and discharge terminals are all classified as LEV systems under the COSHH Regulations. The make-up air system to a room that contains an LEV system may also be considered as an essential part of the system and be included in the LEV classification.

Special requirements

8.153 The supply air system should not distort the unidirectional and stable air pattern required for fume cupboards and microbiological safety cabinets. In general, supply air ceiling diffusers should not discharge directly towards fume cupboards or safety cabinets, unless the terminal velocity is such that the airflow pattern at the front of the cabinet is unaffected. The design should ensure that high air-change rates, and/or the opening and closing of doors, do not have any adverse effect on the performance of safety cabinets or fume cupboards. A damped door closure mechanism may help.

Arrangements for safety cabinet installations

8.154 The manufacture and installation of microbiological safety cabinets will be in accordance with the relevant national standards and guidance issued by the Advisory Committee on Dangerous Pathogens (ACDP).

8.155 A Class 1 microbiological safety cabinet will be specified for routine work involving Group 3 pathogens. It should be housed in a containment level 3 room. Specific

design information on containment rooms is issued by ACDP in conjunction with the Health and Safety Commission.

8.156 Siting and installation of microbiological safety cabinets are of particular importance because:

- the protection afforded to the operator by the cabinet depends on a specific and stable unidirectional airflow through the open front;
- the protection to the environment by the cabinet depends on the high-efficiency particulate air (HEPA) filters. The exhaust air should never be considered as totally free from microbiological hazard.

8.157 Microbiological safety cabinet extract is HEPA filtered prior to being discharged to outside. Current standards permit the installation of microbiological safety cabinets with integral fans, provided that the extract ductwork can be kept short (that is, less than 2 m); such an installation, however, is likely to be noisy and is not recommended for use in new buildings.

8.158 Ductwork and discharge arrangements should be as set out in Chapter 9.

8.159 Discharge should be to outside but where this is impracticable, discharge into the room via a double HEPA filter will be accepted if approved in writing by the VSG.

Arrangements for fume cupboard installations

8.160 The manufacture and installation of fume cupboards will be in accordance with the relevant national standards and associated guidance.

8.161 The primary factors which contribute to the effective performance of fume cupboards include:

- an adequate volume of supply air and its means of introduction;
- an effective exhaust system to promote the safe dispersal of waste products to atmosphere.

8.162 The air velocities through sash openings should be enough to prevent hazardous materials from entering the laboratory while avoiding excess flow rates that interfere with the investigation process. Average face velocities should be between 0.5 and 1 m/s, with a minimum at any point within 20% of the average, the upper end of the range being applicable to the containment of materials of high toxicity. The design velocity should be maintained irrespective of whether the sash opening is varied, or whether doors or windows are open or closed (see BS EN 14175).

8.163 The possibility of a fire or explosion which may not be contained by a fume cupboard should always be considered. A fume cupboard should not, therefore, be sited in a position where exit to an escape route will necessitate passing directly in front of it.

Control of extract systems

8.164 It is desirable to provide local control of safety cabinets in order to maximise the life of the HEPA filter, and to permit the sealing of the cabinet and room for fumigation if spillage occurs.

8.165 To cope with the risk of an accident or spillage outside safety cabinets, a panic button should be provided to switch off the supply to that area and to discharge all extracted air to atmosphere.

8.166 In pathology departments, it will always be necessary to have one or more microbiological safety cabinets and one or more fume cupboards available for use, including weekends; therefore, local overriding controls for all these items and any associated ventilation plant will be necessary.

Hood extract systems

Special requirements

8.167 Extract canopies will be required over steam-and-heat-emitting appliances, for example sterilisers, catering and washing equipment and for the extraction and removal of unpleasant odours. These installations are for the control of non-hazardous airborne contaminants, they are not LEV systems.

8.168 Perimeter drain gulleys and corrosion-proof grease eliminators should be provided on kitchen hoods (see BESA DW 172 – ‘Specification for kitchen ventilation’).

Typical arrangements

8.169 The airflow rate should be enough to ensure an adequate capture velocity in the vicinity of the process. Advice from equipment suppliers should be sought, as excessive velocities will be wasteful of power and generate noise.

8.170 The lowest edge of the canopy should be 2 m above finished floor level, with a minimum of 300 mm overhang beyond the edge of the equipment on all sides.

8.171 A compact arrangement of equipment (but with access for maintenance) will minimise the canopy area, and hence reduce the air volume necessary to achieve the optimum capture velocity.

8.172 Hoods required for the control of heat gain and vapours may be connected to the general extract system when it is convenient to do so, but where non- corrosive ductwork materials are necessary, a separate extract system is preferred.

8.173 Lighting and internal divider plates are often required to be built into the perimeter of large canopies; however, built-in shelving systems are not recommended, as they interfere with the airflow, and constitute a maintenance problem.

Control of hood extracts

8.174 Provided that it does not interfere with the operation of the department when not in use, the ventilation system for the hood extract and any associated supply may be shut down. To this end, local control should be provided.

Plantroom ventilation

General requirements

8.175 Plantrooms are required to be ventilated in order to maintain acceptable temperatures for satisfactory operation of the plant and controls, and for maintenance activities. Natural ventilation through louvred openings protected from infestation by a

mesh with openings of no less than 6 mm and no more than 12 mm are required. Powered plantroom ventilation should only be needed if natural ventilation is not adequate.

8.176 Ventilation requirements should consider all heat sources within a plantroom, and where there are large glazing areas, solar gains. The ventilation rate should limit the maximum temperature within the plantroom to 32ºC.

8.177 Air handling equipment cannot be located in a fire compartment that houses combustion equipment.

8.178 AHUs and other ventilation equipment that serve occupied areas cannot draw their intake air from a plantroom. Neither should extract ventilation plant or medical vacuum pumps discharge air into a plantroom.

8.179 Statutory regulations for plantroom ventilation are contained in the Building Regulations, and further guidance in the CIBSE Guide B2. Note the need to assess the risk of services to AHUs freezing in unheated plantrooms.

9. Equipment Selection Factors

General requirements

9.1 The following gives detailed guidance on the design and selection of ventilation equipment, the distribution system, terminals and control aspects. Designers should take note of the supporting information given in Chapters 10 and 12. Failure at the design stage to make due allowance for the standards to be achieved may mean that the installed ventilation system will not be acceptable to the client's validator at handover.

Location and access

9.2 The plant should be located so that it is remote from possible sources of contamination, heat gains and adverse weather conditions. The design should ensure that wind speed and direction have a minimal effect on plant throughput.

9.3 Safe access to and around plant is essential to facilitate inspection, routine maintenance, repair and plant replacement.

9.4 Air-handling units (AHUs) should be located in an accessible area secured from unauthorised entry. They may be grouped together in dedicated plantrooms or distributed around the building with AHUs located adjacent to or within the area that they serve. In the healthcare setting, because of the difficulty in gaining access for routine service and maintenance, mounting ventilation units of any type in ceiling voids above clinical spaces is not permitted.

Note: If it is proposed to install ventilation units of any type in a ceiling void above a non-clinical area, it should be subject to a formal risk assessment and its use being agreed by the ventilation safety group (VSG) prior to design approval. Their assessment will consider how the unit may be safely accessed and maintained.

9.5 AHUs should be located in purpose- built plantrooms or designated service spaces within a building. This will allow for routine service and maintenance (which is a statutory requirement) to be carried out at any time of day and regardless of weather conditions. It will also protect the plant from contamination by bird droppings, so reducing the risk of fungal spore contamination of the air supplied by the AHU. Control of pests and vermin will be simpler and while not in themselves a source of airborne contamination, their corpses can become a reservoir of biological material that may lead to insect infestations within the AHU.

Note: In a new building it is not envisaged that there will be any need to locate AHUs outside. The design of the building should incorporate central or distributed plant spaces of sufficient size to accommodate the plant required to service the building.

9.6 When refurbishing or changing the use of an existing building, plant space should be created to house the ventilation plant and other services. If located on a roof they should be enclosed in a plantroom with a safe means of access. If located at ground level they should be secured within a plantroom to prevent unauthorised access. Measures should be taken to exclude vehicles from the vicinity to ensure that exhaust fumes will not be drawn into intakes. Intakes for ground level AHUs should

be extended to a height and distance from contamination sources that allows them to draw in unvitiated air.

9.7 In the unlikely event that an internal or external plant room cannot be provided, and ventilation units have to be located outside, they should be fully weatherproof to IP65 and secured from unauthorised access. Protection against the elements should also be provided for personnel carrying out routine inspection and maintenance activities. As an example, when two units are outside, and they are installed with their access doors facing each other, if the gap between them is roofed over and the open ends capped, the AHUs themselves create what is in effect a plant room (see photographs).

9.8 Water will be used during routine cleaning or spilt when maintenance is being undertaken. The area around plant should be tanked to prevent water penetration to adjacent areas and adequately drained

Figure 5 AHU formed plant room (external)

Figure 6 AHU plant room (internal)

Note: Plant rooms should be provided with a sink so that glass drainage traps may be cleaned out and staff can wash their hands after handling contaminated/dirty filters. A source of domestic hot water (DHW) with a valved hose connection point will also be required so that AHUs can be washed out internally as part of their routine maintenance. Plant rooms at roof level should be served by a lift.

9.9 Fire precautions should be incorporated in accordance with the Health Technical Memorandum 05 Firecode series. Guidance is available in Chapter 1 of this document.

9.10 Combustion equipment cannot be located in a fire compartment that houses air handling equipment

Standard requirements

Identification and labelling

9.11 All ventilation systems should be clearly identified with a permanent (traffolyte type preferred) label in accordance with the requirements of Chapter 13. The label should identify both the AHU and the area that it serves. The lettering should be at least 100 mm high and be screwed or riveted onto the AHU in an easily visible place near the fan of the unit, adjacent to the local electrical isolator. Any subsystems and the principal branch ducts should be similarly labelled.

Note: The AHU identification code should conform to the plant identification system in use at the premises (see Chapter 13).

9.12 The nature of air and direction of flow should be clearly marked on all ducts using the symbols given in BS 1710.

9.13 All airflow test-points should be clearly identified with a permanent label and the design information given (for example, TPS 1 – Anaesthetic supply; 400 × 300; Design 185 L/s).

Plant minimum standards

9.14 Plant should comply with the minimum standards set out in Table 8.

9.15 External finish to be corrosion resistant and may be available in a variety of colours at no additional cost. This can aid identification by colour-coding of units in a plantroom (for example, green for general ventilation; blue for theatres; red for laboratories and isolation facilities; grey for extract).

9.16 Organic materials or substances that can support the growth of microorganisms cannot be used in the construction of the plant or its distribution system. The water fittings and materials directory list suitable materials for sealants and gaskets (see also BS 6920).

9.17 AHU internal wiring should comply with BS 7671 and be installed in a cable containment system providing suitable mechanical protection. The wiring and its containment system should not allow air bypass at the filters. The wiring, its containment system, connection boxes and fixings should permit the effective internal cleaning and inspection of the AHU.

9.18 Plastic-bladed dampers and plastic plate heat exchangers should not be fitted. This accords with the national policy to reduce the use of plastics.

9.19 Motorised spring-return low-leakage (BS EN 1751 class 3) isolation dampers should be located at the intake, supply, return air and discharge duct connections of an AHU and associated extract unit. They should be of the opposed-blade type and be fitted with end switches. They should close automatically in the event of power failure or plant shutdown to prevent any reversal of the system airflow. They will also function to isolate the plant from the distribution system when undertaking cleaning or maintenance.

Note: Internal plant dampers or provision for the fitting of shut-off plates, also known as dagger plates, between elements within an AHU are not required.

9.20 Access to elements that require routine service such as filters, fans and all types of heat-transfer device should be via hinged doors. In horizontal units the doors should be wide enough: 500 mm minimum at a unit height >1 m. For smaller units the doors need to be at least 600 mm wide, to allow easy access. Items requiring infrequent access such as attenuators may be via removable panels fitted with lifting handles, or access hatches. All doors and panels should be secured from casual access, close-fitting and without leaks.

Table 8: Plant minimum standards

AHU Element	Minimum Standard	Notes
Construction	Double metal or composite skin with sandwiched insulation to "Euroclass A" fire rating Smooth internal surface without channels or ridges No projecting spire or tech screws inside the unit.	Note: Capping projecting spire screws is not acceptable.
Internal surface finish	Non-corrodible, washable and smooth and of a colour that allows accumulations of dirt to be easily seen	Stainless steel or white powder coated mild steel or with an equivalent protective treatment; but NOT surface galvanised
Thermal transmittance	BS EN 1886 Class T2	Manufacturer's declaration
Thermal bridge	BS EN 1886 Class TB2	Manufacturer's declaration
Deflection	BS EN 1886 Class D2	Manufacturer's factory test
Factory airtightness test – pre-delivery	BS EN 1886 Class L2	Test at +700 Pa and –400 Pa
Site airtightness test	BS EN 1886 Class L2	+700/–400 Pa
Filter frame bypass leakage	BS EN 1886 Section 7	
Supply and extract intake and discharge isolation dampers	BS EN 1751 C3 (low loss)	Motorised opening and fitted with an end switch and spring return
Access doors	Secured from casual access. Fan chamber doors to be fitted with a two-stage latch	Key or similar device required to open access doors Door hinges should be adjustable to so that leakage can be eliminated on site
Specific fan power -Internal (SFPint)	Current Eco design requirement for energy-related products (ErP)	EU 1253 – 2014
Specific fan power - System (SFPsyst)	UK Building Regs	Part L2
Energy recovery	Current ErP EU 1253	Run-around coil – 68% Heat pipes – 73% Plate heat exchanger – 73% Thermal wheel – 73% Heat pump – EU 2281/201 Any other device – see standard

9.21 All access doors should be fitted with seals and have adjustable hinges so that leakage can be eliminated once the unit is installed on site. Access doors to fan chambers should have a two-stage opening sequence to prevent the door blowing violently open if it is unlatched while there is still residual pressure in the unit.

Note: Providing the AHU is located in a plantroom or area secured from unauthorised entry, its access doors can only be opened with a key or similar device, the fan door is fitted with a viewing port and a two-stage opening latch and there is a fan electrical isolation switch adjacent to the fan-chamber access door, there is no requirement to fit an internal fan chamber mesh guard.

9.22 In the healthcare setting it can be difficult to turn off AHUs in order to inspect filters and drainage trays. Viewing ports and internal illumination will therefore facilitate routine inspection of such items. Viewing ports should be at a convenient height so that temporary ladders are not required. In double-stacked units the viewing ports in the upper section will be located in the lower portion of their access doors. Internal illumination should be provided by fittings to at least IP55 rating. Light fittings should be positioned inside the unit (not on the access doors) so that they provide illumination for both inspection and task lighting. All lights in a unit should be operated by a single switch and be powered independently of the AHU main switch. LED lights are preferred.

9.23 Access to air intakes and discharges, AHUs and items in the distribution system such as filters or auxiliary trimmer batteries located in a plantroom or plant area above 1.5m should be via platforms, fixed ladders, hook ladders, pulpit style movable steps or access platforms. The method of access chosen should reflect the frequency and nature of the maintenance requirement. The installation of distribution ductwork and other electrical or mechanical services should provide sufficient clearance to allow access equipment to be moved into position.

Chiller units: heat rejection devices

9.24 The design conditions given in Chapter 8 make no allowance for the elevated temperatures that can occur on the roof of buildings. Refrigeration condensers and chiller units should, if practicable, be shaded from direct solar radiation, or the design adjusted to take account of the gain. Care should be taken to ensure that there is sufficient clearance around the plant to allow effective air movement. Allowance may also be needed for the effect of walls, obstruction or other equipment in the area and for the prevailing wind direction.

9.25 Air-cooled condensers and/or dry coolers will always be the first choice for heat rejection from any refrigeration plant. The use of heat pump systems is also an option. Wet evaporative cooling systems cannot be used in healthcare premises unless limitations of space mean that they are the only way that the cooling load can be met. If they are used, national guidance on preventing and controlling Legionella should be closely followed (see the Health and Safety Executive's (HSE) Approved Code of Practice and guidance document HSG274 'Legionnaires' disease: the control of Legionella bacteria in water systems').

9.26 Traditional refrigerants are being phased down and some of their replacements at the time of writing have a degree of flammability. The level of risk this poses should be formally addressed at the design stage and agreed with the client or their fire safety representative. The selection of a refrigerant should be made with reference to the F-Gas Regulations and should take account of the life expectancy of the plant versus the future availability and increasing cost of the refrigerant. Ultimately, choosing refrigerants with the lowest global warming potential is the ideal and will ensure that

greenhouse gas emissions are minimised. Refrigerant gas monitoring must be included where required under BS EN 378.

Chiller selection: size and resilience

9.27 There is a tendency to meet the calculated maximum chiller load by specifying multiples of a standard size of chiller (for example, the calculated load to be met by three chillers each capable of 33% and an extra chiller of the same size to achieve the N+1 resilience requirement). This approach does not lend itself to efficient operation. It is preferable to split the load with, for example, two chillers capable of 40% each and two capable of 25% each. This will give an overall minimum capacity of 90% resilience at maximum summer design conditions and allow for the actual part load demand to be met in the most energy-efficient way.

Supply AHUs and associated extract units

Typical sequence of components

9.28 The AHU should be arranged so that most of the items are under positive pressure. Cooling coils and humidifiers will require a drain and should be on the positive pressure side of the fan. The following arrangement of components is typical, although in many instances not all elements will be required:

- fresh air intake;
- motorised isolation damper;
- fog coil if energy recovery fitted or frost coil if no energy recovery fitted;
- pre-filter;
- energy-recovery device (possible location);
- attenuator1;
- supply fan;
- attenuator1;
- energy-recovery device (possible location);
- cooling coil;
- eliminator (for face velocities above 2 m/s);
- heater-battery;
- humidifier (if required);
- final filter;
- motorised isolation damper.

9.29 AHUs may be configured as horizontal, linear single or double-stacked; or as cabinet type units. For double-stacked supply/extract units, the fans should be located on the bottom deck where possible as it will make them simpler and safer to change (see Figures A1–A3 in Appendix 1 for possible arrangement.).

Intakes and discharges

9.30 Air intakes and discharge points should preferably be located at high level, to minimise the risks of noise nuisance to surrounding buildings, contamination and vandalism.

9.31 Intakes and discharges should be designed and located so that wind speed and direction have a minimal effect on the plant throughput.

9.32 Helicopter landing pads in the vicinity of ventilation intakes and discharges can result in large short-term pressure changes. This can cause pressure surges in supply systems and reverse airflows in extracts. Exhaust fumes from the helicopter may also be drawn into intakes.

Note: It is not appropriate to "plan to turn the ventilation off when a helicopter lands" as a means of permitting the location of a helipad adjacent to ventilation intakes and discharges.

9.33 Intake points should be situated away from cooling towers, heat sources, boiler flues, vents from oil storage tanks, fume cupboards and other sources of contaminated air, vapours and gases and places where vehicle exhaust gases may be drawn in.

Note: Attenuators may be located in the intake and discharge duct if they are of a suitable type and provided with cleaning access both sides (see paragraph 9.116).

Note: Steps should be taken to prevent birds landing or roosting in the vicinity by removing ledges or fitting anti-pigeon spikes.

9.34 On the rare occasions where intakes have necessarily to be sited at or near ground level, the surrounding area should be paved or concreted to prevent soil or vegetation being drawn in. In addition, intakes should not be situated near established gardens/trees so as to avoid intake of environmental microorganisms. They should be caged or located within a compound to restrict unauthorised access and prevent rubbish being left in the vicinity. The likely proximity of vehicle exhausts should also be taken into account when determining the protected area around the intake and additional filtration may be required. The VSG should be consulted about the standard of air quality required. There should be a minimum 4 m clear zone around the intake (see paragraph 9.50 and paragraphs 9.63–9.64).

9.35 The discharge from an extract system will be located so that vitiated air cannot be drawn back into the supply air intake or any other fresh air inlet. Ideally, the extract discharge will be located on a different face of the building from the supply intake(s). At all times, there has to be a minimum separation of 4 m between them, with the discharge mounted at a higher level than the intake.

Note: Ventilation intakes and discharges cannot face each other across a passageway or courtyard even if they are 4 m or more apart.

9.36 Each intake and discharge point should be fitted with a corrosion-resistant weatherproof (BS EN 13030 class B) louvre or cowl to protect the system from

driving rain. Louvres should be sized based on a maximum face velocity of 1.5 m/s in order to prevent excessive noise generation and pressure loss.

Note: If there is a bend in the ductwork directly behind a louvre, it will affect the air velocity through the louvre. This may result in moisture carry-over or increased noise.

9.37 The inside of the louvres should be fitted with a mesh of not less than 6 mm and not more than 12 mm to prevent infestation by vermin.

9.38 The duct behind a louvre should be self-draining. If this is not practicable, it should be tanked and provided with a drainage system.

9.39 Cleaning access should be provided either from the outside via hinged louvres or by access doors in the plenum behind the louvre. Where a floor-level common plenum is provided, cleaning access should be via a walk-in door. High-level plenums should be able to be safely accessed by temporary or permanent means

Note: Builders' work plenums or intake ducts will need to have a smooth finish and be surface-sealed to prevent dust shedding (see paragraph 10.5).

Fans

9.40 Direct-drive electronically commutated (EC) fans are the preferred choice for ventilation systems. If necessary, resilience and an increased capacity can be achieved by installing two or more EC fans with gravity or motorised dampers to prevent backflow.

Note: At the time of writing the concept of a "fan wall" made up of multiple small variable speed fans all controlled as a single unit was under development. This concept has several advantages as the failure of one fan can be accommodated by speeding up the rest. Because the fans cover the full area of the duct, it will result in a more uniform air velocity downstream at the battery face. This will increase the heat transfer efficiency and may allow a reduction in battery size. Nothing in this document will preclude the use of such innovation that improves resilience and reduces energy usage.

9.41 For an application outside of the capacity range of EC fans, direct-drive plug fans controlled by an inverter mounted externally to the air stream may be selected.

9.42 In either case, the fan motor will be protected with a high-temperature safety cut-out.

9.43 Whichever type of fan is selected, if it serves a critical area it will be fitted in a way that allows it to be changed within 20 minutes. Mounting the fan unit on slide rails with plug and socket connections for power and control cables will facilitate this. Whenever possible, both supply and extract fans should be located on the bottom deck of a double-stacked AHU.

9.44 Selecting fans from a preferred size range will reduce the number of spares held.

9.45 Belt- and pulley-driven fans should not be installed in healthcare ventilation systems.

9.46 Supply fans should be positioned to blow through the central plant so that the cooling coil and humidifier drains (when fitted) will be under positive pressure. The energy-

recovery device may be either side of the fan and should have a drainage system on the extracted air discharge side.

9.47 In extract systems where the air is potentially contaminated, explosive, aggressive or has a high moisture content, the extract fan motor will be located outside the air stream and be capable of being changed without the need to access or change the fan impeller.

Control

9.48 Where two or more fans are fitted in a fan wall, the preferred normal operation is all fans running in parallel. In case of a single fan failure the remaining fan(s) should provide at least 80% of the design output.

9.49 For most healthcare applications, the fan output should be set to give a constant volume of air. This should be controlled by measuring the pressure drop across the fan suction nozzle using a sensing ring and associated volume controller that will automatically integrate the fan K factor to determine and control the preset output air volume. The fan output will then in air volume terms remain constant regardless of changes of system resistance. The actual volume delivered will be related to the air-change rate for the application.

Note: Measuring the air pressure in the main supply duct and using that to set the supply fan speed as a percentage of its rated output and using that to set the extract fan speed as a percentage of the supply fan speed is not a satisfactory, accurate or an acceptable way of controlling the desired supply and extract air volumes.

Filters

9.50 The purpose of filtration is to reduce the level of airborne contamination in an air stream. It is generally carried out in stages

9.51 Filters should be securely mounted in well-fitting frames designed so that the airflow pushes the filter into its housing to minimise air bypass. Vertical supports with seals should be provided to master the joints between filters and eliminate bypass. Mounting frames that withdraw so that the filter can be changed without having to reach into the unit are preferred.

9.52 Filters need to be readily accessible, so a hinged access door should be provided. The upstream side of the filter should be visible for inspection through a viewing port with internal illumination.

9.53 For AHUs, provided that each filter's pressure drop is monitored by a sensor linked to the BMS, direct reading gauges or manometers will not be required. Capped pressure tappings should be provided so that a portable manometer can be connected for diagnostic purposes when necessary.

9.54 General air filters (see Table 9) are divided into four categories, related to the size of particle (in microns (μm)) that they can remove as a percentage of the load.

- coarse filters – remove less than 50% of 10 μm particles;
- PM10 medium filters – remove 50 to 95% of 10 μm particles;

Table 9: General filters: typical healthcare selections

ISO 16890 Class	Notes and typical healthcare
ISO Coarse 60%	May be used as temporary addition filtration at an air intake when building or demolition works are being undertaken in the vicinity
ISO ePM10 ≥50%	Panel pre-filter or return air filter to protect the energy-recovery device
ISO ePM2.5 ≥50%	Supply air filter for areas with temporary occupancy
ISO ePM1 ≥50%	Supply air filter for areas with permanent occupancy

- PM2.5 medium filters – remove 50 to 95% of 2.5 µm particles;
- PM1 fine filters – remove 50 to 95% of 1 µm particles.

Note: Ventilation filters can only remove particles from the incoming air. Most particles that could cause an infection originate from the occupants and activities within the building. In AHUs the pre-filter and return air filter will keep the energy-recovery device, cooling coil and heater-batteries clean and working efficiently. The secondary filter will keep the distribution ductwork and supply air terminals clean.

Note: For additional information on filter selection and indoor air quality, see the Specialised Ventilation for Healthcare Society's (2018) SVHSoc.02 – 'Change in air filter test and classification standards'.

9.55 In areas of high atmospheric pollution, a higher standard of filtration may be required in order to meet the indoor air quality standard (IAQ).

9.56 Compact filters are preferred, because bag filters are often incorrectly oriented and prone to damage when changed.

Efficiency and high efficiency particulate air (EPA and HEPA) filters

9.57 These filters are designed to provide filtration of particles in the sub-micron size range. EPA and HEPA filters self-select the particle that they are least able to trap and are graded against that "most penetrating particle size" (MPPS) (see Table 10):

- efficiency particulate filters (EPA): three grades E10 to E12;
- high efficiency particulate filters (HEPA): two grades H13 to H14;
- ultra-low particulate air filters (ULPA): three grades U15 to U17.

Table 10: EPA and HEPA filters: typical healthcare selections

Typical healthcare application	Minimum filter grade to BS EN 1822 - 2019	% Efficiency @ MPPS
UCV theatre terminal	EPA – E10 – (EU10)	85
No standard healthcare application	EPA – E11 – (EU11)	95
Immunosuppressed and neutropenic patient rooms or wards	EPA – E12 – (EU12)	99.5

Typical healthcare application	Minimum filter grade to BS EN 1822 - 2019	% Efficiency @ MPPS
No standard healthcare application	HEPA – H13 – (EU13)	99.95
Pharmacy aseptic preparation facility supply Containment level 3 room extract	HEPA – H14 – (EU14)	99.995
*Incorporates ISO 29463 tests methods.		

Note: ULPA filters are designed to remove particles below a size that is either surgically or aerobiologically significant. There would have to be exceptional circumstances in order to justify their use in a healthcare ventilation system.

9.58 EPA and HEPA filters are expensive, so their use should be kept to a minimum. When used they should be of the replaceable panel type with leakproof seals and installed in a manner that permits the validation of the filter and its housing (see Chapter 12).

9.59 In supply systems an EPA or HEPA filter will have a non-shedding metal case.

Return air and extract air filters

9.60 Return air filtration will always be required where heat recovery devices are installed. Return air filters are also used to reduce the load on EPA filters in recirculating applications such as ultra clean operating suite ventilation canopies and pharmacy aseptic preparation facilities. They should be the same grade as their AHU pre-filter.

9.61 EPA or HEPA filters are sometimes fitted in extract systems to capture hazardous substances or organisms. Design provision should be made for the subsequent safe handling of contaminated filters by maintenance staff. This may be achieved by:

- sealing the hazardous substance into the filter before it is removed;
- providing a system to fumigate the filter to kill any organisms;
- housing it in a “safe change” unit that permits the filter to be ejected into a bag and sealed without personnel having to come into direct contact with it.

Notes:

1 In view of the costs and problems associated with placing EPA or HEPA filters in extracts, it is essential that a full risk assessment be carried out at the design stage. This should include defining the true need for a filtered extract, the validation of its performance at installation, the method of safely changing a contaminated filter, and its subsequent disposal.

2 General extracts from mortuaries and post-mortem rooms may contain odours, but these are not in themselves hazardous to health and do not require filtration prior to discharge. In high-risk post-mortems (for example, known or suspected tuberculosis cases), the infected organs will be removed and then dissected in a class 1 microbiological safety cabinet provided under the COSHH Regulations.

Extracts from infectious disease Isolation rooms or wards do not normally require filtration prior to discharge. However, if the discharge cannot be made in a safe location and it is likely that the vitiated air could be drawn back into the building or there are people in its vicinity (for example, a discharge into a courtyard), filtration would be required

9.62 Extract EPA or HEPA filters should have a particleboard or plywood case so that they can be incinerated.

Activated carbon filters

9.63 Activated carbon filters can remove gases and vapours from an air stream and are graded according to the range of substances they can remove. They are not normally fitted in air-conditioning supply systems. They are occasionally fitted retrospectively because an air intake has been poorly sited and is drawing in noxious fumes or the outdoor air quality is exceeding WHO levels for NOX/O3 or SOX. Where used they should be protected by or incorporated into a particulate air filter.

9.64 Activated carbon filters are more commonly used in specialised fume extraction systems when the location of the discharge means that dilution cannot be relied upon to disperse noxious fumes.

Energy-recovery devices

General requirements

9.65 Energy recovery will be fitted to all supply and extract healthcare ventilation systems. It may be omitted only where permitted by the current ErP Directive EU 1253/2014.

9.66 For most systems in healthcare premises, a plate heat exchanger, “run- around coil” system or thermal wheel would be appropriate. Selection should be based on the relative locations of the supply and extract units, ease of maintenance and practicality. Cleaning access will be required to both sides of any energy-recovery device.

Note: Plate heat exchangers are the preferred option as they require the least maintenance to retain their energy transfer efficiency. Thermal wheels may be used, as the degree of air transfer from extract to supply is not sufficient to cause aerobiological problems and in any event the air will be filtered before being supplied to the user. Run-around coils are used when the supply and extract units are separate or in case of space problems.

9.67 At the time of writing, the following are the minimum energy transfer efficiencies required under EU 1253 for devices handling equal air volumes:

- run-around coil – 68%;
- plate heat exchanger – 73%;
- thermal wheel – 73%;
- heat pipe – 73%;
- heat pump or any other device – see specific regulations.

Note: These efficiencies are regularly reviewed and are likely to be increased periodically.

9.68 If a plate heat exchanger is chosen, the plates should be constructed of metal; in coastal areas stainless steel is preferred. Plastic should not be used for the plates, internal bypass dampers or gears. (This is in keeping with the reduction in the use of single use plastics.)

9.69 If a thermal wheel is selected, only a sensible heat wheel should be used that incorporates a purge sector. In order to reduce bypass leakage, brush seals should not be used; enhanced airtightness seals should be fitted.

9.70 Whichever energy-recovery device is chosen, the extract side should be protected by at least an ISO ePM10 ≥50% filter and provided with a drainage system as described in paragraphs 9.105−9.112, to remove condensate. Note that most condensate will occur at intermediate rather than at extreme outside air conditions.

9.71 The energy-recovery device should be located downstream of the fog coil and pre-filter, before the cooling coil and main heater-battery. It may be on either side of the supply fan.

9.72 It is essential to consider the set points and control of the fog coil, energy- recovery device, cooling coil and heater- battery in order to achieve the most efficient operation for the maximum time. The primary energy provided by the fog coil will directly reduce the heat exchange of the energy-recovery device. To this end, the off-coil setting of the fog coil should be the minimum possible to keep the pre-filter dry (2 to 3 K above intake air temperature) (see paragraph 9.75 onwards for further guidance).

9.73 The energy-recovery device should be controlled in sequence with the main heater-battery and should incorporate a control to prevent the transfer of unwanted heat when the air-on condition rises above the required plant set-point.

9.74 In instances where the plant is cooling the air, it may be possible to remove heat from the supply air at high ambient conditions, under the dictates of enthalpy sensors in the intake and extract ducts.

Heater-batteries

General requirements

9.75 Fog coils are installed to protect the downstream filters from low temperature, high humidity intake air conditions. They should raise the incoming air temperature by 2 K so that it is above its dew-point when it arrives at the filter. As they handle unfiltered air they should be constructed of plain tubing without fins and be as near to the outside as possible to minimise condensation during cold weather. Access for cleaning should be provided to both sides of the coil. In order to prevent them freezing they should be controlled as constant flow variable temperature devices.

9.76 Traditionally frost coils were set to raise the incoming air temperature to between +2ºC and +5ºC to protect the batteries downstream. All new AHUs should be equipped with an energy-recovery device (see paragraph 9.65); the greater the temperature difference across this device, the more heat will be recovered. Also, the

device will now provide the frost protection. Where an energy-recovery device is fitted, the frost coil will be replaced by a fog coil.

9.77 Where steam coils are used for a fog or frost coil, they may be constructed using spiral finned copper tube. As they will be prone to fouling, the tube layout and spacing should permit easy access for regular cleaning.

9.78 Main and branch heater-batteries should be constructed of solid drawn copper tube coils with copper fins, generally connected in parallel. In coastal and particularly exposed areas the client may require an anti-corrosion treatment.

9.79 Where there is a wet heating system in the areas served, the main heater-battery should be sized, in conjunction with the energy-recovery device, for the ventilation requirements only and not for the building fabric loss. Ventilation should only be used for heating the building fabric if the room specification precludes the use of heat emitters and it is not within the heated volume of the building (for example, a cleanroom or operating theatre with external walls).

9.80 Access for cleaning will be provided to both sides of all fog coils and heater-batteries.

9.81 Main heater-batteries may be water or steam. Electric heaters are expensive to operate, and their efficiency is particularly dependent on the air velocity through them. Their use should be restricted to branch trimming control.

9.82 Where steam supplied heater- batteries are used, their control, venting and trapping systems should be designed so that a vacuum cannot occur within the coil. The condensate drainage arrangements should not allow pressure to build in the condensate main as this will result in a back-up of condensate in the battery.

9.83 Where possible, wet trimmer heater- batteries should be located in plant areas.

9.84 Where it is necessary to locate heater- batteries in false ceilings etc, consideration should be given to the use of electric heaters (note that additional fire detection may be required). If this is not practicable and a LPHW system is used, a drip-tray should be installed under the control valve assembly to protect the ceiling. A moisture sensor and alarm should be fitted in the tray. In any event, to facilitate maintenance access, they should be located above corridors or other non-clinical areas and never above patient-occupied spaces

9.85 Auxiliary fan coil units are not to be installed in the ceiling above a patient- occupied space. They should be accessible for routine maintenance and cleaning without the need to cause significant disruption to the operation of the area that they serve.

Cooling coils and drift eliminators

9.86 Cooling coils supplied with chilled water are the preferred option. For small loads, or where chilled water cannot be made available, direct expansion (DX) coils may be used.

Note: For DX coils, it may be necessary to divide the chiller circuits unevenly in order to achieve efficient operation under part-load conditions. The turn- down ratio should allow stable control down to 10% of the peak load.

9.87 Cooling coils should be periodically decontaminated so the fin spacing needs to be ≥2.5 mm and the fins rigid enough to withstand cleaning (for example, ≥0.25 mm thick). Hinged access doors with viewing ports and illumination inside the AHU or duct should be provided both sides of the coil.

9.88 In an AHU when the cooling-coil face velocity is greater than 2 m/s a drift eliminator will be required downstream of the coil. The eliminator will be an entirely separate device mounted on slide rails so that it can be easily removed without the need for tools. If the size of the AHUs precludes the use of slide rails, and the eliminator is constructed in sections which maintenance personnel will have to enter the unit to remove, each section should have lifting handles. In order to reduce the use of plastics, alternative materials should be considered for the eliminator elements.

Note: For small DX coils and in fan coil units, the eliminator may take the form of a joggled extension of the fins.

9.89 All cooling coils are to be fitted with their own independent drainage system as specified in paragraph 9.105 onwards. A baffle or similar device should be provided in the drip-tray to prevent air bypassing the coil. The tray should be large enough to capture the moisture from the coil headers and drift eliminator.

9.90 Where coils are greater than 1.8 m high and the air velocity is >2 m/s, either intermediate drip-trays will be required or the fin spacing should be increased to ≥3 mm.

9.91 In order to minimise electrolytic action resulting from condensation on the air side, cooling coils constructed from copper tubes with copper fins and electro- tinned after manufacture are preferred. Aluminium fins should only be used if vinyl- coated.

9.92 All parts of the coil and its associated ductwork in contact with moisture will be manufactured from corrosion-resistant materials. Pressed steel coil headers, even if treated, have been shown to be prone to corrosion over time and should not be used. Steel mounting frames and casings present similar problems so stainless steel is preferred.

9.93 Where a cooling coil has to be located above a ceiling, a drip-tray should be installed under the battery and control valve assembly to protect the ceiling from leaks and condensation drips. A moisture sensor and alarm should be fitted in the tray. To facilitate maintenance access, they should be located above corridors or other non-clinical areas and never above patient- occupied spaces. The air velocity should be below 2 m/s to avoid the need for a drift eliminator. All drainage piping should be rigid type not flexible hose.

9.94 Auxiliary fan coil units should not be installed in the ceiling above an occupied space. They should be accessible for routine maintenance and cleaning without the need to cause significant disruption to the operation of the department that they serve. The drainage of such items is often problematic. If a suitable fall in the drain line cannot be achieved, a pump out system should be provided. Drainage piping should be rigid type (not flexible hose).

Humidifiers

9.95 Humidification was originally required for some healthcare applications in order to control the risk associated with the use of flammable anaesthetic gases. The use of such gases has now ceased. Humidification is therefore no longer required unless there is a very specific application requirement (see Chapter 8 and associated SHPNs/HBNs).

Note: In an operating theatre, if high humidity is required to help prevent tissue drying during surgery, it should be provided when required using sterile water in a disposable nebuliser driven by medical air, and not from a humidifier installed in the ventilation system. In that way the quality of the moisture delivered will be assured.

9.96 If it is unclear at design stage whether humidification is required, provision for retrofitting in terms of space provision and a capped drainage system may be provided either in the AHU or in a zone branch duct. The need for such provision and the amount of space allowed for it should be agreed in writing with the client.

9.97 If a humidifier is required, the manufacturer's instructions regarding selection, capacity, installation and control need to be followed. Incorrectly sized, installed or operated humidifiers can become a source of fungal and microbiological contamination within a ventilation system. This may result in a significant airborne infection risk to patients and staff.

9.98 Only steam injection manifold-type humidifiers are considered suitable for use in health building air-conditioning systems. The injected steam will be generated locally either by mains steam or electricity, within or adjacent to the humidifier. Water-curtain, water mist or spray humidifiers of any type cannot be used.

Note: Jacketed lance mains steam humidifiers will always be a source of heat within the system during the cooling season unless completely isolated when not required.

9.99 All parts of the humidifier and its associated ductwork in contact with moisture should be manufactured from corrosion-resistant materials. Stainless steel is preferred.

9.100 For self- and locally-generated steam humidifiers, the cleanliness of the water supply is essential for their safe operation. The water supply should be derived from a wholesome source or demineralised supply. Chemical treatments cannot be added to the water supply to humidifier units. The electrodes of self-generating electrode boiler-type humidifiers should be stainless steel.

9.101 If the quality of the water supply to a self-generating humidifier unit cannot be assured, an ultraviolet (UV) system to control microbiological growth may be installed. However, given the limitations of UV systems, this will require high-quality water filtration to ensure the effectiveness of exposure of organisms to the UV irradiation. As with all water treatment systems the unit should be of proven efficacy and incorporate UV monitors so that any loss of transmission can be detected.

9.102 Provision should be made for draining down supply pipework and break tanks for periodic disinfection and cleaning during the seasons when they are not required in service. The humidifier branch water supply isolation valve will be located at the junction with the "running" main to prevent the creation of a dead leg. All parts of the system should be capable of being cleaned or disinfected as necessary. Hinged

access doors with viewing ports and internal illumination should be provided. A label warning that the device emits live steam and should be isolated prior to opening should be affixed to the access door.

9.103 A zone humidifier, if required, may be installed in a supply branch. The ductwork in which the humidifier is mounted and for at least 1 m downstream should be stainless steel.

9.104 All humidifiers wherever installed will be fitted with their own independent drainage systems as detailed in paragraph 9.105 onwards and be completely accessible for cleaning.

Drainage

9.105 All items of plant wherever located that could produce moisture should be provided with a drainage system. The system will comprise a drip-tray, glass trap, air break and associated drainage pipework.

9.106 The drip-tray should be constructed of a corrosion-resistant material (stainless steel is preferred) and be so arranged that it will completely drain. To prevent “pooling”, it is essential that the drain connection should not have an up-stand; and that a slope of approximately 1 in 20 in all directions should be incorporated into the drain outlet position.

9.107 In AHUs that have access doors large enough for a person to enter, the drip-tray should be easily accessible for inspection and cleaning.

9.108 In AHUs with access doors too small for a person to enter, the complete drip- tray should be capable of being withdrawn. It should be clamped into the AHU with thumb screws so that it can be removed without the need for tools (see photograph).

Figure 7 Removable AHU drainage tray

9.109 Each drip-tray should be provided with its own drain trap. The drain trap should be of the clear (borosilicate) glass type. This permits the colour of the water seal to be observed, thus giving an early indication of corrosion, biological activity or contamination within the duct. The trap should have a means for filling and incorporate couplings to facilitate removal for cleaning. It should be located in an easily visible position where it will not be subject to casual knocks. The pipework connecting the drainage tray to the trap should have a continuous fall of not less than 1 in 20.

9.110 Traps fitted to plant located outside or in unheated plant rooms need to be trace heated in winter. The trace heating should not raise the temperature of water in the trap above 5ºC.

9.111 Water from each trap will discharge directly via a clear air gap of at least 15 mm above the unrestricted spill-over level of either an open tundish connected to a foul drainage stack via a second trap, or a floor gully (or channel). A support should be provided to ensure that the air gap cannot be reduced. More than one drain trap may discharge into the tundish providing each has its own air-break.

9.112 Drainage pipework from the tundish may be thermoplastic, copper or stainless steel. Glass should not be used. The pipework should be a minimum diameter of 22 mm and have a fall of at least 1 in 60 in the direction of flow. It should be well- supported and located so as not to inhibit access to the AHU.

Note: In the case of fan coil units, the glass trap and air-break may be omitted and a pump out system fitted. The unit drainage should connect to the main drainage system via a waterless trap that does not allow discharged water to return. The drainage tray itself will be easily removable for routine inspection and cleaning.

Attenuators

9.113 Provided care is taken in the design and construction of low pressure systems to avoid significant noise generation in the ductwork, attenuation should only be needed to absorb fan noise

9.114 Fans radiate noise through both the inlet and outlet connections, and it may be necessary to provide attenuation to limit the noise from both of these connections. It is always preferable and more economic to control noise and vibration at source, or as close to source as possible. It should be noted that attenuators offer a resistance to airflow and by causing turbulence can be the cause of regenerated noise in a system.

9.115 A thorough assessment of the design should be made to assess the potential noise problems. It should consider the following factors:

- fan and plant noise generation;
- airflow-generated noise in ductwork fittings and dampers;
- noise generated at grilles, diffusers and other terminals;
- noise break-in and break-out of ductwork;
- cross-talk and similar interference;
- the noise limitations for the building and surrounding areas;
- external noise generation.

A method of assessment of these factors and the sound attenuation requirements of ductwork systems is given in CIBSE Guide B

Note: Attenuators fitted in distribution ducts can themselves become a source of regenerative noise if the air velocity through them exceeds their tested performance value.

9.116 Attenuator units with a sound- absorbing in-fill suitable for the quality of air being handled and protected by a perforated sheet metal casing are the preferred option. Absorption of moisture, dirt and corrosive substances into the “in- fill” and the release of fibrous particles into the airstream should be prevented using a membrane with a declared service life of at least 25 years. If these conditions can be met, the attenuator may be located in the supply ductwork downstream of the final filter. Cleaning access should be provided at both ends of the unit.

9.117 Sound-absorbing material should not be applied to the inside surface of a duct.

9.118 End of line mixing and VAV boxes may be supplied lined internally with sound-absorbing material. The material will be non-particle-shedding, protected from casual damage during maintenance and be fire-resistant.

9.119 See paragraph 9.149 onwards for guidance on distribution and point of use noise control.

Note: Developments in “dynamic attenuation” may replace the more traditional physical attenuators and overcome noise “break in” and point of use noise regeneration issues.

Recirculation – minimum fresh air requirement

9.120 Where return air is recirculated, fresh air should be introduced equivalent to at least 20% of the supply air volume, or that required by the Building Regulations, or at least 10L/s/person, whichever is greater.

Distribution system

9.121 The CIBSE guide B2 provides the standard design Information for ventilation systems, their ductwork and terminal devices. The guidance in this SHTM highlights the specific factors that are required for or excluded from healthcare ventilation installations.

9.122 For normal applications in healthcare buildings, low velocity systems are recommended; velocities below 2 m/s are unlikely to be justified.

9.123 The site will often dictate the main routing of ductwork systems, as will the location of the AHU relative to the load. Grouping AHUs in centralised plantrooms results in large vertical service shafts and long main duct runs. Decentralising AHUs into service spaces adjacent to the load results in a more compact duct layout.

9.124 Whichever option is chosen, the design should seek to make the layout as symmetrical as possible; that is, the pressure loss in each branch should be as nearly equal as possible. This will aid balancing and may reduce the number and variety of duct fittings that are needed.

9.125 Main distribution ductwork should not be routed above sleeping areas. Where there is no alternative route, additional external acoustic insulation may be required.

9.126 Where auxiliary air-conditioning units, fans, filters or trimming devices are installed in the distribution system, they will be independently supported and fitted with a suitable drainage system where appropriate. If they are a source of vibration, they should be linked to the distribution ductwork via flexible connections.

Ductwork materials and construction

9.127 The choice of duct material should take account of the nature of the air or gas being conveyed and the environment in which the duct will be placed.

9.128 Galvanised sheet steel is suitable for normal ventilating and air-conditioning applications. Its inherent mechanical strength renders it resistant to casual damage both during the construction phase and throughout its service life when mechanical and electrical services around it are accessed. It may also readily withstand the impacts sustained when rotary equipment is used to clean it internally.

9.129 In instances where moisture levels and/or corrosive elements in the air being conveyed are very high, aluminium, stainless steel, PVC or GRP ducts should be used. Stainless or black steel are the only suitable materials for high temperature ductwork.

9.130 Where other ductwork materials are considered, care should be taken to ensure that the material is satisfactory for the application having regard to the likely service life, possibility of mechanical damage and performance in the event of a fire. Where used it will be installed strictly in accordance with its manufacturer's instructions.

9.131` Rectangular ducting with an aspect ratio of 1:1 is preferred but ratios of up to 3:1 are acceptable where there are space constraints. Circular spiral-wound or flat- oval are also acceptable providing they meet the leakage standard when tested (see Note after paragraph 9.136). Flexible ductwork is not suitable for air distribution in healthcare applications. In situations where solid ductwork cannot be used, flexible ductwork may be used to make the final connection to a terminal providing it does not exceed 0.5 m in length, is extended as far as possible and is never used in lieu of a bend (see paragraph 9.160).

9.132 The inside of the ductwork should be free from structural projections and as smooth as possible. Flanged gasketed joints between sections are preferred for rectangular ductwork, blind-riveted mastic- sealed slip-joints for circular and flat-oval.

9.133 In inherently wet areas, such as the base of fresh air inlet ducts and some extract systems, the ductwork may require draining to prevent a build-up of standing water. The layout of the drains should be as specified in paragraph 9.105 onwards.

9.134 Where builders' work plenum chambers or ducts are employed, all internal surfaces should have a smooth finish and be sealed to prevent dust shedding.

9.135 All types of ductwork should be manufactured and installed to the appropriate current BESA specification.

9.136 Ductwork should be supported with threaded rod and channel. Note that sheet metal ductwork cannot use bolt-through supports. Gripple wire may only be used for circular galvanised spiral-wound or flat-oval ductwork.

Note: All installed ductwork whether new or reused should be subject to a leakage test on site prior to the application of any insulation. The leakage test will be to BESA DW144 but with a permissible leakage rate of not greater than 3%.

Fire aspects: damper types and locations

9.137 It is essential that all relevant fire aspects of ducting systems are agreed with the fire officer before the design is finalised (see paragraph 1.15 onwards).

9.138 Ductwork will be fire-stopped where it penetrates fire compartment walls, floors and enclosures, cavity barriers and subcompartment walls or enclosures, and provided with weatherproof collars where roofs or external walls are penetrated.

9.139 Fire and smoke dampers should be provided at the locations required by the Health Technical Memorandum 05 series of documents. The damper mounting frame should be securely attached to the building fabric strictly in accordance with the manufacturer's tested details. Where a fire and smoke damper is not mounted directly in a fire compartment wall, it must be correctly supported and the ductwork between it and the fire wall must possess the same fire rating as the fire wall that it penetrates. The fire-rated portion of ductwork must not be penetrated by test holes or inspection hatches (see also BESA DW145).

9.140 Any non-standard fire duct or damper arrangement should be agreed in writing by the client's fire advisor and subsequently tested and signed off by the installer.

9.141 An access hatch should be provided adjacent to each fire and smoke damper so that its correct operation can be directly observed. The hatch will be as large as necessary to permit inspection, testing and maintenance. The damper test switch should be mounted adjacent to the inspection hatch so that the routine test and visual confirmation of the damper operation can be carried out by a single person. For circular ductwork, rectangular saddle mounted hatches should be fitted (see BESA DW144).

9.142 Smoke-diverting dampers will be provided on recirculation air systems to automatically divert any smoke-contaminated return air to the outside of the building in the event of a fire. It should be arranged so that the normally open diverting damper in the return air branch to the input unit closes and all the return air is exhausted to outside (see paragraph 5.53 onwards).

Duct sections

9.143 When sizing ductwork, the designer should consult the CIBSE B2 guide.

9.144 All fittings should conform to the current BESA specification. Wherever possible, long radius bends, large radius main branches, not more than 45º angle sub-branches and long taper transformations should be used.

9.145 Bad design in relation to airflow can lead to vibration of flat duct surfaces, an increase in duct-generated noise, pressure loss in ductwork, unpredictable behaviour in branch fittings and terminals, and adverse effects on the performance of installed plant items, such as trimmer batteries.

Thermal insulation

9.146 In order to reduce energy consumption, achieve efficient energy recovery and prevent condensation in service voids, all supply and return air ductwork should be thermally insulated. Insulated ductwork runs outdoors should be weatherproofed.

9.147 The thermal insulation of intake and discharge ductwork will be dependent on its location in heated or unheated plant spaces and risk of surface condensation.

9.148 In normal circumstances, the insulation thickness for heat resistance is sufficient to prevent surface condensation, but in extreme conditions the insulation thickness for vapour resistance may be greater than that for heat resistance. When cold ducts pass through areas of high dew- point, carefully selected vapour barriers should be applied externally to the insulation.

Noise generation within the ductwork

9.149 Noise is generated in ductwork at sharp edges, by tie rods, damper blades, duct obstructions, sharp bends, etc. This airflow-generated noise becomes an important factor if it is about the same or greater level than the upstream noise level. Airflow-generated noise is often referred to as regenerated noise.

9.150 The noise level generated by airflow in ductwork is very sensitive to the velocity. The sound power of this noise is approximately proportional to the sixth power of the velocity; that is, a doubling of the duct velocity will increase the sound power by a factor of 64 (or about 18 dB). The duct velocities should therefore be kept as low as possible. In general, duct fittings which have lower pressure loss factors in similar flow conditions will generate less noise.

9.151 Ductwork serving quiet areas should not be routed through noisy areas, where noise break-in can occur and increase the noise level in the ductwork.

9.152 Grille register and louvre noise should be kept to the minimum by selecting types having low noise-producing characteristics, without high tonal noise; and should be fitted with acoustically treated external inlet and outlet louvres.

9.153 Cross-talk attenuators may be necessary where noise intrusion between adjacent spaces can arise and where individual room confidentiality is required. They will normally be of the “through-the- ceiling, up-and-over” type and may include a fire and smoke damper.

Volume control damper locations

9.154 In order to be able to carry out a full proportional balance, manually operated dampers are typically needed:

- in branches of zone ducts;
- in sub-branch ducts serving four or more terminals;
- in dedicated sub-branch ducts serving a room;
- at terminals not covered by any of the above.

9.155 Dampers integral with terminals are to be avoided for final trimming of air volumes, as they often create noise and air distribution problems.

9.156 Dampers in rectangular ducts should be opposed-blade multi-leaf type. In circular ducts, iris-type dampers are recommended. Dampers should be accessible, incorporate a position indicator and means of locking in the commissioned position. They should be installed with the adjusting handle or knob at the lower vertical edge

so that they are accessible for the commissioning team once the ceilings are in place. Dampers should be located as far away as possible from adjacent branches or plant items.

Duct cleaning and access door locations

9.157 Cleaning and access doors are required to facilitate access to plant items and ductwork components for inspection, maintenance, cleaning and replacement, and should be of sufficient size to permit safe access for the required functions.

9.158 Recommended locations for access doors are given in the current BESA TR/19 specification and are generally provided to give access to:

- every regulating damper;
- every fire-and-smoke, and motorised damper;
- filters (to facilitate filter withdrawal);
- both sides of trimmer cooling/heating coils;
- zone humidifiers;
- auxiliary fans;
- ducts, where required for cleaning.

9.159 Care should be taken when siting access doors to ensure that no other services to be installed will prevent reasonable access.

Flexible ducting

9.160 Flexible ductwork can only be used to make the final connection between rigid ductwork and a terminal in exceptional circumstances where a solid connection is not possible. Where used it will cause a significant frictional loss and may be difficult to clean, so it should take the most direct route and be as short as possible, never exceeding 0.5 m in length. It can never be used in lieu of a bend and will possess the same fire rating as the ductwork it is connected to.

Terminal fittings selection and sizing

9.161 The effectiveness of all ventilation and air-conditioning systems depends on the methods by which air is introduced to, and vitiated air is removed from, the space. The usual results of poor air-terminal selection and/or positioning are:

- draughts;
- stagnation;
- poor air quality;
- large temperature gradients;
- excessive noise.

9.162 Air can be supplied to a space in a number of ways, although any device can be broadly placed into one of two categories:

- that producing a diffused supply;

- that producing a perpendicular jet.

Diffusers may be radial or linear, and normally utilise the coanda effect (that is, adhesion of the air stream to an adjacent surface) to reduce the risk of excessive room air movement. A perpendicular jet is formed by discharging air through grilles, louvres or nozzles, which are generally adjustable.

9.163 Supply air terminals can be incorporated into any room surface, for example, floors, walls (high or low level), desktop.

9.164 As they operate on the jet principle, the use of sidewall and linear grilles is restricted to areas where air-change rates are low, that is, less than 10 per hour.

Perforated rectangular diffusers can provide acceptable conditions within the occupied zone at up to 15 ac/h. In areas where a higher air-change rate is required, square or circular ceiling-mounted diffusers should be used.

9.165 The performance of supply air terminal devices is based on three criteria – throw, spread and drop:

- throw is defined as perpendicular or parallel distance from the terminal to the point at which the air velocity is;
- 0.5 m/s isovel;
- Spread is defined as the width of the;
- 0.5 m/s isovel;
- Drop is defined as the vertical distance from the centre line of the terminal to the bottom edge of the 0.25 m/s isovel.

9.166 It is necessary to consider each of these parameters in both summer and winter conditions to ensure satisfactory operation of the air terminal device, as warm jets behave very differently from cold jets.

9.167 A warm jet tends to rise until it attaches itself to a horizontal surface, while a cold jet falls. Care should be taken to ensure that this does not lead to unacceptable temperature gradients in winter, or excessive air velocities in the occupied zone in summer.

9.168 In order to ensure satisfactory air movement within a space, it is necessary to consider interaction between air movement from adjacent terminals, and ceiling-mounted fixtures (light fittings, etc), as well as interaction between air movement and room surfaces.

9.169 If the supply and extract terminals are too close, short-circuiting may occur, while if they are too far apart, stagnant zones may be formed. Where two opposing air streams meet, the individual velocities should not be greater than 0.25 m/s. Further guidance on the selection of grilles and diffusers is given in the CIBSE Guide B

9.170 In operating theatres, the supply terminals should be able to produce a movement of air in the operating zone 1 m above floor level of between 0.2 and 0.3m/s:

- ceiling-mounted diffusers with fixed directional vanes that provide a downward turbulent airflow are the preferred option: 600 × 600 four-way blow or circular “air-master” style;
- plenum boxes fitted with perforated screens to produce a laminar downflow are also acceptable;
- linear ceiling-mounted diffusers that provide a downward-flowing air curtain around the operating theatre may also be used (additional supply terminals may be located within the area bounded by the linear diffusers to provide ventilation within the;
- air-curtained zone).

9.171 The following terminal types are not suitable for use in operating theatres because they do not produce an appropriate pattern of air distribution:

- swirl diffusers;
- single- or multi-outlet adjustable directional nozzles or jets of any type;
- sidewall-mounted linear diffusers that utilise the coanda effect to send air across the ceiling and “droop” it into the operating zone.

9.172 Extract terminals should be of an easy-to-clean design and, in order to assist identification when commissioning and subsequently measuring, be of a different design style to the supply terminals. Extract terminals mounted at low level should be of the spring clip retained, pull off face type to enable ease of cleaning. The terminal should be mounted on an angled face to prevent it becoming occluded by movable equipment or stores (see Appendix 9 for examples). Perforated plates are not to be fitted in extract terminals or extract plenums as they quickly become blocked with lint. Extract terminals do not need any directional adjustment so fixed-vane or “egg-crate” styles are preferred.

UCV terminal canopy

9.173 UCV canopies should be fitted with one or more non-electronic, mechanical, direct reading pressure gauge(s) to indicate the pressure drop across either a representative terminal EPA filter or the pressure in each zone of the canopy.

9.174 If a UCV canopy incorporates a method of adjusting the air discharge direction so that the canopy can be “tuned” to the room in which it is installed, the directional adjustment device(s) are to be capable of being locked in position once commissioning is complete to prevent future casual alteration.

9.175 Ceiling-mounted canopy diffusion screen(s) can become contaminated with blood spatter when in use. If the UCV canopy is fitted with perforated diffusion screens the blood spatter can penetrate, so the screens should be capable of being hinged down for cleaning between theatre cases. The screen retaining mechanism will have a double action to release the screen. Mono-filament diffusion screens should be retained by clip-in profiles or an alternative system that allows them to be easily removed when necessary.

9.176 For the validation of UCV terminal canopies, see Chapter 12.

Transfer grille: size and location

9.177 Air transfer grilles in walls, partitions or doors form an integral part of the building's air distribution system. Modern door sets have very low leakage rates so cannot be relied upon to permit even quite small airflows. Failure to make adequate provision for air to move from room to room will result in excessive pressure differentials and "door whistle".

9.178 Transfer grilles are required in locations where there is a significant imbalance between the supply and extract rates in a room. They will relieve any pressure differentials which may affect the operation of the spaces and/or the ventilation system and permit airflow in a known direction.

9.179 Care needs to be taken to ensure that the positioning of transfer grilles does not interfere with the fire or smoke integrity of the building. In general, the air transfer grilles should not be installed within fire- resisting boundaries, although if this is unavoidable, they should be fitted with fire or smoke dampers.

9.180 Where installed, transfer grilles should be of the non-vision type, sized for a maximum face velocity of 1.5 m/s.

Note: Cross-talk attenuators may be necessary where noise intrusion between adjacent spaces can arise and where individual room confidentiality is required.

Pressure stabilisers: size and location

9.181 Pressure stabilisers are required in areas where it is necessary to maintain a pressure differential between adjacent rooms and to prevent reversal of airflows for example, in operating suites, isolation facilities and cleanrooms (see paragraph 8.24).

9.182 Fire precautions for pressure stabilisers are the same as for transfer grilles. If the pressure stabiliser is fitted with a fire and smoke damper, the damper test switch should be easily accessible from, in airflow terms, the least clean side of the damper.

9.183 Pressure stabilisers should be of the balanced blade type, with the facility to make fine adjustment of the pressure setting. They should be silent in operation and give a seal as tight as practicable when closed. The materials of construction and method of assembly should allow for cleaning and disinfection.

9.184 Pressure stabilisers should be wall- mounted in a visible location so that their operation can be readily observed. For sizing criteria, refer to the manufacturer's information. When fitted at low level, they may require a stand-off cage to prevent occlusion (see photograph).

Figure 8 Pressure stabiliser with stand-off cage

9.185 Pressure stabilisers may need to be fitted with a stand-off baffle on their discharge side to prevent a sight line in situations where a laser will be used, and may be lead-lined for radiological protection if required (see photograph after paragraph 9.184). Baffles may also be needed to preserve privacy or prevent discharge air causing draughts within an anaesthetic room or bedroom. A stand-off baffle will always be needed on the theatre side of the pressure stabiliser between a “Lay-up” preparation room and a UCV theatre to prevent perturbation of the UCV canopy air pattern

Note: Baffles should be easy to clean and where radiological or laser protection is not required can be made of a rigid transparent material so that the action of the pressure stabiliser can be easily observed.

Distributed air-conditioning elements

Active and passive chilled beams

9.186 See paragraph 5.18 onwards for information on the use of these devices in healthcare premises and CIBSE Guide B for technical guidance.

Constant volume boxes

9.187 These are units fitted in or at the termination of ductwork that contain a mechanism to maintain a constant output air volume regardless of variation in the air pressure to the supply side of the unit. Where fitted they should be accessible for maintenance as the internal mechanism that controls the constant output will need periodic cleaning.

Variable Air Volume (VAV) boxes

9.188 Variable air volume systems are all-air systems which achieve local control by varying (throttling) the amount of air being supplied to each space, room or zone.

Standard type VAV systems deliver air that has been cooled to a set temperature (usually 13ºC) and then control the temperature in a space by varying the quantity of air supplied rather than the supply air temperature – which is kept constant.

VAV boxes are used as terminal devices at the supply end of ductwork to modulate the quantity of supply air to the space.

There are variations to standard VAV systems which allow air supply temperatures to modulate upwards with the aim of:

- reducing energy usage by allowing higher air supply temperatures at part-load conditions;
- improving ventilation effectiveness at part-load by having higher airflows
- – VAV can be as low as 10% of peak at low-load conditions depending on the equipment used;
- allowing the system to operate using warm air in winter for pre-heating warm-up in well-insulated buildings where heating is only used in very cold weather and for building pre- heat.

9.189 In most critical areas of a hospital a fixed air-change rate is required when they are in use. VAV is therefore generally limited to non-clinical applications.

Stand-alone air-conditioners

9.190 See paragraph 5.25 onwards for information on these units. The ceiling void should never be used as a plenum either for the primary air supply or fan coil supply or return air paths. (See CIBSE Guide B for installation notes.)

Powered air terminal filter units

9.191 This is an air-distribution-supply terminal box fitted with a fan and EPA or HEPA filter. Their use in the healthcare setting would be confined to spaces where a high air quality is required for a single room in an area supplied by a general AHU (for example, a local cleanroom).

9.192 They are not suitable for use in patient bedrooms due to the fan noise and maintenance access issues.

AHUs: automatic control

9.193 Chapter 6 of this document gives guidance on energy control strategies and Chapter 7 gives guidance on the point of use factors. Chapter 8 contains guidance to specific healthcare departments and their environmental and functional requirements. This section gives guidance on the control of the AHU and its subsystems. When developing a “controls specification”, the designer should consider the guidance given in all of these chapters.

9.194 Various options for control of single- and multi-zone air-conditioning systems are given in CIBSE Guide B.

General requirements

9.195 The basic requirements for an automatic control system are as follows:

- plant start, run, set-back and stop sequence;
- control of the volumetric airflow;

- control of the system or room pressure;
- temperature control and indication;
- humidity control and indication;
- devices to monitor and indicate the plant's operating state;
- alarms to indicate plant failure, low airflow, and filter state;
- the facility to collect data of actual usage and energy consumption.

The control functions actually provided will depend on the purpose of the ventilation system.

9.196 The designer should consider whether it is necessary for the supply and extract fans to be interlocked, either so that the supply fan will not operate unless airflow is established within the extract system, or vice-versa depending on the required pressures within the rooms being served.

9.197 The sequence switching of units in order to prevent transient reverse airflows will be particularly important in laboratory and pharmacy areas that also contain fume cupboards, safety cabinets and other LEV systems.

9.198 There will also be a need to determine the control strategy in the event of a fire either within the zone being served or within an adjoining zone and as detailed in the fire alarm cause and effect statement (see paragraph 7.16 onwards).

9.199 All supply AHUs should have a smoke sensor linked to the fire control panel and mounted in the main supply duct immediately downstream of the AHU. In the event of a fire in the AHU or smoke being drawn into the system from an outside source, it should cause the supply air fire damper to close and shut down the AHU.

Note: In certain critical departments, it is preferable to maintain the ventilation in the case of a fire within the area. For example, in an operating department while undergoing surgery the patient cannot always be easily moved without significant risk. In the event of a fire in a staff or support area of the department or adjoining zone, the continued supply of air to a theatre will maintain it at a positive pressure and protect the patient and staff from the effects of smoke.

This will allow time for the patient to be stabilised so that they can be safely.

Location of controls

9.200 Facilities to start, set-back and stop the plant should be provided in the plantroom. Remote start and set-back control and indication, if required, should be provided at a manned staff location, for example, at the reception or staff base.

9.201 Many ventilation systems may be completely shut down when the area served is not in active use. Alternatively, where there is a need to maintain a background condition, the ventilation output may be reduced by "setting back" the system. This will significantly reduce energy consumption and extend the life of filters and other system components. Controls to facilitate this should be triggered by the actual occupancy of the area rather than by a fixed time program (see paragraph 6.2 and associated Note).

Start up and shut down control sequence

9.202 The AHU should start and shut down in a pre-determined sequence. It should ensure that the fan does not start until the main dampers are open and the energy- recovery device is operational. On shut down there may be a need for a “run on” time to purge the area served before stopping the fan and closing the main dampers. Whether the supply or extract fan should start first and stop last will be determined by the pressure regime for the area served.

Set-back control

9.203 In previous times when fan motors only had two speeds, turning the system to “Set back” meant switching to the lower fan speed. With modern fans the speed is widely variable so “Set back” is not a fixed fan speed but rather a control strategy that reduces the system output in order to maintain a desired minimum condition. This may be related to the air velocity at a fixed point, air-change rate, pressure differential, temperature, humidity or a combination of these parameters. Providing a dew-point sensor in an internal space that brings the system onto “Set back” is a simple way of maintaining a minimum condition.

AHU running controls

Fog/frost coil control

9.204 Fog coils supplied by low pressure hot water (LPHW) should be controlled using the Proportional mode. Their sensor should be located downstream of the coil to give “closed loop” control. The coil should raise the incoming air temperature by 2 K in order to ensure that air entering the pre- filter is above its dew-point, thus keeping it dry. The greater the energy put into the incoming air by the fog coil, the lower will be the efficiency of the energy-recovery device.

9.205 If the temperature downstream of the fog coil, as sensed by a serpentine thermostat, falls below the required set point over any part of the coil, the plant should automatically shut down in order to prevent damage to the other batteries. The serpentine thermostat cannot be in direct contact with the coil and should cover the entire coil face.

9.206 Steam-supplied fog or frost coils should be operated as an on/off device to ensure that there is no standing condensate at the base of the coil. They should be fitted with a serpentine sensor mounted upstream of the coil but not in contact with it. This will give “open loop” control; a set point of +1ºC is recommended.

Energy-recovery device

9.207 The energy-recovery device is normally controlled by sensors in the air intake downstream of the supply fan, before the cooling coil and the extract duct from the ventilated space.

Supply & extract fans

9.208 The ErP Directive 1253/2014 requires a means of adjusting the fan speed. For plug fans this is provided by a separate inverter unit; for EC fans the control is integral to the fan motor. It should be remembered that most healthcare applications require known amounts of air to be delivered while the system is in use. Constant volume systems that deliver specified air-change rates are therefore the norm. Duct- or room-

pressure-controlled variable-volume systems have a limited application in healthcare. However, fan-speed control is beneficial when “setting back” the system.

9.209 Inverters should not be mounted inside the air stream within the AHU. Ideally, they will be mounted on a frame with the control valves. Where inverters are mounted inside a control box with a safety master switch to cut the power supply when the box is opened, the inverter control and indicator pad will be located on the outside of the box. This will allow on- site staff to view the operating parameters and switch the system to manual control if a fault occurs with the automatic control system.

9.210 It is necessary to ensure that should the computer control system or its software develop a fault, the fan can be switched to manual operation. This is particularly important for critical systems serving operating suites, high dependency care units of any type, patient isolation facilities, laboratories and pharmaceutical production suites.

Note: In the healthcare setting it is important to recognise that “off-site” software support is no substitute for the ability of “on-site” staff to override the automatic control and keep the system operating in an emergency. Under these circumstances actions that may shorten the life of the plant are considered of secondary importance to that of preserving the health and safety of patients and staff.

Heater-batteries

9.211 The main heater-battery should be controlled in the same manner under the dictates of an off-coil temperature sensor, or a room temperature sensor, or the return air temperature depending on the plant configuration and method of control. Trimmer heater-batteries are generally controlled by a temperature sensor within the room, or by averaging temperature sensors within a zone.

9.212 Heater-battery control valves should drive closed on system shutdown or fan failure. The control system should then automatically set to provide frost protection.

Cooling coils

9.213 There are two basic methods of control for cooling coils:

- off-coil control – used in multi-zone systems or single-zone systems where close humidity control is required, to provide a constant maximum off- plant condition which satisfies the temperature and humidity requirements of the zone with the highest load;
- sequential control – used in single- zone systems, or multi-zone systems with averaging sensors where close control is not required. A room or duct temperature sensor controls the cooling coil and heater-battery in sequence to maintain constant room conditions.

9.214 The advantage of off-coil control is that accurate humidity control can be provided without relying on humidity sensors, which are prone to inaccuracy and drift. Off-coil control is expensive to operate in terms of energy consumption because of the lack of feedback of room loads. As a result, at low loads and in systems where there are large zonal variations, significant over-cooling and reheating will occur.

9.215 The control logic should prevent the cooling coil and heat recovery and/or heater-battery being on at the same time.

Humidifier control

9.216` Accurate humidity control can only be provided on single-zone systems, or multi-zone systems with zonal humidifiers. In the above systems, humidity sensors control the humidifier for low-level humidity control, and override the temperature controls to open the cooling-coil valve for high-level humidity control.

9.217 Multi-zone systems are more usually controlled by a minimum humidity sensor located in the supply duct(s) following the last heater-battery.

9.218 Overriding controls separate from the normal plant humidistat should be installed. Their purpose is to prevent excessive condensation in the conditioned space when starting up. A time delay should be incorporated into the humidifier control system such that the humidifier does not start until 30 minutes after the ventilation/ plant start-up. In addition, a high limit humidistat should be installed to limitthe output of the humidifier so that the saturation in the duct does not exceed 70%. This humidistat is to control the added moisture; it is not necessary to install a dehumidifier to reduce the humidity of the incoming air if it already exceeds 70% (part load control).

9.219 The humidifier control valve should close when the ventilation system is in “set back”. In addition, on system shutdown, low airflow or fan failure, the humidifier should be isolated.

9.220 In a self-generating humidifier, if the humidifier is unused for a period exceeding 48 hours, it should automatically drain its water content, including that contained in the supply pipework, right back to the running main and leave itself empty.

9.221 With certain types of steam humidifier, it may be necessary to install a thermostat in the condensate line from the humidifier’s steam supply, to ensure that the steam at the control valve is as dry as possible before it is injected into the air supply.

9.222 The humidifier control system should ensure that it is switched off with the fan. It is preferable to design the control system so that the humidifier is isolated for an adequate time before the fan is turned off to purge humid air from the system.

Control valves: general

9.223 The fog/frost battery control valve should fail-safe, that is open in the event of power or airflow failure. All other valves will stop in their current position in the event of power failure and should drive closed in the event of airflow failure.

9.224 Control valves should be located in an accessible position. Isolation valves should be provided to enable the control valve to be removed for service or replacement without the need to drain down the system

9.225 Care should be taken to ensure that the installation of control valves and their associated pipework do not obstruct access to the AHU inspection doors, removable drainage trays, eliminator units and access hatches.

Note: There are practical advantages in locating all control valves for an AHU in a bank (at a convenient height) at one end of the unit. (This should not result in an

additional control lag.) The bank will hold the control valves and actuators, and fan inverters/controllers as necessary, and can be constructed “off site” (see also paragraph 9.209).

Monitoring and alarms

9.226 Monitoring of the plant performance should be via a BMS to the estates and maintenance department.

9.227 The “plant failure” and “low airflow” alarm should be initiated by a sensor located in the main air supply duct. This should operate when the air quantity fails to reach or falls to around 80% of the design value and will give indication of fan failure, damper closed, access door left open, or any other eventuality that could cause a reduction of air quantity. Monitoring the current drawn by the fan motor is not a substitute for a sensing device that is directly affected by the airflow. The sensing ring fitted to plug and EC fans will fulfil this function.

9.228 The “filter fault alarm” should be initiated by a predetermined increase of pressure differential across the filters, thereby indicating a dirty filter. The filter fault indication and alarm is information for the maintenance department; it should not appear on any point of use indicator or control panel.

9.229 Visual indication that the AHU is operating within its prescribed parameters should be provided in critical areas at a manned staff location, for example, the reception or staff base. These need only take the form of a green light to show the system is operational and a red light to show that it is not.

Room temperature control

9.230 The limits for room temperature set point are generally between 18ºC and 25ºC depending on the particular application, and in some specialised instances (for example, operating departments) are adjustable within a predetermined range by the user.

9.231 The selection of temperature set point for each room or zone may be by a control facility in the room/zone, or remotely at the control panel or BMS. Where the control device is mounted within the room/zone and adjustable by the user, it should be marked either “raise” and “lower” or “+” and “–“. It should control within a specified temperature range to suit the user requirement with a control tolerance of +1 K. All other control set points should be selectable either on the control panel or at the BMS interface.

9.232 Where local control is provided, an indication of temperature will be required locally, or at a staff base (if appropriate), using an analogue or digital indicator. The indicator should be large enough to be read from the normal working position (for example, at the operating table in a theatre). This may be mounted in a supervisory control panel, with the signal repeated on the main system control panel or BMS. It is important that this indicator displays the actual measured temperature and not the selected temperature.

Local exhaust ventilation (LEV)

9.233 Devices that use an inflow of air to control exposure of staff to hazardous substances are classified as LEV systems under the COSHH Regulations.

9.234 An LEV system will typically comprise a unit where the airborne hazard is captured, ductwork to convey the extract air to the fan and a discharge stack. The extract air may be filtered or centrifugally separated to remove any particulate material prior to discharge. HSG 258 produced by the Health & Safety Executive gives detailed guidance.

9.235 It is important to recognise at the design stage whether an extract is being provided for comfort, to remove odours or to remove hazards, in which case it will be an LEV system. Chapter 8 lists typical devices used in healthcare applications.

9.236 The quantity and location of the terminals supplying the make-up air is an important factor in the design of LEV systems.

9.237 LEV systems are statutory items that will be subject to an independent examination and test at least every 14 months by a competent person.

Extract ductwork and fan

9.238 Extract ductwork for an LEV system should, where possible, be installed outside of a building. Where it has to be inside, it should take the most direct route through, with as few bends or changes of direction as possible.

9.239 All ductwork joints should be sealed and ideally there should be no access hatches. Where access hatches have to be provided, they should be of a type that has a hermetic seal.

9.240 Some substances are particularly corrosive, so the choice of material for the ductwork, and type of extract fan fitted, should reflect the nature of the substance being conveyed.

9.241 The ductwork should either be fire rated or fitted with intumescent collars where it passes through fire compartments within the building. This will ensure that the extract system is unobstructed and always open to atmosphere up to the discharge point.

9.242 Some LEV systems (for example, microbiological safety cabinets) HEPA-filter the extract air within the cabinet unit, but it should not be assumed that the exhaust air will be totally free from microbiological or other hazardous material.

9.243 The extract ductwork should as far as practicable be kept under negative pressure while inside the building. The extract fan should be located outside of the building or if this is not practicable, as close as possible to the outside so that any ductwork on the discharge side inside the building is kept to an absolute minimum.

9.244 The extract fan drive motor should be out of the airstream and it should be possible to change the motor without disturbing the fan or its casing.

9.245 Duplex fans are only required when several LEV systems share a common extract system (for example, multiple fume cupboards in a large pathology department where it can be anticipated that at least one cupboard will always be in use or need to be

available for use). In such a situation each cupboard should be fitted with a non-return damper at the point that it joins the common system and be capable of being isolated from the common extract system. The common extract duct should be large enough to handle the combined extract volume from all the systems that feed into it.

9.246 If extract filters are fitted in the ductwork the system design should allow them to be changed safely.

9.247 Current standards permit the installation of microbiological safety cabinets with integral fans, provided that the extract ductwork can be kept short (that is, less than 2 m); such an installation, however, is likely to be noisy and is not recommended for use in new buildings.

LEV discharge stack arrangements

9.248 Roof-level discharge, wherever practicable, is preferred since it removes much of the uncertainty over air re- entering the building through ventilation inlets or windows. In such an installation, the extract fan should be situated separate from the LEV captor unit and close to the discharge stack to maintain the duct within the building under negative pressure.

9.249 The discharge point on a flat roof should be through a terminal at least 3 m above roof level but as high as necessary to limit re-entry into supply air inlets or other plant openings. This will protect those who may need to access the roof. Terminals at other roof types need to be high enough to prevent the wind blowing across the roof from causing downdrafts.

9.250 Where there are adjacent buildings with opening windows, or where downdraughts are likely to occur, it may be necessary to increase the height of the discharge stack in order to achieve adequate dispersal. In complex locations, airflow modelling or wind tunnel tests may be required to determine the optimum height.

9.251 The discharge stack should have an open end. It may be fitted with a collar to reduce its area and so increase the air efflux velocity at the point of discharge (known as the venturi effect). To ensure that air leaving the terminal is not deflected down but allowed to disperse freely, the terminal cannot be fitted with any sort of cover or hat. A drain may be required at the base of the discharge stack to remove any rain that enters (see photograph).

Figure 9 Typical LEV discharge stacks

LEV system information and identification

9.252 Once installed, all elements of each LEV system should be uniquely identified with a permanent label as described in Chapter 13. There is a statutory requirement to have information on the design and required operational performance of an LEV system available to those who are responsible for its operation and

9.256 maintenance. The designer should ensure that this information is available at handover.

10. Installation Standards

General

10.1 AHUs, ductwork sections and associated elements of the ventilation system will be delivered to site suitably packaged to protect them from damage and casual contamination. They should remain protected when stored on site awaiting installation.

10.2 Ductwork should be installed to the “Advanced Level” as defined in BESA’s (2019) ‘TR/19: Guide to good practice – internal cleanliness of ventilation systems’. Should any doubt exist as to whether the guidance has been observed, the ducts should be cleaned internally to restore them to this standard and be visibly clean before being taken into use.

10.3 When the ventilation elements are installed, all open ends have to be sealed to prevent the ingress of construction dust as installation progresses. The access doors and panels of AHUs should be kept closed. All AHU dampers and fire dampers should be covered to prevent casual contamination during the construction phase. This is particularly important for fire dampers mounted in the plantroom floor. The damper blades should be wiped clean before final connection to the distribution ductwork.

10.4 The area around the supply air intake should be kept free of vegetation, waste, rubbish, builders’ debris or any other possible source of contamination.

10.5 “Builders’ work” ducts of brick or concrete should have a smooth internal finish and be surface sealed to prevent the release of dust before being taken into use. They should be fitted with a drainage system if not self-draining.

10.6 Every effort should be made to prevent the internal contamination of the ventilation system during the construction phase as once contaminated, it is extremely difficult to completely remove dust and debris. In particular, extract and recirculation fans should not be run up until the area is at least “builders clean” – that is, the floors swept and wet-mopped – otherwise the energy-recovery device in the AHU could become contaminated and its efficiency significantly reduced.

AHUs

10.7 Units should have a working life of up to 20 years; it can be anticipated that over this period there will be a need to access every element within the unit for deep cleaning. It is also quite possible that during the life of the unit, the main fan and all control valves will need replacement. Heater and cooling coils may also need to be repaired or replaced. Suitably positioned service connection joints and adequate spacing should permit these items to be isolated and withdrawn without the need to drain down entire systems or dismantle other installed plant.

10.8 Care should be taken during installation to ensure that electrical and mechanical services are not installed in positions that will reduce or impede access. Mounting all control valves and fan controllers on a frame positioned adjacent to the unit is the

preferred option. This approach has the advantage that the frame and its components can be built and tested “off-site”.

10.9 In order to reduce the effects of galvanic corrosion, black iron fittings should not be used in the pipework installation. Rolled jointed stainless-steel pipework is preferred.

10.10 Vibration from a remote plantroom can be transmitted by the structure of the building, and may be regenerated and sometimes magnified many times. Pipe and ductwork should incorporate anti-vibration couplings, pipe hangers and supports, preferably in two planes at right angles, as close to the vibration source as possible.

10.11 The service connection points for pipework and electrical conduits will have been made during construction of the unit. The unit will then have been leak-tested in the factory prior to delivery to site. If there is a need to drill through the AHU casing or panels (for example, to mount a sensor), the hole should be as small as practicable and sealed to prevent air leakage.

10.12 It is essential that the AHU/ductwork is mounted far enough from the floor to permit the correct installation of drainage systems for cooling coils, humidifiers and heat recovery systems. If the AHU is located on a roof, it will require a clearance of 600 mm to provide access to maintain the building structure below. Sufficient height for the installation of drainage pipework and traps should always be allowed. Easy access for maintenance of drainage systems and their associated pipework should be provided. It should be possible to fully withdraw the drainage tray if it is of the removable type.

10.13 AHUs should be positioned so that all parts are easily and safely accessible for routine inspection and service. If a unit is located against a wall or backs onto another unit, access to all parts should be available from the front. Units greater than 1 m wide should preferably have access from both sides or access doors large enough to permit the full and safe entry of maintenance personnel.

10.14 Air filters, cooling-coil drainage trays and drift eliminators are all items that should be changed, inspected or withdrawn on a regular basis. The installation of the AHU should permit this without the need for tools or to dismantle other plant or systems.

10.15 Access to air intakes and discharges, AHUs and items in the distribution system such as filters or auxiliary trimmer batteries located in a plantroom or plant area should be via fixed ladders, hook ladders, pulpit style steps or other moveable access platforms. The installation of distribution ductwork and other electrical or mechanical services should provide sufficient clearance to allow access equipment to be moved into position.

Distribution systems

10.16 Where ductwork penetrates a roof, it should be protected by an upstand to prevent water penetration. Where it penetrates an outside wall, the method of installation should prevent water tracking along the ductwork into the building or its wall cavity.

10.17 The installation of all services in service ducts and above ceilings should be coordinated so that cable trays, medical gas and other pipework do not obstruct or

prevent access to the ductwork cleaning doors, dampers and any auxiliary plant elements. The use of BIM should highlight clashes at the design stage.

10.18 Plant elements such as VAV boxes, trimmer heaters or cooling coils, humidifier lances or branch filters that are located outside of plant spaces should be accessible for routine inspection and have a cleaning access door on both sides. They cannot be installed above any of the following areas:

- operating theatres;
- preparation rooms or sterile pack stores;
- anaesthetic rooms or recovery areas;
- rooms containing imaging equipment;
- pharmacy cleanrooms;
- containment laboratories;
- patient bedrooms and isolation rooms.

10.19 Rectangular ductwork sections should be joined by bolted or clipped gasketed flanges. Circular and flat-oval slip-joints should be mastic-sealed and held with blind rivets, not screws. The mastic used should not support biological growth. The ductwork installation will be leak-tested prior to acceptance.

10.20 Volume control dampers (VCD) should be oriented so that their adjusting handles or knobs are located at the lower vertical edge or bottom of the damper when mounted above ceilings. The means of adjusting the damper will be within sight and reach from a designated ceiling void access hatch once the ceiling is complete. Volume control dampers mounted in any location should have the control adjuster mounted to allow easy access for the commissioning team and for future access when a post-cleaning rebalance is undertaken.

10.21 Access to VCDs or local auxiliary fans mounted above ceilings should be via low-leakage access hatches mounted in the ceiling or hatches integral to a light fitting.

Note: Obtaining access by removing a light fitting is not acceptable.

10.22 Where ducts are drilled to provide test holes or to mount sensors, the swarf should be removed, and the hole deburred before the fan is started.

Note: Care should be taken to prevent the inadvertent drilling of attenuators.

10.23 Flexible ductwork may only be used if there is no other way of connecting an air terminal to a duct. The flexible duct should be not more than 0.5 m in length, be as fully extended as possible and never used in lieu of a bend. The fire rating of the flexible duct should be no less than that of the fixed duct that it is connected to (see also paragraphs 9.131 and 9.160).

10.24 Fire and smoke dampers must be installed strictly in accordance with their manufacturer’s instructions. There will be a rectangular access hatch (saddle mounted for circular ducts) and test switch adjacent to the damper so that a single person can trigger the damper and directly observe its operation during the annual

test (see photograph). When pressure stabilisers incorporate a fire damper, the test switch is to be located in an easily accessible position on the less clean side of the pressure stabiliser.

Figure 10 Fire damper with test switch and inspection hatch

Point of use

10.25 Items of equipment that require access for inspection and cleaning should not be accepted if they are installed in locations that prevent easy access.

10.26 Items of equipment that require access for inspection and cleaning such as fan coil units will not be accepted if they are installed directly above medical or diagnostic equipment.

Note: A common problem occurs because installation layout drawings show fan coil or similar units on the room plan. These are often only “indicative” of the fact that there will be a unit in the room but are taken as the desired position by those carrying out the installation. As an example, the installation drawing for an interventional imaging room shows a fan coil unit in the centre of the ceiling. If it is installed in this position it will be directly above the scanner once that is installed. The fan coil unit will then not be accessible for routine inspection and maintenance, and should it leak water, it will put the scanner out of action.

10.27 The installed position of ceiling terminals in storerooms (for example, a theatre's bulk sterile pack store) should coordinate with the siting of the storage racking. The airflow at the terminals should be routinely measured, so the racking and its contents should not obstruct access to the terminal when using a calibrated hood. The same problem can occur in recovery rooms and ward areas where bed curtain rails and bed hoist tracks can prevent the measurement of airflow from ceiling terminals.

10.28 Low-level extract grilles should be of the pull off face type for ease of cleaning.

10.29 See pictures of low level extract installations in Appendix 9.

Service penetrations

10.30 Where services penetrate the fabric of the building, they should be sealed to prevent any uncontrolled air leakage between rooms and service spaces or voids. Situations where this occurs will be:

- service spaces behind IPS panels at wash basins and scrub troughs;
- cased in wall-mounted medical gas pipeline units and ceiling-mounted pendants;
- electrical trunking and bedhead rail systems;
- boxed-in main and local drainage pipework;
- ceiling-mounted operating lights, examination lights and other pendant-supported items.

10.31 The sealing should be at the point that the service penetrates the wall, ceiling or floor and not at the access panels or covering shrouds as these will need to be removed from time to time. Sealing of the penetrations should be done at first-fix stage as access will become progressively more difficult once final covers and finishes are applied. In certain applications, permeability testing will be carried out at first-fix stage to ensure that this has been done.

Note: The "clean zone" is not the same as the overall size of the canopy, and it is vital to consult the UCV canopy supplier in order to get the position and size of the zone correct, as mistakes are expensive to rectify.

11. Commissioning Systems

General

11.1 Commissioning is the process of advancing a system from physical completion to an operating condition. It will normally be carried out by specialist commissioning contractors working in conjunction with equipment installers. Commissioning of the ventilation system will normally be the responsibility of the main or mechanical contractor who should coordinate the process.

11.2 Commissioning is often subdivided into sections (for example, air handling unit, automatic controls, air side balance, building fabric and fittings). Each section may be commissioned by its specialist installer, and they are often accepted in isolation.

11.3 Commissioning is an essential process for ventilation systems. It is therefore important that adequate provision for the process be made at the design stage of the project. Procedures for commissioning air-handling systems are given in CIBSE Commissioning Codes and BSRIA BG 49 – Commissioning Air Systems.

11.4 The duct design process should take into account the requirements of system balancing. The position and number of regulating dampers included in the design should be sufficient for this purpose.

Location of dampers and test holes

11.5 Balancing/commissioning dampers will be required in each branch of the distribution ductwork. In a critical system such as an operating suite, the branch to each room and each location where it is required to carry out a proportional balance should have a balancing damper.

11.6 Test holes for the measurement of airflow will be required at carefully selected points in main and all branch ducts. The number and spacing of holes are given in the BSRIA BG 49/2015 Commissioning Air Systems. Their positions should be identified at the design stage.

11.7 The test positions need to be accessible for commissioning to take place. They may also be required for subsequent annual verification of the system performance, so they should not be covered by permanent lagging.

11.8 The measurement point should be in a straight length of duct as far away as possible from any upstream bends, dampers or other elements that could cause disturbance to the airflow. The actual location should be:

- at least 1.5 duct diameters upstream of sources of turbulence such as dampers and bends;
- if this is not possible, ten diameters downstream of dampers, bends or tees, and five diameters downstream of eccentric reducers;
- where there is enough space round the duct to insert the pitot tube and take readings;
- where the duct has a constant cross- sectional area.

Test holes for measuring total airflow from a fan should be located either four diameters upstream or ten diameters downstream of the fan. Provision should also be made for measuring the fan's speed of rotation.

Note: Plug and EC fans are supplied with a measuring ring so their output can be read directly. This needs to be connected to an external pressure tapping or electronic fan control unit.

Information to be provided

11.9 It is essential that the designer should pass on the system-design intent fully to the commissioning engineer by providing:

- relevant parts of the specification;
- schematic drawings indicating data listed in Table 11;
- equipment schedules;
- controller and regulator schedule;
- fan performance curves;
- wiring diagrams for electrical equipment, including interlock details

Table 11: Information to be provided on schematic drawings

Items in system	Information to be provided
Fans	Fan total pressure Volume flow rate at normal and set back speed Maximum motor current
Plant items	Type and identification numbers from equipment schedules Fluid and air volume flow rates Fluid and air side pressure losses Dry bulb temperatures Wet bulb temperatures Humidity
Dampers, including motorised and fire dampers	Identification numbers from equipment schedules Location Identification number Volume flow rate
Main and branch ducts	Dimensions Volume flow rates and velocities Identification numbers from equipment schedules
Test holes and access panels	Location and size of duct Identification number Design airflow rate
Room supply and extract terminals	Location Identification number Grille or diffuser factor Volume flow rate and neck velocity Operating static pressure
Pressure cascade	Room differential pressures Airflow direction between rooms Pressure stabiliser and transfer grille locations
Internal environment conditions	Design room conditions and adjustable range Specific room air velocity if specified Noise level
Controllers	Set points

Notes: Fan total pressure is the difference between the total pressure (static pressure + velocity pressure) at the fan outlet and the total pressure at the fan inlet. Where volume flow rates are variable, maximum and minimum values should be provided.

Commissioning personnel

11.10 It is unlikely that all the required commissioning skills will be possessed by one individual; a commissioning team is therefore usually needed. The objective of commissioning is to ensure that the necessary performance and safety requirements are met.

11.11 During the commissioning process a great deal of information will be generated which will form an invaluable future source of reference about the plant. It is essential to ensure that it is collected together in the form of a commissioning manual and handed over to the client on completion of the contract together with the “as fitted” drawings.

11.12 In order to be successful the commissioning process will need to start before practical completion, as many parts of the system will become progressively less accessible. The correct installation of those parts should be witnessed and leak rate tests carried out as construction proceeds. Failure to establish responsibility for commissioning early enough will delay the completion of the project or lead to unsatisfactory plant performance (see CIBSE Commissioning Code M).

Commissioning brief

11.13 The commissioning team will require a detailed brief from the system designer. This should include:

- a “user” brief comprising a description of the installation and its intended mode of operation;
- the precise design requirements with regard to the scheme of air movement, room static pressures, supply and extract airflow rates and acceptable tolerances;
- full details of the design conditions both inside and out, for winter and summer, together with the control strategy;
- equipment manufacturers’ type test data, commissioning, operation and maintenance recommendations;
- drawings showing the layout of the system, positions of airflow measurement test points, dampers, regulating devices and filters within the duct runs, together with sizes of ducts and terminal fittings. It will save time if these drawings are annotated with the design volumes and static pressures required at each branch and outlet point;
- wiring diagrams for all electrical equipment associated with the air- handling systems, including motor control circuit details and any interlocking and safety devices.

11.14 CIBSE Commissioning Code A – ‘Air distribution’ or BSRIA BG 49 – ‘Commissioning air systems’ provide full guidance on the information that will be required by the commissioning team.

11.15 Designers should specify the type of measuring instruments and test procedures. They should include in the contract documents instructions on verifying the accuracy of test instruments, which should be supported by reference to relevant calibration certificates.

11.16 The system, on completion, should be operated by the contractor as a whole and subject to performance tests in accordance with the contract requirements. These will include independent validation of the system performance on behalf of the client.

11.17 The commissioning process should be carried out in the order in which it appears in this guidance document. That is to say, the static checks and visual inspections itemised in paragraphs 11.20–11.26 should be followed by the dynamic tests described in paragraphs 11.27–11.46, the performance tests listed in paragraphs 11.47–11.64 and finally the handover procedures set out in paragraphs 11.63–11.65.

11.18 Once the system is shown to meet the design intent, the handover documentation should be completed. In the event of performance not being acceptable, the matter should be dealt with in accordance with the contract arrangements.

Pre-commissioning checks

11.19 The pre-commissioning checks consist of visual inspection, manual operation of equipment, static measurements and functional tests of individual components. They should be carried out prior to setting the system to work and undertaking the dynamic commissioning process set out in paragraph 11.27 onwards.

Note: Before commencing commissioning, it is essential that builders' work in the area served by the system is complete. The doors and windows should be fitted, floor finishes applied, walls and ceilings completed and their final finish applied. Fans should not be run until the area is clean (see paragraph 10.6).

Standard of installation

11.20 During the installation of the system the following will be witnessed:

- that the plant and installations have been provided and installed in accordance with the design specification and drawings;
- that only approved sealants have been used in the installation;
- that all components function correctly;
- that the satisfactory sealing of access doors and viewing ports has been carried out;
- that the AHU airtightness test as per BS EN 1886 has been carried out;
- that air-pressure tests and air-leakage tests on ventilation ducting have been carried out in accordance with the methods set out in the BESA DW143 – 'Ductwork leakage testing' but the leakage rate to be not greater than 3% (it is usual to carry out these tests a section at a time as the ductwork is installed and before its insulation is applied. The results will be recorded in the commissioning manual);
- that gaps around doors and hatches are as specified in the design;

- that the permeability tests are carried out as per paragraph 12.17;
- that the correct operation of pressure stabilisers, control dampers, isolating and non-return dampers have been checked;
- that test holes have been provided in their specified locations and are sealed with suitable grommets;
- that control dampers are secured and their quadrants fitted correctly;
- that any interlocks are operative and in accordance with specification;
- that the electric circuits are completed, tested and energised;
- that electric motors have been checked for correct direction of rotation both at full speed and set back;
- that cooling and heating media are available at correct temperatures and pressures and in specified quantities
- that the air-conditioning plant components and controls function correctly;
- that the air-conditioning plant interlocks and safety controls function correctly;
- that the plant is physically complete, insulation is applied and all ducts and pipework are identified as specified;
- that all service penetrations of the fabric of the area are sealed at the point of penetration (see also paragraph 10.30);
- that the building housing the ventilation plant is generally in a fit condition for commissioning and performance tests to commence, that is, windows, doors, partitions, ceilings, etc. are completed, surfaces sealed and their final finish applied;
- that the areas containing the ventilation plant and those being served by it are clean;
- that access to all parts of the system is safe and satisfactory.

Certification of equipment

11.21 The following test certificates should be assembled by the commissioning team and be available for inspection at any time during the contract period. They will form part of the handover information and should be placed in the commissioning manual:

- type test performance certificates for fans;
- pressure test certificates for:
  - heater-batteries;
  - cooling coils;
  - humidifier (if appropriate);
- type-test certificates for attenuators;
- type-test certificates for primary and secondary filters;
- individual test certificates for EPA or HEPA air filters.

Equipment tests

11.22 Prior to setting the system to work the following will be witnessed and proving tests should be carried out as detailed:

Filters

11.23 The quality of filter housing and in particular, the seals, is a critical factor in maintaining the efficacy of the filtration system by ensuring that air does not bypass the filter elements. Therefore, the following checks should be made:

- filter seals should be fitted and in good condition;
- filters should be installed correctly with respect to airflow;
- bag filters should be installed so that the bags are vertical and their pockets free;
- all filters should be checked to ensure they are free of visible damage;
- EPA or HEPA filters should be scanned with an LSAPC to prove that they and their housings achieve the specified filter efficiency;
- the differential pressure indicators should be checked for accuracy and that they are marked with the initial and final filter resistance.

Drainage arrangements

11.24 The drain should conform in all respects to the standard set out in paragraph 9.105 onwards. In addition, the following should be proved:

- that the drain tray is easily removable or completely accessible;
- that the drift eliminator (if fitted) is removable without the use of tools;
- that a borosilicate glass trap is fitted and is easily removable;
- that the trap discharge point to drain has a clear air-gap of at least 15 mm;
- that the pipework is supported so that the air-break cannot be reduced;
- that the drain system from each drain tray is independent up to the air- break.

11.25 The operation of the drainage system is then proved by introducing water into the duct at the drain tray and observing that it completely drains out. This check is to be repeated both at normal speed and set back once the fans have been commissioned. At this time the clear trap can be marked to indicate the normal water level with the fan running.

Fire dampers

11.26 The following will be witnessed and proving tests should be carried out as detailed:

- the operation of all fire and smoke dampers (fire dampers fitted with a thermally actuated “memory metal” mechanism should be proved using a hot air heat source);
- the access provided to enable the dampers to be visually inspected and/ or reset should be sufficient for the purpose;
- indication should be provided of the dampers’ position (open/tripped);

- indication of the fire dampers' location should be provided both on the ductwork and at a visible point on the building fabric if the ductwork is concealed.

Dynamic commissioning

Air-handling and distribution system

11.27 Before commencing the dynamic commissioning all rubbish should have been removed and the floors swept and wet- mopped (see paragraph 10.6). Any IPS panels should be in position, access hatches closed, light fittings in place and ceiling tiles clipped down as necessary.

11.28 The fan drive, direction of rotation, speed and current drawn should be set in accordance with their manufacturer's instructions. In the vast majority of healthcare applications, the fan output should be set to give a constant volume of air. This to be controlled by measuring the pressure drop across the fan using a sensing ring and associated volume controller that will automatically integrate the fan 'K' factor to determine and control the pre-set output air volume. The fan output will then in air volume terms remain constant regardless of changes of system resistance. The actual volume delivered will be related to the air-change rate for the application.

11.29 After the installation has been checked to ensure that it is in a satisfactory and safe condition for start-up, it should be set to work and regulated to enable the plant to meet its design specification. The proportional balancing method described in the CIBSE Commissioning Code A should be followed. The airflow rates will be set within the tolerances laid down in the design brief. This will normally be the design airflow rate +10%; –0%.

Note: Plug fans are fitted with a measuring ring so that the design volume flow can be set when first started. It can then be reset as the airflow balance progresses. This method will result in the correct airflow with the least total system resistance once balancing is completed.

Air commissioning measuring equipment standards

11.30 All test and measuring equipment used will have a certificate to prove that its calibration has been checked within the previous 12 months at a facility using traceable national standards.

11.31 System performance should be measured at the main and branch duct supply and extract test points using a pitot and manometer or a thermal anemometer.

11.32 Supply and extract air volumes at the room terminals should be measured using a calibrated hood with back pressure compensation. If a hood correction factor is applied, it should be determined by a direct comparison with a duct measurement immediately adjacent to a terminal and not a general comparison between air at the main supply duct and the total as measured at the terminals. For multi-directional terminals a correction cross will be fitted in the measuring hood.

Note: Measurements taken with a "home- made" hood or cone will not be accepted.

11.33 Measurements at extract grille faces should, where possible, be taken using a calibrated hood. Alternatively, they may be measured with a rotating vane anemometer fitted with a hood, or as a last resort, scanned using a rotating vane anemometer and a free area factor applied. The grille face free area and factor used should be stated in the commissioning report.

Order of commissioning

11.34 When combined supply and extract systems are to be balanced and the area that they serve is to be at or above atmospheric pressure, the supply should be balanced first with the extract fan switched off, and then the extract balanced with the supply fan(s) on. The supply balance should then be rechecked.

11.35 For combined systems where the area that they serve is to be below atmospheric pressure, the extract should be balanced first with the supply fan switched off and then the supply balanced with the extract fan on. The extract should then be rechecked.

11.36 On completion of the balance, all volume airflows in supply and extract ducts and from grilles and diffusers will be measured and recorded. The true air- change rate can then be calculated from the data obtained.

Note: For accuracy the room dimensions should be actually measured on site rather than deriving them from design drawings.

11.37 All supply and extract duct volume control dampers should be locked and their position marked and the fan motor settings noted and recorded.

11.38 All grille and diffuser volume control registers should be locked to prevent alteration and their final position marked.

Room air distribution

11.39 The pressure relief dampers and pressure stabilisers will be set to achieve the specified room differential pressures and locked. The grille direction control vanes and diffuser cones will be set to give the specified air movement pattern. Visualisation techniques may need to be employed to prove the required airflow pattern is being achieved and detect any adverse coanda effects (see paragraph 9.162).

Note: When balancing combined supply/ extract cascade ventilation systems (for example, operating suites, cleanroom suites), the airflow through the extract terminals in the adjacent corridors may need to be adjusted outside of their original design values in order to achieve the desired room pressure differentials.

Air-conditioning plant

11.40 The specified flow rate and/or pressure drops will be set for all heater- batteries, cooling coils and humidifiers. The methods described in the CIBSE Commissioning Codes W and R should be followed. On completion their regulating devices will be locked to prevent alteration.

Control system

11.41 The control system should not be commissioned until both the air distribution system and air-conditioning equipment have been commissioned.

11.42 Because of the specialised nature of control systems and the fact that each manufacturer's system will contain its own algorithms and settings, commissioning should be completed by the supplier, and witnessed and documented by a representative of the client (for example, the healthcare organisation's appointed validator).

11.43 In the vast majority of healthcare applications, the fan output should be set to give a constant volume of air. This to be controlled by measuring the pressure drop across the fan using a sensing ring and associated volume controller that will automatically integrate the fan factor to determine and control the pre-set output air volume. The fan output will then in air volume terms remain constant regardless of changes of system resistance. The actual volume delivered will be related to the air-change rate for the application.

Note: Measuring the air pressure in the main supply duct and using that to set the supply fan speed as a percentage of its rated output and using that to set the extract fan speed as a percentage of the supply fan speed is not a satisfactory, accurate or acceptable way of controlling the desired supply and extract air volumes.

11.44 The location of all control and monitoring sensors should be checked and their accuracy proved.

11.45 The control system's ability to carry out its specified functions will need to be proved. The correct operation of any alarm systems should also be proved.

11.46 If the plant is provided with a "users" control panel in addition to the one located in the plantroom, the operation of both should be proved. This will typically apply to operating departments and laboratory systems.

Specific performance standards

11.47 The performance of the system should be measured and compared with information provided by the designer.

Plant capacity and control

11.48 When setting to work and proving the design, both the manufacturer of the air handling plant and the control specialist should attend site together and jointly commission the system.

11.49 If any doubt exists as to the capacity of the installed system, its ability to achieve the specified inside design conditions with the plant operating at winter and summer outside design conditions should be proved. Artificial loads will be required in order to simulate the internal gains/losses and the outside design conditions.

11.50 On completion of the plant performance test, recording thermo- hygrographs should be placed in each room/ area served by the plant and also the supply air duct upstream of the fog coil. The plant should be run for 24 hours with all doors closed.

During this period the inside conditions should stay within the tolerances specified. Alternatively, the BMS may be used to obtain the information required.

Noise levels (general)

11.51 The commissioning noise level is that measured with a sound level meter in the unoccupied room, taking account of the external noise together with the noise generated by the ventilation system. Chapter 8 and Table 1 in Chapter 4 give information for many applications.

11.52 The noise levels apply at the maximum velocity for which the system is designed to operate. Acoustic commissioning tests should be carried out with all plant and machinery running normally and achieving the design conditions of airflow, temperature and humidity.

11.53 An industrial-grade Type 2 sound level meter will normally be sufficient to check the noise level. Its accuracy should be checked using a calibrated sound source before use.

11.54 The noise level readings are to be taken at typical normal listening position 1.5 m above floor level and at least 1 m from any surface and not on any line of symmetry. In critical rooms the noise should be measured at the centre of the room and at the centre of each quarter. The mean of the five readings should then be calculated

11.55 In the event of a contractual deficiency a Type 1 precision-grade sound level meter should be used and the noise level determined by the procedure given in Scottish Health Technical Memorandum 08-01.

Filter challenge

General ventilation filters

11.56 In-situ performance tests will not normally be required for primary and secondary filters and their housings. However, the filters should be visually inspected for grade, tears, orientation and fit within their housing. Filters should be clean and a replacement set available. Bag filters should be installed so that their bags are vertical and spaced so that air can move through them freely.

11.57 Air leakage around a filter housing significantly reduces the filter efficiency. The as-fitted filter housing and access door arrangement should not permit air to bypass.

EPA or HEPA filters (for exhaust protective enclosures and laboratories)

11.58 Pathogenic material may be discharged through damaged or badly installed EPA or HEPA terminal filters. The complete installation should be tested using the method set out in BS EN ISO 14644 and ISO 17141.

The challenge tests may be carried out using either of the following techniques:

- a light scanning airborne particle counter (LSAPC) and a natural challenge to detect leaks;
- dispersed oil particle (DOP) to provide the challenge and a photometer to detect leaks.

11.59 In both cases the upstream challenge should be measured. A measurement of particle penetration through a representative section of the EPA filter media is then taken and used as the reference background level. These two readings enable the range of the detecting instrument to be set.

11.60 With an LSAPC the filter face is sampled at several points to establish the smallest non-penetrating particle size. This will directly relate to the grade of filter under test. The filter face, its seal and housing are then scanned, and if a significant number of particles at or above this size are detected, there is deemed to be a leak at or near the test position.

11.61 With DOP a challenge aerosol of inert particles of the type produced by a dispersed oil particle generator is introduced into the air, upstream of the EPA or HEPA filter. The downstream face of the filter, its mounting seal and housing are then scanned for leakage using a photometer. A leak should be deemed to have occurred if a steady and repeatable reading on the photometer at any point exceeds 0.01% of the upstream reading.

11.62 Should the EPA or HEPA filter fail this test, it will be replaced. Should the filter mounting seal or housing fail this test, it may be repaired and the test repeated.

Ventilation system commissioning records

11.63 Following commissioning, the main contractor will collate the individual commissioning reports together with the plant user manuals ready for handover.

11.64 The fire dampers will have been tested by a specialist, and a written statement detailing which fire dampers were tested, when and by whom should be provided. If any fire dampers in the system were not tested, they should be listed and appended to the statement.

11.65 The airflow balancing report compiled by the commissioning engineers should be available to the validator. The report should include copies of the equipment calibration certificates.

12. Acceptance Testing: Validation

12.1 All new and refurbished ventilation systems should be independently validated prior to acceptance by the client.

12.2 Validation differs from commissioning in that its purpose is to look at the complete installation from air intake to extract discharge and assess its "fitness for purpose as a whole". This involves examining the fabric of the building being served by the system and inspecting the ventilation equipment fitted as well as measuring the actual ventilation performance. Validation is not a snagging exercise; see the Note after paragraph 12.30.

12.3 Validation is a process of proving that the system in its entirety is fit for purpose and achieves the operating performance originally specified. It will normally be a condition of contract that "*The system will be acceptable to the client if at the time of validation, it is considered fit for purpose and will only require routine maintenance in order to remain so for its projected life*."

Appointment of validator

12.4 In order to ensure that the complete system operates correctly it will be necessary to validate it as a whole from the air intake through to the extract discharge. It is unlikely that the client's in-house staff will possess the knowledge or equipment necessary to undertake this process. Validation should therefore be carried out by a suitably qualified competent engineer appointed by the client. The validator would be the client's AE(V) (see Chapter 2 in Part B of Scottish Health Technical Memorandum 03-01) or someone of similar standing who is familiar with the ventilation requirements for healthcare facilities. They will be completely independent of the system designers, contractors, suppliers, installers, commissioners and those who will subsequently operate and maintain the system.

12.5 To retain independence, the validator should be appointed and paid directly by the client. The validator will act as the client's representative to inspect the system, check its performance and recommend acceptance, or not, to the client.

Note: "Client" means the healthcare provider, not a contractor or service provider.

Design proposal review

12.6 It is essential that whoever has been appointed to carry out the final validation acceptance of the system should be involved in the initial client's brief and design specification, preferably prior to the project being put out to tender. They will then be fully aware of the client's requirements and any limiting factors.

Note: While it is beneficial to involve the client's validator in the design process, it should be remembered that the appointed designer carries the "design risk" and advice from the validator will not obviate this.

12.7 It is important that the validator understands the complete project and not just the obvious ventilation aspects. Decisions about the type of ceilings, doors, access

hatches, fire compartmentation, floor markings, room functions, their adjacency and the proposed workflow patterns all have a direct effect on the likelihood of being able to achieve the desired ventilation performance. It is not sufficient to consider the ventilation in isolation.

12.8 During this process any derogations proposed by the contractor/supplier should be clearly defined, agreed and documented with the client (for example, through the VSG). All parties will then be clear as to what will be the acceptable standard of installation and performance when finally validated.

12.9 The ventilation designer(s) should provide the validator with system information listed in Table 11. The information should be in the form of an annotated drawing for each ventilation system to be validated. They should also provide any other design or specification information that will assist the validation process.

12.10 The contract arrangement should give the validator the right to visit the site as often as they deem necessary during the contract period.

First fix inspection

12.11 The validator should carry out a physical walk-around inspection of the installation at a point in the project when the AHU is “on site” and the main and branch ductwork is for the main part installed, but prior to the ductwork being concealed behind wall panelling or ceilings.

12.12 If possible, the following airtightness tests should be witnessed during the inspection:

- AHU installation leakage (BS EN 1886);
- supply and extract duct leakage (BESA DW/143);
- initial permeability test (see paragraph 12.17).

12.13 The quality of the installation, compliance of the AHU, suitability of the basic installation, location and future accessibility of commissioning dampers, location and compliance for testing of fire dampers, etc., can all be assessed during the visit.

12.14 When validating large projects that have many AHUs, it is worthwhile to visit the AHU manufacturer to inspect a specimen unit and agree its compliance before all remaining units are built and transported to site. At that time the leakage and deflection tests can be demonstrated by the AHU supplier in their factory.

12.15 Once units are delivered to site, it is useful to get all mechanical and electrical services connected to a specimen AHU. The location of pipework joints, drain points, anti-vibration couplings, isolating and control valves can all be agreed, as can the route of cable ways and control wiring. The object will be to create an agreed “exemplar unit”. If all other AHUs are installed in an identical fashion, they will normally be considered compliant at the time of final validation.

12.16 On completion of the first fix visit the validator should provide the client with a short report identifying items that are not compliant with the specification.

Permeability testing

12.17 The following areas will require permeability testing:

- isolation suites of any type;
- operating suites of any type;
- pharmacy aseptic preparation facilities;
- IAP cleanrooms in central decontamination units (containment leak test in accordance with BS EN ISO 14644-3:2019);
- category 3 and 4 containment facilities;
- any other area specified within the contract.

The methodology for permeability testing is set out in BSRIA document BTS 3 – 'Air permeability testing of isolation facilities'.

12.18 An initial permeability test should be witnessed at first-fix stage when the envelope of the suite is physically complete but before wall, ceiling and floor finishes are applied. The objective will be to find and eliminate any construction leaks (for example, between a floor slab and curtain wall) before they become covered up during the fit-out stage (see paragraph 10.30).

12.19 A full permeability test in accordance with the methodology given in BSRIA BTS 3 will be carried out at practical completion to ensure that all service penetrations have been adequately sealed.

Note: Any leaks discovered during the test are to be sealed at the point of penetration of the building fabric envelope and NOT at the gaps around IPS panels, ceiling hatches or bedhead trunking covers, etc. (see also paragraph 10.30).

Follow-on inspections

12.20 Dependent on the size and complexity of the installation, a second and further inspection visits may be required. The validator should attend site as frequently as necessary in order to try to eliminate any installation issues as the project develops and while trades are still in attendance, rather than having to resolve them at the time of final acceptance.

Final acceptance inspection: validation

12.21 The commissioning of a ventilation system will normally be carried out by the suppliers of the various elements. The final acceptance validation will check that all of the elements work as a whole to achieve the project aim.

12.22 The following regime of inspection and testing should be applied to the validation of all new and refurbished ventilation systems. It may also be applied to systems that have undergone significant changes such as the replacement of a fan or other major component.

Basic requirements

12.23 The area served by the ventilation system to be validated should be physically complete with final finishes applied. The doors should fully close against the design pressure differential with IPS panels fitted and any access hatches closed. All ventilation plant serving it should be operating correctly and have been commissioned in accordance with the project contract.

> **Note**: In projects on existing sites, the area of the building being built/refurbished is often sealed off from the “in use” part to prevent dust penetration. At final validation the seals need to be at least temporarily breached in order to be able to determine the ventilation performance in “normal” conditions.
>
> If this is not possible, validation will be conditional on a final “actual” performance check when the seal is removed at the time of handover.

12.24 The area served should be free of any rubbish, debris, obvious dust and have been wet-mopped before the validation is undertaken.

> **Note**: There is no need to clean the area to the point that the validator needs to gown up in order to enter it. A certain amount of disturbance to hatch seals, ceilings, panels, etc. will be inevitable during
>
> the validation process, so the area will require a final “clinical” clean prior to being taken into use.

12.25 The validation process should be a continuation of the earlier site inspections and will in many cases be carried out in parallel with the commissioning process.

12.26 Unless stated elsewhere in the design specification, the conditions in the principal space served by the ventilation system being validated should be stable and within the given ranges.

Temperature: 18–22ºC dry bulb.

Humidity: 30–70% Relative humidity.

12.27 Any test or measuring equipment used should have a certificate to prove that it has been calibrated within the previous 12 months at a facility using traceable national standards.

12.28 In the case of a noise meter, its “matched sound source” should have a certificate to prove that it has been calibrated within the previous 12 months at a facility using traceable national standards. The noise meter should be calibrated to the sound source on each occasion that it is used.

12.29 The validator has the right to either witness readings taken by the commissioning team or to independently take such readings and measurements as they deem fit in order to satisfy themselves as to the actual performance of the system.

Validation process

12.30 The validation process should follow the sequence given below. Any failures discovered during the process should be rectified before continuing. The validator should check the following:

- the location of the air intake and discharge and their position relative to each other and other intakes and discharges;
- inspection and cleaning access to the vermin mesh and as necessary throughout the installation;
- the security, suitability of and access to the AHU location;
- sufficient space and access arrangements for service and maintenance;
- that the AHU is uniquely identified (see paragraph 13.17) and complies with the minimum standards set out in Chapter 9;
- that the AHU and distribution system have been leak-tested and comply with the design;
- that the AHU and supply ductwork system are clean and free of visible dust;
- that all fire and smoke dampers have been inspected and tested for correct installation and operation. A certificate to that effect, signed and dated by the inspector and tester, will be available for inspection;
- that the area served by the ventilation system is complete and free from significant defects that could invalidate the validation process;
- that the supply and extract airflow rates are in accordance with the design +10%; –0% and the system terminals are in balance. Note that the total supply and extract air volumes measured at the AHU should equate to those measured at the terminals. A discrepancy in the totals would indicate a leak in the system which should be resolved before proceeding further;
- that the air-change rate calculated from the measured airflow and room dimensions accords with the design specification;
- that the room differential pressure regime is in accordance with the design and that if pressure stabilisers are fitted, they operate correctly and silently;
- the air velocity at a specific location(s) if required in the application specification;
- that the noise level does not exceed the design value;
- that the system indicators correctly and clearly show whether or not the ventilation system is in an operational state;
- that any user controls fitted operate correctly (for examples of “cause and effect testing”, see Appendix 10);
- that the temperature and humidity in the space being ventilated are accurately indicated on the user panel and that they can be adjusted within the specified limits, if applicable;
- that the estates control functions operate correctly and the plant condition is clearly shown both on the plant control panel and at the BMS/ BEMS interface;
- that the fire cause and effect strategy has been demonstrated and operates correctly. This may be carried out by others, in which case a statement signed

and dated by the person carrying out the test will form part of the handover information;

- that any additional tests called for in the project specification have been carried out and witnessed by the validator or the client's appointed expert.

Note: Validation is not a "snagging" inspection. The main contractor has presented the installation as being complete, fully commissioned, achieving the specified level of performance and ready for handover. The validator's role is to check on behalf of the client that the contractor is correct in that assertion.

If the validator discovers that there are a significant number of snags and non-compliances, the validation should be terminated. It is the contractor's responsibility to snag the project, carry out remedial works and re-present the installation for acceptance. The validator will then need to repeat the validation process. The client is entitled to deduct any resulting additional validation fees incurred from the contractor.

12.31 It is vitally important to complete the validation process before the system is accepted by the client. Due to the nature of the ventilation installation and the intensity of use in the healthcare setting, it will not be possible to correct any faults or non- compliances once the system has been accepted and taken into use. There are also medico-legal aspects around taking a non- compliant system into use. Pre-announced handover or occupancy dates are not a reason for the validator or client to accept a non-compliant installation.

Validation report

12.32 Following validation, a full report detailing the findings will be produced and sent to the client's lead project manager. The report should conclude with a clear statement on whether the system achieved or did not achieve the standard set out in the agreed design specification.

12.33 The client's lead project manager should lodge a copy of the validation report with:

- head of the user department;
- infection prevention and control;
- estates and facilities.

Additional specialist tests

12.34 Certain critical areas will require additional testing and validation in addition to the process given above.

UCV theatres

12.35 The following regime of inspection and testing should be applied to the validation of new installations designed to provide ultra-clean conditions in an operating suite. The test regime has been devised to ensure that the system as installed fully achieves the operational requirement for these systems as set out in Chapter 8.

UCV canopy validation procedure

12.36 The validation procedure set out in paragraph 12.30 onwards should have been satisfactorily completed prior to attempting to validate the UCV canopy. The

operating suite to be validated should be physically complete with final finishes applied. All ventilation systems serving it should be operating correctly and delivering their design airflow rates.

12.37 Tests to validate the suitability and performance of a UCV canopy should be undertaken in the order that they appear below. If an item fails to meet the required standard it should be rectified and successfully retested before passing on to the next test.

Summary of test regime

12.38 Leakage tests should ensure that:

- the UCV canopy is correctly assembled and sealed so that no air will bypass the filters;
- the canopy terminal filters are correctly sealed in their housings;
- the canopy terminal filters are of a uniform quality and undamaged.

12.39 Air velocity measurements should ensure that:

- a sufficient quantity of air is being delivered by the canopy;
- the airflow has sufficient velocity to reach the operating site plane.

12.40 An entrainment test should ensure that contaminants arising outside of the UCV canopy footprint are not drawn into it.

12.41 Visualisation techniques should gain an understanding of the overall system performance.

12.42 Noise measurement should ensure that working conditions are satisfactory.

12.43 Control system “cause and effect” checks should ensure that the system operates and indicates as specified (for example, see Appendix 10).

12.44 The successful completion of the test regime will ensure that the system will be effective if used correctly.

Test and measuring background conditions

12.45 The entire theatre suite should be clean and free from debris and visible dust. It should be in a condition that if the validation is successful the suite will only require a final clinical clean before being taken into use (see paragraph 12.24).

12.46 All doors should remain closed when readings and scans are being taken.

12.47 The conditions in the operating theatre should be stable and within the given ranges.

Temperature: 18–22ºC dry bulb.

Humidity: 30–70% Relative humidity.

Test and measuring equipment

12.48 Any test or measuring equipment used should have a certificate to prove that it has been calibrated within the previous 12 months at a facility using traceable national standards.

12.49 In the case of a noise meter, its “matched sound source” should have a certificate to prove that it has been calibrated within the previous 12 months at a facility using traceable national standards. The noise meter should be calibrated to the sound source on each occasion that it is used.

Test grid – vertical flow canopies

12.50 A test grid should be constructed on the floor within the UCV canopy footprint as projected by the inside dimensions of the side walls or boundary air curtain. A suitably marked test sheet will provide a consistent standard of test grid.

Note: The entire clean zone footprint of the UCV canopy will be designated by a contrasting coloured inlay in the floor covering. A line marked on or cut into the floor covering is not sufficient and will not be accepted.

12.51 The test grid should comprise test squares of 280 mm × 280 mm dimension.

12.52 The test grid should be aligned along the centre lines of the canopy footprint with its centre under the centre point of the canopy.

12.53 Any test square with 80% of its area within the UCV footprint should be used as a test position.

12.54 An inner zone will be designated that is not less than 36% of the total footprint. It will be made up of a number of test squares distributed symmetrically about the canopy footprint centre line. Regardless of the size or shape of the canopy footprint, the inner zone will comprise a minimum grid of 6 × 6 test squares.

12.55 Unless specified otherwise, a test position should be in the geometric centre of a test square.

12.56 Test position 1 will be the left-most test square in the row nearest to the operating theatre wall that houses the theatre control panel. (For an example of a grid for a 2.8 m × 2.8 m canopy, see Figure 11.)

UCV canopy leakage tests

12.57 The diffuser screen fitted below the face of the canopy terminal filters should be lowered or removed while the leakage tests are being carried out.

12.58 The installed terminal EPA filters are to be checked to ensure that their grade accords with the design specification and that their performance has been certified by their manufacturer.

Test equipment

12.59 An LSAPC connected to an isokinetic fishtail scanning probe will be used to detect the size and number of particles present.

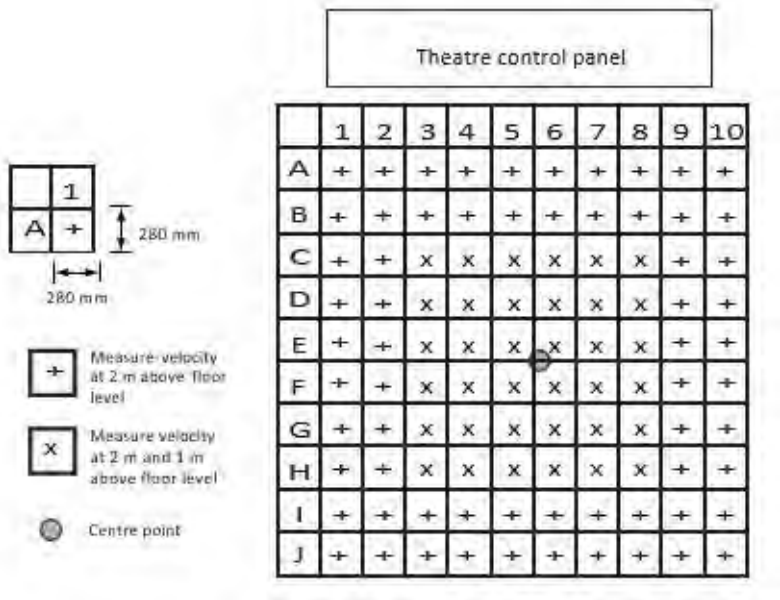
12.60 Spot readings are taken at several filter faces to establish the smallest non-penetrating particle size. If particles at or above this size are detected when subsequent scans are made, there is deemed to be a significant leak at, or near, the test position.

UCV canopy clean zone leak test

12.61 The test will confirm that there is no unfiltered air leakage in the canopy.

12.62 The construction joints and service penetration points under the UCV canopy within its side walls or boundary air curtain should be scanned to prove that there are no leaks.

Figure 11: Example of a test grid for a 2.8 m × 2.8 m UCV terminal



Note: For larger UCV terminals, add extra (280 mm x 280 mm) test squares symmetrically around the periphery of the grid and increase the inner zone in accordance with the guidance in paragraphs 12.50–12.56 of Scottish Health Technical Memorandum 03-01 Part A.

12.63 A leak is defined as a significant and repeatable rise above the background level.

Terminal EPA filter seal leak test

12.64 The test will confirm that there is no unfiltered air bypassing the EPA filter seal.

12.65 Each EPA filter seal should be scanned to prove that there are no leaks.

12.66 A leak is defined as a significant and repeatable rise above the background level.

EPA filter media leak test

12.67 The test will confirm that the EPA filters have not sustained damage while being installed.

12.68 The face of each EPA filter should be scanned to prove that there are no leaks.

12.69 A leak is defined as a significant and repeatable rise above the background level.

Vertical flow UCV canopy air velocity tests

Test setup

12.70 The canopy face diffuser screen should be in place for these tests.

12,71 Take spot readings to establish that the room is within the specified temperature and humidity test conditions.

12.72 Set out the test grid as described previously.

12.73 Swing the operating lamp arms and any other stem arms so that they align to present the least resistance to airflow, are perpendicular to the front edge of the test sheet and face the back edge. Any lamp and equipment heads should as far as practicable be outside of the UCV canopy footprint (see photographs).

Test instrument

12.74 The measuring instrument should be a thermal anemometer with a digital readout. The instrument resolution should be at least 0.01 m/s, have a tolerance of ±0.015 m/s or 3% and be calibrated down to 0.15 m/s or lower. An alternative instrument may be used providing it is of no lesser specification.

Test method

12.75 The instrument should be mounted on a test stand and set to take a mean reading over a 10-second sample interval.

12.76 The test instrument should record readings automatically for later download or be connected to a printer.

12.77 The test stand should be positioned on each test point in turn and the reading taken when the instrument has stabilised.

12.78 When taking a reading, the test person should not stand within the same quadrant as the test instrument.

12.79 Readings are to be taken at the test positions with the instrument probe facing the wall housing the theatre control panel commencing at the first test position. Readings are taken either working along the rows from left to right or for all test positions in one quadrant at a time.

12.80 When all test positions under one half of the canopy have been covered, readings of temperature and humidity are taken at the specified height in the centre of the canopy. The readouts from the theatre control panel should be recorded at this time.

12.81 Having completed one half of the test grid, the operating lamp arms and any other stem arms should be swung round through 180º and the test stand reversed so that the wall housing the theatre control panel is behind the test person. Readings are recommenced starting at the right of the test row and working from right to left or a quadrant at a time, as above.

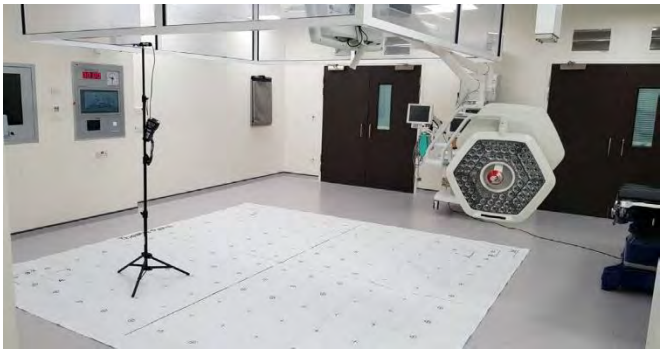
UCV canopy high level discharge velocity test

12.82 Measurements of air velocity are to be taken at every test position 2 m above floor level and the results averaged. The average of the total readings taken is to be not less than:

- 0.38 m/s for a canopy with no side walls or side walls that terminate at 2 m above floor level.
- 0.30 m/s for a canopy with side walls that terminate 1 m above floor level.

12.83 For UCV canopies that are an assembly of two or four units, each fed by a recirculation fan, the average air velocity for each unit should not exceed ±6% of the measured average velocity for the canopy.

Figure 12: UCV 2m air velocity test set-up



UCV canopy low level air velocity test

12.84 Measurements of air velocity are to be taken at each of the inner zone test positions 1 m above floor level.

12.85 The measured velocity at every test position in the inner clean zone should be not less than 0.20 m/s.

Figure 13: UCV 1m air velocity test set-up

UCV canopy entrainment test

Rationale for the entrainment test

12.86 The performance of a UCV canopy may be compromised by room air being drawn into the ultra clean airflow, a phenomenon known as entrainment. Significant levels of entrainment could lead to microbial contamination of items left exposed on instrument trolleys laid out beneath the canopy.

12.87 UCV canopies having permanently fitted side walls that terminate 1 m above floor level do not need to be tested, as the walls physically prevent entrainment.

Principle of the test

12.88 A source of particles is produced outside of the UCV canopy footprint and is used to challenge the system. A sample probe and detector are placed within the ultra clean airflow and used to determine the percentage penetration of the test particles at predefined locations under the UCV canopy footprint. The source and sample probe are moved in tandem around the UCV canopy and pairs of readings taken at the detector, from which the percentage penetration at specified locations is calculated. The degree of penetration should be below specified maximum limits if entrainment is to be declared not significant.

Test setup

12.89 The challenge will be provided by using non-EPA-filtered air emerging from the preparation room via the pressure stabiliser or transfer grille and ducted to the specified release position.

12.90 The canopy face diffuser screen should be in place for these tests.

12.91 The test is performed without any theatre equipment in place beneath or closely adjacent to the UCV canopy. All doors in the theatre suite should be closed and remain so for the duration of the test.

12.92 The operating lights and support booms should be moved to a central position beneath the canopy and raised to 2 m above floor level, so as not to interfere with the peripheral airflows (see photograph).

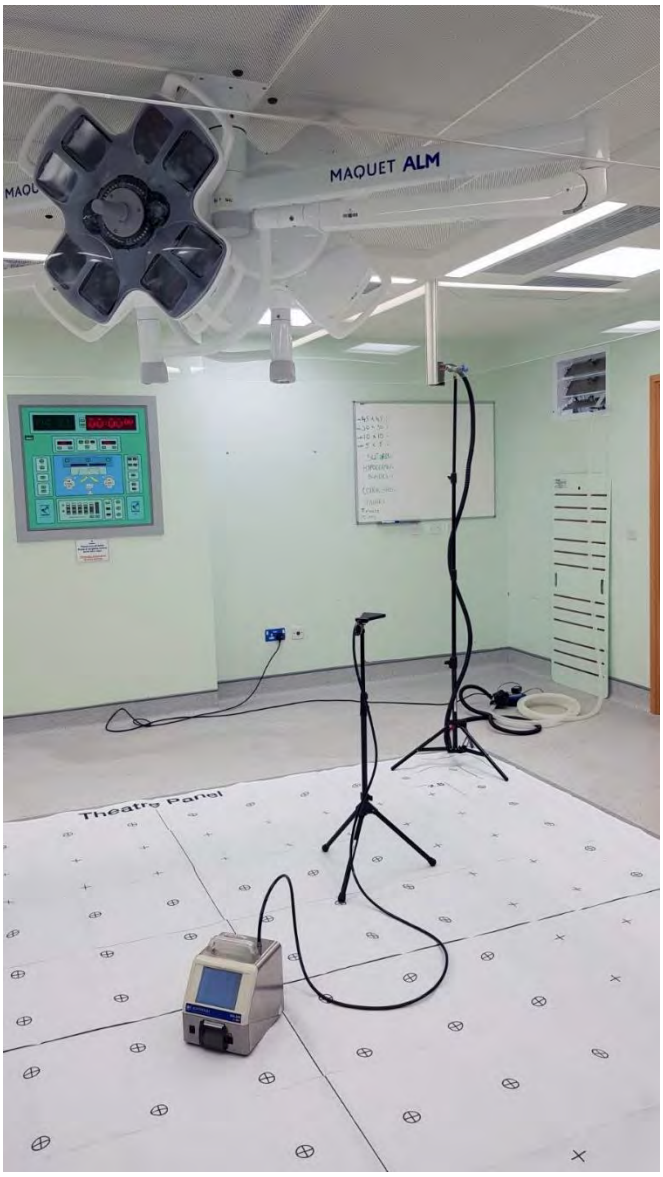
12.93 Spot readings are taken at the centre of the canopy, 1 m from floor level, to establish that the room is within the specified temperature and humidity limits (see paragraph 12.47).

12.94 The test grid is set out as described previously (see paragraph 12.50).

Test equipment

12.95 The source unit will be a fan/blower or other method that ducts non-EPA- filtered air (see paragraph 12.89) and expels it via a delivery head mounted on a test stand or clamped to the UCV canopy sidewall at the specified release position to provide the particle challenge. The challenge air will be delivered vertically downwards from a position 2 m above floor level alongside the outside edge of the side wall or in line with the downward air curtain if the canopy does not have side walls. The challenge airflow velocity should be the same as the measured average velocity at the 2 m level for the canopy under test.

Figure 14 UCV entrainment test setup



12.96 The detector will be an LSAPC capable of sampling a minimum of 28.3 L of air (1 ft3) per minute and providing readings for particle sizes from to 5 µm to 0.3 µm. Measuring instruments should be compliant with the requirements of BS EN ISO 14644 or ISO 17141 to reflect the type of test. An alternative instrument may be used providing it is of no lesser specification

12.97 The sampling head will be an isokinetic fishtail scanning probe mounted horizontally on a test stand 1 m above floor level and connected to the LSAPC by a hose no longer than 2 m

Test positions and orientation of source and detector sampling probe

12.98 The test positions will be at the centre of each test square, as defined for the velocity test (see paragraph 12.50).

12.99 For rectangular UCV canopies, measurements of penetration are to be taken at the four corner test squares of the test grid and at intermediate positions along the line of test squares between the corners. The number of intermediate test positions will be

as equally spaced as possible around the periphery, with not fewer than three and not more than five complete test squares between test positions.

12.100 A further series of measurements are to be obtained around the periphery of the inner zone (defined in paragraph 12.54). Measurements of penetration are to be taken at the four corner test squares of the inner zone of the test grid and if necessary at intermediate positions along the line of test squares between the corners as equally spaced as possible, with not fewer than three and not more than five complete test squares between test positions.

12.101 The centre of the challenge particle source delivery head is aligned with the centre of the designated test square, with its longer edge against the outer edge of the side wall or air curtain and delivering the challenge 2 m above floor level. The air containing challenge particles is directed vertically downward. Where there is physical interference due to obstructions such as gas pendants, the source will be moved to the next available non-obstructed test square location nearest to the stipulated test position. The sampling probe will then also be moved to remain opposite the source.

12.102 In the case of non-rectangular canopies, an interpretation of the above strategy should be adopted that will yield a no less searching examination of the unit's ability to control entrainment.

Test method

12.103 A measurement of particle penetration through a representative section of the EPA filter media is to be taken. The smallest non-penetrating particle size will be used as the reference background level and set in the detector instrument. The detector instrument should be set to take a reading over a 15-second sample interval and record the number of particles at the non-penetrating particle size determined above.

12.104 An initial sample of air at the source delivery head should be taken to check that there are sufficient particles of the considered size present. The challenge will be considered suitable if:

- the particles are within the size range 5 to 0.3 µm and thus capable of remaining airborne for a substantial time;
- the particles should not be able to penetrate the canopy EPA filters in sufficient numbers to cause a background count that is more than 0.1% of the challenge count;
- the number of particles present will enable a minimum of three logarithm (1000-fold) range of counts to be recorded between the source and background readings. A concentration of approximately 105 particles per cubic metre of source air has been shown to be adequate.

Note: The same equipment should be used to measure both the challenge source and penetration so as not to bias results through particle losses within the test equipment.

12.105 The sampling probe of the detector instrument is mounted on a test stand with its orifice facing outwards horizontally from the centre of the UCV canopy, 1 m above floor level. The sampling probe will be orientated at right angles to the partial wall

when sampling along the sides of the test grid but will be set to bisect the angle when measuring at the corner test positions. (See Figure 15 for test locations and see photograph of entrainment test equipment in Figure 13.)

12.106 The test will commence at the first test position; this being designated the left-most corner of the test grid when facing the wall housing the theatre control panel. The penetration will also be measured at the corresponding test point on the inner zone commencing at the corner nearest to the first test position.

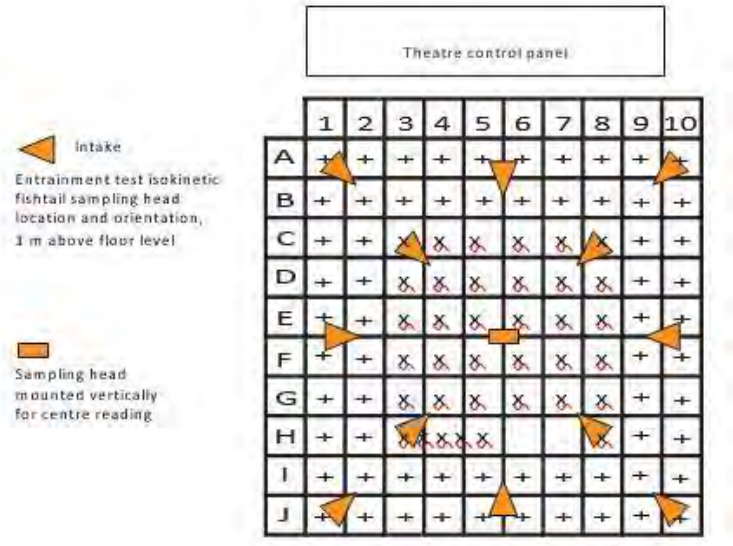
When these tests have been completed, the source distribution head and sampling probe will be moved to the next test positions, working around the test grid in a clockwise direction.

12.107 The test stands will be positioned on each test point in turn and a pair of readings (challenge, then penetration) taken when the instrument has stabilised.

12.108 When taking a reading, the test person should stay within the UCV canopy footprint but on the side opposite the sampling probe.

12.109 A single measurement will be taken at the geometrical centre of the UCV canopy footprint. The centre measurement will be taken with the sampling probe mounted vertically 1 m above floor level

Figure 15: Entrainment test locations for a 2.8 m ×2.8 m UCV terminal



Note: Test grid layout is as for Figure 11. Entrainment test set-up and guidance is given in paragraphs12.86 onwards.

For this test the challenge source distribution head will be placed at the test position that yielded the greatest penetration at the periphery of the canopy footprint.

Analysis and interpretation

12.110 The following standard is to be achieved:

- penetration to be no greater than 10% of the challenge at each test position in the outer zone;

- penetration to be no greater than 1% of the challenge at each test position in the inner zone;
- penetration to be no greater than 0.1% of the challenge at the centre of the test grid.

12.111 If a result is close to or above the given limits, a further reading should be obtained using a longer time base (1 minute) and the penetration should not exceed the given limit.

UCV canopy flow visualisation

12.112 The use of smoke to gain an understanding of the overall performance of the canopy may prove useful at this stage in the validation process but cannot be relied on to produce a contractually definitive measure of performance.

UCV canopy noise level

12.113 An industrial-grade sound level meter to BS EN 61672 Type 2 fitted with a muff will be used to check the noise level. The instrument should be calibrated using a matched sound source prior to each set of readings.

12.114 The noise level readings are to be taken at a typical normal listening position 1.5 m above floor level and at least 1 m from any surface and not on any line of symmetry. Measurements should be taken under the centre of each quadrant and in the centre of the canopy, and the five readings averaged.

12.115 The readings should be taken with the UCV canopy at operational speed and repeated with it at set back.

12.116 For UCV operating suites, the noise level should not exceed:

- operating theatre and spaces without doors that are open to it (for example, the scrub): 53 dB(A);
- all other peripheral rooms of the suite: 48 dB(A).

UCV terminal control system checks

Temperature

12.117 The readings of temperature taken under the UCV canopy should be within ±1ºC of the readout on the theatre control panel.

Humidity

12.118 The readings of humidity taken under the UCV canopy should be within±5%RH of the readout on the theatre control panel.

Direct reading differential pressure gauges

12.119 The differential pressure across the terminal filter should be measured to confirm the accuracy of the indicated reading of any gauge.

Control functions

12.120 The operation of all control functions provided on the theatre control panel should be checked for conformity with the design specification (see Appendix 10).

12.121 If an auxiliary panel has been fitted, its interlocking with the main theatre control panel control functions will be checked for conformity with the design specification.

Panel indicator lights

12.122 The panel indicators should illuminate as appropriate when the control functions are selected, or warning levels are reached (see Appendix 10 for an example “cause and effect” test regime).

BMS interface

12.123 The operation, monitoring and alarm functions should be checked for conformity with those set out in the design specification.

UCV theatre microbiological tests

12.124 There is little value in performing microbiological sampling in an empty operating theatre supplied with ultra clean ventilation. The foregoing filter challenge tests, air velocity measurements and entrainment test will have proved that the system operates satisfactorily and achieves the contracted level of performance. The EPA filters will remove bacteria-sized particles from the air supplied through the UCV canopy. Therefore, there will be an insignificant number of bacterial and/or fungal cfus present until the theatre is actually used.

12.125 Following full validation, in-use microbiological sampling during a surgical procedure will not be required unless specified by the client’s VSG.

UCV operating suite validation report

12.126 Following validation, a full report detailing the findings will be produced and sent to the client’s lead project manager. The report should conclude with a clear statement on whether the UCV operating suite as a whole achieved or did not achieve the standard set out in the agreed design specification.

12.127 The client’s lead project manager should lodge a copy of the report with:

- theatre manager;
- infection prevention and control;
- estates and facilities.

Pharmacy aseptic preparation facilities

12.128 The following regime of inspection and testing should be applied to the validation of new installations. The test regime has been devised to ensure that the system as installed fully achieves the operational requirement for these systems as set out in EUGGMP and the design specification.

Basic requirement

12.129 The validation procedure set out in paragraphs 12.1–12.33 should have been satisfactorily completed prior to attempting to validate the aseptic preparation facility. The suite to be validated should be physically complete with final finishes applied and have been completely cleaned. All ventilation systems serving it should be operating correctly and delivering their design airflow rates.

Aseptic preparation facility validation procedure

12.130 Tests to validate the suitability and performance of the aseptic preparation facility should be undertaken in the order that they appear below. Should an item fail to meet the required standard it should be rectified and successfully retested before passing on to the next test.

Summary of test regime

12.131 Challenge tests should ensure that:

- the supply terminal HEPA filters are sealed in their housings so that no air will bypass them;
- the terminal filters are of a uniform quality and undamaged.

12.132 Differential pressure measurements should ensure the correct pressure cascade.

12.133 Particle counting should be carried out at a specified number of test positions in order to determine the individual cleanroom classification in accordance with ISO EN 14644 and ISO 17141.

12.134 Control system checks should ensure that the system operates as specified.

12.135 Microbiological sampling should check the air quality.

Test and measuring conditions

12.136 While validating the aseptic preparation facility, the conditions in the cleanrooms should be stable and within the given ranges.

Temperature: 19–23ºC dry bulb.

Humidity: 30–70% relative humidity.

Test and measuring equipment

12.137 Any test or measuring equipment used should have a certificate to prove that its calibration has been checked within the previous 12 months at a facility using traceable national standards.

Supply terminal EPA or HEPA filter seal leak test

12.138 The test will confirm that there is no unfiltered air bypassing the EPA or HEPA filter seal.

12.139 Each EPA or HEPA filter seal should be scanned using a light scattering airborne particle counter (LSAPC) to prove that there are no leaks.

12.140 A spot reading will be taken at the face of the filter to determine the background particle level. A leak is defined as a significant and repeatable rise above the background level.

Terminal (EPA or HEPA) filter media leak test

12.141 The test will confirm that the terminal filters have not sustained damage while being installed.

12.142 The face of each terminal filter should be scanned using an LSAPC to prove that there are no leaks.

12.143 A leak is defined as a significant and repeatable rise above the background level.

Cleanroom particle count

12.144 The test will confirm the number and size of particles present and therefore the classification of the cleanroom in terms of ISO 14644 or EUGGMP as specified in the project brief.

12.145 The number of test positions is determined by reference to Table A.1 in ISO 14644-1.

12.146 The complete test methodology will be as set out in ISO 14644.

Cleanroom biocontamination control

12.147 BS EN 17141 gives details on cleanroom biocontamination control.

Radiopharmacy aseptic preparation facilities

12.148 Validation will be as for a pharmacy aseptic preparation facility.

12.149 Additional radiological tests as specified in the project brief will be required. These will be carried out and/or witnessed by the client's appointed specialist.

Inspection, assembly and packing (IAP) rooms in central decontamination units

12.150 Validation will be as for the standard practice described in paragraphs 12.1–12.33.

12.151 The pressure cascade and associated automatic monitoring sensors and alarms should be tested for correct operation in accordance with the design specification.

Note: The detail of the sealing between the instrument washers, transfer hatches and sterilizers that penetrate the walls of the IAP room will be critical in attaining the specified room pressure.

12.152 Following the satisfactory validation, the IAP room should be physically cleaned using specialist contractors. Particle counts at locations related to the floor area as set out in table A.1 of ISO 14644 Part 1, along with instructions from ISO 17141 will then be used to establish whether the room achieves a Class 8 cleanroom standard.

Containment level 3 laboratories

12.153 Validation will be as for the standard practice described in paragraphs 12.1–12.33.

12.154 The room will be subject to a permeability test as set out in paragraph 12.17.

12.155 The pressure cascade and associated automatic monitoring sensors and alarms should be tested for correct operation in accordance with the design specification.

Isolation rooms

12.156 Validation will be as for the standard practice described in paragraphs 12.1–12.33.

12.157 See Scottish Health Planning Note 4 Supplement 1 for details of the test regime.

Microbiological sampling

12.158 It is essential that all parts of the validation test specified above have been successfully completed and the areas thoroughly cleaned prior to any microbiological sampling.

12.159 Microbiological sampling will not normally be required for either general or local exhaust ventilation (LEV) systems unless otherwise specified within the contract.

12.160 The procedure for carrying out microbiological sampling in cleanrooms is set out in ISO 17141.

Microbiological sampling conventional theatres

12.161 The level of airborne bacteria introduced by the supply air can be checked by closing all doors and leaving the operating room empty with the ventilation system running for 15 minutes. An active air sampler set to 1 cubic metre and mounted on the operating table should then be activated remotely. Aerobic cultures on non-selective media should not exceed 10 bacterial and/or fungal colony forming units per cubic metre (CFU/m3).

12.162 The results should be examined to establish the broad category of organisms present. A high preponderance of fungal organisms may be an indication of inadequate filtration for the particular installation. Precise guidance is inappropriate and will depend on local circumstances.

12.163 It may be appropriate to carry out a check of airborne bacteria during a surgical operation. If required, this should be carried out as soon as possible after handover. Unless there are unusually high numbers of personnel or extensive activity in the room, the number of airborne bacterial and/or fungal CFU averaged over any five-minute period, would be unlikely to exceed 180 per cubic metre.

12.164 Information on the microbiological testing of UCV Operating suites is given in clauses 12.124 and 12.125.

13. Information

Records required

13.1 There is a requirement under the Building Regulations to provide documentary evidence of the design, commissioning and subsequent performance of ventilation systems as well as recommended maintenance routines (Building Regulations. 2010, Part 8, Paragraph 39).

13.2 Electronic records should be in a format that is compatible with the client's archive and retrieval system.

Handover

13.3 The following general information is required at plant handover:

- "as fitted" drawings of the plant showing the location of all items and listing the size of ducts, grilles and diffusers together with their factors;
- "schematic" drawing of the air distribution system showing design and actual airflows from all outlets together with the design and actual airflows in each duct. The duct centre correction factors should be given and the grille factors;
- the location of all volume control dampers should be marked on the "as fitted" and "schematic" drawings;
- a floor plan of the area served by the plant showing all doorways, hatches, transfer grilles, pressure relief dampers, pressure stabilisers, supply and extract terminals. The total supply and extract volumes should be shown for each room served by the plant. The volume flow and direction of flow through transfer grilles, pressure relief dampers and pressure stabilisers should also be shown, together with the room pressures in pascals measured with regard to atmospheric pressure. For operating suites the "key" door should be identified;
- a fire plan of the area served showing the fire zone and location of all fire and smoke dampers and detectors. An explanation of the ventilation strategy in the event of an in-zone fire, adjacent zone fire or smoke being drawn into the airhandling unit from an outside source should be provided.
- wiring diagrams for all electrical equipment associated with the air handling systems including motor control circuit details and any interlocking and safety devices such as emergency stop buttons adjacent to the item of plant;
- manufacturer's operating instructions and "setting to work" guidance for all specialist components incorporated in the systems;
  - a schematic of the control system showing the location of all plant sensors;
  - control algorithm(s) of the actual plant operation and the set points entered during commissioning together with the control panel access codes and keys.

Plant design information

13.4 The following plant design information is required at plant handover:

- a simple statement of the design intent;
- a description of the plant's intended mode of operation;
- winter outside design temperature in ºCdb;
- winter outside design humidity in % saturation;
- winter room supply air design temperature in ºCdb;
- winter room supply air design humidity in % saturation;
- winter inside design temperature for each room in ºC;
- winter inside design humidity for each room in % saturation;
- summer outside design temperature in ºCdb;
- summer outside design humidity in% saturation;
- summer room supply air design temperature in ºCdb;
- summer room supply air design humidity in % saturation;
- summer inside design temperature for each room in ºC;
- summer inside design humidity for each room in % saturation;
- winter psychrometric chart showing the condition of the air between all items of plant and the design outside, supply and room air conditions;
- summer psychrometric chart showing the condition of the air between all items of plant and the design outside, supply and room air conditions;
- the design mass airflow rate used to size the plant in kg/s;
- the design volumetric flow rate in m 3/s.

Individual equipment information

Heater-batteries including energy recovery

13.5 The following information concerning heater-batteries is required at plant handover:

- the size of the battery, number of passes and fin spacing;
- the design flow and return temperatures and flow rate in L/s;
- the pressure drop across the water side of the battery in Pa;
- the number of phases, supply voltage, current drawn and number of steps if electric;
- the maximum rated capacity of the battery and actual design rating in kW;
- the design and actual face velocity in m/s;
- the pressure drop across the air side of the battery in Pa;
- the design on and off coil air temperature and humidity at winter and summer design conditions

Cooling coils

13.6 The following information concerning cooling coils is required at plant handover:

- the size of coil, number of passes and fin spacing;
- the design flow and return temperatures and flow rate in L/s if chilled water;
- the pressure drop across the water side of the coil in Pa;
- the supply pressure and mass flow rate if direct expansion;
- the maximum rated capacity of the coil and actual design rating in kW;
- the contact factor;
- the design sensible and latent cooling loads in kW;
- the design and actual face velocity in m/s;
- the pressure drop across the air side of the coil in Pa;
- the design on and off coil air temperature and humidity at summer design conditions.

Humidifiers

13.7 The following information concerning humidifiers is required at plant handover:

- the size of the humidifier and number of lances;
- the supply pressure and mass flow rate of the steam;
- the number of phases, supply voltage, current drawn and number of steps if electric;
- the maximum rated capacity of the humidifier and actual design rating in L/hour;
- the design and actual face velocity in m/s;
- the design upstream and downstream air temperature and humidity at winter design conditions

Filters

13.8 The following information concerning filters is required at plant handover:

- the size of the filter and number in bank;
- its grade;
- the design and actual face velocity in m/s;
- the initial pressure drop across the filter when clean in Pa;
- the final pressure drop across the filter when dirty in Pa;
- the manufacturer’s name and filter identification code.

Fans

13.9 The following Information concerning fans is required at plant handover:

- the size of the fan and its type;
- the fan curve;
- speed and direction of rotation;

- the drive motor frame size;
- the number of phases, voltage and maximum design and actual current drawn;
- the design and actual delivered air volume in m3/s;
- the fan suction pressure at high and low speed in Pa;
- the fan delivery pressure at high and low speed in Pa;

Attenuators

13.10 The following information concerning attenuators is required at plant handover:

- the size of the attenuator and number in bank;
- the design and actual face velocity in m/s;
- the initial pressure drop across the attenuator in Pa;
- the upstream sound level in dB(A); the downstream sound level in dB(A).

System information

13.11 The preservation of information and records of ventilation systems and their performance is a legal requirement. It is therefore essential that when new systems are completed, full information as to their purpose, design, layout and actual commissioned performance are handed on to the client. If any derogations were agreed from this standard, they should be noted and the reason for them explained. The system information if electronic (for example, BIM model) should be in a form that is compatible with the client's IT standard and can be accessed and searched by it.

13.12 In new "green field" developments an inventory of the installed ventilation systems should be compiled. In existing developments the client will normally have an inventory of their installed systems, and all new systems should be added to it.

13.13 The inventory will be subdivided into the following categories:

- local exhaust ventilation systems (LEV) – note these are statutory items;
- critical healthcare ventilation systems (CHV).

(These are systems the loss of which would seriously limit the delivery of healthcare – for example, operating suite, SCBU, critical care areas, interventional imaging suite, aseptic preparation facility.)

- general ventilation system [supply and extract] (GVS);
- general extract systems (GES);
- systems installed for smoke clearance in the event of a fire, classed as smoke and heat exhaust ventilation systems;
- – (SHEVS) (for example, smoke extract fans in stairwells, automatic smoke clearance dampers in atria).

Note: During the design and contract process, ventilation systems are often given "construction" codes for drawing reference and site identification purposes. It is

imperative that prior to handover the actual identification codes and labels affixed to the systems conform to the inventory in use at the site or desired by the client. Each system code should be unique and conform to the categorisation format for the client's inventory given above.

For ease of future reference, a list of design and construction references for drawings and plant, cross-referenced to the client's building designations and plant inventory codes, should be produced.

13.14 For each ventilation system the inventory should contain the following details:

- a unique system identification code (for example, LEV 001; CHV 001) as appropriate;
- the location of the ventilation fan unit or supply and extract AHU(s);
- the location of the fresh air inlet;
- the location of the extracted air discharge;
- the specific area(s) served by the system;
- the date the system was installed;
- the date the system was validated and accepted by the client.

13.15 Each ventilation system should have a logbook (physical or electronic) that contains the following information:

- the unique system identification reference;
- purpose of the system;
- date of installation;
- details of the installed equipment and ductwork layout;
- detail of the fire plan and location of fire and smoke dampers;
- design performance parameters (for example, airflow rates, air-change rates, pressures);
- commissioned date and performance;
- record of the system validation and acceptance;
- records of the annual inspection and verification;
- maintenance records and plant information (for example, fan specifications and filter sizes).

13.16 The records should be linked to the inventory and stored in such a way as to be readily available in the event of plant breakdown or other incident.

13.17 Every ventilation system should be clearly identified with a permanent label. The label should show in lettering 100 mm high the inventory reference code of the AHU and clearly identify the area that it serves. The label should be mounted with screws or rivets in an easily visible place near the fan of the unit adjacent to the local electrical isolator. The system control panel should have a duplicate label. Any subsystems and the principal branch ducts should be similarly labelled.

13.18 The nature of air and direction of flow should be clearly marked on all ducts using the symbols given in BS 1710.

13.19 All airflow test-points should be clearly identified with a permanent label and the design information given (for example, TPS 1 – Anaesthetic supply; 400 × 300; Design 185 L/s).

13.20 If two ventilation systems supply a common room or an outlier from another zone, the room identification label should state the relevant ventilation identification codes, for example: Theatres 5&6 Utility; [CHV 012 and CHV 015], as should the labels on their individual AHUs.

13.21 Any ventilation system that conveys a hazardous substance or is affected by a hazardous radiation must be clearly marked with the appropriate symbol.

Fire and smoke dampers

13.22 A complete schedule of dampers fitted, their location and unique identification code should be provided.

13.23 A statement of when they were tested and by whom should be included.

Spares

13.24 Unless otherwise agreed with the site maintenance department, spares should be stored on a rack in the entrance of the relevant plantroom and preserved from casual damage or contamination.

13.25 The scale of spare fans to be provided should relate to the number of AHUs using fans of the same size. The spare fans should be pre-wired with power and control connectors so that when used they are plug and play.

13.26 A complete set of new filters should be handed over.

13.27 A complete set of any other consumable item installed in the installation should be handed over.

BIM status

13.28 If the installation was modelled using BIM during construction, the BIM model should be brought up to date and all asset tags incorporated prior to handover.

13.29 Training for estates staff who will be tasked with keeping the BIM model in date should be given, ideally while the original BIM team is available.

Maintenance routines

13.30 Any product or installation-specific maintenance routines should form part of the handover documentation and, if necessary, training.

13.31 Information on routine inspection and maintenance is given in Part B of Scottish Health Technical Memorandum 03-01.

Expected service life

13.32 Air handling units (AHUs) have an expected service life of 20 years. Part B of this SHTM states that ventilation systems should be taken out of service, deep cleaned, their controls renewed and recommissioned after 10 years. The handover information will both assist this process and help inform the selection of replacement plant.

Additional end user information

13.33 The information itemised above is intended to fulfil the contract requirement and provide a record for the client and their appointed operational management and maintenance teams. There is also a need in some circumstances to provide the end-user with information as to the role that them and their patients from airborne contaminants.

13.34 In operating suites and interventional imaging suites of any type, a simplified plan of the suite showing the principal direction of air movement should be displayed at the entrance to the suite. The following bullet points should be appended to the plan:

- the air supplied to each room is intended to dilute any airborne contaminants;
- the airflow between rooms will ensure that contaminants do not enter;
- people are the main source of airborne contaminants; they disperse such contaminants as they move around: the more people, the more movements, the more airborne contaminants;
- optimum conditions exist when all doors are closed;
- in order to ensure that the system operates correctly and efficiently:
  - routine checks should be carried out of the system performance;
  - the system should be taken out of use periodically to carry out essential maintenance.

13.35 The VSG should advise if other applications require similar explanatory information.

Staff training

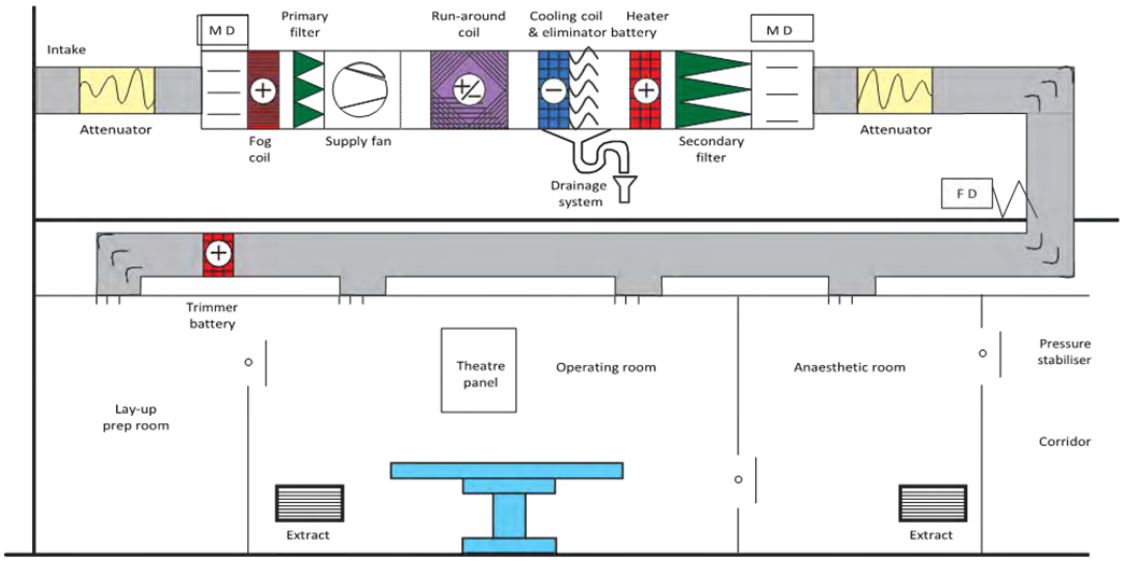
13.36 On completion of the project, training in the correct use, operation and routine maintenance of the installed systems should be given as appropriate to the following staff groups:

- the end-users;
- those who will operate and maintain the installed systems.

Appendix 1: Typical AHU Plant Layouts

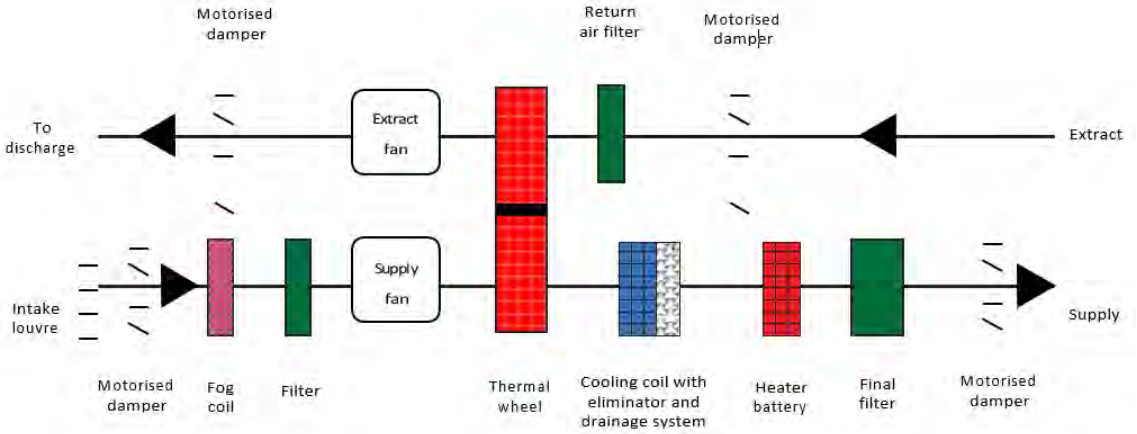
Supply AHU with remote extract unit

Figure A1: Schematic of typical operating suite AHU with energy recovery by run-around coil from a remote extract fan unit



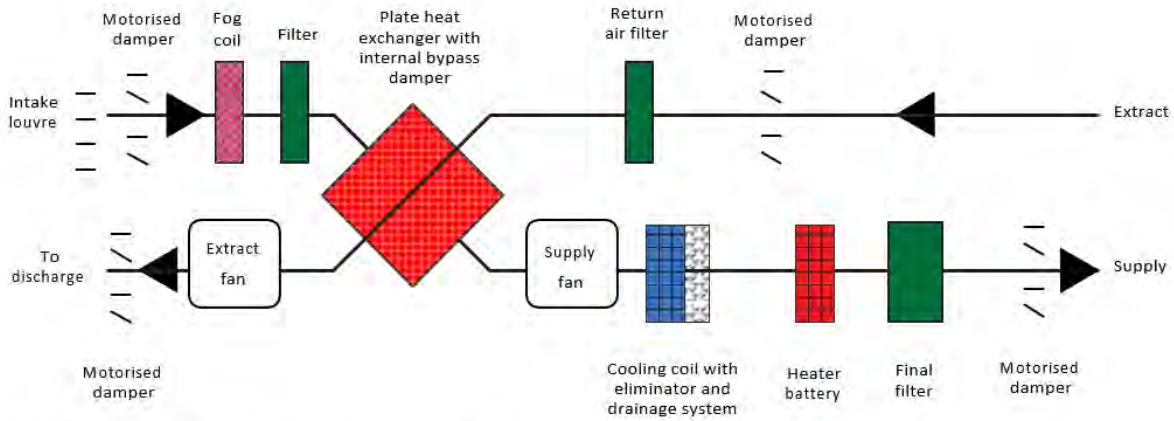
Double-stacked supply and extract AHU

Figure A2: Schematic of typical double-stacked AHU with energy recovery by thermal wheel



Note: Other configurations are possible

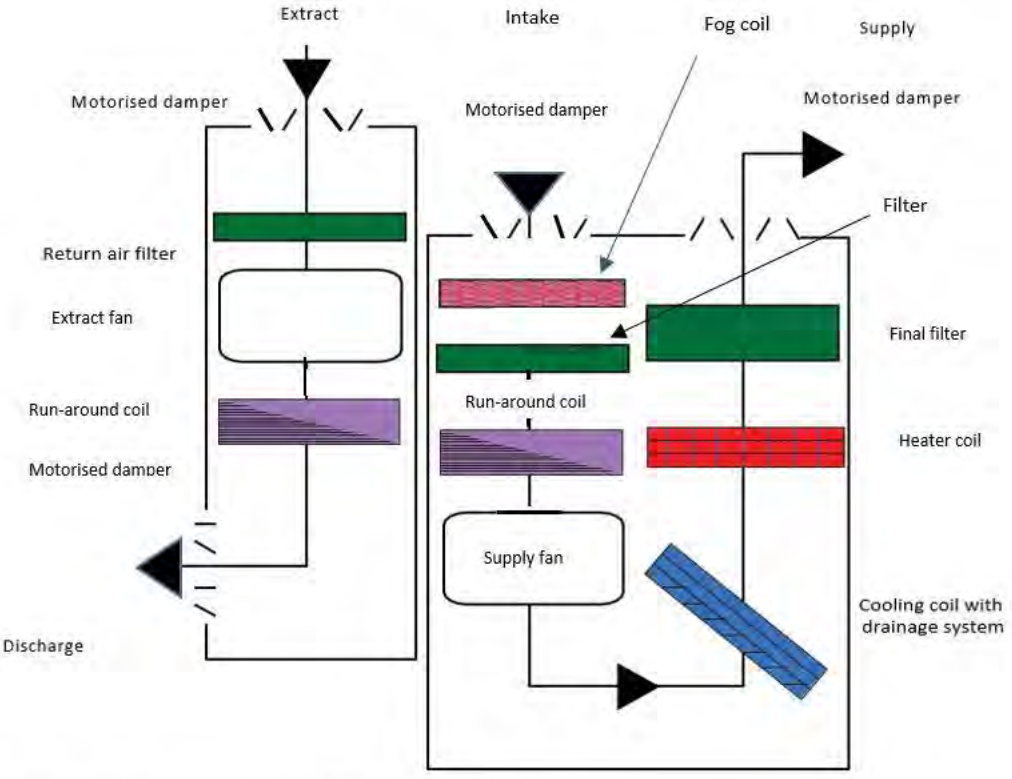
Figure A3: Schematic of typical double-stacked AHU with energy recovery by plate heat exchangerCabinet AHU



Note: Other configurations of the fan positions are possible

Cabinet AHU

Figure A4: Schematic of typical cabinet-style AHU with energy recovery by run-around coil



Note: Other types of compact vertical AHUs are possible

Appendix 2: Summary of design conditions

Table A1 Design conditions for miscellaneous rooms

Application	Ventilation	Air-change rate (ac/h)	Pressure (Pascal Pa)	Supply filter grade (BS EN 16798 or BS EN 1822-1)	Noise (dB(A))	Temp (°C)	Comments (for further information see Chapter 8)
General ward (level 0 and 1 care)	S/N	6	–	SUP2	35	18–28	
Communal ward toilet	E	6	–ve	–	45	–	
Single room	S/E/N	6	0 or –ve	SUP2	35	18–28	
Single room WC	E	>10	–ve	–	45	–	
Clean utility	S	6	+ve	SUP3	45	18–22	
Dirty utility	E	6	–ve	–	45	–	
Ward isolation room (PPVL)	S	10	Lobby +10 Room 0	SUP2	35	–	See Scottish Health Planning Note 4 (Supplement 1)
Infectious diseases isolation room	E	10	–5	SUP2	35	–	See Table 4
Neutropaenic patient ward	S	10	+10	E12	35	–	See Table 3
Critical care areas (Level 2 and 3 care)	S	10	+10	SUP1	35	–	Isolation room may be –ve pressure or PPVL. See Table 3
Birthing room	S & E	10	0	SUP2	45	20–25	See Table 5
NICU/SCBU	S & E	10	+ve	SUP1	35	20–28	Isolation room may be –ve pressure
Operating department recovery room	S & E	15	0	SUP2	45	18–25	Provide clean airflow path
Catheterisation room	S & E	10	+ve	SUP2	45	18–22	
Interventional or non-interventional Imaging room of any type	S & E	10	+ve	SUP2	48	–	Stable conditions as specified for the imaging equipment
Sedation recovery room as in paragraph 8.16	S & E	15	S/E	SUP2	45	18–28	
Endoscopic procedure room	S & E	15	-5	SUP2	40	20–25	See Table 2
Endoscope reprocessing wash room	E	10	–ve	–	45	–	
General treatment room	S & E	10	Neutral	SUP2	45	20–25	See Table 2
Emergency department waiting area	S & E	6	–	SUP2	–	18–25	See Table 2

Application	Ventilation	Air-change rate (ac/h)	Pressure (Pascal Pa)	Supply filter grade (BS EN 16798 or BS EN 1822-1)	Noise (dB(A))	Temp (°C)	Comments (for further information see Chapter 8)
Containment level 3 laboratory	#	>20	#	H14*	–	18–22	# See ACDP guide; *Filter in extract See Table 4
Post-mortem room	S & E	S = 10 E = 12	–ve	SUP2	45	18–22	Provide clean airflow path
Specimen store	E	–	–ve	–	–	–	Fan accessible from outside of store

Notes:

For general and UCV operating suites and associated rooms, see specific guidance in Chapter 8 and typical design solutions in Appendix 7

Waiting and circulation areas should be directly or indirectly ventilated to provide a comfortable environment and control airborne contamination and odours.

18–22°C indicates the range over which the temperature may float.

18-22°C indicates the range over which the temperature should be capable of being controlled at any point within that range.

S = Supply

E = Extract

N = Natural ventilation where possible where natural ventilation is used the design must reflect clauses 5.2 to 5.9

SUP refers to the supply air quality as defined in BS EN 16798

Appendix 3: Hierarchy of cleanliness

Table A2 Hierarchy of cleanliness

Class	Room	Nominal pressure (Pa)a	Airflow rate for bacterial contaminant dilution Flow in or supply (m3/s)	Flow out or extract(m3/s)
Sterile	Preparation room lay-up sterile pack store Operating theatre Scrub bay	 35 25 25 25	See standard schemes in Appendix 7 and detailed calculation process in Appendix 8 for recommended design values	
Clean	Sterile pack store Anaesthetic room Scrub room	+ve 15c 15	6 ac/h The greater of 15 ac/h or 0.15 –	– The greater of 15 ac/h or 0.15 0.10 mind
Transitional	Recovery room Clean corridor General access corridor Changing rooms	0 0 0 3	15 ac/he (See note f) (See note f) 7 ac/h	15 ac/he 7 ac/h 7 ac/h 7 ac/h
Dirty	Service corridor Utility room	0 –5 or 0	– –	(See note g) 0.40 or 0.10

Notes:

Nominal room pressures are given to facilitate setting up of pressure-relief dampers, the calculation process, and the sizing of transfer devices. In practice, the resultant pressures are not immutable provided the desired airflow rates and movement directions are achieved.

An open or semi-open bay is considered to be part of the operating theatre; a low-level extract under the scrub trough is required. (See Chapter 8 paragraph 8.45 onwards and “Note” for more information.)

For design purposes, anaesthetic should be assumed to be at 15 Pa. When commissioning, equal to or greater than 10 Pa is considered suitable.

May need to be increased if scrub is large to promote scouring.

15 ac/h is considered necessary for the control of anaesthetic gas (see Appendix 9).

Supply airflow rate necessary to make up 7 ac/h after taking into account secondary air from cleaner areas.

No dilution requirement. Temperature control requirements only.

Appendix 4: Leakage flows in m3/s through closed door gaps

Pressure difference (Pa)

Table A3 Leakage flows through closed door gaps

Type	5	10	15	20	25	30	35	40
Single door	0.03	0.05	0.06	0.06	0.07	0.08	0.09	0.10
Single door + half	0.04	0.06	0.07	0.08	0.09	0.10	0.11	0.12
Double door	0.05	0.08	0.10	0.11	0.12	0.13	0.14	0.15

Designers' notes:

The door gaps assumed are 4 mm along the bottom, 3 mm at the top and sides, and 2 mm between double leaves.

If doors are fitted with cold smoke seals, these will significantly reduce the door leakage rate when new and undamaged. It is therefore recommended that provision for the design leakage be factored into the size of the appropriate transfer grille or pressure stabiliser. Failure to do this will result in air-gap whistles and doors being held partially open by air pressure.

Factory-assembled door-sets with a steel frame and pre-hung leaves are becoming common. There is effectively no leakage across these doors when closed. Therefore, when this type of door assembly is fitted, the door leakage can be ignored and the design airflow into the room reduced accordingly. The design airflow would then become that required either (i) for open door protection (Appendix 5), or (ii) to achieve the specified air-change rate – whichever is the greater.

Appendix 5: Recommended airflow rates in m3/s through a doorway between rooms of different cleanliness to control cross-contamination

Table A4 Flows through dooorways

Room class		Dirty	Transitional	Clean	Sterile
Sterile	Hatch Single door Double door	0.3 0.47 0.95	0.24 0.39 0.75	0.18 0.28 0.57	 0 or 0.28a 0 or 0.57a
Clean	Single door Double door	0.39 0.75	0.28 0.57	0 or 0.28a 0 or 0.57a	
Transitional	Single door Double door	0.28 0.57	0 or 0.28a 0 or 0.57a		
Dirty	Single door Double door	0 0	Open single door = 0.80 m x 2.01 m high Open double door = 1.80 m x 2.01 m high	Open single door = 0.80 m x 2.01 m high Open double door = 1.80 m x 2.01 m high	Open single door = 0.80 m x 2.01 m high Open double door = 1.80 m x 2.01 m high

Designers' notes:

The degree of protection required at an open doorway between rooms is dependent on the degree of difference in cleanliness between them.

Flow-rate required between rooms within the same class tends to zero as class reduces.

If two rooms are of equal cleanliness, no flow is required (in practice there will be an interchange in either direction) and the design of the air movement will assume zero airflow. In certain cases, however, interchange is not permitted, and a protection airflow of 0.28 is assumed in the design – for example, in the case of a preparation room used as a "lay up".

Appendix 6: Typical approximate pressures in an operating suite when a given door is open

Typical approximate effect on other rooms

Table A5 Pressure in room with open door

Door open between	Typical approximate resultant	Room	Pressure (Pa) pressure in these rooms (Pa)
Operating theatre and corridor or Scrub bay and corridor	0	Anaesthetic Preparation – lay-up Utility Preparation – sterile pack store	0 12 –6 5
Operating theatre and anaesthetic room (or other series room with double doors)	17	Preparation – lay-up Utility Preparation – sterile pack store	26 –9 22
Operating theatre and Utility room or Operating theatre and preparation room	25	No change	
Anaesthetic room and corridor (or other series room with double doors)	0	Preparation – lay-up Utility Operating theatre Preparation – sterile pack store	30 –6 20 25
Preparation room and corridor or Utility room and corridor	0	No change	
Utility room and outer corridor	0	No change	

Notes:

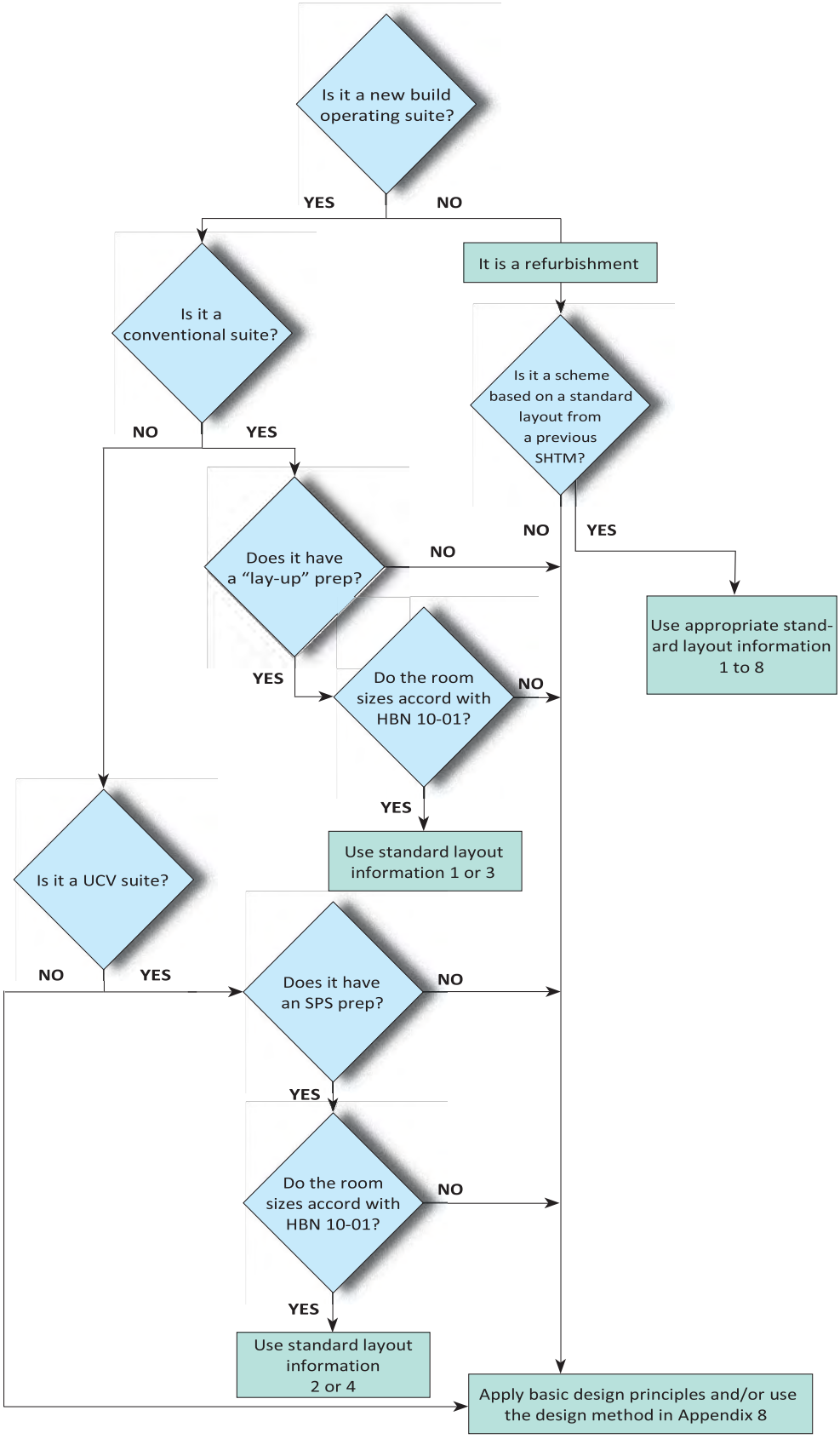
The room differential pressure protects against reverse flows when the door is closed.

The flow of air through a doorway protects against reverse airflow when the door is open.

Pressure stabilisers control flow and ensure a known airflow path between rooms when doors are closed and also reduce backflow between rooms when doors to other rooms are open.

Appendix 7: Operating suite design logic

Figure A5 Operating suite design logic



Standard layout 1 – Two-corridor conventional operating suite with “lay-up” prep

Table A6 Two corridor conventional operating suite with “lay up” prep design criteria

Room	Size (m3)‡	Air-change rate (ac/h)	Nominal pressure (Pa)	Flow rate (m3/s)
Theatre	165	≥22	25	Primary = 0.73 From Prep = 0.28 Total = 1.010
Anaesthetic	57	15	Design 15 Commissioned ≥10	0.24
Lay-up prep	36	≥22	35	0.28**
Scrub	*	–	25	–

Notes:

‡ Derived from Health Building Note 10-01 (2021). If room sizes differ from those given, recalculate the design air flows to achieve the air change rate or door protection.

*This is a separate scrub and is not considered as being part of the theatre volume.

**Interchange is not permitted between the theatre and lay-up prep; therefore, as in Appendix 5, an airflow protection of

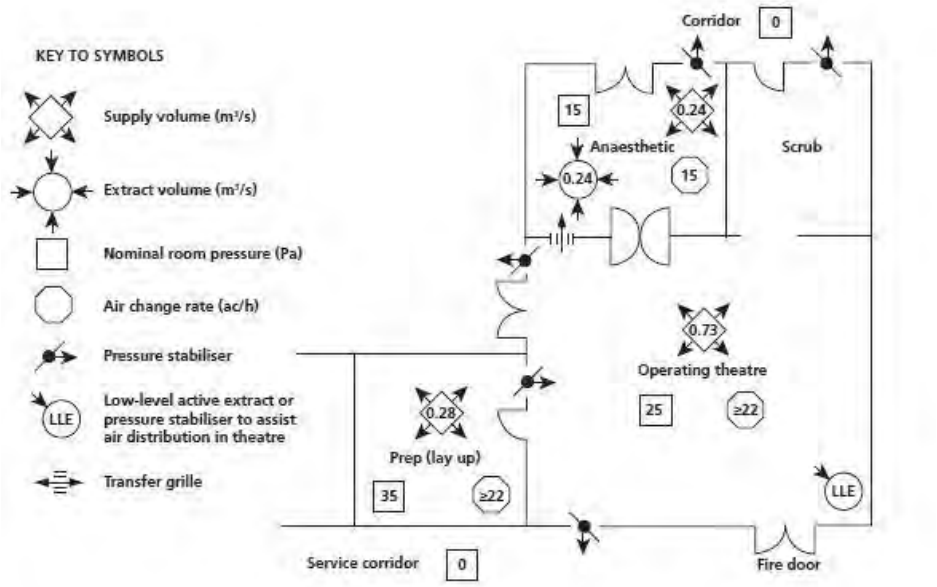
0.28 m3/s is required as a minimum (but see also the “designers’ notes” in Appendix 4).

N.B.If the lay-up prep also has a door or hatch to the corridor, its supply airflow volume would increase to 0.35 m3/s

The volume of air to be extracted from the theatre should be determined by subtracting the airflow required for door protection at the key door from the total air entering the space. The balance should be equally divided between the passive or active extract locations.

The extracts within the theatre and scrub may be either passive and fitted with pressure stabilisers or active and connected to the extract system. They should where possible be located at low level and positioned to promote the active ventilation and scouring of all areas of the space (see paragraph 8.92). Air transfer from theatre to anaesthetic room may be by pressure stabiliser or transfer grilles (see paragraphs A8.51 and A8.52 in Appendix 8). The anaesthetic room extract will be at low level (see Appendix 9).

Figure A6 Two corridor conventional operating suite with “lay up” prep, schematic layout



Standard layout 2 – two-corridor UCV operating suite with SPS prep

Table A7 Two corridor UCV operating suite with SPS design criteria

Room	Size (m3)‡	Air-change rate (ac/h)	Nominal pressure (Pa)	Flow rate (m3/s)
Theatre	165	≥22	25	# 1.01
Anaesthetic	57	15	Design 15 Commissioned ≥10	0.24
Sterile pack store prep	36	10	25	0.10
Scrub	*	–	25	–

Notes:

‡ Derived from Health Building Note 10-01 (2021). If room sizes differ from those given, recalculate the design air flows to achieve the air change rate or door protection.

* This is a separate scrub and is not considered as being part of theatre volume.

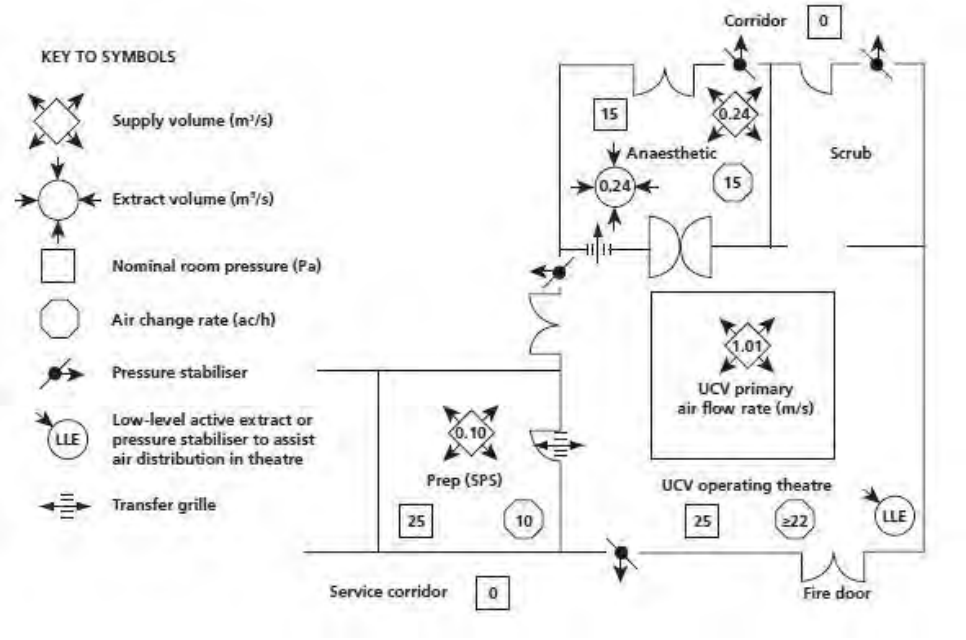
Primary fresh-air volume to UCV canopy only or ≥22 or door protection

The volume of air to be extracted from the theatre should be determined by subtracting the airflow required for door protection at the key door from the total air entering the space. The balance should be equally divided between the passive or active extract locations.

The extracts within the theatre and scrub may be either passive and fitted with pressure stabilisers or active and connected to the extract system. They should where possible be located at low level and positioned to promote the active ventilation and scouring of all areas of the space (see paragraph 8.92). Air transfer from theatre to anaesthetic room may be by pressure stabiliser or transfer grilles (see

paragraphs A8.51 and A8.52 in Appendix 8). The anaesthetic room extract will be at low level (see Appendix 9).

Figure A7 Two corridor UCV operating suite with SPS schematic layout



Standard layout 3 – single-corridor conventional operating suite with “lay-up” prep

Table A8 Single corridor conventional operating suite with “lay up” prep design criteria

Room	Size (m3)‡	Air-change rate (ac/h)	Nominal pressure (Pa)	Flow rate (m3/s)
Theatre	165	≥22	25	Primary = 0.73 From Prep = 0.28 Total = 1.01
Anaesthetic	57	15	Design 15 Commissioned ≥10	0.24
Lay-up prep	36	≥22	35	0.35**
Scrub	*	–	25	–
Utility	36	–	–5	0.40

Notes:

‡ Derived from Health Building Note 10-01 (2021). If room sizes differ from those given, recalculate the design air flows to achieve the air change rate or door protection.

* This is a separate scrub and is not considered as being part of the theatre volume.

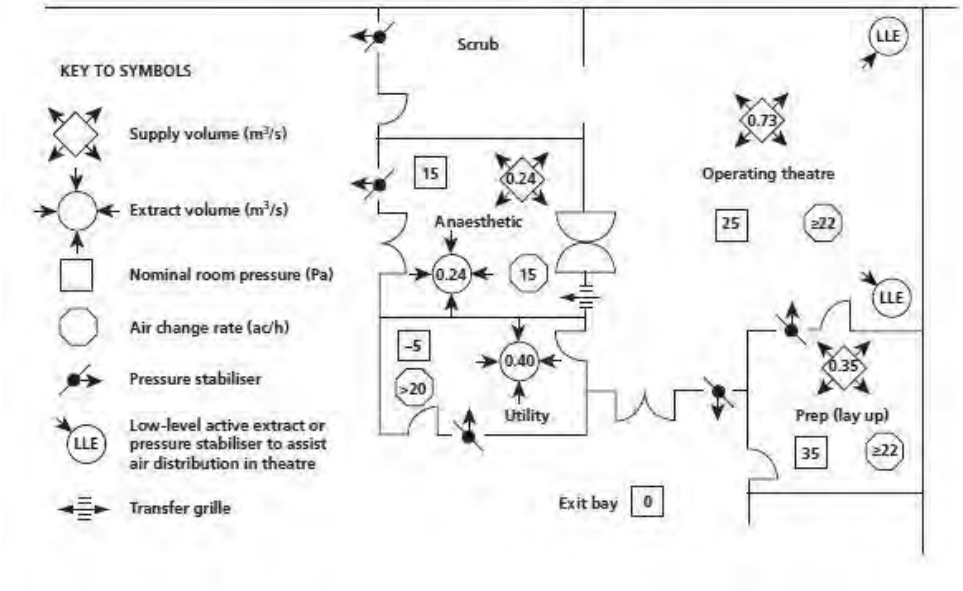
** Interchange is not permitted between the theatre and lay-up prep; therefore, as in Appendix 5, an airflow protection of 0.28

+ 0.07 closed-door airflow is required as a minimum (but see also the “designers’ notes” in Appendix 4).

The volume of air to be extracted from the theatre should be determined by subtracting the airflow required for protection at the key door from the total air entering the space. The balance should be equally divided between the passive or active extract locations.

The extracts within the theatre and scrub may be either passive and fitted with pressure stabilisers or active and connected to the extract system. They should where possible be located at low level and positioned to promote the active ventilation and scouring of all areas of the space (see paragraph 8.92). Air transfer from theatre to anaesthetic room may be by pressure stabiliser or transfer grilles (see paragraphs A8.51 and A8.52 in Appendix 8). The anaesthetic room extract will be at low level (see Appendix 9).

Figure A8 Single corridor conventional operating suite with “lay up” prep schematic layout



Standard layout 4 – single-corridor UCV operating suite with Lay-up prep

Table A9 single-corridor UCV operating suite with Lay-up prep design criteria

Room	Size (m3)‡	Air-change rate (ac/h)	Nominal pressure (Pa)	Flow rate (m3/s)
Theatre	165	≥22	25	#1.01
Anaesthetic	57	15	Design 15 Commissioned ≥10	0.24
Sterile pack store prep	36	≥22	35	0.35**
Scrub	*	–	25	–
Utility	36	–	–5	0.4

Notes:

‡ Derived from Health Building Note 10-01 (2021). If room sizes differ from those given, recalculate the design air flows to achieve the air change rate or door protection.

* This is a separate scrub and is not considered as being part of the theatre volume.

** Interchange is not permitted between the theatre and lay-up prep; therefore, as in Appendix 5, an airflow protection of 0.28

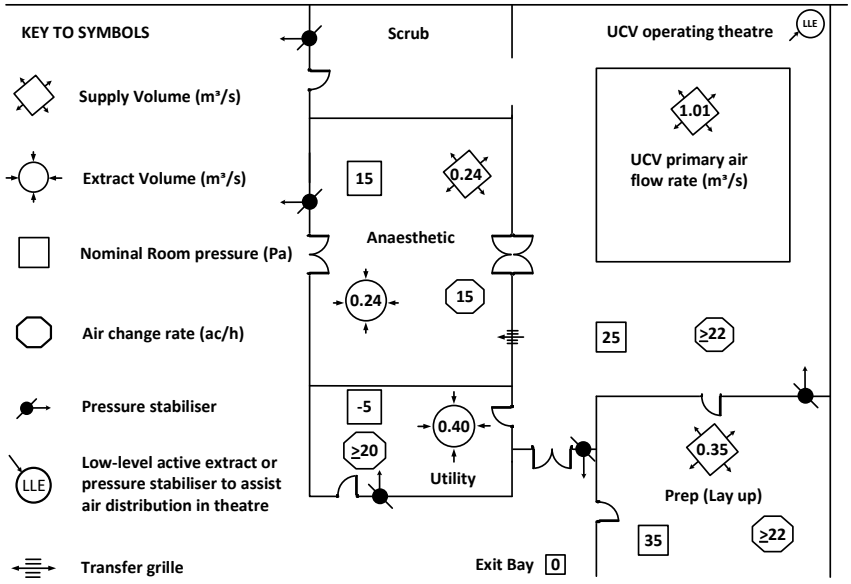
+ 0.07 closed-door airflow is required as a minimum (but see also the “designers’ notes” in Appendix 4).

Primary fresh-air volume for the UCV canopy or ≥22 ac/h or door protection

The volume of air to be extracted from the theatre should be determined by subtracting the airflow required for protection at the key door from the total air entering the theatre space. The balance should be equally divided between the passive or active extract locations.

The extracts within the theatre and scrub may be either passive and fitted with pressure stabilisers or active and connected to the extract system. They should where possible be located at low level and positioned to promote the active ventilation and scouring of all areas of the space (see paragraph 8.92). Air transfer from theatre to anaesthetic room may be by pressure stabiliser or transfer grilles (see paragraphs A8.51 and A8.52 in Appendix 8). The anaesthetic room extract will be at low level (see Appendix 9).

Figure A9 single-corridor UCV operating suite with Lay-up prep schematic layout



Standard layout 5 – (ex SHTM 2025 Plan 1b): single-corridor conventional operating suite with “lay-up” prep

Note: This layout and data is for historical purposes only. The information is to be used for the evaluation of existing systems, the fitting out of existing shell schemes or rebalancing of such systems following cleaning.

Table A10 (ex SHTM 2025 Plan 1b): single-corridor conventional operating suite with “lay-up” prep design criteria

Room	Size	Air-change rate (ac/h)	Nominal pressure (Pa)	Flow rate (m3/s)
Theatre	* See Notes below	≥22	25	# See Notes below
Anaesthetic	* See Notes below	15	Design 15 Commissioned ≥10	~ Supply and extract to achieve the air change rate
Lay-up prep	* See Notes below	≥22	35	0.35**
Scrub	* See Notes below	–	25	–
Utility	* See Notes below	>20	–5	0.40

Notes:

* Existing theatre suite rooms to be measured on site

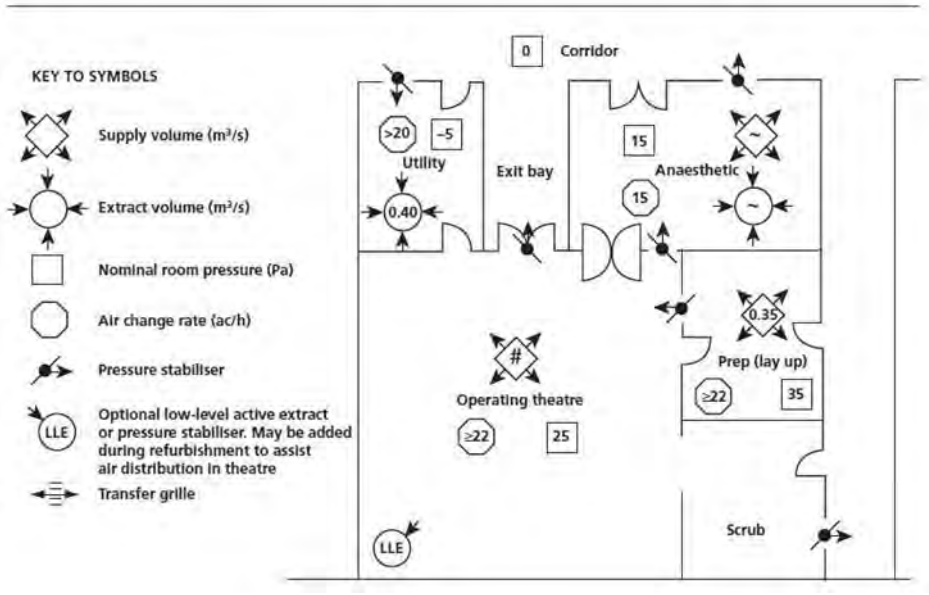
Total airflow related to volume of theatre to give ≥22 ac/h or door protection value = primary theatre supply + 0.28 m3/s from the Lay-up Prep pressure stabiliser

** See the “designers’ notes” in Appendices 4 and 5.

The utility layout design figures will remain the same if a hatch is fitted instead of a door onto the service corridor.

The extracts within the theatre and scrub may be either passive and fitted with pressure stabilisers or active and connected to the extract system. They should where possible be located at low level and positioned to promote the active ventilation and scouring of all areas of the space (see paragraph 8.92). Air transfer from theatre to anaesthetic room may be by pressure stabiliser or transfer grilles (see paragraphs A8.51 and A8.52 in Appendix 8). The anaesthetic room extract will be at low level (see Appendix 9).

Figure A10 (ex SHTM 2025 Plan 1b): single-corridor conventional operating suite with "lay-up" prep schematic layout



Standard layout 6 – (ex SHTM 2025 Plan 1a): single-corridor UCV operating suite with SPS prep

Note: This layout and data is for historical purposes only. The information is to be used for the evaluation of existing systems, the fitting out of existing shell schemes or rebalancing of such systems following cleaning. If difficulties are experienced with entrainment around the periphery of the UCV, adding a low-level active or passive extract in the location indicated will usually resolve the problem.

Table A11 (ex SHTM 2025 Plan 1a): single-corridor UCV operating suite with SPS prep design criteria

Room	Size	Air-change rate (ac/h)	Nominal pressure (Pa)	Flow rate (m3/s)
Theatre	* See Notes below	≥22	25	# See Notes below
Anaesthetic	* See Notes below	15	Design 15 Commissioned ≥10	~ Supply and extract to achieve the air change rate
Sterile pack store prep	* See Notes below	10	25	0.1
Scrub	* See Notes below	–	25	–
Utility	* See Notes below	–	–5	0.4

Notes:

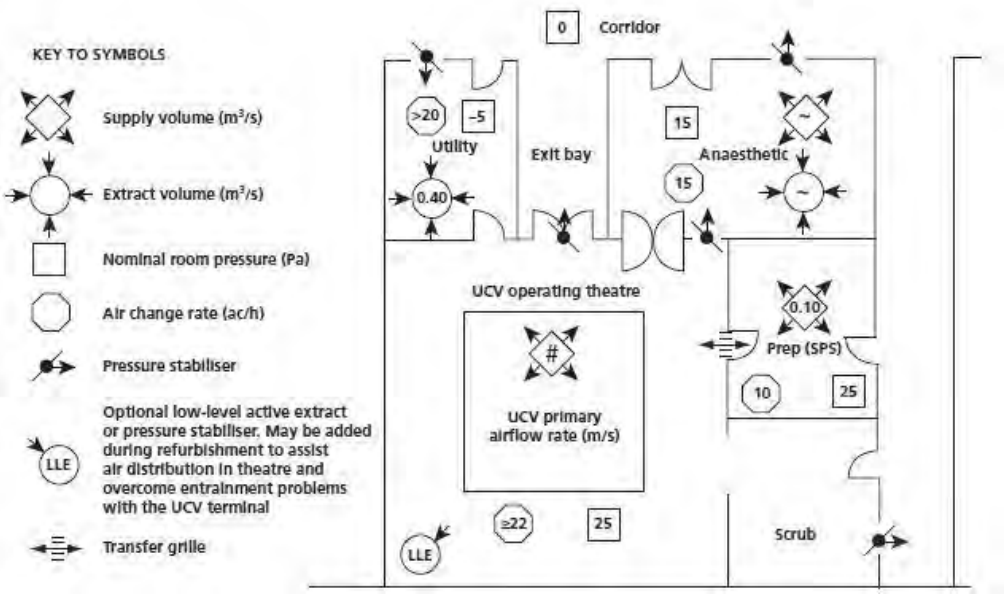
* Existing theatre suite to be measured on site

Theatre total airflow related to volume of theatre to give ≥22 ac/h or door protection value

The utility layout design figures will remain the same if a hatch is fitted instead of a door onto the service corridor.

The extracts within the theatre and scrub may be either passive and fitted with pressure stabilisers or active and connected to the extract system. They should where possible be located at low level and positioned to promote the active ventilation and scouring of all areas of the space (see paragraph 8.92). Air transfer from theatre to anaesthetic room may be by pressure stabiliser or transfer grilles (see paragraphs A8.51 and A8.52 in Appendix 8). The anaesthetic room extract will be at low level (see Appendix 9).

Figure A11 (ex SHTM 2025 Plan 1a): single-corridor UCV operating suite with SPS prep schematic layout



Standard layout 7 – (ex SHTM 2025 Plan 5b): two-corridor conventional operating suite with “lay-up” prep

Note: This layout and data is for historical purposes only. The information is to be used for the evaluation of existing systems, the fitting out of existing shell schemes or rebalancing of such systems following cleaning.

Table A12 (ex SHTM 2025 Plan 5b): two-corridor conventional operating suite with “lay-up” prep design criteria

Room	Size	Air-change rate (ac/h)	Nominal pressure (Pa)	Flow rate (m3/s)
Theatre	* See Notes below	≥22	25	# See Notes below
Anaesthetic	* See Notes below	15	Design 15 Commissioned ≥10	~ Supply and extract to achieve the air change rate
Lay-up prep	* See Notes below	≥22	35	0.35**
Scrub	* See Notes below	–	25	–
Utility	* See Notes below	–	0	0.1

Notes:

* Existing theatre suite to be measured on site

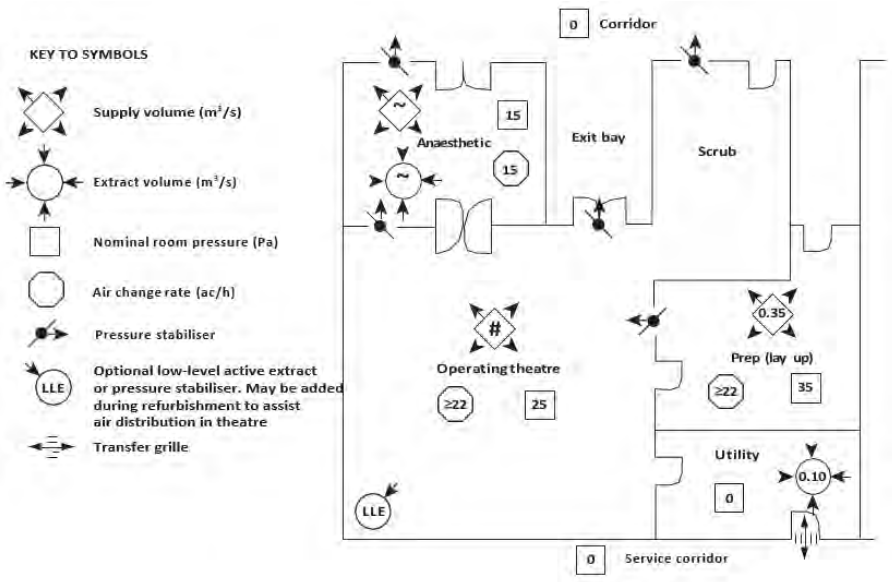
Theatre total airflow related to volume of theatre to give ≥22 ac/h or door protection = primary theatre supply + 0.28 m3/s from Lay-up Prep pressure stabiliser

** See the “designers’ notes” in Appendices 4 and 5

The utility design figures will remain the same if a hatch is fitted instead of a door onto the service corridor. Alternatively, if the operating department has a central waste processing station, the utility room may be omitted and replaced with a hatch between the theatre and service corridor.

The extracts within the theatre and scrub may be either passive and fitted with pressure stabilisers or active and connected to the extract system. They should where possible be located at low level and positioned to promote the active ventilation and scouring of all areas of the space (see paragraph 8.92). Air transfer from theatre to anaesthetic room may be by pressure stabiliser or transfer grilles (see paragraphs A8.51 and A8.52 in Appendix 8). The anaesthetic room extract will be at low level (see Appendix 9).

Figure A12 (ex SHTM 2025 Plan 5b): two-corridor conventional operating suite with “lay-up” prep schematic layout



Standard layout 8 – (ex SHTM 2025 Plan 5a): two-corridor UCV operating suite with SPS prep

Note: This layout and data is for historical purposes only. The information is to be used for the evaluation of existing systems, the fitting out of existing shell schemes or rebalancing of such systems following cleaning. If difficulties are experienced with entrainment around the periphery of the UCV, adding a low-level active or passive extract in the location indicated will usually resolve the problem.

Table A13 (ex SHTM 2025 Plan 5a): two-corridor UCV operating suite with SPS prep design criteria

Room	Size	Air-change rate (ac/h)	Nominal pressure (Pa)	Flow rate (m3/s)
Theatre	* See Notes below	≥22	25	# See Notes below
Anaesthetic	* See Notes below	15	Design 15 Commissioned ≥10	~ Supply and extract to achieve the air change rate
Sterile pack store prep	* See Notes below	10	25	0.1
Scrub	* See Notes below	–	25	–
Utility	* See Notes below	–	0	0.1

Notes:

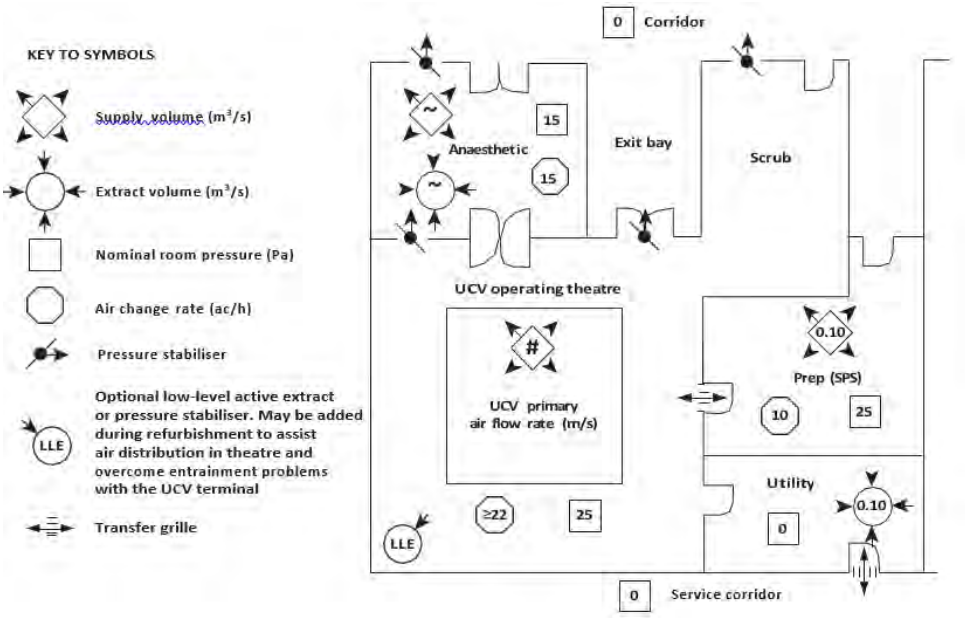
* Existing theatre suite to be measured on site

Primary fresh supply air for the UCV canopy is related to volume of theatre to give ≥22 ac/h or door protection

The utility design figures will remain the same if a hatch is fitted instead of a door onto the service corridor. Alternatively, if the operating department has a central waste processing station, the utility room may be omitted and replaced with a hatch between the theatre and service corridor.

The extracts within the theatre and scrub may be either passive and fitted with pressure stabilisers or active and connected to the extract system. They should where possible be located at low level and positioned to promote the active ventilation and scouring of all areas of the space (see paragraph 8.92). Air transfer from theatre to anaesthetic room may be by pressure stabiliser or transfer grilles (see paragraphs A8.51 and A8.52 in Appendix 8). The anaesthetic room extract will be at low level (see Appendix 9).

Figure A13 (ex SHTM 2025 Plan 5a): two-corridor UCV operating suite with SPS prep schematic layout



Appendix 8: Design of air- movement control schemes for operating theatres

General

A8.1 Standard operating suite design solutions are given in paragraphs 8.27–8.74 and Appendix 7. If these standard solutions cannot be used, the following procedure should be adopted, which will result in an acceptable design. Note that the method employed may equally be used to provide a design solution to a ventilated suite of rooms for any application.

A8.2 The method is concerned with the calculation of air-flow rates to ensure that correct air movement occurs between rooms when any one door is open. Under most circumstances, the air quantities required for air-movement control will approximate to those for either temperature control or bacterial contaminant dilution. This flow rate is sufficient to control the effects of any slight reverse flows occurring when a door is opened.

A8.3 The progression through the design procedure is shown in the air-flow design procedure chart (Figure A24) and is supported by worksheets WS1 to WS7 described in paragraph A8.4. It is recommended that a plan of the suite and an air-flow network be made (Figure A23) to collate all information. Flow rates, air- transfer devices etc should be entered as required. The remainder of this Appendix may be treated as reference data to assist in the various steps. The following symbols are used:

SS – supply air-flow rate for summer temperature control;

SW – supply air-flow rate for winter temperature control;

SD – supply air-flow rate for dilution of bacterial contaminants;

SL – supply air-flow rate for heat loss;

SG – supply air-flow rate for heat gain;

ED – extract air-flow rate for dilution of bacterial contaminants;

SF – final supply air-flow rates

EF – final extract flow rates;

SAMC – air-supply flow rate for air- movement control;

EAMC – air-extract flow for air- movement control;

LOUT – leakage air-flow rate outward;

LIN – leakage air-flow rate inward;

∑OUT - total air-flow rate outward;

∑IN total air-flow rate inward.

A8.4 To simplify the procedure, standard worksheets (WS1 to WS7) have been devised. For each operating suite, a set is required comprising one each of WS1, WS3, WS5, WS6a, WS6b and WS7, one WS4 for each corridor and one WS2 to cover each peripheral room. WS2 has five versions:

WS2a single flow,

WS2b parallel/series multi-flow,

WS2c parallel multi-flow or series multi-flow (unbalanced);

WS2d series multi-flow (balanced); and

WS2e bay (semi-open).

Peripheral room type

A8.5 The rooms in the operating suite other than the operating theatre and corridor are referred to as peripheral rooms. Peripheral rooms have been classified according to the flows in and out. These room classifications are defined in paragraphs A8.6–A8.11.

Single flow

A8.6 This is a room with only one door and a net surplus of supply or extract air.

Parallel multi-flow

A8.7 This is a room with two or more doors through each of which the air flows either outwards (high pressure) or inwards (low pressure) (for example the Prep (lay- up) in standard layout 5 in Appendix 7).

Parallel/series multi-flow

A8.8 This is a room having a net surplus of supply or extract and with two or more doors. One or more doors will be to an area of equal cleanliness and need not be protected; hence, the flow may vary between inwards and outwards, the remaining door being to an area of greater or lesser cleanliness (for example the Prep (SPS) in standard layout 6 in Appendix 7).

Series multi-flow (unbalanced)

A8.9 This is a room having a net surplus of supply or extract and with two or more doors. Air flows inwards through one or more doors and outwards through one or more doors.

Series multi-flow (balanced)

A8.10 This is a room as in paragraph A8.9 above, but having either no mechanical ventilation or no net surplus of supply or extract (for example an anaesthetic room).

Bay

A8.11 A room which has a permanent opening to the operating theatre may be considered as a bay off the latter (for example a scrub). Two categories exist:

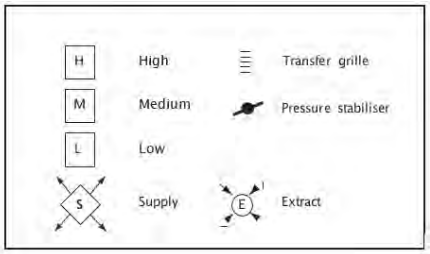
open bay – the opening is larger than a normal single door opening. The bay may be considered as part of the main room;

semi-open bay – the opening is no larger than a normal single door opening. In this case it is possible to protect the bay from the main room by provision of air supply or extract in the bay, or by passing air to or from another area.

Air-movement control in peripheral rooms

A8.12 For the design of air-movement control, two types of air-transfer device are considered. These are transfer grilles and pressure stabilisers. Each has a particular field of application within the design, as described in paragraphs A8.34– A8.43. Air movement is controlled in each of the different room types described in paragraphs A8.13–A8.31.

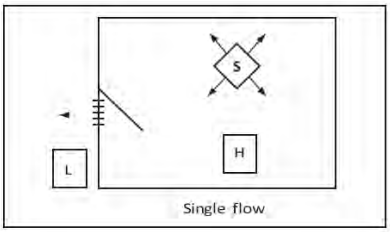
Figure A14 Key to symbols



Single flow rooms

A8.13 An appropriately-sized transfer grille should be located in or adjacent to the door of each single flow room to relieve the pressure differences across the door when closed.

Figure A15 Single flow room solution high–pressure room



Parallel multi-flow rooms

A8.14 The pressure difference across the closed doors should be relieved, but transfer grilles are not appropriate where two doors lead to areas of different pressures, because reverse flow could occur when the other door is open. For this reason, pressure stabilisers are used.

Figure A16 Parallel, multi-flow room solution high-pressure

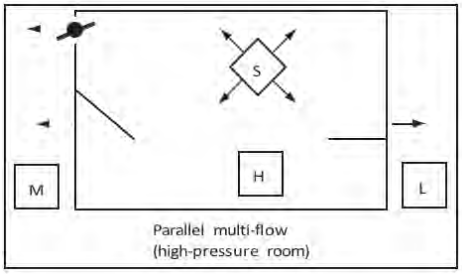
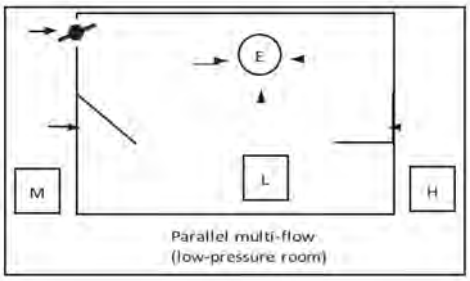


Figure A17 Parallel, multi-flow room solution low-pressure



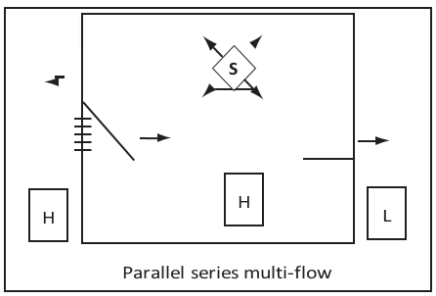
A8.15 These rooms will be either high- pressure or low-pressure with respect to the adjacent areas (see preparation lay-up room and disposal room, respectively, in standard layout 5 of Appendix 7). The pressure-relief damper is always situated between the room and area, which results in the smaller differential pressure to ensure best use of air.

A8.16 Just as reverse flow can occur if transfer grilles are used, it can similarly occur via door gaps when the other door is opened. It is not possible to avoid this, except by using air locks, but due to the low flow rates and short durations involved, this is not considered to be of importance.

Parallel-series multi-flow rooms

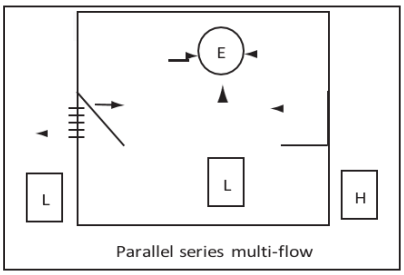
A8.17 These rooms are similar to those in paragraph A8.14 above, but because the room is of equal cleanliness to one of the adjacent rooms, the nominal pressures will be equal and air may flow through the adjoining doorway in either direction (for example the Prep (SPS) in standard layout 6 of Appendix 7).

Figure A18 Parallel, series multi-flow room solution high-pressure



A8.18 Where the nominal room pressure equals that of the higher-pressure adjacent room, the best use of air is by supplying air required for bacterial dilution only and allowing this to exhaust via a transfer grille to the area of equal cleanliness. The doorway to the lower pressure area is protected by the combination of the supply air and the air that will flow inwards through the transfer grille from the area of equal cleanliness.

Figure A19 Parallel, multi-flow room solution low-pressure

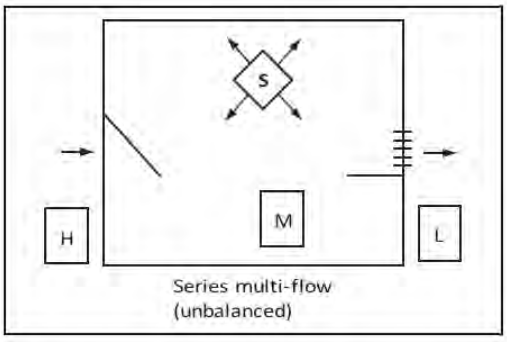


A8.19 Conversely, where the nominal pressure equals that of the lower-pressure adjacent room, extract ventilation and a transfer grille to the lower pressure adjacent room should be provided (for example the disposal room in standard layout 8 of Appendix 7).

Series multi-flow (unbalanced)

A8.20 These rooms are somewhat similar to those in paragraph A8.15 above, but because the pressure lies between that of the rooms on either side, the back-flow problem does not exist.

Figure A20 Series, multi-flow room solution medium-pressure



A8.21 Where the room has a net surplus of mechanical supply air, a transfer grille should be located in or adjacent to the door through which air flows outwards, and the mechanical supply flow rate to the room should be chosen to give protection when this door is open.

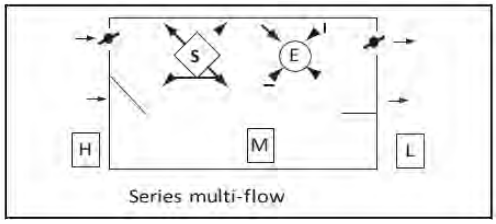
A8.22 Where the room has a net surplus of mechanical extract air, a transfer grille should be located adjacent to the door through which the air flows inwards, and the mechanical extract flow rate to the room should be chosen to give protection when this door is open.

A8.23 The grille should be sized for the protection requirement of the opposing door when open. When the room on the high-pressure side depressurises, there is a possibility of back-flow through gaps around the door, but this problem may be ignored.

Series multi-flow (balanced)

A8.24 In these rooms, a transfer device adjacent to each doorway is required in order to provide a flow path for the air required to protect the opposing door when opened.

Figure A21 Series, multi-flow room solution medium-pressure



A8.25 These transfer devices will normally be pressure stabilisers, although transfer grilles may be used where a large amount of excess air is to be exhausted from the operating theatre when all doors are closed (for example anaesthetic rooms).

A8.26 The calculation procedure is to assume that pressure stabilisers are being used; then – if there is sufficient excess air – change to transfer grilles as described in paragraph A8.50.

Bay

Open bay

A8.27 A bay of the open type (for example scrub-up) is considered to be part of the operating theatre. There should be an active or passive extract/pressure stabiliser under, or directly adjacent to, the scrub trough.

Semi-open bay

A8.28 In a bay of the semi-open type, protection of one area from the other is possible (for example scrub-up).

A8.29 As stated previously, the need for protection between operating theatre and scrub-room is not very great. Better use of air can therefore be achieved in this case by installing a pressure stabiliser between the scrub-room and clean corridor. This will allow a flow of air through the scrub-room at all times, except when a door is opened elsewhere in the suite. The pressure stabiliser will then close and the air will be diverted to the other door. When it is considered necessary to protect the scrub-room at all times, either a transfer grille to the corridor or mechanical extract in the scrub-room should be provided.

Operating theatre

A8.30 Once the peripheral rooms have been considered, the operating theatre requirements may then be decided and the supply flow rate required for air-movement control calculated. This flow rate should be such that, with any one door open, the correct air movement directions are maintained. There will be one door in the suite that will require the largest supply flow rate to the operating theatre for protection when open. This is called the “key door” and is discussed separately in paragraph A8.33. Use of this concept avoids repetitive calculations for each door in turn. Having established the required supply flow rate, a relief route should be provided to the clean corridor for any excess air when the doors are closed. This would be via transfer grilles or pressure stabilisers through a series-flow room or via pressure stabilisers to the clean corridor directly.

Corridors

A8.31 All surplus air from the suite, except that lost through structure leakage and any passing to the outer corridor, will arrive in the patient/staff corridor. Should this air be insufficient to achieve the required air- change rate (see Appendix 3), some additional air supply should be provided. (The air balance should take account of structural leakage.)

A8.32 Whereas the resulting pressures are dependent on ductwork layout, room relationships and characteristics of the fan, the generalisations shown in Appendix 6 may be used to estimate the change in room pressure when a door is opened.

A8.33 The “key door” will be the open double door which leaves the operating theatre at the highest pressure, and/or requires the largest air flow. This should be determined using the procedure in worksheet WS3.

Transfer grilles

A8.34 These may be used to limit the pressure differences across the closed door of a single-flow room or, in some instances, for protection of a series-flow or parallel-series-flow room. They allow air flow in both directions and may not be suitable for all applications.

A8.35 The free area of a grille is calculated from the following equation:

$$A = \frac{Q}{0.84\sqrt{\Delta P}}$$

where:

A is free area (m2)

Q is flow rate (m3/s)

P is pressure difference (Pa)

0.84 is the grille's resistance- correction factor.

A8.36 The flow through a grille at a different pressure may be found from the following equation:

$$Q_2 = Q_1 \sqrt{\frac{\Delta P}{\Delta P^1{}_2}}$$

where:

Q_1 and P_1 are original flow and differential pressure

Q_2 and P_2 are new flow and differential pressure.

A8.37 The transfer grille may be replaced by carefully proportioned door undercuts of the equivalent free area.

A8.38 The function of the transfer grille is to provide a means of air-flow control by which the volume and pressure loss can be established. If a grille is used, it should have an easily removable core to facilitate cleaning.

Pressure-relief dampers

A8.39 The functions of a pressure-relief damper are now carried out by pressure stabilisers. Accordingly, all mention of them has been removed from this document.

Pressure stabilisers

A8.40 Pressure stabilisers can be adjusted to hold the pressure constant over a wide range of flow rates. They are used where requirements exist for accurate room- pressure control or rapid shut-off on pressure fall.

A8.41 The installation of a grille or baffle in association with a stabiliser will alter the operating characteristics. It is recommended that a location be chosen to avoid the need for visual screening, for example, at high level. The location should be chosen to minimise the likelihood of damage.

A8.42 The stabilisers used should be virtually silent in operation, adjustable on site, maintenance-free and of a type which cannot be wrongly inserted. They should not be used in external walls or where the pressure difference is less than 5 Pa. The required size of a pressure stabiliser is dependent on the design pressure difference across it and flow rate through it. The manufacturer should provide data relating pressure difference to mean velocity (or flow rate per unit area). From this, the required area can be calculated and then rounded-up to the nearest size manufactured or nearest combination of smaller sizes.

A8.43 It is sometimes possible to arrange for a pressure stabiliser to perform two tasks. In an anaesthetic room, for example, the two pressure stabilisers may be made to pass the open door protection air, and also control the operating and anaesthetic room pressures with the door closed. To achieve this, the stabilisers are sized for the flow rate required with one of the doors open, but the pressure setting is adjusted to be the value required with the doors closed.

This is shown in Figure A22.

Door leakage flows

A8.44 For an air-movement control scheme to work satisfactorily, it is essential that the estimates of door-gap leakage made at the design stage are closely related to those which are achieved in practice. The calculation of gap-flows is complicated by the fact that such flows generally fall into the transition region between laminar and turbulent flow and hence do not follow the normal flow equations. The gaps assumed are 4 mm along the bottom, 3 mm at the top and sides, and 2 mm between double leaves. Doors should not have wider gaps than these. Tighter gaps would result in lower flow-rate requirements and hence lower fan power, but care should be taken to ensure that all doors in the suite have similar gap dimensions. It may be possible to

ignore the door leakage and so reduce the air-flow requirement (see the “designers’ notes” in Appendix 4).

Room temperature estimation

A8.45 The air-flow rate required to prevent back-flow through an open door is dependent on the temperature difference across the door. The design figures shown in Appendix 6 are based on the temperature differences that will normally occur in practice, assuming heat gains and losses in accordance with Appendix 4.

A8.46 At step 11 of the air-flow design process, the temperature differences across the doors of all rooms classed as “sterile” are calculated. Worksheet WS6 is recommended for the calculations, using the following criteria:

a. assume that the operating theatre is being controlled at 20ºC and calculate the incoming air-supply temperature as shown on worksheet WS6;

b. the calculation should be repeated for both summer and winter conditions, with an operation in progress;

c. assume all doors are closed;

d. use the room supply flow rates from WS1;

e. use the inward air flows through air-transfer devices and closed door leakages from WS2a to WS2E;

f. the formula used in worksheet WS6 is as follows:

$$T = \frac{(t_1 Q_1 + t_2 Q_2 + \ldots + t_n Q_n) + 0.828H}{(Q_1 + Q_2 + \ldots Q_n)}$$

where:

Q = flow rate from source (m3/s)

t = the temperature of source (ºC)

H = the room heat gain (kW).

A8.47 If the evaluated temperature differences between rooms do not exceed 2ºC, the solution is satisfactory; otherwise proceed as follows:

(i) check the assumption on which the heat gains are based;

(ii) take steps to reduce the heat gains;

(iii) if the door is to a corridor, the flow through the open door will be larger than the value given in Appendix 6. Calculate on WS3, assuming it is the “key door” with door-flow unknown, and the supply as known;

(iv) if the door leads to a room with mechanical supply, install a trimmer heater in the supply to the room controlled by either a differential thermostat or a

thermostat slaved to the operating theatre thermostat to ensure that T is minimised;

(v) if the door leads to a room with no mechanical supply, increase the door protection flow as follows:

$$Q_{new} = Q_{old} \quad \frac{2}{[\Delta T + 1]}$$

A8.48 These options should be considered in this order, and (i), (ii) and (iii) should be investigated thoroughly before proceeding to (iv) or (v). The mechanical supply may need to be increased in order to achieve the desired air-change rates.

Relief of excess air from operating theatre when all doors are closed

A8.49 As the mechanical supply to the operating theatre is sized to provide an appropriate flow outwards through any door which is opened, it follows that when all doors are closed, there will be more air supplied to the operating theatre than can exit from it via leaks etc. This “excess” air can be relieved by either of the two methods described in paragraphs A8.50– 8.54.

By transfer devices via the anaesthetic room

A8.50 The transfer device (pressure stabiliser or transfer grille) between the theatre and anaesthetic room needs to accommodate an air volume of 0.46 m³/s at 20 Pa (see Appendix 6) when the door between the anaesthetic room and corridor is open. An additional 0.11 m³/s will pass through the door gaps of the theatre to anaesthetic door to give a total door flow protection figure of 0.57 m³/s through the open door between the anaesthetic room and corridor. The optimum duty for this device with all the doors closed would be 0.33 m³/s at the room differential of 10 Pa. The following equation shows how this figure is arrived at:

$$Q = \frac{Q_1}{\left(\sqrt{\frac{\Delta P2}{\Delta P1}}\right)}$$

$$= \frac{0.46}{\left(\sqrt{\frac{\Delta 20}{\Delta 10}}\right)}$$

$$= 0.33 m^3/s$$

where:

Q = excess air to be vented with doors closed

$Q1$= airflow required for door protection through the transfer device

$\Delta P1$= nominal differential pressure with door to operating theatre closed and door to corridor closed

$\Delta P2$= nominal differential pressure between the operating theatre and anaesthetic room when the corridor door is open.

A8.51 If the excess air is less than 0.33 m3/s, a pressure stabiliser is required to ensure that the correct pressure and protection airflow is available to pass through the door.

A8.52 If the excess air is greater than 0.33 m3/s, a transfer grille is acceptable because at all times the airflow will exceed the flow required for pressure and door protection.

By pressure stabilisers to the corridor

A8.53 If it is undesirable to pass all the extra remaining air volume through the anaesthetic room after the door flow- protection volumes have been achieved, it may be passed from the theatre directly to the corridor via a separate pressure stabiliser.

A8.54 If there is sufficient excess air, the transfer grille solution at paragraph A8.52 should be adopted, as it provides the simplest solution and, once set up, will require no further maintenance. With less excess air, it is recommended that the air be passed through the anaesthetic room via the pressure stabilisers as at paragraph A8.51, thus keeping the number of pressure stabilisers to a minimum. Both these solutions increase the air-change rate in the anaesthetic room, but care should be taken to avoid passing excessive amounts through that would cause discomfort to the occupants.

Figure A22: Pressure stabilisers performing two tasks

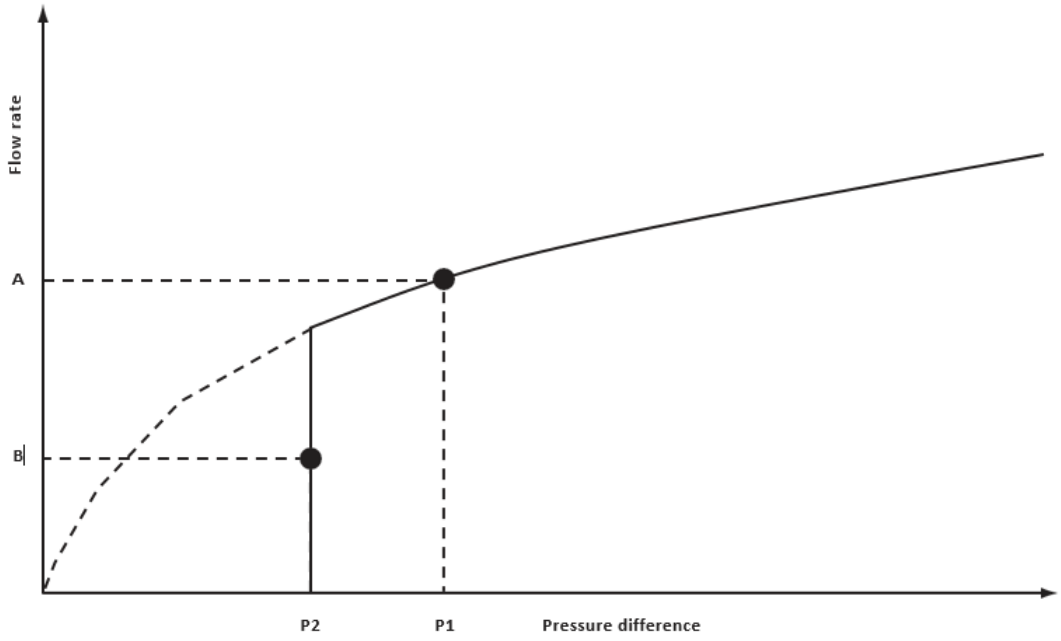


Figure A23: An example of an air-flow network

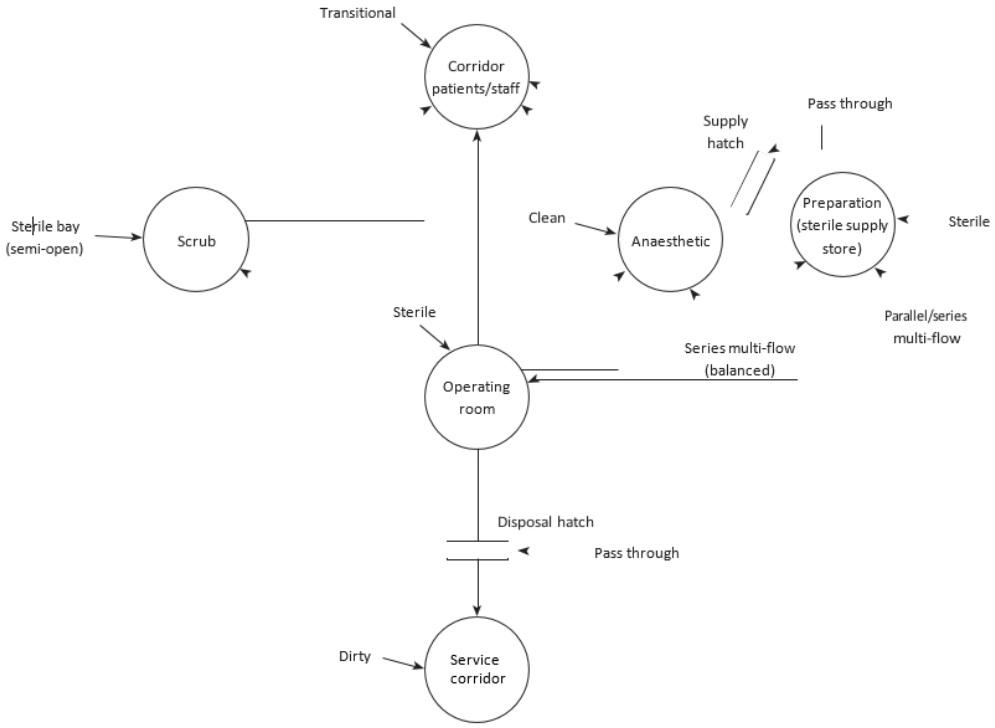
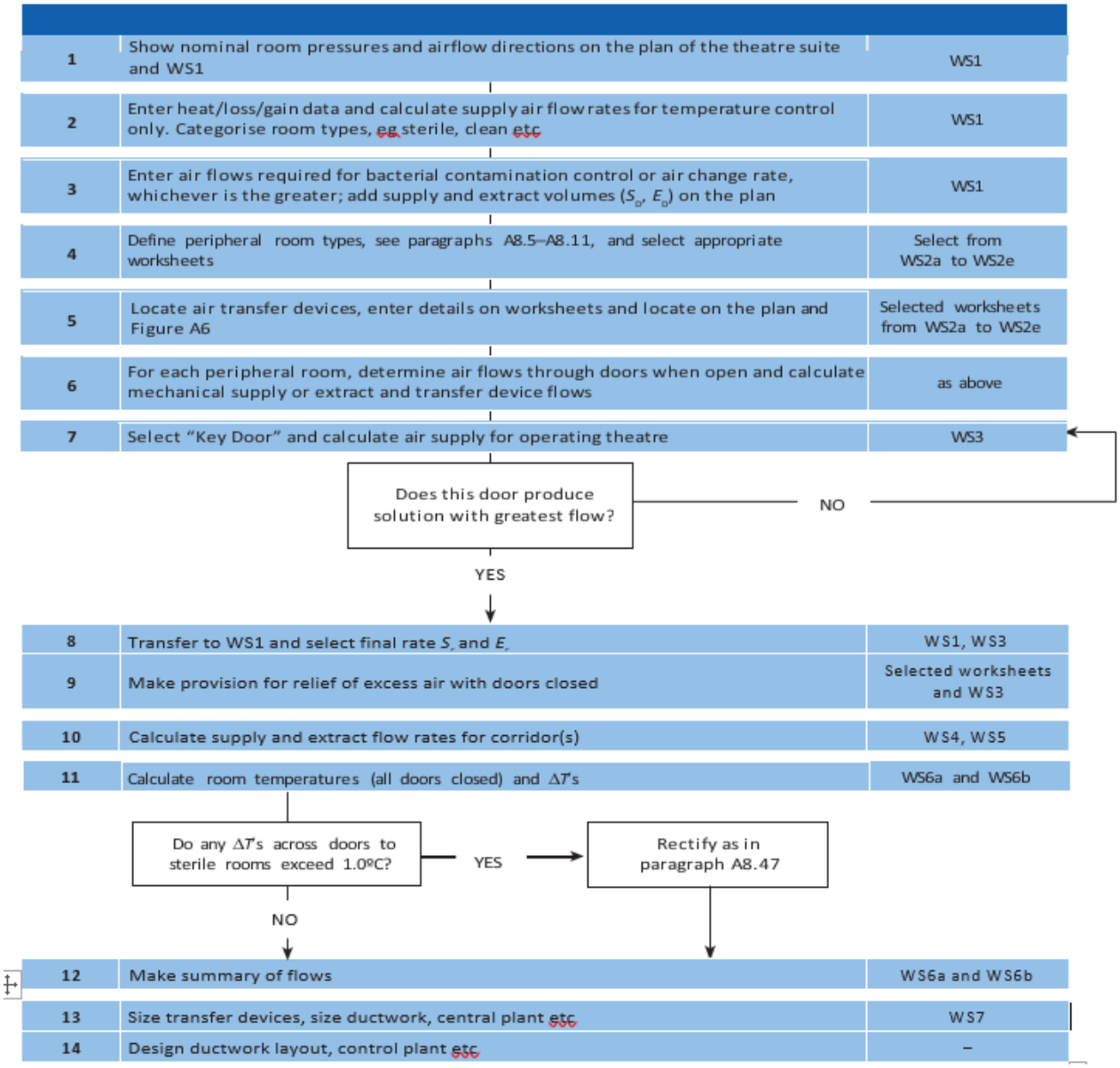


Figure A24: Air-flow design procedures



Calculation sheet for flow rates

Worksheet WS1
Reference:

Room name						
1. Summer temperature control Heat gain	kW					
2. Acceptable Δt	ºC					
3. Air flow rate (S_G) $= \frac{\text{Gain}}{\Delta t \times 1.2}$	m^3/s					
4. Winter temperature control Heat loss	kW					
5. Acceptable Δt	ºC					
6. Air flow rate (S_L) $= \frac{\text{Loss}}{\Delta t \times 1.2}$	m^3/s					
7. Dilution of bacterial contaminants Air flow rate S_D or E_D	m^3/s					
8. Desired air change rate $\frac{\text{AC/hr} \times \text{room volume } (m^3)}{3600}$	AC/hr					
	m^3/s					
9. Maximum of S_G, S_L, S_D or E_D or air change rate from step 8	m^3/s					
10. Air movement control Air flow rate for air movement control S_{AMC} or E_{AMC} (from WS2, WS3 or WS4)	S m^3/s					
	E m^3/s					
11. Final supply flow rate (S_F)	m^3/s					
12. Final extract	m^3/s					
13. Total supply	m^3/s					
14. Total extract	m^3/s					

Designer ..... Date .....

Template A1 Worksheet WS1

Air movement control **Peripheral room ..... type, single flow**	**Worksheet WS2a Reference:** **Nominal pressure:_____Pa**

Consider door to ..... open

			Air flow, m³/s		
	Pa	Δ*t*	Out	In	Remarks
Flow required through doorway to give protection					
Total					

S_{AMC} ($\sum_{OUT} - \sum_{IN}$) m³/s

or

E_{AMC} ($\sum_{IN} - \sum_{OUT}$) m³/s

Transfer S_{AMC} or E_{AMC} to WS1

Consider door to ..... closed

	Pa	Δ*t*	Out	In	Remarks
Closed door leakage					
Total					

Return S_F and E_F to WS1 _____ _____

Flow through transfer grille outward ($S_F - E_F - L_{OUT}$) _____

or

Flow through transfer grille inward ($E_F - S_F - L_{IN}$) _____

Designer ..... Date .....

Template A2 Worksheet WS2a

Air movement control **Peripheral room ..... type, parallel/series multi-flow**	**Worksheet WS2b Reference:** **Nominal pressure:_____Pa**

Door from this room to ..... (room of equal cleanliness) is not to be protected.
A transfer grille is located in, or adjacent to, this door

Consider other door to ..... open.

Room pressure now becomes or or Pa (see Appendix 6)

			Air flow, m3/s		
			Out	In	Remarks
Flow required through doorway to give protection					
At above pressures leaks through closed doors	Pa	ΔP			
Mechanical supply or extract (S_F/E_F)					
		Total			

X $(\sum_{OUT} - \sum_{IN})$ or Y $(\sum_{IN} - \sum_{OUT})$

Transfer grille required
from high-pressure zone Flow = X
or at ΔPa
to low-pressure zone Flow = Y
Size of transfer grille (free area) A1

Consider doors and hatch closed – room pressure becomes Pa (nominal)

Closed door leakage from Appendix 4 (assuming no transfer grille)	Pa	ΔP	Out	In	Remarks
Mechanical supply or extract					
		Total			

Air flow required through transfer grille = IN – OUT = Z'

or OUT – IN = Z'' _____

Transfer grille required flow Z' or Z'' _____ @ _____ ΔP

Size of transfer grille (free area) A2 = _____

Select larger of A1 or A2 _____

Designer ..... Date .....

Template A3 Worksheet WS2b

Air movement control **Peripheral room ..... type, parallel multi-flow high/low or series multi-flow (unbalanced)**					**Worksheet WS2c Reference:** **Nominal pressure:_____Pa**
Consider door from this room to ..... open. Room pressure now becomes or or Pa (see Appendix 6)					
Flow required through open doorway to give protection			Air flow, m³/s Out	In	Remarks
At above pressures leaks through closed doors are:	Pa	ΔP			
Total					
S_1 ($\sum_{OUT} - \sum_{IN}$) or E_1 ($\sum_{IN} - \sum_{OUT}$)					
Consider door from this room to ..... open. Room pressure now becomes or or Pa					
Flow required through open doorway to give protection			Out	In	Remarks
At above pressures leaks through closed doors are:	Pa	ΔP			
Total					
S_2 ($\sum_{OUT} - \sum_{IN}$) or E_2 ($\sum_{IN} - \sum_{OUT}$)					
Consider doors closed. Closed doors leakage from Appendix 4					
Door to:	Pa	ΔP	Out	In	Remarks
Total					
Return S_F and E_F from WS1 _____ Flow through transfer device outward ($S_F - L_{OUT}$) or _____ to ..... Flow through transfer device inward ($E_F - L_{IN}$) Transfer grille _____ Pressure relief damper from					

Designer ..... Date .....

Template A4 Worksheet WS2c

Air movement control **Peripheral room ..... type, series multi-flow (balanced)**	**Worksheet WS2d Reference:** **Nominal pressure:_____Pa**

Note: In this type of room the supply and extract air flow rates are equal and take no part in the air movement control (AMC)

First, open door to higher pressure area.

Room pressure then becomes or or Pa (see Appendix 6)

			Air flow, m3/s		
			Out	In	Remarks
Flow required through open doorway to give protection. See Appendix 6					
At above pressures leaks through closed doors are:	Pa	ΔP			
Total					

Q_1 ($\sum_{IN} - \sum_{OUT}$) (+ve inwards) _____

Next, open door to lower pressure area.

Room pressure then becomes or or Pa

			Out	In	Remarks
Flow required through open doorway to give protection					
At above pressures leaks through closed doors are:	Pa	ΔP			
Total					

Q_2 ($\sum_{OUT} - \sum_{IN}$) (+ve outwards)

Flow through transfer device (TD1) to protect

door 1 = $Q1$ _____ at resultant

ΔP .....

Flow through transfer device (TD2) to protect

door 2 = $Q2$ _____ at resultant

ΔP .....

Designer ..... Date .....

Template A5 Worksheet WS2d

Air movement control **Peripheral room ..... type bay (semi-open)**	**Worksheet WS2e Reference:**
	Nominal pressure:_____Pa

Note: If the room is of the open bay type (ie opening is larger than normal single doorway), the room should be considered part of the main room. No air movement control considerations need then be made, and this sheet can be discarded. Supply and/or extract flow will be based on air distribution considerations.

Consider permanent opening

			Air flow, m3/s		
			Out	In	Remarks
Flow required through opening to give protection					
Leaks through closed doors to:	Pa	ΔP			
Total					

E_{AMC} _____ or flow outward through transfer device ($\sum_{IN} - \sum_{OUT}$) _____

Transfer S_{AMC} or E_{AMC} to WS1

Transfer device – transfer grille _____

– pressure stabiliser _____

Size select transfer device for flow rate _____ @ ΔP _____

Note: A door from the bay is considered with the peripheral room to which it leads or, if it leads to the corridor, it is considered with the main room

Designer ..... Date .....

Template A6 Worksheet WS2e

Air movement control Operating room	**Worksheet WS3 Reference:**
	Nominal pressure:_____Pa

Note: To avoid considering each door open in turn, the "key door" concept is introduced. This is the door which requires the greatest mechanical flow when open. See paragraph A8.33

Select "key door" (see above).

Consider this door open – room pressure now becomes _____ Pa (see Appendix 6)

See Appendix 7 for room pressures

			Air flow, m^3/s		
			Out	In	Remarks
Flow required through doorway to give protection					
Air flow "out" or "in" via doors, transfer devices etc	Pa	ΔP			
Mechanical extract					
Total					

S_{AMC} ($\Sigma_{OUT} - \Sigma_{IN}$) _____ transfer S_{AMC} to WS1

Consider all doors closed.

Return S_F from WS1 _____ Room pressure now_____ Pa (nominal)

Air flow "out" or "in" via door leakage, transfer devices etc	Pa	ΔP	Out	In	Remarks
Mechanical extract and supply					
Total					

Flow ($\Sigma_{IN} - \Sigma_{OUT}$) through transfer device _____ @ΔP _____ to .....

For final selection of transfer device see paragraphs A8.50–A8.54

Designer ..... Date .....

Air movement control Corridor			**Worksheet WS4 Reference:**		
			Nominal pressure:_____Pa		
Consider all doors closed					
			Air flow, m^3/s		
			Out	In	Remarks
Flow required through doorway to give protection					
Leaks through closed doors, transfer devices, permanent openings etc	Pa	ΔP			
Total flow inwards (S_1)					
Add mechanical input (S_2) if necessary to increase S_1 to give 7 AC/hr					
Total flow outwards and inwards					
$S_{AMC} = (\sum_{OUT} - \sum_{IN} + S_2)$ _____ Transfer to WS5					
or $E_{AMC} = (\sum_{IN} - \sum_{OUT} + S_2)$ _____ Transfer to WS5					

Note: this sheet to be used for each individual operating theatre suite (or pair of suites if they share a preparation room)

Designer ..... Date .....

Template A8 Worksheet WS4

Air movement control		**Worksheet WS5** **Reference:**
Summary of air supply and extract for an operating suite		
Air flow to corridor	All doors closed	Anaesthetic (key door open)
	m^3/s	m^3/s
From preparation		
From operating theatre		
From scrub		
From anaesthetic		
Total (a)		
Air flow to corridor From utility		
From other source		
Total (b)		
Other room supplies ..... Total (c)		
Total air supply (a) + (b) + (c)		
Consider corridor ventilation (see Appendix 3) and calculate air volume required, based on 7 AC/hr (see Note 1)		
Air flow required to ventilate corridor (m^3/s)		
Air flow required to ventilate service corridor (see Note 2) (m^3/s)		
If the air flow from the operating suite (a) and (b) is greater than the calculated required volume, no further supply air is necessary		
Additional air to ventilate corridor (m^3/s)		
Additional air to ventilate service corridor (see Note 2) (m^3/s)		
Air extract (m^3/s) The size of the extract plant should be of the order of 10% below the supply to assist in maintaining the department under positive pressure relative to the outside departments		
Extract plant = Supply less leakage (m^3/s)		
Less 10% of supply		
Total extract (see Note 3)		

Notes:

1. In the case of a multi-theatre operating department, the air balance for the corridor should be considered as a separate exercise, taking into account the final dispersal of excess air.
2. Omit these if only one corridor in operating suite.
3. The extract volume includes 0.24 m^3/s from the anaesthetic room for a balanced condition

Designer ..... Date .....

Room temperature – summer	**Worksheet WS6a Reference:**

Find summer supply temperature $T_{ss} = 20 - 0.828H(O/R)$ _____

$= T_{ss}$ $Q(O/R)$ _____ _____ºC

Note: the temperature of a space may be calculated from

$$T = \frac{t_1Q_1 + t_2Q_2 + \ldots\ldots\ldots + t_nQ_n + (0.828H)}{Q_1 + Q_2 + \ldots Q_n}$$

Where t_1 is temperature of source 1 (ºC)
Q_1 is flow from source 1 when all doors are closed (m^3/s)
H is heat gain in space (kW)

Room	Heat gain kWh	Supply		Flows inwards										Temperature ºC T
		Q	T_{ss}	From		From		From		From		From		
				Q	t	Q	t	Q	t	Q	t	Q	t	

Check doors to sterile areas

Door between	Calculated room ΔT (ºC)	Maximum ΔT permitted	Remarks

Designer ..... Date .....

Room temperature – winter	**Worksheet WS6b Reference:**

Find winter supply temperature $T_{sw} = 20 - 0.828H(O/R)$ _____
$= T_{sw}$ _____ºC
$Q(O/R)$ _____

Note: the temperature of a space may be calculated from

$$T = \frac{t_1Q_1 + t_2Q_2 + \ldots\ldots\ldots + t_nQ_n + (0.828H)}{Q_1 + Q_2 + \ldots Q_n}$$

Where t_1 is temperature of source 1 (ºC)
Q_1 is flow from source 1 when all doors are closed (m^3/s) H is heat gain in space (kW)

Room	Heat gain kWh	Supply		Flows inwards										Temperature ºC T
		Q	T_{sw}	From		From		From		From		From		
				Q	t	Q	t	Q	t	Q	t	Q	t	

Check doors to sterile areas

Door between	Calculated room ΔT (ºC)	Maximum ΔT permitted	Remarks

Designer ..... Date .....

Template A11 Worksheet WS6b

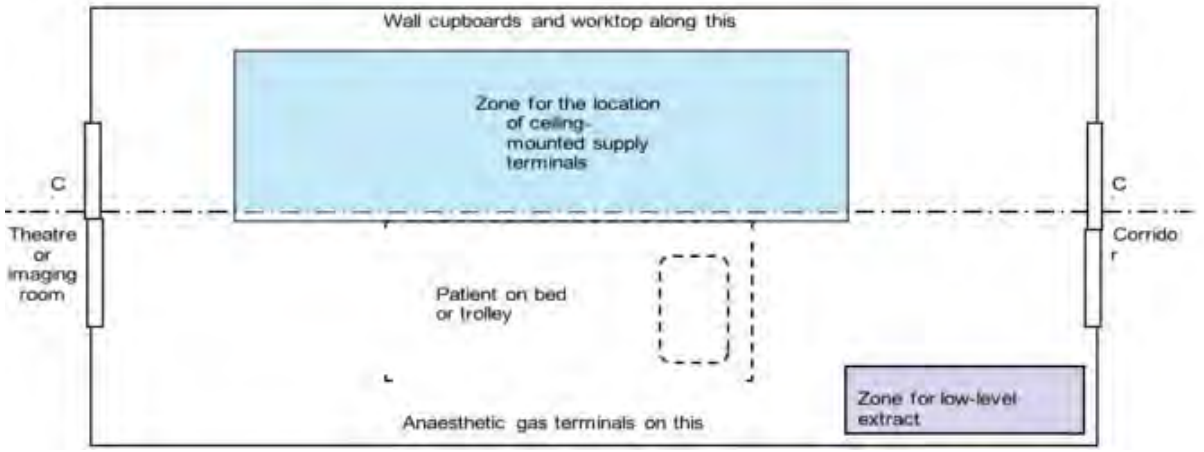
Transfer grilles, pressure relief dampers and pressure stabilisers							Worksheet WS7 Reference:
Transfer grilles – see paragraphs A8.34–A8.38							
No	Location	Pressure difference Pa	Flow rate m^3/s	Free area m^2	Model	Resultant Δp Pa	Remarks
Pressure relief dampers – see paragraph A8.39							
No	Location	Pressure difference Pa	Flow rate m^3/s	Free area m^2	Pressure setting Pa	Remarks	
Pressure stabilisers – see paragraphs A8.40–A8.43 Note: where a stabiliser is acting both as series room door protection and operating pressure control, “pressure difference” and “flow rate” are from WS2d; “pressure setting” is from WS3							
No	Location	Pressure difference Pa	Flow rate m^3/s	Free area m^2	Pressure setting Pa	Remarks	

Designer ..... Date .....

Appendix 9: Design of air- movement control scheme for anaesthetic room

General

Figure A25 Schematic of suitable supply and extract solution



The above shows the typical zones for the positioning of ceiling-mounted supply and low-level extracts in an anaesthetic room. The objective is to comply with the COSHH Regulations and SHTM 03-01 Part A by providing a clean airflow path for staff working in anaesthetic rooms and so reduce their risk of casual exposure to waste/leaking anaesthetic agents.

Note 1: Supply terminals should not be positioned above wall-mounted cupboards as this will prevent their output being measured directly with a balometer. It will also negatively impact on the air distribution within the room.

Note 2: See photographs below for details of the recommended low-level extract installation.

Note 3: Low-level extracts should have a spring-clip-retained pull-off grille face for ease of cleaning.

Low-level extract installation

Traditional installation (not recommended)

- Low-level extract easily obstructed by equipment
- Extra corners to clean around

Figure A26 Low level extract traditional installation (not recommended)

Recommended installation

- low-level extract cut back at 80º and stops short of the floor;
- no added detail to floor covering or coving;
- no additional corners to clean around;
- not easily obstructed by equipment;
- pull-off grille face for ease of cleaning;
- grille still accessible for airflow measurement.

Figure A27 Low level extract recommended installation

The photograph is for illustrative purposes only and shows a cutback of approximately 65º. This was found to make airflow measurement quite difficult, hence the change to an 80º cutback so that measurement can be easily taken with a balometer.

Operating theatre to anaesthetic room air-transfer device

The air-transfer device between an operating theatre and anaesthetic room may be either by a transfer grille or pressure stabiliser. The choice will be determined by the volume of air to be transferred.

Paragraphs A8.51 and A8.52 in Appendix 8 give details.

Appendix 10: Example cause-and- effect check-sheets

Example cause-and-effect check-sheet for general theatre or imaging suite

Site			Date	
Area served			System ID	

	Test	AHU Checks	Y/N	TCP Indication	Y/N
1	AHU Off	Supply and extract dampers closed		Red	
2	Switch AHU "On"	Supply damper open Extract damper open		Red	
		Supply fan start and run Extract fan start and run		Red	
		Prove airflow		Green	
3	Switch AHU to "Set Back"	Supply fan slows Extract fan slows		Red	
4	Switch AHU to Operational speed	Supply fan speeds up Extract fan speeds up		Green	
5	End of day 10 minute warning that system will switch to "Set Back" *(Not all TCPs have this facility)*			Yellow display information box	
	Do nothing	System goes to "Set back"		Red	
	Reset to full speed			Green	
6	End of day 10 minute warning that system will switch to "Set Back" *(Not all TCPs have this facility)*			Yellow display information box	
	Press "Continue"	System stays at full speed for 1 hour		Green	
7	Supply fan fail	System shuts down		Red	
	Reset system to normal			Green	
8	Extract fan fails	Warning on TCP and BMS. AHU locks out if fault not rectified by following day		Yellow display information box	
	Reset system to normal			Green	
9	Theatre/Imaging room temperature to be stable at 20°C at the start of this test.				
	Reduce set point temperature to lowest possible on TCP	Chiller battery valve opens fully Record min temp reached and time taken to stabilise.		Set temp: °C Measured: °C Ind (TCP) °C Time taken mins	
10	Increase set point temperature to highest possible on TCP	Heater battery valve opens fully. Record max temp reached and time taken to stabilise.		Set temp: °C Measured: °C Ind (TCP) °C Time taken mins	
	Reset set point to 20°C			Green	
11	Switch AHU "Off"	Extract fan stops Supply fan stops Extract damper closes Supply damper closes		Red	

Template A13 Example cause-and-effect check-sheet for general theatre or imaging suite

Example cause-and-effect check-sheet for ultra-clean theatres

Site		**Date**	
Area served		**System ID**	

	Test	AHU/UCV Checks	Y/N	TCP Indication	Y/N
1	AHU Off	Supply and extract dampers closed		Red	
2	Switch AHU "On"	Supply damper open Extract damper open		Red	
		Supply fan start and run Extract fan start and run		Red	
		Prove airflow UCV "Off"		Red	
3	Switch AHU to "Set Back"	Supply fan slows Extract fan slows		Red	
4	Switch AHU to Operational speed	Supply fan speeds up Extract fan speeds up		–	
5	AHU at operational speed	Switch UCV on in "Low speed"		Amber = "Conventional Theatre mode"	
	Press "UCV mode"	UCV goes to "Full speed"		Green "UCV Theatre Mode"	
	Press "Conventional Theatre mode"	UCV goes to "Low speed"		Amber	
6	Switch AHU to "Set Back"	UCV goes to "Low speed" or "Off"		Red	
	Reset system to normal	UCV stays in "Low speed"		Amber	
7	Switch UCV "Off"	UCV fans stop		Red	
	Reset system to normal with UCV at full speed			Green	
8	Fail each UCV quadrant fan in turn and Coanda fans (4 + 2)			Red	
	Reset system to normal with UCV at full speed			Green	
9	Trigger HEPA filter high pressure switch			Green plus Blue light	
10	End of day 10 minute warning that system will switch to "Set Back" or "Off" *(Not all Theatre Control Panels have this facility)*			Yellow display information box	
	Do nothing	AHU & UCV go to "Set back" or "Off"		Red	
	Reset to full speed including UCV			Green	
11	End of day 10 minute warning that system will switch to "Set Back" or "Off" *(Not all Theatre Control Panels have this facility)*			Yellow display information box	
	Press "Continue"	System stays at full speed for 1 hour		Green	
12	Supply fan fails	System shuts down. UCV to "Low speed or Off"		Red	
	Reset system to normal			Green	
13	Extract fan fails	Warning on TCP and BMS.AHU locks out if fault not rectified by following day		Yellow display information box	
	Reset system to normal and UCV to full speed			Green	

Site		**Date**	
Area served		**System ID**	

Test		AHU/UCV Checks	Y/N	TCP Indication	Y/N
14	Theatre temperature to be stable at 20°C at the start of this test.				
	Reduce set point temperature to lowest possible on TCP	Chiller battery valve opens fully Record min temp reached and time taken to stabilise		Set temp: °C Measured: °C Ind (TP) °C Time taken mins	
15	Increase set point temperature to highest possible on TCP	Heater battery valve opens fully Record max temp reached and time taken to stabilise		Set temp: °C Measured: °C Ind (TP) °C Time taken mins	
	Reset set point to 20ºC			Green	
16	Switch AHU “Off”	Extract fan stops Supply fan stops Extract damper closes Supply damper closes UCV drops to “Set back”		Red	
Note any additional tests or checks below					

Template A14 Example cause-and-effect check-sheet for ultra clean theatre

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Note: In all cases the most recent version of any Legislation, Regulation, Standard or Guidance document should be consulted

Appendix 12: Abbreviations used in this document

Table A15: Abbreviations and their meanings

Abbreviation	Meaning
ac/h	Air changes per hour
ACDP*	Advisory Committee on Dangerous Pathogens*
ACOP	Approved Code of Practice
AE(V)	Authorising Engineer (ventilation)
AGP	Aerosol-generating procedure
AHU	Air handling unit
AP(V)	Authorised Person (ventilation)
BESA	Building Engineering Services Association
BIM	Building Information Model
BMS	Building Management System
BEMS	Building Energy Management System
BS EN	British Standard European Number
BSRIA	Building Services Research and Information Association
CCA	Critical care area (Level 2 & 3 care)
cfu	Colony forming unit
CIBSE	Chartered Institution of Building Services Engineers
COSHH	Control of Substances Hazardous To Health
CP(V)	Competent Person (ventilation)
CT	Computed tomography (imaging)
DIPC	Director of Infection Prevention and Control
DOP	Dispersed oil particles
DX	Direct expansion (refrigeration cycle)
EC	Electronicaly commutated (fan)
EPA	Efficiency particulate air filter (E10 to E12)
ErP	Energy related products
EU GGMP	European Guide to Good Manufacturing Process (pharmacy)
GRP	Glass reinforced polymer
HBN	Health Building Note
HEPA	High efficiency particulate air filter (H13 to H14)
HIS	Healthcare Infection Society
SHTM	Health Technical Memoranda
IAP	Inspection, assembly and packing (room)
ISO	International Standards Organisation
Level 0 care	Patients whose needs can be met through normal ward care in an acute hospital
Level 1 care	Patients at risk of their condition deteriorating, or recently relocated from higher levels of care, whose needs can be met through normal ward care with additional advice and support from the critical care team.

Abbreviation	Meaning
Level 2 care	Patients requiring more detailed observation or intervention, including support for a single failing organ system or post-operative care and those 'stepping down' from higher levels of care.
Level 3 care	Patients requiring advanced respiratory support alone or monitoring and support for two or more organ systems. This level includes all complex patients requiring support for multi-organ failure.
LEV	Local exhaust ventilation
LSAPC	Light scattering airborne particle counter
MDR-TB	Multi-drug-resistant tuberculosis
MRI	Magnetic resonance imaging
NICU	Neonate intensive care unit
PFI	Private Finance Initiative
PPVL	Positive pressure ventilated lobby (isolation room)
PVC	Polyvinyl chloride
RH	Relative humidity
SCBU	Special care baby unit
SPATA	The Swimming Pool and Allied Trades Association
SUP	Supply air quality
SVHSoc	Specialised Ventilation for Healthcare Society
TB	Tuberculosis
TCP	Theatre control panel
UCV	Ultra clean ventilation
ULPA	Ultra low particulate air filter (U15 to U17)
UV	Ultraviolet
VAV	Variable air volume
VCD	Volume control damper
VSG	Ventilation Safety Group
WEL	Workplace exposure limit

Table A16: Symbols

Symbol	Meaning
ºC(db)	Degrees centigrade (Dry bulb) temperature
K	Kelvin (temperature difference)
% RH	Percentage relative humidity
L/s	Litres per second
µm	Micrometres, microns
ePM1, 2.5, 10	Particle size in micrometres
≥	Equal to or greater than

* ACDP Containment levels

Category 1 biohazard: a biological agent unlikely to cause human disease

Category 2 biohazard: a biological agent that can cause human disease and may be a hazard to employees; it is unlikely to spread to the community and there is usually effective prophylaxis or effective treatment available.

Category 3 biohazard: a biological agent that can cause severe human disease and presents a serious hazard to employees; it may present a risk of spread to the community, but there is usually effective treatment or prophylaxis available.

Category 4 biohazard: a biological agent that causes severe human disease and is a serious hazard to employees; it is likely to spread to the community and there is usually no effective prophylaxis or treatment available.

Note: This publication can be made available in a number of other formats on request.

Scottish Health Technical Memorandum 03-01 Specialised ventilation for healthcare premises (Interim Version – Additional guidance related to COVID 19 to be added in an update in 2022)

Part B: The management, operation, maintenance and routine testing of existing healthcare ventilation systems

February 2022
Interim Version 2.0

Contents

Preface

Note: This SHTM was prepared prior to the COVID-19 pandemic caused by the severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2). It has been reviewed against the known transmission evidence available at the time of publication. Ventilation is one of many mitigations against the virus and should be part of a package of infection prevention and control measures. The ventilation rates recommended in this document are likely to provide a lower risk environment for COVID-19 airborne transmission.

Emerging evidence will continue to be reviewed as and when available.

About Health Technical Memoranda

Health Technical Memoranda (SHTMs) give comprehensive advice and guidance on the design, installation and operation of specialised building and engineering technology used in the delivery of healthcare.

The focus of Scottish Health Technical Memorandum guidance remains on healthcare-specific elements of standards, policies and up-to- date established best practice. They are applicable to new and existing sites, and are for use at various stages during the whole building lifecycle.

Language usage in technical guidance

In SHTMs, SHPNs and HBNs, modal verbs such as “must”, “should” and “may” are used to convey notions of obligation, recommendation or permission. The choice of modal verb will reflect the level of obligation needed to be compliant.

The following describes the implications and use of these modal verbs in SHTMs/SHPNs/HBNs (readers should note that these meanings may differ from those of industry standards and legal documents):

- “Must” is used when indicating compliance with the law;
- “Should” is used to indicate a recommendation (not mandatory/ obligatory), i.e. among several possibilities or methods, one is recommended as being particularly suitable – without excluding other possibilities or methods;
- “May” is used for permission, i.e. to indicate a course of action permissible within the limits of the HBN, SHPN or SHTM.

Typical usage examples

- “All publicly-funded organisations must ensure that all contracts established to collect and treat waste conform to the Public Contracts Regulations.” [obligation]

Note: This guidance is not mandatory (unless specifically stated). However, any departures/ derogations from this SHTM – including the measures implemented – should provide a degree of safety not less than that achieved by following the guidance set out in this SHTM.

- “All low voltage (LV) distributions should be configured as TN systems.” [recommendation]
- “Alcohol hand gels that do not contain siloxanes may be rinsed out and the packaging recycled or placed into the municipal waste stream.” [permission]

“Shall”, in the obligatory sense of the word, is never used in current SHTMs/SHPNs/HBNs.

Project derogations from the Technical Guidance

Healthcare facilities built for the NHS are expected to support the provision of high-quality healthcare and ensure the NHS Constitution right to a clean, safe and secure environment. It is therefore critical that they are designed and constructed to the highest and most appropriate technical standards and guidance. This applies when organisations, providers or commissioners invest in healthcare accommodation (irrespective of status, for example Foundation and non-Foundation trusts).

Note: Statutory standards plus technical standards and guidance specific to NHS facilities:

Health Building Notes/Scottish Health Planning Notes

Scottish Health Technical Memoranda/ Health Technical Memorandum (where no SHTM equivalent exists)

Complete list of NHS estates-related guidance

The need to demonstrate a robust process for agreeing any derogation from Technical Guidance is a core component of the business case assurance process.

The starting point for all NHS healthcare projects at Project Initiation Document (PID) and/or Strategic Outline Case (SOC) stage is one of full compliance.

Derogations to standards will potentially jeopardise business case approval and will only be considered in exceptional circumstances. A schedule of derogations will be required for any project requiring external business case approval and may be requested for those that have gone through an internal approvals process.

While it is recognised that derogation is required in some cases, this must be risk-assessed and documented in order that it may be considered within the appraisal and approval process.

Derogations must be properly authorised by the project’s senior responsible owner and informed and supported by appropriate technical advice (irrespective of a project’s internal or external approval processes).

Sustainability and ‘Net Zero Carbon’ targets

Healthcare provision is a significant contributor to the UK’s carbon footprint. (In 2019, this was estimated to be around 5.4% of our greenhouse gases.) Accordingly, all

NHS organisations have their part to play in meeting Net Zero Carbon targets alongside other sustainability measures.

In January 2020, Health chief Sir Simon Stevens announced three steps the NHS will take during 2020 to tackle this problem:

- NHS England has established an expert panel to chart a practical route map to enable the NHS to get to 'net zero'. The panel will submit an interim report to NHS England in summer 2020 and a final report ahead of the November 2020 UN Climate Change Conference (COP26) in Glasgow. The panel will consider changes the NHS can make in its own activities; in its supply chain; and through wider partnerships;
- the NHS Long Term Plan commits to better use of technologies to make up to 30 million out-patient appointments redundant, sparing patients thousands of unnecessary trips to and from hospital. It is estimated that 6.7 billion road miles each year are from patients and their visitors travelling to the NHS;
- the panel will consider changes that can be made in the NHS's medical devices, consumables and pharmaceutical supply, and areas the NHS can influence such as the energy sector as the health service moves to using more renewable energy.

For specific ventilation-related measures, see the "Net Zero Carbon" section on page 10.

Executive Summary

Preamble

Scottish Health Technical Memorandum 03-01 – 'Specialised ventilation in healthcare premises' is published in two parts:

Part A: The concept, design, specification, installation and acceptance testing of healthcare ventilation systems.

Part B: The management, operation, maintenance and routine testing of existing healthcare ventilation systems.

The documents give comprehensive advice and guidance on the legal requirements, design implications, maintenance and operation of specialised ventilation in healthcare premises providing acute care. The use of these premises is very intense, the occupancy level high and the patients may be particularly susceptible to airborne infection risks. Their condition may also require close control of the environment.

The ventilation of non-healthcare facilities within the hospital curtilage should be designed to suit the application and specific guidance relating to the activity should be followed, for example pharmacy, decontamination unit, etc. However, as they are on the hospital site, the means of providing ventilation should not adversely impact upon the hospital (for example, evaporative cooling towers should not be installed, sound levels should be appropriate and if the facility is within or attached to an area accessed by patients, their needs and the risk of airborne contamination should be considered).

In other types of healthcare facility that are outside of the hospital curtilage, for example GP practices, health centres, minor injuries units, dental, ophthalmic and podiatry clinics, mental health facilities, respite and long stay care homes and hospices, etc, a risk assessment of the nature of the treatment being delivered, condition of the patients and intensity of use needs to be undertaken by those responsible for the facility in order to determine the extent to which this guidance will be applicable.

The guidance contained in Part A of this Scottish Health Technical Memorandum applies to new installations and major refurbishments of existing installations and should be considered as the standard to be achieved.

The guidance contained in Part B of this Scottish Health Technical Memorandum applies to all ventilation systems installed in healthcare premises irrespective of the age of the installation and should be considered as the standard to be achieved.

Scottish Health Technical Memorandum 03-01 (2022) supersedes all previous versions of Scottish Health Technical Memorandum 03-01 – 'Specialised ventilation in healthcare premises' (2011). It also supersedes SHTM 2025 (1994) and DV4 (1983).

Who should use this guidance?

This document is aimed at specifiers, designers, suppliers, installers, estates and facilities managers and operations. Elements of the document will also be relevant to managers concerned with the day-to-day management of healthcare facilities and senior healthcare management.

Main changes since the 2011 edition

- design information for specific healthcare applications has been revised and information on the reason for ventilation given. For example, endoscopy rooms may now be either negative (to contain and remove odours and manage airborne risks to staff) or positive pressure (to maintain a higher level of cleanliness where it is intended to puncture body membranes with the endoscope). These endoscopy-specific risks (i.e. waste anaesthetic gases and pathogenic material (for example, multi-drug- resistant tuberculosis) discharged by the patient during the procedure being undertaken) were identified prior to the SARS-CoV-2 pandemic. As with other elements in Part A, the application of this change is not retrospective but applies to new installations and major refurbishments (see Preamble above);
- the client's needs and legal requirements are more clearly explained;
- this edition of Scottish Health Technical Memorandum 03-01 introduces the concept of the Ventilation Safety Group in healthcare organisations (similar to the Water Safety Group in Scottish Health Technical Memorandum 04-01 and the Electrical Safety Group in Scottish Health Technical Memorandum 06-01). This is a multidisciplinary group whose remit will be to assess all aspects of ventilation safety and resilience required for the safe development and operation of healthcare premises;
- the SHTM introduces a standard method of identifying and labelling ventilation systems and the creation of an inventory of installed systems;
- the issues of resilience and diversity are addressed;
- guidance is provided on refurbishments or when changing the use of an existing installation;
- guidance is given on lifecycle and the updating of mid-life plant;
- design information for specific healthcare application has been extensively revised;
- issues around rooms where anaesthetic agents are used are addressed;
- airflow rates are more tailored to the applications to take advantage of new fan and control technology and so reduce energy consumption;
- revised air quality and filter standards are given;
- new and emerging technologies are catered for;
- advice is given on installation standards and the appointment of an independent validator;
- more detailed information is given on the commissioning process;
- validation acceptance standards and methodology has been completely revised;

- routine inspection and maintenance guidance has been revised and updated.

Net zero carbon

Scottish Health Technical Memorandum 03-01 supports UK legislation to bring all greenhouse gas emissions to net zero by 2050, and promotes sustainable methods of ventilation in healthcare facilities.

The SHTM's core principle is that the default method of ventilation should as far as possible be natural ventilation followed by mixed mode (natural with mechanical ventilation), with mechanical ventilation being the last option.

The energy consumption of ventilation systems should be further minimised by specifying solutions with the lowest lifecycle environmental cost. The basic objective of energy-saving strategies in this SHTM is to provide the required ventilation service using the minimum energy. To this end, Scottish Health Technical Memorandum 03-01 recommends switching a system "off" when not required to be the most energy-efficient policy. If the system is needed to maintain a minimum background condition, reducing its output by "setting back" to the minimum necessary to achieve and maintain the desired condition is the next best option.

Fans represent an enormous potential for energy savings to reduce carbon emissions, as they are among the largest single users of energy (they use approximately 40% of all electricity in ventilation systems). The European Regulation 1253/2014, implementing the Energy-related Products (ErP) Directive, has significantly reduced the power to drive fans. Accordingly, Scottish Health Technical Memorandum 03-01 recommends using electronically commutated fans, as these have been proven to be the most energy-efficient, while also advising that belt-driven fans should no longer be installed.

There have been many legislative changes aimed at reducing energy consumption and technical advances that have increased operational efficiency. This revised SHTM incorporates those changes and has amended many of the design parameters for healthcare ventilation. Designs that are simply repeated from previous installations designed to superseded standards and guidance will not meet the revised energy or operational standards and will not produce a compliant result.

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1. Introduction

Preamble

1.1 Scottish Health Technical Memorandum 03-01

'Specialised ventilation in healthcare premises' is published in two parts: Part A deals with the concept, design, specification, installation and acceptance testing of ventilation systems; Part B covers the management, operation, maintenance and routine testing of existing healthcare ventilation systems.

1.2 The document gives advice and guidance to healthcare management, design engineers, estates managers and operations managers on the legal requirements, design implications, maintenance and operation of specialised ventilation in all types of healthcare premises.

1.3 The guidance contained in Part B of this Scottish Health Technical Memorandum applies to all ventilation systems installed in healthcare premises irrespective of the age of the installation.

1.4 This revision of Scottish Health Technical Memorandum 03-01 supersedes the 2011 version of Scottish Health Technical Memorandum 03-01.

Ventilation in healthcare premises

1.5 Ventilation is used extensively in all types of healthcare premises to provide a safe and comfortable environment for patients and staff. It is provided to help control airborne infection risks in areas such as operating departments, critical care facilities, isolation rooms and treatment areas.

1.6 It may also be installed:

- to maintain a suitable environment by removing odours and controlling temperature;
- to ensure compliance with the quality assurance requirements of items processed in pharmacies and decontamination units;
- to protect staff from harmful organisms or toxic substances, for example in laboratories and anaesthetic rooms;
- to contain the spread, and clear smoke as part of the fire strategy.

Statutory requirements

The Health Act 2009

1.7 The Health Act places a duty of care on healthcare providers. Increased health risks to patients will occur if ventilation systems do not achieve and maintain the required standards. The link between surgical site infection and theatre air quality has been well established. If the ventilation plant has been installed to dilute or contain harmful

substances, its failure may expose people to unacceptable levels of contamination. Breaches of the statutory requirements can result in prosecution and may also give rise to a civil suit against the operators.

Health and Safety at Work etc. Act 1974

1.8 The Health and Safety at Work etc. Act 1974 is the core legislation that applies to ventilation installations. As these installations are intended to prevent contamination, closely control the environment, dilute contaminants or contain hazards, their very presence indicates that potential risks to health have been identified.

COSHH

1.9 The Control of Substances Hazardous to Health (COSHH) Regulations 2002 (as amended) place upon management an obligation to ensure that suitable measures are in place to protect their staff and others affected by the work activity. These methods may include both safe systems of work and the provision of a specialised ventilation system. In laboratories the requirements are often met by the provision of fume cupboards and microbiological safety cabinets.

1.10 Where specialised ventilation plant is provided as part of the protection measures, there is a statutory requirement that it be correctly designed, installed, commissioned, operated and maintained. The local exhaust ventilation (LEV) section of COSHH requires that the system be examined and tested at least every 14 months by a competent person (P601 certified) and that management maintain comprehensive records of its performance, repair and maintenance.

1.11 Certain substances have workplace exposure limits (WELs) set out in the Health and Safety Executive's Guidance Note EH40

'Workplace exposure limits' contains the list of workplace exposure limits for use with the Control of Substances Hazardous to Health Regulations 2002 (as amended). If specialised ventilation systems are provided in order to achieve these standards, they will be subject to the COSHH Regulations as above.

Workplace (Health, Safety and Welfare) Regulations

1.12 These state that all enclosed workplaces must be ventilated by natural or artificial means.

1.13 Any plant provided under this legislation shall include an effective device to give an audible or visual warning of plant failure where necessary for health and safety.

1.14 The Regulations require that ventilation systems are "maintained in an efficient state, in efficient working order and in good repair".

Building Regulations

1.15 These apply to domestic and non- domestic buildings.

1.16 They clarify satisfactory methods of providing ventilation and give ventilation rates.

1.17 They set minimum standards for:

- the protection of the supply position;

- precautions against Legionella;
- the purity of recirculated air;
- access for service and maintenance;
- documentation and proof of performance.

Fire regulations

1.18 The fire regulations require that, if ventilation ductwork penetrates the fabric of a building, it should be designed and installed to contain the spread of fire and smoke (see the Health Technical Memorandum 05 series for guidance).

1.19 When a ventilation system was originally designed, it will have conformed to an agreed fire strategy. This will have determined the provision of fire-rated ductwork, the siting of fire and smoke dampers and an agreed control action for the ventilation fans in the event of a fire.

1.20 It is management's responsibility to ensure that the fire strategy applied during the design and installation of a system is not reduced during the subsequent operation and maintenance of the equipment.

1.21 If a ventilation system is upgraded or altered to suit a change of use, it will be necessary to reassess the fire strategy.

Plant installed for units manufacturing medicinal products

1.22 Plant installed for units manufacturing medicinal products to the standards set out in the current European guide to good manufacturing practice may also be subject to particular legislation with regard to their operation in addition to that mentioned above.

1.23 There are specific requirements under the Medicines Act 1968 to maintain accurate records of plant performance, room conditions and maintenance events. Such records would need to be preserved for at least 25 years as part of a quality assurance audit trail.

Plant installed for laboratories

1.24 Specialised ventilation plant installed for laboratories dealing with research, development, testing or other specialist applications (this could concern medicinal products, IVF, tissue, animals or genetically modified organisms) may be subject to particular legislation with regard to their operation in addition to that mentioned above.

Codes of practice and guidance

1.25 All ventilation systems should conform to the principles set out in the Health and Safety Executive's (HSE) Approved Code of Practice and guidance on regulations – 'Legionnaires' disease: the control of Legionella bacteria in water systems' (commonly known as L8), and Scottish Health Technical Memorandum 04-01 – 'Safe water in healthcare premises'.

1.26 The HSE has published complementary technical guidance in HSG274, which is split into three specific areas:

- Part 1 – evaporative cooling systems
- Part 2 – hot and cold water systems
- Part 3 – other risk systems.

1.27 The Department of Health publication 'The Health and Social Care Act (2013) Code of Practice on the prevention and control of infections and related guidance' (the HCAI Code of Practice) is a code of practice that helps NHS bodies to plan and implement how they can prevent and control healthcare-associated infections. It sets out criteria by which managers of NHS organisations are to ensure that patients will be cared for in a clean environment and where the risk of healthcare-associated infections is kept as low as possible. Specialised ventilation systems often play a significant role in achieving this objective.

Management responsibilities – general

1.28 It is a management responsibility to ensure that inspection, service and maintenance activities are carried out safely without hazard to staff, patients or members of the public.

1.29 Those required to monitor and/or maintain ventilation equipment will need to show that they are competent to do so (see Chapter 2).

1.30 Maintenance procedures should be reviewed periodically to ensure that they remain appropriate.

1.31 The preservation of information and records of ventilation systems and their performance is a legal requirement. It is therefore essential that records are kept in a form that when archived can be accessed when necessary. Keeping records on a dedicated computer drive unit within the estates department, while satisfactory for day-to-day operation, is not adequate for archival storage.

1.32 Estates statutory maintenance records will be retained and managed through the healthcare provider's information governance arrangements. Estates departments should periodically archive their records of statutory and critical systems.

System information

1.33 An inventory of all ventilation systems installed and in use or capable of being used will need to be kept. The inventory should be readily accessible within the operational section of the estates department in hard copy and electronic form.

1.34 The inventory should be subdivided into the following categories:

- local exhaust ventilation systems - (LEV) – note these are statutory items;
- critical healthcare ventilation systems – (CHV). (These are systems the loss of which would seriously limit the delivery of healthcare, for example operating suite, NICU, critical care area, interventional imaging suite, aseptic suite);

- general ventilation system [supply and extract] (GVS);
- general extract systems (GES);
- systems installed for smoke clearance in the event of a fire, classed as smoke and heat exhaust ventilation systems (SHEVS) (for example, smoke extract fans in stairwells, automatic smoke clearance dampers in atria).

1.35 For each ventilation system the inventory should contain the following details:

- a unique system identification code for example LEV 001; CHV 001 etc as appropriate;
- the location of the ventilation fan unit or supply and extract air-handling unit(s) (AHU(s));
- the location of the fresh air inlet;
- the location of the extracted air discharge;
- the specific area(s) served by the system;
- the date the system was installed;
- the date the system was first commissioned;
- the date of its annual inspection;
- the date and details of any significant alterations or replacements made to the system.

1.36 When systems are removed or replaced, their unique identification code should be transferred from the inventory to an archive together with all its records.

These should be retained for a minimum of five years (25 years for a manufacturing pharmacy) (see paragraphs 1.31 and 1.32).

1.37 New or replacement systems should be allocated a new unique identification and added to the inventory.

1.38 Each ventilation system should have a log (physical or electronic) that contains the following information:

- the unique system identification reference;
- purpose of the system;
- date of installation;
- details of the installed equipment and ductwork layout;
- detail of the fire plan, any fire-rated ductwork and location of fire and smoke dampers;
- design performance parameters, for example airflow rates, air-change rates, pressures, etc.;
- commissioned date and performance;
- record of the system validation and original acceptance;

- records of the annual inspection and verification;
- maintenance records and plant information, for example fan specifications and filter sizes.

1.39 The records should be linked to the inventory and stored in such a way as to be readily available in the event of plant breakdown or other incident.

1.40 When new ventilation systems are accepted for use, full information as to their designed mode of operation together with recommended maintenance procedures should be provided as part of the handover procedure (Building Regulations 2010 Part 8 Para 39). Part A of this Scottish Health Technical Memorandum gives design parameters for new installations and lists the handover information required.

1.41 Many new installations are designed and stored electronically within a building information modelling (BIM) program. It is important to update the BIM model if there are any physical changes made or design parameters modified during the life of the system.

1.42 In existing systems, original design and commissioning information will often not be available. It will be necessary to determine a suitable level of system performance based on the function, purpose and age of the installation. This information should be entered in the system log file and form the baseline for the annual verification.

1.43 Chapter 3 of this document sets out the minimum standards for all air handling units (AHUs) and their air distribution systems irrespective of when they were installed.

Note: The minimum standards were first set out in Scottish Health Technical Memorandum 2025, 1994.

1.44 All system records must be kept for at least five years (25 years for a manufacturing pharmacy). The Health and Safety Executive and other interested bodies such as the Care Quality Commission (CQC) have a statutory right to inspect them at any time (see paragraph 1.31).

Action in the event of an incident

1.45 In the event of a reportable incident connected with ventilation equipment or the area that it serves, copies of all records and plant logbooks may need to be collected as evidence. The requirements of the Reporting of Injuries, Diseases and Dangerous Occurrences Regulations (RIDDOR) will apply.

Note: In the event of an incident, while there may be a legal requirement to hand over information and records to the investigator, it is essential that the healthcare provider retains copies as they will be necessary for the continued safe operation and maintenance of the system, which is a legal requirement.

Frequency of inspections and verifications

1.46 In order to comply with the Workplace (Health, Safety & Welfare) Regulations and Building Regulations, it is essential that all ventilation systems must be subject to at least a simple visual inspection annually.

1.47 In order to comply with the provisions of the Health Act, all CHVs should be inspected quarterly and their performance measured and verified annually. The quarterly inspection should be a simple visual check; the annual verification will be a more detailed inspection of the system together with the measurement of its actual performance.

1.48 Chapter 4 sets out the annual inspection and verification requirements and a supporting set of specimen checklists is given in the Appendices. Equipment manufacturers and suppliers may also recommend specific maintenance inspections.

1.49 The LEV section of the COSHH regulations contains a statutory requirement that systems installed to contain or control hazardous substances be examined and tested at least every 14 months by a competent person (P601 certificated). The statutory inspection and test must be of the complete system from the point of capture to the point of discharge.

1.50 Regular tests, at intervals agreed with the local fire prevention officer, will need to be carried out in order to demonstrate the continuing efficiency of the fire detection and containment systems. These may be in addition to the inspections detailed above. Records of these tests must be kept.

Lifecycle of ventilation systems

1.51 Plant should be scheduled for replacement after 20 years. CIBSE Guide M gives advice on plant lifecycle and the risk assessment of plant condition. In order to secure funding and programme downtime for the area served, a site-wide plant replacement programme should be in place. As an example, if a site has 40 AHUs then at least two will need to be replaced every year. The plant replacement should coincide with a refurbishment of the area served.

Note: If the site was a new build with all plant of the same age, then assessment of the replacement programme should commence after 10 years as it will not be practical to replace all units simultaneously at the 20-year mark.

1.52 The Ventilation Safety Group (VSG) (see Chapter 2) will prioritise the replacement programme. Failure to plan for plant replacement has led to unplanned system failures with a consequent loss of the facility that they serve and cancellation or disruption to patient services.

1.53 In order to maintain efficiency, ventilation systems should be refurbished at their mid-life point (typically 10 years after original installation). The complete system should be taken out of use and thoroughly inspected. The AHU and its distribution ductwork should be cleaned as appropriate, any internal corrosion investigated and treated, the complete control system up-graded and the entire installation rebalanced and recommissioned. The performance of the system should be validated (see Chapter

12 in Part A of this Scottish Health Technical Memorandum) before being returned to service.

Note: During this process the opportunity should be taken to replace any belt- driven fans with the most energy- efficient fans available, for example electronically commutated (EC) plug fans or direct-drive plug fans. (Chapter 9 in Part A of this Scottish Health Technical Memorandum gives details of fan types and preferred selection and installation strategies.)

1.54 Whenever an area of the healthcare estate is being refurbished, the condition and energy performance of its ventilation plant should be reviewed. The plant should be upgraded, refurbished or replaced as appropriate in order to take advantage of the most energy-efficient equipment and control methods available at the time.

Competency

1.55. The Board and their supply chain must ensure that the competence of all parties is considered at the point of their introduction and on an ongoing basis. The philosophies that are included in the HSE leaflet INDG368 (current revision), "Using Contractors" should be adopted. In addition, the outputs from the "Setting the Bar" report should be adopted as they are introduced through legislation. Evidence that the recommendations of "Setting the Bar" are being implemented in advance of the legislation would be considered to be good practice, particularly for high risk buildings. BSI Flex 8670 “Built environment. Core criteria for building safety in competence frameworks. Code of practice” should also form part of the project planning.

2. Functional responsibilities

Management responsibilities

2.1 Clear lines of managerial responsibility should be in place so that no doubt exists as to who is responsible for the safe operation and maintenance of the equipment.

2.2 A periodic review of management systems should take place in order to ensure that the agreed standards are being maintained.

2.3 Those required to inspect, verify or maintain ventilation equipment will need to show that they are competent to do so. As a minimum they should have sufficient knowledge of its correct operation to be able to recognise faults.

2.4 Training in the validation and verification of specialised healthcare ventilation systems for Authorised Persons (APs) and Competent Persons (CPs) is available from a variety of providers. While there is a duty on post holders to keep their knowledge up to date, as reflected for APs in their CPD record, there is no requirement to routinely attend any specific refresher course.

Designated staff functions

2.5 A person intending to fulfil any of the staff functions specified below should be able to prove that they possess sufficient skills, knowledge and experience to be able to safely perform the designated tasks (see Chapter 3 in Scottish Health Technical Memorandum 00 for more detailed information).

Management (Duty Holder)

2.6 Management is defined as the owner, occupier, employer, general manager, chief executive or other person who is ultimately accountable for the safe operation of premises.

Designated Person

2.7 This person provides the essential senior management link between the organisation and professional support. The Designated Person should also provide an informed position at board level and confirm the appointment of the following staff in writing.

Authorising Engineer (Ventilation) (AE(V))

2.8 The AE(V) is defined as a person designated by Management to provide independent auditing and advice on ventilation systems, to review documentation on verification and validation and witness the process as necessary.

Note: Authorising Engineers should be able to show that they are free to provide independent advice and have been subject to an assessment of their competence by a registration body.

Authorised Person (Ventilation) (AP(V))

2.9 The AP(V) will be an individual possessing adequate technical knowledge and having received appropriate training, appointed in writing by the Designated Person (in conjunction with the advice provided by the AE(V)), who is responsible for the practical implementation and operation of Management's safety policy and procedures relating to the engineering aspects of ventilation systems.

Competent Person (Ventilation) (CP(V))

2.10 The CP(V) is defined as a person designated by Management to carry out maintenance and periodic testing of ventilation systems.

Infection Prevention and Control Person

2.11 The Infection Prevention and Control Doctor or consultant microbiologist is the person nominated by management to advise on monitoring the infection control policy and microbiological performance of the systems.

User

2.12 The User is the person responsible for the management of the unit in which the ventilation system is installed (for example head of department, operating theatre manager, laboratory manager, production pharmacist, head of research or other responsible person).

Contractor

2.13 The Contractor is the person or organisation responsible for the supply of the ventilation equipment, its installation, commissioning, validation, verification or decommissioning. This person may be a representative of a specialist ventilation organisation or a member of the general manager/chief executive's staff.

Appointment of post holders

2.14 All post holders should be appointed in writing by the "Designated Person" (see paragraph 2.7). A record should be kept of those appointed to carry out the functions listed above. The record should clearly state the extent of the post holder's duties and responsibilities, and to whom they are to report.

2.15 Substitute or replacement staff should be designated in order to cover for sickness, holidays and staff transfers.

Ventilation Safety Group (VSG)

2.16 The management of the ventilation systems of a healthcare provider should be overseen by the Ventilation Safety Group (VSG). The VSG should have clearly defined roles and responsibilities, be part of a healthcare organisation's governance structure and report to the designated person at Board level. It will be led and chaired by a person who has appropriate management responsibility, knowledge, competence and experience (for example the Designated Person).

2.17 The VSG should be a multidisciplinary group and will typically comprise:

- an AE(V)/independent adviser for ventilation;
- an Infection Prevention and Control Person (as defined above);
- the AP(V);
- estates (operations and projects) staff;
- clinicians and specialist departments (for example theatres, critical care, pharmacy, medical microbiology, nursing);
- personnel from the finance department with accountability for capital and revenue evaluation;
- other stakeholders as appropriate;
- co-opted expertise, for example ventilation designers, consultants and suppliers.

2.18 The VSG remit will be to assess all aspects of ventilation safety and resilience required for the safe development and operation of healthcare premises. It should inform the following areas:

- the design process for new healthcare premises;
- the design process for modifications to existing premises;
- the commissioning and validation process;
- operational management and maintenance;
- annual verification and performance testing;
- prioritising the plant replacement programme;
- decommissioning and removal of redundant equipment.

Note: Where estates-and-facilities provider services are part of a contract (including PFI), it is essential that these providers participate fully in all those aspects of estates-and-facilities management that can affect patients. This includes responding to specific requests from the VSG, which may be in addition to relevant guidance and documentation.

2.19 It is important that decisions affecting the resilience, safety and integrity of the ventilation systems and associated equipment are not taken without the agreement of the VSG. The VSG should ensure that appropriate expertise and competence is available when making such decisions. Whenever significant building work is undertaken, the VSG should consider its effects on the existing ventilation system air intakes. These may need to be protected from airborne dust during construction by the fitting of temporary additional filtration. There will also be a need to identify any risks to construction personnel working in the vicinity of extract air discharges.

2.20 When building work is undertaken inside a building, the VSG should be consulted to determine its effects on the occupants. The VSG may need to specify the extent to which the area is to be sealed off from the operational parts of the building and the need for a temporary extract unit in order to maintain the worksite at a negative pressure to prevent the spread of contaminants into the rest of the building.

2.21 The healthcare provider, through its VSG, will be able to demonstrate that they have suitable governance, competence and accountability arrangements in place to

provide safe critical ventilation systems and appropriate clinical environments in their premises.

Ventilation policy document

2.22 The VSG will produce a ventilation policy document for the healthcare provider. In its simplest form this may just be a statement that the healthcare provider will follow the guidance contained in Scottish Health Technical Memorandum 03-01 Parts A and B as appropriate. It may also specify any departures from that guidance in terms of local additional requirements or derogations.

2.23 The policy document will be endorsed by the healthcare provider's board.

Specific health and safety aspects

2.26 Staff engaged in the service and maintenance of extract ventilation systems from pathology departments, mortuaries, laboratories, isolation facilities and other areas containing a chemical, biological or radiation hazard may be particularly at risk. In these cases, the risk should be identified and assessed.

2.27 The VSG should be consulted as to the means by which the system can be rendered safe to work on and a permit-to-work system implemented. Appendix 3 gives an example of a typical equipment release certificate (ERC) that could be used for routine inspection and maintenance by competent persons.

2.28 Training in the exact procedures should be given to all staff involved.

2.29 Some healthcare facilities may contain specialised units that are subject to access restrictions (for example pharmacy aseptic suites). Estates or contract staff requiring access may need additional training or be accompanied when entering the unit.

2.30 See also the following guidance published by the Health and Safety Executive:

- 'Safe working and the prevention of infection in clinical laboratories and similar facilities'.
- 'The management and operation of microbiological containment laboratories'.
- HSG 283 – 'Managing infection risks when handling the deceased: guidance for the mortuary, post- mortem room and funeral premises, and during exhumation'.

3. Ventilation systems – minimum standards

General requirements

3.1 All ventilation systems irrespective of when they were installed are to be inspected annually to ensure conformity with minimum standards required by the Building Regulations. These are designed to:

- assure the quality of intake air;
- ensure that extract air is discharged in a suitable location;
- prevent or control risks associated with Legionella and other potential hazardous organisms;
- ensure safe access when carrying out routine service and maintenance activities;
- provide documentary proof of performance.

3.2 All AHUs and their associated ventilation systems should achieve the minimum standard set out below.

Note: These standards have not changed since Scottish Health Technical Memorandum 2025 was issued in 1994 so all systems currently in use should therefore achieve them.

Location and access

3.3 All ventilation plant should be secured from unauthorised access.

3.4 It is a requirement to uniquely identify individual plantrooms on site and fix a list just inside the door detailing the major plant elements within and the areas that they serve.

3.5 Plantrooms should, where possible, be provided with a sink so that glass drainage traps may be cleaned out and staff can wash their hands after handling dirty filters. A source of DHW with a hose connection point will also be required so that AHUs can be washed out internally as part of their routine maintenance.

3.6 Units located on roofs should have a safe and permanent means of access and adequate illumination as they may need to be accessed at any time. Suitable precautions should be in place to prevent personnel or equipment from falling off during maintenance activities.

3.7 Units located outside at ground level should be secured within a compound to prevent unauthorised access or preferably within a plantroom. Vehicles should be excluded from the vicinity to ensure that exhaust fumes will not be drawn into intakes.

3.8 All parts of the AHU should be easily and safely accessible for routine inspection, service and maintenance.

3.9 The area around an AHU within a building should be tanked to prevent water penetration to adjacent areas, and should be adequately drained.

3.10 Fire precautions should be in accordance with the Health Technical Memorandum 05 series.

3.11 Combustion equipment must not be located in a fire compartment that houses air-handling equipment.

3.12 Plantrooms that house AHUs should not be used for general storage. Care should be taken to ensure that the amount of combustible material in a plantroom is kept to an absolute minimum. Ventilation stock such as filters should be kept in a central store.

3.13 If a spare set of filters is kept in the plantroom they should be kept in their original packing to preserve them from contamination and stored off the floor so that they cannot become wet. The number stored should be kept to a minimum to reduce the fire load in the plantroom. Used filters should be placed in an empty box or bag and removed immediately.

3.14 Spare fans should be stored on a purpose-built rack near the plantroom entrance. Staff should be instructed to “spin” the fan every time they enter the plantroom to help prevent the bearings settling.

Identification and labelling

3.15 All ventilation systems should be clearly identified with a permanent label in accordance with the requirements of paragraph 1.33 onwards. The label should identify both the AHU and the area that it serves. The lettering should be at least 100 mm high and be mounted in an easily visible place near the fan of the unit adjacent to the local electrical isolator. Any subsystems and the principal branch ducts should be similarly labelled as should any associated control panels.

3.16 The nature and direction of airflow should be clearly marked on all main and branch ducts (see BS1710).

3.17 All airflow test-points should be clearly identified with a permanent label and the design information given (for example TPS 1 – Anaesthetic supply; 400 × 300; Design 185 L/s).

Basic requirements

3.18 The ventilation system should not contain any material or substance that could support the growth of micro- organisms.

3.19 Access to items that require routine service, such as filters, fog coils and cooling coils, should be via hinged doors.

3.20 Items requiring infrequent access such as attenuators may be via clipped or bolted-on lift-off panels.

3.21 All doors and panels should be close- fitting and without leaks.

3.22 Access to plant and equipment above 1.5 m should be via platforms, fixed ladders, hook ladders, pulpit-style movable steps or access platforms.

3.23 Electrical and mechanical services should not restrict or impede access to those parts of the plant that require inspection.

3.24 Viewing ports and internal illumination should be fitted in order to inspect filters and drainage trays.

3.25 Internal illumination should be provided by luminaires to at least IP55 rating. Fittings are to be mounted inside the unit so that they provide illumination for inspection and task lighting when the access doors are open.

3.26 A single clearly labelled switch should operate all the lights in a unit.

AHU intakes and discharges

3.27 Intake and discharge points should not be situated where they will cause vitiated air to be drawn into a system (paragraph 9.30 onwards in Part A of this Scottish Health Technical Memorandum gives detailed information). In existing systems, it may be necessary to extend the intake or discharge point to a suitable position.

Note: Steps should be taken to prevent birds landing or roosting in the vicinity by removing ledges or fitting anti-pigeon spikes.

3.28 Each intake and discharge point should be fitted with corrosion-resistant weatherproof louvres or cowls to protect the system from driving rain. The inside of the louvres should be fitted with a mesh of not less than 6 mm and not more than 12 mm to prevent infestation by vermin and prevent leaves being drawn in.

3.29 The duct behind a louvre should be self-draining. If this is not practicable, it should be tanked and provided with a drainage system. Cleaning access should be provided either from the outside via hinged louvres or by an access hatch or door in the plenum behind the louvre. Where a common plenum is provided, cleaning access should be via a walk-in door. If the intake plenum is a builder’s work duct, all of its surfaces should be sealed to prevent dust being shed into the airflow.

Plant drainage system

3.30 All items of plant that could produce moisture should be provided with a drainage system. The system will comprise a drip-tray, borosilicate glass trap, air gap and associated drainage pipework.

3.31 Some older units may not have been mounted far enough above the floor to permit the correct installation of a drainage system. If the AHU cannot be raised to an adequate height, an alternative arrangement (such as a pump-out system) should be provided.

3.32 The drip-tray should be constructed of a corrosion-resistant material (stainless steel is preferred) and be so arranged that it will completely drain. To prevent “pooling”, it is essential that the drain connection should not have an upstand and that a slope of

approximately 1 in 20 in all directions should be incorporated to the drain outlet position.

3.33 In AHUs that have access doors large enough for a person to enter, the drip-tray should be easily accessible for inspection and cleaning.

3.34 In AHUs with access doors too small for a person to enter, the complete drip-tray should be capable of being withdrawn. It should be clamped into the AHU with thumbscrews so that it can be removed without the need for tools.

3.35 Each drip-tray should be provided with its own drain trap. The drain trap should be of the clear (borosilicate) glass type. This permits the colour of the water seal to be observed, thus giving an early indication of corrosion, biological activity or contamination within the duct (see Table 3 in Chapter 5).

3.36 The trap should have a means for filling and should incorporate couplings to facilitate removal for cleaning. It should be located in an easily visible position where it will not be subject to casual knocks. The pipework connecting the drainage tray to the trap should have a continuous fall of not less than 1 in 20.

3.37 Traps fitted to plant located outside or in unheated plantrooms may need to be trace-heated in winter. The trace heating should be checked for operation. It should be ensured that the temperature of water in the trap does not exceed 5°C.

3.38 Water from each trap must discharge via a clear air gap of at least 15 mm above the unrestricted spill-over level of either an open tundish connected to a drainage stack via a second trap, or a floor gully (or channel) or directly onto a roof (if in a location that will not cause a slip hazard). A support should be provided to ensure that the air gap cannot be reduced. More than one drain trap may discharge into the tundish, providing each has its own air gap.

3.39 Drainage pipework from the tundish may be copper, thermoplastic or stainless steel. Glass should not be used. The pipework should be a minimum diameter of 22 mm and have a fall of at least 1 in 60 in the direction of flow. It should be well supported, and located so as not to inhibit access to the plant.

Dampers

3.40 All AHUs should be fitted with motorised low-leak shut-off dampers at their intake and discharge ends. The damper actuators should be fitted with end switches and be spring-return so that they close automatically on power failure. Note that all new plant will in addition have motorised dampers at the supply and return air ends of an AHU.

Fans and their drives

3.41 Belt-and-pulley fan drive-trains external to the AHU, whether supply or extract, should be easily visible without the need to remove access covers. Protecting the drive-train with a mesh guard is the preferred option. For weatherproof units located outside, the fan drive should be enclosed. It should be easily visible through a viewing port with internal illumination and be accessed via a lockable hinged door.

3.42 Plug and EC fan units are mounted inside the AHU. Their access door should have a viewing port and internal illumination. The door should be fitted with a two-stage opening latch so that if the door is inadvertently opened when the fan is running it will not blow outwards.

3.43 The motor windings of induction-drive “plug” motor arrangements, EC fans and in-line axial fans having a pod motor within the airstream must be protected from over-temperature by a thermistor and lock- out relay.

3.44 It is necessary to ensure that – should the computer control system or its software develop a fault – the fan in an AHU serving a critical healthcare application can be switched to a fixed speed and manual operation.

Heater-batteries

3.45 Access for cleaning will need to be provided to both sides of all fog coils and heater-batteries.

Cooling coils

3.46 All cooling coils, whether within the AHU or a branch duct, should be fitted with their own independent drainage system as specified above. A baffle or similar device in the drip-tray will prevent air bypassing the coil. The tray should be large enough to capture the moisture from the eliminator, bends and headers.

3.47 The cooling-coil control valve should close upon selection of low speed, system shut-down, low airflow or fan failure.

3.48 Where auxiliary wet cooling coils are located in false ceilings, they should be fitted with a catch tray and leak alarm. The catch tray should be installed under both the battery and the control-valve assembly to protect the ceiling from leaks. A moisture sensor and alarm should be fitted in the tray.

Eliminators

3.49 Where fitted they should be removable so that the face of the cooling coil can be inspected and cleaned as necessary. In new units the eliminator will be mounted on slide rails for ease of removal. In existing systems, if bolted in position it should be secured with thumbscrews (not tech/spire screws) and fitted with lifting handles to enable removal and replacement without the use of tools.

Humidifiers

3.50 Humidifiers are not generally required. Chapters 8 and 9 in Part A of this Scottish Health Technical Memorandum give examples of where humidification may be required.

3.51 Where they are fitted, but have been out of use for a significant period of time, they should be removed. All associated supply pipework must also be removed back to its

junction with the running main. Their drainage trap should be removed and the tray capped off.

3.52 Where humidifiers are fitted and their use is still required, they should fully conform to the installation standard set out in Chapter 9 of Part A of this Scottish Health Technical Memorandum.

3.53 The section of ductwork containing the humidifier may need to be periodically decontaminated. Hinged access doors with viewing ports and internal illumination should be provided.

3.54 All humidifiers should be fitted with their own independent drainage system as detailed in paragraph 3.30 onwards.

3.55 Only steam-injection humidifiers, whether mains steam fed or locally generated, are suitable for use in ventilation systems within healthcare facilities. Water humidifiers, if fitted, must be removed.

3.56 Self-generating steam humidifiers must be supplied with wholesome water. The installation should be capable of being isolated, drained and cleaned.

3.57 Some steam generators require regular cleaning and descaling. The installation should enable them to be physically isolated from the air duct in order to prevent contamination of the air supply by cleaning agents.

3.58 The humidifier control system should fully conform to the standard set out in Chapter 9 of Part A of this Scottish Health Technical Memorandum.

Filtration

3.59 Filters should be securely housed in well-fitting frames that minimise air bypass. Air bypass significantly reduces filter efficiency; the higher the filter grade, the greater the effect. In horizontal AHUs the mounting frames should be designed so that the airflow pushes the filter into its housing to help eliminate air bypass. Supports with seals will master the joints between filters.

3.60 All filters should be of the dry type. Panel filters are generally used as prefilters and should be positioned on the inlet side of the supply fan, downstream of the fog/ frost coil. Where required, secondary filters (these will be bags or pleated paper) should be on the positive-pressure side of the fan.

3.61 The filter installation should provide easy access to filter elements for cleaning, removal or replacement; therefore, a hinged access door should be provided. The upstream side of the filter should be visible for inspection through a viewing port with internal illumination.

3.62 All filters should be provided with a means of checking the differential pressure across them. Direct-reading dial-type gauges marked with clean and dirty sectors are preferred.

Note: Direct-reading gauges may be omitted (if desired) providing the filter differential pressure is continuously monitored by a sensor connected to the BMS and there are capped tappings so that a portable gauge can be attached when required for diagnostic purposes or fault-finding.

Efficiency (EPA) and high- efficiency (HEPA) filters

3.63 Where fitted, EPA or HEPA filters should be of the replaceable-panel type with leak-proof seals. Their installation should permit the validation of the filter and its housing.

3.64 EPA or HEPA filters fitted in supply ducts should have a metal case so that they cannot support fungal growth.

3.65 EPA or HEPA filters are sometimes used in extract systems to prevent the escape of hazardous substances or organisms. They may be supplied with a particleboard or plywood case so that they can be disposed of by incineration.

3.66 When used for the containment of hazardous substances, the installation should incorporate design provision for the subsequent safe removal and handling of contaminated filters by maintenance staff (see paragraph 5.16).

Note 1: In view of the costs and problems associated with placing EPA or HEPA filters in extracts, it is essential that a full risk assessment be carried out in conjunction with the VSG. It should include defining the true need for a filtered extract, the validation of its performance at installation, the method of safely changing a contaminated filter, and its subsequent disposal.

Note 2: General extracts from mortuaries and post-mortem rooms may contain odours, but these are not in themselves hazardous to health and do not require filtration prior to discharge. In high-risk post-mortems (for example, known or suspected tuberculosis cases), the infected organs will be removed and then dissected in a class 1 microbiological safety cabinet provided under the COSHH Regulations. Extracts from infectious disease Isolation rooms or wards do not normally require filtration prior to discharge. However, if the discharge cannot be made in a safe location and it is likely that the vitiated air could be drawn back into the building or there are people in its vicinity (for example, a discharge into a courtyard), filtration would be required.

Energy recovery

3.67 Energy recovery, where fitted, will require cleaning access to both sides of the device.

3.68 Whichever type of energy recovery device is fitted, the extract side should be protected by an ISO ePM10 ≥ 50% filter and provided with a drainage system to remove condensate.

3.69 The energy-recovery device should be controlled in sequence with the main heater-battery, and may need to incorporate a control to prevent the transfer of unwanted heat when the air-on condition rises above the plant’s required set-point.

Attenuation

3.70 Cleaning access should be provided at both ends of any attenuator unit.

Pressure stabilisers

3.71 Pressure stabilisers should be unobstructed and silent in operation. (See Chapter 5 for maintenance requirements.)

3.72 Pressure stabilisers that direct air into a UCV operating theatre will need to be baffled on the theatre side to prevent the air jet disturbing the UCV canopy air pattern. Pressure stabilisers between the theatre and anaesthetic room may also need to be baffled if the jet of air from them creates uncomfortable conditions for patients or staff.

3.73 Where a pressure stabiliser incorporates a fire and smoke damper, the damper test switch or trip mechanism should be accessible from the corridor side without the need to remove the grille face, if fitted.

Chilled beams – active and passive types

3.74 Chilled beams should not be installed above a patient's bed or diagnostic medical equipment without the agreement in writing of the VSG. Where currently fitted they should be easily accessible for cleaning. In a room with openable windows, the window frame must have a switch to automatically turn the cooling off when the windows are opened (see paragraph 5.18 onwards in Part A of this Scottish Health Technical Memorandum).

Stand-alone air-conditioners

3.75 Stand-alone air-conditioners include fan coil units, split-comfort air-conditioners, room conditioners and cassette units. They should not be installed above a patient's bed or diagnostic medical equipment and should be easily accessible for cleaning.

3.76 To avoid fungal-spore contamination, the ceiling void should not be used as a plenum either for supply, extract or as a return air path. All air connections will be ducted directly to the fan coil unit and ceiling terminals.

Portable air-conditioners

3.77 Portable air-conditioners are not recommended for use in healthcare premises. The need for them is to be assessed by the VSG for every occasion that they are requested. If used, they will be subject to a strict cleaning and maintenance regime (see Chapter 5). Units no longer required will need to be stripped down, cleaned and decontaminated before being used again.

3.78 Stand-alone units that draw in outside air should do so through a bespoke sealable air intake through a wall, roof or window. They should not just be placed in front of an open window.

Portable recirculating filter units

3.79 The need for portable recirculating air-filter units will be risk-assessed by the VSG for every occasion that they are considered. If used, they will be subject to a strict cleaning and maintenance regime (see Chapter 5). Units no longer required will need to be stripped down, cleaned and decontaminated before being used again.

Low-level extracts

3.80 Low-level extracts should not be obstructed by fixed or portable equipment, furniture or fittings. If necessary, stand-off guarding will need to be fitted.

3.81 Low-level extract grille faces should be of the pull-off type to facilitate routine cleaning. (See Chapter 9 in Part A of this Scottish Health Technical Memorandum for further information).

Fire and smoke dampers

3.82 All fire and smoke dampers must be fixed directly to the fabric of the building. They should have an access door with a test switch adjacent so that the actual operation of the damper can be directly observed during the annual test and be undertaken by a single operative. (See also the Health Technical Memorandum 05 series for detailed guidance).

Control panels

3.83 Ventilation control panels of any type and purpose must be clearly marked with the unique identifier of the plant that they control and the area/zone that the plant serves.

3.84 Inverters are not to be located within the airstream inside an AHU. They should be mounted externally with the readouts of their control pads and plant data screens visible at a convenient height. Their settings may be password-protected but they should be able to be switched to manual, without the need to isolate plant or unlock access panels.

Theatre, imaging and treatment room panels

3.85 Local control panels should have a clear means of indicating that the ventilation is operating to a satisfactory standard for the application. The minimum requirement would be a green light for “On” and a red light for “Set back”, “Off” or “Fault”. The panel should also display the room temperature and have a means of adjusting it. (See Chapter 9 in Part A of this Scottish Health Technical Memorandum).

Note: The Specialised Ventilation for Healthcare Society’s (2017) SVHSoc.01 – ‘Operating theatres: energy control strategies and the surgeon’s panel’ provides additional information of minimum standards for a variety of panel types.

Energy efficiency

3.86 The basic objective will be to provide the necessary service utilising the least amount of energy possible. To this end switching a system “Off” when not required is the most energy-efficient policy.

3.87 If the system is needed to maintain a minimum background condition then reducing its output to the minimum necessary to achieve and maintain the desired condition is the next best option.

Note on “Set back”: In many existing systems the fan motor has two speeds so turning the system down means switching to the lower fan speed and hence air volume. With inverter-controlled or EC fans the speed can be adjusted across a wide range so “Set back” need not be a fixed fan speed but rather a control strategy that reduces the system output in order to maintain a desired minimum condition. This may be related to the air velocity at a fixed point, air-change rate, pressure differential, temperature, humidity or a combination of any of these parameters.

3.88 The system should only run at full output when needed to achieve and maintain the defined “in use” operational condition.

3.89 Care should be taken to discover the true “in use” operational condition. Overstating the condition will lead to oversized plant, unstable control and excessive energy consumption.

3.90 A ventilation system should not be run at full output “just in case it will be needed”. This is particularly a problem in operating departments where the ventilation is often run out of hours as it is believed that it will “maintain sterility” in the operating suite. This is not true as airborne contamination in operating theatres is caused by the people in them when they are in use. The theatre ventilation is provided to cater for this “in use” biological load. When the theatre is not in use, there is no biological load so the ventilation can be turned off and set to automatically start at “Set back” (see above note) in order to maintain a minimum background condition, for example room temperature, if needed. The time taken to start the ventilation and achieve full operating conditions in an emergency will be less than the time taken to bring a patient to theatre and prepare the staff and instruments ready for emergency surgery to commence. A similar situation applies to obstetrics theatres and “special” delivery rooms.

Note: UCV theatre ventilation can be completely switched off when the theatre is not in use but the room temperature should not be allowed to drop below 18ºC (see also paragraph 8.96 in Part A of this Scottish Health Technical Memorandum). The AHU and UCV control should be interlocked so that when the AHU goes to “Set back” the UCV also goes to “Set back”, and if the AHU goes “Off”, the UCV terminal fans also switch “Off”. There is no aerobiological benefit in keeping the UCV terminal fans running when the theatre is not in use, it merely wastes.

3.91 The selection of set points for an AHU and associated extract system will have a significant impact on the overall energy consumption and efficiency of the system as a whole.

3.92 The control strategy for existing systems should be reviewed in line with the above guidance. (See Chapters 6 and 9 in Part A of this Scottish Health Technical Memorandum for further information.)

Note: Energy-recovery devices have been mandatory for all new and refurbished AHUs since 2016. Where installed they provide a significant portion of the heating requirement, and the size of the AHU heater-battery will have been reduced as a consequence. It is therefore essential that the energy-recovery device operates as intended and is well maintained.

4. Annual inspection and verification requirements

Ventilation systems inspection

4.1 All ventilation systems will be subject to at least a simple visual inspection annually.

4.2 The purpose of the inspection is to establish that:

- the system is still required;
- the plant conforms to the minimum standard (see Chapter 3);
- the fire containment has not been breached;
- the general condition of the system is adequate for purpose;
- the system overall is operating in a satisfactory manner.

4.3 It is recommended that a simple check sheet be used to record the result of the inspection. Examples are given in Appendices 1 and 2.

Critical healthcare ventilation systems

4.4 All critical healthcare ventilation systems will be inspected quarterly and verified at least annually. In some circumstances the verification may need to be carried out more frequently.

4.5 The quarterly inspection should be as detailed in paragraphs 4.1–4.3.

4.6 The purpose of the annual verification will be to additionally ensure that the system:

- achieves minimum standards specific to the application;
- is operating to an acceptable performance level;
- remains fit for purpose.

Definition of a critical system

4.7 Ventilation systems serving the following are considered critical:

- operating suites of any type including rooms used for interventional procedures and their recovery areas;
- airborne isolation facility;
- critical care units, neonatal and special care baby units;
- invasive treatment, endoscopy and bronchoscopy rooms;
- containment level 3 laboratory;
- pharmacy aseptic suite;

- inspection, assembly and packing (IAP) room in a decontamination unit;
- MRI, CAT and other types of emerging imaging technologies that require particularly stable environmental conditions to remain within calibration;
- any system classified as an LEV system under the COSHH Regulations;
- any other system that clearly meets the definition that “a loss of service from such a system would seriously degrade the ability of the premises to deliver optimal healthcare”.

Note: If any doubt exists as to whether a system falls within this definition, the VSG should be consulted regarding the risk to patient safety and business continuity.

Annual verification

4.8 The annual verification is intended to establish that:

- the system is still required;
- the AHU conforms to the minimum standard (see Chapter 3);
- the fire containment has not been breached;
- the general condition of the ventilation system is adequate;
- the fabric of the area served is suitable for the function;
- the system performance is adequate with respect to the functional requirement – this will require:
  - the measurement of all system supply and extract airflow rates;
  - the calculation of room air-change rates if applicable;
  - the measurement of room differential pressures if applicable;
  - the measurement of room noise levels;
  - temperature, humidity and any application-specific air velocity measurements;
  - a check of the control functions;
  - microbiological air-quality sampling if required;
  - any other application-specific tests or measurements as required.

4.9 An assessment should then be made by the AP(V) as to whether the system overall is fit for purpose and operating in a satisfactory manner. If any doubt exists, the AE(V) and/or VSG should be consulted.

Fabric of the area served

4.10 The building elements in the room or rooms served by a critical ventilation system should also be suitable for the function. As an example, in a suite of rooms comprising an operating theatre complex, the following elements should be checked:

- the ceiling should be complete and free from holes, gaps, cracks or obvious air leakage paths. All light fittings, access hatches and suspended fittings should be sealed to prevent uncontrolled air leakage. It is important to check for air-leakage

paths behind the cover shrouds where operating-lamp stems and medical- gas and monitor-suspension booms penetrate the ceiling;

- the walls and floors should be free from significant construction and finish defects;
- windows and their trickle vents should be sealed and locked shut;
- the doors should close completely, and the door closers should be correctly adjusted to hold them against the room pressure gradient;
- all service penetrations should be sealed to prevent uncontrolled airflow between rooms and service voids;
- steps should be taken as necessary to prevent portable equipment and stock items from obstructing low-level supply, transfer or extract airflow paths.

4.11 Failure to achieve a suitable standard will render even the most sophisticated ventilation system ineffective.

4.12 All fire and smoke dampers should be tested as part of the annual verification unless the local policy dictates otherwise.

4.13 Table 1 provides a model for the verification of critical ventilation systems.

4.14 LEV systems will be subject to an examination and test by a competent person at least every 14 months. An individual who holds an in-date P601 certificate will be considered competent.

Critical healthcare ventilation systems – verification standards

Note: The following standards apply to the performance of all existing in- use ventilation systems. Performance standards for new or refurbished systems are given in Chapter 12 in Part A of this Scottish Health Technical Memorandum.

4.15 When measured at the annual verification the following air change rates should be achieved:

a. the primary air supply to a conventionally ventilated operating theatre, UCV operating theatre or “lay up” preparation room, regardless of when it was built, should not result in fewer than 18 air changes per hour in the room;

Note: If the scrub is in effect a separate room that is open (no door) to the operating theatre and it has a low-level pressure stabiliser discharging onto a corridor or an active low-level extract at its far end, so that air has to travel through the scrub to leave the operating theatre, then the volume of the scrub will not be counted as being a part of the operating theatre room volume.

If the scrub is a trough on the wall or in an open bay within the operating theatre, the volume of space it occupies will be considered part of the operating theatre room volume for the purpose of calculating the operating-theatre air supply.

b. the primary air supply to an operating suite anaesthetic room that is equipped with a N2O (nitrous oxide) terminal or in which an anaesthetic agent is delivered

to the respiratory tract of a patient using a carrier gas or an operating department recovery room should not result in fewer than 12 air changes per hour;

c. the primary air supply to any other room that is fitted with a N2O (nitrous oxide) or N2O/O2 (entonox) terminal or in which an aneasthetic agent is delivered to the respiratory tract of a patient using a carrier gas or in which the patient is subsequently recovered should not result in fewer than 8 air changes per hour. (Note that in these rooms the patient is generally only sedated rather than fully anaesthetised.)

4.16 Unless otherwise specified in paragraph 4.15 above, for all other applications the ventilation system should achieve not less than 80% of the design air-change rate given in Chapter 8 and Appendix 2 of Part A of this Scottish Health Technical Memorandum, or its original design parameters.

Note: It is to be expected that over the lifetime (typically 20 years) of a ventilation system its performance will gradually reduce due to wear in components, increasing friction due to internal surface degradation and ductwork and access door seals breaking down over time. However, any rapid change in performance should be thoroughly investigated as it is likely to be caused by a failure of a component or control software. Trend analysis of the annual verification results will highlight sudden changes in performance.

Table 1: Operational management and routine verification process model

Step	Question	Information/standard required	Comment
1	Is the system still required?	Why was it installed?	Is that function still required?
2	Does the AHU achieve the minimum standard?	Health and safety aspects Intake/discharge positions Inspection access Legionella control and drainage Fire and electrical safety Leaks, cleanliness and insulation Filtration	Inspect to ascertain compliance with minimum standards set out in Chapter 3 of Scottish Health Technical Memorandum 03-01 (Part B)
3	Is the air distribution system satisfactory?	Access Fire dampers Cleanliness Insulation Identification Room terminals Pressure stabilisers	Inspect to ascertain continued fitness for purpose
4	Does the measured system performance still accord with the design intent and achieve a minimum acceptable standard?	Design air velocities Design airflow rates Room air-change rates Pressure differentials Noise levels Air quality	Establish the design values Measure the system output to verify its performance
5	Does the control system function correctly?	Desired environmental conditions Control sequence logic Run; set-back; off philosophy	Establish the true “as used” requirement Inspect/test to verify performance
6	Having regard to the foregoing, is the system “fit		Yes or No!

Step	Question	Information/standard required	Comment
	for purpose" and will it only require routine maintenance in order to remain so until the next scheduled verification?		
7	What routine service and maintenance will be required for the system to remain fit for purpose and function correctly until the next scheduled verification?	Filter changes System cleaning Performance indication Performance monitoring Performance measurement	Decide inspection frequency and maintenance schedule

4.17 The pressure regime should achieve not less than 80% of the design value given in Chapter 8 and Appendix 2 of Part A of this Scottish Health Technical Memorandum, or its original design parameters; and the pressure gradient relationships with regard to surrounding areas should be maintained.

4.18 The sound levels given in Table 2 are maximum permissible levels and should not be exceeded. Measurements should be made using at least a Type 2 sound meter fitted with a muff. Its accuracy should be checked using a calibration sound source before use.

Vertical flow ultra-clean ventilated (UCV) operating theatres

4.19 The following additional measurements should be taken:

- the average air velocity at the 2 m level under the UCV canopy: it should achieve a minimum average of 0.38 m/s for a partial or no wall system and 0.3 m/s for a full wall system when all four walls are in place;
- the average air velocity at the 2 m level for each quadrant or actively ventilated section of the UCV canopy should not exceed ±6% of the measured average velocity for the whole canopy at 2 m;
- the air velocity within the inner zone at the 1 m level: every reading should achieve a minimum velocity of 0.20 m/s.

4.20 The air velocity measurements are to be taken using the equipment, test grid and method set out in Chapter 12 in Part A of this Scottish Health Technical Memorandum.

Note: There is no requirement to carry out a filter scan or entrainment test at the annual verification unless the EPA filters or recirculating air fans are changed, or the system in some other significant way is disturbed or altered. Changing the filters in the AHU or the recirculating air filters in the UCV canopy does not constitute a significant disturbance to the UCV unit.

Table 2: Maximum sound levels (service noise only) for existing systems

Area	Room Overall noise level – dB(A)
Operating suite including prep, operating theatre, anaesthetic, scrub and utility. Interventional and diagnostic imaging suites – all rooms	50
UCV Operating theatre and adjacent open-plan areas only	55
Treatment rooms, Consulting rooms, Sleeping areas, Recovery rooms	35
Pharmacy aseptic suites – all rooms	45

Area	Room Overall noise level – dB(A)
Sanitary facilities	45
Industrial areas	50
Circulation areas	50

4.21 Should the UCV canopy fail to achieve a suitable standard, resulting in the need to disturb or replace the canopy EPA filters or its auxiliary fans, the unit should be revalidated using the procedure given in Chapter 12 in Part A of this Scottish Health Technical Memorandum.

Horizontal flow ultra-clean operating theatre terminals

4.22 The following additional measurements should be taken:

- a line of test positions should be marked on the floor 1 m in front of the face of the UCV terminal;
- a test position will be marked in the centre of the line. Additional test positions will be marked at 280 mm spacing along the line either side of the centre position, up to the full face width of the unit;
- the discharge velocity test at 1 m, 1.5 m and 2 m levels in front of the terminal are taken at each test position;
- the average velocity should be not less than 0.40 m/s.

4.23 The measurements are to be taken using the equipment and method set out in Chapter 12 of this Scottish Health Technical Memorandum.

Note: There is no requirement to carry out filter scanning at the annual verification unless the EPA filters or recirculating air fans are changed; or the system is in some other significant way disturbed or altered. Changing the filters in the AHU or recirculating air filters does not constitute a significant disturbance to the UCV terminal.

4.24 Should the horizontal UCV fail to achieve a suitable standard, resulting in the need to disturb or replace the canopy EPA filters or auxiliary fans, the unit should be revalidated using the procedure given above.

Containment level 3 laboratories

4.25 These areas should conform to the requirements of current information published by the Advisory Committee on Dangerous Pathogens and the Health and Safety Executive:

- ‘The management, design and operation of microbiological containment laboratories’
- ‘Biological agents: managing the risks in laboratories and healthcare premises’
- ‘Biological agents: the principles, design and operation of Containment Level 4 facilities’.

4.26 The Head of Department will be able to advise on any mandatory plant inspection and maintenance frequencies and particular control strategy. The performance measurement of a containment laboratory is normally contracted out to a specialist.

Pharmacy aseptic suites

4.27 Pharmacy aseptic suites should conform to the requirements of the European guide to good manufacturing practice (https://ec.europa.eu/health/ documents/eudralex/vol-4_en) and the requirements of the Medicine Inspectorate if a licensed manufacturing unit.

4.28 The Chief Pharmacist will be able to advise on any mandatory plant inspection, maintenance frequencies and particular control strategy. The performance measurement of the aseptic suite is normally contracted out to a specialist.

Decontamination Unit – IAP

4.29 IAP rooms should conform to BS EN ISO 14644 Class 8, and any additional requirements for the processing of medical devices, as applicable (see also Scottish Health Planning Note 13 Parts 1, 2 or 3 [Central Decontamination Unit, Local Decontamination Unit, Endoscopy Decontamination Unit]).

4.30 The Head of Department will be able to advise on any mandatory plant inspection, maintenance frequencies and particular control strategy. The performance measurement of the IAP room is normally contracted out to a specialist.

Local exhaust ventilation (LEV) systems

4.31 LEV systems should conform to the latest version of the Health and Safety Executive's guidance document HSG258 'Controlling airborne contaminants at work: a guide to local exhaust ventilation (LEV)'.

4.32 LEV systems must be examined and tested at least every 14 months by a competent person. The person must hold an in-date P601 certificate.

4.33 Each LEV system must be examined and its performance measured and/or visualised from the point of capture of the hazard to its point of discharge. A full report of findings and a clear statement as to whether the system does or does not achieve an acceptable standard must be provided by the inspector.

Note: Having an annual service contract for an item of equipment such as a safety cabinet does not necessarily fulfil the statutory requirement for an annual LEV examination. The annual LEV examination must test and quantify the performance of the complete system including the location of the item, its interaction with any room ventilation, its discharge arrangement and suitability of the discharge location.

Critical system verification failure

4.34 Should a critical system be unable to achieve the standard set out above, it should not be returned to service and the duty manager who signed the system over for the annual verification will need to be informed immediately. Copies of the verification report stating the reason(s) for non-compliance should be sent to the head of the user department, nominated infection prevention and control person and the healthcare provider's AP(V) as soon as practicable.

4.35 If a critical system is refurbished in order to bring it to a suitable standard, it will be subject to the full validation procedure set out in Chapter 12 in Part A of this Scottish

Health Technical Memorandum or other application-specific guidance as appropriate before being taken back into use.

5. Routine inspection and maintenance

General

5.1 Inspection and maintenance activities should be risk-assessed to ensure that they do not create a hazard for those who undertake the work or for those who could be affected by it.

5.2 The degree and frequency of inspection and maintenance should relate to the function of the system, its location, its general condition and the consequence of failure.

5.3 Specimen inspection and maintenance checklists are given in the Appendices.

Inspection and maintenance of critical systems

5.4 The loss of service of these systems would seriously degrade the ability of the premises to deliver optimal healthcare. In order to ensure reliable service provision, critical systems should be subject to a quarterly inspection and maintenance regime.

5.5 For many of these systems an equipment release or permit-to-work certificate will need to be completed to ensure that taking the ventilation system out of service does not compromise the activities of the user department. In any event, it will be necessary to liaise with the user department when switching the system off to carry out routine inspection and maintenance.

Note: A specimen equipment release certificate is given in Appendix 3.

AHU routine inspection

5.6 All AHUs should be visually inspected at least every three months. The inspection should note the general condition of the unit in terms of:

- its external and internal condition;
- pipework and electrical connections;
- sensor and control elements;
- the unit's continued ability to maintain the desired condition in the spaces that it serves.

Note: Where fitted, energy-recovery devices provide a significant portion of the heating requirement, and the size of the AHU heater-battery will have been reduced as a consequence. It is therefore essential to check that the energy- recovery device operates as intended.

AHU drainage

5.7 AHU drainage systems comprise a drainage tray, glass trap, connecting pipework and an air gap. The system should be inspected to ensure that it is clean and operating correctly. The cleanliness of the drainage tray and colour of the water in the trap will give an indication of a fault condition (see Table 3).

Filter changing

5.8 Dirty supply air filters may pose a general dust hazard when being changed.

5.9 Dirty extract and return air filters may pose an increased level of hazard. This will relate to the particular contamination within the air that they have filtered. Filters handling extract air from general areas are unlikely to present a significantly greater hazard than that posed by dirty supply air filters.

5.10 Care should be taken to protect staff from inhaling the dust. If there is a need to enter the duct when changing filters, a dust mask or respirator to BS EN 149 should be worn. Dirty filters should be carefully removed and placed in a bag or the box that contained the replacement filters. On completion of the work, the dirty filters should be removed from the plantroom and disposed of appropriately.

Note: Dirty general supply or extract filters are not classed as hazardous waste.

5.11 The duct in the area of the filter housing should be carefully vacuumed using a cleaner with a filtered exhaust before fitting the replacement filters. This will prevent particles (that is, those that are shed when the dirty filters are disturbed) being blown downstream into the system when it is switched on.

5.12 It is important to ensure that replacement filters are fitted in the correct orientation. Most panel filters are manufactured with a membrane or wire support mesh on their downstream side. Alternatively, they may be colour-coded. The manufacturer's instructions regarding fitting should be followed.

5.13 Bag filters should be fitted with the pockets vertical. Care should be taken to remove any transit tapes and to ensure that the individual pockets are separate and free to inflate.

Note: The preferred option is to replace bag filters with rigid assembly filter packs; however, whichever type is fitted, it is vital not to puncture or damage them during installation.

5.14 Whichever type of filters are fitted it is essential to ensure that air cannot bypass them.

Changing extract filters containing hazardous substances

5.15 Filters handling extract air from an LEV system will present a hazard and should be subject to a safe system of work.

5.16 Filters used in an extract system for the containment of hazardous substances or organisms should incorporate design provision for their safe removal when so contaminated. This may be achieved by:

- coating the filter with a water-based paint to seal the hazardous substance onto the filter prior to removal;
- a system to fumigate the filter to kill any organisms;
- housing it in a “safe change” unit that permits the filter to be ejected into a bag and sealed without staff having to come into direct contact with it.

The method chosen should reflect the nature of the hazard.

5.17 Filters fitted to remove hazardous substances from extract air are classed as hazardous waste and should be handled and disposed of accordingly.

Air terminals

5.18 Sooty marks around supply terminals should be vacuumed or wiped clean. Excessive soot marks around supply diffusers indicate an inadequate filter or significant filter bypass.

5.19 Extract grilles need to be regularly cleaned to remove dust and bits of fluff. Low-level spring-retained extract grilles should be regularly pulled off so that they can be washed and the debris in the duct behind them vacuumed out.

UCV canopies

5.20 UCV canopies fitted with perforated plate-type diffusers should have them removed and both sides wiped clean at the quarterly inspection. Any canopy side screens should be wiped down on both sides to remove surface contamination and bone dust.

5.21 UCV canopies fitted with monofilament diffuser screens do not need to be removed as blood splatter does not easily penetrate. Any visible surface contamination should be carefully wiped off in accordance with the manufacturer’s instructions. If the monofilament screen is cut, punctured or physically damaged it will need to be replaced, not repaired.

5.22 The return air grilles for all types of canopies will need to be regularly cleaned to remove lint and the return air filters replaced as necessary.

Pressure stabilisers

5.23 Plate and bar stabilisers need to have their screws tightened, pivots cleaned and adjusted, and the sorbo rubber stop inspected and replaced as necessary if they are to operate correctly and silently.

5.24 All types of pressure stabilisers to be checked for correct and silent operation and cleaned as necessary.

Note: Pressure stabilisers may need to be retrofitted with a stand-off baffle on their discharge side to preserve privacy or prevent discharge air causing draughts within an anaesthetic room or bedroom. A stand-off baffle will always be needed on the theatre side of the pressure stabiliser between a “lay-up” preparation room and a UCV theatre to prevent perturbation of the UCV canopy air pattern.

Transfer grilles

5.25 Both sides of a transfer grille should be vacuumed to remove dust and fluff.

Ventilation system cleaning

5.26 The intake section of a ventilation system should be vacuumed-out as necessary to remove visible particles.

5.27 AHUs should be vacuumed-out and wiped or washed down internally as necessary to remove obvious dust and dirt.

5.28 Drift eliminators (if fitted) should be removed, and cooling coils, humidifier units, energy-recovery devices and their drainage systems should be washed down with hot water annually to remove visible contamination. Using a hose connected to the DHW is the simplest way. Pressure washers should not be used as they will damage the battery fins or energy transfer matrix.

5.29 Supply air distribution ductwork conveys air that has been filtered. It will require internal cleaning only when it becomes contaminated with visible dirt. The frequency of cleaning will depend on the age of the system and grade of the AHU final filter but will typically be in excess of ten years. There is no requirement to clean supply ductwork annually. A rapid build-up of visible dirt within a supply duct is an indication of a failure of the filtration or its housing.

5.30 On completion of cleaning, the supply ductwork should not be “fogged” with chemicals. This treatment has no lasting biocidal effect and is responsible for initiating the breakdown of the galvanised coating of ductwork. This results in accelerated corrosion of the inside of the duct, with the products of corrosion being shed into the air stream. It will also significantly shorten service life.

Note: If after duct cleaning there are persistent problems with fungal spores being discharged from the supply terminals and there is no evidence of final filter bypass, air samples should be taken at the AHU intake, AHU discharge and at least one supply terminal in each branch of the system. This should pinpoint the actual source of the problem. The affected section should then be inspected and cleaned and finally fogged only if that proves to be necessary.

5.31 Extract air systems handle unfiltered air. They should be cleaned as frequently as necessary in order to maintain their operating efficiency. Room extract terminals, particularly those sited at low level in critical care areas, will need regular cleaning.

Table 3: Colour of water in glass trap

Colour of water	Probable cause and comment
Normal	Satisfactory
Green	Copper corrosion of pipework Possible leak in battery tubing
White	Aluminium corrosion of battery fins
Black	General dirt Filter faulty allowing air bypass Possible Aspergillus contamination System is overdue for a thorough clean Urgent action required
Brown/Red	Iron corrosion (rust) within the AHU which may indicate a specific Legionella hazard Immediate action required
Bubbly/slimy	Microbiological activity within the AHU which may indicate a specific Legionella or similar hazard Immediate action required
Dead wildlife	Failure of filtration – immediate action required

5.32 Following duct cleaning, all service hatches should be checked to ensure that they have been correctly replaced and do not leak.

5.33 Duct-cleaning equipment that uses rotating brushes or a vacuum unit can easily damage flexible sections of ductwork. On completion of cleaning, all flexible duct sections should be checked for rips and tears. The opportunity should be taken to reduce flexible ducts in length to the absolute minimum and replace any being used in lieu of bends with rigid duct sections. The straps that secure them to rigid duct sections and air terminals should also be checked to ensure that there is no air leakage.

Note 1: If the system has mixing or VAV boxes, the cleaning contractor should be alerted and use a method that avoids damaging any internal acoustic lining.

Note 2: Duct-mounted sensors and the elements of electric and fins of heating or cooling trimmer batteries can also be easily damaged during duct cleaning. Sensor probes may need to be temporarily removed and the battery elements protected during the process.

5.34 It is always necessary to re-balance the ventilation system following cleaning as balance dampers and registers will have been disturbed. The system will then need to be validated in accordance with Chapter 12 in Part A of this Scottish Health Technical Memorandum.

Chilled beams – active and passive types

5.35 The efficiency of these units will rapidly decline if they become blocked with fluff/lint. They should be inspected every three months and cleaned as appropriate.

Split and cassette air- conditioning units

5.36 These units incorporate internal recirculation air filters and a drainage system to remove condensate from the cooling coil. The systems should be inspected and cleaned every three months and the drainage system checked.

Fan coil units

5.37 These units incorporate internal recirculation air filters and a drainage system to remove condensate from the cooling coil. The systems should be inspected and cleaned every three months and the drainage system checked.

Portable room air- conditioning units

5.38 Portable units are sometimes kept in-store or hired-in to cope with temporary local situations giving rise to excessive temperatures. They typically incorporate internal recirculation air filters and a drainage system to remove condensate from the cooling coil. The VSG should be consulted before these types of unit are deployed.

5.39 The units should be inspected and thoroughly cleaned before being taken into use. Units that are to be used in areas containing immunocompromised patients will, unless new, need to be fully decontaminated before use.

5.40 All portable units should be inspected and cleaned every week that they remain in use.

5.41 Units that have been used in isolation rooms or areas containing infectious patients will need to be fumigated before being used in other locations, returned to store or to the supplier.

5.42 Units employing an internal water reservoir and wick to promote evaporative cooling are not to be used in healthcare premises.

Self-contained mobile filter and/or ultraviolet (UV) light units

5.43 The VSG will be consulted before these types of unit are deployed. The efficacy of these units is directly related to their cleanliness. In this respect, the manufacturer's instructions regarding initial use, service and maintenance, lamp and filter replacement should be closely followed (see also paragraph 3.79).

5.44 Units that have been used in isolation rooms or areas containing infectious patients will need to be fumigated before being used in other locations, or returned to store.

5.45 Filters fitted to remove hazardous substances from the recirculated room air are classed as hazardous waste and should be handled and disposed of accordingly (see also Health Technical Memorandum 07-01 – 'Safe management of healthcare waste').

Inspection and maintenance records

5.46 Records of inspection and maintenance activities should be kept for at least five years (see paragraphs 1.31 and 1.44).

Appendix 1 – Annual inspection of critical ventilation systems – AHU and plantroom equipment

Definition of terms used on survey form

General condition

End of useful life

This should be clear from the condition of the AHU and its associated services and plant. The main indicators will be:

- extensive internal and/or external corrosion of the AHU casing;
- failure of filter housings to prevent air bypass;
- general corrosion of heater and cooling battery fins, attenuator surfaces etc;
- significant failure to meet minimum standards;
- associated plant services and control elements in a poor condition or not able to fulfil their purpose;
- AHU aged 20 years or more.

Action: Urgent replacement indicated.

Poor

Should be fairly apparent but would include an assessment of the degree of corrosion; cleanliness of coils and batteries; quality of filter mountings and their ability to prevent air bypass; fan and drive train condition; the control system elements' ability to fulfil their function; condition of the access doors and inspection covers. The age of the AHU is generally less important.

Action: Extensive refurbishment or programmed replacement indicated.

Average

Some faults but generally free of significant corrosion, clean internally and conforming to minimum standards.

Action: Faults capable of correction at next maintenance period.

Good

Conforming to the minimum standards, obviously cared for and subject to routine maintenance.

Action: Routine maintenance will preserve standard of the equipment.

Compliance with minimum standards (questions 2 to 23, 32 and 33)

Poor

More than three answers are negative.

Action: Management action required by estates/facilities department.

Average

No more than three answers are negative.

Action: Maintenance action required.

Good

No answers are negative, full compliance.

Action: None.

Maintenance quality (questions 5, 12, 26 to 31 and 34 to 40)

Poor

More than three answers are negative.

Action: Management action required by estates/facilities department.

Average

No more than three answers are negative.

Action: Maintenance action required.

Good

No answers are negative.

Action: None.

Annual inspection of critical ventilation systems – AHU and plantroom equipment

Template A1 Annual inspection of critical ventilation systems – AHU and plantroom equipment

Hospital

Plantroom

Air handling unit | Age of unit

Area served by unit

Date of Survey | Name

General Condition: End of useful life | Poor | Average | Good

Compliance with minimum standards (Questions 2 to 23, 32 and 33) | Poor | Average | Good

Maintenance Quality (Questions 5, 12 26 to 31, 34 to 40) | Poor | Average | Good

No	Survey question	Yes	No	Comments
1	Plant running?			
2	Is the unit and its associated plant secure from unauthorised access?			
3	Is the unit safely accessible for inspection and maintenance?			
4	Is the air intake positioned to avoid short-circuiting with extract or foul air from other sources such as gas scavenging outlets?			
5	Are all inspection lights operating?			
6	Are motorised dampers fitted to the intake and discharge?			
7	For belt driven fans, is the drive visible without the need to remove covers?			
8	For plug and EC fans, is the fan visible through a viewing port?			
9	Is the cooling coil located on the discharge side of the fan?			
10	Is an energy-recovery system fitted? (state type)			
11	Are condensate drainage systems fitted to all energy recovery systems, cooling coils and humidifiers in accordance with Chapter 3 of Scottish Health Technical Memorandum 03-01, Part B?			

No	Survey question	Yes	No	Comments
12	Are drainage traps clean and filled with water? (see Table 3 in Scottish Health Technical Memorandum 03-01, Part B)			
13	Is the drain trap air break at least 15 mm?			
14	If a humidifier is fitted, state the type	–		
15	Is the humidifier capable of operation?			
16	Is there space to safely change the filters?			
17	Are there test holes in the principal ducts?			
18	Are the test holes capped?			
19	What is the general condition of the exterior of the AHU?	–		
20	Are the principal ducts lagged?			
21	What is the general condition of the associated control valves and pipework?	–		
22	Is the pipework adequately lagged?			
23	Is the system clearly labelled?			
24	Record prefilter differential pressure	–		
25	Record main filter differential pressure	–		
	Switch plant off. Fit padlock to isolator			
26	Did all motorised dampers close on plant shut-down?			
27	Is the vermin/insect screen clean?			
28	Is the intake section including the fog coil clean?			
29	Are the prefilters correctly fitted with no air bypass?			
30	Are all drive belts correctly aligned and tensioned?			
31	Is the cooling-coil matrix clean?			
32	Are all drip-trays fully accessible or capable of being removed for cleaning and have a fall to drain?			
33	Are the drainage trays stainless?			
34	Are the drainage trays clean?			
35	Is the internal base of the AHU free from any sign of ponding?			
36	Is the matrix clean for each heater-battery?			
37	Have the main filters been correctly fitted with no air bypass?			

No	Survey question	Yes	No	Comments
38	Is AHU and its associated main ductwork clean internally?			
	Energise plant			
39	Did unit restart satisfactorily?			
	Test automatic fan-motor change-over, if fitted			
40	Did automatic change-over operate satisfactorily?			

Additional comments

(For example: air leaks from access doors; control valves leaking or passing; general cleanliness of the area around the unit; or any other items of concern.)

Are there any issues of particular concern that would prevent the plant being taken back into use?

Competent Person/Authorised Person

.....

Appendix 2 – Operating suite annual verification

Definition of terms used on survey form

Assessment of compliance with Health Building Note 10-01 and Scottish Health Technical Memorandum 03-01 (all questions relevant to the type of theatre)

Poor

Air-change rate is less than 18 per hour; room pressure differentials do not ensure a flow from clean to less clean areas; supply or extract air diffusers are not clean; pressure stabilisers not clean and/or not operating correctly; significant faults or failures of indicators on surgeon's panel; visible faults in the fabric of the suite; doors unable to close completely; general air of neglect.

Action: Urgent management action required.

Average

Air volumes and room pressure differentials approximate to the original design values; supply air diffusers clean but extracts visibly fouled; most pressure stabilisers clean and operating correctly; some of the indicators on the surgeons' panel not working; minor faults in the fabric and décor of the suite.

Action: Maintenance action required.

Good

Better than average.

Action: None.

Maintenance quality (all questions relevant to the type of theatre)

Poor

More than three answers are negative.

Action: Management action required by estates/facilities department.

Average

No more than three answers are negative.

Action: Maintenance action required.

Good

No answers are negative.

Action: None.

Annual verification of theatre ventilation systems Theatre suite information

Template A2 Annual verification of theatre ventilation systems Theatre suite information

Hospital

Theatre name/no | Type of Theatre

Date if survey | AHU

Location and ID Name

Compliance with HBN/SHPN & SHTM

Poor | Average | Good

Maintenance quality

Poor | Average | Good

No	Survey question	Yes	No	Comments
1	Has the annual verification of the AHU been carried out?			
2	Are windows hermetically sealed?			
3	Are the ceilings in the theatre and prep room complete and sealed?			
4	Is the fabric of the rooms within the suite free of any significant faults?			
5	Are room light fittings correctly sealed?			
6	Do all doors close completely and hold against the room pressure?			
7	Are the pressure stabilisers operating correctly and silently?			
8	Are all supply and extract air terminals and pressure stabilisers visibly clean?			
9	Measure and record the operating theatre temperature	–		
10	Does this accord with that displayed on the surgeon's panel?			
11	Measure and record the operating theatre relative humidity	–		
12	Does this accord with that displayed on the surgeon's panel?			
13	Measure and record the supply and extract air flow in the principal ducts	–		

No	Survey question	Yes	No	Comments
14	Measure and record the air flow at all supply and extract terminals	–		
15	Does the derived air-change rate achieve at least 18 ac/h in the Theatre, 12 ac/h in the Anaesthetic room and at least 80% of the design flow in all other rooms?			
16	For UCV units, also measure and record the air velocities within the canopy using the method set out in Chapter 12 of Scottish Health Technical Memorandum 03-01 (Part A)	–		
17	Do the air velocities achieve the standard appropriate for the type of canopy?			
18	Measure and record the room differential pressures	–		
19	Do the room differential pressures ensure a flow of air from the clean to the less clean areas?			
20	Measure and record the noise levels in the principal rooms of the suite	–		
21	Do the noise levels fall below the limits set out in Table 2 of Scottish Health Technical Memorandum 03-01, Part B?			
22	Check the operation of all ventilation control functions represented on the surgeon's panel.	–		
23	Do the indicators accurately represent the operational state of the ventilation system(s)?			
24	For UCV systems: Are the UCV and AHU interlocked to ensure that the AHU runs at full speed when the UCV is at full operating speed or at low speed? (See SHTM 03-01; Part B; Chapter 3; paragraph 3.90 Note.)			
25	With the UCV running at low speed, does the system maintain the standard of a conventional operating theatre?			
26	For all theatres: with the system running at set-back, does it maintain a flow of air from the clean to the less clean areas?			

Additional Comments

(For example: the general décor; are the suite and its ventilation systems suitable for their designated functions?)

Are there any issues of particular concern that would prevent the suite being taken back into use?

Competent Person/Authorised Person .....

Appendix 3 – Equipment Release Certificate

Template A3 Equipment Release Certificate

Equipment release certificate

Certificate No: **Job No: .....**

Issuing Dept: ..... Date & time of issue: .....

Issuing officer (print name): .....

Issued to (print name and company): .....

This certificate is issued for the purpose of carrying out the following task. The MAINTENANCE / SERVICE / REPAIR (delete as appropriate and attach job card to certificate) of the equipment specified below. It is valid for 48 hours.

Location: ..... Equipment: ..... Serial No: .....

		Yes	No
1	Is the task routine for this equipment?		
2	Are you a fully trained service engineer or have you carried out this task at least 3 times previously?		
3	Has one of the following authorised personnel (circle the name) given permission for the service to take place? Authorised Person(s):		
	Note: If the answer to all of the above questions is YES, proceed to Step 4. If the answer to any of the above questions is NO, **do not proceed**. Return this Certificate to the issuing officer and obtain a Permit to Work.		
4	Obtain the signature of the person identified at Step 3 above. Name:..... Signature: ..... Date:.....		
5	Isolate the equipment and carry out the task.		
6	Reinstate all services and test-run the equipment.		
7	On completion, the person doing the work to print name, and sign. Name:..... Signature: ..... Date:.....		
8	Is the equipment serviceable? If YES, go to Step 9. If NO, isolate equipment and go to Step 10.		
9	Hand equipment back to the person identified in Step 4. Obtain signature. Name:..... Signature: ..... Date:.....		
10	Return this certificate to the issuing authority. Receiving officer to sign. Name:..... Signature: ..... Date:.....		
	Note: The issuing authority to retain this certificate for 12 months		

References

Acts and regulations

Building Regulations 2010. SI 2010 No 2214. http://www.legislation.gov.uk/uksi/2010/2214/contents/made

Control of Substances Hazardous to Health Regulations 2002. SI 2002 No 2677. http://www.legislation.gov.uk/ uksi/2002/2677/regulation/7/made

Health Act 2009. HMSO, 2009.

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Editorial

The hospital-built environment: biofilm, biodiversity and bias

Despite recognition of the link between the hospital-built environment and patient ill-health in 1860 by Florence Nightingale ('the first requirement of a hospital is that it should do the sick no harm'), hospitals can still be responsible for patient deaths within days of opening. This issue describes widespread contamination of the water system with a range of Gram-negative organisms including *Cupriavidus* spp. in a new hospital, and associated patient transmission [1].

The contribution of the built environment has fallen in and out of favour over time, ranging from denial in the 1970s to renewed interest in recent years, particularly in terms of coronavirus disease 2019 and room ventilation. By favouring folklore over scientific research, human bias set back progress in recognizing the role of water systems in the transmission of organisms other than *Legionella* spp. for more than 40 years. In 1967, Kohn published evidence of the transmission of *Pseudomonas aeruginosa* from water outlets to patients, but this was derided by the establishment in favour of the common belief that organisms went from the patient to the handwash station and not vice versa [2]. For mythology to over-rule science for such a protracted time required an ally — our myopia to recognize outbreaks with sensitive strains of *P. aeruginosa*. The literature describing waterborne outbreaks in adults is over-represented by highly resistant organisms, as these attract attention and are therefore more likely to be investigated and published. The situation with regard to *P. aeruginosa* is further complicated by endogenous carriage in adults, thereby creating difficulties in recognition of hospital-acquired transmission. No baseline has been established for accepted levels of endogenous carriage beyond which cross-infection should be suspected on a unit. This is exemplified by an outbreak with a sensitive strain of *P. aeruginosa* on a burn unit in Switzerland which took 3 years to identify, as it was not clear initially if the levels merely represented endogenous carriage [3]. Halstead *et al*. used whole-genome sequencing to demonstrate ongoing transmission of sensitive strains of *P. aeruginosa* from water outlets in three of four hospitals, validating the difficulties associated with recognizing cross-infection with sensitive strains [4]. Endemic unrecognized transmission of sensitive *P. aeruginosa* may be the norm on adult high-dependency units.

While Florence Nightingale had to battle human nature, she would have been unaware of another adversary — biofilm. Even when a link between the environment and patient infection is suspected, the ingenuity of biofilm may supervene.

Although antibiotic-resistant determinants on highly promiscuous plasmids add to the diversity of an outbreak spreading across genera, the biodiversity of biofilm is a confounding variable. The close proximity and density of organisms contained within biofilm may facilitate dissemination of genetic material. The recent finding that some antibiotics are incorporated into biofilm (biologically active antibiotic may be excreted in large quantities in urine and faeces into drainage systems) could favour incorporation of antibiotic-resistant strains. However, it is the presence of several strains of the same organism within biofilm which may be critical to our ability to detect outbreaks. Traditionally, when organisms suspected in an outbreak have been cultured on agar, one colony is taken for typing in the belief that it is a homogeneous population. Where a strain predominates in the biofilm, outbreak detection will be facilitated, introducing bias into published outbreaks. However, this is not always the case with environmental samples. When legionellae are cultured from water samples, a mixture of strains is often present, and several different cupriavidus strains were isolated from the contaminated water system in Glasgow. In a 3-year prospective study of *P. aeruginosa* in intubated patients, Valles *et al*. [5] picked off four colonies from environmental *P. aeruginosa* isolates and found that $\geq$28% of specimens contained more than one strain, which was reflected in some patients being colonized with more than one strain (polyclonality reflected in patient samples) [5]. Similarly, in investigating a hospital PA outbreak linked to drains, Berrouane *et al*. found that, of the five drains testing positive, three had four different strains and two had three different strains [6]. Weber *et al*. reported an outbreak of *Stenotrophomonas maltophilia* originating from tap aerators, and found five different strains infecting or colonizing patients and four environmental isolates [7]. There are other reports of polyclonality, including *Burkholderia cepacia* [8,9]. Biodiversity has also been well described for *Aspergillus fumigatus* in environmental and patient isolates. Fingerprinting of >700 clinical and environmental isolates from four hospitals demonstrated an extremely diverse population [10]. Two hundred and seventy-six genotypes were identified from 376 environmental isolates from one of the hospitals. The majority of patients were noted to harbour at least two strains of *A. fumigatus*. The authors recommended that assessment of fungal hospital-acquired infection requires typing of a large number of isolates from the environment and multiple patient samples. A study conducted by Symoens *et al*. concluded that the huge biodiversity of the *A. fumigatus* population causes extreme difficulty in ascertaining a hospital source [11].

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Further information is required to guide how many colonies should be typed from environmental samples (and linked clinical specimens) to identify biodiversity in order to fully recognize transmission. In investigating variation, it might be anticipated that there will be differences between biofilms. Small areas of biofilm may be more homogeneous due to their restricted size [i.e. biofilm involving a single thermostatic mixer valve in comparison with widespread biofilm within a water system (as in Glasgow)], but ultimately this may relate more to how the biofilm was formed. Drain biofilm is frequently exposed to a wide range of new organisms from contaminated water, patient secretions or retrograde contamination from the main sewer adding continually to diversity. Other factors include the genus of the organism and the impact of biocides and antibiotics. An alternative approach for organisms such as *P. aeruginosa* is to establish endogenous carriage through screening on admission to a unit and then regular screening, typing isolated strains with a view that if infection control practices are good at preventing patient-to-patient transmission, the bulk of acquisition is likely to be environmental in origin. Where acquisition occurs, an attempt should be made to find the same organism in the environment.

The range of potential environmental sources may be a further confounding variable as there is the risk that some sources may not be identified. Incorrect water sampling techniques, such as not taking a true pre-flush sample (rarely audited), runs the risk of missing contamination of the periphery of the water system. Studies looking at transmission of *P. aeruginosa* often focus on water samples, ignoring drains and other potential sources, and therefore underestimating the burden of transmission. This is reflected in clinical practice where water sampling is undertaken on augmented care units but the necessary discipline around the use of water services is omitted, allowing routes of transmission from drains etc. to go unaddressed. There are other challenges. With surface swabbing, there can be only a 25% chance of getting the bacteria off the surface on to the swab, and a further 25% chance of getting it off the swab on to the plate [12].

Whole-genome sequencing is used increasingly to characterize the relatedness of organism strains. However, sequencing small numbers of isolates will fail to capture the diversity of complex environmental biofilms. Constantinides *et al*. used a combination of whole-genome sequencing and a metagenomic approach to investigate the prevalence and characterize *Escherichia coli* and *Klebsiella* spp. from hospital sink drains. Combination approaches such as these can provide information on species diversity and resistance mechanisms present [13]. Metagenomics screening suggests that clinical isolates may be more widely present in environmental reservoirs than observed from culture-based comparisons. Wendel *et al.*, reporting an outbreak of GIM-1-producing *P. aeruginosa*, compared conventional culture with a molecular probe for the resistance genes [14]. Eighty-nine drain samples were positive on molecular testing compared with 29 using conventional culture. Additionally, an inflatable hair wash basin implicated in the outbreak was positive on all occasions by the molecular technique, but only on one-third of occasions using conventional culture. Biofilm diversity can impact in several ways. Results of clinical specimens sent for typing ahead of environmental sampling that show a variety of strains may be interpreted as precluding an outbreak and further investigation. At the new build University Hospital of Coventry and Warwickshire, which opened in 2006, six patients were detected with *P. aeruginosa* (sensitive strain) on the same day (a 30-bedded unit). Typing of isolates revealed five different strains (i.e. one episode of cross-infection). This might not have been taken any further, but due to concerns over contamination of the water system, the water was tested. The predominant strain in water samples matched the two indistinguishable patient isolates, adding a completely different interpretation to the initial findings. As a result of further investigation, widespread contamination of the hospital water systems with both *P. aeruginosa* and *S. maltophilia* was uncovered (M. Weinbren, personal communication).

Antibiotic-resistant outbreaks attract our attention but is there another factor at play? When typing organisms with an identifiable marker such as antibiotic resistance, this preselection by increasing the chances the strains will be related reduces 'background noise'. When sensitive isolates are sent for typing, there will be high background noise from the natural endogenous carriage of *P. aeruginosa*. Thus typing may show great diversity and only a small percentage of matches may occur (low rates of transmission are noted with environmental outbreaks). Being able to detect an outbreak is complicated by biodiversity in the environmental source together with biodiversity in patient typing results from endogenous carriage. Thus, an environmental source should still be considered where only a small number of typing results indicate cross-infection.

Bias favours bacteria in other ways. Whilst environmental source outbreaks can be explosive in nature (e.g. legionella in the new Pompidou hospital), they also occur at low frequency over a prolonged period of time. Where a succession of concurrent events is required for both transmission and detection, opportunities for identification of acquisition may be intermittent. In units where discipline around the use of sinks is poor, the necessary events might be expected to line up more frequently. The implication for infection control teams is the requirement to look for trends indicating potential outbreaks over prolonged periods of time. The low frequency and time delay between successive transmission events means that individual members of teams (clinical, microbiology, infection prevention and control) may only be aware of one case at the most, and therefore do not suspect an outbreak. The ability of resistance plasmids to transfer across genera further complicates recognition. Infection control analysis is very much driven by location, looking for outbreaks on a specific ward. Environmental outbreaks can occur on a much wider scale, ranging from global, as with *Mycobacterium chimaera* and cardiac bypass heater coolers, to hospital-wide via the drainage system, as described by Breanach *et al*. [15]. Outbreak detection not only requires analysis by ward but also across the whole hospital site.

The drainage system links any room with water services in a healthcare facility. Carbapenemase-producing Enterobacterales outbreaks have arisen from clinical handwash sinks, patient sinks, ward kitchen sinks, main hospital kitchen sinks and showers. Despite the drain being common to all sinks, the bias is to design handwash stations alone to minimize the risk of drain transmission (i.e. water does not hit the drain directly, adequate activity space) but not patient sinks. Is it logical to install showers where the patient is forced to stand on the drain whilst bathing? Will common sense prevail in changing these flawed designs or will patients be forced to endure the pain of another

40 years of infections if *Pseudomonas* spp. and water outlets are anything to go by?

Highly antibiotic-resistant organisms have established citadels within the very fabric of healthcare facilities. Perversely, the very antibiotic-resistant organisms we fear are providing us with an insight into deficiencies in the built environment, and a tremendous opportunity to improve and rectify the situation. The impact of getting this right will far exceed the burden of antibiotic-resistant transmission events, as it is the 'sensitive' organisms blending into the background ('stealth bacteria') which may be causing more damage to patients and driving antibiotic usage. To judge the appropriate investment into improving the built environment requires the ability to gauge or infer the true burden of disease for which it is responsible. Biofilm, a structure honed by nature over billions of years, is only slowly relinquishing its secrets. The diversity of biofilm may be one of them, confounding our ability to detect transmission from the built environment. As Cimolai *et al*. stated in 1997, 'an outbreak may occur with more than one epidemic strain and that strain heterogeneity itself does not exclude an outbreak' [16].

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Response of Formed-Biofilm of *Enterobacter cloacae*, *Klebsiella oxytoca*, and *Citrobacter freundii* to Chlorite-Based Disinfectants

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Abstract: Bacterial biofilms formed on equipment surfaces are potential sources of cross-contamination and can be responsible for the spread of bacteria involved in food spoilage, such as some *Enterobacteriaceae* family members. In this study, the effect of chlorite-based disinfectants, including sodium hypochlorite (SH), chlorine dioxide (CD), strongly acidic electrolyzed water (StAEW), and neutral electrolyzed water (NEW), on inactivation of mono-biofilms of *Enterobacter cloacae, Klebsiella oxytoca*, and *Citrobacter freundii* was evaluated separately. All the strains were enumerated by the viable plate-count method after disinfection for 30 min. A comparison of the surviving cells after disinfection indicated that *E. cloacae* biofilms were more resistant to disinfectants than the biofilms of the other two strains, and treatment with all the disinfectants improved sanitizing. SH (200 mg/L) was the most effective in the reduction of cell number in the biofilms of all strains. Considering the safety of use and environmental protection, electrolyzed oxidizing water, especially StAEW, was a good suggestion for the inactivation of cells in *K. oxytoca* or *C. freundii* biofilms. These results suggest that the cells in biofilm of *E. cloacae, K. oxytoca*, and *C. freundii* were highly sensitive to chlorite-based disinfectants and provide insights into the efficacy of disinfectants in killing bacteria.

Keywords: chlorite-based, disinfectants, *Enterobacteriaceae*, formed-biofilm, inactivation

Practical Application: The *Enterobacteriaceae* biofilms formed on equipment surfaces, which can cause cross-contamination and food spoilage, are greatly challenging bacterial contaminants of food products. Electrolyzed oxidizing water is a novel, environmentally friendly disinfectant that can effectively treat *Enterobacteriaceae* biofilms. The results of this study may be used to design effective measures to disinfect biofilms on equipment contact surfaces.

The *Enterobacteriaceae (ENT)* family, of which *Enterobacter cloacae, Klebsiella oxytoca*, and *Citrobacter freundii* are the most predominant strains, has been used as a hygiene indicator in foodstuff processing (Ojerusoz et al., 2013), and members of this family are the most challenging bacterial contaminants of raw and processed meat products (Almutairi, 2011), fish (Phuvasate & Su, 2010), and vegetables (Naik, Shashidhar, Rath, Bandekar, & Rath, 2017). These bacteria can form biofilms, which are architecturally complex communities of microorganisms and can grow on biotic and abiotic surfaces and interfaces (Jahid & Ha, 2014; Sun, Zhang, Chen, & Han, 2012). Attachment of bacteria to surfaces is the predominant form of the survival of bacteria in nature and in man-made ecosystems, such as food-processing factories, where the bacteria then contaminate the food products in contact with these surfaces. Such contamination may lead to product spoilage and shorter product shelf-life, due to factors such as discoloration and off flavor, which results in enormous economic losses to manufacturers and consumers. For example, Zhang et al. (2010) reported that two psychrotrophic and saprophytic strains of *C. freundii* caused tilapia fillets to become soft and sticky with a green coloration and unpleasant odors after 5 days of incubation at 8 °C. Moreover, in food-related settings, biofilms allow the embedded bacteria to survive stress factors commonly encountered within food-processing environments (for example, refrigeration, acidity, salinity, and disinfection) and act as persistent sources of microbial contamination and potential cross-contamination, increasing food safety risks (Giaouris et al., 2014; Simões, Simões, & Vieira, 2010; Toté, Horemans, Berghe, Maes, & Cos, 2010).

Control of biofilms is dependent on effective cleaning and disinfection procedures (Craveiro, Alves-Barroco, Barreto Crespo, Salvador Barreto, & Semedo-Lemsaddek, 2015). If the disinfection process is ineffective, microorganisms may form biofilms on equipment surfaces. Disinfectants must be carefully chosen. Disinfectants such as sodium hypochlorite (SH) are traditionally used in the food and personal care product industries. Chlorine dioxide (CD) is newly reported to have broad bactericidal effects with some advantages over chlorinated water due to its lower toxicity and better stability in water (Burfoot et al., 2015). Recently, electrolyzed oxidizing water (EOW), including strongly acidic electrolyzed water (StAEW) and neutral electrolyzed water (NEW), has exhibited antimicrobial activity against a variety of microorganisms in a relatively short amount of time (usually within 5 to 20 sec) in food products and on food processing surfaces (Ding et al., 2015; Hao, Li, Wan, & Liu, 2015; Monnin, Lee, & Pascall, 2012). EOW has been recognized as a promising alternative decontamination agent and has been used in Japan for several years (Rahman, Khan, & Oh, 2016).

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Pseudomonas spp. are the main bacteria involved in food spoilage. There has been a substantial amount of research in recent years into bactericides effective against *Pseudomonas* spp. biofilms (Behnke & Camper, 2012; Byun, Kim, Kim, Kim, & Jo, 2007; Malheiro et al., 2016; Pagedar & Singh, 2015). However, little research has been done to inactivate cells in *ENT* biofilms, and few studies have used disinfectants to treat *ENT* biofilms. Most studies have investigated the planktonic *ENT* in suspension cultures. Mazzola, Jozala, Novaes, Moriel, and Penna (2009), for example, applied decimal reduction time to demonstrate the resistance of *E. cloacae* planktonic cells to six disinfectants. Izumi, Nakata, and Inoue (2016) investigated the lethal effect of electrolyzed water mixed with agricultural water on coliform bacteria. Few Studies focusing on comparing the efficacy of different disinfectants on *ENT* biofilms have been reported. Therefore, the aim of this study was to assess disinfectant efficacy of commonly used chemicals such as SH, CD, StAEW, and NEW against *ENT* cells grown as biofilms on stainless steel surfaces.

Materials and Methods

Bacterial culture and biofilm formation

The bacterial strains were collected from both spoiled chicken carcasses and conveyor belt surfaces in a slaughter plant in 2015 in accordance with the carcass sampling method for microbiological analysis (SN/T 4092-2015) and the methods for sampling techniques from surfaces in the food industry for export (SN/T 4426-2016). The strains of *ENT*, including *E. cloacae* (NCM 84H), *C. freundii* (NCM 94R), and *K. oxytoca* (NCM 95S), were verified by 16sDNA sequences and by typical biochemical reactions before being subjected to the disinfectant challenge for all the experiments. The strains were maintained at National Center of Meat Quality and Safety Control (NCM). Cultures were stored at −20 °C and then revived in 6 mL of trypticase soy broth (TSB; Hope-Biotechnology, Co. Ltd., Beijing, China) at 30 °C for 24 hr without shaking. The primary bacterial concentration was adjusted to $OD_{600} = 0.15$, which corresponds to approximately 10^4 CFU/mL, using a multimode microplate reader (SpectraMax M2e, Molecular Devices Company, CA, U.S.A.).

Food grade stainless steel coupons (75 × 25 × 1 mm, 304 type, 2B finish; Zhongyi Stainless Steel Materials Co. Ltd., Dongguan, China) were used for biofilm formation. Stainless steel is the most frequently used material for food processing surfaces and is more resistant to high and low temperatures, chemical treatment by oxidizing agents, and other disinfectants used in food industry (Cvetkovski, 2012). Prior to use, the coupons were cleaned as described by Poimenidou et al. (2009). A 2.3 mL cell suspension was prepared as described above and transferred into a sterile container containing 230 mL of normal TSB (control, pH 7.2) with stainless steel coupons to a final concentration of 10^2 CFU/mL. After hermetically sealed with sterilized cling film, the container was then incubated at 20 °C for 5 days without agitation. The stainless steel coupons were half submerged into fluid, and the other half of the coupons were exposed to the air.

Biofilm inactivation using four chlorite-based disinfectants

Four disinfectants (SH, CD, StAEW, and NEW) were used for biofilm removal. The StAEW (pH of 2.70 to 2.90, available chlorine concentration [ACC] of 20 and 40 mg/L, oxidation-reduction potential [ORP] of 1100 to 1160 mV) was generated by an Electrolyzed Water Generator (XL-150; Baoji Xinyu Optics-Mechanics-Electricity Co., Ltd. Baoji, China). The NEW (pH of 6.00 to 6.50, ACC of 20 and 40 mg/L, ORP of 840–900) was generated by another Electrolyzed Water Generator (CE7300-30, Guangzhou Saiai Environmental Protection Technology Development Co., Ltd., Guangzhou, China). SH (pH of 7.35 to 7.45, ACC of 100 and 200 mg/L) and CD (pH of 7.20 to 7.30, ACC of 20 and 40 mg/L) solutions were prepared by diluting with deionized water to produce the target concentrations. The pH, ORP, and ACC were measured immediately before each lethal experiment. The pH and ORP of the disinfectants were measured using a pH/ORP meter (Fisher Scientific, PA, U.S.A.) with an electrode and ORP electrode. The ACC values of the disinfectants were determined by a Digital Chlorine Test Kit (model 16900; Hach Co., Ltd. Loveland, CO, U.S.A.).

Each stainless steel coupon containing a biofilm was rinsed three times with 0.9% NaCl solution to remove the nonattached cells. The rinsing phase was performed in three 80 mL centrifuge tubes with 60 mL 0.9% NaCl solution. The tweezer was used to clamp the stainless steel coupon and was moved up and down to remove the nonattached cells in the first centrifuge tube. The same rinsing phase was then conducted in next two centrifuge tubes. The coupons were then immersed in 40 mL of a disinfection solution. At different time points (5, 10, 15, 20 25, and 30 min), the coupons were immediately immersed in sterile stomacher blender bags containing 40 mL of a neutralizing buffer solution (0.8% sodium thiosulfate solution, pH 7.2). The attached biofilm cells were removed from the coupons using a homogenizer (BagMixer 400VW; Interscience, Co. Ltd., France) after pummeling for approximately 1 min in second gear. Then, serial dilutions with 0.9% NaCl solution were prepared. The control was exposed to 40 mL sterile 0.9% NaCl solution instead of disinfectants. All measurements were maintaining at room temperature. Biofilm cell counts were determined in five independent experiments by trypticase soy agar (TSA; Hope-Biotechnology, Co. Ltd., Beijing, China) after 24 hr at 28 °C.

Statistical analysis

The results were transformed to $\log_{10}$ of the colony-forming units per cm^2 (CFU/cm^2). Data were subjected to a one-way Duncan's ANOVA test using SPSS (SPSS Inc., Chicago, IL, U.S.A.) to assess whether significant differences ($P < 0.05$) existed between the susceptibility of tested *ENT*.

Results

The effect of the four disinfectants on *E. cloacae* biofilms

The concentration of the initial inoculum used to form biofilms on stainless steel coupons was approximately 2 log CFU/mL, and 8.26 log CFU/cm^2 were found attaching to the surfaces after 5 days of incubation with *E. cloacae*, which was confirmed by TSA plates. The inactivation of biofilm cells treated by four disinfectants significantly increased in a concentration-dependent manner, and the percentage of cells killed was over 99% for all four disinfectants. After exposure to SH, the number of viable cells on the stainless steel coupons was similarly reduced to 0.7 log CFU/cm^2 with a log reduction (LR) value of 7.56 for the two concentrations ($P > 0.05$; Figure 1). Compared to the treatment with SH, the bactericidal action of CD, StAEW, and NEW was not so remarkable, and incomplete killing of the biofilms grown on stainless steel coupons was observed. Upon treatment with CD (20 and 40 mg/L), the number of cells was reduced by 4.74 and 5.55 log CFU/cm^2, respectively. StAEW

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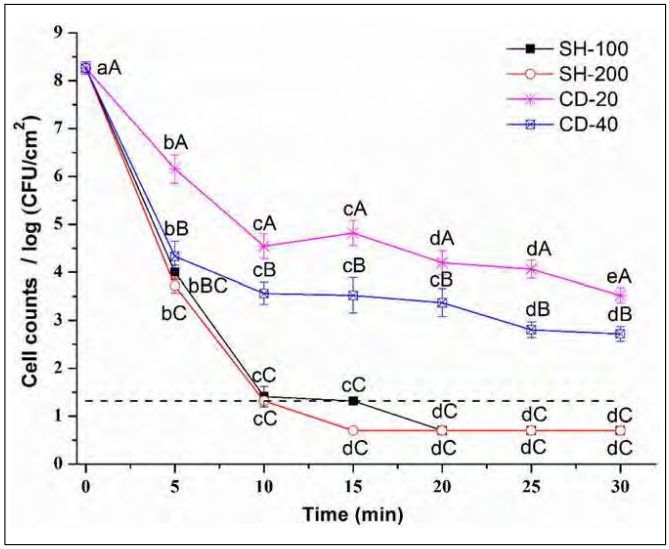

Figure 1–The lethal effect of SH and CD to *Enterobacter cloacae* mature biofilms. ■, biofilms treated by 100 mg/L SH; ○, biofilms treated by 200 mg/L SH; ✳, biofilms treated by 20 mg/L CD; ☒, biofilms treated by 40 mg/L CD. Dash line represents detection limit of 1.32 log CFU/cm^2. Each symbol indicates the mean ± standard deviation of five independent experiments (n = 5). A to E: Comparisons made between treatments with different time in same concentration of one disinfectant were significantly different (p < .05); A–C: Comparisons made between treatments with different disinfectants in same time were significantly different (p < .05). (SH, sodium hypochlorite; CD, chlorine dioxide).

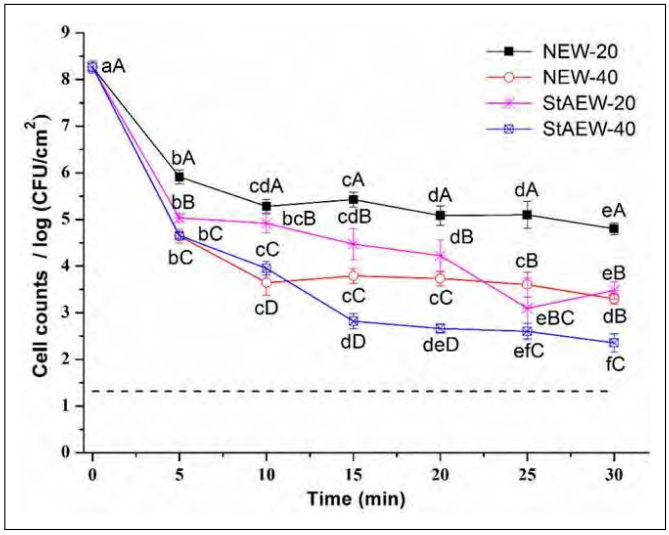

Figure 2–The lethal effect of StAEW and NEW to *Enterobacter cloacae* mature biofilms. ■, biofilms treated by 20 mg/L NEW; ○, biofilms treated by 40 mg/L NEW; ✳, biofilms treated by 20 mg/L StAEW; ☒, biofilms treated by 40 mg/L StAEW. Dash line represents detection limit of 1.32 log CFU/cm^2. Each symbol indicates the mean ± standard deviation of five independent experiments (n = 5). A–F: Comparisons made between treatments with different time in same concentration of one disinfectant were significantly different (p < .05); A-D: Comparisons made between treatments with different disinfectants in same time were significantly different (p < .05). (StAEW, strongly acid electrolyzed water; NEW, neutral electrolyzed water).

exhibited an efficacy similar to CD, with LR values of 4.78 (20 mg/L) and 5.91 (40 mg/L). In contrast, NEW showed the weakest reduction in the number of viable *E. cloacae* cells, with LR value of 3.46 (20 mg/L) and 4.96 (40 mg/L; Figure 2). Thus, it can be seen that SH was the most effective against the *E. cloacae* biofilm, followed by StAEW and CD, although NEW was the least effective, although a good reduction of the biofilm was achieved.

The effect of the four disinfectants on *C. freundii* biofilms

The bactericidal effect of different disinfectants on *C. freundii* appeared to be better than the effect observed on *E. cloacae*. For *C. freundii*, the concentration of the initial inoculum used to form biofilms on stainless steel coupons was approximately 2 log CFU/mL, and 7.73 log CFU/cm^2 of bacteria attached to the surfaces were recovered from the SS coupons after 5 days of incubation. After treatment with NEW and CD, the number of viable *C. freundii* cells on the stainless steel coupons was greatly decreased, with an LR value of 6.41 when treated with 20 mg/L of NEW and CD and 7.03 then treated with 40 mg/L of NEW and CD. Although the LR value was the same, the lethal curve of CD stabilized after a 10-min treatment while that of NEW took 30 min of treatment (Figure 3 and 4). The least number of biofilm cells was killed after exposure to SH, with a LR value of 5.16 upon treatment with 100 mg/L SH for 25 min and 7.03 upon treated with 200 mg/L SH for 15 min (Figure 3). StAEW exhibited the highest bactericidal activity and killed nearly all the biofilm cells, with an LR value of 7.03 after a 15-min treatment with 20 and 40 mg/L (Figure 4). In terms of the reduction of *C. freundii* biofilm cell numbers, the treatments were ranked as follows: StAEW>CD>NEW >SH.

The effect of the four disinfectants on *K. oxytoca* biofilms

For *K. oxytoca*, the initial inoculum used to form biofilms on stainless steel coupons was approximately 2 log CFU/mL, and 7.12 log CFU/cm^2 of bacteria attached to the surfaces were recovered from the SS coupons after 5 days of incubation. The four disinfectants had similar bactericidal effects on *K. oxytoca*. Except for the treatment with 100 mg/L SH, which exhibited an LR value of 4.69, and the treatment with 20 mg/L StAEW, which exhibited an LR value of 5.80, the other treatments exhibited a good effect, with 6.42 log CFU/cm^2 of dead cells (Figure 5 and 6). For the treatment of 200 mg/L SH and 20 mg/L CD, SH exhibited better efficacy than CD for 20 min (P < 0.05), after which the curves overlapped, indicating that the two treatments had the same bactericidal effect. The 40 mg/L CD treatment exhibited the same LR value after 15 min treatment (Figure 5). The lethal curve of 40 mg/L NEW exhibited a stable decreasing trend for 20 min, with a LR value of 6.42, and that of StAEW decreased for 5 min longer, although the treatment with 20 mg/L NEW exhibited no change from 10 to 15 min and then slowly decreased to 0.7 log CFU/cm^2 after 30 min of treatment (Figure 6). In terms of the lethal effect on *K. oxytoca* biofilm cells, the treatments were ranked as follows: CD>NEW>StAEW>SH.

Discussion

With the constant advancement of food industrialization, biofilms have become a public health issue and economic concern due to the potential for cross-contamination of instruments and surfaces that contact with food. The factors responsible for attachment and biofilm formation, such as bacterial strains, temperature, and contact surfaces, which are commonly encountered during food processing, are critical for biofilm removal (Fernándezdelgado et al., 2015; Vivas et al., 2008). Most studies regarding the control of biofilms have focused on the biofilms grown in standard lab

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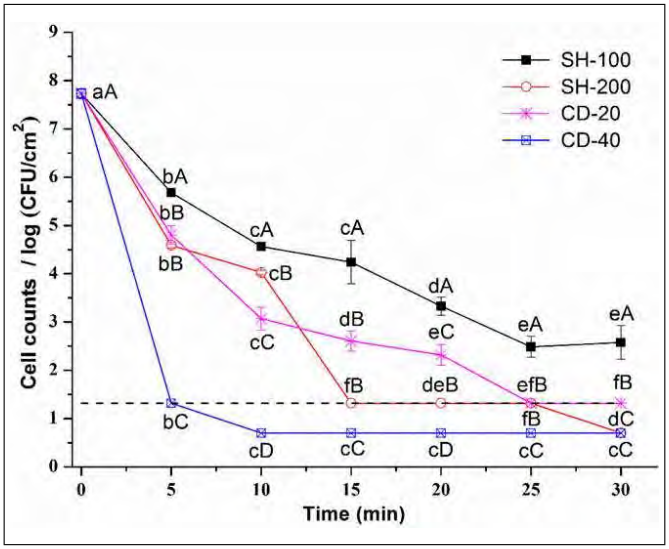

Figure 3–The lethal effect of SH and CD to *Citrobacter freundii* mature biofilms. ■, biofilms treated by 100 mg/L SH; ○, biofilms treated by 200 mg/L SH; ✳, biofilms treated by 20 mg/L CD; ☒, biofilms treated by 40 mg/L CD. Dash line represents detection limit of 1.32 log CFU/cm^2. Each symbol indicates the mean ± standard deviation of five independent experiments (n = 5). A-f: Comparisons made between treatments with different time in same concentration of one disinfectant were significantly different (p < .05); A–D: Comparisons made between treatments with different disinfectants in same time were significantly different (p < .05; SH, sodium hypochlorite; CD, chlorine dioxide).

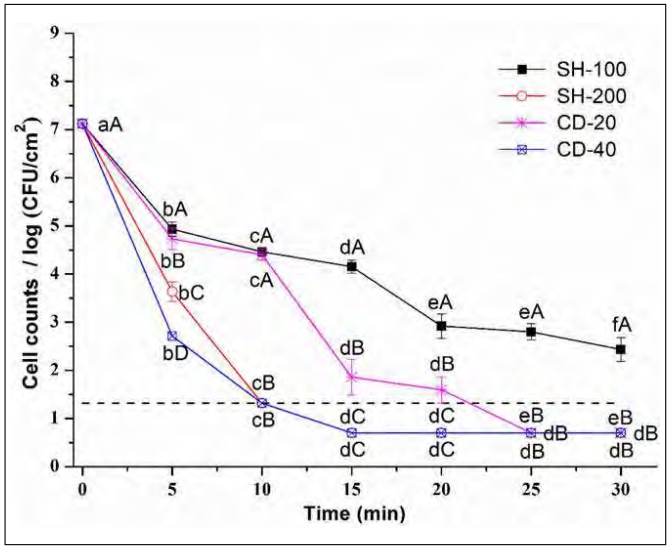

Figure 5–The lethal effect of SH and CD to *Klebsiella oxytoca* mature biofilms. ■, biofilms treated by 100 mg/L SH; ○, biofilms treated by 200 mg/L SH; ✳, biofilms treated by 20 mg/L CD; ☒, biofilms treated by 40 mg/L CD. Dash line represents detection limit of 1.32 log CFU/cm^2. Each symbol indicates the mean ± standard deviation of five independent experiments (n = 5). A-e: Comparisons made between treatments with different time in same concentration of one disinfectant were significantly different (p < .05); A–D: Comparisons made between treatments with different disinfectants in same time were significantly different (p < .05; SH, sodium hypochlorite; CD, chlorine dioxide).

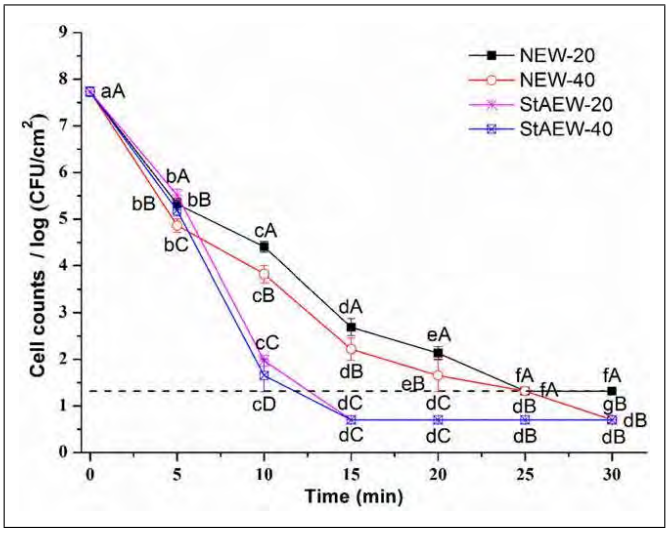

Figure 4–The lethal effect of StAEW and NEW to *Citrobacter freundii* mature biofilms.■, biofilms treated by 20 mg/L NEW;○, biofilms treated by 40 mg/L NEW;✳, biofilms treated by 20 mg/L StAEW;☒, biofilms treated by 40 mg/L StAEW. Dash line represents detection limit of 1.32 log CFU/cm^2. Each symbol indicates the mean ± standard deviation of five independent experiments (n = 5). A-g: Comparisons made between treatments with different time in same concentration of one disinfectant were significantly different (p < .05); A-D: Comparisons made between treatments with different disinfectants in same time were significantly different (p < .05; StAEW, strongly acid electrolyzed water; NEW, neutral electrolyzed water).

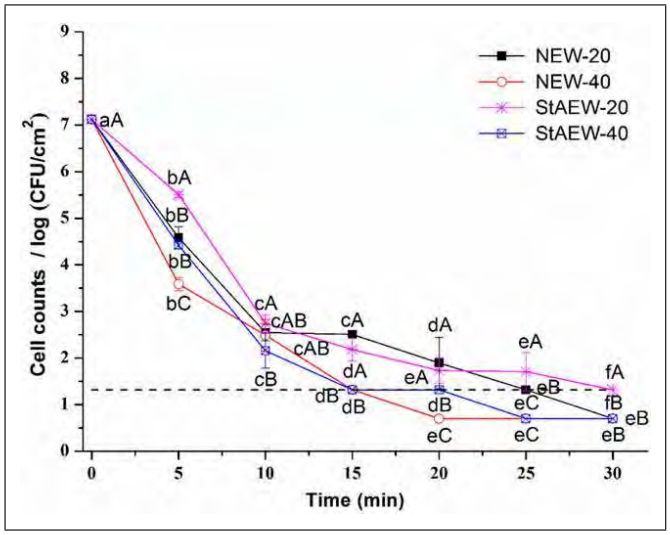

Figure 6–The lethal effect of StAEW and NEW to *Klebsiella oxytoca* mature biofilms.■, biofilms treated by 20 mg/L NEW;○, biofilms treated by 40 mg/L NEW;✳, biofilms treated by 20 mg/L StAEW;☒, biofilms treated by 40 mg/L StAEW. Dash line represents detection limit of 1.32 log CFU/cm^2. Each symbol indicates the mean ± standard deviation of five independent experiments (n = 5). A-f: Comparisons made between treatments with different time in same concentration of one disinfectant were significantly different (p < .05); A–C: Comparisons made between treatments with different disinfectants in same time were significantly different (p < .05; StAEW, strongly acid electrolyzed water; NEW, neutral electrolyzed water).

conditions and are not applicable to food processing environments. The frequent entries and exits of people in slaughterhouses result in temperature fluctuation. Through large amount of data collection and investigation, the actual temperature was determined to usually be 20 °C during working hours. Stainless steel, as the main surface material in the modern poultry and meat processing industries, is remarkably easily contaminated upon coming in contact with carcasses, which increases the probability of cross-contamination and makes it easy for biofilm to attach to themselves to stainless steel surfaces. In factories, concentrations of SH ranging from 50 to 200 mg/L are traditionally used as a strategy for the treatment of surfaces that come in contact with food. However,

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microorganisms have been increasingly to possess resistance to such agents and can survive and grow under increasingly higher concentrations of the disinfectant. So, various alternative disinfectants have been developed. These disinfectants are normally applied at concentrations ranging from 20 to 40 mg/L to eliminate the bacteria found on the contact surfaces during food processing.

Currently, polystyrene microplate assays are widely used to quantify biofilm in well-defined laboratory conditions (Díez, 2012). However, the poor efficiency of this method in determining survival conditions makes the viable plate-count method a better alternative. Classification of the activity spectrum of each sanitizing agent according to the LR value for each microorganism facilitates the development of a cleaning, disinfection, and sterilization program for the food industry. It is important to state that there is no disinfecting agent suitable for all situations with preestablished specifications for use because the choice of disinfectant depends on the types of microorganisms to be destroyed. Disinfectants should reduce cell numbers by 5 log in the presence of a neutralizer (Jahid & Ha, 2014), although the guidelines established by the Association of Official Analytical Chemists for the Germicidal and Detergent Sanitizing Action of Disinfectants test state that a decrease of ≥ 3 log units is an acceptable target for disinfectant efficacy against biofilms (Dequeiroz & Day, 2007). For the four disinfectants tested, the experimental results demonstrated that, for *E. cloacae,* higher concentrations of CD reduced the biofilm populations by 5 log CFU/cm^2 (Figure 1), whereas NEW and lower concentrations of StAEW can also reduce the biofilm populations by 3 to 5 log CFU/cm^2 (Figure 2). The four disinfectants reduced the populations of *K. oxytoca* and *C. freundii* biofilms by 5 log CFU/cm^2. Recently, SH is the most widely used disinfectant in the food industry, especially in food-manufacturing factories, because of its broad antimicrobial spectrum, ability to dissolve organic matter and low cost. In this study, the two concentrations of SH exhibited two opposing trends: 100 mg/L exhibited the lowest reduction in cell numbers, except in *E. cloacae*, whereas 200 mg/L exhibited the highest reduction in cell numbers, indicating that after cleaning procedure, 100 mg/L SH is the best choice to disinfect against *E. cloacae*, and 200 mg/L SH can be a good alternative for three strains. In fact, the disinfection by SH is greatly dependent on the strains of bacteria. Jahid and Ha (2014) reported reductions of 6.5 and 6.7 log CFU/cm^2 after a 30-min treatment with SH of *Aeromonas hydrophila* planktonic cells, whereas similar effects have been observed with 2000 and 4000 mg/L for biofilm cells, and in a recent study, SH was not very effective in killing biofilms (Pagedar & Singh, 2015). The presence of organic materials can also decrease the bactericidal effect of disinfectants along with a decrease in the ACC (Fukuzaki, 2006). Mazzola et al. (2009) found that chloride-based solutions reacted with organic materials, and the bactericidal activity of these solutions decreased based on the concentration present. Thus, the concentration of the disinfectant must be sufficient to kill the microorganisms tested, which could be the reason for the difference in the efficacy of 100 and 200 mg/L SH treatments in this study. Duan, Wang, Xue, Li, and Xu (2017) found that SH treatments (50 and 100 mg/L) were inefficient in reducing the total viable counts, exhibiting no significant ($P > 0.05$) difference to water alone, whereas StAEW (58 mg/L) was the most efficient, which was similar to the results of this study. For SH, some health concerns regarding the production of harmful products such as trihalomethanes and chloroacetic acid should also be considered (Malheiro et al., 2016).

In comparison to *C. freundii* and *K. oxytoca*, the *E. cloacae* biofilm was more resistant to the four disinfectants. In recent years, *E. cloacae* has emerged as an important contaminant and has been isolated from food-processing plants, meat and ready-to-eat foods (Nyenje, Green, & Ndip, 2013; Nyenje, Tanih, Green, & Ndip, 2012). As a food contaminant, *E. cloacae* exhibits psychrotrophic and proteolytic activity, and these characteristics are associated with the spoilage of proteinaceous refrigerated food of animal origins (Dos, Martins, de Araujo, Mantovani, & Vanetti, 2012). Previously, researchers have tried to control *E. cloacae* contamination with photocatalytic disinfection, which only decreased the cell numbers by 3 to 4 log CFU/mL, and was not ideal (Ede, Hafner, Dunlop, Byrne, & Will, 2012; Ibáñez, Litter, & Pizarro, 2003). Currently, EOW has gained immense popularity as a novel disinfectant, and the antimicrobial mechanisms of EOW have been reported to be composed of several factors, including the presence of chlorine, high ORP values, increase of membrane permeability, and the oxidation of key metabolic systems (Hricova, Stephan, & Zweifel, 2008; Rahman et al., 2016). Sun et al. (2012) confirmed that EOW is very effective in eliminating bacterial biofilms from stainless steel surfaces. Ayebah, Hung, Kim, and Frank (2006) also reported that EOW, at a concentration of 44 mg/L, leads to a > 6 log reduction of biofilms. In our study, the survival characteristics of three strains after exposure to EOW are presented in Figure 2, 4, and 6. The biofilm cell number of *C. freundii* and *K. oxytoca* was decreased to below the detection limits after EOW treatment, and a similar result was presented by Park, Hung, and Kim (2002). Zeng et al. (2010) also reached the 100% disinfection rate at 1 to 3 min with ACC values of 12.40 and 37.30 mg/L, while disinfection of *E. cloacae* biofilms varied from 3 to 6 log CFU/cm^2, and the lethal effect ended just after the treatment for 10 min, which was consistent with the results of Han et al. (2017). In this study, EOW treatment of *E. cloacae* biofilms was less effective than other disinfectants, perhaps because of the limited ability of the chlorine in EOW to penetrate the attached microbial cell layers and due to the production of extracellular polymeric substances (EPS). The EPS plays an important role in the biofilm physiology and persistence. Acting as a defense barrier, EPS helps the biofilm cells to resist multiple stress conditions, such as the presence of disinfectants. Studies have shown that the production of extracellular polysaccharides can increase the resistance of bacteria to disinfectants (Ryu & Beuchat, 2005). Dynes et al. (2009) found that the modifications of EPS composition, quantity and the spatial distribution are important components of resistance to disinfectants. In previous work, thicker biofilm and a greater intensity in special ATR-FTIR spectra were found in *E. cloacae* and *K. oxytoca*, and few noticeable signals assigned to C–O and C–C stretching in carbohydrates was found in *C. freundii* (Wang et al., 2017). Boualam, Quilã¨S, Mathieu, and Block (2002) also observed several high peaks of functional groups associated with amideI, amideII,and polysaccharides in biofilm formed by *E. cloacae*. Hence EPS quantity and composition vary from one bacteria species to another, which could also affect the efficacy of disinfectants. In addition to EOW, CD has also shown a weaker bactericidal effect toward *E. cloacae* biofilms than toward other strains. In fact, CD has some advantages over SH and has 2.5-fold greater oxidizing power than liquid chlorine. The lethal activity of CD is stable over a wider pH range (3.0 to 8.0) compared to SH whose lethality is decreased at neutral pH (Bang et al., 2014). In this study, CD was not an ideal choice as a single disinfectant toward *E. cloacae* biofilms, but a synergistic treatment could be considered in further studies.

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Some researchers found that the treatment of CD increased the sensitivity to other stress factors such as drying or heat (Hoikyung, Haeyoung, Bang, Beuchat, & Jeehoon, 2010). Kim, Lee, Ryu, and Kim (2017) combined CD and hot-air drying to inactivate *Bacillus cereus*, and the cell numbers were reduced to below the detection limit (1.7 log CFU/sample).

Conclusion

The finding in this study suggested that the responses of *C. freundii*, *K. oxytoca*, and *E. cloacae* to four different disinfectant treatments were greatly different. *E.* cloacae exhibited the highest survival rate, which means this bacteria exhibited the strongest resistance. SH (200 mg/L) and EOW were shown to be effective in the inactivation of the three strains. The response to disinfectants in this study can provide meaningful information for control of formed biofilm in food processing environments. Further research objectives of great value will include the assessment of the synergistic effect of various disinfectants, the investigation of response of mixed-species biofilms to disinfectants, and the evaluation of the role of EPS in both adaptation and resistance.

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Authors' Contributions

Linlin Cai contributed to experimental part of researches and drafted the manuscript. Huawei Wang, Lijiao Liang, and Guangyu Wang performed the experiments. Xinglian Xu and Huhu Wang planned the experiment and guided some of the work.

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Title Page

Estimating the burden of Invasive and Serious Fungal Disease in the United Kingdom

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ABSTRACT

Background: The burden of fungal disease in the UK is unknown, but was estimated in 2002 by the Health Protection Agency. A few data are systematically collected. We have re-estimated the annual burden of invasive and serious fungal disease.

Methods: We used several estimation approaches including voluntary laboratory reports. We searched and assessed published estimates of incidence, prevalence or burden of specific conditions in various high-risk groups; studies with adequate internal and external validity allowed extrapolation to estimate current UK burden. For conditions without adequate published estimates, we sought expert advice.

Results: The UK population in 2011 was 63,182,000 with 18% aged under 15 and 16% over 65. The following annual burden estimates were calculated: invasive candidiasis (IC) 5,142; *Candida* peritonitis complicating chronic ambulatory peritoneal dialysis 88 and the remainder captured under IC; *Pneumocystis* pneumonia 207 to 587 cases, invasive aspergillosis (IA), excluding critical care patients 2,901 to 2,912, and IA in critical care 387 to 1,345 patients, utilizing different external assumptions, <100 cryptococcal meningitis cases. We estimate 178,000 (50,000–250,000) allergic bronchopulmonary aspergillosis cases in asthma, and 873 adults and 278 children with cystic fibrosis. Chronic pulmonary aspergillosis is estimated to affect 3,600 patients, based on burden estimates post tuberculosis and in sarcoidosis.

Conclusions: Much uncertainty is intrinsic to most burden estimates due to diagnostic limitations, lack of national surveillance systems, few published studies and methodological limitations. The largest uncertainty surrounds IA in critical care patients. Further research is needed to produce a more robust estimate of total burden.

Word count: 250

BACKGROUND

Invasive fungal disease is thought to be increasing in frequency in the United Kingdom (UK) due to a variety of factors including increased survival time from previously lethal illnesses and an increase in prevalence of conditions and treatments leading to immunosuppression. Understanding of the overall burden of invasive fungal disease in the UK is limited as there is no formal systematic or mandatory surveillance programme specific to fungal infections, although active surveillance networks exist for candidaemias (voluntary laboratory reporting[1]) and specifically for candidaemias in neonates (voluntary reporting[2]). In addition, several debilitating chronic and allergic fungal diseases, amenable to antifungal therapy have come to greater prominence. An analysis of laboratory reports of fungal infections was carried out in 2001[3], which highlighted the likelihood of underestimating total burden due to the challenges involved in laboratory diagnosis and the voluntary nature of the laboratory reporting system. In 2008, the UK health Protection Agency issued a report entitled "Fungal Diseases in the UK: The current provision of support for diagnosis and treatment: assessment and proposed network solution"[4]. A rough annual burden estimate of many fungal diseases was made in this report, but not subsequently published. The UK community of experts in this area has been active in developing best practice standards for the UK and beyond for the diagnosis and clinical management of fungal disease[5,6,7,8,9]. A necessary next step for healthcare and research prioritisation is to quantify this burden with improved tools and an expanded range of serious fungal infections.

METHODS

We used the UK Office for National Statistics 2011 Census data[10] to estimate UK population size. We used this as the 2011 census is the most recent census in the UK.

We have estimated the annual incidence of the following invasive fungal infections: cryptococcal disease and meningitis, *Pneumocystis* pneumonia, invasive aspergillosis, candidaemia and *Candida* peritonitis, as well as oesophageal candidiasis. In addition, we have estimated the prevalence of chronic pulmonary aspergillosis, allergic bronchopulmonary aspergillosis (ABPA) and severe asthma with fungal sensitisation (SAFS). Information on incidence, prevalence and total burden of these conditions in the UK is limited. Where such information was available for the UK or certain countries within the UK (where UK estimates were not available), we included it in the study. One example is data from the voluntary surveillance of candidaemia in England, Wales and Northern Ireland[1].

Where the information was not available we used a pragmatic approach: for each fungal condition, we considered which populations were most at risk of the condition, sought published estimates for incidence or prevalence measures for the condition in these specific risk populations, and applied these rates to available published estimates of size of these high risk populations in the UK (or certain countries within the UK where UK estimates were not available).

Where multiple estimates of incidence or prevalence were published, we considered both internal and external validity of the studies in deciding on which estimate to use. The methods used for estimating burden of the specific fungal conditions are outlined below.

Selection criteria for published estimates of incidence: for many of the severe fungal infection, there is a paucity of published estimates of incidence, therefore we had to be pragmatic in our approach. Where more than one published estimate was available, we prioritised studies with the best applicability to the UK population (i.e. where UK studies were available we used these, if not we used studies from countries with as comparable a population as possible, where non-UK studies were selected, this is made clear in italics in the fungal infection section of the methods) and those with the largest sample sizes (where multiple studies were considered, this is made clear in the fungal infection section of the methods).

Pneumocystis pneumonia

First method

Prior to March 2013, no published estimates of incidence, prevalence or total burden were available for England except for AIDS patients (PHE HIV in the UK report[16]) therefore our initial approach was pragmatic.

The high risk populations identified and the data source used to estimate their current size included AIDS patients (PHE HIV in the UK report[16]) and patients who had received various transplants (Tx) - Heart Tx, Kidney Tx, Liver Tx and Lung Tx or Heart and Lung Tx patients (Organ donation and Transplantation Activity Report 2013/14[11]).

An estimate of total burden amongst the AIDS patient population for 2011 to 2013 was published in the PHE HIV in the UK report[16], we divided this estimate by three to obtain an average yearly estimate.

The incidence rates specific to transplant high risk populations were found from a variety of studies including: Cardenal et al.[12] for Heart Tx patients; Wang et al.[13] for Kidney Tx, Liver Tx and Lung Tx/ Heart + Lung Tx patients.

Second method

A UK study estimating the incidence of *Pneumocystis* pneumonia over an 11 year period using 4 data sources was published in March 2013[14]. This showed that the incidence had increased significantly over the study period. We aimed to estimate the total burden for the most recent year of the study (2010) based on figures reported in the paper for each of the 4 data sources: Hospital Episode Statistics (HES) data - the paper reported the number of cases in 2010; Routine Laboratory Reporting - the paper reported a range for number of cases in 2008-2010, we used the central point of this range; Death Certificate Data - the paper reported the number of cases in 2010; HIV Surveillance Data - the paper did not report a number or range for total number of cases in the later years of the study, we obtained an estimate by extrapolating from figure 3 of the paper.

Cryptococcal meningitis:

No published estimates of incidence, prevalence or total burden were found for the UK. We obtained an estimate based on a simple direct question to the largest mycology referral laboratories in the UK (Bristol, Leeds and Manchester) of the frequency of positive cryptococcal antigen test results. One publication was found which reported on trends in incidence and numbers of fungal meningitis[15], but this covered all fungal infections and was not specific to cryptococcal infection.

The high risk populations identified included newly diagnosed HIV infection. We used the PHE HIV in the UK report[16] to estimate the current size of this population. The incident rate for this high risk population was obtained from Patel et al.[17]

Invasive aspergillosis

We took a pragmatic approach to estimating the burden of invasive aspergillosis. The high risk populations identified and the data source used to estimate their current size included: Allogeneic hematopoietic stem cell transplantation (HSCT) and autologous HSCT patients (The British Society of Blood and Marrow Transplantation Registry [18]); Heart Tx, Lung Tx, Liver Tx and Kidney Tx (Organ donation and Transplantation Activity Report 2013/14[11]); AIDS patients (HPA HIV in the UK report[16]); Acute myeloid leukaemia (AML), Acute lymphoblastic leukaemia (ALL), Chronic myeloid leukaemia (CML), Chronic lymphocytic leukaemia (CLL), Non Hodgkin lymphoma (NHL), Hodgkin lymphoma (HL) and Myeloma patients (UK Cancer Registry [19]); Chronic granulomatous disease (CGD) patients (Jones et al.[20]); Chronic obstructive pulmonary disease (COPD): emergency hospital admissions (Di Santostefano et al.[*21]); Critical Care Patients (Hospital Episode Statistics, Adult Critical Care in England: April 2013 to March 2014[22]); patients with lung cancer (UK Cancer Registry[19])

The incidence rates specific to the above high risk populations were found from a variety of studies: Lortholary et al.[23] (for Allogeneic and Autologous HSCT patients, and for Heart Tx, Lung Tx, Liver Tx, and Kidney Tx patients) –*these estimates were not for the UK population but the French population*; Keshishian C. Health Protection (HPA) Mycology Network - Rapid evaluation of incidence estimates (Unpublished)[24] (for AIDS patients); Pagano et al.[25,†] (For AML, ALL, CML, CLL, NHL, HL and myeloma patients) –*these estimates were not for the UK population but the Italian population*; Beauté et al.[26,‡] (for CGD patients) –*this estimate was not for the UK population but the French population*; Guinea et al.[27] (for COPD: emergency hospital admissions) –*this estimates were not for the UK population but the Spanish population*, another study reporting an incidence estimate was considered (Xu et al[28]) but the sample size for the study was significantly smaller than that of Guinea et al so we did not include it; A wide range of estimates from different studies[29] for critical care patients, see

[*] We used the HES-based 4 year study to estimate yearly average number of COPD emergency admissions. We excluded the day cases as these were unlikely to develop invasive aspergillosis. We used the estimated incidence in the last year of the study (2007)

[†] The paper reports total yearly number of cases of invasive mould infections according to malignancy type. It also reports that 90% of mould infections were caused by *Aspergillus* spp. We calculated malignancy-specific incidence rates for invasive aspergillosis by applying the 90% rate to the total number of cases of mould infection per malignancy type and dividing this by the total number of patients with the malignancy.

[‡] The paper reported an overall incidence of invasive fungal disease (IFD) per patient year, and reported that 40% of IFDs were cause by invasive aspergillosis. The overall incidence rate was applied to the estimated population size, and 40% of the resulting estimate of overall IFD burden was used for the burden of invasive aspergillosis.

sensitivity analysis discussion below –*these estimates were not for the UK population but the Belgian and Spanish populations*; Yan X et al.[30] for patients with lung cancer –*this estimate was not for the UK population but the Chinese population*.

Critical care patients: Sensitivity analysis

The largest risk-group population by far for invasive fungal infection in our study was patients in critical care at risk of invasive aspergillosis, regardless of which type of critical care unit is considered. Therefore any variation in incidence rate could lead to a significant change in estimated burden. We carried out a sensitivity analysis to reflect this.

Activity data is available for a broad range of critical care units in England[22]. The most common type of admission to ICU amongst cases of invasive aspergillosis is medical admission, and the most common reasons for admission respiratory and cardiovascular disease[31], therefore we considered two broad groups of critical care units in the sensitivity analysis. The first was medical intensive care units (ICUs) and other ICUs where length of patient stay is likely to be similar to that of medical ICUs[§], the second was all ICUs, excluding spinal units.

There is a wide range of published estimates for incidence of invasive aspergillosis in patients in critical care: from 0.3% to 19%[29]. Key factors include: the type of critical care unit considered, and whether or not studies were autopsy controlled. Further complications include the facts that no non-invasive diagnostic test (for example isolation of *Aspergillus* from respiratory cultures) is sensitive or specific enough to establish definite diagnosis[32], and that it is difficult to distinguish colonisation with *Aspergillus* from infection with *Aspergillus*[32].

We focused on those studies that specifically examined the incidence of invasive aspergillosis in critical care units. Four such studies were found, one had a small sample size (n=24) and did not report an incidence estimate so was not considered here[33]. The other three, from which incidence rates estimates were used, are listed in table 4 with their characteristics and the populations they apply to.

We adjusted estimates of burden to account for double counting of patients already counted in groups were we assumed that the majority of those who developed invasive aspergillosis would require ICU admission (solid organ transplant patients and COPD emergency admissions).

Chronic pulmonary aspergillosis

[§] Critical care episodes were counted from table 14 of the Critical Care report 2013-14[22], critical care unit functions included in this group were: Non-specific general adult critical care, Medical adult patients, Liver patients predominate, Renal patients predominate

Chronic pulmonary aspergillosis complicates a wide spectrum of underlying lung disease of which the commonest conditions are pulmonary tuberculosis (PTB), non-tuberculous mycobacterial lung infection, COPD, sarcoidosis, and allergic aspergillosis complicating asthma[39].

An estimate of the annual number of patients with chronic pulmonary aspergillosis after pulmonary tuberculosis (PTB) has recently been published[34]. For most countries, this was based on a 22% rate of chronic pulmonary aspergillosis after PTB in those with cavities of 2.5cm or greater and 2% in those without a residual cavity, but in the absence of UK data, the assumed rate or residual cavitation after PTB was 12% (range in other countries 21-35%[35,36,37]). To generate a 5 year period prevalence a 15% attrition rate was assumed, accounting for surgical resection and death.

An estimate of the rate of chronic pulmonary aspergillosis complicating sarcoidosis in the UK was also recently published[38]. Numerous other antecedent underlying pulmonary conditions are found in patients with chronic pulmonary aspergillosis[39], and the relative proportions of these were used to estimate the total UK burden.

A separate approach was taken using referrals to the National Aspergillosis Centre from the north west of the UK, based on population and regional variation in directly age-standardised mortality rates (DSR). Just over 100 new patients are referred annually to the National Aspergillosis Centre[40]. It was assumed that referral was near complete in the NW of the UK to the National Aspergillosis Centre because of excellent clinical links and proximity. Using published directly age-standardised respiratory disease mortality rate for under year 75 olds (DSR)[41] and regional populations[42], we derived an annual potential diagnosable burden, based on current respiratory medicine practice, which approximates to an annual incidence (table 3).

Allergic bronchopulmonary aspergillosis (ABPA)

ABPA complicates asthma and cystic fibrosis (CF). The global burden of asthma has been re-estimated recently, a total of 334 million in all ages (4.85% of the global population)[43] and 193 million adults with active asthma[44]. The UK has one of the highest rates of asthma in the world, an estimated 16-18.2% of adults with clinical asthma[45], or nearly 8.2-9 million (age 15 and older) [46]. Other more recent data of asthma prescription data from the UK, put the total rate at ~5.4 million, including children. As the prevalence in children is 88% of the adult rate, we derived an adult number of asthmatics of 4.4 million (our lowest and base case estimate).

There are no population data for ABPA or any surrogate marker such as IgE from the UK. An abstract from one hospital tracking IgE and Aspergillus IgE levels in 330 consecutive referrals to an asthma clinic found a 1.5% rate of probable ABPA with most diagnostic features and 13% with both an elevated total IgE and Aspergillus IgE[47]. A base case estimation of ABPA rates in adults was made, using a median prevalence of 2.5% from referrals to secondary care. This 2.5% rate is derived from rates of 0.78% and 4.1%[44,48] from 6 national studies all done in consecutive referrals over a defined period to a specialist chest physician for problematic asthma. Deterministic sensitivity analyses relating to different asthma populations rates and ABPA rates were also derived.

ABPA is reported in children, but is probably rare[49], and there are no epidemiology studies published to estimate a rate.

We ascertained the number of individuals in the UK over the age of 18 with CF from 2011 annual report. Using the distribution frequency described by Baxter et al[50], we derived the likely numbers of adults with aspergillosis in CF in the UK. ABPA in CF is well recognised in older children and teenagers, and we have used the annual CF report for this purpose[51].

Severe asthma with fungal sensitisation (SAFS)

As SAFS is another distinctive pattern of asthma usually associated with sensitisation to multiple fungi and responsive to antifungal medication[52,53,54,55] we estimated the UK burden of this entity. While recently described in children[56], it is rare, and so not estimated. Severe asthma is defined by a poor level of current clinical control including a risk of frequent severe exacerbations (or death) and/or chronic morbidity. Severe asthma includes untreated severe asthma, difficult-to-treat severe asthma, and treatment-resistant severe asthma. In a multi-country comparison of the role of fungal sensitisation in severe asthma, 21% were defined as severe[57]. In other studies[58] lower frequencies of severity are recorded[59], including a recent estimate of 3.6%, depending on many factors, and we have used an arbitrary figure of 5% as our base case to embrace both severe refractory and compliant difficult to control asthmatics. We have also computed a sensitivity analysis.

Fungal sensitisation becomes more common the worse the asthma, with rates ranging from ~25% of patients referred to a specialist to 75% for those repetitively admitted to hospital. We have used a rate of 60% to be conservative. [60,61,62,63]

Candidaemia

There is a voluntary surveillance system in England that collects laboratory reports of all microorganisms isolated (including fungi) at approximately 400 NHS and other laboratories throughout England, Wales and Northern Ireland. The database which compiles this data is called LabBase2[1]. Surveillance reports are published in PHE weekly Health Protection Reports[64].

Blood culture has a poor sensitivity for detecting Candida species: a 2011 systematic review of the diagnostic accuracy of PCR techniques for invasive candidiasis[65] identified 10 studies reporting the sensitivity of blood cultures. The pooled culture positivity rate in patients with proven or probable invasive candidiasis was 0.38 (95%CI: 0.29 to 0.46)[65]. A more recent US study using PCR and beta 1.3-D-glucan detection derived a similar figure[66]. Therefore we made the assumption that the total number of positive blood culture samples represented 38% cases of proven or probable invasive candidiasis tested by blood culture techniques.

Candida peritonitis

We took a pragmatic approach to estimating the burden of Candida peritonitis.

The two main risk groups for this condition in the UK are: surgical ICU patients and patients on chronic ambulatory peritoneal dialysis (CAPD).

Surgical ICU patients

We assumed that the majority of cases in surgical ICU patients would be counted in the estimate of total number of cases of invasive candidiasis discussed above.

CAPD patients

To estimate the number of patients on CAPD in England every year, we used data from the NICE Clinical Guideline 125: Kidney disease: peritoneal dialysis: Costing report, Implementing NICE guidance[67].

To estimate the incidence of peritoneal candidiasis in patients on CAPD, we used an estimate reported on the Leading International Fungal Education (LIFE) website[68]. This incidence estimate was reported as episode per patient year. In our calculation of attributable burden, we assumed that all CAPD patients in England stay on CAPD for at least a year.

Oesophageal candidiasis

The main risk group for this condition in the UK is probably AIDS patients. Oesophageal candidiasis is an AIDS defining illness. The number of cases reported in the UK between 2011 and 2013 was reported in the PHE HIV in the UK report[16]. We divided this figure by three to obtain a yearly estimate of burden.

Another approach to estimating the burden was also taken using published estimates of yearly incidence amongst HIV patients on anti-retroviral therapy[69] -*this estimate was not for the UK population but the USA population*- and estimates of numbers of HIV patients on anti-retroviral therapy in the UK[16].

Mucormycosis

Occasional cases of mucormycosis occur in the UK, usually highly immunocompromised patients, occasionally in intravenous drug addicts, burn or trauma victims or diabetic patients, and rarely related to hospital transmission (Lancet tongue depressors). Most diagnoses are made histologically or on direct microscopy specimens, culture sensitivity is low. No data are collected systematically.

To estimate the number of mucormycosis cases in the UK, we applied *the French population incidence* found from published studies[70],[71] to the UK population (no UK estimate of incidence available).

Other rarer infections

Other rarer infections are not well tracked in the UK, including imported endemic mycoses (histoplasmosis and coccicioidomycosis for example) and are rare from experience of experts at the national Aspergillus centre. Likewise serious infections related to unusual filamentous fungi such as

Fusarium or Scedosporium do occur, the former in leukaemic patients, the latter in some cystic fibrosis patients and rarely as an invasive pathogen.

Results

RESULTS

The UK population in 2011 was 63,182,000 with 18% aged under 15 and 16% over 65[10].

Pneumocystis pneumonia:

An average yearly total burden of 157 *Pneumocystis* pneumonia (PCP) diagnoses was found for the AIDS patient population in the UK[16] using our first estimation approach.

The estimates of population size, population-specific incidence rate and yearly burden of disease obtained for patients who had received various transplants in the UK are outlined in table 1

Table 1: Estimates of population size, specific incidence rates and yearly burden of Pneumocystis pneumonia for solid organ transplant populations.

Population	Population size	Incidence rate	Yearly burden of disease
Heart Tx	195	5.5%	11
Kidney Tx	2,244	0.3%	7
Liver Tx	830	1.15%	9
Lung Tx or heart and lung Tx patients	397	5.78%	23
Total			50

The total estimate of burden of PCP for both AIDS patients and solid organ transplant populations in the UK was **207**. This estimate ignores other immunocompromised patients, such as haematological malignancy and severe autoimmune disease.

Second method

Our second estimation approach yielded a total UK burden of **587 cases** of PCP for 2010.

Cryptococcal disease and meningitis:

An estimate of up to **100 cases** per year for the UK was obtained from the reference laboratories

It is unclear whether this is an underestimate or an overestimate as it is estimated that in 2011 there were a total of 51 fungal meningitis cases (all fungi, based on culture). However this 2011 estimate is based on voluntary laboratory reporting and furthermore, there is some evidence that cryptococcal infections are under-reported[15]. Many diagnoses of cryptococcal disease are based on cryptococcal

antigen alone, and while meningitis is the commonest manifestation of disease, other organs are affected. It is likely that the vast majority of these cases were in HIV-infected individuals and in 2013 ~6,000 new HIV infections were diagnosed[16 above].

Invasive aspergillosis

The estimates of population size and (p), population-specific incidence rate (i) and burden of disease (n) obtained for high risk populations in the UK excluding critical care units patients are outlined in table 2

Table 2: Estimates of population size, specific incidence rates and yearly burden of Invasive aspergillosis for well recognised at risk groups

Population	Population size	Incidence rate	Yearly burden of disease
Allogeneic HSCT	1,615	8.1%	131
Autologous HSCT	2,225	0.9%	20
Heart Tx	195	4.8%	9
Lung Tx	397	4.1%	7
Liver Tx	830	0.8%	7
Kidney Tx	2,801	0.3%	8
AIDS patients	320	0.6% to 4%	2 to 13
AML	2,921	7.1%	207
ALL	654	3.8%	25
CML	675	2.3%	15
CLL	3,233	0.5%	16
NHL	12,783	0.8%	103
HL	1,845	0.4%	7
Myeloma	4,792	0.2%	9
CGD	119	$i_{all\ IFD}$= 0.040/patient-years**	$n_{all\ IFD}$= 4.76, n_{CGD}=2
Total			**568 to 579**

Therefore **a total of 568 to 579 patients in well recognised at risk groups**. Some cases in haematological patients will have been prevented with antifungal prophylaxis. Only lung Tx recipients with true IA are included, omitting those with airways infection and colonisation, all of whom are treated.

The estimate for patients with pulmonary disease are outlined in table 3

Table 3: Estimates of population size, specific incidence rates and yearly burden of Invasive aspergillosis for pulmonary disease

Population	Population size	Incidence rate	Yearly burden of disease

** Overall incidence of invasive fungal disease (IFC)

COPD emergency hospital admissions	89,466	1.3%	1,163
Patients with lung cancer	44,488	2.63%,	1,170

Therefore the estimate for the total yearly burden of IA in the UK for the all of the above groups is **2,901 to 2,912**

Sensitivity analysis

Table 4: Sources of estimates of the incidence of invasive aspergillosis in critical care patients

Study	Study characteristics	Population studied
Meersseman et al. Invasive aspergillosis in critically ill patients without malignancy. Am J Respir Crit Care Med, 2004[72].	-Sample size: n=127 -Autopsy controlled -Study aim: to determine the incidence of IA in medical ICUs -Retrospective, single centre	Patients in medical critical care units
Garnacho-Montero et al. Isolation of *Aspergillus spp*. from the respiratory tract in critically ill patients: risk factors, clinical presentation outcome. Crit Care 2005[73]	-Sample size: n=1,756 -Not autopsy controlled -Study aim: describing characteristics of patients with positive samples for *Aspergillus* species -prospective, multi-centre (73 mixed ICUs)	Patients in any type of critical care unit
Vandewoude et al. Clinical relevance of *Aspergillus* isolation from respiratory tract samples in critically ill patients. Critical Care 2006[32]	-Sample size: n=172 -Not autopsy controlled -Study aim: describing characteristics of patients with positive samples for *Aspergillus* species -Retrospective, single centre, mixed ICU	Patients in any type of critical care unit

Table 5: Sensitivity analysis for estimation of burden of invasive aspergillosis amongst patients in critical care in the UK

Risk group	Number in Risk Group	Incidence Rate	Number of expected cases
Patients admitted to medical ICUs	166,645	5.8%[72]	9,665
Patients admitted to any ICU (Spinal Units excluded)	248,811	1.1%[73]	2,737
Patients admitted to any ICU (Spinal Units excluded)	248,811	0.33%[32]	821

The results of the sensitivity analysis of IA in critical care are displayed in table 2. The variation between highest and lowest burden estimates for medical type ICUs and all type ICUs (spinal units excluded) was over 10-fold. This highlights the level of uncertainty over this estimate of burden. Our view is that the rate of IA in the UK is probably at the low end of the estimates above, with ~50% of the cases occurring in COPD patients[72], even though IA is the most common missed infectious diagnosis at autopsy[74]. So a total ICU caseload of between 821 and 2,737 is likely, of which 50% is attributable to COPD. Adjusting downwards by 50% for probable double counting of cases of COPD emergency hospital admissions (we assumed most of these would be admitted to ICU), and solid organ transplant recipients (n=24) resulted in adjusted estimates of **387 to 1,345 cases**.

The total estimate of burden of IA amongst the high risk populations is **2,901 to 2,912** (excluding ICU populations) and **3,288 to 4,257** (including ICU populations). This estimate ignores those with solid tumours other than lung tumours, autoimmune disease, liver failure and other conditions treated with corticosteroids.

Chronic pulmonary aspergillosis

Chronic pulmonary aspergillosis complicates a wide spectrum of underlying lung disease of which the commonest conditions are pulmonary tuberculosis (PTB), non-tuberculous mycobacterial lung infection, COPD, sarcoidosis, and allergic aspergillosis complicating asthma[39]. Some estimates of the annual incidence and 5 year period prevalence have been published for pulmonary tuberculosis and pulmonary sarcoidosis complicating an estimated 16,270 cases of pulmonary sarcoidosis in the UK[38]. The anticipated annual incidence of each was 118 and 240 respectively. Together these two conditions account for about 30% of patients with CPA[38] and so an annual diagnosable incidence is around 358 cases for these conditions and a total of **1,193 cases**. We compared this total, with current referral to the National Aspergillosis Centre (Table 3), which is actually 110 per year and should be about **204**, if all cases are diagnosed and referred in the NW of the UK. Either estimate suggests major underdiagnosis.

Computing prevalence and assuming a 15% annual mortality, including 370 cases following PTB[34] and 830 (range 415-1660). Together these 2 conditions account for about 30% of patients with CPA[38], consistent with a total UK burden of CPA of **~3,600 cases**. As many are asymptomatic in the early stages, this number is an over-estimate of those at the more severe end of the spectrum requiring therapy.

Table 6: Estimated maximum annual national referral rates for chronic pulmonary aspergillosis in England (2011).

England Region	**Region population <75s (Mid year estimate 2014, ONS)**	**Age standardised DSR for under 75 mortality respiratory disease as a whole for all persons (per**	**Region DSR as a Proportion of NW DSR**	**Unadjusted Referrals per Year**	**Referrals / Million for NW**	**Estimated Region Referrals per Year Adjusted by DSR**

		100,000)				
North East	2,394,771	41.2	0.954	13		13
North West	6,556,394	43.2	1.000	36	5.491	36
Yorkshire and The Humber	4,924,259	38.6	0.894	28		25
East Midlands	4,254,679	32.1	0.743	23		17
West Midlands	5,242,342	34	0.787	28		22
East	5,489,835	25.7	0.595	30		18
London	8,079,584	31.2	0.722	40		29
South East	8,107,490	27.2	0.630	45		28
South West	4,892,429	26.4	0.611	27		16
TOTAL				**270**		**204**

DSR = directly age-standardised mortality rate

Allergic bronchopulmonary aspergillosis (ABPA)

Using our base case of a rate of 2.5% for ABPA among patients with asthma, **110,667 to 235,070 adults would be expected in the UK.** However, the sensitivity analyses vary by over 10-fold from 34,528 to 385,515 affected patients. The only partial population based studies from southern Ireland and the USA[75,76] suggests rates at the lower estimate of published estimates. Referral and discharge patterns across the UK are not uniform, so ABPA is likely to be diagnosed in some areas more often than others. However ABPA is only one fungal complication of asthma, as discussed below under SAFS.

Table 7: Sensitivity analyses of ABPA prevalence in adults with asthma in the UK

	Asthma in UK adults using different estimates		
	Low	Medium	High
Asthma cases	4,426,699	8,288,978	9,402,809
ABPA prevalence			
0.78%	34,528	64,654	73,342
1.5%	66,400	124,335	141,042
2.5%	110,667	207,224	235,070
3.5%	154,934	290,114	329,098
4.1%	181,495	339,848	385,515
Severe asthma prevalence			
3.6%	95,617	179,042	203,101
5%	132,801	248,669	282,084

10%	265,602	497,339	564,169
Fungal asthma prevalence			
50% overlap	121,734	227,947	258,577
33% overlap	163,124	305,449	346,494
20% overlap	194,775	364,715	413,724

Of the 4933 adults with CF in the UK, we estimate that 873 adults have ABPA (95% CIs 597-1243) and 631 people over 15 years old (12.5% of 5062 patients) were documented, indicative of a diagnostic gap of 242. The annual CF report also described 278 children and adolescents with ABPA (7.4% of 3,732 children). In addition, an estimated 1480 (95% CI 1125-1894) have *Aspergillus* bronchitis. If all patients with ABPA and *Aspergillus* bronchitis benefit from therapy (which needs to be established), this totals 2,353 patients.

Severe asthma with fungal sensitisation (SAFS)

Asthma severity and fungal sensitisation rise in parallel[63]. There are ~65,000 admissions to hospital with asthma annually, ~40,250 in adults[77]. Fungal sensitisation rates are not well studied in the UK, especially as patients may be sensitised to one or more fungi[62]. In a series of 121 patients with severe asthma in the UK, sensitisation rates by either skin prick testing or IgE were *Aspergillus fumigatus* 45%, *Candida albicans* 36%, *Penicillium* spp. 29%, *Cladosporium herbarum* 24%, *Alternaria alternata* 22%, and *Botrytis* spp. 18%; 41 (34%) were not sensitised to any fungus tested[62]. The minimum proportion of poorly controlled asthmatics who would be sensitised to a fungus is about 35%, rising to >75% in the worse patients[60]. Using a uniform estimate of 60% fungal sensitisation of the most severe asthmatics (3.6-10%) between 95,617 and 564,169 UK adults have SAFS or severe asthma with ABPA (Table 4).

There is some duplication between ABPA and SAFS, as sensitisation to *A. fumigatus* is common to both and some ABPA patients have severe asthma. These patients are grouped by some authors as having 'fungal asthma' or 'fungal-associated airways disease'. Part of the definition of severe asthma is continuous use of corticosteroids, which is advocated for ABPA, irrespective of the control of asthma. Therefore the overlap is uncertain, and requires detailed study. However given that 75% of SAFS patients are sensitised to *A. fumigatus* and that only a minority of ABPA patients remain on long term steroids, we show a sensitivity analysis with 20%, 33% and 50% overlap in Table 4, using the mid-point estimates for ABPA (2.5%) and severe asthma (5%).

The overall estimate of adults with 'fungal asthma' varies by 3.4 fold, from **121,734 to 413,724**, primarily dependent on the number of adults with asthma.

Invasive Candidiasis

Candidaemia

A total of 1,700 laboratory reports of candidaemia were reported in 2013. Assuming that these represent 38% cases of proven or probable invasive candidiasis tested by blood culture techniques,

the resulting estimate for the total number of cases in England, Wales and Northern Ireland in 2013 was: **4,473**.

Scotland had a rate of candidaemia of 4.8 cases per 100,000 population per year shortly after the millennium[78], yielding an additional 254 bloodstream and **669** invasive *Candida* cases annually.

The total estimate of invasive candidiasis burden for the UK was therefore: **5,142.**

This estimate of burden of candidaemia is likely to be an underestimate as reporting from laboratories is voluntary, therefore likely to be a degree of under-reporting. Population based estimates have been reported in Northern Ireland and Scotland with rates of 6.1 and 4.8 per 100,000 population[78,79] which if extrapolated to the whole population would suggest 2,995 to 3,806 cases annually, as compared to the 1,700 reported for England and Wales (~90% of the population). Further a six sentinel hospital study in England and Wales found an incidence of 18.7 episodes of candidaemia per 100,000 finished consultant episodes (or 3.0/100 000 bed days) in 1997-1999[80] which translates for 2014-15 for England only to 3,497 as there were 18.7 million Finished Consultant Episodes[81], assuming no substantial change in *Candida* bloodstream rate over time.

Considering that the estimate is likely to be an under-estimate, within the range of UK candidaemia burden estimates between 2,995 and 5, 142, we selected the higher end of the range (5,142) as our estimate.

These data indicate a population rate in the UK of candidaemia and invasive candidiasis of 3.1/100,000 and 10.1/100,000 respectively.

Candida peritonitis

CAPD patients

The estimated number of patients on CAPD in England every year was 1,768 year. The estimated number of episodes per patient year attributable to *Candida* in this patient group was 0.05. The resulting estimate for total yearly burden in England was **88 cases**.

Oesophageal candidiasis

An average yearly total burden of **43 diagnoses** was found as AIDS indicator infections.

Many additional cases occur, and one estimate was 0.5% of those on anti-retroviral treatment annually[69]. If applied to the UK population of 73,300 on anti-retroviral treatment in 2013[16], this would equate to **367 episodes annually**, although these data derive in part from patients without full HIV suppression, so could be an over-estimate. Other patient groups also get oesophageal candidiasis, but modelling is not realistic currently.

Mucormycosis

The UK population in 2011 was 63,182,000 [10], and the estimated population incidence of Mucormycosis in France was 0.09 per 100,000 population per year (averaged over 10 years). This resulted in a UK estimate of **57 cases** per year.

Other rare infections

Based on expert view, there are probably **fewer than 25** such patients annually in the UK.

Totals

Table 5 summarises the estimates for total expected number of cases for each invasive fungal infection and rates per 100,000 population.

Table 8: Total estimates of burden

Invasive Fungal Infection	Risk Group	Number of cases expected	Rates per 100,000 population
Pneumocystis pneumonia	All risk groups	**207 to 587**	**0.33 to 0.93**
Cryptococcal meningitis	Primarily AIDS	**100**	**0.16**
Invasive aspergillosis	All risk groups except Critical Care patients	**2,901 to 2,912**	**4.59 to 4.61**
	Critical Care patients	**387 to 1,345**	**0.61 to 2.13**
Chronic pulmonary aspergillosis - all	All risk groups	**204 to 3,600**	**0.32 to 5.70**
Allergic bronchopulmonary aspergillosis (ABPA)	All risk groups	**110,667 to 235,070**	**175 to 372**
Severe asthma with fungal sensitisation (SAFS)	All risk groups	**121,734 to 413,724**	**192 to 654**
Invasive candidiasis	All risk groups	**5,142**	**8.14**
Candida peritonitis	CAPD patients	**88**	**0.14**
Oesophageal candidiasis	AIDS patients	**43 to 367**	**0.07 to 0.58**
Mucormycosis	All risk groups	**57**	**0.09**
Other rare infections	All risk groups	**25**	**0.04**

Total		**241,525 to 662,987**	**382 to 1,049**

The estimated total burden of invasive fungal illness in the UK is between **241,525 to 662,987** cases per year.

DISCUSSION

Estimating the burden of invasive fungal infection accurately is challenging due to the lack of a dedicated mandatory systematic surveillance system, and the wide range of incidence estimates for the largest high-risk populations. This is likely to be compounded by the combination of lack of clinical suspicion and limited sensitivity of traditional diagnostic tests used for invasive fungal illness, making it difficult to obtain laboratory confirmation for a significant number of cases. This issue is exemplified for IA as this was the commonest major error in infection diagnoses missed in critical care patients examined at autopsy[74].

There is a significant level of inaccuracy as our estimation methods have relied on limited published information, and there is a wide range of estimates for some of the published incidence rates. This high level of uncertainty is reflected in the results of our sensitivity analysis for the estimation of the burden of invasive aspergillosis in ICU patients, and in the difference between the estimates of *PCP* burden resulting from the two different calculation methods used.

The estimate of burden for PCP obtained by the first method is likely to be an under-estimate as other high risk populations, notably patients with haematological malignancy and those on high dose corticosteroid regimens were not included as no overall incidence rate of PCP could be found in the literature for this group.

The estimate of burden for PCP obtained by the second method should be considered in the light of methodological limitations outlined in the paper used: laboratories may be under-reporting as samples are not processed for *Pneumocystis* diagnosis unless clinically requested, and cytological techniques can also be used (cases diagnosed in this manner would not be counted in this study) and there is potential for double-counting of cases captured both in the HES data set and the Laboratory reporting data set. In addition many cases are clinically diagnosed and treated, many correctly, without a respiratory sample being obtained to enable laboratory diagnosis.

The estimates of chronic respiratory disorders associated with *Aspergillus* and other airborne moulds is much larger than any prior estimate, even if the more conservative assumptions are made. There is certainly some double counting which we have adjusted for but the population prevalence range of fungal asthma of 121,734 to 413,724 is still substantial. Clearly epidemiological studies done in general practice are required to establish a more precise estimate. Our data excludes children, in whom fungal asthma occasionally occurs[82,56].

The lower end of our estimate of total invasive fungal diseases burden range is likely to be an under-estimate, as some condition-specific estimates are for England only. There was potential for double-

counting of cases, however were this was known to be likely, we attempted to account for it by adjusting total estimates.

Estimates of the burden of serious fungal disease for individual countries have been published for Austria, Belgium, Brazil, Czech Republic, Denmark, Dominican Republic, Germany, Greece, Hungary, Ireland, Israel, Jamaica, Kenya, Mexico, Nepal, Nigeria, Qatar, Russia, Senegal, Sri Lanka, Tanzania, Trinidad and Tobago, Uganda, Ukraine, Vietnam have been published along with estimates of chronic and allergic aspergillosis in India[83]. Burden estimates for many other countries and other prospective epidemiology studies are in press and can be used to compare the relative rates of infections to address strategies for prevention and clinical management.

We have not attempted to estimate mortality related to fungal disease in the UK, although others have done so for other countries. The reasons we have not attempted this is because overall and attributable mortality is not always clearly discernable, the estimates we have provided have much uncertainty attached to them, and adding mortality in addition is likely to add another layer of uncertainty. However we do know that undiagnosed invasive fungal infections such as PCP and IA are always fatal without specific therapy and Candida bloodstream infections and invasive candidiasis have mortalities in excess of 90%, untreated. With treatment, mortality falls especially with PCP in AIDS (~10% mortality) and ~30% with IA in non-ICU patients. So an estimate of mortality also requires judgements of specific therapy rates, which is unknown for most of these disorders.

Strengths and limitations of the study: We acknowledge that the estimates produced in this paper and the methods reached to achieve them are crude and vulnerable to significant error due to lack of robust surveillance information and paucity of published burden studies in the field. We have however made the best attempt possible by: drawing on surveillance data were available; rigorously identifying the relevant high risk groups, the best available estimates of population size for these, and the best available population-specific incidence rates for these; being explicit about the methods used for each individual estimate; and attempted to account for under and over-estimations well as potential double-counting. We are not aware of any other comprehensive burden study for serious and invasive fungal disease in the UK and therefore would argue that although imperfect, this study is a useful contribution to the limited body of knowledge in this field.

CONCLUSION

There is a high degree of uncertainty around the total estimate of burden due to: diagnostic limitations, the lack of a systematic national surveillance system, the limited number of studies published on the topic and the methodological limitations of calculating the burden.

To our knowledge, this is the first attempt at a comprehensive estimation of burden of invasive fungal infection in the UK. Further studies will likely need to combine methods (pragmatic and surveillance-based), take into account any new published information on specific incidence rates, and consider using alternative data sources such as the Hospital Episodes System (HES). An accurate estimate of total burden will ultimately rely on improved diagnostic testing and laboratory reporting.

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EPIDEMIOLOGY

Increasing incidence of Cryptococcosis in the United Kingdom

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Summary

The incidence of infection with *Cryptococcus neoformans* in the United Kingdom during the years between 1953 and 1981 is compared with that between 1982 and 1991. The patients were those from whom samples were submitted to the PHLS Mycological Reference Laboratory (MRL), or those in whom the disease was confirmed elsewhere in the United Kingdom and reported to PHLS Communicable Disease Surveillance Centre (CDSC). In all, 83 cases were identified between 1953 and 1981 and 322 between 1982 and 1991, 201 of which were known to be HIV-associated. The incidence of infection with *Cryptococcus neoformans* has increased four-fold in the last decade. It is an increasing cause of infection in immunosuppressed patients, most notably those with HIV infection. Currently, 4·0% patients with AIDS in the United Kingdom are known to have developed cryptococcosis.

Introduction

Cryptococcosis is a fungal infection caused by the encapsulated yeast, *Cryptococcus neoformans*. Worldwide it is amongst the most prevalent of the systemic mycoses and it is an increasing cause of infection in the immunosuppressed, especially those with defects of cell mediated immunity. The usual route of entry is probably via the lungs, commonly with progression to involvement of the central nervous system. There are two varieties, *C. neoformans* var. *neoformans* and *C. neoformans* var. *gattii*, which differ in their geographical distribution. The more prevalent in Europe is *C. neoformans* var. *neoformans* which has been cultured from many environmental sites, particularly those associated with bird droppings. *C. neoformans* var. *gattii* is largely confined to tropical areas and an association with eucalyptus trees has recently been described.[1] It is of interest that infections in patients with AIDS seem to be entirely confined to var. *neoformans*,[2] even in those presumed to have been infected outside the U.K. Disseminated cryptococcosis is an AIDS-defining disease for patients who are HIV positive and for those not HIV-tested who have immunosuppression for which no other cause can be found.[3]

The availability of commercial test systems for detection of cryptococcal

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Table I *Cases of United Kingdom cryptococcal infection*

Year	Total	HIV+	% HIV+
1953–81	83	–	–
1982	13	1	8
1983	13	1	8
1984	14	4	29
1985	22	9	41
1986	25	13	52
1987	26	17	65
1988	50	35	70
1989	53	38	72
1990	40	28	70
1991	66	55	83
Total	405	201	

polysaccharide antigen has allowed rapid and reliable diagnosis of this life-threatening mycosis.

Materials and methods

All cases were confirmed by culture and/or antigen detection in CSF and/or serum. All antigen titres quoted were determined by the IMMY-mycologics Inc. (Norman-Oklahoma) latex test, which has been in use in the Mycological Reference Laboratory since 1985. It was not always practicable to run tests in parallel (with a positive sample from an individual patient being compared with a previous one in the same test), but because earlier experience had shown that different batches of the IMMY test kit gave consistent titre values, simultaneous comparative titrations were not considered necessary.

Cultures were referred from hospital microbiology departments who had made the primary isolation. Identification was based on the following features: absence of fermentation; negative nitrate test; positive urease; brown pigmentation on niger seed agar; appropriate carbohydrate assimilations; and morphology. Following confirmation of identity, differentiation of biovars var. *neoformans* and var. *gattii* was performed by the method of Kwon-Chung.[4] All strains were deposited in the National Collection of Pathogenic Fungi held within the laboratory. HIV status was ascertained either from the request form accompanying specimens to MRL and/or by cross-checking with the data base held at the PHLS AIDS centre.

Results

There were 405 cases of cryptococcal infection reported to the MRL and CDSC between 1953 and 1991. Between 1953 and 1981 83 cases were recorded; and between 1982 and 1991 322 cases. 201 of the latter were known to be HIV associated (Table I).

The diseases most likely to predispose to cryptococcosis were those

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Table II *Diseases predisposing to cryptococcal infection in the United Kingdom*

Predisposition	Number of patients
HIV-positive	201
Hodgkins lymphoma	26
Non-Hodgkins lymphoma	10
Lymphoma (type not stated)	6
Leukaemia	18
Sarcoid	14
Post-transplant	14 (renal 12, liver 1, heart 1)
Systemic lupus erythematosus	12
Cirrhosis	5
Diabetes mellitus	4
Steroid therapy	4
Hepatitis	3
Myeloma	3
Renal failure	2
Autoimmune disease	2
Amyloid	1
Other	13
Not known	46
None	21
Total	405

associated with immunosuppression (Table II). Some patients reported in the 'not known' category may also have had undiagnosed immunodeficiency. Of the 46 patients in this group, 24 were male and 14 female (in eight the sex was not stated). The age range for the 25 patients in this group whose age was stated, was between 8 and 80 years (mean 38·4). Twenty-one patients were described as having no predisposing illness.

Age distribution for AIDS patients with cryptococcosis was similar to that for AIDS cases generally, with the majority (62 %) being in the 26–40 year age group. For non-AIDS patients the age distribution was wider, with 52 % patients being more than 40 years old. This may reflect loss of immunocompetence and increase of immunosuppressive disease with ageing.

Sex distribution for AIDS cases with cryptococcosis was that for AIDS cases generally, 91·5 % being male and 8·5 % female. In non-AIDS cases males outnumbered females 2:1, which may reflect under reporting of HIV infected cases.

Types of disease caused by *Cryptococcus neoformans* are shown in Table III. The most common, particularly in AIDS patients, was meningitis.

Antigen titres at presentation were higher in the AIDS group than in non-AIDS patients. The geometric mean of serum titre in AIDS patients was 1529 (range 0–8000000), and non-AIDS patients 539 (range 0–100000). For CSF the geometric mean titre in AIDS patients with meningitis was 784 (range 1–100000), and non-AIDS patients 435 (range 5–10000). When both CSF and serum were examined at presentation, the majority of AIDS patients (40/52;

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Table III *Types of diseases caused by* Cryptococcus neoformans

Disease type		AIDS	Non-AIDS
Cryptococcal	meningitis	178 (88%)	133 (65%)
	fungaemia	14	25
	pneumonia	3	8
	hepatitis	1	–
	skin disease	–	8
	abscess*	–	16
	osteomyelitis	–	1
	not known	7	13
Total		201	204

*Bone/joint, 7; lung, 3; skin, 3; brain, 2; peritoneal 1.

77%) with meningitis had lower CSF titres than those found in serum, whilst for non-AIDS patients (26) there was no clear correlation.

Information on the time interval from first sample to death for the AIDS group was collected by cross-referencing with data reported to PHLS AIDS centres. A total of 109 patients with known dates of death were identified. Survival time ranged from < 1 to 53 months. Median survival time was 5·5 months, with 71% patients having died within 12 months. The extent to which cryptococcosis contributed to the death of these patients is not known. Survival data for the non-AIDS group were insufficient for any valid comparison to be made. Antigen titres were analysed in those patients who survived for more than 12 months when multiple samples were submitted. In the AIDS group 34 such patients were identified, 26 of whom had multiple serum samples and 19 multiple CSF samples. Serum titres decreased in 21/26 (80%) and CSF titres in 17/19 (89%). In the non-AIDS group 11 patients were identified, eight of whom had multiple serum samples and eight multiple CSF samples. Serum titres decreased in 8/8 and CSF titres in 8/8. In all cases a greater than two-fold decline in titre was deemed to constitute a decrease.

Cryptococcal infections occurred in 4·0% reported AIDS patients in the United Kingdom up to 31 December 1991. In three of four Thames health regions cases of cryptococcal infections in AIDS patients exceeded those in non-AIDS patients.

HIV exposure category of AIDS patients with cryptococcal infections (Table IV) showed that the majority (111/155) were homosexual. The second most common exposure category was heterosexual. In the heterosexual group 28/31 patients had lived in or travelled to Africa.

Cases reported to the PHLS AIDS centre which were said to have had extrapulmonary cryptococcal infection, were checked against those reported to MRL and CDSC. A total of 144 such patients diagnosed as having an AIDS defining illness before the end of September 1991 (allowing 3 months for specimens to be sent to MRL and/or reports to CDSC) were identified and 34 (24%) were not known to the MRL or CDSC.

A total of 276 isolates of *Cryptococcus neoformans* were identified from 214 patients. Only six isolates, from five patients, were var. *gattii*, (one patient was

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Table IV *Exposure category for AIDS patients with cryptococcal infection*

Exposure category	Total*	Number with cryptococcal infection
Homosexual men	4256	111
Heterosexual men + women	462	31
Injecting drug user (IDU)	252	4
IDU and homosexual man	84	1
Blood/blood products recipient	376	5
Other/undertermined	126	3
Total	5556	155

*At 31 December 1992.

known to be from Nigeria, the origin and history of the rest were not known). The remaining 270 isolates were var. *neoformans*. All isolates from HIV-positive patients (158 from 117 patients), were var. *neoformans*.

Discussion

The last decade has seen a dramatic increase in the number of cases of cryptococcosis. The incidence in 1991, 66 cases, was four-fold greater than in 1982.

Immunodeficiency predisposes to cryptococcosis. In addition to HIV infection, increased numbers of patients receiving immunosuppressive therapy for lymphoma, leukaemia and after organ transplants have contributed to the higher incidence. However the main cause of the increase is infection with HIV, 83% cases in 1991 being associated with AIDS. Some patients whose predisposition was classified as 'not known' were those whose immune status was either not examined at all, or only within the scope of tests available at the time of diagnosis. Some of these were almost certainly undiagnosed AIDS cases. In the early 1980s there were a number of patients whose clinical diagnosis was 'atypical lymphoma' or 'T cell deficiency' who were not accurately diagnosed before death. However, cryptococcosis does undoubtedly also occur in immunocompetent patients.

Comparison of cases reported to MRL and CDSC with those reported to the PHLS AIDS centre as having extrapulmonary cryptococcosis, indicated a reporting rate of 76% to MRL and CDSC. It is expected that this proportion will decrease, as those hospitals with large numbers of AIDS patients perform their own antigen tests. Cases reported to the PHLS AIDS centre included some from Scotland, as did those reported to MRL. Under-reporting of non-AIDS cases is impossible to assess but it is likely to be less than that for AIDS cases, given the multiplicity of infections occurring in AIDS and the desire to preserve confidentiality.

Most cryptococcal infections progressed to meningitis. For some patients whose disease was described as septicaemia, only serum or an isolate from blood was sent for examination. Meningitis may also have been present. AIDS patients with meningeal infection, for example, often do not have meningism

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and CSF may therefore not be examined. Lack of specific symptoms in AIDS patients may lead to later diagnosis and this may account for their higher CSF and serum antigen titres at presentation than are found in patients without AIDS. Alternatively, the disease may progress at a much faster rate. Many centres treating AIDS patients now screen serum on a regular basis in order to detect cryptococcal infection before the patient becomes symptomatic. It is interesting to note that in AIDS patients who had both CSF and serum examined the majority (77%) had CSF titres which were lower than in their serum.

For AIDS patients developing cryptococcal infection the outcome has, in the past, been poor. Of the 109 patients for whom dates of death were known, median survival was only 5·5 months. The extent to which cryptococcosis contributed to death is not known. Antifungal therapy in AIDS patients with cryptococcosis is rarely curative. Cessation of primary antifungal treatment causes relapse in more than 50% patients.[5] This has led to the introduction of lifelong maintenance antifungal therapy, which should improve life expectancy.

The overwhelming majority of AIDS patients who survived longer than 12 months had a decrease in CSF (89%) and serum (80%) antigen titres. Although the number of non-AIDS patients from whom multiple CSF or serum samples were examined was small, all patients surviving longer than 12 months had a decrease in serum and/or CSF antigen titres. Decrease in antigen titres is an indicator of good prognosis.

The overall rate of cryptococcal infection in AIDS patients in the United Kingdom is 4·0%. Three of the Thames regions had an excess of AIDS over non-AIDS cases. This is not surprising, given the prevalence of AIDS in these regions. However, for non-AIDS patients across all health regions, the average of cases of cryptococcosis was 0·36 per 100000. If this figure is taken as the 'background' rate of infection, it is exceeded in all four Thames regions and the north-western region. This may indicate an increased prevalence of the organism in the environment, increased awareness of the disease, or reporting of AIDS cases as non-AIDS. It may also indicate referral of specimens to laboratories other than MRL, although data gathered from CDSC did not show any evidence of this.

Examination of the exposure category shows, as expected, that the largest number of cases of cryptococcosis occurs in men who have sex with men. Cryptococcosis in patients in whom the exposure category was heterosexual intercourse comprised 20% of the total. This higher than expected percentage is probably due to the inclusion in this group of a high proportion of patients who had lived in or visited Africa (28/31). Increased incidence in African patients has been reported from elsewhere in Europe.[6] Travel histories were not always available, but a total of 39 patients from the AIDS and non-AIDS groups were known to have lived in or visited Africa. This may or may not equate with infection in Africa as some patients had travelled to other countries, or been resident in the United Kingdom for some time. It may indicate an increased prevalence of the organism in Africa or an increased genetic susceptibility of African patients. In some areas of Africa, cryptococcosis rates approaching 30% have been reported in AIDS patients.[7]

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Two patients in this series were known to be sexual partners, heterosexually infected with HIV. Both developed cryptococcal meningitis. Further epidemiological studies are needed to elucidate the possibility of transmission of cryptococcal infections.

This review of national data has provided evidence of the increase in cases of cryptococcosis over a 38 year period. Comparison of data from various sources supports the view that our reporting system was reasonably complete, and gives a good overall view of the incidence of cryptococcosis.

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Cluster of *Cryptococcus neoformans* Infections in Intensive Care Unit, Arkansas, USA, 2013

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Release date: September 16, 2015; Expiration date: September 16, 2016

Learning Objectives

Upon completion of this activity, participants will be able to:

- Assess the epidemiology and clinical presentation of *C. neoformans* infection
- Distinguish the clinical presentation and outcomes of *C. neoformans* infection in the current study
- Analyze exposure variables associated with *C. neoformans* infection in the current study
- Identify clinical variables associated with *C. neoformans* infection in the current study

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We investigated an unusual cluster of 6 patients with *Cryptococcus neoformans* infection at a community hospital in Arkansas during April–December 2013, to determine source of infection. Four patients had bloodstream infection and 2 had respiratory infection; 3 infections occurred within a 10-day period. Five patients had been admitted to the intensive care unit (ICU) with diagnoses other than cryptococcosis; none

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had HIV infection, and 1 patient had a history of organ transplantation. We then conducted a retrospective cohort study of all patients admitted to the ICU during April–December 2013 to determine risk factors for cryptococcosis. Four patients with *C. neoformans* infection had received a short course of steroids; this short-term use was associated with increased risk for cryptococcosis (rate ratio 19.1; 95% CI 2.1–170.0; p<0.01). Although long-term use of steroids is a known risk factor for cryptococcosis, the relationship between short-term steroid use and disease warrants further study.

Cryptococcus neoformans is an encapsulated yeast found in soil throughout the world, particularly in soil contaminated with pigeon guano (*1*). Persons become infected by inhaling fungal spores (*2*), and the infection is usually asymptomatic. In some persons, latent infections can be established in the lungs and hilar lymph nodes (*3*). Cryptococcal disease typically manifests when latent infection is reactivated after a person becomes immunosuppressed (e.g., receives long-term steroids or immunosuppressive medications for an organ transplant or has advanced HIV infection) (*4*). Meningitis and pneumonia are the most common manifestations, and bloodstream infection (BSI) occurs far less frequently (*5*). Because cryptococcosis rarely results from acute fungal exposure and because person-to-person transmission is exceedingly uncommon (*6*,*7*), clusters of patients with this disease are unusual.

Hospital A is a community hospital in northwestern Arkansas, USA, with ≈300 beds, 38 of which are intensive care unit (ICU) beds. *C. neoformans* was isolated from 6 patients during 2013: 4 patients had *C. neoformans* BSI, and 2 had bronchoalveolar lavage (BAL) specimens yielding *C. neoformans.* Three of the 4 *C. neoformans* BSI cases occurred within a 10-day period in April–May 2013. Although *C. neoformans* infection is not a reportable condition in Arkansas, an astute infection control practitioner (ICP) at hospital A noted the unusual number of *C. neoformans* BSIs in a short period and contacted the Arkansas Department of Health. Preliminary investigation revealed that most case-patients had been admitted to the hospital A ICU, which prompted concern that the ICU might be the source of acute cryptococcal infection. All case-patients died, most within days of their positive *C. neoformans* culture. This unusual set of circumstances—clustering in time of an uncommon disease among patients with exposure to a single hospital unit—combined with the high death rate led to an on-site investigation to further characterize clinical illness among patients in this cluster and identify possible sources of and risk factors for infection.

Methods

A case was defined as culture-confirmed *C. neoformans* infection in an inpatient admitted to hospital A during 2013. We reviewed microbiology records at hospital A for 1992–2013 to identify all cases and establish a background rate for positive cryptococcal cultures at hospital A. We telephoned microbiology staff and ICPs at surrounding hospitals to inquire about any recent changes noted in rates of isolation of *Cryptococcus* spp.

Case-patients' medical records were reviewed, and data were abstracted by using a standardized case report form that included demographic and clinical information. Case-patients' family members (or case-patients, if alive) were interviewed by using a standardized questionnaire to identify potential exposures to *Cryptococcus.* Questions included whether patient had contact with pigeons or other birds and whether case-patients had engaged in any common activities in the community that could have resulted in a common acute exposure to *C. neoformans* before hospital admission. We interviewed laboratory managers and technicians at hospital A to assess specimen collection and processing methods and to identify any potential sources for contamination of specimens with *C. neoformans*.

To assess the possibility of acute, nosocomially acquired *C. neoformans* infection, we took several steps. Case-patient charts were reviewed for commonalities in physical location, procedures, and providers. ICU staff, hemodialysis staff, and ICPs at hospital A were interviewed to gain an understanding of how patients are cared for in the ICU, dialysis procedures, and infection control practices. We also asked hospital leadership about any known history of illegal activity or recent disciplinary action of ICU staff members. We asked facilities management staff about any bird habitats at the hospital and recent construction activity. Because *C. neoformans* thrives in bird guano, we also interviewed all ICU staff members about contact with birds and sampled the hands using Handi-wipes (*8*) and homes using Sponge-Sticks (3M Co., St. Paul, MN, USA) and vacuum filter socks (X-Cell 100 Dust Sampling Sock, Midwest Filtration Co, Cincinnati, OH, USA) (*9*) of ICU staff members who reported substantial bird exposure and had contact with case-patients. Environmental sampling was conducted in the ICU with Sponge-Stick swabs.

Finally, we conducted a retrospective cohort study to identify factors associated with cryptococcosis. Patients admitted to the hospital A ICU during April 1–December 31, 2013 (the period during which the cases occurred), were included. Patients were identified by querying the electronic medical record database. Data extracted from the medical record included length of stay in the ICU, receipt of glucocorticoids in the ICU, type of steroid if one was administered, and whether the patient was cared for by a specific respiratory therapist. For the purposes of the cohort analysis, only case-patients who were admitted to the ICU were included (n = 5). Poisson regression models were fit to the data to examine the relationship between the

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potential risk factors and cryptococcosis and to estimate the rate ratios between different exposure groups.

Clinical isolates were confirmed as *C. neoformans* by melanin production on L-DOPA media and by lack of growth after inoculation on canavanine-glycine-bromothymol blue media (*10*). Isolates were subtyped by using multilocus sequence typing (MLST). The *URA5, IGS1, CAP59, LAC1, GPD1, PLB1,* and *SOD1* gene fragments were amplified as described (*11*) for all isolates. Allele numbers and sequence types were determined by using the online *C. neoformans* MLST database (*12*). Environmental samples were processed and plated onto birdseed benomyl agar, incubated at 35°C, and observed for growth at 4, 7, and 14 days.

Results

Case-Patient Descriptions

We identified 6 cases of *C. neoformans* infection at hospital A during 2013: 4 case-patients had BSI, and 2 case-patients had respiratory specimens (obtained from BAL) that yielded *C. neoformans.* One of the patients with a BSI also had *C. neoformans* isolated from cerebrospinal fluid (CSF) and urine specimens. The positive cultures were obtained from case-patient 1 on April 6 (respiratory specimen), from case-patient 2 on April 29 (blood), from case-patient 3 on May 1 (blood), from case-patient 4 on May 9 (blood, CSF, urine), from case-patient 5 on June 12 (respiratory specimen), and from case-patient 6 on December 31 (blood).

Case-patient ages ranged from 51 to 82 years; 3 were men (Table, http://wwwnc.cdc.gov/EID/article/21/10/15-0249-T1.htm). Underlying chronic medical conditions included diabetes in 3 patients, asthma/emphysema in 2 patients, and malignancy in 2 patients; 1 patient had metastatic lung cancer, 1 had chronic lymphocytic leukemia, 1 had chronic renal disease requiring hemodialysis, and 1 had received a kidney transplant. None were known to be infected with HIV.

Case-patients were admitted with a variety of diagnoses or symptoms: 3 (50%) had pneumonia with sepsis or respiratory failure, and 1 (17%) each had severe anemia and acute renal failure; nausea, vomiting, and confusion; and chest pain. Three case-patients were directly admitted to the ICU from the emergency department, 2 case-patients were admitted to the ICU 24–48 hours after hospital admission because of new clinical deterioration, and 1 case-patient was never admitted to the ICU. Cultures yielding *C. neoformans* were obtained 1–45 days after hospital admission. In 3 of the 4 cases of *C. neoformans* BSI, case-patients had at least 1 negative blood culture before *C. neoformans* BSI was diagnosed, indicating that the disease likely developed while the patient was in the hospital. All case-patients died; 5 died within 5 days after collection of their clinical sample that yielded *C. neoformans*, 4 before culture results were available. One case-patient, a kidney transplant recipient who exhibited nausea, vomiting, and confusion, received a diagnosis of cryptococcal meningitis on the basis of a positive CSF culture and BSI and did not require admission to the ICU. He survived to hospital discharge but died several months later of unrelated causes. Two case-patients had a serum cryptococcal antigen (CrAg) test: case-patient 1, who had respiratory *C. neoformans* infection and whose CrAg test result was negative, and case-patient 4, who had meningitis and a BSI, whose CrAg test result was positive. No autopsies were performed.

Background Rates of *Cryptococcus* spp.

Review of microbiology laboratory records at hospital A identified a median of 2 patients (range 0–8) per year with positive *C. neoformans* cultures during 1992–2012; most were from respiratory samples. Only 4 blood cultures yielded *C. neoformans* during this time: 1 in 2004, 2 in 2007 (February and August), and 1 in 2008 (Figure). In contrast, 4 BSIs occurred during 2013, with 3 occurring within 10 days of each other. Laboratory staff and ICPs at 4 surrounding hospitals had reported no increase in the

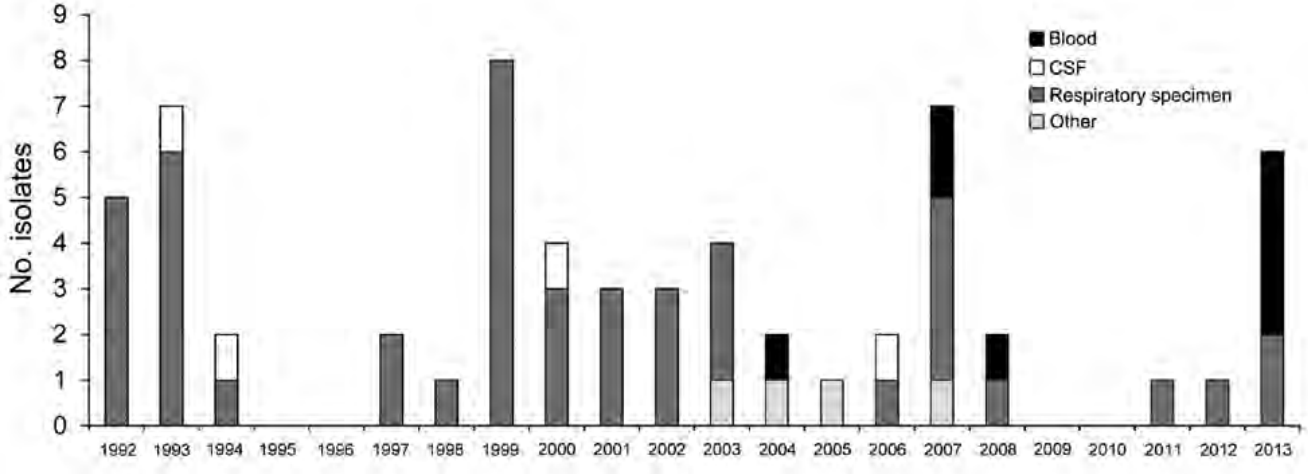

Figure. Culture-confirmed *Cryptococcus* isolates at hospital A, Arkansas, USA, 1992–2013. CSF, cerebrospinal fluid.

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number of *C. neoformans* isolates since January 2013, indicating that the increase in cases, especially BSI cases, was only occurring at hospital A.

Evaluation of Specimen Procurement and Processing

Detailed assessment of specimen procurement and hospital laboratory processing methods did not reveal any evidence of laboratory contamination to suggest that this was a pseudo-outbreak. Specimens from case-patients were procured by different personnel in different parts of the hospital (emergency room, medical floor) on different days. Blood cultures were processed in a closed system (BACTEC; Becton Dickinson, Franklin Lakes, NJ, USA), and in-laboratory location, growth media, and method of processing BAL and blood cultures differed.

Evaluation for Common Exposures

Interviews with family members of case-patients did not reveal common community exposures. Case-patients lived in 4 different towns and did not work or attend religious services or social events in the same places. None of the case-patients had any recent exposure to birds, including pigeons.

Five of 6 case-patients were admitted to the ICU before their culture was positive: case-patients 1, 2, and 3 were in adjacent ICU rooms during April 6–April 14, 2013. All 5 case-patients in the ICU were also cared for by the same ICU physician; 4 of 5 had been cared for by 1 respiratory therapist (RT). No other recognized commonalities were found between case-patients in terms of procedures, devices (including hemodialysis machines and ventilators), or personnel involved in their care.

We interviewed 112 hospital staff members who might have had contact with ICU patients; 8 reported contact with birds. Types of contact included hunting pheasants, feeding backyard chickens, and maintaining outdoor bird feeders. One RT reported having 2 pet cockatiels at home with whom she spent up to 2 hours each day. The RT had cared for 4 of the 5 case-patients who were admitted to the ICU. Among the 7 other staff members with any bird contact, 2 persons, a pharmacist and an x-ray technician, had come into contact with 4 of 5 case-patients in the ICU. Sampling of hands of these 3 health care workers and a vacuum sample of the cockatiel aviary (a sunroom in the house where the birds were kept) belonging to the RT did not yield *C. neoformans.* Hospital leadership indicated that there was no concern about illegal activity or recent disciplinary action against any ICU staff members.

Interviews with facilities management staff revealed that the ICU roof had been leaking for ≈3 years in several locations, including the time case-patients 1–3 were in the ICU, before it was replaced during April 22–May 19, 2013. Notably, staff reported that the roof had been a roost for pigeons approximately 6 years earlier, and the hospital had undertaken pigeon exclusion measures at that time. Environmental swab samples taken in July 2013, ≈8 weeks after the roof replacement was completed, from the ICU rooms where case-patients 1–3 had overlapping stays did not yield *C. neoformans*. Culture of the external air filter leading into the ICU HVAC system also did not yield *C. neoformans.*

Cohort Study to Assess Risk Factors for Cryptococcosis

A total of 1,606 patients, including 5 of 6 case-patients who had *C. neoformans* infection, were admitted to the hospital A ICU during April 1–December 31, 2013. The remaining case-patient, who had received a renal transplant and exhibited cryptococcal meningitis and cryptococcal BSI, was not admitted to the ICU and was therefore not included in this analysis.

Overall, 125 (7.8%) of the 1,606 patients admitted to the ICU during this period received some type of steroid in the ICU. Four (80%) of the 5 *C. neoformans* case-patients admitted to the ICU received steroids in the ICU before their positive culture: 2 received hydrocortisone for treatment of refractory septic shock (1 for 4 days and another for 11 days); 1 received methylprednisolone for 1 day for tumor lysis syndrome followed by an oral prednisone taper over 21 days (100 mg daily for 3 days, 80 mg daily for 3 days, 40 mg daily for 3 days, and 20 mg daily for 12 days); and 1 received methylprednisolone (5 days) and hydrocortisone (8 days) for treatment of refractory septic shock and ongoing respiratory failure. None of these patients had been receiving steroid treatment before hospital admission. Approximately 8% (121/1,601) of patients without cryptococcosis received steroids in the ICU: 7 received oral prednisone, 22 received hydrocortisone, 73 received methylprednisolone, and 19 received dexamethasone. The rate of cryptococcosis was 40.1 cases per 10,000 person-days in the ICU among persons receiving steroids, compared with 2.1 cases per 10,000 person-days in the ICU among persons not receiving steroids (rate ratio 19.1; 95% CI 2.1–171.1; p = 0.008). Exposure to the RT was also assessed as a risk factor for cryptococcosis, but no significant difference was found.

Multilocus Sequence Typing (MLST) of Clinical Isolates

Clinical isolates from all 6 case-patients were confirmed at CDC as *C. neoformans* with 3 separate MLST patterns. Isolates from case-patients 1 and 3 had MLST patterns that were indistinguishable from each other, isolates from case-patients 2 and 4 shared a second MLST pattern, and isolates from case-patients 5 and 6 had a third MLST pattern distinct from the other 2 patterns.

Discussion

We investigated 6 cases of cryptococcosis that occurred in 2013 in a community hospital ICU. For most of the case-patients, the disease appears to have developed while they

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were in the ICU after admission for other diagnoses. The patients experienced a fulminant clinical course after the diagnosis of cryptococcosis and died soon thereafter. There was no identifiable point source for the infections in the hospital or the community. Receipt of short-term steroids in the ICU was significantly associated with cryptococcosis in this cohort.

The cluster was characterized by several atypical clinical features. First, active cryptococcal disease is usually associated with HIV infection or organ transplant–associated immunosuppression. Five of 6 patients in this cluster were non–HIV-infected and nontransplant patients (NHNT); however, each did have other predisposing conditions, including chronic renal failure, chronic lung disease, hematologic malignancies, and other malignancies that might have put them at risk for cryptococcal disease (*13*). Second, *C. neoformans* BSI is extremely uncommon, especially among NHNT patients (*14*,*15*), yet 4 case-patients had blood cultures yielding *C. neoformans;* only 1 case-patient (the renal transplant recipient) had meningitis, a more typical manifestation of this disease. Next, acute respiratory failure and overwhelming sepsis, as experienced by 5 patients in this cluster, are atypical manifestations of cryptococcal disease (*16*); cryptococcosis is generally a subacute infection with insidious onset of nonspecific symptoms (*5*), especially among NHNT patients, who may have prolonged symptoms before diagnosis (*17*). In contrast, the 5 NHNT patients in this cluster had a relatively short duration of symptoms and experienced respiratory failure, septic shock, or both and died within days of their positive culture.

Because *C. neoformans* infections rarely result from acute fungal exposure, and because person-to-person transmission of cryptococcosis—if it exists at all—is exceedingly uncommon (*6*,*7*), focal clusters or outbreaks of cryptococcosis are not expected and, to our knowledge, have not previously been reported. Disease usually results from reactivation of latent infection in immunosuppressed hosts; reactivation in 1 host is an independent event that is not necessarily linked to reactivation in another host. The cases we investigated were clustered in space (ICU) and time (2013, with 3 cases occurring with 10 days of each other in late April through early May). The atypical patients and the unusual clinical manifestations involved in this cluster may be an indication that the source or mechanisms of infection and disease, though not identified during the investigation, were not typical for cryptococcosis. If this were a chance clustering of independent occurrences of reactivation of latent cryptococcal infection, we would have expected to see more patients who fit the typical risk profile and have more common manifestations of the disease, and all would not have occurred at a single hospital.

We searched for a point source in both the community and hospital settings. There has been no precedent for *C. neoformans* being found in the hospital environment or being transmitted from health care worker hands, but we investigated these possibilities because they have been implicated in outbreaks with other organisms. We conducted a thorough investigation to identify any hospital sources of *Cryptococcus* spp. but did not find a hospital source through environmental assessment. However, this outcome was limited by the fact that samples were taken ≈12 weeks after the first 3 cases occurred. The meaning of the 3 different MLST patterns among the 6 case-patient isolates is unclear. This finding may be consistent either with a single point source containing multiple strains of *Cryptococcus* spp. (as demonstrated previously) (*17*) or a different, non–point-source cause of infection.

Although nearly two thirds of patients who seek treatment with cryptococcal disease have advanced HIV infection or have received an organ transplant (*3*), long-term oral steroid use is also a known risk factor for cryptococcal disease. In a study of cryptococcal disease among NHNT patients, the median daily dose of prednisone or prednisone-equivalent that patients were receiving was 20 mg, and the median duration of immunosuppression before cryptococcal disease was 7 months (*15*). Although use of steroids in the treatment of sepsis is generally not favored, steroids may be used for a short term in cases of septic shock not responsive to other interventions. A single 10-day tapering course of hydrocortisone used to treat refractory septic shock, as was administered to some of these case-patients, is roughly equivalent to getting 20 mg of prednisone for 15–20 days. Although cases of cryptococcal disease developing in patients receiving low-dose and short-term oral corticosteroids have been reported (*18*), clusters of cryptococcal disease in an ICU setting after receipt of short-term steroids have not been previously described. A combination of multiple chronic underlying conditions, including diabetes, renal failure, and malignancy, which are also known but less frequently associated risk factors for cryptococcosis, and short-term steroid use in the ICU may have contributed to reactivation disease or dissemination of acute infection acquired from an unknown source in the community or the hospital. Further research should be conducted to better understand the relationship between short-term steroid use and the risk for opportunistic infections, including cryptococcal disease.

This investigation has several limitations. First, we considered that all patients with positive *C. neoformans* cultures had cryptococcosis. However, the manifestations were unusual, raising the possibility that some or all case-patients might not have had true cryptococcal disease. Unfortunately, serum CrAg testing results, pathologic specimens, and autopsy findings, all of which might have helped definitively determine if true cryptococcal disease was present, were not available for most case-patients.

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Second, although we cannot definitively rule out the possibility of a pseudo-outbreak from laboratory contamination of specimens, *C. neoformans*, unlike environmental molds, is not typically a laboratory contaminant. Thus, we believed that laboratory contamination was a less likely explanation for the cluster. The findings of *C. neoformans* in different types of specimens also made laboratory contamination less likely.

Third, we did not investigate the possibility of a common contaminated intravenous medication as a source for these infection and therefore cannot rule out this explanation as a cause of the outbreak. Again, given the different sites of infection (both respiratory and bloodstream) among case-patients, a common-source contaminated intravenous fluid also appeared unlikely.

Finally, we were only able to look at a limited number of co-variates in the cohort study because of the reliance on an automated query of the electronic database. Individual chart review to determine severity of illness or underlying conditions was not possible for all 1,600 patients in the ICU. Therefore, we could not control for differences in reasons for admission to the ICU and severity of underlying illness.

Although we did not find a point source for infections in the hospital or community, we found that short-term steroids used in the ICU were associated with case status. To clarify whether this association between short-term steroid use and cryptococcosis is generalizable, similar studies examining rates and duration of ICU steroid use and cryptococcosis should be conducted at other hospitals. *C. neoformans* infection may need to be included in the differential diagnosis of a patient receiving short-term steroids in the ICU setting.

We recommended heightened vigilance for cryptococcal infection among ICU patients at hospital A, especially those receiving steroid treatment. We also asked that physicians carefully assess the need for steroid use in patients admitted to the ICU and weigh the risk for possible cryptococcal infection against the benefits of steroid use in each patient's case.

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MICROBIAL GENOMICS

OUTBREAK REPORT

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MICROBIOLOGY SOCIETY

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Genomic epidemiology of a *Cryptococcus neoformans* case cluster in Glasgow, Scotland, 2018

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Abstract

In 2018, a cluster of two cases of cryptococcosis occurred at the Queen Elizabeth University Hospital (QEUH) in Glasgow, Scotland (UK). It was postulated that these cases may have been linked to pigeon droppings found on the hospital site, given there have been previous reports of *Cryptococcus neoformans* associated with pigeon guano. Although some samples of pigeon guano taken from the site yielded culturable yeast from genera related to *Cryptococcus*, they have since been classified as *Naganishia* or *Papiliotrema* spp., and no isolates of *C. neoformans* were recovered from either the guano or subsequent widespread air sampling. In an attempt to further elucidate any possible shared source of the clinical isolates, we used whole-genome sequencing and phylogenetic analysis to examine the relationship of the two *Cryptococcus* isolates from the QEUH cases, along with two isolates from sporadic cases treated at a different Glasgow hospital earlier in 2018. Our work demonstrated that these four clinical isolates were not clonally related; while all isolates were from the VNI global lineage and of the same mating type (MATα), the genotypes of the two QEUH isolates were separated by 1885 base changes and belonged to different sub-lineages, recently described as the intercontinental sub-clades VNIa-93 and VNIa-5. In contrast, one of the two sporadic 2018 clinical isolates was determined to belong to the VNIb sub-lineage and the other classified as a VNIV/VNI hybrid. Our work demonstrated that the two 2018 QEUH isolates and the two prior *C. neoformans* clinical isolates were all genetically distinct. It was not possible to determine whether the QEUH genotypes stemmed from independent sources or from the same source, i.e. pigeons carrying different genotypes, but it should be noted that whilst members of allied genera within the *Tremellomycetes* were isolated from the hospital environment, there were no environmental isolations of *C. neoformans*.

DATA SUMMARY

FASTQ sequences were deposited in the NCBI Short Read Archive under the BioProject accession number PRJNA597039 (https://www.ncbi.nlm.nih.gov/bioproject/?term=PRJNA597039).

INTRODUCTION

Cryptococcus species are present in a range of environments, especially soil and in association with trees and decaying wood. A number of *Cryptococcus* species, most notably *Cryptococcus neoformans* and *Cryptococcus gattii*, also cause opportunistic infections of humans [1]. *C. neoformans* and related species belong to a large group of *Tremellomycetes* that are commonly associated with bird droppings. For example, the two rarely isolated species *Cryptococcus uniguttulatus* (*Filobasidium uniguttulatum*) and the related species *Papiliotrema laurentii* (previously *Cryptococcus laurentii*) have both been isolated from droppings and cloacal swabs of feral pigeons (*Columba livia*) in Malmö, Sweden, but rarely cause human infection [2]. In contrast, *C. neoformans* is a ubiquitous environmental fungus and a major cause of illness in people living with human immunodeficiency virus (HIV)/AIDS, with an estimated 220000 cases of cryptococcal meningitis occurring worldwide each year [3].

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Keywords: *Cryptococcus neoformans*; Glasgow; infection cluster; mycosis; United Kingdom; whole-genome sequencing.

Abbreviations: CNV, copy number variation; HIV, human immunodeficiency virus; QEUH, Queen Elizabeth University Hospital.

Data statement: All supporting data, code and protocols have been provided within the article or through supplementary data files. Three supplementary figures are available with the online version of this article.

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C. neoformans can colonize the intestines of avian species including pigeons and is commonly found in pigeon guano, a natural selective medium that supports mating, unlike its closest relative *C. gattii* [4]. *C. neoformans* is found in both urban and suburban areas, and has been found in up to 8.1% of samples of pigeon droppings in Iran (*n*=11/136) [5], and up to 15% pigeon dropping samples (*n*=30) from various provinces in the Nile Delta in Lower Egypt [6]. Proliferation of *C. neoformans* will occur in pigeon guano, particularly in environments protected from sunlight, such as in lofts [7]. Epidemiological and genetic data support transmission of *C. neoformans* from environmental sources including pigeon guano to humans. Infections originate by inhalation of spores directly into the lungs and can be asymptomatic, with some latent cases persisting for months or years before reactivation [8–10].

In 2018, two patients were diagnosed with *C. neoformans* infections at the Queen Elizabeth University Hospital (QEUH) in Glasgow, Scotland (UK). Due to the epidemiological linkage of these cases, an investigation was initiated to search for a common source, including pigeon guano found on the hospital site. In this study, we employed whole-genome sequencing and phylogenetic analysis to understand the pathogen genetics underpinning these cases.

Outcome

Cryptococcus neoformans is a ubiquitous environmental fungus and a major cause of illness in people with compromised immune systems. Genomic studies of *C. neoformans* have demonstrated a huge phylogenetic diversity within the species complex, including sporadic hybrid isolates stemming from two different lineages in both clinical and environmental settings. The high resolution offered by whole-genome sequencing allows the source and cause of clusters of infections to be better understood, and by tracing infection sources may suggest potential remedial measures. In 2018, two cases of cryptococcosis occurred at the Queen Elizabeth University Hospital in Glasgow, Scotland (UK). It was postulated these cases may have been linked to pigeon droppings found on the hospital site, as there have been previous reports of *C. neoformans* associated with pigeon guano. Whole-genome sequencing and phylogenetic analysis of these isolates and two other sporadic infections treated at a different Glasgow hospital earlier in 2018 revealed that none of those isolates from Glasgow were clonally related, as they belonged to well separated sub-clades. Our work therefore suggests that the patients were independently infected. Increased sampling from both hospitals and the environment is necessary to search more precisely for genotypes, and thereby reveal the environmental sources that present the greatest risk for future nosocomial infections.

METHODS

Clinical case summaries

Infections were diagnosed based on blood cultures that were positive for *C. neoformans*, following episodes of pyrexia. This prompted referral to the infection control team for investigation. The 73-year-old female patient was undergoing treatment for relapsed T cell lymphoma and the 10-year-old male had recently completed treatment for Burkitt's lymphoma. Both patients had received fluconazole prophylaxis during their hospital stay; however, due to development of side effects or interactions, both patients had a time period with a gap in cryptococcal cover, where the antifungal was either discontinued or they were switched to another agent. This was a risk factor for cryptococcal acquisition or reactivation.

Epidemiological investigation

Due to the epidemiological link in time and place, further investigations by the infection control team and estates colleagues were initiated, and revealed evidence of pigeons and pigeon guano in the plant room on the top floor of the hospital and in various external areas, such as window ledges and courtyards. Limited environmental sampling was undertaken to search for a source of the infections and before implementation of control measures. Following cleaning and pest-reduction measures on site, no further cases of cryptococcal infection were identified. Numerous hypotheses were investigated; however, the exact route of transmission has not been elucidated. There were pitfalls to the initial environmental sampling. Following the finding of pigeon guano, superficial swabs were taken from areas of contamination within the plant room. This was not deemed a sufficient quantity of material by the veterinary laboratory, which requested further pigeon guano sampling in the form of several pots or specimen containers. At the time of the repeat sampling, the plant room had been cleaned; pigeon guano was retrieved from another area of the campus, with no detection of *C. neoformans*. Similarly, with regard to air sampling, initial agar plates were incubated for 5 to 7 days and were overgrown with other environmental fungi such as *Aspergillus*. However, ideally these plates should have been read for *Cryptococcus* from 48 h with the use of a selective agar. Subsequent air sampling was again undertaken after the plant room had been cleaned.

Cryptococcus isolation, genomic DNA isolation and DNA sequencing

The four isolates of *C. neoformans* analysed here were recovered from blood cultures from four independent patients, the two patients from the cluster of cases at QEUH and two unrelated patients from independent hospitals in the same city (Glasgow). Isolate identity was confirmed at the UK National Mycology Reference Laboratory by MALDI-TOF MS analyses, as described elsewhere [9], after confirmation of isolate purity by culture on CHROMagar *Candida* chromogenic media. Fungal genomic DNA for whole-genome sequencing was extracted from 4-day-old cultures grown

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on Sabouraud agar. *C. neoformans* cells were harvested by scraping into sterile water, subjected to bead-beating for 2×30s at 6.5 m/s in a FastPrep-24 instrument (MP Biomedicals) and liberated DNA was purified using Qiagen MiniBlood extraction columns, according to the manufacturer's instructions. Genomic DNA extracted from approximately 5×10^9 cells was eluted in 200 µl final volumes of sterile water and the DNA concentration was measured using Qubit dsDNA HS reagent. Libraries were constructed using the Illumina Nextera Flex protocol and sequenced on an iSeq 100 to generate paired 150 bp reads. Total sequence coverage of the H99 reference genome [11] ranged from 37× to 54× depth.

Genome alignment, SNP identification and phylogenetic analysis

Illumina reads were aligned to the *C. neoformans* var. *grubii* H99 genome version CNA2 [11]. For the hybrid isolate 18E21177, reads were aligned to both H99 and the VNIV genome JEC21 isolate [11] using BWA-MEM v0.7.4 [12] with default parameters and converted to sorted BAM format using SAMtools v1.8 [13]. Variants were called using the same tools and parameters used by Desjardins *et al.* to analyse 387 *C. neoformans* genomes [14]. Briefly, variants were identified using Genome Analysis Tool Kit (GATK) version 3.4 [15]. First, indels were locally realigned, HaplotypeCaller was invoked in GVCF mode with ploidy=1, and genotypeGVCFs was used to predict variants in each isolate. All variant call format (VCF) files were then combined and sites were filtered using VariantFiltration with QD <2.0, FS >60.0 and MQ <40.0. Individual genotypes were then filtered if the minimum genotype quality was <50, per cent alternate allele <0.8 or depth <10.

VCF files from the three newly sequenced isolates were merged with the 387 isolates analysed by Desjardins *et al.* [14] using VCFtools vcf-merge [16]. The multi-sample VCF file was converted to FASTA with a ECATools (https://github.com/rhysf/ECATools) with the following criteria: (i) ignore any non-homozygous or non-single base allele for a given isolate, (ii) exclude sites that were >10% ambiguous amongst the 390 isolates, and (iii) use an 'N' for any site that was ambiguous but not excluded, resulting in 1196579 sites per isolate. A phylogenetic tree was reconstructed using FastTree v2.1.3 SSE3 [17]. Principle component analysis was performed using SmartPCA v4 [18]. Evidence for aneuploidy or copy number variation (CNV) was assessed using non-overlapping 10 kb windows of normalized depth of coverage plots.

RESULTS

Case description and epidemiological evaluation

In 2018, two patients were diagnosed with *C. neoformans* infections at the QEUH in Glasgow, Scotland. These infections were identified over a 17 day period in late 2018. Both patients (one adult and one child) had underlying haematological malignancies. Prior to blood culture testing, both patients had been in hospital for a prolonged period of time (the child for several months and the adult patient for 15 days). Both patients were from the UK, and there was no recent history of overseas travel, contact with birds or occupational risk factors. A single case of *C. neoformans* in an adult patient may ordinarily have been deemed sporadic and likely representative of reactivation. However, the development of a second case 17 days later in a child who had not left hospital for over 3 months led to the consideration of whether the *C. neoformans* infections were hospital acquired from a potential source on the site. Pigeon droppings contained culturable yeast from genera related to *Cryptococcus* but have since been classified as *Naganishia* or *Papiliotrema* species, and some sources linked this finding with the patient cases [19].

Genomic analysis of QEUH isolates

Sequence and phylogenetic analysis revealed that the two isolates from the 2018 QEUH cases were not clonally related. By identifying variants and comparison to a set of 387 diverse *C. neoformans* isolates [14], phylogenetic analysis demonstrated that the two QEUH isolates belong to the global VNI lineage of *C. neoformans* var. *grubii* (serotype A); they fall within two different sub-clades of the VNIa sub-lineage (Figs 1–3). Two additional isolates from sporadic infections earlier in 2018, from independent Glasgow hospitals, displayed even higher genetic divergence; one (18E26410) belonged to the VNIb clade, while a fourth isolate (18E21177) was a *C. neoformans* var. *grubii* (serotype A)/*C. neoformans* var. *neoformans* (serotype D) hybrid and, thus, excluded from phylogenetic analysis.

To determine how genetically distinct the two QEUH *C. neoformans* isolates were (thereby determining how genetically distinct the VNIa-93 sub-clade is from VNIa-5), we compared variant sites between the two case isolates 36917 and 38484 (see below), which identified 1885 genetic differences, most of which were found in intergenic and intronic regions. Genetic differences mapped to predicted H99 transcripts revealed 455 changes between the two clades, including 166 single base changes, 88 of which caused non-synonymous changes in coding sequences. No readthrough or nonsense mutations were detected between the two sub-clades, although 23 differences involved frameshifts. Thus, the two sub-clades are slightly different at both the genetic and predicted transcript level.

The first 2018 isolate from QEUH (isolate 36917) belongs to the VNIa-93 sub-clade, based on the assignment of other isolates that fell within the same sub-clade, including isolate RTC1 from Ashton *et al.* [20], and RTC1 and Bt3 from Desjardins *et al.* [14]. Both RTC1 and Bt3 were collected from HIV^+ patients in Botswana [21, 22]. The VNIa-93 sub-clade is the most common sub-clade found in Uganda and Malawi, but is also common in Vietnam (12%, *n*=44/762) and found more rarely elsewhere in the world, including Botswana, Laos, France and Brazil [20]. Indeed, this lineage accounted for 20% of all isolates in the Ashton *et al.* study, and was suggested to be one of the three sub-clades responsible for recent population expansion of *C. neoformans* [20]. VNIa-93 was also associated with better outcomes than other major

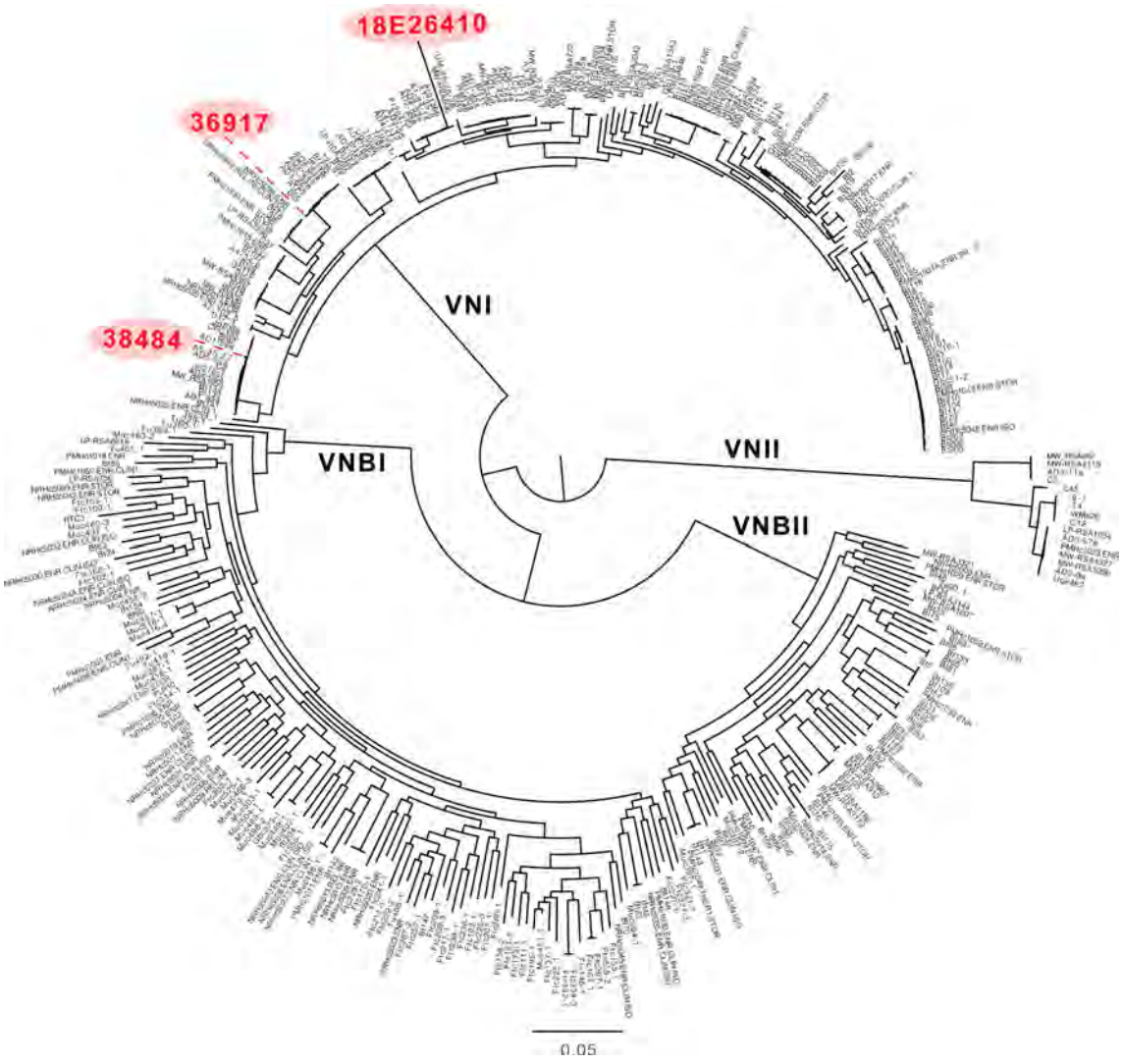

Fig. 1. FastTree based on the isolates from the Desjardins *et al.* paper [14], along with the three non-hybrid isolates from the QEUH study highlighted in red. Branch lengths/scale bar show the number of substitutions per site.

global *C. neoformans* sub-clades VNIa-4 and VNIa-5, which predominate in South-East Asia [20].

The second 2018 isolate from QEUH (isolate 38484) belongs to the VNIa-5 sub-clade, based on the assignment of other isolates that fell within the same clade, including AD1-86a in both Ashton *et al.* [20] and Desjardins *et al.* [14]. VNIa-5 is the second of the three sub-clades responsible for the recent population expansion of *C. neoformans* [20]. VNIa-5 predominates in South-East Asia, but has also been reported in a few patients in Africa, USA, China and Japan [20]. VNIa-5 accounted for 21% isolates (n=163/762) analysed in the Ashton *et al.* study [20]. Importantly, we confirmed that the VNIa-93 isolate 36917 and the VNIa-5 isolate 38484 are genetically distinct, and represent discrete ancestral histories, and that the cases at QEUH in Glasgow, UK, were caused by isolates from two separate sub-clades.

Based on the sequence analysis, both QEUH isolates were haploid and lacked any evidence for aneuploidy (Fig. S1, available with the online version of this article). Our analysis also demonstrated little evidence of CNV. Both aneuploidy and CNV have been previously observed in *C. neoformans* and can contribute to drug resistance [23, 24].

Two further isolates were identified from another hospital in the same city in 2018. 18E26410 was a blood culture isolate from a 72-year-old male and 18E21177 was a blood culture isolate from a 68-year-old male. These cases were determined to be sporadic as they were not linked in time, place or person. Neither patient had a history of a significant hospital stay prior to their positive result, although one patient spent 48 h in the same hospital as the cluster under investigation, in April 2018. Isolate 18E26410 belonged to VNIb and was included in the phylogenetic analysis (Figs 1–3). Based on

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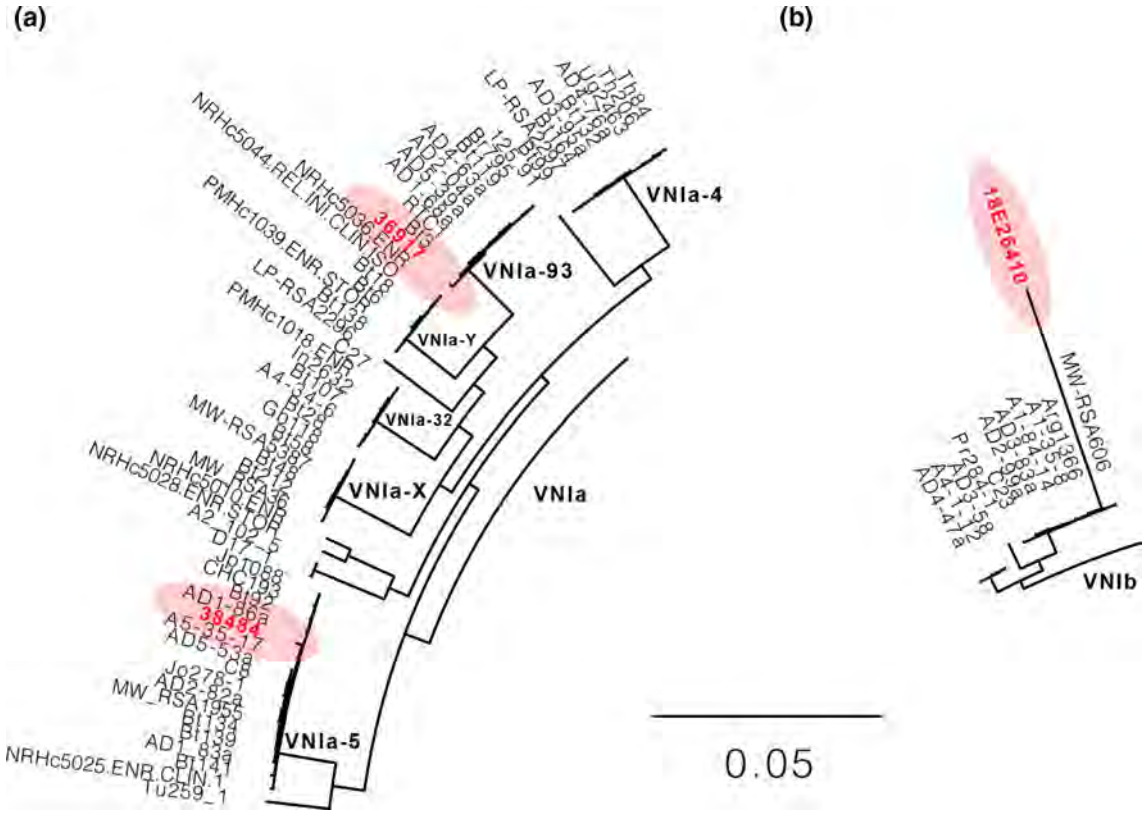

Fig. 2. A subsection of Fig. 1 showing the relationships of the non-hybrid isolates 38484, 36917 (a) and 18E26410 (b) from the QEUH study highlighted in red, compared with other sub-clades presented in the Desjardins *et al.* paper [14]. Branch lengths/scale bar show the number of substitutions per site.

phylogenetic and genome analysis, isolate 18E21177 is a *C. neoformans* var. *neoformans* (VNIV)/*C. neoformans* var. *grubii* (VNI) hybrid, and was subsequently excluded from the phylogenetic analysis (Figs S2 and S3).

DISCUSSION

In this study, we used whole-genome sequencing to investigate the relationship between a cluster of two contemporaneous and hospital-linked cases of *C. neoformans,* two additional local isolates, as well as a globally collected data set. Both QEUH isolates were assigned to the VNIa global sub-lineage although they belong to different clades. The large number of variants that differentiate the two isolates from 2018 supports a model of independent acquisition by each patient, rather than transmission of a clonal isolate.

Only one other cluster of *C. neoformans* infections in hospitalized patients has been reported in the literature. In Arkansas in 2013, six patients in a community hospital developed bloodstream and respiratory infections. Bird habitats at the hospital and staff who had contact with birds were investigated, but no definitive source was established, and environmental sampling was negative. Isolates from these clinical cases appeared genetically diverse, as three separate MLST (multilocus sequence typing) types were identified [25].

In the 2018 Glasgow incident, it is possible that patients acquired *C. neoformans* from plant-room contamination entering the ventilation system or voids, or from ingress of spores into the building from external air. Alternatively, cryptococcal reactivation or recent infection prior to hospitalization is a possibility, but would seem less likely in the context of epidemiological links in time, place and person with a feasible source.

If whole-genome comparisons had revealed that the two QEUH isolates were highly genetically similar, this would have strengthened the argument that they arose from a point source and, thus, were likely to be linked to a single nosocomial source. However, the fact that they are genetically distinct does not necessarily rule out a common source of infection, given that pigeon guano from different birds, and even from the same bird, may contain a variety of unrelated genotypes due to the general diversity of environmental isolates. Although other *Tremellomycetes* yeasts were found in the locality, there was no environmental isolation of *C. neoformans* from the hospital buildings or from the wide-scale air sampling undertaken following the identification of the second case, which would have added an extra dimension to the study.

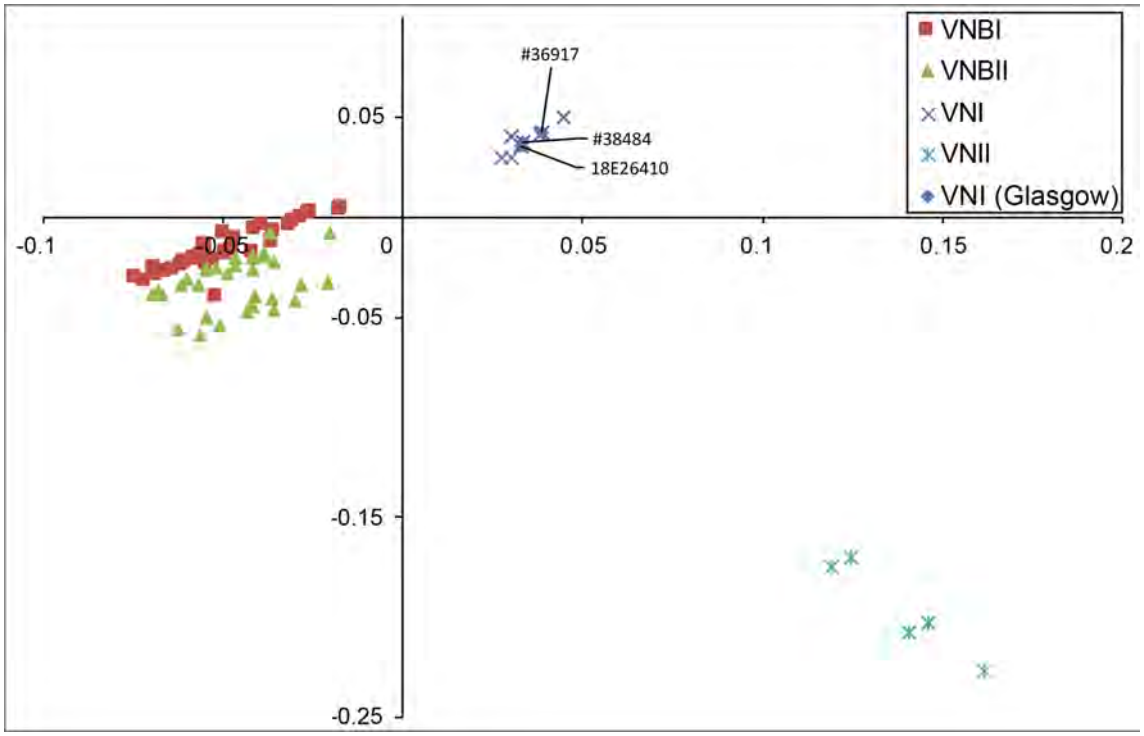

Fig. 3. Principle component analysis based on SmartPCA. All isolates from the QEUH cluster together with other VNI clade isolates.

While an epidemiological link in time and place to a pigeon infestation and guano detection on the hospital site suggested a common source, genome sequencing of the two cryptococcal isolates involved did not provide evidence of a single genotype causing infection. However, there were several limitations in the environmental sampling, including both culturing conditions and the cleaning of potential source sites, which may have decreased the likelihood of detecting *C. neoformans* in subsequent samples. Therefore, we cannot exclude a point source consisting of multiple cryptococcal strains. Indeed, genetic diversity of clinical and environmental isolates within a city has been described [26]. While wider sampling might reveal some isolates with closer genetic links, this study, including isolates from two other infections from the same geographical area, highlights the diversity of genotypes causing infection in the UK.

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Conflicts of interest
The authors declare that there are no conflicts of interest.

Ethical statement
This article does not contain any studies with human or animal subjects performed by any of the authors. Since identification and typing of the isolates in the current study was part of routine microbiological testing and subsequent infection-control investigations, ethical approval was not required.

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Mandatory - Healthcare Infection, Incident and Outbreak Reporting Template (HIIORT)

Initial assessment to be completed within 24 hours for all HIIAT Red and Amber; for HIIAT Green complete only if HPS Support requested.

Section 1 :Contact Details	
NHS Board/Care organisation	Greater Glasgow and Clyde
Date and time of reporting	02.07.20
Person Reporting and designation	Lead IPCN Gillian Bowskill / Prof A Leanord
Telephone number and email	[redacted]
Section 2: Infection Incident/outbreak Details	
Care facility/hospital	Queen Elizabeth University Hospital
Clinical area/ward and speciality	Ward 6A – Currently occupied by decanted paediatric Haemato-oncology population (Inpatient and day care services)
Section 3: Initial assessment	
Type: Incident/outbreak/ data exceedance e.g. Gastrointestinal, decontamination failure	Weak positive *Cryptococcus* test result for 1 patient.
Infectious agent known or suspected	*Cryptococcus*
Case definition	Positive reaction on Cryptococcal antigen test

Date of first case (if applicable)	26.06.20		
Total number of confirmed patient cases: 0	Total number of probable patient cases: 0	Total number of possible patient cases: 1	Total number of staff cases: 0

Number of patients giving clinical cause for concern as a consequence of this incident/outbreak	None.
Number of deaths as a consequence of this incident/outbreak	Nil
Was the infectious agent cited as a cause of death on a **death certificate* (**if yes, state which part of the certificate**)**	N/A
Are infection prevention and control measures as per National Infection Prevention and Control Manual (NIPCM) implemented? If not, state reason.	Yes
Has additional information regarding this Incident/outbreak i.e. leaflets been provided to patients/relatives. Provide details:	No

Additional Information:
Weak positive Cryptococcus isolated from plasma.
CSF *Cryptococcus* antigen negative.
Samples have been sent to Bristol Mycology reference Lab.

Section 4: Healthcare Infection Incident Assessment Tool (HIIAT) (link to tool)		
Severity of illness	Minor/Moderate/Major	Moderate
Impact on services	Minor/Moderate/Major	Minor
Risk of transmission	Minor/Moderate/Major	Minor
Public anxiety	Minor/Moderate/Major	Minor
HIIAT Assessment	Red Amber Green	Green
Section 5: Organisational Arrangements		
PAG/IMT meeting held	Yes - IMT	Date: 02.07.2020 Chair: Prof A Leanord
Next planned IMT	To be scheduled when further results are available	Date: TBC
Press statement (proactive press statements **must** be sent with HIIORT)	Proactive N	***Must** be sent prior to release*
	Release N	*Direct to SG comms within 48hrs*
	Holding N	*Direct to SG comms within 48hrs*
HPS support requested	Y	Date.....02.07.2020.....
Other information: e.g. decisions from IMT		

Complete this section if:
Red: complete daily or as agreed between IMT and HPS (a minimum of weekly)
Amber: complete twice weekly or as agreed between IMT and HPS (a minimum of weekly)
Green: complete if HPS support required (a minimum of weekly)

Section 6: Update						
On this date:	02.07.20	09.07.20				
Cumulative total of confirmed patient cases	0	0				
Cumulative total of probable patient cases	0	0				
Cumulative total of possible patient cases	1	1				
Cumulative total of staff cases	0	0				
Total number of symptomatic patients today	0	0				
Number of patients giving cause for concern	0	0				
Total number of deaths as a consequence of the incident since last HIIORT report	0	0				
Is the ward/services closed	No	No				
Is a service restricted	No	No				
HIIAT assessment	Green	N/A				

Organisation update certification information)	*Comments (including changes to any control measures, case definition or death)*
Date: 02.07.20	IMT held today 02.07.20 HIIAT Green Severity of illness – Moderate Impact on Services – Minor Risk of Transmission – Minor Public Anxiety – Minor <u>Situation</u> – [redacted] child. Excision of Medulloblastoma January 2020. Has been receiving intensive [redacted]. Recently competed 5th cycle. Admitted with mucositis and pyrexia. Weak positive *Cryptococcus* result on 3 serum samples from lateral flow test using neat serum. Taken as part of semi routine screening following admission with pyrexia. CSF *Cryptococcus* antigen negative. <u>Hypothesis</u> – Environmental, either community or hospital. Latency infection. False Positive. <u>Actions undertaken</u> – Samples sent to Bristol Mycology reference Laboratory for further testing. Family informed of result by clinical staff. <u>Actions planned</u> – Plant rooms will be inspected by microbiologist. Wait on results from Mycology Reference Lab. Clinical team will provide an update for ward staff. No change to current antifungal prophylaxis regime. IMT will reconvene when results from Bristol are available. Next IMT - TBC

09.07.20	Update – The patient was discharged on Sunday, well and on Fluclonazole. **In summary** CRAG lateral flow +ve NEAT serum. Pan fungal PCR negative. CSF no positive microbiology. It has been confirmed from the UK Mycology Reference lab that CRAG lateral flow for the CSF received was negative. We are left with 2 possibilities: 1. An early clinical infection that has been ameliorated with antifungals. Microbiology colleagues in QE are going to perform further sampling to try and answer this question 2. A false positive result in a case with no clinical indicators of Cryptococcus infection. Plant rooms inspected by microbiologist – no issues. No further action required at this time. IMT closed.

ONCE COMPLETED, EMAIL TO: NSS.HPSInfectionControl@nhs.net

microorganisms

MDPI

Review

Exposure to *Aspergillus* in Home and Healthcare Facilities' Water Environments: Focus on Biofilms

Malcolm Richardson * and Riina Rautemaa-Richardson

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Abstract: *Aspergillus* conida are ubiquitous in the environment, including freshwater, water for bathing, and in drinking water. Vulnerable patients and those suffering from allergic diseases are susceptible to aspergillosis. Avoidance of *Aspergillus* is of paramount importance. Potential outbreaks of aspergillosis in hospital facilities have been described where the water supply has been implicated. Little is known regarding the risk of exposure to *Aspergillus* in water. How does *Aspergillus* survive in water? This review explores the biofilm state of *Aspergillus* growth based on recent literature and suggests that biofilms are responsible for the persistence of *Aspergillus* in domestic and healthcare facilities' water supplies.

Keywords: *Aspergillus* species; *Aspergillus fumigatus*; drinking water; biofilms

1. Introduction

Aspergillosis is caused by the filamentous mould *Aspergillus*. The term describes a wide spectrum of diseases from invasive disease to evoking allergic responses [1,2]. The disease can occur in most body organs in humans and animals. Humans have highly efficient innate and immune mechanisms to prevent themselves from being infected by *Aspergillus* species. It is when these mechanisms are defective or absent that *Aspergillus* can grow within the body. Most people who may develop life-threatening aspergillosis are those with a weakened or compromised immune system due to corticosteroid therapy, due to being managed in intensive care, following transplant surgery, or as a consequence of cancer therapy. In contrast, aspergillosis can occur in immunocompetent individuals with no known suppression of their immune system, where previous tissue damage has occurred due to heavily scarred pulmonary tissue as a result of tuberculosis, chronic obstructive pulmonary disease, bronchiectasis where the airways become abnormally widened, or some other underlying pulmonary disease.

Many different manifestations of aspergillosis are well-described, including allergic aspergillosis (rhinosinusitis and bronchopulmonary) (>10 million worldwide), chronic pulmonary aspergillosis (~3 million worldwide), invasive aspergillosis (incidence >300,000 annually), and superficial disease (notably keratitis, otomycosis, and trauma or burn wound infections) [1,2]. These conditions are seen worldwide (https://www.gaffi.org/).

The genus *Aspergillus* includes over 300 species. *Aspergillus* spores (conidia) are commonly found in outside air, water, food items, soil, plant debris, rotten vegetation, manure, sawdust litter, bagasse litter, animal feed, bark chippings, on animals, and in the built environment. Exposure to *Aspergillus* occurs worldwide, mainly by inhalation from the outdoor or built environment. Water may be an alternative source of *Aspergillus* conidia. This will be explored in this review.

Around 20 species have so far been reported as causative agents of opportunistic infections in humans, although many cryptic species are now implicated, so the term complex is added to species

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names, unless definitive identification has been conducted. Among these, *Aspergillus fumigatus* is the most commonly isolated species, followed by *A. flavus* and *A. niger. A. nidulans*, *A. terreus*, *A. calidoustus*, and *A. versicolor* are among the other species less commonly isolated.

Multi-locus DNA sequence analysis has enabled the description of previously unknown 'cryptic' *Aspergillus* species, whereas phenotypic-based identification of *Aspergillus* can only identify isolates down to the species complex [3]. There are two main features of these 'cryptic' *Aspergillus* species. Firstly, the prevalence of these in clinical samples is relatively high compared with other filamentous fungal taxa, such as the agents of mucormycosis, *Scedosporium*, or *Fusarium*. Secondly, it is mandatory to identify these species because of the high frequency of antifungal drug-resistance. Matrix-assisted laser desorption/ionization-time of flight mass spectrometry (MALDI-TOF MS) enables the identification of molds and yeasts with an accuracy similar to that of DNA sequence-based methods [4]. MALDI-TOF MS is well-suited to the routine clinical laboratory workflow and facilitates the identification of common and 'cryptic' *Aspergillus* species. However, more reliable databases have to be developed to accommodate these. The fungal databases are the key components of commercial MALDI-TOF platforms. Commercial databases contain a large collection of common fungi, but more unusual and 'cryptic' species are not well-represented. Open-source databases of unusual fungi are becoming more accessible. Moreover, these databases have to contain fingerprints of multiple strains of the same fungus. Further development of these and other platforms will lead to a better understanding of the epidemiology and clinical importance of these previously unrecognized *Aspergillus* species.

The mycobiome of indoor and external environments, for example, air, dust, and soil, has been studied in some detail and comparisons have been made with the mycobiome of the respiratory tract [5]. *Aspergillus* species have been found in varying proportions in both, but no one study has focussed on the link between the mycobiome of water and human disease.

2. Water as a Reservoir for *Aspergillus*

Water entering a building is not sterile. Homes and healthcare facilities typically receive potable water from their local public water system or municipality. Potable water is used extensively in the healthcare environment. It is used for drinking, patient bathing and showering, handwashing, rinsing medical devices, hydrotherapy pools, and to make ice. Potable water is not sterile. It contains a high bacterial load. Fungi also have frequently been isolated from drinking water [6]. Opportunistic pathogens represent a significant proportion of the microbiome of drinking water and have emerged as a significant public health issue. Drinking water also contains fungi pathogens, such as *Aspergillus* spp. and *Fusarium* spp. [6]. However, little is known about the dynamics of fungal communities during the treatment of drinking water. Studying fungal populations in drinking water over time should identify areas and times where *Aspergillus* may proliferate. There are large gaps in our knowledge regarding the dynamics of fungal ecology during the drinking water treatment process and final delivery, and operational factors that shape the community structure. Contaminated water presents a number of exposure pathways. Water-related fungal infectious risks exist in both healthcare and community environments. Individuals can be directly exposed to these organisms either through bioaerosols and water, after ingestion, inhalation, and skin contact, and through mucous membranes.

In 2016, the present authors highlighted the scarcity of studies on the topic of *Aspergillus* in drinking water and that there were a number of aspects that remained poorly understood [7]. There was a plea for research to further explore the importance of drinking water as an environmental source of fungi in vulnerable or at-risk population groups. The expectation was that greater knowledge on the importance of the ingestion of *Aspergillus* in drinking water, as opposed to inhalation, as an exposure pathway, will ensure that mitigation measures for at-risk patients are appropriate.

In 2017, an in-depth, exhaustive review on fungal contaminants in drinking water was published [6]. Here, we summarize the body of knowledge reviewed by these authors, and others, in relation to *Aspergillus* spp., followed by a focus on biofilms in domestic and healthcare facility water supplies.

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Babić and colleagues reviewed how the chemical properties of water influence the growth and survival of fungi in water systems, and vice-versa [6]. Fungi are actively involved in the dissolution and corrosion of rocks and the precipitation of minerals. In general, rocks with an alkaline pH are more susceptible to fungal colonization than rocks with an acidic pH. In addition to limestone, a range of other rock types positively influence the growth of *A. niger*. Surface water is rich in the products of organic matter degradation, which promotes the growth of plant degrading filamentous fungi, including *Aspergillus* spp. In comparison, groundwater contains more inorganic ions and less organic matter and therefore fungi have not been isolated so frequently. Environmental water in areas that are densely populated contain high amounts of organic waste, as well as a number of pollutants, including organo-halogens, pesticides, and long-chain aromatic hydrocarbons such as benzene and xylene. *Aspergillus* species are able to break-down long-chained pollutants and have been isolated from contaminated waters. *Aspergillus* has also been isolated from waters heavily contaminated with bacteria and algae, which results in low oxygen concentrations. *Aspergillus* can grow under hypoxic conditions.

The effect of sunlight and water temperature on fungi is not well-documented. Babić and colleagues have reviewed the few studies that have been conducted [6]. The effect of solar-UV-radiation varies with the time of day, and is lower during cloudy days, in large volumes of water, and in water with high amounts of organic matter with increased turbidity. UV-radiation will also raise the water temperature. High levels of *Aspergillus* have been found in surface water during summer months, being replaced by other filamentous fungi during the cooler seasons.

Drinking water quality deteriorates during transportation through drinking water distribution systems (DWDS), reviewed in reference [8]. Microbial activity and ecology, particularly within biofilms that occur on the inner-pipe surface of DWDS, are emerging as important drivers in the degradation process. More recent reviews, for example, by Douterelo and colleagues [9,10], reinforce the view that the delivery of high-quality, potable drinking water primarily depends on the optimal operation of the DWDS. DWDS are complex pipe networks which function as discrete ecosystems which are dominated by microorganisms that are attached to the inner pipe surfaces and grow into the lumen of the pipes. Microbial dynamics in any ecosystem are determined by interactions between microorganisms and the surrounding environment. However, within these water transportation systems, the dynamics of microbial populations and a change in their composition over time remain largely unexplored.

Water after filtration is usually still not suitable for human drinking. Additional primary and secondary disinfection, such as UV-irradiation and ozonation, is often used. UV-irradiation does not appear to be optimal for *A. fumigatus*. Ozone does appear to be effective against a range of fungi, including *A. fumigatus*. Both processes are usually combined with chlorination. However, *A. fumigatus* appears to be resistant to calcium hypochlorite in some studies [6].

Despite well-developed raw water cleaning processes, fungi have been discovered in tap water systems as single cells or hyphal fragments, and as a part of biofilms, reviewed in reference [11]. An accumulation of research studies from 19 European countries has shown the difference between fungi communities in surface water and groundwater versus tap drinking water [11]. More than 400 different species have been found to inhabit different water sources: *Aspergillus* species were reported from 17 out of 19 countries (89.5%), followed by *Cladosporium* and *Penicillium* (both were reported from 84.2% of countries), *Trichoderma* (73.7%), *Alternaria* and *Fusarium* (both 68.4%), and *Aureobasidium* and *Mucor* (both 52.6%). Most fungi were isolated from both raw water sources (surface- and groundwater) and tap water, while species from the genera *Mucor*, *Trichoderma*, and *Penicillium* were found more often in surface water samples. These studies were carried out mainly using traditional cultivation techniques and may thus not be inclusive. Next generation sequencing techniques have the potential to elucidate the mycobiome of water supplies even further.

When employing direct microscopy, fungal elements can be seen in biofilms; however, it is virtually impossible to definitively identify the species unless the mould is sporulating. Next-generation sequencing of biofilms has identified opportunistic yeasts such as *Candida albicans, C. parapsilosis,* and *Exophiala dermatitidis*, but has scarcely mentioned *Aspergillus* species [11,12].

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An understanding of fungal biofilms in water supplies has been the main focus of water mycology over the past two years [11,12]. Because of the expected climate change, it is probable that in the future, the earth's warming will lead to a rise in the temperature of surface water, water distribution systems, and pipe networks. Opportunistic fungi, including *Aspergillus* species, which are capable of growing in drinking water, are often adapted to higher temperatures. Several species of *Aspergillus* are thermotolerant. As temperatures rise, these organisms could therefore occur more frequently in the microbial populations in drinking-water-related environments.

2.1. Diversity of Fungi in Water—Regional

As an illustrative example, the load and presence of environmental, mycotoxin-producing, and potentially pathogenic fungi in man-made water systems (domestic dwellings, hospitals, and shopping centers) connected to the municipal water distribution network in Istanbul, Turkey, was investigated [13]. The mean fungal load found in different water samples was 98 colony-forming units (CFU)/100 mL of water in shopping centres, 51 CFU/100 mL in hospitals, and 23 CFU/100 mL in homes. The dominant fungal species were *Aureobasidium pullulans* and *Fusarium oxysporum*. Aflatoxigenic *A. flavus* and ochratoxigenic *A. westerdijkiae* were only detected in hospital water samples. *Alternaria alternata, A. clavatus, A. fumigatus*, and *Cladosporium cladosporioides* were also detected in the samples. This study demonstrated that in a big metropolitan area, water supplies contained environmental, pathogenic, allergenic, and mycotoxin producing fungi. It was concluded that the current disinfection policies and procedures in place were inadequate.

A number of studies from different regions of Europe have underscored the great biodiversity of fungi surface sources and groundwater, reviewed in [12]. Several pathogenic species have been found, including *A. fumigatus*, and rarer species known to be less sensitive to antifungal agents, including *A. calidoustus* and *A. viridinutans*. The dominance of *Aspergillus* species in these and other studies could reflect their high frequency in the surrounding air, reviewed in [6].

2.2. Water Systems—Freshwater

Fungi are much less common in freshwater biomes predominated by bacteria (often present as biofilms), cyanobacteria, archaea, algae, viruses, and protozoa, reviewed in [14]. Nonetheless, microscopic fungi are present in freshwater communities, although they exist in relatively lower concentrations, are rarely planktonic (free-living), and are even more rarely pathogenic.

Water could be the preferred habitat of certain fungal species. A quantitative evaluation of the taxa isolated from water was shown to depend on its origin: surface water presents a higher risk of colonization compared to deeper samples, such as groundwater [15].

Potentially pathogenic fungal microorganisms are found in a variety of freshwater sources, including surface waters, drinking water, and public bathing and swimming facilities. Fortunately, fungal infections as a result of freshwater exposure or trauma are rare. The most common entities appear to be fungal keratitis, otitis externa, and tinea pedis. Well-documented reports describe deep fungal infections resulting from freshwater exposures following natural disasters or near-drowning episodes. As with most cryptic fungal infections, freshwater-related or otherwise, this etiology should be suspected when bacterial cultures or molecular tests are normal or when the infection inexplicably worsens or fails to resolve with appropriate antibacterial therapy.

Like *Legionella pneumophila* and other bacteria, fungi may be associated with or be harbored by free-living amoebas in freshwater, including tap and potable water [16]. The importance of this association is still being elucidated. In addition to adjacent soil, one source of freshwater fungi contamination by fungi is atmospheric dust (dispersed by wind, excavation, and other soil-disturbing activities) [5]. It is to be expected that there are regional variations in species diversity. A variety of potentially pathogenic fungi may be found in various bodies of water, sometimes as the result of runoff or sewage contamination. The presence of some fungal contaminants in drinking water may be related to their establishment of biofilms in portions of the water distribution system upstream

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from household or commercial establishment plumbing systems, as discussed below. Hageskal and colleagues provided an informative review of the methodological challenges and difficulty in interpretation of microbiological assessments [17].

3. Aspergillus Biofilms

There are a number of key factors to consider [11]: (1) Water entering a home or healthcare facility is not sterile; (2) the design of a domestic or hospitals plumbing system and patterns of water use allow biofilms to form; (3) fungal pathogens establish themselves as biofilms in plumbing networks; (4) fungal pathogens associated with plumbing biofilms have been epidemiologically linked to healthcare acquired infections; and (5) risk of infection can be reduced through the development and implementation of a water management program.

Recent studies have suggested that biofilm formation by *A. fumigatus* in humans may be one of the most important virulence factors in chronic pulmonary aspergillosis, invasive disease, and fungal balls in the sinuses and lungs (aspergilloma) [18]. Fungal biofilms forming on host surfaces or cells are comprised of whole cells, cell wall components, secondary metabolites, drug transporters, and extracellular material. The biofilm phenotype of the fungus is refractory to most conventional antifungals. Thus, over the past few years, an in-depth analysis and understanding of *A. fumigatus* biofilms has been carried out to devise newer and better antifungal targets for treating complex *A. fumigatus* biofilm-associated diseases. Does what we know about *Aspergillus* biofilms in the clinical setting translate to *Aspergillus* biofilms in water delivery systems in the home and healthcare facilities?

A number of laboratory studies may provide some pointers as to how *Aspergillus* biofilms grow in the lumen of water distribution systems [19]. The formation of *A. fumigatus* biofilms is similar, regardless of the provenance of the isolate, but differences are apparent according to the ambient temperature. Stages of biofilm development include the following: Firstly, adhesion to an inanimate surface (typically over a 4 h period) followed by cell co-aggregation and the formation of extracellular matrix substance (EMS); secondly, conidial germination into germlings (8–12 h—for example, *A. fumigatus* conidia will germinate within 6 h under favourable conditions), followed by hyphal development, hyphal elongation, and expansion with channel formation (16–20 h); thirdly, biofilm maturation as follows: mycelia development, stratifying of hyphal layers, channel formation within these hyphal matrixes, and high structural arrangement of the mycelia that include anastomosis of adjacent hyphae and extensive production of EMS (24 h). The EMS covers, surrounds, and strengthens the mycelial meshwork, particular at 37 °C. When using clinical isolates, irregular fungal structures, such as micro-hyphae that are short and slender hyphae seem to occur; finally, regarding cell dispersion, soil isolates exhibit higher conidial formation than clinical isolates, which have the capacity to germinate and generate new mycelia growth. Shedding of fungal elements from the biofilm most likely occurs. It is highly likely that *Aspergillus* attaches to pre-existing bacterial biofilms, for example, *Pseudomonas aeruginosa*, which is often considered as the architect of the biofilm, due to its ability to produce an exopolysaccharide or glycocalyx matrix. It is highly likely that other filamentous fungi form biofilms in a similar way, for example, *Fusarium*.

3.1. Optimal Conditions for the Formation of Aspergillus Biofilms

A report from the Netherlands has shown that the season of the year influences the growth of *Aspergillus fumigatus* [20]. Using molecular tools, it was demonstrated that fungi, including *A. fumigatus*, generally occur in drinking water in the Netherlands, and are capable of multiplying in distribution systems and indoor installations. Drinking water temperatures between 5 °C and 22 °C had no influence on the number of fungi. *A. fumigatus* appeared to be capable of multiplying in distribution systems and/or indoor installations. Drinking water temperatures around 20 °C resulted in higher counts of *A. fumigatus* than at temperatures around 7 °C. However, the authors emphasise that it is still unclear whether the occurrence of the strains of *A. fumigatus* found in water would cause clinical disease.

Prior to the time period of the current review, the concept of fungal biofilms in water supply systems was introduced [14]. The authors discussed the need for standardized methods to investigate water for fungi and presented data showing that fungi did form biofilms. The major part of the fungal biofilm biomass in drinking water distribution systems is attached to pipe surfaces. Several factors influence biofilm development, including temperature, nutrients, residual disinfectant, the hydraulic regime, and characteristics of the network surface/substratum. This work also demonstrated the concept of mixed fungal biofilms, a situation well-recognised with mixed fungi-bacteria biofilms in a number of clinical scenarios.

The materials used for manufacturing water supply networks have been shown to influence the microbiological quality of water and the formation of biofilms [6]. Network pipe systems are constructed from a range of materials which may interact with residual chlorine and chlorination by-products. These materials may also influence the microbiological quality of the water by promoting biofilm formation. In general, bacteria and fungi are more likely to form biofilms in pipe systems made from iron or steel, in comparison to PVC [6]. The lumen of the pipes can become rough, inducing changes in water flow and causing a reduction in shear forces, enabling the easy attachment of microbial cells. The number of fungal cells inside biofilms may be 5000 times higher than in running water. Under experimental conditions, *Aspergillus* biofilms were fully formed within 48 h from the start of an experiment mimicking real conditions in tap systems [6]. *Aspergillus* biofilms have been found in taps in private homes, hospitals, and industrial premises. Once established, fungal biofilms are difficult to eradicate from the pipe system, resulting in altered taste, odor, the production of allergenic compounds, and mycotoxins [11,12].

3.2. Implications of Aspergillus Biofilms in Drinking Water Distribution Systems

Fungi growing as biofilms inside taps and in drinking and cooking water will affect the taste and produce an odor which will directly impact the chlorination process in use, due to the release of a large number of products known as secondary metabolites (extrolites) [11]. These are very diverse and specific for different fungal species and some are known mycotoxins. It is clear that the role of secondary metabolites in specific ecological niches is to defend their habitat and suppress the growth of competitors. However, a number of mycotoxins may be detrimental to human health in higher concentrations or as a result of prolonged, chronic exposure. Fungal cell wall components, fungal allergens, and the fungal biomass itself may drive allergies and result in opportunistic and systemic infections, mainly in profoundly immunocompromised individuals [1]. Even though fungi are recognized as causative agents of systemic respiratory, mucosal, rhinocerebral, cutaneous, and subcutaneous infections, they remain largely overlooked in the regulations of water quality and human consumption. There are many possible reasons for this, including: a lack of knowledge of the concentration of fungi in water, different culture methods, and the low number of reports making connections between the presence of fungi in tap water and the occurrence of diseases in humans. Recent natural disasters, such as tsunamis and hurricanes, have highlighted the possibility of drinking water contamination with pathogenic fungi, including *Aspergillus*.

The identification of pathogenic fungi from water in healthcare facilities such as *Aspergillus, Fusarium, Penicillium, Scedosporium*, and agents of mucormycosis and the unavoidable formation of a polymicrobial biofilm in waterlines is of concern. To prevent a risk of fungal infection in this setting, health authorities have implemented a number of measures to mitigate this: ultraviolet radiation to treat the incoming water, continuous chemical treatment or thermal shock within the pipe network, or filtration at points of use, reviewed in [11]. It is highly likely that *Aspergillus* conidia are released from contaminated water in bioaerosols, or the aerosolization of a moldy aquatic niche (wet cell) constituting additional exposure pathways in addition to the familiar dispersal of conidia from visible and interstitial mould growth.

Following on from our understanding of how *Aspergillus* biofilms form and resist antifungal treatment in the human respiratory tract, an additional concern when discussing biofilms in water distribution systems is that within a biofilm, sessile microorganisms become less susceptible or

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sometimes totally resistant to different antimicrobial compounds, compared to microorganisms growing planktonically. This resistance is partially explained by the presence of persister cells, which are highly tolerant to biocides, antibiotics, and antifungals, especially in the deeper layers of the biofilms [11]. Persisters are dormant variants of regular conidia and hyphal structures that form stochastically in biofilms and are highly tolerant to antifungals. *Aspergillus* biofilms can be considered as reservoirs of fungal contamination of water systems by the periodic or sustained release of hyphal fragments or longer lengths of hyphae which are isolated or in clusters embedded in an extracellular matrix. Biofilms grow at an interface such as the one existing between air and water, and may sporulate. These conditions are found in water systems, and in community and hospital environments, for example, in shower heads. This is also the case in endoscopy reprocessing units, dialysis units, and dental units.

4. The Medical Implications of Exposure to *Aspergillus* in Water in Indoor Environments

It is clear that water constitutes an exposure pathway. Individuals are exposed to pathogenic fungi, including *Aspergillus*, in a number of different situations: drinking water; bathing and showering; or indirectly due to the use of household appliances connected to the water supply, such as dishwashers and washing machines (Figure 1). Increasingly, a number of other environments are being recognised as potential sources of *Aspergillus*, such as bottled water, dental lines, and haemodialysis units (reviewed below).

4.1. Direct Contact with Aspergillus

Many fungi survive in moist environments. *Aspergillus* conidia can survive for many years when stored in water in the dark (unpublished data, M Richardson). *Aspergillus* biofilms can develop in shower hoses and shower heads. An association has been claimed between showering and the effect of bioaerosols containing *Aspergillus*, and exacerbation of asthma and hypersensitivity pneumonitis (extrinsic allergic alveolitis) [6]. Hospital water may also act as a source of hospital outbreaks of aspergillosis.

4.2. Indirect Contact with Aspergillus

Dishwashers and washing machines harbor a variety of filamentous fungi and black yeasts, but *Aspergillus* does not appear to feature in the mycobiome surveys of these appliances [11].

5. Potential Exposure to *Aspergillus* in Special Aqueous Environments

5.1. Swimming Pool Facilities

Contamination of swimming pools with pathogenic organisms and impact on human health has long been of concern. The possible transmission pathways of fungi in indoor swimming pool facilities have been assessed in different areas of swimming pool facilities by the culture and typing of the fungal isolates [21]. Air, water, and surface samples were collected from seven different indoor swimming pools. Species identification was based on DNA internal transcribed spacer (ITS) sequences. The maximum concentrations were found on surfaces, in water and air. Over 450 isolates were recovered, belonging to 111 fungal species, of which 50 were clinically relevant. *Phialophora oxyspora* (13.3%) and *Trichosporon dohaense* (5.0%) were the most frequently isolated species and mainly detected on floors, as were *Trichophyton interdigitale* and *T. rubrum*. *Penicillium* spp. and *Aspergillus* spp. were the dominant molds in water and air. The highest fungal concentrations posing the highest risk of contamination were areas where swimming pool visitors converged while moving from one room (e.g., dressing room) to another (e.g., shower room) and walking barefoot. As suggested in numerous other studies, the dispersal of fungi on floors is most likely facilitated by the pool visitors and cleaning machines of various types. The authors advocate that preventive measures such as cleaning should minimize the burden of clinically relevant fungi in swimming pools and similar 'sub-tropical paradises' since these potentially pose a health risk to vulnerable individuals, especially children and the elderly.

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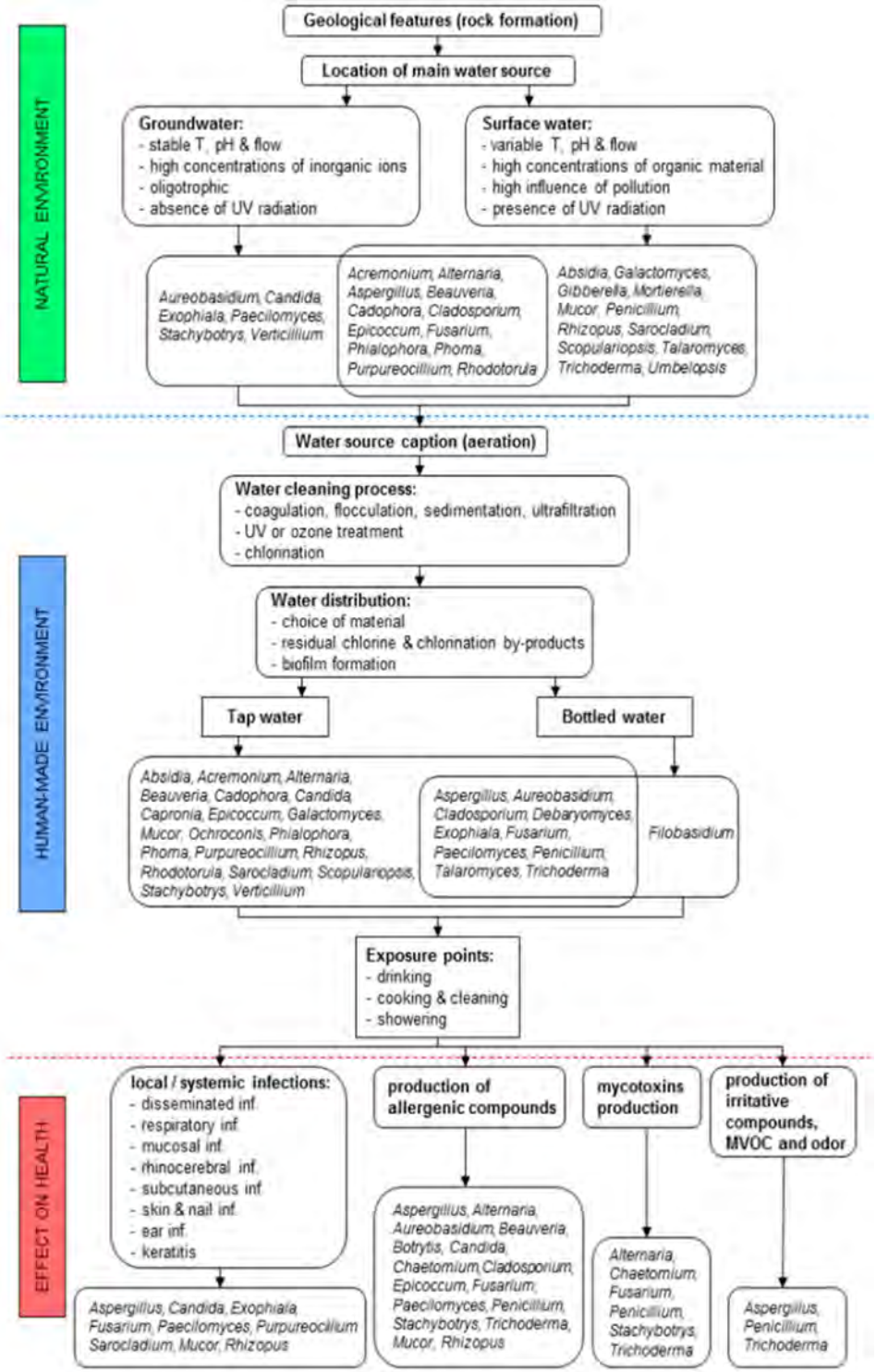

Figure 1. Abiotic, biotic, and anthropogenic factors influencing fungal presence in groundwater, surface water, tap water, and non-mineral bottled water, with a possible effect of fungi on human health via different exposure points. The most common factors having an influence on the fungal presence and diversity in different water sources are divided into factors influencing fungal presence, mainly in raw water sources in the natural environment (indicated with green colour), anthropogenic factors influencing fungal presence during the production of tap and non-mineral bottled water, and exposure points of fungi via water-related activities (indicated with blue colour). Red colour indicates the most frequently detected fungal genera from tap and bottled water with their possible effects on human health. Reproduced from [6], open access and with authors' permission.

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5.2. Haemodialysis Units

Haemodialysis is a type of treatment for kidney failure. It uses a haemodialysis machine, dialyzer, dialysis solution, catheters, and needles, all of which favor biofilm formation. Do pathogenic fungi form biofilms in dialysis equipment? To explore this, *Aspergillus* and *Fusarium* biofilms were grown in liquid culture containing dialysate or dialysate supplemented with glucose [22]. The biofilms were incubated at 30 °C for 72 h, quantified using violet crystal staining, and viewed under the transmission electron microscope. All the fungi formed biofilms under all test conditions. However, Bonferroni analysis (an adjustment made to *P* values when several dependent or independent statistical tests are being performed simultaneously on a single data set) revealed that the dialysate supported the growth of *Aspergillus*, whereas both the dialysate and dialysate supplemented with glucose promoted the development of *Fusarium oxysporum* biofilms. Scanning electron microscopy of biofilms that grew on catheters after 72 h revealed that *Aspergillus* had germinated and formed abundant hyphae; when *Aspergillus* was grown in the dialysate, an extracellular matrix was visible on the surface of some hyphae. The authors conclude that their study may contribute to the formulation of new strategies to monitor biofilm formation and to increase knowledge associated with fungal biofilms in the dialysis environment.

5.3. Showers

During showering, people are exposed to fungal propagules (conidia and hyphal fragments) via bioaerosols released into the environment [11,23]. Inhalation of water droplets containing these fungal components is the most relevant route of pulmonary and systemic infection for vulnerable patients. Any situation that enhances the air-borne dispersion of mould propagules increases the exposure of patients to such pathogens. Thus, special attention is paid to bioaerosols released in bathrooms in hospital environments. Recent research conducted on shower hose biofilms revealed the presence of a number of opportunistic pathogens: *A. glaucus*, *Cladosporium* spp., *Exophiala mesophila*, *Fusarium fujikuroi* species complex, *Malassezia restricta*, *Penicillium* spp., and *Schizophyllum commune* [6,23]. In a seminal study, Anaissie and colleagues reported a shift in the fungal population in the air and on surfaces between and immediately after showering [5]. Showering increased the presence of filamentous fungi, including *Aspergillus*. Molds were recovered in 70% of 398 water samples. The authors suggested that hospital water distribution systems may serve as a potential indoor reservoir of *Aspergillus* and other molds, leading to the aerosolization of fungal spores and potential exposure for patients.

5.4. Centralised Water Treatment Systems

Centralized water treatment plants are facilities where large volumes of water are treated at high flow rates in a “central” location and the water is then distributed via networks of pipelines, channels, and intermediate reservoirs. Centralized water treatment mainly operates in major urban areas of most parts of the developed world. A number of studies suggest that centralized drinking water treatment dictates the composition of the final drinking water microbial population via the selection of community members and that the eukaryotic community is controlled by physical treatment processes [24]. The effect of centralized water treatment processes on the diversity of fungal populations in drinking water has not been previously evaluated. Interestingly, it has been shown that the relative abundance of *Aspergillus* spp. significantly increased through the water treatment process, especially following disinfection, suggesting that this fungus is less efficiently removed by the conventional water treatment process or is more resistant to the selection pressure posed by water treatment processes. The relative abundance of *Aspergillus* spp. increased significantly from raw water to post-disinfection water. Interestingly, there was an increase in the relative abundance in water samples from post-filtration to post-disinfection. ‘Linear discriminant analysis Effect Size’ analysis also showed that *Aspergillus* spp. were significantly enriched post-disinfection.

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5.5. Bottled Water

Ribeiro and colleagues conducted a 12-month survey of a drinking water bottling plant in Portugal to evaluate the diversity of the mycobiota [25]. The predominant fungal genera ranked in order of the highest numbers isolated were *Penicillium*, *Cladosporium*, and *Trichoderma*, followed by *Aspergillus*, *Paecilomyces*, and others. As expected, the highest numbers of isolates were collected during the warmer, late spring, and early summer months of the year. The authors advocated that during those times of the year when fungal contamination is high, filters should be changed on a regular basis. In order to assess whether contamination was from a focal or multiple points in the bottling facility, molecular methods were used specifically to identify *Penicillium brevicompactum*. Fungal contamination arose from multiple sources. Some *P. brevicompactum* strains were very similar in profile and were detected at different sampling times, indicating that they were endogenous to the bottling plant. There was no evidence to suggest that fungi detected in the source water contaminated other parts of the bottling plant. However, there was evidence that *P.* brevicompactum strains isolated from water filters were detected elsewhere in the plant, underscoring the importance of changing filters on a more regular basis during periods of high fungal contamination.

6. Conclusions

The recognition of *Aspergillus* biofilms in water delivery systems over many years has more recently helped to understand the formation of these fungal communities on and in various body spaces, leading to aspergillosis and presenting a formidable target for antifungal therapy. *Aspergillus* has been found to contaminate water supplies throughout Europe and beyond. It is not surprising that this filamentous fungus has the propensity to form communities on abiotic surfaces, such as water pipes. Furthermore, fungal biofilms have been seen to increase in complexity over time in water supplies, making them more difficult to eradicate.

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Aspergillus Biofilms in Human Disease

Craig Williams, Ranjith Rajendran, and Gordon Ramage

Abstract

The biofilm phenotype of *Aspergillus* species is an important and accepted clinical entity. While industrially these biofilms have been used extensively in important biofermentations, their role in clinical infection is less well defined. A recent flurry of activity has demonstrated that these interesting filamentous moulds have the capacity to form biofilms both *in vitro* and *in vivo*, and through various investigations have shown that these are exquisitely resistant to antifungal therapies through a range of adaptive resistance mechanisms independent of defined genetic changes. This review will explore the clinical importance of these biofilms and provide contemporary information with respect to their clinical management.

Keywords

Aspergillus biofilm • Filamentous moulds • Fungal infections • Aspergillosis • Antifungal drugs

1 Introduction

Fungal biofilms are an important clinical problem (Ramage and Williams. 2013). The widespread use of indwelling medical devices, broad-spectrum antibiotics, and an aging and more immuno-compromised patient population, has created an opportunity for yeasts and moulds to form infections in the form of biofilms. This chapter will discuss the anatomical areas where A*spergillus* biofilms may be important and the evidence that they exist and discuss the treatment of aspergillus infection.

A biofilm is composed of microorganisms attached to surfaces or one another and enclosed within an extrapolymeric matrix. The biofilm mode of growth is the preferred form of growth of microorganisms and accounts for up to 65 % of all clinical infections. This mode of growth

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gives the organism a number of advantages including high level antimicrobial resistance which may cause problems for the clinician attempting to treat such infections (Donlan and Costerton. 2002). Over recent years there has been a growing appreciation that pathogenic fungal species both have the ability to form biofilms and that these biofilms may impact clinical practice (Ramage et al. 2009; Sayed et al. 2012; Fanning and Mitchell. 2012; Williams and Ramage. 2015).

Fungi can be broadly divided into yeasts and moulds. In terms of the number of infections, *C. albicans*, a normal commensal of human mucosal surfaces and opportunistic pathogen in immunocompromised patients, is the most clinically important of fungi species in terms of the production of clinically relevant biofilms. These biofilms have much in common with *Aspergillus* biofilms, which are the subject of this chapter. A candidal biofilm begins with yeast cells attaching to a relevant surface using defined adhesins, followed by the formation of a microcolony with yeast cells undergoing morphological switching to pseudo- and true-hyphae, which results in the rapid formation of a meshwork of hyphae interspersed with budding yeast cells (Ramage et al. 2002). As the biofilm matures it becomes enclosed in a glucan rich polymeric matrix (Nett et al. 2010) which provides protection from host defenses and treatment with antifungal agents. Within the biofilm there are a range of niches and hypoxic areas, which influence filamentation (Bonhomme et al. 2011). Flow of fluids across the surface of the biofilm may then result in the dispersion of daughter cells, which attach to a new substrate and the cycle starts again (Uppuluri et al. 2010). This entire process is controlled by various transcription factors, such as Bcr1p, Ace2p, Efg1p and Zap1p, which are involved in precisely regulated molecular pathways (Finkel and Mitchell 2011; Nobile et al. 2006; Zhao et al. 2006; Fanning et al. 2012). The molecular biology of *Aspergillus* biofilms is less well understood, but it is a rapidly developing area of microbiology (Beauvais et al. 2007; Bom et al. 2015; Gravelat et al. 2008; Gravelat et al. 2010; Mowat et al. 2007; Ramage et al. 2011; Winkelstroter et al. 2015). Figure 1 illustrates the morphological complexity of these filamentous moulds.

2 Where May Aspergillus Biofilms Be Important?

2.1 Upper Airways

Sinusitis (or rhinosinusitis) is defined as an inflammation of the mucous membrane lining the paranasal sinuses. It may be acute or chronic, however, subacute and acute exacerbation of

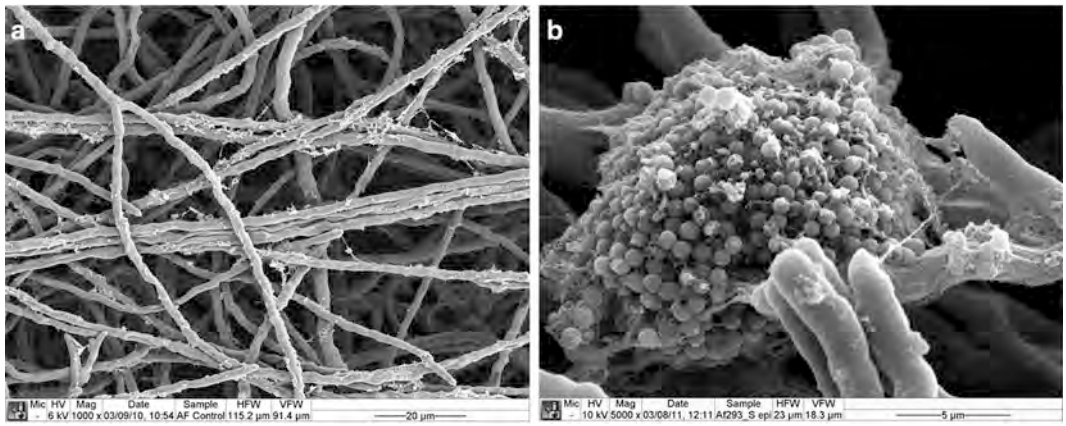

Fig. 1 Scanning electron micrographs of biofilms formed by (**a**) an *Aspergillus fumigatus* and (**b**) an co-culture of *Aspergillus fumigatus* and *Staphylococcus epidermidis*

chronic diseases has also been described and as all types have similar symptoms it is often clinically difficult to distinguish these. Around ninety percent of adults have had some symptoms of sinusitis at some time. There is a growing appreciation that chronic rhinosinusitis is typified by biofilm growth (Foreman et al. 2011; Keir et al. 2011; Ebbens et al. 2009a). While there is increasing evidence for the role of bacterial biofilms in this infection, there role of fungi remains controversial. (Ebbens et al. 2009b). Paranasal sinus fungus balls have been described (Grosjean and Weber. 2007; Karkas et al. 2013), which share some of the features of fungal biofilms (Harding et al. 2009; Mowat et al. 2008a, b). In a recent study of 118 patients with chronic sinusitis, nasal discharge, headache and visual disturbance, over a 14 year period 23.7 % had a sphenoidal fungus ball in which Aspergillus *fumigatus* and *Aspergillus nidulans* hyphae were observed microscopically (Karkas et al. 2013). In terms of infections associated with foreign bodies *A. fumigatus* infection within the maxillary sinus associated with a zygomatic implant has been reported (Sato et al. 2010). Experimental studies have shown that *A. fumigatus* biofilms form in a primary human sinonasal epithelial model (Singhal et al. 2011) and in a sheep model of induced sinus biofilms *A. fumigatus* readily forms biofilms often associated with *Staphylococcus aureus* (Boase et al. 2011). These data suggest that fungal biofilms, alone or more likely in mixed species biofilms with other organisms, may play a role in sinus infection however there is little evidence to support the role of fungi in other upper airway biofilm infections such as otitis media (Bakaletz. 2007; Martin et al. 2005; Yao and Messner 2001).

2.2 Lower Airways

Lower respiratory tract infection may be due to biofilm infection, the archetype of which is *Pseudomonas aeruginosa* in cystic fibrosis patients (Singh et al. 2000). It is also now recognised however that fungal biofilms present in the lung may also contribute to infection.

Filamentous fungi, mainly *A. fumigatus,* may cause a spectrum of respiratory disease including a discrete lesion in a pre-existing cavity, aspergilloma, wheezing mediated by an immune response, allergic bronchopulmonary aspergillosis (ABPA) and invasive aspergillosis (IA) (Denning. 1998). A bronchopulmonary lavage (BAL) of these individuals often reveals the presence of numerous intertwined hyphae in the form of a complex multicellular structure when examined histologically (Jayshree et al. 2006), this is indicative of a biofilm phenotype (Harding et al. 2009; Mowat et al. 2008a, b). The recently described *Aspergillus* bronchitis may also be biofilm associated and is characterized by bronchial casts containing mycelia forming compact masses (Young et al. 1970). It is clear that *Aspergillus* species form medically important biofilms (Ramage et al. 2011; Gutierrez-Correa et al. 2012) and understanding their clinical role in is crucial, as with all biofilms, these structures are highly resistant to antifungal therapy (Mowat et al. 2008a, b; Seidler et al. 2008).

Infection in CF patients is also commonly associated with *S. aureus and Haemophilus influenzae*, and recent advances in culture-independent, next generation sequencing technologies, have revealed that the microbiome of the CF lung is much richer than previously appreciated comprising of a diverse range of bacterial and fungal pathogens, of which *A. fumigatus* is the most prevalent filamentous fungi (Ramage et al. 2011). *A. fumigatus* has a prevalence rate of between 10 and 57 % (Pihet et al. 2009; Bauernfeind et al. 1987), though other fungi have been isolated from the lungs including, *Scedosporium* species, *Aspergillus niger, Aspergillus flavus, Aspergillus nidulans, Aspergillus terreus* (Sudfeld et al. 2010; Cimon et al. 2003). Lungs of CF sufferers are lined with a thick viscous mucus layer susceptible to polymicrobial infections, leading to recurrent infections and continuous inflammation (Rowe et al. 2005). The interplay between the pathogens residing in the lung may be responsible for the

acute exacerbations associated with CF, where the balance is tipped towards an environment with excess inflammatory, oxidative and proteolytic activity. Several studies have identified an association between *A. fumigatus* and *P. aeruginosa,* whereby co-infection saw decreased pulmonary function in comparison to those with a mono-infection (Amin et al. 2010), a phenomenon also reported with *Candida* species and *P. aeruginosa* (Chotirmall et al. 2010). Evidence is therefore increasing for the improved clinical management of these patients (Delhaes et al. 2012). Indeed, interkingdom interactions of the CF lung, and elsewhere, may lead to adverse clinical outcomes (Leclair and Hogan 2010). The ability of these microbes to form strong mixed species biofilms likely contributes towards their persistence, making it extremely difficult to eradicate the infection (Seidler et al. 2008; Lutz et al. 2012). *P. aeruginosa* has also been shown to inhibit *A. fumigatus* filamentation via the release of molecules involved in intra-cellular communication (Mowat et al. 2010). Investigations into the interactions between these two are limited, however the release of small molecules designed to inhibit fungal growth appear to be the primary form of interaction. One particular group of metabolites known as phenazines, have been reported to inhibit *A. fumigatus* biofilm formation, however it was also found that *A. fumigatus* was able to convert these metabolites released by *P. aeruginosa* to produce fungal siderophores, which may in turn influence CF progression (Moree et al. 2012). Furthermore, *P. aeruginosa* releases the metalloprotease elastase, which has been shown to be toxic to host cells (Smith et al. 2015). It was found that elastase production was constitutive, but became significantly increased in the presence of *A. fumigatus* during biofilm co-culture. Furthermore, elastase was cytotoxic to human lung adenocarcinoma cells, and therefore the presence of both of these pathogens could contribute towards enhanced pathogenicity (Smith et al. 2015). Thus, in general, evidence suggests that the co-isolation of both of these organisms indicates a poorer prognosis; however the relationship between the two remains poorly understood and requires further investigation into their polymicrobial interactions. Indeed, these studies highlight potential battles going on within a polymicrobial environment such as the CF lung, which plays a crucial role in the overall pathogenesis of disease (Peters et al. 2012), exemplified by studies in a Drosophila model of polymicrobial infection in which microorganisms from CF showed a different outcome depending on the presence or absence of *P. aeruginosa* (Sibley et al. 2008a, b). Collectively, these provide evidence for the need to consider earlier use of antifungals to improve clinical management of these patients (Delhaes et al. 2012).

3 Wounds

Non-healing wounds, such as diabetic foot ulcers (Seth et al. 2012) represent a significant clinical burden to patients, and are associated with the presence of microbial biofilms. *S. aureus* and *P. aeruginosa* are often isolated together in these patients and have been shown to have a non-random association within the wound site (Fazli et al. 2009). Evidence is emerging that pathogenic fungal species may play a role in these infections (Branski et al. 2009).

Wounds acquired in combat situations especially with persistent evidence of wound necrosis often contain fungi with mould isolates found in 83 % of cases (*Mucorales*, n = 16; *Aspergillus* spp, n = 16; *Fusarium* spp, n = 9), commonly with multiple mould species among infected wounds (28 %). Clinical outcomes included 3 related deaths (8.1 %), frequent debridements and amputation revisions (58 %) (Warkentien et al. 2012).

A next generation sequencing approach to venous leg ulcers reveals that *C. albicans, C. glabrata* and *Aspergillus* species are present, but intriguingly the authors report that individuals seem to have unique microbial profiles, (Wolcott et al. 2009). A further retrospective molecular analysis of 915 chronic wound infections, pressure ulcers, diabetic foot ulcers, non-healing surgical wounds and venous

leg ulcers, showed that 208 (23 %) of these contained pathogenic fungi (Dowd et al. 2011). Yeasts were the most abundant fungi (*Candida* spp.), but *Aureobasidium, Cladosporium, Curvularia*, *Engodontium, Malessezia*, *Trichtophyton,* and *Ulocladium* were also present. Overall, fungal species represented over 50 % of the microbial burden in the majority of specimens examined but direct evidence that the fungi were present as biofilms is lacking.

4 Medical Devices

Broad-spectrum antibiotics, parenteral nutrition, immuno-suppression due to chemotherapy and radiotherapy, and disruption of mucosal barriers due to surgery, are among the most important predisposing factors for invasive fungal infection (Odds 1988). *Candida* species predominate and are the fourth most common cause of bloodstream infection in patients requiring intensive care and the most common etiologic agent of fungal related biofilm infection. However, other filamentous fungi biofilm related infections have also been increasingly described, including *Aspergillus* (Escande et al. 2011). *Aspergillus* species have been reported to cause serious biomaterial related biofilm infections, involving catheters, joint replacements, cardiac pace makers, heart valves, and breast augmentation implants (Escande et al. 2011; Langer et al. 2003; Rosenblatt and Pollock 1997; Jeloka et al. 2011; Golmia et al. 2011). Fungal biofilms are also associated with building fabrics and hospital infrastructure (Short et al. 2011; Siqueira et al. 2011; Richardson 2009; Anaissie et al. 2002).

5 Antifungal Treatments

Guidelines exist for a number of Aspergillus infections. The guidance for Chronic Pulmonary aspergillosis (Denning et al. 2016), which does not mention biofilms, recommends, a minimum of 4–6 months oral triazole therapy initially and patients who deteriorate in this period should be deemed failures and an alternative regimen used. Micafungin, Caspofungin Liposomal Amphotericin and Amphotericin B (AmB) deoxycholate are also recommended.

For Invasive aspergillus three major sets of guidelines are available, ECIL (Maertens et al. 2011), ESCMID (Ullmann et al. 2012), and IDSA (Walsh et al. 2008). Again, none specifically reference the presence of biofilm and they all recommend either azoles, AmB or echinocandins with different grades of evidence. A useful review by Leroux and Ullmann (2013) highlight the methodological differences between these studies and tabulates the recommendations (Leroux and Ullmann 2013). So when considering aspergillus infection it is clear that AmB, including a variety of lipid formulations and members of the azole class, which includes fluconazole, itraconazole, voriconazole (VRZ) and posaconazole, are effective in the treatment of invasive aspergillosis (IA) and are the mainstay treatment for the disease (Denning et al. 1989; Oren et al. 2006; Raad et al. 2008; Sambatakou et al. 2006).

One consideration in the choice of treatment is the presence of triazole resistance. High rates of triazole resistance in *A. fumigatus* were first reported in the Netherlands and in the UK. Subsequently the rate of triazole resistance in *A. fumigatus* has been reported in Europe at rates from 1.7 to 29.6 %. More worrying is a reported increase in the yearly rate of resistance by 6 % per annum in patients without prior exposure to antifungal therapy (Goncalves et al. 2016).

Although the triazoles have proven efficacy with good safety profiles, they have been shown to be associated with resistance through their continuous use (Howard et al. 2009; Meneau et al. 2005; Mosquera and Denning 2002). Azoles actively target the 14-α-demethylase enzyme, blocking ergosterol biosynthesis and destabilizing the cell membranes of actively growing cells. Mutations within the ergosterol biosynthesis pathway have been reported to cause azole cross-resistance through mutations within the *cyp51A* gene (Howard et al. 2009; Mellado et al. 2007; Snelders et al. 2008;

Snelders et al. 2010). However, a recent study reported that 43 % of azole-resistant isolates did not carry the *cyp51A* mutation, indicating that other mechanisms of resistance were responsible (Bueid et al. 2010). In addition to this mechanism of resistance the presence of biofilm may require consideration of other mechanisms of resistance (Ramage et al. 2011; Rajendran et al. 2013; Ramage et al. 2012; Robbins et al. 2011).

6 Efflux Pumps

Azole resistance may be mediated by multidrug resistance (MDR) pumps, which are involved in the active extrusion of antimicrobial molecules, including azole (Rajendran 2011). MDR efflux transporter genes of the ATP-binding cassette (ABC) and the major facilitator superfamily (MFS) classes have been shown to be clinically important in different pathogenic fungi (Cannon et al. 2009; Morschhauser 2010). Sequence analysis suggests that *A. fumigatus* has 278 different MFS and 49 ABC transporters (Nierman et al. 2005). *A. fumigatus MDR* (*AfuMDR*) pumps have been described in several studies and have been shown to be associated with increased resistance to itraconazole (da Silva Ferreira et al. 2004; Nascimento et al. 2003). Recently, it has been shown that non-cyp51a mediated itraconazole resistance may be associated with efflux pump activity through cdr1B (Fraczek et al. 2013).

In an *A fumigatus* biofilm model azole resistance was shown to increase 16–128-fold in the 12 h phase and >512-fold at the 24 h phase compared to 8-h germlings (Rajendran et al. 2013). An Ala-Nap uptake assay demonstrated a significant increase in efflux pump activity in the 12-h and 24-h phases ($P < 0.0001$). In addition efflux pump activity of the 8-h germling cells was significantly induced by VRZ. Inhibition of efflux pump activity with the competitive substrate MC-207,110 reduced the VRZ MIC values for the *A. fumigatus* germling cells by 2–8-fold . Quantitative expression analysis of AfuMDR4 mRNA transcripts also showed a phase-dependent increase as the mycelial complexity increased, which was coincidental with a strain-dependent increase in azole resistance. This demonstrates that efflux pumps are expressed in complex *A. fumigatus* biofilm populations and that they contribute to azole resistance. Moreover, VRZ treatment induces efflux pump expression (Rajendran et al. 2013).

7 Extracellular Matrix

Biofilms are encased in an extracellular matrix (ECM). In *A fumigatus* the ECM is composed mainly of polysaccharides, hydrophobin, and melanin (Beauvais et al. 2014). This matrix is considered to be an important virulence factor and is also related to their high resistance to antifungal agents. Previous studies with cultures of *A. fumigatus* maintained under static aerial conditions have demonstrated the presence of an ECM on the colony surface of colonial mycelia that colonies encased with ECM are extremely hydrophobic and display more resistance to antifungal polyenes AmB and nystatin (Beauvais et al. 2007). It is thought that ECM may act as a physical barrier that decreases the access of antifungals to cells embedded in the biofilm community. The penetration of the drugs is a function of the amount and nature of ECM, as well as the physicochemical properties of the antifungal agents. Thus anything that disrupts the biofilm may increase the sensitivity to antifungal agents. cspA encodes a repeat-rich glycophosphatidylinositol-anchored cell wall protein in *A. fumigatus*. A deletion of cspA resulted in a rougher conidial surface, reduced biofilm formation and decreased resistance to antifungal agents (Fan et al. 2015). Another example is the oligosaccharide OligoG which is an alginate derived from seaweed, SEM and AFM both showed that OligoG (≥2 %) markedly disrupted fungal biofilm formation, both alone, and in combination with fluconazole. Calculation of Fractional Inhibitory Concentration Index showed that for *A. fumigatus* at the higher concentrations of OligoG used synergy occurred between the compound and AmB and VRZ (Tondervik et al. 2014).

Aspergillus ECM was initially thought to be composed of galactomannan, alpha-1,3 glucans, melanin and other proteins including hydrophobins (Beauvais et al. 2007). However our work has demonstrated the presence of extracellular DNA (eDNA) in *A. fumigatus* biofilm ECM, which is released upon fungal autolysis (Rajendran et al. 2013). We suggested that the role of eDNA is maintenance and stability of biofilms and biofilm resistance to antifungal drugs (Krappmann and Ramage 2013). When *A. fumigatus* biofilms are treated with DNAse there is improved antifungal susceptibility to AmB or caspofungin. These findings together demonstrated the important role of eDNA in *Aspergillus* ECM biofilm. The role of eDNA in biofilm formation and stability has been confirmed by another group who added exogenous eDNA in an *in vitro* biofilm model (Shopova et al. 2013). They also showed that eDNA improved surface adhesion of fungal spores and also co-localised with ECM biofilm polysaccharides, becoming part of the ECM surrounding the biofilm cells.

Other components of the ECM may also be targeted to improve therapeutic response to antifungals. When biofilms are treated with alginate lyase (AlgL) both fractional inhibitory concentration index values and time kill analyses show synergy between AlgL and amphotericin. In addition a combination of AlgL and amphotericin showed a reduction in hyphal thicknesses (Bugli et al. 2013).

8 Previous Therapy

As described earlier triazoles are the mainstay of treatment for aspergillosis. Failure to respond clinically or refractory infections may necessitate a switch to other antifungal agents, including AmB. One study explored the possibility that in *A. fumigatus* biofilms sequential antifungal therapy may impact adaptive resistance mechanisms (Rajendran et al. 2015). *A. fumigatus* sensitivity to AmB was decreased when it was tested in combination with VRZ. The mechanism of this increase may be twofold. Depletion of eDNA by DNase treatment enhanced AmB activity against VRZ-exposed cells by eight-fold, which visually could be explained by destabilisation of the biofilm when examined microscopically. Pharmacological inhibition of Hsp90 by GDA also significantly improved biofilm susceptibility to AmB by 4–8-fold. Suggesting that *A. fumigatus* pre-exposure to VRZ concomitantly induces eDNA release and activates the stress response, which collectively confers AmB resistance in vitro (Rajendran et al. 2013).

9 Other Approaches

Undoubtedly the most effective and logical way of dealing with clinically important fungal biofilms is to either inhibit their development, use mechanical force to disrupt them or simply remove and replace an implicated medical device. Wound fungal biofilms are managed with surgical debridement (Warkentien et al. 2012). In severe wounds, such as those occurring from combat trauma, liposomal AmB, VRZ and posaconazole have been used, often as combinational therapy, although the clinical outcomes were variable. Nevertheless, it has been reported that in the management of a case of fungal osteomyelitis combined use of VRZ and terbinafine along with surgical debridement was able to successfully control a *Scedosporium inflatum* infection and salvage the limb (Cetrulo et al. 2012).

These studies suggest that wound fungal biofilms may have a different structural composition, as they respond to azoles more effectively than other fungal biofilms. Many of these infections are polymicrobial, and undergo repeated debridement with topical antiseptics. Moreover, wound dressings containing antimicrobial molecules are used, so it is not surprising that fungal wound biofilms respond to azole therapy in this context.

10 Concluding Remarks

From review of the available literature it is evident that *Aspergillus* biofilms may play a significant role in clinical medicine. These fungi have

been shown to form biofilms in both hard and soft tissue, and upon implanted medical devices. Diagnosing the presence of a fungal biofilm is difficult, however recently published guidelines hope to improve this situation (Hoiby et al. 2015). In general clinical awareness of the possibility of the presence of biofilm is important in making the diagnosis, which could be supported by diagnostic testing, but at present there is no definitive test for an *Aspergillus* biofilm. Promising avenues of research include transcriptional and metabolomics, but this is someway off finding its way to the clinical laboratories.

Removal and replacement of medical devices, or surgical debridement of soft tissue, where appropriate, represents the first line in clinical management, followed by antifungal management. Treatment is with conventional antifungal agents the choice of which is dictated on by the site of infection.

Liposomal formulations of AmB and azole agents show the greatest efficacy against aspergillius biofilms. Methods to augment antifungal activity, such as matrix degrading molecules, natural products and microbially derived molecules have been demonstrate experimentally, however, their use in clinical situations is anecdotal. Nonetheless, our knowledge of the adaptive resistance within the biofilm has revealed potential therapeutic targets. Clearly more work needs to be done in order to provide a guarantee of successful management of *Aspergillus* biofilms. In addition, further consideration needs to be given to how interactions between prokaryote and eukaryote in polymicrobial biofilm infections impact clinical management (O'Donnell et al. 2015).

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EFFICACY OF PREVENTION BY HIGH-EFFICIENCY PARTICULATE AIR FILTRATION OR LAMINAR AIRFLOW AGAINST *ASPERGILLUS* AIRBORNE CONTAMINATION DURING HOSPITAL RENOVATION

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ABSTRACT

OBJECTIVE: To evaluate efficacy of laminar airflow facilities plus high-efficiency particulate air (HEPA) filtration and HEPA filtration alone in preventing environmental *Aspergillus* contamination during hospital renovation. To show the usefulness of environmental surveillance to facilitate protection of patients at risk for invasive pulmonary aspergillosis.

DESIGN: Prospective sampling of air and surfaces for *Aspergillus* conidia during 2-year period.

SETTING: A hematological department adjacent to building renovation at a university hospital.

RESULTS: 1,047 air samples and 1,178 surface samples were collected from January 1996 to December 1997. Significantly more air samples were positive for *Aspergillus* species during the period of building renovation than during the periods before and after renovation in a unit without a protected air supply adjacent to the building work area (51.5% vs 31.7%; odds ratio [OR], 2.3; 95% confidence interval [CI_{95}], 1.4-3.7; $P<.001$). A major increase in the frequency of positive air samples was also found in another adjacent unit that was protected with HEPA filtration alone (from 1.8% to 47.5%; OR, 48.9; CI_{95}, 12-229; $P<10^{-7}$). In addition, in this unit, the mean count of *Aspergillus* conidia in positive air samples increased significantly during construction (4 colony-forming units [CFU]/m^3 to 24.7 CFU/m^3; $P=.04$) and the proportion of positive surface samples showed a significant increase during renovation (from 0.4% to 9.7%; OR, 28.3; CI_{95}, 3.4-623; $P=10^{-4}$). However, none of 142 air samples collected during renovation in the area protected with laminar airflow plus HEPA filtration showed *Aspergillus* conidia. In a unit distant from the building renovation site, the results of air and surface samples were not affected by renovation.

CONCLUSION: This study showed a strong association between building renovation and an increase in environmental *Aspergillus* contamination. Results confirmed the high efficacy of laminar airflow plus HEPA filtration and a high air-change rate. Although filtration with HEPA was effective during normal conditions, it alone was unable to prevent the rise of *Aspergillus* contamination related to building renovation. This study emphasized the necessity of an environmental survey of airborne contamination related to construction, to facilitate prevention of nosocomial aspergillosis outbreaks. A standardized protocol for aerobiological surveillance is needed (*Infect Control Hosp Epidemiol* 1999;20:508-513).

Advances in medical and surgical therapies have increased the frequency, duration, and intensity of immunosuppression.[1,2] Invasive pulmonary aspergillosis (IPA) remains a major threat during treatment of hematologic malignancies with prolonged neutropenia (eg, acute myelogenous or lymphocytic leukemia) or allogeneic bone marrow transplantation.[3-5] The incidence of IPA in patients with hematologic malignancies varies from 0% to 25%[2-4,6,7] and increases approximately 1% per day before the third consecutive week of neutropenia and approximately 4.3% per day after 3 weeks of neutropenia.[8] The overall attributable mortality rate remains high, around 50%, and can reach 95% in bone marrow transplant recipients.[3,5,9] Since *Aspergillus* are saprophytic and ubiquitous fungi, IPA usually is acquired through inhalation of *Aspergillus* conidia.[4] *Aspergillus fumigatus* is the predominant species encountered in invasive diseases, and its environmental reservoirs are organic debris, soil, dust, bird droppings, and building material.[3,6,10-12] Several studies have established an association between outbreaks of aspergillosis and hospital construction or contaminated ventilation systems.[13-20] We report the results of environmental sampling for *Aspergillus* in a hematological department during a 2-year period that included 6 months of building renovation. We compared the level of *Aspergillus* contamination prior to, during, and after the period of construction in two units adjacent to the renovation site and in one distant unit. We attempted to evaluate the capacity of high-efficiency particulate air (HEPA) filtration alone and HEPA filtration plus laminar airflow and a high air-

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change rate to reduce *Aspergillus* contamination during building activities.

METHODS

Hematologic Department and Building Renovation

This study was performed over a 2-year period, from January 1996 to December 1997, in the hematologic department of Hôtel-Dieu Hospital, a university hospital located in the center of Paris, in the Isle of the City. The hematologic department comprises four units (Figure).

- Unit A is located next to the renovation site, on the fourth floor, and comprises two parts: the A_1 area, composed of six rooms protected with HEPA filtration under positive air pressure (from 0.1 to 0.2 cm H_2O) and high renewal air, and the A_2 area, composed of three rooms protected with HEPA filtration plus laminar airflow and a higher air-change rate. In units A_1 and A_2, outside fresh air from the hospital yard side is filtered with similar installations that consist of three different filters: a first filter with 80% efficiency at the entrance of the unit, a second filter with 95% efficiency after the air lock and a high-efficiency filter (99.97%) in each patient room. The air-change rates are approximately 50 per hour in unit A_1 and 400 to 500 per hour in unit A_2 under the vertical laminar flow.
- Unit B also is located next to the renovation site, on the fourth floor, and consists of 10 rooms without any protective facilities against fungal spores.

Patients remained hospitalized (in units A and B) during the building renovation period.

- Unit C, the hematologic day-care unit, is located approximately 100 m distant from the renovation site, on the ground floor. There is no special equipment against fungal spores in this unit.
- Unit D is the building renovation site. Renovation was performed during a 6-month period, from November 6, 1996, to April 15, 1997, in order to equip unit D with HEPA filtration under positive pressure, which is known to minimize *Aspergillus* spores in air.[1,21]

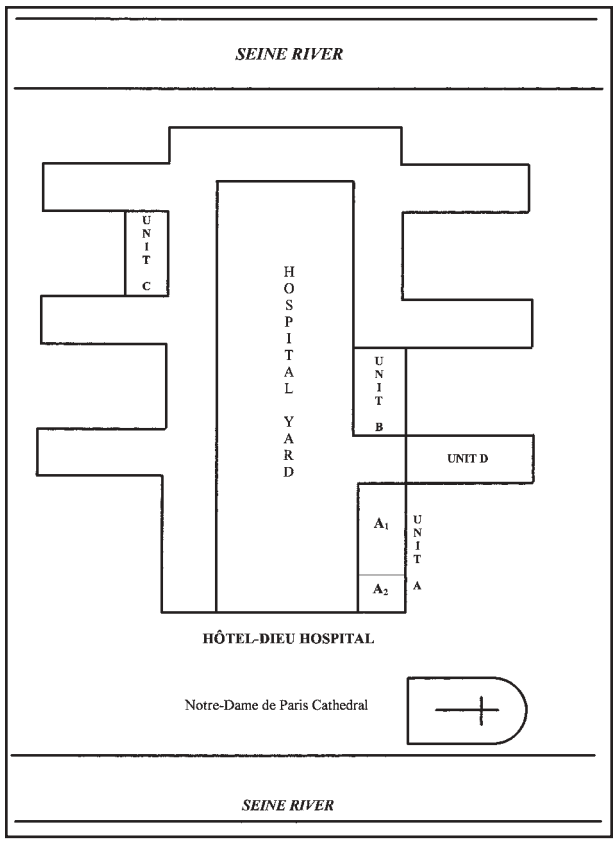

FIGURE. Map of Hôtel-Dieu Hospital and location of hematological units. Unit A_1: protected with high-efficiency particulate air (HEPA) filtration alone; unit A_2: protected with HEPA filtration plus laminar airflow; unit B: nonprotected; unit C: nonprotected; unit D: building renovation unit.

Environmental Sampling

Air and surface samples were collected every 2 weeks during the 2-year study period.

Air samples were obtained in patient rooms, nursing stations, and corridors in units A, B, and C. They were obtained with a Bio-Impactor 100.8 (Air Stratégie, Courtabœuf, France) collector, which draws in air at 100 L/min onto Sabouraud dextrose agar plus chloramphenicol plates (Sanofi Diagnostics Pasteur, Marnes la Coquette, France). The mean volume sampled was 250 L.

A total of 1,047 air samples were collected from January 1996 to December 1997. Four hundred three were obtained during the 10-month period prior to building renovation (period 1, from January to October 1996): 144, 154, and 105 in units A, B, and C, respectively. Two hundred thirty were obtained during the 6-month construction period (period 2, from November 1996 to April 1997): 68, 99, and 63 in units A, B, and C, respectively. Four hundred fourteen were obtained during the 8-month period after construction (period 3, from May 1997 to December 1997): 135, 174, and 105 in units A, B, and C, respectively. Of these 1,047 air samples, 142 were collected in unit A_2, the laminar airflow area.

Surface samples: dry swabs were taken of approximately 25-cm^2 surfaces from ventilation grilles, footlights, window ledges, and toilets in patient rooms. Swabs were inoculated on Sabouraud dextrose agar plus chloramphenicol plates.

We collected a total of 1,178 surface samples during the study period: 446 prior to renovation (144, 224, and 78 in units A_1, B, and C, respectively), 282 during renovation (72, 144, and 66 in units A_1, B, and C, respectively), and 450 after renovation (120, 256, and 74 in units A_1, B, and C, respectively). No surface samples were collected in unit A_2.

Air and surface samples were incubated at 37°C for 3 days. *Aspergillus* species were identified by their cultural and morphological characteristics. Colony counts were expressed as colony-forming units (CFU)/m^3 in the air and as the number of colonies per 25 cm^2 for surface samples.

Statistical Analysis

Statistical analysis was performed using Epi Info (version 6.04; Centers for Disease Control and Prevention, Atlanta, GA). Chi-square or Fisher's Exact tests were used

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TABLE 1
RELATION BETWEEN POSITIVITY OF AIR SAMPLES FOR *ASPERGILLUS* SPECIES AND BUILDING RENOVATION IN THE HEMATOLOGICAL WARD

				Renovation vs No Renovation			
						CFU/m³	
Unit	Period*	Renovation?	Positive/Total Samples (%)	*P*	OR (CI_{95})	Mean±SD†	*P*
A_1				$<10^{-7}$	48.9 (12-229)		.04
	1	No	2/90 (2.2)			4	
	2	Yes	19/40 (47.5)			24.7±18	
	3	No	1/75 (1.3)			4	
A_2							
	1	No	0/54				
	2	Yes	0/28	—	—	—	—
	3	No	0/60				
B				.0003	2.3 (1.4-3.7)		NS
	1	No	50/154 (32.5)			21.1±17	
	2	Yes	51/99 (51.5)			41.8±44.6	
	3	No	54/174 (31)			21.4±15.3	
C				NS	1.2 (0.7-2.2)		NS
	1	No	33/105 (31.4)			20.3±32.5	
	2	Yes	27/63 (42.9)			28.2±34	
	3	No	47/105 (44.8)			22.6±19.2	

Abbreviations: CFU/m³, colony-forming units/m³; CI_{95}, 95% confidence interval; NS, not significant; OR, odds ratio; SD, standard deviation.
* Periods 1, 2, 3: before, during, and after renovation, respectively.
† Included only positive samples.

for contingency-table data. Means were compared with Student's *t* or Kruskal-Wallis tests. A *P* value less than .05 was considered statistically significant.

We compared the level of environmental *Aspergillus* contamination in the three units (A, B, C) of the hematologic department during three periods: prior to, during, and after building renovation. We also compared results of the environmental surveillance obtained in the area only protected with HEPA filtration (unit A_1) to those obtained in the nonprotected area (unit B).

RESULTS

Over the three study periods, 27% of air samples were positive for *Aspergillus* species, whereas only 6% of surface samples revealed *Aspergillus* conidia ($P<10^{-7}$).

Results for *Aspergillus* aerial contamination (Table 1) showed that positive samples were significantly more frequent during the period of building renovation (period 2) than during the periods without renovation (periods 1 and 3) in both units adjacent to the renovation site (unit A_1: 47.5% vs 1.8%; odds ratio [OR], 48.9; 95% confidence interval [CI_{95}], 12-229; $P<10^{-7}$; unit B: 51.5% vs 31.7%; OR, 2.3; CI_{95}, 1.4-3.7; *P*=.0003, respectively). In addition, in unit A_1, the mean count of *Aspergillus* conidia in positive air samples increased from 4 CFU/m³ prior to renovation to 24.7 CFU/m³ after renovation had begun (*P*=.04). In other units, the increase in *Aspergillus* counts was not statistically significant. During the renovation period, the frequency of positive samples for *Aspergillus* species in unit A_1 protected only with HEPA filtration, was similar to the frequency in the nonprotected unit B (47.5% and 51.5%, respectively; *P*=.7), whereas it was significantly lower during the period without renovation (1.8% vs 31.7%; OR, 0.04; CI_{95}, 0.01-0.13; $P<10^{-7}$). Similarly, the mean levels of *Aspergillus* spore concentrations were comparable in the HEPA-protected unit and the nonprotected unit during renovation (24.7 CFU/m³ and 41.8 CFU/m³, respectively; *P*=.3), but it was significantly lower in the HEPA-protected area during the period without renovation (4 CFU/m³ vs 21.3 CFU/m³; *P*=.01). Despite this major rise in *Aspergillus* contamination during renovation, none of the 142 air samples collected in unit A_2, protected with laminar airflow, showed *Aspergillus* conidia during the whole study period. In unit C, located far from the renovation site, results for aerial *Aspergillus* contamination were similar during and out of renovation (42.9% and 38.1%, respectively; *P*=.5).

We found an increase in positive surface samples during renovation only in unit A_1 (Table 2). Although there was a large increase in the risk of positive surface samples, the change was not significant because positive samples were rare in this unit during the whole study period (8/336). In units B and C, the frequencies of positive surface samples were similar during and out of renovation (9.7% vs 8%; *P*=.5, and 10.6% vs 5.3%; *P*=.1, respectively).

Results of air and surface samples collected after renovation were similar to those collected prior to renovation in the three units, with one exception: positive aerial samples were more frequent in unit C after renovation than before (44.8% vs 31.4%; *P*=.05).

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TABLE 2
RELATION BETWEEN POSITIVITY OF SURFACE SAMPLES FOR *ASPERGILLUS* SPECIES AND BUILDING RENOVATION IN THE HEMATOLOGICAL WARD

				Renovation vs No Renovation			
						Colonies/25 cm² Sampled	
Unit	Period*	Renovation?	Positive/Total Samples (%)	*P*	OR (CI_{95})	Mean±SD†	*P*
A_1				10^{-4}	28.3 (3.4-623)		NS
	1	No	1/144 (0.7)			1	
	2	Yes	7/72 (9.7)			4.3±5.8	
	3	No	0/120				
A_2							
	1	No	—			—	
	2	Yes	—	—	—	—	—
	3	No	—			—	
B				NS	1.2 (0.6-2.4)		NS
	1	No	21/224 (9.4)			2.2±1.3	
	2	Yes	14/144 (9.7)			2.1±1.2	
	3	No	18/256 (7)			1.9±0.5	
C				NS	2.1 (0.7-6.9)		NS
	1	No	5/78 (6.4)			1	
	2	Yes	7/66 (10.6)			2±1	
	3	No	3/74 (4)			3.2±2.2	

Abbreviations: CFU/m³, colony-forming units/m³; CI_{95}, 95% confidence interval; NS, not significant; OR, odds ratio; SD, standard deviation.
* Periods 1, 2, 3: before, during, and after renovation, respectively.
† Included only positive samples.

Over the three periods, *A fumigatus* was isolated from 78% of the positive air and surface samples; *Aspergillus niger,* 19%; and *Aspergillus flavus,* 2%. *A niger* was significantly more frequent in surface samples as compared to air samples in unit B (52% vs 13%; $P<10^{-6}$) and in unit C (57% vs 26%; $P=.0004$). The distribution of species in air and surface samples was similar over the three periods (data not shown).

DISCUSSION

Our study comprised a large sample size with numerous specimens collected over a 2-year period that included 6 months of renovation, and our results confirmed the efficacy of laminar airflow as protection against *Aspergillus* environmental contamination.[21-24] The comparison between unit A_1 and unit B clearly confirmed the efficacy of HEPA filtration in standard conditions and a reduction of this efficacy when the environmental *Aspergillus* contamination increased dramatically. In contrast to the dramatic rise in *Aspergillus* contamination observed in unit A_1, no air samples collected in unit A_2, protected with laminar airflow and a high air-change rate, revealed *Aspergillus* conidia. The protective efficacy of the laminar airflow remained high even with a major increase in airborne aerial *Aspergillus* contamination related to building renovation. By contrast, the protective efficacy of HEPA filtration without laminar airflow that was seen prior to and after the renovation period disappeared during renovation, suggesting that the capacity of HEPA filtration alone to reduce *Aspergillus* contamination might be saturated when the level of *Aspergillus* contamination increases dramatically. The HEPA filtration unit was correctly maintained, and no technical problem with these installations was reported during the study period. The positive air pressure in rooms and corridors was regularly controlled. To our knowledge, failure of HEPA filtration to prevent *Aspergillus* contamination during renovation has not been demonstrated previously through an environmental survey. However, other authors have suggested that HEPA filtration supplies alone are not sufficient to prevent nosocomial aspergillosis, because outbreaks of IPA have been described in units with HEPA filtration.[5,17,25] By contrast, Opal et al have reported the control with HEPA filters of an IPA outbreak related to construction activities.[14]

Our results showed a dramatic increase in *Aspergillus* environmental contamination in the two units adjacent to the renovation site, whereas this contamination remained stable in a distant unit, confirming the strong association previously described between construction and environmental *Aspergillus* contamination.[13,14,16-19,26,27] The association between *Aspergillus* infections, especially IPA, and environmental exposure is now well known; construction has been recognized frequently as a risk factor for IPA.[4,11,15,17-20,28-30] Thus, in this study, the major increase in *Aspergillus* contamination and the proximity of severely immunocompromised patients led us to recommend additional protective measures to reduce fungal spore exposure. The building work site was separated from other units by an airtight wall, two large vacuum

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cleaners were used in the renovation site to vacuum dusty air, rubble was systematically wetted before disposal outside, and windows of hematological units were taped during renovation.

In a few studies, the relation between outbreaks of IPA, rises in *Aspergillus* environmental contamination, and construction remained unclear. Some authors have found no evidence of increased spore counts in air during aspergillosis outbreaks related to construction.[30-32] In our study, despite the dramatic rise in *Aspergillus* contamination during the renovation period, we did not observe a significant increase in the incidence of IPA (data not shown). However, the frequency of bone marrow transplantation was reduced during the renovation period. Since the patients during the periods with and without construction were not comparable with regard to their degree of immunodeficiency, our study can not assess the possible association between *Aspergillus* environmental contamination and the incidence of IPA.

Mean counts of *Aspergillus* conidia obtained in both HEPA-filtered and nonprotected units were higher than previously reported from North America.[3,21] The variability between studies may reflect the sampling methods used, with large differences in air volumes sampled and frequency of sampling. The lack of standardized protocols and reference values for fungal environmental surveillance impairs the comparison between studies. The high counts observed in our study also might be related to the location of Hôtel-Dieu hospital in the Isle of the City, surrounded by the Seine River.

Only a few studies have distinguished the different species of *Aspergillus* in environmental sampling. Our results are in agreement with others that have shown *A niger* and *A flavus,* respectively, as the second and the third most common species isolated in air samples, after *A fumigatus.*[12,23] Interestingly, *A niger* was significantly more frequent in surface samples than in air samples in units B and C. Our study is the first to show a difference in the frequency of *Aspergillus* species (ie, *A fumigatus* and *A niger)* between air and surface samples, suggesting different reservoirs or capacity of adherence and settlement for these two species. These results cannot be explained by the methods used in our study, which commonly have been recommended and used by others.[18,33]

The strong association between building renovation and increased environmental *Aspergillus* contamination should encourage those involved in hospital construction to take measures to minimize the exposure of immunocompromised hosts. Procedures such as sealing off the building work site, wetting all the rubble and the working area, taping windows, and limiting traffic in wards housing patients at risk for aspergillosis may be effective in reducing fungal exposure. This study emphasizes the utility of environmental surveillance for airborne contamination to facilitate prevention of nosocomial aspergillosis outbreaks related to construction or the inappropriate maintenance of protective facilities. The development of a standardized protocol for aerobiological surveillance is of major interest.

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INFECTION CONTROL AND HOSPITAL EPIDEMIOLOGY SEPTEMBER 2007, VOL. 28, NO. 9

ORIGINAL ARTICLE

Risk of Bioaerosol Contamination With *Aspergillus* Species Before and After Cleaning in Rooms Filtered With High-Efficiency Particulate Air Filters That House Patients With Hematologic Malignancy

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OBJECTIVE. To examine the impact of cleaning and directional airflow on environmental contamination with *Aspergillus* species in hospital rooms filtered with high-efficiency particulate air (HEPA) filters that house patients with hematologic malignancy.

DESIGN. Detailed environmental assessment.

SETTING. A 475-bed tertiary cancer center in the southern United States.

METHODS. From April to October 2004, 1,258 surface samples and 627 bioaerosol samples were obtained from 74 HEPA-filtered rooms (in addition, 88 outdoor bioaerosol samples were obtained). Samples were collected from rooms cleaned within 1 hour after patient discharge and from rooms before cleaning. Positive and negative airflows were evaluated using air-current tubes at entrances to patient rooms.

RESULTS. Of 1,258 surface samples, 3.3% were positive for *Aspergillus* species. Univariate analysis showed no relationship between cleaning status and occurrence of *Aspergillus* species. Of 627 bioaerosol samples, 7.3% were positive for *Aspergillus* species. Multiple logistic analysis revealed independently significant associations with detection of *Aspergillus* species. Cleaned rooms positive for *Aspergillus* species had a higher geometric mean density of colonies than that of rooms sampled before cleaning (18.9 vs 5.5 colony-forming units [cfu] per cubic meter; $P = .0047$). Rooms with positive airflow had a detection rate for bioaerosol samples equivalent to that of rooms with negative airflow (7.3% vs 7.8%; $P = .8$). There was no significant difference in the density of *Aspergillus* species between rooms with negative airflow and rooms with positive airflow (12.5 vs 8.4 cfu/m^3; $P = .33$).

CONCLUSIONS. Concentration of bioaerosol contamination with *Aspergillus* species was increased in rooms sampled 1 hour after cleaning compared with rooms sampled before cleaning, suggesting a possible correlation between reentrained bioaerosols (ie, those suspended by activity in the room) after cleaning and the risk of nosocomial invasive aspergillosis.

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Molds are ubiquitous organisms present in all indoor environments.[1] In hospitals, viable *Aspergillus* spores can cause nosocomial invasive aspergillosis, which is associated with high morbidity and mortality in immunocompromised patients, particularly those with hematologic malignancy.[2,3] Cancer patients are at greater risk of developing this infection and it has a significantly higher fatality rate among them, compared with the rate among immunocompetent patients.[4,5] Aspergillosis infections represent 57% of nosocomial fungal infections and are the second most common opportunistic fungal infections in patients with underlying hematologic malignancy.[6] In addition, hospitalizations for aspergillosis are often lengthy and costly.[7,8]

In 2003, the Joint Commission issued a sentinel event alert focusing on the prevention of nosocomial infections in hospitals.[9] There is plenty of speculation about the causes of invasive aspergillosis cases in hospitals, and pursuing the latest environmental fix is costly and may be counterproductive.[2] A multifaceted approach that focuses on the environment, engineering controls, cleaning methods, and the relationship between the patient and the environment may be required.

Current literature indicates that contaminated bioaerosols inhaled by immunocompromised patients with leukemia and transplant recipients are a possible source of infection.[4] Our study objective was to determine the impact of cleaning on the risk of contamination with *Aspergillus* species in patient rooms. Furthermore, we evaluated the effects of directional airflow on environmental contamination with *Aspergillus* spe-

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cies in selected patient rooms filtered with high-efficiency particulate air (HEPA) filters.

METHODS

Study Overview

This study was conducted from April to October 2004 in the inpatient building of a comprehensive cancer research hospital in the southern United States. The inpatient building has 12 floors, spanning a total area of 70,212 m^2. The areas of interest for this project were the tenth floor, which houses patients receiving treatment for gynecologic cancers, endocrine cancers, and leukemia, and the eleventh floor, which houses bone marrow transplant recipients and candidates.

All patient rooms have bathrooms with toilets, sinks, and showers. Room sizes range from 14 m^2 to 19 m^2, and bathroom sizes range from 3 m^2 to 5 m^2, with airflow directed into the bathroom. Airflow direction at the doorway is generally from the patient room into the hallway and nursing areas. Directional airflow checks were conducted at room entrances with the doors ajar.[10]

Air in patient rooms is introduced through an air handler on the eighth floor; air is filtered through a 30% prefilter, is pretreated to reduce moisture content, and is then filtered through HEPA filters. Return air for patient rooms goes through the same filtration steps before mixing with incoming, filtered fresh air and then returning to patient rooms. Each room sampled during this study had approximately 6 air changes per hour.

To detect low levels of airborne spores, large volumes of air must be sampled. Sampling involved collecting air and surface samples from rooms on the tenth and eleventh floors during a 27-week period (allowing for seasonal variation) within 60 minutes after the terminal discharge of a patient, either before or after the room was cleaned. Eight rooms were surveyed each week (4 rooms per floor) during the collection period. After the discharge of patients, 2 rooms on each floor were sampled before terminal cleaning, and 2 rooms on each floor were sampled within 1 hour after cleaning. The sampling procedures revolved around patient discharges and housekeeping schedules, so that 74 rooms were sampled repeatedly.

After collection, air and surface samples were incubated for 5 days at room temperature inside a laboratory biosafety cabinet. Identification of isolates was based on morphological traits observed using a microscope (Nikon). All positive samples suspected of containing *Aspergillus* species were submitted to a commercial laboratory for genus and species identification.

Housekeeping Procedures

Cleaned rooms underwent standard terminal cleaning procedures within 1 hour after patient discharge. These detailed procedures adhered to 2003 industry standards.[11] Manufacturer's guidelines were followed for the use of standard hospital cleaning products.

Surface Samples

A total of 1,258 surface samples were collected. Surface sampling was conducted using dry, sterilized transport swabs (Fisher Scientific International). The round, plastic sticks were tipped with inert, nontoxic rayon. Sampling was conducted by rubbing the swab tip over the exterior surface of ceiling diffusers and in at least 2 openings inside the diffuser, to collect material on the surfaces. Samples from shower heads were collected by running the swab tip over the showerhead surface, and drain samples were collected by inserting the swab tip inside the drains to draw out any available surface material.

Surface samples were cultured on Sabouraud dextrose agar plates (Becton Dickinson). Samples were collected from each of the following surfaces: the patient-room air-return diffuser ($n = 211$), the bathroom air-return diffuser ($n = 209$), patient-room air-supply diffusers ($n = 210$), shower-head surfaces ($n = 209$), inside the shower drain ($n = 209$), and inside the sink drain ($n = 209$).

Air Samples

Bioaerosol samples were collected using an N6 Single Stage Viable Impactor (Thermo Electron), which achieves a cutoff diameter of 0.65 μm—thereby capturing larger particles and allowing smaller particles to pass through the sampler. Three types of bioaerosol samples were collected (for each type, a total of 209 samples were collected): (1) at the center of patient rooms, on a tripod placed 0.3 m above the bed for 35 minutes at 28.3 L/minute, for a total of 990 L; (2) at the shower edge, on a tripod placed 1.5 m above the floor while the shower was running, for 10 minutes, for a total of 283 L; and (3) the toilet area, on a tripod placed 0.3 m above the toilet while the toilet was flushed once and the air sampled for 1 minute, for a total of 28.3 L. On each day that indoor sampling was performed, 1 bioaerosol sample was collected outdoors on Sabourand dextrose agar plates for 10 minutes, for a total of 283 L.

Directional Airflow Evaluation

Airflow direction was evaluated using air-current tubes (MSA Ventilation Smoke Tube Kit part 458481) to visualize airflow patterns. Positive and negative airflow directions at the patient room door and air vents were recorded. Airflow from bathrooms to patient rooms was not evaluated in every room but was occasionally noted, to verify airflow into the bathroom. The procedure for checking protective rooms for patients with tuberculosis was followed.[10]

Statistical Analysis Methods

Multiple samples were collected from individual patient rooms. To take this into consideration, Cochran-Mantel-Haenszel tests were performed to assess univariate association of categorical factors with detection of *Aspergillus* species. Stratified, conditional, multiple logistic regression was used to evaluate the

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TABLE 1. Univariate Analysis of the Association Between Environmental Variables and Surface Concentrations of *Aspergillus* Species

Variable	Proportion (%) of samples positive for *Aspergillus* (N = 1,258)	P
Directional airflow		.55
Positive pressure	9/716 (1.3)	
Negative pressure	11/518 (2.1)	
Undetermined pressure	1/24 (0)	
Cleaning status		.55
Cleaned	8/626 (1.3)	
Not yet cleaned	13/632 (2.1)	
Floor		.50
10th	9/631 (1.4)	
11th	12/627 (1.9)	
Season		.01
Spring	1/386 (0.3)	
Summer	9/631 (1.4)	
Fall	11/241 (4.6)	
Location sampled		.0024
Air-return diffuser in room	13/211 (6.2)	
Air-return diffuser in bathroom	5/209 (2.4)	
Air-supply diffuser in room	3/211 (1.4)	
Shower or sink	0/627 (0)	

adjusted effect of the factors on contamination with *Aspergillus* species. Furthermore, for contaminated indoor bioaerosol samples, the density data for *Aspergillus* species were transformed into a log scale, and a mixed linear model was applied to investigate the factors that impacted the density of *Aspergillus* species. A P value of .05 or less was considered statistically significant. All statistical analyses were performed using SAS software, version 9.1 (SAS Institute).

RESULTS

Surface Samples

Of 1,258 surface samples from 74 patient rooms, 21 (1.6%) were positive for *Aspergillus* species on culture. Contamination was significantly associated with season (the contamination rate was 0.3% for spring, 1.4% for summer, and 4.6% for fall; P = .01) and sample location (the contamination rate was 6.2% for room air-return diffusers, 2.4% for bathroom air-return diffusers, 1.4% for room air-supply diffusers, and 0% for showers and sinks; P = .002). The adjusted effects of season and sample location on contamination with *Aspergillus* species remained significant (P = .002 and $P < .0001$, respectively) in a multiple logistic regression analysis (data not shown). According to univariate analyses, environmental contamination with *Aspergillus* species in patient rooms was not associated with the following factors: cleaning status (P = .55), airflow direction (P = .55), and hospital floor on which the room was located (P = .50) (Table 1).

Outdoor Bioaerosol Samples

A total of 88 outdoor bioaerosol samples were collected. The rate of contamination with *Aspergillus* species was much higher among outdoor samples than among indoor samples (60.2% vs 7.3%; $P < .0001$).

Indoor Bioaerosol Samples

There were 627 indoor bioaerosol samples collected from 74 patient rooms. Univariate analyses showed that the rate of contamination with *Aspergillus* species was 6.1% in clean rooms, compared with 8.6% in rooms sampled before cleaning (P = .058). Season was significantly associated with contamination of bioaerosol samples with *Aspergillus* species (P = .005). Contamination was more likely to occur in summer (contamination rate, 12.7%) than in fall; for spring, the contamination rate was zero. Samples collected from patient rooms (11%) and shower areas (9.1%) were more likely to contain *Aspergillus* species than were those collected from toilet areas (1.9%) (P = .0002). Samples positive for *Aspergillus* species were more likely to have been collected in the afternoon than in the morning (8.7% vs 5.4%; P = .048) (Table 2).

A multiple logistic analysis, adjusted for potential confounders, found that cleaning status, sample location, and

TABLE 2. Univariate Analysis of the Association Between Environmental Variables and Bioaerosol Concentrations of *Aspergillus* Species

Variable	Proportion (%) of samples positive for *Aspergillus* (N = 627)	P
Directional airflow		.8
Positive pressure	26/357 (7.3)	
Negative pressure	20/258 (7.8)	
Undetermined	0/12 (0)	
Cleaning status		.058
Cleaned	19/312 (6.1)	
Not yet cleaned	27/315 (8.6)	
Floor		.38
10th	26/315 (8.3)	
11th	20/312 (6.4)	
Season		.13
Spring	0/192 (0)	
Summer	40/315 (12.7)	
Fall	6/120 (5)	
Location sampled		.0002
Room	23/209 (11)	
Shower	19/209 (9.1)	
Toilet	4/209 (1.9)	
Time[a]		.048
Morning	13/241 (5.4)	
Afternoon	32/366 (8.7)	

[a] Time stamp data was not available for some samples, which meant that 1 positive sample and 19 negative samples were excluded from the time analysis.

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collection time were independently significantly associated with contamination with *Aspergillus* species. Rooms that had not been cleaned ($n = 301$) were 2.7 times (95% confidence interval [CI], 1.2-6.2) more likely to be contaminated with *Aspergillus* species, compared with rooms that had been cleaned ($n = 306$) ($P = .017$). Samples collected in the afternoon ($n = 366$) were 2.9 times (95% CI, 1.2-7.5) more likely to contain *Aspergillus* species than were those collected in the morning ($n = 241$) ($P = .024$). (Time stamp data was not available for some samples, which meant that 1 positive sample and 19 negative samples were excluded from the time analysis.) Toilet-area samples ($n = 209$) were 0.1 times (95% CI, 0.0-0.4) more likely to contain *Aspergillus* species than samples from patient rooms ($n = 209$) ($P = .0043$), whereas there was no significant difference in contamination with *Aspergillus* species between patient room samples and shower samples ($n = 209$).

A mixed linear model showed that cleaning status and sample location had a significant effect on the density of *Aspergillus* species. Among 627 indoor bioaerosol samples, 46 samples from 26 rooms were contaminated with *Aspergillus* species Among the contaminated rooms, rooms sampled before cleaning had a lower density of *Aspergillus* species than that of cleaned rooms (ratio of geometric means, 0.3 [95% CI, 0.1-0.7]; $P = .0047$). Compared with samples from patient rooms, samples from shower and toilet areas had a higher density of *Aspergillus* species ($P = .0005$). The ratio of geometric mean concentrations of *Aspergillus* species in colony-forming units (cfu) per cubic meter was 2.7 (95% CI, 1.2-6.2) between the shower areas and the patient rooms and was 15.4 (95% CI, 3.3-72.7) between the toilet areas and the patient rooms (Table 3).

Directional Airflow Checks

Air samples collected with airflow into the hallway ($n = 357$) did not have significantly different detection rates for *Aspergillus* species than did those collected with airflow into the room ($n = 258$) (7.3% vs 7.8%; $P = .8$).

Aspergillus Species Density in Bioaerosol Samples

The amount of *Aspergillus* species in air samples was normalized against the volume of air collected (cfu/m^3 of air) for each sampling location. In the analysis, a geometric mean was used for air-sample comparisons, to offset distortions of the data. The geometric mean values are given in Table 3.

DISCUSSION

The location of the surface-sample collection was significant when air-return diffusers in patient rooms were compared with other ceiling diffusers. Samples collected on air-return grills in patient rooms were the samples most likely to have *Aspergillus* spores. This may be indicative of spore impaction on the diffuser as the ventilation system draws the spores out of the room. This may also be the case for bathroom air-return diffusers, which were the next most likely surfaces to have spores.

Aspergillus niger was the most commonly detected species indoors and outdoors; less commonly isolated were *Aspergillus flavus* and *Aspergillus tamari. Aspergillus* spores were more common outdoors in a large city in the south than they were inside this treatment center for cancer patients, which validates the use of the ventilation and filtration systems currently in operation and indicates that safer air is being provided to patients.

Bioaerosol samples collected in the afternoon were more likely to contain *Aspergillus* species than were those collected in the morning. The time frame for detection of *Aspergillus* species may be related to patient and visitor traffic; most patients were released in the afternoon, causing more samples to be collected then, possibly affecting the results.

The location of air-sample collection in rooms, along with the associated activity (eg, showering), displayed significant effects on the air-sample density of *Aspergillus* species. Density was higher in samples collected near the toilet and shower than in samples collected in the patient rooms. The bathroom is the only source of water and wet surfaces; this may account for the higher densities there and for the fact that only a few samples were positive and the collection volumes were much lower for the shower and toilet air samples.

Although further study of the presence of contaminants other than *Aspergillus* species is needed, initial findings suggest that directional airflow at room entrances is not a factor in protection against airborne *Aspergillus* spores in HEPA-filtered rooms. Given the limited number of these types of rooms, this finding may result in more rooms becoming available for patients awaiting room assignment based on diagnosis.

The most significant result of this study is the higher probability of detecting *Aspergillus* spores in rooms at 1 hour before cleaning than at 1 hour after cleaning. However, positive samples from rooms after cleaning had a higher spore

TABLE 3. Mixed-Linear-Model Analysis of Bioaerosol Samples from Patient Rooms Containing *Aspergillus* Species

Variable	Geometric mean density of colonies	Ratio of geometric means (95% CI)	*P*
Cleaning status			.0047
Cleaned	18.9	1.0 (ref)	
Not yet cleaned	5.5	0.3 (0.1-0.7)	
Directional airflow			.33
Positive	8.4	1.0 (ref)	
Negative	12.5	1.5 (0.7-3.4)	
Location sampled			.0005
Room	3.0	1.0 (ref)	
Shower	8.0	2.7 (1.2-6.2)	
Toilet	45.5	15.4 (3.3-72.7)	

NOTE. CI, confidence interval; ref, reference.

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density than did those from rooms before cleaning. We theorize that cleaning disturbs the materials settled on surfaces in patient rooms, causing the density in the air to increase and remain elevated for a period after cleaning. Surprisingly, despite the higher density, the detection rate was not elevated. One theory is that clumping of materials during cleaning causes smaller amounts of individual particles to be captured; concurrently, the clumped spores have a higher growth potential. Additional studies are needed to determine the duration of particle resuspension and to estimate the risk of infection based on the occupation of recently cleaned rooms.

Because sampling was not performed on a set schedule, but rather when rooms became available, it was dependent on the number of discharged patients. The study was also affected by the high demand for a timely turnover of rooms by housekeeping and patient management staff; sampling was difficult to complete in the rooms sampled before cleaning. Because of the short sampling time allowed, the settling times of spores were not measured. Also, no quantitative or qualitative assessment of housekeeping practices was completed, to verify that procedures were being followed as written.

This study suggests that admittance of immunocompromised patients with hematologic malignancy to rooms within 1 hour after terminal cleaning may expose them to higher bioaerosol levels of *Aspergillus* species and possibly put them at risk for nosocomial invasive aspergillosis. Further examination incorporating facility design, maintenance, and additional contaminants is warranted.

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REVIEW

Cryptococcal meningitis: epidemiology and therapeutic options

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Abstract: Cryptococcal meningitis causes morbidity and mortality worldwide. The burden of disease is greatest in middle- and low-income countries with a high incidence of human immunodeficiency virus (HIV) infection. Patients taking immunosuppressive drugs and some immunocompetent hosts are also at risk. Treatment of cryptococcal meningitis consists of three phases: induction, consolidation, and maintenance. Effective induction therapy requires potent fungicidal drugs (amphotericin B and flucytosine), which are often unavailable in low-resource, high-endemicity settings. As a consequence, mortality is unacceptably high. Wider access to effective treatment is urgently required to improve outcomes. For human immunodeficiency virus-infected patients, judicious management of asymptomatic cryptococcal antigenemia and appropriately timed introduction of antiretroviral therapy are important.

Keywords: cryptococcosis, HIV, immunosuppression, antifungal therapy, immune reconstitution inflammatory syndrome, antiretroviral therapy

Introduction

Cryptococcosis is an important infectious disease globally. The majority of illness is among patients with defective cell-mediated immunity. Human immunodeficiency virus (HIV) infection is the main risk factor, accounting for 95% of cases in middle- and low-income countries (MLICs)[1] and 80% of cases in high-income countries (HICs).[2] Individuals taking immunosuppressive drugs (eg, transplant recipients) constitute most of the remaining caseload, although immunocompetent hosts are susceptible in some settings.

The most common clinical presentation is cryptococcal meningitis (CM), with over 1 million cases and 600,000 deaths per year.[3] Nonmeningeal (eg, pulmonary and cutaneous) presentations also occur,[4] and bloodstream infection (cryptococcemia) may disseminate to multiple sites.[5]

This review describes the epidemiology and management of cryptococcal disease. Worldwide distribution of the pathogen is outlined, incidence trends in patients with varying risk factors are assessed, and the prognostic implications of differing treatment protocols are highlighted.

Epidemiology of the infectious pathogen

Cryptococci are encapsulated saprophytic yeasts. Two species, transmitted by inhalation, are the principal human pathogens: *Cryptococcus neoformans* and *Cryptococcus gattii*.[6] *C. neoformans* was identified by Sanfelice in 1894,[7,8] and may be divided into two subtypes on the basis of capsular agglutination assays.[9] *C. neoformans* var.

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grubii (capsular serotype D) is the most common, and causes 82% of cryptococcal disease worldwide. Var. *neoformans* (capsular serotype A) is responsible for 20%–30% of HIV-associated CM in northern Europe (notably France, Italy, and Denmark),[9–11] but is less common in other global regions.[12,13] Although both subtypes predominantly cause disease in immunocompromised individuals, several reports from the US[14] and Asia[15] suggest that var. *grubii* cryptococcosis in patients with normal immune systems is more common than previously assumed. The environmental reservoir of both subtypes is avian guano, decaying organic matter, and soil.[8,16]

C. gattii is traditionally associated with illness in immunocompetent individuals[17–19] from tropical and subtropical regions, including Thailand,[20] northern Australia,[21,22] New Zealand, and Papua New Guinea.[23–26] More recently, four molecular subtypes of *C. gattii* have been identified with distinct epidemiological characteristics that challenge this perspective.[6] Whilst VGI (var gattii I) is the main subtype in Australasia, an outbreak of disease attributable to VGII has been described in immunocompetent patients from British Columbia, Canada.[27–29] Between 1999 and 2010, 218 cases were identified on Vancouver Island.[30,31] In 2006, a further case was reported on Orcas Island, Washington, USA,[32] and *C. gattii* is now endemic throughout the Pacific Northwest of the US.[29] Sporadic disease has also been notified in other parts of North America, including Florida, North Carolina, Rhode Island, New Mexico, Michigan, Georgia, and Montana.[33] Additionally, *C. gattii* subtypes VGIII and -IV are more likely to be found in HIV-infected than immunocompetent patients. These strains may account for 2.4%–30% of HIV-associated cryptococcosis in some parts of Central and South America[6] and southern Africa.[34–37] The burden of human disease due to *C. gattii* is probably underrecognized, as many laboratories do not undertake detailed speciation of cryptococci.[6]

The environmental reservoirs of *C. gattii* are incompletely understood. In Australia, India, and other Asian countries, it has been isolated in eucalyptus trees.[38] In British Columbia, it has been isolated from noneucalyptus tree species, soil, air, freshwater, and seawater.[29] Discovery of this organism in heterogeneous biogeoclimatic zones suggests that its ecological niche was previously underestimated or that its distribution is expanding.[39,40] Possible explanations for a changing distribution include climate change or altered land-use practices, such as logging.

HIV as a risk factor

The largest influence on the epidemiology of cryptococcal disease over the last 30 years has been the evolution of the HIV pandemic. Figure 1 shows that a fivefold increase in the incidence of cryptococcosis in France from 1985 to 1993 was almost entirely due to burgeoning disease in HIV-infected patients, while the number of cases in HIV-uninfected patients remained stable.[41] Similar trends were observed in other HICs. In the UK, the number of annual cryptococcal case notifications rose from 13 (8% HIV-associated) in 1982 to 66 (83% HIV-associated) in 1991.[42] Of 517 cryptococcal infections in New York City in 1991, 96% were HIV-related.[43]

HIV-infected patients are mainly at risk of cryptococcosis when they become very immunosuppressed and their CD4 count drops below 100 cells/μL.[44,45] Consequentially, Figure 1 indicates that after the development of effective combination antiretroviral therapy (ART) in 1997, the upsurge in new cases of cryptococcal disease from HICs was reversed and incidence began to decline.[46–48] From 1997–2001, France saw a 46% decrease in cases,[41] from 1996 to 2007, incidence per 1,000 persons in the UK fell from three to 0.2,[49] and from 1992 to 2000, incidence per 1,000 persons in Atlanta, Georgia, USA fell from 66 to seven.[50]

Figure 2 shows that disease trends in MLICs have been much worse. It is well recognized that sub-Saharan Africa has been the global region most heavily affected by HIV, with an estimated 2.6 million new infections per year at the peak of the epidemic in 1997.[51] Contemporaneously, in the 1990s, CM became the leading cause of adult meningitis in many African countries, including Malawi

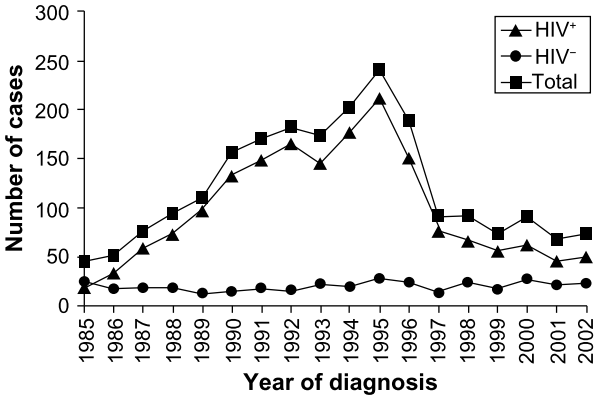

Figure 1 Evolution of the incidence of cryptococcosis, by year of diagnosis in France (1985–2001), as reported to the National Reference Centre for Mycosis.
Note: Reproduced with permission from Dromer F, Mathoulin-Pelissier S, Fontanet A, Ronin O, Dupont B, Lortholary O, Epidemiology of HIV-associated cryptococcosis in France (1985–2001): comparison of the pre- and post-HAART eras, *AIDS*, 18:555–562.[41] Promotional and commercial use of the material in print, digital or mobile device format is prohibited without the permission from the publisher Lippincott Williams & Wilkins. Please contact journalpermissions@lww.com for further information.
Abbreviation: HIV, human immunodeficiency virus.

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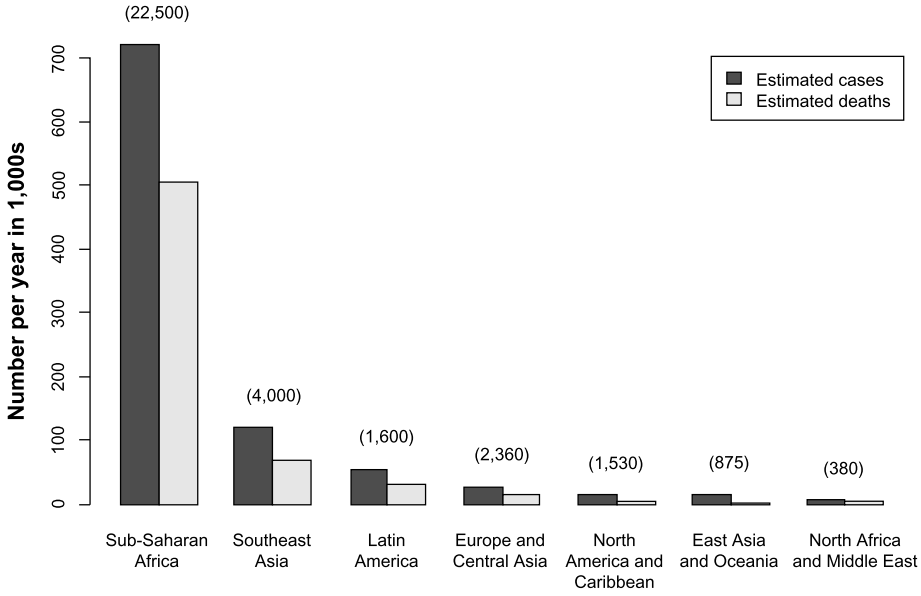

Figure 2 Global incidence and mortality from cryptococcal meningitis among United Nations global regions from 1997 to 2007.
Notes: Figures in brackets and italics indicate human immunodeficiency virus prevalence in 1,000s from each region during the period studied. Data from Park et al.[3]

(27% of cases),[52] Zimbabwe (45% of cases),[53,54] and South Africa (31% of cases).[55] Delayed and incomplete access to ART meant that unlike Europe and North America, the incidence of CM did not recede after the turn of the millennium; a tertiary referral hospital in Botswana described *C. neoformans* growth from 15% of all cerebrospinal fluid (CSF) samples submitted for analysis in 2003,[56] and a report from Cape Town, South Africa noted that CM still accounted for 31% of all inpatient days in new ART patients in 2007.[57] A similar persistent elevation of the cryptococcal disease burden since the 1990s has been described from MLICs in Southeast Asia[56,58] and Latin America.[59]

In addition to disparities in incidence between HICs and MLICs, there are well-documented differences in outcomes (Figure 2).[3] A combination of earlier access to ART and availability of fungicidal drugs has contributed to falling mortality in HICs,[2,60,61] while the death rate in MLICs has been relentlessly high.[62] Analysis of pooled data from case series, surveillance reports, and clinical trials has estimated that the 90-day case-fatality rate from HIV-associated CM in East Asia, Oceania, Western Europe and the US is 9%, compared with 55% in other parts of Asia and South America and 70% in sub-Saharan Africa.[3] Even acknowledging that some North American studies exclude the sickest patients,[63] and some studies in MLICs show better case-fatality rates than others,[64–67] these results are unacceptable.

Other risk factors

Although HIV is the largest driver of cryptococcal disease, it is important to acknowledge other factors. Prior to the HIV era in the UK, the incidence of cryptococcosis per 1,000 persons increased from 1.4 in 1963–1968 to 7.4 in 1973–1978.[68] This was predominantly attributable to disease in patients on immunosuppressive medications. Use of potent immunosuppressants (eg, corticosteroids, calcineurin inhibitors,[69] cytotoxic agents,[70] and monoclonal antibodies[71,72]) for transplant conditioning or treatment of cancer and inflammatory conditions has continued to expand in HICs over the last 30 years, sustaining a small but important minority of cryptococcal illness in settings where HIV-related cases are in decline.[73]

Cryptococcosis disease occurs after 2.8%–8% of solid-organ transplants, and is the third-commonest invasive fungal infection in this setting, after *Candida* and *Aspergillus*.[69,74] In a retrospective review of US data from 1996 to 2010, kidney-transplant recipients were most often affected, followed by liver, heart, lung, and pancreas recipients.[5] The median time to diagnosis after solid-organ transplantation is 20 months, and the etiology is normally reactivation of latent disease.[5,74,75] Symptoms may emerge sooner after lung or liver transplants, perhaps because the required level of postoperative immunosuppression is higher.[69] The overall likelihood of cryptococcal disease does not vary between patients using tacrolimus, cyclosporine, or azathioprine as the primary immunosuppressive agent, but patients who

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are coadministered high-dose corticosteroids may be at higher risk.[5]

Infrequently, cryptococcal infection is acquired from donor tissue. This is particularly suspected if disease occurs within 30 days of transplantation, at surgical graft sites, or in multiple organ recipients of a single donor.[75–77] Screening of donors is not routinely performed, but should be undertaken if the donor has unexplained pulmonary lesions, undiagnosed neurological illness, or unexplained fever with relevant comorbid risk factors.[76,77]

Cryptococcal disease is rare following hematopoietic stem cell transplant or corneal tissue transplant.[78] Data from a consortium of US transplant centers (Transplant-Associated Infection Surveillance Network) revealed an incidence of only 0.6% in hematopoietic stem cell-transplant recipients between 2001 and 2006.[79,80] For unknown reasons, the risk is higher in autologous than allogenic transplants.[78]

Non-HIV-infected, nontransplant recipients with cryptococcosis are a heterogeneous group. Except for *C. gattii* outbreaks in immunocompetent hosts, most patients have immune dysfunction related to the pathophysiology or treatment of an underlying autoimmune disease, malignancy, or innate immunological disorder. It is difficult to generalize about these cases, but in HICs they tend to experience higher mortality than their HIV-infected counterparts. The reasons for this include the effects of underlying illness and late diagnosis, because the pathogen was not initially suspected.[5,73,81]

Clinical presentation

Epidemiological variables, including the nature of immunosuppressive risk factors and pathogen species, influence the presentation of cryptococcal disease. CM is the leading presentation overall,[19,41,42,78] but nonmeningeal manifestations are proportionally more frequent in non-HIV-infected individuals.[5,42,73,82] Transplant-associated cryptococcosis is often limited to the lungs,[83,84] with disseminated or neurological disease in 52%–61% of cases.[69,84]

Presentation of *C. gattii* infection in immunocompetent hosts varies according to molecular subtype. In Australia, where the majority of disease is due to VGI, CM is most common,[6,85] but in North America, VGII disease presents with respiratory symptoms in 76%, neurological symptoms in 7.8%, and both respiratory and neurological symptoms in 10.1% of cases.[19,24,31]

The commonest features of CM are subacute headache and confusion. Intracranial pressure (ICP) is often elevated, and may cause cranial nerve palsies or seizures. Classical features of "meningism" (eg, neck stiffness) occur in less than 20% of patients.[86] Altered mental state is associated with higher mortality.[5,50,87]

Neurological infection may be complicated by mass lesions (cryptococcomas). This is more common with *C. gattii* than *C. neoformans*. Clinical sequelae of cryptococcomas include hydrocephalus and blindness.[88,89] Some patients require neurosurgical intervention.[17,18]

Forty percent of patients with CM have ocular involvement, including papilledema and uveitis with multifocal chorioretinitis.[90,91] Immune-mediated optic nerve dysfunction and blindness have been particularly reported amongst *C. gattii* patients from Papua New Guinea.[54,89,92] The spectrum of pulmonary illness ranges from asymptomatic colonization to severe, progressive pneumonia and cryptococcomas in the lungs. Skin lesions often contain the infecting organism. In severely immunocompromised individuals, disseminated disease (involvement of two or more sites) may present as fever and rash before other symptoms and signs appear.

Investigations

Confirmation of CM requires lumbar puncture (LP) and examination of CSF, as shown in Figure 3A. Lack of LP equipment may result in underestimation of the disease burden in MLICs.[93] Typical CSF features include a raised opening pressure (reflecting elevated ICP), lymphocytic pleocytosis, and evidence of inflammation. However, CSF may be normal in 10%–17% of patients,[54,94] especially in HIV-endemic populations.[5] Identification of the infecting organism is traditionally done by light microscopy after India ink staining, but this method is user-dependent with variable sensitivity. Detection of cryptococcal antigen (CrAg)

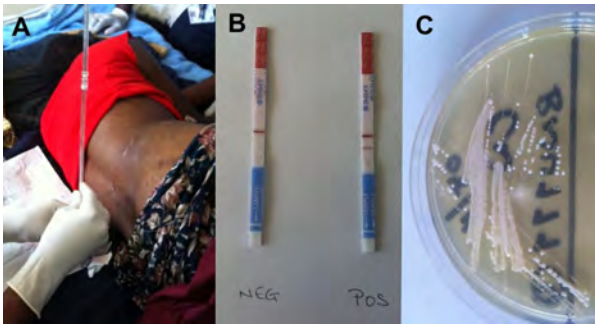

Figure 3 (**A**–**C**) Diagnosis of cryptococcal meningitis. (**A**) Lumbar puncture being performed on a human immunodeficiency virus-infected patient with suspected meningitis in Malawi. (**B**) Lateral flow immunoassay test strips for cryptococcal antigen detection (the strip on the left shows a negative result, indicated by a single horizontal "control" band in the center; the strip on the right shows a positive result, indicated by adjacent horizontal "control" and "test" bands). (**C**) *Cryptococcus neoformans* growing on Sabouraud media. Images kindly supplied by Kate Gaskell, College of Medicine, University of Malawi, and Brigitte Denis, Malawi Liverpool Wellcome Trust Clinical Research Programme.

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by a latex-agglutination test[63] or lateral flow immunoassay (LFA) is better (Figure 3B). The lateral flow immunoassay is cheaper than latex agglutination,[95,96] and may be applied to urine samples when CSF is unobtainable.[97,98] Fungal culture of CSF on Sabouraud media is required to isolate the organism for antimicrobial susceptibility testing. Characteristic colonies grow after 36 hours (Figure 3C).

Radiology has little role in the diagnosis of CM, but computed tomography and magnetic resonance imaging scans are necessary to detect complications (eg, cryptococcomas and noncommunicating hydrocephalus). These modalities are generally unavailable in MLICs.

Nonmeningeal cryptococcosis may be confirmed by tissue sampling for microbiological analysis. Cryptococcemia is identified from fungal blood cultures or CrAg detection in serum samples. Asymptomatic antigenemia (a positive serum CrAg in the absence of clinical disease) has been described in HIV-infected patients, and may predict impending CM. Screening and treatment for asymptomatic antigenemia will be discussed later.

Treatment and prognosis

The Infectious Diseases Society of America (IDSA)[4] and World Health Organization (WHO)[99] have recently issued updated treatment guidelines to reflect advances over the last decade, but routine practice in MLICs continues to be impeded by poor drug availability. Figure 4 summarizes current recommendations.

Induction and consolidation antifungal therapy for HIV-associated CM

CM treatment consists of three phases: induction, consolidation, and maintenance. IDSA and WHO guidelines emphasize the importance of potent fungicidal drugs during induction therapy, because the rate of fungal clearance from the CSF during the first 2 weeks, known as early fungicidal activity (EFA),[100] predicts 10-week survival,[101] and CSF sterilization by 14 days predicts long-term prognosis.[63]

Amphotericin B (AmB), the drug with the greatest EFA, is administered intravenously for 14 days during induction therapy whenever possible. Its activity is concentration-dependent,[102] but the required dose (0.7–1.0 mg/kg) of the commonest preparation (AmB deoxycholate [AmBd])[33,63–65] can be nephrotoxic.[103,104] A solution in HICs is the use of lipid drug formulations with fewer renal side effects, including liposomal AmB (LAmB; 3–6 mg/kg/day) and AmB lipid complex (ABLC, 5 mg/kg/day).[105–107] The cost of these (over US$1,000 per day[108]) is prohibitive for MLICs, so alternative strategies, including preemptive hydration and electrolyte supplementation, have been developed to minimize the toxicity of AmBd.[99] Studies in Kampala,[62] Cape Town,[65] and Bangkok[109] support this approach.

Even a 2-week course of AmBd (US$12–$15 per day) is too expensive for some LICs.[110] In this scenario, data from South Africa and Malawi have demonstrated that 5–7 days of AmBd is better than treatment that is restricted to less fungicidal drugs.[64,111] AmBd-treated patients who survive the first 6 months have a subsequent 5-year survival rate of 88%.[112] This advocates for investment in early AmBd to achieve satisfactory long-term outcomes.

Flucytosine should accompany AmB during induction therapy at an intravenous or oral dose of 100 mg/kg/day.[100,113–115] Omission of this agent has been associated with higher rates of mortality,[113] treatment failure,[116] and late relapse.[117] Toxic cytopenias can occur during flucytosine therapy, and so regular full blood counts and therapeutic drug monitoring (TDM) are advised by IDSA guidelines.[4,57,118] TDM is arduous, and the absolute need for it in MLICs was questioned by a recent study in Vietnam that did not use TDM but demonstrated safe and effective use of AmBd-flucytosine.[113]

Despite its value, flucytosine remains unlicensed in most African and Asian countries,[114,119,120] so alternative agents have been considered for combination with AmB. The obvious contender is fluconazole, which is freely distributed in MLICs (http://www.pfizer.com/responsibility/global_health/diflucan_partnership_program), but is fungistatic rather than fungicidal in the normal human dose range. Definitive evidence to support AmB-fluconazole induction therapy is lacking, but reports from several countries describe rapid EFA when intravenous AmBd (0.7–1 mg/kg/day) is prescribed alongside oral fluconazole (800–1,200 mg/day).[109,113,121,122] A meta-analysis of various induction strategies in resource-poor settings has described AmBd-fluconazole as cost-effective.[123] The WHO recommends this approach when flucytosine cannot be obtained.[99]

After a 14-day induction phase, treatment proceeds with a consolidation phase of 400 mg once daily (od) for a further 8 weeks. This dose may be increased to 800 mg when gold-standard induction therapy with AmB-flucytosine is unavailable.

Gaps in drug provision leave fluconazole as the only agent for induction and consolidation therapy in many high-burden countries, contributing to significant variation in prognosis. The response to this requires discussion. Until recently, the routine dose of fluconazole for CM monotherapy was 200–400 mg od, and 8-week mortality was 78%–90%.[86,124] In

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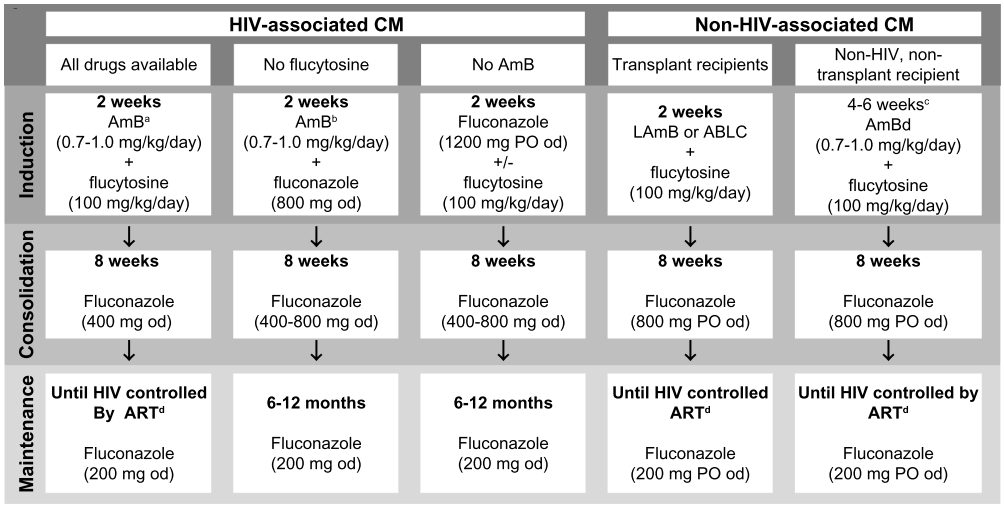

Figure 4 Treatment options for cryptococcal meningitis (CM), summarized from Infectious Diseases Society of America and World Health Organization guidelines.
Notes: [a]In HIV-infected patients with renal impairment or concern about nephrotoxicity, LAmB or ABLC should be used. [b]In settings of limited AmB availability or difficulty with toxicity monitoring, an abbreviated 5- to 7-day induction course of AmB may be used. [c]Non-HIV, nontransplant patients are a heterogeneous group, including individuals with hematological malignancies and immunocompetent hosts with *Cryptococcus gattii* infection. There is no consensus on optimal treatment; some authors suggest identical induction and consolidation therapy as for HIV-associated CM. [d]Undetectable HIV viral load and CD4 >100/μL should be demonstrated on two occasions 6 months apart before stopping fluconazole.
Abbreviations: HIV, human immunodeficiency virus; AmB, amphotericin B; LAmB, liposomal amphotericin B (3–6 mg/kg/day); ABLC, amphotericin B lipid complex (5 mg/kg/day); od, once daily; PO, per os (by mouth); ART, antiretroviral therapy.

one South African study from 2006, median patient survival on induction- and consolidation-phase fluconazole (400 mg od) was only 76 days.[125]

Such poor outcomes prompted dose escalation. Clinical studies in Uganda and Malawi based on 800 mg od induction and 400 mg od consolidation therapy reported improved 10-week mortality rates of 58%–60%.[87,126] A further induction-phase dose increase to 1,200 mg was associated with faster EFA[126] but did not improve survival,[126,127] and a pharmacokinetic–pharmacodynamic bridging study from a mouse model indicated that 1,200 mg od will fail to achieve fungal stasis in the CSF of 33% of patients.[128] An exploratory clinical trial has suggested that induction with 1,600–2,000 mg of fluconazole would be more efficacious,[126,129] but additional evaluation of these doses is required. WHO guidelines currently advocate that where fluconazole monotherapy is the only option, 1,200 mg od should be used for 2-week induction therapy followed by a consolidation phase of 800 mg od for 8 weeks.[99]

A final option when intravenous drug administration is not feasible is a fully oral induction phase of fluconazole and flucytosine. Trials in Malawi have confirmed that fluconazole (1,200 mg od) and flucytosine (100 mg/kg/day) achieve faster EFA and lower 10-week mortality than fluconazole alone,[70,111,127] suggesting that fluconazole monotherapy should be augmented by induction-phase flucytosine wherever possible.

Overall, reduced availability of fungicidal drugs continues to compromise outcomes in high-burden countries. An ongoing multicenter clinical trial (Advancing Cryptococcal meningitis Treatment in Africa [ACTA][130]) in sub-Saharan Africa hopes to confirm the shortest, simplest effective regimens, but will require backup by universal provision of medicines for routine care.

Maintenance antifungal therapy for HIV-associated CM

After consolidation therapy, secondary prophylaxis with fluconazole (200 mg od) minimizes the risk of CM relapse.[131] Alternative, less effective maintenance regimens include oral itraconazole (200 mg od)[117] and intravenous AmBd (1 mg/kg/once weekly).[132]

The required duration of maintenance therapy has recently been examined, particularly as the 1-year default rate from secondary prophylaxis in some African settings exceeds 90%.[133,134] In the pre-ART era, lifelong fluconazole was recommended after a presentation with CM, but it now appears that late relapse is unlikely during successful ART.[135–138] International guidelines state that immune restoration by ART permits discontinuation of maintenance therapy (Figure 4). However, evidence to support cessation of

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secondary prophylaxis is weaker when induction/consolidation therapy is not fungicidal (eg, fluconazole monotherapy), and isolated CM relapses have been described in patients on ART with CD4 counts up to 495 cells/μL.[139]

Differences in antifungal therapy for non-HIV-associated CM

Treatment of non-HIV-associated CM varies from that described above, dependent on characteristics of the host and pathogen (Figure 4). Patients developing CM after solid-organ transplant often take nephrotoxic immunosuppressants (tacrolimus, cyclosporine or sirolimus) to prevent graft rejection, and 25% of transplant recipients have renal dysfunction at CM diagnosis. Therefore, kidney-friendly liposomal preparations of AmB (eg, LAmB or ABLC) are recommended during induction therapy.[4] It is uncertain whether immunosuppressive therapy should be stopped during CM treatment; this may accelerate eradication of the pathogen, but poses a risk of proinflammatory immune reconstitution syndrome or transplant rejection.[140] Although clear evidence is lacking, some authors report good outcomes with a staged reduction in immunosuppressive therapy alongside antifungal drugs.[141]

Secondary fluconazole prophylaxis in transplant recipients may stop after 6–12 months, as the late cryptococcal relapse rate is only 1%–3%.[142] There is no standard regimen for non-HIV, nontransplant patients with CM. Some authors advocate a longer (4–6 weeks) induction phase of AmB/flucytosine (Figure 4), while others favor a standard 2-week induction phase. Consolidation and maintenance therapy are identical to transplant recipients. *C. gattii* infection should be treated with the same drugs as *C. neoformans*, but the response to therapy may be slower, due to higher azole minimum inhibitory concentrations[143,144] and poor drug penetration of cryptococcomas.[17,18,85]

Asymptomatic antigenemia and primary prophylaxis

Between 4% and 20% of patients with newly identified HIV infection and a CD4 count <150 cells/μL have a positive serum CrAg test in the absence of clinical cryptococcosis.[145–147] Asymptomatic antigenemia predicts impending CM,[148] and is associated with increased mortality.[149] Serum CrAg screening of new HIV patients is being implemented in South Africa,[150] prompting debate on the use of preemptive therapy for those at highest risk.

Treatment of asymptomatic antigenemia is not recommended in HICs,[4] but some studies support fluconazole therapy for serum CrAg-positive patients in MLICs.[151–153] A management algorithm is shown in Figure 5.[154] However, deployment of preventive screening and therapy strategies is operationally difficult, and an implementation study in Kenya achieved effective fluconazole administration for only 52% of eligible patients.[155] The benefit of presumptive therapy for asymptomatic antigenemia will depend on the logistics of integrating this strategy into routine practice at ART clinics.

An alternative means of CM prevention is primary prophylaxis with fluconazole for all patients with CD4 counts <100 cells/μL, irrespective of serum CrAg testing. Studies of this approach in Thailand[156] and Uganda[157] demonstrated that fluconazole 200 mg once daily reduced the incidence of CM, but there was no reduction in overall mortality and rates of fluconazole-resistant *Candida albicans* infection increased.[158] The cost-effectiveness of no preventive treatment, therapy for asymptomatic antigenemia, or primary prophylaxis is likely to vary between regions, based on the underlying epidemiology of cryptococcal infection and availability of ART.

Additional therapeutic considerations

Outcomes from CM may be improved by reduction of raised ICP during early therapy, careful management of immune reconstitution inflammatory syndrome (IRIS) and appropriately timed ART initiation for HIV-infected patients.

Reducing raised intracranial pressure

Increased ICP (>25 cm/H_2O) is associated with greater CSF fungal burden[159] and higher mortality.[160] Regular CSF drainage by serial LPs is recommended.[115,161–164] Insertion of a temporary CSF-drainage catheter[165] or ventriculoperitoneal shunt may also be used.[166] Drug therapy (eg, acetazolamide or corticosteroids) to reduce CSF pressure or prevent blindness in CM patients is not beneficial, and acetazolamide may cause harm.[88,160,167]

Managing immune reconstitution inflammatory syndromes

IRIS in CM patients occurs when host immune recovery triggers inflammatory reactions to persistent fungal antigens. There are two main forms: unmasking and paradoxical (Figure 6).[168]

Unmasking IRIS occurs in HIV-infected patients when subclinical cryptococcal disease emerges after ART is commenced. This might be prevented by careful pre-ART screening. However, late ART is generally associated with

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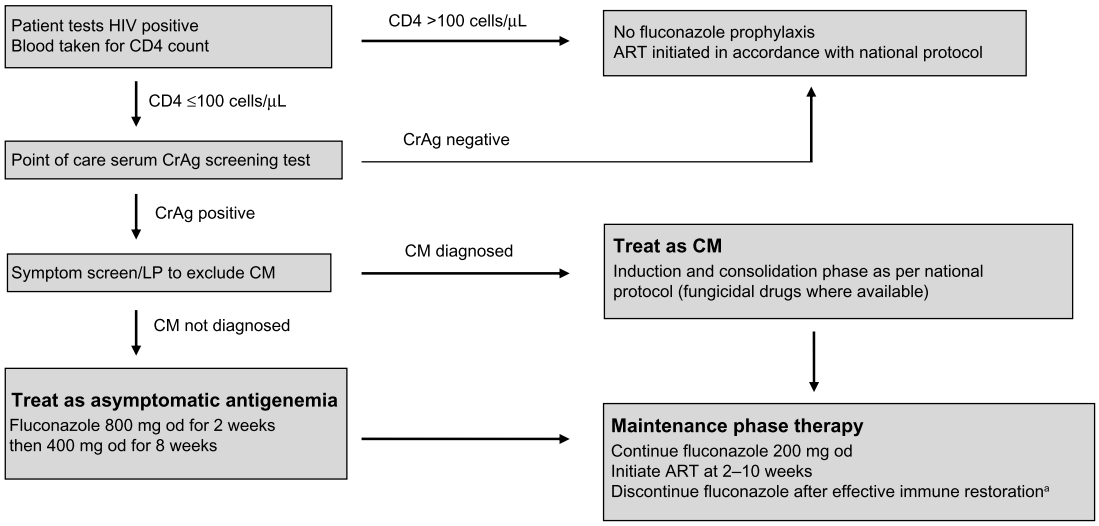

Figure 5 A screening and management strategy for asymptomatic antigenemia.
Notes: [a]Undetectable HIV viral load and CD4 >100/μL should be demonstrated on two occasions 6 months apart before stopping fluconazole. Jarvis JN, Govender N, Chiller T, et al, *J Int Assoc Physicians AIDS Care (Chic)* (11), pp 374–379, copyright © 2012 by SAGE Publications. Adapted by permission of SAGE Publications.[154]
Abbreviations: HIV, human immunodeficiency virus; CrAg, cryptococcal antigen; LP, lumbar puncture; CM, cryptococcal meningitis; od, once daily; ART, antiretroviral therapy.

lower survival,[169] and patients who are already on HIV therapy when they present with CM tend to have better outcomes,[64,170] so excessive delays should be avoided.

Paradoxical IRIS is best described in HIV-associated CM patients who initially respond to antifungal drugs and then deteriorate within 12 months of starting ART. Studies from South Africa and Ethiopia estimate an incidence of 7%–33%.[171–173] Paradoxical IRIS also affects solid organ-transplant patients when antirejection medications are interrupted during CM therapy,[141] and apparently healthy hosts may suffer from reactivation of immune defenses that were previously overwhelmed by high fungal burden.

Paradoxical IRIS in the central nervous system has a mortality of up to 36%.[174,175] Risk factors include severe disease at presentation and slow fungal elimination.[176,177] The benefit of anti-inflammatory drugs (eg, corticosteroids[100]) is unproven.[178] Highly fungicidal induction-phase therapy and rapid CSF sterilization is the best way to minimize unwanted reactions.[179,180]

Combining anticryptococcal and anti-HIV medications

In HIV-associated CM, IRIS is more likely during immune reconstitution from lower baseline CD4 counts, and is

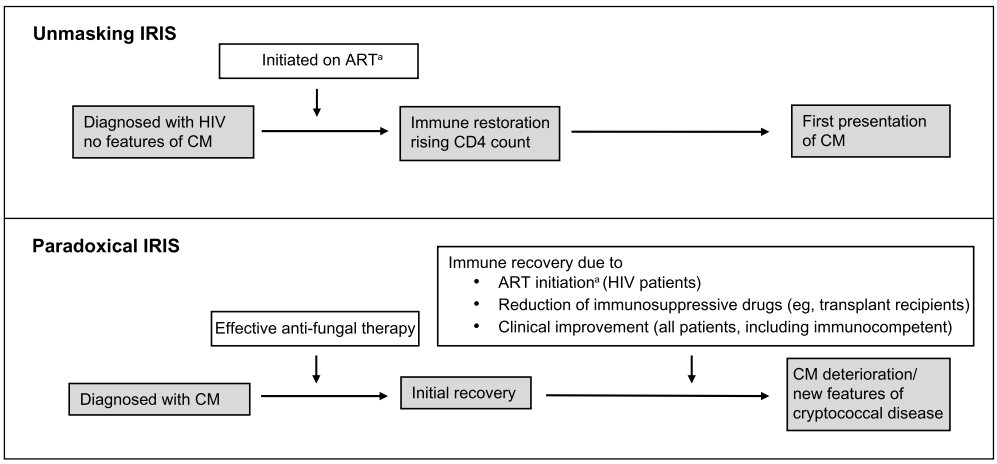

Figure 6 Types of immune restoration inflammatory syndrome (IRIS) in cryptococcal disease.
Note: [a]HIV-associated CM IRIS should occur within 12 months of ART initiation.
Abbreviations: ART, antiretroviral therapy; HIV, human immunodeficiency virus; CM, cryptococcal meningitis.

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Table 1 Prospective open-label randomized trials to assess optimal timing of antiretroviral therapy (ART) initiation in human immunodeficiency virus (HIV)-infected patients with cryptococcal meningitis (CM)

Study and site	Study design	Baseline CD4 count, cells/μL, median (IQR)	CM induction-phase drugs	Initiation of ART during CM therapy	Study outcomes
Zolopa et al,[182] USA[a] and South Africa	282 patients with OIs (35 with CM) 48-week follow-up	29 (10–55)	Not stated	<2 weeks versus 4–32 weeks	All patients: fewer AIDS events/deaths in early (20 of 141 [14%]) versus late (34 of 141 [24%]) ART (OR 0.5, 95% CI 0.3–0.9) CM patients: no difference in AIDS events/deaths in early (one of 13 [8%]) versus late (three of 22 [14%]) ART (OR 0.5, 96% CI 0.1–5.7)
Makadzange et al,[184] Zimbabwe	54 patients with CM 3-year follow-up	37 (17–69)	Fluconazole only	<72 hours versus >10 weeks	Higher mortality in early (23 of 28 [82%]) versus late (12 of 26 [46%]) ART (HR 2.3, 95% CI 1.1–4.9)
Bisson et al,[183] Botswana	27 patients with CM 24-week follow-up	29 (11–50)	AmB + fluconazole	<7 days versus >28 days	No difference in mortality in early (two of 13 [15%]) versus late (five of 14 [36%]) ART (OR 0.3, 95% CI 0.1–2.1)
Boulware et al,[185] Uganda and South Africa	177 patients with CM 6-month follow-up	19 (9–69)	AmB + flucytosine	<14 days versus >28 days	Higher mortality in early (40/88 [45%]) versus late (27 of 89 [30%]) ART (HR 1.7, 95% CI 1.1–2.8; *P*=0.03)

Note: [a]Includes patients from Puerto Rico.
Abbreviations: IQR, interquartile range; AIDS, acquired immunodeficiency syndrome; OR, odds ratio; HR, hazard ratio; CI, confidence interval AmB, amphotericin B; OIs, opportunistic infections.

influenced by the timing of ART introduction. Balancing the danger of early mortality from advanced immunosuppression against that of accelerated immune recovery is difficult, and best practice remains to be established. A retrospective study of mortality after ART initiation in Thailand at time points 1–12 months into CM therapy did not show any association between timing of ART and outcome.[181] Table 1 summarizes subsequent prospective trials.[135,136,182–185] The most convincing data come from a recent study in Uganda and South Africa, which was terminated early because ART initiation within the first 28 days of CM treatment led to a higher risk of IRIS and death.[185] Introduction of ART 4–10 weeks after starting antifungal treatment is currently considered the safest approach.

Conclusion

Advanced HIV infection continues to drive cryptococcal disease worldwide. Patients on immunosuppressive drugs and some immunocompetent hosts are also at risk. Although treatment with potent drug combinations provides effective cure, poor availability of fungicidal drugs in MLICs results in high case-fatality rates. Expanded provision of fungicidal treatment is urgently required. Ongoing research on management of asymptomatic antigenemia and optimal timing of ART initiation is important to improve the prognosis of HIV-associated CM.

Disclosure

The authors report no conflicts of interest in this work.

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Summary of legislation and guidance for routine microbiological water tests carried out at QEUH Adults and RHC

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Version 2.2

Table of Contents

Background and scope

This document focuses on legislation and guidance as they apply specifically to the routine water sampling for microbiological testing that is undertaken at QEUH Adults and RHC, notably requirements and recommendations regarding:

- Where water sampling should be carried out (general and/or high-risk areas)
- How frequently water samples should be collected
- Which microbiological tests should be performed

Other requirements and recommendations related to the construction, maintenance, and operation of a water system are outside the scope of this brief summary. Only sampling for microbiological testing of hot and cold water distribution systems is considered. Separate guidance exists for specialist

applications (e.g. cardiopulmonary bypass heater cooler units, endoscopy rinse water, dental unit waterlines, hydrotherapy pools), but these are not covered here.

The first sections of this brief summary outline the general and healthcare-specific legislation and guidance applicable to microbiological testing of water. Requirements and recommendations specific to Legionella and *Pseudomonas aeruginosa* testing are outlined, followed by a brief overview of other microbiological tests. The last section places the routine microbiological water testing regime at QEUH Adults and RHC into the context of these requirements and recommendations.

General statutory requirements

Water supplied by Scottish Water to any healthcare premise in Scotland for domestic purposes, which include drinking, personal hygiene, and cooking, must meet the wholesomeness standards outlined in The Public Water Supplies (Scotland) Regulations 2014[1]. Notably, water must not contain '(i) any micro-organism, (ii) any substance, or (iii) any parasite at a concentration or value which would (whether in conjunction with another parameter in the water or otherwise) constitute a potential danger to human health'[1]. Public water supplies undergo routine testing for total viable counts at 22°C and 37°C, which give an indication of overall microbial load but do not have pre-defined thresholds that must be met. They also undergo more specific tests that can indicate faecal contamination (coliforms, *Escherichia coli*, and *Clostridium perfringens*). These tests have strict thresholds (zero counts per 100mL) that must be met for the water to be considered wholesome.

Once water enters a healthcare premise, The Health and Safety at Work etc Act 1974 applies, placing a duty of care on employers to ensure, as far as is reasonably practicable, the health, safety, and welfare of the patients, staff, and public who may be affected by workplace activities, including aspects related to the water supply, storage, and distribution services[2].

The Control of Substances Hazardous to Health Regulations 2002 (COSHH) apply not only to chemicals used to control the growth of microorganisms in water, but also to biological agents, which are defined as 'a micro-organism, cell culture, or human endoparasite, whether or not genetically modified, which may cause infection, allergy, toxicity or otherwise create a hazard to human health'. Potentially hazardous microorganisms that can occur in water systems, notably Legionella, are covered by COSHH, so employers have a duty to ensure the risks from exposure to these microorganisms are adequately assessed and controlled.

Guidance for healthcare settings: SHTM 04-01

The Scottish Health Technical Memoranda (SHTMs) give 'comprehensive advice and guidance on the design, installation and operation of specialised building and engineering technology used in the delivery of healthcare'.[3] Equivalent guidance in England is outlined in the Health Technical Memoranda (HTMs). The SHTMs focus on the elements of standards, policies, and best practice that are applicable to new and existing healthcare sites. SHTM 04-01, entitled 'Water safety for healthcare premises', includes specific guidance for Legionella and *Pseudomonas aeruginosa* testing, as well as some general guidance on other types of test (notably total viable counts, TVCs). These will be summarised in separate sections below, with, where appropriate, reference to additional guidance documents.

Legionella testing

These are outlined in the following key legislation and guidance documents:

- SHTM 04-01 Part B: Operational management (2014)[4]
- SHTM 04-01 Part C: TVC testing protocol (2014)[5]
- Approved Code of Practice L8: Legionnaires' disease. The control of legionella bacteria in water systems (Health and Safety Executive, 2013)[6]
- HSG274 Legionnaires' disease. Part 2: The control of legionella bacteria in hot and cold water systems (Health and Safety Executive, 2014)[7]

Compliance with SHTM 04-01 will generally satisfy the Approved Code of Practice L8.

Where water testing is concerned, these documents are consistent in recommending monitoring for the presence of Legionella only under specific conditions, identified by risk assessment[4]. These include:

1. When storage and/or distribution temperatures are not maintained and a biocide is used: Monthly testing recommended (reduced frequency as confidence in biocide treatment is established)
2. When control regimes are not consistently achieved: Weekly testing recommended until system is brought under control
3. When an outbreak is suspected or confirmed
4. On hospital wards with high-risk patients, notably those that are immuno-compromised

Recommended actions following legionella testing differ based on reported colony counts (cfu/L), with additional actions for healthcare settings with high-risk patients (Table 1).

Table 1. Legionella thresholds for triggering action in general and high-risk settings.

Legionella (cfu/L)	Required action
General actions (outwith high-risk healthcare premises)[7]:	
<100	Acceptable, no further action required.[5]
100 to 1000	Authorised Person and Consultant Microbiologist notified.[5] If minority of samples are positive, the system should be resampled.[4] Where similar results are found again, a review of control measures and risk assessment should be carried out to identify any remedial actions. If the majority of samples are positive, the system may be colonised, albeit at a low level. An immediate review of control measures and risk assessment should be carried out to identify any other remedial action required. Disinfection of the system should be considered.[7]
>1000	Immediate action required.[5] The system should be resampled and an immediate review of control measures and risk assessment carried out to identify any remedial actions, including possible disinfection of the system.[4,7]
Additional actions for high-risk healthcare premises[7]:	
<100	Any detection of legionella should be investigated and, if necessary, the system should be resampled to aid interpretation of the results in line with the monitoring strategy and risk assessment.

Following remedial action, water sampling frequency should be increased to ensure appropriate controls are in place[5]:

1. Initially, samples should be tested weekly
2. After three weekly results below 100 cfu/L, frequency can be reduced to monthly
3. After three monthly results below 100 cfu/L, frequency can be reduced to 3-monthly

Pseudomonas aeruginosa testing

These are outlined in the following key guidance documents:

- SHTM 04-01 Part B: Operational management (2014)[4]
- *Pseudomonas aeruginosa* routine water sampling in augmented care areas for NHSScotland (Health Protection Scotland, 2018 draft)[8]
- Guidance for neonatal units (NNUs) (levels 1, 2 & 3), adult and paediatric intensive care units (ICUs) in Scotland to minimise the risk of *Pseudomonas aeruginosa* infection from water (Health Protection Scotland, 2018)[9]

Outwith healthcare settings with high-risk patients (i.e. augmented care areas), the consensus guidance that has been in place since 2014 recommends no routine testing of water for *Pseudomonas aeruginosa*[4]. The updated 2018 guidance for neonatal units, adult and paediatric intensive care units states that testing is only required outside high-risk areas when a specific reason has been identified, such as a suspected or confirmed outbreak or a series of sequential cases[9].

Separate guidance for *P. aeruginosa* testing specifically in augmented care areas was introduced in 2018, though the main document is still in draft form[8]. It recommends that routine water sampling (using a pre-flush sample) should occur at least six-monthly, or more frequently if any of the following occur:

- Increase in clinical isolates within the care area
- Changes have been made to water distribution and delivery system components/configuration
- Trend analysis of routine samples demonstrates increasing counts (cfu/100mL)

Table 2. *Pseudomonas aeruginosa* thresholds for triggering action (draft 2018 guidance specific to high-risk settings[8]).

P. aeruginosa (cfu/100mL)	Required action
0 (not detected)	No further action required. Re-sample at six-monthly intervals unless any of the criteria for increased frequency are met.
1 to 10	Re-test the outlet with pre- and post-flush samples until three consecutive negative samples are obtained. Continue to sample weekly for four weeks, then reduce frequency to 3-monthly.
>10	Re-test the outlet, risk assess the need to remove the outlet from service, and follow the repeated testing procedure outlined for 1-10 cfu/100mL.

Other testing

While there are clear recommendations for Legionella and *P. aeruginosa* water testing in healthcare settings, guidance is minimal or absent for the other water tests routinely carried out in QEUH Adults and RHC.

Total Viable Count (TVC)

TVCs, usually reported as counts in cfu/mL, give an indication of the total viable microbial load in a water sample. These tests are carried out at two incubation temperatures: 22°C, which favours environmental organisms, and 37°C, which selects for microorganisms that grow well at body temperature, indicating the possible presence of pathogens.

SHTM 04-01 Part B states that, 'apart from situations where there are taste or odour problems, microbiological monitoring for TVCs is not considered necessary'[4] in healthcare settings. The L8 Approved Code of Practice recognises that routine monitoring of TVCs is 'appropriate as an indication of whether microbiological control is being achieved', but goes on to state that it is generally only used for cooling tower systems and spa pools[6].

Although not required by legislation or guidance, SHTM 04-01 Part C acknowledges that many estates personnel choose to use routine TVC testing to provide an early warning of water system problems[5]. Where routine TVC testing is being carried out, SHTM 04-01 Part C recommends that it occur quarterly so that trend analysis can identify significant increases in counts that should trigger some form of action. There are no suggested TVC thresholds for general or high-risk healthcare areas; rather, the recommendation is to look for significant changes in TVCs.

The only situation where TVC testing appears required in the SHTM 04-01 is during the initial water system commissioning process. SHTM 04-01 Part A: Design, installation and testing states that 'after disinfection of the whole system prior to commissioning, water tests (TVC37 and coliforms, including *E. coli*) should be carried out under supervision of IPCT to establish that the work has been satisfactorily completed'[3].

Coliforms and Escherichia coli

These tests, along with TVCs, ensure that water is of potable quality. While they are routinely carried out by Scottish Water on all public water supplies, including those delivered to healthcare premises, legislation and guidance do not require these tests to be carried out within healthcare water systems (with the exception noted in the previous paragraph, during the commissioning of a new water system).

Other organisms: fungal counts, gram negative bacteria, mycobacteria

There is no national guidance for the routine testing of these organisms in healthcare cold and hot water systems.

Water testing at QEUH Adults and RHC

Key documents:

- QEUH Campus Water Systems Written Scheme: Controlling the risks of exposure to Legionella and other harmful bacteria in Water Systems[10]
- Microbiological monitoring QEUH/RHC during and post Chlorine dioxide installation (2018 SOP)[11]
- Standard Operating Procedure WQS-017: Procedures in the event of out of specification sample for Legionella and other monitored bacteria, moulds etc.[12]

The QEUH Written Scheme aims to 'assist in the correct and safe operation of the water systems within the QEUH Campus', outlining 'the specific roles, responsibilities, training requirements and regular maintenance procedures to be followed in order to ensure compliance with statutory and mandatory guidance.'[10] It adheres to the guidance in SHTM 04-01. As such, it does not give specific details on the location, type, and frequency of microbiological water testing, but rather it names specific situations where testing of hot and cold water systems is warranted. Section 4.1.6 of the Written Scheme, entitled 'Sampling: General microbiological and Legionella sampling in hot and cold water systems', states that water sampling is carried out:

- prior alterations to an existing water system
- as part of commissioning process, prior to handover of new building, or introduction of a (altered, refurbished, or new) water system into use
- one week following handover of a new building or new water system
- as part of tank cleaning/disinfection process
- as part of assessment programme
- in response to taste, odour, or sustained discoloured water complaints

Section 4.81 specifies that bacteriological water samples are collected from the base of calorifiers after the annual inspection of calorifiers and expansion vessels. Legionella testing outlined in the Written Scheme is as per SHTM 04-01, whereas the Written Scheme's Pseudomonas SOP refers to the published 2018 HPS guidance[9]. Appendix 2 of the Written Scheme, entitled 'Escalation of sampling results out-of-spec (potable)', lists potable test thresholds for triggering action: 300 cfu/ml for TVC (22°C and 37°C), and any count for coliform and E. coli tests. Appendix 2 also includes the following statement regarding TVC thresholds: 'Please note that there are no definitive guidance limits for TVC. Scottish water advise that there should be 'no abnormal change' and BS 8558 states 'e.g. TVC results in excess of a 2 log difference above that found in incoming mains water, corrective action should be taken.' The Written Scheme does not specify where or how often TVC testing is carried out.

Routine testing in these buildings prior to December 2018 did not follow a fixed schedule, and the summary in Table 3 (below) was extrapolated from the available data sheets rather than any work plan or overview document. Routine testing over this period was mostly carried out by ALcontrol Laboratories, a UKAS accredited water and environmental analysis contractor who undertook both the sample collection and sample testing in their own laboratory. In some specialist units (aseptic pharmacies and RHC Theatre 8), sample collection was instead carried out by clinical teams, with testing by the UKAS-accredited GG&C Environmental Laboratory, located in the Glasgow Royal Infirmary (this arrangement continues to the present day). DMA Canyon Ltd, NHS Specialist Water Service Provider, carried out some reactive sampling in QEUH Adults and RHC from September 2016 onwards (at the request of IPC/IMTs), and some routine potable sampling from April 2018. All samples collected by DMA over this period were tested by the GG&C Environmental Laboratory.

In December 2018, the routine sampling plan was expanded and formalised to coincide with the installation of a chlorine dioxide dosing system. A standard operating procedure for testing during and after deployment of the ClO_2 system was written by Dr Teresa Inkster and Ian Powrie in November 2018, outlining the suite of tests to be carried out, their frequency, and the thresholds to be used in general and designated high-risk areas[11]. This SOP subsequently became part of the QEUH Estates document Standard Operating Procedure WQS-017: 'Procedures in the event of out of specification sample for Legionella and other monitored bacteria, moulds, etc'[12], which specifies the routine sampling schedule in place from December 2018 onwards, for the whole QEUH campus, and which exceeds what is outlined in the Written Scheme. All routine and reactive sampling (with the exception of the specialist units mentioned previously) has been carried out by DMA Canyon Ltd since December 2018. Due to the large increase in sample numbers, samples from the sentinel outlets (approximately 142 per month) are sent by DMA Canyon Ltd to Intertek, a quality assurance company that provides an accredited water microbiology analysis service. The GG&C Environmental Laboratory carries out microbiological testing of all other samples collected by DMA Canyon Ltd.

Table 3 gives a summary of the water tests that have been carried out routinely across QEUH Adults and RHC since 2015, compared with the recommendations outlined in SHTM 04-01 and other guidance documents. Thresholds are from the GG&C Environmental Laboratory's reporting criteria, listed in SOP LP538 Non Legionella Water Testing: Potable Water & Endoscopy Analysis[13], from the 2018 Microbiological Monitoring SOP[11], and from WQS 017[12].

Table 3. Routine microbiological water tests carried out across QEUH Adults and RHC from 2015 to present, with relevant guidance. This does not include reactive microbiological tests requested by IPCT/IMTs as part of incident investigations.

Test	**QEUH Adults and RHC 2015 to Dec 2018**	**QEUH Adults and RHC Dec 2018 to present**	**Requirements or recommendations in SHTM 04-01 and other guidance documents**
Legionella	*Locations and frequency:* Weekly to monthly sampling across Adults and RHC from Apr 2015 to Mar 2018, and in Oct 2018. Predominantly high-risk areas (RHC 2A/2B, Adults 4B, ICU, HDU) but also some general areas *Thresholds to trigger action:* Any count, regardless of serogroup or cfu/L, was considered out of spec	*Locations and frequency:* Monthly sampling of basement tanks/filters, critical care wards*, RHC clinic 1&2, and sentinel outlets** distributed across the new buildings (general and high-risk areas) *Thresholds to trigger action:* Any count in any area, regardless of serogroup or cfu/L, is treated as out of spec, triggering an Incident Report and remedial action, notification of IPCT, and repeated testing	*Locations and frequency:* Routine testing only recommended for high-risk areas, or in response to specific situations (e.g. failure of control systems, outbreaks) *Thresholds to trigger action:* <100 cfu/L acceptable outwith high-risk areas, should trigger re-testing and investigation if in a high-risk area 100-1000 cfu/L should trigger re-testing and possible intervention/remediation >1000 cfu/L requires immediate action

Test	QEUH Adults and RHC 2015 to Dec 2018	QEUH Adults and RHC Dec 2018 to present	Requirements or recommendations in SHTM 04-01 and other guidance documents
P. aeruginosa	*Locations and frequency:* Sampling mostly carried out in specialist and high-risk areas: Weekly to monthly in aseptic pharmacies and RHC Theatre 8. Monthly to 6-7 monthly in PICU (from Sept 2016) and RHC 2A/2B (from Mar 2017). Weekly to monthly across other high-risk areas (mostly Adults HDU, 4B) from Dec 2015 to Mar 2016, with additional testing in Sept and Nov 2016, Feb 2017, then approx. 2-3 monthly from Feb 2018. *Thresholds to trigger action:* >0 cfu/100ml (any count) [GGC Env Lab reporting criteria]	*Locations and frequency:* Monthly sampling of basement tanks/filters, critical care wards*, RHC clinic 1&2, and sentinel outlets** distributed across the new buildings (general and high-risk areas) Weekly sampling of specific high-risk areas (aseptic pharmacy, PICU, RHC 2A/2B) *Thresholds to trigger action:* >0 cfu/100ml (any count) [GGC Env Lab reporting criteria] 10 cfu/100ml [2018 Microbiological Monitoring SOP and WQS 017 – these documents did not originally specify a stricter threshold for high-risk units, but WQS 017 was updated in 2022 to specify that any count in high-risk areas should trigger action]	*Locations and frequency:* For general areas, no routine testing recommended except in specific situations (e.g. outbreak, series of sequential cases). For high-risk areas, draft guidance introduced in 2018 recommends routine testing at least six-monthly, or more frequently in specific situations (clinical cases, changes in water system, increasing routine counts) *Thresholds to trigger action (augmented care areas only, 2018 draft guidance):* 1-10 cfu/100ml should trigger re-testing until three negatives are obtained >10 cfu/100ml should trigger re-testing and risk assess the need to remove outlet from service

Test	QEUH Adults and RHC 2015 to Dec 2018	QEUH Adults and RHC Dec 2018 to present	Requirements or recommendations in SHTM 04-01 and other guidance documents
TVC (22°C and 37°C)	*Locations and frequency:* Weekly to monthly sampling across Adults and RHC from Apr 2015 to Nov 2018. Predominantly specialist and high-risk areas (Aseptic pharmacies, RHC Theatre 8, RHC 2A/2B, Adults 4B, ICU, HDU) but also occasionally in general areas *Thresholds to trigger action:* Specialist units (aseptic pharmacies, RHC Theatre 8): 10 cfu/ml for TVC 37°C, 100 cfu/ml for TVC 22°C [GGC Env Lab reporting criteria] Elsewhere, testing was carried out by the contractor (ALcontrol), and TVCs were reported without any thresholds for flagging out of spec samples	*Locations and frequency:* Monthly sampling of basement tanks/filters, specialist units (aseptic pharmacies, RHC Theatre 8), critical care wards*, RHC clinic 1&2, and sentinel outlets** distributed across the new buildings (general and high-risk areas) Weekly sampling of specific high-risk areas (PICU, RHC 2A/2B) *Thresholds to trigger action:* 10 cfu/ml in high-risk areas, 100 cfu/ml in general areas [2018 Microbiological Monitoring SOP and WQS 017] 10/100 cfu/ml for 37/22°C [GGC Env Lab reporting criteria] Periodic trend analysis carried out by Estates personnel to identify any changes over time	*Locations and frequency:* TVC monitoring is not deemed necessary in general or high-risk areas. Only recommended during commissioning process, after final disinfection of the whole system. Where estates choose to monitor TVCs, guidance is to test quarterly. *Thresholds to trigger action:* No guidance on specific thresholds, only that trends should be monitored for significant increases.
Coliforms, *E. coli*	*Locations and frequency:* Weekly to monthly sampling across Adults and RHC from Apr 2015 to Nov 2018. Predominantly high-risk areas (Aseptic pharmacies, RHC Theatre 8, RHC 2A/2B, Adults 4B, ICU, HDU) but also some general areas *Thresholds to trigger action:* Any count	*Locations and frequency:* Monthly sampling of basement tanks/filters, critical care wards*, RHC clinic 1&2, and sentinel outlets** distributed across the new buildings (general and high-risk areas) Weekly sampling of specific high-risk areas (PICU, RHC 2A/2B) *Thresholds to trigger action:* Any count in high-risk or general areas	*Locations and frequency:* No guidance. Only recommended during commissioning process, after final disinfection of the whole system. *Thresholds to trigger action:* No guidance for healthcare settings. Potable water standards for water utilities require zero counts on both these tests.

Test	QEUH Adults and RHC 2015 to Dec 2018	QEUH Adults and RHC Dec 2018 to present	Requirements or recommendations in SHTM 04-01 and other guidance documents
Fungal counts	None. Routine fungal testing began in Dec 2018.	*Locations and frequency:* Monthly sampling of basement tanks/filters, RHC clinic 1&2, and sentinel outlets** distributed across the new buildings (general and high-risk areas) *Thresholds to trigger action:* 10 cfu/100ml in high-risk and general areas	*Locations and frequency:* No guidance. *Thresholds to trigger action:* No guidance.
Gram negative bacteria	Routine testing for GNBs began in Dec 2018, though reactive testing (for IMT/IPC investigations) occurred prior to that.	*Locations and frequency:* Monthly sampling of basement tanks/filters, RHC clinic 1&2 (general areas) Weekly sampling of specific high-risk areas (PICU, RHC 2A/2B) *Thresholds to trigger action:* Any count in high-risk or general areas	*Locations and frequency:* No guidance. *Thresholds to trigger action:* No guidance.
Atypical mycobacteria (AMS)	None. Routine AMS testing began in Apr 2019.	*Locations and frequency:* Monthly sampling of RHC clinic 1&2 (general areas), RHC PICU and 2A/2B (high-risk areas) *Thresholds to trigger action:* Any count in high-risk or general areas	*Locations and frequency:* No guidance. *Thresholds to trigger action:* No guidance.

*Critical care wards include the following: Adults 4th Floor, 6C, HDU, CCW, 2A, NICU (which is part of the retained estate). Approximately 68 samples are tested per month.

**Sentinel outlets are located in the following areas: Basement, Adult Ground Floor A&E, OPD, Acute; 1st Floor Critical Care, Theatres, Consulting Rooms; 2nd Floor Medical Physics, Endoscopy, Theatres; 5th Floor Ward A, B, C, D; 8th Floor Ward A, B, C, D; 9th Floor Ward C; 11th Floor Ward A, B, C, D. RHC Ground Floor Concourse, OBW; Wards 1C, 2C, 3B. Approximately 142 sentinel outlet samples are tested per month

All routine water testing currently carried out across QEUH Adults and RHC exceeds requirements and recommendations set out in national guidance (where such guidance exists), in terms of testing frequency, locations tested (general as well as high-risk), types of tests performed, and thresholds to trigger action. Much of the routine testing carried out at these sites, notably coliforms, *E.coli*, fungal counts, gram negative bacteria, and mycobacteria, is bespoke to GG&C, as there are no formal requirements or recommendations applicable to these tests.

References

1. Scottish Statutory Instruments. The Public Water Supplies (Scotland) Regulations 2014. (2014).
2. HMSO. Health and Safety at Work etc. Act 1974.
3. Health Facilities Scotland. SHTM 04-01: Water safety for healthcare premises. Part A: Design, installation and testing. (2014).
4. Health Facilities Scotland. SHTM 04-01: Water safety for healthcare premises. Part B: Operational management. (2014).
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6. Health and Safety Executive. L8 Legionnaires' disease. The control of legionella bacteria in water systems. (2013).
7. Health and Safety Executive. HSG274 Legionnaires' disease. Part 2: The control of legionella bacteria in hot and cold water systems. (2014).
8. Health Protection Scotland. Pseudomonas aeruginosa routine water sampling in augmented care areas for NHSScotland. (2018).
9. Health Protection Scotland. Guidance for neonatal units (NNUs) (levels 1, 2 & 3), adult and paediatric intensive care units (ICUs) in Scotland to minimise the risk of Pseudomonas aeruginosa infection from water. (2018).

10. NHS Greater Glasgow & Clyde. QEUH Campus Water Systems Written Scheme: Controlling the risks of exposure to Legionella and other harmful bacteria in Water Systems. 2019 Rev B.
11. Inkster, T. & Powrie, I. Microbiological monitoring QEUH/RHC during and post Chlorine dioxide installation. (2018).
12. NHS Greater Glasgow & Clyde. Standard Operating Procedure WQS-017: Procedures in the event of out of specification sample for Legionella and other monitored bacteria, moulds etc.
13. GG&C Environmental Laboratory. LP538 Non Legionella Water Testing: Potable Water & Endoscopy Analysis.

Revision History

Version	Date	Main author	Significant changes
2.2	2022-12-09	D.L. Chaput	• Added references to GGC Env Lab SOP • Added details in Table 3 about where different thresholds were outlined (GGC Env Lab reporting criteria, or 2018 Microbiological Monitoring SOP and WQS 017)
2.1	2022-06-29	D.L.Chaput	• Added text to the section 'Water testing at QEUH Adults and RHC', outlining the QEUH Written Scheme and Inkster/Powrie SOP • Added references to the Written Scheme, Inkster/Powrie SOP, and WQS 017 • Added a sentence to the SHTM section, specifying that equivalent English guidance is outlined in HTMs
2.0	2022-06-15	D.L. Chaput	• Added text to the section 'Water testing at QEUH Adults and RHC' and a column to Table 3, summarising routine testing from 2015 to Dec 2018 and how it differed from testing carried out since Dec 2018. • Clarified (in Table 3 and in the Pseudomonas testing section) when relevant guidance documents were published. • Specified testing locations in critical care areas and sentinel outlets (Table 3 footnotes). • Specified that Estates carry out trend analysis on TVCs (Table 3).
1.0	2022-06-08	D.L. Chaput	First draft.

Overview of QEUH water testing data files

Dr Dominique Chaput

2023-10-30

Data sets that informed the reopening of RHC Ward 2A/B

- From Sept 2021 to Mar 2022, intensive water sampling was carried out in 2A/2B.
- Samples also collected from floors below and above, for comparison, and sections of pipe from 2A/2B were removed and tested in Dec 2021.

- Data sets were compiled by DMA Canyon into four macro-enabled Excel files (.xlsm), separate from the larger QEUH routine testing data.
- In addition, routine water results from 6A were included in some comparative analyses.

Data sets that informed the reopening of RHC Ward 2A/B

File	Content	Dates covered
2021 NHS QEUH Ward 2A-B Sample Login Sheet	2A/2B pre-opening water testing data	Sept 2021-Mar 2022
2021 NHS QEUH Ward 2A Pipe Swab Sample Login	2A/2B pipe biofilm testing results, Dec 2021	Dec 2021
2021 NHS QEUH Ground & 1st Flr Sample Login Sheet	Water testing data from floors below 2A/2B	Oct 2021-Mar 2022
2021 NHS QEUH 3rd & 4th Flr Sample Login Sheet	Water testing data from floors above 2A/2B	Oct 2021-Mar 2022
2021 NHS QEUH Ward 6A Samples	Routine water testing data from 6A	Jan-Dec 2021

Data sets that informed the reopening of RHC Ward 2A/B

- These DMA data files have a consistent structure with the following separate worksheets:

Worksheet	Data
Login	Lists the samples and their metadata.
Results	Gives the microbiological results returned by the Environmental Laboratory.
Certificate with Recs	The certified data set, with the combined metadata and microbiological results. This sheet is locked to prevent modifications. Data from this sheet were used in all my analyses.
Certificate (Unlocked)	A copy of the ‘Certificate with Recs’ worksheet but unlocked, to allow searching, filtering, and other operations.
Out of Spec Results	Entries from the Certificate with Recs sheet that were automatically flagged as exceeding agreed thresholds.
All Samples With Counts	Entries from the Certificate with Recs sheet that had any count on any test.

Data sets included in the QEUH Adults / RHC summary report
Data sources and overlap

ALcontrol

- Carried out most of the potable and Legionella testing in the new buildings in 2015-2017

Data sheets

- Alcontrol 18 08 2015 samples.xls
- Alcontrol Water Sample 06 01 2016.xls
- Alcontrol 20 01 2017 samples.xls

- Data was not entered into GGC LIMS
- *No overlap among sheets or with any other data sets*

Data sets included in the QEUH Adults / RHC summary report
Data sources and overlap

DMA Canyon

- 2015: Sampled only in the retained estate, not the new buildings
- 2016: Only a small amount of sampling in the new buildings, towards the end of the year (data in the LIMS sheets)
- 2017: Data from the entire campus were kept in a single Excel file
  - 2017 NHS QEUH Sample Login Template (Inc Ps).xls
- 2018: One file for each building on the QEUH campus
  - 2018 NHS QEUH Adult Sample Login Template (Inc Ps&R).xls
  - 2018 NHS QEUH Childrens Sample Login (Inc Ps&R).xlsm

Data sets included in the QEUH Adults / RHC summary report
Data sources and overlap

DMA Canyon

- 2019: QEUH Adults and RHC data kept in the same two files
  - 2019 (01-06) QEUH A&C Sample Login (Inc AMS).xls
  - 2019 (07-12) QEUH A&C Sample Login (Inc AMS).xls
  - Some duplication of Dec 2018 data with entries in the 2018 QEUH Childrens file.

- 2020: QEUH Adults and RHC data kept in the same two files
  - 2020 NHS QEUH AC (01-06) Sample Login Sheet (002) 210720.xlsm
  - 2020 NHS QEUH AC (07-12) Sample Login Sheet (016) 301220.xlsm

- Late 2020: separate files were created for RHC Ward 1D and QEUH Adults Ward 6A
  - 2020 NHS QEUH Ward 1D PICU Samples (008) 241220.xlsm
  - 2020 NHS QEUH Ward 6A Samples (00A) 241220.xlsm
  - Data from Wards 1D and 6A from the beginning of 2020 onwards were copied into the new ward-specific files, so there is duplication of entries between the new building files and the ward-specific ones.

Data sets included in the QEUH Adults / RHC summary report
Data sources and overlap

DMA Canyon

- DMA samples up to Nov 2018 were tested by the GGC Env. Lab.
- From Dec 2018, sentinel outlet samples were sent to Intertek for testing, while the remaining routine and reactive samples were sent to the GGC Env. Lab. DMA sheets have the results from both labs.
  - Lab Reference numbers from Intertek: begin with ‘WS’
  - Lab Reference numbers from the GGC Env. Lab.: YY.[7-digit number].[A-Z]

Data sets included in the QEUH Adults / RHC summary report
Data sources and overlap

LIMS

- GGC Microbiology's Laboratory Information Management System (LIMS), TelePath, is where results from the clinical and environmental microbiology labs are recorded.
- The LIMS data sheets were prepared in Nov 2020 by downloading all potable water testing results for the QEUH campus from the GGC LIMS system and cross-referencing with DMA location metadata.
- Download did NOT include Legionella test results.
- No results from Intertek.
- Results from specialist units with sampling arrangements that do not involve DMA (so are absent from DMA data sheets):
  - Aseptic pharmacies
  - RHC Theatre 8

Data sets included in the QEUH Adults / RHC summary report
Data sources and overlap

LIMS

- Data sheets include all LIMS data fields, including those that were for laboratory information only and would not have been reported back to the requestor.

Data sheets

- 2015-2019: one file per year, named ‘yyyy Potable Water Master File Complete 13.11.20.xls’
- 2020: one file for the specialist unit samples that are not also included in the DMA data, named ‘DC QEUH NON-DMA SAMPLES 1.1.20 - 31.12.20’

- *No overlap among the LIMS sheets*
- *Considerable overlap with DMA data sheets.*

Data sets included in the QEUH Adults / RHC summary report
Data sources and overlap

Identifying overlapping entries in LIMS / DMA data sheets

- Can usually be identified using the Lab Reference number, which should be unique
- Additional indication is the DMA sampling number, but these have been recycled so should not be used alone

Discrepancies in Lab Reference numbers

- Samples booked in for Legionella and other tests were usually given two distinct Lab Reference numbers
  - YY.186… for Legionella, YY.184… for potable and other tests
- LIMS sheets do not include Legionella results so only list the YY.184… number
- DMA lists both numbers in the Lab Reference field, usually with a delimiter (‘&’, ‘/’ or space)

- *Automated string detection will fail to match these samples correctly, unless it allows partial string matches*

Data sets included in the QEUH Adults / RHC summary report Encoding of location data

Location data fields

- In DMA files and in the LIMS, for samples collected by DMA, the main location fields are:
  - **Building**: useful for identifying samples from retained estate, not a reliable indicator of QEUH Adults vs RHC (often grouped under entries including 'A&C', 'Adults & Children', 'Main Building')
  - **Department/Floor**: free-text field, generally reliable but the terms used for specific wards can vary
  - **Unique Outlet Identification**: usually a 3-4 letter code followed by a number. Good indicator of location but difficult to interpret and not always entered.

Ward	Unique Outlet ID codes	Examples of Department/Floor entries (not exhaustive)
RHC 2A/2B	SCH, TCT, DCU	- Schiehallion - Second Floor 2A/2B - 2nd Floor Sch - 2nd Floor TCT - Ward 2A
RHC 1D (PICU)	CCW (also used for Adults HDU)	- 1st Floor 1D - Ward 1D - PICU

Data sets included in the QEUH Adults / RHC summary report Encoding of location data

Location data fields

- For specialist unit data in the LIMS, location data is stored in fields called ‘Organisation’ and ‘Department’

- ALcontrol recorded location data in field called ‘Sample Description’, with additional information sometimes recorded in columns beginning with ‘Client Field’. Location data often limited to unique outlet identification codes.

Data sets included in the QEUH Adults / RHC summary report Named organism data

- All Legionella testing included information on the species/serogroup of any Legionella detected:
  - *Legionella pneumophila* serogroup 1
  - *Legionella pneumophila* serougroups 2-14
  - Legionella species

- Other standard tests (TVC, coliforms, E.coli, Pseudomonas) report counts per vol water. Depending on testing laboratory, additional information about named organisms was sometimes recorded, usually non-target species that grew on Pseudomonas plates
  - Not consistently done (as not required for these tests)
  - Often noted in LIMS 'Laboratory Comments Not Released' field, which would not have been reported to the requestor
- From 2015 to early 2018, most of the named organisms in the data set would have been detected this way, except for reactive testing for specific organisms at the request of ICDs/IMTs

Data sets included in the QEUH Adults / RHC summary report Named organism data

- From Feb 2018, specific requests were made to test for Cupriavidus and other GNBs, with the Env. Lab. instructed to identify and report all colonies that grew
- When fungal testing was introduced in 2018, the Env.Lab. also provided some information on the identity of any colonies that grew

- The introduction of these tests meant that the recording and reporting of named organisms became routine, with the data found in both the LIMS and DMA data sheets.

Data sets included in the QEUH Adults / RHC summary report
Data entry issues and risks of misinterpretations

Entries for samples that were not collected, tested, or reported

- Mostly a feature of the DMA data sheets, since the LIMS and Alcontrol data show only samples that were successfully tested
- Since sampling was routine and followed a pre-determined schedule, entries were made for planned sample collection
- On occasion, planned sampling and/or testing could not take place, e.g.:
  - Access to a room was not granted or possible (sample logged but not collected)
  - Testing did not occur, e.g. due to damaged bottles or laboratory holiday deadlines (sample collected but not tested)

- Entries for these samples remain in the DMA data sheets. They can usually be recognised by character strings (‘no sample’, ‘no access’, ‘not tested’, ‘sample not received’, ‘no result available’, etc.) in one or more fields.
- Other indications of samples that were not collected/tested:
  - Sampling dates that are the Excel default or a placeholder (e.g. 00/01/00 or 1899-12-31)
  - Lab Reference numbers that appear to be placeholders (‘0’)
  - Entries with no microbiological results of any kind, indicated by dashes or empty cells in a results column *(but beware cases where zeros were entered across entire rows, including in results columns)*

Data sets included in the QEUH Adults / RHC summary report
Data entry issues and risks of misinterpretations

Non-numeric entries in numeric columns

- Results columns that should be numeric (e.g. colony counts) often contain non-numeric characters:
  - 'Not Detected' instead of 0
  - '>' to indicate 'greater than', for tests with a reporting ceiling (where exact counts are reported up to a specific value X, and anything higher is shown as >X)
  - Several numerical values separated by tabs, spaces, or other delineators
  - Character strings with named species information, within a numeric column
  - Character strings to specify powers of 10 (e.g. 3x10^2)

- Non-numeric symbols will cause problems if any calculations are carried out
  - Programs like R won't allow calculations to proceed so these issues are relatively easy to detect
  - Excel allows calculations with non-numeric characters – it simply ignores those entries, so can give misleading results

Data sets included in the QEUH Adults / RHC summary report Data entry issues and risks of misinterpretations

Miscellaneous data entry nuances

- Routine fungal testing data entry:
  - First entered as free text in Laboratory Comment or Organism fields, with both colony counts and ID information
  - After introduction of SAB22 and SAB30 fields, at first these were used only for recording positive counts. Where the test was performed but no colonies grew, instead of entering zeros in these fields, the zero result was recorded as a free text comment in another column
  - If only the SAB22/SAB30 columns are considered for this period, it would appear that all samples were positive, which is not correct.

- Intertek Lab Reference numbers
  - A large number of Intertek samples are missing Lab Reference numbers despite having been tested and reported. If data sheets are filtered to remove entries without Lab Reference numbers, these real samples will also be removed.

- Obvious copy/paste errors, typos, etc.
  - Entries pasted into the wrong column (e.g. dates in the Lab.Reference column)
  - Automatic date copying errors: dates increasing sequentially across a batch of samples collected on the same day
  - Different date formats within the same column

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Management of Infection Control incidents in Wards 2A/ RHC During 2017

31/08/2020

Contents

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Background

This papers sets out the response to individual oubreaks and incidents in wards 2a and 2B during the period 1 January 2017 to 31 December 2017.

Ward 2A at the Royal Hospital for Children in Glasgow is a 25 bedded Haemato-oncology ward which cares for some of the sickest children in the hospital. Many of these patients have complex medical conditions and are often very immunocompromised.

NHSGG&C have conducted various levels of investigation around the infection control incidents in this ward during early 2017. This investigation has included:

- Presentations to various committees on infection control management and practices including
    - the Board of NHS Greater Glasgow and Clyde,
    - Oversight Board for NHSGG&C led by Scottish Government;
    - Infection Prevention and Control Governance Sub Group (sub group of Oversight Board)
    - Clinical and Care Governance Committee and
    - Board Infection Control Committee (BICC)

In addition, a desktop review relating to the clinical management of patients using Ward 2A during 2017 has also been completed and NHSGG&C have also developed a 27 point action plan in October 2017 which has involved medical microbiologists and the wider Infection Prevention and Control Team.

Aim

The aim of this report is to provide further analysis of these incidents, particularly in relation to the actions and responses by the Infection Control and Prevention Team and the Incident Management Team (IMT) during early 2017.

The report has been split into key sections to illustrate the various interventions that took place took place during this time. Part 1 of the report lists a summary of key themes and actions taken.

This is followed by Part 2 and 3 which provides a summary of the relevant IMT/ PAG meetings that took place and actions arising from these meetings. A helpful timeline of events is provided within this section which outlines the decisions made by the IMT/ PAG and ongoing monitoring of these decisions.

The report also demonstrates the proactive nature of NHSGG&C in understanding the key issues during this time and our commitment in developing a culture to improve and strengthen infection control practice across all of our patient facing services.

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Position at RHC Ward 2A in early 2017

In early March 2017, a Problem Assessment Group (PAG) was convened to discuss the perceived high number of positive blood cultures in Ward 2A. This group agreed a number of actions including a retrospective look back at blood culture rates on the unit by the IPCT. This revealed a gradual upward trend over the 6 months prior. The HIIAT Score was marked as Green and this was reported to Health Protection Scotland (HPS)


Increase in +ve
Blood Cultures in H

An action plan was developed in response to this. The following incidents/outbreaks followed in the months after and further information on each of these incidents is covered in Part 2 of the report.

- 3 cases of *Elizabethkingia miricola* bacteraemias
- 3 cases of invasive aspergillosis
- Increased incidence of Vancomycin Resistant Enterococci (VRE)
- Rotavirus and Astrovirus outbreak
- Norovirus outbreak
- cases of line associated bacteraemias

In total, 6 incidents required assessment using the Healthcare Infection Incident Assessment Tool (HIIAT) and subsequent reporting to Health Protection Scotland (HPS) and the Scottish Government via the Healthcare Infection Incident and Outbreak Reporting Tool (HIIORT).

Establishment of Quality Improvement Group

One of the critical interventions during early 2017 was the development of a specific group to understand and reduce the rate of line infection. The Central Venous Line (CVL) Quality Improvement Project Steering Group was formed to draw together frontline members of staff working on 2A, with other key stakeholders, including surgeons, anaesthetists, intensivists, radiologists, oncologists and local experts in Quality Improvement methodology, to work collaboratively and share knowledge and expertise on this matter.

The primary aim of this group was to reduce the central line associated blood stream infection (CLABSI) rate in ward 2A (and 2B) As part of this, the group collected two years' worth of retrospective data and presented in the form of a run chart. The initial baseline CLABSI rate per 1000 total line days was 3.25 and the objective of this group was to reduce this to 1 per 1000 *total* line days by Dec 31st 2018.

Benchmarking also took place against the Cincinnati Children's Hospital in Ohio due to the limited data available in the UK as well as the awareness of Cincinnati Hospital being regarded as "best in class" in relation to line infection data. The actions and results from this group can be found on Page 9- Item 13 of this report.

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Part 1- Summary of IPC Actions

The table below contains a range of summarised actions which were implemented by the IPCT. Further detail on each area is provided later in the report.

	Action Taken in Ward 2A	**Current Status**
1	Extensive surveillance of infection on the unit	This action was implemented at the time and is still ongoing
2	x2 Infection Prevention and Control Audits of the unit	These were completed at the time
3	x3 Hand hygiene audits	These were completed at the time
4	x11 Hand hygiene education sessions for staff;	These were completed at the time and education remains a critical part of the function of IPCT
5	Increased presence on the ward by IPCNs providing face to face support and learning	These were completed at the time of the incidents
6	x4 enhanced supervision sessions (monitoring of general clinical practice including line care and supported feedback)	These were completed at the time
7	Provision of parent education sessions	These were completed at the time and is ongoing;
8	Review of general environment including ceiling spaces for fungal growth	This was completed at the time
9	Review of cleaning and maintenance on the unit was completed	This was completed at the time
10	Sampling of water outlets and vents	This was completed at the time
11	Observational review of line practice and review of IV prep guidelines	This was completed at the time
12	Review of physical environment and proposal for additional prep space for reconstitution of IV meds	This was completed at the time and recommendations were made for the new build
13	Liaison with IPCTs in Great Ormond Street Hospital and WoSCC to review their line infection rate improvement plans was completed.	This was completed at the time and further detail is provided in the report
14	Participation in Quality Improvement Group dedicated to improving line associated blood stream infections on 2A was completed IPCT continue to be involved	This was completed at the time and the Chief Nurse for Women and Children's alongside a consultant surgeon led this process. IPCT continue to be involved in this process.
15	Review of external supporting services such as CLIC sargent as a possible source of infection	This was completed at the time
16	Air sampling	This was completed at the time
17	Review of anti-microbial prescribing	This was completed and a report was given to the IMT

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In addition to the above actions, domestic services also increased staffing provisions on the ward with increased domestic auditing and have invited colleagues from different hospital sites to carry out peer audits of the department. The IPCT have also recommended the following actions by the clinical teams during this time which have included

- Regular SICP's audits and hand hygiene audits at least weekly and PDSA cycles to improve practice where poor compliance is recognised was completed. Routine IPCAT audits (standard audit tool for IPCT) are now in place.
- Ensuring staff have completed online Learnpro modules relevant to IPC learning needs. There is organisational wide monitoring of completion of LearnPro statutory/ mandatory e-modules with manager oversight of this process.
- Ensure concerns/improvements are communicated at daily huddle/handover. This process is ongoing
- Cross peer monitoring of the ward by senior staff. This action was completed and is now ongoing.
- Reviewing IV line care and take zero tolerance approach to practice deviations. This has been completed and ongoing at regular intervals.

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Part 2- Detailed interventions taken by IPCT Team

Item	Intervention	Outcome/Progress
1	IPCAT audits	**Two IPCAT Audits were completed in early 2017** 19/04/17 – 87% (SICPs 93%, SPE 65%, TBPs 100%, QI 100%) 01/06/17 – 74% (SICPs 69%, SPE 69%, TBPs 94%, QI 50%) • Questions for staff included in the IPCAT were sent to Senior Charge Nurse for distribution to all staff to improve knowledge. This is a normal part of the IPCAT process and procedures and standard criteria used in every audits which is undertaken • Education for staff was delivered and was repeated later in November 2017
2	Hand hygiene audits	**3 Hand Hygiene Audits were completed** Hand Hygiene Coordinator Audit 8/3/17 – Opportunities taken 100%, Combined compliance 85% Hand Hygiene Coordinator Audit 19/4/17 - Opportunities taken 95%, Combined compliance 70% Hand Hygiene Coordinator Audit 6/6/17 - Opportunities taken 95%, Combined compliance 80% Specific bespoke Hand hygiene education was delivered to medical staff and families.
3	Review of Aseptic Technique and Line care	**Week Long Observation of practice** A week long observation of line practice (beginning 20/03/2017) was carried out by Infection Prevention and Control Nurses. The findings were discussed and reported to Chief Nurse and General Manager and the following actions following this observation were agreed and actioned.

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		• Continuations of ongoing work with the education team to complete policy and implement aseptic non-touch technique and line care; this was carried out as part of the QI work. A draft document had been available to the teams in March 2017 and the new policy was supported by learning sessions from the ANTT team based in London. • A Review of quick reference guideline for administration of IV drugs for use in 2A treatment room was completed; • Purchase of 10 new trolleys for use during IV line care was completed; • Review of environment and treatment areas (see item 6) • IPCT contacted Royal Marsden and Great Ormond Street Hospital to discuss aspects of bacteraemia reduction rates.
4	Review of Antimicrobial prescribing	**Review of Anti-Microbial Prescribing** In May 2017, the IPCT requested a review of anti-microbial prescribing due to increased incidence of VRE in stools and increasing Bacteraemia rates. This was completed and returned to Infection Control Doctor. This demonstrated a spike in Vanc/Teic use coinciding with increase in blood cultures and subsequent increase in VRE colonisations. Further information on actions can be found on Page 15.
5	Enhanced observation of practice by IPCNs	**Enhanced Observation** Further enhanced observation of practice commenced in June/July 2017 due to ongoing outbreaks incidents on Ward 2A. 6 sessions in total carried out. IPCNs observed practice in relation to SICPs, TBPs, environmental cleanliness, aseptic technique and line practice. Feedback given at time of session to nurse in charge and reported out afterwards by email to SCN, LN, CN, GM and ANDIPC. This action was completed.
6	Review of environment particularly in relation to IV medication reconstitution	**Review of Environment** The IPCT reviewed the ward in relation to appropriately sized, stocked and clean treatment rooms for reconstitution of IV medication. In general, it was felt that the treatment room and available work top space was insufficient for the volume of medication required to be made by a large volume of nursing staff. The IPCT suggested alteration works to Teenage Cancer Trust corridor to install a Clinical Handwashing sink, worktop and locked cupboards to allow IV medication to be reconstituted in this area. However It was then recognised that this would not meet building note standards. Suggested alterations sent to Senior Charge Nurse on 11/8/17 and the Estates Management Team. As a result, preparation and treatment rooms have been reconfigured to allow for more focussed space for IV preparation

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7	Staff education	**Hand Hygiene for Staff** Hand hygiene education sessions were carried out throughout June/July 2017. 8 sessions in total were provided in NICU and 2A and all staff from both areas invited to attend. A further 2 dedicated sessions held for medical staff. SICPs education was delivered April/May, 2017 ward 2A and was mainly attended by students and nursing staff. The Infection Control Doctor provided IPC education specifically for Ward 2A Medical staff in July 2017. These sessions were repeated later in 2017- see below. SICPS Education Sessions 2A 24.10.17
8	Parent education	**Education for Parents** Parent education was developed to enhance parental knowledge around Infection Prevention and Control practice and to improve the general environment in Ward 2A. 4 sessions held in total throughout July and August 2018, eight parents attended and these sessions have been repeated. In addition, a dedicated parent IPC information poster was developed and continues to be displayed in every patient room. An Infection Prevention and Control information leaflet for parents was also developed. Parent education RHC July 2017 2.ppt Parent Information Leaflet.docx
9	Water and air testing	**Water and Air Testing** Water outlets were tested in response to incidents/outbreaks on 2A since March 2017. Information on this is presented in Part 4 of the report. Air sampling is carried out routinely.

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10	Review of domestic cleaning	**Domestic Cleaning** Following an outbreak of Rota and Astrovirus in April 2017, the domestic cleaning schedule was reviewed. An audit of environmental cleanliness was carried out by the IPCT and a meeting held between IPCT and facilities management. From this meeting, a number of actions were agreed. This included: • full clean of the ward by domestic services; • full clean of the ward by external contractors; • domestic services audit • cross peer audit by domestic services • Daily review of cleaning by domestic supervisor/manager • Additional domestic hours • Long term daily routine cleaning of the unit with Antichlor plus (this is ongoing)
11	Training for auditors (SICPs and Hand hygiene)	**Training for Hand Hygiene Auditors** In July 2017, the Infection, Prevention and Control team delivered training to the staff Hand hygiene coordinator. This was to ensure that hygiene auditing continues and is recorded accurately. In August 2017, training was delivered by the Lead Infection Control Nurse to support accurate completion of the SICP audit tool.
12	CVC sweeps	**CVC Sweeps** 28/03/17 – CVC sweep in response to increased bacteraemia rates – 58% (only 11 of 19 CVC care plans in place and fully completed). Feedback given to SCN, LN, CN, ANDIC and actions were managed. Locally. Meeting were held in May re plans to improve care in relation to CVCs. 13/10/17 - CVC sweep in response to increased bacteraemia rates – 57% (only 12 of 21 CVC care plans in place and fully completed). Feedback given to SCN, LN, CN, ANDIC and actions were managed both locally and through the Quality Improvement Group that was established.

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<table>
<tr>
<td>13</td>
<td>The QI CLABSI group</td>
<td>
Establishment of QI Group

The QI CLABSI group developed a number of workstreams which has led to significant reduction in line infections. In summary, the line rate has fallen from a baseline median of 3.25 to 1.26. The detail of this work and actions taken are described below. The runchart below provides the rate of line infection over a 6 year period.

clabsi to 23rd June 2020 2.pdf

<table>
<tr><th>Workstream</th><th>Actions taken</th></tr>
<tr><td>Theatre (insertion + subsequent visits)</td><td>• Masks are now worn by all staff in theatre during line insertion;
• The theatre is ‘closed’ during line insertion limiting access to only essential staff;
• All patients are now bathed in the 24 hours prior to line insertion surgery;
• Work is ongoing to include these changes in an amended line insertion bundle.</td></tr>
<tr><td>Access and line maintenance</td><td>• There is now a change of dressing from Mepitel film to IV3000. This is due to superior moisture and secretion handling.
• A trial of Griplock dressings was initiated to minimize sutures along exit site and facilitate cleaning.
• The ward introduced Curos port protectors on the 14th August 2017 which provides passive disinfection and reduces bacterial count by 100,000 times within 3 minutes of application.</td></tr>
<tr><td>Patient and family engagement</td><td>• The group introduced the concept of patients and carers as “Line Guardians”
• The ward admission pack now includes a best practice sheet outlining optimal central venous line care and invites patients and their carers to challenge any deviation from that.
• There is a formalised record of parent and patient training on line care and Curos added to the discharge checklist.</td></tr>
<tr><td>Staff education and training</td><td>• Training for Curos has been delivered for all staff in 2A, 2B, theatres and CT;
• There is enhanced supervision and peer audit weekly.
• Additional support for core 2A/2B education team has been put in place by IPCT</td></tr>
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			• There has been retraining of all domestic staff using the British Institute of Cleaning Sciences (BICSc) lesson plan. • Roll out of Aseptic Non Touch Technique.
14	Twice weekly ward visits	**Ward Visits** The Infection Prevention and Control Team have initiated twice weekly visits to Ward 2A (compared to once weekly in all other areas). This is often increased depending on new patient referrals. These visits allow staff to raise concerns with IPCN and provides an opportunity to share advice and monitor practice.	
15	Weekly reporting to medical director (IPC, clinical SMT, domestic and facilities)	**Enhanced monitoring of Ward 2A** The lead Infection Prevention Control Nurse developed a report tabling all the incidents and outbreaks on the unit since March 2017 and the Board Medical Director had requested weekly updates on progress in 2A during 2017. The update contained a report from IPCT, domestic services, estates and clinical team. IPCT report was issued to Chief Nurse and General Manager each Friday and this was then shared with the Medical Director. Direct reporting has now ceased and has been replaced by extant reporting arrangements including reporting to the South Sector Infection Control Committee, Board Infection Control Committee and Clinical and Care Governance Committee.	
16	Statistical Process Control monitoring	**Statistical Process Control (SPC)** SPCs were developed for environmental organisms and Coag negative Staphylococci organisms found in blood cultures. These are formulated and monitored on a month by month basis by the IPCT.	
17	Review of CLIC Sargent house	**Review external sources of transmission** The Infection Prevention and Control Team carried out a review of CLIC sargent house for any possible route of cross transmission between patients. There was no evidence of cross transmission found.	
18	Consideration of phlebotomy practice	**Review of phlebotomy practice** There was a review of phlebotomy practice amongst the clinical staff in April and October 2017 as the IPCT raised concern around storage of equipment for IV access by phlebotomists. Actions from this are listed below:	

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		1. All phlebotomists were given refresher training by the Practice Development Nurse. Phlebotomists involved in the audit of practice and also given an education session by Vygon. There were no major concerns identified. 2. There were changes to the method of cleaning the phlebotomy trolley (in-between patients). There was also the addition of 1 daily clean also; 3. Changes were made to use a wipeable plastic tray with implementation of aseptic non-touch technique; 4. Training in regards to the introduction of Curos caps (antiseptic impregnated needle-less access device on end of line).
19	Update to local policy following national guidance	**Development of triggers based on updated NICPM** NIPCM updated in June 2017 (appendix 13) to include 4 key environmental organisms. In July 2017, NHSGGC updated local processes to include these environmental organisms. The ICD developed triggers based on the available scientific literature.

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Part 3- Detailed Interventions from PAG/ IMT

February 2017

Date	Incident	IPC Actions	Outcomes
28/02/2017	3 unrelated cases of *Elizabethkingia miricola* isolated from patient line cultures. This is a rare organism and often associated with water and environment. The Gram negative SPC charts did not breach Upper Control Limits.	Problem Assessment Group (PAG) was convened on 3/3/17. • HIIAT Green. • Review of vent cleaning and maintenance by estates. • Lab sampling of vents and water outlets for analysis. • Infection Prevention and Control Nurse (IPCN) carried out visual inspection of environment.	• All 3 strains unique • Water and vent testing proved negative • Water testing of chilled beams was negative • Incident closed 27/3/17

March 2017

Date	Incident	IPC Actions	Outcomes
03/03/2017	An increase in positive blood cultures (the breakdown of isolates is unclear) in Paediatric Haematology patients General upward trend of positive blood cultures since 2014 in Ward 2A/ 2B.	Infection Control actions: Contact estates about vent cleaning regimes. *This actions was completed.* IPCT will look at line devices in use and find out why and when this was changed over from the smart site. P*rocurement has been contacted to find out specific dates.* IPCT to enquire about the short life working group for vascular access.	IMT: Not required. OCT: Not required. Patient – Moderate Services – Minor Risk of Public Transmission – Minor Public Anxiety – Minor **HIIAT Score: Green**

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	13 positive cases in January 2017 and 11 cases in February 2017* SPC charts for Gram positives breached Upper Control Limits in March 2017; Gram negatives remained within normal limits		Report to HPS. No intervention from HPS or escalation. IPCT will feed up to senior management team. No press statement required.

*How the bacteraemia rates compare with other UK tertiary units would be helpful, however given current reporting practices this data is unlikely to be available.

Date	Incident	IPC Actions	Outcomes
03/03/17	Increased bacteraemia rates. General upward trend identified since July 2016. 11-13 positive blood cultures per month.* SPC charts: Upper Warning Limits breached but rates were below Upper Control Limits for both Gram positive and Gram negative organisms	PAG convened 3/3/17. • HIIAT Green • Observational review of line care carried out by IPCNs. Report collated and fed back to clinical team. • Review of environment for reconstitution of medications – inadequate space available for preparation of IV drugs Suggestions for improvements submitted. • Quality Improvement group focusing on Catheter Associated Blood Stream Infections (CLABSI) developed. • Review of line care in Royal Marsden and Great Ormond Street Hospital by Lead IPCN – Findings relayed to CLABSI QI group and local teams.	• Monitoring of bacteraemias within the unit. • QI group continue to meet and work on various aspects of action place specific to line care
03/03/17	Perceived increase of invasive fungal infections (invasive fungal infections require assessment by	PAG was convened 6/3/17. • ICD carried out review of invasive fungal isolates and did not find rates of invasive candida infection to be	• Incident specific to invasive Candida infections closed 06/03/17.

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	clinicians in order to determine if these are infections. This cannot be monitored by positive microbiology so requires intelligence at ward level in addition to microbiological results.	any higher however it was recognised that there had been 3 cases of invasive Aspergillus fumigatus infection within an 8 month timeframe. Incident Management Team arranged for 7/3/17 specific to Aspergillus	
07/03/17	3 cases of invasive Aspergillus resulting in significant morbidity.	IMT convened 7/3/17. **Actions** • HIIAT red and subsequently reported to HPS. • BMT patients on specialist ventilated areas and all other patients in general ward area. • Review of construction and demolition works on and around the site by IPCT and exposure to patients. • Review of CLIC sargent house (Resident facility for patient and families of RHC) as possible risk by IPCT. • Review of general ward environment by IPCT for water leaks/estates. Damp ceiling tiles identified and this was followed by a full inspection of ceiling void and necessary repairs were carried out. • Full terminal clean of ward took place. • Inspection of cooling beams which were reported to leak periodically. • Air sampling ongoing and water sampling carried out. • Hand hygiene audit carried out – Scored 85% • Antifungal prophylaxis administered to ALL patients on commencement of treatment.	• All 3 patient cases recovered from the episode of Aspergillus infection and HIIAT was downgraded to Amber then eventually green once ceiling void repairs had been carried out. This incident was between June 2016 and April 2017. The incident was closed 28/4/17. • Identification of invasive aspergillosis requires a clinical diagnosis due to the complexity of the diagnostic criteria. The IPCT are reliant on the clinical team highlighting all possible cases to the IPCT. • The ICD has worked with estates colleagues to produce a water damage policy and is available on our website under Water Safety. • https://www.nhsggc.org.uk/your-health/infection-prevention-and-control/water-safety-information-hub/

April 2017

Date	Incident	IPC Actions	Outcomes
11/4/17	Increased incidence of Vancomycin Resistant Enterococci (VRE) isolates in stool. [1,2.3] Total of 9 cases of colonisation over 1 month period (previously 2 cases over 6 months). 8 of the 9 are HAI, 1 of which is related to Edinburgh Sick Kids. SPC charts for Gram positives breached UCL in March and May 2017;	• PAG convened 12/4/17. The incident then became an outbreak of Rotavirus and Astrovirus (tabled below). • Review of antimicrobial prescribing carried out which revealed an increase in the use of vancomycin and teicoplanin. This may have been due to increased bacteraemia rates described above, however it is unclear if therapy was empiric or targeted. • All isolates sent for typing – 4 patients had matching strains. The rest were unique • Full terminal clean of ward carried out. • Antichlor cleaning daily previously discontinued across GGC after winter then resumed on a permanent basis for this ward. • Enforce use of Bristol stool chart to accurately record which patients were having loose stools. Further PAG held 28/4/17 after Astrovirus/Rotavirus outbreak was closed. • Action plan developed mainly focused on reduction of bacteraemia rates. • Increased visits to ward by IPCNs to reinforce Standard Infection Control Precautions (SICPs), Transmission Based Precautions (TBPs) and hand hygiene.	• Total cases now 10 with only 1 new HAI since the initial reporting. • Ongoing monitoring by IPCT. • Hot Debrief produced by HPS • Notes 1- This is not uncommon in hemato- oncology patients who have multiple hospitalisations and exposures to anti-microbials including vancomycin and teicoplanin for the treatment of line infections 2- VRE do not cause GI upset however they will be dispersed into the environment if patient having loose stools – a frequent occurrence in patients receiving chemotherapy or stem cell transplantation. 3- It should be noted that screening for VRE is no longer performed in adult allograft patients.

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Date	Incident	IPC Actions	Outcomes
12/4/17	Rotavirus and Astrovirus outbreak. Lasted 14 days affecting 9 patients. Significant impact on service with some cases being diverted to Edinburgh.	PAG convened 12/4/17 initially to review VRE increase. PAGs held over subsequent days then identified the transmission of Rotavirus and Astrovirus. • HIIAT initially Amber then upgraded to Red following transfer of patient to PICU. • Infection Prevention and Control Audit (IPCAT) carried out 20/4/17. Scored within green range (87% overall) • Extensive cleaning carried out and external contractor brought in to terminally clean ward before reopening. • Hand hygiene audit – scored 70%. • Hand hygiene education sessions provided – currently 8 sessions carried out. • Daily IPCN visit to ward, sometimes twice daily. • Daily IMTs. • Staffing levels were increased on the ward to accommodate cohorting of patients. • Meeting held with Infection control doctor, GM facilities and GM of Ward 2A to discuss any concerns	• Ward returned to normal capacity 25/4/17 with an increase in staff numbers to allow for burden of patients in isolation. • SICPs audit repeated with SCN and IPCN. Scored 96% although some environmental issues identified again. • Hand hygiene sessions ongoing. • Agreed to increase domestic cleaning hours in Ward 2A. • SOP to be developed in relation to access to clean arrangements • SLWG to be established by General Manager facilities to look at novel technologies i.e. hydrogen peroxide

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May 2017

Date	Incident	IPC Actions	Outcomes
30/05/17	3 cases of Norovirus on ward, 2 HAI, 1 non HAI. All 3 symptomatic and nursed in rooms in close proximity to each other.	PAG convened 31/05/17. • HIIAT green. • IPCAT audit repeated 1/6/17 – score of 74% (SICPs 69%, SPE 69%, TBPs 94%, QA 50%) • Hand hygiene audit carried out – • Daily visits to ward • Ongoing meetings with facilities management again to discuss cleaning standards on the ward.	• Ongoing daily assessments • Education to be arranged for staff re. SICPs.

July 2017

Date	Incident	IPC Actions
26th July 2017	2 cases of *Stenotrophomonas maltophilia** line related bacteraemias within an 8 day period. Further investigation of these cases identified that they were unrelated There were no breaches of Gram negative SPC charts. *Stenotrophomonas maltophilia is an increasingly recognised pathogen in this patient group, often causing line-related sepsis and may be acquired endogenously or from the environment.	Case 1; Positive blood culture 15/7/17. Case 2; Positive blood culture on 23/7/17. Sadly 1 patient died with *Stenotrophomonas maltophilia and this was recorded on Part 3 of the Medical Certificate of Cause of Death (MCCD)*

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ACTIONS TAKEN		
Date	**What: (action)**	**When**
24/7/17	Terminal clean of bed space for case 1 (discharged at point of referral).	Completed on 24/7/17
25/7/17	Terminal clean of bed space for case 2 (Still an inpatient on ward 2A)	Completed on 25/7/17
25/7/17	Daily domestic chlorine clean of ward	Has been ongoing since April 2017
25/7/17	Audit of environment and staff practice. Last IPCAT audit June 2017- 74%	Enhanced supervision carried out by IPCT. 3 sessions were delivered and final session was completed on 27/7/17.
25/7/17	Continue to improve Hand hygiene	Hand hygiene audits in March and June 2017 (scored 100% and 95% for opportunities taken and 85% and 80% for combined compliance) 11 hand hygiene sessions were carried out in May, June and July 2017
25/7/17	Typing of isolates	Samples were sent to Collingdale for typing. The results revealed the isolates were unrelated on typing.
25/7/17	Enhanced environmental monitoring	There was no evidence of Stenotrophomonas isolation from water or the environment.
25/7/17	Reconfiguration of prep area TCT to increase available space for reconstitution of IV meds – Review proposed alterations and agree plan going forward	Further information on this arrangement are outlined on Page 9- Item 6
26/7/17	IMT held	Completed on 26/7/17
26/7/17	Review of background rates of Stenotrophomonas maltophilia in 2A	Following report of Stenotrophomonas maltophilia blood culture in 2 patients, an incident meeting was held as per NIPCM chapter 3.

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		The ICD requested further water sampling in Ward 2A. 118 samples were taken and all provided negative for SM. The ICD undertook a review of Steno blood cultures. 3 further cases reviewed, 2 of which were documented as HAI also. These were reported to the IMT. On the 4th September, HPS were notified that a patient had sadly died. HPS were asked if any further action was required. We were advised that no further action was required.

Part 4- Results of water sampling

The Board has in place, a number of water assurance systems and processes to ensure the high quality of the water system and supply. This includes the following

- Infection Control in The Built Environment Group established (ICBE); (2019)
- Board Water Group;
- Local Water Groups;
- External Authorising Engineer (AE) appointed;
- Authorised Person (AP) competency checks;

151 water samples were tested between 7/3/17 and 17/11/17 (135 samples form Ward 2A and 16 samples from Ward 2B). All samples were negative for Elizabethkingia, coliforms, Pseudomonas sp. and Legionella. In addition, there was no Stenotrophomonas maltophilia identified within the water system.

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Part 5- Conclusion

In summary, the key conclusions from this review are listed below:

Involvement of national organisations and agencies to advise and provide assurance

- There has been ongoing involvement of external agencies during this time period to seek advice and guidance to help manage incidents and provide independent assurance to improve the ward environment in Ward 2A;
- The IPC Team have followed a set of national mandatory definitions requirement for IC reporting and have complied with the National Infection Prevention and Control Manual including the reporting of incidents to HPS.

Role of the IMT in the identification and management of incidents

- Infection Control incidents in RHC, Ward 2A appear to have been acted upon quickly and the IMT has functioned well to facilitate a multi-disciplinary approach to the management of infection control incidents;
- There has been a diligent approach and due process has been followed within each IMT with clear actions, outcomes and ongoing monitoring;
- The work of Quality Improvement Group to reduce line infection in Ward 2A has been instrumental in helping to reduce the line infection rate from a median rate of 3.5 in 2016 to 1.26 in January 2020;
- Inpatient families and carers of patients within Ward 2A have been kept fully informed of incidents and education sessions have been delivered to encourage good infection control practice.

Review of the environment

- 151 water samples were taken in Ward 2A/2B from March 2017 to November 2017. All samples have been negative.
- The Stenotrophomonas maltophilia isolates that were identified from the patients affected were sent for typing. Results show that these were not linked and there has been no single source of infection found from the environment;

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Governance, reporting and escalation arrangements within NHSGG&C

- The relevant standing committees of the Board, namely Board Infection Control Committee and Clinical and Care Governance Committee have continued to receive regular reports and updates on these incidents and how they were managed. The Board has also continued to receive assurance on the management of these incidents through the quarterly HAIRT.
- There has been further work undertaken by NHSGG&C to investigate the management of infection control incidents within RHC including a review of the clinical aspects of the management of patients with documented Blood Stream Infection in 2A.
- In October of 2017 at the request of the Board Medical Director microbiologist who were raising concerns about the campus were asked to prepare a SBAR to be discussed by senior managers within GGC at a meeting to which the consultant microbiologists were invited. The response to this was a 27 point action plan focusing on improvements to several areas including Ward 2A. Additional reports including one specifically focused on the ventilation system was subsequently commissioned in 2018. The purpose of these additional reports is to ensure the “triangulation” and investigation of any issues which could have led to the increase in infections during this time period.

Official Sensitive

Report on the clinical aspects of the management of patients with documented Blood Stream Infection with an environmentally classified Gram negative organism in the Paediatric Haemato-Oncology service, NHSGGC between June 1st 2015 and September 30th 2019.

Commissioned by NHSGGC Board Deputy Medical Director: Dr Scott Davidson

Status: Confidential

Version: Final

Date: January 14th 2020

TJ Beattie

NHSGGC WCD BSI 2015 – 2019: CLINICAL REVIEW

Introduction and Background

As part of a retrospective integrated review of patients managed in the paediatric Haemato-Oncology service who presented with a blood stream infection (BSI) with an environmentally classified gram negative organism in 2015 – 2019, a brief clinical review of the circumstances and response to the BSI has been undertaken. The findings will be mapped onto a review of contemporaneous input by NHSGGC Infection Control and Surveillance and the wider Clinical Governance response to the incidents.

Terms of Reference/Methodology

The study group involved those patients identified in the HPS report and managed by the above service based in Wards 2A/B RHC and Ward 6A QEUH between June 1st 2015 and September 30th 2019. These patients had a documented BSI involving a gram negative organism that was classified into one of three categories viz. Environmental and Enteric; Environmental and other gram negative not falling into the previous two categories.

The review was undertaken in three consecutive phases, involving three patient cohorts viz.

1. June 1st 2015 to December 31st 2017.
2. January 1st 2018 to September 25th 2018.
3. September 26th 2018 to September 30th 2019.

The locus of the service during the first two cohort dates was Wards 2A/B RHC and Ward 6A QEUH for the third. This report deals with all three cohorts.

Data Collection

The following data was collected in the review:

1. Patient ID and date(s)/time(s) of the BSI incident

2. Clinical presentation leading to investigation that identified the BSI

3. Time from evidence of BSI being available and the onset of treatment

4. Overall assessment of the adequacy/appropriateness of the response to the BSI using the contemporaneous departmental guidance as a reference.

5. Evidence of documentation of communication to parents/carers of the incident

6. Where mortality occurred, review of documentation of evidence of a review process e.g. departmental/hospital M&M, SCI review, Directorate and/or other Clinical Governance groups.

The data was collected by review of the appropriate electronic patient records held on NHSGGC Trakcare and Clinical Portal, predominantly inpatient nursing and medical assessments, medication records and discharge summaries as well as the relevant

laboratory records around the time of the BSI incident. In addition shadow paper records held by the service for the purposes of external accreditation were reviewed with the help and support of the service quality manager and a member of the service research nursing staff.

Results

Using the above case definition, a total of 127 incidents of BSI involving 90 patients were identified during this timeframe. One patient (Case 78) with one BSI incident was excluded from the analysis since no scanned clinical records were available as the patient had not been discharged at the time of the review.

Some limited demographic data, date of incidents and details of the organisms identified in each of the three cohorts are given in the accompanying Tables. The first cohort (Table 1) involved 49 patients (66 BSI incidents), the second cohort (Table 2) involved 29 patients (33 BSI incidents) and the third cohort (Table 3) involved 21 patients (28 BSI incidents). There was one exception to the above case definition (Case 11) in that the organism was Mycobacterium chelani, however the same methodology was applied to this incident.

On two occasions, the BSI incident was recorded when the patient (Cases 71 and 57) was managed in wards 3A and 3B RHC respectively rather than in Wards 2A/B RHC or Ward 6A QEUH. However, since they remained under the overall care of the paediatric Haemato-Oncology service, these incidents were included in the analysis.

All but 7 patients had an underlying primary diagnosis of either a haematological malignancy or a malignant solid tumour however two patients with a non-malignant primary diagnosis had undergone a haematopoietic stem cell transplant (HSCT) prior to the BSI incident. A further 36 patients had had a HSCT prior to the incident or required one later in their clinical course. All but one patient had some form of indwelling vascular access device at the time of the BSI incident and in 68 of the 127 BSI incidents, the patient had an accompanying neutropenia.

18 of the 90 patients had multiple incidents, varying from two to six over the total review period. 7 patients had a recurrence across two cohort periods and one patient (Case 34), had a recurrence across the three cohort periods. It is significant that the patient who had the maximum number of incidents recorded (case 33) was an infant who had a haematological malignancy diagnosed around the age of three months. This patient had a total of 10 indwelling vascular access procedures carried out in a twelve month period reflecting the added difficulties in maintaining sterility of these devices in the pre-continent child.

Clinical presentation leading to investigation that identified the BSI.

In the 126 BSI incidents analysed, the almost invariable clinical presentation was with a new or recurrent episode of pyrexia with varying degrees of systemic upset.

The former presentation was universal in the patients who were admitted from home (49 incidents). In those patients in whom the incident was recorded when they were an

inpatient (61 incidents) or attending as a day patient (16 incidents), the context was more variable in that some patients, particularly those with a complex clinical course who had previous recent febrile episodes unrelated to the particular BSI under review were on a combination of intravenous antibiotic/antifungal therapy at the time of the incident.

Time from evidence of BSI being available and onset of treatment.

In all of the clinical presentations leading to the diagnosis of BSI that were reviewed, the initial evaluation was felt to be appropriately prompt, particularly with the taking of new or further blood cultures, the use of resuscitation measures if required and the introduction of/change in intravenous antibiotics, and consistent with the contemporaneous departmental guidance. Subsequent changes in antibiotic therapy were also made as soon as the organism was identified and anti-bacterial sensitivities known.

Overall assessment of the adequacy/appropriateness of the response to the BSI.

The context for this assessment not only took into account the wide variety of gram negative isolates in all but one of the BSI incidents and of the differing antibiotic sensitivity profiles of these isolates but also and importantly, the clinical status of the patients at the time of the incident.

The finding of Mycobacterium chelani in the blood culture of case 11 occurred in the context of several recent preceding febrile episodes coincident with the use of the central venous line but in the absence of either gram positive or gram negative bacteria on blood cultures. The finding of this very unusual organism led to the appropriate decision for removal of the central line with good effect.

In 87 patients (124 BSI incidents), the clinical status of the patient leading up to and during the incident was relatively stable bearing in mind the nature of the serious underlying primary disease, the phase of treatment and in a small number, the brief requirement for critical care support or advice. In all of these incidents the overall assessment of the interventions and clinical response was satisfactory. It is also worth documenting evidence of the consistent use of both central and peripheral venous access insertion and maintenance bundles in the patient records.

In the remaining two patients (cases 37 and 38) both of whom were inpatients at the time of the BSI, the clinical context was more complex and merits more detailed comment.

The first of these patients was a 10 year old who was in the recovery phase of a first HSCT following relapse of a primary haematological malignancy. At the time of the HSCT and as part of the protocol, routine culture of a sample of the transfused cells revealed the presence of two gram positive organisms. These results became available following the transfusion and although appropriate antibiotics were given, the patient's pre-treatment blood culture was sterile. As is common in the post-transplant period episodic pyrexia required several subsequent courses of intravenous antibiotics in the absence of positive cultures, one potential reason may have been evidence of reactivation of latent adenovirus that required treatment with Brincidofovir. At the time of the recorded BSI incident there

was good evidence of successful engraftment and the peripheral neutrophil count was improving and in the low/normal range.

The onset of the BSI incident was characterised by a recurrence of pyrexia. This was rapidly and appropriately evaluated and intravenous antibiotics were introduced based on the departmental guidance and later on the same day and on the following day, additional intravenous antibiotics were prescribed because of continuing pyrexia. Around 58 hours after the initial pyrexial episode, the clinical team were informed of the results of the blood culture taken at the time of the episode (Stenotrophomonas maltophilia) and of the ant-bacterial sensitivities. Immediate actions were to stop using the central venous access device and to place a peripheral venous cannula. Arrangements were made for removal of the central venous device under general anaesthetic and this took place around 2.5 hours later.

Immediately following the procedure the patient became very unwell with features of septic shock and required significant intravenous fluid resuscitation and at this point intravenous Cotrimoxazole was introduced and after stabilisation, the patient returned to Ward 2A.

Further review of the blood culture data around this time revealed Stenotrophomonas maltophilia from a central venous line sample taken 33 hrs after the initial pyrexial episode, but peripheral venous samples taken shortly before and after the central venous line removal as well as the central venous line tip were sterile.

A chest x-ray the day following removal of the central venous line showed widespread patchy changes, the differential diagnosis of which was infection, fluid overload or ARDS. Thereafter, despite the presence of serial sterile blood cultures, there was a continuing pyrexia, increasing oxygen dependency and evidence of cardiac failure.

Sadly following admission to critical care, there was a relentless requirement for escalating support including the use of extra-corporeal life support but this was ultimately unsuccessful and the patient died 38 days following the BSI incident.

Although this patient was clearly recovering from a major therapeutic intervention, the recovery was still ongoing and the attendant risks relating to treatment induced immunosuppression remained. There is no doubt that the BSI incident precipitated a significant reversal of the clinical recovery, however the clinical assessment and interventions were appropriate albeit these were hampered by the inevitable delay in the identification of the offending organism and the provision of anti-bacterial sensitivities and therefore the introduction of appropriate antibiotic therapy.

It is also relevant that there was an inexorable decline in the patient's clinical condition in the absence of evidence of ongoing sepsis characterised predominantly by myocardial dysfunction, the nature of which remains unexplained and in view of this a more in depth review maybe appropriate.

The second of these patients was a 4 year old with severe aplastic anaemia who had undergone a previous unsuccessful HSCT and following this developed an EBV driven post-transplant lymphoproliferative syndrome refractory to chemotherapy and cytotoxic T cell

therapy. The BSI incident under review took place towards the end of the conditioning chemotherapy prior to the second HSCT and at this point multiple antibiotic/anti-fungal medications were part of the therapeutic regime. Following the recurrence of significant pyrexia, a change in the antibiotic regime was made on a "best guess" basis in view of the spectrum and complexity of the existing treatment and a further change made when the organism (Stenotrophomonas maltophilia) was identified and anti-bacterial sensitivities were known. Blood cultures taken following this change were sterile but the patient's clinical condition deteriorated with the development of progressive respiratory and circulatory failure despite optimal critical care support, and sadly death occurred 9 days following the BSI incident.

In this case it was evident that the patient was critically ill prior to the BSI incident with multiple co-morbidities and had a limited prognosis. Under these circumstances the adequacy of the response to the BSI incident was satisfactory and it is difficult to postulate that the BSI episode although clearly unwelcome, contributed in a major way to his demise.

Evidence of documentation of communication to parents/carers of the incident.

Despite an extensive review of the inpatient medical and nursing assessments and the discharge correspondence, no evidence of documentation of specific communication to parents/carers relating to the fact that the patient had developed an episode of BSI or details of the organism cultured could be found. While this is perhaps unsurprising, it is in my view inconceivable that firstly in this patient group an accompanying parent/carer is not available and secondly, she/he will not have been informed of the working diagnosis of BSI.

What is less likely to take place is a detailed conversation on the nature of the organism underlying the BSI, as most clinicians would feel the priority for parents/carers is that the patient is receiving optimal treatment.

Where mortality occurred, review of documentation of evidence of a review process.

20 patients in this study group died, 9 days to two years following the BSI incident.

In addition to the two cases referred to above who died relatively soon after the date of the BSI under review there was an additional patient (Case 19), who also died relatively soon after the BSI incident date, however the incident date coincided with a decision to re-orientate care and this patient and the remaining 17 others died from progression of the primary disease and unrelated to the BSI incident(s).

In 13 of the patients who died, evidence of a review process was found varying from completed Datix reviews, IMT minute and departmental and hospital M&M meetings.

Of those patients with no documented review process two died under the care of an external paediatric palliative care service however all seven patients remain on the departmental governance agenda for review.

It was also noted that post HSCT patient outcomes are reviewed as part of UK national MDT research and audit programme under the auspices of the UK Bone Marrow Transplant (UKBMT) group. One meeting each year is dedicated to audit/outcomes when each centre

presents their transplant outcomes for the previous year. This meeting is externally moderated, but does not have any regulatory authority, although it does provide peer governance.

Conclusions

The disadvantage of the absence of wider hospital (RHC) and individual service central line associated BSI (CLABSI) data as a denominator in this analysis should be recognised as there are always potential pitfalls in focussing in on a selective patient group such as the current study does but any such disadvantage should be mitigated by the ongoing work of the WCD CLABSI QI forum. With this proviso however, this review revealed no significant concerns over the clinical management of CLABSI in this sub-group of high risk patients.

The response to the BSI incidents consistently adhered to the service guidance and clearly reflects the fact that such guidance is embedded into the day to day clinical management of suspected sepsis in the service. However, the HPS report and this review have also highlighted the wide range of gram negative organisms involved in the BSI incidents as well as the significant differential in antibiotic sensitivities and this reinforces the need to maintain such guidance as up to date as possible.

As stated previously, the lack of written documentation relating to communication of the BSI incident and the details of the incident, are not unsurprising but almost certainly does not reflect an absence of such communication. However, in the light of the Duty of Candour (Scotland) Regulations that came into force during the period of the review (April 1st 2018) and in order to address this apparent deficit, a specific strategy on the recording of communication with parents/carers should be considered.

From: RANKIN, Annette (NHS NATIONAL SERVICES SCOTLAND)
Sent: 02 July 2020 14:40
To: HPSINFECTIONCONTROL (NHS NATIONAL SERVICES SCOTLAND)
Subject: Re: HIIORT RHC/QEUH Ward 6A

Hi Heather
Thanks for this
HPS support was requested and I attended an IMT this morning and I requested a HIIORT and will escalate to HAIPU
Annette

On 2 Jul 2020, at 13:54, HPSINFECTIONCONTROL (NHS NATIONAL SERVICES SCOTLAND) <NSS.HPSInfectionControl@nhs.net> wrote:

Hi Annette,

Been forwarded the attached HIIORT on. Single case of Cryptococcus, weak positive. This is not a confirmed case. HIIORT is assessed as Green with no HPS support requested. Hypothesis is false positive . Child on antifungal regime and is CSF negative.

Just to check with you in view of clinical setting, at risk patient clientele and previous issues do you wish escalation to SG. I can check with Gillian the child is not giving cause for cause for concern as a direct consequence. Noted on HIIAT severity of illness is moderate. We wouldn't normally escalate HIIAT green with no HPS support, but thought this could attract some media attention and potentially escalate!

KR
Heather

From: MCDAID, Kirsty (NHS NATIONAL SERVICES SCOTLAND) [redacted]
Sent: 02 July 2020 13:37
To: HPSINFECTIONCONTROL (NHS NATIONAL SERVICES SCOTLAND) <nss.hpsinfectioncontrol@nhs.net>
Cc: WALLACE, Heather (NHS NATIONAL SERVICES SCOTLAND) [redacted]
Subject: RE: HIIORT RHC/QEUH Ward 6A

Thanks Chloe,

Heather, can you pick this up for me please. I have been on calls all morning and about to go on to another one. Sorry to leave this with you.

Kirsty

From: HPSINFECTIONCONTROL (NHS NATIONAL SERVICES SCOTLAND) <nss.hpsinfectioncontrol@nhs.net>
Sent: 02 July 2020 13:29

To: MCDAID, Kirsty (NHS NATIONAL SERVICES SCOTLAND) [redacted]
Subject: FW: HIIORT RHC/QEUH Ward 6A

Hi Kirsty

Please find attached HIIORT.

Will I send on to anyone else?

Kind regards,

Chloe Stewart

Administrator Infection Control Team

Antimicrobial Resistance & Healthcare Associated Infection Group

Health Protection Scotland
Meridian Court I 5 Cadogan Street I Glasgow I G2 6AT
T: +44(0)141 300 1175
[redacted]
NSS.HPSInfectionControl@nhs.net

<image001.jpg>
Web: www.nhsnss.org
Web: www.hps.scot.nhs.uk

From: Bowskill, Gillian [redacted]
Sent: 02 July 2020 13:26
To: HPSINFECTIONCONTROL (NHS NATIONAL SERVICES SCOTLAND) <nss.hpsinfectioncontrol@nhs.net>
Cc: Leanord Alistair (NHS GREATER GLASGOW & CLYDE) [redacted]; Devine, Sandra [redacted]; Joannidis Pamela (NHS GREATER GLASGOW & CLYDE) [redacted]
Subject: HIIORT RHC/QEUH Ward 6A

Dear All,

Please find attached a HIIORT following IMT today.

Kind Regards

Gillian

Gillian Bowskill
Lead Nurse Infection Prevention & Control South Paediatrics
Royal Hospital for Children
[redacted]
Mobile: [redacted]

<HIIORT 02.07.20.docx>

From: RANKIN, Annette (NHS NATIONAL SERVICES SCOTLAND)
Sent: 07 July 2020 13:18
To: Josephine.Ives[redacted]; HPSINFECTIONCONTROL (NHS NATIONAL SERVICES SCOTLAND)
Cc: IMRIE, Laura (NHS NATIONAL SERVICES SCOTLAND); Rachael.Dunk[redacted]; Lesley.Shepherd[redacted]; Jason.Birch[redacted]
Subject: RE: HIIAT Green ward 6a NHSGGC

Follow Up Flag: Follow up
Flag Status: Completed

Hi Jo

The HIIAT assessment was green based on the comms teams view that public anxiety was minor. As this was a positive antigen test and there are investigations underway to review the plant room: this will be reassessed as more information becomes available.
I will contact the board and ask for an update, particularly on the results that were outstanding from Bristol

Annette

From: Josephine.Ives[redacted]
Sent: 07 July 2020 12:09
To: RANKIN, Annette (NHS NATIONAL SERVICES SCOTLAND)[redacted]; HPSINFECTIONCONTROL (NHS NATIONAL SERVICES SCOTLAND) <nss.hpsinfectioncontrol@nhs.net>
Cc: IMRIE, Laura (NHS NATIONAL SERVICES SCOTLAND)[redacted]; Rachael.Dunk[redacted]; Lesley.Shepherd[redacted]; Jason.Birch[redacted]
Subject: RE: HIIAT Green ward 6a NHSGGC

Hi Annette,

Thank you for the report and apologies for the flurry of emails, I am just back in the (virtual) office and going through emails.

Are National ARHAI Scotland content with the investigations/control measures in place and the HIIAT assessment? I see that another IMT will be held once the results from the lab are back and a further update provided then.

Thanks,
Jo

From: RANKIN, Annette (NHS NATIONAL SERVICES SCOTLAND)[redacted]
Sent: 02 July 2020 15:39
To: Allan L (Lara)[redacted]; Birch J (Jason)[redacted]; Burgess E (Elizabeth)[redacted]; CAIRNS, Shona (NHS NATIONAL SERVICES SCOTLAND)[redacted]; DODD, Susie (NHS NATIONAL SERVICES SCOTLAND)[redacted]; Dunk R (Rachael)[redacted]; FRENCH, Sofie (NHS NATIONAL SERVICES SCOTLAND)[redacted]; McPherson G (Grant)[redacted]; HOOKER, Emma (NHS NATIONAL SERVICES SCOTLAND)[redacted]; HPSINFECTIONCONTROL (NHS NATIONAL SERVICES SCOTLAND) <nss.hpsinfectioncontrol@nhs.net>; IMRIE, Laura (NHS NATIONAL SERVICES SCOTLAND)[redacted]; Ives J (Josephine)[redacted]; LOCKHART, Michael (PUBLIC HEALTH SCOTLAND)

[redacted]; MACDONALD, Jennifer (NHS NATIONAL SERVICES SCOTLAND) [redacted]; MCDAID, Kirsty (NHS NATIONAL SERVICES SCOTLAND) [redacted]; MEDIARELATIONS (NHS NATIONAL SERVICES SCOTLAND) [redacted]; Morris K (Keith) [redacted]; MULLINGS, Abigail (NHS NATIONAL SERVICES SCOTLAND) [redacted]; RANKIN, Annette (NHS NATIONAL SERVICES SCOTLAND) [redacted]; Ross E (Elaine) [redacted]; Shepherd L (Lesley) [redacted]; THOULASS, Janine (PUBLIC HEALTH SCOTLAND) [redacted]; WALLACE, Heather (NHS NATIONAL SERVICES SCOTLAND) [redacted]; WEAVING, Paul (NHS NATIONAL SERVICES SCOTLAND) [redacted]; Wright WA (Billy) [redacted]
Cc: Devine, Sandra [redacted]; Bowskill Gillian (NHS GREATER GLASGOW & CLYDE) [redacted]; Leanord Alistair (NHS GREATER GLASGOW & CLYDE) [redacted]; STORRAR, Ian (NHS NATIONAL SERVICES SCOTLAND) [redacted]
Subject: HIIAT Green ward 6a NHSGGC

Dear all,

National ARHAI Scotland have received a HIIORT following an IMT from NHSGGC.

In summary:

- 1 child reported as having a positive reaction to a Cryptococcus antigen test.
- Weak positive Cryptococcus result isolated from plasma.
- CSF Cryptococcus antigen reported as negative.
- Samples have been sent to Bristol mycology reference laboratory.

The sample was taken as part of semi routine screening following admission to ward 6A (paediatric haemato-oncology) QEUH with pyrexia. The child has been receiving intensive [redacted] in ward 6A since [redacted].
The child is reported as being well (in relation to this result)

Investigations/control measures

- Plant rooms will be inspected by microbiologist.
- Results awaited from Mycology Reference Lab.
- Antifungal prophylaxis will remain unchanged at present

Hypothesis

- Environmental, either community or hospital.
- Latency infection.
- False Positive.

Communications:

- Family informed of result by clinical staff.
- Clinical team will provide an update for ward staff.

HIIAT assessed as GREEN

IMT will reconvene when results from Bristol are available. Next planned update following IMT

Alistair/Sandra/Gillian: please advise of any errors or omissions

[redacted]

Annette Rankin
Nurse Consultant Infection Control

NHS National Services Scotland
Health Protection Scotland
4th Floor
Meridian Court
5 Cadogan Street
Glasgow
G2 6QE
T: [redacted]
Reception: [redacted]
www.hps.scot.nhs.uk/

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From: Leanord, Alistair
Sent: 08 July 2020 14:19
To: RANKIN, Annette (NHS NATIONAL SERVICES SCOTLAND); Allan, Lara; Birch, Jason; Elizabeth Burgess - Scottish Government (External); CAIRNS, Shona (NHS NATIONAL SERVICES SCOTLAND); DODD, Susie (NHS NATIONAL SERVICES SCOTLAND); Rachael.Dunk[redacted]; FRENCH, Sofie (NHS NATIONAL SERVICES SCOTLAND); Grant McPherson; HOOKER, Emma (NHS NATIONAL SERVICES SCOTLAND); HPSINFECTIONCONTROL (NHS NATIONAL SERVICES SCOTLAND); IMRIE, Laura (NHS NATIONAL SERVICES SCOTLAND); Ives, Josephine; LOCKHART, Michael (PUBLIC HEALTH SCOTLAND); MACDONALD, Jennifer (NHS NATIONAL SERVICES SCOTLAND); MCDAID, Kirsty (NHS NATIONAL SERVICES SCOTLAND); MEDIARELATIONS (NHS NATIONAL SERVICES SCOTLAND); Keith Morris - Scottish Government (External); MULLINGS, Abigail (NHS NATIONAL SERVICES SCOTLAND); Ross, Elaine; Shepherd, Lesley; THOULASS, Janine (PUBLIC HEALTH SCOTLAND); WALLACE, Heather (NHS NATIONAL SERVICES SCOTLAND); WEAVING, Paul (NHS NATIONAL SERVICES SCOTLAND); Wright, Billy
Cc: Devine, Sandra; Bowskill Gillian (NHS GREATER GLASGOW & CLYDE); STORRAR, Ian (NHS NATIONAL SERVICES SCOTLAND)
Subject: 2020-07-08 (14.19 ALeanord-OutbreakGroup)HIIAT Green ward 6a NHSGGC -att

Follow Up Flag: Follow up
Flag Status: Completed

Annette

As an update:-

It has been confirmed from the UK Mycology Reference lab that the pan fungal PCR was negative on the patients CSF.

We are left with 2 possibilities:

1. An early clinical infection that has been ameliorated with antifungals. Microbiology colleagues in QE are going to perform further sampling to try and answer this question
2. A false positive result in a case with no clinical indicators of Cryptococcus infection.

Cheers

Al

From: RANKIN, Annette (NHS NATIONAL SERVICES SCOTLAND) [redacted]
Sent: 08 July 2020 12:46
To: Allan, Lara [redacted]; Birch, Jason [redacted]; Burgess, Elizabeth [redacted]; CAIRNS, Shona (NHS NATIONAL SERVICES SCOTLAND) [redacted]; DODD, Susie (NHS NATIONAL SERVICES SCOTLAND) [redacted]; Rachael.Dunk [redacted]; FRENCH, Sofie (NHS NATIONAL SERVICES SCOTLAND) [redacted]; Grant McPherson [redacted]; HOOKER, Emma (NHS NATIONAL SERVICES SCOTLAND) [redacted]; HPSINFECTIONCONTROL (NHS NATIONAL SERVICES SCOTLAND) <nss.hpsinfectioncontrol@nhs.net>; IMRIE, Laura (NHS NATIONAL SERVICES SCOTLAND) [redacted]; Ives, Josephine [redacted]; LOCKHART, Michael (PUBLIC HEALTH SCOTLAND) [redacted]; MACDONALD, Jennifer (NHS NATIONAL SERVICES SCOTLAND) [redacted]; MCDAID, Kirsty (NHS NATIONAL SERVICES SCOTLAND) [redacted];

MEDIARELATIONS (NHS NATIONAL SERVICES SCOTLAND) [redacted]; Morris, Keith [redacted]; MULLINGS, Abigail (NHS NATIONAL SERVICES SCOTLAND) [redacted]; Ross, Elaine [redacted]; Shepherd, Lesley [redacted]; THOULASS, Janine (PUBLIC HEALTH SCOTLAND) [redacted]; WALLACE, Heather (NHS NATIONAL SERVICES SCOTLAND) [redacted]; WEAVING, Paul (NHS NATIONAL SERVICES SCOTLAND) [redacted]; Wright, Billy [redacted]
Cc: Devine, Sandra [redacted]; Bowskill, Gillian [redacted]; Leanord, Alistair [redacted]; STORRAR, Ian (NHS NATIONAL SERVICES SCOTLAND) [redacted]
Subject: [ExternaltoGGC]RE: HIIAT Green ward 6a NHSGGC

Dear all

National ARHAI Scotland have received an update on this incident from NHSGGC

In summary:

The patient was discharged on Sunday, well and on fluconazole.

Tests results to date are

- CrAg lateral flow +ve
- Pan fungal PCR negative
- CSF no positive microbiology
- CSF PCR still awaited: however NHSGGC have reported it would be unusual to be +ve in light of negative micro

The plan is to await CSF PCR result and then close the IMT. Next planned update will be once the results are available and an IMT is either held or closed.

Sandra/Alistair: please advise of any errors or omissions

Annette

From: RANKIN, Annette (NHS NATIONAL SERVICES SCOTLAND) [redacted]
Sent: 02 July 2020 15:39
To: Allan, Lara [redacted]; Birch, Jason [redacted]; Burgess, Elizabeth [redacted]; CAIRNS, Shona (NHS NATIONAL SERVICES SCOTLAND) [redacted]; DODD, Susie (NHS NATIONAL SERVICES SCOTLAND) [redacted]; Rachael.Dunk [redacted]; FRENCH, Sofie (NHS NATIONAL SERVICES SCOTLAND) [redacted]; Grant McPherson [redacted]; HOOKER, Emma (NHS NATIONAL SERVICES SCOTLAND) [redacted]; HPSINFECTIONCONTROL (NHS NATIONAL SERVICES SCOTLAND) <nss.hpsinfectioncontrol@nhs.net>; IMRIE, Laura (NHS NATIONAL SERVICES SCOTLAND) [redacted]; Ives, Josephine [redacted]; LOCKHART, Michael (PUBLIC HEALTH SCOTLAND) [redacted]; MACDONALD, Jennifer (NHS NATIONAL SERVICES SCOTLAND) [redacted]; MCDAID, Kirsty (NHS NATIONAL SERVICES SCOTLAND) [redacted]; MEDIARELATIONS (NHS NATIONAL SERVICES SCOTLAND) [redacted]; Morris, Keith [redacted]; MULLINGS, Abigail (NHS NATIONAL SERVICES SCOTLAND) [redacted]; RANKIN, Annette (NHS NATIONAL SERVICES SCOTLAND) [redacted]; Ross, Elaine [redacted]; Shepherd, Lesley [redacted]; THOULASS, Janine (PUBLIC HEALTH SCOTLAND) [redacted]; WALLACE, Heather (NHS NATIONAL SERVICES SCOTLAND) [redacted]; WEAVING, Paul (NHS NATIONAL SERVICES SCOTLAND) [redacted]; Wright, Billy [redacted]

Cc: Devine, Sandra [redacted]; Bowskill Gillian (NHS GREATER GLASGOW & CLYDE) [redacted]; Leanord Alistair (NHS GREATER GLASGOW & CLYDE) [redacted]; STORRAR, Ian (NHS NATIONAL SERVICES SCOTLAND) [redacted]
Subject: HIIAT Green ward 6a NHSGGC

Dear all,

National ARHAI Scotland have received a HIIORT following an IMT from NHSGGC.

In summary:

- 1 child reported as having a positive reaction to a Cryptococcus antigen test.
- Weak positive Cryptococcus result isolated from plasma.
- CSF Cryptococcus antigen reported as negative.
- Samples have been sent to Bristol mycology reference laboratory.

The sample was taken as part of semi routine screening following admission to ward 6A (paediatric haemato-oncology) QEUH with pyrexia. The child has been receiving intensive [redacted] in ward 6A since [redacted].
The child is reported as being well (in relation to this result)

Investigations/control measures

- Plant rooms will be inspected by microbiologist.
- Results awaited from Mycology Reference Lab.
- Antifungal prophylaxis will remain unchanged at present

Hypothesis

- Environmental, either community or hospital.
- Latency infection.
- False Positive.

Communications:

- Family informed of result by clinical staff.
- Clinical team will provide an update for ward staff.

HIIAT assessed as GREEN

IMT will reconvene when results from Bristol are available. Next planned update following IMT

Alistair/Sandra/Gillian: please advise of any errors or omissions

[redacted]

Annette Rankin
Nurse Consultant Infection Control

NHS National Services Scotland
Health Protection Scotland
4th Floor
Meridian Court

5 Cadogan Street
Glasgow
G2 6QE
T: [redacted]
Reception: [redacted]
www.hps.scot.nhs.uk/

From: Bowskill, Gillian
Sent: 09 July 2020 09:14
To: HPSINFECTIONCONTROL (NHS NATIONAL SERVICES SCOTLAND)
Cc: Leanord Alistair (NHS GREATER GLASGOW & CLYDE); Devine, Sandra; Joannidis Pamela (NHS GREATER GLASGOW & CLYDE)
Subject: 2020-07-09 (09.14 GBowskill-HPSICT) Update HIIORT Ward 6a RHC/QEUH -att
Attachments: HIIORT 09.07.20.docx

Follow Up Flag: Follow up
Flag Status: Completed

Morning,

Updated HIIORT attached for Ward 6a RHC/QEUH – incident closed.

Kind Regards

Gillian

Gillian Bowskill
Lead Nurse Infection Prevention & Control South Paediatrics
Royal Hospital for Children
[redacted]
Mobile: [redacted]

A48408984

From: Steele, Tom
Sent: 13 August 2020 14:37
To: Bustillo, Sandra
Subject: Re: IMT Ward 6A: Draft Notes of Meeting - 2 July 2020

Thanks, looks like a positive outcome for all.

Sent from my iPhone

On 13 Aug 2020, at 12:21, Bustillo, Sandra [redacted] wrote:

For information.

Sandra

From: Rodgers, Jennifer
Sent: 13 August 2020 12:15
To: 'WALLACE, Angela (NHS FORTH VALLEY)' [redacted]
Cc: Redfern, Jamie [redacted]; Mcguire, Margaret [redacted]; Bustillo, Sandra [redacted]; Devine, Sandra [redacted]; Dick, Lorraine [redacted]; Leanord, Alistair [redacted]; Davidson, Scott [redacted]
Subject: RE: IMT Ward 6A: Draft Notes of Meeting - 2 July 2020

Hi All,

By way of update, Jamie, Dr Sastry and I have now met with the family of [redacted] who are currently in ward 6A. Overall the meeting went well.

We opened the meeting by asking what the mums main concerns were and what she wished to get out of the meeting. Mum stated her issues were about the recent media regarding Cryptococcus infections and whether [redacted] had got the infection from the hospital.

We discussed in detail the IMT process, the range of people involved and the investigations taken including air sampling. We explained none of these samples indicated Cryptococcus was present in the areas [redacted] had been within the site. JS explained that the antigen test by nature was not the same as a positive infection result however may have indicated early infection so therefore the clinical decision was to treat promptly in the event that was the case. He also noted Cryptococcus is common in the environment in general meaning exposure could have been anywhere.

Mum expressed thanks for the clinical treatment and the discussion.

I apologised for the additional stress this had caused the family to which she thanked me.

[redacted] We encouraged them to speak to either Dr Sastry or request to speak to Jamie or I if they had any further questions or concerns and we would do our best to resolve them and would be available for further face to face meetings.
The family were satisfied with this approach.

Many thanks

Jen

Jennifer Rodgers
Chief Nurse
Children, Neonates and Young People
Royal Hospital for Children
South Glasgow Hospitals
1345 Govan Road
Glasgow
G51 4TF

Mobile: [redacted]

PA Janice Hackett Tel: [redacted]

[redacted]

The best way to reduce harm ... is to embrace wholeheartedly a culture of learning

From: WALLACE, Angela (NHS FORTH VALLEY) [redacted]
Sent: 13 August 2020 09:58
To: Rodgers, Jennifer [redacted]

Cc: Redfern, Jamie [redacted]; Mcguire, Margaret [redacted]; Bustillo, Sandra [redacted]; Devine, Sandra [redacted]; Dick, Lorraine [redacted]; Leanord, Alistair [redacted]; Davidson, Scott [redacted]
Subject: [ExternaltoGGC]Re: IMT Ward 6A: Draft Notes of Meeting - 2 July 2020

Hi Jen
Many thanks looks like we need to agree the detail re the positive result
I think that's pretty key to the next steps
I hope Al might help us here may have missed him as he was heading off on leave
A

On 13 Aug 2020, at 09:28, Rodgers, Jennifer [redacted] wrote:

> Moring all,
>
> Please see attached final note from the IMT and follow up / IMT closure email.
>
> We will speak to Jairam at the earliest opportunity today and follow up with a meet with family.
>
> Many thanks
>
> Jen
>
> ---
>
> **From:** WALLACE, Angela (NHS FORTH VALLEY) [redacted]
> **Sent:** 13 August 2020 07:22
> **To:** Redfern, Jamie [redacted]
> **Cc:** Mcguire, Margaret [redacted]; Bustillo, Sandra [redacted]; Devine, Sandra [redacted]; Dick, Lorraine [redacted]; Rodgers, Jennifer [redacted]; Leanord, Alistair [redacted]; Davidson, Scott [redacted]
> **Subject:** [ExternaltoGGC]Re: IMT Ward 6A: Draft Notes of Meeting - 2 July 2020
>
> Hi all good morning
> Jamie thanks re the positives that is my understanding but await confirmation too
> Re the 2019 I am happy to discuss of course and it makes sense.. I am just trying to see if that helps this situation which is about this mum and dad about their child now but happy to be guided on that one of course
> A
>
> On 13 Aug 2020, at 06:30, Redfern, Jamie [redacted] wrote:
>
> > Hi Angela
> > The reference to 2019 IMT is in my mind because this is when we re-opened the unit to all admissions, it is when we triggered the CRG and when we started achieving excellent infection control results. It was also the trigger point for when we reviewed / changed our prophylaxis policy although that took some time to fully implement.
> > Happy to discuss though. Cheers
> > Jamie
> >
> > Get Outlook for iOS
> >
> > ---
> >
> > **From:** WALLACE, Angela (NHS FORTH VALLEY) [redacted]
> > **Sent:** Wednesday, August 12, 2020 9:15:42 PM
> > **To:** Redfern, Jamie [redacted]
> > **Cc:** Mcguire, Margaret [redacted]; Bustillo, Sandra [redacted]; Devine, Sandra [redacted]; Dick, Lorraine [redacted]; Rodgers, Jennifer [redacted]; Leanord, Alistair [redacted]; Davidson, Scott [redacted]
> > **Subject:** [ExternaltoGGC]Re: IMT Ward 6A: Draft Notes of Meeting - 2 July 2020
> >
> > Hi everyone
> > Thanks for this Jamie really grateful to you.
> > I await my colleagues who were at the IMT to respond to the fine detail but from my understanding this is broadly accurate.
> > I am unsure about linking this IMT to the 2019 one I will need to be guided by colleagues on that issue and handling. But in relation to this child this seems correct.
> > Jen, Mags and Sandra may wish to advise on the plan to support and ensure the communication with the child's parents and mum in particular are handled with care.
> > We do need an agreed position first thing in the am before start of play as Jamie suggested to prevent any challenge re our timing i think.
> > Happy to discuss and help in anyway
> > Kindest
> > A
> >
> > On 12 Aug 2020, at 19:26, Redfern, Jamie [redacted] wrote:
> >
> > > Hi all
> > >
> > > If I am reading all the paperwork generated around this case correctly
> > >
> > > 1. Child has a disease which is unlikely of generating this type of infection.

2. [redacted] has now been confirmed a positive case for this infection although at time around IMT there was uncertainty to this.
3. Whether [redacted] is positive for infection now is unlikely (although in [redacted] blood sample [redacted] has no fever) but continues to be treated on anti fungal prophylaxis for now as if [redacted] is positive. This is on robust microbiology advice after discussion with consultant.
4. There was no evidence we could find to suggest this is a hospital acquired infection. This includes physical review by microbiology and estates colleagues jointly of all plant rooms supporting wards child has been admitted to (3rd floor, PiC, CDU and Wards 6a/4b).
5. Point 4 and fact there has been no additional cases since IMT in early July is why there has been no follow up IMT. HPS are in agreement with this position.
6. Generally all evidence since closing IMT in Autumn 2019 confirms excellent performance for both CLABSI and GNB infection rates. There remains robust and routine scrutiny on confirming / maintaining this general position - ref CRG.
6. Mum is aware of points 1 to 6 but still unhappy overall and thinks [redacted] has an infection that was contracted in RHC. She remains unconvinced hospital is safe.

It would be good to clarify this is accurate assessment ahead of the meeting with mum and doctor Sastry.
Would it be possible to have a Teams chat with any who are available first thing tomorrow morning. Or even email confirmation with any salient points I've missed. As said I will speak to JRo tomorrow first thing.

Jamie

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From: WALLACE, Angela (NHS FORTH VALLEY) [redacted]
Sent: Wednesday, August 12, 2020 5:54:13 PM
To: Mcguire, Margaret [redacted]; Bustillo, Sandra [redacted]
Cc: Devine, Sandra [redacted]; Redfern, Jamie [redacted]; Dick, Lorraine [redacted]; Rodgers, Jennifer [redacted]; Leanord, Alistair [redacted]; Davidson, Scott [redacted]
Subject: [ExternaltoGGC]RE: IMT Ward 6A: Draft Notes of Meeting - 2 July 2020

Thanks Both,
I had a helpful chat with Al and I think we are able to provide the clarity in relation to the diagnostic process and supporting clinical processes. The IMT was a moment in time and we heard clearly on our multi speciality meeting this week we heard a positive update from our consultant micro colleagues.
As Mags suggests an urgent meeting or virtual discussion that we agree the narrative, ensure any updates since the IMT are documented and communicated and this perhaps form the basis of the support and discussions required between the clinical teams and the family.
What would colleagues prefer as an urgent action, i think if i am understanding correctly that the need to update Dr Sastry and the family is pretty immediate?
Happy to discuss as always
Kindest
Angela

From: Mcguire, Margaret [redacted]
Sent: 12 August 2020 16:22
To: Bustillo Sandra (NHS GREATER GLASGOW & CLYDE)
Cc: WALLACE, Angela (NHS FORTH VALLEY); Devine, Sandra; Redfern James (NHS GREATER GLASGOW & CLYDE); Dick Lorraine (NHS GREATER GLASGOW & CLYDE); Rodgers Jennifer (NHS GREATER GLASGOW & CLYDE); Leanord Alistair (NHS GREATER GLASGOW & CLYDE); Davidson, Scott
Subject: Re: IMT Ward 6A: Draft Notes of Meeting - 2 July 2020

Agree the importance of meeting urgently as we need agreed clarity about the position in order to support and inform the families

Sent from my iPhone

On Aug 12, 2020, at 3:44 PM, Bustillo, Sandra [redacted] wrote:

> Thank you Angela. I understand that the family are very anxious about their child and there is to be a meeting with the child's consultant tomorrow at 11am so I would be keen for an urgent meeting as suggested to review the situation.
>
> Thanks
>
> Sandra

From: WALLACE, Angela (NHS FORTH VALLEY) [redacted]
Sent: 12 August 2020 15:37
To: Bustillo, Sandra [redacted]; Devine, Sandra [redacted]; Redfern, Jamie [redacted]; Dick, Lorraine [redacted]; Mcguire, Margaret [redacted]; Rodgers, Jennifer

[redacted]
Cc: Leanord, Alistair [redacted]; Devine, Sandra [redacted]; Davidson, Scott [redacted]
Subject: [ExternaltoGGC]RE: IMT Ward 6A: Draft Notes of Meeting - 2 July 2020

Dear all,

Thank you for including me in this discussion. I have taking the liberty for ease to include Sandra, Alistair and Scott.

I appreciate there may be conversations happening at the moment, I understanding that the Child parents may be raising concerns at this time.

It feels to me that we need an urgent discussion and plan that we might support and understand the concerns being raised by Dr.S that our IMT minutes are not accurate and that it would seem that we have a family who are looking for urgent clarity.

Jamie and Jennifer – I appreciate that you may have all of this in hand, however I wondered that we might re-group and managed and support the developing situation.

I look forward to your urgent replies.

Kindest regards

Angela

From: "Redfern, Jamie" [redacted]
Date: 12 August 2020 at 12:48:11 BST
To: "Bustillo, Sandra" [redacted], "Dick, Lorraine" [redacted], "Mcguire, Margaret" [redacted]
Cc: "Rodgers, Jennifer" [redacted]
Subject: Fwd: IMT Ward 6A: Draft Notes of Meeting - 2 July 2020

So see below
First thing
[redacted] Most discussion is via mum. [redacted] Child likely to be discharged [redacted] Jairam is going to suggest to mum she comes in tomorrow and together me and him discuss [redacted] / infection with her. I've stressed that we couch this she is not alarmed and we are just trying to clarify matters. Not for her to feel we are going to be heavy handed or anything. I will discuss this tomorrow am with JRo.
Second thing
The IMT minutes as you will see below are inaccurate.
Child was symptomatic. IMT members were informed Child was not symptomatic. Also there was no CT scan completed as reported. I'm not a. Sure why there was inaccuracies of this nature b. What clinical significance this has on IMT decision making and c. Whether at least minute was updated following this email from Dr Sastry. Note he was on holiday during IMT and clinical link to IMT was Dr. Murphy. Dr Murphy is now on leave.
Linked to this is what was said to the family. Dr Sastry has confirmed that mum was made aware of the infection and the seriousness of it and how would be treated. He does not know what was said to mum around how child obtained infection.
Third thing
Child was initially felt to be a false positive case but Dr Sastry says this not accurate. Is confirmed positive. He also says that child now has crypto coccus in blood but no fever. Child continues to be on anti fungals at advice of microbiologist.

I will confirm when I have a time to speak to mum.

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From: Sastry, Jairam [redacted]
Sent: Wednesday, August 12, 2020 11:57:51 AM
To: Redfern, Jamie [redacted]
Subject: Fw: IMT Ward 6A: Draft Notes of Meeting - 2 July 2020

From: Sastry, Jairam
Sent: 08 July 2020 09:40
To: Devine, Sandra [redacted]; Murphy, Dermot (NHSmail) [redacted]; Lang, Ann [redacted]; Bowskill, Gillian [redacted]; Hill, Kevin [redacted]; Leanord, Alistair [redacted]; Rodgers, Jennifer [redacted]; RANKIN, Annette (NHS NATIONAL SERVICES SCOTLAND) [redacted]; Joannidis, Pamela [redacted]; Davidson, Scott [redacted]; Gibson, Brenda [redacted]; Rolls, Gael [redacted]; Murphy, Dermot [redacted]; Mathers, Alan [redacted]; Cook, Claire [redacted]; Somerville, Emma [redacted]; Howat, Angela [redacted]; Bustillo, Sandra [redacted]; 'Jenny.Copeland [redacted]
Cc: HOOD, John (NHS GREATER GLASGOW & CLYDE) [redacted]
Subject: RE: IMT Ward 6A: Draft Notes of Meeting - 2 July 2020

Dear Sandra
Thanks for including me.
[redacted] had respiratory distress briefly on [redacted] June with increase respiratory rate, stridor with oxygen requirement of 2L/min. [redacted] X ray showed ground glass appearance suggestive of opacity –infection. However it is difficult to say what was it due to? [redacted] has had similar episodes following previous febrile neutropenia episodes. However this time 4 different tests are positive for Cryptococcal antigen both here and in Bristol.

[redacted]

I have been in discussion with micro team regarding this for a strategy.

kind regards
Dr. Jairam Sastry
Consultant Paediatric Oncologist
Royal Hospital for Children, Glasgow
Honorary Senior clinical Lecturer,
Glasgow University, School of Medicine
Ground floor, Office block
QEUH, Glasgow
[redacted] (sec)

From: Devine, Sandra
Sent: 08 July 2020 09:17
To: Murphy, Dermot (NHSmail) [redacted]; Lang, Ann [redacted]; Bowskill, Gillian [redacted]; Hill, Kevin [redacted]; Leanord, Alistair [redacted]; Rodgers, Jennifer [redacted]; RANKIN, Annette (NHS NATIONAL SERVICES SCOTLAND) [redacted]; Joannidis, Pamela [redacted]; Davidson, Scott [redacted]; Gibson, Brenda [redacted]; Rolls, Gael [redacted]; Murphy, Dermot [redacted]; Mathers, Alan [redacted]; Cook, Claire [redacted]; Somerville, Emma [redacted]; Howat, Angela [redacted]; Bustillo, Sandra [redacted]; 'Jenny.Copeland [redacted]; Sastry, Jairam [redacted]
Cc: HOOD, John (NHS GREATER GLASGOW & CLYDE) [redacted]
Subject: RE: IMT Ward 6A: Draft Notes of Meeting - 2 July 2020

Hi Ann

Can you update please. We can wait for any additional comments and send out an updated version on Friday.
Thanks
Sandra

Sandra Devine
Acting Infection Control Manager
NHS Greater Glasgow & Clyde
[redacted] (PA Ann Lang)
[redacted]

If you require an urgent response can I please ask you to telephone me as I am often in meetings and away from the office and unable to check voicemail until the end of the day. Thank you

---

From: MURPHY, Dermot (NHS GREATER GLASGOW & CLYDE) [redacted]
Sent: 08 July 2020 09:12
To: Lang, Ann [redacted]; Devine, Sandra [redacted]; Bowskill, Gillian [redacted]; Hill, Kevin [redacted]; Leanord, Alistair [redacted]; Rodgers, Jennifer [redacted]; RANKIN, Annette (NHS NATIONAL SERVICES SCOTLAND) [redacted]; Joannidis, Pamela [redacted]; Davidson, Scott [redacted]; Gibson, Brenda [redacted]; Rolls, Gael [redacted]; Murphy, Dermot [redacted]; Mathers, Alan [redacted]; Cook, Claire [redacted]; Somerville, Emma [redacted]; Howat, Angela [redacted]; Bustillo, Sandra [redacted]; 'Jenny.Copeland [redacted]; Sastry, Jairam [redacted]
Cc: HOOD, John (NHS GREATER GLASGOW & CLYDE) [redacted]
Subject: [ExternaltoGGC]Re: IMT Ward 6A: Draft Notes of Meeting - 2 July 2020

Thanks for this:
A good piece of work.

Some comments on the opening paragraph, changes in red:
Dr Murphy agreed that the patient is well and already had a conversation with the parents to say that the patient could go home once he has had 7 days of intravenous fluconazole with a further 7 day oral course as there is no longer cause for clinical concern . He said there is no clinical evidence of *Cryptococcus* but the patient is being treated as if they have this. Dr Murphy stated that on advice from microbiology a lumber puncture to obtain CSF was also carried out on [redacted]. Initial microbiology of the CSF was negative. A sample of CSF was sent to the Mycology reference laboratory, Bristol for testing.
Sandra Devine noted with regards to the investigation the patient had a CT scan of their chest and this was clear. Dr Murphy commented that the patient was otherwise well except for a spike in temperature on [redacted] and had no respiratory symptoms.

Dr Dermot Murphy
Consultant Paediatric Oncologist
Royal Hospital for Children, Glasgow
Deg phone: [redacted] if phoning from outside)

NB there are numerous telephone blackout spots within the hospital and office block. If you are unable to contact me directly, please phone my secretary. If your enquiry is urgent ask to speak to the on call Haemato-oncology registrar.

Secretary: Ann Hagan
Tele: [redacted]
Email: [redacted]

From: Lang, Ann [redacted]
Sent: 08 July 2020 08:53
To: Devine, Sandra; Bowskill Gillian (NHS GREATER GLASGOW & CLYDE); Hill Kevin (NHS GREATER GLASGOW & CLYDE); Leanord Alistair (NHS GREATER GLASGOW & CLYDE); Rodgers Jennifer (NHS GREATER GLASGOW & CLYDE); RANKIN, Annette (NHS NATIONAL SERVICES SCOTLAND); Joannidis Pamela (NHS GREATER GLASGOW & CLYDE); Davidson, Scott; Gibson, Brenda; Rolls Gael (NHS GREATER GLASGOW & CLYDE); Murphy, Dermot; alan.mathers[redacted]; Cook, Claire; Somerville, Emma; Howat Angela (NHS GREATER GLASGOW & CLYDE); Bustillo Sandra (NHS GREATER GLASGOW & CLYDE); 'Jenny.Copeland[redacted]
Cc: HOOD, John (NHS GREATER GLASGOW & CLYDE)
Subject: IMT Ward 6A: Draft Notes of Meeting - 2 July 2020

Good morning

Please find attached the draft notes of the meeting held on 2nd July 2020.

Can you please let me know if you have any comments regarding these.

Regards

Ann

Ann Lang
PA/Data Manager to Acting Infection Control Manager
Office Block
Level 2
Queen Elizabeth University Hospital

[redacted]
email: [redacted]

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<mime-attachment>

Incident Management Team
Ward 6A

Notes of Meeting
via
Microsoft Teams

2nd July 2020 at 10.30am

Present:

Professor Alastair Leanord (Chair)	Acting Lead Infection Control Doctor
Sandra Devine	Acting Infection Control Manager
Jen Rodgers	Chief Nurse, Paediatrics and Neonates
Dr Dermot Murphy	Consultant Oncologist
Dr Scott Davidson	Deputy Medical Director, Acute
Gillian Bowskill	Acting Lead Nurse, South Paediatrics
Pamela Joannidis	Acting Associate Nurse Director IPC
Gael Rolls	Senior Charge Nurse
Dr Brenda Gibson	Consultant Haematologist
Claire Cook	Senior Communications Officer
Kevin Hill	Director
Sandra Bustillo	Director of Communications and Public Engagement
Dr John Hood	Consultant Microbiologist
Dr Alan Mathers	Chief of Medicine, W&C
Annette Rankin	Nurse Consultant, HPS
Angela Howat	Senior Charge Nurse
Jenny Copeland	Principal Lead Organisation Development
Angela Howat	Senior Charge Nurse

Item		Action
1.	**Introduction**	
	Professor Alistair Leanord welcomed everyone to today's meeting.	
2.	**Reminder of Confidentiality**	
	The group were reminded of the need for patient confidentiality.	
3.	**Incident Update**	
	• General situation statement	
	There has been a positive *Cryptococcus* antigen test result for 1 patient. Gillian Bowskill provided a summary of the patient case. A [redacted] child was admitted to RHC on [redacted] 2020 and **r**eceiving [redacted]. The patient was discharged on [redacted] 2020 and following this the patient had several short and day admissions. The patient has recently completed their [redacted] and after every cycle the patient developed a temperature. This was the case on this admission.	

Item		Action
	• Patient report	
	A routine Cryptococcus antigen screen was carried out on the [redacted] June and reported as a faint line, considered to be positive. Gillian Bowskill informed the meeting that the patient is well and has been for several days. Dr Murphy agreed that the patient is well and already had a conversation with the parents to say that the patient could go home once he has had 7 days of intravenous fluconazole with a further 7 day oral course as there is no longer cause for clinical concern. He said there is no clinical evidence of *Cryptococcus* but the patient is being treated as if they have this. Dr Murphy stated that on advice from microbiology a lumber puncture to obtain CSF was also carried out on [redacted]. Initial microbiology of the CSF was negative. A sample of CSF was sent to the Mycology reference laboratory, Bristol for testing. Sandra Devine noted with regards to the investigation the patient had a CT scan of their chest and this was clear. Dr Murphy commented that the patient was otherwise well except for a spike in temperature on [redacted] and had no respiratory symptoms.	
	• Microbiology report	
	Professor Leanord said there were 3 serum samples from lateral flow test using neat serum. All three were negative by latex agglutination. This was taken as part of a semi routine screening following admission with pyrexia. The samples have been sent to Prof. Elizabeth Johnson, Director, Mycology Reference Laboratory, Public Health England at Bristol and she will run all 3 samples today for further testing to detect if there is any increase in positivity over time. The Aspergillus plasma result was sent to the Virus Lab and was positive for pan-Aspergillus and negative by PCR for A. fumigatus. Professor Leanord said that this IMT is ahead of the diagnostic results at this stage and he needs clarity from the Reference Lab in terms of positivity and the PCR result. He is hoping to have the results either today or by Friday.	
	• Other relevant reports	
	Please note that Dr Hood, in DRAFT, in the following paragraphs below, has changed or added, where he thought it appropriate to make it more clear /understandable and offer appropriate explanations where required.	
	Routine air sampling had been carried out in the QEUH and RHC in 2019 under the instruction of Dr Hood but routine sampling had been suspended in early 2020, due to COVID-19.	

Item		Action
	Professor Leanord informed that he has looked at Cryptococcus antigen tests and the rates over the last two years. 376 tests of Cryptococcus were carried out and the majority were negative. This was reassuring in itself. Dr Hood provided an update on the air sampling that has taken place and said that over 3,500 air samples have been taken from outside air, air from the plant rooms and inside air of the hospital particularly in Wards 4B, 4C and 6A. He reported that *Cryptococcus neoformans* has never been grown in either outside or inside air, from this site. Dr Hood had compared total fungal air counts taken last year from patient rooms in Wards 4B, 6A and 4C and also compared them with previous air counts taken from rooms in the top floor of the Beatson, in the last 2 years of its operation as a BMTU. This was an adult BMTU with both HEPA filtered air and 'protective isolation'. This work compared the total number of sample counts of 0.0 for fungi taken in each of the above Wards. As expected the Beatson had zero counts in 79% of samples, which is pretty good. In Ward 4B the counts were not as good with zero counts of 62% of samples. Ward 4C drops to 40% of samples and Ward 6A dropping to 20% of samples with zero counts. Explanations for the above findings include (but not exclusively) : At the bottom of the corridor at Ward 4B (opposite one of the entrances to 4C) Dr Hood reported that, in certain conditions, when the door to 4C opens then the air, which is less well filtered than that of 4B, can then go into the bottom of Ward 4B. Air sampling results support this. Mitigation of sealing this door, as much as was permitted by the Fire regulations, was undertaken but it is an example of the huge complexity of airflow around the QEUH and its 'lack of control' around critical areas. Similarly, the configuration of the doors at the intersection outside the main entrance into Ward 6A (door to 6B and door to lift area) is not great as depending on the configuration of these doors (open or closed) air can be pulled into 6A from both 6B and the lift area (note the piston-like effect of lift in moving air from the atrium and other levels of the hospital). Again the air sampling results for 6A can, at least in part, be explained by the above. Dr Hood agreed to liaise with Estates to look at the plant rooms but informed the group that he had previously looked at plant rooms (many times) and indeed probably every Plant room on this site, last year. He also reported that he had inspected previously the air handling units (AHUs) as part of his review to ascertain if the Plant room air could have been the source of spores of *Cryptococcus neoformans* (assuming that they were possibly present in the first place) during a final filter change on that AHU. The theory being that this allowed Plant room air to gain access to the duct without the final filter being in place and so potentially getting to the patient. Firstly there were **No** patient cases present in a ward at a time that their relevant AHU had been shut down for a Filter change.	**JH**

Item		Action
	More importantly, when the AHU was shut down and the final filter was removed, rather than the Plant room air being pulled into the duct downwards (minus said filter) towards the patients - the air actually **came up** from the duct below, at some pressure, **not down.** This is known as the 'chimney effect.' Therefore the chance of Plant room air getting into the ventilation system and thence to the patient cases by this postulated route, **is highly highly unlikely**. Dr Hood also commented that the risers (electrical or mechanical services) should be sealed off at the top and bottom (both in plant rooms) so that unfiltered air cannot get into the wards e.g. via the IPS panels. He highlighted that one point to note is that Wards 4C and 6A have F9 filters (previously F7s) which are not HEPA filters. HEPAs will remove 99% of small particles as opposed to, probably, about 80% with the F9. Dr Hood commented that it's extremely difficult to grow *Cryptococcus neoformans* from air. He also informed the group that the incubation period for Cryptococcus neoformans is unknown and that latency/dormancy certainly occurs, as is documented in the literature. Professor Leanord commented that if a patient has not got prior *Cryptococcus* infection that there is a 30% false positivity rate using lateral flow antigen testing. From a clinicians perspective Dr Mathers advised that we should wait until we have all the results before making any major decisions. He said that we need to have a sequence of diagnostic tests that the clinician initiates. In PICU they have a specific regime and he thought an algorithm would be helpful to make it clear for clinicians to have a standard set of diagnostic tests. Dr Murphy stated that he feels they have more close contact with Microbiology colleagues than any other unit and the test is normally discussed with two people i.e. Consultant and Microbiology.	
	• Duty of Candour	
	This will be discussed with the patient's family.	
	• Hypothesis	
	- Environmental – community or hospital - Testing – false positive - Activation of previous latent infection	
4.	**Risk Management/Control Measures**	
	• Patients	
	An inspection of the plant rooms will be carried out by Dr Hood and if there is a concern more air sampling can be carried out. Although it was noted that the patient had been in a number of areas over several months.	**JH**

Item		Action
	• General	
	It was agreed that the current prophylaxis regime has not changed and should not be changed at this stage.	
	• Public Health	
	Public Health were invited to the meeting but no representative was available.	
	• Staff	
	Staff will be updated on the IMT.	
5.	**Further Investigation**	
	Dr Hood to look at the plant rooms.	**JH**
6.	**Healthcare Infection Incident Assessment Tool (HIIAT)**	
	The situation was assessed using the Hospital Infection Incident Assessment Tool (HIIAT) and was classified as GREEN. Severity of illness – MODERATE Services – MINOR Risk of Transmission – MINOR Public Anxiety – MINOR Annette Rankin informed that a HIORT will need to be completed and sent to HPS. Gillian Bowskill agreed to do this.	**GB**
7.	**Communications**	
	• Advice to public	
	It was agreed that as the HIIAT is classified as green and that this will be reviewed if results indicate that another IMT is required.	
	• Advice to professionals	
	Jen Rogers asked if discussions can take place with staff in the unit. Dr Murphy said he was happy to discuss this with medical colleagues and said he will discuss some wording with Jen Rogers. Kevin Hill stated that they will need to agree what is stated is to try and reassure staff. Dr Gibson stated that there needs to be assurance to staff that there is no change to prophylaxis.	**DM/JR**
	• Media	
	It was agreed that no media statement is required at the present time.	

Item		Action
	• HPS / SG HAI Policy Unit (HIIORT)	
	Gillian Bowskill will complete the HIORT and forward this to HPS.	**GB**
8.	**AOCB**	
	Nil to update.	
9.	**Date & time of next meeting**	
	It was agreed to wait until the further testing had been carried out before rearranging another IMT.	

SCOTTISH HOSPITALS INQUIRY

Bundle of documents for Oral hearings commencing from 19 August 2024 in relation to the Queen Elizabeth University Hospital and the Royal Hospital for Children, Glasgow

Bundle 19 – Documents referred to in the Quantitative and Qualitative Infection Link expert reports of Sid Mookerjee, Sara Mumford and Linda Dempster

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