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 21 - Volume 1

Expert Reports by Sid Mookerjee, Sara Mumford, Linda Dempster, Jimmy Walker, Andrew Poplett and Allan Bennett

SCOTTISH HOSPITALS INQUIRY

Table of Contents

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Expert Report

Quantitative analysis undertaken to understand the association between the built environment and rates of gram-negative and fungal bloodstream infections at the Schiehallion unit between the years 2015 and 2022.

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Expert Witness

Data of submission: 9 May 2024

1. Introduction

1.1. The Expert Group was appointed by the Chair of the Scottish Hospitals Inquiry, Lord Brodie PC KC. The members of the group are instructed to prepare a report on several matters relating to the incidence of healthcare associated infections caused by environmental organisms at Queen Elizabeth University Hospital, Glasgow and the Royal Hospital for Children, Glasgow[1].

1.2. The purpose of this report is to provide evidence and expert opinion on matters which may assist the Chair in fulfilling the Inquiry's Terms of Reference, specifically it addresses the question as to whether there is a link, and if so in what way and to what extent, between patient infections and identified unsafe features of the water and ventilation systems.

1.3. As a summary of my professional experience, qualifications, and expertise on the subject at hand – I am a hospital-epidemiologist and healthcare systems specialist, with over 12 years' experience in the public and private health care sector. I hold degrees in biochemistry, health promotion, public health policy, and public health epidemiology, acquired through bachelor's and master's degree programmes. Key highlights from my portfolio of work include – Operational lead and epidemiologist at Imperial College Healthcare NHS Trust, and more recently at University Hospitals Sussex, an academic at Imperial College London's Health Protection Research Unit specialising in healthcare associated infections and antimicrobial resistance, consultant to the Department of Health Fleming Fund unit on healthcare associated infections and antimicrobial resistance, and expert consultant to European Joint Programme initiative on antimicrobial resistance project on epidemiology and healthcare associated infection surveillance. My academic publications over the past decade have focused on healthcare associated infection transmission dynamics, in particular the role of patient movement, characteristics of multi-drug resistant bacteria and the impact of the environment on disease incidence and prevalence. I have lectured on the topic of hospital epidemiology, global health, and

[1] SHI letter of instruction to Dr Mumford, 4 October 2022

statistics at national and international conferences and as part of the junior doctor teaching programme at Imperial College London. I am a member of the Royal Society of Public Health (RSPH) where I am a Fellow.

2. Explanation of the issues as instructed by the Inquiry.

2.1. The Scottish Hospitals Inquiry has prioritised four key questions for the Expert Group, namely:

2.1.1. Key Question (1): From the point at which there were patients within the QEUH/RHC, was the water system (including drainage) in an unsafe condition, in the sense that it presented an additional risk of avoidable infection to patients?

2.1.2. Key Question (2): From the same point and in the same way was the ventilation system in an unsafe condition?

2.1.3. Key Question (3): In the same sense, are these systems now in a safe condition?

2.2. Key Question (4): Is there a link, and if so in what way and to what extent, between patient infections and identified unsafe features of the water and ventilation systems?

2.3. This report sits alongside the 'Qualitative report' [2] by Dr Sara Mumford and Linda Dempster and 'Review of the water system, by Dr Walker[3] and the review of ventilation systems by Allan Bennett[4].

2.4. Declaration of understanding

2.4.1. I am clear that my duties include assisting the Inquiry in an impartial manner.

2.4.2. I acknowledge and understand that it is my duty, both in preparing reports and in giving oral evidence, to assist the inquiry on matters within my field of expertise and that I will continue to comply with that duty.

[2] Qualitative report. Dr Sara Mumford and Linda Dempster
[3] Review of the NHS Greater Glasgow and Clyde: Queen Elizabeth University Hospital/Royal Hospital for Children water and waste-water system from the point at which patients occupied the site in 2015. Dr JT Walker
[4] Allan Bennet – Expert Report for SHI

2.4.3. I have no connection, personal or otherwise, to any core participant in the inquiry other than that I have declared in his report.

2.4.4. I declare that I have no financial or economic interest in the outcome of the inquiry.

2.4.5. I acknowledge and accept the necessity of expressing an independent opinion which is the product of my own consideration and research and that I have complied with the duty to do so.

2.4.6. I acknowledge the duty to set out all material facts, assumptions, methodology or other matters upon which my views and opinions are based, including such matters as may detract from the opinion formed, and that I have complied with that duty.

2.4.7. I acknowledge the duty to address only areas within my own area of expertise and that I have made it clear when a particular question or issue falls outside my expertise and that I have complied with that duty.

2.4.8. I acknowledge, understand, and accept the obligation to state if my opinion is not properly researched because insufficient data are available and to give an indication that the opinion is no more than provisional, and have done so in my report where appropriate.

2.4.9. I acknowledge, understand, and accept the obligation to indicate if any opinion I have expressed is qualified, or subject to revision, and have done so in my report where appropriate.

2.4.10. I acknowledge, understand, and accept that I should, at the earliest opportunity after completing the report, indicate if, for any reason, including as a result of discussions with other experts, my views have been altered or the report requires any correction or qualification, and if so, in what area, and I shall comply with that duty.

3. **Glossary of terms**

Association (epidemiology definition)	An association is defined as an exposure and outcome occurring together more or less often than would be expected by chance.
Antimicrobial resistance	The development by a disease-causing microbe, through mutation or gene transfer, of the ability to

	survive exposure to an antimicrobial agent that was previously an effective treatment.
ARHAI Scotland	Antimicrobial Resistance & Healthcare Associated Infection Scotland is a clinical service providing national expertise for infection, prevention and control, antimicrobial resistance and healthcare associated infection for Scotland
Blood culture	Blood is directly added to a nutrient broth and incubated at an optimal temperature to enable any bacteria present to grow and multiply.
BSI	Blood stream infection (also known as bacteraemia)
Causation	The action of causing something.
Central line/central venous catheter	A tube placed in a large vein in the neck, chest, groin or arm which can stay in place for several months if needed.
Correlation, including cross-correlation	Connection between two or more things
Deprivation	In the UK, the term is used to describe the consequence of a lack of income and other resources, which cumulatively can be seen as living in poverty.
ECOSS	Electronic Communication of Surveillance in Scotland. An electronic system for microbiology laboratories to report to Public Health Scotland
Environmental bacteria	Environmental bacteria are defined as bacterial species that normally spend a substantial part of their lifecycle outside human hosts, but when introduced to humans cause disease with measurable frequency
Enteric bacteria	Enteric bacteria are bacteria that typically exist in the intestines of animals and humans
Epidemiology	The branch of medicine which deals with the incidence, distribution, and possible control of diseases and other factors relating to health

Exposure	A factor which may be associated with an outcome of interest. In epidemiology it denotes contact with something that may be harmful.
Fleming Fund	UK Aid programme, by the UK's Department of Health and Social Care that seeks to gather and share antimicrobial resistance data.
Fungus	In medicine, microorganisms which can occur as yeasts or moulds
Gram-negative	Organisms which do not retain the crystal violet stain used in the gram method of bacterial differentiation.
Gram-positive	The cell walls of certain bacteria (denoted Gram-positive) retain the crystal violet stain and appear violet.
Haematology-oncology	Cancers of the blood, and units which specialise in the care and treatment of those with this condition
HAI	Healthcare associated infection
HEPA filter	High efficiency particulate air filter which traps 99.97% of particulates of 0.3 microns or larger
HPS	Health Protection Scotland
HPV	Hydrogen Peroxide vapour
Immunocompromised	Where an individual’s immune system efficacy at fighting infections is compromised due to a disease or medication.
Incidence (and incidence rate)	The occurrence, rate, or frequency of a disease
ISD(S)1	The standard set of aggregated summary statistics on activity in hospitals and other health care settings in Scotland.
Micro-organisms	Bacteria, viruses, Fungi and protozoa
LIMS	Laboratory Information Management System
NHSE/I	National Health Service England and Improvement
NHS GGC	National Health Service – Greater Glasgow Clyde

NIPCM	National Infection Prevention and Control Manual for Scotland
Nosocomial	Acquired in a hospital
NSS	National Services Scotland
Opportunistic pathogens	A micro-organism which would normally not cause infection or illness in a healthy individual but may cause serious infection in an immunocompromised person
Outcome	Variables that are of interest in the population under investigation or study, in epidemiology equating to, for example, a disease or infection.
Plausibility	The quality of seeming reasonable or probable.
Probability	The quality or state of being probable; the extent to which something is likely to happen or be the case
QEUH	Queen Elizabeth University Hospital
Specificity	In epidemiology, the specificity of a test is its ability to designate an individual who does not have a disease as negative
Temporality	In epidemiology, temporality refers to the overlap in time between the exposure and the outcome.
Time-series	A series of values of a quantity obtained at successive time
Total Viable Count (TVC)	The total number of micro-organisms in a water sample
Total Occupied Bed Days (TOBD)	A total figure for the number of beds available or occupied on each day, as a sum of all the days in the period in question, e.g. a month, a quarter, a year.
UKHSA	United Kingdom Health Security Agency
WGS	Whole genome sequencing
Yeast	A fungus consisting of single cells which reproduce by budding

4. **Overview**

4.1. The epidemiological framework outlined in this section, has been adopted to understand: i) the trend in infection incidence in the Schiehallion patient cohort, and to determine whether there was anything 'unusual' about the rate of infection at any given period of time, between 2015 and 2022, and ii) the nature of the relationship between the incidence of infections recorded in the Schiehallion cohort, water sampling, episodes of laboratory confirmed water microbial contamination, and remedial actions taken at the QEUH and RHC at the time.

4.2. The framework accounts for i) evidence of patient infection episode incidence and rate by way of laboratory confirmed sample information, ii) evidence of contamination of the water and ventilation systems, collectively referred to as the 'built environment', iii) remedial actions undertaken at the QEUH and RHC, impacting on the Schiehallion patient cohort at a patient and environmental level (patient surroundings), and iv) peer organisation infection incidence and rate (accounting for differences in activity).

4.3. At this point I acknowledge the Case Note Review[5] (CNR) published in 2021, which examined individual cases and assigned the likelihood of an environmental source for an infection to each case. In employing an epidemiological framework, I deem it complementary to the methodology adopted by authors of the CNR, by building a longitudinal picture of events at QEUH and the RHC, based on which an assessment of the strength of association (also referred to as correlation) between infections in the Schiehallion patient cohort and their environment is drawn.

4.4. This report is based on information supplied by several parties and sources, with the report based and reliant on the rigour and completeness of the information made available to me as a subject matter expert. Source of information are as follows - NHS Greater Glasgow and Clyde (NHS GGC), Health Protection Scotland (HPS), Health Facilities Scotland (HFS), National Services Scotland (NSS) including Antimicrobial Resistance and Healthcare Associated Infection (ARHAI), freedom of Information requests and national data sets.

[5] QEUH and RHC Case Note Review Overview Report. March 2021

5. **Key considerations.**

5.1. It is important in the first instance to consider the following terms, essential in the application of epidemiological frameworks.

5.2. **Exposure and outcome variables[6].** From an epidemiological standpoint, the central question is understood to be one concerning the **relationship** between an **exposure variable**, in this case microorganisms, specifically Gram-negative bacteria and fungus, evidenced to exist in the water and ventilation systems at QEUH and RHC (the patients' environment) and the **outcome variable** – patient infection episodes over the period 2015 -2022.

5.3. **Association***.* The relationship that exists between the exposure and outcome variable is understood using 'measures of association', determined by epidemiological and statistical tools that estimate the direction and magnitude of the relationship between variables. The term 'association' is therefore understood, in epidemiological terms, to be the statistical relationship between two variables.[7] Kundi[8] (2006) [interpretation of Philips and Goodman, 2004[9]] adds further granularity to our understanding of the term, defining it as the "probability of a disease conditional on the presence of A, higher than in the absence of A" (where A is a determinant of disease).

5.4. **Correlation.** The term is akin to association and 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 on the basis of chance alone. [10]

5.5. **Causation***.* 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" (Kundi,

[6] Rothman KJ and Rothman KJ, *Epidemiology: An Introduction* (Second Edition, Oxford University Press 2012)
[7] Pearce N, 'What Does the Odds Ratio Estimate in a Case-Control Study?' (1993) 22 International Journal of Epidemiology 1189
[8] Kundi M, 'Causality and the Interpretation of Epidemiologic Evidence' (2006) 114 Environmental Health Perspectives 969
[9] Phillips CV and Goodman KJ, 'The Missed Lessons of Sir Austin Bradford Hill' (2004) 1 Epidemiologic Perspectives & Innovations 3
[10] 'Definition of CORRELATION' (24 February 2024) <https://www.merriam-webster.com/dictionary/correlation> accessed 29 February 2024

2006)[11]. It follows, that the exposure variable, which differs between the populations being compared, is understood to be driving the increased incidence of the disease outcome.

5.5.1. **It is important we consider limitations inherent in the use of the term 'causation'**. Firstly, taking Kundi's note on the topic "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 pre- sent knowledge, come to a decision concerning the relationship of an agent and a disease" (Kundi, 2006)[12].

5.5.2. Establishing causality is complex, and often requires actions that are practically and ethically not scientifically reproducible, as in the case where environmental exposures to infections in highly vulnerable patient populations are concerned.

5.5.3. Other definitions of causation[13] lie closer to that of 'association'. i.e. as when the exposure produces the effect, noting two avenues of consideration, namely, i) understanding association and whether a change in exposure results in a change in probability of the outcome, and ii) understanding the time order of events.

5.6. Therefore, for the purposes of this investigation we adopt the 'measures of association' approach, and the accompanying epidemiological and statistical

[11] Kundi M, 'Causality and the Interpretation of Epidemiologic Evidence' (2006) 114 Environmental Health Perspectives 969
[12] Kundi M, 'Causality and the Interpretation of Epidemiologic Evidence' (2006) 114 Environmental Health Perspectives 969
[13] Association vs Causation. Boston University School of Public Health. Association versus Causation (bu.edu) accessed 19/10/23

tools, which in line with the Inquiry's stance on the investigation, i.e. one where we seek to understand, on the balance of probabilities, the relationship or correlation, and the extent or degree of this relationship, between infection episodes and the environment - as highlighted by positive environmental samples and remedial actions carried out to rectify issues at the time.

5.7. The hypothesis is as follows - that there existed a positive association/correlation, defined as one where there exists a higher disease risk than when said exposure is less or absent, between the occurrence of patient infections with environmental organisms and the presence of environmental microbiological contamination at QEUH and RHC between 2015 and 2022.

5.8. The main statistical resources employed in epidemiology[14] to understand association/correlation between variables are broadly concerned with measuring the i) frequency, ii) the strength of association and iii) impact of the exposure on the outcome.

5.9. We acknowledge Bradford Hill's work[15] which proposes nine guidelines, outlining core considerations on the matter of frequency, association and impact, to name a few, to aid epidemiologists in interrogating the available evidence.

5.10. We note Hill's advice against the use of the guidelines as a 'criterion' - "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*".

5.11. The ubiquity of Hill's guidelines within the field of epidemiology necessitates we consider it here and acknowledge Phillips and Goodman's (2006)[16] stance - that Bradford Hill's nine considerations are useful tools in promoting scientific thinking and common-sense deduction.

[14] Kleinbaum, David G., Lawrence L. Kupper, and Hal Morgenstern. *Epidemiologic Research : Principles and Quantitative Methods*. New York: John Wiley & Sons, Inc., 1982. Print

[15] Hill AB, 'The Environment and Disease: Association or Causation?' (1965) 58 Proceedings of the Royal Society of Medicine 295

[16] Phillips CV and Goodman KJ, 'Causal Criteria and Counterfactuals; Nothing More (or Less) than Scientific Common Sense' (2006) 3 Emerging Themes in Epidemiology 5

5.12. **The table below** outlines Hill's nine guidelines together with an explanation of each.

Index	Guideline	Explanation
1	Strength or degree of association	Larger the value of the relative risk (effect size) between the exposed and unexposed groups, the stronger the 'strength of association'
2	Consistency	The event or outcome of interest has been repeatedly observed, and these observations have been made in different circumstances and times.
3	Specificity	Disease outcome is seen in a specific population at a specific site with no other likely explanation, other than the hypothesised exposure.
4	Temporality (including spatial property)	Organism acquisition occurs where and when environmental contamination of present or does not occur where said contamination is absent. Recent additions to this guideline have included 'spatial', to account for the 'where' and 'when'
5	Biological gradient	Greater exposure generally leading to greater incidence, i.e. dose/stressor-response relationship
6	Plausibility	Is the association biologically plausible
7	Coherence	Do epidemiological and laboratory findings agree with each other
8	Experiment	When interventions are applied which reduce the exposure/trigger variable, does the outcome reduce too. OR Is organism acquisition eliminated or reduced when exposure to the environment is subjected to intervention

9	Analogy	Is a comparable association observed between the same outcome and an analogous exposure or the same exposure and an analogous outcome.

6. **Methodology.**

6.1. **The table below** summarises the outcomes of interest and the corresponding epidemiological/statistical tools employed to interrogate the data. The outcomes generated will allow us to gauge, alongside the qualitative investigative methods, the strength or degree of association/correlation between patients' infection episodes and the environment (which for the purposes of this report relates to water sampling and remedial action information).

Outcome of interest	Epi - statistical tool	Explanation	Notes on utility
Temporal pattern of infection incidence over time, contextualised for changes in activity (patient admissions in this case)	**Incidence 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[17] Incidence rate - per 1,000 total occupied bed days (TOBDs) = (Number of cases of positive blood culture	Calculating a rate allows us a measure of incidence (new cases) within the context of the total amount of time the population is at risk of becoming a case (i.e. the activity). Enables us to compare the occurrence of infection across comparator institutions, as it

[17]Dettori JR, Norvell DC and Chapman JR, 'Risks, Rates and Odds: What's the Difference and Why Does It Matter?' (2021) 11 Global Spine Journal 1156

		of given case definition in hospital(s) or speciality/TOBDs in hospital(s) or speciality x 100,000).	allows us to adjust for differing levels of activity. Allows us to quantify the density and consistency[18] with which cases were observed over timepoints, e.g. detection of 'unusual' activity, i.e. rates different to that of comparator units over similar time periods.
Magnitude of difference between rates of infection between institutions	**Incidence rate ratios**	The formula for IRR is as follows: IRR = incidence rate (per 1,000 bed days) in the primary group of interest/incidence rate in the comparator group Interpretation of the rate ratio is as follows: Rate ratio = 1 indicates equal rates in the two groups; a rate ratio greater than 1 indicates an increases risk in the primary group of interest; a rate	Incidence rate ratios allow us to compare the incidence rate, per person-time or bed days, between groups[19], to provide a relative effect. Incidence rate ratio is a rate ratio statistic concerning incidence.

[18] Hill AB, 'The Environment and Disease: Association or Causation?' (1965) 58 Proceedings of the Royal Society of Medicine 295

[19] Dettori JR, Norvell DC and Chapman JR, 'Risks, Rates and Odds: What's the Difference and Why Does It Matter?' (2021) 11 Global Spine Journal 1156

		ratio of less than 1 indicates a decreased risk in the primary group of interest.	
Temporal pattern of infection, environmental contamination, and carrying out of remedial actions, over time – step 1 of understanding association / correlation between variables	**Time series**	Time series plot – which is a graph illustrating the rate of infection over time.	Allows us to observe how the incidence rate of infections over time, and the detection of 'unusual' activity, i.e. rates different to that of comparator units over similar time periods. Allows us to observe the level of synchronicity between the occurrence (via positive sample data) of water contamination, and remedial actions carried out to mitigate environmental contamination, and infection episodes, and compare these variables to each other.
Step 2 of understanding association / correlation between variables of interest	**Cross-correlation**	Correlation is a statistical method used to assess the association between variables of interest. In statistics, it allows us to assess the two-way linear association between two	Allows us to statistically measure the degree of association or correlation between variables of interest.

		continuous variables [20]. It is measured by a statistic called the correlation coefficient, which provides a value denoting the degree of association between the variables of interest. The correlation coefficient can take a value of -1 to +1, which denotes the strength of association. A correlation coefficient value of zero denotes no relationship, whilst closer the value comes to + or – 1, the stronger the relationship between the variables in question. A value closer to -1 denotes an inverse relationship, i.e. when the value of one variable goes down, the other goes	

[20] Altman DG, Practical Statistics for Medical Research (CRC Press 1990)

		up. Whereas a value closer to +1 denotes a direct association or correlation, i.e. when one variable goes up, so does the other.	

6.2. **Using the measures detailed above we aim to critically examine:**

- The trend or pattern in which infection episodes at QEUH and the RHC, specifically in relation to the Schiehallion patient cohort presented over the period 2015 – 2022
- The trend or pattern of infection episodes in comparator institutions over the period 2015-2022[21]
- The timing, frequency and location of water sampling in and around Schiehallion patient cohort wards (at QEUH and RHC), including subsequent laboratory confirmed positive results for the period 2015-2022
- The timing, frequency and location of remedial actions carried out in response to identified concerns regarding water and ventilation systems for the period 2015-2022

7. **Summary of evidence considered.**

7.1. **The table below** summarises the evidence considered for the purposes of this preliminary infection report.

Data	Data specifics	Case definitions	Source	Details of analysis
Patient infection episodes	QEUH including RHC	Gram Negative bacteria – environmental	NHS GGC	Gram-negative and fungal bloodstream infection positives for the

[21] FOI data obtained from comparator paediatric haemato-oncology units performing bone marrow transplants in England and Wales. SHI 2023

		and enteric group and fungi		'Schiehallion patient cohort', i.e. samples taken in wards 2A, 2B, 6A, 4B, for the period 2015-2022.
	Comparator institutions	Gram Negative bacteria – environmental and enteric group and fungi	FOI	Gram-negative and fungal bloodstream infection positives for the paediatric haematology units at GOSH, Cardiff and Vale, Leeds, and Oxford for the period 2015-2022
Activity data	QEUH including RHC	Admission data by month and year	NHS GGC	Admission data for the wards 2A, 2B, 6A, 4B for the period 2015-2022
	Comparator institutions	Admissions data by month and year	FOI	Admission data for the paediatric haematology units at GOSH, Cardiff and Vale, Leeds and Oxford for the period 2015-2022
Water sampling	QEUH and RHC	Water sampling orders and laboratory confirmed positive samples	NHS GGC	Data on water sampling and sample positives pertaining to 'Schiehallion patient cohort', i.e. samples taken in wards 2A, 2B, 6A, 4B, for the period 2015-2022.
Remedial actions data	QEUH and RHC	Remedial actions undertaken concerning Schiehallion patient cohort	NHC GGC	Data on remedial actions undertaken pertaining to 'Schiehallion patient cohort', i.e. samples taken in wards 2A, 2B, 6A, 4B, for the period 2015-2022.

7.2. **Source and nature of data comprising evidence considered**

7.2.1. **Laboratory confirmed blood culture samples** pertaining to the Schiehallion patient cohort for the period 2015-2022. This data has been provided by NHS GGC using their Microbiology Laboratory Information System (LIMS), Telepath, for the period January 2015 to 31 December 2022.

7.2.2. **Activity data in terms of admissions** by month for all wards falling under the speciality of paediatric haematology-oncology and consisting of the Schiehallion patient cohort, for the period 2015-2022.

7.2.3. **Data/information on remedial actions** – what, when they commenced, where they were applied, e.g. ward area, for the period 2015-2022.

7.2.4. **Comparator or peer Acute Trust infection and activity data.** This was obtained via multiple Freedom of Information (FOI) requests as per follows:

- The year of construction of the building housing the paediatric haemato-oncology unit and any subsequent major upgrades to the unit
- The number of admissions to the paediatric haemato-oncology unit, by year, for 2015-2022
- The number of individual patients admitted to the paediatric haemato-oncology unit, by year, for 2015-2022
- The total number of blood cultures taken for patients on the paediatric haemato-oncology unit, by year, for 2015-2022
- The total number of positive blood cultures taken for patients on the paediatric haemato-oncology unit, by year, for 2015-2022
- A list of the numbers of all organisms, by species, isolated from blood cultures from patients on the paediatric haemato-oncology unit (whether deemed significant or not), by site (peripheral venepuncture, peripheral line or central line), by year for 2015-2022, total and de-duplicated numbers for same infection episode.

7.2.5. The following hospitals were contacted as part of the FOI process:

- Birmingham Children's Hospital, (Birmingham Women's and Children's NHS FT)
- Alder Hey Children's NHS FT, Liverpool
- Great Ormond Street Hospital for Children NHS FT
- Great North Children's Hospital (Newcastle Hospitals NHS Foundation Trust)
- Sheffield Children's NHS FT
- Bristol Royal Hospital for Children (University Hospitals Bristol NHS FT)
- University College London Hospitals NHS FT
- University Hospital Southampton NHS FT
- Royal Marsden NHS FT
- Royal Children's Hospital, (Manchester University NHS FT)
- Oxford University Hospitals NHS FT
- Leeds Children's Hospital (Leeds Teaching Hospitals NHS Trust)
- Children's Hospital for Wales, (Cardiff and Vale University Health Board)
- Addenbrooke's Hospital (Cambridge University Hospitals NHS FT)
- St Mary's Hospital, London (Imperial College Healthcare NHS Trust)

7.2.6. Four hospitals, namely, Great Ormond Street, Cardiff and Vale, Leeds, and Oxford returned data (in line with the FOI request detailed in section 4.7.1) which was deemed to be rigorous and complete, and therefore used at this stage of the analysis.

7.2.7. A further FOI request was made for bed-days activity data of the institutions listed in section 4.7.2. Bed days data from Leeds, Cardiff and Vale and Oxford has been received as of 19th of January 2024

7.2.8. Note: As discussed later on in this report, bed days activity data has not been used for the purposes of this report, as it was deemed unrepresentative of the overall inpatient and outpatient activity and the risk of healthcare associated infection it confers to the patient population.

8. Summary of data analysis steps

8.1. Schiehallion patient cohort - infection episode data

8.1.1. The QEUH and RHC dataset of blood stream infections supplied by NHS GGC, covering the period 2015 – 2022 was downloaded from Objective Connect, into MS Excel, wherein the following data cleaning, formatting and final dataset curation steps were undertaken.

8.1.2. The QEUH (including RHC) dataset comprised of 87552 unique CHI (unique anonymised patient records), under which collection dates of blood culture specimens, as and when taken, were detailed.

8.1.3. Rows corresponding to a positive specimen were classified as ‘positive’ and those corresponding to a negative specimen (i.e. no organism growth) classified as ‘negative’.

8.1.4. 15100 unique CHIs, i.e. unique patient records were classified as ‘positive’ with at least one organism identified.

8.1.5. Organisms (falling under positive specimen records) were then aggregated into categories – bacteria and fungi, with the bacteria category further split into – Gram-negative, Gram-positive, Variable Gram stain.

8.1.6. CHIs corresponding to Gram-negative and fungal samples were tagged for inclusion in the final dataset.

8.1.7. In keeping with the remit of the investigation – to understand the association between patient infections and the environment, bacteria understood to be enteric in nature, and unlikely to be transmitted via the environment (water and ventilation) were excluded – i.e. bacterial genera under *Escherichia coli*, *Campylobacter*, *fusobacterium, haemophilus, moraxella, Neisseria,* in addition to one instance of an unidentified genus of gram-negative bacteria.

8.1.8. Ward locations indicating where specimens were taken, were categorised as either ‘inpatient and ‘outpatient’ wards, to allow for easier aggregation and sorting.

8.1.9. Ward locations corresponding to 2A, 2B, 6A and 4B were tagged for inclusion in the final dataset, including both inpatient and outpatient settings (see section 5.2.3. for an explanation).

8.1.10. The penultimate dataset comprised of all CHIs where the ward locations were 2A, 2B, 6A, 4B, (given the focus on Schiehallion patient cohort) AND

where organism found were categorised as either gram-negative and/or fungi.

8.1.11. This penultimate dataset was then split into two age categories – under 19 and over, based on the age of the patient at the time of sample collection (in years).

8.1.12. The gram-negative and fungal positives were then extracted for wards 2A, 2B, 6A, 4B (Schiehallion patient cohort) where patients were below the age of 19 at the time of sample collection (i.e. paediatric patients).

8.1.13. In line with the Case Note Review[22] a 'final dataset' was developed, post a de-duplication step to only include 'unique' infection episodes, defined as a unique CHI-Collection Date-Laboratory lab sample number-organism, with the onus on excluding positive repeat blood culture of bacteria and/or fungi previously isolated from the patient's blood within a 14-day period. This is also in line with national reporting[23].

8.1.14. The Final dataset comprised of 95 CHIs (unique patients), 137 unique patient-cultures, with the number of organisms ranging from 1 to 5 (accounting for poly organism positive cultures) and totalling 187 infection-episodes for the Schiehallion patient cohort covering the period 2015-2022.

8.1.15. The summary table below details the number of infection-episodes (n=187) by the four ward areas that are referred to as the Schiehallion units, by year (2015-2022).

Schiehallion wards - Healthcare associated (HAI) bloodstream infections, Gram-negative and Fungi, by ward, by year, 2015 - 2022					
YEAR	4B QEUH	6A RHC	Ward 2A RHC	Ward 2B RHC	Cumulative
2015			6	1	7
2016			18	9	27
2017			46	20	66
2018		6	29	9	44
2019	2	17			19
2020		8		1	9

[22] QEUH and RHC Case Note Review Overview Report. March 2021
[23] Protocol for National Enhanced Surveillance of Bacteraemia | National Services Scotland (nhs.scot)

2021		8		0	8
2022		2		5	7

8.1.16. **The summary table below** details the number of organisms under each category – gram-negative (n=169) and fungi (n=18).

Organism genus and species	Number of organisms
Gram-negative bacteria	169
Achromobacter denitrificans	2
Achromobacter species	1
Acinetobacter baumannii	10
Acinetobacter baumannii complex	4
Acinetobacter ursingii	9
Aeromonas hydrophila/caviae	2
Brevundimonas species	1
Burkholderia cepacia	1
Burkholderia cepacia group	2
Chryseobacterium species	1
Chryseomonas indologenes	3
Citrobacter braakii	2
Citrobacter freundii	2
Citrobacter koseri	1
Citrobacter youngae	2
Cupriavidus pauculus	2
Delftia acidovorans	4
Elizabethkingia meningoseptica	5
Elizabethkingia miricola	2
Elizabethkingia species	3
Enterobacter cancerogenus	4
Enterobacter cloacae	16
Enterobacter cloacae complex	2
Enterobacter cloacae ssp cloacae	16

Enterobacter hormaechei	2
Klebsiella oxytoca	9
Klebsiella pneumoniae	22
Pantoea species	1
Pseudomonas aeruginosa	5
Pseudomonas putida	4
Pseudomonas stutzeri	2
Rhizobium radiobacter	1
Roseomonas mucosa	1
Serratia liquefaciens	1
Serratia marcescens	9
Sphingomonas paucimobilis	1
Stenotrophomonas maltophilia	14
YEAST	18
Candida albicans	10
Candida fermentati	1
Candida parapsilosis	4
Candida tropicalis	1
Rhodotorula mucilaginosa	2
Grand Total	187

8.2. **Schiehallion patient cohort – activity data**

8.2.1. NHS GGC provided data on the total number of admissions and bed days for each month for the period 2015-2022.

8.2.2. Admissions data was aggregated by year.

8.2.3. Note here that the Schiehallion patient cohort had frequent out-patient attendances to the hospital, also referred to as out-patient stays, in addition to being admitted to a ward (inpatient-stays), both contributing to each patient's cumulative risk of healthcare-associated infections. We know that the Schiehallion patient cohort spent a substantial proportion of their day(s) at these out-patient settings receiving invasive treatment for their condition. These visits are frequent in this patient cohort – involving interaction with the

hospital environment (water and ventilation), hospital staff, dispensing of treatment, acknowledged by national reporting[24], which designates laboratory infections taken in outpatient settings as healthcare associated, in recognition of the frequent prior outpatient admissions in this patient cohort, leading up to the laboratory confirmed sample.

8.2.4. Bed days data, based on in-patient stays, only includes bed occupancy, and excludes out-patient stays. To get an accurate estimate of the rate of infection, it is essential we use the most representative value for the risk accumulated on part of the patients, which in this case is admission data.

8.2.5. And so, in keeping with the above, we have focused on utilising admission data, made available from NHS GGC, to calculate a rate of infection per 1000 admissions, for the Schiehallion patient cohort, for the period 2015 – 2022. Admission data, unlike bed days data, accounts for patients' each and every interaction with the hospital and its environment, and therefore a much more precise estimate of risk for this patient cohort.

8.2.6. Therefore, for the purposes of this report, both infection episodes and admission data from Ward 2B was taken into account, alongside those from 2A, 4B and 6A., with the infection episodes from these four wards classified as healthcare-associated [25].

8.2.7. The above is also important considering we were not able to aggregate BSIs as healthcare-associated, as opposed to community-associated, requiring admission data for each of the Schiehallion patients; data that we did not have access to as part of this analysis.

8.2.8. The summary table below details the total admissions, i.e. activity, year on year, from 2015-2022, for the four Schiehallion patient cohort wards.

[24] 'Protocol for National Enhanced Surveillance of Bacteraemia' (National Services Scotland) <https://www.nss.nhs.scot/publications/protocol-for-national-enhanced-surveillance-of-bacteraemia/> accessed 29 February 2024

[25] 'Healthcare-Associated Infections | Health Topics A to Z | CKS | NICE' <https://cks.nice.org.uk/topics/healthcare-associated-infections/> accessed 29 February 2024

Schiehallion wards - Admissions by ward and year, 2015 - 2022					
Year	4B	6A	2A	2B	Cumulative
2015			241	324	565
2016			479	585	1064
2017			264	663	927
2018	2	68	178	575	823
2019	9	290			299
2020	2	127			129
2021	1	106			107
2022	1	26	129	360	516

8.3. **Comparator institutions – infection episode & activity data**

8.3.1. FOI datasets received from multiple hospitals across the United Kingdom were consolidated into a single dataset under the following variable headings, namely, i) admissions by calendar year, ii) number of positive blood culture samples, iii) number of positive blood culture samples where organism is a gram-negative or fungi, iv) rate of BSI per 1000 admissions, and the corresponding comparator organisations' name.

8.3.2. From the FOI responses received, four hospitals' data was deemed to be rigorous and complete, namely – Great Ormond Street Hospital, Cardiff and Vale University Health Board, Leeds Teaching Hospital, and Oxford University Hospitals.

8.3.3. The hospital's named above, cumulatively had a large number of paediatric haematology-oncology patient admissions, year on year, for the period 2015 – 2022, allowing us to infer that statistics gleaned from them will be representative of paediatric haematology oncology and BMT patients in the UK.

8.3.4. Note that the steps undertaken to arrive at a final dataset of infection episode data for comparator institutions was similar to the process followed for the Schiehallion patient cohort data, including exclusions of certain 'enteric' bacteria genera (See Section 5.1.7).

8.3.5. Leeds hospital were not able to provide the number of positive blood culture samples for the year of 2015, and therefore we weren't able to calculate a rate of BSI per 1000 admissions for that institution, for that year.

8.3.6. The summary table below outlines the comparator institutions' infection episode and activity data.

Comparator hospitals' paediatric haematology patient infection figures 2015 - 2022					
Year	Admissions	Positives	Gram-negative and fungal positives	Rate of BSI per 1000 admissions	Organisation
2015	5443	182	62	11.39	Gt Ormond st
2016	5350	202	58	10.84	Gt Ormond st
2017	5832	248	77	13.20	Gt Ormond st
2018	6053	140	44	7.27	Gt Ormond st
2019	5997	147	96	16.01	Gt Ormond st
2020	6362	146	95	14.93	Gt Ormond st
2021	6389	135	91	14.24	Gt Ormond st
2022	6185	78	49	7.92	Gt Ormond st
2015	2273	60	7	3.08	Cardiff and Vale
2016	3314	81	18	5.43	Cardiff and Vale
2017	2982	50	24	8.05	Cardiff and Vale
2018	3235	70	23	7.11	Cardiff and Vale
2019	2999	58	15	5.00	Cardiff and Vale
2020	2660	57	19	7.14	Cardiff and Vale
2021	3257	30	9	2.76	Cardiff and Vale
2022	2965	55	11	3.71	Cardiff and Vale
2015	5120	NA	NA	NA	Leeds
2016	5892	61	7	1.19	Leeds
2017	5926	202	65	10.97	Leeds
2018	5851	176	77	13.16	Leeds

2019	5488	213	78	14.21	Leeds
2020	5839	194	46	7.88	Leeds
2021	5747	200	71	12.35	Leeds
2022	6352	182	37	5.82	Leeds
2015	2774	55	25	9.01	Oxford
2016	3050	51	28	9.18	Oxford
2017	2673	77	23	8.60	Oxford
2018	2538	53	20	7.88	Oxford
2019	2693	37	17	6.31	Oxford
2020	3045	28	11	3.61	Oxford
2021	3252	52	13	4.00	Oxford
2022	3153	57	16	5.07	Oxford

8.4. **QEUH and RHC - Water sampling data**

8.4.1. NHS GGC provided 18 spreadsheets detailing water sampling data for the period 2015 – January of 2021, compiled by Dr. Dominique Chaput.

8.4.2. A master database was created, combining all water sampling data from the 18 spreadsheets, totalling 29871 rows of water sampling data.

8.4.3. This master database included the columns – consolidated sample date, sample location, lab reference number, *legionella. spp* (count), *pseudomonas. aeruginosa* (count), *pseudomonas.spp* (count), coliform (count), SAB at 30 degrees and mould at 22 degrees, SAB at 22 degrees and yeast at 25 degrees, *Cupriavidus. spp* (count), *Serratia. spp* (count), identified organism column (consolidation of multiple organism columns).

8.4.4. Note that columns flagged as denoting count data, often consisted of instances of organism names, requiring further formatting and cleaning of the dataset.

8.4.5. Further complexity originated from differing column names on spreadsheets, denoting similar sample outputs, approximately 3076 instances of sample dates not recognised as a date, requiring formatting and cleaning.

8.4.6. Water sampling data in this consolidated database covered the following areas: drains, sinks, taps, showers, tanks, equipment and expansion vessels.

8.4.7. There were 151 instances/rows of data where either the sample date or sample comment column flagged that no sample was eventually taken, including one instance where a sample was taken but lacked a sample data. These rows were excluded from the analysis.

8.4.8. Columns pertaining to counts of *Escherichia coli* and the column denoted as 'coliform counts' were excluded from the analysis – the former because it is an enteric organism and unlikely to have an environmental source, and the latter due to the inability to segregate enteric from environmental organisms. The latter column only contributed 0.25% of sampling data (75 rows of output, of 29720 rows of water sampling data), further supporting its exclusion on the basis of ensuring high rigour in the analysis of water data.

8.4.9. Post exclusion of 151 rows of data (section 5.4.7), 29720 rows of water sampling data for the period Jan-2015 to Jan-2021 was saved.

8.4.10. Each of the organism columns noted in section 5.4.3. denoting a positive count was coded as a positive (n=1). The definition used - water sample positive is a positive count from a water sample of any magnitude/count.

8.4.11. In keeping with the objectives, water sampling pertaining to the Schiehallion wards (2A, 2B, 4B, 6A) was extracted. Complexities – multiple variations of ward names, including the added complexity of water tanks being named similar to Schiehallion unit wards, e.g. 2A and 2B water tank (456 rows of data has the word 'tank' alongside the ward name of a Schiehallion unit ward) which needed detailed cleaning and exclusion from the end total.

8.4.12. 6688 rows of water sampling data were extracted and saved for further analysis.

8.4.13. Of the 6688 rows of water sampling data, 419 rows did not have a lab reference number, making it impossible to de-duplicate to get a figure for unique water samples taken by year for the period 2015 – January 2021.

8.4.14. Two separate methodologies were employed at this stage, one to deal with the 419 rows lacking a laboratory reference number – requiring a concatenation of the sample date, location details and organism isolated, to identify unique water samples. A more traditional deduplication method was adopted for the remaining rows of data with a lab reference number.

8.4.15. At this point the column consisting of organism names was cleaned to only include bacterial and fungal genera as follows - *legionella. spp,* (note final

dataset did not contain any positives) *pseudomonas. spp, cupriavidus. spp*, *Serratia. spp, Stenotrophonomas.spp* and a fungus positive column.

8.4.16. The table below details the number of positive samples under each of the columns detailed above, alongside the number of unique water samples taken, for each year, for the period 2015 – 2020 (note we only had data for the month of January of 2021), along with a rate of water positivity (%), calculated by dividing the total positive samples identified for each year by the total unique samples, multiplying the product by 100.

8.4.17. Note that the manner in which the water sampling data was kept in 2015 and 2016, makes it extremely difficult to differentiate samples specific to the Schiehallion unit. Extreme care was taken to accurately extract cases, where it was clear from the sampling location data, that the sample was specific to Schiehallion unit wards.

8.4.18. It is my opinion, that the low numbers of water samples taken in 2015 and 2016 (n = 80 and 47 respectively) is a facet of the issue highlighted in 5.4.17. Water sampling data for subsequent years, 2017 onwards, affords us adequate granularity to easily extract sampling specific to the Schiehallion units.

8.4.19. It is important to address a frequently cited concern regarding small numbers, in this case water samples, when performing statistical analyses. The concern regarding small numbers is justified when statistical analyses on a sample dataset and resulting outputs are used to infer the characteristics of a wider population. This is not the case here, where we attempt to apply epidemiological and statistical tools to understand the observed data on infections, water sampling and remedial actions, and are not using it to infer the characteristics, such as rates of infections, in the wider paediatric haematology patient population, but solely to understand the trend and association of said variables in the Schiehallion patient cohort.

Year	Water samples taken (deduped)	*Pseudomonas.spp* positive (deduped)	Fungal positives (deduped)	*Cupriavidus.spp* positive (deduped)	*Serratia.spp* positive (deduped)	*Stenotrophonomas.spp positive* (deduped)	Cumulative positive	Rate of water positivity (as a proportion of total samples taken)
2015	80	2	0	0	0	0	2	2.5%
2016	47						0	0.0%
2017	196			15			15	7.7%
2018	1158	8	85	104	2	2	201	17.4%
2019	1809	22	76	59	0	43	200	11.1%
2020	1469	4	11	28	0	39	82	5.6%

8.5. QEUH and RHC – Remedial actions data

8.5.1. Information on the remedial or actions to mitigate issues identified with the patients' environment was provided by SHI, aggregated by year, with the following table detailing the key remedial actions by year.

Date	Key interventions
Jan-16	Wash basins removed; HEPA installed
Aug-16	HEPA installed
Mar-17	Anti-fungal prophylaxis
Apr-17	Ward 2A closed to admissions + CD
Jul-17	HEPA filter installation
Sep-17	Bottled water only
Oct-17	Prophylactic antimicrobials given
Mar-18	HPV, POUFs, Alcohol gel only, disposable shower heads
Mar-18	Prophylactic ciprofloxacin given
Apr-18	CD shock dosing, flow straightener replaced, taps replaced
Jun-18	2A admissions restricted
Jun-18	CD dosing, replacement taps, water tank cleaning, water coolers removed
Jun-18	Ward 2A and 2B drains cleaned
Jun-18	Filtration unit and water tank cleaned
Jul-18	Water cooler and taps replacement
Aug-18	CD dosing
Sep-18	Decant from 2A and 2B to 4B and 6A
Sep-18	Restriction of admissions

Sep-18	POUF fitted in 4B and 6A, sink gaskets
Oct-18	CD shock dosing, flow straightener replaced, taps replaced
Oct-18	High level chlorine dosing in 2A and 2B
Nov-18	CD dosing, new showerheads, and hoses
Dec-18	CD dosing
Jan-19	Restriction of admissions to 6A
Jan-19	HEPA filter installation plus 6A patients moved
Jan-19	CD dosing
Jan-19	Decant from 6A
Jan-19	HEPA filters fitted to 6A
Jan-19	General repairs
Feb-19	CD introduced into hot water, vent cleaning, end of 6A decant
Mar-19	CD dosing increased
Jun-19	CD dosing, filters fitted to all outlets serving high-risk patients
Jul-19	QEUH chlorination system fitted
Aug-19	Restriction of admissions to 6A
Nov-19	6A opened to new admissions
Jan-20	Cd dosage increased in backwash areas
Jan-20	Flow straightener restrictors changed every 6 months
Jan-20	Tank levels reduced to allow frequent flushing
Jan-20	Open sump in plant room covered with polythene

9. Summary of findings – Rates of infection

9.1. The summary table below provides the rate of BSI[26] per 1000 admissions, calculated by dividing the number of gram-negative[27] and/or fungal samples by the number of admissions and then multiplying the product by 1000. This is done individually for each of the four Schiehallion units, with an overall rate calculated for each year.

[26] BSI in the context of this paper means blood stream infections caused by gram negative and fungi organisms as defined in the table at 5.1.16.
[27] Where the term ‘gram negative’ is used this means ‘gram negative environmental and enteric group organisms’ as defined in the table at 5.1.16

Schiehallion wards – BSI rate by 1000 admissions, by ward, by year - 2015 - 2022					
	4B QEUH	6A RHC	Ward 2A RHC	Ward 2B RHC	Overall rate
2015	Schiehallion patients not present		24.9	3.1	12.39
2016			37.6	15.4	25.38
2017			174.2	30.2	71.20
2018	0.0	88.2	162.9	15.7	53.46
2019	222.2	58.6	Schiehallion patients not present		63.55
2020	0.0	63.0			69.77
2021	0.0	75.5			74.77
2022	0.0	76.9	0.0	13.9	13.57

9.2. The summary table below provides the overall rate by year for the Schiehallion units alongside the overall comparator institution rate for each year 2015 – 2022, with an IRR value for each year.

Year	Overall Schiehallion rate / 1000 admissions	Overall comparator institution rate / 1000 admissions	Incidence Rate Ratio (IRR)
2015	12.39	7.83	1.58
2016	25.38	6.66	3.81
2017	71.20	10.21	6.98
2018	53.46	8.85	6.04
2019	63.55	10.38	6.12
2020	69.77	8.39	8.31
2021	74.77	8.34	8.97
2022	13.57	5.63	2.41

9.3. In keeping with the methodology section outlining the epidemiology and statistical tools; the following section provides a summary of the findings of investigations as they currently stand against each tool. For purposes of simplicity of summarising the findings, I have consolidated, where necessary, the tools employed.

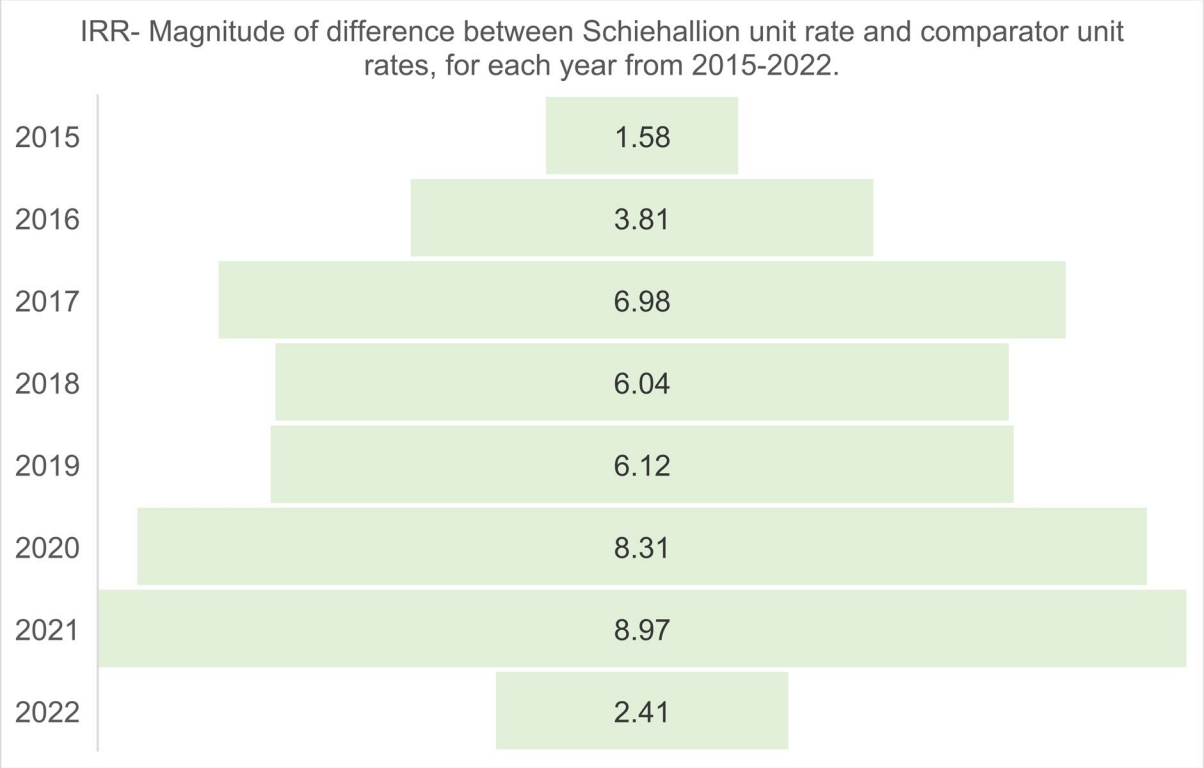
9.4. **Incidence rate** We compared the overall Schiehallion BSI (incidence) rate to the overall comparator institutions' BSI (incidence) rate for each of the years 2015-2022, utilising the Incidence Rate Ratio (IRR) statistical tool.

9.5. **Interpreting Incidence Rate Ratios. IRR** is the statistic derived from dividing the group of interest i.e. overall Schiehallion rate by the overall comparator institution rate for each of the years 2015 – 2022.

- If the IRR is equal to 1, it would indicate the two groups have similar rates
- If the IRR is > 1, it would indicate that the group of interest (Schiehallion unit) has a higher occurrence of the variable of interest (incidence rate) than the comparator group
- If the IRR is <1 then the occurrence of the variable of interest is less in the group of interest, as compared to the comparator group

9.6. Note (see IRR graph below, which illustrates the IRR statistic in graphical terms) that the IRR statistic was maintained at > 1 for each of the years from 2015 – 2022, starting at an IRR of 1.58 in 2015, peaking at an IRR of 8.97 in 2021, returning to an IRR of 2.41 in 2022.

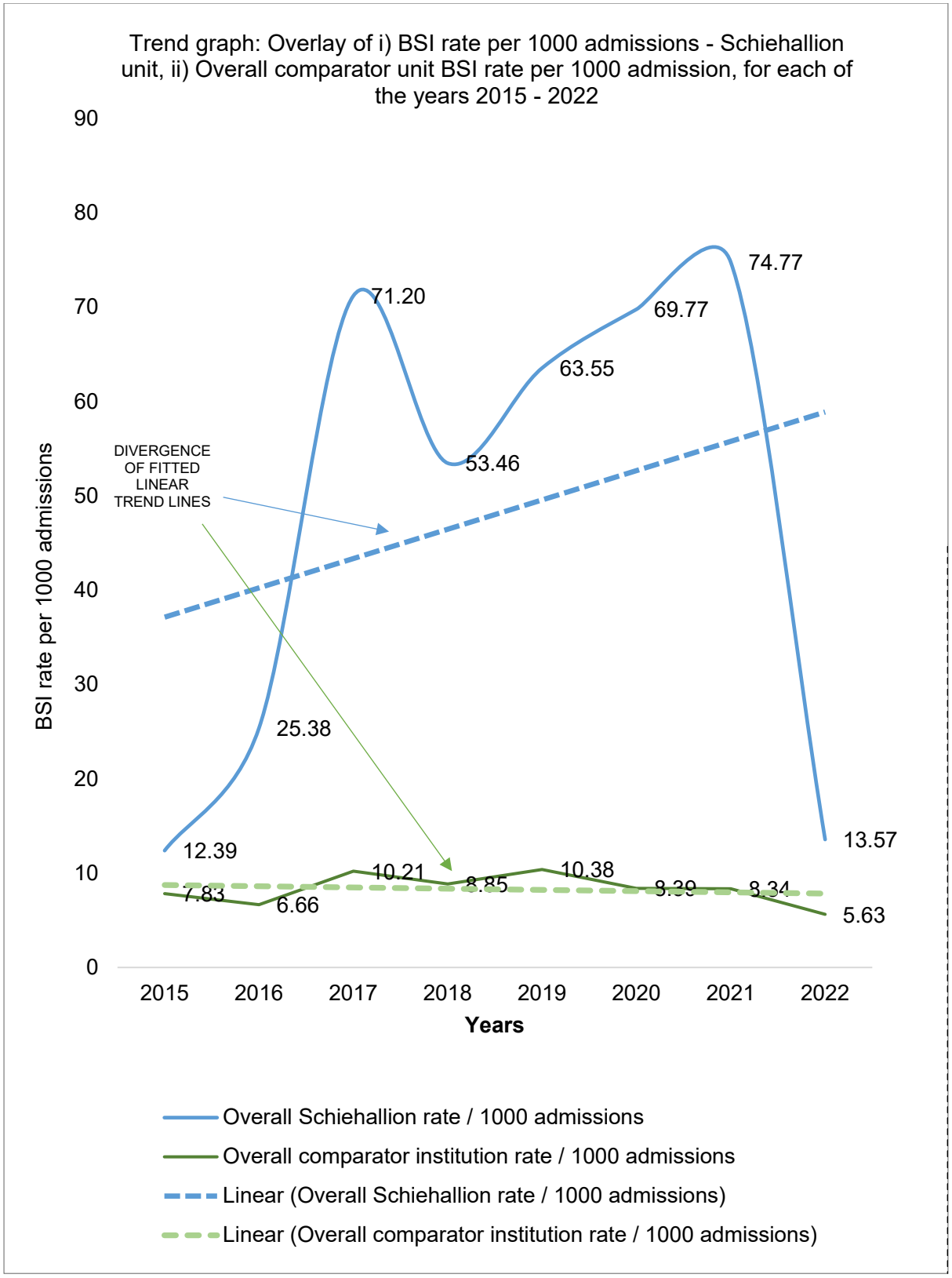
9.7. The IRR statistic is interpreted as the 'magnitude' of the difference between the two groups. In this case, we can summarise the IRR of 1.58 in 2015 as – the overall Schiehallion unit rate in 2015 was approximately 2 times (1.58 to be exact) that of comparator units' overall rate when the Schiehallion unit wards first opened. In the same vein, we note that in 2021, the overall Schiehallion unit rate was approximately 9 times (8.97 to be exact) that of comparator units' overall rate.



9.8. We can explore this difference in rates between that of the Schiehallion and peer-hospital comparator units by noting the **time-series analysis** illustrated by the graph below.

9.9. Note the linear trend lines, one for the Schiehallion BSI rate (blue dotted line) and one for the comparator (peer-hospital) BSI rate (green dotted line). The linear trend lines provide an overall view of the direction of travel, in this case of BSI rates, year on year. The Schiehallion trend is interpreted as an overall ‘upward trend’, on account of its ‘upward slope’, which is in stark contrast to the overall ‘downward trend’ of comparator hospitals over the same time period.

9.10. As an explanation - linear trend lines, draw a line of best fit across the data points. The angle of the trend line denotes the severity of the trend, which as stated in the case of the rate of infections in the Schiehallion patient cohort, is a clearly upward, apart from the dip in 2022 (rate of 13.57).



9.11. The magnitude of the difference in BSI rates between those seen at the Schiehallion versus those seen at comparator units, can be interpreted as 'unusually high' rates of infections, one that had an upward trajectory (slope of the Schiehallion unit trend line) from 2015 – 2021, peaking in 2021, a point at

which the Schiehallion unit rate was approximately nine times that of similar patient populations in peer hospitals.

9.12. These peaks or unusual variations in infection rates, is often an indicate of infection clustering, i.e. lots of infections happening at the same time.

9.13. We can therefore conclude that the Schiehallion patient cohort was consistently experiencing, since it opened in 2015, a higher incidence of gram-negative and/or fungal blood stream infection than peer, comparator institutions, who in stark contrast saw an overall decline in BSI rates (downward slope of the green dotted line) for the period 2015 – 2022, understood as a divergence in rates of infection.

9.14. The number of patient admissions drops significantly in 2019, by 60% compared to 2018, and then by 57% in 2020 compared to 2019, with a further 17% fall in 2021, compared to 2020. Despite this the rate of infection climbs from 53.46 in 2018 (44 infections in 823 admission episodes), 63.55 in 2019 (19 infection of 299 admission episodes), 69.77 in 2020 (9 infections of 129), and 74.77 in 2021 (8 infections of 107), before the reprieve in 2022 (rate of infection – 13.57). This clearly indicates that a higher proportion of the Schiehallion patient cohort developed laboratory confirmed blood stream infections owing to environmental bacterial and fungal pathogens during the period of 2019 to 2021, compared to 2018, a year as we will discuss saw numerous remedial actions taken to mitigate the high rates of infections at the unit. It nonetheless should be stated that it was over 2018 and then into 2019, that patients were decanted from wards 2A and 2B, into 4B and 6A, with the concomitant drop in admissions, a period that saw the discussed rise in infection rates, peaking at 74.77 (the second peak of infections) in 2021.

9.15. When taking the trend graph alongside the IRR graph – it is important to note the consistent difference in infection rates experienced by the Schiehallion patient cohort, as opposed to rates experienced by peer units' experience.

9.16. The trend graph focuses our attention on the two peaks of infection rates (per 1000 admissions), 71.20 in 2017 and 74.77 in 2021. Our retrospective observation of these two peaks, allows us to infer that the rate of infection was greatest in 2017 and 2021. It should not take away from the wider observation, that the rates of infection at the Schiehallion were always higher,

at least 1.58 times when the unit first opened, and at most 8.97 times in 2021, that of comparator units.

9.17. As noted in section 6.14, this magnitude of difference in rates is sustained, in spite of a dramatic fall in admissions to the Schiehallion unit over 2019 to 2021, with rates of infection going from 63.55 in 2019, 69.77 in 2020, 74.77 in 2021, with 2022 bringing a reprieve in the rate – 13.57. This at a time when comparator units were seeing an overall year on year fall in infection rates – 10.38 in 2019 to 8.34 in 2021, and 5.63 in 2022.

10. Summary of findings – Association between infection rates and water positivity

10.1. **Cross-correlation –** As discussed in the methodology section, the correlation coefficient is a statistic that allows us to measure the closeness of association/correlation of variables of interest, in this case the Schiehallion infection episodes and the results of water sampling of the patient environment – rate of water positivity.

10.2. **Correlation-coefficient –** The statistic is derived from comparing the time series data points of the Schiehallion infections and that of water positivity (see table below). For the purposes of this analysis, we compared the five data points, one for each year from 2015 – 2019, using the Pearson's [28] correlation coefficient.

Year	Overall Schiehallion rate / 1000 admissions	Water positivity rate
2015	12.39	2.50%
2016	25.38	0.00%
2017	71.20	7.65%
2018	53.46	17.36%
2019	63.55	11.06%
2020	69.77	5.58%
2021	74.77	
2022	13.57	

[28] Altman DG, Practical Statistics for Medical Research (CRC Press 1990)

10.3. The product of the Pearson's correlation coefficient for the period 2015 to 2019 came to 0.7, which is interpreted [29] as indicating a 'moderate to very strong' positive association between the two variables, i.e. as water positivity increases over the period 2015 to 2019, so does the Schiehallion BSI rate per 1000 admissions.

10.4. We are conscious of the Covid-19 pandemic commencing in 2020, and the resultant consequences such as access to clinical areas, which we understand to weigh on the comparability of water sampling post 2020 versus pre-2020. Therefore, for the purposes of the correlation analysis, we focused our attention on the five-year period between 2015 and 2019.

10.5. We should also remind ourselves of the issue discussed in section 5.4.17 to 5.4.19 – the manner in which the water sampling data was recorded in 2015 and 2016, has meant it lacks the granularity to extract water sampling specific to the Schiehallion units. This improves 2017 onwards. It is my opinion that this issue has lent itself to the low number of water samples and corresponding water positivity rates in 2015 and the 0% in 2016.

10.6. The trend graph below provides an illustration of the Schiehallion BSI rate per 1000 admissions over the period 2015 to 2022 (blue line), alongside the water positivity rate (yellow bars) over the same period. The dotted blue line and the dotted yellow line provide the linear trend of BSI rates and water positivity respectively. Trend lines as discussed when comparing the Schiehallion units' overall infection rate versus that of peer organisations, draw a line of best fit amongst the data points, with the gradient of the slope an indication of how 'severe' the trajectory is.

10.7. We note the upward slope of both the blue and yellow dotted lines, interpreted as an upward trajectory of infection episodes with a concomitant upward trajectory of water positivity over the five-year period 2015 to 2019. It is this concomitant upward trend that the correlation coefficient value of 0.7 represents, i.e. a moderate to very strong correlation between water positivity and infection rates at the Schiehallion unit.

[29] Akoglu H, 'User's Guide to Correlation Coefficients' (2018) 18 Turkish Journal of Emergency Medicine 91

10.8. Note the water positivity trend line is far steeper compared to the infection rate, suggestive in my opinion, and as laid out in the qualitative and water analysis documents by Dr. Mumford, Linda Dempster and Dr Walker, of the high level and rising trend of water contamination over the three-year period of 2017 to 2019.

10.9. Applying Bradford Hill's postulates/guidelines, as discussed in the methodology section, we see that all seven of the applicable postulates (see table below) have been satisfied vis a vie the relationship between the exposure variable – water contamination, and the outcome – infection rates.

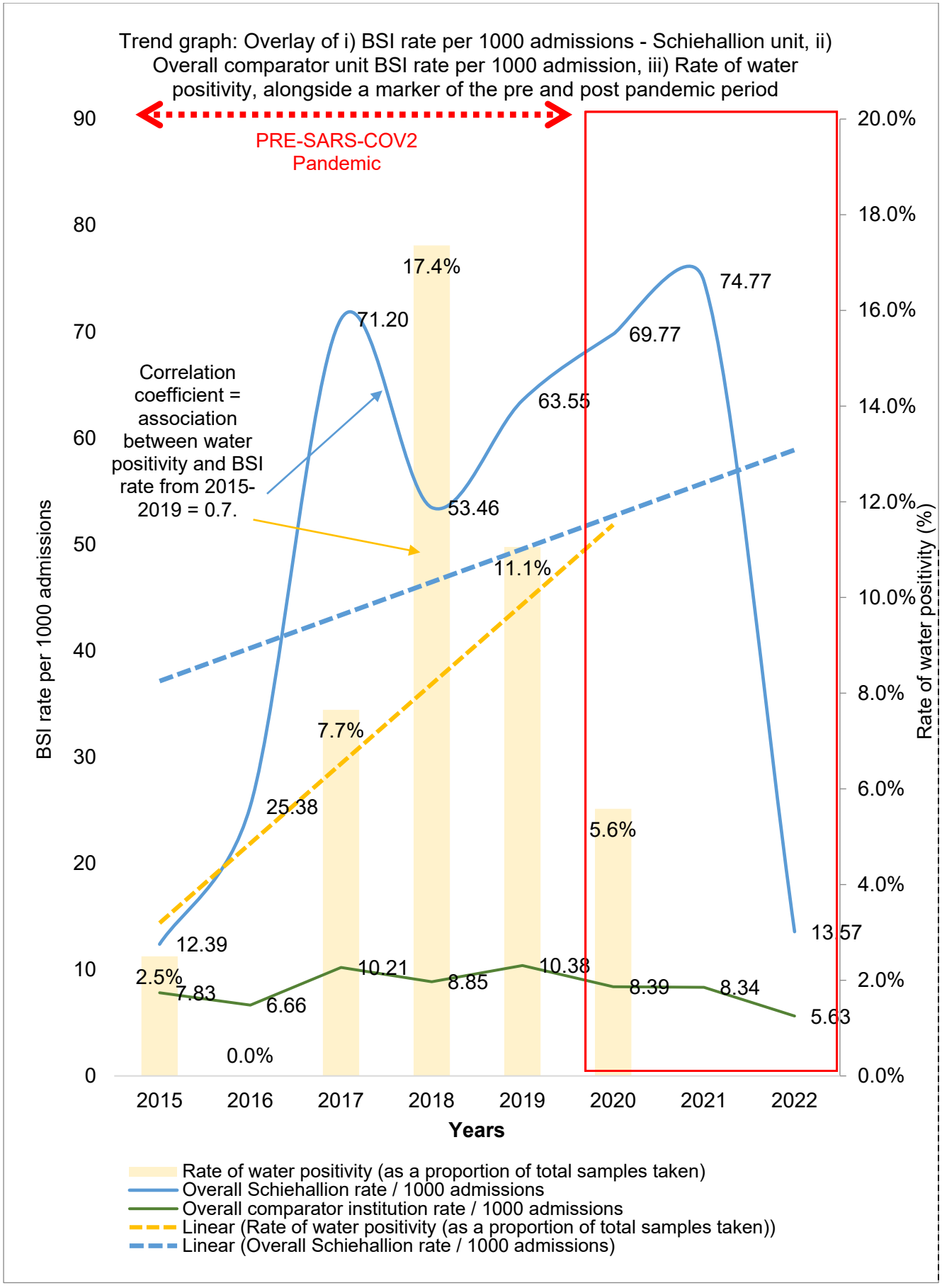
Index	**Guideline**	**Explanation**	**Does the analysis undertaken, to understand the association between infection rates and water contamination rates satisfy the given postulate?**
1	Strength or degree of association	Larger the value of the relative risk (effect size) between the exposed and unexposed groups, the stronger the 'strength of association'	Yes.
2	Consistency	The event or outcome of interest has been repeatedly observed, and these observations have been made in different circumstances and times.	Yes.
3	Specificity	Disease outcome is seen in a specific population at a specific site with no other likely explanation, other	Yes.

		than the hypothesised exposure.	
4	Temporality (including spatial property)	Organism acquisition occurs where and when environmental contamination of present or does not occur where said contamination is absent. Recent additions to this guideline have included 'spatial', to account for the 'where' and 'when'	Yes.
5	Biological gradient	Greater exposure generally leading to greater incidence, i.e. dose/stressor-response relationship	Yes, for the period 2015 to 2019.
6	Plausibility	Is the association biologically plausible	Yes.
7	Coherence	Do epidemiological and laboratory findings agree with each other	Yes.
8	Experiment	When interventions are applied which reduce the exposure/trigger variable, does the outcome reduce too. OR Is organism acquisition eliminated or reduced when exposure to the environment is subjected to intervention	To be discussed in the next section concerning remedial actions and its effect on water positivity.

9	Analogy	Is a comparable association observed between the same outcome and an analogous exposure or the same exposure and an analogous outcome.	N/A

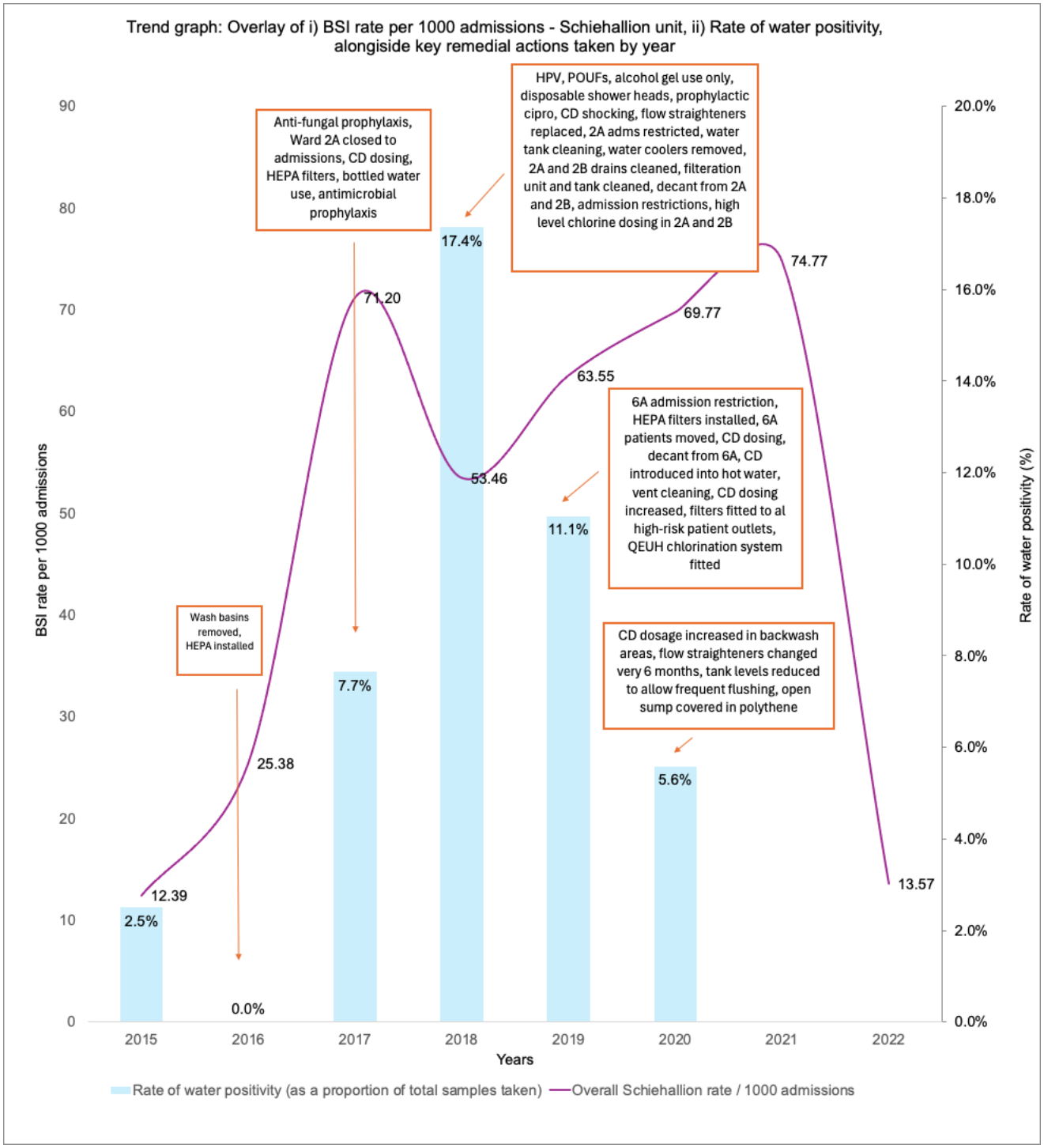
10.10. Following on from the above, we know that with a minimum IRR of 1.58 in 2015, peaking at 8.97 in 2021, that there is a significant difference in the magnitude of infections between that suffered by the Schiehallion patient cohort, versus peer organisations (who were not exposed to the environment at the Schiehallion) over the 7 year period. In the absence of another plausible exposure variable, this satisfies the first of Hill's postulates – **1 – high effect size** between the exposed and unexposed group. Furthermore the analysis thus far laid out, satisfies postulate - **2 - the consistency with which the outcome (infections) were observed over time**, even post the decant of patients from 2A and 2B to 4B and 6A (in fact this led to a higher proportion of the patients suffering infections), **3 – specificity, i.e. we do not have another plausible explanation for the difference in infection rates between Schiehallion and peer organisations**, and therefore we surmise that the level of water contamination was responsible for the infections in the patients, **4 – temporality** – with a correlation coefficient of 0.7, indicating a strong to very strong association, we have proven that positive water samples were being taken in the areas also seeing high rates of infection, and finally **postulates 5 , 6 and 7,** namely the association between water contamination rates and infections followed (in general) a **dose/stressor relationship,** i.e. as contamination increased so did (in general) the infection rates (we will discuss how this was affected by remedial actions taken over these years), that it is a **biologically plausible relationship,** i.e. we know waterborne pathogens cause infections in patients, and we can say this with **laboratory confirmed samples confirming that both the exposure and outcome existed.**

10.11. Satisfying all seven of the applicable postulates lends me, in my opinion, to state that there existed a very strong association between water contamination and rates of infections in the Schiehallion patient cohort.


Trend graph: Overlay of i) BSI rate per 1000 admissions - Schiehallion unit, ii) Overall comparator unit BSI rate per 1000 admission, iii) Rate of water positivity, alongside a marker of the pre and post pandemic period
PRE-SARS-COV2 Pandemic
Correlation coefficient = association between water positivity and BSI rate from 2015-2019 = 0.7.
BSI rate per 1000 admissions
Rate of water positivity (%)
Years
2015
2016
2017
2018
2019
2020
2021
2022
12.39
71.20
53.46
63.55
69.77
74.77
13.57
2.5%
7.7%
11.1%
5.6%
0.0%
7.83
6.66
10.21
8.85
10.38
8.39
8.34
5.63
25.38
Rate of water positivity (as a proportion of total samples taken)
Overall Schiehallion rate / 1000 admissions
Overall comparator institution rate / 1000 admissions
Linear (Rate of water positivity (as a proportion of total samples taken))
Linear (Overall Schiehallion rate / 1000 admissions)

11. Summary of findings – Association between water positivity and remedial actions

11.1. As set out in section 5.5.1, there were key remedial actions carried out for the period in question. The graph below lays out these key measures, by year, over the trend graph we have familiarised ourselves with in the previous sections. The correlation measure was also used to understand the association between rates of water positivity and the undertaking of mitigation/remedial actions at the Schiehallion wards – 2A, 2B, 4B and 6A.



11.2. We note from the table in section 5.5.1 and the graph above, that substantial remedial actions such as chlorine hydroxide dosing, restriction of admissions, decant of patients, treatment and cleaning of water tanks, replacement of showers and installation of point-of-use-filters (POUF), were among a litany of measures undertaken over the period of 2016 to 2020 (Note – we have focused here on consequential remedial actions, which present themselves

over the period of 2016 to 2020. This does not mean that other remedial actions were not taken in 2015, or after 2020).

11.3. The number of remedial actions, as seen from the graph above, is highest over the period of 2018 and 2019, overlapping with the period that saw the highest rates of water contamination – 17.4% and 11.1% in 2018 and 2019 respectively.

11.4. Let us remind ourselves of Bradford Hill's postulate 8, namely, experiment, i.e. when interventions are applied which reduce the exposure/trigger variable, does the outcome reduce too. OR is organism acquisition eliminated or reduced when exposure to the environment is subjected to intervention. Applying this postulate, we can note two things: one that the remedial actions, which were specifically targeting, for the purposes of this paper, the water system, increases in number and consequence as the rate of water positivity rises, and falls as the rate of water positivity falls. This leads us to the second point, that the exposure, water positivity as a marker for the level of water contamination, falls, or is reduced when subjected to interventions, in this case remedial actions aimed at the water system. This therefore satisfies Hill's postulate 8, as we see the drop in water positivity from 17.4%, to 11.1% to 5.6% for the period of 2018, 2019 and 2020 respectively, in response to the variable that makes itself available, i.e. remedial actions.

11.5. In relation to the high rates of infection in 2019, 2020 and 2021 – Firstly, we understand that the high rates of infection in 2019, 2020 and 2021 were seen over a period which saw a concomitant decline in patient admission figures (comparing 2019 to 2018, 2020 to 2019, and 2021 to 2020), i.e. suggesting a higher proportion of the patient admissions were getting infections over this period. Secondly, these high rates of infection also coincided with a drop in water positivity over this period. It is important to note that the rate of water positivity is a marker of the extent of contamination of the water system, seen through the lens of the number of water samples taken. High water positivity is a marker of more comprehensive contamination, versus lower positivity figures which note less comprehensive levels of contamination. Whilst this distinction is important, it is equally important to note that vulnerable patient groups, such as the Schiehallion patient cohort, can develop waterborne bacterial and fungal infections as a consequence of any level of water

contamination. The fact that a higher proportion of the Schiehallion cohort in 2019, 2020 and 2021 were seeing infections owing to waterborne infections, over a time when rates of water positivity was seen to drop, points to the 'system wide' contamination of the water system, unable to be mitigated by short term fixes at the point of water use, i.e. taps, showers etc. Furthermore, the high rates of infections are doubly concerning, as the spike in rates coincides with the decant to 4B and 6A, from 2A and 2B, questioning what the decant achieved as a mitigation step to curb the rates of infection.

12. Conclusion

12.1. The findings laid out in the quantitative paper above ought to be considered alongside those of the water report by Dr Jimmy Walker and the qualitative report by Dr. Sara Mumford and Linda Dempster.

12.2. In light of the outputs discussed above, it is in my professional opinion, *highly unlikely* that the rates of water positivity and rates of infections over the period of 2015 to 2019 are not strongly associated.

12.3. Furthermore, it is clear that the rates of infection per 1000 admissions at the Schiehallion unit were unusually high, and consistently so, as compared to comparator peer-hospitals, over each and every year, from 2015 to 2022.

12.4. In light of no other explanation for the unusually high rates of infection at the Schiehallion unit, and the degree of correlation between rates of water positivity and rates of infection, we understand this as a case of high levels of water contamination at the Schiehallion unit leading to the unusually high rates of gram-negative and fungal blood stream infections in the Schiehallion patient cohort.

13. Appendix 1 - Note on Whole Genome Sequencing

13.1. Whole genome sequencing refers to laboratory procedures which allow for the genome (unique genetic code) of an organism to be understood in terms of the order of nucleotide sequences (A,T,G & C). Understanding the order of the nucleotide sequences, also referred to as the sequence of bases, allows us to distinguish the organism's unique DNA fingerprint[30].

13.2. Genome sequencing is an important tool in the public health arsenal to understand and track the spread of pathogens e.g. bacterial outbreak in a healthcare setting.

13.3. The integration of genomic sequencing into real-time surveillance to mitigate transmission and infection outbreaks is still very much being understood, with one of the major challenges being the incorporation of sequencing outputs alongside conventional gold-standard clinical-epidemiological outbreak mitigation frameworks, within the context of a fluid healthcare environment.

13.4. One of the key considerations is collating the phylogenetic relatedness or lack thereof, communicated by outputs of genomic sequencing, between organisms implicated in patient infections and those found in the patient's environment, and balancing it with knowledge of pathogen evolution in the environment and heterogeneity of bacterial genus strains from different parts of the environment being sampled.[31]

13.5. It is important to acknowledge the granularity that genome sequencing provides, which in combination with the robust analysis and inference made from epidemiological data, can allow clinicians and healthcare managers increased clarity in outbreak settings.

13.6. The expert group are of the collective opinion that sequencing outputs should not be used in a disparate manner to discount possible associations between infections and a source, particularly when epidemiological data collected by and analysed by local actors shows otherwise. In other words - the absence of evidence is not evidence of absence. And so it follows that the robustness

[30] 'Whole Genome Sequencing | CDC' (16 August 2022) <https://www.cdc.gov/pulsenet/pathogens/wgs.html> accessed 31 October 2023)

[31] Establishing Whole Genome Sequencing at the Core of Epidemiological Surveillance | Microbiology Society' https://www.microbiologyresearch.org/content/establishing-whole-genome-sequencing-at-the-core-of-epidemiological-surveillance accessed 31 October 2023

of reliance on the absence of an exact match is very much dependent on the comprehensiveness (including the frequency) of water testing.

14. Appendix 2 – Response to PP2 review of infection rates, specifically addressing points concerning surveillance and epidemiological points.

14.1. NHS GGC's PP2 paper, dated 5th of April 2023, addresses the evidence provided by the Inquiry up to that point.

14.1.1. **In response to paragraph 39, which notes the challenges in comparing rates of infections at the QEUH and RHC to other hospitals** – Weighting the incidence of infection by activity, thereby producing an incidence rate, and then understanding the 'magnitude' of the difference = IRR, is an industry standard methodology. Infection rates taking into account activity and comparison of rates using the above stated method is provided in this paper.

14.1.2. **In response to paragraph 39, which notes the peculiarities of the Glasgow population, in terms of, among others, their level of deprivation, makes it unique, and therefore comparison of infection rates at QEUH and RHC to other peer organisations is difficult** - Evidence that deprivation leads to generally poorer health outcomes is where the evidence focuses on, as a result of inadequate sanitation, screening of infection and general lack of equity when it comes to access to healthcare. As an example of where the literature on the topic lies, a Lancet paper from 2023 [32] provides a summary of poorer health outcomes in the paediatric haematology population. It does not however note that deprivation equals a higher predisposition to healthcare associated infections in a hospital setting. Deprivation does not entail that patients seeking frequent hospital care are subject to higher rates of bacterial and fungal infections in hospital settings. If we assume that the delivery of healthcare is consistent and the kind of patients being referred to QEUH/RHC is from across the demographic space, then one can assume this isn't different to other such centres leading tertiary centres such as those at Great Ormond Street Hospital, Leeds hospital,

[32] Chalfant V and others, 'Impact of Social Disparities on 10 Year Survival Rates in Paediatric Cancers: A Cohort Study' (2023) 20 The Lancet Regional Health – Americas <https://www.thelancet.com/journals/lanam/article/PIIS2667-193X(23)00028-5/fulltext> accessed 1 April 2024

Cardiff hospital, and Oxford hospital, all delivering care to similarly diverse populations, in big cities, with equally inequal populations, and therefore the case mix being compared aren't all that different. And therefore, any difference in rates of infections, e.g. QEUH to the overall pattern observed at the comparator centres is significant.

14.1.3. **In response to paragraph 41 which notes ARHAI reports for the period Q4 2014 – Q2 2022, and surmises that the QEUH and RHC rates of infection were within 'normal variation' –** The ARHAI report for the period in question only dealt with mandatory reportable organisms, which when considering the gram-negative pathogens, would have only included *E.coli*, *Klebsiella. spp.,* and *Pseudomonas. spp*. The focus of the inquiry is on gram-negative and fungal pathogens which are found in the environment, in this case water systems, which excludes *E.coli*, but includes a plethora of other gram-negative bacteria which is not considered by ARHAI in their reports. Therefore the comparison of gram-negative and fungal rates of infections at the QEUH and RHC for the period in question, to ARHAI reports is not possible, as we are not comparing like to like.

14.1.4. **In response to paragraph 42 which compares ARHAI's point prevalence survey (PPS) specifically the data over September and November 2016, a rate of 4.5%, with the QEUH and RHC rate (4 % QEUH and 3.6% RHC) stated to be lower than the PPS rate –** The ARHAI PPS took into account any healthcare associated infection, including *E.coli,* gram-positive organisms such as *staphylococcus.aureus*, in addition to infections linked to urinary tract infections, pnuemoniae, surgical infections, and bone infections– which are not in line with the specific focus on environmental gram-negative and fungal blood stream infections at the Schiehallion. The ARHAI PPS results should therefore be discounted for the purposes of this inquiry, as it includes categories and genus of bacteria, and categories of infection not under investigation, and therefore does not present a like for like comparator to the rates of blood stream infection under investigation at the Schiehallion unit. Lastly, and on the point raised in the previous statement, the ARHAI PPS only included 20 healthcare associated infections from paediatric patients, of which only 4 were blood stream infections, which is an extremely small sample of paediatric blood stream infections to qualify as a meaningful

comparator, even if the focus of the ARHAI PPS had been in line with the remit of the inquiry at hand.

15. Appendix 2.1 - In response to 'Summary of patient safety indicators by Sandra Devine', Appendix 1, NHS GGC PP2, 5th April 2023.

15.1. **Page 21, Deprivation section –** As addressed in section 11.1.2, the literature and therefore the evidence base does not support the hypothesis that deprivation equals a higher predisposition to healthcare associated infections in a hospital setting. If we are to consider poorer health outcomes leading on from a general lack of equity in terms of access to sanitation, screening of infection, access to healthcare, all variables which are linked to deprivation, the comparison of the Schiehallion patient cohort's rate of infection to that of other large tertiary peer organisation clearly shows that the rates of infection at the Schiehallion were 2 times higher for the period of 2015 to 2022. I cannot in my expert opinion attribute deprivation to be reason for this difference in rates.

15.2. **Page 24, National PPS rates of hospital-acquired infections in QEUH during 2016 was 4%, national rate was 4.5%. Children's hospital rates – RHC 3.6%, Royal Aberdeen Children's hospital – 0%, Royal Hospital for Sick children Edinburgh – 7.7%.** The weight of the PPS undertaken in 2016, in terms of its consideration as a comparator to rates of infection at QEUH and RHC, needs to be understood in the context of the methodology adopted by HPS. Firstly, the PPS excluded day patients, which as noted in section 5.2.3, paediatric haematology-oncology patients spend considerable amounts of time as day patients in hospital, receiving treatment, often intravenously, in addition to which they come into contact with the hospital environment, all of which over time, adds substantially to their overall risk of acquiring infection. By only including patients who were admitted to a ward at 8am on the morning of the survey, the PPS, in my expert opinion, cannot be justified as a like for like comparator to the gram-negative bacterial and fungal infection led rate of infections suffered by the Schiehallion cohort since 2015. The HPS 2016 PPS therefore, on the basis of this single, but fundamental methodological point, cannot be used to benchmark rates of infections in the Schiehallion patient cohort.

15.3. **Page 25, ARHAI hospital review of AOP in RHC/QEUH requested by NHS GGC. Hospital attributed cases of *Clostridiodes difficile, E.coli* and *Staphylococcus aureus* bacteraemia for 2016, 2017, and 2018 were compared to peer hospitals with similar patient populations. The QEUH and RHC were not highlighted as an exception in any of the plots.** The comparisons made here are based on 'cases' and do not adjust for activity, furthermore none of the three pathogens are environmental pathogens, i.e. those most likely to be found in the environment, and fall outside the remit of this inquiry, and the question around the association between water systems and infections in the Schiehallion patient cohort.

16. Appendix 3 - In response to November 2019 HPS (ARHAI) review of infection rates in the paediatric haematology oncology patient cohort.

16.1. I have read and critically considered the November 2019 HPS, ARHAI report which reviews the NHS GGC paediatric haematology-oncology data. This report is referenced in Sandra Devine's summary of infections - Appendix 1, NHS GGC PP2, 5th April 2023, where specific points in relation to the 2019 HPS report are noted, namely; i) The incidence of positive blood cultures was lower for gram-positive group throughout the time period - the entire 2015 to 2019 period and specific periods in question – Oct 2017 to Sep 2019 plus Oct 2018 to Sept 2019, and ii) that there was an increase in gram negatives from 2017 to 2019, being driven primarily by increase in enterics rather than environmental organisms, iii) that overall there is no difference in environmental organisms but there is an increase in environmental plus enteric bacteria, and iv) population differences are not directly comparable or due to complex case mix, however logic would suggest that the more vulnerable the population the higher the risk of infection and both population and complex case mix were present in the cohort of children card for in RHC.

16.2. The following summary stands as a critique of the HPS 2019 report and in doing so also responds to the specific points raised by Sandra Davine.

16.2.1. The present inquiry's remit extends to gram-negative and fungal environmental borne infections in the Schiehallion patient cohort, and in keeping with that gram-positive rates of infection fall outside the remit of this

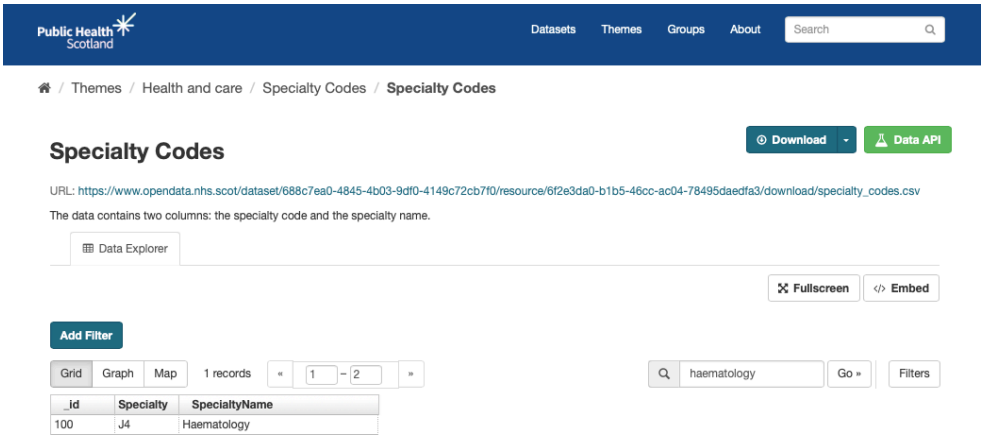
paper, and do not constitute a like for like comparator to the specific infections under investigation by the current inquiry.

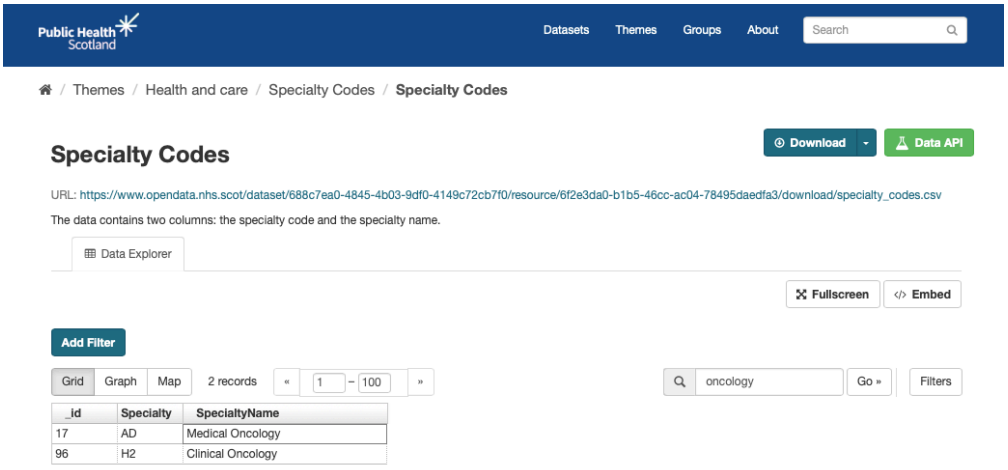
16.2.2. We have already considered the evidence around deprivation and health outcomes, and as stated, comparing QEUH and RHC's paediatric haemato-oncology population to similar cohorts at GOSH, Leeds, Cardiff and Oxford, provides a robust like for like benchmarking of infection rates. The magnitude of the difference in rates (as discussed in this paper) cannot be accounted for by the level of deprivation of the Schiehallion patient cohort alone, if at all.

16.2.3. With specific emphasis on methodology adopted by the 2019 HPS report – it outlines rates of infection calculated using occupied bed days, which as discussed in various points in this paper, does not account for the cumulative risk of numerous day stays and outpatient visits that this patient cohort accumulates over time.

16.2.4. Under the 'review of denominator data' section, page 13, the authors note the denominator data source, namely – ISD(S)1 activity data, with the extract provided by ISD for routine published reports. Figure 2 on page 13 charts the trend in 'haematology' and separately the 'oncology' bed days for the period of July 2013 to August 2019. The authors note that bed days activity data for haematology and oncology was extracted, with NHS GGC activity data being validated against HPS data, but do not provide information on how they differentiated between activity attributable to the paediatric cohort as opposed to the adult patient cohort. The lack of differentiation, or at least overt clarity on this point, lends me to assume they included 'all' haematology oncology activity data when calculating the rates of infections, i.e. activity data for both the adult and paediatric patient cohort, which would clearly lead to an underestimation of the 'true' rate of infection in the paediatric cohort. This is because incidence of infections in the Schiehallion patient cohort should be divided by the activity specific to this patient cohort, which <u>should not</u> include adult haematology oncology activity. Note that the Public Health Scotland website confirms that the ISD(S)1 dataset offers one speciality code under haematology – J4 100, and two for oncology - AD 17

and H2 96, see screenshots below [33], with no paediatric haematology nor oncology specific codes.





16.2.5. I acknowledge their utilisation of free text within the unit location, medical speciality and requesting location fields were used to derive a location and ward specific to the Schiehallion patient units – 2A, 2B, 6A and 4B, which begs the question – how did the authors adjust for the overestimation of activity in their workings which would lead to an underestimation of the rate of infection in the paediatric haematology-oncology patient cohort, seeing the implication of overestimating the denominator.

16.2.6. On page 14, Figure 3, a trend graph of 'day cases' and separately one for 'outpatients' activity for the period of 2014 to 2019 is provided, but no information on how the authors differentiate between the two – day cases and outpatients. Even so, in line with the methodology employed by the HPS

[33] 'Specialty Codes - Specialty Codes - Scottish Health and Social Care Open Data' <https://www.opendata.nhs.scot/dataset/specialty-codes/resource/6f2e3da0-b1b5-46cc-ac04-78495daedfa3> accessed 3 April 2024<https://www.thelancet.com/journals/lanam/article/PIIS2667-193X(23)00028-5/fulltext> accessed 1 April 2024

report, the day cases and outpatient stays have been excluded from the rate of infection calculation, with the rate calculated in terms of 1000 TOBD or Total Occupied Bed Days.

16.2.7. In relation to the SPC charts, figures 4, 5, 6 and 7 on pages 16 and 17 - it is important to note that the rate per 1000 TOBD, unless otherwise specified, is based on the 'total' adult and paediatric haematology and oncology bed days activity data, as discussed in previous sections, and therefore should not be counted as a meaningful representation of the burden of infection in this patient cohort over this period of time.

16.2.8. In relation to page 18, 'Comparison with other health boards' - In terms of comparing the overall hospital rate of infections, and separately the gram-negative environmental and enteric bacterial rates to peer organisations, it is important to compare the paediatric haemato-oncology unit to other leading centres across the country. Crucially, the rate of infection has to be based on activity specific to the paediatric cohort and should not include adult haematology oncology activity. In the absence of information on how the authors extracted bed day activity specific to the paediatric patient cohort from the ISD(S)1 dataset, the comparison made with 'Royal Aberdeen Children's Hospital' and 'Royal Hospital for Sick Children' should be deemed neither rigorous nor accurate.

16.2.9. The point around comparing the QEUH and RHC's paediatric haematology oncology population to other large tertiary acute centres - This is particularly important considering the argument posed by Sandra Davine regarding the weight she noted should be attributed to deprivation vis a vis rates of infections at QEUH and RHC. Large tertiary centres such as GOSH, Cardiff, Leeds, and Oxford, through serving a diverse population of patients within the paediatric haemato-oncology cohort help adjust for inequities posed by deprivation, among other points. If deprivation ought to be considered, and it is my opinion that it cannot account for the disparity in rates of infection in the Schiehallion cohort compared to peer organisations, then the comparisons with NHS Grampian and NHS Lothian hospitals ought to be supplemented by comparisons with large tertiary centres, using accurate 'paediatric bed days activity data'.

16.2.10. The points raised in this section need to be addressed if the HPS 2019 report is to be considered within the portfolio of work looking at rates of infections in the Schiehallion patient cohort. It is my opinion that the HPS 2019 report's analysis is not a rigorous attempt at understanding the trend in rates of infection at QEUH and RHC over the period in question.

17. Appendix 4 – Response to Dr Kennedy's report of October 2018

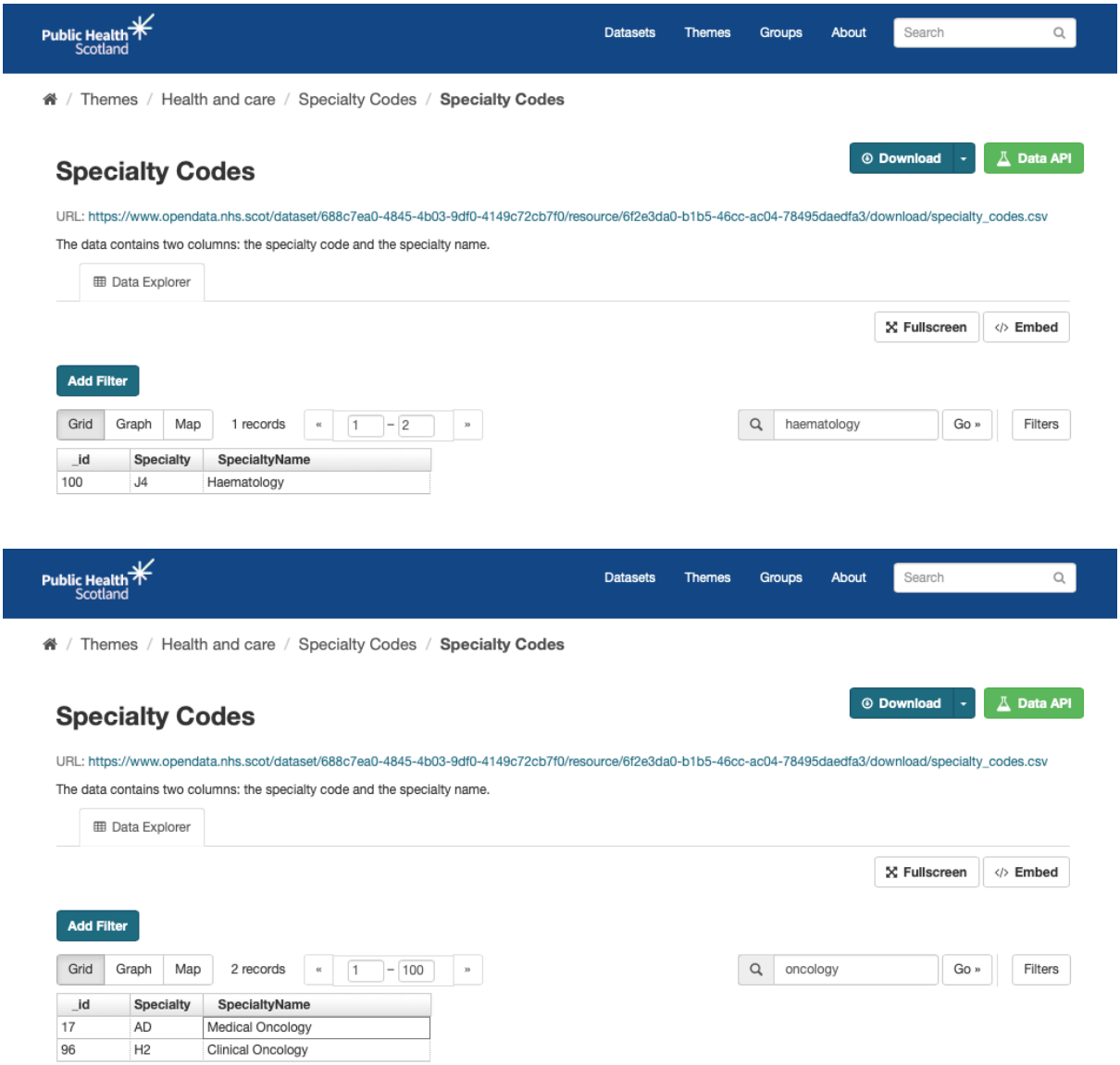
17.1. The paper by Dr. Kennedy is a descriptive epidemiological paper on the 'increase in gram-negative bacteraemia in the RHC, the trend in selected gram-negative bacteraemia in RHC and the old RHSC over a 5-year period has been examined'. The methodology section notes gram-negative organisms reported from key laboratories for patients under the age of 16 from Jul-2013 to Jun-2018 were extracted, and therefore only accounts for episodes of infections prior to the complete decant from 2A and 2B to 4B and 6A.

17.2. The author notes two separate counts, an organism count, and a case count were calculated. The organism count deduplicates on the basis of bacterial genus, as the extract from ECOSS was on the basis of genus and not species, which can lead to an underestimation of infection episodes, and is not in line with HPS and UKHSA standards of deduplicating patient infection episodes. Case count, where the author did not take into account any positive, regardless of whether it was a different organism (bacterial genus in this case) to the one initially found, within a 14-day window, is also not in line with HPS and UKHSA guidance, and will in my view lead to an underestimation of infection episodes.

17.3. The author then notes 'date of result was counted as day one' – I assume this was done to at some point differentiate between hospital and community associated infection. Note that this is not in line with HPS and UKHSA guidance, who note 'date of sample collection' as the key variable in differentiating between hospital and community infection allocation.

17.4. The author notes 'rates were then calculated per 1000 bed days – Note that the industry standard, when using bed days, is a rate of infection per 100,000 bed days, as large Acute-Trust hospital bed days are in the realm of 100,000

– 400,000 a year. Furthermore, no reference is provided as to the source of this data, only that it was provided by the NHS GGC acute service information team. Note that the bed day activity data available nationally in Scotland, referred to as the ISDS1 only offers – ID speciality codes – AD 17 and H2 96 under oncology, and J4 100 under haematology, see screenshots below [34] .



17.5. This inability to curate bed day activity data for the RHC paediatric haemato-oncology cohort is evident from the inpatient and day case csv files available on the Public Health Scotland website [35]. This inability to distinguish the

[34] 'Specialty Codes - Specialty Codes - Scottish Health and Social Care Open Data' <https://www.opendata.nhs.scot/dataset/specialty-codes/resource/6f2e3da0-b1b5-46cc-ac04-78495daedfa3> accessed 3 April 2024<https://www.thelancet.com/journals/lanam/article/PIIS2667-193X(23)00028-5/fulltext> accessed 1 April 2024

[35] 'Data Files - Acute Hospital Activity and NHS Beds Information (Quarterly) - Quarter Ending 30 September 2023 - Acute Hospital Activity and NHS Beds Information (Quarterly) - Publications -

activity data for the cohort in question and being investigated would result is a gross underestimation of the rate of infection, as the denominator being used, namely, the bed days for QEUH/RHC entire haematology and oncology inpatient cohort is a far larger number than the bed days specific to the paediatric haemato-oncology patient cohort.

17.6. The analysis carried out in this paper, based on inappropriate bed day denominator data, in my expert opinion does not justify its inclusion as a robust and rigorous epidemiological analysis of trends in infections at the QEUH and RHC.

17.7. It would be valuable to have the author's response to the above noted criticisms.

18. Appendix 4 – Response to Dr Kennedy's report of July 2019

18.1. In the denominator section of the report the author notes – "denominator needs to be able to account for person-time at risk, for example bed days, or line days". Note that adopting this view of the denominator can be extended to include admissions, and calculating a rate per 1000 admissions, seeing that the cohort in question has extensive hospital contact under the 'day case' or 'outpatient' patient administration flag, something the author appears to adopt (day cases and total outpatient appointments) in addition to bed days data.

18.2. In the methods section the author notes no change to the methodology adopting in calculating infection counts from the 2018 report. Note my criticisms on the methodology adopted by the author when calculating 'case' and 'organism' counts in section 13.2.

18.3. In addition, the author does not explicitly state the methodology adopted in calculating bed days for this report, with the only note suggesting a difference (from the 2018 report) – "considering haematology-oncology separately to the rest of RHC assists with this, as does suggestion of displaying count and denominator data on different axes. Additionally, to account for underestimation of denominator, a combined activity denominator has been used in the updated report (bed days + day case + total outpatient

Public Health Scotland' <https://www.publichealthscotland.scot/publications/acute-hospital-activity-and-nhs-beds-information-quarterly/acute-hospital-activity-and-nhs-beds-information-quarterly-quarter-ending-30-september-2023/data-files/> accessed 3 April 2024

appointments). As noted in my critique of the 2018 paper, the ISDS1 bed days activity dataset, which I presume is the one adopted by the author for the 2018 report and the 2019 report, does not allow for a differentiation between adult and paediatric haematology oncology activity. The inclusion of the combined, undifferentiated bed days for adults and paediatrics will lead to a substantial overestimation of the denominator, leading to an underestimation of the true rate of infection. In my opinion, the RHSC/RHC selected gram negatives graph, providing a case and organism rate per 1000 bed days, does not represent the true rate and trend of infections for the patient cohort in question. Furthermore, the title of the graph – 'RHSC/RHC selected gram negatives' suggests an additional 'selection' step, with the implication that the graph includes a 'curation step' not explicitly outlined in the methodology section of the report.

18.4. The author then provides a graph with title 'Crude case rate for selected gram-negative bacteria in haematology/oncology patients', with a rate per 1000 activities. Note that this is the first mention of the term 'activities' with no explicit explanation in the methodology section of the report as to what 'activities' entails and includes. Furthermore, the reader is left to assume that the case and organism rate, this time specific to haematology/oncology patients, only includes paediatric patients, as the title does not explicitly state that. In view of my criticisms in section 14.3 and 14.4 (current section), and previously in section 13, it is my opinion that this graph does not represent a rigorous and true representation of the rate of infection in the patient cohort in question.

18.5. In the following page, a graph titled 'Case count selected gram-negative bacteria and total activity haematology/oncology' is provided. The author notes just prior to this graph, that one would expect an increase in incidence in line with an increase in activity, as compared to earlier periods – it is left to the reader to assume which 'prior' period is being referred to, secondly an expectation that incidence increases with activity implies that the ratio of cases as a proportion of e.g. admissions or bed days remains consistent, which is an actual increase in the absolute number of infections. The graph – case counts are not weighted for activity, and therefore are not a rigorous representation of the longitudinal trend in infections. Furthermore, the graph

would benefit from application of ‘correlation’ epidemiological tools, to understand how the trends in activity are associated with trends in case counts. A quick and understandable option would be the application of a rate of infection per 1000 activity episodes, which is the industry standard for adjusting for fluctuations in activity.

18.6. In the ‘denominator’ section, the author provides a graph (with a summary) namely ‘Changes in total activity (IP+DC+OP) indexed to 2014 monthly mean. As noted in the previous paragraph, changes in activity can effectively be adjusted for by adopting a ‘rate of infection per 1000 activity’ calculation. Secondly, the inclusion of day case and outpatient episodes alongside bed days data is not in line with accepted epidemiological frameworks, as they represent different proxy markers for activity. Note the use of admission data as the most appropriate activity measure when calculating trends in infection rates as part of the quantitative report.

18.7. As illustrated in the ‘quantitative paper’, it is valuable to compare and benchmark rates of infections at a hospital with other peer hospitals, which is the national, European Centre for Disease Control (ECDC) and the American Centre for Disease Control (CDC) and the World Health Organisation (WHO) standard. This is unfortunately not available as part of Dr Kennedy’s 2018 or 2019 papers.

18.8. In my opinion, and in light of the critique summarised above, I would not consider this report to be one produced in line with accepted epidemiological standards, and therefore not a true representation of the infection rates at the unit and patient cohort in question.

Name Sid Mookerjee

Signature 

Scottish Hospitals Inquiry

Note by Counsel to the Inquiry

Request for a Supplementary Report from

Sid Mookerjee, BSc. MSc. MPH. FRSPH

Introduction

1. On 9 May 2024 the Inquiry issued to CPs a report by Sid Mookerjee, BSc. MSc. MPH. FRSPH entitled "Quantitative analysis undertaken to understand the association between the built environment and rates of gram-negative and fungal bloodstream infections at the Schiehallion unit between the years 2015 and 2022" ("the Quantitative Report").

2. On 31 May 2024 by email NHS GGC raised a number of issues with the Quantitative Report with the Inquiry Team prior to preparing its substantive response under the process set out in Direction 5. Members of the Inquiry Team consulted with Mr Mookerjee and he agreed to produce a supplementary report (the Supplementary Report"). This Note is produced with the intention that it would be provided to Core Participants (CPs) along with the Supplementary Report.

3. On 31 May 2024 NHS GGC raised the following issues:

   1. The data request made to NHS GGC was different from the questions posed in the FOI requests to other hospitals:

   - *In terms of s.21 Notice No. 12, the Board was asked to specify, "1. The number of occupied bed days; and 2. The number of patient admissions for paediatric haematology and oncology patients at the QEUH&RHC from 10 June 2015 to 31 December 2022". The Board's response noted that the inpatient admissions data was calculated "using the admission date, all inpatient or day cases, who stayed overnight (emphasis added), for the period…".*
   - *The Freedom of Information Requests submitted to the comparator hospitals requested, among other data: the number of admissions to the paediatric haemato-oncology unit, by year, for 2015-2022; and the number of individual patients admitted to the paediatric haemato-oncology unit, by year, for 2015-2022.*

   2. There is no information on how the comparator hospitals have interpreted the request, in particular, whether day cases are included. In order to ensure that the Inquiry's expert is assessing comparable datasets, NHSGGC has contacted

the comparator hospitals to try to clarify the parameters of their datasets which were submitted in response to the FOI request.

3. It is clear in the report that the number of "admissions" used to calculate comparison infection rates are significantly different for the comparator hospitals than RHC. The admission numbers are over 10 times higher for GOSH and Leeds and 5 times higher for Oxford and Cardiff. Given the comparable size and scale of the service provided by the RHC, we would not expect to see such a divergence in admissions numbers from those of the comparator hospitals, were the same interpretation of the request used. As a basic calculation, if RHC with 24 beds, had the same number of admissions per bed over the period as the average of these comparators, there would be 38,160 admissions, whereas the number in the report is 4,430.

4. The NHSGGC data submitted excluded stays of less than 1 day, which may explain some of the very obvious differences in number of admissions, compared to the number of patients and beds. NHSGGC is currently conducting investigations into this but, on the basis of an initial further review of data, it has calculated that, if day cases are included, the total number of admissions to RHC increases from 4,430 to 21,238. This may still be an under-estimate compared to the comparator hospitals, depending on their inclusion of ward attendances. This 5-fold increase in the denominator would cause major changes to the Incidence Rate Ratio (IRR).

5. The report has not included admissions via the Clinical Decision Unit which, for many patients, is part of the patient pathway for admissions. This would add another 1,384 admissions.

6. The number of admissions to the Bone Marrow Transplant unit at RHC appears much lower than the number of patients who had BMTs. NHSGGC is currently investigating this.

Initial Further Investigation

4. The Inquiry Team notes that Mr Mookerjee used data on admissions taken from the response by NHS GGC to the Section 21 Notice of 25 August 2023 ("the First Admissions Data Set"). That section 21 notice specifically asked for:

A document, in Microsoft Excel format, that specifies:-

1. The number of occupied bed days; and

2. The number of patient admissions;

in each case, for paediatric haematology and oncology patients at the Queen Elizabeth University Hospital and Royal Hospital for Children from 10 June 2015 to 31 December 2022, broken down by ward and by month.

5. In its email of 31 May 2024 NHS GGC highlighted that its response to the Section 21 Notice of 25 August 2023 specifically stated that the inpatient admissions data was calculated "using the admission date, all inpatient or day cases, who stayed overnight [emphasis added], for the period…". It does appear that NHS GGC have answered the Notice so as to exclude those patients who were admitted to the QEUH and RHC, but who did not stay overnight. Whilst it is unfortunate that the Inquiry Team did not note at the time that NHS GGC had restricted its answer in this way it is also clear that 'admissions' includes both admitted day cases and inpatients. Publicly available confirmation of that definition can be found in the statistics published by *Statistics.Gov.Scot*.[1] In the national statistics for hospital admissions[2] they are defined as:

   Number of admissions to non-psychiatric/non-obstetric hospitals in Scotland. Information presented is for patients treated as inpatients or day cases only.

6. In the Public Health Scotland data for Annual Inpatient and Daycase Activity admissions are defined so as to include admitted day cases as follows: [3]

   Inpatients refer to people who are admitted to an available staffed bed in a hospital (either electively or as an emergency) and either: remain overnight whatever the original intention; or are expected to remain overnight but are discharged earlier. Day cases refer to episodes where a person makes a planned admission to an available staffed bed in a hospital for clinical care, and requires the use of a bed (or trolley in lieu of a bed). For the purposes of national data, a day case episode refers to a patient who is admitted as a day case and is discharged on the same day as planned.

7. The Inquiry Team has now asked NHS GGC to re-answer the Section 21 Notice of 25 August 2023 in such a way as to include all persons admitted in the sense that they have a date of admission on the Board's system whether or not they stayed overnight. It has been made clear to NHS GGC that only those patients with a date of admission recorded on the hospital record system should be included. This data has now been provided by NHS GGC and has been passed to Mr Mookerjee. This second data is "the Second Admissions Data Set".

8. In addition, the Inquiry Team have clarified the role and purpose of the Clinical Decision Unit (CDU) within the RHC and now proceed on the basis that ordinarily patients would be admitted to the CDU for a short period of time before being transferred to one of the other wards or discharged, sometimes after an overnight stay. However the Inquiry Team understands that for a period of

[1] Website managed by The Scottish Government on behalf of all producers of official statistics in Scotland, providing statistics from a variety of organisations such as The Scottish Government, National Records of Scotland, NHS Information Services Division and Transport Scotland. https://blog.statisticsbeta.com/about/
[2] https://statistics.gov.scot/data/hospital-admissions
[3] https://www.opendata.nhs.scot/dataset/annual-inpatient-and-daycase-activity

perhaps five weeks in early 2019 children were decanted from 6A to the CDU. The CDU can be seen on page 8 of the map within page 8 of Bundle 2 from Hearing Commencing 20 September 2021, Material Illustrating Layout of QEUH & RHC Glasgow and is labelled as the "observation ward". The Inquiry Team understands that the CDU is made up of predominately single rooms including two PPVL rooms. The current RHC website describes it as having 18 beds. The minutes of the IMT of 24/1/19, (Bundle 1: Page 287) have an update re CDU where Prof Gibson states that all 17 rooms in CDU were full.

9. I am concerned that the use as a denominator of admissions or bed day data for paediatric haematology and oncology patients in the RHC who were not staying overnight or were not primarily treated in the spaces within the hospital built or later used as the Schiehallion Unit (Wards 2A and 2B and then Wards 6A and 4B) might have the effect of diluting the focus of the study being carried out by Mr Mookerjee which is supposed to have its focus on the rates of gram negative infections in the Schiehallion Unit as a geographically contained space. This concern is addressed by specific request at paragraph 11 below.

Supplementary Report by Mr Mookerjee

10. Mr Mookerjee should now finalise his Supplementary Report addressing the following issues/questions:

    a) Explain why the Quantitative Report considers only the epidemiology of Gram-negative bacteria and fungi and not Gram-positive bacteria and the advantages of this approach. This section should also explain the exclusion of Mycobacterium Chelonae, Aspergillus, Cryptococcus, Fusarium and Mucor from this report and the decision to include Candida infections, Rhodotorula and Exophiala within the data for Gram-negative bacteria.

    b) Explain how in his comparisons between the QEUH/RHC and comparator hospitals he has attempted to compare like with like and any difficulties he has encountered in doing so in respect of: (i) the population of paediatric haematology and oncology patients in the QEUH/RHC, (ii) the geographical space that is the Schiehallion Unit and (iii) the data provided by NHS GGC and (iv) ensuring that the comparator units have treated blood cultures in a consistent manner, applied the same deduplication standards as NHS GGC and included both day case admissions as well as inpatients. At the same time he should explain what he meant by the "the four Schiehallion units" (para 9.1 of the Quantitative Report).

    c) Respond to the critique of his decision to focus on admission data that is set out in paragraph 9 and Question B of the NHS NSS response to the Quantitative Report

d) Explain why his study ends with data to the end of 2022.

e) Explain the basis of the approach to correlation analysis at paragraph 10.2 of the Quantitative Report and how it is possible to use a small number of data points to draw conclusions regarding a correlation between water positivity and infection rates.

f) Provide a definitions for Infection episode case definitions (including the de-duplication criteria used).

g) Explain how inpatient and outpatient specimens were defined and identified.

h) Explain whether infections were extracted for the ward locations only during periods when the patients were cared for in that area or whether was this done by proxy by inclusion of an age parameter.

i) Explain whether marked increase in water samples taken in 2018 after small number were taken in 2015 and 2016 (Table at para. 8.4.19 of the Quantitative Report) may be in response to the IMT investigations and what (if any) biases might this introduce considered in the interpretation of the data? Thereafter to consider whether the correlation between water positivity and infection rates may be affected by such bias and was this considered in the interpretation of the correlation analysis?

j) Explain why he chose to restrict his total number admissions in the table at paragraph 8.2.8 of Quantitative Report only to the columns in the First Admissions Data Set that mention Wards 2A, 2B, 6A and 4B and his broad understanding of that data set in general.

k) Re-run the comparison eventually presented in the Quantitative Report at 9.7 and 9.10 using Grand Total column in the First Admissions Data Set as the denominator for the purpose of calculating rate of infections per 1000 admissions and draw conclusions as to what it says about his earlier work.

l) Re-run the comparison eventually presented in the Quantitative Report at 9.7 and 9.10 using ‘Occupied Bed Days by Ward’ from the First Admissions Data Set instead of admissions (however calculated) and draw conclusions as to what it says about his earlier work.

m) Use data in the summary table at paragraph 8.3.6 of the Quantitative Report to create separate magnitude charts (in the form of the chart after paragraph 9.7) and comparator BSI rate per 1000 admission and 1000 Occupied Bed Days Per Ward for each of the comparator hospitals (Gt Ormand Street, Cardiff and Vale, Leeds and Oxford so as to discover

whether there is any significant difference in the rates of infection between the four comparators and the QEUH/RHC. The results of this exercise should be presented in graphical form and Mr Mookerjee should give is opinion as to whether this impacts on any value that can be take from a comparison between rates in the QEUH/RHC and these hospitals.

n) Use the Second Admission Data Set (including patients admitted with an admission date who did not stay overnight) to repeat his analysis with that new data and draw conclusions as to what it says about his earlier work and the questions he was originally asked.

o) Respond to the observation of NHS GGC in their Direction 5 response to the Quantitative Report that:

[vii] NHSGGC has recalculated the infection rates and Incidence Rate Ratio (IRR) using its routine data for admissions and all day cases. The results show that the IRRs were less than one for many of the years in question. Equally, calculating IRRs between the comparator hospitals show variability with the IRR higher between some comparator hospitals than between RHC and the comparators.

It is likely that the denominator for RHC is still an underestimate as ward attenders are included in some of the comparator hospitals but this recalculation, even with the under-estimate, illustrates that the conclusions of the report are invalid.

11. In order to address the concern described at paragraph 9 above Mr Mookerjee should carry out an analysis of the rates of gram-negative infections on a monthly basis from the opening of the new Schiehallion Unit in 2015 and 2022 first in Ward 2A only for those who stayed overnight there and then after the decant for Ward 6A both for those who stayed overnight only and those who were admitted to Ward 6A irrespective of whether they stayed overnight. He should report the rates in each month, any trend in those rates, any observations he has about correlation, connection or association between those rates and both water testing results in those wards and interventions.

12. Separately within his Supplementary Report Mr Mookerjee should consider the report prepared on 18 May 2021 by Dr SG Agrawal BSc MBChB FRCP FRCPath PhD. The Inquiry Understands that this report was produced by for NHS GGC in respect of an Improvement Notice served on NHS GGC by the Her Majesty's Inspector of Health and Safety which asserted that the board has "failed to ensure, so far is reasonably practicable, that the ventilation system within Ward 4C is suitable and sufficient to ensure that high risk patients who are vulnerable to infection are protected from exposure to potentially harmful airborne microbiological organisms" and which was appealed to the Employment Tribunal. Mr Mookerjee should comment on the epidemiology of this report and whether

he has an opinion on the validity of its epidemiological conclusions (particularly at paragraph 5.5).

13. Given the changes in the data set Mr Mookerjee should provide his opinion and detailed explanations as what conclusions (if any) can be drawn from differences between the results of his earlier analysis in the Quantitative Report and his later analysis in the Supplementary Report and any changes of his approach that he considers justified by his understanding and consideration of the data.

Presentation of this material by the Inquiry Team

14. CPs have Mr Mookerjee's first report and whilst the data sets that lay behind it were not included within the Inquiry Bundles the following CPs have requested and/or have been provided with the underlying data sets and FOI responses from comparator organisations: GGC, NSS, Multiplex and Drs Peters and, Inkster.

15. When Mr Mookerjee's supplementary report is produced it should be provided to CPs along with a copy of this note. In addition, both admissions datasets now provided by NHS GGC along with the FOI responses provided by the comparator hospitals should now be included in the hearing bundle along with Mr Mookerjee's completed Direction 5 questionnaire.

Fred Mackintosh KC

12 July 2024

SCOTTISH HOSPITAL INQUIRY

Supplementary Expert report

Response to CP comments in line with FM note to:

Quantitative analysis undertaken to understand the association between the built environment and rates of gram-negative and fungal bloodstream infections at the Schiehallion unit between the years 2015 and 2022

Prepared by Sid Mookerjee, BSc. MSc. MPH. FRSPH
Expert Witness

Data of submission: 12 August 2024
Version: Final

1. Introduction

1.1. On 9 May 2024 the Inquiry issued to CPs a report written by me, “Quantitative analysis undertaken to understand the association between the built environment and rates of gram-negative and fungal bloodstream infections at the Schiehallion unit between the years 2015 and 2022” (“the Quantitative Report”).

1.2. CP comments were received in the customary manner, in addition to an email from NHS GGC to the Inquiry on the 31st of May 2024, noting a number of issues with the Quantitative report.

1.3. The Inquiry, in response, consulted with me, and we agreed that I should proceed to put together a ‘Supplementary report’ which addresses specific points as outlined in section 10 of the ‘FM Note – Request for a supplementary report from Sid Mookerjee – 12 July 2024’.

1.4. The ‘Supplementary section’ addresses each of the issues/questions noted in the ‘FM note’, detailing the issue/question, followed by my response.

2. Supplementary report

2.1. **(FM 10a) Explain why the Quantitative Report considers only the epidemiology of Gram-negative bacteria and fungi and not Gram-positive bacteria and the advantages of this approach. This section should also explain the exclusion of Mycobacterium Chelonae, Aspergillus, Cryptococcus, Fusarium and Mucor from this report and the decision to include Candida infections, Rhodotorula and Exophilia within the data for Gram-negative bacteria.**

2.2. The decision to consider the epidemiology of gram-negative and fungi, in particular the rates of infection over the period 2015 – 2022, is to answer, ‘Key Question 4’, namely ‘Is there a link, and if so in what way and to what extent, between patient infections and identified unsafe features of the water and ventilation systems?’. As outlined in paragraph 8.1.7 of the Quantitative report, organisms which are, as per published literature, predominantly linked to water and ventilation systems, collectively defined as environmental pathogens were the ones included in the Quantitative report analysis.

2.3. These environmental pathogens include the majority of gram-negative and fungal pathogens, with notable exclusions – bacterial genera under *Escherichia coli*, *Campylobacter*, *fusobacterium, haemophilus, moraxella,* and *Neisseria.* Gram-positive pathogens were also excluded, as this group of bacteria is understood to be unlikely to be found in the patient environment e.g. water sources. The inclusion of gram-negative and fungal pathogens (minus the aforementioned exclusions) is in keeping with the purpose of the inquiry – to understand the risk posed by the environment on the paediatric haematology oncology patient population at the RHC.

2.4. It should also be noted that the pathogens - *Mycobacterium Chelonae*, *Aspergillus, Cryptococcus, Fusarium,* and *Mucor* were not excluded from the Quantitative report analysis, rather it not featuring in the organism list in section 8.1.16 (Quantitative report) is a facet of the focus on the blood culture positives primarily linked to Schiehallion unit wards, i.e. 2A, 2B, 4B and 6A, as per the QEUH and RHC dataset of blood stream infections supplied by NHS GGC, covering the period 2015 – 2022 (as outlined in section 8.1 of the Quantitative report). That is, pathogens such as *Mycobacterium Chelonae* and others mentioned above did not feature within the final curated dataset (including deduplication).

2.5. **Explain how in his comparisons between the QEUH/RCH and comparator hospitals he has attempted to compare like with like and any difficulties he has encountered in doing so in respect of: (i) the population of paediatric haematology and oncology patients in the QEUH/RCH, (ii) the geographical space that is the Schiehallion Unit and (iii) the data provided by NHS GGC and (iv) ensuring that the comparator units have treated blood cultures in a consistent manner, applied the same de-duplication standards as NHS GGC and included both day case admissions as well as inpatients. At the same time he should explain what he meant by the "the four Schiehallion units" (para 9.1 of the Quantitative Report).**

2.6. As noted in section 8.3.4 of the Quantitative report, the steps undertaken to arrive at the number of unique gram-negative and fungal bacteraemia infections for the comparator hospitals (via the FOI datasets received) was followed verbatim to the NHS GGC bacteraemia dataset. This similarity was maintained across the inclusion criteria, the de-duplication process, and the aggregation (summing up) of unique infections by year.

2.7. Admission data from NHS GGC specific to the Schiehallion units – 2A, 2B, 4B and 6A were aggregated by year, with the same process of aggregation applied to the comparator unit data. The intention was to apply a standard framework of steps to both the NHS GGC bacteraemia and admission data and mimic these steps to their counterpart dataset for the comparator units, a like for like.

2.8. In order to identify infections in the Schiehallion patient cohort, in line with the Inquiry's remit, blood culture positives arising from patients on wards 2A, 2B, 4B and 6A, as noted in the 'Location ward' column within the NHS GGC bacteraemia dataset were taken in account. These four wards allowed for as focused piece of analysis, specific to the 'physical spaces' of wards 2A, 2B, 4B and 6A for the period June 2015 – December 2022.

2.9. It should be noted that there were notable issues with the NHS GGC bacteraemia dataset, namely, the dataset contained multiple variations of the same ward, e.g. ward 2A was referred to as 'Ward 2A RHC', and 'Schiehallion ward 2A RHC'. Secondly, blood cultures positive for multiple organisms often appeared in the same row of data, rather than on two separate rows, one for each positive organism identified. Furthermore, the NHS GGC bacteraemia dataset consisted of 214,977 rows of data, spread over 17 columns. The above noted issues, alongside the size of the dataset required extensive data cleaning, curation and analysis, with the issues noted adding complexity to the analysis undertaken.

2.10. These issues extend to both the first and second admissions dataset provided by NHS GGC, where the same ward occurs under different names. See list of all wards for which admission data was provided below, with variations of the same ward names have been highlighted.

RHC Ward 2B
QEUH 6A DCH Day Unit
RHC Area 1B Day surgery
RHC Schiehallion Day Unit 2B
RHC Clinical Decision Unit
RHC Ward 2A
QEUH 6ACH Inpatients
RHC Ward 1A 23 Hour Ward
RHC Ward 2A Schiehallion
RHC Area 1C Day Care Unit
RHC Paediatric Haematology/Oncology
Yorkhill Schiehallion Day Care Unit - Haematology
RHC Ward 2C Beds 1-20
RHC Ward 3B Multiple Spec
RHC Ward 3C
RHC Ward 3A Multiple Spec
RHC Ward 2C Beds 21-40
Yorkhill Day Surgery Unit - XSU
RHC Ward 1D Paediatric Critical Care
QEUH 4BCH Bone Marrow Transplant
RHC Ward 3C Orthopaedics
RHC Ward 1E Cardio/CS
Yorkhill Schiehallion Ward - Haematology
RHC Ward 3C Renal
RHC Ward 2A Clinical Decision Unit
Yorkhill Ward 4A - Medical Paediatrics

2.11. Finally, every attempt has been made to apply a standard analysis framework, by which I mean the steps involved in cleaning, formatting, curating and analysing a dataset, which was applied to the NHS GGC datasets was applied to the FOI dataset from comparator units.

2.12. It is clear from NHS GGC's email on the 31st of May 2024, that they did not correctly interpret the Section 21 Notice of 25 August 2023, whereby the definition of 'admissions', as defined by Statistics Govt.Scot and Public Health Scotland (See FM note paragraph 5 and 6), was not adhered to. NHS GGC's second response to the Section 21 Notice of the 25 August 2023, submitted to the Inquiry in June 2024 has been analysed in keeping with the steps outlined in section 8.2 of the Quantitative report. Note that in keeping with the original NHS GGC admission dataset, sent in response to the Section 21 Notice, the second admission dataset harbours all the issues noted in section 2.9 of this report.

2.13. Lastly, please note that I made an error in the way I referred to the four Schiehallion units, namely 2A, 2B, 4B and 6A, in paragraph 9.1 of the Quantitative report. I did not

intend to refer to the four wards as the four Schiehallion units; rather I intended to refer to them as the four Schiehallion wards.

2.14. **Respond to the critique of his decision to focus on admission data that is set out in paragraph 9 and Question B of the NHS NSS response to the Quantitative Report**

2.15. As set out in section 8.2.3, 8.2.4 and 8.2.5 of the Quantitative report, the analysis centred on understanding the infection risk to a vulnerable patient group – the Schiehallion cohort. I chose to use admissions rather than bed-days as the denominator when calculating rates of infections for the reasons noted in paragraphs 2.16 and 2.17 below. Note that I have applied this reasoning and resulting methodology to both the QEUH/RHC and the comparator units' datasets, and therefore am comparing like for like in the Quantitative report.

2.16. Owing to their specific medical requirements the Schiehallion cohort have frequent interaction with the hospital, and importantly with the environmental exposure in question – water and ventilation issues. This interaction was heterogeneous, i.e. a mix of inpatient stays (staying overnight in a bed), day stays and outpatient visits, which in its entirety makes up the cumulative risk of Schiehallion patients to acquire infections. The healthcare setting – the Schiehallion wards at QEUH and RHC, as highlighted in Dr. Walker's paper, among other evidence, appears to have had systemic contamination of the water system. It is therefore important that an appropriate indicator for this accumulated risk and exposure to risk, i.e. water and ventilation issues is considered, i.e. admissions over time.

2.17. Admission data comes from the EPR, and this goes for all hospitals who have provided data – NHS GGC and the comparators. This means that there is limited manual work required to collate the monthly and annual admission figures requested – essentially a tallying up of unique admissions from the EPR. This lends itself to limited inaccuracies and bias, and a high level of homogeneity in the methodology adopted by NHS GGC and comparator units in curating this data. On the other hand, bed occupancy data, requires in terms of the strictest methodology that someone calculates the occupancy rate at each ward in question, often requiring a visit to the wards in question at the same time everyday for the period being reported on, and then finally aggregate the occupancy figures for the period into a single statistic, e.g. a month, a quarter, a year. This is very labour intensive, and to my knowledge current EPRs do not calculate these figures automatically – as it requires the EPR to have access to bed capacity by ward (which is subject to change over

time) and occupancy at any given timepoint, and therefore the need for the manual element. The issue with this is that it introduces substantial bias and heterogeneity in methodology, both within a hospital site over time, as different actors might have collected, curated and saved this data at different points in time, and between hospital sites, in our case between QEUH/RHC and the comparator units, where there is a lack of confidence in the same methodology being followed, particularly as we did not state how we want the data to be collected in the FOIs nor could we curate this data ourselves. It is for this reason that I have made the decision to go with admission data when comparing rates of infections at Trusts across the country, where my focus has been to mitigate for bias, inaccuracy and heterogeneity of methodology adopted in curating datasets to the extent possible, seeing that I could not extract these datasets myself.

2.18. **With specific reference to Question B - NHS NSS response**

2.19. **In response to Question B (a):** Table 6.1 in the methodology section of the Quantitative paper I gave an example of how incidence rates can be calculated, which in this case was using occupied bed-days. Table 7.1, under section 'Summary of evidence considered' states precisely the analysis carried out and corresponding justification for using admission data in calculating rates of infections, both for the Schiehallion cohort and for the comparator units.

2.20. **In response to Question B (b i-viii):** Note that I received the admissions dataset from NHS GGC, who responded to Section 21 of 25 August 2023. Please refer to paragraph 2.8 of this report, where I note - *In order to identify infections in the Schiehallion patient cohort, in line with the Inquiry's remit, blood culture positives arising from patients on wards 2A, 2B, 4B and 6A, as noted in the 'Location ward' column within the NHS GGC bacteraemia dataset were taken in account. These four wards allowed for as focused piece of analysis, specific to the 'physical spaces' of wards 2A, 2B, 4B and 6A for the period June 2015 – December 2022.*

2.21. Note that when patients moved from 2A to 6A, the bone marrow transplant patients moved into four rooms at 4B. To ensure only paediatric data was included the age at the time the specimen was taken was used to filter out the adult patients.

2.22. As previously noted, I was not able to extract the admission data myself, and accepted the data provided in good faith from NHS GGC. Admission data provided by comparator

units was also taken in good faith, under the assumption that NHS GGC, and the hospitals of Oxford, Leeds, Cardiff and Vale, and GOSH, all understood the ask, their responsibility as public institutions to supply accurate data in line with their knowledge and understanding of definitions such as ‘admissions’, which as we have discussed, are well defined nationally, both in England and Scotland.

2.23. Infection data and admission data for the Schiehallion unit ranged from the month and year the Schiehallion unit opened – June 2015, to the end point in question, Dec – 2022. Utilising data from large institutions such as Oxford, Leeds, Cardiff and Vale and GOSH, for a period of 5 years, allowed for a large number of admissions and infections to form part of the analysis and the calculated comparator rates, over a significant amount of time, thereby providing a high level of confidence in the outcomes extracted and discussed.

2.24. The caveats and nuances expressed by NSS, specifically regarding the NHS GGC dataset and the context it was representing should surely also apply to other large institutions in the UK, all of whom treated and continue to treat this highly vulnerable paediatric haematology oncology population in their position as large tertiary centres.

2.25. **Explain why his study ends with data to the end of 2022.**

2.26. In line with the remit of the Inquiry and the ask as outlined in ‘Key question 4’, the analysis I performed focuses on a set period – Jun-2015 to Dec-2022, i.e. from the month and year the Schiehallion unit opened to the month year up until and including which I was provided complete water sampling data. This is also the period over which issues regarding water contamination commenced, remedial actions undertaken, and infections in the Schiehallion patients recorded. It was therefore deemed to be a sufficient time period to analyse and from which to infer if there was indeed a relationship between water contamination and infection rates at the Schiehallion, and the strength of that relationship or association.

2.27. **Explain the basis of the approach to correlation analysis at paragraph 10.2 of the Quantitative Report and how it is possible to use a small number of data points to draw conclusions regarding a correlation between water positivity and infection rates.**

2.28. The data points, eight in total for rates of infections at the Schiehallion, one for each year 2015 – 2022 (inclusive) is a yearly aggregated value, based on 4430 admissions and 187 infection episodes in total. The high number of admissions and infections and the extensive period over which they span, gives a high level of confidence in the data, data that was provided by NHS GGC.

2.29. The water positivity data points, six in total, one for each year 2015 – 2020 (inclusive) is based on 4759 unique water samples taken and 500 positive samples in total. Like the infection data, the number of water samples and the period over which these results span give us a high level of confidence in the data, data which was provided by NHS GGC.

2.30. **Provide the definitions for infection episode case including the de-duplication criteria used.**

2.31. As noted in section 8.1.13 and 8.1.14 of the Quantitative report – the aim of the de-duplication process was to curate a list of unique ‘Patient, sample date, laboratory lab sample number, organisms’, i.e. an ‘infection episode’. In line with national reporting in England and Scotland, a unique infection episode is identified by way of a positive blood culture with a named organism (pathogen of interest – gram-negative and fungus), and where a repeat blood culture within 14 days of the initial culture is regarded as representing the same infection episode being suffered by the patient, and therefore excluded via the de-duplication process.

2.32. The reasoning behind this is that a patient suffering from an infection, due to an identified organism via a blood culture can continue to have positive blood culture specimens for a period of up to 13 days, as the patient responds to clinical interventions. It therefore follows that a blood culture positive ≥14 days post the initial blood culture is indicative of a new infection episode. The exception to this 14-day rule, is when a second blood culture positive within 14 days of the first, is positive for an organism where the genus or the species is different to the one isolated from the initial culture. This process is well laid out in national guidance, as referenced in the sections 8.1.13 and 8.1.14 of the Quantitative report.

2.33. **Explain how inpatient and outpatient specimens were defined and identified.**

2.34. The analysis undertaken centred on building a longitudinal picture of events at the Schiehallion, both in terms of the incidence and type of infections suffered by the patients in the physical space as defined by wards 2A, 2B, 4B and 6A, and the water sampling undertaken specific to this physical space, which measured the extent of water contamination. The level of aggregation employed was an annual statistic – rate of infections based on all infections by way of blood culture positives linked to 2A, 2B, 4B and 6A, and all admissions to these units, providing us with a yearly infection statistic, one for year of the 8 years, 2015 – 2022 (inclusive). It was therefore not necessary to split the specimens, i.e. the infection episodes into whether they were outpatient or inpatient specimens.

2.35. **Explain whether infections were extracted for the ward locations only during periods when the patients were cared for in that area or whether was this done by proxy by inclusion of an age parameter.**

2.36. Only patients' initial infection episode as outlined in paragraphs 2.31 and 2.32 linked to wards 2A, 2B, 4B and 6A, where the age of the patient was < 19 years was included in the analysis.

2.37. **Explain whether marked increase in water samples taken in 2018 after small number were taken in 2015 and 2016 (Table at para. 8.4.19 of the Quantitative Report) may be in response to the IMT investigations and what (if any) biases might this introduce considered in the interpretation of the data? Thereafter to consider whether the correlation between water positivity and infection rates may be affected by such bias and was this considered in the interpretation of the correlation analysis?**

2.38. As outlined in section 8.4 of the Quantitative report, NHS GGC provided 18 separate water sampling spreadsheets of varying formats which included differences in spreadsheet column names, variability in the use of columns for the data intended, e.g. as noted in section 8.4.4 of the Quantitative report – *Note that columns flagged as denoting count data often consisted of instances of organism names, requiring further formatting and cleaning of the dataset.* Furthermore, there existed multiple columns for the same organism of interest / test undertaken, sampling dates were in variable formats, which are but a few examples of the extent of heterogeneity and poor data formatting encountered by me and the ensuing difficulty in analysing this data.

2.39. Note that as with the bacteraemia data, I was not able to curate these spreadsheets from NHS GGC or QEUH / RHC systems, and therefore relied on NHS GGC to provide me with the data I needed.

2.40. The 18 spreadsheets covered the period 2015 – Jan 2021. I therefore focused the water sampling analysis from the period June 2015 Jun-2015, in line with when the Schiehallion patients moving from Yorkhill to the RHC, to December 2020, the last complete month of data provided by NHS GGC. The analysis calculated the number of unique water samples taken, annually, collating positive results under *legionella. spp, pseudomonas. spp, cupriavidus. spp*, *Serratia. spp, Stenotrophonomas.spp* and a catch-all fungus positive column.

2.41. The correlation coefficient statistic reported in the Quantitative report, to understand the relationship between the rate of infections and water positivity took water positivity data from 2015 to 2019 and excluded the 2020 data. This is because 2020 saw a 20% drop in water testing, compared to 2019, which in addition to change in the hospital context owing to the onset of the Covid-19 pandemic, meant that I decided to restrict the water data to the period 2015 – 2019.

2.42. **In specific response to the question posed in the FM note re whether water sampling in 2018 went up from 2015 – 2017 levels, and if this was in response to IMT investigations:** The analysis focuses on the physical space that is defined by wards 2A, 2B, 4B and 6A for the purposes of infection and water sampling data. For the period 2015 – 2017, an annual average of 107 water samples were taken, which increased by 982% to 1158 water samples in 2018, and then by 56% (1809 samples) in 2019, eventually dropped by 20% in 2020 (1469 samples). I agree with the assessment that the increase in water sampling in 2018 does seem to have increased as rapidly as it did in response to the concurrent spike in rates of infections and the resulting IMT investigations over 2017 and 2018 period, 166.7 / 1000 admissions 160.2 per 1000 admissions respectively, versus a comparator rate of 8.85 per 1000 admissions.

2.43. In terms of bias, we understand the water sampling at certain points over the period 2015 – 2020 to be purposeful, i.e. in response to a rise in infections, as noted in the above paragraph. Given the extent and duration of water contamination as highlighted in Dr Walkers report, one could justifiably assume that if the extent of water sampling done in

the period 2018 – 2020 was done for the earlier period 2015 – 2017, that the resulting water positivity figures would have been more representative and in line with the evidence to hand from Dr. Walker's and Dr. Mumford's papers on the extent of contamination over the period. This would mean that rather than seeing an increase in water positivity rates in 2018 – 2.5% in 2015, 0% in 2016, 7.6% in 2017 and 17.4% in 2018, we would have seen a higher overall level of water positivity for the period 2015 – 2020.

2.44. Bias would indeed be an issue if I were using the water positivity figures specific to wards 2A, 2B, 4B and 6A, and using this statistic to make assumptions about the state of the water estate at QUEH in its entirety. This is not the case. My intention in the Quantitative report has been to overlay the trend in water positivity for the wards in question alongside the rate of infection and apply the relevant statistical tools to understand the relationship between the trends.

2.45. **Explain why he chose to restrict his total number of admissions in the table at paragraph 8.2.8 of Quantitative Report only to the columns in the First Admissions Data Set that mention Wards 2A, 2B, 6A and 4B and his broad understanding of that data set in general.**

2.46. Please refer to paragraph 2.8 of this report, where I note - *In order to identify infections in the Schiehallion patient cohort, in line with the Inquiry's remit, blood culture positives arising from patients on wards 2A, 2B, 4B and 6A, as noted in the 'Location ward' column within the NHS GGC bacteraemia dataset were taken in account. These four wards allowed for as focused piece of analysis, specific to the 'physical spaces' of wards 2A, 2B, 4B and 6A for the period June 2015 – December 2022.* This exact logic was applied to the process of analysing the admission data whereby admissions linked to wards 2A, 2B, 4B and 6A, were extracted, aggregated by year and utilised in the calculation of a rate of infection by year for the period 2015 – 2022 (inclusive).

2.47. Please see paragraph 2.10 for my opinion on the first and second admissions dataset received from NHS GGC.

2.48. **Re-run the comparison eventually presented in the Quantitative Report at 9.7 and 9.10 using Grand Total column in the First Admissions Data Set as the denominator for the purpose of calculating rate of infections per 1000 admissions and draw conclusions as to what it says about his earlier work.**

2.49. A rate calculation includes a numerator, which is defined as the number of cases or episodes of an outcome variable, in this case infections in the Schiehallion patient cohort, divided by the risk, quantified in terms of admissions of that cohort to the RHC, over the corresponding period. It would be inappropriate to calculate a rate of infection based on infection episodes linked to wards 2A, 2B, 4B and 6A in the numerator, against the 'total' admissions from all wards at the RHC in the denominator. This would result in a dilution of the rate of infection calculated resulting in inaccurate and biased figures.

2.50. **Re-run the comparison eventually presented in the Quantitative Report at 9.7 and 9.10 using 'Occupied Bed Days by Ward' from the First Admissions Data Set instead of admissions (however calculated) and draw conclusions as to what it says about his earlier work.**

2.51. Please see paragraphs 2.16 and 2.17 for my justification and reasoning for using admissions rather than bed days in calculating and comparing rates of infection at the Schiehallion to comparator units.

2.52. **Use data in the summary table at paragraph 8.3.6 of the Quantitative Report to create separate magnitude charts (in the form of the chart after paragraph 9.7) and comparator BSI rate per 1000 admission and 1000 Occupied Bed Days Per Ward for each of the comparator hospitals (Gt Ormand Street, Cardiff and Vale, Leeds and Oxford so as to discover whether there is any significant difference in the rates of infection between the four comparators and the QEUH/RCH. The results of this exercise should be presented in graphical form and Mr Mookerjee should give is opinion as to whether this impacts on any value that can be take from a comparison between rates in the QEUH/RCH and these hospitals.**

2.53. Table 1 below is taken from section 8.3.6 of the Quantitative report and illustrates the size in terms of numbers of the comparator dataset, with the comparator rate of infection based on 140,689 admissions, 1232 gram-negative and fungal infections for a period of 8 years, providing us with a high level of confidence in the rates of infection statistic it delivers.

Comparator hospitals' paediatric haematology patient infection figures 2015 - 2022					
Year	Admissions	Positives	Gram-negative and fungal positives	Rate of BSI per 1000 admissions	Organisation
2015	5443	182	62	11.39	GOSH
2016	5350	202	58	10.84	GOSH
2017	5832	248	77	13.20	GOSH
2018	6053	140	44	7.27	GOSH
2019	5997	147	96	16.01	GOSH
2020	6362	146	95	14.93	GOSH
2021	6389	135	91	14.24	GOSH
2022	6185	78	49	7.92	GOSH
2015	2273	60	7	3.08	Cardiff and Vale
2016	3314	81	18	5.43	Cardiff and Vale
2017	2982	50	24	8.05	Cardiff and Vale
2018	3235	70	23	7.11	Cardiff and Vale
2019	2999	58	15	5.00	Cardiff and Vale
2020	2660	57	19	7.14	Cardiff and Vale
2021	3257	30	9	2.76	Cardiff and Vale
2022	2965	55	11	3.71	Cardiff and Vale
2015	5120	NA	NA	NA	Leeds
2016	5892	61	7	1.19	Leeds
2017	5926	202	65	10.97	Leeds
2018	5851	176	77	13.16	Leeds
2019	5488	213	78	14.21	Leeds
2020	5839	194	46	7.88	Leeds
2021	5747	200	71	12.35	Leeds
2022	6352	182	37	5.82	Leeds
2015	2774	55	25	9.01	Oxford
2016	3050	51	28	9.18	Oxford

Table 1: Comparator units' dataset for the period 2015 - 2022

2.54. Figure 1 below provides the Schiehallion unit rate of infection, as per the Quantitative report, alongside the overall comparator institution rate of infection (red dotted line), and the individual comparator units' rate of infections for the period 2015 – 2022.

2.55. Note that the rates of infections of the comparator units all cluster together, and around the overall comparator (red dotted line) rate, indicating that they are similar for each of the

years in question, in stark contrast to the Schiehallion units' rate of infection, which is visible as an outlier for the years 2016 – 2021, with rates in 2015 and thereafter in 2022, more in line with the comparator rates.

2.56. Therefore, if as NHS GGC assert that there is a difference in the manner in which the comparator institutions have individually responded to the FOI requests, it is not evident from the trend in their rates of infections for the period of 8 years from 2015 - 2022 (inclusive). Based on the analysis discussed in the Quantitative report the rate of infection at the Schiehallion is considerably higher than each and every comparator institution rate (see Figure 1) for the entire period 2015 – 2022, to which as far as I'm aware no alternative explanation other than the risk posed by water contamination and issues around the ventilation system has been provided by NHS GGC, one which accounts for the unusually high infection rates at the Schiehallion.

2.57. Note that this difference in rate changes in terms of its magnitude and the time period over which it is higher than comparator rates as evident when I discuss the analysis undertaken using the second admissions dataset provided by NHS GGC. See paragraph 2.66 and 2.67.

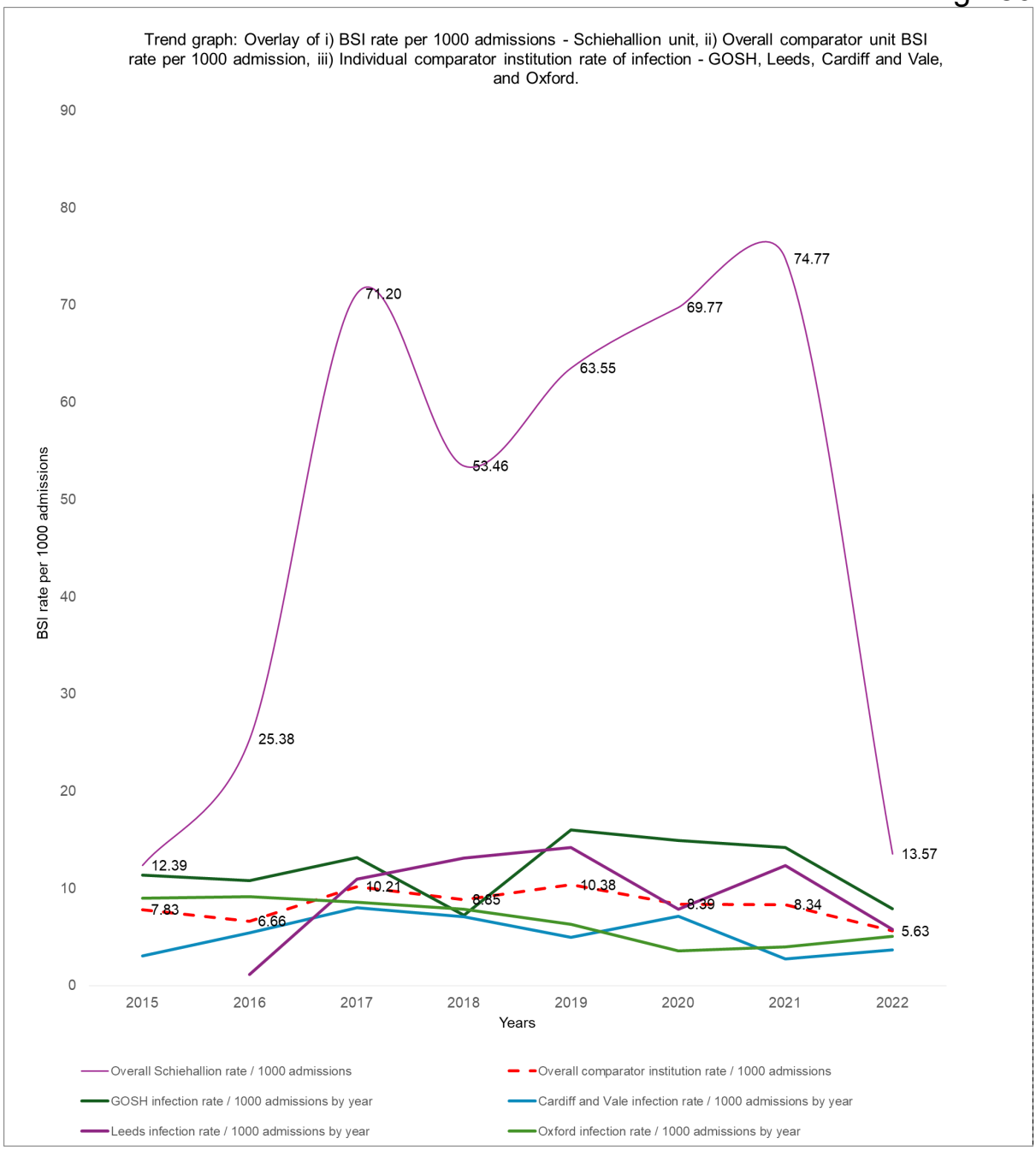


Figure 2: Trend graph comparing Schiehallion overall rate with individual comparator rates for the period 2015 – 2022.

2.58. **Use the Second Admission Data Set (including patients admitted with an admission date who did not stay overnight) to repeat his analysis with that new data and draw conclusions as to what it says about his earlier work and the questions he was originally asked.**

2.59. Table 2 below is from section 8.2.8 of the Quantitative report. Here I wanted to address the assertion by NHS GGC, that the definition of 'admissions' was not adhered to in their initial response to the Section 21 request of 2023, in that certain admissions were omitted from the figures below. It was my understanding that the post decant physical space was

smaller and accommodated fewer beds, in contrast to the pre-decant space, which meant that the number of admissions as a result would be expected to be lower post decant.

2.60. Furthermore, as evidenced in section 2 of Dr. Mumford's 'Direction 5 report' and the IMT minutes of the 5th to 19th September, that the drop in admissions in 2018 was in response to infection rates, a consequence of admissions being restricted to the Schiehallion wards. Patients at this time were being cared for at their local hospital. Thereafter the admission numbers dropped in 2020 as a consequence of Covid-19. The initial admission dataset provided by NHS GGC illustrated this trend. As noted earlier in this report, I took on good faith that NHS GGC like other institutions who were asked for infection and admission data, understood the ask, the definition of a well document term, i.e. 'admissions' and submitted data fit for purpose of the inquiry. This is important as since the publication of the Quantitative report, NHS GGC have had the opportunity to submit a second admission dataset, which the following paragraphs discusses.

Schiehallion wards - Admissions by ward and year, 2015 - 2022					
Year	4B	6A	2A	2B	Cumulative
2015			241	324	565
2016			479	585	1064
2017			264	663	927
2018	2	68	178	575	823
2019	9	290			299
2020	2	127			129
2021	1	106			107
2022	1	26	129	360	516

Table 2: Schiehallion admissions, first admission dataset NHS GGC.

2.61. Table 3 below details admissions under each of the Schiehallion wards – 2A, 2B, 4B and 6A as per the second admission dataset. Note the multiple versions of ward names pertaining to 2A, 2B, 4B and 6A. I have made the decision to aggregate the admissions, that is all admissions under multiple names for ward 2A, under a single column called 'Ward 2A'.

NHS GGC 2nd admissions dataset. Extract of Schiehallion units, i.e. wards 2A, 2B, 4B and 6A									
Year	Cumulative	RHC Ward 2B	QEUH 6A DCH Day Unit	RHC Schiehallion Day Unit 2B	RHC Ward 2A	QEUH 6ACH Inpatients	RHC Ward 2A Schiehallion	QEUH 4BCH Bone Marrow Transplant	RHC Ward 2A Clinical Decision Unit
2015	1303	1049			254				
2016	2266	1772			494				
2017	2568	2292			276				
2018	2517	1695	567		181	72		2	
2019	2356		2040			301		9	6
2020	1532		1400			130		2	
2021	1914		1798			115		1	
2022	1950		324	1468		27	130	1	

Table 3: NHS GGC second admissions dataset

2.62. On comparing the first and second admissions dataset from NHS GGC, I noted that admissions to ward 2A and 4B have remained fairly consistent, apart from 2018. This is not so for 2B and 6A, where admission figures have doubled, tripled, and in some cases increased 11 times from the original figure provided by NHS GGC for a given year.

2.63. In my opinion the most precise analysis I can undertake is where I restrict the infections and admissions to wards 2A and subsequently post decant to 6A, where we have utmost confidence that Schiehallion paediatric haematology oncology patients resided. The following analysis will follow the direction laid out in paragraph 11 and 13 of the FM note.

2.64. **(Paragraph 11 FM note) In order to address the concern described at paragraph 9 above Mr Mookerjee should carry out an analysis of the rates of gram-negative infections on a monthly basis from the opening of the new Schiehallion Unit in 2015 and 2022 first in Ward 2A only for those who stayed overnight there and then after the decant for Ward 6A both for those who stayed overnight only and those who**

were admitted to Ward 6A irrespective of whether they stayed overnight. He should report the rates in each month, any trend in those rates, any observations he has about correlation, connection or association between those rates and both water testing results in those wards and interventions AND (Paragraph 13 FM note) Given the changes in the data set Mr Mookerjee should provide his opinion and detailed explanations as what conclusions (if any) can be drawn from differences between the results of his earlier analysis in the Quantitative Report and his later analysis in the Supplementary Report and any changes of his approach that he considers justified by his understanding and consideration of the data.

2.65. Table 4 below details the admissions for 2A and 6A using the second admissions dataset from NHS GGC, alongside the infections (as per the Quantitative report) for these two wards.

Year	Ward 2A admissions	Ward 6A admissions	Ward 2A infections	Ward 6A infections
2015	254		6	
2016	494		18	
2017	276		46	
2018	181	72	29	6
2019	6	301	0	17
2020		130		8
2021		115		8
2022	130	27		2

Table 4: NHS GGC second admissions and infections for ward 2A and 6A

2.66. Table 5 details the rate of infection per 1000 admissions individually and in aggregated form for 2A and 6A, alongside the overall comparator units' rate, the IRR values comparing the 2A and 6A rate individually to the overall comparator rate, for each year 2015 – 2022. Finally, the water positivity results as noted in the Quantitative report for the period 2015-2020 is provided for ease of reference.

Year	Ward 2A infection rate / 1000 adms	Ward 6A infection rate / 1000 adms	Ward 2A and 6A aggregated rate of infection / 1000 adms	Overall comparator institution rate / 1000 adms	IRR - 2A infection rate versus overall comparator rate	IRR - 6A infection rate versus overall comparator rate	Water positivity rate
2015	23.62		23.62	7.83	3.02	No admissions	2.50%
2016	36.44		36.44	6.66	5.47	No admissions	0.00%
2017	166.67		166.67	10.21	16.33	No admissions	7.65%
2018	160.22	83.33	138.34	8.85	18.09	9.41	17.36%
2019	0.00	56.48	55.37	10.38	No infections	5.44	11.06%
2020		61.54	61.54	8.39	No admissions	7.33	5.58%
2021		69.57	69.57	8.34	No admissions	8.34	
2022	0.00	74.07	12.7	5.63	No infections	13.15	

Table 5: Comparison of rates of infection in 2A and 6A to comparator units' rate.

2.67. Key takeaways with reference to Table 5 and Figure 2 are as follows:

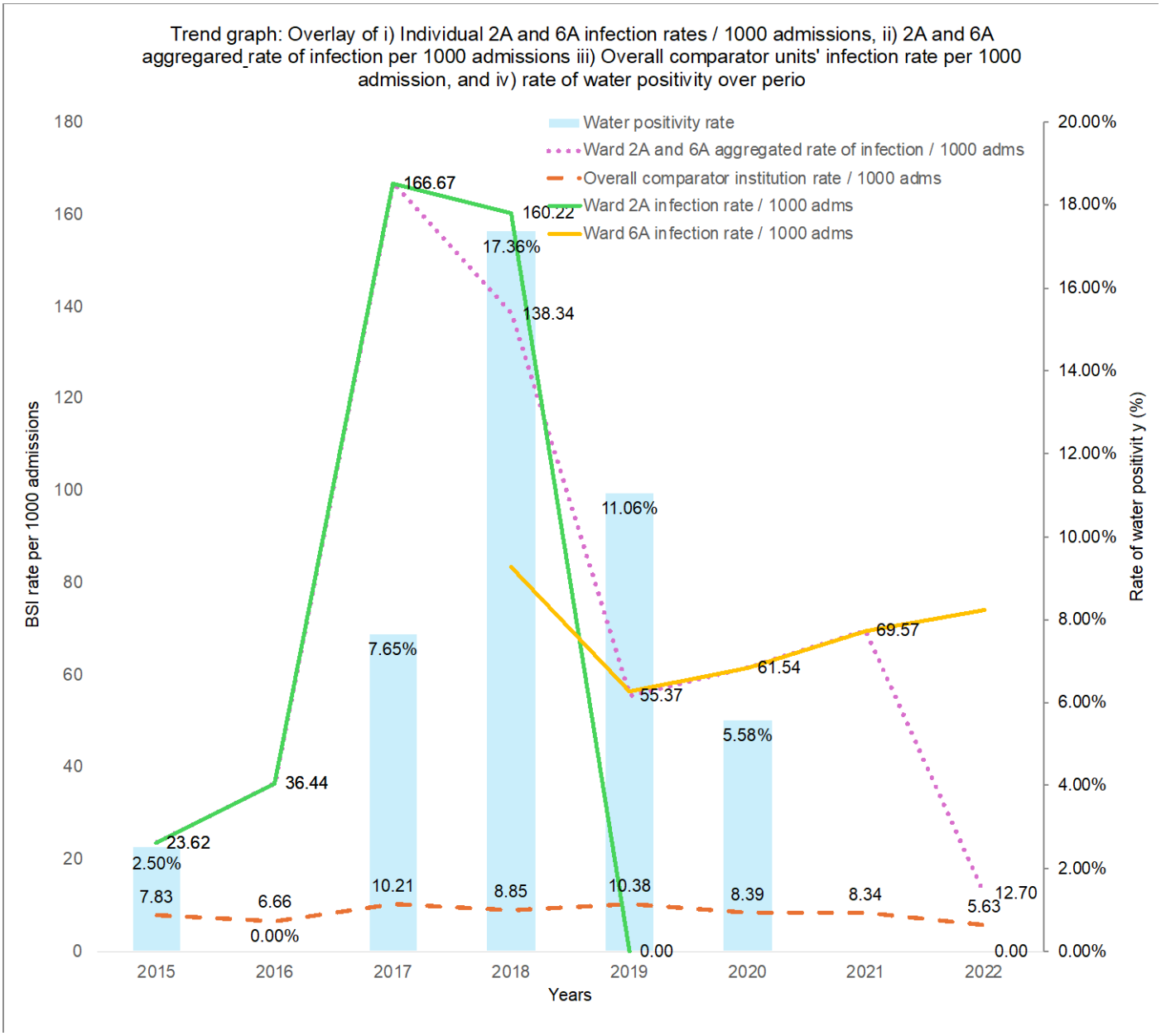


Figure 2: Trend graph for the period 2015 – 2022

- The individual wards' 2A and thereafter 6A rates of infection from 2015 – 2022 were higher for every year over the period of 8 eight years as compared to the overall comparator units' rate.

- The IRR statistic shows that the year the Schiehallion opened – 2015, the magnitude of the difference between the 2A rate versus the comparator units' rate was 3 times. This rose to 18 times in 2018, at the point when patient admissions (among other actions) were restricted and the decant of patients to 6A (primarily) took place. At the time of the decant, the 6A rate was approx. 9 times that of comparator units', dipping to approx. 5, 7 and 8 times over 2019 – 2021, rising to 13 times in 2022 versus comparator units.

- Figure 2 includes both individual 2A and 6A rates, green and yellow respectively, alongside an aggregated 2A and 6A rate in dotted pink, which allows us to follow the rate of infections as the patients commenced their stay in 2A in 2015, to the decant in 2018, and their stay at 6A thereafter. Note the magnitude of the difference as discussed in the previous paragraph, illustrated here in terms of the observable difference between the individual or aggregated 2A and 6A rates, as compared to the comparator rates in dashed orange.

- Note too the double peak in infections, first at 2A in 2017 and 2018, fitting in with our understanding of the concern regarding 'unusually high infections' as evidenced in Dr. Mumford's report, and thereafter a peak in 2021 in ward 6A.

- As discussed in section 7.2 of the Quantitative report, the Pearson's correlation coefficient statistic compares two time series data points over a period of time and provides a figure indicative of how 'associated' these two time series are to each other. Recall that the Pearson's correlation coefficient in section 7.3 was 0.7, indicating a 'moderate – very strong' positive correlation between the trend in Schiehallion infection rates and the trend in water positivity, i.e. contamination. I recalculated the statistic, this time comparing the aggregated 2A and 6A rate against the water positivity figure for the period 2015 – 2019 (see paragraph 2.41 for an explanation of why I excluded the 2020 water positivity figure), with the resulting statistic = 0.6, interpreted as indicating a 'moderation – strong' association between infection rates and water positivity. This is despite including the 0% water positivity figure in 2016, which flags as an anomaly, not fitting with my understanding, evidenced by Dr. Walker's and Dr. Mumford's papers, on the extent and concern regarding water contamination over that period.

- In the absence of an alternative evidence-based explanation for the unusually high rates of infection seen at the Schiehallion, the findings discussed here and in the Quantitative report provide an evidence-based explanation for why the Schiehallion experienced such high rates, sustained over a period of 8 years.

3. Response to Dr. Agrawal's report

3.1. **Separately within his Supplementary Report Mr Mookerjee should consider the report prepared on 18 May 2021 by Dr SG Agrawal BSc MBChB FRCP FRCPath PhD (Bundle 21, Volume 7, Page TBC). The Inquiry Understands that this report was produced by for NHS GGC in respect of an Improvement Notice served on NHS GGC by the Her Majesty's Inspector of Health and Safety which asserted that the board has "failed to ensure, so far is reasonably practicable, that the ventilation system within Ward 4C is suitable and sufficient to ensure that high risk patients who are vulnerable to infection are protected from exposure to potentially harmful airborne microbiological organisms" and which was appealed to the Employment Tribunal. Mr Mookerjee should comment on the epidemiology of this report and whether he has an opinion on the validity of its epidemiological conclusions (particularly at paragraph 5.5).**

3.2. I have read and understood Dr. Agrawal's report, and comment here specifically in relation to Section 5.5, which discusses the burden of hospital acquired infections in Ward 4C.

3.3. Dr Agrawal notes that for the period 1 January 2016 to 31 July 2020, there were two cases of *Aspergillus* infection, two cases of norovirus, two of RSV, five *Pseudomonas* and 5 'pneumocytis'. The report then notes that these are considered 'low rates of infection over a 55-month period'. Dr Agrawal then compares the aforementioned period to a 26.5-month period, at a separate hospital, where 16 cases of *Pseudomonas* and 115 isolates of gram-negative organisms were identified.

3.4. My comments and questions of Dr Agrawal are as follows.

3.5. Firstly, no detail on the species of *Aspergillus* or *Pseudomonas* that were linked to cases of infection at 4C. Furthermore, there is no detail on whether these are bacteraemias, or other.

3.6. The report also conflates infection episodes caused by genus of bacteria, e.g. *Pseudomonas* with syndromes, e.g. pneumocystis (I presume this is the syndrome or condition being referred to by the term 'pneumocytis'). Pneumocystis pneumoniae or PCP is a serious lung infection caused by yeast like fungus *Pneumocystis jirovecii.* It is not clear or evidenced whether this was diagnosed by specific diagnostic tests or imaging changes.

3.7. The report does not provide details on the source of this data, how it was extracted, how it was analysed, and how he arrived at the numbers of infections caused by the given organisms and syndromes over the period 1 January 2016 to 31 July 2020.

3.8. It is also not clear why bacterial infections, like the one caused by *Pseudomonas* are conflated with respiratory viruses, like RSV or diarrhoea and vomiting infections like norovirus.

3.9. It is not clear how the author arrived at the conclusion that the aforementioned numbers of bacterial infections (it is not known if these are bacteraemias, wound cultures or other), respiratory viruses and syndromes such as pneumoniae, together constituted 'low rates of infection'. To calculate a rate one needs a denominator. What was the denominator used and what indeed are the rates of infection? Only absolute number of bacterial infection, viral infections, two cases of diarrhoea and vomiting, and 5 cases of a syndrome, with an un disclosed pathogen is what is provided. Furthermore, to arrive at the conclusion that a rate or indeed a number is low, one has to compare to either a baseline at the same institution, or indeed to comparator institutions.

3.10. The above point is addressed by way of comparing the 'episodes of infections' at 4C to Barts hospital, with an undisclosed data, with no information provided on its source, analysis carried out, or how indeed Dr. Agrawal arrived at 16 cases of infection (were these bacteraemias?) and a further 115 isolates of gram-negative organisms. To compare incidence of infections, one needs a denominator, e.g. admissions for the period of time concerned, to account for changes in activity. This allows the rate to reflect and be weighted for periods of higher activity, e.g. more admissions, to periods of low admissions. It is epidemiologically unsound and biases to compare incidence over time at an institution without accounting for changes in activity. For the purposes of my critique of this report, no activity data is given, neither for 4C nor for the comparator Barts. Dr Agrawal is comparing a miscellaneous mix of bacterial infections, viral infection and syndromes, which only constitutes raw numbers, with Barts, where the comparison is made to cases of bacterial infection caused by *Pseudomonas* (unknown species or whether this is bacteriaemia or other) and 115 isolates of undisclosed types of gram-negative organisms. This is not comparing like with like, secondly the absence of a denominator means Dr Agrawal isn't comparing rates, rather incidence of heterogenous infections, over two hospitals, with an overlap from 1 January 2016 to 15 July 2017 (start of 4C data and end of Barts data).

Given that the report is concerned with the role of ventilation, in particular the legitimacy, interpretation and applicability of the SHTM 03-01 (Bundle 1, Document 8, Page 433 (Part A) and Page 408 (Part B))., I'd have expected a longitudinal rate of infection (incidence over activity, multiplied by a factor of 10 as appropriate) for 4C, compared to a representable sample, i.e. multiple peer organisation, for the same period of time as infections in 4C, using a longitudinal rate of infection for the comparator units.

3.11. Furthermore, it is in line with scientific writing that authors disclose the data used, how they came about it, what the biases and issues with the dataset are, how they went about analysis it, what the results table looks like, such that the reader is able to critique in a step wise manner, how the author came to the conclusions they did. I'm afraid this section of the paper doesn't satisfy any of the scientific writing requirements. Lastly, if we are to understand the role of SHTM 03-01 in stipulating best practice measures to reduce exposure to pathogens found in the environment in clinically vulnerable patient groups, we need to start with a list of organisms that fit the bill, i.e. bacterial, fungal and other groups of pathogens which are found in the environment, a fundamental starting point which this report does not adhere to. In my opinion, the report and its overarching conclusion of this section which states that rates of infection at 4C were lower than a comparator does not hold and will not hold up to any scientific scrutiny.

3.12. Is it unclear how Dr. Agrawal expects the findings of this report to help decide whether a ward like 4C where the application of SHTM 03-01 was deemed inadequate, indeed suffered increased or decreased ill consequences, in terms of infections in the paediatric population, as compared to organisations which are fully or partially compliant with SHTM 03-01. I do not see information pertaining to the extent of water nor ventilation issues at the comparator institution used by Dr. Agrawal. In my view a duplication of the analysis carried out and discussed in the Quantitative report and thereafter in this report is needed to provide an evidence-based counterpoint, if that is the intention, for what led to the unusually high rates of infection at the Schiehallion.

SCOTTISH HOSPITALS INQUIRY

Expert Report

Review of the Link Between Patient Infections and Identified Unsafe Features of the Water and Ventilation Systems at QEUH/RHC

Expert Report prepared for the Scottish Hospitals Inquiry

By Dr Sara Mumford, MB. BS., MSc., FRCPath., SFFMLM.

and Linda Dempster, RN., BSc., MA.

Date of submission: 24 May 2024

Table of contents

1. Introduction

1.1. The Expert Group was appointed by the Chair of the Scottish Hospitals Inquiry, Lord Brodie PC KC. The members of the group are instructed to prepare reports on a number of matters relating to the incidence of healthcare associated infections caused by environmental organisms at Queen Elizabeth University Hospital (QEUH), Glasgow and the Royal Hospital for Children (RHC), Glasgow[1].

1.2. The membership of the Expert Group was initially Dr Sara Mumford, Mrs Linda Dempster and Dr Jimmy Walker. Later additions included Mr Siddharth Mookerjee and Mr Allan Bennett.

1.3. In order to answer the Key Questions, set out at paragraphs 1.6 to 1.10 below, Dr Walker has prepared a report on the water system at QEUH and RHC[2], Sid Mookerjee has prepared an analysis of the environmental infections seen at QEUH and RHC in certain groups of patients[3], and Allan Bennett has prepared a report on the ventilation systems at QEUH and RHC[4]. Dr Mumford and Linda Dempster[5] have prepared this report.

1.4. The purpose of this report is to provide evidence and expert opinion, in line with the author's expertise, on matters which may assist the Chair in fulfilling the Inquiry's Terms of Reference, specifically Key Question (4).

1.5. The authors are reliant upon information from a number of other parties, including the other members of the Expert Group and therefore current analysis can only be based on the available information/evidence provided. Parties include a range of organisations and sources including, but not limited to, NHS Greater Glasgow and Clyde (NHS GGC), Health Protection Scotland (HPS), Health Facilities Scotland (HFS), National Services Scotland (NSS) including Antimicrobial Resistance and Healthcare Associated Infection (ARHAI), Freedom of Information requests and national data sets.

[1] SHI letter of instruction to Dr Mumford, 4 October 2022
[2] Review of the NHS Greater Glasgow and Clyde: Queen Elizabeth University Hospital/Royal Hospital for Children water and waste-water system from the point at which patients occupied the site in 2015. Dr JT Walker
[3] Quantitative analysis undertaken to understand the association between the built environment and rates of gram-negative and fungal bloodstream infections at the Schiehallion unit between the years 2015 and 2022. Sid Mookerjee
[4] Allan Bennett - Expert Report for SHI
[5] Subsequently referred to in this paper as 'the authors'

1.6. The Scottish Hospitals Inquiry has prioritised four key questions for the Expert Group.

1.7. Key Question (1): From the point at which there were patients within the QEUH/RHC, was the water system (including drainage) in an unsafe condition, in the sense that it presented an additional risk of avoidable infection to patients?

1.8. Key Question (2): From the same point and in the same way was the ventilation system in an unsafe condition?

1.9. Key Question (3): In the same sense, are these systems now in a safe condition?

1.10. Key Question (4): Is there a link, and if so in what way and to what extent, between patient infections and identified unsafe features of the water and ventilation systems?

1.11. This report will address Key Question (4). The report is based on available material and sits alongside the quantitative analysis undertaken by Sid Mookerjee[6], the review of the water system by Dr Walker[7], the review of the ventilation system by Andrew Poplett[8] and the review of ventilation by Allan Bennett[9].

2. Professional Backgrounds and Declarations.

Introduction of the Expert Witnesses

Dr Sara Mumford. GMC:3141744

- I completed my medical degree, Bachelor of Medicine and Bachelor of Surgery, at the Medical College of St Bartholomew's Hospital, University of London in 1986. I then went on to complete my pre-registration year at St George's Hospital, London and King's College Hospital, London.

[6] Quantitative analysis undertaken to understand the association between the built environment and rates of gram-negative and fungal bloodstream infections at the Schiehallion unit between the years 2015 and 2022. Sid Mookerjee
[7] Review of the NHS Greater Glasgow and Clyde: Queen Elizabeth University Hospital/Royal Hospital for Children water and waste-water system from the point at which patients occupied the site in 2015. Dr JT Walker
[8] Independent Expert Report Concerning Critical Healthcare Ventilation Systems at Queen Elizabeth University Hospital, Glasgow and the Royal Hospital for Children. Andrew Poplett.
[9] Allan Bennett - Expert Report for SHI

Subsequently I worked as a Senior House Officer in Accident and Emergency at St George's Hospital before commencing Specialist training in Microbiology at Charing Cross Hospital, London in 1989. I completed my microbiology training at St George's Hospital, London and Ashford Public Health Laboratory, Kent, undertaking the Public Health Laboratory Service training in Advanced Infection Prevention and Control (IPC) in 1995, and gaining admission to the GMC specialist register for medical microbiology and virology in April 1999. During my training I gained a Master of Science degree in Clinical Microbiology (1993) and Membership of the Royal College of Pathologists (1998). The then Membership of the College is equivalent to the current Fellowship which I was awarded in 2005 through time served as a member.

- I was appointed Consultant Microbiologist to the Public Health Laboratory Service in 1999. I took a career break from September 2001 to September 2004 to spend time with my young family.
- I was appointed Consultant in Communicable Disease Control in September 2004 to the Kent Health Protection Unit. This role included providing advice and support of all aspects of public health infection matters including outbreak investigation in both community and acute healthcare settings, emergency planning, developing infection control policies for community settings and I taught on the Health Protection MSc modules at the University of Kent at Canterbury.
- In November 2007, I was appointed Director of Infection Prevention and Control (DIPC) and Consultant Microbiologist to Maidstone and Tunbridge Wells NHS Trust (MTW). As Consultant Microbiologist I provided a clinical and diagnostic service to the Trust, interpreting reports leaving the laboratory and advising on all aspects of infection and antimicrobial prescribing.
- When I joined the Trust, it was following an outbreak of *C. difficile* which was subject to a critical Healthcare Commission report published in October 2007 and extensive media reporting. I led the turnaround in performance following the report, achieving top quartile performance with respect to *C. difficile* two years later. I have shared the learning from the outbreak investigation and resolution through speaking at local, national and international conferences.
- I fulfil the statutory duties of the Director of Infection Prevention and Control as laid down in the Health and Social Care Act 2015, ensuring full compliance

with the Hygiene Code, and lead the strategic and operational provision of infection control in the Trust. I sit on the Trust Board and am a member of the Executive team. I have led the turnaround in performance and cultural change in the organisation with the Trust now seen as high performing in the area of infection prevention.

- I lead a team which has twice been named as runner up in the Infection Prevention Society Infection Control Team of the Year. I lead on outbreak investigations, collecting and monitoring surveillance data, reviewing root cause analysis investigations and implementing IPC Patient Safety Alerts. I provide advice on all aspects of infection prevention and work closely with colleagues from other organisations. I have undertaken various infection prevention and control and microbiology peer reviews for other NHS organisations.
- During the Covid-19 pandemic I led the Trust response with respect to infection prevention and control and ensured systems and processes were in place to monitor PPE use, training, fit testing and staff and patient testing for Covid. I worked with teams to find compassionate solutions for families to visit loved ones at the end of life, for Covid positive parents to visit their babies in the neo-natal unit at the earliest opportunity and families generally to keep in touch whilst keeping our staff safe.
- I led the Patient and Staff Safety work stream during Covid planning. I ensured that the Board was fully sighted on the response to Covid and updated the Board Assurance Framework on a monthly basis.
- During the NHS structural transition from Clinical Commissioning Groups to Integrated Care System I was asked to take on the system leadership role for IPC. I led the development, in collaboration with system partners, of the first Kent and Medway 3-year IPC strategy which was approved by the ICB executive in April 2023.
- I continue to have an educational role, teaching junior doctors, nurses, AHPs and also teaching on a post graduate course at the London School of Hygiene and Tropical Medicine (pre-Covid) and teach leadership in the context of the DIPC role on the Healthcare Infection Society/UKHSA foundation course in IPC course.
- During the Covid pandemic I was asked to join the pilot of the NHSE/I Safety Support Scheme. This was designed to support Trusts struggling with infection prevention. My role was to join inspections of Trusts and to provide

expert advice. This also led to me being seconded half-time to another Trust as Interim DIPC following concerns raised by NHS England and the Care Quality Commission (CQC).

- The CQC inspection at the time I was seconded to this Trust in June 2020 resulted in a Section 31 (of the Health and Social Care Act) Order being issued. I led the response and worked closely with the Board, executives and staff at all levels of the Trust, implementing Infection Prevention changes through a targeted action plan, training for all staff, new patient pathways and additional monitoring and audit. I adopted a collaborative approach, being highly visible and supporting front-line teams to improve practice. I re-started the Infection Prevention and Control Committee, Water Safety Group and Decontamination committee which had not met for an extended period of time. I also supported the infection prevention team and staff at all levels to improve practice, empower staff in their decision making through positive feedback and supported cultural change throughout the organisation. In February 2021 the CQC re-inspected the Trust's infection prevention arrangements and gave a positive report which was published on 23 April 2021. The Section 31 Order was also lifted following the inspection.
- Throughout my time at MTW I have undertaken clinical leadership roles including Clinical Director, Associate Medical Director and Deputy Medical Director. I have developed a passion for patient safety and have worked in various roles, including medical lead for patient safety, where I have been able to influence patient safety, enhanced learning from incidents and deaths, and compassionate leadership. I was awarded the Senior Fellowship of the Faculty of Medical Leadership and Management in 2023.
- I am a subject matter expert in the field of Infection Prevention and Control with over 30 years' experience.
- I took up the role of Medical Director at MTW on 1 January 2024.
- In 2022 I was approached by the Scottish Hospitals Inquiry who were wishing to recruit an expert in infection prevention and control to also act as chair of the Expert Group.

Linda Dempster M.A. BSc., RGN

- I am a Registered General Nurse and qualified in 1982 completing my student nurse training at Nottingham School of Nursing. I then practised in general medicine before starting as an intensive care nurse.
- My qualifications are BSc (Hons) Nursing Studies 2:1, Canterbury Christchurch University College 1995, Master of Art Management (Merit) Canterbury Christchurch University College. January 2006, ENB 100 Kent and Canterbury Hospital November 1984, ENB 998 Christchurch University College 1994, Diploma in Infection Control/ENB 329 Royal College of Nursing October 1996. I have also attended the High performing leader's development programme 2013-14 NHS England, and QSIR course NHS England/ NHS Improvement 2019.
- I commenced my first infection prevention and control (IPC) post in 1995 at the Kent and Canterbury Hospital, moving to the Public Health Laboratory Service (PHLS) in 1999 at the William Harvey Hospital. I moved to a Primary Care Trust in 2004 as Associate Director of IPC, where I was also the nurse member of the professional executive committee. This role covered a wide range of different clinical settings across Medway and Swale in Kent.
- I returned to an acute hospital role in 2006 at Medway NHS Foundation Trust as Deputy Director of IPC and Head of Infection control. In January 2017 I moved to the Trust Development Agency and was the regional IPC lead for the South of England.
- In my role as regional IPC lead for the South of England I worked with NHS organisations that were preparing for Foundation Trust status and supported organisations that may have been challenged due to major outbreaks and incidents relating to IPC.
- I became the first National Head of IPC for NHS England/Improvement in January 2017 and I remained in this role until I retired in March 2020. Due to the Covid pandemic I returned to support the Covid 19 IPC Cell at NHSE until July 2020 when I moved to a quality improvement role supporting a wide range of NHS organisations until March 2022. I also worked for UKHSA from January 2022 until March 2023 as a Quality Improvement advisor.
- I am an experienced Infection Prevention and Control practitioner. I have over twenty-five years' experience of working in IPC, working within a wide range of settings including acute hospital, community, and mental health sector of the NHS, having worked at both a regional and national level within NHS England and NHS Improvement.

- I led the national NHS England IPC team in the development and support of the delivery of the Gram-negative reductions and in supporting the development of the Chief Medical Officer's Antimicrobial resistance 5-year action plan and 20-year vision. The plans outline the UK's contribution to containing and controlling antimicrobial resistance (AMR) in health, animals, the environment, and the food chain. My remit was to lead NHS England's IPC commitments.
- I have been in a senior NHS leadership role for over 20 years. The key focus in my later years was around system leadership with the antimicrobial resistance agenda including infection prevention and control, AMR stewardship, diagnostics, and the management of sepsis. I was the IPC advisor to the Chief Nursing Officer for England and was a key member of UK wide groups and committees, including advising the Department of Health and Social Care.
- In 2022 I was approached by the Scottish Hospitals Inquiry who were wishing to recruit an expert in infection prevention and control.

Declaration of Understanding

2.2. We are clear as to what our duties are and clear that they include assisting the Inquiry in an impartial manner.

2.3. We acknowledge and understand that it is our duty, both in preparing reports and in giving oral evidence, to assist the inquiry on matters within our fields of expertise and that we will continue to comply with that duty.

2.4. We have no connection, personal or otherwise, to any core participant in the inquiry other than that we have declared in this report.

2.5. We declare that we have no financial or economic interest in the outcome of the inquiry.

2.6. We acknowledge and accept the necessity of expressing an independent opinion which is the product of our own consideration and research and that we have complied with the duty to do so.

2.7. We acknowledge the duty to set out all material facts, assumptions, methodology or other matters upon which our views and opinions are based,

including such matters as may detract from the opinion formed, and that we have complied with that duty.

2.8. We acknowledge the duty to address only areas within our own areas of expertise and that we have made it clear when a particular question or issue falls outside our expertise, and that we have complied with that duty.

2.9. We acknowledge, understand and accept the obligation to state if our opinion is not properly researched because insufficient data are available and to give an indication that the opinion is no more than provisional, and have done so in our report where appropriate.

2.10. We acknowledge, understand and accept the obligation to indicate if any opinion we have expressed is qualified, or subject to revision, and have done so in our report where appropriate; and

2.11. We acknowledge, understand and accept that we should, at the earliest opportunity after completing the report, indicate if, for any reason, including as a result of discussions with other experts, our views have been altered or the report requires any correction or qualification, and if so, in what area, and we shall comply with that duty.

2.12. **Declaration by Linda Dempster**

- I was approached by Dr Andrew Fraser in my capacity as Head of Infection Control for NHS Improvement (I retired from this role 31 March 2020) to offer infection prevention and control advice to the Queen Elizabeth University Hospital Independent Review, June 2022. This was an advisory role and I made one site visit to the hospital with Dr Fraser, Dr Montgomery and Dr David Jenkins, a microbiologist and Deputy Director of infection prevention and control from Leicester Royal Infirmary. I cannot confirm dates as I no longer have access to my NHS.net account or any documents relating to this.
- Whilst on the site visit to Queen Elizabeth University Hospital we met staff from GGC estates and facilities plus the infection prevention and control (IPC) team. We were taken to Ward 2a that was vacated and a building site and was currently in the process of extensive building remedial works. The team explained the works underway and progress to date. The team were escorted to a second ward area, ward 4a, where patients had been relocated to during the works to ward 2a, accompanied by Professor Leanord and the Infection control manager.

- Whilst on the site visit, I met IPC team members. I have no idea if I met any whistle-blowers as I do not know who they are. I did not have access to any of the statements, interviews etc as referenced in the report. I gave high level feedback, by email, on the findings of the day following our walk round to Drs Fraser and Montgomery.
- I offered general IPC advice based on the observation and scenarios presented at the time of the visit by email. I did not have any input into any decision-making regarding bloodstream infections in the children and there being any connection to the environment.
- Case Note Review**:** I was asked by Gaynor Evans to provide additional IPC expertise to support the case note review; my role was one of reviewing documents such as incident management team notes, action plans, audit reports relevant to certain case of infection by date and locations. This role was one of a specialist IPC reviewer, feeding back findings, evidence and omissions to the case note review core team. I did not have any role in making decisions to what infections were or were not related to the environment. My role did not include linking environmental or water samples to infections/cases which was outside the scope of my role.
- I attended regular meetings with the group Chaired by Mike Stevens and attended by Mark Wilcox and Gaynor Evans and a number of other clinicians and support staff. I have no records, emails or notes relating to this work as it was all on shared secure drives.
- The email I used was my NHS net account which I no longer have access to, I have retained no notes or information related to this review.
- I recall I did join a call with GGC staff to support the review team to comment only on the documents I had reviewed, I do not have details regarding date and attendees, I do not know if these included whistle-blowers.

Glossary of terms and abbreviations

ac/h	Air changes per hour
Aerosol	A suspension of droplets in the air
AHP	Allied Health Professions
Antimicrobial gel	A hand sanitiser, in healthcare this is usually 2% chlorhexidine in 70% isopropyl-alcohol
Antimicrobial prophylaxis	Antimicrobials given to prevent rather than treat infection
ARHAI Scotland	Antimicrobial Resistance & Healthcare Associated Infection Scotland is a clinical service providing national expertise for infection, prevention and control, antimicrobial resistance and healthcare associated infection for Scotland
Blood culture	Blood is directly added to a nutrient broth and incubated at an optimal temperature to enable any bacteria present to grow and multiply.
BMT	Bone and marrow transplant
BSI	Blood stream infection (also known as bacteraemia)
Central line/central venous catheter	A tube placed in a large vein in the neck, chest, groin or arm which can stay in place for several months if needed.
CBU	Chilled beam unit
Decontamination	To remove or destroy contamination and thus reduce the risk of infection to anyone coming in contact with that item or environment.
DIPC	Director of Infection Prevention and Control – a statutory role defined in the Health and Social Care act 2015
ECOSS	Electronic Communication of Surveillance in Scotland. An electronic system for microbiology laboratories to report to Public Health Scotland
Exception Reporting	The reporting of actual data which are deviations from the expected or planned data
Fungus	In medicine, microorganisms which can occur as yeasts or moulds
Gram-negative	Organisms which do not retain the crystal violet stain used in the gram method of bacterial differentiation.
HAI	Healthcare associated infection
HEPA filter	High efficiency particulate air filter which traps 99.97% of particulates of 0.3 microns or larger
HIV	Human immunodeficiency virus
HIAAT	Healthcare Infection Incident Assessment Tool
HPV	Hydrogen Peroxide vapour
HTM/SHTM	Health Technical Memorandum/Scottish Health Technical Memorandum
ICD	Infection Control Doctor
Immunocompromise	Where an individual's immune system is not working due to disease or medication.
IMT	Incident Management Team
IPC	Infection Prevention and Control
IPCC	Infection Prevention and Control Committee
IPCT	Infection Prevention and Control Team
ITU	Intensive Therapy Unit, also sometimes known as Intensive Care Unit. A unit in a hospital for patients with severe or life-threatening illnesses and injuries where constant care using life support equipment and medication is provided

Meningitis	An infection causing inflammation of the membranes surrounding the brain and spinal cord
Micro-organisms	Bacteria, viruses, fungi and protozoa
MRSA	Meticillin-resistant Staphylococcus aureus
NHSE/I	National Health Service England and Improvement
NIPCM	National Infection Prevention and Control Manual for Scotland
Nosocomial	Acquired in a hospital
Opportunistic pathogens	A micro-organism which would normally not cause infection or illness in a healthy individual but may cause serious infection in an immunocompromised person
PAG	Problem assessment group
Pathogen	A disease-causing micro-organism
PIR	Post infection Review
Splash zone	The area around a sink where droplets may land when a tap is run.
Stagnation	Where water does not move or flow
Total Viable Count (TVC)	The total number of micro-organisms in a water sample
TPN	Total parenteral nutrition
UKHSA	United Kingdom Health Security Agency
UV-C	A type of UV light which is used to kill micro-organisms
WGS	Whole genome sequencing
Yeast	A fungus consisting of single cells which reproduce by budding

3. Reporting of Healthcare Associated Infections (HAI)

Principles and Practice of Infection Prevention and Control

3.1. Infection Prevention and Control (IPC) and the risk of HAI affects all aspects of health care, including hand hygiene, surgical site infections, antimicrobial resistance and how hospitals operate during and outside of emergencies. IPC is essential to ensure that people who use health and social care services receive safe and effective care. Effective prevention of infection must be part of everyday practice and be applied consistently by everyone.

3.2. IPC is an established, evidence based and practical approach to prevent harm to patients, visitors and healthcare workers from avoidable infections.

3.3. To be effective, IPC must be a multi-disciplinary approach from clinical, estates and facilities and corporate teams together with users of healthcare facilities. Quality, safe healthcare cannot be achieved without IPC applied at every interaction between health services and patients. In this respect, IPC is unique in its universal reach into all aspects of healthcare.

3.4. IPC affects all aspects of health care, including hand hygiene, surgical site infections, antimicrobial resistance and how hospitals operate during and outside of emergencies. IPC is essential to ensure that people who use health and social care services receive safe and effective care. Effective prevention of infection must be part of everyday practice and be applied consistently by everyone.

3.5. Infection prevention and control should effectively manage risk factors related to the spread of infections within the healthcare setting, whether between patients, from patients to staff or vice versa, from visitors to patients, amongst staff or from the patient environment. Environmental risks include those related to water, ventilation systems or the physical environment.

3.6. For some patients, isolation is an effective way of managing infection risk:

- **Source Isolation:** Where a patient has an infectious disease, which can be passed from person to person, isolation of that individual will protect other patients from acquiring the infection. This is usually done by placing the infectious patient in a single room in which the air pressure is negative (by 5Pa) to the corridor. This will prevent air leaking out of the room when the door is opened due to the higher pressure in the corridor. The extract should be filtered to prevent infectious agents being expelled to the outside.

- **Protective Isolation:** Where a patient is immunocompromised and highly susceptible to infection as a result, they can be placed in protective isolation. This will involve placing the patient in a single room with positive air pressure of +10 Pa to the corridor to prevent ingress of air into the room. The room will be mechanically ventilated with HEPA filtered air to provide 10 air changes per hour, be sealed with a solid ceiling to prevent leakage and air will be extracted through the en-suite bathroom.

3.7. Isolation alone cannot completely mitigate the risk and preventative measures to manage identified risks include hand hygiene, cleaning and disinfecting (environment and equipment), safe management of invasive devices (such as urinary catheters, intravenous devices etc) and appropriate personal protective equipment (PPE).

3.8. The IPC team will consist of a range of experts including nurses, microbiologists, infection control doctors, antimicrobial pharmacists and data/surveillance experts. Team members must maintain competence, knowledge and skills in infection prevention and control practices through continuous professional development. Epidemiological and surveillance systems capable of distinguishing patient case(s) requiring investigation and control are essential to the efficient working of the IPC team. Effective surveillance involves the collection, collation, analysis and dissemination of information. This is essential for the early identification of outbreaks and trends. IPC teams will have responsibility to manage outbreaks and incidents.

3.9. IPC teams have a far-reaching impact across a healthcare system in diverse ways including advising on patient placement and clinical management of infectious conditions, education and training, policy development and implementation, influencing and advising at Board level on relevant issues, involvement in planning new builds or upgrading of facilities and liaising with partner organisations including public health and regulators.

3.10. Effective management and organisational processes are essential to ensure that high standards of IPC are established and maintained. Healthcare organisations will have suitably qualified IPC staff who can provide expert advice on applying IPC in all care settings and on individual and organisational risk assessments, ensuring action is taken as required. Organisational Boards need to gain assurance that systems are indeed safe and effective.

Reporting of Healthcare Associated Infections (HAI)

General purpose of reporting HAI

3.11. A healthcare-associated infection is an infection 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.

3.12. Reporting in the context of HAI can be divided into three main areas; clinical, internal and external reporting.

3.13. **Clinical:**

- This is the process of informing clinicians of positive findings; for example, a positive blood culture suggesting that a bacteraemia is present. The authors base this section on their experience in England, however it reflects best practice which is equally applicable to Scotland.
- The overarching purpose of reporting HAI in this context is to ensure that patients receive the correct care and treatment as soon practically possible.
- Review of clinical cases by the microbiologist/ICD/IPC team will also be able to identify any risk due to the type of HAI and determine any interventions required to prevent harm to the individual or other patients, staff and visitors. Early intervention can prevent further cases/incidents depending on the HAI identified.
- Any HAI caused by a mandatory reportable organism[10] should usually also trigger a post infection review (PIR) to determine how the HAI was acquired by the patient. Notable exceptions to this review process would include Covid-19 HAI as the known causes are well rehearsed.

3.14. **Internal:**

- Preventing and reducing rates of HAI involves infection prevention and control teams using evidence-based interventions. Internal reporting systems enable monitoring of these interventions and key performance indicators
- Surveillance programmes are an important part of this, as they provide essential information on what and where the problems are and how well

[10] These include *Clostridioides difficile* and blood stream infections caused by *E. coli*, Meticillin resistant *Staphylococcus aureus* (MRSA), and Meticillin sensitive *Staphylococcus aureus* (MSSA) in Scotland. In England, *Klebsiella species* and *Pseudomonas aeruginosa* are also reportable.

control measures are working. Surveillance will also identify any 'alert organisms' causing infection in the hospital. Alert organisms are potentially significant for infection prevention and control practices and include environmental organisms identified as HAI. The list of alert organisms applicable in Scotland can be found in the NIPCM at appendix 13[11]

- Local internal reporting systems will ensure that clinical and management teams are aware of monitoring HAI against key performance indicators (KPIs) and that local clinical managers provide assurance on compliance with infection prevention policies and processes.
- Internal reporting systems provide assurance with respect to infection to the hospital/health board committee responsible for reviewing quality. This will include informing the committee of any current or emerging serious problems or hazards related to infection control. In Scotland reporting is through the established governance structure to NHS Boards.
- At NHS GGC, the acute IPCC reports to the Board IPCC. The acute IPCC receives reports on HAI and other IPC related issues.
- Case review as part of a PAG or IMT will identify areas for improvement, with action plans developed and ideally the learning will be shared across the organisation and externally where relevant including with the patient/family.
- In addition, the members of the IPC team attend other meetings including Health and Safety committee, Water Safety Group, Ventilation Group, hospital cleanliness etc and receive reports which may include alerts of environmental infection risks. These groups will also report to the IPCC.

3.15. **External:**

- In Scotland there are national mandatory reporting requirements for MRSA, MSSA, CDI, *E. coli* which have been identified as the main pathogens of interest for HAI. This national data enables comparison at regional and national level, the identification of trends and the setting of baselines and improvement targets. In addition, mandatory surgical site surveillance is undertaken for hip arthroplasty and caesarean section, although this has been suspended since the Covid-19 pandemic, and surveillance of HAI in intensive therapy units.

[11] National IPC Manual National Infection Prevention and Control Manual: Home (scot.nhs.uk)

- In addition, microbiology laboratories are required to submit data to central reporting systems such as ECOSS in Scotland. This supplements the mandatory surveillance data, allows real-time analysis of emerging issues and identification of unusual changes in epidemiology.
- Incidents and outbreaks are classified as laid out in chapter 3 of the National IPC manual and paragraph 9.4 and NHS boards are required to report all HIIAT-assessed Green, Amber and Red reports to ARHAI Scotland through the electronic outbreak reporting tool.
- Any HAI should also be reported to the patient's GP to provide appropriate ongoing care for the patient on discharge.
- In practice, there will be variation in processes however, on the whole, the laboratory team (usually microbiologists) and the IPCT report out to clinicians and others rather than clinicians reporting in to the IPCT, although this does happen in situations such as outbreaks of Norovirus infection which are detected clinically as the microbiological testing is reactive in response to patients developing symptoms.

Process of Reporting

3.16. **Reporting to clinicians** – The laboratory will identify a positive growth in a blood culture or other significant culture, the microbiologist will then phone the result to a clinician caring for the patient to initiate the correct treatment for the identified infection. At this stage it may not be clear whether or not the infection is a HAI or community acquired and this will be determined depending on the patient's admission date, previous admissions and interventions, and the date of the specimen.

3.17. **Post infection review -** a multidisciplinary meeting will be held (a problem assessment group or Incident Management Team in Scotland), to review the case, identify a root cause and identify learning (what went wrong and how can a repeat be prevented) and action plan. Outcomes are reported through the governance route and best practice would be to share any identified learning across the organisation.

3.18. **Surveillance –** Most IPC teams will have an electronic system which interfaces with the laboratory information system (LIMS) and receives real-time notification of surveillance and alert organisms including positive blood cultures. Information received will trigger investigation by the IPCT, review of

the patient and collecting initial data to determine if there is need to undertake further follow up. The IPCT will also maintain databases of HAI, analyse the data collected and report on incidence and trends as described above.

3.19. The IPCT will have standard procedures for dealing with an identified infection to ensure consistency and appropriate action taken including identification of ongoing risks to patient safety.

3.20. Regular reports of HAI are often used to share information with clinical teams. These reports may take the form of integrated dashboards, excel spreadsheets or narrative reports and are distributed to a wide audience. In our experience this is best practice and applies equally to Scotland and other parts of the UK.

3.21. **Reporting to IPCC –** Clinical managers e.g. matrons, provide written and verbal reports to IPCC on performance including numbers of HAI related to the mandatory reportable organisms and any outbreaks. The IPCT may also provide data to the clinical managers to be incorporated into the reports (e.g. PIR outcomes, audit data). In our experience this again represents best practice and requires good communication between the IPCT and clinical teams.

3.22. **Reporting through the local governance route –** usually by a specific report or minutes of the IPCC including any key items for escalation in respect of patient safety risks, outbreaks, incidents and mandatory reporting often delivered by the Director of Infection Prevention and Control or deputy.

3.23. **Board reporting** – In NHS GGC, The Chief Nurse reports to the Board on IPC matters. This will include exception reporting[12] on HAIs and alerting the Board to emerging threats in IPC.

3.24. **Water safety** – the water safety officer will report regularly to the IPCC on matters related to water quality, identifying any risks to patient safety. Local systems may vary, however there must be robust systems in place to provide effective assurance of compliance, learning and feedback.

Potential issues and areas of failure

3.25. **Communication -** poor communication between laboratory, and clinical teams and the IPC team leads to inadequate flagging of cases of interest and

[12] See glossary for definition

a lack of follow up procedures including linking related organisms using typing methodology.

3.26. Where data is not used to analyse the wider picture, cases of interest may not be linked effectively and investigation is impeded.

3.27. Where the Director of Infection Prevention and Control (DIPC) is not a subject matter expert and part of the IPCT, the communication between the team, the ICD and the DIPC is vital. The DIPC should have direct access to the Chief Executive and this is a key route of escalation.

3.28. Where the senior IPC voices are not heard effectively by an organisation and at high enough level, IPC issues are not prioritised and resourced.

3.29. Where the executive with responsibility for IPC is not a subject matter expert, there is a risk that they may not understand the patient safety risks associated with the information provided to them and may in turn not be able to articulate those risks effectively to the executive team.

3.30. **Culture -** The lack of an open culture that supports reporting of cases/incidents in an honest manner, leads to a failure in recognising the learning and ensuring that those lessons are learnt and shared within the organisation, ultimately resulting in the same errors recurring.

3.31. The lack of open culture will also lead to issues not being raised effectively or escalated to senior managers and executives and dealt with in a timely manner.

3.32. Teams working in silos with inadequate communication and sharing of learning between them will result in increased risk of the same errors being repeated.

3.33. **Patient care -** Previous healthcare interventions are important in assessing the risk of patients acquiring HAI. Failing to recognise this may place an individual patient at increased risk. For example, where a healthcare facility has an endemic multi-resistant organism, this places patients who are cared for in the facility at increased risk of acquiring the organism and when they go to another facility, staff may unwittingly increase the risk of the multi-resistant organism infecting the patient e.g. by use of the wrong antibiotic. Transfer of care information can mitigate this risk when used effectively.

3.34. **Information -** Focussing on mandatory data reporting as the only quality measure by which IPC is measured may result in more unusual infections and risks not being prioritised and understood.

3.35. The lack of a robust surveillance/data collection system that flags cases of interest may result in under-reporting of significant infections.

Potential areas for improvement

3.36. Early identification of linked cases is paramount. The more unusual the infections, the more important it is to consider any potential relationship between them. This requires robust communication between the laboratory, consultant microbiologists, ICD, IPC team and clinicians. The infection control doctor should be closely involved with any investigation.

3.37. In the case of unusual infections or where there are suspected links in time and place between infections, the assumption should be made that cases are linked until proven otherwise.

3.38. Any further laboratory work such as typing or whole gene sequencing should be requested without delay.

3.39. Early reporting to the affected clinical areas is vital so that measures can be put in place to prevent further cases.

3.40. Early escalation to senior managers/executives should be considered and the ICD should make the decision on the timing of escalation based on the available information and the potential for serious harm. For instance, it would not be a high priority to escalate two cases of C. difficile but two cases of hospital acquired salmonella infection could represent a major risk to other patients and would require an emergency response.

3.41. Many IPC teams have a data analyst as part of the team or access to a data analyst as required. This is invaluable in interrogating the data collected and highlighting themes and trends.

3.42. A subject matter expert DIPC who works as a member of the executive team is likely to be more effective at reporting upwards and escalating appropriately and in a timely manner.

4. Executive Summary

4.1. This report has been prepared with the benefit of Dr Walker, Sid Mookerjee, Andrew Poplett and Allan Bennett's reports in order to come to a consensus view of the answer to Key Question (4).

4.2. Dr Walker concluded that the water system designed and installed for QEUH and RHC was non-compliant from the point of occupation of the hospital.

4.3. The report largely restricts its analysis to infections seen in paediatric haemato-oncology patients. Wards 2A and 2B at RHC were used to house

these patients when the hospital opened and these wards are also known as the Schiehallion Unit. The patients were subsequently moved to wards 4B and 6A in the adult hospital and the report follows them.

4.4. This report does not seek to repeat work already done in other reports such as the Case Note Review[13].

4.5. This report reviews the infection events overall and in following the Schiehallion Unit cohort of patients, uses this group as a proxy for the wider hospital population. This approach removes variation in the patient risk factors due to their underlying illnesses and therefore looks at non-patient variables in seeking to understand the causes of the infections seen.

4.6. The authors do, however, acknowledge that infections caused by environmental organisms were seen in patients across QEUH and RHC.

4.7. The first unusual infection was recorded in February 2016, a case of Cupriavidus pauculus blood stream infection. We have seen no evidence of this very rare infection being investigated until five months later when the water supply to a sink in the aseptic pharmacy was tested and found to grow the same organism. Subsequent typing confirmed the two organisms matched and measures were taken to rectify the pharmacy sink and plumbing.

4.8. From this point the number of unusual environmental gram-negative blood stream infections increased steadily. We have seen no evidence that there was any overarching surveillance of environmental organisms despite the frequency with which they were occurring.

4.9. PAGs and IMTs were held for some but not all of the infections. Clusters of infection were investigated but single cases were less likely to be. In all of the IMTs the working hypothesis was an environmental cause for the infections.

4.10. The water system was usually identified as the main hypothesis but concern was frequently raised about the chilled beams, their cleanliness and condensation or dripping from them.

4.11. Statistical analysis of the infections and comparison to peer paediatric haemato-oncology centres in the UK has shown that the numbers of environmental infections far exceeded that of other units and that the relative risk to patients of acquiring an environmental infection was more than 6 times that in other centres from 2017 onwards.

4.12. By 2018 extensive testing of the water system showed that the water and waste-water system was contaminated throughout from the cold-water

[13] QEUH and RHC Case Note Review Overview Report. March 2021

storage tanks to the outlets at ward level. Drains were also contaminated with wide range of water borne pathogens.

4.13. A Chlorine dioxide dosing system was implemented to manage the contamination levels alongside point of use filters, temperature control and ultrafiltration.

4.14. Following the implementation of Chlorine dioxide dosing, two cases of *Mycobacterium chelonae* infection were identified. *M. chelonae* is recognised as resistant to chlorine dioxide. One of these cases was matched to an isolate from the water supply. This is the second case of infection with a confirmed link to the water system.

4.15. The existence of a link between infections and the water system appeared to have been accepted when the patients from wards 2A and 2B were moved to ward 6A and 4B(BMT) in QEUH so that 2A and 2B could be refurbished. This major refurbishment work was extended to include the ventilation system and patients returned to wards 2A and 2B in March 2022.

4.16. Following the return to the wards, the infection rate with environmental gram-negative organisms has dropped to the level seen in 2015. However, this is still higher than comparator centres.

4.17. In summary, the water and waste-water systems were demonstrated to be contaminated throughout and a wide range of environmental bacteria were isolated from water samples. The ventilation system was not adequate with low numbers of air changes per hour, lack of pressure gradients, lack of HEPA filtration, mixing of extract and intake air via thermal wheels and a chilled beam system which caused condensation, dripping and accumulation of dust. The inadequacies of these two systems presented an avoidable risk of environmental infection.

4.18. Statistical analysis shows that the number of infections seen in the Schiehallion Unit patients were extremely high compared with other comparable centres and the correlation coefficient, a measure of association, was 0.7 indicating a strong correlation between positive water tests and the rate of blood stream infections.

4.19. There were no hypotheses put forward during Incident Management Group meetings to explain the increase in environmental gram-negative blood stream infections other than an environmental cause.

4.20. Since the remedial work carried out on wards 2A and 2B was completed and the ward reoccupied, the number of environmental gram-negative blood

stream infections has reduced to a level similar to that when the hospital was first occupied in 2015.

4.21. The only possible conclusion in light of the evidence presented is that the environmental infections seen in immunosuppressed patients are strongly associated with the built environment and specifically the water and ventilation systems.

5. Methodology

5.1. Key Question (4) asks whether there is a link, and if so in what way and to what extent, between patient infections and the built environment, notably water and ventilation systems.

5.2. In Inquiry Direction 1 of 16 June 2021, Lord Brodie said:
"The Chair is of the opinion that proof on a balance of probabilities is the appropriate standard for him to adopt. That it is more likely that something has occurred than not, is a rational basis for fact-finding. … The Chair recognises that there may be matters in respect of which, having regard to the evidence, he may wish to express a conclusion with a greater or lesser degree of certainty than that indicated by balance of probabilities. Where appropriate, he will do so but in so doing he will make clear that he is departing from what is otherwise the adopted standard."

5.3. In addressing the question of an infection link it is important to consider the difference between causation and association[14]

- *Association* means a specified health outcome more likely in people with a particular exposure i.e. association is a statistical relationship between two variables. The stronger the association then the more likely there is causation.
- *Causation* means that the exposure produces the effect, for instance an adverse exposure to a pathogen can cause infection.

5.4. The Bradford Hill criteria are widely used in epidemiology to assess whether differing levels of association are likely to be causal.[15] These criteria result in some difficulty in establishing a definite relationship, for example in the evidence of time order, as water testing prior to a patient developing an

[14] Association vs Causation. Boston University School of Public Health. Association versus Causation (bu.edu) accessed 19/10/23
[15] The Bradford-Hill criteria (J Roy Soc Med 1965:58:295-300)

infection, as water testing was, at best, reactive throughout most of the time period in question.

5.5. In the infection incidents under discussion, causality has been accepted by NHS GGC in just two instances, that of a 2016 case of *Cupriavidus pauculus* blood stream infection and that of a *Mycobacterium chelonae* infection. In both cases the infecting organism has been linked by typing to an isolate in the water supply.

5.6. Causal pathways are complex, especially where environmental exposures are involved, and need to consider such variables as source, mode of exposure, absorbed dose vs biologically effective dose and host functions.

5.7. The statistical methodology for determining association as the preferred methodology is discussed in more detail in the Quantitative Report written by Sid Mookerjee.[16]

5.8. Although the earlier Case Note Review[17] examined individual cases and assigned likelihood of an environmental source for an infection to each case, the authors have taken a different approach and not examined individual patient records, duplicating previous work, but examined the overall rate of infection and correlation of infection events within the Schiehallion Unit with evidence of contamination of the water and ventilation systems, changes to the built environment, movement of patients and other factors, including how rates of infection compare to peer UK paediatric haemato-oncology/BMT units[18], to build a collective longitudinal picture of events at QEUH/RHC, from which conclusions regarding the strength of association between infections and the environment may be drawn.

5.9. This approach is intended to examine the infection events overall rather than examining each in detail. This gives an overview which is able to identify links between different infections over time and place.

5.10. Restricting this paper to the Schiehallion Unit patients follows the Unit as it moved within the QEUH/RHC complex and allows for analysis of a cohort with constant patient risk factors due to their underlying co-morbidities. By removing variation in the patient risk factors (which would be present in a

[16] Quantitative analysis undertaken to understand the association between the built environment and rates of gram-negative and fungal bloodstream infections at the Schiehallion unit between the years 2015 and 2022. Sid Mookerjee
[17] QEUH and RHC Case Note Review Overview Report. March 2021
[18] Quantitative analysis undertaken to understand the association between the built environment and rates of gram-negative and fungal bloodstream infections at the Schiehallion unit between the years 2015 and 2022. Sid Mookerjee

wider cohort of patients) the variability in the presence or otherwise of infection cannot be argued to be due to patient factors. We do, however, recognise that there were infections seen caused by environmental gram-negative organisms in other areas of QEUH/RHC.

5.11. This leads to an examination of risk factors external to the patient including the environmental risk.

5.12. The Schiehallion Unit is in effect used as a proxy for the hospitals as a whole to identify overall risk.

5.13. To gain this overview, a data extract from the NHSGGC microbiology Laboratory Information Management System (LIMS) for all blood culture requests with a location code related to QEUH and RHC for the period January 2015 to December 2022[19], later extended to August 2023, was acquired. This data was kindly provided by NHSGGC but the authors and Sid Mookerjee have not been able to independently validate the data set.

5.14. This data extract has been examined using the epidemiological and statistical methodology described in Sid Mookerjee's quantitative analysis.[20]

5.15. Additional information has been gathered by and for the authors including:

- Previously published reviews directly related to QEUH and RHC
- Scientific publications from peer review journals
- Published reviews on environmental organisms in healthcare water systems and their implications for hospital associated infections
- Documentation relating to standards of Infection Prevention in healthcare premises.

5.16. A site visit was undertaken by Dr Walker, Dr Mumford and Mrs Dempster in March 2023 to the QEUH and RHC. The authors would like to express thanks to all the staff that we met during our visit and we are grateful for the time, patience and understanding that they demonstrated during our discussions at the on-site visit.

[19] QEUH Campus blood culture samples 1.1.15-31.12.22

[20] Quantitative analysis undertaken to understand the association between the built environment and rates of gram-negative and fungal bloodstream infections at the Schiehallion unit between the years 2015 and 2022. Sid Mookerjee

6. From what body of evidence might the existence of a link be examined

6.1. The **first body of evidence** is that which answers Key Questions (1) and (2).

6.2. Dr Walker's expert report[21] provides extensive evidence on the condition of the water and drainage system at QEUH/RHC from build, through handover and into occupation of the site in 2015 to 2022.

6.3. This paper incorporates Dr Walker's findings in understanding the nature and frequency of the infections seen in the Schiehallion Unit patient cohort.

6.4. Mr Bennett's[22] report on the ventilation system and the review of the system by Andrew Poplett[23] allow an understanding of associated links between the ventilation system and infection.

6.5. Published peer-reviewed papers on the principles of air management in high-risk patient areas are used in the current analysis (Chapter 9) to examine evidence on ward ventilation from other sources.

6.6. The **second body of evidence** to consider in order to determine whether a link exists is the statistical analysis of infection patterns.

6.7. As described at 5.13, blood culture results have been obtained from QEUH for all such cultures with a location code of QEUH and RHC.

6.8. It is apparent from other evidence such as the timeline annex[24] to the final Oversight Board report that other infections with environmental organisms, which have not resulted in blood stream infections, have also occurred.

6.9. Comparator blood culture data from peer UK institutions with paediatric haemato-oncology and bone marrow transplant inpatient facilities, obtained by a Freedom of Information request, has been used in the quantitative analysis to determine the expected rate of infections with environmental organisms for such a facility.

6.10. Statistical analysis of the patterns of infection seen at QEUH/RHC have been used to identify unusual occurrences and correlate them with known incident/outbreak interventions.

[21] Review of the design, build, commissioning and maintenance of the water and drainage systems within the Queen Elizabeth University Hospital and Royal Hospital for Children to determine whether they had an adverse impact on the risk of healthcare associated infection on patients. Dr Jimmy Walker 2024
[22] Allan Bennett - Expert Report for SHI
[23] Independent Expert Report Concerning Critical Healthcare Ventilation Systems at Queen Elizabeth University Hospital, Glasgow and the Royal Hospital for Children. Andrew Poplett.
[24] Timeline of incidents in the Queen Elizabeth University Hospital and Royal Hospital for Children for the period 2015-2019

6.11. In his statistical analysis[25], Sid Mookerjee also correlates the water testing[26] positivity rate with the infection rate in the Schiehallion Unit. This correlation informs the discussion on the existence of a link.

6.12. A further paper looks at the overall bacteraemia rates in the paediatric haemato-oncology cohort of patients[27].

6.13. The **third body of evidence** considered is the prior reporting and analysis of others. Internal QEUH documents from infection incident investigations prepared by clinicians, including the following, provide a contemporaneous review of the clinical team managing the various infection incidents

- Problem Assessment Groups (PAG) records; PAG's are convened to assess incidents, outbreaks or data exceedance in accordance with the NIPCM.
- Incident Management Team (IMT) records; an IMT is a multidisciplinary group with responsibility for investigating and managing an incidents, outbreaks or data exceedance in accordance with the NIPCM.
- Situation, Background, Assessment, Recommendations (SBAR) reports which may be completed following incidents, outbreaks or data exceedances. These have also been written to raise specific issues relating to the hospital environment[28] [29] [30].

6.14. Assessments from expert bodies and professional people who have previously made assessments of the connection between infections and the built environment including:

- Individuals, including those employed by NHS GGC, who have published peer reviewed papers directly related to the infection concern.[31] [32] [33]

[25] Quantitative analysis undertaken to understand the association between the built environment and rates of gram-negative and fungal bloodstream infections at the Schiehallion unit between the years 2015 and 2022. Sid Mookerjee
[26] Water testing summary for the whole Queen Elizabeth University Hospital campus, 2015-2020. Dr D Chaput March 2023
[27] C. Peters and K Harvey-Wood. Bacteraemia rates and resistance patterns in paediatric haematology/oncology patients 2014-2018. Draft report 10/10/2018
[28] SBAR review of 2017 mortalities in which Stenotrophomonas was isolated. Dr A Mathers Nov 2019
[29] SBAR re Infection Control and Patient safety at QUEH, Dr P Redding, Dr C Peters, Dr A Despande. 3/10/2017
[30] SBAR: 2A patient Accommodation and risk of fungal disease, QEUH ICDs 30/10/2017
[31] T.Inkster, C.Peters, T.Wafer,D,Holloway, T.Makin. Investigation and control of an outbreak due to a contaminated hospital water system, identified following a rare case of *Cupriavidus pauculus*. Journal of Hospital Infection 2021;111:53-64.
[32] T.Inkster,C.Peters, A.L.Seager, M.T.G.Holden, I.F.Laurenson. Investgation of two aces of *Mycobacterium chelonae* infection in haemato-oncology patients using whole genome sequencing and a potential link to the hospital water supply. Journal of Hospital Infection 2021;114:111-116.
[33] T.Inkster, C.Peters, H.Soulsby Potential infection control risks associated with chilled beam technology: experience from an UK hospital. Journal of Hospital Infection 2020;106:613-616.

- Other individual clinicians and experts on whom NHS GGC have relied[34] [35] [36] [37] [38] [39]
- The findings of Dr Dominique Chaput in her reviews of the water microbiology at QEUH/RHC[40] [41]
- Health Protection Scotland (HPS) [42] [43] [44]
- Health Facilities Scotland (HFS) [45]

6.15. External reports including:

- The Case Note Review Overview[46]
- Oversight Board Final Report [47]
- Report of Susanne Lee[48]
- QEUH Independent Review June 2020. Fraser and Montgomery[49]

7. What is a relevant infection

7.1. Since infection concerns were first raised they have centred around increased rates of blood stream infections with environmental organisms in

[34] Report of Cryptococcus Incident Management Team expert advisory sub group. NHS GGC 5.4.22
[35] Descriptive analysis of five-year trends in bacteraemia rates for selected gram negative organisms. Iain Kennedy October 2018
[36] Information request for Supporting Evidence for Prof Thomas Evans Reports with annotated responses from Prof Thomas Evans
[37] Application of whole genome sequencing to identify relationships among isolates of *Cupriavidus* spp*, Enterobacter* spp*.,* and *Stenotrophomonas* spp*.* isolated from clinical samples and from water and drainage associated sources within the healthcare environment. Alistair Leanord and Derek Brown 18.1.23
[38] Microbiological testing of water and environmental samples from the Queen Elizabeth University Hospital (Adults) and Royal Hospital for Children, 2015-2020. Chaput D
[39] Report from the Cryptococcus Incident Management Team Expert Advisory Sub-Group. NHS GGC 5/4/2022
[40] Microbiological testing of water and environmental samples from the Queen Elizabeth University Hospital (Adults) and Royal Hospital for Children, 2015-2020. Dominique L. Chaput, March 2023
[41] Water testing summary for the whole Queen Elizabeth University Hospital campus, 2015-2020. Dominique L. Chaput March 2023
[42] Initial Report on the findings of the NHS GGC: QEUH/RHC water contamination incident and recommendations for NHS Scotland
[43] Situational Assessment wards 2A/B RHC HPS NHS GGC, June 2019
[44] Review of NHS GGC paediatric haemato-oncology data. HPS October 2019
[45] 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. Storrar I and Rankin A.
[46] QEUH and RHC Case Note Review Overview Report. March 2021
[47] The Queen Elizabeth University Hospital/NHS Greater Glasgow and Clyde Oversight Board Final Report. March 2021
[48] Susanne Lee Meeting report 25.4.2018
[49] QEUH Independent Review June 2020. Fraser and Montgomery

immunocompromised paediatric patients and a potential link with the built environment with most attention focussing on the water and waste water systems and ventilation.

7.2. From the evidence available in PAG and IMT minutes, the environmental source hypothesis is the only working hypothesis put forward throughout the period of these infection incidents, 2015-2021.

7.3. Environmental pathogens[50] are defined as micro-organisms that normally spend a substantial part of their lifecycle outside human hosts in the environment, but when introduced to humans cause disease with measurable frequency.

7.4. The key difference between environmental pathogens and other pathogens which affect humans, is their ability to survive and thrive outside the host.

7.5. This report looks at blood stream infections caused by environmental gram-negative organisms (as listed at 5.14) in the Schiehallion Unit cohort of patients i.e. Paediatric haemato-oncology patients, since the opening of QEUH and RHC in 2015 to the end of December 2022. The report also gives a brief overview of infection incidents with environmental gram-negative organisms in the whole patient population.

7.6. The Schiehallion Unit describes wards 2A/B of RHC. The patient group were decanted to wards 6A and three beds on ward 4B (bone marrow transplant unit) at QEUH in September 2018 before returning to the reconstructed 2A/B on 6 March 2022. [51]

7.7. These patients had very frequent contact with the unit, including as out patients/ day cases so all cases of blood stream infection can be assumed to be potentially healthcare associated.

7.8. A healthcare associated infection (HAI) 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[52].

7.9. This definition of HAI is similar to many others including that found in the Scottish National Infection Prevention and Control Manual[53]: '*Infections that occur as a result of medical care, or treatment, in any healthcare setting'*

[50] From outside to inside: Environmental Microorganisms as Human Pathogens. American Society for microbiology 2004. From outside to inside: Environmental Microorganisms as Human Pathogens - NCBI Bookshelf (nih.gov) accessed 19/10/23.
[51] For ease of reading, we refer to ward 2A/B, thereafter 6A and 4B, collectively as the Schiehallion patient cohort.
[52] NICE (2011) *Healthcare-associated infections: prevention and control (PH36)*. National Institute for Health and Care Excellence. http://www.nice.org.uk
[53] National Infection Prevention and Control Manual www.nipcm.scot.nhs.uk (accessed 25/02/2024)

7.10. Using the simple definition set out in para 7.8 enables us to consider patients who have not necessarily been inpatients but have attended hospital for treatment and care, often, in the case of the Schiehallion cohort of patients, on a very frequent basis.

7.11. The authors did not have access to the Electronic Communication of Surveillance in Scotland (ECOSS) system or the Central Line Associated Blood Stream Infection (CLABSI) surveillance system used in previous analyses[54], however previous reports[55] have found them to be comparable with the primary source data, i.e. the NHS GGC microbiology laboratory information system (LIMS) which was used for our analysis.

7.12. An extract of all blood cultures taken with location codes for QEUH and RHC for the period June 2015 to December 2022. This was later extended to include the period 1 January 2023 to 31 August 2023.

7.13. All blood stream infections, as identified by growth of bacteria and fungi in blood culture specimens, caused by environmental and enteric group organisms are relevant here.

7.14. Of the environmental organisms, positive blood cultures from the Schiehallion unit patients were found for species of the following genus[56]: Achromobacter; Acinetobacter; Aeromonas; Brevundimonas, Burkholderia; Chyseobacterium; Citrobacter; Cupriavidus; Delftia acidovorans; Elizabethkingia; Enterobacter; Klebsiella; Pantoea; Pseudomonas; Raoultella; Rhizobium; Roseomonas; Serratia; Sphingomonas; Stenotrophomonas and atypical mycobacteria (Mycobacterium chelonae).

7.15. This list is very similar to the list of infectious agents associated with incidents/outbreaks related to healthcare water found in HPS guidance[57]. However, the list above has additional organisms which have been identified in blood cultures taken from Schiehallion Unit patients and are widely accepted as water-borne and/or environmental organisms (Aeromonas, Brevundimonas, Delftia acidovorans, Raoultella, Rhizobium, Roseomonas and Sphingomonas) over and above those in HPS guidance.

7.16. Fungal infections from the following species have also been included in the analysis: Candida, and Rhodotorula.

[54] QEUH and RHC Case Note Review Overview Report. March 2021
[55] Review of NHSGG&C paediatric haemato-oncology data. Health Protection Scotland. October 2019
[56] QEUH campus blood culture samples 1.1.15 – 31.12.22 provided by NHS GGC
[57] Prevention and management of healthcare water-associated infection incidents/outbreaks. HPS 2019 2019-08-water-incidents-info-sheet-v1.pdf (scot.nhs.uk)

7.17. Cryptococcus has not been included in the quantitative report as the paediatric patient was on the intensive therapy unit (ITU[58]) at the time of diagnosis (see methodology section of Dr Mookerjee's report)[59], however the 2018 cluster is included in the discussion at section 9.37.

8. The scope of the report and the body of evidence considered

8.1. The report is intended to consider existing evidence and comment on whether a view can be drawn in order to answer Key question (4).

8.2. A healthcare associated infection (HAI) 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.[60]

8.3. Although many of the patients admitted to the Schiehallion Unit were day case admissions, their unique susceptibility and frequency of attendance means that any infection they acquire has been taken as healthcare associated in this report and their infections and data have been included in the analysis.

8.4. Because of the greater susceptibility of patients in hospital to infections, due to current or pre-existing illness, the presence of invasive devices and interventions causing relative immune-compromise, environmental or waterborne organisms are more likely to cause infection in healthcare institutions than in the healthy population.

8.5. Waterborne organisms are those which are found in the environment and, by their nature, thrive in water and are transmitted as pathogens to humans through contact with water.

8.6. Such contact may be direct, by ingestion or inhalation, indirect by coming into contact with surfaces exposed to contaminated water, including hands of healthcare workers, the contaminated environment, contaminated equipment or water-based equipment, or by aerosolization including splashing.

8.7. Classic examples of water borne infections are diseases such as cholera and typhoid, however other organisms in contaminated water have the potential to cause disease.

8.8. This section considers the three main sources of evidence:

[58] See glossary for the definition of ITU
[59] Quantitative analysis undertaken to understand the association between the built environment and rates of gram-negative and fungal bloodstream infections at the Schiehallion unit between the years 2015 and 2022. Sid Mookerjee
[60] NICE (2011) *Healthcare-associated infections: prevention and control (PH36)*. National Institute for Health and Care Excellence. http://www.nice.org.uk

- Evidence of the water or ventilation systems being in a state that created an opportunity for patients to be exposed to pathogens
- Infection patterns
- The prior reporting and analysis of others on the question of infection link.

Source 1: evidence of the water or ventilation systems being in a state that created an opportunity for patients to be exposed to pathogens

8.9. The key evidence regarding the safety of the water system is contained within Dr Walker's expert report[61] which provides a thorough examination of the design, build, commissioning and maintenance of the water system at QEUH/RHC.

8.10. The report demonstrates the failings of the system, its maintenance and how the entire water supply to the hospital outlets became contaminated.

8.11. In writing his report Dr Walker has reviewed a large body of evidence including inspection reports, risk assessments, plans of the system and others to come to his conclusions. This report does not re-examine that body of evidence.

8.12. In our opinion, Dr Walker's conclusions are reasonable and we are comfortable to rely on them in reaching our own conclusions.

8.13. Using Dr Walker's evidence, we can demonstrate how the exposure risk increased and the mechanisms by which infection could have spread from the water and drainage system to the patients.

8.14. The water testing data provided by Dr D Chaput[62] and her analysis of the data is also examined.

8.15. The expert papers on ventilation from Andrew Poplett and Allan Bennett assist to demonstrate the link between ventilation systems and infection.

8.16. The standards of ventilation which are widely accepted as being essential for high risk patients are discussed with reference to the available literature and guidance.

[61] Review of the design, build, commissioning and maintenance of the water and drainage systems within the Queen Elizabeth University Hospital and Royal Hospital for Children to determine whether they had an adverse impact on the risk of healthcare associated infection on patients. Dr Jimmy Walker 2024

[62] Microbiological testing of water and environmental samples from the Queen Elizabeth University Hospital (Adults) and Royal Hospital for Children, 2015-2020. Chaput D

8.17. The non-compliances with the guidance are identified together with the mechanisms of infection and key areas of risk for immunocompromised patients.

Source 2: Infection patterns

8.18. The patterns of infections and the associated timeline has been laid out in Annex F[63] of the final report of the Oversight Board[64].

8.19. The timeline provides a comprehensive overview of the recognised clusters of infection from 2015 and 2019 and links them to corporate and remedial actions on the Schiehallion Unit.

8.20. The statistical examination of the infections is described in the quantitative report[65], comparing the rate of blood stream infection caused by environmental organisms in Schiehallion Unit patients, against rates of blood stream infection with the same environmental organisms in comparator units in the UK.

8.21. The findings in the report are set out in such a way as to demonstrate a level of association between the environment (water) and the observed infections in the Schiehallion cohort.

Source 3: The prior reporting and analysis of others on the infection link

8.22. The authors have reviewed a wide range of existing documents and records to consider a possible causal link between the hospital environment and the HAI blood stream infections caused by environmental gram-negative organisms and fungi.

8.23. A list of these evidence sources is found at section 6.13.

8.24. Together these documents, with the other sources of evidence, enable a conclusion based on the balance of probabilities as to whether the observed infections in the Schiehallion Unit patients are linked to the environment and

[63] Timeline of incidents in the Queen Elizabeth University Hospital and Royal Hospital for Children for the period 2015-2019
[64] The Queen Elizabeth University Hospital/NHS Greater Glasgow and Clyde Oversight Board. Final Report. March 2021
[65] Quantitative analysis undertaken to understand the association between the built environment and rates of gram-negative and fungal bloodstream infections at the Schiehallion unit between the years 2015 and 2022. Sid Mookerjee

whether the same conclusion can be drawn about infections seen in QEUH/RHC as a whole.

9. Analysis

9.1. This analysis is intended to build a narrative from which conclusions can be drawn as to what extent we believe that the environment is associated with the infections observed at QEUH/RHC, particularly those in the Schiehallion cohort of patients.

Definitions

9.2. There exist well established definitions for outbreaks and incidents of infections in healthcare settings across the United Kingdom. NHS Scotland has protocols for the delivery of actions related to such occurrences. There has been a National Infection Control Manual (NIPCM) in Scotland since 13 January 2013 published by the Chief Nursing Officer with subsequent updates to the manual, most recently 7 July 2023. The Scottish NIPCM is evidenced-based and is intended to be used by those involved in care provision (NIPCM 2023)[66].

9.3. Chapter 3 of the NIPCM[67] defines healthcare infections incidents, outbreaks, and data exceedances. The terms ‘incident’ and ‘Incident Management Team’ (IMT) are used as generic terms in both incidents and outbreaks.

9.4. The NIPCM defines healthcare infection incidents as follows:

- *An exceptional infection episode* - A single case of any serious illness which has major implications for others (patients, staff and/or visitors), the organisation or wider public health.
- *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.

[66] National Infection Prevention and Control Manual: Home (scot.nhs.uk) accessed 24.10.2023
[67] National Infection Prevention and Control Manual: Chapter 3 - Healthcare Infection Incidents, Outbreaks and Data Exceedance (scot.nhs.uk) accessed 28.10.23

- *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 infection data exceedance* - A greater than expected rate of infection compared with the usual background rate for that healthcare location.

9.5. These definitions and processes have been applied by NHS GGC in the management of many incidents associated with patients and BSI examined by the authors. From the evidence available, it appears that, in some instances, not all processes may have been followed through to their conclusion. Records such as documenting typing results within the IMT record and incident/outbreak closure reports are either incomplete or have not been provided for the authors to review[68].

9.6. Following the issues which are the subject of the Scottish Hospitals Inquiry, Health Protection Scotland (HPS) have produced an interim guidance document to support healthcare establishments to prevent and manage water-based infection incidents.[69]

9.7. The CNR report[70] was critical of the recording of environmental data which was found to be inconsistent and lacked organisation.

9.8. In our view this inability to see an overview of infections, typing and environmental data due to poor record keeping would prevent the clarity needed to identify the environmental risks.

9.9. The HPS document referred to at paragraph 9.6 describes three causes of contamination of water and waste water systems:

- Inadequate design and/or management of water systems
- Inadequate cleaning/decontamination protocols or poor compliance with adequate protocols
- Inappropriate practices/behaviours including disposal of drinks or bodily fluids into clinical sinks, storing items on sinks or preparing drugs within the splash zone of outlets

[68] Examples include PAG 03/03/2017, IMT 21/06/2018, PAG 20/05/2019, PAG 20/11/2020
[69] Prevention and management of healthcare water-associated infection incidents/outbreaks. HPS 2019 2019-08-water-incidents-info-sheet-v1.pdf (scot.nhs.uk)
[70] QEUH and RHC Case Note Review Overview Report. March 2021

Patient environment:

9.10. Since the 19th century, when healthcare professionals were taught by Florence Nightingale[71] that the first essential for a patient 'without which all the rest you can do for him is as nothing' is 'to keep the air he breathes as pure as the external air, without chilling him' we have understood that aspects of the physical environment of hospitals may delay or prevent healing or cause new health problems including infections.[72] Florence Nightingale[73] cited a confusion between 'cold and ventilation' in saying the 'to attempt to keep a ward warm at the expense of making the sick repeatedly breathe their own hot, humid, putrescing (sic) atmosphere is a certain way to delay recovery or to destroy life'.

9.11. In his letter[74] of 2008, the Chief Nursing Officer of Scotland confirmed that in all new build hospitals in Scotland there should be a presumption that all patients will be accommodated in single rooms, unless there are clinical reasons for multi-bedded rooms to be available.

9.12. In the appendix[75] to the letter, a single room was defined as 'a room with space for one patient which normally contains, at a minimum, a bed, locker, clinical wash-hand basin and also sanitary facilities comprising a toilet, shower and wash-hand basin'. The steering group did not consider the requirements for specialised isolation rooms.

9.13. Whilst the advantages of single rooms for privacy, dignity and infection prevention are clear (close proximity of wash hand basin and physical separation from other patients), they are not a simple solution for prevention of HAIs.[76]

9.14. In our experience, single rooms are harder and more time consuming to clean, with more surfaces per bed space, additional sanitary ware and increased floor space, although they have the advantage of being able to be decontaminated, after standard cleaning, using the more advanced methods such as Silver Hydrogen Peroxide (HPV) vapour or UV-C light

[71] Notes on Nursing: what it is, and what it is not. Florence Nightingale 1860 Notes on Nursing. (upenn.edu) (accessed 31/3/2024)
[72] Infection Control and the Built Environment: No Easy Answers - Patient Safety & Quality Healthcare (psqh.com) accessed 21/10/23
[73] Notes on Nursing: what it is, and what it is not. Florence Nightingale 1860 Notes on Nursing. (upenn.edu) (accessed 31/3/2024)
[74] Provision of single room accommodation and bed spacing. CEL 48 (2008)
[75] Provision of single room accommodation and bed spacing. Annex A. CEL 48 (2008)
[76] Infection Control and the Built Environment: No Easy Answers - Patient Safety & Quality Healthcare (psqh.com) accessed 21/10/23

decontamination which cannot be used in the presence of patients (such as in four-bedded bays) at the point of patient discharge

- Silver Hydrogen Peroxide[77] vapour (HPV) is used for surface disinfection and effectively decontaminates the environment by an oxidation process which damages microbial DNA, proteins and cell wall. It can kill micro-organisms in hard to reach areas and is known to be highly effective against bacteria, viruses, yeasts, fungi and spores. HPV has been used in UK healthcare facilities for over two decades. HPV decontamination takes 3-4 hours on top of the routine cleaning and requires ventilation to the room to be switched off during the dwell time. Patients and staff cannot be present in the room during the process.
- UV-C decontamination uses light to break down the outer layer of microorganisms and damage DNA. As UV-C uses no chemicals, it produces no disinfection by-products or residue. It is highly effective against bacteria, viruses, yeasts, fungi and spores. UV-C has the advantage of being quicker than HPV, taking up to an hour depending on the size and complexity of the environment. Light sensors are used around the room to ensure completeness of the decontamination process by measuring the dose of UV-C light. UV-C light is potentially harmful to humans so cannot be used in the presence of patients and staff.

9.15. The terminal (discharge) cleaning protocols[78] for the hospitals are comprehensive and clear, using chlorine-based detergent. However, a SBAR dated 03 October2017[79] suggested that a chlorine-based disinfectant (Actichlor) was not in use at that time despite the protocol.

9.16. There is no mention in these protocols of adjunct environmental decontamination using HPV and UV-C light which provide a second line of decontamination (following conventional cleaning). The concern with using a manual process where there is potentially high environmental contamination of surfaces, is that some areas may be missed no matter how careful the cleaner is.

9.17. In our opinion, HPV and UV-C would be useful tools to give assurance that the environment is decontaminated when dealing with infection concerns of the magnitude experienced at QEUH/RHC and should have been deployed.

[77] Hydrogen peroxide alone is unstable and can decompose to form water and oxygen gas. Silver is added to increase the stability and shelf life
[78] Standard Operating Procedure (SOP)Terminal Clean of Isolation Rooms 2016. NHS GGC
[79] SBAR RE Infection Control and Patient Safety at QEUH. 3/10/2017

9.18. A decision was taken in 2019 not to implement routine HPV discharge post-clean decontamination on ward 6A due to a belief that it would be ineffective[80]. The potential of contamination of surfaces within the patient environment playing a part in the acquisition of infection was not documented as having been considered.

9.19. In our experience, the wider view is that the increased number of water outlets per patient, four per single room compared with one wash hand basin per four-bedded bay plus communal WC and shower, results in a challenge to ensure adequate flow through all outlets.

9.20. Failure to maintain flow throughout all outlets may result in stagnation and contamination of the water system, encouraging the development of biofilm[81]. In our experience, many patients are bed-bound and do not use the showers in their en-suite rooms leading to a need for regular, audited, flushing of outlets. Clinical staff are more likely to use antimicrobial gel for hand decontamination except in prescribed circumstances, further decreasing the use of clinical wash hand basins.

Mechanism of Infection:

9.21. The potential mode of infection from the water to the immunocompromised patients requires examination. Micro-organisms can be transmitted from water to patient in diverse ways[82] and requires three components to be present: a susceptible patient, a water system and the water to be contaminated with opportunistic environmental organisms.

9.22. The infectious dose required to cause infection varies greatly from just a few organisms to hundreds or thousands depending upon the organism in question. The infectious dose of unusual environmental organisms is yet to be identified; however, the level of exposure, i.e. the concentration of organisms in the water and waste water system, can be assumed to play a role in the likelihood of patients developing infections caused by environmental organisms in some measure.

[80] IMT 11/11/2019
[81] Review of the NHS Greater Glasgow and Clyde: Queen Elizabeth University Hospital/Royal Hospital for Children water and waste-water system from the point at which patients occupied the site in 2015. Dr JT Walker
[82] Hospital water and opportunities for infection prevention. BK Decker and TN Palmore, *Curr infect Dis Rep*, 2014 October; 16(10):432

9.23. There are three mechanisms of infection involved with water-associated infection:

Direct aerosol transmission

9.24. Direct aerosol transmission, such as when showering, or aspiration while drinking water (typical examples would include Legionnaire's disease or tuberculosis), and exposure of implanted devices to water e.g. bathing with a central venous catheter improperly covered.

9.25. All patients in hospitals are potentially at risk from waterborne HAI with some at very high risk such as those who are immunocompromised or who have an underlying condition, such as cystic fibrosis, which makes them more susceptible to opportunistic pathogens.

9.26. For these patients, exposure to water, for example during teeth cleaning, may present such a high risk that consideration should be given to supplying them with sterile water for this purpose.

Indirect transmission

9.27. Indirect transmission from items that had contact with contaminated water such as bed linens and non-sterile equipment, food prepared in water, rinsing equipment in tap water, and fluids and drugs contaminated by being prepared within the splash zone of a sink.

9.28. Transmission from a contaminated (through aerosol, splash or direct contact with water) surface (hands, environment, equipment etc) transferring micro-organisms to the patient's skin or mucous membranes. Healthcare worker or carer's hand may become contaminated by failing to perform hand hygiene after contact with a contaminated environment or a patient colonized with infectious organisms.

9.29. *Contamination of hands.* Hand washing with contaminated water or within range of splashback from contaminated sink drains may unwittingly result in further contamination of the hands.

- Whilst hand hygiene is generally recognised as the single most important intervention in preventing HAI, hand washing and rinsing with contaminated water leaves contamination on the hands unless a hand

sanitiser is subsequently used[83]. Where an environmental source of infection is considered possible, this change in practice should be promoted amongst staff.

- Persistence of bacteria on the hands after hand washing allows transfer to the patient's environment and directly to the patient themselves. Best practice is that where patients are in single rooms, hand washing is performed before leaving the room, after removing PPE, and an alcohol-based hand sanitiser is used after leaving the room.[84]
- The hands of patients, visitors and staff can also be contaminated by the environment with bacteria acquired from surfaces, particularly within the splash zone of a water outlet.

9.30. *Contamination of the environment.* It is well documented that the environment can become contaminated by water outlets due to splashing.[85] [86]

- Hota et al showed that when hand washing, drain contents splashed at least 1metre from the sink and only a change in design of the sink to prevent splashing halted an outbreak of *Pseudomonas aeruginosa*[87].
- Breatnach et al showed that the risk of contamination of the environment was greater when water from an outlet was directed directly into the plughole allowing splashing from the sink drain trap[88].
- Best et al highlighted the risk of environmental contamination when flushing a toilet without lowering the lid[89]. They showed that bacteria can be recovered from air sampled up to 25cm above the toilet seat following flushing with surface contamination occurring within 90 minutes.
- The use of point of use filters is widely recognised as increasing the risk of splashing as the distance between the outlet and the basin tends to be

[83] Ferroni A, et al. Outbreak of nosocomial urinary tract infections due to Pseudomonas aeruginosa in a paediatric surgical unit associated with tap-water contamination. J Hosp Infect. 1998; 39(4):301–7.
[84] WHO five moments for hand hygiene Infection prevention and control (who.int) accessed 29/10/23
[85] Outbreak of Multidrug-Resistant *Pseudomonas aeruginosa* Colonization and Infection Secondary to Imperfect Intensive Care Unit Room Design. Hota S et al. *Infect Control Hosp Epidemiol* 2009; 30:25-33
[86] Potential for aerosolization of Clostridium difficile after flushing toilets: the role of toilet lids in reducing environmental contamination risk. EL Best et al. Journal of Hospital Infection 80 (2012) 1-5
[87] Outbreak of Multidrug-Resistant *Pseudomonas aeruginosa* Colonization and Infection Secondary to Imperfect Intensive Care Unit Room Design. Hota S et al. *Infect Control Hosp Epidemiol* 2009; 30:25-33
[88] Multidrug-resistant Pseudomonas aeruginosa outbreaks in two hospitals: association with contaminated hospital waste-water systems. Breathnach AS et al. Journal of Hospital Infection 82 (2012) 19-24
[89] Potential for aerosolization of Clostridium difficile after flushing toilets: the role of toilet lids in reducing environmental contamination risk. EL Best et al. Journal of Hospital Infection 80 (2012) 1-5

reduced[90]. This can cause contamination of the filter itself as well as wider environmental contamination

- Splashing may result in both surface contamination and droplet contamination

9.31. ***Airborne*** transmission involves inhaling aerosols or droplets containing micro-organisms for instance whilst showering or aspiration whilst drinking.

- Splashing from outlets may create aerosols and droplets which remain airborne for some time depending on their size and the adequacy of the air circulation in the area.
- Typical examples of infections which may be acquired by the airborne route include Legionnaire's disease, influenza or tuberculosis.

9.32. All modes of transmission could have potentially played a role in the high numbers of infections seen related to the Schiehallion patients. Where the water is contaminated to a high degree and the number of air changes in a room are low (2.5 air changes per hour in RHC rather than the expected[91] 6 ac/h for a standard patient room and 10 ac/h for an isolation room), the opportunity for micro-organisms to contaminate flat surfaces and equipment is greater and aerosols and droplets remain airborne for longer.

Infection incidents associated with the Schiehallion Unit

9.33. **2016**: There were two incidents relating to this patient cohort for which Problem Assessment Groups (PAGs) were held.

- The first was a single case of *Cupriavidus pauculus* blood stream infection which occurred in an oncology patient who was on ward 3B RHC at the time. This was retrospectively identified following routine water testing in the aseptic pharmacy which prepares total parenteral nutrition feeds. Once *Cupriavidus* was identified in the water, the case (5 months earlier) was identified and subsequent typing of the organisms from both sources at the UK Health Security Agency (formerly Public Health England) laboratory at Colindale confirmed that the two strains were identical. We understand that

[90] Summary of Incident and Findings of the NHS Greater Glasgow and Clyde: Queen Elizabeth University Hospital/Royal Hospital for Children water contamination incident and recommendations for NHS Scotland. HPS/NSS December 2018
[91] SHTM 03-01 part A

this instance of infection has been accepted by NHS GGC as acquired from the environment[92].

- The second incident in August 2016 was for two cases of aspergillus, one definite and one probable. According to the annex F timeline for the final report of the Oversight Board[93], this second case was not confirmed, although the IMT record is incomplete in this respect[94]. Significant issues were found with the ventilation system including tears in the ducting. It was noted that the rooms on 2A did not have HEPA filtered air supply. Condensation was noted on the chilled beams. All of the actions and investigations for this incident were associated with environmental factors.
- There were a further nineteen cases with positive blood cultures due to a total of twenty-two environmental gram-negative organisms and/or candida and including one case of *Mycobacterium chelonae* in 2016[95]. None of these were escalated to a PAG.
- Forty-seven water samples were taken from ward 2A/2B during 2016, all were negative. Dr Chaput refers to this period of time in her report[96] and includes a table which shows that a total of 1885 samples were taken from QEUH and RHC during 2016. In our experience, this is below the expected level of sampling and testing of a high-risk area such as the Schiehallion unit and consequently cannot be used to exclude contamination in the water system at this time.

9.34. **2017:** There were six incidents for which PAGs were held. In all of these investigations the only hypothesis put forward related to an environmental source.

- Three cases of *Elizabethkingia miricola* central line infection were noted occurring over a six-month period up to February 2017[97]. An environmental source was suspected but not confirmed. Condensation on wall panels was of concern
- A PAG was held to discuss a perceived increase in blood stream infections in January and February 2017[98]. The PAG record does not list the

[92] Positioning Paper 2 on behalf of NHS Greater Glasgow And Clyde. April 2023
[93] Timeline of incidents in the Queen Elizabeth University Hospital and Royal Hospital for Children for the period 2015-2019
[94] Increase in Aspergillus Infections in Schiehallion Unit RHC (QEUH Campus). IMT 5.8.16
[95] QEUH blood culture samples1.1.15-31.12.22.
[96] Microbiological testing of water and environmental samples from the Queen Elizabeth University Hospital (Adults) and Royal Hospital for Children, 2015-2020. Chaput D
[97] Problem Assessment Group (PAG) 3/3/17 *Elizabethkingia miricola*
[98] Problem Assessment Group (PAG) 3/3/17 Increase in bacteraemia

organisms concerned however, on triangulating with the blood culture records[99], it is clear that there were five patients with positive blood cultures from central lines containing a total of seven environmental organisms during this period out of a total of 24 positive blood cultures. The PAG was not escalated to an IMT.

- A PAG were held for a perceived increase in candida infections and for three cases of aspergillus, with concerns raised around cleaning standards and mouldy ceiling tiles. This incident was escalated to an IMT for the three cases of aspergillus identified since July 2016 although the first of these patients was the probable case reviewed in the IMT in August 2016. The ventilation and lack of HEPA filtration was identified as an issue. It was also noted that there was a lot of construction work going on around the QEUH campus with demolition work and advice was to be given to patients to wear facemasks outside the building near the demolition works. In addition, a leak in the ceiling void was identified causing mouldy ceiling tiles.
- In May 2017, two years of retrospective data were analysed, showing an increase in line infections from 3.25 per 1000 line days to 6.33 per 1000 line days. This resulted in the establishment of a Quality Improvement central line associated blood stream infection (CLABSI) working group.
- In July 2017, two cases of *Stenotrophomonas maltophilia* line infections occurred within 8 days. Water sampling was completed over a month after the infections occurred and was negative for *Stenotrophomonas.* Drain sampling was not done.
- A further single case of *C. pauculus* was identified in September 2017. A second hand-hygiene sink in the aseptic pharmacy was found to be positive but following assessment was unable to be removed. Successful silver hydrogen peroxide treatment was undertaken
- In October 2017 a further patient with Aspergillus was identified. This was not escalated to an IMT. However, an ongoing risk of airborne infection to neutropenic patients was recognised[100] due to the lack of functioning protective isolation, low number of air changes per hour and dust collecting on chilled beam units with poor air quality on 2A. At this time there were demolition projects ongoing on the QEUH site, increasing the risk of

[99] QEUH Campus blood culture samples 1.1.15-31.12.22
[100] SBAR re Infection control and patient Safety at QEUH October 2017

invasive fungal disease and as a result all neutropenic patients in the Schiehallion unit were given anti-fungal prophylaxis[101] of either Ambisone[102] or posaconazole[103].

- In November 2017 the Acute Infection Control Committee was informed that ward 2A was seeing a high number of outbreaks with central line associated blood stream infection (CLABSI)[104]. There were a further 24 cases of CLABSI with 27 environmental organisms from March to December 2017 including a case of *Cupriavidus pauculus* in September[105].

9.35. **2018:** Multiple IMTs were held for a water contamination incident on ward 2A.

- The first case in January 2018 was a *Cupriavidus* blood stream infection. The patient had received IV chemotherapy prepared in the aseptic pharmacy and in light of the 2016 incident, the focus of attention was water testing in the aseptic unit. The September 2017 case had previously not been thought to have had contact with the aseptic pharmacy but they had subsequently been shown to have received IV chemotherapy prepared in the unit.
- Water testing in the pharmacy was negative and attention turned to ward 2A. Water testing subsequently identified outlets on 2A which were positive for *Cupriavidus*. The working hypothesis of the IMT was that the water outlets were the source of *Cupriavidus.*
- Due to the level of contamination of the water and the multiple outlets affected, silver hydrogen peroxide dosing was carried out as a decontamination treatment of the water system on ward 2A.
- Over the subsequent months, further cases of environmental blood stream infections were seen; in total nine cases of *Stenotrophomonas maltophilia*, 3 *Pseudomonas aeruginosa*, 1 *Pantoea*, 1 *Cupriavidus pauculus*, 6 *Enterobacter cloacae*, 1 *Chryseomonas* and 1 *Acinetobacter* prior to the decant of the ward to 6A and 4B, QEUH
- Concern in the IMTs continued to focus on the link between the water contamination and infections in patients, with the organisms isolated from

[101] SBAR: 2A Patient Accommodation and Risk of Invasive Fungal Disease 30/10/2017
[102] Liposomal Amphotericin B (Ambisone) is an antifungal drug which is given intravenously. Common side effects include anaemia, diarrhoea, liver dysfunction, renal impairment, nausea and vomiting
[103] Posoconazole is an antifungal drug given by mouth or intravenously. Common side effects include nausea, vomiting, diarrhoea, electrolyte imbalance, hypertension, altered taste and skin reactions.
[104] Timeline of incidents in the Queen Elizabeth University Hospital and Royal Hospital for Children for the period 2015-2019
[105] QEUH Campus blood culture samples 1.1.15-31.12.22

the water (*Cupriavidus* and *Sphingomonas*) added to the alert list for infection control across the campus.

- Dr Inkster was concerned that the taps were the reservoir of infection[106] due to their complexity and the presence of flow straighteners which is a known risk for development of biofilm and risk of infection[107].
- In response to the environmental risk to patients all showers were taken out of use for patients, sterile water was provided for drinking, and bottled water and wipes for washing. Staff were advised to use alcohol-based hand gel after hand washing.
- Further positive water results were seen on PICU and ward 3C. Point of use filters were fitted to outlets on 2A, 2B, PICU and 3C
- The IMT recognised that *Cupriavidus* infection is very rare and to have three cases over three years is highly unusual. There was further agreement that there was a strong epidemiological link between the infections and the positive results from water testing.
- A further cluster of blood stream infections caused by Enterobacter cloacae was seen in May 2018. The working hypothesis was that the drains may be colonised and it was noted that black grime was seen in the wash hand basin drains[108]
- In June an IMT was held to discuss the contamination of the drains[109]. Results of sampling the drains on 2A had shown various gram-negative environmental organisms including *Enterobacter cloacae, Pseudomonas aeruginosa, Sphingomonas, Cupriavidus pauculus, Acinetobacter ursingii and Klebsiella oxytoca.* All of these organisms were seen in blood stream infections in Schiehallion unit patients in 2018 (except Sphingomonas seen in 2017).
- It was Dr Inkster's view that the cases of Enterobacter cloacae blood stream infection were associated with the drains[110]. Cleaning of the drains and HPV environmental decontamination was carried out but did not have a lasting effect on drain contamination. Control measures for the outbreak continued to concentrate on environmental risk into September when there

[106] IMT 9/3/2018
[107] Investigation of healthcare-acquired infections associated with Pseudomonas aeruginosa biofilms in taps in neonatal units in Northern Ireland. Walker J et al. J Hosp Inf 86 (2014) 16-23
[108] IMT 29/5/2018
[109] IMT 4/6/2018
[110] IMT 04/06/2018

was a further cluster of seven patients with environmental gram-negative blood stream infections.

- Concern was raised about dust levels and it was hypothesised that the build-up was due to the low number of air changes (2.5 ac/h compared with the recommended 6 ac/h or 10ac/h in high risk isolation rooms).
- A full review of the water systems at QEUH and RHC was proposed[111] in July 2018.
- In July 2018 a PAG was held for a case of aspergillus. The patient was spending time outside their room for [redacted]. No mobile HEPA filters were situated in the corridor. There was ongoing concern about air quality in the ward.
- On 18 September 2018 the decision was made by the Technical Water Group[112] to decant the Schiehallion Unit to 6A QEUH and 4B QEUH for the BMT patients. The move was completed on 26 September 2018[113].
- The hypothesis continued to be that the infections were related to the environment and that completing work (Chlorine dioxide dosing, changing taps, wash hand basins and elements of plumbing) on the water system would resolve the issues.
- A review of the ventilation on 2A/2B in November 2018[114] stated that 'General ward single room ventilation design was derogated from national guidance requirements 6 ACH to 2.5 ACH, in order to adopt chilled beam technology to meet BREAM energy performance targets, on the basis that the fresh air provision of "40 litres per second per single room (8 litres per person per second) for one patient and four others" with the 'proviso' "Negative pressure to be created in the design solution."
- In practice this resulted in the rooms being at slight negative pressure to the corridor enabling air from the corridor to enter the room when the door was opened.
- At this time a briefing paper from the IPCT[115] identified that 23 cases of environmental blood stream infections were linked to the contaminated water system

[111] SBAR Proposed approach to the review of water systems at QEUH and RHC. 05/07/2018
[112] Water Review Meeting – Draft meeting Note.Tuesday 18 September 2018
[113] IMT 28/09/2018
[114] SBAR Ward 2A/2B ventilation Review. 12/11/2018
[115] SBAR QEUH and RHC – bacteria in water system 13/11/2018

9.36. **November/December 2018 - Cryptococcus:** In December 2018 two cases of *Cryptococcus neoformans* blood stream infection were identified in haematology patients (one adult, one paediatric).[116] The adult was on ward 4C and the child on 2A initially, then moved at the time of the decant to 6A (QEUH) and later to PICU. Both infections were HAI and related in time (17 days apart) and place (both inpatients in QEUH). Both cases were unable to take anti-cryptococcal prophylaxis due to [redacted].

- The initial hypothesis of how these infections occurred was that they could be related to a pigeon infestation in a plant room and that aerosols from pigeon guano could enter the ventilation system during routine maintenance. The two cases were extensively investigated; other species of Cryptococcus were found by air testing and culturing pigeon guano including air testing on wards 6A and 4C, no *Cryptococcus neoformans* was isolated[117]. In addition, very high particle counts[118] were found on 6A.
- Concern was high that an airborne source was involved and mobile HEPA filtration units were deployed in wards caring for particularly vulnerable patients including 6A.
- Such was the concern about the air quality, that patients on 6A (and 4C) were given antifungal prophylaxis.
- A second hypothesis related to the external contamination by bird guano on boxes being delivered to wards. This was investigated and rectified.
- Further discussion of Cryptococcus is at section 10.

9.37. **2019:** Due to extended work to the ventilation system in Ward 2A/2B, the Schiehallion cohort remained on ward 6A (with BMT patients on 4B).

- In May 2019 two cases of *Stenotrophomonas maltophilia* blood stream infection were seen on 6A[119]. In the PAG minutes it is stated that one case had not had any hospital contact for 44 days prior to admission. Blood cultures were positive on admission. It was known at the PAG that a basement water tank had grown *Stenotrophomonas maltophilia*, water samples were obtained from ward 6A and the results of testing were awaited. We have not seen any documentation of the results; however, this

[116] IMT 20/12/2018
[117] Cryptococcus Incident Management Meeting 17/01/2019
[118] A particle counter will detect particles in the air of 0.5 microns and larger. These particles include pollen, mould spores, bacteria and dust.
[119] PAG 27/05/2019

was not escalated to an IMT and no further investigation is documented. This incident had the potential to have prevented the subsequent cases starting in June, if the water samples were positive, and illustrates the importance of complete documentation and closure of incidents.

- From June to September, twelve cases of environmental gram-negative blood stream infection were seen (three *Stenotrophomonas maltophilia*, one *Pantoea septica*, three *Enterobacter cloacae,* one *Chryseomonas,* one *Elizabethkingia,* one *Serratia marcescens* and two cases of *Pseudomonas putida*). At IMT a case of *Mycobacterium chelonae* was identified and a previous case a year earlier noted.
- Water sampling from ward 6A had low levels of gram-negative organisms but *M chelonae* had been isolated from a number of outlets. The samples were taken with point of use filters removed. It was hypothesised that as point of use filters were in place on the ward, the *M. chelonae* patient had been exposed to unfiltered water elsewhere on site.
- The hypotheses for the gram-negative infections were initially related to splashing disturbing the drain biofilm and contaminating hands of staff or patients or creating an aerosolization which could contaminate the patient's skin and/or line, however in later IMTs this changed to chilled beams dripping or leaking condensation or access to unfiltered water outside the ward[120].
- The risk to patients was thought to be high enough to send patients to Edinburgh rather than admit to 6A.
- Air samples taken on 15 July 2019 found counts of aspergillus in the patient's en-suite bathrooms. There was also a patient on the ward being investigated for possible fungal infection.
- Concerns were raised[121] that the prolonged decant put patients at risk as ward 6A had 'unacceptable levels of infection risk for immune-compromised patients due to the built environment'
- In September the narrative of the IMT changed from a high rate of gram-negative infections to a low rate of CLABSI despite the gram negatives and that the ward was microbiologically safe[122].

[120] IMT 23/8/2019
[121] SBAR Ward 2A – gram negative bacteria 25/08/2019
[122] IMT 18/9/2019

- Three further cases of environmental gram-negative blood stream infection were identified in the next 18 days. The chilled beam hypothesis was discounted. However, no other hypothesis was put forward and the source of the infections was not confirmed.
- In October, Dr Inkster and Dr Peters produced an SBAR[123] looking at the 6A incident, data and epidemiology. This document argued that the proportion of environmental gram-negative organisms in blood cultures had increased since April 2016 and this was particularly noticeable from July to September 2019. It also confirms that Ciprofloxacin[124] prophylaxis had been implemented in August 2019 for the Schiehallion unit patients. Of note is a graph showing a sustained increase in Enterobacter blood stream infections.
- In November 2019 a SBAR[125] was written to support the reopening of ward 6A to new referrals which states 'currently there remains no direct working hypothesis linking the series of infections which prompted the Incident to Ward 6a environment' and seeks to suggest that there is no connection to previous incidents involving environmental organisms.

9.38. It should be noted that in all the PAG and IMT minutes that we have seen, the hypotheses for the source of the environmental gram-negative infections have always included environmental sources. No other possible sources have been identified or hypothesised.

9.39. Full closure reports for a series of IMTs were not available to the authors. We understand that these were not written due to the direct reporting to the GGC Board or the Scottish Government. Closure reports are useful for sharing learning across organisations and for organisational memory, providing a reference point for any future incidents and, in our opinion, their value should not be underestimated.

9.40. The background of the incidents listed is important to understand in order to place the body of evidence in context.

9.41. With the onset of the COVID pandemic in early 2020, the numbers of patients in the Schiehallion Unit cohort who were admitted to hospital decreased in line

[123] SBAR 6A incident, data and epidemiology, 07/10/19
[124] Ciprofloxacin is an antibiotic which can be given orally or intravenously. It is particularly good at treating (or prophylaxing) gram negative infections. Common side effects include nausea, vomiting, diarrhoea, fever, fungal infection, headache, taste and vision disorders.
[125] SBAR on Paediatric Haematology Oncology Service 14/11/2019

with attempts to treat only those who needed to be in hospital during the pandemic.

Evidence source 1: evidence of the water or ventilation systems being in a state that created an opportunity for patients to be exposed to pathogens

Water System

9.42. In his expert report, Dr Walker[126] describes the design and build of the water system in the new hospital buildings. He identifies issues with the water system which would cause the system to become microbiologically unsafe, both in terms of the system not functioning to prevent microbial proliferation, but also in terms of exacerbating microbial growth and spread within the system, and demonstrates how the QEUH/RHC water system has been non-compliant and unsafe since the opening of the hospitals, creating a risk for patients, particularly the most vulnerable.

9.43. In his report[127] Dr Walker describes an inadequate design of the water system that allowed bypassing of filters (allowing water containing micro-organisms and debris to contaminate the entire hot and cold system), water stagnation (allowing microbial proliferation) and the build-up of sludge, sediment and organic matter, all of which favour microbial growth, and the formation of biofilm. This is identified as the **first cause of contamination** in HPS guidance.[128]

9.44. In addition, failings in the management system were identified in risk assessments in 2015[129] and 2017[130] including no formal management structure, no written scheme for legionella, lack of training and competency records, gaps in the risk reduction systems and processes which were described as haphazard, no Authorised Person for water at QEUH and out of date schematics. This demonstrates further the **first cause of contamination**

[126] Review of the design, build, commissioning and maintenance of the water and drainage systems within the Queen Elizabeth University Hospital and Royal Hospital for Children to determine whether they had an adverse impact on the risk of healthcare associated infection on patients. Dr Jimmy Walker 2024
[127] Review of the design, build, commissioning and maintenance of the water and drainage systems within the Queen Elizabeth University Hospital and Royal Hospital for Children to determine whether they had an adverse impact on the risk of healthcare associated infection on patients. Dr Jimmy Walker 2024
[128] Prevention and management of healthcare water-associated infection incidents/outbreaks. HPS 2019 2019-08-water-incidents-info-sheet-v1.pdf (scot.nhs.uk)
[129] L8 Risk Assessment. DMA Canyon 2015
[130] L8 Risk Assessment. DMA Canyon 2017

in the HPS guidance which relates to inadequate design and/or management of water systems.

9.45. The cold-water distribution system was recorded as having temperatures up to 30°C and the hot water return temperatures were lower than the recommended 55°C at 40-45°C during the 2015 DMA Canyon risk assessment. These water temperatures enable bacterial proliferation in water systems.

9.46. Contamination, with out-of-specification legionella and total viable counts, and risks associated with the water system were identified by external risk assessments by DMA Canyon in 2015[131] and 2017[132], which both contained similar findings suggesting that there were inadequate cleaning/decontamination protocols, or poor compliance where adequate protocols existed, for the water system. This is identified as **the second cause of contamination** in the HPS guidance[133]

9.47. The **third cause of contamination** is recognised in the HPS guidance as inappropriate practices/behaviours of healthcare staff, patients and visitors. Examples would include disposal of food/drinks or body fluids, cleaning of patient equipment in clinical wash hand basins and preparing intravenous drugs within the splash zone of water outlets.

9.48. In 2018, the HPS HFS report on the water contamination incident noted the finding of a yellow film found in hand wash basin drains, from wards 2A/B, which was suggestive of urine being disposed to the drain. The biofilm in these drains had a mustard yellow colour and an odour of ammonia was present.[134]

9.49. In our opinion, education of staff in water hygiene and safety is important to alert them to the risks of contamination by water during everyday activities such as preparing drugs, filling water jugs and hand washing. The authors have not seen any evidence of this type of training for clinical staff at QEUH/RHC.

[131] L8 Risk Assessment. DMA Canyon 2015
[132] L8 Risk Assessment. DMA Canyon 2017
[133] Prevention and management of healthcare water-associated infection incidents/outbreaks. HPS 2019 2019-08-water-incidents-info-sheet-v1.pdf (scot.nhs.uk)
[134] Summary of Incident and findings of the NHS GGC: QEUH/RHC water contamination incident and recommendations for NHS Scotland. HPS 2018

9.50. Water testing results, as analysed in reports by NHSGGC[135] and HPS/HFS[136], demonstrate that the water system was significantly contaminated with multiple organisms throughout the site over a number of years.

9.51. In August 2015 the presence of *L. pneumophila* serogroup 1 in samples taken from outlets exceeding >1000 cfu/l[137] indicated that control parameters, such as temperature, within the water system were not being achieved. This level of contamination would have presented an additional risk of avoidable infection to patients. The treatment of the local area and outlet would only have controlled the microbial risk at that particular outlet. Legionella is known to colonise the deep infrastructure of a water system as well as the distal outlets[138]. The hot water return temperatures recorded at the calorifiers were consistently below 55°C[139], insufficient to control Legionella, which would therefore continue to spread from the central parts of the system towards the outlets.

9.52. In this context, Legionella can be used as a proxy marker of widespread microbial contamination, by which we mean to say that if legionella is found surviving in the water system, then one can assume the environment to be conducive to the growth of other environmental bacteria and fungi.

9.53. In his paper Dr Walker[140] has laid out the high level of persistent contamination of the water system at QEUH/RHC since the hospitals were occupied in 2015 and that this resulted in an unacceptably high risk of infection in patients including:

[135] Microbiological testing of water and environmental samples from the Queen Elizabeth University Hospital (Adults) and Royal Hospital for Children, 2015-2020. Chaput D.
[136] 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. Storrar I and Rankin A.
[137] 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. Storrar I and Rankin A.
[138] Hospital water and opportunities for infection prevention. Decker B and Palmore T. Curr Infect Dis Rep.2014 October; 16(10): 432
[139] Review of the design, build, commissioning and maintenance of the water and drainage systems within the Queen Elizabeth University Hospital and Royal Hospital for Children to determine whether they had an adverse impact on the risk of healthcare associated infection on patients. Dr Jimmy Walker 2024
[140] Review of the design, build, commissioning and maintenance of the water and drainage systems within the Queen Elizabeth University Hospital and Royal Hospital for Children to determine whether they had an adverse impact on the risk of healthcare associated infection on patients. Dr Jimmy Walker 2024

- Between April 2015-August 2015 more than 85% of samples exceeded limits for *L. pneumophila* sg1[141].
- Multiple environmental organisms were found in the cold-water storage tanks including *Cupriavidus pauculus, Aspergillus, Pseudomonas sp, Delftia acidovorans, Stenotrophomonas paucimobilis* etc.
- In 2018, water sampling showed that 20-60% of outlets were positive for Cupriavidus including the treatment room and prep room for ward 2A
- In 2018, examination of shower heads and hoses from ward 2A/B isolated a wide range of gram-negative environmental pathogens and formation of biofilm
- In 2018, published data showed that 76.5%of the outlets in the Schiehallion Unit were positive for *C. pauculus* and 30% of outlets tested were positive across both hospitals[142]
- Widespread contamination of the whole water system across QEUH and RHC evidenced in 2018
- Work undertaken by Intertek[143] showed rapid re-formation of biofilm and recolonisation with micro-organisms in flow straighteners on wards 2A/2B
- High numbers (c 45%) of post flush samples remained positive suggesting widespread contamination of the water system
- Dishwashers which presented a microbial risk to patients as a result of poor maintenance and build-up of residue leading to contamination with fungi also seen causing infection in cystic fibrosis patients[144]
- Increased splashing due to point of use filters resulting in increased contamination of filters and the environment with organisms from the drains, including *Enterobacter sp.*

9.54. In summary, Dr Walker, in his report, describes a water and drainage system which was of inadequate design and contaminated from the outset. The lack of management and awareness of the water system led to the contamination being uncontrolled and consequently presenting a very high risk to patients.

[141] *L. pneumophila* serogroup 1 accounts for over 93% of clinical cases in Europe and the death rate is 40-80% in untreated immune-supressed patients in hospitals
[142] Investigation and Control of an Outbreak Due to a Contaminated Hospital Water System, Identified Following a Rare Case of *Cupriavidus Pauculus* Bacteraemia. Inkster et al. J Hosp Infect 2021 May;111:53-64
[143] Intertek, 'Intertek Report Number ITSS-0718-0001W. Mains Water Inlet Valve with Water Meter.' (n 53).
[144] QEUH. IMT minutes 22/9/2017

Ventilation system

9.55. The ventilation system at QEUH/RHC has come under scrutiny as another possible source of infection. Allan Bennett[145] and Andrew Poplett[146] have written reviews of the ventilation system at QEUH/RHC.

9.56. Both have identified significant failures in the design and implementation of the ventilation system in QEUH and RHC.

9.57. The requirement for good ventilation in healthcare facilities fulfils several purposes including provision of fresh air, maintenance of a comfortable temperature, and dilution and control of airborne pathogenic material.

9.58. The guidance for ventilation is contained within Health Technical Memorandum (HTM) 03-01[147] (England) and SHTM 03-01[148] (Scotland).

9.59. The view of the lead author of the 2021 update to HTM 03-01 is that 'where we have problems, it has generally been clear that the guidance wasn't followed'[149]

9.60. The gold standard of air changes per hour has been long established with the minimum standards unchanged since HTM 2025, published in 1994[150]

9.61. Since the original research into the link between ventilation and infection completed by Lidwell in 1972 it has been accepted that good ventilation reduces infections both in operating theatres and in hospitals in general.

9.62. There is little current research in this area as in general, airborne infection rates in healthcare settings are low.

9.63. Health Protection Scotland advise that ventilation systems must be designed for use within the healthcare setting and appropriate to the susceptibility of patient groups to protect patients from preventable infection as laid out in SHTM 03-01. Ventilation systems should be installed following strict adherence to manufacturer's instructions and national guidance SHTM 03-01.

9.64. SHTM 03-01 is guidance, however, it is clear that it applies to all new builds and major refurbishments and in our opinion, should be considered as the standard to be achieved. This is confirmed in interim SHTM 03-01 2022 which, for the first time, included a process to be followed when derogating

[145] Allan Bennett - Expert Report for SHI
[146] Independent Expert Report Concerning Critical Healthcare Ventilation Systems at Queen Elizabeth University Hospital, Glasgow and the Royal Hospital for Children. Andrew Poplett.
[147] HTM 03-01 2007
[148] SHTM 03-01 2014
[149] Presentation to IHEEM Healthcare Estates conference 2021, Malcolm Thomas, published in Health Estate Journal, January 2022
[150] HTM 2025 Ventilation in Healthcare premises: Design considerations, NHS Estates 1994

from the guidance. Now, the designers must supply a body of evidence to support the proposal and the Ventilation Safety Group must approve any derogation in writing. This new process places a governance process around derogations which ensures that the Authorised Engineer and IPC will be involved in decision-making.

9.65. Concerns were raised about the ventilation and air quality in the bone marrow transplant unit on ward 4B QEUH in 2015[151]. This led to clear advice being given by HPS on the standards required in a protective isolation room[152] and work was carried out to improve the ventilation in the isolation rooms on 4B, over a period of time from 2015-2018, during which the patients were returned to the Beatson centre. The outcome of the work did not match the specification of the Beatson facility; there was no airlock or active monitoring of air pressure, the ward corridor was not ventilated and the minimum air changes per hour of 10 was not achieved.

9.66. The Independent Review[153], Bennett and Poplett all found that the project team regarded the recommendations in SHTM 03-01 as non-mandatory and, in an effort to achieve 'BREEAM Excellent'[154] status, the air changes per hour were reduced, with derogation agreed by NHS GGC Board, from the recommended 6 (or 10 for neutropenic isolation rooms) to 2.5 on the basis that the chilled beams were controlling the ambient temperature and the high energy consumption was saved.

9.67. This failed to consider the other reasons for the higher number of air changes, including dilution and control of airborne pathogens and preventing HAI.

9.68. The ward 2A/2B ventilation review SBAR[155] went further in describing the derogation:

General ward single room ventilation design was derogated from national guidance requirements 6ACH to 2.5 ACH, in order to adopt chilled beam technology to meet BREEAM energy performance targets, on the basis that the fresh air provision of "40 litres per second per single room (8 litres per person per second) for one patient and four others" with the 'proviso' "Negative pressure to be created in the design solution."

[151] SBAR 06/07/2015 Clinical haematology and allogenic transplant service – environmental risks
[152] SBAR Dec 2015 Queen Elizabeth University Hospital (NHSGGC) Bone Marrow Transplant Unit
[153] Queen Elizabeth University Hospital Independent Review 2020 A. Fraser and B Montgomery
[154] Building Research Establishment Environmental Assessment Method
[155] SBAR Ward 2A/2B ventilation review 12/11/2018

9.69. This resulted in single room ventilation rates of 2.5-3 ACH with neutral to slightly negative pressure relative to the corridor, allowing air from the corridor to enter the room when the door was opened.

9.70. The same SBAR noted that:
'the derogation seems to have been applied universally across all single room accommodation regardless of the patient risk group with no allowance for neutropenic patient groups.'

9.71. In addition, the ventilation system was fitted with thermal wheel heat recovery units which were sited in the supply and extract air handling units. Consequently, the supply air handling unit is connected to the toilet extract system via the thermal wheel with the potential for toilet extract air to bypass and enter the supply airstream resulting in a cross-contamination risk.

9.72. Remedial actions recommended[156] included new supply and extract plant with HEPA filtration to provide 10Pa positive pressure and 10 air changes per hour with removal of chilled beam units.

9.73. In our opinion, there is a widespread assumption that single rooms reduce infection risk but this is not the case where other standards of practice are not maintained, including the recommended 6 air changes per hour (ac/h) and the design of air handling systems to ensure separation of supply and extract air.

9.74. The mechanisms of transmission of infection have been discussed at 9.21, including droplet transmission and contamination of the environment. Both of these are reduced where compliant, effective ventilation is in place with the inverse also true; the risks related to transmission of infection by droplet transmission and contamination of the environment are increased when ineffective ventilation is present.

9.75. Derogation from the standards, reducing the recommended air changes per hour, reduces the ability of the ventilation system to mitigate other environmental infection risks.

9.76. In reducing the ac/h from 6 to 2.5, any aerosols generated within the room will take 2.4 times longer[157] to be removed extending the risk to the patient from contaminated water.

9.77. In our experience, the widely accepted view is that in the presence of a risk related to the water and drainage systems, inadequate ventilation increases

[156] SBAR Ward 2A/2B ventilation review 12/11/2018
[157] Allan Bennett - Expert Report for SHI

the risk to patients of transmission of infection by reducing the clearance of contaminants from the environment.

9.78. The use of chilled beam units is cautioned by SHTM 03-01 in specialist ventilation areas and should only be considered with the written approval of the Ventilation Safety Group[158]. The complex maintenance of the chilled beam units makes them impractical for patient rooms.

9.79. Disadvantages of chilled beam units include the production of condensation and difficulty in cleaning[159], including lint from bed linen becoming trapped within the beams. To date there is no published data to quantify the infection control risk associated with chilled beam technology.

9.80. Air is recycled unfiltered through the chilled beam unit, potentially allowing airborne pathogens to also be recirculated and particulate matter to stick to the metal surface.[160]

9.81. In QEUH /RHC the chilled beams are situated above patient's beds resulting in the risk of condensation dripping onto the patient and the potential of contaminated recirculated air immediately above the patient. Condensation encourages mould and bacterial growth potentially creating a reservoir of opportunistic pathogens within patient rooms, directly above a patient's bed[161].

9.82. As chilled beams have hot and cold water running through them, their connections are also prone to leakage (of potentially contaminated water) and have required replacement[162]. This occurred in June 2019 where a child developed a cold foot due to a dripping CBU[163].

9.83. Neutropenic isolation rooms are not compatible with chilled beams as these types of isolation require a clear air flow from clean to dirty with no recycling of unfiltered air.

[158] 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. NSS 2022
[159] Potential infection control risks associated with chilled beam technology: experience from a UK hospital T. Inkster, C. Peters, H. Soulsby Journal of Hospital Infection 106 (2020) 613e616
[160] Potential infection control risks associated with chilled beam technology: experience from a UK hospital T. Inkster, C. Peters, H. Soulsby Journal of Hospital Infection 106 (2020) 613e616
[161] Allan Bennett - Expert Report for SHI
[162] SBAR dated 25 August 2019 - Ward 2A - Gram Negative Bacteria
[163] Email SBAR dated 1 June 2019 - ward 6A - leakage from chilled beams

9.84. In his report, Andrew Poplett[164] notes that the use of chilled beams influenced the sub-optimal airflow performances and added an avoidable risk to a number of highly vulnerable patient areas.

9.85. Various environmental organisms have been isolated from dust on the chilled beams including *Aspergillus sp., Panteoa agglomerans, Stenotromphomona sp, Acintetobacter Sp* and *Klebsiella pneumoniae* which have been identified as the infectious pathogen in infections in Schiehallion Unit patients[165]

9.86. It was also noted in IMTs on 5 August 2016, 5 September 2018 and 10 September 2018 that there was a rapid build-up of dust in patient's rooms and this was thought to be related to the low number of air changes per hour.

Evidence source 2: patterns of infection

9.87. In their draft paper, Peters and Harvey-Wood[166] show that following the move from Yorkhill to RHC there was a steady increase from 10 to16% in the rate of positivity in blood cultures taken from Schiehallion unit patients. There was an associated rise in the number of patients with positive blood cultures from just over 30% when in Yorkhill to greater than 40% by the year June 2017 to18.

9.88. In addition, there was a four-fold increase in polymicrobial cultures with an increase in environmental organisms noticeable from the quarter April to June 2016.

9.89. In quarters April to June 2017 and April to June 2018, environmental organisms form the largest proportion of gram-negative blood culture isolates. It is noted that over time the number of different species isolated increases including rare environmental organisms. The conclusion of the report is that the data supports the hypothesis that environmental factors have been driving the rate of bacteraemia in this cohort of patients.

9.90. The quantitative analysis of the infections associated with the Schiehallion unit is laid out in Sid Mookerjee's paper[167].

[164] Independent Expert Report Concerning Critical Healthcare Ventilation Systems at Queen Elizabeth University Hospital, Glasgow and the Royal Hospital for Children. Andrew Poplett.
[165] Potential infection control risks associated with chilled beam technology: experience from a UK hospital T. Inkster, C. Peters, H. Soulsby Journal of Hospital Infection 106 (2020) 613e616
[166] C. Peters and K Harvey-Wood. Bacteraemia rates and resistance patterns in paediatric haematology/oncology patients 2014-2018. Draft report 10/10/2018
[167] Quantitative analysis undertaken to understand the association between the built environment and rates of gram-negative and fungal bloodstream infections at the Schiehallion unit between the years 2015 and 2022. Sid Mookerjee

9.91. Rates of environmental gram-negative blood stream infections are examined through time with peaks seen in 2017 and again in 2021, although the rates are universally higher than expected throughout the period 2015 to 2022.

9.92. Infection rates are also compared with four comparator haemato-oncology units within the UK: Great Ormond Street Hospital, Cardiff and Vale University Health Board (Children's Hospital for Wales), Oxford University Hospitals NHS Foundation Trust (Oxford Children's Hospital) and Leeds Teaching Hospitals NHS Trust (Leeds Children's Hospital).

9.93. In 2015, on moving into the RHC, the rates of infection were slightly higher than the mean rate seen in comparator units - 12.39 per 1000 admissions in the Schiehallion cohort of patients compared with 7.83 per 1000 admissions – with an associated increased risk ratio for the Schiehallion patients of 1.58. This means that patients in the Schiehallion Unit were 1.58 times more likely to acquire and environmental gram-negative infection than patients at the comparator units.

9.94. In 2016 this rate began to rise further. During this time, we know that there were 22 cases of environmental gram-negative or fungal blood stream infection[168] in haemato-oncology patients including one case of *Cupriavidus pauculus* and one of *Mycobacterium chelonae* in addition to two cases of Aspergillus infection[169]. Only 47 water samples were obtained for wards 2A/2B during 2016 despite the number of environmental gram-negative organisms isolated from blood cultures.

9.95. The low number of water samples tested suggests that either the sampling plan was not followed (the Schiehallion unit would be classed as an augmented care unit and therefore would expect more rigorous testing) or the plan was not sufficiently robust, and that the number of infections was not triggering additional water testing. If the number of infections with environmental organisms had been investigated using the PAG and IMT process, then it is likely that more water sampling would have been carried out.

9.96. In 2017 the infection rate increased again to 71.2 cases per 1000 admission and this correlates with a water positivity rate (in samples taken on the Schiehallion unit) of 7.65%. The number of water samples was low at this point in time and samples were not investigated for unusual environmental

[168] QEUH blood culture samples1.1.15-31.12.22.
[169] IMT 05/8/2016

pathogens on a routine basis. The infection risk ratio at this point in time was 6.98.

9.97. In 2018 the number of admissions dropped by over 10% and the rate of infection also reduced to 53.46 per 1000 admissions. At this time there were actions being taken to control the infection rates including antimicrobial prophylaxis for the patients and this may have contributed to reducing the infection rate but the increased risk ratio for patients, compared to comparator units, remained high at 6.04.

9.98. In 2018 the amount of water testing on the Schiehallion Unit increased almost 10-fold and the rate of positivity rose to 17.4%.

9.99. At the end of 2018 the two cases of Cryptococcal infection were seen and this emphasised concerns about the ventilation system and lack of HEPA filtration for this vulnerable group of patients.

9.100. In 2019, after the unit had moved to ward 6A (and 4B for BMT patients) the number of admissions fell by over 50% and the infection rate rose further to 63.55 per 1000 bed days with an infection risk ratio of 6.12.

9.101. The implementation of mobile HEPA filters appears to have had little impact on the rates of infection suggesting that the mechanism of infection may be more related to direct or indirect contact than to an aerosolization route.

9.102. The rate of infection continues to rise through 2020 and 2021, however the number of admissions reduces significantly, presumably due to the COVID-19 pandemic and these two years cannot be taken as representative.

9.103. The sudden drop in rate in 2022 to 13.57 infections per 1000 admissions coincides with the unit's return to the upgraded and refurbished wards 2A and 2B. This improvement in itself suggests that the changes to the physical environment including the water and waste water systems and the ventilation system have had an impact on the infection rates. The converse is therefore also suggested, i.e. that the lack of these changes to water and ventilation systems was contributing to the infection rate.

9.104. In our opinion there is no doubt that the environmental gram-negative blood stream infection rates seen in the Schiehallion patients were very high compared to the expected mean rate of other comparator units and that this correlated with the contamination seen in the water system.

9.105. The quantitative analysis confirms this demonstrating a correlation coefficient of 0.7 for 2015 to 2019 between the rate of infection and the water positivity rate.

9.106. The above findings are at odds with the HPS review of the infection data[170] which uses Statistical Process Control[171] (SPC) charts based on historical data without validating whether or not the rates seen were as expected compared to peer haemato-oncology units in the rest of the UK. This has led to high upper warning and confidence limits being set which are not reached consistently despite the very high level of environmental blood stream infection seen in the Schiehallion cohort of patients. This allows for monitoring of improvement work to observe the effects of change, but cannot be used as assurance that rates of infection are not high.

9.107. The analysis differed in some aspects; fungi were excluded from the analysis, patients who had central lines placed anywhere other than RHC were excluded, the grouping of micro-organisms differed from Sid Mookerjee's quantitative analysis, occupied bed days was used as the denominator and the comparator units were smaller units within Scotland.

9.108. The use of SPC charts in examining the data is open to question. The fixing of the mean and confidence limits relies on historical data which was highly variable on a month by month basis. In the case of environmental infections, the number of infections should be extremely low. Setting high confidence limits can give false reassurance that all is well when the data they are based on has not been bench-marked to determine whether it is already higher than would be expected and appropriate for comparison.

9.109. It is concerning that although there is a clear uplift, with most of the data points above the mean, in the number of environmental infections seen in 2017, where we have seen the rate of infection was almost seven times that of comparator units in the UK, the upper warning limit was not triggered. This was taken as confirmation that rates of infection remained low.

9.110. The diversity of environmental organisms should have raised questions as to why this had increased since the move from Yorkhill to RHC.

[170] Review of NHSGG&C paediatric haemato-oncology data. HPS. October 2019

[171] SPC charts (Statistical Process Control Charts) are used to measure changes in data over time. Charts consist of a line graph showing data across time (at least 15 data points are ideal to ensure the accurate identification of patterns, trends and anomalies), a horizontal line showing the Mean and two horizontal lines either side of the Mean called the upper and lower control limits. A target line can be added to demonstrate change during improvement work. Data points outside the control limits are outside the expected 'normal variation'. Patterns can be identified; extreme values which fall outside the control limits and trends -where there are 7 consecutive data points showing an upward or downward trend, or a string of data points that are all above, or all below the Mean. The control limits are calculated from the historical results and are usually set at 3 standard deviations from the Mean. The main use of SPC charts in the NHS is to monitor improvement projects, not to give assurance of good performance (unless a national or stretch target can be applied to the chart.

9.111. In our opinion the evidence in the quantitative report[172] clearly shows a correlation between the contamination of the water system and the infections in patients.

9.112. The additional information provided by the HPS report[173] analyses the data through SPC charts which fail to show the increased risk and do not assess the situation accurately. Expressing the data in a different format would have alerted GGC to the increase in environmental gram-negative cases.

Evidence source 3: The prior reporting of others on the infection link

9.113. There have been a number of significant reports related to the QEUH and RHC expressing differing views as to the source of infections. However, the body of evidence and the number of investigations that have been carried out into different aspects of the built environment, strongly suggest that the hypothesis that the environment was in some way connected to the infections in patients is strong.

Oversight Board

9.114. The Oversight Board was established in November 2019 by the Scottish Government and NHS Scotland due to escalation of the Health Board to Stage 4 of the national performance framework.

9.115. The interim report[174] of the Oversight Board was published in December 2020 and the final report[175] in March 2021.

9.116. The interim report described ‘environmentally-based infections’ and that the infection control response was inconsistent across the organisation. It recommended that IPC became ‘mainstreamed’ within NHS GGC and prioritises addressing environmental infection risks.

[172] Quantitative analysis undertaken to understand the association between the built environment and rates of gram-negative and fungal bloodstream infections at the Schiehallion unit between the years 2015 and 2022. Sid Mookerjee
[173] Review of NHSGG&C paediatric haemato-oncology data. HPS. October 2019
[174] The Queen Elizabeth University Hospital/NHS Greater Glasgow and Clyde Oversight Board: Interim Report: December 2020
[175] The Queen Elizabeth University Hospital/NHS Greater Glasgow and Clyde Oversight Board: Final Report: March 2021

9.117. It also recommended that ARHAI review the NIPCM in light of the QEUH infection incidents to consolidate and prioritise content in relation to alert organism surveillance and incorporate specific advice on novel pathogens.

9.118. These recommendations accept that there was a risk associated with the environment and the infections had occurred as a result.

9.119. The final report[176] concludes that the strong possibility of a link (between water contamination and specific infection incidents) has been undeniable.

9.120. The report also found significant evidence drawing attention to the environmental defects in the hospital which could be linked with infection risks.

9.121. It is also noted that through its actions it was clear that the Health Board accepted there were environmental risks.

Case Note Review

9.122. The Oversight Board commissioned a Case Note Review[177](CNR) in January 2020 to examine individual cases of infection caused by a gram-negative environmental micro-organism.

9.123. The CNR examined the cases of 84 patients with 118 episodes of infection.

9.124. Classifying the cases of infection by their relatedness to the environment was not straightforward. The CNR team used data to identify clusters of the same infection; where patients had multiple opportunities for contamination of intravascular devices; unusual bacteria that are uncommon causes of blood stream infection; the finding of the same bacteria from an environmental source as a bacteraemia, etc. The more factors the patient had for an individual infection, the greater the confidence in identifying a probable environmental source of infection.

9.125. One child died six days after identification of an environmental gram-negative blood stream infection. Sepsis was the principal cause of death on the death certificate. The CNR team judged that this case was probably related to the hospital environment.

[176] The Queen Elizabeth University Hospital/NHS Greater Glasgow and Clyde Oversight Board: Final Report: March 2021
[177] QEUH and RHC Case Note Review Overview Report. March 2021

9.126. A second child died 36 days after the last positive culture. The infection was recorded as a contributory factor on the death certificate. The CNR team also judged this case to be probably linked to the hospital environment.

9.127. The authors concluded that the blood stream infection was unrelated to the environment in just 8 (7%) of episodes studied.

9.128. The report concluded that a link between the environment and infection was most likely in 31% of cases.

9.129. In our view the CNR has established a relationship between the environmental risk and the observed infections which is real but not uniform across all patients potentially exposed to the risk.

It is not known whether there is a linear or more variable relationship between time of exposure and acquisition of infection and as such, in our opinion, the absolute level of risk is not measurable. Patients also vary in their susceptibility to environmental sourced infection so assignment of absolute overall risk is not necessarily helpful. These are questions that will remain unanswered due to the lack of data and the passage of time.

Whole Genome Sequencing

9.130. Whole Genome Sequencing (WGS) is an excellent tool which can identify linked cases in an outbreak of infection.

9.131. In our opinion, it is not, however, a panacea which will always provide the answer to the question of relatedness between an infection and a potential environmental source and should not be used to exclude acquisition of infection from a water system to patient owing to the limitations of microbiological testing.

9.132. The paper by Professor Leanord and Dr Brown[178], recognises the limitations of the work in making or excluding any direct connection between infections in patients and the water and drainage systems.

9.133. In this paper there has been no standardised methodology recorded for either taking samples, labelling or culturing organisms from the water and drainage samples. The samples were taken over several years and by an unknown number of people. This brings variation into the process of collection of

[178] Application of whole genome sequencing to identify relationships among isolates of *Cupriavidus* spp.,*Enterobacter* spp., and *Stenotrophomonas* spp. isolated from clinical samples and from water and drainage associated sources within the healthcare environment. A Leanord, D Brown, v9 18.1.23

samples so that it is unknown whether or not the sampling was optimal and enabled the maximum number of organisms to be isolated.

9.134. There is no standardised methodology for picking colonies from the agar culture plates for identification of organisms with no explanation of how many colonies of each individual colonial appearance (morphology) were picked in order to be sure that they were the same organism or different strains/species, although the paper states that “only single colonies were taken and stored from clinical and potable water/environmental samples”.

9.135. According to Susanne Lee[179], statistically in order to not miss any strains, one would have to select and type 30 different colonies from each culture plate to ensure that a particular strain was not missed.

9.136. This means that it is unknown whether, for a particular clinical or water/environmental sample, all of the organisms isolated were identified and stored. There may have been many colonies on the initial culture medium of different strains of the same species of bacteria.

9.137. Consequently, the authors did not know the diversity of the population of bacteria within the water, a point acknowledged within the paper.

9.138. Conventional methods of typing may have led to some organisms being discarded as duplicates when WGS may well have identified the organisms as different strains.

9.139. Once picked and identified there is no standardised methodology recorded for how the organisms were stored and labelled and which organisms were chosen to be saved. This brings the potential for further error to be made and may account for the finding in Prof Leanord’s paper that saved organisms thought to be one species according to the label were identified as a completely different organism on WGS.

9.140. There is no mention in the paper of repeating the identification of stored organisms by more conventional methods in order to ensure that the labelling was correct.

9.141. The paper states ‘Isolates that were collected from environmental swabs (drains, wash hand basins, shower stalls etc) were not routinely saved’. This could result in a large number of environmental strains being discarded in the past and no longer available for testing.

9.142. All of the unknown elements of the process add uncertainty and reduce the confidence with which the report can be viewed when making judgements on

[179] Susanne Lee Meeting report 25.4.2018

the link between infections in patients and the water/drainage system as an environmental source of infection.

9.143. The report acknowledges the significant amount of diversity in the populations of the three organisms studied and also that the full diversity of the environmental population was not sampled.

9.144. An editorial in the Journal of Hospital Infection[180] recognises that 'further information is required to guide how many colonies should be typed from environmental samples (and linked to clinical specimens) to identify biodiversity in order to fully recognise transmission'.

9.145. Thus, whilst no confirmed link has been established (except for the single case of *Cupriavidus pauculus* in 2016 and outside this paper, a case of *M. chelonae*[181]), WGS in this context cannot be used to exclude any link.

9.146. Dr Evans, however, in his three papers on WGS for *Cupriavidus*[182], *Stenotrophomonas*[183] and *Enterobacter*[184] seeks to exclude a link.

9.147. He uses the same stored samples as Leanord and Brown but does not recognise the limitations of the collection, methodology and storage of organisms.

9.148. As a result, he concludes that on the balance of probability the human infections were not acquired from the environmental sources.

9.149. In our opinion this is an erroneous position, as there are too many unknowns and variables to come to any conclusion which excludes a link.

Other Reporting

9.150. In the August 2018 **HPS/HFS report**[185] the authors state that 'testing of the organisms in this incident has not provided an exact link to the patient cases

[180] The hospital-built environment: biofilm, biodiversity and bias. M Weinbren at al. Journal of Hospital Infection 111 (2021) 50-52
[181] Investigation of two cases of Mycobacterium chelonae infection in haemato-oncology patients using whole genome sequencing and a potential link to the hospital water supply. T Inkster et al. Journal of Hospital Infection 114 (2021) 111-116
[182] Report on Cupriavidus infection at Queen Elizabeth University Hospital, Glasgow. T Evans. March 2023
[183] Report on Stenotrophomonas infection at Queen Elizabeth University Hospital, Glasgow. T Evans. March 2023
[184] Report on Enterobacter infection at Queen Elizabeth University Hospital, Glasgow. T Evans. March 2023
[185] 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. Storrar and Rankin, HPS/HFS August 2018

and the water system. Testing in an incident like this can be difficult and should only be used to include cases rather than exclude'.

9.151. In the June 2019 **HPS report**[186], there is an account of the HIIATs received since 2016 and that only four of the fifteen are related to the ongoing water incident. The information in the tables would suggest that at least five and possibly seven of the incidents relate to gram-negative environmental organisms and a further two are also related to the environment (*Aspergillus fumigatus*).

9.152. Looking at the SPC charts for environmental bacteria in blood cultures, the chronological comparison clearly shows that there is an upward trend from June 2016 onward in the rate of positive blood cultures, with exceedance of the upper warning limit and upper control limit from late 2017 and into 2018.

9.153. Exceedances of the upper control limit is also seen on the RHC-Other chart, two of which appear to correlate with known outbreaks on NICU and PICU caused by environmental organisms. Enlarging the scale on the x axis may demonstrate changes through time which are currently undetectable in addition to the data exceedances.

9.154. Figure 4 in the paper demonstrates the increase in environmental infections, not just in ward 2A/2B patients, but in other specialties across the hospital following the move from Yorkhill to RHC. In our experience this would not be the expected outcome when moving to a new facility.

9.155. The December 2018 **HPS report**[187] states that the environmental gram-negative blood stream infections in the first quarter of 2018 were all considered to be linked to the water system as organisms of the same species had been isolated from water samples taken within 2A/2B. In an outbreak investigation where no other reasonable hypothesis has been put forward this would be a natural assumption to make and the IMT[188] at this time were working on this basis.

9.156. **Positioning paper 2[189] -** At paragraph 18 the author states that IPC teams operate on a reverse burden of proof when investigating HAI. In our experience this is not the process. IPC teams first review one or more cases of infection, assess the risk to other patients, identify possible sources

[186] Situational Assessment Wards 2A/B Royal Hospital for Children NHS Greater Glasgow and Clyde. June 2019
[187] Summary of Incident and Findings of NHS GGC QEUH/RHC. HPS, 20 December 2018
[188] IMT 2/3/2018
[189] Positioning paper 2 on behalf of Greater Glasgow and Clyde. April 2023

(usually through knowledge gained by years of experience and expertise) and act to control and mitigate any risks in relation to possible sources.

9.157. Finding the source of an infection, especially when dealing with an environmental organism, is often by exclusion of all other possibilities rather than matching the infection to an organism recovered from the environment, or by making an intervention which has the effect of preventing further cases in an outbreak.

9.158. The notion that in any hospital setting there will be a background rate of infection is correct in relation to some infections; however, it is the responsibility of the IPCT and all the employees of that hospital to ensure that every action is taken to reduce that background rate to the absolute minimum and that no avoidable infections will be seen. This particularly applies to infections caused by environmental organisms. The majority of HAI are avoidable and should not occur. Necessary action includes undertaking surveillance of mandatory reportable organisms as well as alert organisms and unusual pathogens where they arise, acting quickly when infection risks are identified and escalating any concerns for action.

9.159. The intention of a new build hospital should be to design out infection risk. This is one of the reasons why single rooms are advocated.

9.160. The **quantitative analysis**[190] of infection rates with environmental organisms has shown very clearly, using statistical tools, that there is an increase in infections with these organisms in the Schiehallion unit both whilst based in 2A/2B and when moved to 6A/4B. HPS[191] has further shown an increase across the rest of RHC.

9.161. Defining which organisms are part of the environmental group for this purpose has been done by this paper, the CNR[192] and the HPS[193] report.

9.162. It is agreed that infection rates will vary depending on risk factors and for this reason, as explained at para 5.10 the analysis has concentrated on the Schiehallion Unit cohort.

[190] Quantitative analysis undertaken to understand the association between the built environment and rates of gram-negative and fungal bloodstream infections at the Schiehallion unit between the years 2015 and 2022. Sid Mookerjee
[191] Situational Assessment Wards 2A/B Royal Hospital for Children NHS Greater Glasgow and Clyde. June 2019
[192] QEUH and RHC Case Note Review Overview Report. March 2021
[193] Situational Assessment Wards 2A/B Royal Hospital for Children NHS Greater Glasgow and Clyde. June 2019

9.163. Sid Mookerjee's report[194] compares the Schiehallion Unit with peer centres across the UK. This comparison shows that infection rates are high in the Schiehallion Unit for environmental organisms.

9.164. The comparison[195] with other centres in Scotland through mandatory surveillance of *Staphylococcus aureus*, MRSA, *C. difficile* and *E. coli* shows that infection rates with these organisms are comparatively low. This does not mean that all infection rates are low – just those in the mandatory surveillance scheme.

9.165. The national point prevalence survey, discussed in the same paper[196], is carried out once every 4 to 5 years and is a measure of a point in time. It does not look at longitudinal rates of infection, merely HAI during the small window of the survey (usually less than a month) and each ward survey is completed in a single day. This is not comparable with the statistics which show an extended period of increased environmental infections.

9.166. In the first of his two reports[197], Dr Kennedy reviews the epidemiology of the blood stream infections seen in RHC and compares with cases at Yorkhill prior to the move to the new hospital.

9.167. He notes single data point changes, for instance the low rate in June 2017, rather than noting the overall trends and changes over time. For example, from May 2016, the incidence of polymicrobial cultures appears to increase markedly and persistently. Dr Kennedy suggests that this could be due to genuine poly-bacteraemia, colonised lines but not causing systemic infection (any organism in a line has potential to cause infection and lead to sepsis) or a change in laboratory process to identify all organisms in a blood culture. This latter reason, if true, would suggest that the lab was operating outside national guidelines and the consistency of laboratory methods throughout this period is confirmed in Peters and Harvey-Wood's paper[198].

9.168. The earlier paper examines data across the whole hospital using bed day data as the denominator. Given that the RHC has substantially higher bed capacity than Yorkhill, this will mask the increase in infections in the highest

[194] Quantitative analysis undertaken to understand the association between the built environment and rates of gram-negative and fungal bloodstream infections at the Schiehallion unit between the years 2015 and 2022. Sid Mookerjee
[195] Appendix1.Positioning paper 2 on behalf of Greater Glasgow and Clyde. April 2023
[196] Appendix1.Positioning paper 2 on behalf of Greater Glasgow and Clyde. April 2023
[197] Descriptive analysis of five-year trends in bacteraemia rates for selected gram-negative organisms. Dr I Kennedy Oct 2018
[198] C. Peters and K Harvey-Wood. Bacteraemia rates and resistance patterns in paediatric haematology/oncology patients 2014-2018. Draft report 10/10/2018

risk groups which make up a small part of the whole patient population at RHC.

9.169. The comparators chosen add little to the analysis. *E. coli* is not an environmental organism and is the commonest gram-negative organism found in blood stream infections in the UK. *Staphylococcus aureus* is also not an environmental organism and is a common gram-positive cause of blood stream infection. Comparing selected gram-negatives in QEUH is also unhelpful as the masking effect of the increased patient population following the move to the new hospital is even greater than in RHC, although it should be noted that the rate barely reaches 0.5 per 1000 bed days at any point, whereas the rate in RHC is consistently higher and at some data points goes above 1.5 and almost reaches 2 cases per 1000 bed days but this is not commented upon.

9.170. The same can be seen in the data from GRI which is comparable with the QEUH data but again much lower than the rates seen in RHC.

9.171. In his second report[199], Dr Kennedy lists the selected gram-negative organisms. This list is different from the list used in Sid Mookerjee's report in that *Pseudomonas aeruginosa, Acinetobacter baumanii, Klebsiella oxytoca, Serratia marcescens* and *Aeromonas* are omitted.

9.172. The extended graph of all cases in RHC shows a decrease in cases following the implementation of Chlorine dioxide dosing in the water. Dr Kennedy comments on the persistence of *Enterobacter cloacae* infections but does not comment on the possible cause of this. However, from our experience, we would suggest that this is possibly due to the biofilm of Enterobacter cloacae being more resistant to chlorine than that of other organisms[200].

9.173. It is of note that the rate of infection amongst haemato-oncology patients rises again in early 2019, rising to almost 3/1000 bed days in April 2019 although poly-bacteraemia does not occur. This is seen at the same time as a small decrease in activity which probably coincides with concerns about ward 6A, the decant to CDU for a month and the reallocation of patients to Edinburgh.

9.174. Dr Kennedy describes a reduction in the rate of blood stream infections in haemato-oncology patients over a short time period between October 2018 and June 2019. The graph he presents would appear to confirm this although

[199] Descriptive analysis of trends in bacteraemia rates for selected gram negative organisms. Dr I Kennedy July 2019

[200] Cai L et al. Response of Formed-Biofilm of Enterobacter cloacae, Klebsiella oxytoca, and Citrobacter freundii to Chlorite-Based Disinfectants J Food Sci 2018 May;83(5):1326-1332

seven data points would normally be expected to see a trend. However, the analysis done by Sid Mookerjee suggests that the Incidence Rate Ratio (comparing the Schiehallion cohort of patients with comparator units) remains largely the same (6.04 for 2018 and 6.12 for 2019).

9.175. In summary, Dr Kennedy's reports add little additional information to the overall analysis of the environmental infections at QEUH/RHC.

10. Cryptococcus and Aspergillus

Cryptococcus neoformans

10.1. Cryptococcus is a spherical yeast around 4-6 microns in diameter. It is capable of producing a capsule which increases its size up to 25 microns. It is found in soil throughout the world, particularly in soil contaminated with pigeon guano. Infection is acquired by breathing in the fungal particles, often causing a latent infection which may be reactivated if the individual becomes immunocompromised, causing pneumonia, and may spread to the brain via the blood stream. Cryptococcal meningitis has a mortality rate of up to 30%.

10.2. Because of its small size, cryptococcus can evade most filters apart from HEPA filters and individual organisms are able to reach the alveoli of the lungs more easily than other larger organisms.

10.3. Cryptococcal infection is rare in the UK and very rare in non-HIV patients with less than 100 cases seen in the UK in 2011[201]. In the UK around 80% of all cases are in HIV positive individuals[202].

10.4. World-wide, cryptococcal infection is most commonly seen in individuals with HIV infection. Patients taking immunosuppressive drugs, for instance transplant recipients, are also at higher risk of new or reactivated cryptococcal infection. Short term steroid use has been shown to increase the risk of cryptococcal infection 20-fold in certain circumstances.[203]

10.5. As discussed at para 9.36, two cases of Cryptococcal blood stream infection were identified in November and December 2018, following which, a search,

[201] Pegorie et al. Estimating the burden of invasive and serious fungal disease in the United Kingdom. J Infect 2017;74,60-71
[202] Knight FR et al. Increasing incidence of cryptococcosis in the United Kingdom. J Infect. 1993;27:185-191
[203] Vallabhaneni S. et al. Cluster of *Cryptococcus neoformans* Infections in Intensive Care Unit, Arkansas, USA, 2013. Emerging infectious diseases. Vol 21, Oct 2015, 10, 1719-1724

carried out by a consultant microbiologist, identified a total of five cases of cryptococcal infection with positive blood cultures between May and December 2018 and one from May 2016. This is an unusually high number of positive blood cultures considering the rarity of this type of infection. Blood stream infection is extremely uncommon especially in non-HIV, non-transplant patients.[204]

10.6. Infections rarely result from acute fungal exposure and person to person spread is exceedingly uncommon, so focal clusters or outbreaks are not expected. Only one hospital-based outbreak has been reported[205], in which the hospital source was not found despite just 12 weeks elapsing from the first case before full investigations were carried out.

10.7. A sub-group of the IMT for the Cryptococcal incident was formed to examine the cryptococcal risk further. A report was written by the Chair of the subgroup which examined the two cases identified in November/December 2018[206]. Both cases were haemato-oncology patients. Unfortunately, the report does not include examining the other three 2018 patients to assess any links to QEUH nor how the assertion that only two cases are possibly hospital-acquired has been evidenced.

10.8. The report dismisses the ingress of pigeons into plant rooms as a possible source of infection. The cleaning of the plant rooms prior to any microbiological sampling was not helpful in the investigation and removed a potential opportunity to isolate *C. neoformans* from the environment.

10.9. The report identified that despite extensive sampling of the air in and around the hospital, no *Cryptococcus neoformans* was isolated, although other species of cryptococcus were found. Air coming in from the outside into wards with no HEPA filtration (all wards except 4B) was put forward as a possible hypothesis. Dr Hood's view, shared by Dr Inkster[207], is that *Cryptococcus neoformans* is extremely difficult to grow from air[208]

10.10. It was identified however, that the two wards affected, 4C and 6A did not have HEPA filtration so Cryptococcus could potentially have come into the wards from the outside through the ventilation system.

[204] Vallabhaneni S. et al. Cluster of *Cryptococcus neoformans* Infections in Intensive Care Unit, Arkansas, USA, 2013. Emerging infectious diseases. Vol 21, Oct 2015, 10, 1719-1724
[205] Vallabhaneni S. et al. Cluster of *Cryptococcus neoformans* Infections in Intensive Care Unit, Arkansas, USA, 2013. Emerging infectious diseases. Vol 21, Oct 2015, 10, 1719-1724
[206] Report from the Cryptococcus Incident Management Team Expert Advisory Sub-Group. NHS GGC 5/4/2022
[207] Dr Inkster draft statement
[208] IMT 02/07/2020

10.11. It was further identified that flaws in the ventilation design in the bone marrow transplant unit (4B) allowed cryptococcus to enter the ward, through poor airflow at the ward entrance as 4C had a ventilated corridor creating a higher pressure than the unventilated corridor in 4B. This could potentially create a risk for patients on 4B, although the 4B rooms have HEPA filtered ventilation at positive pressure to the corridor.

10.12. The lack of protective isolation was identified as the second potential hypothesis in the development of infection. The ventilation standard for neutropenic patients is for HEPA filtered bedrooms and corridors. The rooms should have 10 ach and +10Pa positive pressure, facilitated by sealed rooms to prevent leakage. All of the rooms in QEUH/RHC (except 4B QEUH) were designed with no HEPA filtration, 2.5 ach and neutral or slightly negative pressure with suspended ceilings. The actual ventilation offered much reduced protection from airborne infection and allowed potential pathogens to enter patient rooms from outside, combined with slow clearance of contamination due to the low air changes.

10.13. The third possible hypothesis put forward was that due to latency of infection, the cases could all have arisen at the same time by chance. This is impossible to evidence and would be remarkable if correct given the links in time and space between the patients.

10.14. Genomic analysis of the two index cases and two earlier cases from 2018 found that all isolates were different. This is not unusual in comparison with the findings of Vallabhaneni et al[209], who found three different genomic types in the six patients in the hospital outbreak they reported despite all patients being cared for on a single intensive care unit within a short period of time.

10.15. Farrar[210] also reported that a lack of a genetic link does not rule out a common source as pigeon guano may contain a variety of unrelated cryptococcal genotypes due to diversity of environmental isolates.

10.16. A further lookback included in Dr Hood's report[211] identified 18 cases over 10 years originating in Greater Glasgow and Clyde including this 5-case cluster in 2018. Seven of the earlier cases were identified as HIV positive.

[209] Vallabhaneni S. et al. Cluster of *Cryptococcus neoformans* Infections in Intensive Care Unit, Arkansas, USA, 2013. Emerging infectious diseases. Vol 21, Oct 2015, 10, 1719-1724
[210] Farrer, RA, Borman, AM, Inkster, T, Fisher, MC, Johnson, EM & Cuomo, CA (2021). Genomic epidemiology of a Cryptococcus neoformans case cluster in Glasgow, Scotland, 2018. *Microbial Genomics*, DOI 10.1099/mgen0.000537
[211] Report from the Cryptococcus Incident Management Team Expert Advisory Sub-Group. NHS GGC 5/4/2022

10.17. Of the 5 cases in the table in 2018, the report identifies that only two were believed to be possibly hospital-acquired. Despite being finalised in 2022 the report does not investigate the additional cases from 2018, dismissing them as community acquired.

10.18. Dr Peters[212] [213] identified that of the six cases with positive blood cultures, four had contact with QEUH within a few months of their symptoms and diagnosis (including the two diagnosed Nov/Dec 2018) and all were immunocompromised either due to their co-morbidities or treatment.

10.19. Two cases were those identified in November and December 2018.

10.20. A third and fourth case had positive blood cultures in August 2018. One had an earlier admission to ward 11A QEUH in April 2018 and the other had an admission to ward 8D QEUH in November 2017, developing chest x-ray changes in December which did not resolve before they represented in August 2018.

10.21. A fifth case had an overnight admission to QEUH in 2015. In this case the link is more tenuous.

10.22. The sixth case was diagnosed in another Glasgow hospital in 2016 and we are not aware of any history of contact with QEUH.

10.23. A seventh case was diagnosed in June 2020 through semi-routine screening having been admitted with fever following intensive chemotherapy. The diagnosis was made by serum cryptococcal antigen which was positive on four occasions. The child subsequently became symptomatic and was treated for invasive cryptococcus, recovered and was discharged.

10.24. This case is the second child to be diagnosed at QEUH. In his paper[214] Dr Hood states that ‘children very rarely contract infection with *C. neoformans’.*

10.25. Following advice[215] from the National Mycology Reference Laboratory that the patient’s cerebrospinal fluid sample was negative for cryptococcal antigen and that the blood showed a faint positive at a 1:2 dilution (indicating a possible false positive rate of 34%), the IMT for this case[216] concluded that it was either an early infection ameliorated by anti-fungal medication or that it was a

[212] Email correspondence from C Peters to T Inkster 23/09/2020
[213] IMT 26/11/2020
[214] Report from the Cryptococcus Incident Management Team Expert Advisory Sub-Group. NHS GGC 5/4/2022
[215] Email from Professor Elizabeth Johnson. 07/07/2020
[216] HIIORT 09/07/2020

false positive. It is understood that NHS GGC do not consider this to be a cryptococcal infection[217].

10.26. It is noted that NHS GGC[218] do not recognise the cases of cryptococcus identified in Dr Hood's report and the list of cases of cryptococcus-positive blood culture samples in Dr Peters' analysis[219]. Although the cases in Dr Hood's report were from the whole of NHS GGC, six of the seven cases identified by Dr Peters have epidemiological links with QEUH/RHC as described earlier in this chapter.

10.27. The QEUH Review report[220] concluded that there was not a 'sound evidential basis on which to make a link between the cryptococcal infections, subsequent deaths and the presence or proximity of pigeons or their excrement'.

10.28. However, failing to provide HEPA filtered mechanical ventilation to the haemato-oncology (neutropenic) wards, minimal air changes per hour, poor air flow and lack of air-locks allowing air to flow from a general ward into the BMT unit (4B), reducing the effectiveness of protective isolation, and allowing pigeon ingress into plant rooms, resulted in unmitigated risks which, in our opinion, have contributed to the risk of patients acquiring airborne infections whilst in QEUH/RHC.

Aspergillus fumigatus

10.29. *Aspergillus fumigatus* is a fungus which is found very widely in the environment. Infection is acquired by the airborne route and commonly presents as pneumonia although more widespread disease is also seen. Usually, only individuals who are immunosuppressed or have chronic lung conditions are at risk of aspergillosis. The incubation period of infection varies from 2 days to 3 months depending on the susceptibility of the individual.

10.30. Aspergillus is capable of surviving in drinking water. It is tolerant to higher temperatures and can also survive in stagnant water where the oxygen level in the water is low.[221] Aspergillus can also form biofilms in water systems.

[217] NHS GGC Response to Request for information dated 15 April 2024 (SHI RFI 26)
[218] NHS GGC Response to Request for information dated 15 April 2024 (SHI RFI 26)
[219] Email correspondence from C Peters to T Inkster 23/09/2020
[220] QEUH Independent Review June 2020. Fraser and Montgomery
[221] Richardson M et al. Exposure to *Aspergillus* in Home and Healthcare Facilities' Water Environments: Focus on Biofilms. Microorganisms 2019 Jan; 7(1):7

10.31. The formation of biofilms is also thought to contribute to the ability of Aspergillus to cause disease[222] and render them resistant to anti-fungal therapies.

10.32. Aspergillus can survive for an extended period of time on surfaces, up to around 26 days. It can be killed by specialist mould cleaners, chlorine-based disinfectants and HPV.

10.33. The five cases of Aspergillosis in wards 2A (RHC) and 6A (QEUH) described at paras 9.34-9.38 were all haemato-oncology patients. One was a BMT patient making them potentially more susceptible to aspergillus due to their level of immunosuppression.

10.34. The number of cases was noted to be higher than expected in IMTs[223]. There was some discussion at this IMT about a new chemotherapy regime which had seen increased rates of aspergillus infection in other centres. It was not felt that there was enough evidence to support this view.

10.35. Despite its ability to survive in water, the commonest route of infection by Aspergillus is by the airborne route where fungal particles are breathed in. However, the presence of aspergillus in cultures of showerheads and taps raises the possibility that they could be transmitted from water outlets.[224]

10.36. The ventilation on wards 2A and 6A was comparable to a general ward at the time these infections occurred. At QEUH/RHC this meant no HEPA filtration, rooms not sealed with suspended ceilings, 2.5 air changes/hour (ACH) and negative or neutral pressure to the corridors.

10.37. Professor Humphreys stated in his expert report to the inquiry[225] that ‘where neutropenic patients are housed in rooms where the HEPA filtration is inadequate, there is a greater risk of aspergillosis and outbreaks have occurred’. He went on to say that ‘it seems reasonable to assume that the greater the deviation in…what is recommended in guidelines or standards, the greater the risk of preventable infection occurring’.

10.38. Particular concern was raised during IMTs about damage to ventilation ducts[226] and dust related to on-campus building works[227].

[222] Williams C et al. Aspergillus Biofilms in Human Disease. Adv Exp Med Biol 2016:931;1-11
[223] IMT 7 March 2017
[224] Hospital water and opportunities for infection prevention. Decker B and Palmore T. Curr Infect Dis Rep.2014 October; 16(10): 432
[225] Professor Hilary Humphreys – Expert Report to SHI. Hearing Commencing 9 May 2022 Bundle 6 – Expert Reports and Statements, page 3
[226] IMT 5 August 2016
[227] Building work is a particular hazard for neutropenic patients as the dust can release fungal spores into the air. These spores can travel significant distances and enter unprotected air intakes.

10.39. Cornet et al[228] examined the efficacy of high efficiency air filtration in preventing airborne aspergillus infection during building works. They found that there was a strong correlation between building work and an increase in aspergillus contamination and showed that laminar air flow plus HEPA filtration and a high air-change rate controlled the level of aspergillus contamination.

10.40. In the absence of HEPA filtration, the risk of contamination of the environment with Aspergillus would be high. Lee et al[229] showed that following cleaning the concentration of bio-aerosol contamination with aspergillus is greater, increasing the risk of nosocomial infection. In practice, this suggests that if there is contamination of surfaces with aspergillus, then this is disturbed and aerosolised during cleaning, increasing the risk of infection.

10.41. Following the move of the Schiehallion Unit from 2A to 6A, concerns were raised about the particle count in the air. Further investigation led to the identification of damage to showers due to water ingress with black mould growth. This had previously been repaired prior to the move, but had reoccurred in early 2019. Aspergillus, in common with other fungi, will grow in moist environments with high humidity.

10.42. The Schiehallion cohort was decanted to CDU for a month whilst further repairs were undertaken. Portable HEPA filters were placed in three bedrooms and in August 2019, HEPA filtered air scrubber fans were installed in the ceiling spaces of the en-suite rooms.

10.43. Air scrubbers recirculate the air within the en-suite space and improve the air quality but have little effect on the air quality in the bedroom area.

10.44. Entry of Aspergillus into a ventilated room can be prevented by HEPA filtration.

10.45. The low ACH in both wards would reduce the clearance from the air by dilution of any fungal particles.

10.46. In our opinion, the lack of positive pressure and HEPA filtration, allowing fungal particles to enter bedrooms, combined with the low ACH presented an avoidable increased risk of airborne infection such as aspergillus.

[228] Cornet M et al. Efficacy of prevention by high-efficiency particulate air filtration or laminar airflow against Aspergillus airborne contamination during hospital renovation Infect Control Hosp Epidemiol 1999 Jul;20(7):508-13

[229] Lee L et al. Risk of bioaerosol contamination with aspergillus species before and after cleaning in rooms filtered with high efficiency particulate air filters that house patients with haematological malignancy. Infect Control Hosp Epidemiol 2007 Sep;28(9):1066-70

11. Conclusion

11.1. The reports of the Expert Group, when taken together, demonstrate the underlying failure of the water and waste-water and ventilation systems and how that failure has led to a significant avoidable risk to vulnerable patients from environmental organisms.

11.2. Water-borne HAI are preventable and there is a large body of recommended guidance, regulation and legislation to ensure that water systems in public buildings remain safe.

11.3. Dr Walker's report shows that patients at QEUH and RHC have been exposed to a range of water-borne pathogens due to a failure of timely and effective management of the water system. This exposure led directly to an increased risk of infection in immunocompromised patients.

11.4. Although the system was not compliant at the point of occupation and classified as high risk in risk assessments, the risk of infection increased over time as biofilm formed and the bacteria were able to multiply in the water system due to the poor temperature control.

11.5. By 2018 when testing increased, there was evidence of widespread contamination and biofilm including on tap components and in drains.

11.6. Drains are known to become contaminated due to dirty water from hand washing resulting in build-up of biofilm. This is exacerbated if patients and staff dispose of other liquids (drinks, IV fluids, TPN etc) down the sink drain.

11.7. Turning on the tap can disturb the biofilm resulting in aerosolization and splashing and contamination of the sink and surrounding area.

11.8. It is difficult to assess the methodology of water testing retrospectively and it is, due to the involvement of people (biomedical scientists), partly subjective. This may build in inaccuracy in the number of different organisms reported.

11.9. It is clear though, that similar strains of bacteria were found in the water as those which caused infection in patients.

11.10. In our experience, it is highly unusual to have such a range of environmental gram-negative bacteria causing blood stream infections. Some of the organisms such as *Cupriavidus*, *Delftia* and *Chryseomonas* are very rare with few cases reported in the literature.

11.11. To see these infections and also isolate them from an environmental source is, therefore, very strong circumstantial evidence that there is an association between them.

11.12. In our experience, it is not unusual for an environmentally-based outbreak to see multiple different organisms involved. This is especially true where contaminated biofilm is present although in some cases there is a 'dominant' organism within the biofilm.

11.13. Throughout the period of time since the hospitals opened there have been numerous incidents that have been reviewed and investigated by NHS GGC. There are some examples of PAGs and IMTs that have a defined hypothesis on how the infections have been acquired; the environment is the key risk identified and controls, mitigations and actions taken are in response to risks identified. The minutes of these meeting do not hypothesise about other potential sources for the environmental gram-negative blood stream infections.

11.14. As Dr Walker reported[230], the risk was reduced but not completely eliminated by applying ultrafiltration, chlorine dioxide dosing and temperature control to the water system together with point of use filters and implementing planned preventative maintenance.

11.15. There was a reliance on the efficacy of chlorine-based cleaning products (when these were used) and the efficiency of domestic staff to clean and decontaminate rooms after occupation by patients. The reluctance to implement more advanced methods of decontamination of the patient environment was due to lack of consideration of the wider patient environment beyond the assumed organism source. In our opinion, these methods of environmental decontamination should have been deployed to minimise contamination and provide a more comprehensive assurance as to the cleanliness of the patient environment.

11.16. Despite evidence of a high risk associated with the water system, the environmental risk was not always taken seriously and was dismissed as a potential cause if typing, by WGS of environmental and patient organisms, did not match. However published reviews[231] have shown that up to 21% of all

[230] Review of the NHS Greater Glasgow and Clyde: Queen Elizabeth University Hospital/Royal Hospital for Children water and waste-water system from the point at which patients occupied the site in 2015. Dr JT Walker

[231] Kiran M Perkins and others, Investigation of Healthcare Infection Risks from Water-Related Organisms: Summary of CDC Consultations, 2014—2017 (2019) 40 Infection control and hospital epidemiology 621

recorded HAIs can be attributed to water and not accepting the risk was present has probably put more patients at risk.

11.17. Dr Walker has shown clearly in his report that the water system was unsafe in a number of ways which presented a significant risk for patients at QEUH and RHC.

11.18. Having established that the increased infection risk has been associated with the water and drainage systems, the risk would, under normal circumstances be expected to be mitigated to some extent by effective ventilation systems in a clinical area as any droplets and aerosolised contamination would, to an extent, be diluted by adequate ventilation and clean air flows.

11.19. This was not the case in the Schiehallion unit, or indeed in the rest of the hospital (apart from ward 4B) as the ventilation system did not meet the expected number of air changes per hour. The windows were sealed so there was complete reliance on the ventilation system which had been designed to save energy without regard to the other function of ventilation in healthcare settings, to dilute and remove airborne pathogens.

11.20. The Schiehallion unit patients were neutropenic and ward 2A should have had HEPA filtered ventilation throughout, with positive pressure of 10Pa in the bedrooms compared with the corridor, sealed ceilings and pipework in order to maintain the positive pressure and 10 air changes per hour with a clean air flow from the bedroom, out through the en-suite to the extract. Other features should have been pressure monitoring and an airlock entrance to the ward, and chilled beam units should not have been fitted.

11.21. The risk created by derogating the ventilation down to no HEPA filtration, neutral or negative pressure compared with the corridor, potential for mixing extract and supply air, unsealed suspended ceilings and just 2.5 air changes per hour with chilled beams fitted has proved to be unacceptably high as evidenced by the level of remedial work carried out in the ward since 2018.

11.22. This patient cohort was moved to ward 6A QEUH in order for works to be carried out on 2A.

11.23. The move took place despite the hospital management being aware that the ventilation standards in 6A were no better than on 2A and that the entire water system was contaminated. Some remedial work was done on 6A ward to repair damage to showers and remove mould but no changes were made to the ventilation prior to the move. Subsequently, after a case of cryptococcus on the ward, mobile HEPA filters were placed in three rooms and HEPA air scrubber fans were fitted in ceilings of the en-suite rooms.

11.24. In our opinion, the move to ward 6A was an additional risk for this cohort of patients.

11.25. The design and installation of the ventilation system was non-compliant to the SHTM standards at the time of commissioning and as a result, in our opinion, caused an avoidable risk to patients.

11.26. Specific questions have arisen about the risks of cryptococcal infection and aspergillosis at QEUH/RHC.

11.27. A total of seven cases of Cryptococcus have been identified in GG&C from 2016 to 2020. We have no information on any link between the 2016 patient and QEUH. Of the five 2018 patients, all have links to QEUH, although quite tenuous in one case and the 2020 patient was an inpatient at the time of diagnosis.

11.28. In 2011, there were fewer than 100 cases of invasive cryptococcal infection recorded in the UK[232]. Around 80% of cases are known to be seen in HIV patients. No current UK data is available, however, if 20 to 30 cases in non-HIV patients were seen in the UK in 2018, it would be highly unusual for five to be found with links to a single hospital, and highly suggestive of an epidemiological relationship.

11.29. Again, adequate ventilation could potentially have prevented these patients, who were all immunosuppressed, developing life threatening infections.

11.30. In summary, several constituents of the commissioned ventilation system; the low air changes, the lack of positive pressure, the lack of HEPA filtration, the use of chilled beam units and the use of thermal wheels, individually and together created an avoidable risk of infection for the Schiehallion cohort of patients.

11.31. Aspergillosis is an unusual infection in haemato-oncology patients. There was a specific risk present on the QEUH/RHC campus as extensive demolition and building work was being undertaken. This is a recognised source of infection for this group of patients and HEPA filtered ventilation with a high air-change rate is required to control the risk. Five cases of aspergillosis were seen in children on wards 2A and 6A which were all potentially avoidable if HEPA filtration had been in place.

11.32. The measures taken by NHS GGC in response to the high infection rate, point of use filters on water outlets, major remedial works to wards 2A and 2B, with

[232] Sloan DJ, Parris V. Cryptococcal meningitis: epidemiology and therapeutic options. Clin Epidem 2014:6 169-182

relocation of patients to 6A and 4B, air scrubbers fitted in 6A, chlorination of the entire water system and decontamination of the healthcare environment, suggest that there was some acceptance of the environmental risk.

11.33. In addition, early indications from 2023 blood culture data show that the rate of infection with environmental organisms has fallen following the move of the Schiehallion Unit patients back to ward 2A/2B, suggesting that the remedial actions taken have resolved some or all of the sources of infection.

11.34. On the balance of probabilities, it is our expert opinion that the cases of environmental gram-negative blood stream infections, *Mycobacterium chelonae,* cryptococcosis and aspergillosis seen in Schiehallion Unit patients were strongly associated with the contaminated water and waste water system and the inadequate ventilation system on wards 2A, 2B and 6A.

Name Dr Sara Mumford Name Linda Dempster

Signature [redacted] Signature [redacted]

SCOTTISH HOSPITAL INQUIRY

Expert Report

Review of the NHS Greater Glasgow and Clyde: Queen Elizabeth University Hospital/Royal Hospital for Children water and waste-water system from the point at which patients occupied the site in 2015.

Report prepared for the Scottish Hospital Inquiry

Expert Report prepared by Dr J.T. Walker, Doctor of Philosophy

Date of Submission: 21st January 2024

Contents

1. Introduction

1.1. Introduction of the Expert Witness

1.1.1. I completed my Bachelor of Science, Microbiology degree at the University of Aberdeen in 1987. My final year laboratory project was studying the influence of oxygen on anaerobic microbial corrosion. I was then employed at the Centre of Applied Microbiology at Porton Down Salisbury in 1988 where I worked as a research microbiologist investigating Legionella biofilms on plumbing materials. This led to the completion of my PhD in 1994 that was entitled "Investigation of biofilms in copper tube corrosion and the survival of *Legionella pneumophila* on alternative plumbing materials". I worked at Porton Down for 30 years (including a two year career break) on a wide range of projects related to water microbiology. I managed a wide range of research projects investigating the presence/rapid detection of waterborne pathogens, involving plate culture and PCR including a range of waterborne pathogens e.g. *Legionella* spp., *Pseudomonas aeruginosa, Clostridium difficile* and non-tuberculous *Mycobacteria* spp.

1.1.2. During my work I have been involved in outbreaks within healthcare establishments and undertaken surveys (of hospital building water systems and wards) and visits to determine the extent of the problem of water borne pathogens and to advise on control strategies.

1.1.3. I undertook research to investigate biofilms in dental unit water lines (dental chairs). This work involved site surveys of buildings as well as laboratory research [1] and led to recommendations for treatment of dental unit water lines. I participated in writing updates within Department of Health guidance (HTM 01-05) [2] to reduce the risk to dental staff and dental patients from microbial pathogens dispersed in droplets and aerosols from the dental unit water lines [3].

1.1.4. The dental research led to investigating the transmission of prions through the reuse of difficult to clean dental instruments [4]. This groundbreaking bioassay work was carried out at PHE Porton and demonstrated the potential for transmission of prions from one patient to another through the reuse of difficult to clean dental files used in root canal treatment. This work led to dental files becoming single use or single patient use [5].

[1] J Walker and others, 'Microbial Biofilm Formation and Contamination of Dental-Unit Water Systems in General Dental Practice' (2000) 66 AEM 3363.
[2] DHSC, 'Decontamination in Primary Care Dental Practices (HTM 01-05) 2013' [2013] GOV.UK.
[3] AM Bennett and others, 'Microbial Aerosols in General Dental Practice' (2000) 189 BDJ 664.
[4] JT Walker and others, 'Implications for Creutzfeldt-Jakob Disease (CJD) in Dentistry: A Review of Current Knowledge' (2008) 87 Journal of Dental Research 511.
[5] DHSC, 'Decontamination in Primary Care Dental Practices (HTM 01-05) 2013' (n 2).

1.1.5. The prion research resulted in participation in the writing of specific Department of Health decontamination guidance for surgical instruments (HTM 01-01) [6], dentistry (HTM 01-05) [7] and endoscopy departments (HTM 01-06) [8].

1.1.6. In 2004 I was seconded from PHE to the United Nations to work as Biological Weapons Inspector as part of the Iraq War.

1.1.7. In 2013 I was appointed the PHE/Porton Down Scientific Leader in Water Microbiology and Decontamination as the lead national expert in this area.

1.1.8. In 2014 I participated in the investigation into the outbreak and fatalities within hospitals in Northern Ireland [9] [10]. The PHE investigation identified that the source of the outbreak that led to the infections and deaths of the preterm babies was the presence of *Pseudomonas aeruginosa* biofilms in the components of the taps used in the hospital wards. This work led to the development of a new Department of Health guidance (HTM 04-01) document for the control of *Pseudomonas aeruginosa* in water systems and the recommendation that outlet fittings should be removed from taps [11].

1.1.9. In 2017 I was part of the PHE expert team that carried out investigations into the microbial contamination of heater coolers involving *Mycobacteria chimaera*. This involved wide ranging collaborations with PHE and with centres of excellence in the UK to assess contamination of heater coolers and control strategies [12] [13] [14].

1.1.10. As a result of my work at PHE and national recognition of my expertise I have worked closely with the Department of Health (DH England) [15] [16] [17] [18] and the Health and Safety Executive (HSG 274 and updated L8 Approved Code of Practice for Legionella) in writing and developing national guidance on the microbiology of water and decontamination in healthcare [19] [20]. I have also participated in the writing of British

[6] DHSC, 'Decontamination of Surgical Instruments (HTM 01-01) 2016' (*GOV.UK*, 2016).
[7] DHSC, 'Decontamination in Primary Care Dental Practices (HTM 01-05) 2013' (n 2).
[8] DHSC, 'Management and Decontamination of Flexible Endoscopes (HTM 01-06) 2016' [2016] GOV.UK.
[9] JT Walker and others, 'Investigation of Healthcare-Acquired Infections Associated with *P. Aeruginosa* Biofilms in Taps in Neonatal Units in Northern Ireland' (2014) 86 JHI 16.
[10] J Walker and G Moore, '*Pseudomonas Aeruginosa* in Hospital Water Systems: Biofilms, Guidelines, and Practicalities' (2015) 89 Journal of Hospital Infection 324.
[11] DHSC, 'HTM 04-01: Safe Water in Healthcare Premises. Part C: Pseudomonas Aeruginosa – Advice for Augmented Care Units 2014' 04–01.
[12] Meera Chand and others, 'Insidious Risk of Severe *Mycobacterium Chimaera* Infection in Cardiac Surgery Patients' (2017) 64 Clinical Infectious Diseases 335.
[13] MI Garvey and others, 'Decontamination of Heater–Cooler Units Associated with Contamination by Atypical Mycobacteria' (2016) 93 JHI 229.
[14] J Walker and others, 'Microbiological Problems and Biofilms Associated with *Mycobacterium Chimaera* in Heater–Cooler Units Used for Cardiopulmonary Bypass' (2017) 96 JHI 209.
[15] DHSC, 'HTM 04-01: Safe Water in Healthcare Premises. Part C: Pseudomonas Aeruginosa – Advice for Augmented Care Units 2014' (n 11).
[16] DHSC, 'Management and Decontamination of Flexible Endoscopes (HTM 01-06) 2016' (n 8).
[17] DHSC, 'Decontamination of Surgical Instruments (HTM 01-01) 2016' (n 6).
[18] DHSC, 'Decontamination in Primary Care Dental Practices (HTM 01-05) 2013' (n 2).
[19] HSE, 'Legionnaires' Disease. The Control of Legionella Bacteria in Water Systems. ACOP 2013'.
[20] HSE, 'HSG 274 Legionnaires' Disease - Technical Guidance Part 2: The Control of Legionella Bacteria in Hot and Cold Water Systems 2014'.

Standard Documents BS 8580-2 Water quality, [21] Part 2: Risk assessments for waterborne pathogens, including Pseudomonas aeruginosa Code of practice and BS 8680 [22] Water safety planning in buildings - Code of practice .

1.1.11. During the COVID pandemic I was part of the European Study Group for Legionella to write guidance for those responsible for managing buildings during and after the pandemic [23] [24] [25].

1.1.12. I am past President of the International Biodeterioration and Biodegradation Society, previous Secretary and former Chair of the Central Sterilising Club (2020-2023).

1.1.13. I am a member of BSI CH/216 Chemical disinfectants and antiseptics, CH/216/0-/01 on antimicrobial hard surfaces, the European Study Group for Legionella, Central Sterilising Club, Infection Prevention Society, Water Management Society and a Fellow of the Royal Society of Public Health.

1.1.14. I am Member of the Department of Health production team for the HTM 04-01 Part A technical bulletin: Management of risks from non-tuberculous mycobacteria in healthcare water systems (2023-2024).

1.1.15. I have taught and lectured on the topic of water microbiology at both undergraduate and postgraduate level and supervised a number of PhD students who have successfully defended their theses. In addition, I have provided water microbiology training to a wide range of personnel working in healthcare including estates and facilities and clinical staff both in the UK and abroad.

1.1.16. I am invited to give lectures at national and international scientific meetings as a keynote speaker on a regular basis.

1.1.17. As a scientific expert I have authored and co-authored an extensive number of peer reviewed publications in the area of water microbiology, biofilms, pathogens and decontamination in public health microbiology. I have worked with the Department of Health (England) and the HSE to provide expertise in the writing of national guidance documents to reduce the risks to patients relating to hot and cold water systems as well as decontamination and disinfection.

1.1.18. In addition, I have authored, co-authored and edited a number book related to water microbiology. Published manuscripts, reports and books can be viewed at Research Gate (https://www.researchgate.net/profile/James-Walker-46) where 210

[21] BSI, 'BS 8580-2:2022 - Risk Assessments for *Pseudomonas Aeruginosa* and Other Waterborne Pathogens. Code of Practice. Https://Standardsdevelopment.Bsigroup.Com'.
[22] BSI, 'BS 8680 - Water Quality. Water Safety Plans. Code of Practice 2020'.
[23] ESGLI, 'ESGLI Guidance for Managing Legionella in Dental Water Systems during the COVID-19 Pandemic 2020'.
[24] ESGLI, 'ESGLI Guidance for Managing Legionella in Hospital Water Systems during the COVID-19 Pandemic 2020'.
[25] ESGLI, 'ESGLI Guidance for Managing Legionella in Nursing & Care Home Water Systems during the COVID-19 Pandemic 2020'.

research items are listed. My most recent book is entitled “Safe Water in Healthcare” and was published in March 2023.

1.1.19. In 2017 I took a two year career break from PHE. In 2019 I formed my consultancy “Walker on Water” and was approached by the Scottish Hospitals Inquiry in 2022 who were looking to engage an expert in water microbiology.

1.1.20. The Inquiry is investigating issues that arose from the planning, design, construction and management of the water and waste-water system of the QEUH and RHC. Particular issues arose related to waterborne pathogens and hospital acquired infections (HAI).

1.1.21. As a water microbiologist I have used my expertise and experience to assist the Inquiry by assessing the microbiological status of the water and waste water system in the QEUH and RHC from the point at which patients’ occupation took place. This included assessing and understanding transmission routes through which the patients were exposed from the water and waste-water systems. I understand my duty to be impartial in presenting and assessing that evidence and that my expert opinion would help the ‘court’ with its task.

1.1.22. The key questions which I have used my expertise and experience to assist the Inquiry are as follows:

1. *From the point at which there were patients within the QEUH/RHC was the water system (including drainage) in an unsafe condition, in the sense that it presented an additional risk of avoidable infection to patients?*

2. *Is the water distribution system no longer in an unsafe condition in the sense that it now presents no additional avoidable risk of infection?*

1.1.23. A number of ancillary questions were provided by the Inquiry

3. *In what ways did the issues narrated in the History of Infection Concern impact upon patients?*

4. *Did the hospital’s proximity to the Shieldhall waste water treatment works create a risk of infection to patients?*

5. *In relation to the reporting of Healthcare Associated Infections, what lessons have been learned from the experiences within the QEUH; what remaining or additional issues require to be addressed?*

6. *What contribution to the provision of unsafe features of the water and ventilation systems, and to the exposure of patients to these unsafe features, was made by the following arrangements for delivery of the hospital; how might that contribution have been avoided; what has been done to prevent this happening again:*

7. *The frameworks and arrangements of the sort mentioned in Term 2 put in place by public bodies to deliver the key stages of the project;*

8. *The arrangements made within GGC for delivery of the project in relation to (a) governance, (b) operational management and (c) provision of information by/to key stakeholders and advisers;*

9. *The arrangements of the sort referred to in Term 6 made by GGC regarding (a) inspection and testing, (b) commissioning, validation and verification and (c) the provision of information and training to end users about operation and maintenance; and*

10. *The arrangements in place at the time as regards governance, oversight and support of the project by national public bodies?*

11. *What contribution to the provision of unsafe features in the water and ventilation systems, and to the exposure of patients to these, was made by failures to raise concerns about those features including as regards impacts upon patients; whether that came about as a result of deliberate act; and what arrangements including policy or culture there was within the organisation in question to encourage and enable the raising of such concerns?*

1.1.24. I am clear as to what my duties include in assisting the Inquiry in an impartial manner.

1.1.25. I acknowledge and understand that it is my duty, both in preparing reports and in giving oral evidence, to assist the Inquiry on matters within my field of expertise and that I will continue to comply with that duty.

1.1.26. I have no connection, personal or otherwise, to any core participant in the Inquiry other than that which I have declared in this report.

1.1.27. I declare that I have no financial or economic interest in the outcome of the Inquiry.

1.1.28. I acknowledge and accept the necessity of expressing an independent opinion which is the product of my own consideration and that I have complied with the duty to do so.

1.1.29. I acknowledge the duty to set out all material facts, assumptions, methodology, or other matters upon which my views and opinions are based, including such matters as may detract from the opinion formed, and that I have complied with that duty.

1.1.30. I acknowledge the duty to address only areas within my own area of expertise and that I have made it clear when a particular question or issue falls outside my expertise and that I have complied with that duty.

1.1.31. I acknowledge, understand and accept the obligation to state if my opinion is not properly researched because of insufficient data are available and to give an indication that the opinion is no more than provisional, and have done so in my report where appropriate.

1.1.32. I acknowledge, understand and accept the obligation to indicate if any opinion I have expressed is qualified, or subject to revision, and have done so in my report where appropriate.

1.1.33. I acknowledge, understand and accept that I should, at the earliest opportunity after completing the report, indicate if, for any reason, including as a result of discussions with other experts, my views have been altered or the report requires any correction or qualification, and if so, in what area, and I shall comply with that duty.

2. Executive Summary and Conclusion

2.1. Background

2.1.1. I was invited in 2022 to undertake a historical review of the water and waste-water system from the point at which patients started to occupy the new hospital. This report represents my assessment of the water and wastewater system at the Queen Elizabeth University Hospital and Royal Hospital for Children in Glasgow.

2.1.2. Concerns about contamination of the water system during building, commissioning and prior to occupation by patients of the QEUH and RHC in June 2015 have been reported in other publications and are not included this expert report.

2.1.3. In November 2019 NHS GGC was escalated to Stage 4 of NHS Scotland's National Performance Framework because of infection incidents at the QEUH and the RHC. Reports indicated that a high number of children and young adults experienced episodes of infection due to Gram-negative environmental (GNE) bacteria, from 2015 to 2019.

2.1.4. NHSGGC investigated the contaminated water system and drainage system across the Queen Elizabeth University Hospital (QEUH) and Royal Hospital for Children (RHC) using NHS GGC laboratories as well as independent laboratories and multiple reports were published between 2015 and 2023.

2.1.5. This expert report covers the period in 2015 when patients started to occupy the site through to 2023. I was asked to:

- Describe the QEUH and RHC water and drainage system when patents started to occupy the buildings
- Discuss what is meant by a water and wastewater system that is unsafe in terms of creating an avoidable additional risk to patients
- Identify the key aspects of the QEUH and RHC water and wastewater system that created a risk to patients
- Assess whether the water system is no longer in an unsafe condition in the sense that they now present no additional avoidable risk of infection

2.1.6. I have set out my answer to the key questions (as set in paragraph 1.1.22 above) throughout this report as I address particular aspects of the water and waste water system, but my overall findings in relation to the water and waste water systems at the QEUH and RHC are as follows:

2.1.7. As waterborne healthcare associated infections are preventable then duty holders, including employers, those in control of premises and those with health and safety responsibilities for the QEUH and RHC hospital water and wastewater systems are required to comply with their legal duties [26]. These legal duties are

[26] HSE (n 19).

defined in the HSE Legionnaires' disease, The control of Legionella bacteria in water systems - Approved Code of Practice and guidance regulation.

2.1.8. The lack of timely and effective management of the water system, e.g. not rectifying high risk issues (requiring remedial action as soon as possible by senior management) identified in the DMA 2015 [27] risk assessment resulted in unsafe water and waste systems. Patients were therefore at an increased risk of infection and exposed to a range of water borne pathogens.

2.1.9. **Evidence provided through risk assessments [28] [29] demonstrated that there was a lack of planned preventative maintenance of critical components as well as insufficient inspection and servicing of the water system and associated equipment from the period when patients started to occupy the site in 2015 and through to 2018**.

2.1.10. **The 2015 Legionella risk assessments demonstrated that the management of the water system was not compliant with guidance (HSE and SHTM) from the time that patients occupied the QEUH and RHC in 2015. This non-compliance was still evident in risk assessments and Authorising Engineer audit reports in 2017 [30] (lack of a 2016 report was non-compliant). In 2023 it was identified that the previous site risk assessment (RA) carried out in 2018 was not compliant with current guidance** [31].

2.1.11. **The 2017 Legionella risk [32] assessment identified the same problems as reported in 2015 suggesting that those high risk issues were not addressed as soon as possible by senior management. These issues included debris (sponges) in the cold water tanks, and hot water operating at lower than recommended temperatures and the presence of flexible hoses and non-flow through expansion vessels. Significant non-compliant findings were also identified in the Written Scheme which had not been updated, the lack of a planned preventative maintenance programme for the water tanks and taps and retrograde contamination from drains**.

2.1.12. **The 2017 DMA Legionella risk assessment continued to classify the water system and control regime as high risk with ongoing instances of low hot water temperatures in wards 2A/2B and thermal gain in the cold water system with a continued lack of cleaning and disinfection of showers and tap components such as filter strainers**.

[27] DMA, 'L8 Risk Assessment NHS GGC South Glasgow University Hospital. 2015.'
[28] DMA, 'L8 Risk Assessment NHS GGC South Glasgow University Hospital. 2015.' (n 27).
[29] DMA, 'Legionella Risk Assessment QEUH (Adult) Hospital and the Adjoining RHC 2017'.
[30] D Kelly, 'Legionella Control AE Audit – Queen Elizabeth University Hospital – 2017'.
[31] D Kelly, 'Legionella Control AE Audit – Queen Elizabeth University Hospital 2023'.
[32] DMA, 'Legionella Risk Assessment QEUH (Adult) Hospital and the Adjoining RHC 2017' (n 29).

2.1.13. Microbiological evidence from NHS GGC, hospital microbiological laboratories and independent microbiological laboratories were reviewed from the time that patients started to occupy the QEUH and RHC in 2015 through to 2023 [33] [34].

2.1.14. The published NHS GGC [35] and independent microbiological reports [36] [37] [38] identified that the water and waste system from the cold water storage tanks, expansion vessels through to the taps, showers, drains and ancillary equipment was microbially contaminated with a wide range of Gram-negative waterborne pathogens and biofilm. The presence of the microbial pathogens and biofilms in the water system peripheral components presented a risk to the patients in the QEUH and RHC.

2.1.15. Microbiological evidence demonstrated that there was wide scale systemic microbial and biofilm contamination of the entire water system from the water tanks through to the outlets and waste system to which the patients were exposed. Microorganisms identified in the water and biofilms in the QEUH and RHC had been identified in published literature as being associated with HAI.

2.1.16. Microorganisms detected in the QEUH and RHC water samples and biofilms from the cold water tanks, expansion vessels, showers and hoses as well as taps were similar strains to those causing infections in patients. In some cases the patient strains matched the water isolate providing evidence of a link between the water and the patient infection.

2.1.17. Following recognition of the systemic contamination of the entire water and waste system NHS GGC undertook remediation strategies to address the presence of microorganisms within the water and wastewater system. Remediation strategies involved both physical and chemical treatment of the water and waste system as well as improving infection control practices to address the waterborne infection risk to patients.

2.1.18. **The implementation of temperature control, application of biocides (including continual dosing of chlorine dioxide), planned preventative maintenance, fitting of an additional ultrafiltration system, point of use filters as well as the introduction of extensive infection and control strategies to prevent patient exposure to water and waste water provides evidence that water was recognised as a risk to patients**.

[33] DL Chaput, 'Microbiological Testing (2015-2020) of Water and Environmental Samples from the QEUH (Adults) and RHC, Overview of Sample Numbers and Test Results.' [2023] NHS GGC.
[34] DL Chaput, 'Dr Dominique Chaput Raw Data Files 2023 - Excel Spread Sheets Supplied by NHS GGC'.
[35] Chaput, 'Microbiological Testing (2015-2020) of Water and Environmental Samples from the QEUH (Adults) and RHC, Overview of Sample Numbers and Test Results.' (n 33).
[36] Intertek, 'Intertek Report Number ITSS-0718-0001W plus per Floor Contamination of Flow Straighteners Debris and Sponges 2018'.
[37] Intertek, 'Intertek ITS 1018-0001 2018 Microbiological Analysis of Flow Straighteners over Time New to Three Months'.
[38] Intertek, 'ITSS- 0719-0001 Expansion Vessel Investigation Report for QUEH Glasgow. 2019'.

2.1.19. However, I have identified several areas that are currently of concern that have been previously reported through authorising engineers (water) reports, risk assessments, Healthcare Improvement Scotland reports and Expert Group (EG) visits and include (but are not limited to):

- **Frequency and timeliness of risk assessments that are reflective of changes in the hospital water and wastewater system.**
- **High counts and heavy biofilm contamination in the last two metres including pipework and tap components (Horne Optitherm taps) related to frequency of use, temperature control of water to the outlets that pose a risk through exposure of unfiltered water.**
- **Training and education of staff to recognise the risks posed from water and wastewater including preparation of sterile medical equipment within the splash zone, cleaning of tracheostomies in wash hand basins, difficult to access sink units, clutter and medical equipment stored in or around sink units and damaged sealant in and around sinks/showers that will result in biofilm accumulation.**
- **Concerns with current wash hand basins and sink use including splashing of equipment from sinks, accessibility, clutter resulting in accumulation of moisture and biofilm growth under equipment and containers left within the splash zone of sinks, drains requiring cleaning and broken sealant that traps biofilm**.

2.2. Methodology for expert report

2.2.1. The aims of this expert report were to examine the issues in relation to water contamination occurring following the occupation of the hospital by patients and to assess the microbial contamination of the water and waste water in the QEUH and RHC.

2.2.2. A number of areas were researched including:

- Background and history of the QEUH campus;
- Design, building, commissioning and maintenance hospital with specific reference to the built environment and the water system following patient occupation;
- Operation and management of the water system from patient occupation and how this may have led to an unsafe water system and patient exposure;
- Review of water microbiology and waterborne pathogens associated with hospital acquired infections;
- Exposure and transmission routes of waterborne pathogens;
- Identification of unsafe parameters in the as built QEUH and RHC from a historical perspective that would lead to microbial contamination of the water system, components and drains;

- Implications of contaminated water, outlets, drains and equipment and how these could be unsafe for patients in terms of exposure and transmission routes;
- The present-day assessment and identification of waterborne pathogens and biofilms that would lead to exposure to patients and whether the water and waste water system were now safe for patients; and
- Recommendations and action plans and progress against them from previous published risk assessments, audits, microbiological results related to the issues under investigation.

2.2.3. Information gathered for this expert report includes several key elements including:

- Previously published reviews directly related to the QEUH and RHC;
- Published reviews on water borne pathogens and their implication for hospital acquired infections;
- Scientific publications from peer review journals;
- Reviewing the documentation related to the design, building and commissioning;
- Assessing documentation and standards as available at the time of the design, construction, and commissioning of the QEUH campus;
- Accessing documentation related to the operation and management of the water system and drains since handover including external risk assessments; and
- Understanding the remedial measures that have been undertaken in relation to the water and drainage systems.

2.2.4. A site visit to the QEUH and RHC was undertaken by the Expert Group in March 2023 and I also visited in September 2023.

2.3. Methodology for assessing unsafe water systems

2.3.1. Guidance is available for Scottish hospitals to assess the risks of waterborne pathogens such as *Legionella* and *Pseudomonas aeruginosa* including:

- L8 ACOP Legionnaires' disease: The control of Legionella bacteria in water systems [39];
- HSG274 Part 2 Legionnaires' disease: The control of Legionella bacteria in hot and cold water systems [40] ; and
- Scottish Health Technical Memorandum 04-01 (A-G) [41].

2.3.2. The above well-established documents provide comprehensive advice and guidance about the governance, legal requirements, design applications, maintenance and operation of hot and cold water supply, storage and distribution systems including the risk from outlets in hospitals.

[39] HSE (n 19).
[40] HSE (n 20).
[41] HFS, 'Water Safety (SHTM 04-01) Part A-G.'

2.3.3. Where there are susceptible individuals e.g. in acute hospital settings including those in paediatric haemato-oncology units at risk of infection all aspects of the guidance may need to be followed.

2.3.4. Hospital water supplies are not sterile. However, waterborne infections can be prevented by careful design, implementation of control strategies, planned preventative maintenance schedules, due diligence, governance, training and education.

2.3.5. Current statutory legislation [42] [43] requires both management and staff to be aware of their individual and collective responsibility for the provision of wholesome, safe hot and cold water supplies, and storage and distribution systems in healthcare premises.

2.3.6. The HSE have identified contributing factors in outbreaks of waterborne infections where water systems were considered unsafe including inadequate management, lack of training and poor communication [44]. Therefore it is important that all those people involved in assessing risk and applying precautions are competent, trained and aware of their responsibilities.

2.3.7. Hospital water systems could be considered as being unsafe where issues have been identified with the following [45] [46]:

- governance and management
- competent personnel
- appropriate and timely risk assessment
- addressing gaps in risk assessments
- addressing high risk remedial actions in risk assessments
- Written Scheme
- authorised person
- schematics
- paperwork and records
- planned preventative maintenance programmes such as servicing equipment
- removal of taps that are not compliant with guidance e.g. Horne Optitherm taps
- control strategies e.g. maintenance of hot water temperature
- annual authorising engineer audits
- training of Authorising Person Water
- training of estates and facilities as well as clinical staff to understand exposure risks water systems including taps, basins, sinks, showers and drains
- understanding of risks of preparing intravenous medication within splash risk
- the clinical wash hand basins/sinks

[42] HSE (n 19).
[43] HSE (n 20) 2.
[44] HSE (n 20) 274.
[45] HSE (n 20).
[46] HSE (n 19).

- risk awareness of cleaning patient medical equipment in wash hand basins
- understanding of out of specification microbiological results demonstrating high counts and heavy biofilm contamination
- coordination between inhouse estates and contractors
- of clarity on who was responsible for flushing of little used outlets
- recognition of little used clinical/patient wash hand basins and sinks
- systemic contamination of the water and waste system with a range of Gram-negative microorganisms that have been associated with patient infections
- attendance at water safety group meetings

2.3.8. The HSE have identified that inadequate management, lack of training and poor communication are all contributory factors in outbreaks of Legionnaires' disease [47].

2.3.9. The above examples of unsafe issues have been identified within the large number of documents that have been supplied relating to the QEUH and RHC. This expert report contains examples of the above unsafe issues in greater detail as cited in risk assessments, authorising engineer audit reports, microbiological reports and Healthcare Improvement Scotland reports. The above are given as examples only and is not an exhaustive list but are discussed in greater detail within this report.

[47] HSE (n 19).

3. Background history

3.1. Brief history of the QEUH campus

3.1.1. This background information has been compiled from a wide range of documents made available to me and represents my understanding of the hospital and water system and wastewater as described in those documents from the point at which patients occupied the site.

3.1.2. The QEUH is an acute hospital campus built on the site of the former Southern General Hospital and is operated by NHS Greater Glasgow and Clyde (NHS GGC. This was a long term project spanning 13 years from initial inception in 2002 to handover and opening in 2015 [48].

3.1.3. The QEUH is a 14-floor hospital with 1109 beds with 100% ensuite single side rooms with en-suite shower and toilet facilities on (with the exception of critical care). The campus has a total of 1,860 beds with a full range of healthcare specialities, including renal medicine, transplantation, vascular surgery and diagnostic services and a major emergency department. The hospital was handed over to the Board on 26th January 2015 with patient migration commencing from 24th April 2015 until 7th June 2015 [49].

3.1.4. The Royal Hospital for Children, while retaining a separate identity, is adjoined and integrated with the adult hospital with 256-beds and 5 floors [50]. Around 80% of the paediatric beds are single en-suite rooms for children and young people up to the age of their 16th birthday along with designated space for overnight accommodation for parents.

3.1.5. The hospital campus also retains a number of other services in adjacent facilities including maternity services, the Institute of Neurological Sciences, and the Langlands Building for medicine of the elderly and rehabilitation. The RHC was also handed over to the Board on 26th January 2015 and migration of patients occurred between 10th and 14th June 2015. Both QEUH and RHC were fully occupied from 15th June 2015 [51].

3.1.6. The retained buildings on the QEUH site include the Maternity Unit, the Institute of Neurological Sciences, the Langlands Unit for medicine of the elderly, and a laboratory building opened in 2012 [52].

3.1.7. While some parts of the QEUH campus have their own distinct identity and dedicated specialist staff, such as the Royal Hospital for Children, each is completely integrated with linkages for patient transfer, diagnostic services, emergency care and

[48] I Storrar and A Rankin, 'Report on the Findings of the NHS GGC: QEUH/RHC Water Contamination Incident and Recommendations for NHS Scotland 2018'.
[49] Storrar and Rankin (n 48).
[50] Storrar and Rankin (n 48).
[51] Storrar and Rankin (n 48).
[52] Storrar and Rankin (n 48).

even a rapid access lift from the emergency helicopter pad on the roof of the adult hospital [53]. The children's hospital is not only linked to the adult hospital but also both the adult and children's hospitals are linked to the maternity building and to the Neurosciences Institute.

3.1.8. The QEUH hosts services relocated from the Western Infirmary and the Victoria Infirmary as well as some services from the Glasgow Royal Infirmary (GRI) and a range of inpatient services from Gartnavel General Hospital. In addition, the Royal Hospital for Children (RHC) which was based at Yorkhill in the west end of Glasgow, was relocated to a building adjoining the adult hospital and renamed the "Royal Hospital for Children, Glasgow" [54].

3.2. Construction of the QEUH campus

3.2.1. NHS Greater Glasgow undertook a review to develop a strategy to address a number of challenges relating to the delivery of acute services. This culminated in an Acute Services Strategy being approved in January 2002, which NHS Greater Glasgow planned to deliver across a number of phases. One of these phases constituted the significant reconfiguration of services provided at the Southern General Hospital site, seeing the co-location of adult, children, and maternity services [55].

3.2.2. In 2006, NHS Greater Glasgow absorbed a large portion of the former Argyll and Clyde Health Board and took on the designation NHS Greater Glasgow & Clyde (NHS GGC) [56].

3.2.3. In 2008, NHS GGC submitted an outline business case to the Scottish Government proposing the creation of a new acute hospital to replace facilities at various aging Glasgow hospital sites (Table 1) [57]. The project was initially to be procured through a Public Private Partnership (PPP) route where a delivery partner would design, finance, build, and maintain the facility for 25 years during which NHS GGC would pay back all project costs. However, the model for the project contract changed to a Two Stage Design & Build route using public capital funding, preserving the construction budget.

3.2.4. Brief history of the key points in the development and building of the QEUH campus [58] .

[53] Brookfield, 'Design Strategies for the New South Glasgow Hospitals. SECTION 3.1: ARCHITECTURAL DESIGN STRATEGY 3.1 2009'.
[54] S Stevens, G Evans and MH Wilcox, 'Queen Elizabeth University Hospital and Royal Hospital for Children Case Note Review Overview Report March 2021.'
[55] NHS GGC, 'Greater Glasgow Health Board Acute Services Strategy – Phase II. NEW SOUTH GLASGOW HOSPITALS PROJECT. AGREEMENT FOR THE APPOINTMENT OF TECHNICAL ADVISERS. May 2007. OJEU Ref :2007/S 97-119682. .'
[56] NHS GGC, 'Greater Glasgow Health Board Acute Services Strategy – Phase II. NEW SOUTH GLASGOW HOSPITALS PROJECT. AGREEMENT FOR THE APPOINTMENT OF TECHNICAL ADVISERS. May 2007. OJEU Ref :2007/S 97-119682. .' (n 55).
[57] NHS GGC, 'New South Glasgow Hospitals Full Business Case. SHI Objective Connect.'
[58] SHI, 'Summary of "Narrative Concerning the Reference Design of the RHSC/DCN" from 2010 to 2015 ART RHCYP Archive'.

Table 1 – Build stages

Date	Activity
April 2008	Outline Business Case
Oct 2010	Full Business Case
Dec 2010	Design and build of QEUH and RHC
Jan 2015	Completion certified of QEUH and RHC
To Feb 2015	Commissioning of the water system
Feb 2015	Handover of the hospital
April 2015	Migration of Adult hospital commences

3.2.5. September 2008 Currie & Brown were appointed as Lead Consultant on a wide-ranging role covering design, project management, design support services, and site supervision [59]. The Lead Consultant then prepared the Employer's Requirements to capture NHS GGC's brief for the project.

3.2.6. In December 2009 following a tender process known as 'Competitive Dialogue' Brookfield Multiplex ("Multiplex") were appointed as the main contractor to undertake design works and secure the necessary planning consents for the Full Business Case (FBC) to be approved [60].

3.2.7. During this time NHS GGC amended the Lead Consultant's scope to reflect the finalised delivery plan and discontinued their design support services. Thereafter, the Project Board appointed a supervisor (previously known as Capita Symonds, now Capital Property and Infrastructure Limited) to undertake a review of the design and monitor that the works were installed and commissioned in line with the various construction contracts [61].

3.2.8. At the time of construction the hospital was Scotland's largest ever publicly funded NHS construction project, with £842 million allocated to the build [62]. Originally termed South Glasgow University Hospital, it was granted the right to use the name "Queen Elizabeth University Hospital" by HM Queen Elizabeth II.

3.2.9. In 2011 construction commenced and the hospital was handed over to the Board on 26th January 2015 with patient entry commencing from 24th April 2015 until 7th June 2015 and the QEUH became fully operational during summer 2015 [63].

[59] NHS GGC, 'New South Glasgow Hospitals Full Business Case. SHI Objective Connect.' (n 57).
[60] NHS GGC, 'New South Glasgow Hospitals Full Business Case. SHI Objective Connect.' (n 57).
[61] Storrar and Rankin (n 48).
[62] HPS, 'Summary of Incident and Findings of the NHSGGC: QUEH/RHC Water Contamination Incident and Recommendations for NHS Scotland. Final V2'.
[63] Storrar and Rankin (n 48).

3.2.10. The retained buildings from the former Southern General Hospital, notably the Institute of Neurological Sciences, also underwent an upgrade to bring their appearance in-line with the new hospital buildings. The contract value of this work was around £10 million. The three Glasgow universities also have extensive laboratory, research and teaching facilities on the site.

3.2.11. A physical above-ground link for patients and staff from the main adult building into the Maternity and Neurosciences Institute buildings was constructed, allowing most of the campus to be accessible without going outside.

3.3. Overview of water contamination before and after handover

3.3.1. The following is a brief overview of concerns relating to the water system and microbiological contamination of the water system before and after handover.

3.3.2. Prior to handover problems were identified in the water system design (over capacity and lack of detail in water components), build (unhygienic plumbing practices, deadlegs, stagnation after filling between build and commissioning, inappropriate tap fittings), commissioning (inappropriate concentrations and contact time period and high total viable counts post commissioning) and pre-handover (lack of written scheme and training of NHS GGC).

3.3.3. Following the water microbiology testing in December 2014, NHS GGC refused to accept the handover of the hospital and insisted that disinfection of the water was undertaken prior to the handover taking place to improve the microbiological quality of the water.

3.3.4. There was a lack of NHS GGC staffing and training to assess and manage the water system before and after handover.

3.3.5. Through the different stages of pre- (2011-2015) and post-handover (2015 to 2018) there was a lack of planned preventative maintenance of critical components in the water as well as insufficient inspection and servicing of water system.

3.3.6. Post-handover problems were identified as part of an L8 Legionella Risk Assessment [64] including a lack of planned preventative maintenance, issues with temperature control, deadlegs (stagnant water) in the water system, maintenance of temperature control, microbial contamination from the water tanks through to the tap outlets, use of flexible hoses, lack of access for maintenance, presence of biofilm in the water system and a lack of a written scheme.

3.3.7. Microbiological assessment of plumbing components [65] [66] indicated that there was extensive microbial contamination and biofilm formation on components including

[64] DMA, 'L8 Risk Assessment NHS GGC South Glasgow University Hospital. 2015.' (n 27).
[65] Intertek, 'ITSS- 0719-0001 Expansion Vessel Investigation Report for QUEH Glasgow. 2019' (n 38).
[66] Intertek, 'Intertek Report Number ITSS-0718-0001W plus per Floor Contamination of Flow Straighteners Debris and Sponges 2018' (n 36).

water tanks, expansion vessels, tap fittings (Horne Engineering) and drain components [67].

3.3.8. NHS GGC identified a number of bloodstream infections within ward 2A Royal Hospital for Children (known as the Schiehallion Unit).

3.3.9. Independent risk assessments [68] [69], scientific investigations [70] and extensive water testing following handover (2015 to 2018) [71] identified a range of Gram-negative microorganisms and biofilm associated with components in the water tanks, expansion vessels, tap outlets, showers and drain components indicating that the water system was contaminated with Gram-negative waterborne pathogens.

3.4. Brief overview of the remedial works

3.4.1. The Legionella Risk Assessment by DMA carried out in 2015 identified a number of defects and problems with the water system that required significant investigation and remedial action as soon as possible [72].

3.4.2. When DMA carried out a second risk assessment in 2017 [73] many of the significant high risk issues identified in the 2015 DMA [74] had not been addressed or remediated.

3.4.3. Over time substantial remedial and precautionary measures related to the water system were implemented at the QEUH and RHC by NHS GGC, as a response to issues raised in risk assessments [75] [76]. A number of the remedial measures were related directly to treating the water system and others were related to infection prevention and control measures to reduce the exposure of patients to waterborne pathogens present in the water system (Table 2). Each of these remedial measures implemented by NHS GGC over time will be discussed in greater detail (section 6 of this report).

3.4.4. Examples of remedial actions to control microbial contamination at the QEUH and RHC.

[67] Intertek, 'Intertek Report on Glasgow Royal Infirmary'; Intertek, 'Intertek Report Number ITSS-0718-0001W plus per Floor Contamination of Flow Straighteners Debris and Sponges 2018' (n 36); Intertek, 'ITSS- 0719-0001 Expansion Vessel Investigation Report for QUEH Glasgow. 2019' (n 38).
[68] DMA, 'L8 Risk Assessment NHS GGC South Glasgow University Hospital. 2015.' (n 27).
[69] DMA, 'Legionella Risk Assessment QEUH (Adult) Hospital and the Adjoining RHC 2017' (n 29).
[70] Intertek, 'Intertek Report Number ITSS-0718-0001W plus per Floor Contamination of Flow Straighteners Debris and Sponges 2018' (n 36).
[71] Chaput, 'Microbiological Testing (2015-2020) of Water and Environmental Samples from the QEUH (Adults) and RHC, Overview of Sample Numbers and Test Results.' (n 33).
[72] DMA, 'L8 Risk Assessment NHS GGC South Glasgow University Hospital. 2015.' (n 27).
[73] DMA, 'Legionella Risk Assessment QEUH (Adult) Hospital and the Adjoining RHC 2017' (n 29).
[74] DMA, 'L8 Risk Assessment NHS GGC South Glasgow University Hospital. 2015.' (n 27).
[75] DMA, 'L8 Risk Assessment NHS GGC South Glasgow University Hospital. 2015.' (n 27).
[76] DMA, 'Legionella Risk Assessment QEUH (Adult) Hospital and the Adjoining RHC 2017' (n 29).

Table 2 – Remedial Actions

Activity of Remedial Actions related to the water system	**Reference**
Issues identified in the Capita Symons supervisors' reports during the build phase	Capita Symonds, 'NEW SOUTH GLASGOW HOSPITAL ADULT AND CHILDREN'S HOSPITAL AND ENERGY CENTRE. NEC 3 SUPERVISORS REPORT NO. 26. May 2013' [2013] SHI.
Recommendations (169 separate items) from the DMA report e.g. uncapped pipe ends and spurs that were too long ( ), replacement of flexible hoses	DMA, 'L8 Risk Assessment NHS GGC South Glasgow University Hospital. 2015.'; DMA, 'Legionella Risk Assessment QEUH (Adult) Hospital and the Adjoining RHC 2017'.
Cleaning and disinfection of the cold water storage tanks	I Storrar and A Rankin, 'Report on the Findings of the NHS GGC: QEUH/RHC Water Contamination Incident and Recommendations for NHS Scotland 2018'.
Improving the effectiveness of the Energy centre to achieve appropriate hot water temperatures	Storrar and Rankin.
Implementation of point of use filters for aps and showers across the hospital	S Stevens, G Evans and MH Wilcox, 'Queen Elizabeth University Hospital and Royal Hospital for Children Case Note Review Overview Report March 2021.'
Increased number of water sampling and microbiological testing	DL Chaput, 'Microbiological Testing (2015-2020) of Water and Environmental Samples from the QEUH (Adults) and RHC, Overview of Sample Numbers and Test Results.' [2023] NHS GGC.
Installation of a third ultrafiltration system	NHS GGC, 'Response to RFI-8 Filtration. SHI Objective Connect'. No date on the document
Localised chemical treatment system of pipework and outlet including dosing with silver hydrogen-peroxide	Gov Scot, 'Timeline of Incidents in the Queen Elizabeth University Hospital and Royal Hospital for Children for the Period 2015 to 2019. Https://Www.Gov.Scot'.
Provision of portable hand wash basins	Stevens, Evans and Wilcox. (2021)

Activity of Remedial Actions related to the water system	**Reference**
Augmented chlorination of the entire water supply	Stevens, Evans and Wilcox. (2021)
Widespread replacement of taps other fittings e.g. basins	T Inkster and others, 'Investigation and Control of an Outbreak Due to a Contaminated Hospital Water System, Identified Following a Rare Case of *Cupriavidus Pauculus* Bacteraemia.' [2021] J Hosp Infect.
Drain cleaning and replacement of waste pipes and hydrogen Peroxide Vapour cleaning of drains. Signs were put up warning families and staff not to put liquids (tea, coffee etc) down clinical hand wash basins.	Inkster and others, 'Investigation and Control of an Outbreak Due to a Contaminated Hospital Water System, Identified Following a Rare Case of *Cupriavidus Pauculus* Bacteraemia.' 2021
Remediation of drains associated with sinks and hand wash basins	Inkster and others, 'Investigation and Control of an Outbreak Due to a Contaminated Hospital Water System, Identified Following a Rare Case of *Cupriavidus Pauculus* Bacteraemia.' 2021
Full scale dosing system using chlorine dioxide	QEUH Review, 'QEUH Hospital Independent Review U Pdate #2. Https://Www.Nhsggc.Org.Uk/Media/258434/Qeuh_independent_review_bulletin_002.Pdf'. 2019
Extensive infection prevention and control measures to reduce exposure of patients to contaminated water including Immunocompromised patients were not to wash using water from sinks or showers, bottled water for washing and teeth brushing. Bone marrow transplant patients were to use sterile (not bottled) water. Parents and staff could use sinks but had to use hand gel thereafter. All rooms in the RHC housing immunocompromised patients were to receive twice daily Actichlor cleans. Nursing staff had to use additional hand hygiene before performing line care.	Stevens S, G Evans and MH Wilcox, 'Queen Elizabeth University Hospital and Royal Hospital for Children Case Note Review Overview Report March 2021.'
Cleaning, sampling and taking out of use the dishwashers	Storrar and Rankin.2018
Removal of water coolers from patient areas	Storrar and Rankin.2018
Closing of the Schiellallion unit Wards 2A and 2B (with relocation of services to Ward 6A and 4B) to refurbish	Stevens S, G Evans and MH Wilcox, 'Queen Elizabeth University Hospital and Royal

Activity of Remedial Actions related to the water system	**Reference**
	Hospital for Children Case Note Review Overview Report March 2021.'
Prescribing prophylaxis (Ciprofloxacin) to high risk patients on Wards 2A and 2B246	Stevens S, G Evans and MH Wilcox, 'Queen Elizabeth University Hospital and Royal Hospital for Children Case Note Review Overview Report March 2021.'

4. Description of the water and drainage system from patient occupation

4.1 Introduction

4.1.1. This report provides an overview and description of the water and waste-water system as it is understood to have been at the time patients began to occupy the QEUH and RHC. Descriptions, diagrams and photographs have been used to describe the water system as built at the time.

4.1.2. Other sections discuss the impact on microbial growth as a result of how the water system was managed and how this impacted on the potential microbial exposure, transmission routes to patients and infections that may be related to the waterborne pathogens in the water and drainage system.

4.2. Applicable standards used

4.2.1. NHS GGC described the design parameters and guidance in their Employer's Requirements (ERs). These documents (Table 3) set out the legal requirements and guidance which had to be observed with respect to water systems during design, construction, commissioning and maintenance in accordance with all appropriate Scottish Hospital Technical Memoranda, Codes of Practice and relevant British and European Standards, Scottish Water Regulations (Byelaws) and to the approval of the local Water Authority and Appendix A (Table 3). However, at the time of publication some documents referred to in the Employer's Requirements were incorrectly referenced, superseded at the time of construction and therefore, were misleading.

4.2.2. Requirements of legislation.

Regulations and industry standards specifications to which the hot and cold water system were designed, built and commissioned. These documents were originally cited in the Employer's Requirements[77], however, dates were not provided in that original document. Many of the documents referred to in this section were incorrectly referenced [78], superseded at the time of construction and therefore could be misleading. Being historical, archived or superseded documents may mean that the dates referenced below are not necessarily correct as very few dates if any were provided with these documents the Employer's Requirements[79].

[77] NHS GGC, 'NSGACL - ITPD Volume 2_iss1_rev1 Invitation to Participate in Competitive Dialogue Volume 2/1 Employer's Requirements (Hospitals)'.
[78] Storrar and Rankin (n 48).
[79] NHS GGC, 'NSGACL - ITPD Volume 2_iss1_rev1 Invitation to Participate in Competitive Dialogue Volume 2/1 Employer's Requirements (Hospitals)' (n 77).

Table 3. Relevant Documentation

Mandatory documentation	**Description**
HTM 02 Part A	Medical gas pipeline systems Part A 2012
SHTM 2027	Hot and cold water supply, storage and mains services 2011
HTM 04-01 Part A	Control of Legionella...drinking systems Part A (2008/2009)
HTM 04-01 Part B	Control of Legionella...drinking systems Part B (2008/2009)
Draft for Consultation SHTM 04-01 Part A	Control of Legionella...drinking systems Part A Published 2014
Draft for Consultation SHTM 04-01 Part B	Control of Legionella...drinking systems Part B Published 2014
SHTM 2030 (2001)	Washer disinfectors
	Part 1 Design considerations
	Part 2 Operational management
	Part 3 Validation and verification
HBN 00-02	Sanitary spaces (updated 2016)
SHTM 2010 (2001)	Sterilization: Parts 1 – 6 (incl)
SHTM 2031 (2001)	Clean steam for sterilization
SHTM 2040 (2011)	The control of legionellae in healthcare premises – a code of practice
	Part 1 Overview and management responsibilities
	Part 4 Validation and verification
	Part 5 Good practice guide
	Part 6 supplementary guidance applicable to intermittently used healthcare premises
	SHTM 2040 forms
SHTM 64	Sanitary assemblies 2009
The Water Supply (Water Fittings) Regulations 1999 and Water for Scotland 2nd Edition 2007	Water Supply Fittings

In the Employer's Requirement, the Board set out what it considered to be NHS Guidance documentation.

Document	**Title**
HSE Document L8	Legionnaires' disease. The control of Legionella bacteria in water systems. Approved Code of Practice. Updated 2013
SHGN (1998)	"Safe" hot water and surface temperatures (The Health Guidance Note HGN "Safe Water Temperatures"

Document	Title
	noted was incorporated into SHTM 04-01.)
SHTN 2	Domestic Hot and Cold Water Systems for Scottish Health Care Premises
SHTN 6	The Safe Operation and Maintenance of Thermostatic Mixing Valves
SHPN 03	General Design Guidance
SHPN 13 Part 2	Decontamination Facilities: Local Decontamination Units
SHPN 27	Intensive care unit
HBN 23	Hospital accommodation for children and young people
HBN 54	Facilities for cancer care centres

The Employer's Requirement noted that the Contractor shall comply with all Law and Consents and comply with the standards and documents as cited including:

Documentation related to all Law and Consents with standards and documents

- Health and Safety Legislation, including Construction (Design and Management) Regulations 2007;
- The Technical Standards complying with the Building Standards (Scotland) Regulations 1990 as amended by all subsequent Amendment Regulations;
- Disability Discrimination Act 1995;
- Current British Standards, European Standards, and Codes of Practice, as appropriate; [including BSG 6700, BS 8558, BSEN 15154-2 and BSEN 12845];
- The Board's Approved Codes of Practice, Procedure and Policy documents as listed in the site master plan;
- Control of Substances Hazardous to Health;
- Health Department Letters (or Management Executive Letters) as appropriate published by SEHD;
- NHS QIS (Quality Improvement Scotland) 2003;
- NHS Model Engineering Specifications;
- The Building (Scotland) Act 2003;
- The Building (Scotland) Regulations 2004;
- Requirements of the utilities companies;
- Building Research Establishment Digest Recommendations;
- Local Byelaw and Regulations;
- Scottish Centre for Infection and Environmental Health guidance / recommendations;
- All other bodies and authorities having jurisdiction;

- Standards for Intensive Care Units, A Joint Document for the Intensive Care Society and the Intercollegiate Board for Training in Intensive Care Me;
- National Overview – Adult Renal Services (March, 2003) NHS Quality Improvements Scotland;
- The higher European Pharmacolela (EP) XV1 standard :'Water for diluting concentrated haemodialysis solutions';
- ISO 13959: 'Water for haemodialysis and related therapies' or AAMI (Association for the Advancement of Medical Instrumentation) standards;
- European Renal Association Best Practice Guidance – 4th Edition 2007. NB New guidelines are due in 2009 and should be considered at that time:
- BREEAM Wat 1
  Low flow fixtures and fittings will be fitted in every ward, public area and staff accommodation:
- BREEAM Wat 4 Shut off valves are specified to the toilet blocks to reduce potable water consumption through leaks or faulty taps; and
- CIBSE Guide W BS EN 806 Specifications for installations inside buildings conveying water for human consumption.

4.3. Supply of wholesome water

4.3.1. Water delivered in Scotland by the water supplier is considered as "wholesome water" which is fit to use for drinking, cooking, food preparation or washing without any potential danger to human health [80].

4.3.2. The site water mains was supplied by Scottish Water to comply with the requirements of Water for Scotland 2nd Edition 2007, and to the requirements of the Water Authority.

4.3.3. The specification for the QEUH and RHC included the provision of [81] [82] [83] :

- Site wholesome water mains
- Filtered water storage tanks and raw water storage tanks
- Wholesome cold water
- Boosted wholesome water
- All domestic water shall be wholesome.

4.3.4. Wholesome water is not sterile and will contain microorganisms. Whilst wholesome water may be safe for most patients, the provision of the supply of this water in areas where vulnerable patients are present should be risk assessed to prevent infection in susceptible patient groups. Vulnerable patients may also be

[80] DWQR, 'The Water Supply (Water Quality) (Scotland) Regulations 2001 (Superseded)' [2001] DWQR.
[81] Wallace Whittle TUV SUD, 'TUV SUD Specification Hot and Cold Water Systems Rev C April 2014. Document Ref: ZBP-XX-XX-SP-500-103'.
[82] NHS GGC, 'NSGACL - ITPD Volume 2_iss1_rev1 Invitation to Participate in Competitive Dialogue Volume 2/1 Employer's Requirements (Hospitals)' (n 77).
[83] Brookfield (n 53).

present in non-high risk areas through the hospital and need to be identified and assessed on a case by case basis. The implications of water that is not wholesome will be discussed in other sections of this report. Where water systems are not managed according to guidance [84] [85] then that water will not remain wholesome and will present a risk to patients.

4.4. Overview of the cold water system

4.4.1. There are two incoming cold water mains that supply mains water to the filtration and storage tanks and the hot and cold water system located within the hospital basement (Figure 1). The incoming mains water is supplied to the raw water storage tanks before passing through the ultrafiltration plant and then to the filtered water storage tanks. The water was designed to be stored in a 'wholesome' condition in the filtered water storage tanks and is then distributed to all sanitary fitting points. There is not a separate drinking water distribution system for the hospital. The cold water passes through electronic water conditioning devices to reduce the build-up of scale within equipment and distribution systems. Water booster sets pump the filtered water from the filtered water storage tanks in the basement to the cold water distribution systems throughout the hospital and also supply the domestic hot water systems. At each floor, distribution branch pressure regulating valves, maintain similar water pressure at all levels in the building providing convenience of use and minimizing water consumption. All distribution systems were designed to be capable of being chemically cleaned and disinfected.

4.5. Overview of the domestic hot water system

4.5.1. The booster pumps supply cold water from the filtered water storage tanks to the domestic hot water systems. The domestic hot water is generated and stored within the building using calorifiers comprising buffer vessels linked to rapid recovery plate heat exchangers. The calorifiers are located within the plant rooms. The domestic hot water systems were configured with a pumped flow and return to maintain temperatures within the system. The pumped return system was designed to minimise "dead legs" and reduce water consumption by providing the correct temperature of water at the outlet with minimum delay. The hot water storage system was designed to be capable of achieving higher storage temperatures for carrying out a pasteurising process to minimise contamination from Legionella bacteria within the storage vessel. The distribution system was designed to minimise conditions of low flow within pipework. The hot and cold water system pressures were designed to be equalised at each service outlet for successful blending of hot and cold water through anti-scalding devices (thermostatic valves or tap) prior to use. The anti-scalding devices (thermostatic valves or tap) were designed to be used throughout the hospital where service outlets provide water for personal hygiene washing. At each floor distribution branch pressure regulating valves maintain similar water pressure at all levels in the building providing convenience of use and minimizing water consumption.

[84] HSE (n 19).
[85] HSE (n 20).

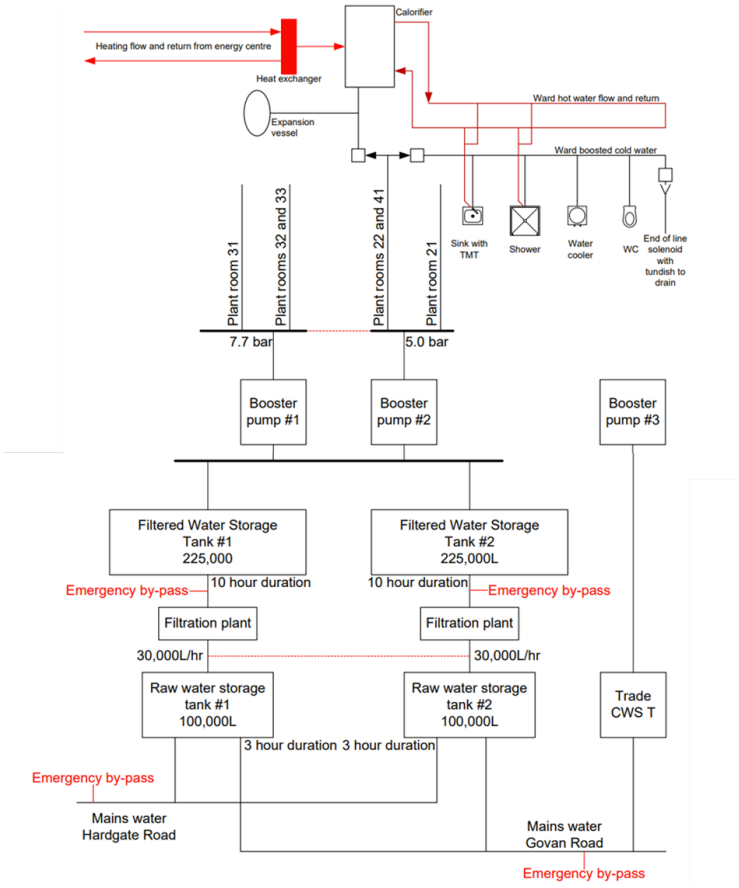


Figure 1. Overview of water supply and domestic water system for the QEUH site [86]

4.6. Incoming mains town supply

4.6.1. The QEUH and RHC were developed and designed [87] to be supplied by two 150mm incoming town mains water supplies from Scottish Water (Figure 2 – 5) which are known as [88]:

- Hardgate Road water supply (Figure 2, 3 and 4) [89]
- Govan Road water supply (Figure 2, 3 and 5) [90]

[86] Mercury Mechanical, 'PR32 - DOMESTIC WATER SYSTEM DESCRIPTION' [2014] Objective Connect, SHI.
[87] Brookfield (n 53).
[88] Mercury Mechanical (n 86).
[89] DMA, 'L8 Risk Assessment NHS GGC South Glasgow University Hospital. 2015.' (n 27).
[90] DMA, 'L8 Risk Assessment NHS GGC South Glasgow University Hospital. 2015.' (n 27).

Figure 2. Site design plan[91].

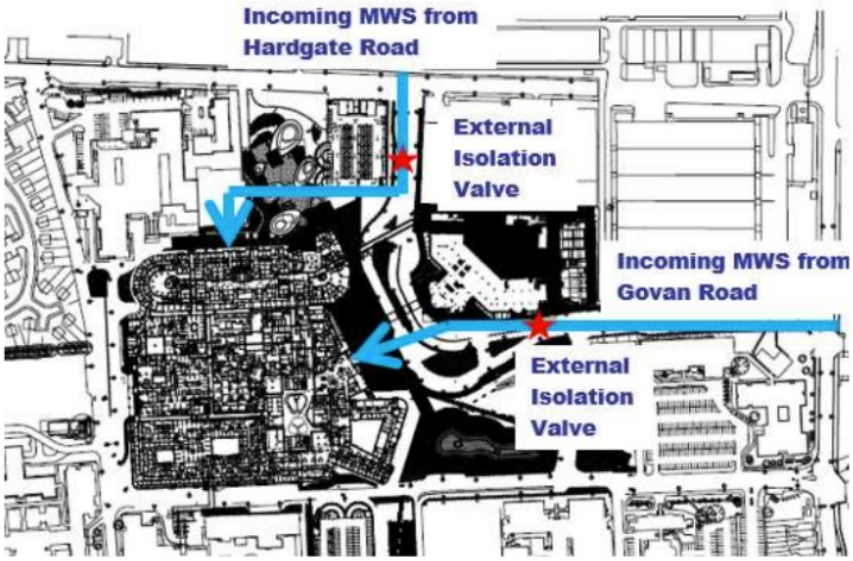


Figure 3. Schematic of the location of delivery of the mains water supplies from Govan Road and Hardgate Road [92].

[91] Brookfield (n 53).
[92] Brookfield (n 53).

Figure 4. Hardgate mains water supply Image [93].

Figure 5. Govan Road mains water supply [94]

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4.6.2. The mains cold water is derived from both the separate street public water mains water supplies with a separate water main entering the site from each main. The two 150mm respective site water mains run in a shared trench with the fire and gas mains supply.

4.6.3. The two incoming town mains water supplies from Scottish Water to the QEUH and RHC provide redundancy in the event that there is a failure with one supply to ensure continuity of water supply.

4.6.4. In the event of mains failure (e.g. damage, contamination or for servicing and maintenance) from either incoming mains water supplies the two site mains are linked

[93] DMA, 'L8 Risk Assessment NHS GGC South Glasgow University Hospital. 2015.' (n 27).
[94] DMA, 'L8 Risk Assessment NHS GGC South Glasgow University Hospital. 2015.' (n 27).

by a valve chamber with a normally closed valve for sole use by Scottish Water if and when required to ensure that water can be delivered from either mains supply.

4.6.5. Fire mains: The two separate water main connections from Govan Road and Hardgate Road each have branches to run as fire mains around the site to serve fire hydrants. The fire mains form a ring around the building interlinked by a normally closed Fire Brigade valve to ensure resilience to the site fire main network. The fire mains will be unmetered unless specifically requested by the local water authority.

4.6.6. The two separate mains water supplies also supply water to the Laboratory Building and a single supply from the connection nearest to Govan Road to serve the Energy Centre [95].

4.6.7. Both incoming mains town water supplies enter the building in the basement manifold room and basement tank room and both have double check valves, water meters, port isolation valves and Keraflow float valves all located within the tank room. The Keraflow float valves are located in the raw water tank and filtered water storage tanks and maintain the water level within the tanks, are adjustable and can be used to reduce the water storage volume if water turnover is slow (Figure 6).

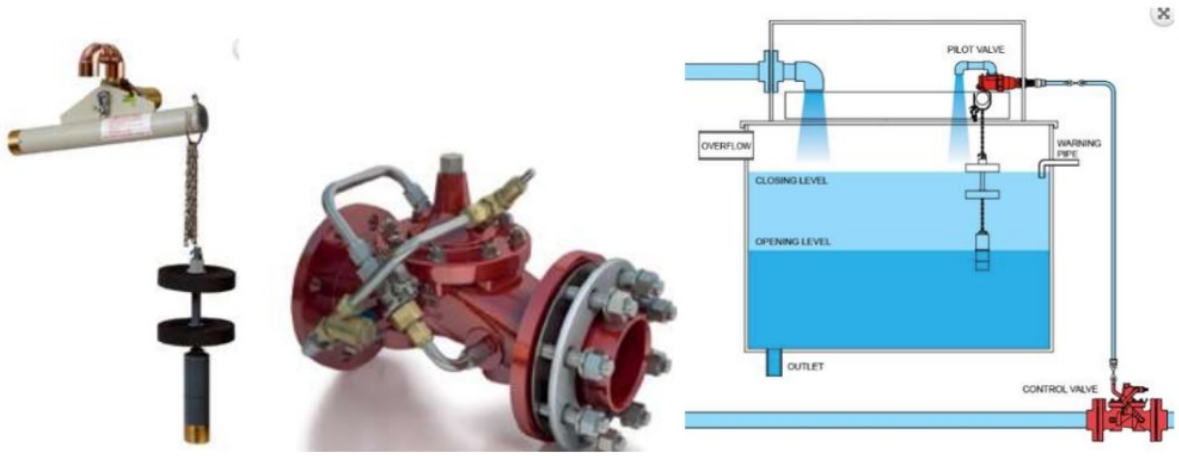


Figure 6. Images and position of the Keraflow float valves in the cold water storage tanks [96].

4.6.8. The incoming mains water meters are linked to the building management system (BMS) to allow cross reference to the quantity of water used against the quantity indicated on the external meter. The difference in usage would highlight if there were any leaks on the external water main. The 2 port isolation valves allowed

[95] Wallace Whittle TUV SUD (n 81).
[96] NHS GGC, 'Description of the Domestic Water System_67002452_1'.

the alternative use of each incoming main supply every 7 hours to prevent stagnation of the incoming mains supplies.

4.7. Raw water storage tanks

4.7.1. Both incoming mains water supplies supply water to the two raw water storage tanks (Figure 6 & 7), known as raw water storage tank number 1 (Figure 8) and raw water storage tank number 2 (Figure 9). Table 4.

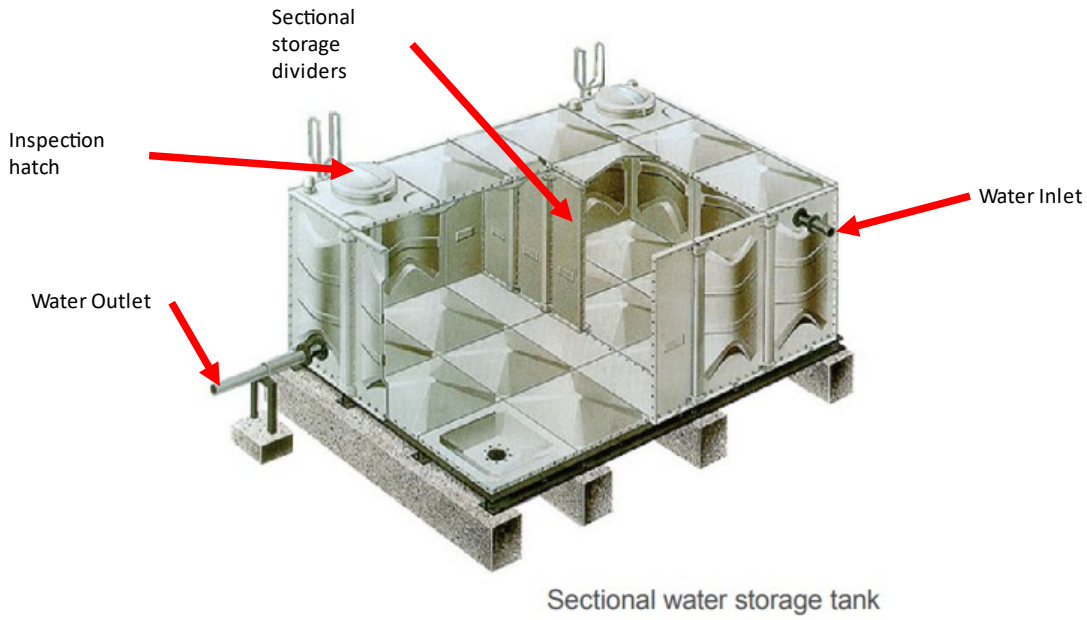


Figure 7. Schematic of water storage tank with typical storage dividers [97]

4.8. Description of the raw water storage tanks

4.8.1. Each raw water storage tank has a capacity of 100,000 litres, giving a total raw water storage of 200,000 litres (Figure 8 and 9).

[97] Brookfield (n 53).

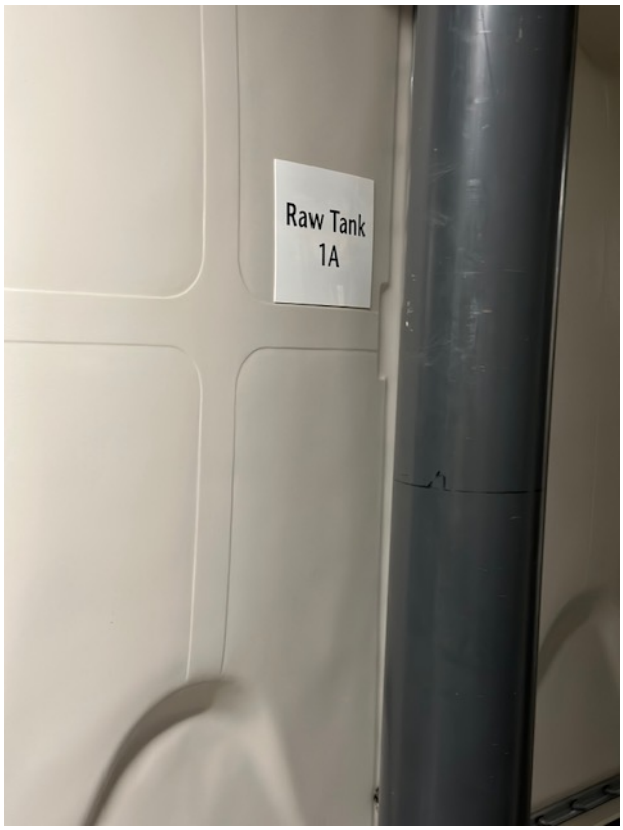


Figure 8. Raw water storage tank 1A.

Figure 9. Raw water storage tank 2B.

4.9. Trade water storage tanks

4.9.1. The Trades Water tank (Figure 10) and water system supplies various outlets such as bib taps (wall-mounted tap that offers the ability to connect a hose) in plant rooms, irrigation connections points and the 12th floor helipad fire suppression system (Table 4).

Figure 10. Trade water tanks

4.10. Ultrafiltration plant

4.10.1. The Employer's Requirements[98] stated that the "Contractor shall filter the site potable water to the criteria set out in SHTN02 with 0.2 micron filtration and that the pipework shall be stainless steel. SHTN02 was published in 2009 to address the problems experienced by the NHS in Scotland in consequence of the corrosion of copper pipework systems. Scientific research concluded that copper pipework in domestic hot and cold water services in hospitals and other healthcare premises in many areas of Scotland (and elsewhere), with soft water, and / or where high levels of sediment were found, had a high propensity to failure [99]. As a result filtration was no

[98] NHS GGC, 'NHS GGC New South Glasgow Hospitals (NSGH) Project INVITATION TO PARTICIPATE IN COMPETITIVE DIALOGUE VOLUME 2/1 EMPLOYER'S REQUIREMENTS'.
[99] CW Keevil and others, 'Detection of Biofilms Associated with Pitting Corrosion of Copper in Scottish Hospitals' [1989] Biodeterioration Journal 99.

longer to be regarded as a desirable optional extra as its inclusion brings many benefits that offset the capital and revenue costs in the longer term.

4.10.2. The water from the raw water storage tanks is passed through ultrafiltration plants (Elga, UK[100]) (Figure 11) to remove dirt, debris and organisms before being stored in the filtered water storage tank. A filter membrane is a thin barrier with holes, or pores. Some particles, such as water, are small enough to pass through the membrane pores, while larger particles cannot pass through and are retained on the membrane. Membrane filtration is used as a step in the multi-barrier approach for water treatment.

4.10.3. Description of the Elga ultrafiltration plant:

- The Elga ultrafiltration (UF system) is a self-contained water treatment package that is complementary to the Elga range of media filters, deionisers and reverse osmosis plant. The mains feed water must already have been filtered for suspended solids above 50 microns.

- Ultrafiltration is a low pressure membrane separation process employing cross flow and dead ended membranes with pore sizes in the range 10-200 Angstroms.

- Owing to the small pore size and geometry of the system, the process is capable of removing contaminants from water without suffering adversely from fouling.

- Examples of impurities which can be efficiently removed include suspended solids, colloids (silica, iron, organics etc), and High Molecular Weight Organic molecules. The membrane module in the Ultrafiltration unit has a MWCO of 100-150 kDaltons and an output of 5000 litres per hour per membrane.

- Filtration can be classified according to the diameter of the pores in the membrane, or by the molecular weight of contaminants the membrane retains

- The system incorporates safety features and automatic controls for ease of operation.

- Elga UF plants are skid mounted systems intended for pre-treatment applications and are assembled and wet tested before despatch.

- The UF is fully automatic during normal service requiring only the minimum of supervision.

- This filtration system is used to remove organisms and fungi including *Legionella*, *Pseudomonas*, *Cupriavidus* and *Aspergillus spp*. which are generally in excess of than 0.3 micron [101].

[100] ELGA, 'Elga Ultrafiltration Unit Treatment System for the QEUJ and RHC. Operators Manual March 2011'.
[101] Fraser, 'Queen Elizabeth University Hospital Review (June 2020)' [2020] Patient Safety Learning - the hub.

Figure 11. Elga ultrafiltration unit

4.10.4. Filtration unit 1 supplies filtered water storage tanks 1A & 1B and filtration unit 2 supplies filtered water storage tanks 2A & 2B.

4.11. Filtered water storage tanks

4.11.1. Following filtration the water is pumped to two filtered water storage tanks. Filtered water storage Tanks 1A and 1B are linked, with 2A and 2B also linked. Table 4.

4.12. Description of the filtered water storage tanks

4.12.1. Both filtered water storage tanks have two compartments and are piped to allow tank maintenance without disrupting the water supply to the building. Float switches are present within the tanks to provide the “enable (supply)” and “stop” signals based on the water level within the tanks. These levels can be adjusted to suit the water demand so that an optimal turnover of water can be achieved. The tanks are arranged to give two streams of flow with 1/3 of storage capacity in the 2 raw water break tanks and 2/3 of storage capacity in the 2 filtered water storage tanks [102].

[102] NHS GGC, ‘Description of the Domestic Water System_67002452_1’ (n 96).

4.12.2. There are a total of 5 water storage tanks in the building (as shown in Table 4).

4.12.3. Description of the water storage tanks. Please note discrepancy in tank size stated in different literature, however, schematic in Figure specifies 225,000 litres.

Table 4. Water Storage Tanks

Number of Water Storage Tanks	Description
2	100,000 Litre Raw water storage (break) tanks supplied by the incoming mains water
2	225,000 Litre filtered water storage tanks supplied post filtration [103]* 275000 Litre filtered water storage tanks supplied post filtration [104]*
1	2,800 Litre Trade water storage tank

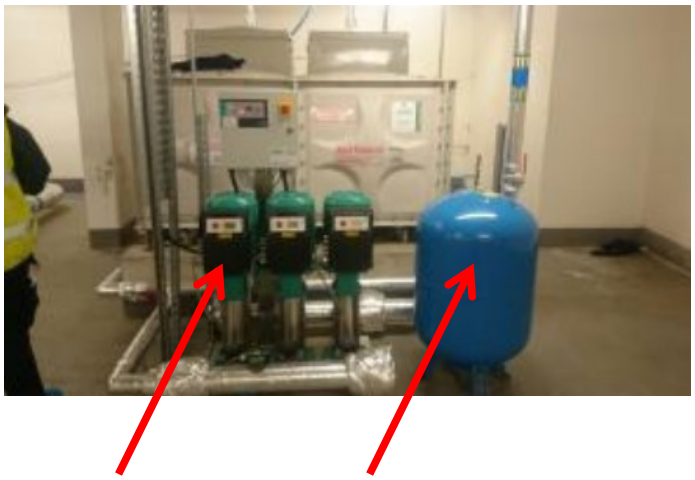
4.13. Booster pumps

4.13.1. The water is pumped from filtered water storage tanks to serve the building via two booster pump sets (Figure 12). The whole of the domestic water services installation is boosted in pressure to ensure adequate flow throughout the building to the respective plant rooms (Figure 13).

- Booster pump S01 – Feeding Plantroom PR31, PR32 & PR33 - 7.7 Bar
- Booster pump S02 – Feeding Plantroom PR21, PR22 & PR41 – 5.0 Bar

4.13.2. Each booster pump is set to a different set point pressure depending on which plant room it serves and each booster set has two set points which will allow either serve the building via an emergency link in the event of failure. The booster pump sets to ensure adequate flow at all outlets points, such as showers. Expansion vessels are attached to the CWST booster sets.

[103] Storrar and Rankin (n 48).
[104] DMA, 'L8 Risk Assessment NHS GGC South Glasgow University Hospital. 2015.' (n 27).



Trade booster pumps (green) with manifold and expansion vessels (blue)– source DMA L8 RA VT2.0

Figure 12. Trade booster pumps. Source DMA L8 RA VT2.0.

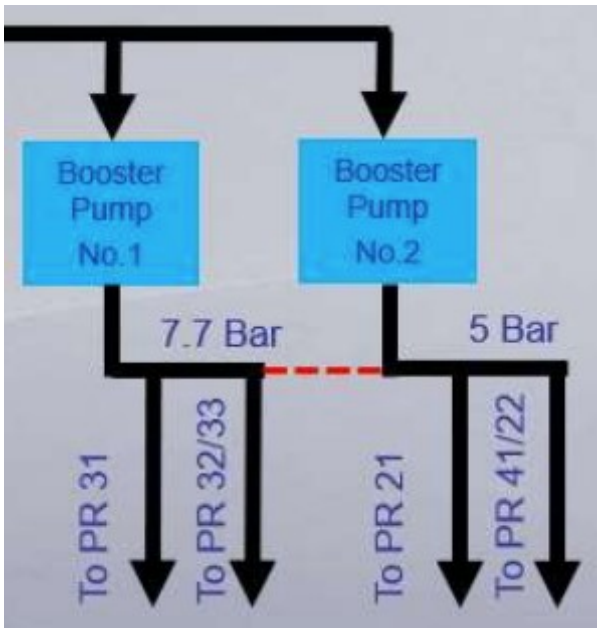


Figure 13. Schematic of booster pumps supply the various plant rooms.

4.13.3. Each booster pump serves different areas of the facility. The higher pressure systems Booster pump no 1 (7.7 bar) serves mainly the tower of the QEUH (plant rooms 31, 32 and 33) and the lower pressure system Booster pump no 2 (5.0 bar) serves mainly the RHC (plant rooms 21, 22 and 41).

4.14. Plant rooms

4.14.1. From the filtered water storage tanks, the boosted cold-water services are pumped via the main distribution risers to service three different roof plant rooms (Figure 14). The water entering each plant room has a meter to allow consumption to be monitored.

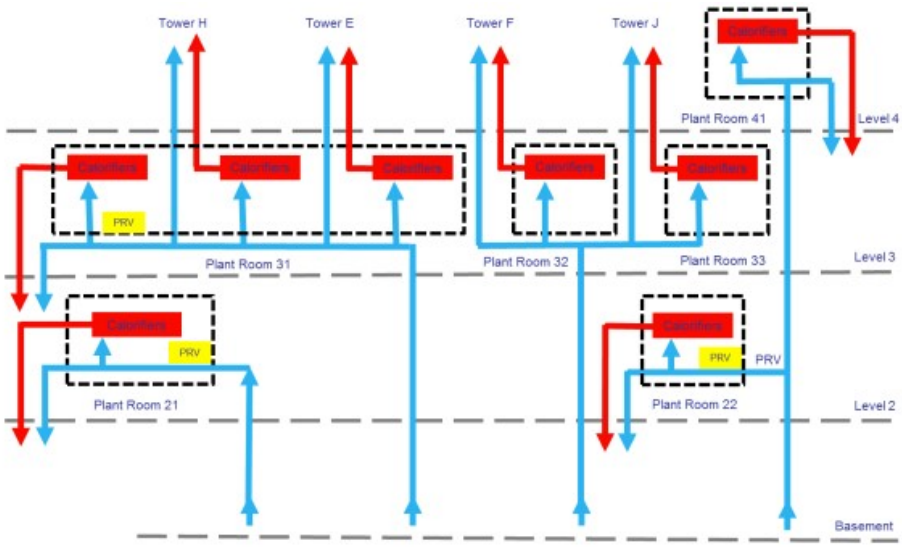


Figure 14. Schematic of the hot and cold water system from the basement to different plant rooms, towers and levels.

4.14.2. Once the boosted cold water reaches the satellite plant rooms it branches out to supply cold water across the different departments and wards and to supply cold water to the energy centre.

4.15. Pipework

4.15.1. The Employer's Requirements stated that, in respect of water systems and filtration, "*Pipework shall be stainless steel with compatible accessories*" [105]. However the photographic evidence (P6 of the DMA 2015 report and item 6 photo in Storrar and Rankin) only indicates the presence of copper for the main domestic hot and cold water system [106]. This copper system was installed using crimp joint connections

[105] NHS GGC, 'NSGACL - ITPD Volume 2_iss1_rev1 Invitation to Participate in Competitive Dialogue Volume 2/1 Employer's Requirements (Hospitals)' (n 77).
[106] DMA, 'L8 Risk Assessment NHS GGC South Glasgow University Hospital. 2015.' (n 27).

made using a bespoke tool and 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. Section 6.3.2 discusses the historical problems previously associated with the use of copper piping in Scottish hospitals.

4.15.2. The water services pipe work was integrated into prefabricated modules and erected on site along with other services [107].

4.16. Supply of filtered cold water to different departments

4.16.1. Cold water is supplied to the various departments and wards for use at the point of use e.g. at handwash outlets, showers, toilets, utility sinks and other equipment such as water coolers. There are of end line dump values (controlled by solenoids) to discharge the water into the drain when the water temperature increased above 23°C. as there is a reasonably foreseeable Legionella risk in water systems if the water temperature in all or some part of the system is greater than 20°C [108]. As per design and guidance there is only a cold water flow from the supply to the point of use terminals and there is no return pipework on the cold water services.

4.16.2. The warmer the cold water then the greater likelihood of microbial growth. Therefore, the dumping of cold water when the temperature reaches 23°C serves several purposes:

- Removal of microorganisms that have multiplied in the water phase (but not biofilm which is attached to the pipe walls);
- Reduction of the water temperature to less than 23°C; and
- Replenish the chemical disinfection concentration as per the supply water.

4.17. Supply of hot water to the different departments

4.17.1. The cold-water service pipework is routed via the basement to vertical risers where the pipework is distributed to the various plantrooms for the generation of hot water (Figure 1) [109]. Cold water is supplied to the energy centre and is pumped to a bank of eight calorifiers (Figure 15). Each calorifier skid consisted of a storage cylinder, shunt/de-stratification pump, plate heat exchanger, expansion vessel and associated pressure, temperature and vacuum safety valves.

[107] HFS, 'Water Management Issues Technical Review NHSGGC – QEUH and RHC HFS – March 2019'.
[108] HSE (n 20) 274.
[109] Storrar and Rankin (n 48).

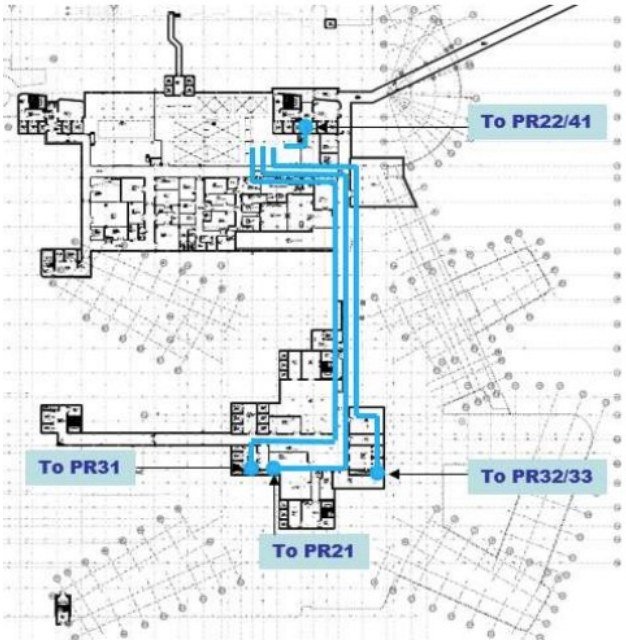


Figure 15. Illustration of the routing of the cold-water service pipework via the basement to vertical risers where the pipework is distributed to the various plantrooms for the generation of hot water in the plant rooms.

4.18. Calorifiers

4.18.1. Domestic hot water is generated within plantrooms PR21, PR22, PR31, PR32, PR33 & PR41 utilising plate heat exchangers and calorifiers or buffer storage vessels (Figure 16 and 17) [110]. This provides instantaneous heated water with reduced storage capacity. The domestic hot water is in-directly heated via a plate heat exchanger (feed from the Medium Temperature Hot Water circuit) and operates on a hot water flow and return pipework system. The hot water flows from the calorifier to the point of use and is returned using pumps that run continuously to the plates heat exchangers for reheating to maintain hot water through the system.

[110] DMA, 'L8 Risk Assessment NHS GGC South Glasgow University Hospital. 2015.' (n 27).

Typical calorifier set up – source DMA L8 RA VT2.0

Figure 16. Typical set up and layout of calorifiers [111]. Source DMA L8 RA VT2.0.

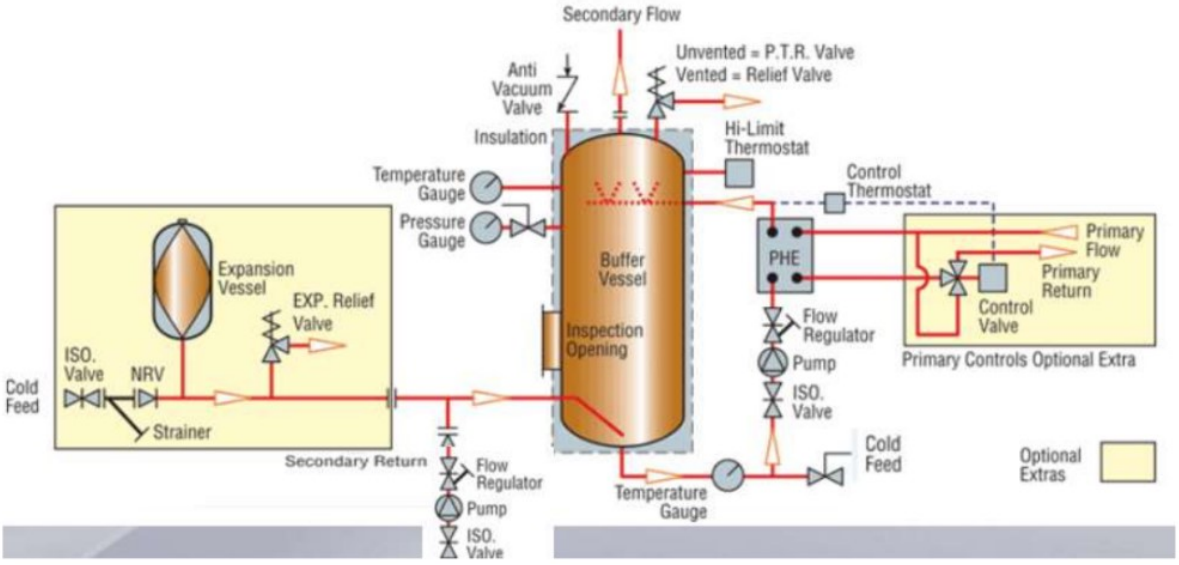


Figure 17. Typical schematic layout of a calorifier and expansion vessel [112].

[111] DMA, 'L8 Risk Assessment NHS GGC South Glasgow University Hospital. 2015.' (n 27).
[112] NHS GGC, 'Description of the Domestic Water System_67002452_1' (n 96).

4.19. Expansion vessels

4.19.1. Expansion vessels were fitted in various parts of the hot and cold water system (Figure 18) [113]. An expansion vessel (or tank) is a small container that is used to protect the hot and cold water systems from excessive pressure. The vessel contains a rubber diaphragm that contains air. As the hot water heats up it expands in volume and as a consequence the water pushes against the bladder which is full of air. The bladder then acts like a spring, or shock absorber, to absorb the excessive pressure as the water expands and contracts, helping to keep the system stable. Basically, the expansion vessel is used as an overflow tank for the hot water system.

Trade booster pumps (green) with manifold and expansionvessels (blue)– source DMA L8 RA VT2.0

Figure 18. Example of expansion vessel - source DMA L8 RA VT2.0

4.20. Distribution of pipework to point of use outlets

4.20.1. The whole of the domestic water services installation is boosted in pressure to ensure adequate flow throughout the building and to allow for equal pressures at the outlets between the hot and cold water [114].

4.20.2. Both the cold and hot water pipe work are routed together horizontally in the ward corridors on each floor e.g. the cold and hot water pipework in the Schiellallion Unit) (Figure 19).

[113] DMA, 'L8 Risk Assessment NHS GGC South Glasgow University Hospital. 2015.' (n 27).
[114] NHS GGC, 'Description of the Domestic Water System_67002452_1' (n 96).

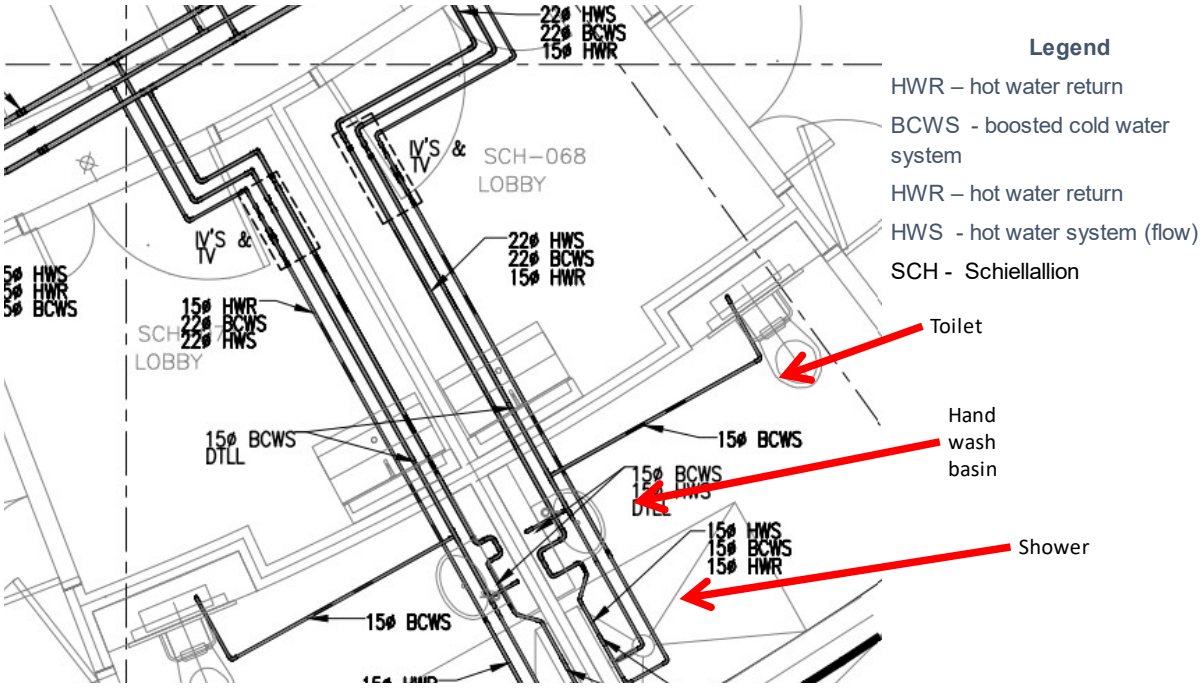


Figure 19. Layout of the cold and hot water flow and return pipes in the Schiellallion Unit [115]

4.20.3. The cold water storage is sized for 24 hours supply.

4.20.4. The hot water is circulated (flow) to the outlet and back (return) to the calorifiers by a hot water return pump so that temperature is maintained throughout the system.

4.20.5. There are Kemper thermostatic balancing valves installed on the system in line with the design (Figure 20) [116]. These are installed on the hot water return pipework to provide isolation for maintenance activity and automatically regulate the water flow rate to maintain temperatures throughout the system to ensure hot water is available within 2 minutes at every outlet.

[115] Brookefield, 'ZBP-ZC-02-PL-500-023_A. Domestic and Gas Layout Second Floor NCH Schiehallion Ward'.
[116] NHS GGC, 'Description of the Domestic Water System_67002452_1' (n 96).

Figure 20. Thermostatic balancing valves provide isolation for maintenance and automatically regulate the water flow rate to maintain temperatures throughout the system.

4.21. Single occupancy room

4.21.1. The QEUH Glasgow is a hospital with 100% ensuite single side rooms. Single room occupancy provides for privacy, dignity as well as infection prevention and control reasons and the design was for a single room ward design [117]. The attractions for privacy and dignity are self-evident; the advantages for infection control are separation of patients with a physical wall rather than a curtain and en-suite facilities (sink in the bedroom; sink, toilet and shower in the adjoining room). However single rooms with en-suite facilities resulted in at least four water outlets (sink in the bedroom; sink, toilet, and shower in the adjoining room as well as clinical wash hand basin for every patient) patient when the hospital was opened.

4.22. Layout of the hot and cold water pipes in the Schiellallion unit

4.22.1. The installed hot water pipe loop (flow and return) was built in the corridor or ceiling voids [118]. The hot water was designed for 60°C flow and 55°C return [119]. From the hot water flow and return pipework a single hot water flow pipe (known as a spur or deadleg) was dropped from the flow and return circuit (Figure 21) which provides flow to the ancillary equipment such as outlet basin/sinks or showers. The pipes would have dropped down behind the removable panel to each hot outlet. These spurs were

[117] Fraser (n 101); Scottish Government, 'Scottish Government. Chief Nursing Officer Directorate CEL 48 PROVISION OF SINGLE ROOM ACCOMMODATION AND BED SPACING. NHS Scotland. 2008.'
[118] DMA, 'L8 Risk Assessment NHS GGC South Glasgow University Hospital. 2015.' (n 27).
[119] NHS GGC, 'NSGACL - ITPD Volume 2_iss1_rev1 Invitation to Participate in Competitive Dialogue Volume 2/1 Employer's Requirements (Hospitals)' (n 77).

designed to be less than 3m and were recorded as having been reduced to 2.89m in length (Table 2) [120].

4.22.2. Within hot and cold water systems the flow and return pipes ensure that the water is constantly flowing from the calorifier, at least 60°C and returning to the calorifier at least 55°C. Such a configuration will enable the hot water at each outlet to reach 55°C within one minute of turning on the tap. Where the hot water flow and return are not local to the outlet then the excessively long deadleg will provide optimum temperatures for the growth of microorganisms, including Legionella [121]. As per national Guidance [122] the hot water return should be local to the outlet otherwise HSE indicates that excessive deadlegs that will encourage microbial growth will fail to return to the hot water system.

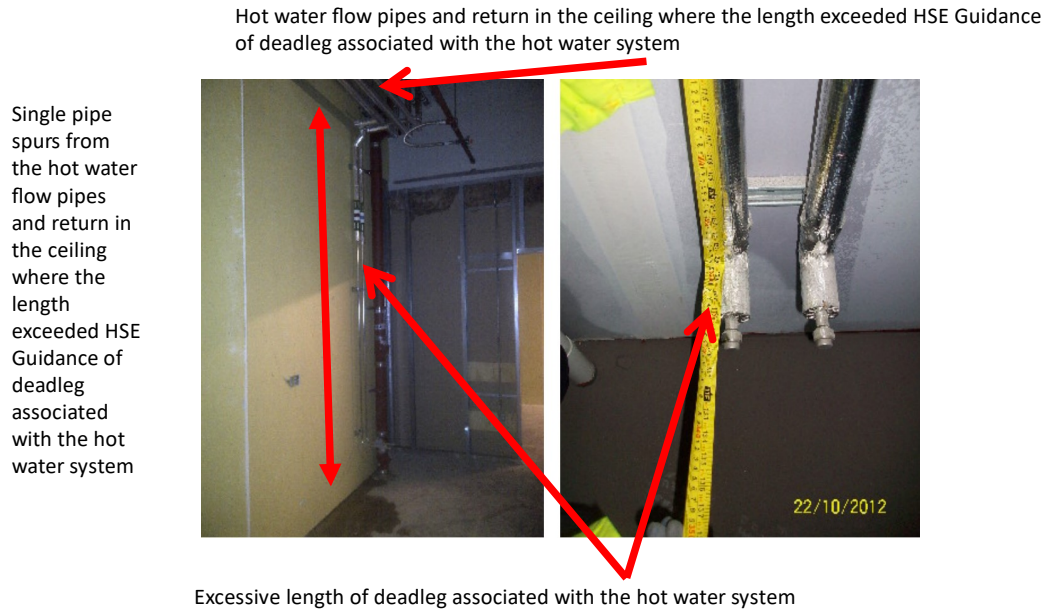


Figure 21. Demonstration of excessive length of deadlegs on hot water system [123].

4.23. Soil, waste and drain system

4.23.1. The soil and waste system across the QEUH and RHC takes waste from all wash hand basins, water closets and sinks (Figure 22) [124]. All points of discharge into the system are fitted with a water trap e.g. to provide a water seal to prevent foul air from entering the system (Figure 23). The waste stacks from the domestic wash hand

[120] Capita, 'New South Glasgow Hospital Adult and Children's Hospital and Energy Centre. NEC 3 Supervisors Report NO. 19. October 2012.' [2012] Capita Symonds.
[121] HSE (n 20).
[122] HSE (n 20).
[123] Capita (n 120).
[124] Mercury Mechanical, 'Soils and Waste System Description. Facilities Management Information NSGH A&C Hospitals'.

basins and WCs are installed using 2” Terrain PVC pipe and fittings (Figure 24). As well as discharging waste by gravity the stack allows foul odours to be vented to the atmosphere (Figure 25). Rodding eyes are installed at each WC and WHB and at 1200mm above the floor level on all vertical drops. The soil and waste on each floor are discharged to common stacks installed in >2” Ensign cast iron pipework across the hospital site that run vertically through each floor (Figure 24). The drainage system operates under gravity with anti-siphon ventilation stacks to atmosphere for the ground floor upwards [125]. As such the soil and waste from each floor is discharged to the ground floor via common stacks where it connects to the underground foul waste system.

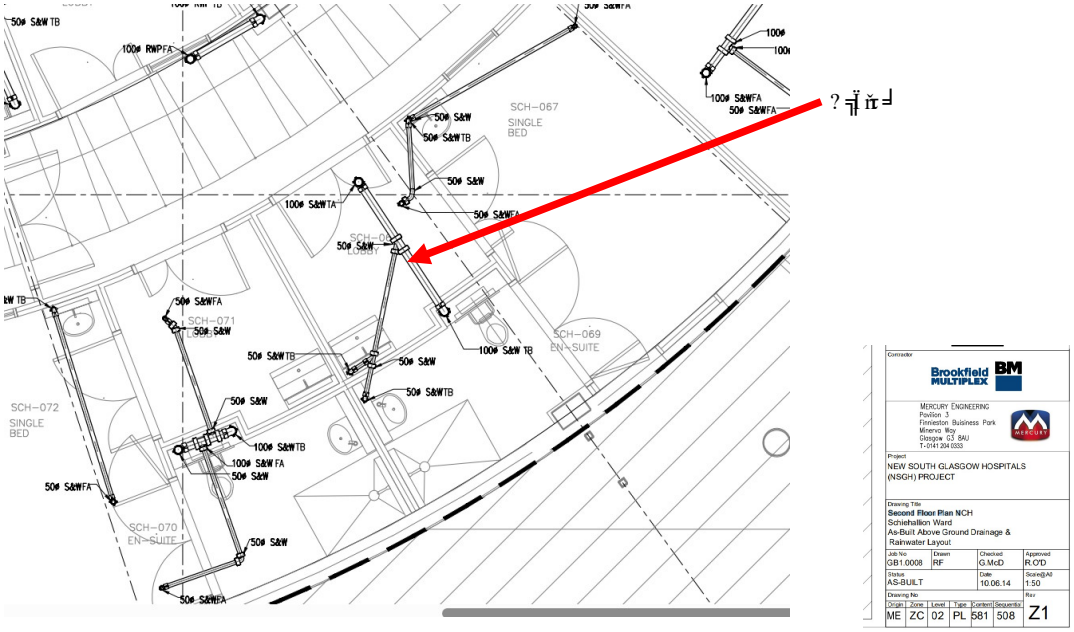


Figure 22. Floor plan of the soil and waste drainage system as designed for the Schiehallion Ward [126].

[125] NHS GGC, ‘Description of the Above Ground Drainage_67002466_1. NHS GGC. Objective Connect SHI’.
[126] Brookfield Multiplex, ‘Second Floor Plan NCH - Schiehallion Ward - As-Built Above Ground Drainage & Rainwater Layout. ME-ZC-02-PL-581-508_Z1’.

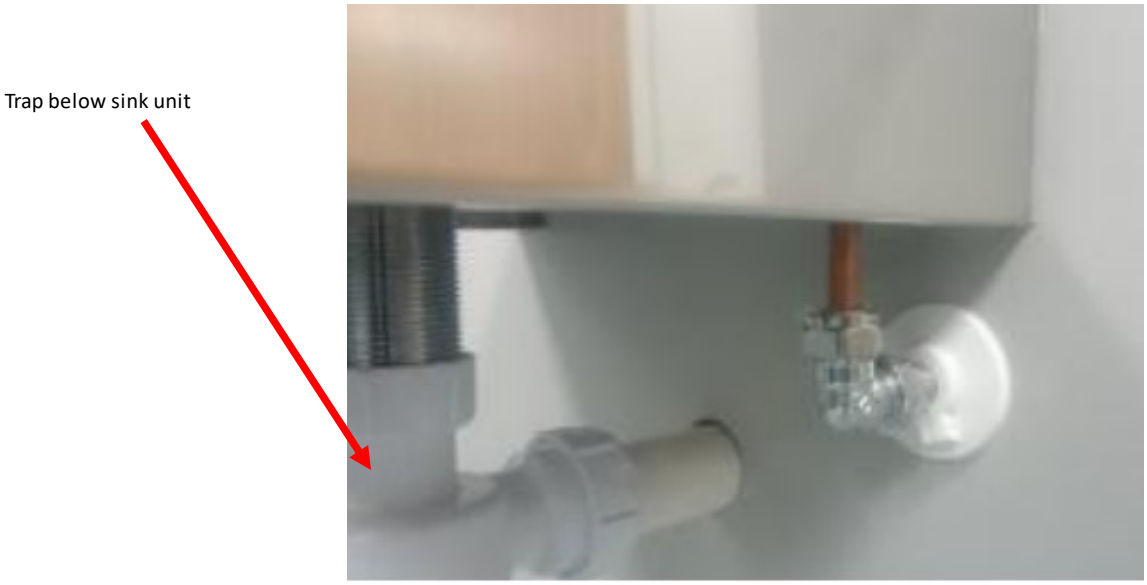


Figure 23. Position of trap below a sink unit.

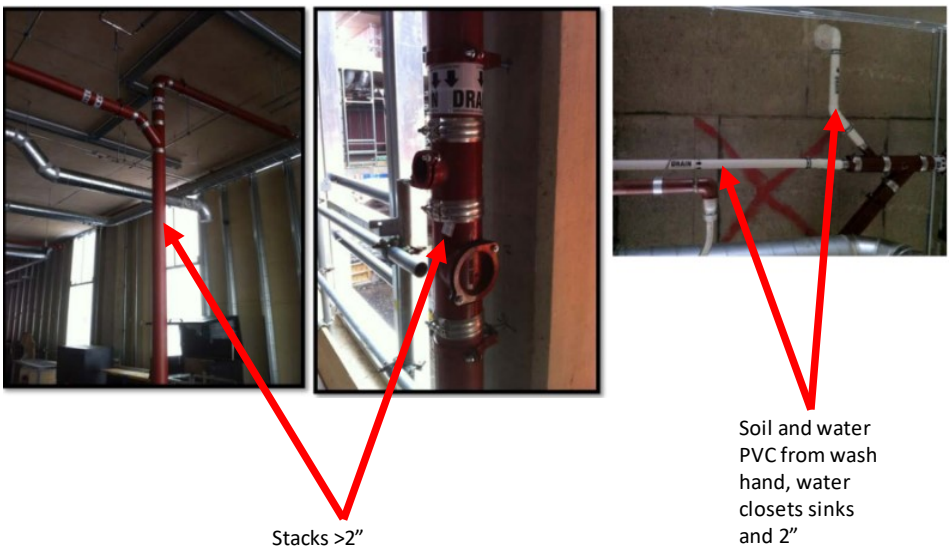


Figure 24. Soil and waste pipework within and between floors.

4.23.2. A simplified schematic of the gravity discharge of the soil and waste from the basins, sinks, toilets and showers is presented below (Figure 25).

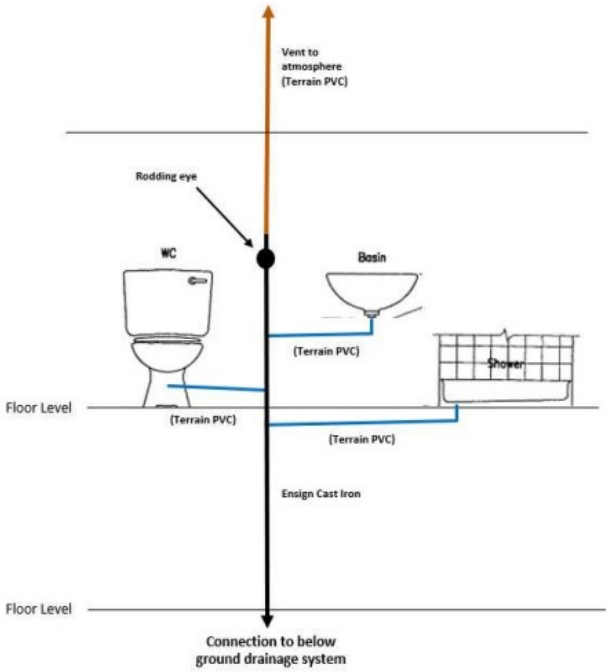


Figure 25. Simplified schematic of the soil and waste discharge to the vertical stacks.

4.23.3. The basement soil and waste feeds into a sump located in Pump room FMB-024 (Figure 26). From this sump the soil and waste are pumped back into the ground floor and underground foul waste system.

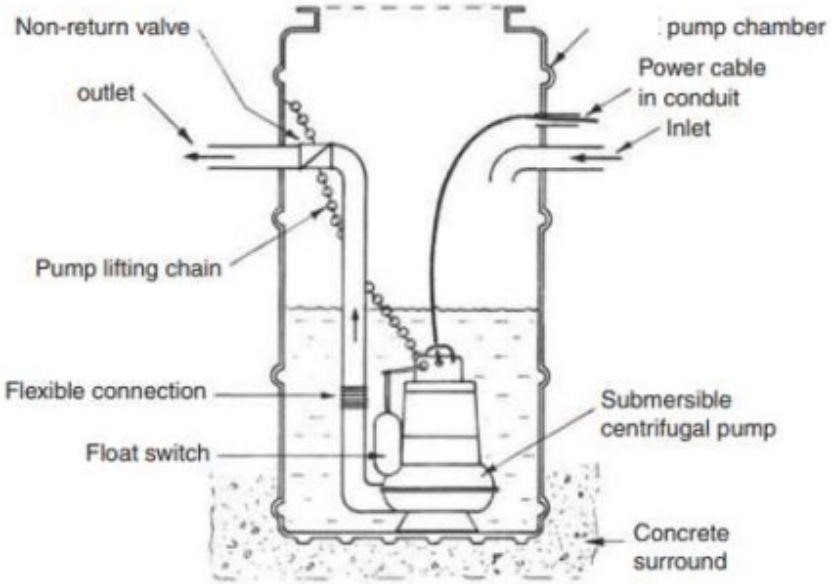


Figure 26. Schematic of typical sump and pump arrangement located in the basement.

4.23.4. There are several other permanent sump pumps within the basement; these provide pumped drainage for the following:

- Water filtration backwash;
- Emergency overflows for the cold water storage tanks;
- Emergency overflows for the sprinkler system tanks;
- Emergency overflows for the renal concentrate storage tanks; and
- Emergency drainage for Core G lift sump.

4.23.5. Approximately two thirds of the foul flows from the new hospital were connected at a number of locations to the 300mm diameter combined drain which runs under the access road immediately to the east of the building. These flows ultimately connect to the public sewer to the north of the site under Govan Road. The remainder of the foul flows taking the proposed Childrens Hospital, Laboratory and FM buildings were to be directed to a new point of connection on the public combined sewer to the west of the site in Hardgate Road [127].

4.23.6. There is no separate water supply for specialist wards such as the renal department. This means that the water system needs to be carefully managed in terms of ensuring that any disinfectants are removed prior to the delivery of that water to specialist units such as the renal unit where patients would be harmed by the presence of disinfectants in the water.

4.24. Metering of water usage

4.24.1. The cold feed to the calorifiers is also metered. The meter is located at the calorifier skids.

4.24.2. Water meters were provided as indicated on the design drawings to measure cold water consumption to various systems and parts of the building. In addition, sub meters were provided to key ‘cost centres’ such as restaurants, kitchens and retail units. All water meters will be fitted with isolation valves and non-return valves.

4.25. Cold water dump valves

4.25.1. The purpose of the dump or flushing valve is to reduce water stagnation by automatically purging water from the cold-water distribution system to reduce the deadleg providing favourable condition for the growth of microorganisms where effective turnover cannot be achieved [128] (Figure 27). Dump valves were used to pull water through both small and large areas of the overall piping network which can be flushed to holding tanks, irrigation systems and pools.

4.25.2. The design philosophy by Mercury Mechanical was that the distribution pipe work is laid out in such a way that higher use outlets are at the end of lines (or branches) to improve flow [129] [130]. This design is used to ensure good turn-over of water through the water distribution system through normal usage such as hand wash

[127] Brookfield (n 53).
[128] Mercury, ‘Excellence in Engineering NNSGH Domestic Water Services Powerpoint Presentation’.
[129] Mercury, ‘PR41 - Domestic Water System Description Facilities Management Information Management NSGH A&C Hospitals’.
[130] Mercury (n 128).

basins. That is those outlets at the end of lines that are frequently used would pull water through the whole systems downstream to replace stagnant water. These designs are based on those recommended within HSE guidance. [131]

4.25.3. Where this turnover could not be achieved, temperature operated dump valves were installed to allow water to flow to the drain when the building managing system detected a cold water temp of 23°C (Figure 27) [132]. The dump valve would then cease operating when the cold water temperature returned to 20°C.

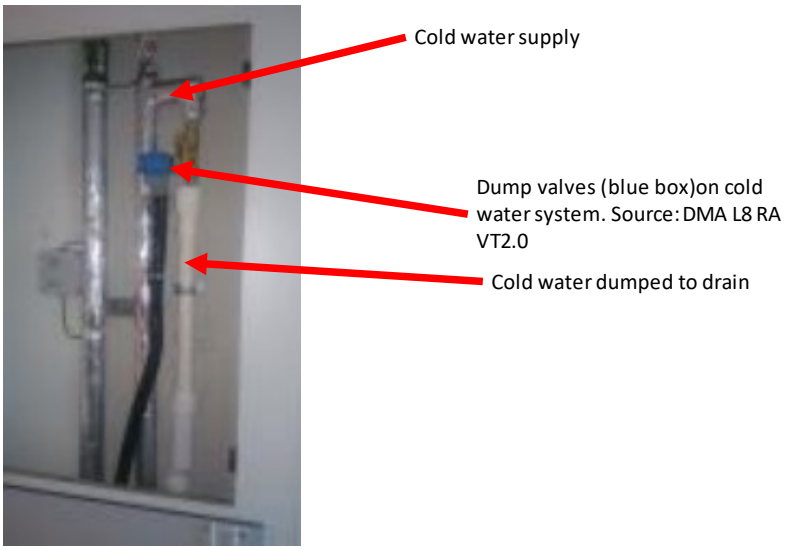


Figure 27. Demonstration of the dump valves on the cold water supply [133].

4.26. Flexible hoses/tails

4.26.1. The invitation to Participate in Competitive Dialogue: Volume 2 stated that flexible hoses were prohibited [134] in the build however these were found to have been fitted in the water system (see section 5) [135] (Figure 28) .

4.26.2. Flexible hoses, also known as 'tails', are often used in the supply of water to connect the 15 mm copper pipework of the hot and/or cold supply to ancillary equipment such as wash hand basin, bath, shower, sluice, ice making machines, dish / glass washers, high-low baths, drink vending machines, drinking fountains, endoscope washers, clothes washing machines and hoses for washing down other equipment or areas and any other equipment deemed necessary. They may also be

[131] HSE (n 20).
[132] Mercury (n 129).
[133] DMA, 'L8 Risk Assessment NHS GGC South Glasgow University Hospital. 2015.' (n 27).
[134] NHS GGC, 'NSGACL - ITPD Volume 2_iss1_rev1 Invitation to Participate in Competitive Dialogue Volume 2/1 Employer's Requirements (Hospitals)' (n 77).
[135] DMA, 'L8 Risk Assessment NHS GGC South Glasgow University Hospital. 2015.' (n 27).

connected to system components such as pressure reducing valves*, non-return valves, strainers, thermostatic mixing valves and shower mixers.

4.26.3. The outer casing of flexible hoses is typically braided steel or stainless steel with a synthetic rubber inner lining such as EPDM (ethylene propylene diene monomer). Flexible hoses were fitted in a number of circumstances [136].

4.26.4. *Pressure reducing valves equilibrate the pressure of the hot and cold water system to successfully blend the hot and cold water through anti-scalding devices such as thermostatic mixing valves.

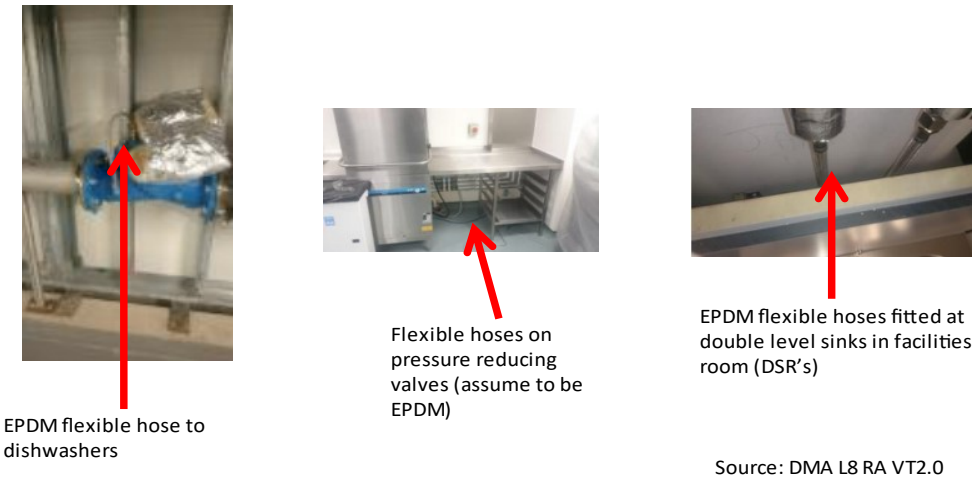
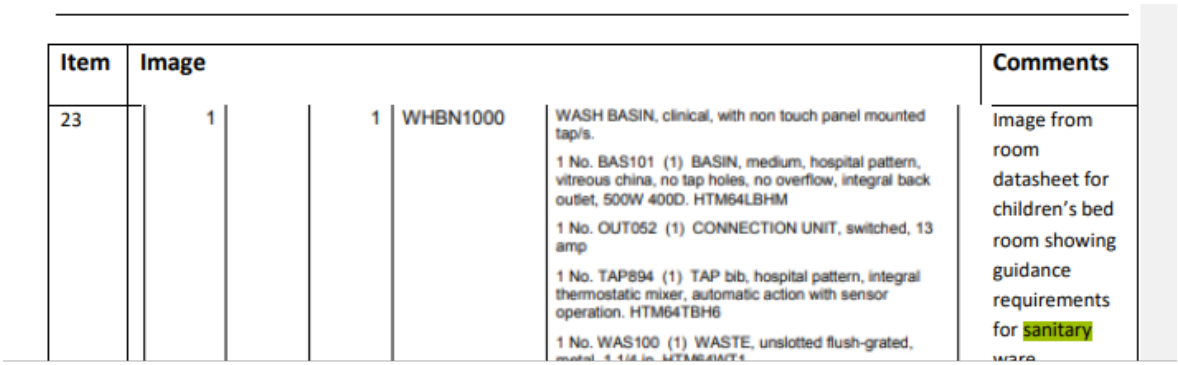


Figure 28. Images demonstrating the fitting of flexible hoses.

4.27. Wash Hand Basin Taps

4.27.1. The room datasheets compiled by the Architect detail the requirements for each room. An example of this was graphically demonstrated in the Storrar and Rankin report (shown in Appendix 2 of) [137]. The Architect had noted the guidance document the sanitary ware should comply with, but not the actual manufacturer which was reflected in the detailed layout drawings (Figure 29).

[136] DMA, 'L8 Risk Assessment NHS GGC South Glasgow University Hospital. 2015.' (n 27).
[137] Storrar and Rankin (n 48).



Item	Image					Comments
23	1		1	WHBN1000	WASH BASIN, clinical, with non touch panel mounted tap/s. 1 No. BAS101 (1) BASIN, medium, hospital pattern, vitreous china, no tap holes, no overflow, integral back outlet, 500W 400D. HTM64LBHM 1 No. OUT052 (1) CONNECTION UNIT, switched, 13 amp 1 No. TAP894 (1) TAP bib, hospital pattern, integral thermostatic mixer, automatic action with sensor operation. HTM64TBH6 1 No. WAS100 (1) WASTE, unslotted flush-grated,	Image from room datasheet for children's bed room showing guidance requirements for sanitary

Figure 29. Specification for wash hand basin and tap in each room (as reproduced in Storrar and Rankin)

4.27.2. The design specification ("Specification N13") provided for either "Pillar taps" or "Armitage Shanks" taps.

4.27.3. In and around July 2012 the Contractor proposed the Horne Optitherm thermostatic bib tap (Figure 30) to NHS GGC Project Team which were fitted in the QEUH and NHC[138]. The Horne Optitherm thermostatic bib tap units will be described in greater detail in other sections of this report.

4.27.4. NHSGGC produced a paper "Installation of Taps" (entitled 962 New South Glasgow Hospital Project Installation of Taps 27th July 2012) 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 [139].

4.27.5. As part of the benchmarking it is noted that the Horne tap had previously been installed and used at Monklands Hospital and Vale of Leven Theatre Suite.

[138] Horne Engineering, 'Horne Opitherm Thermostatic Bib Tap Type TBT02 Installation, Commissioning, Operation and Maintenance Instructions'.
[139] Storrar and Rankin (n 48).

Figure 30. Horne Optitherm taps as fitted in the QEUH and RHC.

4.28. Wash hand basins

4.28.1. The Mechanical and Electrical Services designer/Architect indicated which guidance document the sanitary ware should comply with but did not specify the type of hand wash basins to be installed [140]. The room datasheets compiled by the Architect detail the requirements for each room (Figure 29) and the range of clinical and non-clinical wash hand basins chosen and fitted by the contractor were manufactured by Armitage Shanks from their Contour 21 range [141].

4.28.2. The connection to the drainage pipe work from the sink is via an aluminium spigot with a silicone gasket or washer. PVC spigots were also fitted but exact locations were unknown at the time of fitting (Figure 31). 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.

[140] Wallace Whittle TUV SUD (n 81).
[141] Armitage Shanks, 'Contour 21 Sanitary Ware Https://Www.Armitageshanks-Mena.Com/Fileadmin/Resource/Content/Download/Contour21_Armitage.Pdf'.

Figure 31. Wash hand basin, spigot and drain connector [142].

4.29. Description of stainless steel sinks and taps

4.29.1. Stainless steel sinks were installed in a wide range of areas through the QEUH and RHC.

4.30. Showers

4.30.1. The showers as installed were mainly manufactured by Horne Engineering and from their “TSV-1” range (Figure 32) [143].

[142] Storrar and Rankin (n 48).
[143] Horne Engineering, ‘Horne Engineering TSV1 Shower Data Sheet (T108A2L). Https://Www.Horne.Co.Uk/Media/3717/T108a2l_new_datasheet.Pdf’.

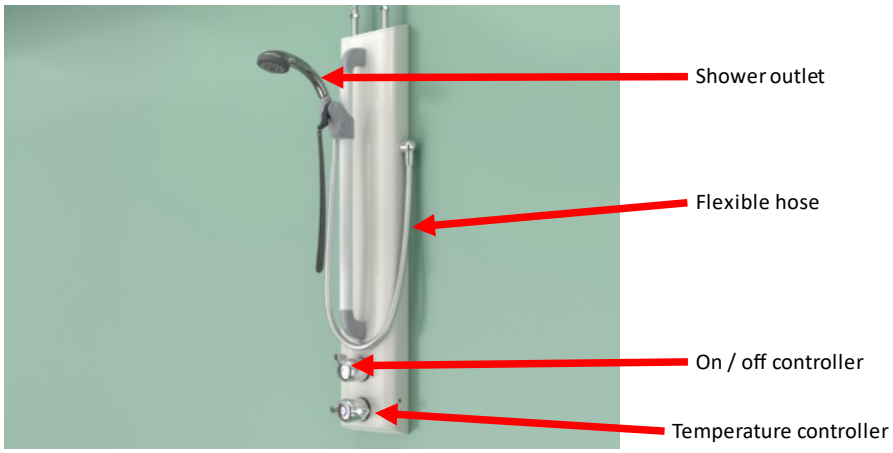


Figure 32. Optitherm shower unit – source Optitherm website.

4.30.2. These showers include:

- Integral type 3 thermostatic shower valve
- BS3800 compliant lever
- Integral fine mesh strainers to provide essential protection to internal mechanism of the valve and ancillary fittings
  Flushing facility to allow water supplies to be flushed clean during commissioning

4.30.3. Other showers which were fitted were integral, for example, as part of the specialist baths from Arjo Huntleigh.

4.31. Water coolers

4.31.1. Water coolers were provided under the contract at various locations throughout QEUH and RHC [144]. Water coolers, drinks and vending machines were supplied and installed by others. The Sub-contractors were to supply services to the coolers and vending machines at locations shown on the design drawings as agreed with the Contractor.

4.31.2. Water coolers were supplied by third parties and either connected on to the mains cold water system or standalone units with water bottles and will be discussed in later sections.

[144] Storrar and Rankin (n 48).

4.32. Dishwashers

4.32.1. Dishwashers were plumbed into kitchen and ward areas [145] and were connected using flexible hoses - which were prohibited on site according to The Invitation to Participate in Competitive Dialogue: Volume 2 [146] . The background to flexible hoses is described in 5.15.2 and the implication for patients are described in 6.24.

4.33. Building Management System

4.33.1. As part of the design a Building Management System (BMS) was designed, installed and commissioned [147]. 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.

4.33.2. It is noted that the specification called 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 was not supplied under the contract.

4.34. Energy Centre

4.34.1. To provide an efficient source of heating and power for QEUH, RHC and other parts of the QEUH campus a new separate Energy Centre was built next to the laboratory block to house the Combined Heat and Power Unit (CHP) and boilers [148]. The single building is separated into two separate compartments each containing half of the required plant and separated by a 4 hour fire wall with each half of the energy centre capable of independent operation and incorporating the necessary requirements for resilience and maintenance.

4.34.2. There are 7Nr 5MW heat output medium temperature hot water dual fuel natural gas/oil fired boilers, and 3Nr 1.2MW thermal output naturally gas fired combined heat and power units (CHP), located within the Energy Centre building [149]. Heat generators are currently utilised to provide MTHW to the Adult & Children's Hospital, and Laboratory Building, via underground distribution pipework.

[145] DMA, 'L8 Risk Assessment NHS GGC South Glasgow University Hospital. 2015.' (n 27).
[146] NHS GGC, 'NSGACL - ITPD Volume 2_iss1_rev1 Invitation to Participate in Competitive Dialogue Volume 2/1 Employer's Requirements (Hospitals)' (n 77).
[147] TUV SUD, 'TUV SUD Specification for Building Management Systems and Automatic Controls Rev F March 2014. Document Ref: ZBP-XX-XX-SP-660-401'.
[148] Storrar and Rankin (n 48).
[149] NHS GGC, 'ENERGY CENTRE Forensic Analysis Report'.

4.34.3. 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 three 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 RHC plant room plate heat exchangers convert the MTHW to Domestic Hot water (DHW) and Low Temperature Hot Water (LTHW) (Figure 33) to serve the hot water and heating circuits respectively, for the wards and ancillary spaces. The boilers were programmed to maintain a flow temperature of 105°C, and operate on a lead/lag, timed, step sequence control basis.

4.34.4. The intended primary MTHW heating system flow and return temperatures to serve the Adult & Children's Hospital were designed on the basis of 105°C and 75°C respectively, thereby affording a temperature differential of 30°C.

4.34.5. The Energy Centre was designed to deliver hot water at 60°C flow and 55°C return.

Figure 33: Low Temperature Hot Water (LTHW) pumps [150]

4.35. Sprinkler system and wet risers for fire control

4.35.1. The automatic sprinkler installation for the hospitals was designed to protect the building from serious fire damage and was designed to comply with BS EN 12845, LPC standards, SHTM 82 and BS EN 12845:2004 Annex E. The water supply for the fire suppression system comprised two multistage electric pump sets drawing water from trade tanks located in the basement of the building (Figure 1 and 10). Sprinkler protection was installed at ceiling level throughout the protected areas from Level 1 to Level 12 in the adult hospital and Level 1 to Level 4 in the children's hospital, with the pipe work concealed in the ceiling void. The installation was subdivided into zones in accordance with Annex D and Annex F of the BS EN12485. Each zone valve

[150] Capita Symonds, 'NEW SOUTH GLASGOW HOSPITAL ADULT AND CHILDREN'S HOSPITAL AND ENERGY CENTRE. NEC 3 SUPERVISORS REPORT NO. 26. May 2013' [2013] SHI.

arrangement comply with the Life Safety requirements and each zone will not exceed 2,400 m^2. Sprinkler protection was provided throughout the building apart from optional permitted exceptions, so that if a fire starts at any location in the building it is suppressed and controlled and/or extinguished quickly and efficiently, preventing fire spread to other parts of the building. All the monitored sprinkler equipment such as pumps valves and flow switches are wired to an addressable panel. A flow alarm switch will be provided on the alarm valve riser to give remote alarm indication.

4.35.2. The wet riser's system in the Adult and Children's hospital was provided with a landing valve at each floor and each staircase. The water supply for the riser system is supplied from the electric booster pump set which supplies water from the trade tank. Four wet risers were be installed in the adult hospital and two in the Children's hospital. The booster pumps provide a duty and standby with automatic changeover. The landing valve provided at each floor level is where personnel can connect and fill hose lines before entering the fire compartment. Each landing valve is sited in the stairway enclosure and is protected and installed within a box in accordance with BS 5041-2.

4.35.3. In all cases where town's mains supply is involved, the capacity of the mains is important. Generally a water supply capable of providing a minimum of 1500 L/min at all times will be required.

4.35.4. There was an assumption that the town's main supply would not provide sufficient pressure and capacity to provide the necessary supply, each fire main should be fed from two interconnected tanks of nominal equal capacity and having a total minimum capacity of 45 000 l. The tanks will be automatically supplied from a town mains controlled by ball valves and the capacity of these mains together with the contents of the tanks should be such as to maintain a flow of water capable of supplying two firefighting jets for 45 mins when water is being used at a total rate of 1 500 1/min. Each tank will be fitted with isolating valves to enable one tank to be taken out of service for maintenance or repair.

5. Description of "unsafe" water and wastewater (drains) system

5.1. Introduction

5.1.1. This section of the expert report considers key aspects of water systems that have been identified to be microbiologically unsafe and hence result in an increased risk of HAI. The generic scenarios described have been identified from guidance and peer reviewed published literature.

5.1.2. To assess whether a water and wastewater system are unsafe then a number of parameters need to be taken into account including [151]:

- The physical water and waste-water system
- The manner in which it is operated
- Evidence of microbial contamination
- Mitigation and control measures

5.1.3. 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 [152].

5.1.4. All patients in hospitals are potentially at risk from waterborne HAI, and through risk assessment, some patients are identified to be at increased risk, e.g. due to their immunocompromised condition and may have to be supplied with sterile water. The implementation of standard infection control precautions (IPC) through the water safety group can assist in mitigating / preventing HAI being transmitted to patients [153] [154].

5.1.5. Additional IPC measures can be used to reduce HAI. For example, where evidence has been provided that the water in the built environment is unsafe for the patients then antibiotic prophylaxis can be administered to mitigate the 'additional burden of risk' and help reduce the likelihood of the development of HAIs [155].

[151] HSE (n 20).
[152] NICE, 'National Institute for Health and Care Excellence. Healthcare-Associated Infections. Nice.Org.Uk/Topics/Healthcare-Associated-Infections'.
[153] HSE (n 20).
[154] NHS GGC, 'Standard Operating Procedure (SOP) for Minimising the Risk of *Pseudomonas Aeruginosa* Infection from Water. Applicable in All Adult and Paediatric Intensive Care Units and Neonatal Units (Levels 1, 2 and 3)'.
[155] SHI, 'Scottish Hospitals Inquiry Meeting Minutes Bundle Of Documents as Referenced in QEUH HOIC PPP'.

5.1.6. The publication of international and national reports on HAI associated mortality [156]has resulted in greater awareness, increased scrutiny on healthcare delivery and resulted in improving patient care [157].

5.1.7. Over the last few decades guidelines and standards have been published that allow those involved in the design, construction and operation of the built environment – the hospital, to better understand what is required to provide a safe environment (ventilation and water) for patients [158].

5.1.8. HAI associated with the built environment should not be accepted as an inevitable consequence of being admitted to a hospital to access lifesaving treatment. Indeed it was in 1858 that Florence Nightingale stated so eloquently “it may seem a strange principle to enunciate as the very first requirement in a hospital that it should do the sick no harm” [159].

5.1.9. In hospitals, a safer built environment could be considered one in which HAI has been significantly reduced. This can be achieved through a water safety plan approach including engineering, planned preventative maintenance, training, compliance, risk assessment and following guidance implemented by competent staff and a water safety plan [160] [161].

5.1.10. The importance of safe water and wastewater systems in preventing waterborne HAI is described in guidance [162] [163] [164].

5.1.11. Where mitigation strategies including water safety plans, water safety groups, risk assessments. planned preventative maintenance programmes and training have not been maintained then water and waste system will present an “additional risk of avoidable infection to patients [165] [166] [167] [168]:

- The physical water and waste-water system
- The manner in which it is operated
- Evidence of microbial contamination
- Mitigation and control measures – to reduce microbial contamination and consequently the additional risk to patients

[156] NICE (n 153).
[157] HSE (n 19).
[158] HFS, ‘Water Safety (SHTM 04-01) Part A: Design, Installation and Testing 2014’.
[159] Heather P Loveday, ‘Revisiting Florence Nightingale: International Year of the Nurse and Midwife 2020’ (2020) 21 Journal of Infection Prevention 4.
[160] HSE (n 20).
[161] WHO (ed), ‘Water Safety in Buildings. Https://Www.Who.Int/Publications/i/Item/9789241548106’.
[162] HSE (n 20).
[163] HSE (n 19).
[164] HFS, ‘Water Safety (SHTM 04-01) Part A-G.’ (n 41).
[165] BSI, ‘BS 8680 - Water Quality. Water Safety Plans. Code of Practice 2020’ (n 22).
[166] HSE (n 19).
[167] HSE (n 20).
[168] DHSC, ‘HTM 04-01: Safe Water in Healthcare Premises. Part C: Pseudomonas Aeruginosa – Advice for Augmented Care Units 2014’ (n 11).

5.1.12. Water systems need to be maintained to reduce the risk from “unsafe water and wastewater systems”. To maintain, service and operate a “safe” water system requires trained and competent staff to implement a written scheme, a water safety group and water safety plan.

5.1.13. The water safety group (WSG) is a multidisciplinary group of people formed to undertake the commissioning, development and ongoing implementation and management of the water safety plan (WSP). The WSG requires to have the skills and responsibility to ensure that the water is safe at the point of use for all uses and all users of water within buildings. The WSG composition and role varies depending on the design, size and complexity of the systems and risk assessments based on types of hazards, hazardous events, routes of exposure and transmission for all intended uses and users of the system or device. The WSG need to be able to risk assess the water and waste system to monitor, identify and control microbial proliferation thereby mitigating patients’ risk of exposure to harmful levels of microorganisms [169] [170].

5.1.14. The water safety plan is a strategic plan which defines and documents the arrangements that are required for the safe use and management of all water systems together with all associated systems and equipment within each building or estate to prevent harm arising from all forms of exposure.

5.1.15. There are three components required for HAI to occur: i) water system, ii) patients and iii) opportunistic waterborne microorganisms [171].

i) Water system: There are different types of water systems including closed and open systems.
   - Closed water system: the water systems associated with chilled beam heaters are known as a closed water system where there is no environmental exposure directly from the water within the chilled beam.
   - Open water system: Domestic hot and cold water systems have outlets such as taps, showers and other medical equipment through which patients can be exposed.

ii) Opportunistic waterborne microorganisms: Where water safety plans, mitigation strategies, risk assessments and planned preventative maintenance programmes have not been carried out according to agreed guidance [172] [173] then the lack of such actions would result in an ‘unsafe’ water system. Indications of an unsafe water system include inadequately controlled hot and cold water temperatures and microbial counts that have exceeded set thresholds [174] [175].

iii) Patients: the presence of patients who are exposed to ‘unsafe’ microbially contaminated water will be at increased risk of contracting a HAI.

[169] HSE (n 20).
[170] HFS, ‘Water Safety (SHTM 04-01) Part A-G.’ (n 41).
[171] Amy S Collins, ‘Preventing Health Care–Associated Infections’ in Ronda G Hughes (ed), *Patient Safety and Quality: An Evidence-Based Handbook for Nurses* (Agency for Healthcare Research and Quality (US) 2008).
[172] HSE (n 19).
[173] HSE (n 20).
[174] Chaput, ‘Microbiological Testing (2015-2020) of Water and Environmental Samples from the QEUH (Adults) and RHC, Overview of Sample Numbers and Test Results.’ (n 33).
[175] Storrar and Rankin (n 48).

5.1.16. Where the growth of waterborne microorganisms has occurred in the water and wastewater system, patients can be exposed through:

- Inhalation of aerosols and breathable water droplets;
- Drinking water;
- Drains;
- Ingestion of ice;
- Ingestion of food prepared using water;
- Skin contact through washing, bathing (including use of baths/pools) and showering;
- Contact with endoscopes and medical instruments; and
- Contact with others (staff, visitors and other patients).

5.1.17. As discussed in section 4.3 water delivered to Scottish hospitals is required to be 'wholesome' . The following sections describe wholesome water in more detail and circumstances where i) the provision of the wholesome water in wards can be a risk for high risk patients and ii) the lack of risk assessments, planned preventative maintenance programmes and control strategies result in water that is not wholesome, which increases the risk to patients [176] [177] [178].

5.2. What is 'wholesome water'?

5.2.1. In Scotland all water intended for human consumption is required by legislation to comply with the quality standards laid down by the Drinking Water Quality Regulator (DWQR) with powers as laid down in Section 7 of the Water Industry (Scotland) Act 2002. DWQR can force the statutory water authority to comply with the standards set out in the Water Supply (Water Quality) (Scotland) Regulations 2001[179]. In essence the requirements are that the water should not contain (i) any micro-organism (within parameters) or parasite; or (ii) any substance (within parameters), at a concentration or value which would constitute a potential danger to human health.

5.2.2. The incoming water supply has to legally comply with the drinking water regulations [180] and only those microbial tests that are specified in the regulations are undertaken.

5.2.3. Specifically, from a microbiological perspective there should be an absence of *Clostridium perfingens* and Coliforms and there should be no abnormal change (i.e. the total colony count should be within set parameters) in the total colony count (number per ml) performed at either 22°C or 37°C [181].

[176] HFS, 'Water Safety (SHTM 04-01) Part A-G.' (n 41).
[177] HSE (n 19).
[178] HSE (n 20).
[179] DWQR (n 80).
[180] Scottish Water, 'Water Byelaws' <https://www.legislation.gov.uk/sdsi/2014/9780111024782/regulation/4> accessed 11 February 2021; DWQR, 'Drinking Water Quality Regulator for Scotland. The Water (Scotland) Act 1980.'
[181] DWQR (n 181).

5.3. Supply of wholesome water

5.3.1. Normally, the source of water supply to healthcare premises is by one or more service pipe connections from the mains of the water supply authority [182]. Water supplied to hospitals in Scotland is disinfected by the water supply authority. The Drinking Water Quality Regulators (DWQR) monitor the Water Authority to ensure that the Regulations are complied with, and the 2001 Regulations detail the acceptable levels of certain characteristics, elements and substances allowed in drinking water for which these permissible levels are known as Prescribed Concentration of Value (PCV) [183].

5.4. Responsibility for ensuring safe water in buildings

5.4.1. The employer, or someone in control of premises, including landlords, must understand the health risks associated with Legionella bacteria and other microorganisms and their ability to proliferate where the conditions could be considered to be unsafe [184].

5.4.2. The approved code of practice [185] places a duty of care on designers, manufacturers, suppliers and installers to ensure that water systems that may create a risk of exposure to Legionella bacteria must ensure that, so far as is reasonably practicable that the water systems is so designed and constructed that it will be safe and without risks and without risks to health and safety [186].

5.4.3. Hot and cold water storage and distribution systems should be designed so as to avoid the risk of microbial contamination of the water supply [187]. Such contamination may be caused by backflow, interconnections between potable and non-potable water supplies, stagnation, contact with unsuitable materials or substances, Legionella growth [188]. The Scottish Water Byelaws 2004 require the identification, by colour-coding or labelling, of all pipework carrying fluids other than wholesome water .

5.4.4. The European Drinking Water Directive (98/83/EC) [189], which is translated into the Water Supply (Water Quality) (Scotland) Regulations 2001 [190] & 2010 [191], lay down that bodies must "…take measures to ensure that water intended for human consumption is wholesome and clean…" and it further states that this requirement is to be measured at the point of supply which, for the purposes of this Guidance Document [192], is to be taken to mean the outlet of the tap.

[182] HFS, 'Water Safety (SHTM 04-01) Part A: Design, Installation and Testing 2014' (n 159).
[183] DWQR (n 80).
[184] HSE (n 20).
[185] HSE (n 20).
[186] HSE (n 19).
[187] HSE (n 20).
[188] HSE (n 20).
[189] EC, 'European Drinking Water Directive (98/83/EC)',.
[190] DWQR (n 80).
[191] 'The Water Quality (Scotland) Regulations 2010'.
[192] HFS, 'Water Safety (SHTM 04-01) Part A: Design, Installation and Testing 2014' (n 159).

5.4.5. Patients in hospitals including those patients in high risk and non-high risk areas are vulnerable to infections from Legionella and other microorganisms [193].

5.4.6. The provision of the supply of water in high risk locations such as wards and specialist areas where occupants are vulnerable needs particular consideration and the risk assessment should consider the relative risks of Legionella [194].

5.4.7. Therefore, the person(s) responsible for managing risks, as appointed by the employer, or someone who is in control of premises needs to understand the water systems, the equipment associated with the system such as pumps, heat exchangers, showers etc, and its constituent parts and whether they are likely to create a risk from exposure to Legionella and other microorganisms [195].

5.4.8. Duty holders and those in control of premises and those with health and safety responsibilities for others are required to identify and assess sources of risk, prepare a scheme to prevent or control risk, implement, manage and monitor precautions, keep records of precautions and appoint a manager responsible for others[196]. Risks assessing includes identifying the relevant additional risks in some parts or component parts of the water system where there are additional risk of growth and proliferation [197]. Where there are susceptible individuals' special considerations should be applied proportionately, e.g. in an acute hospital setting where there are likely to be a larger number of susceptible patients at risk of infection [198].

5.4.9. These additional risks identified in hospitals include[199]:

- water temperature in the cold water system is above 20°C or where the hot water temperatures is below 55°C
- water is stored or re-circulated as part of your system
- sources of nutrients such as rust, sludge, scale, organic matter and biofilms
- conditions that are likely to encourage bacteria to multiply
- exposure to water droplets and aerosols dispersed over a wide area, e.g. showers and aerosols from cooling towers
- employees, residents, visitors etc who are more susceptible to infection due to age, illness, a weakened immune system etc and whether they could be exposed to any contaminated water droplets

[193] HSE (n 19).
[194] HSE (n 20) 274.
[195] HSE (n 20).
[196] HSE (n 19).
[197] HSE (n 20).
[198] HSE (n 20).
[199] HSE (n 20).

5.4.10. Clinical surveillance of patient infections may provide supportive data to determine whether HAI are related to the built environment, particular where multiple HAI are occurring due to environmental microorganisms over a long time period [200].

5.5. What are healthcare-associated infections?

5.5.1. A healthcare-associated infection (HAI) 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 [201].

5.5.2. The factors influencing whether or not a hospital patient acquires a waterborne pathogen can be considered to be multifactorial, including the susceptibility of the host or patient, the presence of waterborne bacteria, the concentration of microbial contamination, and the exposure to the source of pathogen [202].

5.5.3. Patients vary in their susceptibility to HAI with those who are very young, very old, those with certain medical conditions e.g. diabetes or cystic fibrosis, and those with weakened immune systems, either owing to a pre-existing condition or as a side effect of treatment such as chemotherapy, being most at risk of HAIs.

5.5.4. Pathogens themselves vary in their virulence/pathogenicity, i.e. the capacity to cause disease and the severity of the subsequent illness with antibiotic resistant strains resulting in greater challenges due to increased virulence increasing transmissibility. The interaction between the microbial pathogen (i.e. virulence of the bacterium, virus or fungus) and the patient (immune response), governs whether or not the patient gets an infection, and if so, the severity of the subsequent infection.

5.5.5. Environmental factors include the physical environment such as unsafe water, ventilation, contamination of the patient's environment and medical equipment, inadequately decontaminated instruments used during surgery and overcrowding in hospitals but also the human factor, particularly professional practice, e.g. poor compliance with hand hygiene.

5.5.6. Whilst susceptibility to HAIs may be multifactorial they can be broadly categorised as being a result of either "intrinsic" or "extrinsic" risk factors where:

i) Intrinsic risk factors: refer to those risks that relate to a) patient vulnerability e.g. age, drugs that weaken the immune system (e.g. high dose corticosteroids), underlying diseases such as cancer and diabetes mellitus, and their general state of health including obesity.

[200] T Inkster and others, 'Investigation of Two Cases of *Mycobacterium Chelonae* Infection in Haemato-Oncology Patients Using Whole-Genome Sequencing and a Potential Link to the Hospital Water Supply' (2021) 114 J Hosp Infect 111.
[201] NICE (n 153).
[202] Brooke K Decker and Tara N Palmore, 'The Role of Water in Healthcare-Associated Infections' (2013) 26 Current opinion in infectious diseases 345.

ii) Extrinsic risk factors: refer to those external to the patient and include the environment (water or ventilation), professional practice (hand hygiene), cleaning and decontamination and the use of interventional drugs such as prophylactic antibiotics.

5.5.7. Hence, any infection prevention and control programme or HAI prevention strategy should be multi-modal and include reducing the risk from both an intrinsic and extrinsic capacity e.g. advice for an obese patient to lose weight prior to surgery as well as improving professional practice (compliance with hand hygiene), addressing hospital hygiene, instrument sterilization and ensuring that there is appropriate ventilation and that safe water is provided for patients at higher risk of infection such as patients with haematological malignancies [203].

5.5.8. Healthcare-associated infection (HAI) is associated with increased morbidity and mortality resulting in excess costs [204]. In Scotland 58,010 (95% CI: 41,730-74,840) bed-days were estimated to be lost to HAI during 2018/19, costing £46.4 million (19m-129m). The total annual cost in the UK is estimated to be £774 million (328m-2,192m) [205].

5.5.9. Water remains one of the most overlooked and underestimated sources of hospital associated infections [206]. Published reviews have estimated that approximately 21.6% of all recorded HAIs can be attributed to water [207]. There is no reason to suspect that these figures would be any different in Europe or in the UK or Scotland.

5.5.10. Healthcare-associated infections related to the built environment are preventable, and strategies should be in place to provide effective and safe patient care". [208]

5.6. Why does a water system become microbiologically unsafe?

5.6.1. Current statutory legislation [209] [210] requires both ' hospital management' and 'staff' to be aware of their individual and collective responsibility for the provision of wholesome through microbial control strategies and storage and distribution systems in healthcare premises. This applies whether premises are NHS owned or procured via PFI/PPP and operated by Consortia Facilities Management staff or subcontractors.

[203] Stevens, Evans and Wilcox (n 54).
[204] S Manoukian and others, 'Bed-Days and Costs Associated with the Inpatient Burden of Healthcare-Associated Infection in the UK' (2021) 114 JHI 43.
[205] Manoukian and others (n 205).
[206] Claire Hayward and others, 'Water as a Source of Antimicrobial Resistance and Healthcare-Associated Infections' (2020) 9 Pathogens 667 <https://www.mdpi.com/2076-0817/9/8/667> accessed 20 November 2021.
[207] Kiran M Perkins and others, 'Investigation of Healthcare Infection Risks from Water-Related Organisms: Summary of CDC Consultations, 2014—2017' (2019) 40 Infection control and hospital epidemiology 621; Hajime Kanamori, 'Healthcare Outbreaks Associated with a Water Reservoir and Infection Prevention Strategies | Clinical Infectious Diseases | Oxford Academic' <https://academic.oup.com/cid/article/62/11/1423/1745014> accessed 17 April 2019.
[208] C Vincent and Rene Amalberti, 'Safer Healthcare Strategies for the Real World. Springer Open.'
[209] HSE (n 20).
[210] HSE (n 19).

5.6.2. To maintain a wholesome supply throughout the hospital, the water system needs to be risk assessed and managed. Where issues have been identified that would lead to microbial proliferation then mitigated measures need to be implemented.

5.6.3. When the wholesome water supply enters buildings the opportunistic waterborne microorganisms in the water will be exposed to conditions that will encourage microbial growth and proliferation (e.g. the cold water may increase in temperature e.g. >20°C and or it may become stagnant) to such an extent that the water could be considered unsafe.

5.6.4. A water system that is considered to be unsafe could be one in which there is a i) lack of control of temperatures, ii) lack of planned preventative maintenance iii) stagnation and lack of use of outlets, iv) where colony counts are above the threshold and or water borne pathogens are being detected and v) where environmental microorganisms are responsible for HAI.

5.6.5. Opportunistic waterborne pathogens proliferate in water systems as they:

- survive in low nutrient (or oligotrophic) environment
- survive in low flow and stagnant conditions
- tolerate chemical disinfectants
- persist and grow inside amoeba
- form biofilms on the surfaces of water system infrastructure

5.6.6. A wide range of waterborne microorganisms are able to survive in potable water, drains and wastewater systems due to the favourable conditions for growth [211].

5.6.7. General mitigation strategies for microbial control in healthcare water systems are considered to be:

- hot water should be stored at least at 60°C and distributed so that it reaches a temperature of 55°C in healthcare premises within one minute at the outlets with a return temperature to the calorifier from each loop of at least 55°C in healthcare [212]
- cold water should be maintained at a temperature below 20°C [213]
- keeping water system clean – remove debris and sediment
- keeping water flowing – encourage regular movement to avoid stagnation
- implementation of a water safety plan and water safety group

[211] Storrar and Rankin (n 48).
[212] HSE (n 20).
[213] HSE (n 20).

5.6.8. Mitigation strategies should include the training of competent staff to maintain the water system as per HSG 274 [214], ACOP [215] and SHTM [216] as well as the implementation of a water safety group and a water safety plan [217] [218].

5.7. Range of waterborne pathogens resulting in unsafe water

5.7.1. A wide range of microorganisms are cited in the published peer reviewed literature as being associated with healthcare associated infections are listed below [219].

Table 1. List of microorganisms cited in peer reviewed published literature associated with waterborne hospital-associated infections.

Microorganism	**References**
Acinetobacter baummannii	Car La Forgia, C. *et al.* Management of a multidrug-resistant *Acinetobacter baumannii* outbreak in an intensive care unit using novel environmental disinfection: a 38-month report. *Am J Infect Control* **38**, 259–263 (2010). Umezawa, K. *et al.* Outbreak of drug-resistant *Acinetobacter baumannii* ST219 caused by oral care using tap water from contaminated hand hygiene sinks as a reservoir. *Am J Infect Control* **43**, 1249–1251 (2015).
Acinetobacter junii,	Kappstein, I., Grundmann, H., Hauer, T. & Niemeyer, C. Aerators as a reservoir of *Acinetobacter junii*: an outbreak of bacteraemia in paediatric oncology patients. *J Hosp Infect* **44**, 27–30 (2000).
Achromobacter spp.,	Hugon, E., Marchandin, H., Poirée, M., Fosse, T. & Sirvent, N. *Achromobacter bacteraemia* outbreak in a paediatric onco-haematology department related to strain with high surviving ability in contaminated disinfectant atomizers. *J Hosp Infect* **89**, 116–122 (2015).
Burkholderia spp.,	Nasser, R. M. *et al.* Outbreak of *Burkholderia cepacia* bacteremia traced to contaminated hospital water used for dilution of an alcohol skin antiseptic. *Infect Control Hosp Epidemiol* **25**, 231–239 (2004).
Citrobacter freundii,	De Geyter, D. *et al.* The sink as a potential source of transmission of carbapenemase-producing *Enterobacteriaceae* in the intensive care unit. *Antimicrobial Resistance & Infection Control* **6**, 24 (2017).

[214] HSE (n 20).
[215] HSE (n 19).
[216] HFS, 'Water Safety (SHTM 04-01) Part A-G.' (n 41).
[217] WHO, 'Water Safety Plan Manual (WSP Manual)' <https://www.who.int/publications-detail-redirect/9789241562638> accessed 7 February 2023.
[218] BSI, 'BS 8680 - Water Quality. Water Safety Plans. Code of Practice 2020' (n 22).
[219] Storrar and Rankin (n 48).

Microorganism	References
Cupriavadus pauculus	Uzodi, A. S., Schears, G. J., Neal, J. R. & Henry, N. K. *Cupriavidus pauculus* bacteremia in a child on extracorporeal membrane oxygenation. *ASAIO J* **60**, 740–741 (2014).
Elizabethkinga meningoseptica,	Balm, M. N. D. *et al.* Bad design, bad practices, bad bugs: frustrations in controlling an outbreak of *Elizabethkingia meningoseptica* in intensive care units. *J Hosp Infect* **85**, 134–140 (2013). Hoque, S. N., .Graham, J., Kaufmann, M. E. & Tabaqchali, S. *Chryseobacterium* (*Flavobacterium*) *meningosepticum* outbreak associated with colonization of water taps in a neonatal intensive care unit. *J Hosp Infect* **47**, 188–192 (2001).
Enterobacter cloacae,	Kac, G. *et al.* Molecular epidemiology of extended-spectrum beta-lactamase-producing *Enterobacteriaceae* isolated from environmental and clinical specimens in a cardiac surgery intensive care unit. *Infect Control Hosp Epidemiol* **25**, 852–855 (2004). Wolf, I. et al. The sink as a correctable source of extended-spectrum β-lactamase contamination for patients in the intensive care unit. Journal of Hospital Infection 87, 126–130 (2014).
Klebsiella oxytoca,	Lowe, C. et al. Outbreak of extended-spectrum β-lactamase-producing *Klebsiella oxytoca* infections associated with contaminated handwashing sinks(1). Emerg Infect Dis 18, 1242–1247 (2012). Leitner, E. *et al.* Contaminated handwashing sinks as the source of a clonal outbreak of KPC-2-producing *Klebsiella oxytoca* on a hematology ward. *Antimicrob Agents Chemother* **59**, 714–716 (2015).
Klebsiella pneumoniae	Starlander, G. & Melhus, Å. Minor outbreak of extended-spectrum β-lactamase-producing *Klebsiella pneumoniae* in an intensive care unit due to a contaminated sink. *J Hosp Infect* **82**, 122–124 (2012). Su, L. H. *et al.* Molecular investigation of two clusters of hospital-acquired bacteraemia caused by multi-resistant *Klebsiella pneumoniae* using pulsed-field gel electrophoresis and in frequent restriction site PCR. Infection Control Group. *J Hosp Infect* **46**, 110–117 (2000).

Microorganism	References
Legionella pneumophila	Schuetz, A. N. *et al.* Pseudo-outbreak of *Legionella pneumophila* serogroup 8 infection associated with a contaminated ice machine in a bronchoscopy suite. *Infect Control Hosp Epidemiol* **30**, 461–466 (2009). Oren, I. *et al.* Nosocomial outbreak of *Legionella pneumophila* serogroup 3 pneumonia in a new bone marrow transplant unit: evaluation, treatment and control. *Bone Marrow Transplant* **30**, 175–179 (2002)
Non-tuberculosis mycobacteria (NTM) *M. chelonae* and *M. abscessus*	Kline, S. *et al.* An outbreak of bacteremias associated with *Mycobacterium mucogenicum* in a hospital water supply. *Infect Control Hosp Epidemiol* **25**, 1042–1049 (2004). Baird, S. F. *et al.* Cluster of non-tuberculous mycobacteraemia associated with water supply in a haemato-oncology unit. *J Hosp Infect* **79**, 339–343 (2011).
Pseudomonas aeruginosa	Aumeran, C. *et al. Pseudomonas aeruginosa* and *Pseudomonas putida* outbreak associated with contaminated water outlets in an oncohaematology paediatric unit. *J Hosp Infect* **65**, 47–53 (2007). Trautmann, M., Michalsky, T., Wiedeck, H., Radosavljevic, V. & Ruhnke, M. Tap water colonization with *Pseudomonas aeruginosa* in a surgical intensive care unit (ICU) and relation to Pseudomonas infections of ICU patients. *Infection Control & Hospital Epidemiology* **22**, 49–52 (2001).
Pantoea agglomerans,	Yablon, B. R. *et al.* Outbreak of *Pantoea agglomerans* Bloodstream Infections at an Oncology Clinic-Illinois, 2012-2013. *Infect Control Hosp Epidemiol* **38**, 314–319 (2017).
Pseudomonas fluorescens,	Wong, V., Levi, K., Baddal, B., Turton, J. & Boswell, T. C. Spread of *Pseudomonas fluorescens* due to contaminated drinking water in a bone marrow transplant Unit. *Journal of Clinical Microbiology* **49**, 2093–2096 (2011).
Pseudomonas putida,	Aumeran, C. *et al. Pseudomonas aeruginosa* and *Pseudomonas putida* outbreak associated with contaminated water outlets in an oncohaematology paediatric unit. *J Hosp Infect* **65**, 47–53 (2007).
Staphylococcus aureus,	Embil, J. M. *et al.* An outbreak of methicillin resistant *Staphylococcus aureus* on a burn unit: potential role of contaminated hydrotherapy equipment. *Burns* **27**, 681–688 (2001).

Microorganism	References
Serratia marcescens,	Kotsanas. “Down the drain”: carbapenem-resistant bacteria in intensive care unit patients and handwashing sinks - Kotsanas - 2013 - Medical Journal of Australia - Wiley Online Library. (2013). Horcajada, J. P. *et al.* Acquisition of Multidrug-Resistant *Serratia marcescens* by Critically Ill Patients Who Consumed Tap Water During Receipt of Oral Medication. *Infection Control & Hospital Epidemiology* **27**, 774–777 (2006).
Stenotrophomonas maltophilia	Anaissie, E. J., Penzak, S. R. & Dignani, M. C. The hospital water supply as a source of nosocomial infections: a plea for action. Archives of Internal Medicine 162, 1483–1492 (2002). Cervia, J. S., Ortolano, G. A. & Canonica, F. P. Hospital tap water as a source of *Stenotrophomonas maltophilia* infection. *Clin Infect Dis* **46**, 1485–1487 (2008).
Aspergillus spp.,	Garner, D. & Machin, K. Investigation and management of an outbreak of mucormycosis in a paediatric oncology unit. J Hosp Infect 70, 53–59 (2008).
Fusarium spp.,	Anaissie, E. J. et al. Fusariosis Associated with Pathogenic Fusarium Species Colonization of a Hospital Water System: A New Paradigm for the Epidemiology of Opportunistic Mold Infections. Clinical Infectious Diseases 33, 1871–1878 (2001). Litvinov, N. et al. An outbreak of invasive fusariosis in a children’s cancer hospital. Clinical Microbiology and Infection 21, 268.e1-268.e7 (2015).
Exophiala jeanselmei,	Nucci, M. et al. Nosocomial outbreak of Exophiala jeanselmei fungemia associated with contamination of hospital water. Clin Infect Dis 34, 1475–1480 (2002).
Rhizomucor spp.	Garner, D. & Machin, K. Investigation and management of an outbreak of mucormycosis in a paediatric oncology unit. J Hosp Infect 70, 53–59 (2008).

5.7.2. *L. pneumophila*, *P. aeruginosa* and non-tuberculosis mycobacteria (NTM) account for the majority of cases of hospital associated infections [220].

5.7.3. *L. pneumophila* serogroup 1 accounts for over 93% of clinical cases in Europe [221] and the *death rate* may be as high as 40–80% in untreated immuno-suppressed

[220] Decker and Palmore (n 203).
[221] ECDC, ‘Legionnaires’ Disease - Annual Epidemiological Report for 2019’ [2021] European Centre for Disease Prevention and Control.

patients in hospitals [222]. The results demonstrated that *L. pneumophila* serogroup 1 counts exceeded the 1000 cfu/l threshold which would have resulted in an increased unacceptably high risk for patients [223].

5.7.4. Description of Legionella counts and actions required as per guidance [224]. Where Legionella results are:

- less than 100 CFUs/Litre - 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.
- in excess of 100, but less than 1,000 CFUs/Litre – the Authorised Person (Water) and Consultant Microbiologist would provide interpretation on the results and confirm the necessary actions prior to bringing the water system into use.
- in excess of 1,000 CFUs/Litre immediate action must be taken - the Consultant Microbiologist and Authorised Person (Water) 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.

5.7.5. The presence of *L. pneumophila* serogroup 1 in the water system exceeding >1000 cfu/L would indicate that control parameters within the water system were not achieved and presented an additional risk of avoidable infection to patients.

5.7.6. However, there are a wide range of microorganisms that when identified in a water system would result in that water being described as being unsafe (Table 2).

5.7.7. Most waterborne organisms are Gram-negative, with the exceptions being the Gram-positive non-tuberculous mycobacteria (NTM including *M. abscessus* and *M. chelonae*) and fungi (*Fusarium* spp.).

5.7.8. A number of the opportunistic waterborne pathogens have developed extensive antibiotic resistance, particularly against the carbapenem group of antibiotics, known as carbapenem-resistant organisms (CROs) which has implications for treatment of infections. Carbapenem-resistant infectious agents that are part of the Enterobacterales family (e.g. *Klebsiella* spp., *Enterobacte*r spp., Serratia spp.) are categorised as carbapenem-resistant *Enterobacterales* (CREs) and have been involved in a number of large scale waterborne and drain associated hospital outbreaks [225] [226]. Where these microorganisms have been associated either with water or wastewater systems within a hospital then those systems would be unsafe.

[222] WHO, 'Legionellosis'.
[223] ECDC, 'Legionnaires' Disease - Annual Epidemiological Report for 2021'.
[224] HSE (n 20) 274.
[225] V Decraene and others, 'A Large, Refractory Nosocomial Outbreak of *K Pneumoniae* Carbapenemase-Producing *E Coli* Demonstrates Carbapenemase Gene Outbreaks Involving Sink Sites Require Novel Approaches to Infection Control' (2018) 62 Antimic Agents Chemo.
[226] Kotsanas, '"Down the Drain": Carbapenem-resistant Bacteria in Intensive Care Unit Patients and Handwashing Sinks' [2013] Medical Journal of Australia.

5.7.9. One of the key sources of hospital-associated waterborne infections is the contaminated water distribution system, including; cold water storage tanks and reservoirs, pipe work, faucets/taps/outlet fittings, sinks, hand-wash sinks, sink traps, drains, showerheads, shower hoses, baths and drains as well as equipment that use water [227] [228] [229] [230] [231] [232].

5.7.10. Whilst it is acknowledged that the mains supply water will contain microorganisms it is generally considered that it is the failures in design, build, commissioning, training, management and operation of healthcare water distribution systems and associated components, fittings and equipment that have enabled incoming microorganisms to survive and proliferate to unsafe numbers, i.e. beyond set thresholds [233] [234] [235] [236].

5.8. Where are pathogens and biofilms located in water systems?

5.8.1. Bacteria will be present in the water (planktonic) phase and as a biofilm on the various surfaces throughout the water system. Biofilm consists of a consortium of microorganisms that preferentially attach to surfaces where they can harvest nutrients from the environment [237] [238]. As the biofilm develops, the bacterial biofilm cells attached to the surface will become detached and be released into the water flow and be carried downstream to contaminate other parts of the water system. In healthcare, biofilms have developed niches on plumbing components that have seeded and contaminated the water systems [239].

5.8.2. Biofilm is often unseen as it grows on pipes and surfaces within the water system. However, biofilm can be observed in cold water storage tanks (when inspected), on strainers, outlets of taps and or drinking water fountains/coolers or in

[227] Yasuaki Tagashira and others, 'A Cluster of Central Line-Associated Bloodstream Infections Due to Rapidly Growing Nontuberculous Mycobacteria in Patients with Hematologic Disorders at a Japanese Tertiary Care Center: An Outbreak Investigation and Review of the Literature' (2015) 36 Infection Control and Hospital Epidemiology 76.
[228] HP Loveday and others, 'Association between Healthcare Water Systems and Pseudomonas Aeruginosa Infections: A Rapid Systematic Review' (2014) 86 JHI 7.
[229] Leighann O Parkes and Susy S Hota, 'Sink-Related Outbreaks and Mitigation Strategies in Healthcare Facilities' (2018) 20 Current Infectious Disease Reports 42 <https://doi.org/10.1007/s11908-018-0648-3> accessed 26 June 2021.
[230] Alice E Kizny Gordon and others, 'The Hospital Water Environment as a Reservoir for Carbapenem-Resistant Organisms Causing Hospital-Acquired Infections-A Systematic Review of the Literature' (2017) 64 Clinical Infectious Diseases 1435.
[231] Michelle Moffa and others, 'A Systematic Review of Nosocomial Waterborne Infections in Neonates and Mothers' (2017) 220 International Journal of Hygiene and Environmental Health 1199.
[232] Decker and Palmore (n 203).
[233] HSE (n 20) 274.
[234] SF Baird and others, 'Cluster of Non-Tuberculous Mycobacteraemia Associated with Water Supply in a Haemato-Oncology Unit' (2011) 79 The Journal of Hospital Infection 339.
[235] Arthur W Baker and others, 'Two-Phase Hospital-Associated Outbreak of Mycobacterium Abscessus: Investigation and Mitigation' (2017) 64 Clinical Infectious Diseases 902.
[236] HPS, 'Summary of Incident and Findings of the NHSGGC: QUEH/RHC Water Contamination Incident and Recommendations for NHS Scotland. Final V2' (n 62).
[237] Hans-Curt Flemming and Jost Wingender, 'The Biofilm Matrix' (2010) 8 Nature Reviews Microbiology 623.
[238] JW Costerton, 'Overview of Microbial Biofilms' (1995) 15 J Indust Microbiol 137.
[239] Raquel Vannucci Capelletti and Ângela Maria Moraes, 'Waterborne Microorganisms and Biofilms Related to Hospital Infections: Strategies for Prevention and Control in Healthcare Facilities' (2016) 14 J Wat Hlth 52.

renal units outlets [240]. The majority of the microorganisms in the water will be present as biofilm and the bacteria will slough from the biofilm and will seed and contaminate the downstream water system. As such when a tap outlet has been disinfected it will readily become re-

5.8.3. contaminated if there is biofilm upstream in the water system. The presence of biofilm containing waterborne pathogens results in HAI in patients be they preterm babies, transplant, or burn patients and exact a cost in patient mortality [241].

5.9. Patient groups and clinical settings at increased risk

5.9.1. There is no doubt that patients defined as immunocompromised as a result of their disease, age or treatment and those with underlying health conditions are high-risk and at increased risk of HAI when exposed to unsafe water containing waterborne organisms. Such patient groups are generally being cared for in augmented care settings [242] [243] [244].

5.9.2. Waterborne outbreaks occurring in a range of clinical settings have been identified (Table 5) [245]. Patient populations most frequently affected by waterborne healthcare-associated infections, and considered as high-risk patients, include haematology, cardiology and oncology patients, bone marrow and stem cell transplant patients, neonatal, paediatric and adult ICU patients, transplant patients, and any other patients that are severely immunocompromised through disease or treatment (e.g. burn patients, patients with compromised skin integrity and cystic fibrosis patients). Patients with non-intact skin or indwelling peripheral venous catheters may also be at risk from healthcare associated infections.

Clinical setting for HAI waterborne outbreaks in hospitals	**Microorganisms associated with HAI**	**References**
Most common units	**Opportunistic Waterborne pathogens identified in particular units**	
Haematology and oncology units	*Pseudomonas aeruginosa* and spp. non-tuberculous mycobacteria *Legionella pneumophila*	HPS, 'Summary of Incident and Findings of the NHSGGC: QUEH/RHC Water Contamination Incident and Recommendations for NHS Scotland. Final V2'.

[240] Walker and others, 'Investigation of Healthcare-Acquired Infections Associated with *P. Aeruginosa* Biofilms in Taps in Neonatal Units in Northern Ireland' (n 9).
[241] Costerton (n 239).
[242] HPS, 'Pseudomonas Aeruginosa Routine Water Sampling in Augmented Care Areas for NHSScotland'.
[243] HPS, 'Guidance for Neonatal Units (Levels 1, 2 & 3), Adult and Paediatric Intensive Care Units in Scotland to Minimise the Risk of <i>P. Aeruginosa(/i) Infection from Water' [2013] National Services Scotland.
[244] Storrar and Rankin (n 48).
[245] Storrar and Rankin (n 48).

Clinical setting for HAI waterborne outbreaks in hospitals	**Microorganisms associated with HAI**	**References**
	Cupriavadus pauculus *Sphingomonas* spp. *Enterobacter cloacae* *Klebsiella oxytoca*, *Achromobacter* spp. *Pantoea agglomerans* *Ochrobactrum anthropi* *Stenotrophomonas maltophilia* Fungi	Stevens, Evans and Wilcox. Inkster et al., 2023 Waterborne Infections in Haemato-Oncology Units – a Narrative Review. JHI
Bone marrow and stem cell transplant wards	*E. cloacae,* *E. jeanselmei* *F . solani* *P. fluorescens* *P. aeruginosa* *K. pneumoniae* *L. pneumoniae* Non-Tuberculous Mycobacteria.	O Lyytikäinen and others, 'Outbreak Caused by Tobramycin-Resistant Pseudomonas Aeruginosa in a Bone Marrow Transplantation Unit' (2001) 33 Scan J Infect Dis 445. I Oren and others, 'Nosocomial Outbreak of Legionella Pneumophila Serogroup 3 Pneumonia in a New Bone Marrow Transplant Unit: Evaluation, Treatment and Control' (2002) 30 Bone Marrow Transplantation 175 . JL Kool and others, 'More than 10 Years of Unrecognized Nosocomial Transmission of Legionnaires' Disease among Transplant Patients' (1998) 19 Infection Control and Hospital Epidemiology 898.
Adult and paediatric intensive care units (ICUs)	*baumannii* *P. aeruginosa* *K. pneumoniae* *K. oxytoca* *L. pneumophila* *S. marcescens* *S. maltophilia*	[1]Matthias Trautmann and others, 'Tap Water Colonization with *Pseudomonas Aeruginosa* in a Surgical Intensive Care Unit (ICU) and Relation to *Pseudomonas* Infections of ICU Patients' (2001) 22 Infection Control & Hospital Epidemiology 49. Emilie Bédard and others, 'Post-Outbreak Investigation of *Pseudomonas Aeruginosa* Faucet Contamination by Quantitative Polymerase Chain Reaction and Environmental Factors Affecting Positivity' (2015) 36 Infection

Clinical setting for HAI waterborne outbreaks in hospitals	Microorganisms associated with HAI	References
		Control & Hospital Epidemiology 1337. MS Rangel-Frausto and others, 'Persistence of Legionella Pneumophila in a Hospital's Water System: A 13-Year Survey' (1999) 20 Infection Control and Hospital Epidemiology 793. G Starlander and Å Melhus, 'Minor Outbreak of Extended-Spectrum β-Lactamase-Producing Klebsiella Pneumoniae in an Intensive Care Unit Due to a Contaminated Sink' (2012) 82 The Journal of Hospital Infection 122.
Neonatal units (NNUs)	*P. aeruginosa* *E. meningoseptica* *L. pneumophila* *S. maltophilia*	JT Walker and others, 'Investigation of Healthcare-Acquired Infections Associated with *P. Aeruginosa* Biofilms in Taps in Neonatal Units in Northern Ireland' (2014) 86 JHI 16. Trautmann and others. Panayiotis K Yiallouros and others, 'First Outbreak of Nosocomial Legionella Infection in Term Neonates Caused by a Cold Mist Ultrasonic Humidifier' (2013) 57 Clinical Infectious Diseases: An Official Publication of the Infectious Diseases Society of America 48. SN Hoque and others, 'Chryseobacterium (Flavobacterium) Meningosepticum Outbreak Associated with Colonization of Water Taps in a Neonatal Intensive Care Unit' (2001) 47 The Journal of Hospital Infection 188. PE Verweij and others, 'Nosocomial Outbreak of Colonization and Infection with Stenotrophomonas Maltophilia in Preterm Infants Associated with Contaminated Tap Water' (1998) 120 Epidemiology and Infection 251.

Other units associated with waterborne HAI include surgical units performing cardiac surgery, general surgery, neurosurgery, paediatric surgery, transplant units, liver and kidney, pacemaker implantation unit, bronchoscopy suite, burns units, cardiac wards, ears, nose throat department, HIV unit, long term care facilities, nephrology wards, private or military hospitals and respiratory wards.

Table 2. Clinical settings associated with waterborne infections.

5.10. Aspects of water systems that results in unsafe water

5.10.1. In the hospital setting the potable or domestic water supply has been identified as being the most common source of unsafe water [246]. The water system will be composed of:

- water storage tanks;
- different types of piping (copper or steel plastic);
- expansion vessels;
- flexible hoses;
- shower;
- tap outlets;
- wash hand basins (clinical and non-clinical);
- sinks for cleaning and catering purposes;
- baths;
- other equipment including drinking water outlets, ice machines and heater coolers used in heart bypass surgery); and
- drains.

5.10.2. Publications have demonstrated that the above water systems and associated component have resulted in HAI [247].

5.11. What are the foreseeable risks that result in unsafe water?

5.11.1. Water stored and used in a hospital water system presents a risk of infection and therefore that risk has to be controlled. There are a number of ways of gathering evidence that the risk has not been controlled and as such that a water system can be said to be unsafe and presents a foreseeable risk to patients.

5.11.2. Such evidence would include (but not limited to):

- Temperature monitoring
- Water usage to indicate flow
- Assessing the microbiological quality of the water

[246] HSE (n 20).
[247] Storrar and Rankin (n 48).

- HAI surveillance and look back assessment

5.11.3. There are several aspects of water systems that result in an increased risk of microbial contamination including:

5.11.4. Firstly the physical infrastructure – where the physical infrastructure could be considered as *creating an avoidable additional infection risk:*

- Oversized cold water storage tanks that would lead to stagnation and accumulation of sediment and biofilm [248]. NB: in healthcare premises, a nominal 12 hours total onsite storage capacity is recommended [249]
- Debris, dirt, washers and sponges in cold water storage tanks [250]
- Non-compliant expansion vessels enabling the growth of microbial pathogens as a biofilm [251]
- Non-compliant flexible hoses harbouring water borne pathogens
- Non-compliant taps with outlets that would encourage biofilm growth containing microbial pathogens [252]
- Inappropriate piping such as copper and galvanised steel (where these have historically been proven to be problematic [253] [254].

5.11.5. Secondly the management and operation of the water system:

- Lack of adherence to Health and Safety Guidance to enable employers, those in control of premises and those with health and safety responsibilities for others, to help them comply with their legal duties [255].
- Lack of provision of a written scheme, identification of competent responsible staff as well as those with operational and management duties that are required to operate a safe water system in a healthcare building [256].
- Inability of the water system to maintain an appropriate temperature regimen in the hot and cold water to prevent the growth of waterborne pathogens [257].
- Lack of flow leading to stagnation [258].
- Lack of or not having a fully functioning water safety plan and water safety group

5.11.6. Thirdly, and perhaps most fundamentally, microbial contamination of the water system:

[248] Storrar and Rankin (n 48).
[249] HSE (n 20).
[250] Intertek, 'Intertek Report Number ITSS-0718-0001W plus per Floor Contamination of Flow Straighteners Debris and Sponges 2018' (n 36).
[251] DMA, 'L8 Risk Assessment NHS GGC South Glasgow University Hospital. 2015.' (n 27).
[252] HFS, 'Water Safety (SHTM 04-01) Part A: Design, Installation and Testing 2014' (n 159).
[253] NHS GGC, 'NSGACL - ITPD Volume 2_iss1_rev1 Invitation to Participate in Competitive Dialogue Volume 2/1 Employer's Requirements (Hospitals)' (n 77).
[254] HFS, 'Water Safety (SHTM 04-01) Part E. Alternative Materials and Filtration.'
[255] DMA, 'Legionella Risk Assessment QEUH (Adult) Hospital and the Adjoining RHC 2017' (n 29).
[256] DMA, 'L8 Risk Assessment NHS GGC South Glasgow University Hospital. 2015.' (n 27).
[257] DMA, 'L8 Risk Assessment NHS GGC South Glasgow University Hospital. 2015.' (n 27).
[258] DMA, 'L8 Risk Assessment NHS GGC South Glasgow University Hospital. 2015.' (n 27).

- A water system might be said to be unsafe insofar as there is evidence of the water supply, equipment and components within the hospital being compromised i.e. being contaminated with a range of opportunistic waterborne pathogens that are associated with HAI [259].

5.12. Identifying key defects in water and waste systems

5.12.1. *Lack of temperature control*

5.12.2. Temperature is one of the main mitigation measures used to control the presence of microbial pathogens in water systems [260] [261] [262]. Where effective temperature control measures have not been implemented and managed then that water system could be categorised as unsafe.

5.12.3. Opportunistic water borne pathogens will grow in the temperature range of 25-45°C [263]. Hence guidance encourages the following:

- keep the cold water cold i.e. at or below 20°C and preventing heat gain in the cold water system
- hot water should be stored at least at 60°C and distributed so that it reaches a temperature of 55°C in healthcare premises within one minute at the outlets with a return temperature to the calorifier from each loop of at least 55°C in healthcare. The microbial growth range for Legionella and other waterborne pathogens is approximately 25-45°C and hence these temperatures should be avoided (Figure 34). It is in this range that microbial growth will occur such that contaminated water will be unsafe for patients.

[259] T Inkster and others, 'Investigation and Control of an Outbreak Due to a Contaminated Hospital Water System, Identified Following a Rare Case of *Cupriavidus Pauculus* Bacteraemia.' [2021] J Hosp Infect.
[260] HSE (n 19).
[261] HSE (n 20).
[262] HFS, 'Water Safety (SHTM 04-01) Part A: Design, Installation and Testing 2014' (n 159).
[263] DMA, 'L8 Risk Assessment NHS GGC South Glasgow University Hospital. 2015.' (n 27).

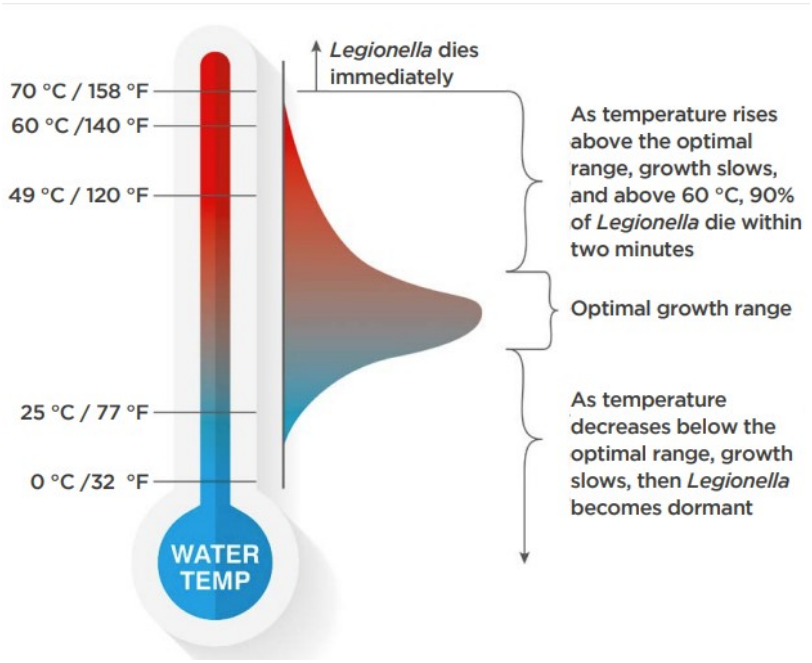


Figure 34. Schematic of the temperatures that encourage and control growth of waterborne pathogens such as legionella in water systems [264].

5.13. Stagnation and lack of flow results in unsafe water

5.13.1. Lack of water flow leads to stagnation and the growth of microbial pathogens.

5.13.2. Where stagnation of the water occurs the cold water will increase in temperature above 20°C and the hot water will decrease below 45°C resulting in conditions that will favour microbial growth.

5.13.3. This applies to all the hot water principal, subordinate and tertiary loops (ensuring the system is balanced) to ensure the water is flowing and that the hot water temperature is being maintained at greater than 55°C.

5.13.4. Stagnation will also occur at outlets.

5.14. Presence of debris and deposits results in unsafe water systems

5.14.1. The cleanliness of a water system is extremely important. This is especially important as historically (1980's and 1990's) copper pipework in Scottish hospitals, where there was soft water and high levels of sediment, had a high propensity to fail [265]. Through investigations a number of scientific groups identified the particular

[264] Walker JT, 'Combating Legionella by Focusing on the Right Species' [2023] Health Estates Journal 33.
[265] HFS, 'Water Safety (SHTM 04-01) Part E. Alternative Materials and Filtration.' (n 255).

pinhole failures to be as a result of microbial growth on the copper surfaces and this is discussed in 6.3.2 [266] [267] [268].

5.14.2. Legionella and other opportunistic water borne pathogenic bacteria are more likely to grow in a water system containing deposits either from the supply or introduced during construction and or commissioning when by-passing the primary filtration system [269].

5.14.3. National guidance including SHTM 04-01 Part E states that Legionnaires' disease is considered preventable and that appropriate water filtration equipment should be introduced to assist in maintaining hygiene and reducing detritus in pipework systems. Such mitigation measures would have been considered appropriate for the control of not only for Legionella but also other Gram-negative microorganisms.

5.14.4. Such deposits, debris and sediment on the surfaces of pipes, water storage tanks and will have become entrapped in strainers/outlet fittings and will have provided nutrients for the growth of aquatic and biofilm bacteria particularly where stagnated water was present. In addition the warming of the cold water and cooling of the hot water when stagnant in outlets would have exacerbated the microbial growth.

5.15. Type of materials that result in microbial and biofilm growth

5.15.1. Microbial growth will occur when the water temperatures are not maintained as per SHTM [270] and HSG guidance [271] [272]. Growth of microorganisms will increase where water is stagnating, debris or sediment is present or where natural materials are present on surfaces. Natural materials such as rubber, hemp, linseed oil-based jointing compounds and fibre washers provide additional nutrients promote the growth of waterborne pathogens [273]. Whilst water fittings and components should be used that comply with the Water Regulations Advisory Scheme (WRAS) approval scheme which lists products that have been tested and comply with BS 6920 these too will form biofilms containing waterborne pathogens under particular conditions [274].

5.15.2. For example, healthcare premises are advised against the use of:

i) ethylene propylene diene monomer (EPDM) lined flexible hoses (tails) as these have been shown to be a risk of microbial colonisation and may support

[266] Gill G Geesey and others, 'Unusual Types of Pitting Corrosion of Copper Tubes in Potable Water Systems' (1993).
[267] D Wagner and AHL Chamberlain, 'Microbiologically Influenced Copper Corrosion in Potable Water with Emphasis on Practical Relevance' (1997) 8 Biodegradation 177.
[268] Keevil and others (n 99).
[269] DMA, 'L8 Risk Assessment NHS GGC South Glasgow University Hospital. 2015.' (n 27).
[270] HFS, 'Water Safety (SHTM 04-01) Part A: Design, Installation and Testing 2014' (n 159).
[271] HFS, 'Water Safety (SHTM 04-01) Part A-G.' (n 41).
[272] HSE (n 20).
[273] HSE (n 20) 274.
[274] HFS, 'Water Safety (SHTM 04-01) Part A: Design, Installation and Testing 2014' (n 159).

the growth of microorganisms including Legionella [275]. EPDM is a rubber based material that provides nutrients and a high surface area for the proliferation of biofilm and water borne pathogens including *L. pneumophila* [276] [277];

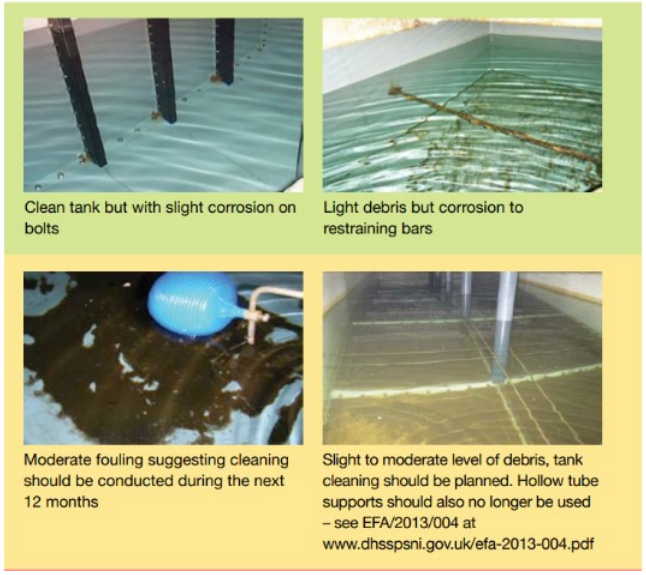
ii) expansion vessels contain internal bladders made of synthetic rubber such as EPDM that support the growth of Legionella and other microorganisms and so a 'flow through' design should be used as this would provide less opportunity for water to stagnate and become contaminated [278];and

iii) rosettes, flow straighteners, outlets and aerators have been found to be heavily colonised with biofilm including *P. aeruginosa* which have been implicated in patient deaths [279] and therefore outlet fittings should be subject to risk assessment to prevent waterborne infections [280].

5.16. Cold water storage tanks

5.16.1. HSG guidance [281] has identified that where cold water storage tanks do not have sufficient flow then this will result in stagnation of the water and accumulation of debris within the tanks resulting in increased microbial growth and biofilm formation including waterborne pathogens [282] (Figure 35).

[275] Julie Rogers and others, 'Influence of Plumbing Materials on Biofilm Formation and Growth of *L Pneumophila* in Potable Water Systems' (1994) 60 AEM 1842; Miriam M Moritz, Hans-Curt Flemming and Jost Wingender, 'Integration of *Pseudomonas Aeruginosa* and *Legionella Pneumophila* in Drinking Water Biofilms Grown on Domestic Plumbing Materials' (2010) 213 International Journal of Hygiene and Environmental Health 190 <https://www.sciencedirect.com/science/article/pii/S1438463910000520> accessed 4 June 2022; Paul L Waines and others, 'The Effect of Material Choice on Biofilm Formation in a Model Warm Water Distribution System' (2011) 27 Biofouling 1161.
[276] Waines and others (n 276).
[277] Rogers and others (n 276).
[278] HSE (n 20).
[279] Walker and others, 'Investigation of Healthcare-Acquired Infections Associated with *P. Aeruginosa* Biofilms in Taps in Neonatal Units in Northern Ireland' (n 9).
[280] HFS, 'Water Safety (SHTM 04-01) Part A: Design, Installation and Testing 2014' (n 159).
[281] HSE (n 20).
[282] RM Vickers and others, 'Determinants of Legionella Pneumophila Contamination of Water Distribution Systems: 15-Hospital Prospective Study' (1987) 8 Infection control: IC 357.



Sourced from HSG 274 Part 2

Figure 35. Sediment deposition on the floor of a cold water storage tank as identified in HSG 274.

5.16.2. HSG 274 guidance is relevant to many hospitals as examples of microbiological issues identified are common in healthcare buildings [283] :

- non-compliant hollow supports in cold water storage tanks
- dirt and debris in the cold water storage tanks (Figure 35)
- lack of flow within and from the cold water storage tanks
- biofilm tide marks and scum in the cold water tanks

5.16.3. All of the issues above result in microbial growth in cold water storage tanks [284]. The consequence is that all the contaminated water leaving the cold water storage tanks contaminates the entire water system right through to the ancillary equipment such as outlets, showers and drinking fountains. Even when “microbially positive” outlets or section of piping in wards are decontaminated, they can quickly become contaminated and present a risk to patients in a relatively short time scale (months) [285].

5.17. Hot water storage tanks

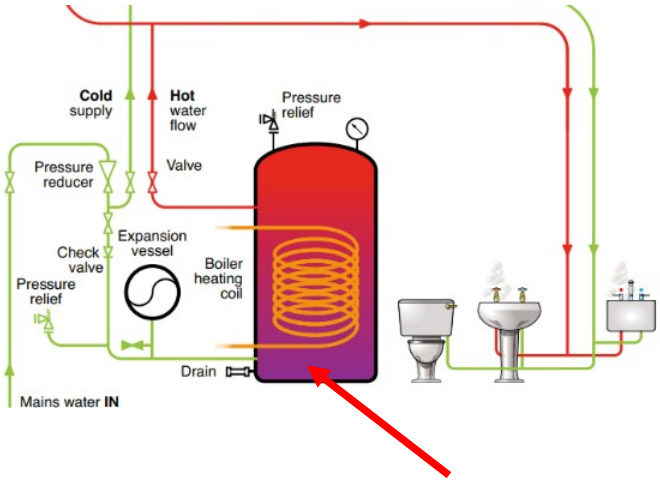
5.17.1. To control Legionella the HSE guidance describes that the hot water should be stored in calorifiers at 60°C and distributed so that it reaches a temperature of 55°C within one minute at the outlets with a return temperature of at least 55°C [286]. However

[283] HSE (n 20).
[284] Intertek, ‘Intertek Report Number ITSS-0718-0001W plus per Floor Contamination of Flow Straighteners Debris and Sponges 2018’ (n 36).
[285] Walker and others, ‘Investigation of Healthcare-Acquired Infections Associated with *P. Aeruginosa* Biofilms in Taps in Neonatal Units in Northern Ireland’ (n 9).
[286] HSE (n 20); HSE (n 19).

where temperatures are 40-45°C then microorganisms will start to proliferate [287]. It is my experience that 40-45°C water will be drawn off into taps and other outlets where microorganisms will continue to grow and present an avoidable risk to patients.

5.17.2. Calorifiers will accumulate rust and debris in the cool zone below the heating element leading to growth of waterborne pathogens including Legionella (Figure 36) [288].

5.17.3. Where the hot water regimens are not maintained then the dirty microbially contaminated water flows from the calorifier round the hot water system and returns back to the calorifier. The contaminated hot water will reach the ancillary equipment such as taps which will also become microbially contaminated.



Sedimentation of rust and debris at the base of the calorifier where there will be lower temperatures below the heating element

Figure 36. Sedimentation of rust and debris on the base of the calorifier where the temperature will be cool enough to encourage microbial growth [289].

5.18. Expansion vessels

5.18.1. HSE 274 [290] has previously identified that expansion vessels with the EPDM rubber linings provide a stagnant and highly nutrient rich growth environment for the growth of waterborne microbial pathogen such as Legionella. .

[287] DMA, 'Legionella Risk Assessment QEUH (Adult) Hospital and the Adjoining RHC 2017' (n 29).
[288] ID Farrell and others, 'A Field Study of the Survival of *Legionella Pneumophila* in a Hospital Hot–Water System' (1990) 104 Epidemiology & Infection 381.
[289] HSE (n 20) 274.
[290] HSE (n 20) 274.

5.19. Strainer filters

5.19.1. Strainers serve as pre-filters to remove debris, however, in doing so accumulated debris on strainers provides a niche environment for the growth of biofilms and pathogens including *P. aeruginosa* (Figure 37)[291].

5.19.2. HSG 274 indicates that where needed, strainers or filters associated with TMVs should be inspected, cleaned, descaled and disinfected [292].

5.19.3. Strainers and filters associated with TMVs are important components in water systems as they are situated at the periphery of the water system. When taps are not used this water will be stagnant and water temperatures will not be appropriate for microbial control. Strainers, filters and tap components have been identified as being contaminated with *P. aeruginosa* in neonatal units in Northern Ireland in which neonates died [293] [294].

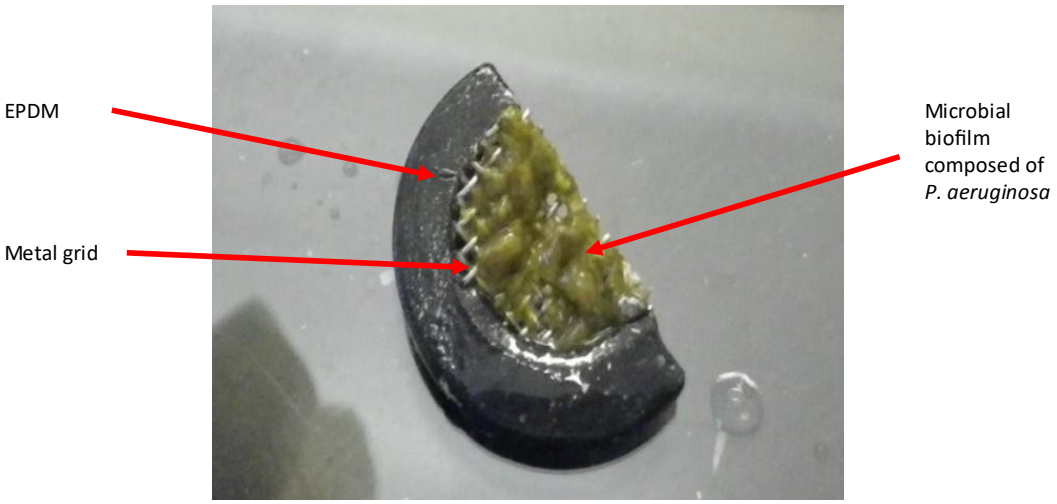


Figure 37. In line strainer from an outbreak investigation of water supply contaminated with P. aeruginosa [295].

[291] Walker and others, 'Investigation of Healthcare-Acquired Infections Associated with *P. Aeruginosa* Biofilms in Taps in Neonatal Units in Northern Ireland' (n 9).
[292] HSE (n 20) 274.
[293] RQIA, 'Independent Review of Incidents of *Pseudomonas Aeruginosa* Infection in Neonatal Units in Northern Ireland.'
[294] Walker and others, 'Investigation of Healthcare-Acquired Infections Associated with *P. Aeruginosa* Biofilms in Taps in Neonatal Units in Northern Ireland' (n 9).
[295] Walker and others, 'Investigation of Healthcare-Acquired Infections Associated with *P. Aeruginosa* Biofilms in Taps in Neonatal Units in Northern Ireland' (n 9).

5.20. Taps

5.20.1. Taps and water outlets used in handwashing are often complex in terms of their design, which varies between manufacturers. Taps are used to provide blended hot and cold water from the water distribution system for a range of purposes including handwashing, catering and for domestic utilities. However, their infrequent use often leads to the stagnation of the hot and cold water pipes at temperatures that are favourable for the growth of water borne pathogens [296]. Taps and outlet components have been associated with outbreaks where HAI and fatalities have occurred [297] [298] [299].

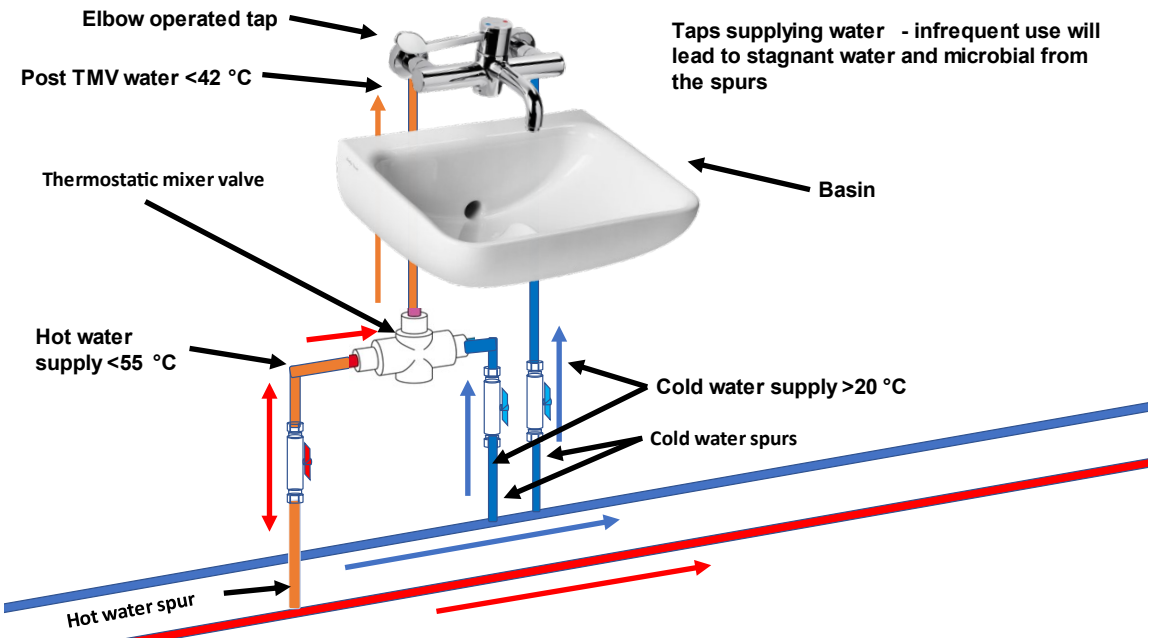


Figure 38. Example of a handwash basin with taps - adapted from [300]

5.20.2. Tap fixtures include complex fittings such as:

- inside of tap bodies has been demonstrated to be extremely rough which increases the surface area available for microbial growth.
- thermostatic mixer valves and taps (Figure 30 and 38) are used to blend hot and cold water to prevent scalding. However this mixture of the hot and cold water can lead to stratification in the water temperature within the valve water, which in addition to the valves themselves consisting of a range of components, exacerbates microbial growth.
- Outlet fittings (e.g. flow straightener or aerator)

[296] HFS, 'Water Safety (SHTM 04-01) Part A: Design, Installation and Testing 2014' (n 159).
[297] C Aumeran and others, '*P. Aeruginosa* and *P Putida* Outbreak Associated with Contaminated Water Outlets in an Oncohaematology Paediatric Unit' (2007) 65 JHI 47.
[298] Walker and others, 'Investigation of Healthcare-Acquired Infections Associated with *P. Aeruginosa* Biofilms in Taps in Neonatal Units in Northern Ireland' (n 9).
[299] Loveday and others (n 229).
[300] Walker JT and others, 'Safe Water in Healthcare - 1st Edition' [2023] Elsevier.

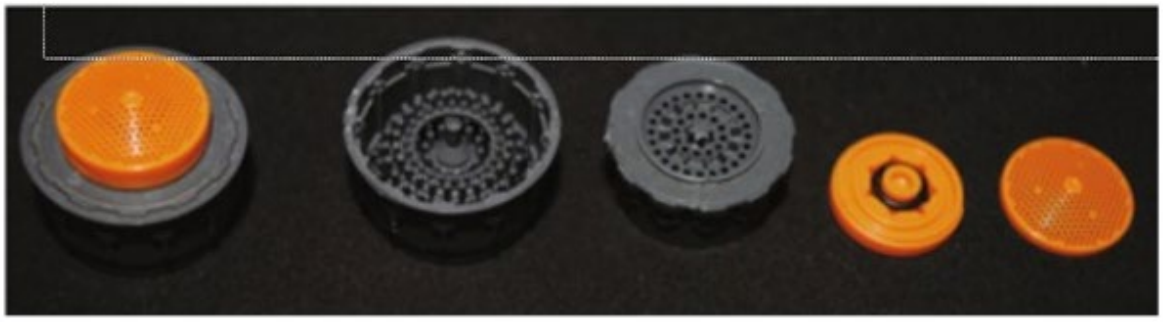
5.20.3. Outlet fittings are used for a range of purposes including i) flow regulator to reduce the flow, ii) flow straighteners to provide laminar or smooth flow (to reduce splashing) and iii) aerators to mix the water and air to conserve water (Figure 39).

5.20.4. Outlet fittings can be very complex and multilayered resulting in a large surface area over which biofilms develop resulting in outbreaks due to the exposure of patients to water borne pathogens [301]. Previous outbreaks have investigated biofilm growth on outlet fittings and their complexity (Figure 39) [302]. The tap outlet fittings from the QEUH have similarly been identified as being colonised by biofilms and are similarly complex providing large surface areas for microbial growth (Figure 40) [303] [304].

Biofilms on outlet fittings

Figure 39. Biofilms composed of *P. aeruginosa* (left hand image) on an outlet fitting and a fitting deconstructed (right hand image) to demonstrate the high surface area to volume ratio that would encourage microbial growth [305].

[301] Walker and others, 'Investigation of Healthcare-Acquired Infections Associated with *P. Aeruginosa* Biofilms in Taps in Neonatal Units in Northern Ireland' (n 9).
[302] Walker and others, 'Investigation of Healthcare-Acquired Infections Associated with *P. Aeruginosa* Biofilms in Taps in Neonatal Units in Northern Ireland' (n 9).
[303] Intertek, 'Intertek ITS 1018-0001 2018 Microbiological Analysis of Flow Straighteners over Time New to Three Months' (n 37).
[304] Intertek, 'Intertek ITSS 1018-0001 2019 Microbiological Analysis of 31 Flow Straighteners to Compare against Previous 2018 Results'.
[305] Walker and others, 'Investigation of Healthcare-Acquired Infections Associated with *P. Aeruginosa* Biofilms in Taps in Neonatal Units in Northern Ireland' (n 9).



Deconstructed outlet fittings to demonstrate the complexity and large surface area to volume ratio

Figure 40. Fully dismantled flow straightener as demonstrated above were found to be fitted in previous tap related HAI outbreaks [306].

5.21. Hand wash basins

5.21.1. The water from outlets are discharged into the wash hand basin (Figure 38) The design and matching of the basin to the water flow is important as excess flow and discharge into the drain results in splashing which will act as a transmission route for waterborne pathogens [307].

5.21.2. Hand wash basin drains can be in the central base of the basin, in which case the water will discharge directly in the drain and will splash into the ward by up to 2m [308] [309]. The basin drain strainer or sieve (metal and permanent) in the central position of the basin will act as a growth area for microbial growth. In addition, sink manufacturers have provided plastic sieves for rear facing drain that become colonised with biofilm (Figure 41 and 42). Water splashing from the drain may result in transmission of waterborne microorganisms.

5.21.3. Alternatively rear facing drains have been designed to alleviate splashing into the ward from a central basin drain. Manufacturers of rear facing drains produce a plastic sieve (Figure 42) that can placed into the recessed rear drain hole to prevent large items from being discarded into the drain. These plastic sieves promote the growth of biofilms.

5.21.4. Rear shelves on a clinical hand wash basin can encourage the placement of items on the ledge (Figure 41). The base of the items will be damp and will encourage

[306]

[307] G Döring and others, 'Generation of *P. Aeruginosa* Aerosols during Handwashing from Contaminated Sink Drains, Transmission to Hands of Hospital Personnel, and Its Prevention by Use of a New Heating Device' (1991) 191 Internat J Hyg Environ Med 494.

[308] MI Garvey and others, 'The Sink Splash Zone' (2023) 135 The Journal of Hospital Infection 154.

[309] D Roux and others, 'Contaminated Sinks in Intensive Care Units: An Underestimated Source of Extended-Spectrum Beta-Lactamase-Producing *Enterobacteriaceae* in the Patient Environment' (2013) 85 JHI 106.

microbial growth. The rim of the rear of the basin is often sealed with silicone sealant. As the silicone is damaged, wears and perishes water and biofilm will be trapped in the crevices.

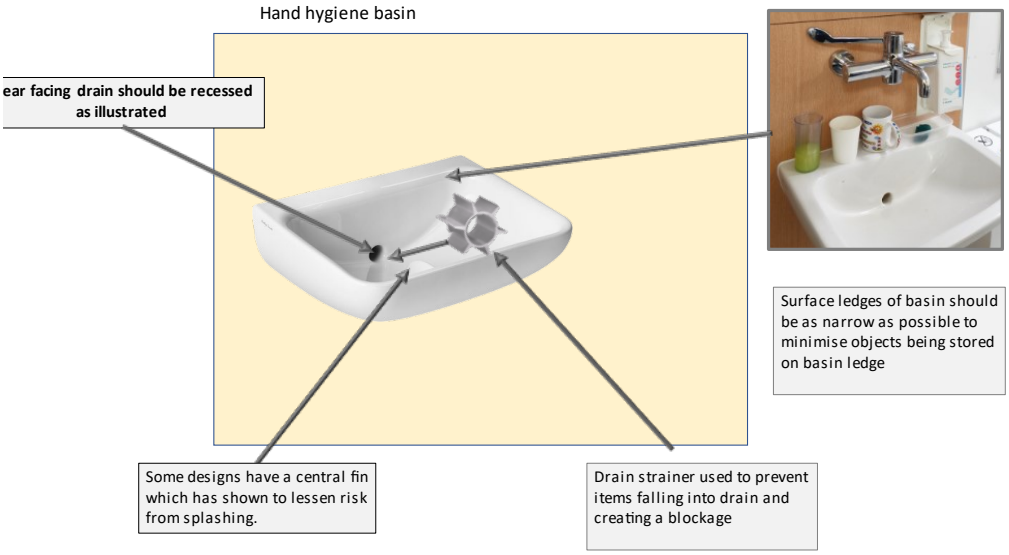


Figure 41. Clinical hand wash basin and drain strainer [310]

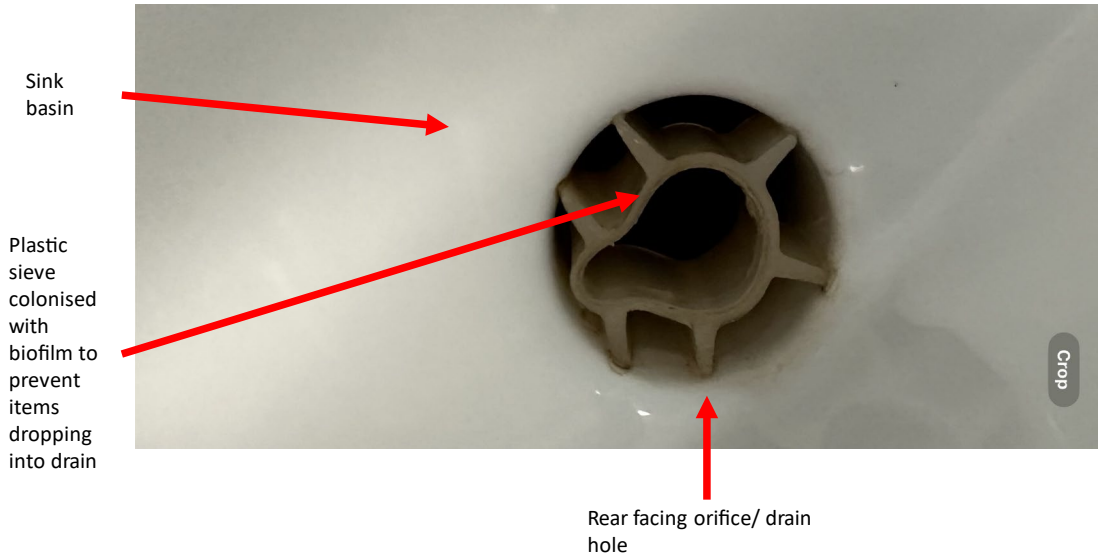


Figure 42. Photo of plastic sieve used in rear facing drain orifice that has been colonised by biofilm (JW personal photo).

5.22. Utility room/kitchen sinks

5.22.1. Stainless steel sinks in utility rooms have been demonstrated to play a role in large hospsital outbreaks [311]. Stainless steel utility sinks have are deep, with an

[310] Walker JT and others (n 301).
[311] Decraene and others (n 226).

overhanging tap such as a swan neck tap. The outlet of the swan neck tap can be positioned over the outlet drain. Where the drains are not cleaned they will have biofilm and debris present in the drain area and ubend/p-trap. Such traps and biofilm have been demonstrated to harbour highly resistant bacteria *E. coli* [312]. When the tap is the used the water entering the drain area creates a high energy stream of water that results in splashing of the unsafe water (Figure 43). In addition once the the base of the sink unit has been contaminated, kitchenware such as drinking jugs are placed in to the bottom of the sink for filling with water resulting in the base of the jugs being contaminated whch are then provided to patients on the ward [313].

Demonstration of carbapenemase resistant microorganisms being dispersed from a sink drain due to the force of the water – courtesy of Ryan George.

Demonstration of how patient water jugs and kitchen equipment wouldbe contaminated with carbapenemase microorganisms from a sink drain

Figure 43 Sink unit use demonstrating splashing and contamination of surrounding areas with drain associated waterborne pathogens (courtesy of Ryan George and Michael Weinbren) [314].

5.23. Showers

5.23.1. The HSE described that sources of risk should be identified including where water temperatures are between 20-45°C, there is a means of creating and disseminating breathable droplets such as aerosols and where susceptible at risk people may be exposed [315]. Taking the above criteria in to consideration then showers are equipment that are described as presenting an HAI risk. Shower controllers contain a thermostatic mixer valve (to prevent scalding), a flexible hose and shower head. Thermostatic mixer valves can promote microbial growth due to the close proximity of the hot and cold water pipes and a range of different materials creating favourable conditions for microbial/biofilm growth. The shower flexible hose may be

[312] Decraene and others (n 226).
[313] Decraene and others (n 226).
[314] Decraene and others (n 226).
[315] HSE (n 19).

lined with EPDM which has been shown to promote microbial growth [316]. The materials in the shower head have been shown to promote the growth of microorganisms such as Legionella and other microorganisms and creates water droplets and aerosols for transmission [317]. Risk assessments should take into consideration that the shower head should not be in contact with the floor and drain area and that the shower head should not reach a sink or toilet due to the risks of contamination. Combined with infrequent use and stagnation of the water, showers are considered a risk for microbial transmission and particularly for patients who may be at risk of central lines infection who may be showering in hospital [318] [319] [320].

5.24. Waste-water drains

5.24.1. Water from each basin and sink flows to drain visa the sink outlet [321]. In hand wash basins/sinks the drain encompasses the connection of a pipe onto the basin/sink that connects to a trap and or u-bend [322]. The purpose of the u-bend is to hold water to prevent sewer gases from entering the home. Whilst a sieve or strainer is used to prevent debris and physical items from entering the basin the trap can often hold a wide range of products. Drains have been identified as being the source of a wide range of antibiotic resistant strains that have been associated with patient infections [323] [324].

5.25. Splashing

5.25.1. Hand wash basins and sink units receive water from the hot and cold water supply. When hands are washed in hand wash basins then splashing will occur, i) as the water is discharged over the hands and ii) from water hitting the base of the wash hand basin where the water is already flowing (Figure 44 and 45).

[316] Waines and others (n 276).
[317] GE Bollin and others, 'Aerosols Containing *Legionella Pneumophila* Generated by Shower Heads and Hot-Water Faucets.' (1985) 50 Applied and Environmental Microbiology 1128.
[318] HSE (n 20) 274.
[319] Gina Kemp and others, 'Back to Basics: CLABSI Reduction Through Implementation of an Oral Care and Hygiene Bundle' (2019) 36 Journal of Pediatric Oncology Nursing 321.
[320] Stevens, Evans and Wilcox (n 54).
[321] Armitage Shanks (n 142).
[322] Armitage Shanks (n 142).
[323] KK Yuen, Eric WM Lee and SM Lo, 'The Fight against SARS: A Backfilling Connection for the Prevention of Drying out of Floor Drains' U-traps' (2003) 21 Structural Survey 114.
[324] D De Geyter and others, 'Sink Drains as Reservoirs of VIM-2 Metallo-β-Lactamase-Producing *P Aeruginosa* in a Belgian Intensive Care Unit: Relation to Patients Investigated by Whole-Genome Sequencing' (2021) 115 JHI 75.

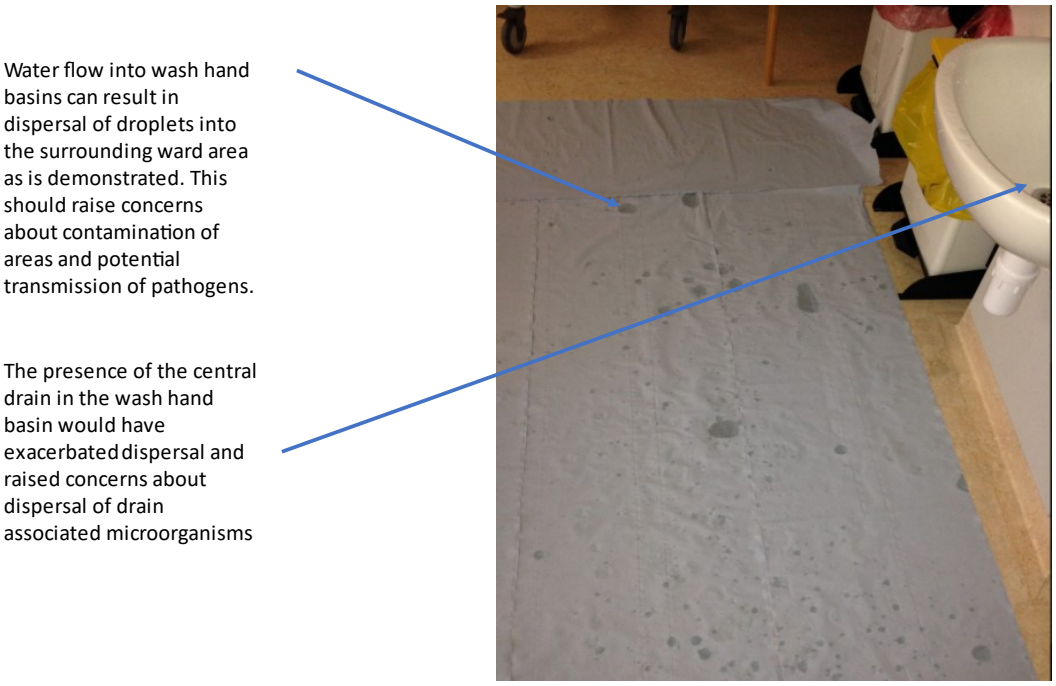


Figure 44. Splash zone as demonstrated using blue paper placed on the floor whilst someone has washed their hands in an intensive care unit (JW personal photo).

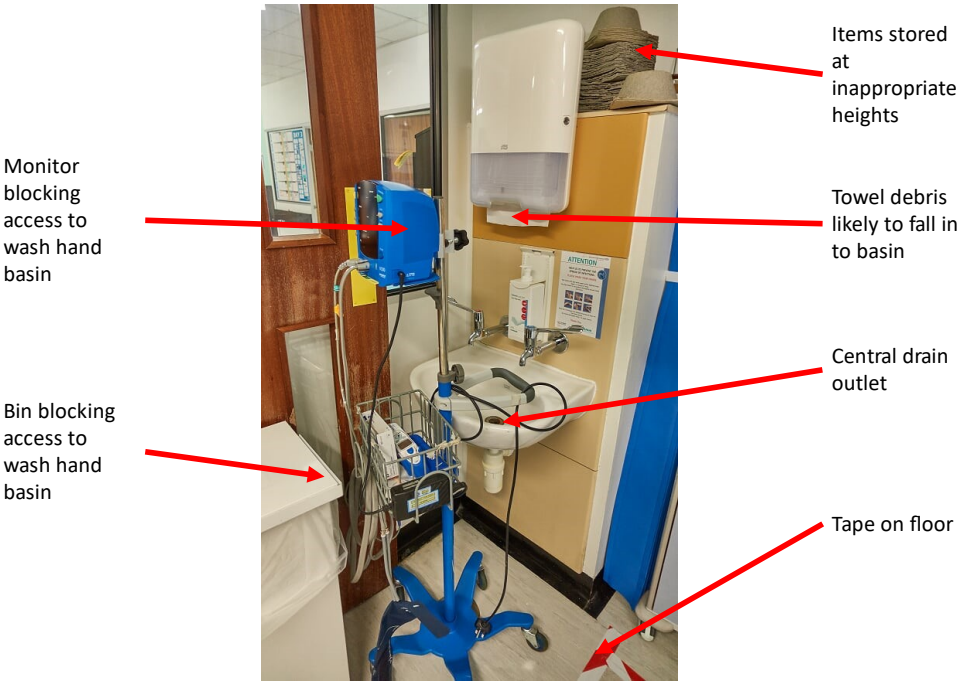


Figure 45. Example of equipment blocking access to clinical hand wash basin [325]

[325] Walker JT and others (n 301).

5.25.2. Where drains are contaminated then this water will regurgitate from drain into the sink unit and will be splashed across the ward environment when the water flows into the sink [326].

5.25.3. Visible water droplets can be observed from hand washing basins during hand washing up to 2m away (Figure 44) [327]. A range of medical and invasive equipment is often placed within the 2m splash zone of the handwash basin which blocks access to the basin for clinical staff to wash hands (Figure 45). Contamination of equipment and transmission of infection through splashing has been recognised since the 1990s [328].

5.26. Medical equipment that uses water

5.26.1. Any medical equipment that uses water from a contaminated water distribution system will be contaminated with a range of opportunistic waterborne pathogens including dishwashers. As such the water to which patients are then exposed from contaminated medical equipment would be considered to present an increased risk to patients. The following list is not exhaustive but demonstrates a range of medical equipment where the contaminated water will pose a risk to patients.

5.27. Water coolers

5.27.1. Chilled water coolers and other drinks dispensers are prone to microbial contamination [329]. Outbreaks due to *P. aeruginosa* have been recorded [330]. Due to concerns about the exposure risk to patients the presence of water coolers should be risk assessed and removed if they are deemed to be an infection control risk [331] .

5.28. Ice machines

5.28.1. Ice machines are supplied by water from the water distribution system and have been linked to several outbreaks of hospital-associated infections including from *L. pneumophila* [332], *Mycobacterium chelonae* [333], *Enterobacter cloacae* [334], and *P.*

[326] Kotsanas (n 227).
[327] Garvey and others (n 309).
[328] S Heard and others, 'A Pseudo-Outbreak of Pseudomonas on a Special Care Baby Unit' (1990) 16 The Journal of Hospital Infection 59.
[329] B Lévesque and others, 'Comparison of the Microbiological Quality of Water Coolers and That of Municipal Water Systems' (1994) 60 Applied and Environmental Microbiology 1174.
[330] D Costa and others, 'Nosocomial Outbreak of *Pseudomonas Aeruginosa* Associated with a Drinking Water Fountain' (2015) 91 The Journal of Hospital Infection 271.
[331] Storrar and Rankin (n 48).
[332] Max Bencini and others, 'A Case of Legionnaires' Disease Caused by Aspiration of Ice Water' (2005) 60 Archives of Environmental & Occupational Health 302.
[333] S Laussucq and others, 'Nosocomial *Mycobacterium Fortuitum* Colonization from a Contaminated Ice Machine' (1988) 138 The American Review of Respiratory Disease 891.
[334] AS Breathnach and others, 'An Outbreak of Wound Infection in Cardiac Surgery Patients Caused by *Enterobacter Cloacae* Arising from Cardioplegia Ice' (2006) 64 The Journal of Hospital Infection 124.

aeruginosa [335]. It is likely that as well as the supply tubing that the internal flexible piping, ice chute and pan area can also be contaminated with biofilms [336].

5.28.2. Routes of exposure have included i) swallowing (ingestion) contaminated ice or melt water can lead to gastrointestinal infections [337], ii) inhalation (aspiration) of melting water from ice will predispose patients to pneumonia with a range of organisms that may be entrapped within the ice, such as Legionella spp. or P. aeruginosa [338], and iii) wound infection (direct contact) in cardiac surgery patients caused by *Enterobacter cloacae* arising from cardioplegia ice [339].

5.29. Mitigation and control measures

5.29.1. Control and mitigation strategies are not limited to but may include:

- Compliance with regulations and standards;
- Training of competent staff to maintain the water system as per L8, ACOP and SHTM;
- Implementation of a water safety plan and water safety group;
- Physical controls e.g. primary filtration, temperature controls, adequate flow;
- Monitoring of temperature, flow; and
- Microbiological assessment of the water system.

5.29.2. Wholesome water is supplied to a hospital site and the mitigation and control measures assist in controlling microbial growth through the hospital. As described earlier in terms of microbiology there should be no *C. perfingens* or Coliform bacteria and “no abnormal change” in the number/1ml at 22°C at the consumers taps.

5.29.3. Water is stored in large water tanks to meet demand and retain water in the event that there is a problem with the supply.

5.29.4. The water from the tanks is distributed round the site to provide drinking water, for food preparation and for supply to other equipment requiring a cold feed.

5.29.5. The cold water will also be pumped to an energy plant where hot water will be generated to supply hot water to showers, baths and tap outlets.

5.29.6. Control strategies may include:

- Primary filtration of the incoming supply water to maintain a clean supply
- Maintaining the cold water below 20°C

[335] SWB Newsom, ‘Hospital Infection from Contaminated Ice’ (1968) 292 The Lancet 620.
[336] Anubhav Kanwar and others, ‘A Cold Hard Menace: A Contaminated Ice Machine as a Potential Source for Transmission of Carbapenem-Resistant *Acinetobacter Baumannii*’ (2017) 45 Am J Infect Cont 1273.
[337] P Ravn and others, ‘Nosocomial Outbreak of Cryptosporidiosis in AIDS Patients’ (1991) 302 BMJ (Clinical research ed.) 277.
[338] SP Blatt and others, ‘Nosocomial Legionnaires’ Disease: Aspiration as a Primary Mode of Disease Acquisition’ (1993) 95 The American Journal of Medicine 16.
[339] Breathnach and others (n 335).

- Maintaining the hot water flow at 60°C and return above 55°C
- Ensuring that there is water flow with little or no stagnation

5.29.7. Understanding the water system as a whole is paramount to the implementation of control strategies.

5.29.8. For example in a hospital where there is a suspected HAI it maybe decided to sample the water from the tap. Whilst this sounds simple it requires all the skills of a well-trained and competent water safety group to carry this out effectively and to understand the implications and mitigation strategies required.

5.29.9. In a situation where a Horne Engineering Optitherm tap is present then sampling of the tap would entail the taking of pre (immediate sample of water) and post flush (after flushing for 1-2mins) water samples from the:

- Cold water supply
- Blended Hot water supply

5.29.10. If the results were to identify adverse microbiological results for the preflush then this would indicate that the tap outlet was positive e.g. with C, pauculus

5.29.11. In such circumstances then the mitigation may be

- treating the tap and outlet with a biocide
- removing and cleaning/decontaminating or sterilising the tap outlet
- replacing the tap with a new one.

5.29.12. Testing would then be caried out for a number of weeks to determine if that outlet was still negative.

5.29.13. If the adverse microbiological results were in the post flush then there is a high likelihood that the water system per se was contaminated including:

- Cold water tanks contaminated with dirt, debris, washers and sponges contaminated with C. pauculus, P. xanthomonas, S. paucimobilis and fungi
- Presence of contaminated non-flow through expansion vessels
- Presence of contaminated flexible hoses

5.29.14. Where any of the above were to be positive for a range of Gram-negative waterborne pathogens then each of the above components would continually seed the entire water system even after the outlet have been decontaminated or changed for a new unit.

5.29.15. Maintaining a wholesome and safe supply requires the water safety to work together to understand the entire water system and particularly that the fitting of point of use filters or disinfecting outlets or terminal ward sections of the water system is a sticking plaster approach when microbiological evidence demonstrates that the entire water system is systematically contaminated.

5.29.16. Health professionals in the Netherlands as well as those in the UK have recognised the benefits of reducing the patient's exposure to unsafe water and drains to reduce the number of HAI . The removal and reduction of water outlets and drains in wards has led to significant decreases in the number of HAI thus providing a safer built environment for the patient [340].

5.29.17. Where the water is considered an HAI risk the mitigation strategies in hospitals may include:

- Additional filtration of the water supply system
- Reducing exposure of patients to water
- Provision of bottled water for washing and brushing teeth
- Removal of wash hand basins
- Disposable showerheads and hoses
- Removal of water coolers
- Single use equipment
- Increased flushing
- Increased water sampling
- Addition of Gram-negative microorganisms to the Alert List
- Addition of water to the risk register
- Fitting of point of use filters
- Replacement drains
- Thermal disinfection
- Disinfection/dosing treatment of parts of the water system
- Full scale continual dosing of the entire water system

5.30. Summary of what is meant by an unsafe water system

5.30.1. Water delivered in Scotland by the water supplier is considered as "wholesome water" i.e. is fit to use for drinking, cooking, food preparation or washing without any potential danger to human health. From a microbiological perspective this "wholesome water" whilst not being sterile would be considered to be "safe" for use by most patients in hospitals.

5.30.2. However, once the "wholesome water" is supplied to a hospital, those responsible for the building have a duty of care to ensure that the water is wholesome at the point of use i.e. through to the outlets [341].

5.30.3. Where that water is not maintained as "wholesome" then microorganisms will proliferate and contaminate the water system to an extent that water may become unsafe for patients in a hospital. Unsafe water could be described as water where the thresholds of agreed / industry standard total viable counts for waterborne pathogens have been exceeded. This 'excess' of waterborne pathogens in unsafe water can go on to cause infections, deemed to be preventable, with a plethora of guidance

[340] Joost Hopman and others, 'Reduced Rate of Intensive Care Unit Acquired Gram-Negative Bacilli after Removal of Sinks and Introduction of "Water-Free" Patient Care' (2017) 6 Antimicrob Resist Infect Cont 59.
[341] HSE (n 20).

produced over many years to mitigate its risk, especially in immunosuppressed patients.

5.30.4. Where waterborne microbial pathogens have been allowed to grow in the water and as surface associated biofilms then they will present an additional a risk of infections in patients which would be termed water borne hospital associated infections (HIA). A water system which does not properly control the microbial risk would be regarded as “unsafe”.

5.30.5. The risks associated with hospital water systems requires regular risk assessments and the associated equipment requires servicing and maintenance to ensure that defects in the water system are managed.

5.30.6. Those responsible for the hospital have a duty of care to ensure the water system is maintained, rendering it ‘safe’ and consequently that patients are not exposed to an additional risk / burden of waterborne pathogens, which might lead to avoidable infection [342]. The lack of timely and effective management of the water system, e.g. not rectifying issues when identified, can lead to a water system which is ‘poor or unfit’, where the proliferation of waterborne pathogens isn’t being stemmed, leading to an ‘unsafe’ water system, putting patients at increased risk.

[342] HSE (n 20).

6. Unsafe aspects of the QEUH/RHC water system

6.1. Risk and control of risk

6.1.1. Waterborne healthcare associated infections are preventable. The design, maintenance and operation of hot and cold water supply, storage and distribution systems in healthcare premises is subject to statutory regulation and guidance including that contained in Scottish Health Technical Memorandum 04-01 parts A to G (A 2014, B 2014, C 2015, D 2011, E 2015, F 2011 and G 2015) [343], issued by Health Facilities Scotland; Legionnaires' disease, the control of Legionella bacteria in water systems, Approved Code of Practice and guidance on regulations, L8, issued by the Health and Safety Executive (HSE) [344]; and HSG274, Legionnaires' disease Part 2: The control of Legionella bacteria in hot and cold water systems, also issued by HSE [345].

6.1.2. In terms of that guidance, Management (defined as the owner, occupier, employer, general manager, chief executive or other person who is ultimately accountable, and on whom the duty falls, for the safe operation of healthcare premises") has the overall responsibility for the implementation of procedures to ensure that safe, reliable hot and cold water supply, storage and distribution systems operate within an organisation [346]. Management is ultimately responsible for the provision of a wholesome water supply in the premises under its authority [347].

6.1.3. All premises in Scotland are required (SHTM 04-01 Part B para 2.1) [348] to have a Legionella risk assessment and a written scheme to control identified risks in accordance with the Health and Safety Executive's Approved Code of Practice L8. (part B para 5.1) [349]. Management is required to appoint, amongst others, a "Designated Person"; an "Authorising Engineer" to provide an annual audit to the Designated Person; and a "Legionella Risk Assessor" to provide a Legionella Risk Assessment [350]. It is provided that a "Water Safety Group" commission and develop a "Water Safety Plan" including a risk assessment which should be reviewed on an annual basis (SHTM part B) [351] .

6.1.4. Where the growth of microorganisms has not been controlled and the thresholds or specifications are exceeded then the water will not be "wholesome" and present an unacceptable risk to patients [352].

[343] HFS, 'Water Safety (SHTM 04-01) Part A-G.' (n 41).
[344] HSE (n 19).
[345] HSE (n 20).
[346] HFS, 'Water Safety (SHTM 04-01) for Healthcare Premises Part B: Operational Management.' [2014] National Services Scotland.
[347] HFS, 'Water Safety (SHTM 04-01) for Healthcare Premises Part B: Operational Management.' (n 347).
[348] HFS, 'Water Safety (SHTM 04-01) for Healthcare Premises Part B: Operational Management.' (n 347).
[349] HSE (n 20).
[350] BSI, 'BS 8580-1 Water Quality - Risk Assessments for Legionella Control. Code of Practice' (2019).
[351] HFS, 'Water Safety (SHTM 04-01) for Healthcare Premises Part B: Operational Management.' (n 347).
[352] HSE (n 19).

6.1.5. To reduce the Legionella risks to patients, advice is provided in HSG 274 Part 2 and Part B of SHTM 0401 [353] on actions to take where Legionella is detected in the hospital water system, and both cite action levels for Legionella where counts are greater than 100 cfu/litre i.e. considered as being out of specification [354] [355].

6.1.6. NHS GGC have their own procedures to be followed in the event of out of specification sample for Legionella and other monitored bacteria, moulds etc. (SOP WQS 00-17) [356].

6.1.7. As an example NHS GGC indicate that "total viable counts at 22°C and 37°C that are less than 100 CFU/ml are considered "acceptable" (i.e. written as TVCs - 22°C & 37°C: Counts greater than 100 CFU/ml are considered out of specification (i.e. written as - If levels are >100 CFU/ml, lab should identify the bacteria) [357].

6.1.8. SOP WQS-017 also specifies that there should be zero detection of *E. coli* & *Coliforms*, *Pseudomonas* spp. in augmented care. In addition, *Cupriavidus* and Fungi should be <10 CFU/100ml and other Gram-negative microorganisms in any area are treated as an out of spec in the absence of any National guidance.

6.1.9. Appendix 1 provides and extensive profile of the presence of microorganisms across the QEUH and RHC hospitals. In my opinion, the presence of such an extensive list of microorganisms recovered from such wide ranging locations across the hospital site provides evidence of increased risk to patients when exposed to water in the hospital.

6.2. L8 Legionella water system risk assessment 29th April 2015

6.2.1. The L8 Legionella Risk Assessment carried out in 2015 [358] identified:

- failings in the management system i.e. there was no formal management structure, written scheme (for Legionella control) or communication protocols and there were significant communication issues between parties involved."
- a lack of records relating to training and competency and the absence of established training records indicated which was non-compliance with current guidance [359] [360].
- the water system was contaminated i.e. microbial results (counts) were out of specification at the time of occupation in 2015

[353] HSE (n 20) 274.
[354] HSE (n 20) 274.
[355] NHS GGC, 'SOP WQS – 017. Procedures in the Event of out of Specification Sample for Legionella and Other Monitored Bacteria, Moulds Etc.'
[356] NHS GGC, 'SOP WQS – 017. Procedures in the Event of out of Specification Sample for Legionella and Other Monitored Bacteria, Moulds Etc.' (n 356).
[357] NHS GGC, 'SOP WQS – 017. Procedures in the Event of out of Specification Sample for Legionella and Other Monitored Bacteria, Moulds Etc.' (n 356).
[358] DMA, 'L8 Risk Assessment NHS GGC South Glasgow University Hospital. 2015.' (n 27).
[359] HSE (n 19).
[360] HFS, 'Water Safety (SHTM 04-01) Part A-G.' (n 41).

6.2.2. From my perspective the DMA 2015 risk assessment identified a number of failings at the time of occupation in 2015 which would have been contributing factors in the contamination of the QEUH and RHC water system including inadequate management, lack of training and poor communication as per HSG 274 part 2 paragraph 16 [361].

6.2.3. The DMA risk assessors recommended in 2015 that "urgent action" be taken by senior management to review control procedure. Many of those recommendations requiring urgent action by senior management were still outstanding in the DMA risk assessors report in 2017. It is my view that as the urgent actions were not addressed there was therefore a lack of control measures that led to widespread microbial growth and biofilm proliferation in the water system which would have increased the risk of HAI in patients (Appendix 1).

6.3. Risks associated with the cold water system – 2015 L8 Report

6.3.1. The DMA Legionella risk assessment January 2015 [362] (pages 2&3) noted that an 'emergency bypass' had been left in place and open between the Hardgate Road town mains supply (Figure 43) and the booster pump sets (Figure 44). The risk assessment stated that this was 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 ("connecting in after the Booster Pumps") bypassing the filtration plant running for an unknown length of time.

6.3.2. This bypass was noted during DMA's initial site walk round and reported to Estates (Jan 2015) and was again noted (April 2015) during the L8 Risk Assessment and again reported to Estates (Figure 45). The mains water from both the Govan Road and Hardgate Road supplies was designed and built such that the mains water was supplied directly to both the raw water storage tanks (Figure 1 and 46) [363] [364]. The raw water was designed to pass through the ultrafiltration unit into the filtered water storage units. As described elsewhere the requirement for filtration was a result of corrosion of copper piping in central Scotland due to the presence of high levels of sediment and bacteria [365] [366] [367] [368]. To prevent a reoccurrence of this problem the Employer's Requirements stated that the site potable water was to be filtered according to SHTN02 with 0.2 micron filtration and that the pipework shall be stainless steel [369]. SHTN02 was updated in SHTM Part E which states that "all incoming cold

[361] HSE (n 20) 274.
[362] DMA, 'L8 Risk Assessment NHS GGC South Glasgow University Hospital. 2015.' (n 27).
[363] NHS GGC, 'NSGACL - ITPD Volume 2_iss1_rev1 Invitation to Participate in Competitive Dialogue Volume 2/1 Employer's Requirements (Hospitals)' (n 77).
[364] Brookfield (n 53).
[365] Wagner and Chamberlain (n 268).
[366] Geesey and others (n 267).
[367] CW Keevil, 'The Physico-Chemistry of Biofilm-Mediated Pitting Corrosion of Copper Pipe Supplying Potable Water' (2004) 49 Water Science and Technology 91.
[368] Walker JT, 'Doctor of Philosophy, 1994. Open University. Investigation of Biofilms in Copper Tube Corrosion and the Survival of Legionella Pneumophilia on Alternative Plumbing Materials'.
[369] NHS Scotland, 'SHTN 2 Domestic Hot and Cold Water Systems for Scottish Healthcare Premises.'

water supplies destined for domestic use within NHS Scotland premises should be filtered" [370].

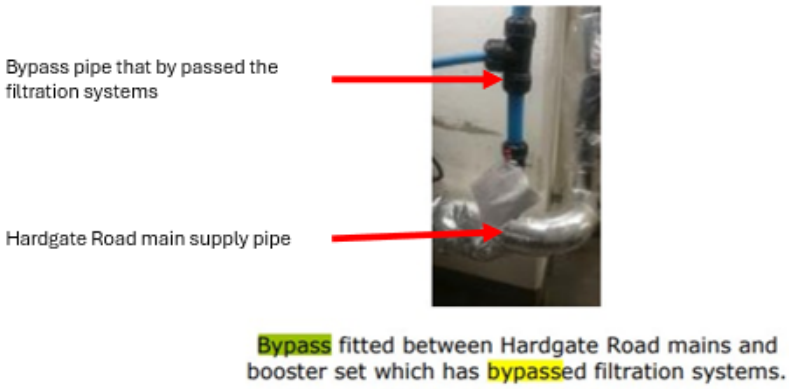


Figure 46. DMA photo demonstrating the connection of the bypass to the Hardgate Road mains pipe [371].

[370] HFS, 'Water Safety (SHTM 04-01) Part E. Alternative Materials and Filtration.' (n 255). HFS, 'Water Safety (SHTM 04-01) Part E. Alternative Materials and Filtration.' (n 255).
[371] DMA, 'L8 Risk Assessment NHS GGC South Glasgow University Hospital. 2015.' (n 27).

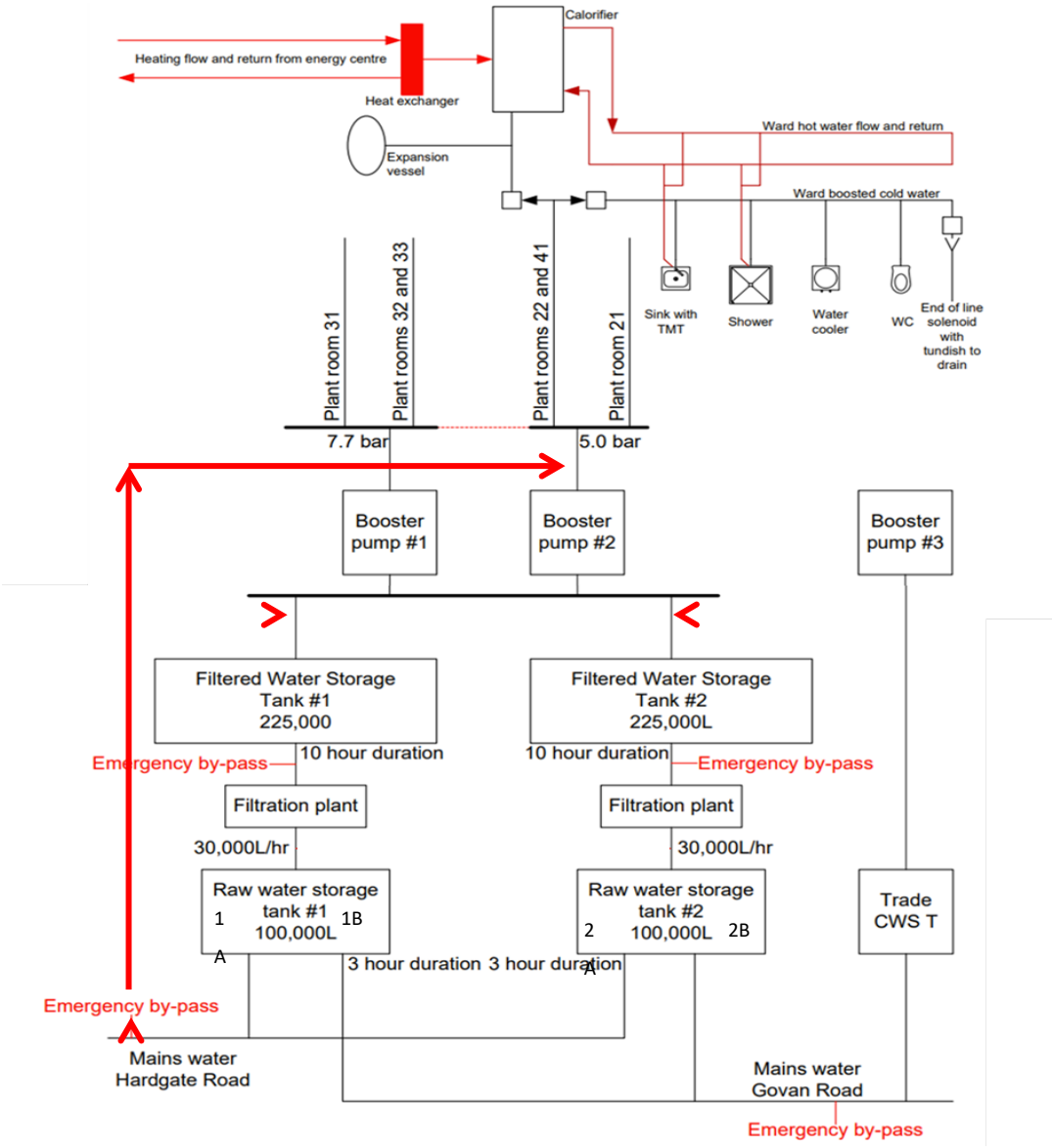


Figure 47. Diagrammatic representation of the route of the pipework that bypassed the ultrafiltration system according to the DMA Legionella risk assessment 2015 [372].

6.3.3. The bypassing of the ultrafiltration system (Figure 46) in 2015 was non-compliant with SHTM Part 5 E which states that it "is essential for healthcare premises pipework systems to be filtered to maintain hygienic conditions" [373].

6.3.4. As previously described the purpose of the ultrafiltration system was to remove microorganisms and debris from the raw incoming mains supply water prior to the water being pumped to the cold water storage tanks and distribution system. As a consequence of by passing the ultrafiltration units contaminated water including debris and bacteria were introduced into the hot and cold water distribution system

[372] DMA, 'L8 Risk Assessment NHS GGC South Glasgow University Hospital. 2015.' (n 27).
[373] HFS, 'Water Safety (SHTM 04-01) Part A-G.' (n 41). HFS, 'Water Safety (SHTM 04-01) Part A-G.' (n 41).

throughout the hospital and to all outlets and any associated equipment supplied with this water.

6.3.5. My view is that the installation of the bypass pipe resulted in water bypassing the ultrafiltration system leading to contamination of the water system downstream with debris and microorganisms. Debris would have provided nutrients and where there was poor control of temperature then growth of waterborne microorganism's would have occurred.

6.3.6. Due to historical corrosion problems of copper piping in Scottish hospitals the Employer's Requirements stated that the pipework shall be stainless steel [374]. The DMA 2015 report [375] identified the use of copper pipe in tails (page 6) . The installation of the bypass introduced contaminated water including debris and bacteria into the hot and cold copper pipework system. **From the historical publications it is my view that the presence of this debris and the growth of bacteria will result in microbial associated corrosion on the surface of the copper pipework.**

6.3.7. DMA identified a lack of temperature control within the cold distribution system [376] (page 4). On the day of the risk assessment the majority of the cold water temperatures recorded by DMA were more than 5°C higher than those recorded at the water tanks with peak temperatures of 30°C.

6.3.8. My view is that the excessively high cold water temperatures provided conditions for microorganisms and waterborne pathogens to proliferate resulting in increased risk to patients in the hospital when exposed to this water from the outlet or ancillary equipment.

6.3.9. The Hardgate Road mains supply into Raw Water Tank 1A had been isolated for a number of weeks pending repair and as the water was not flowing through tank 1A the water would have created a deadleg [377] (p 3 of that report).

6.3.10. **It is my view that as the cold water stagnated then this created a favourable environment for microbial and biofilm proliferation and the conditions for microbial proliferation would have been exacerbated by the lack of tank inspections** (see 6.10.2).

6.3.11. Filtered water storage tank 2B contained debris and steel washers in the tank providing nutrients for microbial and biofilm proliferation.

6.3.12. It is my view that the presence of the debris and the washers provided additional nutrients for the growth of water borne pathogens.

[374] NHS GGC, 'NSGACL - ITPD Volume 2_iss1_rev1 Invitation to Participate in Competitive Dialogue Volume 2/1 Employer's Requirements (Hospitals)' (n 77).
[375] DMA, 'L8 Risk Assessment NHS GGC South Glasgow University Hospital. 2015.' (n 27).
[376] DMA, 'L8 Risk Assessment NHS GGC South Glasgow University Hospital. 2015.' (n 27).
[377] DMA, 'L8 Risk Assessment NHS GGC South Glasgow University Hospital. 2015.' (n 27).

6.3.13. The contaminated water in the filtered water storage tank 2B was then pumped to the hot and cold domestic water system, in which there was a lack of temperature control (7.4.7).

6.3.14. In my opinion the contaminating bacteria and sloughed biofilm from the filtered water storage tank 2B continued to contaminate and multiply within the hot and cold water system through to the hot and cold domestic water system through to outlets.

6.3.15. To control the cold water temperature, dump valves were located on the end of pipe runs to be operated through the BMS when heat gain had resulted in the cold water being recorded at 23°C. The water would then be dumped to return the cold water temperature to 20°C to reduce microbial growth [378]. On the day of the risk assessment the majority of the cold water temperatures recorded by DMA were more than 5°C higher than those recorded at the water tanks with peak temperatures of 30°C and that the valves were not discharging [379].

6.3.16. It is my view that as the dump valves were not operational i.e. not connected to the BMS, the warmer temperature in the dead legs would have resulted in microbially contaminated stagnant water due to a lack of flow and increased temperature. The microbial contaminated water from these deadlegs would have seeded and contaminated the water upstream increasing the risk of HAI.

6.3.17. The majority of the cold water distribution system temperatures were more than 5°C higher than those recorded at the water tanks, with peak temperatures of 30°C. Maintaining the cold water at 20°C or below is cited in guidance as method for controlling microbial growth - such examples of heat gain of cold water at 30°C in the cold water system are non-compliant with guidance.

6.3.18. **In my view such high temperature gains at 30°C result in microbial growth and increased risk to patients who are exposed to this water** [380] [381] [382].

6.4. Risks associated with the hot water system – 2015 L8 Report

6.4.1. DMA identified a lack of temperature control within the hot water distribution system as calorifiers were operating at lower than recommended temperatures with hot water return temperatures of 40-45°C due to issues with the Energy Centre and there were no records of remedial or corrective actions [383].

6.4.2. Hot water return temperatures operating at 40-45°C provide conditions for growth of water borne pathogens and was not-compliant with guidance [384].

[378] HSE (n 20).
[379] DMA, 'L8 Risk Assessment NHS GGC South Glasgow University Hospital. 2015.' (n 27).
[380] HFS, 'Water Safety (SHTM 04-01) Part A: Design, Installation and Testing 2014' (n 159).
[381] HSE (n 20).
[382] HSE (n 19).
[383] DMA, 'L8 Risk Assessment NHS GGC South Glasgow University Hospital. 2015.' (n 27).
[384] HSE (n 19).

6.4.3. A calorifier had been offline for over three months, creating deadlegs on the supply pipe from the incoming cold supply, hot flow and hot return to the calorifier [385]. DMA noted "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." DMA also noted that "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."

6.4.4. **My view is that as the calorifier had been offline for over three months then the water in the deadlegs in the i) incoming supply pipe, ii) calorifier and iii) hot water flow and return would have resulted in stagnation under favourable conditions for microbial growth and hence the water would have been contaminated with microorganisms. The consequence was that if the calorifier and associated pipework was then reinstated without flushing pasteurisation of disinfection the microbially contaminated water then all the associated pipework and outlets would have been microbially contaminated**.

6.4.5. The DMA risk assessment described that the domestic hot water systems did not operate on a conventional flow and return system, with principle, sub-ordinate and tertiary loops. Instead a return circuit was used that resulted in longer "deadlegs" to the outlets than SHTM 04-01 advised, and which did not comply with guidance [386].

6.4.6. **In my view as the Guidance [387] indicates that the hot water return should be local to the outlet then deadlegs of excessive length of up to 2.9-3m result in microbial growth including Legionella** [388].

6.5. Risks associated with the ancillary equipment – 2015 L8 Report

6.5.1. Flexible hoses were identified in connections for dishwashers, facility rooms, dirty utility rooms and arjo baths (both connections to the hot/cold system and internally within the actual bath) [389] despite being prohibited in the Employer's Requirements[390]. Guidance advises against the use of ethylene propylene diene monomer (EPDM) lined flexible hoses (tails) as these rubber based hoses have been shown to create a risk of microbial colonisation and as such are non-compliant with guidance [391] [392] [393].

[385] DMA, 'L8 Risk Assessment NHS GGC South Glasgow University Hospital. 2015.' (n 27).
[386] HFS, 'Water Safety (SHTM 04-01) Part A: Design, Installation and Testing 2014' (n 159).
[387] HSE (n 20).
[388] HSE (n 20).
[389] DMA, 'L8 Risk Assessment NHS GGC South Glasgow University Hospital. 2015.' (n 27).
[390] NHS GGC, 'NSGACL - ITPD Volume 2_iss1_rev1 Invitation to Participate in Competitive Dialogue Volume 2/1 Employer's Requirements (Hospitals)' (n 77).
[391] NHS GGC, 'NSGACL - ITPD Volume 2_iss1_rev1 Invitation to Participate in Competitive Dialogue Volume 2/1 Employer's Requirements (Hospitals)' (n 77).
[392] HSE (n 20).
[393] NHS NSS, 'SHFN 30 Part A: Manual Information for Design Teams, Construction Teams, Estates & Facilities and Infection Prevention & Control Teams'.

6.5.2. In my experience the presence of the rubber based EPDM flexible hoses that were fitted in the QEUH / RHC provided surfaces for the proliferation of biofilms consisting of waterborne pathogens. These tenacious biofilm bacteria on the surface of the flexible hoses, will continually flow in to the water phase and flowing into the ancillary equipment exposing patients to an increased risk of HAI.

6.5.3. Expansion vessels were not 'flow-through' [394] and were therefore non-compliant [395].

6.5.4. **It is my view that the use of non-flow through expansion vessels with the EPDM rubberised bladders provided nutrients and surfaces for the growth of waterborne pathogens and is discussed supported further with independent microbiological evidence in section 6.17 and Appendix** 1 [396]

6.5.5. Ancillary equipment (water coolers/dishwashers etc) had not been connected to the water system outlets **[397]. My view is that as the ancillary equipment had not been connected to water system then those water system outlets, were deadlegs full of stagnant water in which microorganisms and biofilm proliferated. When ancillary equipment was eventually connected then the microbial pathogens would have flowed into the new equipment creating microbial risk of exposure**.

6.6. Water microbiology - 2015 DMA L8 Report

6.6.1. The DMA risk assessors were advised that the NHS sampling programme highlighted a number out of specification Legionella and total viable counts [398] (page 15). In response to out of specification total viable counts, sanitisation of the water system was undertaken with some impact and a reduction in total viable counts in most areas. However, the Risk Assessment indicated that were still a number of areas with higher than normally acceptable levels of total viable counts. The original Legionella counts are described on page 43 and tabulated in Appendix 2 item 6 of the HPS HFS report [399] where counts as high as 1360 cfu/l were described.

6.6.2. It is my opinion that such high Legionella counts raise concerns for high risk patients.

[394] DMA, 'L8 Risk Assessment NHS GGC South Glasgow University Hospital. 2015.' (n 27).
[395] HFS, 'Water Safety (SHTM 04-01) Part A: Design, Installation and Testing 2014' (n 159).
[396] Intertek, 'ITSS- 0719-0001 Expansion Vessel Investigation Report for QUEH Glasgow. 2019' (n 38). Intertek, 'ITSS- 0719-0001 Expansion Vessel Investigation Report for QUEH Glasgow. 2019' (n 38).
[397] DMA, 'L8 Risk Assessment NHS GGC South Glasgow University Hospital. 2015.' (n 27).
[398] DMA, 'L8 Risk Assessment NHS GGC South Glasgow University Hospital. 2015.' (n 27).
[399] Storrar and Rankin (n 48).

6.7. Legionella Audit by Authorising Engineer - May 2017 [400]

6.7.1. The Authorising Engineer identified that there were gaps in the existing risk reduction systems and processes. The report stated that "in the event of a Legionella based incident at the hospital NHSGGC would not be in a strong position with regards to its stance on risk reduction and compliance with existing guidelines". Issues identified in the 2017 by the Authorising Engineer included:

- There is a need to complete a new Legionella Risk Assessment as the previous risk assessment was completed over two years ago.
- The existing system for risk reduction processes and procedures system appears to be in places haphazard.
- There were tasks missing from the paperwork and also there does not appear to be an escalation and recording of remedials process.
- There was no Authorised Person for water in post at the QEUH.
- There was also a need to clarify the management structure, and also to ensure that all involved personnel, from both NHS GGC and also contractors' staff are trained and have an adequate level of competency in order to deliver the required level of water-based risk reduction in the QEUH.
- Schematics were out of date.
- Very few hot water temperatures recorded in the records.
- There was no risk assessment or monitoring of the tank on the 12th floor.
- There was no evidence that the risk assessment remedial actions from the 2015 L8 Risk assessment had been completed despite the having been identified as requiring significant investigation & remedial action required as-soon as-is reasonably practicable

6.7.2. The Legionella audit carried out by the Authorising Engineer was the first since the hospital was occupied in April 2015. Such audits by the AE should be carried out annually and therefore the lack of an annual audit in 2016 would have been non-compliant with SHTM [401].

6.7.3. It is my view that the 2017 audit by the Authorising Engineer reiterated the findings of the 2015 L8 Legionella Risk Assessment[402]. This confirmed that the risk assessment remedial actions (from 2015 Legionella Risk Assessment) had not been carried out since 2015. Consequently, NHS GGC were non-compliant with guidance from the HSE [403] [404] and SHTM[405] which increased the risk of patients to waterborne HAI.

[400] Kelly, 'Legionella Control AE Audit – Queen Elizabeth University Hospital – 2017' (n 30).
[401] HFS, 'Water Safety (SHTM 04-01) Part A-G.' (n 41). HFS, 'Water Safety (SHTM 04-01) Part A-G.' (n 41).
[402] DMA, 'L8 Risk Assessment NHS GGC South Glasgow University Hospital. 2015.' (n 27). DMA, 'L8 Risk Assessment NHS GGC South Glasgow University Hospital. 2015.' (n 27).
[403] HSE (n 20).
[404] HSE (n 19).
[405] HFS, 'Water Safety (SHTM 04-01) Part A: Design, Installation and Testing 2014' (n 159). HFS, 'Water Safety (SHTM 04-01) Part A: Design, Installation and Testing 2014' (n 159).

6.8. Water Systems Audit by compliance officer – August 2017

6.8.1. This audit assessed compliance with the Scottish Hospital Technical Memorandums (SHTM)[406] and associated legislation at the QEUH and confirmed the findings from the L8 Risk Assessment and the Authorising Engineers Audit that NHS GGC were non-compliant with guidance. [407] This included identifying in Point 9 "Legionella Management - Significant gaps were identified in the Legionella Management on site."

6.8.2. My opinion is that this audit identified many of the problems that were previously identified in the 2015 DMA report and also in the 2017 independent Authorising Engineer report. The issues that had been identified as requiring urgent remedial action had not been addressed which increased the risk to patients from waterborne infections.

6.9. Legionella Risk assessment - September 2017

6.9.1. NHS GGC commissioned a Legionella Risk Assessment in September 2017 [408]

The risks identified in the Executive summary of this report are similar to those highlighted in the April 2015 report. A number of points raised in 2015 had been identified as requiring significant investigation & remedial action as-soon as-is reasonably practicable. However, as identified in the 2017 report many of these issues identified in 2015 had still not been addressed. An extensive but not exhaustive list from the DMA report was highlighted by HPS [409].

6.9.2. It is my opinion that as the 2017 report identified gaps that had not been addressed since 2015 then the lack of actions would have resulted in an increased risk of waterborne HAI.

6.9.3. Significant non-compliant findings in the gap analysis:

- 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 'Authorised Person Water' had 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.
- there is no Authorised Person training in place

[406] HFS, 'Water Safety (SHTM 04-01) Part A-G.' (n 41).
[407] P Urquhart, 'ATO 102NHS Greater Glasgow and Clyde Property, Procurement & Facilities Management Directorate Water Systems Audit at the Queen Elizabeth University' [2017] NHS GGC.
[408] DMA, 'Legionella Risk Assessment QEUH (Adult) Hospital and the Adjoining RHC 2017' (n 29).
[409] Storrar and Rankin (n 48).

6.9.4. **In my view the above demonstrates that the Estates Manager and the Authorised Person were not provided with adequate training.** HSE states that "inadequate management, lack of training and poor communication can be contributory factors in outbreaks" [410].

- "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.

  In my opinion the advice on corrective action and Legionella management being identified as high risk provides the evidence that there were significant risks with management regards to waterborne contamination in the water system the QEUH and RHC.

- Significant gaps were present that required corrective actions to be taken as a matter of immediate urgency 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.

- **In my view the significant gaps in the control of Legionella above by DMA 2017 describe a water system that was high risk for waterborne pathogens including Legionella and other bacteria**.

6.9.5. In terms of the Written Scheme QEUH the risk assessors identified that:

- The Written Scheme for QEUH had been written by DMA and was dated December 2016 [411] and had not been updated to provide the current Legionella Management Structure and planned preventative maintenance programme on site.

  In my view the Written Scheme was high risk as it was out of date, did not reflect the current Legionella Management Structure nor the planned preventative programme on site.

- It was reported by DMA that whilst the out of date Written Scheme was specifically oriented towards Legionella, it was noted that in light of recent incidents it should consider wider organism infection [412].

  In my view the DMA 2017 Risk assessment reflected that there was a problem with a wider range of microorganisms than just Legionella.

[410] HSE (n 20).
[411] DMA, 'DMA Written Scheme for Legionella Control QEUH RHC 2016'.
[412] Storrar and Rankin (n 48).

6.9.6. Raw Water tanks

- The risk assessors identified that one of the raw water tanks had a lower turnover than the other tanks and therefore **the water within that particular tank that would have resulted in microbial growth.**

  In my view the low turnover resulted in stagnation and encouraged the growth of microorganisms.

- Various items of debris, washers and sponges were found in the water tanks (2B). The heavy tide mark indicate that biofouling and microbial contamination had occurred.

  It is my opinion that the presence of the small debris including washers that were previously identified in 2015 reflects that there was a lack of an updated written scheme and planned preventative maintenance programme from 2015 to 2017. The presence of the debris and washers provided nutrients for and encouraged the growth of waterborne pathogens as reported by Intertek, the independent microbiological company (section 6.16 and Appendix 1). The range of microorganisms that were identified colonising the water storage tanks is detailed in later sections and in Appendix 1.

6.9.7. The return temperatures recorded at the calorifiers were consistently below 55°C [413] was not compliant with guidance [414].

6.9.8. It is my view that temperatures lower than 55°C resulted in microbial growth.

6.9.9. When the calorifier drains plugs were opened at the QEUH very dirty water was observed indicating a lack of maintenance providing nutrients and surface area for the growth of pathogens [415].

6.9.10. It is my opinion that the dirty water present at the bottom of the calorifier, where the temperature is lower resulted in the growth of microorganisms. As indicated in guidance [416] calorifiers should be inspected and purged of rust or sludge annually. There was no evidence recorded that the calorifiers had been purged to remove the contaminated water (page 9 of DMA Report).

6.9.11. The following sections reference taps, thermostatic mixer valves, strainers and showers.

[413] DMA, 'L8 Risk Assessment NHS GGC South Glasgow University Hospital. 2015.' (n 27).
[414] HSE (n 20).
[415] DMA, 'Legionella Risk Assessment QEUH (Adult) Hospital and the Adjoining RHC 2017' (n 29).
[416] HSE (n 20).

6.9.12. The DMA (2017) reported that " We understand no servicing of any of these valves' (sic TMV), and the associated strainers in non-high risk areas has been carried out since the hospital opened and there has been a very limited program of servicing in 'high risk' areas [417].

6.9.13. It is my opinion that as the water system at the QEUH/RHC was systematically contaminated (Appendix 2) and when combined with i) poor temperatures control, ii) lack of regular routine maintenance of the TMVs, and iii) lack of inspection, cleaning, descaling and disinfection of the strainers that there was an increased risk of microbial contamination and risk of HAI due to exposure to this water.

6.9.14. These taps should be demounted for servicing but according to the 2017 DMA report the required facilities had not yet been completed or commissioned. The lack of servicing facilities indicates that the Horne Optitherm Taps was not taking place in non-high risk clinical areas since the hospital had opened in 20 15 [418]. DMA stated in the 2017 Legionella risks assessment that "we understand no servicing of any of these valves and the associated strainers in non-high risk areas has been carried out since the hospital opened and there has been a very limited programme in "high risk areas". According to the QEUH Written Scheme TMV taps should be serviced quarterly including cleaning / disinfection of strainers.

6.9.15. In my experience the lack of servicing of the taps results in the tap components becoming contaminated with a range of waterborne pathogens to which patients would have been exposed.

There were no records for the disinfection of shower heads or hoses.

HSE Approved Code of Practice [419] cites that those with responsibilities for the control of premises should identify and assess sources of risk including if there is a means of creating and disseminating breathable droplets such as aerosol created showers and if there are susceptible exposed to contaminated aerosols**. It is my view the lack of records for the disinfection of shower heads of hoses, the length of time that the shower heads had been in place and the patient groups at risk indicates that there was an increased risk to patients.**

6.9.16. **It is my view that with no servicing taking place of the Horne Optitherm taps, valves, strainers and no disinfection of shower heads and hoses the consequences are that these components will have accumulated microbial contamination and presented a microbial risk to patients**. The microbial contamination was confirmed in the analysis carried out by Intertek which is presented later in this expert report [420]. As no servicing was taking place then NHS GGC were non-compliant with guidance [421].

[417] DMA, 'Legionella Risk Assessment QEUH (Adult) Hospital and the Adjoining RHC 2017' (n 29).
[418] DMA, 'Legionella Risk Assessment QEUH (Adult) Hospital and the Adjoining RHC 2017' (n 29).
[419] HSE (n 19).
[420] Intertek, 'Intertek Report Number ITSS-0718-0001W plus per Floor Contamination of Flow Straighteners Debris and Sponges 2018' (n 36).
[421] HSE (n 20) 274.

6.9.17. The view of the risk assessors was that "As the building is used by persons with acute underlying medical conditions then compliance to L8, HSG 274 and SHTM 04 - 01 is of paramount importance" and that many findings were identified as being non-compliant with guidance.

6.9.18. The risk assessors indicated that they would describe the Legionella management on site as being "High Risk" and as a consequence NHS GGC were non-compliant with SHTM, L8 and HSG 274.

6.9.19. In summary, my opinion is that the "High Risk" nature of the management of Legionella would have resulted in increased microbial risk to patients from both Legionella and other waterborne microorganisms.

6.10. Legionella Audit by Authorising Engineer - July 2018

6.10.1. This audit by the Authorising Engineer in July 2018 [422] identified the risks associated with the water system as being "very high" and requiring immediate remedial action. Examples of the findings included:

- lack of flushing of little used outlets flushing
- cleaning and descaling of the showers and hoses only being carried out in the retained estates i.e. not in the QEUH or RHC
- no records for tank inspections
- lack of records for showers/spray heads in the high risk areas (ward 4a) indicating that some cleaning schedules were not undertaken.
- lack records for servicing thermostatic mixer valves in non-high risk areas
- lack of hot water temperature records - not acceptable
- incomplete cold sentinel records
- lack of servicing of thermostatic mixer taps and valves (either to the manufacturer's instructions or to D 08 recommendations [423])
- it was pointed out that no Legionella sampling was being carried out whilst the filters were in place,

6.10.2. The findings of the 2018 Legionella audit again identified that NHS GGC were not compliant with HSE or SHTM guidance.

6.10.3. **In my view the 2018 audit by the Authorising Engineer reflects a water system that is non-compliant with current guidance, nationally [424] [425] and locally, SHTM's [426] and that those responsible for with the control of premises were not complying with their legal duties (HSE ACOP page 5 para 2). A complete lack of sampling for Legionella means that there is a complete lack of knowledge as to**

[422] D Kelly, 'Legionella Control AE Audit – Queen Elizabeth University Hospital – July 2018'.
[423] HTM, 'HTM 04-01: Supplement Performance Specification D 08: Thermostatic Mixing Valves (Healthcare Premises'.
[424] HSE (n 20).
[425] HSE (n 19).
[426] HFS, 'Water Safety (SHTM 04-01) Part A-G.' (n 41).

the risk of Legionella to the vulnerable patients in the hospital – monitoring can indicate whether you are achieving control and sampling for Legionella is a means of checking the system is under control (HSE ACOP page 5 para 2c). In addition, section 6.27 describes *M. chelonae* HAI where the hypothesis was that patients had been exposed to unfiltered water sources in the hospital indication that filters are not a panacea when the underlying problem is waterborne pathogens present in the water system.

6.11. Legionella Risk Assessment December 2018

6.11.1. This risk assessment was carried out in December 2018 and delivered in January 2019. The risk rating report in January 2019 classified the water systems and the control regime as High Risk based on the following statements [427]:

- Potential for system to pose a hazard – Possible (Mitigated by the control measures implemented during 2018)

- Condition of system being assessed (deficiencies/non-compliances found) - Major

6.11.2. Detailed findings in the 2019 Legionella risk report included:

- Expansion vessels are not of a flow through design and are not insulated.
- Multiple instances of hot temperatures dropping off and being recorded at <55°C in wards 2A & 2B during December 2018.
- Cold water temperatures recorded varied with some indicating heat gain on the cold water system.
- Issues were identified with WHB drains backing up, which in light of the issues identified with potential retrograde contamination from drains to taps, along with the potential reduction in use of outlets where WHBs not draining freely should be rectified.
- No cleaning and disinfection of shower heads and hoses or replacement regime is in place at present.
- A gap analysis identified gaps in the PPM programme and areas where the Written Scheme and Governance procedures could be amended and expanded upon.
- Records for tasks advised as completed by NHS Estates were not always available for assessment at the time of issue.

6.11.3. My opinion is that this Legionella risk assessment that was carried out in 2018 and delivered in 2019 described a water system that was not compliant with HSE and SHTM guidance for the control of microorganisms in the hot and cold water system. The lack of the control of the hot water system in wards 2A and 2B where the hot water was less than 55°C and the heat gain in the cold water indicated that the water system had the capability to support the growth

[427] DMA, 'Water System Risk Assessment - Legionella Risk Assessment QEUH and RHC 2019'.

of water borne pathogens. There was no cleaning regimen of the shower heads and hoses, which according to HSG 274, the showers should have been dismantled and cleaned quarterly. As indicated in the HSE ACOP those responsible for the control of premises should identify where the water temperature is between 20-45°C, there is a means of aerosol dissemination and there are "at risk" susceptible patients - those responsible were not complying with their legal duties according to the HSE ACOP (page 5 para 2).

6.12. Water microbiology testing following occupation

6.12.1. Water sampling (500-600 sentinel points) was carried out (April to December 2015) and processed in a United Kingdom Accreditation Service (UKAS) accredited testing facility and examples of the primary source data are presented in the report [428]. The primary source data identified that more than 85% of the samples (April 2015 [429] - August 2015) exceeded the limits for *L. pneumophila* sg 1 and 46% as being out of specification for *Legionella* spp. [430] [431]. The original results also note that total viable counts were in excess of 300 cfu/ml which are out of specification.

6.12.2. **In my view such high numbers (i.e. individual counts) and the high number of percentage positives across the hospital presented an increased risk of legionnaires' disease occurring** .

6.12.3. Storrar and Ranking indicate that there was anecdotal evidence of targeted water treatment on certain parts of the RHC as a result of water quality issues.

6.12.4. From my experience that targeted water treatment local areas and outlets would only have a temporary transient impact where the rest of the water system was not appropriately controlled as discussed in the DMA risk assessments and Authorising Engineer audits.

6.12.5. 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 [432].

6.12.6. In my view and that in HSG 274 such high out of specification Legionella counts of 4800 cfu/l would have presented an additional risk of avoidable infection to patients.

6.12.7. Test results for Ward 4A also provided from July and August 2017 demonstrated *Legionella* spp positive results post disinfection of the system [433].

[428] Storrar and Rankin (n 48).
[429] NHS NSS, 'Water Sample Report April to December 2015 - NHS NSS'.
[430] HFS, 'Water Safety (SHTM 04-01) Part A-G.' (n 41).
[431] HSE (n 20).
[432] Chaput, 'Microbiological Testing (2015-2020) of Water and Environmental Samples from the QEUH (Adults) and RHC, Overview of Sample Numbers and Test Results.' (n 33).
[433] Storrar and Rankin (n 48).

6.12.8. In my view the detection of Legionella spp. and high total viable counts in the water supply provides evidence that the conditions were favourable for the growth of both Legionella and other Gram-negative waterborne pathogens which would have presented a microbial risk to patients and that the targeted disinfection was not effective.

6.12.9. Test results from Ward 1D of the RHC Paediatric Intensive Care Unit (PICU) [434] detected *Cupriavidus pauculus* in the pre and post flush samples as well as the presence of *Pseudomonas* spp and *Stenotrophomonas maltophilia* in the water samples.

6.12.10. From my experience positive pre and post flush results would indicate that both the water outlets and water from the upstream pipework (i.e. further back in the water system) were positive for *C. pauculus* (Appendix 1). This is important in terms of disinfection – where the local outlet was disinfected then as soon as water was drawn from the upstream water system then that outlet would have become positive in one month (section 6.21).

6.12.11. The NHS GGC Report [435] also provides evidence that water samples from the new hospital (Adults and RHC) were positive for *Legionella*, *Pseudomonas*, *Cupriavidus M. chelonae*, *Acinetobacter*, coliforms, *Elisabethkingia miricola*, *Burkholderia*, *Stenotrophomonas*, *Serratia* and atypical mycobacteria.

6.12.12. The report also confirmed that ”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).

6.12.13. The results also noted out of specification total viable counts in some areas (highest 620 cfu/ml 2 days at 37º C and 320 cfu/ml 3 days at 22º C) [436].

6.12.14. The reports demonstrate that out of specification counts were recorded for both 22°C and 37°C across the QEUH campus including the new (adults and RHC) and the retained estate from 2016 through to 2020.

6.12.15. **In my opinion the results from NHS GGC indicate that *Legionella* spp., *C. pauculus, P. aeruginosa and S.* maltophilia, other environmental and enteric group Gram-negative bacteria, atypical Mycobacteria and fungi were present in the hospital water distribution system *i.e.* microbial contamination was**

[434] NHS GGC, ‘PICU Pseudomonas Test Results 04.10.2016 Spreadsheet. In Storrar and Rankin. (2018)’.
[435] Chaput, ‘Microbiological Testing (2015-2020) of Water and Environmental Samples from the QEUH (Adults) and RHC, Overview of Sample Numbers and Test Results.’ (n 33).
[436] Alcontrol, ‘18 08 2015 Samples Spreadsheet. As Identified in Water Management Issues Technical Review NHS GGC – QEUH and RHC Facilities Scotland – March 2019’.

identified in the hot and cold water domestic water distribution system from the water tanks to the outlets. Consequently such widespread contamination of the water system would have presented a microbial HAI risk to patients.

6.12.16. As a result of positive water results e.g. for Legionella local thermal disinfection took place and taps were replaced (Storrar and Rankin page 45). Final test results for the outlets passed.

6.12.17. In my view this presents a short term problem in the analysis and microbial control of the water system. The outlet passed the test immediately after thermal disinfection and replacing the tap. However, DMA reports provided that microbial recontamination occurred within one to two months resulting in an increased HAI risk to patients [437].

6.13. Microbiological assessment of water system assets

6.13.1. There follows an assessment of the microbiological results from the domestic hot and cold water system that includes the incoming water, water tanks, expansion vessels, the water system, showers, shower hoses, taps, flow straighteners, drains and other identified equipment. A number of expert reports by an external company (Intertek) will be referred to as they provide microbiological evidence. However, the nomenclature of these reports is confusing as the same report numbers are used on more than one occasion, but the reports have different content [438] [439]. I have provided descriptive titles for the references where appropriate as an aid. 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).

6.13.2. A chronological list of the microbiological data that has been made available of the water system and water components is presented in Appendix 1.

6.13.3. It is my view that these results provide a pictorial and temporal evidential database that the entire domestic hot and cold water system was contaminated with a wide range of waterborne pathogens that would have presented a HAI risk to patients from the date of occupation.

[437] Intertek, 'Intertek Report Number ITSS-0718-0001W plus per Floor Contamination of Flow Straighteners Debris and Sponges 2018' (n 36).
[438] Intertek, 'Intertek Report Number ITSS-0718-0001W plus per Floor Contamination of Flow Straighteners Debris and Sponges 2018' (n 36).
[439] Intertek, 'Intertek Report Number ITSS-0718-0001W. Mains Water Inlet Valve with Water Meter.'

6.14. Water asset list

6.14.1. A number of NHS GGC reports indicate that there was not a complete asset list for the water associated equipment and outlets [440]. HSG 274 details that a checklist should include an asset register of all associated plant, pumps, strainers, outlets and other relevant items page 53 para 3).

6.14.2. It is my opinion is that if water assets including plant, pumps, strainers, thermostatic mixer taps, spray taps and showers have not been identified then those assets will not have been included in the checklist for hot and cold water systems as per HSG 274 (see table 2.1 in HSG 274). The lack of an asset list would have been non-compliant with guidance [441] [442].

6.15. Incoming Mains Water supply to cold water storage tanks

6.15.1. A mains water inlet valve and water meter were analysed for microbial contamination (11/07/2018) [443]. Deposits were found on the internal surface of the pipe and on the casing of the meter fan and were white in colour and solid to the touch." Microbiological analysis demonstrated that there was greater than 10^{10} cfu per gram of material.

6.15.2. In my view this is extremely heavy deposits and microbial colonisation that should be prevented from entering a hospital water system. The extent of this microbiological contamination demonstrates i) the importance of the ultrafiltration system (as per SHTM guidance Part E) that was in place to protect the domestic hot and cold water system from contamination and ii) the extent of the fouling and debris that passed into the QEUH and RHC water system when the ultrafiltration system was bypassed.

6.16. Cold Water Storage Tanks

6.16.1. Debris, sponges and sediment were identified in the cold water storage tanks and were positive for the presence of biofilm indicating that the tanks were microbially contaminated [444].

6.16.2. In the QEUH the following issues were identified in the storage tanks [445] [446]:

- non-compliant hollow supports were found in the cold water storage tanks
- dirt and debris in the cold water storage tanks
- washers and sponges in the cold water storage tanks

[440] Urquhart (n 408).
[441] HFS, 'Water Safety (SHTM 04-01) Part A-G.' (n 41).
[442] HSE (n 20) 274.
[443] Intertek, 'Intertek Report Number ITSS-0718-0001W. Mains Water Inlet Valve with Water Meter.' (n 440).
[444] Intertek, 'Intertek Report Number ITSS-0718-0001W plus per Floor Contamination of Flow Straighteners Debris and Sponges 2018' (n 36).
[445] DMA, 'L8 Risk Assessment NHS GGC South Glasgow University Hospital. 2015.' (n 27).
[446] DMA, 'Legionella Risk Assessment QEUH (Adult) Hospital and the Adjoining RHC 2017' (n 29).

- lack of flow from the cold water storage tanks
- biofilm tide marks and positive results for “a large biofilm presence”

6.16.3. The following microorganisms were recovered from the cold water storage tanks (Appendix 1)

- *Cupriavidus pauculus*
- *Aspergillus*
- *Pseudomonas xanthomonas*
- *Delftia acidovorans*
- *Pseudomonas xanthomonas*
- *Mexicana*
- *S paucimobilis,*
- *M oxydans*

6.16.4. It is my view that the DMA reports provided evidence of contamination e.g. debris, washers and biofilm tide lines in the water tanks for an extensive period of time between 2015 and 2017. The independent laboratory evidence demonstrates that water tanks were contaminated with a wide range of water borne pathogens. The microbially contaminated water from the tanks would have been pumped to the hot and cold water system from 2015 to 2017 resulting in microbial contamination of the water system pipes and components such as taps and showers that would have presented an increased risk of HAI.

6.17. Expansion vessels

6.17.1. Investigations (June 2019) identified that the metal holding plates of the non-flow through expansion vessels were extensively corroded and the bladder of the expansion vessel was found to be covered in a range of deposits [447]. When examined the holding plate and the bladder were found to exhibit a strong reaction for biofilm.

6.17.2. Scientific analysis [448] indicated that 75% of the samples analysed from the expansion vessels were positive for *Cupriavidus* spp.

6.17.3. My view is that these expansion vessels which were identified as being non-compliant [449] in 2015 (DMA Report) were later identified as being contaminated with *Cupriavidus* spp [450]. From 2015 the contaminated water from the expansion vessels would have continually seeded the hot water system, tap outlets, showers and water coolers with these waterborne pathogens. With the hot water being less than 55°C and there being heat gain in the cold water growth of microorganisms would have taken place increasing the risk of HAI.

[447] Intertek, ‘ITSS- 0719-0001 Expansion Vessel Investigation Report for QUEH Glasgow. 2019’ (n 38).
[448] Intertek, ‘Intertek Report Number ITSS-0718-0001W plus per Floor Contamination of Flow Straighteners Debris and Sponges 2018’ (n 36).
[449] HFS, ‘Water Safety (SHTM 04-01) Part A: Design, Installation and Testing 2014’ (n 159).
[450] Intertek, ‘ITSS- 0719-0001 Expansion Vessel Investigation Report for QUEH Glasgow. 2019’ (n 38).

6.18. Water microbiology results – ground, basement and per floor

6.18.1. Results of water samples per floor (1-11) were supplied by the hospital to the analytical laboratory who determined that between ~20% to 60% of samples were positive per floor including the basement tanks (three of which were positive for *Cupriavidus*) [451]. There is a statement on page 2of the report that "As the testing primarily focused on the detection of Cupriavidus". Does this indicate that all these positive results are for *Cupriavidus* spp?

6.18.2. In my view these results indicate a high percentage of positive results from the basement and through every floor. The high percentage of positives results indicate a microbial contamination problem in the entire water system at all floor levels i.e. the entire water system is contaminated.

6.19. Shower and shower hoses

6.19.1. Water samples on ward 2A were positive for *C. pauculus* . Shower heads and shower hoses were also removed from wards 2A and 4B and a sample sent for microbiological analysis. The laboratory identified *Cupriavidus pauculus* in shower heads and shower hoses and also detected *Sphingomonas paucimobilis*, Delfia acidovorans, *Burkholderia gladioli, Brevundimonas* sp, *Candida guillermondii* and fungus indicating a wide range of Gram-negative waterborne pathogens. The laboratory identified *C. pauculus* in shower heads and shower hoses and also detected *Sphingomonas paucimobilis*, Delfia acidovorans, *Burkholderia gladioli, Brevundimonas* sp, *Candida guillermondii* and fungus indicating a wide range of Gram-negative waterborne pathogens.

6.19.2. In my view the detection of *Cupriavidus pauculus*, other waterborne pathogens and fungi in the shower heads and hoses from multiple different patient rooms in wards 2A and 4B indicated that these microorganisms had established as a biofilm on the components examined. HSE ACOP identifies that showers disseminate aerosols that create a risk of someone acquiring an HAI. Consequently the presence of the waterborne pathogens in the showers presented an increased risk of HAI.

6.20. Taps

6.20.1. *C. pauculus* was isolated from water samples taken from a tap on a wash hand basin within the aseptic suite of the pharmacy department of ward 2A RHC where the parenteral nutrition was made that the child in ward 2A RHC had received in February 2016 [452] [453]. Typing by Colindale reference laboratory confirmed the isolate from the

[451] Intertek, 'Intertek Report Number ITSS-0718-0001W plus per Floor Contamination of Flow Straighteners Debris and Sponges 2018' (n 36).
[452] SHI, 'Scottish Hospitals Inquiry Meeting Minutes Bundle Of Documents as Referenced in QEUH HOIC PPP' (n 156).
[453] HPS, 'Summary of Incident and Findings of the NHSGGC: QUEH/RHC Water Contamination Incident and Recommendations for NHS Scotland. Final V2' (n 62).

wash hand basin and the patient were the same [454]. The wash hand basin was subsequently removed as a result.

6.20.2. In addition rooms 3,15,16, and 26 also tested positive for *Cupriavidus* and one outlet in room 3 has tested positive for *P. aeruginosa* [455].

6.20.3. Scotland-wide pseudomonas guidance was published in 2013 [456] [457] stating that "Biofilm can develop on flow straighteners, and it is recommended that these are removed from taps." [458]

6.20.4. In my view there are a number of high risk issues with the Horne Taps that were fitted in the QEUH and RHC. i) the presence of the plastic outlet fitting that provides a high surface area and volume ratio for the growth of microorganisms [459] (see Figure 39 as an example of a biofilm contaminated outlet fitting from an outbreak associated with HAI fatalities and a new dismantled unused outlet from those taps* (Figure 40) [460], (an exploded view of a Horne flow straightener is provided elsewhere [461]) ii) users are more likely to only operate the blended mixed water (left hand lever). As a consequence the right hand lever that operates the cold supply will be used less often and as the cold water feed stagnates there will be heat gain from ambient temperature. The combination of the stagnation and the heat gain will result in favourable conditions for the growth of microorganisms and biofilm that will contaminate the tap surfaces and outlet fittings, and ii) the instructions for use of the taps are complex such that staff require training [462]. From the literature provided it is apparent that staff were not trained in the operation of the taps [463]. Through the continued use of these Horne taps there was an increased risk of HAI which were compounded by the lack of servicing and lack of temperature control of the water system as discussed elsewhere.

6.20.5. A further single case of *C. pauculus* was identified in September 2017. NHSGGC reported that a second hand-hygiene sink was found to be positive but following assessment was unable to be removed. Silver hydrogen peroxide treatment was undertaken and repeat testing resulted in zero total viable counts from this outlet [464].

[454] SHI, 'Scottish Hospitals Inquiry Meeting Minutes Bundle Of Documents as Referenced in QEUH HOIC PPP' (n 156).
[455] SHI, 'Scottish Hospitals Inquiry - IMT Minutes Bundle 1 of Documents for the Oral Hearing Com' 2023.
[456] Scot Execut Hlth Dept, 'Water Sources and Potential Infection Risk to Patients in High Risk Units – Revised Guidance 2013'.
[457] HPS, 'Guidance for Neonatal Units (Levels 1, 2 & 3), Adult and Paediatric Intensive Care Units in Scotland to Minimise the Risk of <i>P. Aeruginosa(/i) Infection from Water' (n 244).
[458] HPS, 'Guidance for Neonatal Units (Levels 1, 2 & 3), Adult and Paediatric Intensive Care Units in Scotland to Minimise the Risk of <i>P. Aeruginosa(/i) Infection from Water' (n 244).
[459] Intertek, 'Intertek Report Number ITSS-0718-0001W plus per Floor Contamination of Flow Straighteners Debris and Sponges 2018' (n 36).
[460] RQIA (n 294).
[461] Storrar and Rankin (n 48).
[462] Horne Engineering (n 139).
[463] Storrar and Rankin (n 48).
[464] SHI, 'Scottish Hospitals Inquiry - IMT Minutes Bundle 1 of Documents for the Oral Hearing Com' (n 456).

6.20.6. In my view and based on my experience the last two metres of any water system is high risk for HAI, particularly sieves(strainers), solenoids, thermostatic mixer valves, tap body and plastic outlet fittings [465]. **Following the use of an outlet the water flow stops and the water becomes stagnant until the outlet is used again. During this stagnation period the hot water will cool and there will be thermal gain in cold water pipe to ambient temperature (above 20°C) creating temperatures suitable for the growth of microorganisms (20-45°C) as cited by the HSE ACOP. Silver hydrogen peroxide biocide treatment was undertaken, and the taps were replaced. However, due to the extensive microbial contamination that was identified throughout the rest of the water system (Appendix 1) prior to the pharmaceutical preparation room the new outlets were then supplied by water that was contaminated by waterborne microbial pathogens. Microbiology results presented by Intertek demonstrated that these outlets were re-**

6.20.7. contaminated by water borne pathogens within a few months with an increased risk of HAI [466].

6.20.8. When the taps were analysed flow straighteners were "somewhat slimy" [467] around the rubber ring and the metal mesh in one of the taps contained debris and a distinct sulphurous odour.

6.20.9. **My view is that the presence of slime around the rubber ring of the flow straightener indicates an established biofilm that would have formed over time due to the presence of these plastic components which were non-compliant with Scottish Guidance** [468].

6.20.10. Debris was present in the metal mesh (sieve or strainer to protect the tap components). SHTM Part A indicates that "Strainers can be a source of Legionella and Pseudomonas bacteria and should be removed after commissioning has been satisfactorily completed".

6.20.11. My opinion is that the collected debris in the strainer indicates that the water system was contaminated with debris and that large particles were contaminating the water system. This debris provides nutrients for microbial growth. The Intertek report indicated that i) expansion vessels were extensively corroded, and the bladder of the expansion vessel was found to be covered in a

[465] Walker and others, 'Investigation of Healthcare-Acquired Infections Associated with *P. Aeruginosa* Biofilms in Taps in Neonatal Units in Northern Ireland' (n 9).
[466] Intertek, 'Intertek ITS 1018-0001 2018 Microbiological Analysis of Flow Straighteners over Time New to Three Months' (n 37).
[467] C Peters, 'Report on Environmental Sampling on 2A and 4B. Dr Christine Peters 22/03/18.'
[468] HFS, 'Water Safety (SHTM 04-01) Part A: Design, Installation and Testing 2014' (n 159).

range of deposits [469] and ii) calorifier drains contained very dirty water indicating a lack of maintenance and a potential zone for microbial growth [470].

6.20.12. The DMA report indicated that there was no servicing of the strainers in non-high risk areas and only limited servicing in high risk areas [471] [472] and as a consequence the contaminated strainers seeded the outlets with microbial pathogens.

6.20.13. The presence of sulphurous odours would indicate the presence of a thick biofilm in which sulphate reducing bacteria were growing - these were detected in the Scottish hospital water system in the 1990's and had resulted in corrosion of the copper pipework at the time – hence SHTM Part G indicates that stainless steel tubing should be used and as was specified in the Employer's Requirements[473].

6.20.14. The presence of *C. pauculus* in the water samples taken from taps was confirmed as being the same as that from the patient providing evidence of transmission from the water system to the patient.

6.21. Colonisation of flow straighteners on Ward 2A and other wards

6.21.1. Slime (biofilm) was visible [474] on the QEUH/RHC outlet fittings and an extremely high microbial count of >10^7 cfu per outlet fitting was detected [475]. Flow straighteners that had been in place in taps for 1 week had up to 3.0 x 10^4 cfu per straightener (biofilm score of <0.5) with those in place for 1-2months having a count of 10^7 and 10^8 cfu per straightener (biofilm score of 1.5 and >4)[476]. Identification of microorganisms was only reported for the flow straighteners which had been in place in the ward for 1 month and *Cupriavidus* was detected on flow straighteners that had been installed for more than one month [477] [478].

6.21.2. Published data from the QEUH and RHC in 2018 confirmed that 76.5% of the outlets in the haemato-oncology unit were positive for *C. pauculus* and 30% of outlets were positive across both hospitals [479]. In addition, nine of the flow straighteners examined were visually soiled and 12 had heavy biofilm present on testing. [480]

[469] Intertek, 'ITSS- 0719-0001 Expansion Vessel Investigation Report for QUEH Glasgow. 2019' (n 38).
[470] DMA, 'Legionella Risk Assessment QEUH (Adult) Hospital and the Adjoining RHC 2017' (n 29).
[471] DMA, 'L8 Risk Assessment NHS GGC South Glasgow University Hospital. 2015.' (n 27).
[472] DMA, 'Legionella Risk Assessment QEUH (Adult) Hospital and the Adjoining RHC 2017' (n 29).
[473] NHS GGC, 'NSGACL - ITPD Volume 2_iss1_rev1 Invitation to Participate in Competitive Dialogue Volume 2/1 Employer's Requirements (Hospitals)' (n 77).
[474] C Peters, 'Report by Christine Peters March 2018 Ward 2a 2b'.
[475] Intertek, 'Intertek Report Number ITSS-0718-0001W plus per Floor Contamination of Flow Straighteners Debris and Sponges 2018' (n 36).
[476] Intertek, 'Intertek Report Number ITSS-0718-0001W. Mains Water Inlet Valve with Water Meter.' (n 440).
[477] Peters (n 468).
[478] Intertek, 'Intertek Report Number ITSS-0718-0001W. Mains Water Inlet Valve with Water Meter.' (n 440).
[479] Inkster and others, 'Investigation and Control of an Outbreak Due to a Contaminated Hospital Water System, Identified Following a Rare Case of *Cupriavidus Pauculus* Bacteraemia.' (n 260).
[480] Inkster and others, 'Investigation and Control of an Outbreak Due to a Contaminated Hospital Water System, Identified Following a Rare Case of *Cupriavidus Pauculus* Bacteraemia.' (n 260).

6.21.3. Microbiological analysis of flow straightener biofilm from wards 2A and 4B detected widespread contamination of tap components and the presence of *C.* the presence of *C. pauculus*, *S. maltophilia*, *Chryseobacterium* *Sphingomonas paucimobilis*, *Delftia acidovorans*, *Brevundimonas* sp, and *Serratia fonticuli* [481] [482].*maltophilia* and *Chryseobacterium* [483].

6.21.4. In June of 2018 the water technical group with the purpose of reviewing the options for replacing the Horne Optitherm Thermostatic Mixing Tap (TMT) with a suitable TMT without Plastic Flow regulator\Straighter device [484]. The Water Technical Group (WTG) concluded that these "Horne Optitherm TMT taps bust be replaced with Taps that can facilitate the provision of safe temperature water delivery without utilising the plastic material, matrix type flow straightener that have a known propensity to develop biofilm."

6.21.5. In my opinion the issues with microbiological problems with outlet fittings has been recognised since 2012 [485] [486]. In 2013 Scotland-wide pseudomonas guidance was published [487] [488] stating that "Biofilm can develop on flow straighteners, and it is recommended that these are removed from taps." [489]. Guidance was also produced by the Department of Health (England) in 2014. In 2018 the water technical group concluded that the "Horne TMT must be replaced with taps without plastic flow straighteners". However, from the SHI evidence the risks from these outlets fitting to patients has not been addressed despite multiple guidance documents across the UK and in Scotland demonstrating the microbiological risk to patients.

6.21.6. My opinion is that with such heavy contamination the taps and outlet fittings were unsafe i.e. presented an increased risk of HAI. The presence of slimy, green biofilm growth indicates that the tap components were heavily fouled with biofilm and the microbiological results presented evidence that *Cupriavidus* was part of the biofilm community and this biofilm formation occurred within weeks.[490] [491] The plastic outlet fittings examined were deconstructed and found to be extremely complex with a large surface for the

[481] Intertek, 'Intertek ITS 1018-0001 2018 Microbiological Analysis of Flow Straighteners over Time New to Three Months' (n 37).
[482] Peters (n 468).
[483] Intertek, 'Intertek ITS 1018-0001 2018 Microbiological Analysis of Flow Straighteners over Time New to Three Months' (n 37).
[484] NHS GGC 05062018, 'Queen Elisabeth University Hospital\Royal Hospital for Children Review of Horne Optitherm Taps for Use within Designated Critical Areas. 5/06/2018'.
[485] RQIA (n 294).
[486] Walker and others, 'Investigation of Healthcare-Acquired Infections Associated with *P. Aeruginosa* Biofilms in Taps in Neonatal Units in Northern Ireland' (n 9).
[487] Scot Execut Hlth Dept (n 457).
[488] HPS, 'Guidance for Neonatal Units (Levels 1, 2 & 3), Adult and Paediatric Intensive Care Units in Scotland to Minimise the Risk of <i>P. Aeruginosa(/i) Infection from Water' (n 244).
[489] HPS, 'Guidance for Neonatal Units (Levels 1, 2 & 3), Adult and Paediatric Intensive Care Units in Scotland to Minimise the Risk of <i>P. Aeruginosa(/i) Infection from Water' (n 244).
[490] Inkster and others, 'Investigation and Control of an Outbreak Due to a Contaminated Hospital Water System, Identified Following a Rare Case of *Cupriavidus Pauculus* Bacteraemia.' (n 260).
[491] Peters (n 468).

growth of microorganisms [492] look as complex as those that were in the taps that were associated with outbreaks in Northern Ireland [493] [494].

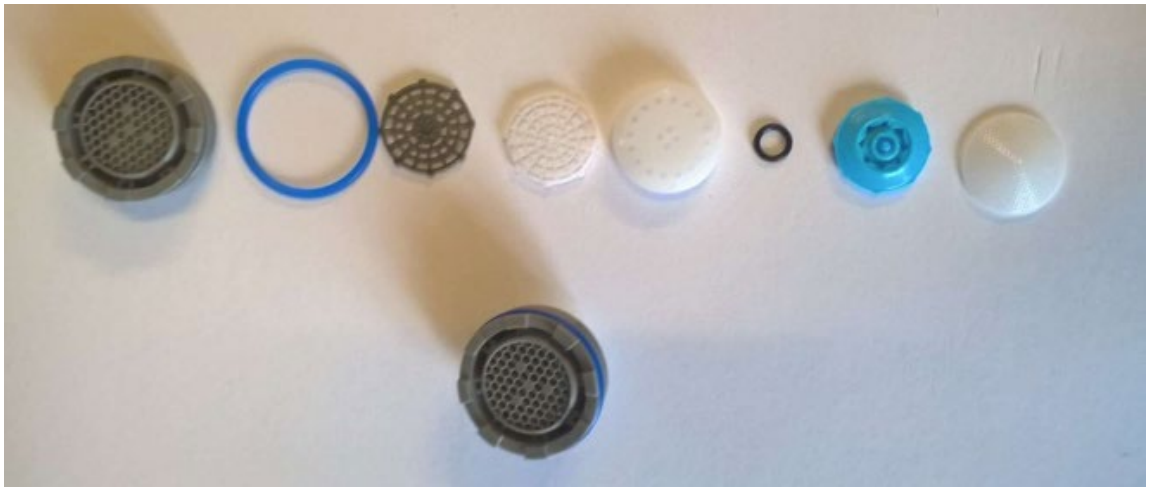


Figure 48. Fully dismantled flow straightener as demonstrated in the Intertek report [495]

6.21.7. In my view and from past experience the last 2m of a water system presents an increased risk of HAI. The above results (sections 7.21 and sections 7.22) present the evidence as to why the taps at the QHEU and RHC were a particular risk for HAI. Following the deaths of patients in 2011/2012 in Northern Ireland the Department of Health (England) produced HTM 0401 Part C entitled "Pseudomonas aeruginosa – advice for augmented care unit" [496]. HTM 0401 Part C describes the particular patient groups at risk and identified methodologies to control and minimise the risks of morbidity and mortality due to *P. aeruginosa* associated with water outlets. HTM 0401 Part C states that "Owing to their high surface-area-to volume ratio and location at the tap outlet, certain designs of flow straightener may present a greater surface area for colonisation and support the growth of organisms. Therefore, when selecting new taps, where possible flow straighteners should be avoided/ not included." Health Facilities Scotland were acknowledgement for being part of the Steering Group. SHTM Part A states that "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" SHTM 0401 Part G recognises that there

[492] Intertek, 'Intertek ITSS 1018-0001 2019 Microbiological Analysis of 31 Flow Straighteners to Compare against Previous 2018 Results' (n 305).
[493] RQIA (n 294).
[494] Walker and others, 'Investigation of Healthcare-Acquired Infections Associated with *P. Aeruginosa* Biofilms in Taps in Neonatal Units in Northern Ireland' (n 9).
[495] Intertek, 'Intertek ITSS 1018-0001 2019 Microbiological Analysis of 31 Flow Straighteners to Compare against Previous 2018 Results' (n 305).
[496] DHSC, 'HTM 04-01: Safe Water in Healthcare Premises. Part C: Pseudomonas Aeruginosa – Advice for Augmented Care Units 2014' (n 11).

are a combination of factors that facilitate *P. aeruginosa* becoming a clinical problem including water system materials (plastic and rubber components in TMVs and flexible hose liners) and water outlets with thermostatic mixer valves (TMVs) designed to regulate water temperature and minimise the risk of scalding, which may also have increased the risk of other waterborne pathogens. Due to the microbiological results available the microbial risk of plastic outlet fittings was recognised yet the outlet fittings were still present in the taps in the QEUH and RHC and in my experience increased the risk of microbial contamination and growth of biofilm at the outlet.

6.22. Analysis of pre- and post-flush samples

6.22.1. Analysis indicated that 33% of pre-flush (first sample when the tap has been opened) samples and 44% of post-flush (sample taken after the tap has been flushed) samples were positive [497] .

6.22.2. The preflush positive results indicate that 33% of outlets were positive.

6.22.3. The post flush positive results (44%) demonstrated that the contamination is present in the water supplying the outlets i.e. widespread contamination further back in the water system known as systemic contamination.

6.22.4. The extent of the preflush analysis would indicate that approximately 30% of outlets were positive for Cupriavidus and that approximately 45% of the post flush samples were positive.

6.22.5. **It is my view that such a high percentage of positive results for pre-flush (representing the last 2 metres) and post-flush (representing water further back in the water system) samples would indicate that there was widespread systemic microbial contamination of the water system (as evidence in Appendix 1) that presented an HAI risk to patients.[498] [499] This systemic contamination would have been compounded by the lack of temperature control and planned preventative maintenance of the water system (DMA 2015 and 2017 RA**).

6.23. Drains and drain traps (u-bends)

6.23.1. Drain and Traps – analysis of the drain traps from Ward 3C detected significant evidence of solids contamination [500]. A large piece of plastic film (50mmX40mm) was imbedded in the debris indicating that this plastic material had been deposited in the drain. The metal fitting at the base of the trap showed significant levels of corrosion to the surface.

[497] Intertek, 'ITSS- 0719-0001 Expansion Vessel Investigation Report for QUEH Glasgow. 2019' (n 38).
[498] Peters (n 468).
[499] Peters (n 468).
[500] Intertek, 'Intertek Report Number ITSS-0718-0001W plus per Floor Contamination of Flow Straighteners Debris and Sponges 2018' (n 36).

6.23.2. Reports indicated that thick black and yellow slime was visible in the drains in ward 2A and that the finding from the drains matched 2 of the cases reported [501].

6.23.3. Clumps of hair were identified in debris shown protruding from the pipe and the side of the debris. The remaining debris consisted of decaying organic matter. A rubber seal attached to the fitting was split and showed high levels of decay throughout the seal – **this would not have been watertight and would have soiled any materials stored underneath.** A biofilm test indicated a very strong instant reaction indicating the presence of a large mature biofilm.

6.23.4. A range of waterborne pathogens were detected in the water, drains and outlet components including [502] [503] [504] [505] (Appendix 1).

- *Sphingomonas paucimobilis*
- *Stenotrophomonas maltophilia*
- *Micobacterium laevaniformans*
- *Acidovorax temperans*
- *Chryseobacterium* spp
- *Caulobacter*

6.23.5. It is my view that the drains traps contained a wide range of materials including plastics, hair and slimy debris. Such gross fouling provided nutrients and surfaces for the colonisation and growth of biofilms containing a wide range of pathogens that increased the risk of HAI not just from the microbially contaminated water sources but also from the drains (section 5.24 and Appendix 1). The contaminated drains would have resulted in the basin being contaminated, either as i) bacteria from the drain were washed out of the drain when the drain was occluded or ii) when splashing occurred during the use of the sink. This splashing of droplets (section 5.25) would have led to retrograde contamination of the taps, outlets, basins, POU filters and the surrounding area for up to 2m particularly with antibiotic resistant strains [506] [507]. The contamination of the drains would have been compounded by the contamination from the water system, taps and outlets and lack of planned preventative maintenance and the lack of awareness and training concerning the microbial contamination associated with handwash basin and drains as grime was visible in the drains. Examples of concerns related to the hand wash basins and sinks in 2023 in the QEUH and RHC are presented in Appendix 2.

[501] SHI, 'Scottish Hospitals Inquiry Meeting Minutes Bundle Of Documents as Referenced in QEUH HOIC PPP' (n 156).
[502] SHI, 'Scottish Hospitals Inquiry Meeting Minutes Bundle Of Documents as Referenced in QEUH HOIC PPP' (n 156).
[503] Intertek, 'Intertek Report Number ITSS-0718-0001W plus per Floor Contamination of Flow Straighteners Debris and Sponges 2018' (n 36).
[504] Intertek, 'Intertek ITS 1018-0001 2018 Microbiological Analysis of Flow Straighteners over Time New to Three Months' (n 37).
[505] Inkster and others, 'Investigation and Control of an Outbreak Due to a Contaminated Hospital Water System, Identified Following a Rare Case of *Cupriavidus Pauculus* Bacteraemia.' (n 260).
[506] Decraene and others (n 226).
[507] Roux and others (n 310).

6.24. Dishwashers

6.24.1. Fungal (*Exophialia*) infections were identified in patients (e.g. in Cystic Fibrosis patients) over an 11 month period. There were 19 cases in total with one out-patient and the others being inpatients [508].

6.24.2. An engineer reviewed two of the dishwashers and the following issues were identified [509]:

- bottom filter found to have build-up of residue;
- hoses supplying machine from containers were wrong way round i.e. rinse aid hose was in the detergent container and the detergent hose was in rinse aid container.
- detergent container found to be crystallising in bottom of container resulting in uptake into hoses and on into machine.

6.24.3. The dishwashers were swabbed and tested and were found to be positive for fungi which matched the fungi colonisation on the patients (Storrar and Rankin, p. 51).

6.24.4. In my opinion the matching of the environmental strain to the patient strain provides evidence of the source and transmission route.

6.24.5. As the hoses for the rinse aid and the detergent were the wrong way round then this may have impacted on the ability of the dishwasher to undertake microbial control which would have led to microbial contamination of the dishwasher and the associated items being cleaned.

6.24.6. In addition as the detergent was crystallising in the bottom of the container would have prevented the required volume of detergent to be taken into the dishwasher for effective decontamination to take place. This is likely to have arisen due to a lack of training (competency), not understanding the implications of inappropriate use, not following the manufacturer's instructions, lack of a planned preventative maintenance programme and not identifying who was responsible for cleaning the dishwashers.

6.24.7. In 2015 it was identified that where present dishwashers had been connected to the plumbing system using flexible hoses [510]. The Invitation to Participate in Competitive Dialogue: Volume 2 [511] as it stated in 7.9.6 (h) that the use of flexible hose connections is prohibited. The using of flexible hose connection as described in section 4.25 present an increased risk for microbial growth including water borne pathogens and fungi.

[508] SHI, 'Scottish Hospitals Inquiry Meeting Minutes Bundle Of Documents as Referenced in QEUH HOIC PPP' (n 156).
[509] SHI, 'Scottish Hospitals Inquiry - IMT Minutes Bundle 1 of Documents for the Oral Hearing Com' (n 456) 1.
[510] DMA, 'Water System Risk Assessment - Legionella Risk Assessment QEUH and RHC 2019' (n 428).
[511] NHS GGC, 'NSGACL - ITPD Volume 2_iss1_rev1 Invitation to Participate in Competitive Dialogue Volume 2/1 Employer's Requirements (Hospitals)' (n 77).

6.24.8. **It is my view that the supply of contaminated water to the dishwashers led to a build-up of residue on the filter. The presence of the flexible hoses provided an increased surface for microbial growth. Nutrients for bacterial growth were provided by the debris and the flexible hoses and nutrients. The hoses connected the wrong way round and crystallisation of the detergent increased the risk of colonisation that presented an increased microbial risk of exposure to patients** [512].

6.25. Water coolers

6.25.1. Water coolers were provided under contract at various locations throughout QEUH and RHC [513]. The microbiological quality of water from coolers was considered to be of a poor standard and therefore potentially posed a risk to patients, particularly those who were immunosuppressed. Historically there have been concerns over maintenance and cleaning of water coolers and where responsibility for them sits (similar to the issue with dishwashers). As a consequence all water coolers were removed from the RHC [514].

6.25.2. **In my opinion standalone water coolers increase the risk for patients and in this case there was evidence of poor water microbiology.** There was a lack of knowledge and understanding of the risks from these units and issues over who was responsible for servicing and maintenance of them which can result in microbial contamination.

6.26. Point of use filters

6.26.1. The L8 Legionella risk assessment in 2017 [515] reported that point of use filters had been installed with ward 2A due to the detection of *C. pauculus* in the water samples and filters were then fitted in other high-risk areas [516]. These filters were absolute filters and would have removed all microorganisms from the water passing through each filter were fitted in the high-risk and non-high risk areas.

6.26.2. However, it is my view that the point of use filters in place resulted in the end of the water filter being closer to the wash hand basin surface (shortening the distance between the end of the outlet and the basin surface) and water causing splashing from the basin to the surrounding ward environment in some cases breaching the category 5 air gap requirements (to prevent backflow of contaminated water into the water system) [517]. Samples from the drains were positive for a wide range of environmental microorganisms (Appendix 1).

[512] SHI, 'Scottish Hospitals Inquiry - IMT Minutes Bundle 1 of Documents for the Oral Hearing Com' (n 456) 1.
[513] Storrar and Rankin (n 48).
[514] SHI, 'SHI - SBAR Bundle 4 – NHS NSS Situation, Background, Assessment, Recommendation (SBAR) Documentation for the Oral Hearing Com' 2023, 4.
[515] DMA, 'Legionella Risk Assessment QEUH (Adult) Hospital and the Adjoining RHC 2017' (n 29).
[516] DMA, 'Legionella Risk Assessment QEUH (Adult) Hospital and the Adjoining RHC 2017' (n 29).
[517] WRAS, 'The Water Supply (Water Fittings) Regulations 1999'.

6.26.3. It was hypothesised that this splashing was a factor in contamination of the environment and individuals by Enterobacter present in the drains [518].

6.27. *Mycobacterium chelonae* contamination of the water system

6.27.1. In June 2019 it was recognized that an usually high number of cases of *M. chelonae* had been identified within a 12-month period.

6.27.2. *M. chelonae* was isolated during water sampling from different areas (in two paediatric haemato-oncology inpatient wards and an operating theatre) in the hospital [519]. The hypothesis was that patients had been exposed to unfiltered water sources in the hospital [520]. Whole genome sequencing confirmed that the isolate from one patient was closely related the environmental samples from water outlets [521].

6.27.3. In my view the high number of *M. chelonae* cases is unacceptable due to the presence of filters on the water outlets. These filters should have protected patients from exposure to *M. chelonae*.

6.27.4. In addition it is concerning that atypical mycobacterial species were detected when sampling point of use filters [522]. These are absolute filters i.e. bacteria should not be detected through the filter. Therefore, it was hypothesised that patients were exposed to unfiltered water. This was either due to i) patients being exposed to unfiltered water, from sink taps that did not have filters fitted or ii) leakage from poorly fitting filters to the tap outlet (resulting in unfiltered water contamination the filter body) resulting in exposure to unfiltered water.

6.28. Conclusion of the historical assessment of the key unsafe aspects

6.28.1. Microbiological evidence has been reviewed including that from NHS GGC, hospital microbiological laboratories and independent microbiological laboratories from the time period that patients started to occupy the QEUH and RHC in 2015.

6.28.2. A wide range of waterborne pathogens including Gram-negative, microorganisms and fungi were isolated from the cold water tanks, hot and cold water systems, taps, drains and associated ancillary equipment.

6.28.3. I have reviewed the data and evidence from when patients started to occupy the QEUH and RHC (24th April 2015). My view is that the water and waste

[518] SHI, 'Scottish Hospitals Inquiry - IMT Minutes Bundle 1 of Documents for the Oral Hearing Com' (n 456) 1.
[519] SHI, 'Scottish Hospitals Inquiry - IMT Minutes Bundle 1 of Documents for the Oral Hearing Com' (n 456).
[520] SHI, 'SHI - SBAR Bundle 4 – NHS NSS Situation, Background, Assessment, Recommendation (SBAR) Documentation for the Oral Hearing Com' (n 515) 1.
[521] Inkster and others, 'Investigation of Two Cases of *Mycobacterium Chelonae* Infection in Haemato-Oncology Patients Using Whole-Genome Sequencing and a Potential Link to the Hospital Water Supply' (n 201).
[522] DL Chaput, '28 March Royal Hospital for Children Ward 2A/2B Water Test Results'.

system from the cold water storage tanks through to the taps, showers, drains and ancillary equipment was microbially contaminated with a range of waterborne pathogens from the date at which patients occupied the QEUH and RHC (Appendix 1). These microbial pathogens posed a risk to the patients in the QEUH and RHC.

6.28.4. The evidence presented from risk assessments demonstrated that NHS GGC and the water system were not compliant with guidance (HSE and SHTM) from the time that patients started to occupy the QEUH and RHC in 2015 and that this non-compliance was still evidenced in risk assessments and audits through to late 2017.

6.28.5. Appendix 1 Location and timeline of water sample, taps, showers outlets and drain positives for various microorganisms throughout the water system.

7. Present-day assessment – is the water and waste system safe?

7.1. Background to the present day assessment

7.1.1. In November 2019, NHS Greater Glasgow and Clyde (NHS GGC) was escalated to Stage 4 of NHS Scotland's National Performance Framework as a result of a continuing series of infection incidents at the Queen Elizabeth University Hospital (QEUH) and the Royal Hospital for Children (RHC).

7.1.2. Reports indicated that a high number of children and young adults experienced episodes of infection due to Gram-negative environmental (GNE) bacteria, from 2015 to 2019 [523].

7.1.3. NHS Greater Glasgow and Clyde (NHSGGC) investigated the contaminated water system across the Queen Elizabeth University Hospital (QEUH) and Royal Hospital for Children (RHC).

7.1.4. Water testing by NHS GGC and independent laboratories revealed widespread contamination of the water and drainage system [524]. Tap outlets were heavily contaminated, including flow straighteners and drains [525] [526] [527] [528] with widespread contamination (tanks, expansion vessels, taps and showers) of the water system and wastewater drainage system with a wide range of Gram-negative bacteria, fungal and non-tuberculous mycobacteria. A number of strains were identified as being distinct among the patient and tap-water samples.

7.1.5. HPS reports hypothesised that the cause of the widespread contamination was the water system with the most likely cause being a combination of the following hypothesis B and C [529].

A: Ingress contamination
B: Regressional contamination
C: Contamination at installation / commissioning

[523] Stevens, Evans and Wilcox (n 54).
[524] Chaput, 'Microbiological Testing (2015-2020) of Water and Environmental Samples from the QEUH (Adults) and RHC, Overview of Sample Numbers and Test Results.' (n 33).
[525] Intertek, 'Intertek Report Number ITSS-0718-0001W plus per Floor Contamination of Flow Straighteners Debris and Sponges 2018' (n 36).
[526] Intertek, 'Intertek ITSS 1018-0001 2019 Microbiological Analysis of 31 Flow Straighteners to Compare against Previous 2018 Results' (n 305).
[527] Intertek, 'Intertek ITS 1018-0001 2018 Microbiological Analysis of Flow Straighteners over Time New to Three Months' (n 37).
[528] Intertek, 'ITSS- 0719-0001 Expansion Vessel Investigation Report for QUEH Glasgow. 2019' (n 38).
[529] Storrar and Rankin (n 48).

7.2. Remediation strategies

7.2.1. Regular microbiological analysis from 2015 confirmed microbial contamination of the water and drainage/waste-water system and a range of remedial measures were implemented to address the microbial contamination [530].

7.2.2. In addition to the remediation work on the water and wastewater system, a wide range of infection prevention and control practices were implemented at the QEUH and RHC to reduce exposure of the patients to the waterborne pathogens.

7.2.3. Examples of changes to the physical infrastructures as well those involving infection prevention and control strategies are provided as follows:

7.2.4. Physical / chemical treatments

- Additional primary ultrafiltration plant installed to filter the incoming water supply system resulting in three filtration plants
- Disposable showerheads and hoses
- Fitting of point of use filters to taps and showers
- Thermal disinfection of the water system
- Disinfection/dosing treatment of parts of the water system
- Increased flushing
- Full scale continual dosing of the entire water system with chlorine dioxide
- Cleaning and replacement of drains
- Removal of wash hand basins to remove direct transmission risk
- Removal of water coolers
- Increased water sampling

7.2.5. Infection prevention and control strategies

- Reducing exposure of patients to water
- Management of central venous lines
- Provision of bottled water for washing and brushing teeth
- Increased use of single use equipment
- Addition of other Gram-negative microorganisms to the Alert List
- Addition of “water” to the risk register

7.2.6. It is my view that extent of the remedial strategies employed at the QEUH and RHC provides evidence that the water and wastewater systems were recognised by microbiologists, hospital engineers, haematologists and managers as transmission routes for Gram-negative environmental microorganisms.

[530] Chaput, ‘Microbiological Testing (2015-2020) of Water and Environmental Samples from the QEUH (Adults) and RHC, Overview of Sample Numbers and Test Results.’ (n 33).

7.3. Microbiological Evidence

7.3.1. Raw microbiological data [531] and presentations [532] [533] [534] have been provided by NHS GGC based on the extensive range of microbiological sampling, testing and analysis that was carried out from 2015 through to 2023.

7.4. Water sampling data from 2015 to 2020

7.4.1. The QEUH whole campus water testing report provides a breakdown of the microbiological sampling and results for 2015-2020 [535].

7.5. Detection of Legionella spp.

7.5.1. Whilst *L. pneumophila* serogroup 1 was detected in the new build (QEUH and RHC) in 2015 it was only rarely detected from 2018 to 2020. *L. pneumophila* serogroup 2-14 was almost entirely absent from the new buildings over the entire period. Whilst *L. pneumophila* serogroup 1 was rarely detected in the retained estates, *L. pneumophila* serogroup 2-14 were detected frequently.

7.5.2. It is my view that such frequent and consistent detection of *L. pneumophila* serogroup 2-14 across the retained estates should be raised as an issue of concern due the risk to patients from water outlets in those areas.

7.6. Detection of *Pseudomonas* sp

7.6.1. New buildings had a lower percent of out of specification results (1.8% / 0.95% corrected) than the retained buildings (2.3%). However the detection of Pseudomonas spp would indicate a risk to patients.

7.7. Detection of total viable (potable) counts

7.7.1. The results indicated that the new buildings had a higher percentage of out of specification results, with 5.9% out of spec compared to 3.3% in the retained estates (3.3%).

[531] Chaput, 'Dr Dominique Chaput Raw Data Files 2023 - Excel Spread Sheets Supplied by NHS GGC' (n 34).
[532] Chaput, '8 February 2022 Presentation by Dominique Chaput, Healthcare Scientist, Scottish Microbiology Reference Laboratories (1)'.
[533] Chaput, '1 March 2022 Presentation by Dominique Chaput, Healthcare Scientist, Scottish Microbiology Reference Laboratories (1)'.
[534] Chaput, '18 Feb 2022 Presentation by Dominique Chaput, Healthcare Scientist, Scottish Microbiology Reference Laboratories (1)'.
[535] Chaput, 'Microbiological Testing (2015-2020) of Water and Environmental Samples from the QEUH (Adults) and RHC, Overview of Sample Numbers and Test Results.' (n 33).

7.8. Detection of other Gram negative bacteria (GNB)

7.8.1. The majority of samples for *C. pauculus* and other GNB were from the new buildings with 4.4% positive for *C. pauculus* (280 samples) and a further 15.6% (988 samples) negative for *C. pauculus* but positive for at least one other GNB, giving a positivity rate for any GNB of 20%. *C. pauculus* and other GNB was detected regularly from 2018 (start of routine testing) through to 2020.

7.9. Detection of fungal contamination

7.9.1. Routine fungal testing began in the new buildings in December 2018. Of the 6 samples from the retained estate, 2 were out of specification (33.3%), whereas in the new buildings, 605 samples (10.0%) were out of specification.

7.10. Detection of atypical mycobacteria test results

7.10.1. Only samples from the new buildings underwent testing for atypical mycobacteria with 9.1% being out-of-specification.

7.10.2. In response to reports of children and young adults experiencing episodes of infection as a result of Gram-negative environmental (GNE) bacteria, from 2015 to 2019, water microbiology sampling was obviously increased. An extensive range of bacterial taxa were detected across the QEUH campus, including *Cupriavidus* spp, *Stenotrophomonas* spp, *Pseudomonas* spp., *Klebsiella* spp., *Acinetobacter* spp. and atypical mycobacteria.

7.11. RHC Ward 2A/2B water test results Tuesday, 8 Feb 2022

7.11.1. Following the chlorine dioxide dosing system installation in 2018 there was an increase in sample numbers analysed to monitor and assess decontamination of the water systems [536].

7.11.2. Bacterial numbers were relatively low and were considered to be acceptable with no significant difference in both the pre and post ultra filtrated water.

7.11.3. There was a higher fungal count in the incoming mains water with a significant reduction ($p<0.5$) post filtration.

7.11.4. The results indicated that at the time of testing (up to 27 Jan 2022) that the ultra-filtration units were maintaining low bacterial counts and reducing fungal counts in the post filtered water or main and concluded that the microbiological contamination of the raw and cold water storage tanks was under control.

[536] Chaput, '8 February 2022 Presentation by Dominique Chaput, Healthcare Scientist, Scottish Microbiology Reference Laboratories (1)' (n 533).

7.11.5. However, in my view even the detection of low counts does not mean that there should be complacency in terms of risk to patients. Any microbial count in the cold water tanks will be dispersed through the water system and when the conditions are favourable (through a combination of temperature, stagnation and nutrients and lack of planned preventative maintenance and servicing) then those microorganisms will proliferate e.g. in ancillary equipment and on filter strainers, cartridges, outlet fittings.

7.11.6. The ward had been closed for refurbishment for an extended period of time and chlorine dioxide dosing of the water system of wards 2A/2B did not significantly decrease the total viable counts which were detected in water samples from wards in September and October 2021 [537]. Microbiological testing detected the presence of Gram-negative environmental microorganisms including *Acidovorax temperans*, *Sphingomonas paucimobilis*, and *Cupriavidus pauculus*.

7.11.7. **In my view the lack of efficacy of the chlorine dioxide dosing system reflected the extensive microbial contamination and biofilm formation that had formed through the hot and cold water system due to a lack of servicing and planned preventative maintenance. Such high counts of these microorganisms would indicate that there would have been a potential risk to patients**.

7.11.8. Microbial testing following refurbishment of wards 2A and 2B indicated that the chlorine dioxide dosing system was not effective in terms of the concentrations and contact times required to reduce the presence of these bacteria.

7.11.9. In my opinion the high microbial counts may have been a reflection that the ward was unoccupied and that there was a lack of flushing (compared to actual use of clinical wash hand basins when the ward is fully functional).

7.11.10. Microbial/biofilm contamination of components (e.g. filter strainers and cartridges) in the last two metres of the pipework to outlets was confirmed when pipe sections and cartridges (TMV from taps) were analysed and water testing in Sept-Oct 2021 detected heavily colonisation of *S. paucimobilis* and *Cupriavidus pauculus* [538].

7.11.11. Colonisation of tap associated components have previously been reported by Intertek be heavily fouled by a range of microbial pathogens within the QEUH [539] [540].

7.11.12. In my opinion the microbiological testing demonstrated that despite major refurbishment of wards 2A and 2B and extensive biocide treatment that the water system components were heavily colonised with a wide range of

[537] Chaput, '8 February 2022 Presentation by Dominique Chaput, Healthcare Scientist, Scottish Microbiology Reference Laboratories (1)' (n 533).
[538] Chaput, '8 February 2022 Presentation by Dominique Chaput, Healthcare Scientist, Scottish Microbiology Reference Laboratories (1)' (n 533).
[539] Intertek, 'Intertek Report Number ITSS-0718-0001W plus per Floor Contamination of Flow Straighteners Debris and Sponges 2018' (n 36).
[540] Intertek, 'Intertek ITSS 1018-0001 2019 Microbiological Analysis of 31 Flow Straighteners to Compare against Previous 2018 Results' (n 305).

Gram-negative microorganisms. The presence of these Gram-negative microorganism associated with pipe material and cartridges from taps demonstrated the importance of the water safety group and clinical and nursing staff understanding the microbiological contamination of the water system and the risk to vulnerable patients.

7.11.13. This was reflected in the decision to increase flushing of the water system in response to the microbial counts where high risk patients would have been resident [541].

7.11.14. In my opinion flushing would only have reduced the microbial count in the water phase and would not have removed the biofilm from the pipework, cartridges or strainers. As such when the flushing was terminated the waterborne microbial pathogens in the biofilm would have sloughed into and contaminating the water phase and patients would have been exposed next time that outlet was used.

7.11.15. Installation of taps at the QEUH / RHC was discussed in 2014 when the decision was taken to retain the Horne Engineering Optitherm tap in the QEUH and RHC. This was at a time when the Northern Ireland incident in 2011/12 resulted in national guidance to remove outlet fittings as a consequence of patient fatalities from exposure to tap water from fittings contaminated with *P. aeruginosa*. In Northern Ireland the results demonstrated that all the components associated with taps (tap outlets, filter strainers and cartridges were contaminated with *P. aeruginosa*) [542].

7.11.16. The Written Scheme [543] specifies that:

- The following actions must be undertaken every three months (p 58):
- Inspect, clean and disinfect filters / strainers by removing and immersing in a solution of 1000ppm free residual chlorine (50cc ClO_2 in 5 litres of water) in water for 5 minutes.
- All HORNE Optitherm taps MUST have the flow straightener replaced during three monthly service tasks.

7.11.17. However, 2020 AE Report cited that only a limited number of TMT/TMV's were inspected and only for a fail-safe check i.e. the microbially contaminated filter strainers had not been replaced.

7.11.18. In my opinion the failure to follow the Written Scheme i.e. to inspect, clean and disinfect filters/strainers would have resulted in bacterial contamination of the outlets. Independent analysis by Intertek (as at s.7.11.11 above) provided

[541] Chaput, '8 February 2022 Presentation by Dominique Chaput, Healthcare Scientist, Scottish Microbiology Reference Laboratories (1)' (n 533).
[542] Walker and others, 'Investigation of Healthcare-Acquired Infections Associated with *P. Aeruginosa* Biofilms in Taps in Neonatal Units in Northern Ireland' (n 9).
[543] NHS GGC, 'QEUH Campus Water Systems WRITTEN SCHEME: Controlling the Risks of Exposure to Legionella and Other Harmful Bacteria in Water Systems'.

evidence that the outlets were microbially re-contaminated following one week of use.

7.11.19. Cleaning of the filter strainers on a regular basis was highlighted as an issue in the *Pseudomonas* risk assessment in 2016 [544].

7.11.20. **It is my view that the risk assessments and Written Scheme highlighted the risk of microbiological contamination of tap components. However, even after refurbishment and extensive biocide treatment the inherent risks of microbiological contamination in the water system had not been sufficiently controlled**.

7.11.21. Analysis [545] indicated that there was no significant difference between the pre and post results for the new taps indicating that the biofilm contamination of those specific outlets had been reduced by replacing the taps.

7.11.22. Therefore, only by changing out the old Marwick taps for new Marwick taps in January 2022 were the microbial counts reduced confirming that the microbial contamination was occurring at the periphery of the outlet. However, *Acidovorax temperans* and *Cupriavidus pauculus* were still detected in the water samples and would have proliferate when temperatures, stagnation and nutrients were available.

7.11.23. There have been a number of reports where positive results have been recorded after taking water samples through point of use filters in 2018 (p60) [546] and in 2022 [547]. In 2018 the POU filters were sent back to the manufacturer for detailed analysis to determine the cause of the failure. The manufacturer's letter dated 1st May 2018 confirmed that there was no fault found in the filter [548].

7.11.24. In my opinion it is concerning that microbial counts were being detected through point of use filters [549] as these are absolute filters i.e. bacteria should not be detected through the filter. As the manufacturer confirmed that there was no fault with the filters the contamination occurred either through i) retrograde contamination of filters particularly from the contaminated drains or washing of medical devices in the clinical wash hand basin and a subsequent risk to patients or ii) through the water sampling process.

7.11.25. Additional pre and post sampling across Ward 2A and 2B continued to confirm the presence of *C. pauculus* across a range of rooms and across Floor 2 (page 6) [550].

[544] DMA, 'Pseudomonas Report on Water Delivery System'.
[545] Chaput, '1 March 2022 Presentation by Dominique Chaput, Healthcare Scientist, Scottish Microbiology Reference Laboratories (1)' (n 534).
[546] HFS, 'Water Management Issues Technical Review NHSGGC – QEUH and RHC HFS – March 2019' (n 107).
[547] Chaput, '28 March Royal Hospital for Children Ward 2A/2B Water Test Results' (n 523).
[548] HFS, 'Water Management Issues Technical Review NHSGGC – QEUH and RHC HFS – March 2019' (n 107).
[549] Chaput, '28 March Royal Hospital for Children Ward 2A/2B Water Test Results' (n 523).
[550] Chaput, '1 March 2022 Presentation by Dominique Chaput, Healthcare Scientist, Scottish Microbiology Reference Laboratories (1)' (n 534).

7.11.26. **In my view the presence of the waterborne microbial pathogens continued to demonstrate a preventable risk to patients when exposed to unfiltered water**.

7.11.27. Despite the counts being low the detection of significantly more *C. pauculus (14-22 February 2022)* in the preflush samples (i.e. immediately when the tap was switched on) indicated that *C. pauculus* may already have started to form biofilms on the new tap components and therefore would have presented a risk to patients when exposed to unfiltered water. These findings supported the Intertek report that reported regrowth of tap component biofilm within a matter of weeks and months [551]. **The growth of *C. pauculus* may have been as a result of growth on the filter strainers which according to the AE reports [552], were not being cleaned.**

7.12. RHC Ward 2A/2B water test results Tuesday, 28 March 2023

7.12.1. Following closure for refurbishment RHC Ward 2A/2B was reopened on 9 March 2022 the results indicated that from February 2022 the TVC results for ward 2A/2B were in most cases <10 CFU/ml.

7.12.2. A number of water samples (July 2022 to January 2023) continued to demonstrate the sporadic presence of *Pseudomonas*, GNBs and AMS. A number of these positives were from water samples that had point of use water filters attached which **would indicate that the positive results were due to retrograde contamination which may have been a result of** :

- **Hand contact with the filters**
- **Washing of patient medical equipment in the clinical wash hand basin**
- **Discarding of patient and other products down the clinical wash hand basin**

7.12.3. In summary the March 2023 report reported that:

- Legionella, coliforms, *E.coli* or Cupriavidus were detected from 9 March 2022 to 15 March 2023.
- 98.9% of tests were in specification for TVC37, and 99.7% were in specification for TVC 22 (CFU/mL < 10)

7.12.4. However, a small percentage of GNBs including *Pseudomonas* and atypical mycobacteria were out of specification (i.e. detected) [553]. So whilst the authors suggested that these results point to a “well-performing system”, where conditions favourable for microbial growth then there will be proliferation of these bacteria and a risk of exposure of patients to unfiltered water.

[551] Intertek, ‘Intertek ITS 1018-0001 2018 Microbiological Analysis of Flow Straighteners over Time New to Three Months’ (n 37).
[552] D Kelly, ‘Legionella Control AE Audit – Queen Elizabeth University Hospital 2022’.
[553] Chaput, ‘28 March Royal Hospital for Children Ward 2A/2B Water Test Results’ (n 523).

7.12.5. In my view I still have concerns about the water system (see also photographic evidence from visit to QEUH and RHC (Appendix 2).

7.13. Risk Assessments

7.13.1. NHS GGC engaged a specialist water company to undertake a Risk Assessment of the water systems within the Hospitals in accordance with "Scottish Health".

7.13.2. The lack of an up to date annual risk assessment was initially identified in the authorising engineers 2020 [554] report and was also cited it the 2021 [555], 2022 [556] and 2023 [557] reports.

7.13.3. The previous Risk Assessment of the site was undertaken in 2018 stated that "the water systems and the control regime would be classified as High Risk" was out of date[558] and did not comply with guidance [559] [560].

7.13.4. It is my view that year on year identification of non-compliant issues such as a lack of risk assessments and written schemes should have been addressed as soon as possible.

7.13.5. A risk assessment of only wards 2A/ 2B was carried out in 2022 [561] and was a four gap since the 2018 risk assessment. The 2022 risk assessment described the refurbishment and remediation measures that were undertaken in 2018 and early 2019 including:

- Removal of wash hand basins from anterooms
- Bringing the flow and return lines closer to the outlets
- Replacement of Horne Engineering taps with Marwick 21 TMT taps
- Basins replaced with those with fins (anti splash design)
- Chlorine dioxide dosing units installed in the risers.

7.13.6. After these initial upgrade works were completed, the wards reopened as a general ward with the original patient group remaining in Ward 6A within the adult's hospital [562].

7.13.7. In late 2019 further work was undertaken after which the schedule for these works was interrupted and delayed by the Covid-19 pandemic through 2020 and 2021.

[554] D Kelly, 'Legionella Control AE Audit – Queen Elizabeth University Hospital – 2020'.
[555] D Kelly, 'Legionella Control AE Audit – Queen Elizabeth University Hospital – 2021'.
[556] Kelly, 'Legionella Control AE Audit – Queen Elizabeth University Hospital 2022' (n 553).
[557] Kelly, 'Legionella Control AE Audit – Queen Elizabeth University Hospital 2023' (n 31).
[558] Kelly, 'Legionella Control AE Audit – Queen Elizabeth University Hospital 2023' (n 31).
[559] HFS, 'Water Safety (SHTM 04-01) for Healthcare Premises Part B: Operational Management.' (n 347).
[560] HSE (n 20).
[561] DMA, 'L8 Risk Assessment. Royal Hospital for Children Ward 2A & 2B 2022'.
[562] DMA, 'L8 Risk Assessment. Royal Hospital for Children Ward 2A & 2B 2022' (n 562).

7.13.8. During construction works flushing regimens were undertaken and as described above, microbiological testing in September 2021 highlighted out of specification results (specifically for potable analysis and Gram Negative Bacteria/Cupriavidus). The water system was then disinfected but had little impact on the microbiological results in the tap water analysed due to the build of biofilm in the TMV cartridges [563]. Replacing the taps resulted in lower counts that were considered to be within specification.

7.13.9. In my opinion contamination of the older taps demonstrated that the periphery of the water system was contaminated with a range of Gram-negative microorganisms that posed a risk to high risk patients.

7.13.10. In addition, it was highlighted that the flow and return were not circulating properly, and the correct hot water temperatures were not being achieved with multiple tertiary loops found to be failing. As the hot returns were not circulating the return loop was cooling when not in use resulting in temperatures that would have been favourable for the growth of microorganisms.

7.13.11. In my view the problems identified with the hot water flow and return increased the risk of microbial proliferation in the water system.

7.13.12. There was also:

- uninsulated cold supply pipes were in direct contact with the hot return pipes – this would have resulted in thermal gain in the cold pipe leading to proliferation of bacteria and biofilm formation.
- Uninsulated hot and cold water pipes

In my view the presence of uninsulated cold water pipes that were in direct contact with the hot return pipe is a basic and fundamental issue that leads to the multiplication of microorganism and is non-compliant with guidance [564] (para 80) and the Written Scheme [565] indicated that checks should be undertaken to ensure that all local pipework to and from the calorifier is in good order and all insulation is intact and that checks should be undertaken for missing or damaged pipework insulation.

7.13.13. Therefore, in my view after refurbishment, there were clearly still problems associated with the infrastructure within ward 2A and 2B that were not identified until a specific specialised L8 Legionella risk assessment was carried out.

7.13.14. As a consequence, additional work had to be carried out and point of use water filters fitted to protect the patients from the microbially contaminated water.

[563] Chaput, '8 February 2022 Presentation by Dominique Chaput, Healthcare Scientist, Scottish Microbiology Reference Laboratories (1)' (n 533).
[564] HSE (n 19).
[565] NHS GGC, 'QEUH Campus Wide WRITTEN SCHEME Controlling the Risks of Exposure to Legionella and Other Harmful Bacteria in Water System 2018'.

7.13.15. In my view the 2022 risk assessment indicated that parts of the 2A and 2B water system were still in an unsafe condition in the sense that they presented an avoidable risk of infection particularly upon exposure to unfiltered water.

7.13.16. As an onsite L8 Legionella risk assessment survey has not been carried out for the rest of the QEUH since 2018 then it would bring into question the safety of the water system and other water systems and ongoing potential risk of hospital associated infections in patients.

7.14. Authorising Engineer Audits – Annual Review - 2020

7.14.1. NHSGGC engaged an external Authorising Engineer – Water (AEW) to undertake an annual review of how the operational teams implement both the Water Safety Policy and the Written Scheme.

7.14.2. AE reports were provided for 2018 and 2020, 2021, 2022 and 2023. The Written Scheme indicates that the appointed Authorising Engineer for Water Safety will produce an annual report for management review and therefore**, in my view, the absence of a report for 2019 was non-compliant with NHS GGC guidance [566] at a time when the hospital water systems were undergoing a high level of scrutiny**.

Annual Review 2020

7.14.3. The 2020 AE [567] audit report included 43 recommendations (23 very high risk: 4 high risk) which reflected wide ranging concerns regarding delivery of the required risk reduction tasks. There were also concerns that the correct processes and procedures were being delivered and recorded. Issues identified included:

- No site risk assessment carried out since 2018 (carried out October-December 2018 and delivered to the site January 2019 see 1.1) and was still in draft form with a recommendation that a review of the outstanding risk assessment remedial actions is completed and a programme to address the outstanding actions is put into place as soon as possible - identified as very high risk and therefore requiring urgent remedial action.
- No evidence of removal of deadlegs (see 4.5).
- No evidence of inspections of tanks (p28)/calorifiers (page 28).
- It could not be confirmed that flushing of the expansion vessels was taking place (page 25) (some were non-flow through (single entry) - identified as a risk in 2015 [568].

[566] NHS GGC, 'QEUH Campus Water Systems WRITTEN SCHEME: Controlling the Risks of Exposure to Legionella and Other Harmful Bacteria in Water Systems' (n 544).
[567] Kelly, 'Legionella Control AE Audit – Queen Elizabeth University Hospital – 2020' (n 555).
[568] DMA, 'L8 Risk Assessment NHS GGC South Glasgow University Hospital. 2015.' (n 27).

- There was only one partial record for TMT/TMV's inspection (page 25) and only for fail-safe check i.e. no strainer filters replaced as required in the Written Scheme [569].
- Low hot water return temperatures (page 29 and 30, 36) with no records available for particular periods and no evidence that these low hot water return temperatures had been remediated. A folder contained a number of non-conformances but no further information on any remedial actions relating to these non-conformances.
- Hot water outlets were recorded as being <55°C (page 36).
- No representative hot and cold temperatures taken in the hospital (page 31).
- No evidence that all the chlorine dioxide weekly and monthly tasks are being completed as per HSG 274 guidance para 2 (page 40).
- Confusion across the site as to who (DMA, QEUH Estates department, NHS GGC clinical and cleaning staff and Scotmas) was responsible for what tasks (page 33) - it was suggested that that this confusion may have contributed to lack of control of the microbiological problems in the QEUH/RHC extending over a number of years.
- Recommended that the need for little used outlet flushing throughout the QEUH is reviewed and is implemented and recorded where required (page 34).

7.14.4. **In my view the 2020 annual review by the Authorising Engineer identified an excessive number of high risk and very high risk issues related to the water system and its management, which had previously been identified by DMA in 2015 and 2017. In addition the previous audit was carried out in 2018 - the Written Scheme [570] states that "3.10 External audit procedure A duly appointed Authorising Engineer (Water) will audit the entire Legionella and Water Safety Systems within NHS Board annually" and there the timeline is non-compliant with the Written Scheme.**

7.15. Authorising Engineer Audits – Annual Review 2021

7.15.1. The 2021 AE report identified that the 2018 risk assessment was still out of date (previously identified in the 2020 AE (W) report).

7.15.2. In my view the fact that this was identified as being very high risk and therefore requiring urgent remedial action and had previously been identified in the 2020 authorising engineer audit and had still not been carried out reflects a lack of management of the water system.

7.15.3. No drawings/schematics created where changes had been made to the water system since the installation of the chlorine dioxide system in November 2018 - as per

[569] NHS GGC, 'QEUH Campus Water Systems WRITTEN SCHEME: Controlling the Risks of Exposure to Legionella and Other Harmful Bacteria in Water Systems' (n 544).
[570] NHS GGC, 'QEUH Campus Wide WRITTEN SCHEME Controlling the Risks of Exposure to Legionella and Other Harmful Bacteria in Water System 2018' (n 566).

the Written Scheme, schematic drawings of the water system and pipework should have been reviewed annually as they are an integral part of the water safety plan.

7.15.4. In my view engineering drawings are fundamentally important when issues arise with microbial problems as it enables an understanding of the water system layout and how the components interact with each other.

7.15.5. Written Scheme not compliant with HSG274 as indicates that target temperatures for the hot water system were 50°C and not the 55°C – the setting of target temperatures at 50°C would allow proliferation of microorganisms.

7.15.6. Monthly chlorite tests as recommended in HSG274 Part 2 had not been carried out for the last year.

7.15.7. In my view as the majority of temperatures are recorded through TMV/TMT's there is a lack of information about the temperature of the hot and cold feeds to each outlet. The BMS has end of line sensors and alarms if they are out of specification though there is no information in the AE report as to what actions have been taken when the sensors have alarmed.

7.15.8. Two months (March and October) of temperature data were missing.

7.15.9. Servicing of the TMV's is not dated and there no records of recommended follow up work and whether filter strainers are being cleaned/ replaced/replaced.

7.15.10. It was recommended that calorifiers are inspected internally on an annual basis as recommended in the HSG 274 document and also in SHTM04-01.

7.16. Authorising Engineer Audits – Annual Review 2022

7.16.1. The March 2022 audit was a review of the previous audit in 2021. The 2022 AE report commented that a number of the outstanding actions in the 2020 and 2021 reports had been completed but identified that the Risk assessment that was carried out in 2018 had still not been updated which was non-compliant with both SHTM [571] and HSG 274 [572].

7.16.2. In addition:

- There was a lack of information on the temperatures to the hot and cold supply to the TMV/TMT's as well in the secondary and tertiary loops.
- Missing temperature records for 2020 were still missing.
- There was a concern that all the other water related equipment in the hospital was not being risk assessed, for instance, the hydrotherapy pool.

[571] HFS, 'Water Safety (SHTM 04-01) Part A-G.' (n 41).
[572] HSE (n 20).

- Lack of valves on the expansion vessels resulting in a lack of flushing - previous evidence that expansion vessels were a source of Cupriavidus [573].

7.16.3. In my view it is very concerning that a hospital in which high risk patients were present did not have a risk assessment update from 2018 especially as this had been identified on annual basis. In addition the lack of information on temperatures of the hot and cold supply to TMV/TMT's and in other places bring into question the confidence in the microbiological safety of the water system.

7.17. Authorising Engineer Audits – Annual Review 2023

7.17.1. The 2023 AE(W) audit report was completed on the NHS GGC QEUH and RHC properties only and was a completely new full audit of the management of the water system risk reduction processes.

7.17.2. The audit noted that "The recommendations in last year's audit have been virtually addressed and it was pleasing to note that the recommendations from the extant risk assessment had been completed. A summary of the current situation with regard to the water systems at the QEUH/RHC hospital is that the delivery of the required risk reduction processes and procedures is in safe hands and is virtually complete. There are some recommendations in this regard to improve this further. The level of knowledge and understanding of the onsite Estates' staff is extremely high and a diligent approach is taken to ensuring that the water systems are operated in a manner required to deliver high quality risk reduction processes and procedures."

7.17.3. High risk concerns identified included:

- "Two of this year's "high risk" recommendations are for the provision of a new, in date, risk assessment".

7.17.4. The last risk assessment survey of the site was undertaken in 2018 and this was identified in the 2020, 2021, 2022 and 2023 AE(W) reports.

7.17.5. A risk assessment was undertaken of wards 2A/2B in February 2022.

7.17.6. HSE L8 document (paragraph 61) and HSG 274 document (paragraph 14) respectively indicate that "it is important to review the risk assessment regularly and specifically if there is reason to suspect it is no longer valid, for example changes in the water system or its use" and "An indication of when to review the assessment and what to consider should be recorded and this may result from, e.g. a change to the water system or its use";

[573] Intertek, 'ITSS- 0719-0001 Expansion Vessel Investigation Report for QUEH Glasgow. 2019' (n 38).

7.17.7. In my view there were issues of concern raised in the 2023 AE(W) report including:

- Lack of recorded data for actual hot and cold water temperatures supplying TMT or TMV blended outlets.
- Presence of single entry expansion vessels that cannot be flushed and are therefore non-flow through - identified in 2015 DMA RA and Intertek identified extensive biofilm accumulation [574] inside the non-flow through expansion vessels as well as the presence of *Cupriavidus* spp [575].
- Only one service per year of the site TMVs/TMTs and the recommendation that this should be carried out every three months [576]
- NB – there is no comment here on whether the TMV/TMT service is only for failsafe of the TMV/TMT or whether it includes *a clean of the strainer filters at least once a year as per HSG 274.*
- Lack of records to demonstrate that risk reduction tasks have been completed and identified as being high risk and requiring urgent remedial action.
- Lack of risk assessment of the 15 other water systems in the two hospitals and was also identified as high risk therefore requiring urgent remedial action – also identified in the 2020, 2021 and 2022 AE (W) reports.

7.18. Written Scheme

7.18.1. The operational management of the water system is set out in QEUH campus Written Scheme [577].

7.18.2. The Written Scheme indicates in Section 1.2 that risk assessments should be reviewed to reflect any changes.

7.18.3. As cited in the Authorising Engineers reports changes have been made to various parts of the water system of the QEUH and RHC since 2019 and as such these changes should have triggered the requirement for the new risk assessment to be updated.

7.18.4. However, the AE (W) reports (2020-2023) identify that the Risk Assessment for the site had not been updated since the last on site survey in 2018.

7.18.5. The Written Scheme indicates that there should be an annual review of drawings and schematics however the Authorising Engineers Reports[578] indicate that drawings and schematics had not been updated.

[574] Intertek, 'ITSS- 0719-0001 Expansion Vessel Investigation Report for QUEH Glasgow. 2019' (n 38).
[575] Intertek, 'Intertek Report Number ITSS-0718-0001W plus per Floor Contamination of Flow Straighteners Debris and Sponges 2018' (n 36).
[576] NHS GGC, 'QEUH Campus Wide WRITTEN SCHEME Controlling the Risks of Exposure to Legionella and Other Harmful Bacteria in Water System 2018' (n 566).
[577] NHS GGC, 'QEUH Campus Water Systems WRITTEN SCHEME: Controlling the Risks of Exposure to Legionella and Other Harmful Bacteria in Water Systems' (n 544).
[578] Kelly, 'Legionella Control AE Audit – Queen Elizabeth University Hospital – 2020' (n 555).

7.18.6. The Written Scheme also indicates that drawing and schematics should be reviewed annually. The AE cites that there are NO schematics in the risk assessment document but that as fitted drawings for both hospitals are available elsewhere (Zutec) [579].

7.18.7. Due to the number of changes that had taken place in the QEUH and RHC water system the as fitted drawings would not have provided an accurate nor up to date description.

7.18.8. **In my view, by not updating the risk assessments, drawings and schematics following changes and not following their own guidance (e.g. lack of servicing of TMTs/TMVs) then NHS GCC were non-compliant with their own guidelines (including the Written Scheme and SHTM 04-01) [580] and that of the HSE [581].**

7.19. Healthcare Improvement Scotland inspection Report 2019

7.19.1. The 2019 Report[582] identified that NHS GGC must improve the governance around estates and facilities issues in regard to cleaning, environmental damage and water management and areas of concern included:

- correct procedure to clean a wash hand basin.
- removable grime on panels below wash hand basins in patient areas
- water ingress above a wash hand basin
- risk of splash contamination as domestic staff were emptying dirty water into the ward's sluice room sink.
- not clear about who was responsible for carrying out water flushing; unused baths that had not been identified by staff as infrequently used water; bath not been working for 3 years: Staff were unaware that ensuite showers, would require regular flushing; lack of flushing closed patient room due to a leaking ensuite shower; no records water flushing: inconsistent recording evidence that water flushing had taken place.
- member of medical staff preparing an intravenous infusion in an area of the clean preparation room very close to a sink within splash contamination distance of this sink.

7.19.2. The requirements were that NHS Greater Glasgow and Clyde must ensure that:

- Requirement 3: all staff involved in the running of water are clearly informed of their roles and responsibilities in this and a clear and accurate record is kept to allow early identification of any water outlets that are not being run.

[579] Kelly, 'Legionella Control AE Audit – Queen Elizabeth University Hospital – 2020' (n 555).
[580] HFS, 'Water Safety (SHTM 04-01) Part A-G.' (n 41).
[581] HSE (n 20).
[582] Unannounced Inspection Report- Safety and Cleanliness of Hospitals, QEUH and RHC. Healthcare Improvement Scotland 29-31 January 2019

- Requirement 10: staff with suitable and functioning domestic services rooms to minimise the risk of cross contamination from the disposal of soiled water after the cleaning regime.
- Requirement 11: senior management must ensure all staff are aware of the correct method for cleaning hand wash basins, and the correct cleaning products are used to clean all sanitary fittings in line with current national guidance.

7.19.3. In my view the statement that "NHS GGC must improve the governance around estates and facilities issues in regard to cleaning, environmental damage and water management and areas of concern provides a very critical report of NHS GGC. My own observations in this area in 2023 (Appendix 2) provides evidence of sinks being blocked by equipment, sink areas being used as storage sites, sinks that are not accessible due to their location and environmental damage to sink and shower room and floor sealant that results in water and biofilm accumulation.

7.20. Healthcare Improvement Scotland inspection Report 2022

7.20.1. The inspection of the Queen Elizabeth University Hospital campus NHS Greater Glasgow and Clyde 7–8 and 20 June 2022 [583] identified that NHS GGC must take steps to improve the governance and reporting of critical systems within the built environment and included:

- Must ensure attendance by members of committees in the infection prevention and control governance structure, such as the NHS board water safety group, is a priority.
- The governance water management structure is either fully applied or adapted to reflect the requirements of the reporting structure to ensure the NHS board is fully informed of any NHS board water safety group issues.
- Review the system currently in place for quarterly reporting of flushing of water outlets to ensure a robust and effective process
- Including a clear formal update in line with the governance reporting structure provided by NHS GGC within the updates or reporting within the BICC minutes.
- Must ensure cleaning of tracheostomies is in line with guidance, not performed in clinical wash hand basins and staff have the correct information and support to do this safely.

7.20.2. For water management, it was reported that:

- there was still a lack of awareness around flushing of less frequently used water outlets although improvements had been identified
- risk assessments for water safety had not been carried out for several years

[583] HIS, 'Healthcare Improvement Scotland. Inspection Report. Unannounced Inspection to The QEUH Campus NHS Greater Glasgow and Clyde. 7–8 and 20 June 2022'.

- low compliance rates with some water flushing requirements had been raised as a concern estates and facilities
- observed staff in clinical preparation room preparing intravenous (IV) medications within splash distance of the disposal sink used to dispose of ice
- one area using a clinical wash hand basin to clean tracheostomy tubes and a lack of assurance around flushing regimens.

7.20.3. In my view this is a particularly critical report that identifies that NHS GGC must take steps to improve the governance in that i) it was highlighted that NHS GGC must ensure attendance by members of committees in the infection prevention and control governance structure, such as the NHS board water safety group, as a priority and ii) tracheostomy tubes being washed in a clinical hand wash basin – such practice leads to contamination of the tracheostomy with water borne pathogens and contaminates the sink area with patient strains.

7.21. Expert Group visits 2023

7.21.1. The Expert Group visited the QEUH and RHC in March 2023 (S Mumford, L Dempster and J Walker) and J Walker undertook a follow up visit in September 2023.

7.21.2. The findings of the Healthcare Improvement Scotland inspections in 2019 and 2022 described staff as being unsure how to clean a wash hand basin, staff preparing an IV infusion in the splash zone of the sink in the clean preparation room and an area using a clinical wash hand basin to clean tracheostomy tubes and a lack of assurance around flushing regimens.

7.21.3. The findings of these audits provide evidence that risks from the water and wastewater systems were at the time not being considered or recognised by staff. However, if staff are not provided with training, then how can they be aware of the risks to patients.

7.21.5. During the Expert Group site visits in March and Dr Walker's visit in September 2023 there were a number of issues where I had concerns related to the water and wastewater system that impact on patient safety (Appendix 2 of photographs). These issues suggest that the current staff training and education is not sufficient. These issues included:

- **Partially blocking access to clinical wash hand basins – resulting in lack of use, stagnation, and potential microbial growth. Review storage use.**
- Presence of Horne Optitherm taps – review compliance with guidance. In addition, review water use in these Optitherm outlets as users are more likely to only use the blended mixed water through the thermostatic mixer valve leading to stagnation in the cold supply. **My view is that as the cold water feed stagnates there will be heat gain from ambient temperature. The combination of the stagnation and the heat gain will result in favourable conditions for the growth of microorganisms and biofilm that will contaminate the tap surfaces and outlet fittings.**

- Containers, wipes, eating and drinking utensils including, patient water jugs, medical devices and toys cluttering the area around and within the splash zone of clinical hand basin and stainless steel sinks – **review requirement for these containers as the area underneath such containers will retain moisture leading to biofilm formation.**
- Potential for splashing from clinical hand wash basins and in particular deep troughed stainless sinks to surrounding area to the left and/or right hand side – **review the installation of splash guards to prevent dispersal of drain associated pathogens in the patient environment**.
- **Potential for breaching category 5 air gap due to point of use filter fitted in small stainless steel sink.**
- Damaged sealant in and around sinks and floor/ceiling joints in shower rooms **- review repairs to prevent moisture build up and fungal/ biofilm growth.**
- Sinks situated in hard to access areas e.g. too near corner/wall **– review requirement for retention of little used outlets and risk assess requirement for splash guards.**
- **Review cleanliness of patient drains in sinks and showers and treat to reduce microbial biofilm accumulation where required.**

7.21.6. Following the September visit to the QEUH and RHC a number of files were provided. The Excel sheet "Copy of Example of correspondence from Water Service provider - 2023 QEUH A^0C Sample Login Sheet Inc High Risk(v2) 210923" re: High Risk Area Out of Specification sheet where lines 111 and 115 identifies out of specification counts for Optitherm taps.

7.21.7. These very high counts >10,000 cfu at 22°C and 37°C were recovered from water samples from outlets that were fitted with Optitherm taps.

7.21.8. In other sheets that were provided “Example of TMT checks and temperatures at outlets” the “strainer condition” for Optitherm taps is described as “heavy debris”.

7.21.9. Whilst these are a limited set of results that have been provided only the Optitherm taps are identified as having strainers as being fouled with “heavily debris”.

7.21.10. **The results indicate that these Optitherm taps are suffering from biofilm build up with the strainers**.

7.21.11. The Intertek microbiology reports on flow straighteners demonstrated that the outlet fitting from Optitherm taps were significantly fouled with microorganisms’/biofilm after 1 month [584]. Such results demonstrate the inherent recognisable risk associated with particular taps.

7.21.12. Where “heavy debris” has been identified, this would indicate an increased risk of microbial transmission from this outlet and should be identified on the risk

[584] Intertek, ‘Intertek Report Number ITSS-0718-0001W plus per Floor Contamination of Flow Straighteners Debris and Sponges 2018’ (n 36).

assessment as these strainers will be fouled after more than 1 month and therefore present an avoidable risk to patients.

7.22. Summary of risk assessments and audit reports

7.22.1. The implementation of temperature control, the application of biocides (including continual dosing of chlorine dioxide), planned preventative maintenance and the fitting of additional ultrafiltration, point of use filters system and multiple infection prevention and control practices have all been implemented following microbiological evidence that the water and wastewater system has been systematically contaminated with a wide range of pathogens.

7.22.2. There is great concern that from 2015 to 2023 that the following have been identified year on year through authorising engineers' (water) reports, risk assessments, Healthcare Improvement Scotland reports and Expert Group visits and include (but not limited to):

- Frequency of risk assessments that are reflective of changes in the hospital
- Biofilm contamination in the last two metres including pipework and tap components related to frequency of use, temperature control of water to the outlets.
- High counts and heavy biofilm debris associated with Horne Optitherm taps
- Training and education of staff to recognise the risks posed from water and wastewater including but not limited to:

1. preparation of sterile medical equipment within the splash zone and
2. cleaning of tracheostomies in wash hand basins
3. risk from difficult to access sink units
4. clutter and medical equipment stored in or around sink units
5. awareness around the flushing of little used outlets
6. damaged sealant in and around sinks/showers leading to biofilm accumulation

8. Bibliography – selected documents

8.1. DMA Risk Assessment dated April 2015

8.2. DMA Canyon L8 Risk Assessment based on surveys in September and October 2017 and a management review meeting for gap analysis on 30 January 2018

8.3. HPS Summary of Incident and Findings of the NHS Greater Glasgow and Clyde: Queen Elizabeth University Hospital/ Royal Hospital for Children water contamination incident and recommendations for NHS Scotland dated 20/12/18

8.4. HPS 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 (cited by Dr Walker by reference to its authors, Storrar and Rankin)

8.5. Report by Dr Dominique Chaput, dated 3 March 2023, Microbiological testing of water and environmental samples from the Queen Elizabeth University Hospital (Adults) and Royal Hospital for Children 2015-2020

8.6. Intertek reports

8.7. P Urquhart, 'ATO 102NHS Greater Glasgow and Clyde Property, Procurement & Facilities Management Directorate Water Systems Audit at the Queen Elizabeth University' [2017] NHS GG (this is a brief report by the GGC Compliance Manager Phyllis Urquhart dated 18 August 2017, the purpose of which was to assess compliance with SHTM 04-01)

8.8. Report by Dr Christine Peters on environmental sampling on wards 2A and 4B, 22/3/18;

8.9. The Inquiry's PPP 5 HOIC

8.10. Bundles for Inquiry hearings;

8.11. Legionella Management and Compliance Audit May 2017

8.12. The Timeline attached to the final report of the GGC Oversight Board

8.13. Leiper, 'NHS GGC – QEUH/RHC Review of Issues Relating to Hospital Water Systems' Risk Assessment' (this is an internal GGC report on its response to the DMA Risk Assessment of 2015)

8.14. Report by Dr Susanne Lee April 2018

8.15. The Case Note Review.

9. Expert Witness CV

9.1.1. Dr James Walker is a microbiologist with over 30 years' experience in water microbiology and decontamination. He previously worked for Public Health England (PHE) where he managed a range of projects on biofilms and pathogens involving *Legionella* spp., *Pseudomonas aeruginosa* and nontuberculous Mycobacteria. Through PHE, he worked with the Department of Health (DH England) and the Health and Safety Executive in writing and developing national and international guidance on the microbiology of water and decontamination in healthcare. He has an extensive publication record including editing and writing water microbiology books. He is currently the Chair of the Central Sterilising Club.

9.1.2. Qualifications

Doctor of Philosophy, 1994. Open University. Investigation of biofilms in copper tube corrosion and the survival of *Legionella pneumophilia* on alternative plumbing materials
Bachelor of Science, Microbiology, 2 ii. 1987, University of Aberdeen.
Higher National Diploma in Biology. 1985, Bell College, Scotland.

9.1.3. Employment

Director of Walker on Water
2018 to date
Health Protection Agency, Porton, Salisbury SP4 0JG, England - Biosafety Group

2013 – 2018	Scientific Leader in Water Microbiology and Decontamination
2012 - 2013	Senior Expert in Water Microbiology
2008 - 2102	Principal Investigator - decontamination
2000 - 2008	Senior Microbiologist, Research
1994 - 1999	Microbiologist, Research
1988 - 1994	Basic Grade Microbiologist, Research

9.1.4. Experience

- Over 30 years' experience in public health water microbiology and decontamination with an international reputation in experimental microbiology for research in decontamination, particularly the control of biofilms in public health.
- Extensive experience of writing project proposals and reports.
- Over 100 publications including six books (Ed and author).
- Experience of working with a range of pathogens including *Legionella pneumophila*, *Pseudomonas aeruginosa*, *Escherichia coli* O157 and HCAI microorganisms.
- Working experience of ACDP 3 and ACDP 4 microorganisms and assisted in the laboratory in the manufacture of a vaccine for H5N1.

- Managed a wide range of microbiological surveys/audits of water systems including industrial water systems, domestic hot and cold water systems, cooling towers, heating/chilling systems and aerobiology surveys of dental practices.
- Supervised two PhD studentships on *Pseudomonas aeruginosa*.
- Invited to attend national and international meetings, undertakes PhD examinations and is a referee for a number of leading microbiological journals.
- Committee member on a number of Department of Health and Health and Safety Executive and Healthcare Infection Society groups concerning waterborne pathogens.
- Participant in the writing of a number of BSI documents including BS8580-1 Water Quality – Risk assessment for *Legionella* and BS8580-2 Part 2: Risk assessments for *Pseudomonas aeruginosa* and other waterborne pathogens — Code of practice.
- Member of the Department of Health production team for the HTM 04-01 Part A technical bulletin: Management of risks from non- tuberculous mycobacteria in healthcare water systems (2023-2024).

9.1.5. Other positions include past Chair of the Central Sterilising Club (2020-2023) and President of the International Biodeterioration and Biodegradation Society (2000-2003)

10. Engagement with QEUH prior to joining the Inquiry

10.1 I formerly worked for Public Health England as the PHE Scientific Lead for Water Microbiology. As a recognised water microbiology and biofilm expert I had been involved with other PHE experts in the hospital outbreaks in Northern Ireland where patients had died due to exposure to *Pseudomonas aeruginosa* from water outlets (taps) in 2012 [585] [586].

Following this outbreak I worked with the Department of Health (England) and other experts between 2012 and 2014 to author and publish guidance [587].

10.2 The DH (England) guidance identified that "owing to their high surface-area-to volume ratio and location at the tap outlet, certain designs of flow straightener may present a greater surface area for colonisation and support the growth of organisms. Therefore, when selecting new taps, where possible flow straighteners should be avoided/ not included. Health Building Note 00-09 also advises against using aerators in outlets [588]".

10.3 The Department of Health thanked the Steering Group for their advice and support on the HTMs, and all those who contributed to the consultation phase of the document including Mr Ian Storrar from Health Facilities Scotland.

10.4 I was invited as a PHE representative and water microbiology expert to a meeting at in the Labs FM Block at the South Glasgow Hospital on the 5th of June 2014 to discuss the findings from the Northern Ireland outbreak to explain the issues and problems associated with microbial biofilm and waterborne pathogen colonisation of tap components.

10.5 At that meeting I presented the PHE reports and findings from Northern Ireland and discussed concerns about the various taps' components, including low straighteners / aerators / rosettes, that were contaminated by P. aeruginosa. The minutes of the meeting provide the breakdown of those present. The minutes of the meeting, my response to the minutes and my Powerpoint presentation that I provided at the meeting on the 5th of June 2014 can be made available to the Inquiry. As an external representative expert from PHE I was not involved in the decision making process by those present at the meeting representing National Services Scotland.

10.6 As a water microbiologist I have published widely on research I carried out at PHE, outbreaks, written books and reviews and presented at national and international conference with a number of other UK recognised water microbiology experts.

[585] RQIA (n 294).
[586] Walker and others, 'Investigation of Healthcare-Acquired Infections Associated with *P. Aeruginosa* Biofilms in Taps in Neonatal Units in Northern Ireland' (n 9).
[587] DHSC, 'HTM 04-01: Safe Water in Healthcare Premises. Part C: Pseudomonas Aeruginosa – Advice for Augmented Care Units 2014' (n 11).
[588] DHSC, 'Health Building Note HBN 00-09: Infection Control in the Built Environment' 47.

10.7 I have co-authored a number of narrative reviews with UK experts relating to water microbiology in hospitals included Dr Teresa Inkster and Dr Michael Weinbren [589] [590] [591] [592].

10.8 In 2023 I coauthored a published book on safe water in health care with Dr Michael Weinbren and Dr Susanne Lee [593]. To improve the content a number of national experts assisted by commenting on chapters including Dr Teresa Inkster.

10.9 As an expert in water microbiology I have been invited to various national and international conferences over the last decade. I have been involved in conferences at which Dr Inkster has participated online [594] [595], involved in conference with Dr Weinbren both online [596] and in person [597] [598] and Dr Lee in person [599] [600] [601].

Name_____

Signature_____

[589] J Walker, T Inkster and M Weinbren, 'Aspects and Problems Associated with the Water Services to Be Considered in Intensive Care Units' (2023) 24 Journal of Infection Prevention 60.
[590] T Inkster and others, 'Factors to Consider in the Safe Design of Intensive Care Units – Part 1: Historical Aspects and Ventilation Systems' [2023] J Infect Prev.
[591] M Weinbren, 'Implementing Changes to Reduce Infections in ICU Patients. Water Services and Waste Systems.' (2023).
[592] T Inkster, J Walker and M Weinbren, 'Waterborne Infections in Haemato-Oncology Units – a Narrative Review' (2023) 138 JHI 60.
[593] Walker JT and others (n 301).
[594] ESGLI, 'ESGLI Legionella Conference Crete 21-15th October 2023'.
[595] ESCMID, 'ESCMID An Introduction to Healthcare Associated Waterborne Infections: Ecology, Prevention, Mitigation and Control Belfast.31st Oct to 2nd Nov 2023'.
[596] ESCMID (n 596).
[597] IPS, 'IPS National Conference. Water Workshop 17-19th Oct 2023'.
[598] Oslo, 'Norwegian Water Microbiology Course - Oslo, Norway. 2023 28th November.'
[599] ESCMID (n 596).
[600] Oslo (n 599).
[601] ESCMID (n 596).

11. Appendix 1

Location and timeline of water sample, taps, showers outlets and drain positives for various microorganisms throughout the water system

Position /Equipment	Microorganism	Reference	Date
Water system	*L. pneumophila* serogroup 1 >1000/l		April – Dec 2015
Wards 1d (pre and post flush)	*C. pauculus* pre and post *Pseudomonas Stenotrophomonas*	[602]	Sept 2015
Water system	TVC – HIGH		No/Dec 2015
Wards 2A Pharmacy - water sample from tap	*C. pauculus* *Comamonas testosteroni* TVC >300cfu/ml	[603]	2016
Wards 4A	*Legionella* spp		July Aug 2017
Adult and paediatric hospitals	water contamination was extensive,	[604]	February – April 2018
Haematoncology unit	*C. pauculus* (79% of samples positive)	[605]	February 2018
QEUH and RHC	*C. pauculus* (30% of samples positive)	[606]	February 2018
Paed-haem ward water samples 4 patient bedrooms, prep room and treatment room	*C. pauculus*	[607]	February 2018
Wards 2A Water (treatment and prep room)	*Cupriavidus pauculus*,	[608]	March 2018
Wards 2A 4B Showers heads and hoses	*Cupriavidus pauculus*, *Sphingomonas Paucimobilis*, *Ochrobactrum anthropi* and *Brevundimonas* sp	[609]	Marc 2018

[602] NHS GGC, 'PICU Pseudomonas Test Results 04.10.2016 Spreadsheet. In Storrar and Rankin. (2018)' (n 435).
[603] Storrar and Rankin (n 48).
[604] Inkster and others, 'Investigation and Control of an Outbreak Due to a Contaminated Hospital Water System, Identified Following a Rare Case of *Cupriavidus Pauculus* Bacteraemia.' (n 260).
[605] Inkster and others, 'Investigation and Control of an Outbreak Due to a Contaminated Hospital Water System, Identified Following a Rare Case of *Cupriavidus Pauculus* Bacteraemia.' (n 260).
[606] Inkster and others, 'Investigation and Control of an Outbreak Due to a Contaminated Hospital Water System, Identified Following a Rare Case of *Cupriavidus Pauculus* Bacteraemia.' (n 260).
[607] Inkster and others, 'Investigation and Control of an Outbreak Due to a Contaminated Hospital Water System, Identified Following a Rare Case of *Cupriavidus Pauculus* Bacteraemia.' (n 260).
[608] Peters (n 468).
[609] Peters (n 468).

Position /Equipment	Microorganism	Reference	Date
Wards - PICU	*Cupriavidus* and *Sphingomonas*	[610]	March 2018
Wards	*Delftia* sp, *Commanonas* sp, *Achromobacter* sp and *Cupriavidus* Fungal	[611]	March 2018
Drains 2B, RHC and ward 4B,	*Stenotrophomonas*, *Elizabethkingia* and *Pseudomonas* species	[612]	March 2018
Theatres	Delftia		March 2018
Wards 2A 4B Taps and flow straighteners	*Cupriavidus* pauculus, *Sphingomonas Paucimobilis*, *Ochrobactrum* anthropi and *Brevundimonas* sp	[613]	March 2018
Water system the QEUH and RHC sites	Gram-negative pathogens and fungal counts some Fungal greater than 100/ml	[614]	April 2018
Basement tank room CWST Drain Cock Tank 2A	Aspergillus	[615]	April 2018
Basement tank room - filtered water storage tank 1A	*Cupriavidus pauculus* Aspergillus		April 2018
Basement tank room – Raw CWST 2A	*Delftia acidovorans Cupriavidus pauculus, Pseudomonas xanthomonas Mexicana S paucimobilis, M oxydans*	[616]	April 2018
Basement tank room CWST 2A Drain	*S paucimobilis, M oxydans*	[617]	April 2018
Basement tank room CWST 2B	*Delftia acidovorans*	[618]	April 2018

[610] 'THE SCOTTISH HOSPITALS INQUIRY NHS NATIONAL SERVICES SCOTLAND RESPONSE TO THE SECTION 21 NOTICE ISSUED ON 4 MAY 2023 (WATER) Response to S21 30.05.23 - FINAL Tap Story Full and Frank'.
[611] SHI, 'Scottish Hospitals Inquiry - IMT Minutes Bundle 1 of Documents for the Oral Hearing Com' (n 456).
[612] SHI, 'Scottish Hospitals Inquiry - IMT Minutes Bundle 1 of Documents for the Oral Hearing Com' (n 456).
[613] Peters (n 468).
[614] Inkster and others, 'Investigation and Control of an Outbreak Due to a Contaminated Hospital Water System, Identified Following a Rare Case of *Cupriavidus Pauculus* Bacteraemia.' (n 260).
[615] DMA, 'Legionella Risk Assessment QEUH (Adult) Hospital and the Adjoining RHC 2017' (n 29).
[616] DMA, 'Legionella Risk Assessment QEUH (Adult) Hospital and the Adjoining RHC 2017' (n 29).
[617] DMA, 'Legionella Risk Assessment QEUH (Adult) Hospital and the Adjoining RHC 2017' (n 29).
[618] DMA, 'Legionella Risk Assessment QEUH (Adult) Hospital and the Adjoining RHC 2017' (n 29).

Position /Equipment	Microorganism	Reference	Date
Wards 2A 4B flow straighteners	*S. maltophilia, Chryseobacerium sp, Sphingomonas paucimobilis, C. pauculus, Acidovorax temperans, Caulobacter spp. and Microbacterium laevaniformans*	[619]	June 2018
System wide (all floors	*Cupriavidus* spp	[620]	June 2018
Water tank sponges	*Biofilm*		June 2018
Water tank debris	*Biofilm*		
Taps Flow straighteners	*Biofilm* *Cupriavidus*	[621]	June 2018
Expansion Vessels	75% of samples positive for C. pauculus, C. gilardii, Delftia acidovorans	[622] [623]	June 2018
Drains and or water 2A 2B	*E. cloacae, S. maltophilia, P. putida, P. aeruginosa, Klebsiella pneumoniae, Pantoea agglomerans and Acinetobacter ursingi*	[624] [625]	June 2018
Water system Pre and post flush	*Cupriavidus*	[626]	June 2018
Water system and drains	*Sphingomonas paucimobilis* *Stenotrophomonas maltophilia* *Micobacterium laevaniformans* *Acidovorax temperans* *Chryseobacterium spp*	[627]	June 2018

[619] Inkster and others, 'Investigation and Control of an Outbreak Due to a Contaminated Hospital Water System, Identified Following a Rare Case of *Cupriavidus Pauculus* Bacteraemia.' (n 260).
[620] Intertek, 'Intertek Report Number ITSS-0718-0001W plus per Floor Contamination of Flow Straighteners Debris and Sponges 2018' (n 36).
[621] Intertek, 'Intertek Report Number ITSS-0718-0001W plus per Floor Contamination of Flow Straighteners Debris and Sponges 2018' (n 36).
[622] Intertek, 'Intertek Report Number ITSS-0718-0001W plus per Floor Contamination of Flow Straighteners Debris and Sponges 2018' (n 36).
[623] Inkster and others, 'Investigation and Control of an Outbreak Due to a Contaminated Hospital Water System, Identified Following a Rare Case of *Cupriavidus Pauculus* Bacteraemia.' (n 260).
[624] Inkster and others, 'Investigation and Control of an Outbreak Due to a Contaminated Hospital Water System, Identified Following a Rare Case of *Cupriavidus Pauculus* Bacteraemia.' (n 260).
[625] Intertek, 'Intertek Report Number ITSS-0718-0001W plus per Floor Contamination of Flow Straighteners Debris and Sponges 2018' (n 36).
[626] Intertek, 'Intertek Report Number ITSS-0718-0001W plus per Floor Contamination of Flow Straighteners Debris and Sponges 2018' (n 36).
[627] Intertek, 'Intertek Report Number ITSS-0718-0001W plus per Floor Contamination of Flow Straighteners Debris and Sponges 2018' (n 36).

Position /Equipment	Microorganism	Reference	Date
	Caulobacter		
Two paediatric haemato-oncology inpatient wards 6A and an operating theatre	*Mycobacterium chelonae* (46% positive)	[628]	June 2019
Paediatric drains (of trough sink) bed space 1 (bay 1-4)	Serratia marcescens		June 2019
Mains samples	*Mycobacterium chelonae*	[629]	June 2019

Table 7 Location and timeline of water sample, taps, showers outlets and drain positives for various microorganisms throughout the water system.

12.

[628] Inkster and others, 'Investigation of Two Cases of *Mycobacterium Chelonae* Infection in Haemato-Oncology Patients Using Whole-Genome Sequencing and a Potential Link to the Hospital Water Supply' (n 201).
[629] Inkster and others, 'Investigation of Two Cases of *Mycobacterium Chelonae* Infection in Haemato-Oncology Patients Using Whole-Genome Sequencing and a Potential Link to the Hospital Water Supply' (n 201).

Appendix 2: Photographs from EG visits March and September 2023

Figure 49. Storage of equipment and boxes that i) will prevent access to sinks and ii) will be splashed by contaminated water from the sink

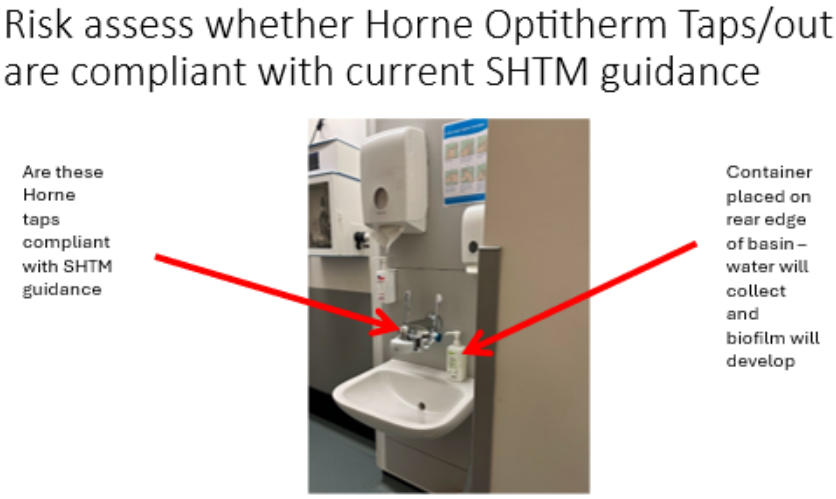


Figure 50. Risk assess compliance of Horne Taps

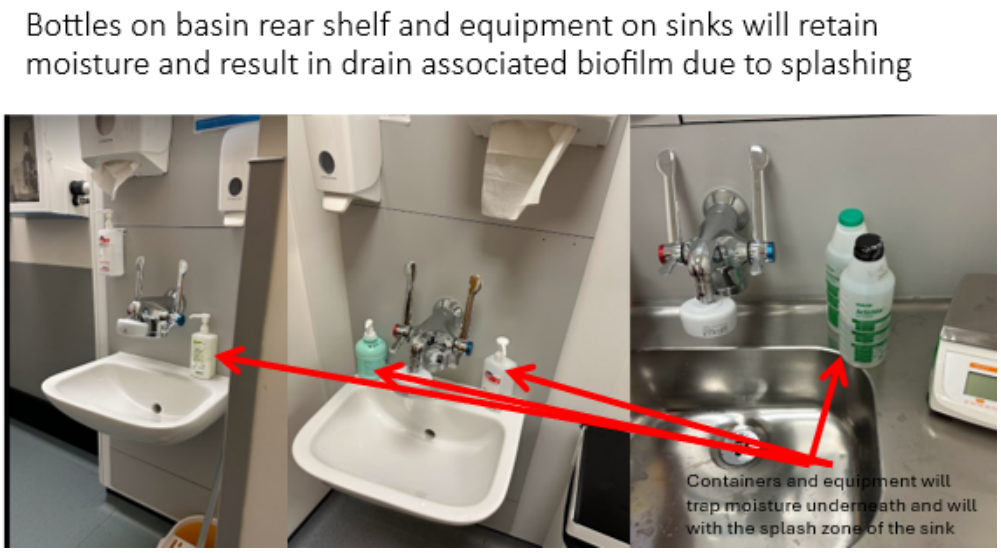


Figure 51. Containers on basins will trap water and biofilm contamination

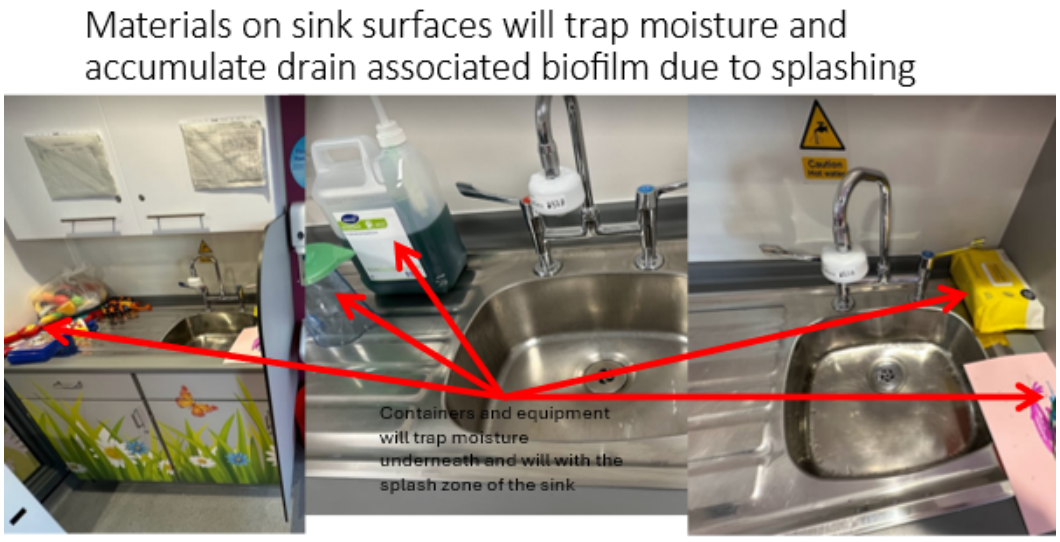


Figure 52. Inappropriate storage of items on sinks surfaces that will be contaminated by drain microorganisms and will retain moisture and biofilm

Figure 53. Inappropriate storage of materials within the splash zone of the sink

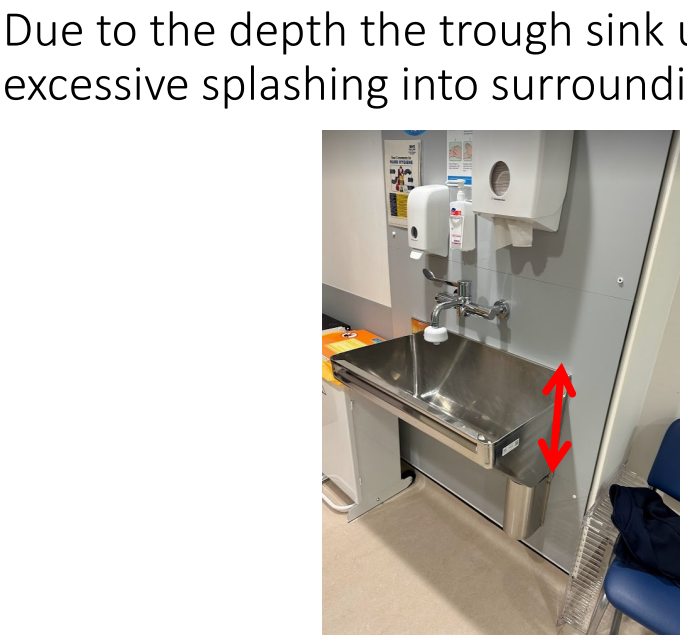


Figure 54. Excess splashing due to deep trough sink

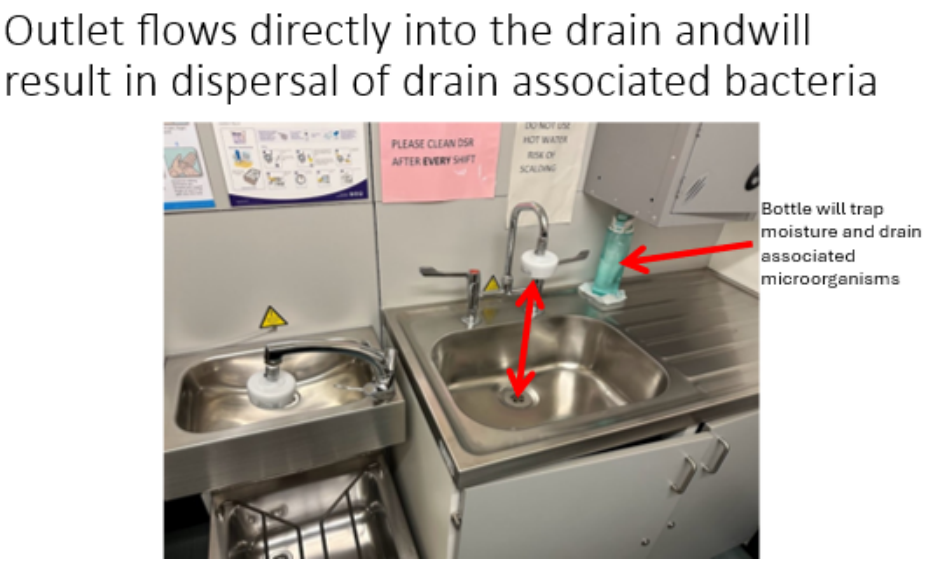


Figure 55. Excessive splashing of drain related microorganisms and inappropriate storage of items on sink.

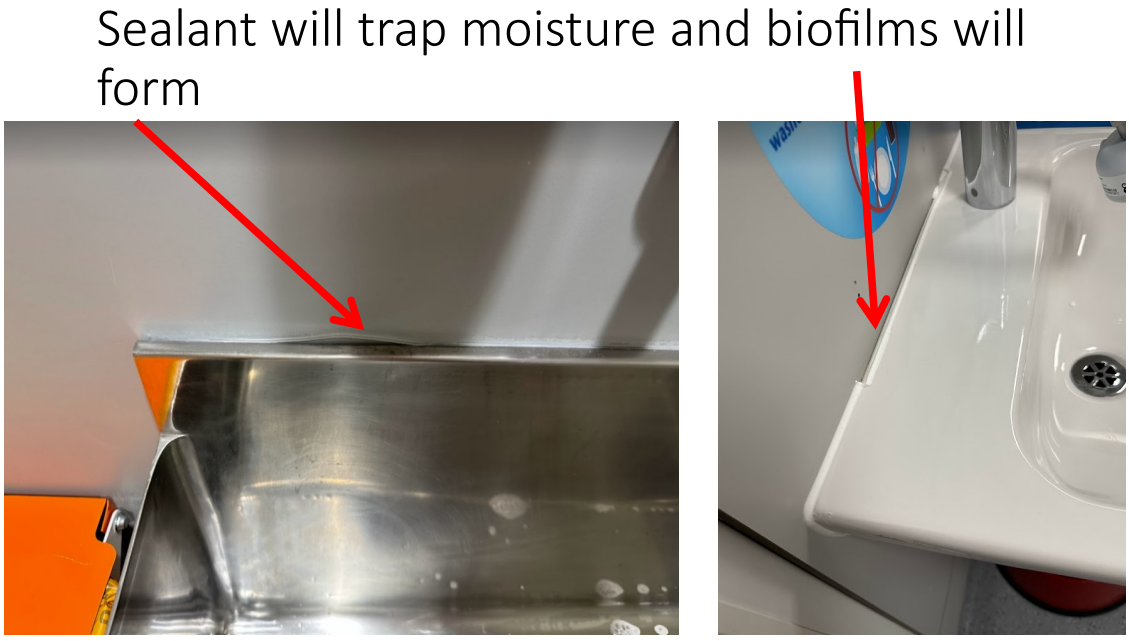


Figure 56. Sealant not being maintained which will lead to water and biofilm retention

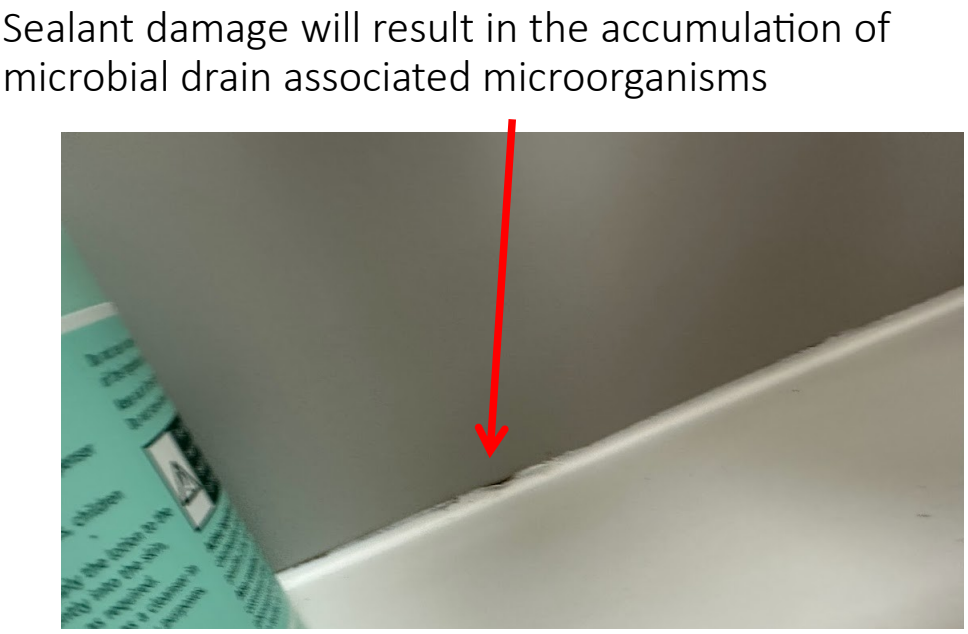


Figure 57. Sealant damage will result in moisture and biofilm retention

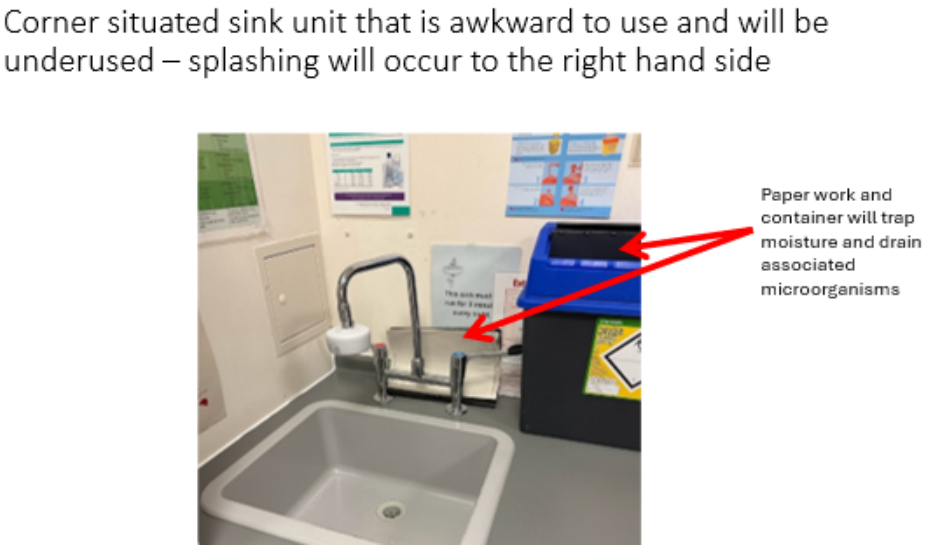


Figure 58. Corner sink unit will be underused and items on countertop will be splashed leading to surfaces contamination and biofilm under the container

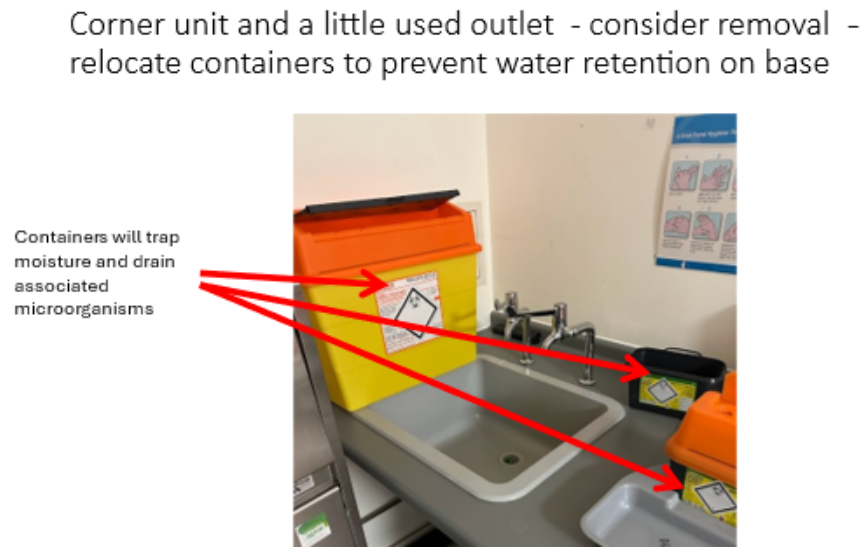


Figure 59. Inappropriate storage of items within the splash zone of the sink.

Figure 60. Lack of storage space, inappropriate placing of items within the splash zone and sink unit difficult to use due to placement of equipment

Poor drainage reported with some showers – improve cleaning of drain to dislodge slime and grime to reduce biofilm dispersal and splashing

Figure 61. Staff reported poor drainage of showers and drain was visibly dirty.

Deterioration of sealant between floor and wall linoleum that will trap drain associated biofilm

Figure 62. Gaps in sealant will retain moisture and drain related biofilm

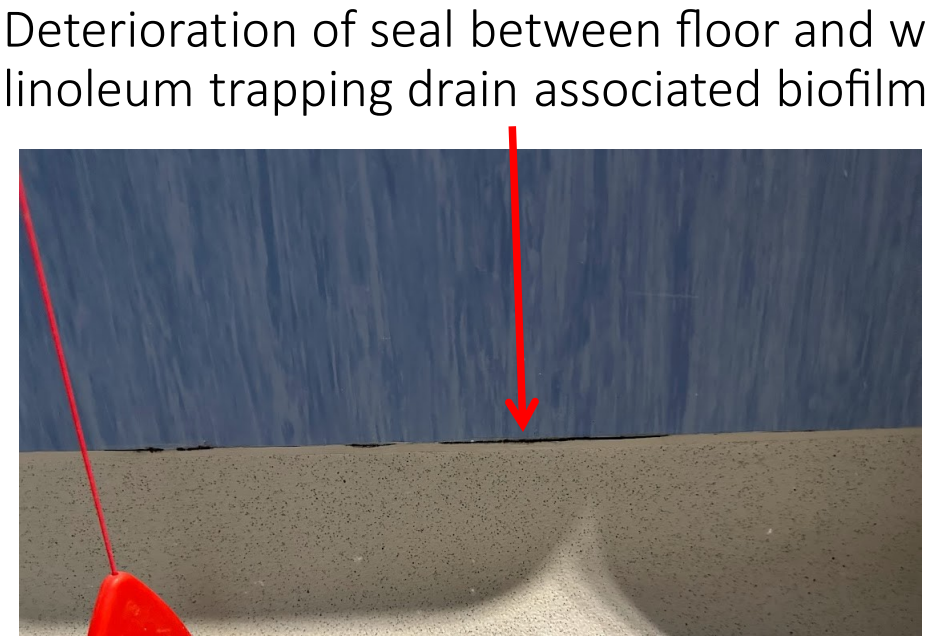


Figure 63. Deterioration of sealant will trap moisture and drain related biofilm

SCOTTISH HOSPITALS INQUIRY

Independent Expert Report

Concerning Domestic Hot and Cold Water Systems

at

The Queen Elizabeth University Hospital, Glasgow,

and The Royal Hospital For Children

Contents

Table of Contents

1. Introduction

1.1 Introduction of the Expert Witness

1.1.1 I have provided within appendix 1 of this report details on my qualifications, experience, and knowledge to act as an expert witness in relation to the healthcare domestic water systems. I am an Authorising Engineer (AE) and currently employed as an independent healthcare consultant, where my role is to provide input/expertise to health facilities in relation to the design review, installation, validation and operational management of water and ventilation systems. As an AE I act as an independent professional adviser to the healthcare organisation. I have been peer-reviewed and operate now as a registered AE for both water and specialist ventilation systems (separately). The peer review process (by the Institute of Healthcare Engineering and Estate Management (IHEEM)) provides a level of assurance that I have been assessed by their peers to work and act in a manner and standard which meets the institutes code of practice and conforms to the requirements of the SHTM. I have over 35 years' experience of healthcare estates management working in that time as a contract installer, operational engineer and manager (within the NHS) and as an external independent consultant (AE).

1.1.2 The Inquiry has provided me with the following topics and questions insofar as they are within my areas of expertise (Domestic Water Systems) and it is possible to address them on the evidence and data available to me:

- From the point at which there were patients within the QEUH/RHC were the water systems (including drainage) in an unsafe condition, in the sense that it presented an additional risk of avoidable infection to patients?
- Are the water systems no longer in an unsafe condition in the sense that they now present no additional avoidable risk of infection?

1.1.3 I am clear that my duties include assisting the Inquiry in an impartial manner.

1.1.4 I acknowledge and understand that it is my duty, both in preparing reports and in giving oral evidence, to assist the inquiry on matters within my field of expertise and I will continue to comply with that duty.

1.1.5 I have no connection, personal or otherwise, to any core participant in the Inquiry other than that I have declared in this report.

1.1.6 I declare that I have no financial or economic interest in the outcome of the Inquiry.

1.1.7 I acknowledge and accept the necessity of expressing an independent opinion which is the product of my own consideration and I have complied with the duty to do so.

1.1.8 I acknowledge the duty to set out all material facts, assumptions, methodology, or other matters upon which my views and opinions are based, including such matters as may detract from the opinion formed, and I have complied with that duty.

1.1.9 I acknowledge the duty to address only areas within my own area of expertise and that I have made it clear when a particular question or issue falls outside my expertise and I have complied with that duty.

1.1.10 I acknowledge, understand and accept the obligation to state if my opinion is not properly researched because of insufficient data are available and to give an indication that the opinion that the opinion is no more than provisional, and I have done so in my report where appropriate.

1.1.11 I acknowledge, understand and accept the obligation to indicate if any opinion I have expressed is qualified, or subject to revision, and have done so in my report where appropriate.

1.1.12 I acknowledge, understand and accept that I should, at the earliest opportunity after completing the report, indicate if, for any reason, including as a result of discussions with other experts, my views have been altered or the report requires any correction or qualification, and if so, in what area, and I shall comply, and I shall comply with that duty.

1.2 Scope of Report

1.2.1 This report has been instructed by the Scottish Hospitals Inquiry to provide an independent expert report that addresses the following Key Questions in respect of Domestic Water Systems:

- From the point at which there were patients within the QEUH/RHC were the water systems (including drainage) in an unsafe condition, in the sense that it presented an additional risk of avoidable infection to patients?
- Are the water systems no longer in an unsafe condition in the sense that they now present no additional avoidable risk of infection?

1.2.2 In addition to these two principal Questions a number of ancillary questions have been raised through the review process which include the following technical water related issues:

1.2.3 Did the hospital's proximity to the Shieldhall wastewater treatment works create a risk of infection to patients?

1.2.4 What contribution to the provision of unsafe features of the water systems, and to the exposure of patients to these unsafe features, was made by the following arrangements for delivery of the hospital; how might that contribution have been avoided; what has been done to prevent this happening again:

(i) The arrangements made by GGC regarding

- inspection and testing,
- commissioning, validation and verification and
- the provision of information and training to end users about operation and maintenance;

(ii) The arrangements made within GGC in relation to

- governance,
- operational management and
- provision of information by/to key stakeholders and advisers

1.2.5 In order to deliver a comprehensive and cohesive report it has also been necessary to provide in lay-person terms an explanation of the various elements and processes involved in the water and drainage systems of a healthcare facility.

1.3 Schedule of Assumptions

1.3.1 Much of the information referenced has been provided by the Inquiry team through information requests and disclosures. The information has been reviewed and assessed where necessary using samples to reflect multiple information submissions. The accuracy and validity of the submissions has been taken at face value and reviewed on the basis of them being accurate and complete. Where information has not been available then this has been clearly stated and to the best of my abilities and knowledge no other assumptions have been made in the preparation of this report.

1.4 Exclusions/Limitation of the Report

1.4.1 I have been asked to provide a written Expert Witness Report to the Scottish Hospitals Inquiry (SHI) with regards my knowledge and familiarity with the English guidance of the Health Technical Memoranda (HTM) 04-01, on which the Scottish guidance, Scottish Health Technical Memoranda (SHTM) 04-01 series, is based. I have also been asked to provide a report with

regards to my knowledge and experience in design, installation, commissioning and validation of water systems in hospitals.

1.4.2 The review process has involved limited time (four months with substantial evidence produced within only four weeks of report completion) and significant levels of documents and in many cases assessments have been undertaken on a sample basis to establish compliance levels; where no failures or non-compliances have been found I cannot guarantee that none exist, however every effort has been made to ensure that where issues exist they have been considered and appropriately recorded.

1.5 Building Overview

1.5.1 The Queen Elizabeth University Hospital (comprising the Royal Hospital for Sick Children and the Adult's Hospital) is a 1109 bedded Adult Hospital and a 256 bedded Children's Hospital. This facility has the biggest Critical Care complex and one of the biggest Emergency Departments in Scotland. The facility offers acute specialist inpatient care, medical day care services and also outpatient clinics servicing the local population.

1.5.2 The 14-floor adult hospital and contains 1,109 beds and state of the art Emergency, Acute Receiving, Critical Care, Theatres and Diagnostic Services.

1.5.3 The new children's hospital, with a separate identity and entrance, is adjoined to the adult hospital, with 256 beds over five storeys replacing the original Royal Hospital for Sick Children located in Yorkhill.

1.5.4 The children's hospital provides a large number of specialist services to the West of Scotland and the wider population of Scotland in addition to the full range of secondary care services to people of Greater Glasgow and Clyde. Specialist services include: cardiology and cardiac surgery, renal and bone marrow transplantation. For a number of these specialised services, the children's hospital is recognised as the sole provider in Scotland.

1.5.5 The construction phase ended in January 2015 with phased occupancy of patient areas beginning in April 2015 and full working occupancy achieved in the summer of 2015.

2. Executive Summary

2.1.1 This report has been instructed by the Scottish Hospitals Inquiry to provide an independent expert report that addresses the following Key Questions in respect of the domestic hot and cold water systems.

- From the point at which there were patients within the QEUH/RHC were the domestic hot and cold water systems in an unsafe condition, in the sense that it presented an additional risk of avoidable infection to patients?
- Are the domestic hot and cold water systems no longer in an unsafe condition in the sense that they now present no additional avoidable risk of infection?

2.2 Design, Installation and Commissioning process

2.2.1 The domestic water systems at the point of handover / patient occupation were in a sub-optimal condition. The principal issues for this are as follows:

- The original design had included installation of incoming water filtration (as recommended by the SHTM 04-01 Part E), however this was supplemented with a very high grade secondary ultrafiltration system in 2019. The reason and need for this very high grade of filter (0.02 micron has not been provided.
- The system had a significant level of identified issues and potential risks (as identified by the pre-occupation risk assessment).
- The commissioning process had failed to follow the requirements of the SHTM and involved wet testing, partial draining down and refilling of water systems prior to being made fully operational.
- No formal validation process was followed and where failed water sampling was found no formal process for retesting appears to be have been in place as outlined in section 5.9 of this report. The result of this was that no assurance was provided as to the water quality or satisfactory operational condition at handover.
- There is no evidence of the TMV/TMT commissioning and stabilisation tests being completed (which is a critical element of the

NHS anti-scalding process which has a classification by the NHS as a never event, in other words a wholly avoidable and preventable issue which has the potential to cause harm to a patient/user and should never occur. Full details of which are outlined in section 6.2 of this report.

2.2.2 Overall the system was not fully compliant and issues were known and acknowledged. The system was accepted into operation and at that time the NHSGCC did not have all of the necessary controls or processes in place to manage or address the potential risks, as detailed in the following section.

2.3 Assessment of Derogation Management at QEUH

2.3.1 It would appear that the process of managing/agreeing derogations of changes within the project at QEUH were restricted to a Project Board level, and outcomes would suggest that not all interested stakeholders were appropriately or fully consulted on all issues.

2.4 Maintenance and Operation of the water system

2.4.1 At the point of handover it would appear from the evidence provided and comments made during the site inspection that estates resources were predominantly occupied with addressing issues identified as defects rather than full maintenance issues. This can be evidenced by the issue that full O&M information was not provided for at least 6 months after handover. The O&M information contains the requirements for the provision of maintenance specific for the equipment installed and the minimum requirements to ensure safe operation and compliance to any warrantees and legislative standards under the Workplace Regulations (Workplace health, safety and welfare. Workplace (Health, Safety and Welfare) Regulations 1992. Approved Code of Practice and guidance L24).

2.4.2 Formal PPM schedules were not in place, and gaps remain to this day in areas such as TMV/TMT maintenance and stabilisation tests following replacement.

2.5 Current Condition and Potential Issues and Risks

2.5.1 The latest AE(W) Audit report from 2023 highlights a number of issues to be addressed, however it should be stressed that these types of issue are not uncommon within many healthcare establishments and generally the level of control and maintenance provision appears to be satisfactory.

2.5.2 The water safety group is in place and operating effectively with a clear route to escalate issues when needed, although a formal quarterly update/status report from the lead RP/AP(W) would be a useful system improvement.

2.5.3 The current water safety plan/policy is considered appropriate and suitable for the management of the water systems at QEUH.

2.6 Conclusion and Areas of Potential Improvement to minimise risk of future patient infections associated with water provision.

2.6.1 The latest AE(W) Audit report from 2023 highlights a number of issues to be addressed, however it should be stressed that these types of issue are not uncommon within many healthcare establishments and generally the level of control and maintenance provision appears to be satisfactory.

2.6.2 The water safety group is in place and operating effectively with a clear route to escalate issues when needed, although a formal quarterly update/status report from the lead RP/AP(W) would be a useful system improvement.

2.6.3 The current water safety plan/policy is considered appropriate and suitable for the management of the water systems at QEUH.

2.6.4 All staff working within the hospital environment should receive a basic level of water hygiene awareness training and especially those involved in the flushing, cleaning or use of the water services need to have a reasonable understanding of waterborne pathogens, routes of transmission, control and impact to patient safety (see section 7.6.2 of this report).

2.6.5 A full multi-disciplinary assessment of each clinical speciality should be completed for all clinical areas to identify current areas where water systems are a significant potential risk factor in patient safety. Each identified area should have the current provision of water services assessed to identify where systems may require amendment, for example removal of excessive hand wash basins or inadequate space provision around water outlets to prevent/minimise water splashing or cross contamination, along with a clinical and IPC agreed minimum performance standards (informed from the current SHTM and best practice). This assessment process should include waste water systems and drainage locations (see section 7.9 of this report).

2.6.6 It is entirely possible that following the assessment phase of review that it is impractical to modify existing facilities and in such circumstances clinical activities may need to be suspended or stopped until suitable compliant facilities can be provided/identified. This may result in a reduction of clinical activity or bed numbers as a means to accommodate suitable water provision or room layouts or other essential building services.

2.6.7 All improvement works would need to be subject to fully compliant commissioning and independent validation reviews to ensure the works are effective in providing the agreed minimum performance standards.

2.6.8 The Water Safety Group and Board need to agree a formal process to manage all derogations for all NHS standards (SHTM’s and SHBN’s), and develop a suitable process to agree, record, review and manage all essential derogations moving forwards, and include a suitable assessment

process of these as an integral element of any planned clinical service developments or moves.

2.6.9 In some cases it may prove necessary to temporarily or even permanently to suspend clinical services whilst areas are modified to achieve agreed minimum standards. If practical limitations of plant space or current building structure prevent achievement of minimum standards then the clinical activities should be suspended until such time as a suitable and fully compliant facility can be provided.

2.6.10 The current provision of maintenance and estates management staff (AP(W)'s and CP(W)'s) needs to be reviewed and potentially increased to ensure adequate assurance can be provided to the Board of on-going progress on improvement works and operational compliance, including but not limited to the review of all maintenance records and timely corrective action to all identified issues. For the avoidance of doubt AP(W) stands for Authorised Person (Water) and CP(W) stands for Competent Person (Water). These roles have clearly defined definitions under SHTM 04-01 Part B as below:

2.6.11 Competence (Clause 5.2 of SHTM 04-01 Part B).

2.6.12 Management should implement a programme of staff training to ensure that those appointed to devise strategies and carry out control measures are appropriately informed, instructed and trained, and should be assessed as to their competency. It is also essential that they have an overall appreciation of the practices affecting water hygiene and safety and that they can interpret the available guidance and perform their tasks in a safe and technically competent manner. The rate of change in building service technology is not great, but knowledge of harmful bacteria continues to grow and management should review the competence of staff on a regular basis, and refresher training should be given; records of training attendance would need to be maintained. Although training is an essential element of ensuring

competence, it should be viewed within the context of experience, knowledge and other personal qualities that are needed to work safely. Competence is dependent on specific needs of individual installations and the nature of risks involved.

2.6.13 Authorised Person (Clause 6.8 of SHTM 04-01 Part B).

2.6.14 The Authorised Person (Water) has the key operational responsibility for the service, qualified and sufficiently experienced and skilled for the purpose. He/she will be nominated by the Authorising Engineer (Water) and be able to demonstrate his/her application through familiarisation with the system and attendance at an appropriate professional course;

- a level of experience;
- evidence of knowledge and skills.

2.6.15 The Authorised Person (Water) will be appointed in writing as the single person with sole responsibility for the Written Scheme for an individual water system.

2.6.16 No work will be carried out on the water system without the knowledge and written consent of the Authorised Person. An important element of the Authorised Person’s role is the maintenance of records, quality of service and maintenance of system safety (integrity) together with responsibility for ensuring that delegated projects comply with the NHS Board’s Legionella policy and procedures.

2.6.17 The Authorised Person (Water) will also be responsible for establishing and maintaining the roles and validation of Competent Person (Water) who may be employees of the organisation or appointed contractors.

2.6.18 Larger sites may require more than one Authorised Person (Water) for a particular service. Administration duties, such as record keeping, should be

assigned to specific Authorised Persons (Water) and recorded in the operational policies.

2.6.19 Competent Person (Clause 6.9 of SHTM 04-01 Part B).

The Competent Person (Water) provides skilled installation and/or maintenance of the specialist service. He/she will be appointed, or authorised to work (if a contractor) by the Authorised Person (Water). He/she will demonstrate a sound trade background and specific skill in the specialist service, working under the direction of the Authorised Person (Water) in accordance with operating procedures, policies and standards of the service.

3. Overview of Healthcare Water Systems

3.1.1 The NHS through the department of Health produces specific standard for the management of water systems in healthcare settings. This standard is known as HTM 04-01 and provides guidance towards a holistic management of water systems via Water Safety Groups (WSGs), the Water Safety Plans (WSPs) and other initiatives, and synchronises the general legislative guidance of L8 (2013) and HSG 274 with the healthcare specific standards of HTM 04-01.

3.1.2 It draws together guidance and includes recommendations for the safe management of water systems, via the integration of the principle of WSGs and WSPs, and how to manage and minimise the risks to health from various aspects, ranging from clinical risks, microbial and chemical contamination, changes to the water system, resilience of the water supply etc.

3.1.3 The WSG is a multi-disciplinary group of those involved in the management of water systems. The group membership will typically include:

- Director/Head of Estates
- Estates Responsible Person (Water)

- Consultant Microbiologist, Infection Prevention and Control Doctor
- Head of Infection Prevention and Control
- Facilities Services Manager
- Authorising Engineer Water
- Other key representatives may be co-opted onto this committee as and when required.

3.1.4 A Water Safety Plan (WSP) provides information relating to a brief explanation of what Legionnaires Disease, Pontiac fever, the relationship between waterborne pathogens and temperature, and who is at risk and legal responsibilities. The WSP also typically contains guidance relating to “Pseudomonas aeruginosa”, advice for augmented care units. ACOP L8 (4th Edition) 2013 including HSG 274 Parts 1, 2 and 3.

3.1.5 The WSP is a series of modules which provide guidance and procedures for the effective management of hospital water systems. The WSP will typically consist of the following modules:

- Guidance, background and legal responsibilities
- Legionella prevention
- Pseudomonas prevention
- Water sampling and disinfection
- Closure and disinfection of a contaminated water system
- Associated services
- Appendices including:
    - Legionella/Pseudomonas major incident plan
    - Contractors Site Guidelines
    - Water sampling procedure
    - New design and technology

3.1.6 A WSP contains information to help the Trust to fulfil their responsibilities and comply with HTM04-01, The Control of Legionella Hygiene, “safe” Hot

Water, Cold water and drinking water systems and the approved Code of Practice for Legionnaires Disease L8 (4th Edition 2013).

3.1.7 The WSP should be reviewed annually by the WSG.

3.2 Control Measures

3.2.1 The principal means of managing or controlling legionella is temperature. For legionella if the water is:

- Below 20°C then the organism is dormant
- 20°C to 50°C the organism has the ability to multiply/grow with 37°C being the optimum temperature for growth to occur
- At 50°C the organism will die after 2 hours
- At 60°C it will be dead after 2 mins
- At 70°C it will be dead after 2 secs (practically instantly)
- Pasteurisation which is the process to thermally treat or disinfect a hot water system involves raising all parts of the system (every outlet/tap) to 70°C and maintaining it at that temperature for 1 hour.

3.2.2 Similarly Pseudomonas Aeruginosa bacteria cannot survive in hot water. Although unlike legionella it can multiply in cooler water temperature (any temperature above 0.5°C).

3.2.3 Other control measures can be used including chemical/biocidal treatments (Chlorine Dioxide, Copper or Silver Ionisation, Ozone or Ultraviolet), or physical treatment i.e. filtration (normally through tap or point of use filters). Filtration is principally used for Pseudomonas Aeruginosa on cold water systems where temperature control cannot be practically used.

3.2.4 In addition, if the level of dissolved solids such as calcium or “Hard Water” can be reduced, the bacteria have less nutrients and therefore water softening can be used to reduce risk of water system colonisation.

3.2.5 In summary, the design philosophy should be to minimise storage, and to ensure good throughput and avoid stagnation:

- Cold Water System (CWS) temperature at all taps should be below 20°C within 2 minutes.
- Hot Water System (HWS) temperature at all taps should be between 50°C to 60°C within 1 minutes (unless a TMV is fitted).
- If outlets aren't used regularly (daily) water in the pipes can become stagnant.
- Stagnant water can lead to water temperatures where legionella could grow and multiply.
- All little used outlets MUST be flushed at least twice per week for at least 2 to 3 mins.
- This flushing MUST be recorded.
- A little used outlet is any tap, shower, or toilet which is not used every week.

3.3 A definition of the term 'Domestic Hot and Cold Water systems' and what that means in the context of the QEUH/RHC.

3.4 Cold Water System (CWS) Overview

3.4.1 There are two incoming mains water supplies serving the adult's and children's hospital building. These enter the building in the basement manifold room and basement tank room and run into the tank room to serve two raw water storage tanks. These incoming mains both have double check valves, water meters, isolation valves and 'kera-flow' float valves all located within the tank room.

3.4.2 The water meters are linked to the BMS system and allow the user to cross reference the quantity of water used against the quantity indicated on the external meter. This is designed to highlight if there are any leaks on the external water main. The isolation valves are designed to allow the alternative use of each incoming main every seven hours. From the raw

water storage tanks the water is then filtered through the filtration plant before being stored in the potable bulk cold water storage tanks.

3.4.3 All cold water storage tanks are twin compartment tanks and are piped in such a way as to allow tank maintenance without disrupting the water supply to the building. Float switches within the tanks give the filtration plant the enable and stop signals based on the water level within the tanks. These levels can be adjusted to suit the water demand so that an optimal turnover of water can be achieved.

3.4.4 The filtered water is then pumped to serve the building via two booster sets. Each booster set is set to a different set point pressure depending on which plant room it serves (see below). Each booster set has two set points which will allow either pump serve the building, in the event of the failure of one of the pumps.

3.4.5 There are five water storage tanks in the building:

- 2 No. 100,000 Litre Raw water storage break tanks
- 2 No. 275,000 Litre Potable bulk cold water storage tanks
- 1 No. 2,800 Litre Trade water storage tank

3.4.6 There are two water booster sets in the building:

- BS01 – Feeding Plantroom 31, 32 and 33 - 7.3 Bar
- BS02 – Feeding Plantroom 21, 22 and 41 – 5.1 Bar

Note - The Bar is a metric unit of measurement of pressure defined as 100,000 Pa (100 kPa), though not part of the International System of Units (SI). A pressure of 1 Bar is slightly less than the current average atmospheric pressure on Earth at sea level (approximately 1.013 Bar).

3.4.7 Plant room 32 is served from booster set BS01 at 7.3 Bar. The boosted water is pumped directly from the basement to PR32. As it enters the plant

room the water flow rate is metered. The pressure is not reduced as it only serves the higher floors.

3.4.8 From the plant room the Boosted Cold Water Service (BCWS) is distributed to each riser and the bank of calorifiers. 32CAL01, 32CAL02 and 32CAL03. The water in the calorifiers is heated via a plate heat exchanger (feed from the Medium Temperature Hot Water (MTHW) circuit) on each calorifier skid. Each calorifier skid consists of a storage cylinder, shunt/de-strat pump, plate heat exchanger, expansion vessel and associated pressure, temperature and vacuum safety valves.

3.4.9 The BCWS and HWS Flow and Return (F&R) are then distributed together allowing for equal pressures at the outlets between the hot and cold water. The hot water is circulated to the outlet and back to the calorifiers by a hot water return pump so that temperature is maintained throughout the system. There are Kemper thermostatic balancing valves installed on the system in line with the design to ensure hot water is available within 2 minutes at every outlet.

3.4.10 The cold feed to the calorifiers is also metered. The meter is located at the calorifier skids.

3.4.11 The design philosophy is that the distribution pipe work is laid out in such a way that areas of high use are at the end of lines. This ensures good turn-over of water within the system. Where this cannot be achieved temperature operated dump valves are installed.

3.4.12 Filtration is typically only included within hot and cold water distribution systems as an integral part of any thermostatic mixing valve (TMV) arrangements in the form of strainer baskets, although other components can include similar filters to protect moving parts, such as pumps on hydrotherapy pools or water circulation pumps, or water meters. These devices should be inspected and cleaned after the initial flushing exercise

and then periodically throughout the operation of the facility. Point of Use filters can also be considered, but these should only be considered if there is a significant operational issue and as a temporary protection precaution to users/patients whilst an issue is being addressed. Point of Use (POU) filters filter the water at the point of discharge from the tap or outlet and whilst they can remove particles from the water supply they add significant resistance to the flow of water and restrict flow rates which in itself is a principal control measure. If left in place for extended periods of time they can also become colonised with microbiological contamination and can potentially act as a 'seed bed' for further system colonisation.

3.4.13 There is a significant variation in the recommended approach between the English and Scottish Health Technical Memorandum. The HTM 04-01 (English) suggesting that in exceptional circumstances or the use of private water supplies filtration should be considered. Whereas within the SHTM the use of incoming filtration is recommend for all but process (non-domestic) water. The variance can be seen below in a comparison of extracts from the two standards.

3.5 HTM 04-01 Part A

3.5.1 Filtration

7.2 In exceptional circumstances, additional on-site filtration may be required as part of a multi-barrier point-of-entry treatment system. Advice should be sought from the appropriate undertaker on the need and form of such treatment.

3.5.2 Point-of-use filtration

4.22 For pathogenic waterborne organisms including multi-drug-resistant strains, at a minimum, and in accordance with the organisation's water safety plan, a risk assessment should be made in order to determine whether sterilising-grade point-of-use filters should be installed or whether taps need to be changed (see American Standard Test Method (ASTM)

F838-05 – ‘Determining bacteria retention of membrane filters utilised for liquid filtration’).

3.6 SHTM 04-01 Part A

3.6.1 5.4 On-site filtration has been regarded by some as an optional provision despite its inclusion being mandatory since 1999. It is stressed that opting out of installing such plant should not be the default situation. Any decision to exclude filtration would be dependent on careful consideration of the following issues. This list is not exhaustive:

- whether a project comprises an additional building (or buildings) on an existing site without filtration plant;
- a risk assessment taking into account the type of accommodation served;
- a risk assessment based on the type and vulnerability of patients served;
- an assessment of the practicality of introducing filtration for the likes of a ward refurbishment project that involved extending or upgrading part of an existing (unfiltered) system;
- analysis of samples of incoming water supplies.

3.6.2 The last issue is particularly important. In existing premises, an examination of maintenance records would determine whether strainers were routinely becoming clogged as an indicator of a history of suspended solids being present in the water authority’s incoming supplies.

3.6.3 Before the installation and maintenance of on-site filtration plant is dismissed as an unaffordable burden, the following benefits and associated savings must be balanced against capital and revenue costs of filtration plant.

- The requirement for periodic removal of sediment from storage tanks is eliminated along with the precautions associated with working in confined spaces;

- The need for a separate or divided storage tank to allow supplies to be maintained during sediment removal is eliminated;
- Cold water storage tank lids would not require to be completely and readily removable for access to clean and de-sludge, leaving only the need to provide inspection covers;
- The amount of suspended solids carried into the piping network would be virtually eliminated as they would be retained within the filtration plant so that strainers could be omitted from shower thermostatic mixing valve assemblies. In filtration retrofit situations, existing strainer cartridges could be removed. In these situations removal of strainers would also remove a catchment for biofilm and bacteria build-up.

3.7 SHTM 04-01 Part E

3.7.1 Water filtration

2.77 As stated earlier, Section 5 of Part A of this SHTM seeks to reduce the propagation of Legionellae in DHCW services systems by temperature control and maintaining high standards of cleanliness, both during the installation of pipework systems and throughout their subsequent operation. This can be achieved by the introduction of modified work practices and high standards of filtration of water, air vents and water overflows.

3.7.2 2.78 It is emphasised, however, that extremely high degrees of filtration, such as might be achieved by, say, nano-filtration or osmosis, are not required for use in normal potable water services in hospitals (dialysis units, etc. are special cases).

3.7.3 2.79 To help achieve the above and minimise the formation of bio-films in pipework, the following guidelines should be followed in selecting appropriate levels of filtration:

- for the range of approved thermoplastics pipework covered by this SHTM a maximum cut off of 5 microns should be specified.

- for stainless steel pipework covered by this SHTN a maximum cut off of 0.5 micron should be specified. This can be relaxed to 5 microns on receipt of written guarantees from the pipework and fittings manufacturers that the system should have a life-span not less than that provided by a plastic pipework installation.
- in a situation where the recommendation of this SHTM is not adhered to and copper pipework is installed it is strongly recommended that a filtration level of 0.5 micron absolute is specified.

3.7.4 8.2 Quality of water is coming under increasingly close scrutiny. Examinations of domestic water systems in numerous Scottish hospitals have revealed that significant deposits of sediment and debris can occur in pipework. These deposits can give rise to breeding grounds for health debilitating bacteria as well as biofilms which can ultimately cause deterioration of adjacent material surfaces. To avoid these potentially damaging circumstances, all incoming cold water supplies destined for domestic use within NHSScotland premises should be filtered. Further guidance on this issue can be found in SHTM 04-01 Part A Section 5.

3.7.5 8.3 Filtration should be introduced to:

- ensure that domestic water supply and hence all associated pipework is maintained at high standard of cleanliness, from the supply point to all potable water outlets.
- reduce the build-up in water systems of sediments and deleterious biofilms, which may act as nutrient sources for bacteria.

3.7.6 It is worth noting that the location of any filtration system is likely to have a potentially significant impact on the level of improvement and patient protection or efficacy due to the potential sources of contamination and routes of transmission or microbiological growth. Therefore whilst the provision of incoming filtration is recommended within the SHTM and not the

HTM it cannot be used to manage or eliminate the risk potential of system colonisation after the incoming point of supply.

3.7.7 There is no clear or specific evidence of the decision process undertaken to determine the need to install the current filtration system. It is understood through the inquiry RFI process that it has been confirmed that detailed records of the decision making by the board to include filtration as recommended by the guidance, is not available, however the provision complies with the guidance.

3.7.8 The Invitation to Participate in Competitive Dialogue (ITPD) Vol 2/1 Employer's Requirements (Hospitals) "NSGACL – ITPD Volume 2_iss1_rev1" included, at section 8.1.18, the board requirements for potable water to have 0.2 micron filtration to the criteria set out in SHTN 2: Domestic Hot and cold water systems for Scottish Healthcare Premises. This specification of 0.2 micron grade filtration is in excess of the guidance standard of 0.5 microns. However, the original filter media pore size was specified and installed to a 0.02 micron size which may have impacted the available flow rate of the incoming water supply.

3.8 Domestic Hot Water System Overview

3.8.1 The domestic hot water system (DHWS) is provided from a number of strategically located plantrooms across the site using MTHW to feed plate heat exchangers and calorifiers as outlined below:

3.8.2 The calorifiers are situated in various plantrooms on the 2nd, 3rd and 4th floors of the building, feeding designated zones within the hospital.

3.8.3 Each set of calorifiers is a bank of 3 linked calorifiers fed from the boosted Bulk Water system, with heat source being via a plate heat exchanger on the outside of each calorifier fed from the MTHW system. The MTHW system provides the primary heat source for the cold water feed to the plate heat exchanger. For the avoidance of doubt the MTHW system is a closed heating system and does not directly mix with either the hot or cold water systems. A circulating pump on each calorifier/plate heat exchanger ensures the water is circulated throughout each vessel to maintain temperature.

3.8.4 In 2015 at the pre-occupation water risk assessment process the distribution temperatures were almost invariably above 50°C at all outlets (Supply to TMVs) with direct hot feeds above 55°C. The return temperatures recorded at the calorifiers were consistently below 55°C which were advised as the control set point for these, though when calorifiers were at full temperature the returns were reaching 50°C. This performance was below the recommended limits within the SHTM and the control set points were amended to achieve a return temperature of 55°C, as part of the process to address the identified compliance issues from the initial pre occupation risk assessment.

3.8.5 It was also noted that increasing the calorifier temperatures may have the beneficial effect of increasing the cold water usage as more cold water will be required at TMVs to blend water to TMV set point and so may assist in reducing the high cold water temperatures being recorded within the system. For the avoidance of doubt the calorifier water temperature can be

increased by adjustment to the control set point and is not directly linked to the primary MTHW temperature or flow rates.

3.8.6 It is also worth noting that the specification (Employer's Requirements) 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 minimised. This demonstrates that whilst the project requirements specified the need to eliminate potential areas of risk within the water systems the actual installation initially failed in that respect and required subsequent rectification works to be completed. These works are understood from the latest risk assessments and water safety plan to have been completed.

3.8.7 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. This guidance (CEL 08(2013)5, SHTM 04-01 Part A and HPS guidance) was produced in response to an incident in a Northern Ireland Hospital and published in 2013.

3.9 Derogation Management

3.9.1 Derogating from, or managing compliance to, NHS standards is often a complex and potentially contentious issue with very long term implications. It can often involve legal issues, and the legal status of NHS specific guidance, and include a range of challenges.

3.9.2 The following protocol outlines a process for all aspects to be considered and stages to follow when assessing and managing any potential derogation

and is intended for use on all technical disciplines. It should be noted that a derogation in one area may have implications to other areas and all aspects need to be adequately identified, assessed, and documented when determining if a derogation is appropriate.

3.10 Definition of a derogation

3.10.1 In the simplest of forms (the dictionary definition) a derogation is an exemption from or relaxation of a rule or law or standard. As it applies to NHS guidance such an exemption must be appropriately recorded with all implications understood and accepted by all parties, and approved at an agreed appropriate level; and where applicable alternative and equivalent mitigation agreed for the risks or implications of the derogation.

3.10.2 The need to demonstrate a robust process for agreeing any derogation from Technical Guidance is a core component of the assurance process and as such must provide a clear auditable trail.

3.10.3 Derogations to guidance will potentially increase risks to the organisation and potentially clinical activity or patient safety and should only be considered in exceptional circumstances. A schedule of derogations will be required for any/all project(s). This schedule is not a simple list of derogations which can be stored in a project file. It is required to be comprehensive and stored where it can be easily referenced by all stakeholders and kept under regular review and monitored to ensure it remains safe and appropriate.

3.10.4 While it is recognised that derogation is required in some cases, this must be risk-assessed, agreed and documented in order that it may be considered within the appraisal and approval process.

3.10.5 Derogations must be properly authorised by the project's senior responsible owner and informed and supported by appropriate technical, Infection

Prevention and Control (IPC) and clinical advice (irrespective of a project's internal or external approval processes).

3.11 NHS Standards (mandatory, guidance, minimum standards, or simply best practice?)

3.11.1 Over the years the NHS has developed a comprehensive range of documents to provide standards and advice for those involved in the design, construction and operation of healthcare facilities. These include Health Building Notes (HBNs and SHBNs), Health Technical Memorandum (HTMs and SHTMs), Health Guidance Notes (HGNs), Health Facilities Notes (HFNs) and Fire Practice Notes (FPNs), to name just a few, with some of these standards now archived or superseded. It must also be noted that within the devolved administrations there are a number of documents which contain subtly differing guidance, although the process by which these can be managed can be universally applied. For the avoidance of doubt the process of managing derogations is not influenced by the standard being derogated from.

3.11.2 Debate over the status of all of these documents can be highly contentious and generally is not definitively defined, however the following elements need to be considered:

3.11.3 **Legal** - In my experience any failures to follow these documents has been used in court proceedings to find against hospital Trusts. These are most likely to be in connection with Health and Safety Executive prosecutions or possibly civil or medical malpractice cases. The various Devolved Administrations agree that the documents produced are guidance documents. They become a requirement when they form part of a contract, however the guidance documents are generally considered as an Approved Code of Practice or at the very least good practice. This is summarised below from a general assessment of the status and use of these guidance standards.

3.11.4 ‘DoH guidance is relevant and is generally taken to be authoritative by the relevant authorities and the court, but this is not conclusive. However, if the guidance isn’t followed, the Trust would be expected to justify why and to demonstrate what measures they took to satisfy the requirement of taking all reasonably practicable steps to protect people affected.

3.11.5 Also the Health and Social Care Act (2012), Health and Social Care Act (Regulated Activities) Regulations 2014, and the Care Quality Commission (Registration) Regulations 2009 are all used as the basis for CQC registration and certification. As such these regulations are used as the reference by the CQC for all healthcare providers (including the NHS).

3.11.6 Health and Social Care Act 2008 (Regulated Activities) Regulations 2014: Regulation 15 These Regulations outline 20 key criteria under which all healthcare providers must operate. The intention of this regulation is to make sure that the premises where care and treatment are delivered are clean, suitable for the intended purpose, maintained and where required, appropriately located, and that the equipment that is used to deliver care and treatment is clean, suitable for the intended purpose, maintained, stored securely and used properly. Providers retain legal responsibility under these regulations when they delegate responsibility through contracts or legal agreements to a third party, independent suppliers, professionals, supply chains or contractors. They must therefore make sure that they meet the regulation, as responsibility for any shortfall rests with the provider.

3.11.7 15(1)(c) suitable for the purpose for which they are being used, Premises must be fit for purpose in line with statutory requirements and should take account of national best practice. Any alterations to the premises or the equipment that is used to deliver care and treatment must be made in line with current legislation and guidance. Where the guidance cannot be met,

the provider should have appropriate contingency plans and arrangements to mitigate the risks to people using the service.'

3.11.8 The NHS guidance documents are not mandatory (unless specifically stated). They do however state that, any departures/derogations including the measures implemented, should provide a degree of safety not less than that achieved by following the guidance set out in the various documents.

3.11.9 **Minimum Standard or Best Practice** – Often this is defined by the parties on either side of a debate around derogation. In practice the answer can be both, the guidance sets safe minimum standards which should not be relaxed where they impact patient safety or operational resilience including lifespan. However there isn't an alternative guidance document which could be described as best practice or 'compliance plus' standards, as the NHS guidance are generally considered by many as world leading, it is not unreasonable to describe them as best practice or even an Approved Code of Practice, at least in some circumstances. For the avoidance of doubt the NHS standards such as SHTMs and SHBNs contain both minimum standards and in some cases represent current best practice, but are considered as the appropriate standard to conform to within a healthcare setting.

3.12 Reasons or drivers to consider derogating

3.12.1 Typically there are many reasons cited to derogate from elements of even entire HTM's or HBN's, including but not limited to:

- Refurbishment of existing buildings, facilities or services (including the limitations associated with existing footprints etc.),
- Room allocation and sizes,
- Cost or budget allowance, (however cost should never be the sole consideration, as the budget should be set to reflect full compliance),
- Scope of project,

- Omission of compliance issue at business case/design/construction stage, or
- We haven't done it before or had it agreed on a previous scheme.

3.12.2 At times a derogation is a sensible and safe option to consider, however the full implications of any such consideration must be carefully balanced and a full and detailed record made of the impact, risks, cost consequences, practical limitations of a scheme or site, and a formal review and approval process. This process may also identify other forms of mitigation or control measures and should also include a post project 'in use' assessment to ensure the decision was justified with the benefit of operational hindsight.

3.13 What cannot be derogated

3.13.1 In HTMs 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.

3.13.2 The following describes the implications and use of these modal verbs in HTMs/HBNs:

- "Must" is used when indicating compliance with the law. These cannot be the subject of derogation.
- "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. These are elements which in extreme or specific circumstances could be considered for an area of derogation, however the organisation must be able to clearly demonstrate the circumstances/reasons for the derogation and if required provide evidence of what measures they took to satisfy the requirement of taking all reasonably practicable steps to protect people affected.

- “May” is used for permission, i.e. to indicate a course of action permissible within the limits of the HTM/HBN. Again, these elements could be considered for an area of derogation, however the organisation must be able to clearly demonstrate the circumstances/reasons for the derogation and if required provide evidence of what measures they took to satisfy the requirement of taking all reasonably practicable steps to protect people affected.

3.14 The process of derogation

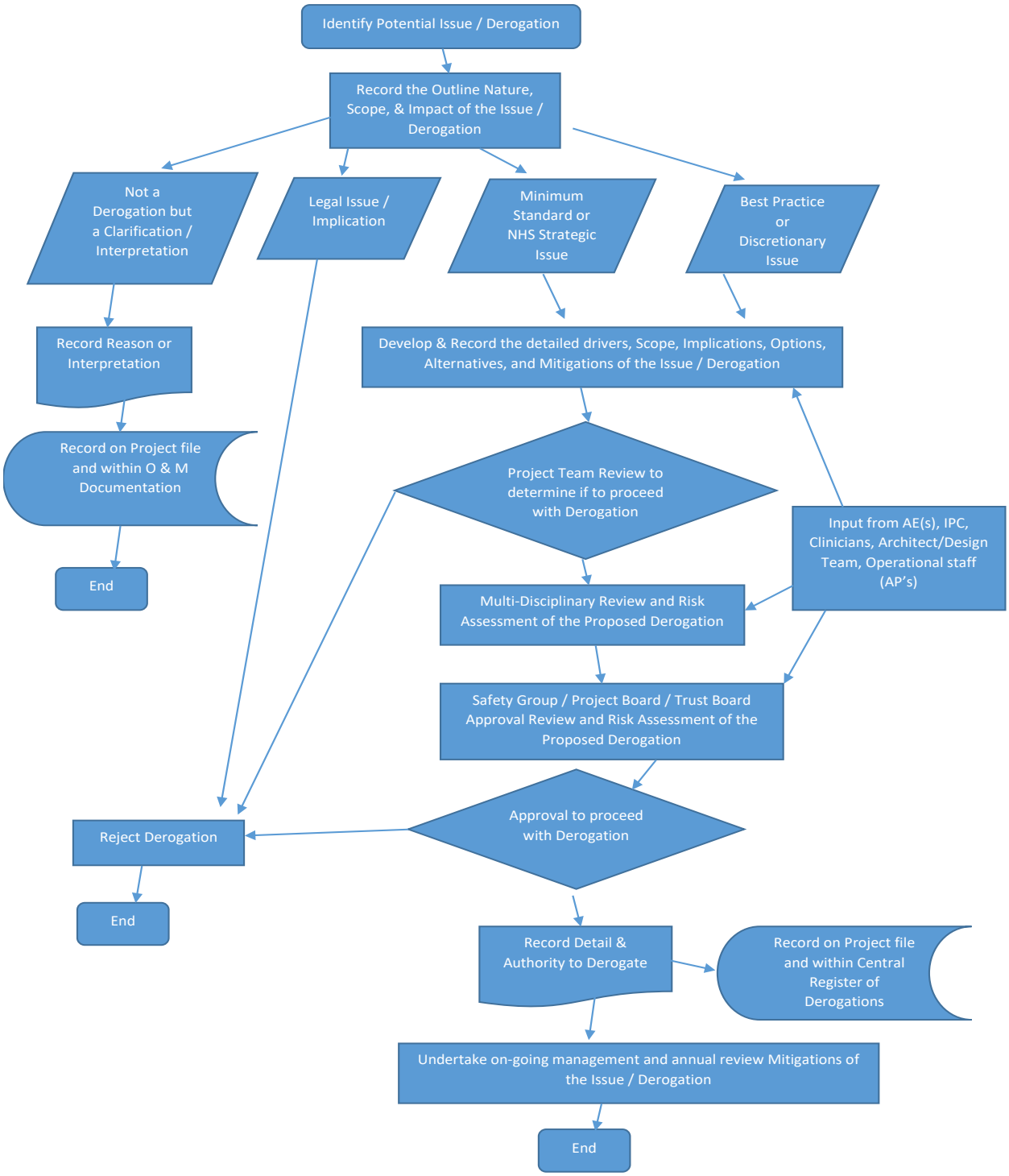
3.14.1 When considering a derogation, the initial question needs to be clearly established as to who has the authority to agree a derogation and who ultimately holds the responsibility for the decision.

3.14.2 Once a derogation has been identified as potentially being required or desired the issue needs to be very clearly defined by the requester as to the exact nature and extent of the potential derogation. This should include full details of the clause or area of derogation, the reason(s) for the inability to conform to the relevant standard, the predictable consequences of the derogation and what, if any mitigation is being proposed to minimise or remove the residual risk of non-conformance.

3.14.3 Following the request the project team should log the request and undertake a review to assess the request with input from the appropriate working safety group and Authorised Person(s) for the discipline(s) involved. If considered necessary the opinion/comment from the Authorising Engineer for the specific discipline should also be sought to ensure all aspects have been suitably identified and considered. For the avoidance of doubt the review must be comprehensive and include representation for all stakeholders including clinicians, IPC, Operational Estates and Facilities and the Project team, it must not be done in isolation by the project team. If a derogation is not reviewed and considered by all appropriate stakeholders as outlined above there is a potential risk that critical safety or other factors

may not be adequately assessed which could result in ill-informed decisions being made with potentially safety critical risks being accepted based on incomplete or a lack of all available information.

Derogation Flow Diagram



3.15 Essential Considerations

3.15.1 The review process must consider a wide range of potential implications and consequences including but not limited to:

- Patient, staff, or visitor safety
- Patient, staff, or visitor comfort
- Maintainability
- Changes in guidance/best practice since publication of an HTM or HBN
- Advances in technology since publication of an HTM or HBN
- Clinical Activity and clinical process/development or creep
- Timescales (both in terms of project programme and lifespan of the development)
- Practical limitations (e.g. space and existing building restrictions)
- Life span and whole life costings
- Energy consumptions and running costs
- Cost (reduced capital costs must not be put ahead of whole life or revenue costs)

3.16 Risk Assessment

3.16.1 Once all of these elements have been considered, and the scope of the impact of the potential derogation agreed, a risk based assessment should be completed. This risk assessment is essential to enable the ultimate decision to be made by the Designated Person for the respective system/service, with a full understanding of the consequences of the approval or rejection decision.

3.17 Records

3.17.1 A full and detailed schedule must be developed and retained for all proposed derogations or clarifications considered during a project or scheme. This schedule should be comprehensive and include as a minimum the following information (per derogation):

Reference No of Standard	For example HBN/HTM reference
Specific Clause Reference	
Derogation/Clarification	Details of what is being proposed for derogation including the exact extent and scope of the derogation requirement.
Derogation Reason/Driver	Details of the reason/explanation of why, extent/impact and details of any proposed alternative design solutions.
Derogation Proposed by	Name of individual or company proposing/requesting the derogation
Date	
Comments by Project team lead	Name of individual with details/commentary to evidence initial design review and a recommendation to approve or reject proposed derogation.
Date	
Comments by Authorised Person (AP)	Name of individual with details/commentary to evidence any recommendation to approve or reject proposed derogation.
Date	
Comments by Authorising Engineer (AE)	Name of individual with details/commentary to evidence any recommendation to approve or reject proposed derogation.
Date	
Working Safety Group (if applicable) comments/risk assessment	Details/commentary to evidence any recommendation to approve or reject proposed derogation.
Date	
Risk Assessment / Details of potential consequences	Details of any risks or potential consequences as a result of the proposed derogation
Mitigation / Control measures to address identified risk elements.	Details of any mitigation or supplementary control or management issues which could be used to reduce or address identified risks
Comments/Review Recommendations for Board Level Designated Person consideration	Consensus assessment of all stakeholders to the proposed derogation with if practical a recommendation to accept or reject.
Executive Board Level Designated Person assessment	Sign off by the DP or similar level board member to accept or reject derogation

Date	
Status	Approved or rejected, (including a time limit if appropriate).

3.17.2 For the avoidance of doubt, the Duty Holder or Designated Person MUST make the final decision to accept or reject a request for a derogation even where that decision is informed by advice from either external advisors or working multidisciplinary safety groups.

3.17.3 This schedule would form the basis of a live document register which should be accessible to all stakeholders for review purposes and information. Where considered necessary the schedule or register of derogations may also lead to the inclusion onto the organisation's risk register to ensure approved derogations do not get overlooked or forgotten.

3.18 Recording file structure

3.18.1 All approved derogations must be kept in such a manner as to enable regular (at least annual) review to ensure the decisions taken remain appropriate for any potential usage changes. As such it is recommended that a filing structure or database system is developed to centrally record and manage derogations. One approach is to allocate a referencing system to any agreed derogation incorporating the following details as a minimum:

- Site reference
- Building reference
- Level or floor reference (this could be all floors if it applies to an entire building)
- Guidance reference (HTM or HBN reference)
- Date

3.18.2 The above file structure or referencing system should enable specific elements for example any ventilation derogations (HTM 03-01) to be filtered or chosen as a condensed schedule to enable the respective working group to undertake an annual review exercise. The specific clause and derogation detail and reasoning would be stored under this searchable file structure.

3.19 On-Going Management and Review of Agreed Derogations

3.19.1 The majority of derogations tend to be considered in connection to capital investment projects, however, there are also circumstances when operational derogations are required. These can relate to a relaxation of testing or inspection, due to resource shortages or other operational considerations such as access or external circumstances (like a global pandemic). Under these circumstances operational decisions are taken, however it is rare to find these incidents recorded as derogations whether temporary or permanent.

3.19.2 All derogations need to be kept under constant and on-going review to ensure that operational changes, clinical activity or condition surveys and investment planning is undertaken with the full knowledge that areas of the estate may not be fully compliant. An example of this could include an area converted to manage emergency admissions due to the pandemic becoming a more long-standing or permanent facility even after immediate pressures have passed. A non-compliant heat recovery unit (which doesn't conform the HTM 03-01 standards for AHU's) intended as a short-term fix (say 18-month period) becomes a semi-permanent ventilation solution to the area. Or the use of temporary tent style isolation facilities become a permanent solution, when a more substantial permanent provision could be developed and installed to provide a safer and more robust solution. In emergency situation people can make sub-optimal decisions and these issues should be kept under review to ensure they remain appropriate or with the benefit of hindsight lessons are learned to avoid repetition.

3.19.3 One option for this review process could be to incorporate the review into the standing agenda of the relevant working safety group. This would provide a forum for the majority if not all of the agreed derogations which would be held on a central register. It may also be appropriate to ensure that any agreed derogation is recorded on the trust or divisional/departmental risk register as an accepted risk to ensure both operational and management staff are aware of the status and accepted associated risks.

3.20 Assessment of Derogation Management at QEUH

3.20.1 It would appear that the process of managing/agreeing derogations of changes within the project at QEUH were restricted to a Project Board level, and outcomes would suggest that not all interested stakeholders were appropriately or fully consulted on all issues. An example of this can be evidenced by the only seen derogation form for the scheme (provided to date) was for the deviation of air change rates (QEUH DER – V001 dated 18th September 2019). This derogation appears to be a retrospective assessment based on performance since 2015 and an acceptance of non-conformance to the SHTM standards. No other evidence of a pro-active management process of derogations is available, although strong evidence does exist of poor compliance to standards. These include, but are not limited to:

- Water systems being ‘wet tested’ and not consistently flushed
- EPDM flexible hoses installed with are contrary to SAN(SC)09/03

Derogation Recording Form Template

The following form is an example of the type of information required and details/signatures required to record an approved derogation.

Element	Detail / Comment	Signature
HTM/HBN Reference No of Standard	For example HBN/HTM reference	
Specific Clause Reference		
Derogation/Clarification	Details of what is being proposed for derogation including the exact extent and scope of the derogation requirement.	
Derogation Reason/Driver	Details of the reason/explanation of why, extent/impact and details of any proposed alternative design solutions.	
Derogation Proposed by	Name of individual or company proposing/requesting the derogation	
Date		
Comments by Project team lead	Name of individual with details/commentary to evidence initial design review and a recommendation to approve or reject proposed derogation.	
Date		
Comments by Authorised Person (AP)	Name of individual with details/commentary to evidence any recommendation to approve or reject proposed derogation.	
Date		
Comments by Authorising Engineer	Name of individual with details/commentary to evidence any recommendation to approve or reject proposed derogation.	

(AE) (if considered necessary)		
Date		
Working Safety Group (if applicable) comments/risk assessment	Details/commentary to evidence any recommendation to approve or reject proposed derogation.	
Date		
Risk Assessment / Details of potential consequences	Details of any risks or potential consequences as a result of the proposed derogation	
Mitigation / Control measures to address identified risk elements.	Details of any mitigation or supplementary control or management issues which could be used to reduce or address identified risks	
Comments/Review Recommendations for Board Level Designated Person consideration	Consensus assessment of all stakeholders to the proposed derogation with if practical a recommendation to accept or reject.	
Executive Board Level Designated Person assessment	Sign off by the DP or similar level board member to accept or reject derogation	
Date		
Status	Approved or rejected, (including a time limit if appropriate).	

4. QEUH/RHC Design, Installation, Commissioning and Validation (Point of Occupation)

4.1.1 The domestic hot and cold water systems design at QEUH was generally in line with the principles as set out in the guidance at the time (SHTM 04-01), however, the subsequent requirement to install a secondary incoming water ultrafiltration system and water treatment plant indicate that the system had areas of concern. The detailed equipment selection of tap outlets and the potential operational impact of installing point of use filtration was not fully appreciated or considered.

4.1.2 The site has a very complex water distribution system and during commissioning and the pre-occupation risk assessment review process a number of significant installation issues were identified which could have been designed out at an early stage. The pre-occupation risk assessment process identified large numbers of cold water outlets with excessively high temperature gain, which resulted in the installation of dump valves to increase water flow through and reduce stagnation and heat gain. In addition, the use of EPDM flexible hoses installed contrary to SAN(SC)09/03, areas that could not be accessed for flushing, and water tanks had various degrees of detritus at handover

4.1.3 It is also worth noting that the extensive provision of items such as hand wash basins would be today considered as potentially excessive (based on emerging IPC evidence and current best practice) and the operational impact of this should be reviewed as part of the infection prevention and control process to identify where the provision of these items may be contributing to waterborne pathogen transmission risk.

4.1.4 From the information provided there is no evidence that the project or NHSGGC Board had a comprehensive process for the management of derogations and as such the process for the management of variations from the SHTM standards is unclear.

4.1.5 The classification and vulnerability of the patient group was clearly well understood and the impact of the water systems in regard to the risk of system colonisation, transmission to patients and the appropriate measures to minimise these risks through the design, installation, commissioning, and validation process through to the initial occupation and operation can best be described as sub-optimal. Evidence for this includes (but is not limited to) the use of ‘wet’ pressure testing, the lack of comprehensive flushing of systems once wetted, the failure to adequately protect pipework from contamination during installation, and the poor performance of the cold water distribution pipework to maintain appropriate outlet water temperatures.

4.1.6 Specialised Systems

4.1.7 SHTM 04-01 Water safety for healthcare premises Part A : Design, installation and testing (Jul 2014) clearly states in clause 8.25 that:

4.1.8 Where water supplies are required for specialised systems such as endoscope cleaning installations, dialysis units etc, the designer should consult the hospital infection prevention and control team (IPCT) to establish any specific water treatment requirements for the process, and also the local water supply authority to clarify any special precautions that may be necessary, such as backflow prevention devices. The advice of the water supply authority should also be sought as to any possible variation in the quality of supply or possible change in the source of supply (see also Health Building Note 07-01 (2008): ‘Facilities for renal services: Satellite dialysis unit’).

4.1.9 An example of these specialist systems would be for renal facilities where water of the appropriate quality used in the preparation of dialysis fluid is an essential requirement of haemodialysis and related therapies. Standards

exist to ensure the installation of fit for purpose water treatment systems for haemodialysis and to safeguard the routine production of dialysis water. Quality requirements for the water and concentrates used to prepare dialysis fluid, and for dialysis fluid, are provided in a series of standards issued by the British Standards Institute:

- BS EN ISO 13959; 2015: Water for haemodialysis and related therapies
- BS EN ISO 13958:2015: Concentrates for haemodialysis and related therapies
- BS EN ISO 11663: 2015: Quality of dialysis fluid for haemodialysis and related therapies
- BS EN ISO 26722: 2015: Water treatment equipment for haemodialysis and related therapies
- BS EN ISO 23500: 2015: Guidance for the preparation and quality management of fluids for haemodialysis

4.1.10 It would be normal practice to recommend that new build renal units should have a direct feed (drinking/potable) water supply separate from that of the hospital water supply. If water treatment systems use a hospital water supply there should be awareness of the potential risks that may arise from the introduction of chemicals into the hospital water supply by hospital engineering staff. To prevent the occurrence of adverse effects arising from such actions, the introduction or addition of chemicals into the hospital water supply should not be undertaken without prior consultation with Renal Services.

4.1.11 The QEUH site clearly has a number of specialist clinical areas where the requirements for high quality water for both potential process activities and patient vulnerability could be considered a very high risk. I would therefore have expected to see a specific risk assessment at the design stage to identify and agree with all stakeholders where such areas were and to what extent specialist design features were required. From the evidence reviewed no such risk assessments have been identified.

4.1.12 The potential capital cost benefit of not including elements such as incoming water filtration and supplementary water treatment systems is unclear and is outside the scope of this technical review, although it is clear that any capital savings/reductions at the design stage have been more than exceeded in the system alterations and improvements.

4.1.13 Domestic Hot Water Temperature and Heat Source (Energy Centre)

4.1.14 As an integral element of the commissioning and subsequent safe operation of the domestic hot water systems the water temperature is used as a primary means for the control of waterborne pathogens. Hot water flow temperature should be set to at least 60°C and the minimum temperature of all return legs to the vessel or water heater should be no less than 50°C. The individual outlets, taps, mixing valves or other outlet devices will be served from the distribution system; this should be designed such that the minimum temperature at the most distant taps or outlets is 55°C.

4.1.15 In May 2018 Innovated Design Solutions were commissioned to undertake a forensic analysis report of the energy centre performance. This review identified a number of control issues with the MTHW heating system, used as the primary heating water for the domestic hot water systems. It identified that the control set points for the hot water temperature control had been adjusted from 60°C to 65°C, however this change had not been appropriately recorded. From information observed during the forensic analysis evidence was recorded that although this adjustment had been made the flow temperatures were at times as low as 58.1°C. Whilst this is a clear non-conformity of set-point performance, it should be noted that at no time did the return water temperature fall below 53.2°C which provides evidence of suitable and safe overall water temperature control. The failure to appropriately record the system temperature control adjustment should have been formally recorded within the water safety plan for the site and

agreed with the water safety group, however no evidence has been provided to confirm this and I have therefore assumed it did not occur.

4.2 Pre-Occupation Water Risk Assessment (2015)

4.2.1 In April 2015 the NHSGGC Board commissioned an independent water risk assessment to identify any potential areas of concern. This review resulted in a detailed water risk assessment which identified a total of 494 issues or defects, (183 classified as high risk (Red), 304 as medium risk (Amber) and 7 low risk (Green). Given that this was a then brand new installation which was designed and built to be fully compliant to the relevant healthcare SHTM standards, this level of defects is considered completely unacceptable. The scheme should have been defect free however was identified as suffering from a range of issues including but not limited to:

- All EPDM flexible hoses should be removed and replaced with hard piped connection.
- Aeration at outlet(s). Investigate and correct.
- Hot water temperature too low. Investigate and correct.
- Cold water temperature too high. Investigate and correct.
- Hot outlets do not comply with latest SHTM regulations, though achieving temperatures of 50°C. Wherever possible/practical remedial action should be carried out to increase temperatures to 55°C.

4.2.2 In 2017 the water risk assessment process was repeated and demonstrated some significant improvement in the overall level of issues, however a total of 168 remained to be addressed (65 classified as high risk (Red), 99 as medium risk (Amber) and 4 low risk (Green). The remaining issues included multiple instances of:

- Evidence of heat gain in cold water - investigate and correct.
- Include Unused outlets into site flushing regime.

4.2.3 For a new system, which had been designed to fully conform to the then current SHTM standards this is considered as a highly unsatisfactory

situation, although it does provide evidence of positive progress to identify and address issues by the NHSGCC Board and Estates team.

4.2.4 The full potential implications of the water system issues and the need to address them through the phased instruction for improvement works, highlighted by the initial risk assessment process clearly demonstrate an acceptance by the NHSGGC Board that the systems were not fully compliant. The NHSGGC Board also accepted that remedial works were needed as the identified issues could pose a risk to patients.

4.3 Ancillary Considerations

4.3.1 Did the hospital's proximity to the Shieldhall waste water treatment works create a risk of infection to patients?

4.3.2 In my professional experience the close proximity to the sewage treatment works has no direct impact on the domestic water systems at QEUH. Nor does it represent any additional risk to the water systems at QEUH, although it may have impacted the ventilation systems and general ventilation strategy due to odour control issues, but has no direct impact to the operation of the water systems.

5. Commissioning at handover

5.1 Commissioning

5.1.1 The term commissioning is a general heading for a wide and multi-phased set of activities to ensure a designed water system operates correctly and as intended. Commissioning will normally include the following individual activities, the timing of which can be spread throughout the project programme, the following is a summarised list of typical activities taken from SHTM 04-01 Part A chapter 16, 17, and 18:

1. Preparation of a detailed Design review and the agreement of a Commissioning Water Safety Plan including a Water Risk Assessment
2. Physical inspection (during installation and prior to application of thermal insulation)
3. Inspection and testing of joints and connections (typically a sample of between 2 to 5 fitting cut out and inspected for and inspected)
4. Pressure testing (using inert gas (medical grade air) where possible in healthcare settings)
5. Pre-commissioning checks (as per HTM 15.27/SHTM 16.24/16.27)
    - systems have been provided and installed in accordance with the specification and drawings;
    - the system is charged with water, vented, and free from leaks;
    - water storage vessels are free from leaks and are properly supported and secured;
    - distribution pipework is rigidly supported, insulated, and incorporates adequate provision for venting, drainage, expansion, isolation, and measurement of flow, temperature and pressure;
    - pipework systems, storage cylinders etc have been pressure-tested;
    - pipework systems, calorifiers and cisterns are correctly identified and marked;
    - regulating valves and flow control devices operate freely;
    - all control and regulating valves are labelled or marked to correspond with reference numbers on contract drawings;
    - electrical isolation, cross-bonding and wiring of system components is installed in accordance with the current edition of BS 7671;
    - up-to-date system schematics are displayed in a frame in the relevant plantroom.
6. Flushing, this should be undertaken following pressure testing and should be the first action once a system is ‘wetted’ for the first time, after which the system should be subject to regular twice weekly simulated ‘in use’ flushing to ensure stagnation of the system is minimised.

7. Water circulation and checking, this will typically involve taking of flow readings and balancing the system to ensure adequate water circulation is achieved throughout the system.
8. Temperature control and checking, for cold water systems this is to ensure no excessive heat gain is experienced within the system (no more than 2 °C between incoming water temperature and outlet temperature, this requires all other services to be completed and in operation). For hot water systems this is to ensure appropriate circulation and design water temperatures are present at all outlets within 1 minute of opening/operation).

9. The full schedule of commissioning activities should be documented within the commissioning water safety plan but will typically include (as per HTM 15.29/ SHTM 16.26/16.30):

    - Drain-down points flow when released and are free from leaks when shut, that air vents and release valves open correctly and are airtight when shut off, and that overflows run freely and discharged water does not cause flooding or damage.
    - Float-operated valves function satisfactorily and are adjusted to achieve the correct water level.
    - All temperature and other controls are adjusted and calibrated to agreed design limits of system performance.
    - All electrical circuits are tested and the pump motor direction of rotation is correct, and that electrical controls and alarms function correctly.
    - Operation of any safety or anti-flood device is satisfactory.
    - Circulating and pressurisation pumps are free from excessive noise, vibration and leaks and that pressurisation vessels are filled to the correct water level.
    - Expansion vessels where installed are filled to the correct water level.

- Control valves operate correctly and shut-off valves close tightly.
- Heat exchangers operate satisfactorily.
- Primary heating circuits are adjusted and regulated, and thermostatic settings are correct; and that bypass circuits and automatic control valves operate correctly.
- Remote and automatic control of pumps (if appropriate) is satisfactory, and there are no leaks at joints under maximum flow conditions.
- The cold water and hot water circulating and distribution systems are vented and regulated.
- Thermostatic mixing devices and regulating valves are adjusted and set to desired values (TMVs require hot and cold water for testing and commissioning, and should be commissioned in accordance with Chapter 11 of HTM 04-01: Supplement – ‘Performance specification D 08: thermostatic mixing valves (healthcare premises)’).
- All taps, mixers and outlets operate satisfactorily and that all strainers and shower outlets have been cleaned and are free from contamination.
- Water flow quantities at all plant items, regulating valves and flow-measuring valves are recorded.
- Mass flow rates from taps, main and other outlets in positions shown on contract drawings are satisfactory.
- Pressure drop at heat exchangers at full design demand flow is tested and recorded.
- Hydraulic balancing of hot water secondary circulation system is carried out to ensure that minimum temperatures are achieved in all parts of the circuit.
- Full load current of components does not exceed the recommended values.

- The running current of components does not exceed the recommended values.
- Pump thermal overload trips are set.

10. Disinfection, pipework under pressure from the mains should be disinfected through an injection point and the disinfectant residual measured at the end of the pipeline. BS6700: 2006, BS EN 806-1-5: 2000-2012 and also BS8558: 2012 and the Approved Code of Practice L8 advise 50 mg/litre (ppm) for one hour or 20mg/litre (ppm) for two hours; it is usual practice to leave the chlorine solution in the pipes for 24 hours before thoroughly flushing out with fresh water. Junctions that are to be inserted into existing pipelines should be disinfected prior to installation.
11. Second flushing/simulation, this is the regular simulated operation of the system to ensure stagnation is minimised and the systems remain clean.
12. Water sampling, the level and extent of water sampling should be agreed as part of the commissioning water safety plan and undertaken in full consultation and agreement of the local water safety group.

5.2 System Pressure Testing and Flushing

5.2.1 Any open end of pipework on a system should be kept capped to ensure the risk of contamination by dirt/debris is minimised. Once the system is physically complete the risk of contamination by ‘foreign materials’ should be minimal, and whilst pressure testing does not have any action on this, as it should be undertaken using inert gas and not water, the initial flushing and thereafter the regular flushing is intended to minimise the risk of contamination entering or remaining in the system.

5.2.2 It is understood that the domestic water systems within the QEUH were subject to ‘wet testing’ using mains water which was in some cases then drained down and left until final connection and disinfection. This process has the significant potential to 'seed' the water system with microorganisms and biofilm. If the system does become contaminated as a result of this

process then a single shock disinfection process may not be effective to achieve appropriate system cleanliness. Evidence from the A&C Hydraulic testing of domestic water systems method statement[1] Clearly states the use of wet testing for these systems.

5.2.3 Certification provided indicates the flushing of the whole water system was completed on 16 January 2014. Scottish Hospital Technical Note (SHTN) 2, published December 1999 defines a specific process to flush a system. To flush a whole system, all parts of the system must be complete. The provided evidence indicated this was completed in January 2014. Subsequent commissioning records indicate that the water tanks were not tested and the cold water booster pumps were not commissioned until March 2014.

5.2.4 Invitations to witness flushing in plantrooms at various later dates indicates that the flushing was not undertaken as a whole system flush and contradicts the certificate provided certifying flushing was completed in Jan 2014.

5.3 HTM 04-01 Part A

5.3.1 Hygienic installation and storage practices

1.21 Installers should adopt practices that reduce the likelihood of cross-contamination from tools, clothing or the environment. Separate clothing and tools used for other non-wholesome services such as sewerage and drainage systems should be kept separate and not used when working on hot and cold water systems.

3.44 Where possible, leak-testing should be carried out using nitrogen or medical quality compressed air or oil-free dry compressed air. This must be

[1] A&C Hydraulic testing of domestic water systems method statement

carried out by competent personnel (see HSE's GS4 – 'Safety requirements for pressure testing').

5.3.2 Flushing the system after the initial 'wetting' is designed to simulate use and reduce the risk of stagnation and microbiological colonisation. Although the flushing reduces the risk of microbiological proliferation and colonisation, it cannot be guaranteed to prevent it. The level and frequency should be agreed with the WSG to minimise this, but twice weekly of all outlets is the generally accepted/recommended base standard for healthcare installations.

5.3.3 Strainer baskets are either an integral element of a TMV, or a separate in-line component prior to the TMV, and act as a filter for debris. Strainers or the TMV units are designed to be dismantled to remove and clean the strainer mesh/basket. After the initial flushing all strainers should be checked and cleaned, and thereafter subject to regular inspection and cleaning (typically every 6 months).

5.4 TMVs and Thermostatic Mixing Taps (TMT) Commissioning

5.4.1 No Handover documentation was provided specifically detailing the flushing of Thermostatic Mixing Taps (TMT) or Thermostatic showers prior to commissioning. There are no records of hot water supply temperatures from each of the hot water inlets which should have been taken during failsafe checks. Consequently, the records provided do not accurately capture all required information, on both hot and cold water temperatures, to properly commission a Thermostatic Mixing Tap or Thermostatic mixing shower in line with the manufacturer's requirements or the RAMS.

Evidence reviewed including samples of TMV testing records[2] show that whilst TMV's have been subject to routine testing and maintenance the level of information

[2] 2310 RHC TMV Servicing Clinic 6(vA71827875)

recorded and the stabilisation testing of replace TMV or TMT cartridges does not follow the current SHTM standards.[3]

5.4.2 The process and tests involved in the commissioning of a TMV is set out by the manufacturer and should follow as a minimum the steps laid out in Health Technical Memorandum 04-01: Supplement Performance specification D 08: thermostatic mixing valves (healthcare premises) 2017 edition.

Commissioning procedure

Check that the TMV is appropriate for the application of use.

Check that the water supplies are appropriate for the installation of the TMV.

Check that the mixed water temperature is appropriate for the application; if required, adjust the mixed water temperature up to a maximum application temperature in accordance with the manufacturer's instructions.

The following frequency of in-service testing, immediately following commissioning should be followed.

The frequency of in-service testing and the specific requirements detailed in the risk assessment undertaken by the Water Safety Group may change due to a number of factors such as varying supply conditions and water quality as these may alter the TMV's performance.

Six to eight weeks after commissioning.

Twelve to fifteen weeks after commissioning.

Depending on the results, several possibilities exist:

- If no significant changes (for example ≤1 K) in mixed water temperatures are recorded between commissioning and the times given in clause F.1.1,

[3] 170802-0804 Adults W 4A TMV Servicing

or between commissioning and the times given in clause F.1.2, the next in-service test can be deferred to 24 to 28 weeks after commissioning.

- If small changes (for example 1–2 K) in mixed water temperatures are recorded in only one of these periods, necessitating adjustment of the mixed water temperature, then the next in-service test can be deferred to 24 to 28 weeks after commissioning.
- If small changes (for example 1–2 K) in mixed water temperatures are recorded in both of these periods, necessitating adjustment of the mixed water temperature, then the next in-service test should be carried out at 18 to 21 weeks after commissioning.
- If significant changes (for example >2 K) in mixed water temperatures are recorded in either of these periods, necessitating service work, then the next in-service test should be carried out at 18 to 21 weeks after commissioning.

5.5 HTM 04-01 Supplement (DO8) (2017) Chapter 11 - In-service test

5.5.1 Purpose

The purpose of in-service testing is to maintain assured performance and to provide records of the thermal performance of the TMV, all of which should be consistent with this document and the risk assessment carried out by the Water Safety Group.

In-service test procedure

Carry out the following in-service test sequence:

a. For all outlets, measure and record the temperature of the mixed water at the maximum available flow. If required, the mixed water temperature may be readjusted up to a maximum temperature as indicated (Table below) or as determined by risk assessment (see note below).

b. Isolate the cold water supply to the mixing valve and observe the mixed water outlet.

If there is a flow stream after 5 seconds then collect any water discharging into a suitably graduated measuring vessel for 60 seconds; if the volume of water collected is greater than 120 ml, then recommissioning or service work is needed.

If there is no flow or if the volume of water collected is less than or equal to 120 ml, then restore the cold water supply; after seconds record the mixed water temperature.

Verify that this temperature does not differ by more than 2°C from the temperature taken in (a) (this is a restoration test after a failure of the cold water supply and some deviation of the mixed water outlet temperature may be expected).

If the mixed water temperature differs by more than 2°C from the set temperature taken at (a), then recheck the supply conditions or recommission.

The valve must then be readjusted and recommissioned in accordance with the manufacturer's instructions.

Note: After risk assessment, a temperature that is lower than the maximum temperature allowable for the designated installation (vulnerable people) can also be set if deemed appropriate to do so.

Application/Designation	**Initial set temperature of mixed water (at outlet) °C (max)**
Bidet (B)	38°C max
Shower (S)	41°C max
Washbasin (W)	41°C max
Bath (44°C fill – T44)	44°C max
Bath (46°C fill – T46)	46°C max
Diverter Bath/Shower (D44)	Bath fill 44°C/Shower 41°C max
Diverter Bath/Shower (D46)	Bath fill 46°C/Shower 41°C max

Table 17

Note Set the mixed water outlet at the above initial temperature settings. During the cold water restoration stage the mixed water temperature can deviate by 2 °C from these initial maximum settings.

5.6 System Balancing

5.6.1 The balancing of the water system is the term used to describe the process undertaken to ensure all parts of the system are set-up to achieve appropriate circulation of water and stagnation or short circuiting of water flow does not occur. This balancing is typically undertaken in two stages. The first element is considered as a fundamental element of the design process with the provision of suitably located commissioning sets or double regulating valves which enable, in the second on-site stage, the flow rates to be taken and system resistance adjusted to ensure a balanced overall flowrate is achieved.

5.7 System Disinfection

5.7.1 The initial system disinfection is a ‘one off’ process to ensure the water system is clean and safe to put into operational use. The critical elements of the disinfection process should be clearly recorded and identify that the disinfection was carried out at the correct stage of the overall commissioning process. It should be undertaken to the appropriate standard (see above), and finally following disinfection, the system must be adequately flushed (Second flushing/in use simulation. Following the disinfection process it is normal to ensure representative water samples are taken to provide evidence of disinfection adequacy. The results of the initial post disinfection water samples included a number of failures, and whilst some of these results were subject to re-testing and passed a small number appear to have remained in an unsatisfactory state.

5.8 Treatment

5.8.1 HTM 04-01 Part A clearly states in clause 4.11 there is no single water treatment regimen that is effective and appropriate in every case, and each system has both merits and limitations. The implementation of an on-going biocide regimen together with maintaining temperature control requires constant vigilance to ensure the safety of particularly vulnerable patients in healthcare premises. For example, dedicated treatment and supply arrangements may be required for renal and haemodialysis units or for making up infant feeds where concentrations of biocides in the water would be harmful to patients. For the avoidance of doubt an on-going biocide regime is a different and separate process to the initial post installation disinfection.

5.9 Validation

5.9.1 Validation of a water system is a process undertaken after or during commissioning and would typically involve the witnessing and review of records via an independent Authorising Engineer or other suitably qualified and experienced independent engineer, on behalf of a health board or project team. The validation process also includes the collection and sampling of water samples to establish the cleanliness of the water system and demonstrate, as far as practically, the efficacy of the disinfection process.

5.9.2 Water sampling is one element of the commissioning process and is used to provide evidence that the system is operating correctly and safely. The process of water sampling is highly involved and technically complex, however it should be undertaken by suitably competent persons in accordance with BS 7992:2008 (Legionella), BS EN 806, BS 8558:2011 and BS 8554:2015. A summary of the process and purpose is outlined within HSG 274 Part 2 (Microbiological monitoring and Cleaning and disinfection.

5.9.3 A sample of evidence for the witnessing of the water systems following commissioning is as below for Plant room 31.

5.9.4 The “Witness of Testing” cover sheets provided for plantroom 31 is unsigned in relation to the recording of Domestic Water Return Temperatures although the document records the work was done on 18 Sept 2014.

5.9.5 The Domestic Water Outlet Temperatures of the hot and cold water systems and the testing of the anti-scald function on Thermostatic Mixing Taps are signed as having taken place on 23 Dec 2014.

5.9.6 A sterilisation certificate dated Dec 2014 records that the hot and cold Domestic Water Services served by plantroom 31 had been disinfected and the system dosed with Sanosil Super 25 at a dosage rate of 150ppm for 1 hour. The certificate is part of a document which identifies the locations of sentinel outlets where water samples were taken for microbiological analysis.

5.9.7 Theses samples were taken on the 21 Dec 2014. Dates on the document record disinfection was carried out on the 20 Dec 2014 and a fallow period of 48 hours is required between disinfection and water sampling.

5.9.8 The reports provided show evidence of failed samples. Most of the failed areas were re-tested and passed on 25 Jan 2015 and 11 Feb 2015 however there are no certificates to verify the 3 failed samples that are referenced as being re-tested on 18 Jan 2015. There is no evidence that the system was fully re-sterilised despite the RAMS stating that to be the process following failed samples.

5.9.9 Once all of the commissioning and validation processes have been completed the installer will typically be responsible to operate and maintain the systems until practical completion or handover to the operational team,

at which point the systems can be deemed as operational and in use. The users and supporting maintenance team then assume responsibility for the systems under the guidance of the water safety group, who should ensure that the systems are operating in a safe and appropriate condition.

5.9.10 Validation is the process by which the healthcare organisation is able to have assurance that the water systems are operating correctly and safely and without this critical review or assurance they cannot be confident that the systems are safe. The primary reason for the validation process is to independently confirm safe operation.

5.10 Key information Necessary Prior to Occupation

5.10.1 Whilst every scheme or project is likely to require different levels of information and assurance the basic components should include the following, as a minimum:

- Original design phase commissioning plan and risk assessment
- All commissioning and setting to work records
- Inspections
  - Pressure testing
  - Flushing
  - Commissioning
  - Balancing

With reference to all of the points raised above, the following information was not available or present at the time of handover, including but not limited to:

- All records relating to the flushing or in use simulation works completed with evidence of competency for those undertaking the work.
- Full water related operating and maintenance information.

- Initial water safety plan including comprehensive water risk assessment
- Evidence of water safety group terms of reference and evidence of assurance and control systems (minutes of meetings, AE(W) audits, competency of principle role holders with evidence of training assessments and competency.

5.10.2 From the information reviewed and the examples outlined above it can be concluded that the domestic water systems were not designed, installed, or commissioned in accordance with the SHTM 04-01 standards.

5.11 Automatic Flushing or Dump Valve Description and Purpose

5.11.1 A ‘dump valve’ is a term used to describe a valve which operates either on a timed or temperature controlled basis to ensure water which is normally only subject to movement or flow when used (e.g. a none circulating domestic cold water system) has the ability to flush or dump a volume of water. This water is typically flushed to waste and is designed to ensure water temperature within the water system is maintained. Generally, these devices are used in systems which are subject to sporadic use or, where in use, testing identifies an excessive temperature gain, where such a temperature gain could enable microbiological proliferation or colonisation.

5.11.2 Drinking water has a limited ‘shelf life’. If stagnation occurs, drinking water can absorb substances from the installation materials as well as temperature from the environment. Both can lead to a changed drinking water quality that is harmful to human health. A temperature increase to over 25°C is of specific concern or an increase in temperature of more than 2°C above that of the incoming water temperature, as microorganisms such as Legionella can multiply significantly. A temperature of no more than 20°C is regarded as safe for cold water by the SHTM’s for water.

5.11.3 In general terms the four principal areas for concern and therefore control can be summarised as:

- Temperature
- Flow
- Usage or turnover
- Cleanliness

5.11.4 **Temperature -** The aim of the water system both in the design and operational stages should be to ensure as far as practically possible that the hot water stays hot (above 55°C in healthcare) and the cold water remains cold (below 20°C or no more than a 2°C rise from the incoming cold water temperature).

5.11.5 **Flow -** In terms of hot water systems this is achieved by ensuring the hot water is circulated, and any single pipework runs to outlets are kept as short as possible. This is tested in operation through regular temperature testing of sentinel outlets where the hot water temperature must reach 50°C within one minute of opening an outlet. In cold water systems this flow is harder to maintain as circulation only occurs when an outlet is opened (e.g. cold water systems do not generally circulate). Similar routine water temperature testing is used to monitor this where water at an outlet must be at or below 20°C within two minutes of operation. If this level of performance is not achieved in operation of a cold water system then the installation of manual or automatic flushing can be used. These automatic flushing valves are also commonly referred to as ‘dump’ valves.

5.11.6 Usage or turnover – This is closely associated with flow (above), but in cold water systems it is desirable to ensure the cold water is subject to regular change or turnover. In healthcare, the maximum quantity or volume of stored water should be less than 12 hours at normal usage, and this is intended to ensure regular turnover of incoming water and minimise the risk of stagnation.

5.11.7 **Cleanliness –** Finally it is critical to keep all domestic water systems either hot or cold clean and free from debris and the build-up of deposits (such as scale or biofilm which can harbour micro-organisms). This is achieved with the use of WRAS approved fittings and components, the flushing and commissioning process, and regular visual inspections of water at outlets and storage vessels such as tanks.

5.11.8 Provision of backflow protection

5.11.9 In all cold water installations it is important that adequate protection be provided to all supplies against backflow. In healthcare facilities, there should be a high degree of protection not only to the water in the water supply authority's mains, but also within the installations to protect the patients and staff. In addition to backflow protection at all points of use, the whole installation protection should be provided as required by the Scottish Water Byelaws 2004.

5.11.10 Healthcare buildings and medical premises have been identified as involving Fluid Category 5 backflow risks (see Schedule 1 "Fluid Categories" from Byelaw 1 in the Scottish Water Byelaws 2004 which are defined as points of use or delivery of water where backflow is likely to involve fluids contaminated with human waste). Within healthcare facilities, water usage covers a wide range of applications, from domestic use by patients and staff to specialised use in operating departments and pathology laboratories, and with equipment such as bedpan washers and haemodialysis machines. In addition, many apparently "commercial" usages may be classed as high-risk because they are for healthcare purposes, such as centralised laundries.

5.11.11 The hot and cold water storage and distribution systems should be designed so as to avoid the risk of contamination of the water supply. Such contamination may be caused by backflow, interconnections between potable and non-potable water supplies, stagnation, contact with unsuitable

materials or substances, Legionella growth etc. The Scottish Water Byelaws 2004 require the identification, by colour-coding or labelling, of all pipework carrying fluids other than wholesome water.

5.11.12 Comprehensive guidance on the measures required to prevent contamination of the water supply is given in the WRAS 'Water Regulations Guide' and in relevant parts of BS6700: 2006, BS EN 806-2: 2005 and BS8558: 2011.

In February 2020 a Scottish Water Bylaws Inspection[4] was undertaken which identified a significant number of instances where inadequate backflow protection issues where present (42 items raised including a number of multiple instances). In March 2023 a return visit was completed and this demonstrated a significant number of areas remained to be addressed (35).[5] These reports and the level of progress achieved provides evidence of poor progress in rectifying identified areas of non-compliance to the statutory obligations of the Scottish Water Bylaws.

5.11.13 Selection of taps

5.11.14 When selecting new taps, HBN 00-09 advises against using aerators, strainers and flow restrictors at the point of discharge. Taps, components and fittings should be removable and easily dismantled for cleaning and disinfection. Consideration to the potential need to install point of use filters or similar devices also needs to be considered when selecting taps with suitable spouts and sufficient distance to maintain suitable gaps to basins and wastes and not breech Scottish Water Bylaws 2004.

5.11.15 The Water Supply (Water Fittings) Regulations 1999 place limits on the flow of water to draw-offs where plugs are not provided. Spray-type mixer taps are not recommended in healthcare premises; therefore, the type of tap

[4] Scottish Water Bylaws Inspection Report on QEUH – 28th February 2020
[5] Scottish Water Bylaws Report on QEUH– 10th March 2023

should be carefully selected to minimise the formation of water droplets and aerosols. Water flow profile should be compatible with the shape of the wash-hand basin to avoid splashing. The fitting and basin combination should be such that the water stream never discharges directly into the basin's waste outlet (see HBN 00-10 Part C – ‘Sanitary assemblies’).

5.11.16 All taps and pipeline components should as far as practical minimise the number of components and materials used in fittings and ensure internal surfaces which have direct contact with water are as smooth as possible to minimise surfaces where micro-organisms can colonise or grow. This also includes avoiding the use of flow straightening devices in tap spouts and outlets to minimise the areas where bio-film or microorganisms can colonise or grow.

5.11.17 Component Quality and WRAS Approvals

5.11.18 Any materials that come into contact with the water in a hot and cold water installation must comply with the requirements of the Scottish Water Byelaws 2004. A list of products and materials that have been assessed for compliance with the requirements of these Regulations is given in the current edition of ‘Water Fittings and Materials Directory’, which is updated every six months. Further information on the selection of materials can be found in BS6700:2006, BS EN 806-2: 2005, BS8558: 2011 and BS6920-1: 2000. At QEUH a number of components present in the domestic water systems were understood not to be WRAS approved including: flexible hoses and none flow through expansion vessels.

5.11.19 Pipework Materials

5.11.20 SHTM 04-01 Part A states within section 11 that the materials generally used for the conveyance of water in healthcare premises are stainless steel

or plastics. Copper is only used in exceptional circumstances such as, an extension to existing premises with short life expectancy, or very small stand-alone premises. Where this is specified, only lead-free solders should be used.

5.11.21 Substances leached from materials of construction of pipes, cisterns or other water fittings in contact with water must not adversely affect the quality of water stored or drawn for domestic or food production purposes (Scottish Water Byelaws 2004).

5.11.22 Whatever the preferred material for the pipework distribution system it must be of a suitable quality and as outlined above be in conformance to the Scottish Water Bylaws 2004.

5.11.23 Drainage and Waste Water Systems

5.11.24 Foul or waste water drainage systems form an integral element of effective and safe water management systems being a complementary service to the water system and if not correctly integrated and managed then it can be a significant potential risk and source of contamination and transmission source of infection.

5.11.25 For this reason in my opinion it is essential to include elements of the internal drainage systems under the remit of the WSG and as such to include essential elements of its management into the water safety plan and policies of the organisation.

5.11.26 The best way of reducing the risk posed by drainage systems is to only have water outlets and therefore their drainage connections where they are essential and particular attention and consideration should be given to the provision of water outlets in very high infection risk areas, such as ICU’s. There is good research evidence to indicate that the waste water drainage

systems can act as a major transmission route for pathogens around a healthcare facility.

5.11.27 Maintenance Options and Frequencies - Hospitals are designed to be used intensively, for different types of patients, in different care settings, using different treatments and equipment. Drainage systems are, therefore, also complex, and can be a significant source of potential contamination, infection and risk to all users if they do not work correctly or suffer breakdowns, leaks or blockages. Sewage backing up behind a blockage and flooding a hospital ward is not uncommon - and it can mean having to move patients to other busy wards while the area is cleaned.

5.11.28 Key elements of an effective drainage management strategy.

5.11.29 Drainage system records and information it is essential to have good records for all of the drainage systems including information on pipework routes, rodding points, and open vented soil stacks, etc. Plans are often inaccurate or incomplete. Misconnections and even inappropriate connections in hospital pipework are not uncommon.

5.11.30 Identifying the source of drainage problems - such as blockages, seepage or ground contamination - can be harder, and planning solutions harder still. Responding quickly to service-critical emergencies may be impossible.

5.11.31 An accurate plan/record of the drainage installation is the starting point of a drainage maintenance strategy - identifying what needs to be done as a matter of urgency, and what can be left until later.

5.11.32 Establishing effective Planned Preventative maintenance (PPM) is essential, especially because of the unique demands placed on drainage systems. In older hospital buildings, many downpipes are cast iron, so their capacity can

be reduced by oxidisation. Caustic chemicals can accelerate this process. Sanitation gels and detergents can build up in pipes.

5.11.33 Blockage problems outside buildings can affect patient services, too. Tree root infestation and drain collapses are a common cause of sewer blockages.

5.11.34 What problems can occur with my drain without drain maintenance?

5.11.35 Drainage problems unfortunately can occur over time. Whether due to build up, a root intruding on the system, vermin, or un-flushable items such as face wipes and kitchen roll being flushed down the system, there are certain issues that can occur over time. Those issues include blockages, leaks, cracks, and, in extreme scenarios, collapsed drain pipes.

5.11.36 Areas to consider include, monitoring of any slow draining toilets, wash hand basins or showers, ALL users should report any slow draining units immediately to the estates maintenance team for investigation.

5.11.37 SFG20 advises that all shower trays should be subject to quarterly cleaning (51-01) whilst this may not be practical in hospitals given the size and number of drains an annual clean is recommended as a minimum planned preventative maintenance activity.

5.11.38 Shower Tray - Waste outlet – frequency 3M - Clean and unblock waste outlet trap as necessary. If possible fit top access waste trap. More frequent maintenance may be necessary depending upon frequency of use.

5.11.39 Using this approach for all waste outlets/drains including wash hand basins and sinks may not be considered practical, however an annual visual inspection should be considered as a minimum.

5.11.40 Note – The NHS National Cleaning Specification (2007) advises that routine cleaning of showers, hand wash basins, sinks, etc… should include a surface clean of the drain and removal or any visible debris (hairs) by the use of tweezers.

5.11.41 User Actions - Control what goes down the drains

5.11.42 What patients and healthcare workers do at home, they will do in hospital. So thousands of sanitary products and wet wipes will be disposed wrongly down hospital toilets every day. In hospital canteens and kitchens, fats and oils will find their way into drains, either in residual amounts or through irresponsible disposal. These can combine and congeal to cause 'fatbergs' in hospital drain lines.

5.11.43 With macerated waste already disposed of down drains in ward sluice rooms, hospital drainage systems are under particular pressure. This makes it important to do everything possible to control what is put down drains.

5.12 Types of Automatic flushing or dump valves

5.12.1 Typically there are two principal types of these devices. Both are automatic, and once installed and commissioned will open and close at set times throughout a given period (daily, weekly, or as set). Alternatively, they can operate on a temperature basis, so if the cold water shows a temperature rise via a temperature sensor to a given set limit the valve will operate either for a set period (usually minutes) or until such time as the water temperature sensor indicates a drop in temperature to a set lower limit. So it may be set to open at 20°C and either run for a set period say 10mins or then close or run until the water temperature reaches say 18°C. If a set time period is used to control the flush then if after this time the water remains above the set point the valve would re-open and continue to flush for a further 10mins.

5.12.2 The practical impact of using automatic flushing valves is that they can lead to very high water usage and potential water wastage, which is against the guidance of HTM 07-04; however, water quality should always take priority. I would also normally recommend that some arrangement is made to measure water throughput via flushing, either by manual water metering, or many of the systems on the market include automatic flow monitoring and reporting and even allow for remote adjustment of set points and flow rates/usage.

5.13 Conclusions relating to the Design, Installation and Commissioning process

5.13.1 The domestic water systems at the point of handover/patient occupation were in a sub-optimal condition. The principal issues for this are as follows:

- The original design had included installation of incoming water filtration (as recommended by the SHTM 04-01 Part E), however, this was supplemented with a very high grade secondary ultrafiltration system in 2019. The reason and need for this very high grade of filter (0.02 micron has not been provided.
- The system had a significant level of identified issues and potential risks (as identified by the pre-occupation risk assessment).
- The commissioning process had failed to follow the requirements of the SHTM and involved wet testing, partial draining down and refilling of water systems prior to being made fully operational.
- No formal validation process was followed and where failed water sampling was found, no formal process for retesting appears to be have been in place, as outlined in section 5.9 of this report.
- There is no evidence of the TMV/TMT commissioning and stabilisation tests being completed (which is a critical element of the NHS anti-scalding process which has a classification as a never event) as outlined in section 6.2 of this report.

5.13.2 Overall the system was not fully compliant and issues were known and acknowledged the system was accepted into operation and at that time the NHSGCC did not have all of the necessary controls or processes in place to manage or address the potential risks, as detailed in the following section.

5.13.3 The type of components installed within the water systems did not minimise the number of components or elements within components and this may have provided additional surface areas or ‘nooks and crannies’ where microorganisms could colonise and produce bio-film.

5.13.4 The lack of adequate backflow protection as identified by the Scottish Water Bylaw inspections also raises significant concern over the adequacy of the design and installation process.

6. Maintenance and Operation of the water system

6.1 Water Safety Plan/Policy (Water Written Scheme and Operational Procedures)

6.1.1 The site has had in place a number of documented Policies and Water Safety Risk Assessments, Written Schemes, and Water Safety Plans over the period since handover.

6.1.2 The Water Policy, since 2015, has been evolving and has had a number of revisions and amendments, often overlapping with the policy duration. Drafting and revisions of the Water Safety Policy were undertaken by members of the Water Safety Group.

6.1.3 The NHSGGC Water Systems Safety Policy (January 2020) was reviewed and found to be comprehensive if generic in content and format and contained limited site specific information.

6.1.4 The current Policy Document ‘Water Systems Safety Policy January 2024 (V2)’ is considered comprehensive in terms of content, however remains limited on site specific information and detail, although this is covered in supporting documents including the QEUH Campus Water System Written Scheme-2023 Rev H.

6.1.5 Following a review of the current Policy and Written scheme they appear satisfactory and comprehensive, although there is a potential query relating to the frequency of TMV/TMT testing which is detailed below as six monthly, which is compliant but referenced as quarterly within the written scheme.

6.2 Thermostatic Mixing Valves

6.2.1 There is clear evidence of on-going routine six monthly testing of installed TMVs, however, it should be noted that the formal recording forms/excel information provided does not include full technical details such as water

volumes and timings of fail-safe results, although it does clearly record results. It is also noteworthy to record that the testing programme, where remedial actions identify the need to replace TMVs/TMTs the stabilisation tests at six and 12 weekly intervals is not recorded.

6.2.2 Within the records reviewed there are also a small number of instances where access was not possible and tests were not completed, with no clear records of how these tests were subsequently completed.

6.3 Water Temperatures

6.3.1 From the evidence provided, there are comprehensive records for the routine testing of both hot and cold water temperatures. These records have been sampled and found to be suitable, adequate, and in line with the recommendations of the SHTM standard.

6.3.2 **2015:** All available sentinel tap temperature, calorifier and water storage tank temperature records.

6.3.3 **2016:** All available sentinel tap temperature, calorifier, water storage tank and representative tap temperature records from TMV servicing.

6.3.4 **2017:** All available sentinel tap temperature, calorifier, water storage tank and representative tap temperature records from TMV servicing.

6.3.5 **2018:** All available sentinel tap temperature, calorifier and representative tap temperature records from TMV servicing.

6.3.6 **2019 to 2021:** All available sentinel tap temperature, calorifier and representative tap temperature records

6.3.7 **2022 to 2023:** All available sentinel tap and representative tap temperature records.

6.3.8 BMS Monitoring Records have been recorded since 2018.

6.3.9 Calorifiers are sited within the plantrooms. The flow and return temperatures are recorded electronically every 15 minutes. Each calorifier has an individual flow sensor however each set of three calorifiers has a common return temperature. The available date range varies for these records. Plantroom 31 has nine calorifiers and each of the other plantrooms have three calorifiers. Records are provided in an excel format with the date ranges as follows:

- Plantroom 21: February 2018 to present day
- Plantroom 22: March 2018 to present day
- Plantroom 31: 1 to 3: January 2018 to present day
- Plantroom 31: 4 to 6: January 2018 to present day
- Plantroom 31: 7 to 9: January 2018 to present day
- Plantroom 32: March 2018 to present day
- Plantroom 33: January 2018 to present day
- Plantroom 41: September 2021 to present day

6.4 Common Domestic Hot Water flow and return temperatures

6.4.1 There are monitoring points on the common hot water flow and return pipework on each level of the hospital. These temperatures are recorded and stored on the BMS system.

6.5 Cold water temperatures

6.5.1 There are monitoring points on the cold water pipework on each level of the hospital. These temperatures are recorded and stored on the BMS system.

6.6 Water Sampling

6.6.1 SHTM 04-01 Water safety for healthcare premises Part B: Operational management (Jul 2014) clearly states that routine water testing is not strictly a requirement, as below:

6.6.2 Clause 9.1 – Apart from situations where there are taste or odour problems, microbiological monitoring for TVCs is not considered to be necessary. However, many estates management staff continue to test for TVCs notwithstanding any conflict with the requirements of L8 as any obvious changes in monitored levels provide a useful rule of thumb early warning of possible emerging problems.

6.6.3 If performed for these purposes, the detection of low TVCs is not necessarily an indication of the absence of Legionella, but is an indication of the overall water quality and signifies a generally unfavourable environment for bacteria.

6.6.4 All microbiological measurements should be approved methods and/or be carried out by the appropriate United Kingdom Accreditation Service (UKAS) accredited laboratories. Dip slides are not acceptable.

6.6.5 The SHTM 04-01 Water Safety for Healthcare Premises Part B: Operational Management (Jul 2014) goes on to state that although routine water testing is not strictly a requirement, as below:

6.6.6 Chapter 10 - Testing for Legionella highlights under clause 10.1;
Legionella can exist within many systems at extremely low levels or below the threshold of decision making (100 cfu/litre). Up to now, in the absence of evidence of healthcare-associated infection, testing (which is complex and expensive) has not been considered necessary.

6.6.7 Clause 10.2 – The infection prevention and control team, however, will need to consider the level of risk before deciding that Legionella testing is indicated. For example, testing may be required:

- when storage and distribution temperatures do not achieve those recommended under the temperature control regime and systems are treated with a biocide regime, a monthly frequency of testing for Legionella is recommended. This may be reduced as confidence in the efficacy of the treatment regime is established;
- in systems where the control regimes are not consistently achieved, for example temperature or biocide levels (weekly checks are recommended until the system is brought under control);
- when an outbreak is suspected or has been identified;
- a Written Scheme is to be prepared indicating all sentinel taps. This is the responsibility of the designer;
- on hospital wards with at-risk patients – for example those who are immuno-compromised.

6.6.8 Clause 10.3 As a minimum, samples should be taken as follows:

- from the cold water storage and the furthermost outlet from the tank, on every loop;
- from the calorifier flow, or the closest tap to the calorifier, and the furthermost tap on the hot water service circulating system;
- additional samples should be taken from the base of the calorifier where drain valves have been fitted;
- additional random samples may also be considered appropriate where systems are known to be susceptible to colonisation.

6.6.9 The temperature control regime is the preferred strategy for reducing the risk from Legionella and other waterborne organisms in water systems. This will require monitoring on a regular basis.

6.6.10 The recommended test frequencies for various outlets are set out in Table 2 in Section 7.

6.6.11 Clause 10.4 – The sampling method for Legionella should be in accordance with ISO 11731: 2004. A UKAS-accredited laboratory that takes part in the Health Protection Agency's water external quality assessment (EQA) scheme for the isolation of Legionella from water should test samples. The laboratory should also apply a minimum theoretical mathematical detection limit of ≤100 Legionella bacteria/litre sample.

6.6.12 The nature of clinical care and patient profile within QEUH clearly fits a number of the recommended criteria for routine water sampling. From the expert witness report on Quantitative analysis undertaken to understand the association between the built environment and rates of gram-negative and fungal bloodstream infections at the Schiehallion unit between the years 2015 and 2022. In the report prepared by Sid Mookerjee, it can be seen that some degree of routine water sampling was undertaken over the stated period. See Expert Report on Quantitative analysis undertaken to understand the association between the built environment and rates of gram-negative and fungal bloodstream infections at the Schiehallion unit between the years 2015 and 2022. Prepared by Sid Mookerjee, BSc. MSc. MPH. FRSPH (extract below clause 5.4.19).

Year	Water samples taken (deduped)	*Pseudomonas.spp* positive (deduped)	Fungal positives (deduped)	*Cupriavidus.spp* positive (deduped)	*Serratia.spp* positive (deduped)	*Stenotrophonomas.spp positive* (deduped)	Cumulative positive	Rate of water positivity (as a proportion of total samples taken)
2015	80	2	0	0	0	0	2	2.5%
2016	47						0	0.0%
2017	196			15			15	7.7%
2018	1158	8	85	104	2	2	201	17.4%
2019	1809	22	76	59	0	43	200	11.1%
2020	1469	4	11	28	0	39	82	5.6%

6.6.13 The analysis within the report demonstrates that the level of water sampling undertaken in the initial years after handover were substantially lower in number than in subsequent years (after 2017).

6.6.14 This reduced level of testing in the initial years of operation is in direct contradiction to the issues of temperature control highlighted in the Pre-occupation risk assessment which highlighted high numbers of outlets with higher than compliant cold water temperatures. Note – I have deliberately excluded any microbiological analysis of the results of this sampling regime and restricted my observations to the technical compliance to the respective SHTM standard.

6.7 Cold Water Storage Tanks

6.7.1 The cold water storage tanks are located in the basement plant room. Water is delivered on site into raw water tanks before being drawn through a filtration system and then stored in the bulk water storage tanks. This water is then distributed throughout the site. The stored temperatures are recorded electronically every one hour.

7. Post completion works/improvements to address identified Issue present from handover

7.1 Domestic hot water expansion vessels

7.1.1 Following installation and completion of the Chlorine Dioxide system, a programme of replacing the domestic hot water expansion vessels took place. This was to comply with an action identified in the risk assessment advising the vessels should be of the flow through type. The pipework was amended to accommodate the new design of these vessels and on completion, the vessels, calorifiers and pipework were disinfected, the vessels commissioned to the required system pressure and placed back into service.

7.2 March 2019 filtration system

7.2.1 An additional filtration unit was fitted and commissioned in March 2019 in the basement plantroom, increasing the number of units from two to three. Commissioning of the units was by the installer, Veolia, and satisfactory certification provided. The three units were commissioned within the BMS system by Schneider to operate on a duty-duty stand-by rotation allowing one unit to be off line for planned maintenance when required, leaving two units operational.

7.3 March 2022 RHC Ward 2A/2B

7.3.1 Ward 2A/2B underwent refurbishment which included a partial re-design of the water system, and was re-opened in March 2022. Prior to handover, testing, temperature checks, disinfection and microbiological sampling were undertaken. This was followed by a revised and updated water systems risk assessment.

7.4 Verification of operation for water systems since handover

7.4.1 A water safety plan and a written scheme for the operational management of water systems provides the framework for verification of maintenance, for local accountability and statutory obligations. The written scheme lays out a template for operational procedures including frequency of tasks and a hierarchy of control. The operational implementation of this written scheme is managed by the Authorised Person for Water (APW).

7.4.2 Prior to the QEUH and RHC being occupied, a pre-occupation risk assessment was undertaken by DMA and issued in April 2015. This included a site-specific written scheme for the QEUH and RHC to adopt.

7.4.3 NHSGGC had an Authorising Engineer for Water (AEW) for all properties under the control of the Board. The AEW recommends the appointment of an APW, however, there is no record of an APW being appointed in writing for QEUH and RHC until June 2018. From Handover in 2015, the management and implementation of planned and reactive tasks relating to the water systems was undertaken by Estates Officers and Estates Managers who had transferred to the new facility from other locations.

7.4.4 In 2015, the required Operation and Maintenance (O&M) manual showing a proposed, and generic, schedule of Water Systems Plant and Equipment Planned Preventative Maintenance was not uploaded until November 2015. There are limited records available demonstrating planned maintenance or monitoring was undertaken. As the site was less than a year into operation no annual AEW audit was undertaken in 2015.

7.4.5 In 2016, a review of the pre-occupation Risk Assessment was undertaken in March 2016. The review indicated that there were still a significant number of tasks not being undertaken. There is evidence that the estates team were developing maintenance schedules in 2016 and there are limited records available to evidence that planned maintenance or monitoring in line with

the proposed maintenance schedules was being undertaken. No AEW audit was undertaken in 2016.

7.4.6 In May 2017, a Water Systems Safety Policy, Written Scheme and Operational Procedures document was published and approved by the Board Infection Control Committee (BICC). This document was for the whole of GGC and was therefore relevant to QEUH and RHC. Also in May 2017, the first AEW audit was undertaken on the new site. The auditor noted that there was a system of water management in place however there were limited records recording planned maintenance or monitoring of systems available at the time of the audit. The auditor provided a list of recommendations including that a full Written Scheme, in accordance with the requirements as outlined in Appendix 2 of the HSG 274 document should be created for the site. The auditor recommended that a new Risk Assessment be undertaken for the site which was undertaken in October of 2017, however, it was not presented for review until 2018. Post audit records are available for some areas and indicate work was undertaken by contractors in relation to servicing Thermostatic Mixing Taps.

7.4.7 In 2018, the Written Scheme was developed through the early part of 2018 for the QEUH Campus naming those persons with appointed duties in the monitoring and management of the water system. A further draft was produced in December 2018 (Version E). The new Risk Assessment commissioned in 2017 was issued in April 2018 in accordance with the recommendation of the 2017 AE Audit. The annual AEW audit was undertaken in July 2018 in which the auditor noted “that there have been significant improvements and advances in the delivery of the water system risk reduction processes and since the previous audit was completed in 2017”. APW appointments were made in June 2018 and August 2018. In September 2018, a further risk assessment was instructed to be undertaken. The scope of the new assessment was agreed by the Compliance Manager and a contractor engaged to undertake some

maintenance and monitoring activities in 2018 in accordance with identified tasks within the Written Scheme. NHS Estates staff undertook other identified tasks within the written scheme.

7.4.8 In 2019, there was no AE audit undertaken. The Chlorine Dioxide dosing system came on line in February 2019 and records for ClO2 measurement were implemented to verify the system was operating correctly. In conjunction with this, programmes for increased water sampling, point of use filter (POUF) exchanges, shower head and hose exchanges and sentinel temperature recording across the hospital were put in place and records kept to verify this work being done. A Written Scheme review was undertaken in by the Compliance Manager and the Lead APW in May 2019 to reflect changes to the system. DMA, with expanded tasks, continued to be engaged as a contractor to undertake maintenance activities in 2019 in accordance with identified tasks within the Written Scheme. Scotmas provided assurance on the efficacy of the ClO2 dosing system. NHS Estates staff undertook other identified tasks within the written scheme.

7.4.9 In 2020, an AEW audit was undertaken. The auditor commented that many of the required tasks are being completed, however, he made recommendations to improve record keeping to evidence that planned maintenance or monitoring in line with the proposed Written Scheme was evidenced as being undertaken. DMA continued to be engaged as a contractor to undertake maintenance and monitoring activities in 2020 in accordance with identified tasks within the Written Scheme. Scotmas provided assurance on the efficacy of the ClO2 dosing system. NHS Estates staff undertook other identified tasks within the written scheme.

7.4.10 In 2021, a further AEW audit was undertaken and the auditor reported that there were now significant improvements in all aspects of the water management on site. The recommendations made by the auditor were primarily administrative tasks. DMA remained engaged as a contractor to

undertake maintenance and monitoring activities in 2021 in accordance with identified tasks within the Written Scheme. Scotmas provided assurance on the efficacy of the ClO2 dosing system. NHS Estates staff undertook other identified tasks within the written scheme.

7.4.11 In 2022, the now routine AEW audit was undertaken and the auditor reported a high level of completion of the required tasks at both hospitals and a continued improvement on the performance of the management and control systems since 2021. The auditor also highlighted that the close working relationship between the NHS GGC Estates Department and the contractors, DMA and Scotmas, which appears to be important in delivering the required risk reduction processes and procedures. The recommendations made by the auditor included that a new QEUH/RHC risk assessment be commissioned as soon as possible. An instruction to undertake a Risk Assessment for the whole campus had been issued, and was underway for other water systems in the campus. Further recommendations included a review of the monitoring system for temperatures although the system was being monitored and managed in a safe manner. DMA remained engaged as a contractor to undertake maintenance activities in 2022 in accordance with identified tasks within the Written Scheme. Scotmas provided assurance on the efficacy of the ClO2 dosing system. NHS Estates staff undertook other identified tasks within the written scheme.

7.4.12 In 2023, the AEW audit was undertaken and the auditor reported, in regard to the water systems at the QEUH/RHC hospitals, that the delivery of the required risk reduction processes and procedures was virtually complete. The auditor further stated that the level of knowledge and understanding of the onsite Estates' staff is extremely high and a diligent approach is taken to ensuring that the water systems are operated in a manner required to deliver high quality risk reduction processes and procedures. The auditor included a recommendation that a new QEUH/RHC risk assessment is

commissioned. In total, the audit identified nine key recommendations which demonstrates a positive improvement from the previous year, down from 23 recommendations.

1. It is recommended that NHS GGC ensure that an updated risk assessment for the QEUH and RHC buildings is completed as soon as possible.
2. It is recommended that a check is made to confirm when the other water systems are going to be risk assessed by a competent supplier for these particular types of water systems.
3. It is recommended that a process that ensures that any changes made which require updated drawings can be passed to the CAD manager for inclusion in the drawings file.
4. It is recommended that schematic drawings are reviewed at least annually and amended and updated to reflect any water system changes.
5. It is recommended that the requirement for CP training for the QEUH staff is evaluated and that appropriate training, if required, is delivered to the appropriate staff members.
6. It is recommended that non TMT'd or TMV'd outlets are used to record the temperatures of the actual hot water temperatures going to the TMT or TMV, or that temperatures are recorded from the surface of hot water pipes going to the TMT's/TMV's.
7. It is recommended that non TMT'd or TMV'd outlets are used to record the temperatures of the actual cold water temperatures going to the TMT or TMV, or that temperatures are recorded from the surface of cold water pipes going to the TMT's/TMV's.
8. It is recommended that until the expansion vessels are converted to flow through, that a flushing programme is initiated as soon as possible
9. It is recommended that the practicability of twice yearly servicing of the TMVs/TMTs is reviewed and that a confirmed, risk assessed and agreed way forward for TMV/TMT servicing is created.

7.5 NHSGGC Water Safety Group

7.5.1 A formal Water Safety Group (WSG) should have been in place throughout the design development process and been engaged to review and comment on design proposals. Given that this was not the case then a WSG should have been established at the point of handover to provide an assessment of compliance and assurance that the NHSGGC Board had received a fully compliant domestic water installation. It should be noted that ideally this approach should have been replicated for all significant building/engineering services.

7.5.2 It is understood that the WSG was effectively founded in 2017 and instigated and oversaw the appointment and activities of the Authorising Engineer (Water). Whilst progress had been made from the time of handover to the appointment of the AE(W) this was the first time that clear evidence and external assurance was provided for the water systems, and since 2017 both the management of the systems, and progress to address issues has significantly improved.

7.5.3 It is recommended that the Lead RP/AP(W) should produce a quarterly status report to supplement and support the annual AE(W) Audit process using the format outlined below (subject to local agreement and alteration as appropriate and agreed with the WSG).

7.6 Provision of personnel and resources

7.6.1 From the evidence provided and findings from the AE(W) audit reports it would appear that the site was handed over and became operational without an appropriate planned preventative maintenance (PPM) programme in place. Site Estates staff were providing a reactive service and in many cases trying to address defects or snagging issues left from the construction process. The level of resource availability for given roles was repeatedly

highlighted as a concern and this remains a potential area of increased risk to the current day (see section on areas for potential improvement below).

7.6.2 Training and competency for staff

7.6.3 All personnel who are engaged with tasks and duties in connection to the safe operation of the domestic water systems should have as a minimum an appropriate level of awareness of the water systems and the potential implications and risk associated with their role in the management of these systems. The level of awareness needs to cover both the general issues associated with the water systems and the specific training and skills to undertake any specific operational tasks, such as flushing, cleaning, or maintenance activities.

7.6.4 SHTM 04-01 Part B clause 6.2 clearly states that any person intending to fulfil any of the staff functions specified should be able to prove that they possess sufficient skills, knowledge and experience to be able to perform safely the designated tasks.

7.6.5 Water hygiene training – Individuals to whom tasks have been allocated need to have received adequate training in respect of water hygiene and microbiological control appropriate to the task they are responsible for conducting. The training and competence assessment should be clearly defined and should include those responsible for simple housekeeping tasks such as outlet flushing and the cleaning of handwash basins, through to maintenance staff and up to individuals who define strategy and develop procedures. It is important that any person working on water distribution systems or cleaning water outlets should have completed a water hygiene awareness training course so that they can gain an understanding of the need for good hygiene when working with water distribution systems and water outlets, and of how they can prevent contamination of the water supply and/or outlets.

7.6.6 From the AE(W) Audit reports it is clear that whilst the Estates technical and managerial staff are now extremely well versed in the issues of water safety and the members of the water safety group are also suitably experienced there is little to no evidence of general staff such as domestic services or contractors being provided with or providing assurance of a general water safety awareness training or assessment process.

7.7 Quarterly WSG Operational Update Report

7.7.1 As part of the provision of assurance from the AP(W) to the WSG it is recommended that a suitable summary status report should be used to provide a regular (quarterly) update on critical elements and ongoing issues. The concept of this report is to produce an overview or summary of water management and control systems on an operational site basis to members of the Water Safety Group (WSG) to provide assurance that appropriate management controls are in place to maintain a safe water system and minimise the risks to the organisation associated with the water systems and comply to legal obligations. Typical elements to cover should include:

7.7.1.1 **Hot and cold water trend analysis graph –** Provide a graph of water temperatures over the reporting period (three months) ideally showing hot water flow and return temperatures at the calorifier/plantroom, and incoming or cold water tank temperatures. This data should be available from the BMS system and be plotted onto a simple line graph for easy interpretation by WSG members. Any spikes or deviations from norms should have an accompanying explanation and details of corrective actions taken to manage the issue.

7.7.1.2 **Operational incidents (by exception) –** Provide details outside temperature issues (reported above) that have occurred (e.g. leaks, service interruptions, significant breakdowns, etc.).

7.7.1.3 **PPM's and reactive works requests within quarter –** Provide details of PPM's generated and completed, and water related reactive requests received and completed with details of any work still in progress. Also provide information to root causes for delayed completion such as access etc.

7.7.1.4 **Flushing of little used outlets –** Provide a statement of compliance or details of areas which are not fully recorded as being flushed in line with organisations SOP/policies. Provide a schedule of outlets which the WSG may want to consider removal of to eliminate the need for flushing.

7.7.1.5 **Water sampling test results (if undertaken) –** Provide details of any water sampling undertaken (total number of samples) and any notifiable or actionable readings by exception including location, level of count, and corrective actions taken to address and if available status of any re-sampling where required.

7.7.1.6 Water Risk Assessment Remedial Action Progress – Provide a summary of the current WRA identified remedial actions. Include date of current assessment, number of red, amber or green remedial actions originally identified and current number of remaining remedial actions under each RAG rating.

7.8 Conclusions relating to the maintenance and operation of the water system

7.8.1 At handover there was not an appropriate Water Safety Group in place. As a result of this, the information available at handover was not highlighted as inadequate and the identified defects from the design, installation, commissioning, and validation stages (as evidenced by the pre-occupation risk assessment) were not adequately managed.

7.8.2 At the point of handover it would appear from the evidence provided and comments made during the site inspection that estates resources were predominantly occupied with addressing issues identified as defects rather than full maintenance issues. This can be evidenced by the issue that full O&M information was not provided for at least six months after handover.

7.8.3 Formal PPM schedules were not in place, and gaps remain to this day in areas such as TMV/TMT maintenance and stabilisation tests following replacement.

7.9 Current condition and potential issues and risks

7.9.1 The latest AE(W) Audit report highlights a number of issues to be addressed, however, it should be stressed that these types of issue are not uncommon within many healthcare establishments and generally the level of control and maintenance provision appears to be satisfactory.

7.9.2 The water safety group is in place and operating effectively with a clear route to escalate issues when needed, although a formal quarterly update/status report from the lead RP/AP(W) would be a useful system improvement.

7.9.3 The current water safety plan/policy is considered appropriate and suitable for the management of the water systems at QEUH. However, given the

issues identified in the design, construction, and handover process it is considered appropriate to recommend a review of the water system provision as outlined below. This review/assessment would provide a baseline from which subsequent routine reviews and assurance monitoring can be measured from.

7.9.4 A full multi-disciplinary assessment of each clinical speciality should be completed for all clinical areas to identify current areas where water systems are a significant potential risk factor in patient safety. Each identified area should have the current provision of water services assessed to identify where systems may require amendment, for example, removal of excessive hand wash basins or inadequate space provision around water outlets to prevent/minimise water splashing or cross contamination, along with a clinical and IPC agreed minimum performance standards (informed from the current SHTM and best practice). This assessment process should include waste water systems and drainage locations.

7.9.5 It is entirely possible that following the assessment phase of review that it is impractical to modify existing facilities and in such circumstances clinical activities may need to be suspended or stopped until suitable compliant facilities can be provided/identified. This may result in a reduction of clinical activity or bed numbers as a means to accommodate suitable water provision or room layouts or other essential building services.

7.9.6 All improvement works would need to be subject to fully compliant commissioning and independent validation reviews to ensure the works are effective in providing the agreed minimum performance standards.

7.9.7 The Water Safety Group and Board need to agree a formal process to manage all derogations for all NHS standards (SHTM’s and SHBN’s), and develop a suitable process to agree, record, review and manage all essential derogations moving forwards, and include a suitable assessment

process of these as an integral element of any planned clinical service developments or moves (see section 3.19 of this report).

7.9.8 In some cases it may prove necessary to temporarily or even permanently to suspend clinical services whilst areas are modified to achieve agreed minimum standards. If practical limitations of plant space or current building structure prevent achievement of minimum standards then the clinical activities should be suspended until such time as a suitable and fully compliant facility can be provided.

8. Other Influencing Factors

8.1 BREEAM

8.1.1 BREEAM for new construction is a performance based assessment method and certification scheme for new buildings. The primary aim of BREEAM New Construction is to mitigate the life cycle impacts of new buildings on the environment in a robust and cost effective manner. This is achieved through integration and use of the scheme by clients and their project teams at key stages in the design and procurement process. This enables the client, through the BREEAM Assessor and the BRE Global certification process, to measure, evaluate and reflect the performance of their building against best practice in an independent and robust manner. This performance is quantified by a number of individual measures and associated criteria stretching across a range of environmental issues (see below), which is ultimately expressed as a single certified BREEAM rating.

BREEAM 2011 New Construction environmental sections and assessment issues

Energy

- Reduction of CO2 emissions
- Energy monitoring

- Energy efficient external lighting
- Low or zero carbon technologies
- Energy efficient cold storage
- Energy efficient transportation systems
- Energy efficient laboratory systems
- Energy efficient equipment (process)
- Drying space

Water

- Water consumption
- Water monitoring
- Water leak detection and prevention
- Water efficient equipment (process)

Waste

- Construction waste management
- Recycled aggregates
- Operational waste
- Speculative floor and ceiling finishes

Transport

- Public transport accessibility
- Proximity to amenities
- Cyclist amenities
- Maximum car parking capacity
- Travel plan

Materials

- Life cycle impacts
- Hard landscaping and boundary protection
- Responsible sourcing of materials
- Insulation
- Designing for robustness

Land use and ecology

- Site selection
- Ecological value of site/protection of ecological features
- Mitigating ecological impact
- Enhancing site ecology
- Long term impact on biodiversity

Pollution

- Impact of refrigerants
- NOx emissions
- Surface water run-off
- Reduction of night time light pollution
- Noise attenuation

Health and wellbeing

- Visual comfort
- Indoor air quality
- Thermal comfort
- Water quality
- Acoustic performance
- Safety and security

Management

- Sustainable procurement

- Responsible construction practices
- Construction site impacts
- Stakeholder participation
- Service life planning and costing

Innovation

- New technology, process and practices

8.1.2 The project design and ultimately the ‘agreed’ performance specification appears to have been strongly influenced by the desire to achieve a certain BREEAM rating. The BREEAM assessment system is not specifically designed for healthcare buildings and should never be used as a primary performance driver where clinical or Infection prevention and control needs could be jeopardised or compromised.

9. Conclusion on Current Technical Management Arrangements and Areas of Potential Improvement to minimise risk of future patient infections associated with water provision.

9.1.1 The following are recommendations for the future management of water systems based on the information reviewed for the site and from the authors' professional opinion and experience:

9.1.2 The latest AE(W) Audit report highlights a number of issues to be addressed, however, it should be stressed that these types of issue are not uncommon within many healthcare establishments and generally the level of control and maintenance provision appears to be satisfactory.

9.1.3 The water safety group is in place and operating effectively with a clear route to escalate issues when needed, although a formal quarterly update/status report from the lead RP/AP(W) would be a useful system improvement.

9.1.4 The current water safety plan/policy is considered appropriate and suitable for the management of the water systems at QEUH.

9.1.5 All staff working within the hospital environment should receive a basic level of water hygiene awareness training and especially those involved in the flushing, cleaning or use of the water services need to have a reasonable understanding of waterborne pathogens, there transmission, control and impact to patient safety.

9.1.6 A full multi-disciplinary assessment of each clinical speciality should be completed for all clinical areas to identify current areas where water systems are a significant potential risk factor in patient safety. Each identified area should have the current provision of water services assessed to identify where systems may require amendment, for example, removal of excessive

hand wash basins or inadequate space provision around water outlets to prevent/minimise water splashing or cross contamination, along with a clinical and IPC agreed minimum performance standards (informed from the current SHTM and best practice). This assessment process should include waste water systems and drainage locations.

9.1.7 It is entirely possible that following the assessment phase of review that it is impractical to modify existing facilities and in such circumstances clinical activities may need to be suspended or stopped until suitable compliant facilities can be provided/identified. This may result in a reduction of clinical activity or bed numbers as a means to accommodate suitable water provision or room layouts or other essential building services.

9.1.8 All improvement works would need to be subject to fully compliant commissioning and independent validation reviews to ensure the works are effective in providing the agreed minimum performance standards.

9.1.9 The Water Safety Group and Board need to agree a formal process to manage all derogations for all NHS standards (SHTMs and SHBNs), and develop a suitable process to agree, record, review and manage all essential derogations moving forwards, and include a suitable assessment process of these as an integral element of any planned clinical service developments or moves.

9.1.10 In some cases it may prove necessary to temporarily or even permanently to suspend clinical services whilst areas are modified to achieve agreed minimum standards. If practical limitations of plant space or current building structure prevent achievement of minimum standards then the clinical activities should be suspended until such time as a suitable and fully compliant facility can be provided.

9.1.11 The current provision of maintenance and estates management staff (AP(W)'s and CP(W)'s) needs to be reviewed and potentially increased to ensure adequate assurance can be provided to the Board of ongoing progress on improvement works and operational compliance, including but not limited to the review of all maintenance records and timely corrective action to all identified issues.

Declaration

I understand that my duty is to help the Inquiry on matters within my expertise and that this duty overrides any other obligation.

I have stated the substance of all material instructions, on the basis of which the report is written. My evidence is my independent product, uninfluenced by external pressures.

The opinions I have expressed are objective, unbiased and based on matters within my own expertise and I have not adopted the role of an advocate. I have made clear if a question or issues falls outwith my area of expertise.

I have considered whether there is a conflict of interest and declared any potential conflict identified.

I have given details of any literature or any other material relied on in making the report.

I have set out the substance of all facts which are material to the opinion expressed in this report or upon which my opinions are based.

I have said when there is a range of opinion on a relevant issue and summarised the range of opinions and I have formed my own independent view as to the appropriate point in that range applicable to this case and given reasons for that view.

I have made clear which of the facts stated in the report are within my own knowledge. Those that are within my own knowledge I confirm to be true. The

opinions I have expressed represent my true and complete professional opinions on the matters to which they refer.

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Date: 10/06/24

Mr Andrew Poplett

10. Appendices

10.1 Appendix 1 – CV and Professional Qualifications

Detailed CV Statement - Andrew Poplett - IEng, MIHEEM, ACIBSE, AffIFE

I am an Authorising Engineer (AE) and currently employed as an independent healthcare consultant, where my role is to provide input/expertise to health facilities in relation to ventilation and water. An AE acts as an independent professional adviser to the healthcare organisation. The AE should be appointed by the organisation with a brief to provide services in accordance with the relevant Health Technical Memorandum (HTM). The professional status and role required may vary in accordance with the specialist service being supported. The AE acts as assessor and makes recommendations for the appointment of Authorised Persons (APs), monitors the performance of the service, and provides an annual audit to the Designated Person (DP). To effectively carry out this role, particularly with regard to audit, the AE should remain independent of the operational structure of the healthcare organisation.

Experience and Expertise

I started my career as an apprentice engineer in 1985, working for an installation building services company. During my six years with the company I undertook various aspects of design, contract supervision and installation work across a range of industrial and healthcare building services projects. I was later made redundant from this role, however was successful in gaining employment within the NHS as an operational estates officer working at an acute district general hospital.

Within this role I began to specialise in ventilation within some of the critical units within that hospital as well as general estate management. Due to my role I moved between a number of NHS trusts, often as a result of trusts mergers. This led to me taking up the role of head of estates for a learning disabilities trust in Northumberland, which later merged to form the then largest mental health trust in England and I took up the role of head of property and planning. In 2010 an opportunity arose for me leave the

NHS, which I chose to do and set myself up as an independent healthcare consultant. I now provide independent, impartial and bespoke consultancy services such as system auditing, personnel assessments and awareness training, compliance reviews and action planning to assist and guide clients through the maze of NHS, HSE guidelines, legislation and compliance. I act as an Authorising Engineer, and present my knowledge on subjects such as healthcare ventilation and water system management, service improvements and incident investigations.

During the last 14 years as a healthcare consultant, I have undertaken various support consultancy roles for a number of both private and NHS healthcare providers. Following the Health Technical Memoranda (HTM) 00 recognising the role of Authorising Engineer (AE) I began to practise as an AE for specialist ventilation and water, formally registering through IHEEM, which is the Institute of Healthcare Estates and Engineering Management. An Authorised Engineer is independent and appointed (normally by an NHS Trust or PFI Principle Service Provider) to take responsibility for effective management of safety guidance recommended by the Department of Health. Part of the AE role is to undertake an annual audit of the operation of facilities. The role and remit of an AE is the same in both the HTM and SHTM.

I have been peer-reviewed and operate now as a registered AE for both specialist ventilation and for water separately. The peer review process (by the Institute of Healthcare Engineering and Estate Management (IHEEM)) provides a level of assurance that the AE has been assessed by their peers to work and act in a manner and standard which meets the institutes code of practice and conforms to the requirements of the HTM. This role keeps me busy and I currently practice as an independent AE for around 35 to 40 healthcare organisations, principally NHS trusts, but I also act on behalf of trusts for a number of private healthcare providers through Private Finance Initiative (PFI) or Local Improvement Finance Trust (LIFT) arrangements.

I am an incorporated engineer registered with the Engineering Council and a full member of IHEEM. I am an associate member of the Chartered Institute of Building

Services Engineers, (CIBSE) and an affiliate member of the Institute of Fire Engineering. I am currently a committee member of the Northeast Regional IHEEM Committee and Chair of the national IHEEM ventilation technical platform. I am also a founder member of the Specialist Ventilation in Healthcare Society (SVH), which is an independent society that was set up by Malcolm Thomas, the President, who is the lead author of the previous and current ventilation Health Technical Memoranda (HTM), such as HTM 2025, HTM 03-01 2007, and lead author on HTM 03-01 2021. The SVH Society was formed in November 2014 with the aim of bringing together those who were practicing or wished to become Authorising Engineers (Ventilation) (AE(V)) or who have a more general interest in Ventilation in the Healthcare setting. At this time I am only a member of the SVH and have no details on the membership but know it holds a register of practicing AEs and draws up competencies for prospective AEs. Those interested in ventilation for healthcare can also subscribe to association membership. A significant portion of the Society meetings is given over to discussing and clarifying interpretation of HTM 03-01 and other healthcare ventilation standards.

As a member of the SVH Society, I have been lead author and published various guidance or supplementary guidance documents on aspects of ventilation within a healthcare setting. I have also lead authored a couple of guidance notes and supplementary briefing notes for IHEEM's ventilation technical platform, and written numerous articles on ventilation-related issues and the management of ventilation for the Health Estates Journal, which is the magazine of IHEEM and healthcare engineering. Attached at Appendix 1is a summary overview of my work history and involvement with articles and guidance for the institutes and Societies to which I belong.

Employment History and Resume of Andrew Poplett – IEng, MIHEEM, MSVHSoc, ACIBSE, AffIFE

Summary Employment History

Trained and qualified as a mechanical building services engineer (BTec HNC) (1985-89)

September 1985 to September 1991 : Haden Young Limited Newcastle upon Tyne

Worked as a specialist project engineer (commissioning and snagging) 1992 started work for the NHS as an operational Engineer

January 1992 to April 2000 – Newcastle General Hospital / Newcastle City Health NHS Trust

Following the completion and implementation of the Newcastle Services Review (NSR) became an Operational Engineer (Specialist Services) Newcastle General Hospital within the newly formed Newcastle City Health NHS Trust, where through internal promotion became Acting Estates Manager.

Lead engineer on Aspergillus “outbreak” in Newcastle (1998) helped develop containment precautions for Aspergillus control standards (NDSC Ireland)

April 2000 to March 2006 - Northgate and Prudhoe (NHS) Trust

In 2000 became Head of Estates for Northgate and Prudhoe NHS Trust

April 2006 to May 2009 - Northumberland Tyne and Wear (NHS) Trust

Due to a merger of three existing NHS Trust’s became Head of Property and Planning for Northumberland Tyne & Wear (NHS) Trust

May 2009 to present - Andrew Poplett Enterprises Ltd

Left NHS in 2009 to become an independent healthcare estates consultant and AE for specialist healthcare ventilation and water.

Over 35 years of experience in healthcare engineering

Chair of the IHEEM Ventilation Technical Platform, Member of IHEEM Regional Committee, and Member of the Water Technical Platform AE(W) Peer Review Panel. Founder Member of the SVHSoc, Associate member of CIBSE, and Affiliate member of IFE

Lead Author of the following Supplementary Guidance Notes

- IHEEM Ventilation Technical Platform (VTP)- Briefing Note - VTP/BN/001 - Potential Increased Risk of Aspergillus Infection due to COVID-19 and the Associated Essential Precautions and Control Measures to Consider
- IHEEM Ventilation Technical Platform (VTP)- Guidance Note - VTP/GN/001/V1.0 March 2021 - Design Output and Performance Specification Guidance for the Ventilation Strategy / Systems for Dental Care Facilities
- SVH Society - Updated Briefing and Guidance on Considerations for the Ventilation Aspects of Healthcare Facilities for Coronavirus – Revision Number 03-V5 8th June 2020
- SVH Society – Guidance Note - Air Handling Unit Condition and Risk Based Monitoring Briefing Document
- SVH Society - Guidance on Critical Ventilation System Risk Assessment Process and Factors
- SVH Society - Fire Damper Briefing Document
- SVH Society - Cryptococcus Briefing for AE(V)’s, AP(V)’s and Estates Professionals

Contributing Author of the following Supplementary Guidance Notes

Health Technical Memorandum (2021) 03-01 Specialised ventilation for healthcare premises;

- 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

HBN 16-01 Mortuaries - Facilities for mortuaries, including body stores and post mortem services.
National Guidelines for the Prevention of Nosocomial Invasive Aspergillosis During Construction/Renovation Activities via production of the Newcastle-upon-Tyne City Health Trust Estates Department – Operational Policy for Aspergillus Management EOP53 (Version 1 updated 2nd February 2000)

Author of the following Health Estate Journal (HEJ) Articles and IHEEM Presentations

- Aspergillus fumigatus – a ubiquitous foe – October 2014
- L8 – Consider the ventilation aspects – November 2014
- Fire Safety – Importance of Regular Inspection stressed – January 2015
- Who should appoint AE's and AP's – April 2019
- The Estates Manager's Guide to Cryptococcus in Healthcare Ventilation - June 2019
- When to seek derogation, and the best approach – September 2021
- AE's and AP's – Jack of all trades but masters of none? March 2022

10.2 Appendix 2 – Bibliography and Supporting Documents/Standards

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

Guidance and specifications

Legal reference documents for water systems are as follows:

- 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 (2014)
- Scottish Water Byelaws 2004

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.

It should be noted that the ER were written prior to the publication of SHTM 04-01 in August 2011. The inclusion of the references to this document in the ER notes that SHTM 04 was in consultation phase of production.

- The Health Technical Memorandum is noted as (S) HTM 04-01. 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)
- The Health Guidance Note (HGN) “Safe Water Temperatures” noted was incorporated into SHTM 04-01.
- CIBSE Guide W (2010)
- 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.

10.3 Appendix 3 – Glossary of Terms and Abbreviations

In addition to the definitions listed below, other definitions can be found in the Water Supply (Water Fittings) Regulations 1999; BS 6100; BS 8558; and BS EN 806.

Augmented care units/settings – There is no fixed definition of “augmented care”; individual providers may wish to designate a particular service as one where water quality must be of a higher microbiological standard than that provided by the supplier. While this document provides broad guidance, the water quality required will be dependent on both the type of patient and its intended use. Most care that is designated as augmented will be that where medical/nursing procedures render the patients susceptible to invasive disease from environmental and opportunistic pathogens such as Pseudomonas aeruginosa and other alert organisms. In broad terms, these patient groups will include:

- those patients who are severely immunosuppressed because of disease or treatment: this will include transplant patients and similar heavily immunosuppressed patients during high-risk periods in their therapy;
- those cared for in units where organ support is necessary, for example critical care (adult paediatric and neonatal), renal, respiratory (may include cystic fibrosis units) or other intensive care situations;
- those patients who have extensive breaches in their dermal integrity and require contact with water as part of their continuing care, such as in those units caring for burns.

Backflow – Flow upstream, that is in a direction contrary to the intended normal direction of flow, within or from a water fitting.

Biofilm – a complex layer of microorganisms that have attached and grown on a surface. This form of growth provides a niche environment for a wide range of microorganisms to interact and where the secretion of exopolysaccharides by bacteria will form an extracellular matrix for both bacteria and other unicellular organisms such as amoebae and flagellates to remain in a protected state.

Dead-leg – a length of water system pipework leading to a fitting through which water only passes infrequently when there is draw off from the fitting, providing the potential for stagnation.

Healthcare-associated infections (HCAI) – encompasses any infection by any infectious agent acquired as a consequence of a person's treatment or which is acquired by a healthcare worker in the course of their duties.

Healthcare facility/building – all buildings, infrastructure, equipment, plant, embedded systems and related items that support the delivery of healthcare and services of all types, irrespective of their ownership or operation by third parties.

Healthcare organisations: organisations that provide or intend to provide healthcare services for the purposes of the NHS.

Point-of-use (POU) filter – a filter with a maximal pore size of 0.2 µm applied at the outlet, which removes bacteria from the water flow.

Redundant pipework (also known as blind end): a length of pipe closed at one end through which no water passes.

Thermostatic mixing valve: valve with one outlet, which mixes hot and cold water and automatically controls the mixed water to a user-selected or pre-set temperature.

Waterborne pathogen: microorganism capable of causing disease that may be transmitted via water and acquired through ingestion, bathing, or by other means.

Water outlet: (In this document) refers mainly to taps and showerheads, but other outlets, as indicated by risk assessments, may be considered important.

Water Safety Group (WSG): A multidisciplinary group formed to undertake the commissioning and development and ongoing management of the water safety plan (WSP). It also advises on the remedial action required when water systems or outlets are found to be contaminated and the risk to susceptible patients is increased.

Water safety plan (WSP): A risk-management approach to the safety of water that establishes good practices in local water distribution and supply. It will identify potential hazards, consider practical aspects, and detail appropriate control measures.

Water supply [to the healthcare facility]: The water supplied can be via:

- the mains water supply from the local water undertaker;

- a borehole (operated by the healthcare organisation as a private water supply);
- a combination of mains water and borehole supply;
- emergency water provision (bulk tankered water or bottled drinking water).

Water undertaker – the role of a water undertaker is defined in a number of sections of the Water Industry Act 1991.

Wholesomeness: standards of wholesomeness are defined in section 67 of the Water Industry Act 1991. Separate legislation for public and private supplies sets out the prescribed concentrations and values for water and are detailed in the following legislation: the Water

Supply (Water Quality) Regulations 2000 for water from a public supply; or the Private Water Supplies Regulations 2009 for water from a private supply.

Abbreviations

AEW – Authorising Engineer for Water

APW – Authorised Person for Water

BCWS – Boosted or pumped Cold Water Service

BICC - Board Infection Control Committee

BMS – Building Management System (computerised control system for building engineering services)

COSHH – Control of Substances Hazardous to Health [Regulations]

CQC – Care Quality Commission

CWS – Cold Water Service/System

DHWS – Domestic Hot Water Service/System

DWI – Drinking Water Inspectorate

EA – Environment Agency

EPDM – ethylene propylene diene monomer

ER – Employers Requirements (Contract Document term)

F & R – Flow and Return (referring to water distribution systems)

HBN – Health Building Note

HSE – Health and Safety Executive

HSG274 Part 2 – The Health and Safety Executive's technical guidance on the control of Legionnaires' disease in hot and cold water systems

HTM – Health Technical Memorandum

HWS – Hot Water System (same as DHWS above)

MTHW – Medium Temperature Hot Water (Process Heating Water)

O&M – Operation and Maintenance

POU – point of use (Filter)

PPM – Planned Preventative Maintenance

PWTAG – Pool Water Treatment Advisory Group

RAMS – Risk Assessment and Method Statement

RP(W) – Responsible Person for Water

SHTM – Scottish Health Technical Memorandum

TMV – Thermostatic Mixing Valve

UKWIR – UK Water Industry Research

WRAS – Water Regulations Advisory Scheme

WSG – Water Safety Group

WSP – Water safety plan


SCOTTISH
HOSPITALS
INQUIRY

SCOTTISH HOSPITALS INQUIRY

SHI Ventilation Report

Independent Expert Report Concerning Critical Healthcare Ventilation Systems at the Queen Elizabeth University Hospital, Glasgow and The Royal Hospital for Children

Prepared by Andrew Poplett

Contents

1. Executive Summary

1.1 This report has been instructed by the Scottish Hospitals Inquiry to provide an independent expert report that addresses the following Key Questions in respect of ventilation.

- From the point at which there were patients within the Queen Elizabeth University Hospital and the Royal Hospital for Children (QEUH/RHC) were the ventilation systems in an unsafe condition, in the sense that it presented an additional risk of avoidable infection to patients?
- Are the ventilation systems no longer in an unsafe condition in the sense that they now present no additional avoidable risk of infection?

Design

1.2 The ventilation systems as designed, installed and commissioned at QEUH were clearly not fully compliant to all of the relevant NHS standards at the time. The decision to install chilled beam systems and as a direct result lower room air change rates and the subsequent impact on potential contamination of patient spaces is clear. The extent of the resulting clinical and infection risk is outside of the scope of this report, however in my opinion the failure to involve all stakeholders and to ensure a multi-disciplinary review approach contributed to a sub-optimal final design.

1.3 The principal areas of concern from a purely ventilation perspective can be summarised as follows:

- low air change rates and the use of chilled beams to achieve or prioritise BREEAM accreditation

- inconsistent provision of high efficiency particulate air filter (HEPA) filtration to all appropriate clinical environments where contamination from external sources was a known risk issue
- lack of air permeability testing of designated patient isolation rooms (room air leakage)
- poor commissioning process
- complete lack of independent validation of ventilation systems
- poor/inadequate management process for derogations
- poor pre-occupational operational maintenance practices – lack of comprehensive or suitable Planned Preventative Maintenance Plans (PPM's)
- poor/inadequate assessment or provision of operational estates resources to manage and provide adequate assurance of ventilation system operational performance
- lack of suitable Ventilation Safety Group (VSG) to provide oversight and assurance of compliance of all aspects of ventilation performance

1.4 From the reviewed information and subject to any additional information being provided, the overall ventilation strategy for the building was non-compliant to the basic principles of healthcare ventilation as outlined in the Scottish Health Technical Memorandum (SHTM) standard 03-01 (2007). General ward areas were not designed to achieve the minimum standards of 6 air changes per hour and some specialist areas were also not designed to achieve clinically appropriate standards. The overall ventilation design philosophy appears to have been driven by a desire to achieve a certain environmental performance rating (BREEAM), and a lack of understanding of critical clinical risks associated with the ventilation system. The design was agreed to significantly derogate from normal healthcare ventilation performance parameters and therefore provided a sub-optimal patient care environment from a ventilation perspective. The use of chilled beams in critical

clinical care areas also influenced the sub-optimal airflow performances and added an avoidable risk to a number of highly vulnerable patient areas. The design was recognised as an issue after occupation as some rectification/improvement works were commissioned, however these failed to address all of the original design deficiencies and a number of the systems remain in a sub-optimal state as outlined in the following sections of this report.

Commissioning and validation

1.5 The commissioning process was undertaken by specialist contractors under the remit of the contract and no independent validation was completed. From the available evidence reviewed I have assumed that a formal ventilation commissioning report was not produced or provided to the NHS Board. I consider this assumption to be very likely correct given the absence of validation documentation.

1.6 Validation is important as it tests the whole system against the design and any derogations to demonstrate that the system is fit for purpose prior to use – it also sets the benchmark for future verifications. Following a review of wards 4B and 4C I have assumed that no validation was completed prior to handover. I consider this assumption to be very likely correct given the absence of validation documentation pre-handover.

1.7 Without the formal confirmation through the validation process it would not normally be advisable to accept a critical healthcare ventilation system into use and the failure to appropriately undertake the validation process enabled the systems to operate in a sub-optimal state, potentially exposing patients to an elevated level of risk.

Operational issues and management

1.8 In the initial period following completion of the facility a number of critically important patient safety and legal compliance issues remained outstanding or inappropriately managed, with a number of the on-going or persistent issues not escalated or highlighted to an appropriate level.

1.9 The audit reports do highlight a number of serious issues and whilst it acknowledges progress, the speed and extent of improvement was poor. Each year the audit report stated that the ventilation systems were safe to continue in use, with the proviso that supervision of the authorising engineer (ventilation) (AE(V)) should continue. From the information of the identified sub-optimal compliance and nature of the potential risks present I would suggest very limited assurance of compliance could be taken from these audit findings.

1.10 I have assumed that the process of managing/agreeing derogations or changes within the project at QEUH were restricted to a Project Board level, and outcomes would suggest that not all interested stakeholders were appropriately or fully consulted on all issues. I consider this assumption very likely based on the available information I have reviewed. The primary example would be the prioritisation of BREEAM status over that of air change rates.

What could be done to the QEUH/RHC ventilation systems for the whole site to meet the appropriate SHTM-03-01 standards without exception?

1.11 In practical terms the options available to address all of the above issues is limited, however as an initial assessment and prioritisation exercise (some of which may have already been undertaken) the following would be my recommendation:

1.12 A full multi-disciplinary assessment of each clinical speciality should be completed to identify current areas where ventilation plays a significant factor in patient safety. Each identified area should have the current performance parameters established via testing and an assessment made of plant/system condition and limitations, along with a clinical and Infection, Prevention and Control (IPC) agreed minimum performance standards (informed from the current SHTM and best practice).

1.13 Following this assessment to establish minimum acceptable ventilation performances standards and current compliance there with a prioritised schedule of improvement works can be developed. These works would likely involve removal of current chilled beams from critical clinical areas and replacement of current ventilation plant and ductwork distribution systems with improved capacity and fully compliant systems, which would be both expensive and involve significant duration and clinical disruption.

1.14 It is entirely possible that following the assessment phase of the review that it is impractical to modify existing facilities and in such circumstances clinical activities may need to be suspended or stopped until suitable compliant facilities can be provided/identified. This may result in a reduction of clinical activity or bed numbers as a means to accommodate suitable ventilation or other essential building services.

1.15 All improvement works would need to be subject to fully compliant commissioning and independent validation reviews to ensure the works are effective in providing the agreed minimum performance standards.

1.16 The Ventilation Safety Group and Board need to agree a formal process to manage all derogations for all NHS standards (SHTM’s and SHBN’s), and develop a

suitable process to agree, record, review and manage all essential derogations moving forwards, and include a suitable assessment process of these as an integral element of any planned clinical service developments or moves.

1.17 In some cases it may prove necessary to temporarily or even permanently suspend clinical services whilst areas are modified to achieve agreed minimum standards. If practical limitations of plant space or current building structure prevent achievement of minimum standards then the clinical activities should be suspended until such time as a suitable and fully compliant facility can be provided.

1.18 The current provision of maintenance and estates management staff (AP(V)s and CP(V)s) needs to be reviewed and potentially increased to ensure adequate assurance can be provided to the Board of on-going progress on improvement works and operational compliance, including but not limited to the review of all annual verifications and timely corrective action to all identified issues.

1.19 Finally I would suggest that the Authorising Engineer (Ventilation) audit schedule should be increased from annual to 6 monthly to provide an external and independent assessment of progress and compliance until such time as the VSG and Board have complete assurance of the appropriateness of the ventilation services.

2. Scope of Report

2.1 This report has been instructed by the Scottish Hospitals Inquiry to provide an independent expert report that addresses the following Key Questions in respect of ventilation.

- From the point at which there were patients within the QEUH/RHC were the ventilation systems in an unsafe condition, in the sense that it presented an additional risk of avoidable infection to patients?
- Are the ventilation systems no longer in an unsafe condition in the sense that they now present no additional avoidable risk of infection?

2.2 In order to deliver a comprehensive and cohesive report it has also been necessary to provide in lay-person terms an explanation of the various elements and processes involved in the ventilation of a healthcare facility.

3. Schedule of Assumptions

3.1 All information referenced has been provided by the Inquiry team through information requests and disclosures. Where information has not been available then this has been clearly stated and to the best of my abilities and knowledge no assumptions have been made in the preparation of this report.

4. Exclusions/Limitations of the Report

4.1 I have been asked to provide a written Expert Witness Report to the Scottish Hospitals Inquiry (SHI) with regards to my knowledge and familiarity with the English guidance of the Health Technical Memoranda (HTM) 03-01, on which the Scottish guidance, Scottish Health Technical Memoranda (SHTM) 03-01, is based. I have also been asked to provide my knowledge and experience in design, installation, commissioning and validation of ventilation systems in hospitals.

5. Overview of Healthcare Ventilation Systems

5.1 In healthcare premises, critical ventilation systems will generally be required 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.

- to remove, contain or dilute specific contaminants and fumes
- to ensure the isolation of one space from another
- to preserve a desired air-flow path from a clean to a less clean area
- to provide control of the cleanliness of a space
- to provide close control of temperature
- to provide close control of humidity

5.2 The primary driver for ventilating healthcare spaces, particularly within critical areas such as operating theatres, is the dilution of airborne contamination that is generated within the space because of surgical procedures or the people who are present. As well as dilution, you can use ventilation to isolate or control one area from another, so for an infectious patient, the aim is to try and ensure that the air which is being contaminated or potentially contaminated by that infection does not leak into surrounding areas.

5.3 The use of ventilation will also protect vulnerable immunocompromised or those patients who have virtually no immune system as a result of illness or treatment, so they are not exposed to potential airborne pathogen either from surrounding areas or indeed outside air. This patient group would include those receiving organ transplant, bone marrow transplant as part of their medical treatment. These patients have a reduced immune response so they do not reject

the transplanted organ or material, but that makes them susceptible and vulnerable to pathogens that they otherwise might not be vulnerable to.

Role of ventilation in hospital setting

5.4 Ventilation is the provision of air which should be filtered where it needs to be filtered, and tempered into a space either to achieve minimum building regulation compliance for the dilution of contamination and an appropriate indoor air quality or, where certain clinical activities are being undertaken, to provide an appropriate level of dilution for contamination that is potentially generated within the space to keep it at appropriate levels. The filtering of natural ventilation can be something as simple as a fly screen to prevent insects entering and landing on sterile instruments/areas. Any filtration however does add a degree of resistance to the airflow.

5.5 In providing an explanation of ventilation within healthcare setting I believe an understanding of contaminants will also assist in understanding why ventilation is important. Contaminants basically fall into three broad categories of airborne risk, these are viruses, bacteria and fungal spores. Each have their own unique properties but can be considered harmful to patients in some circumstances.

- Viruses are generally very small, generally short-lived outside of the body, but not always, with COVID being an example. They transport or travel within a medium, such as water droplets or droplet nuclei expelled from a person.
- Bacteria, of which there are many, some harmful, some not, can live for longer periods outside of the body, but they generally travel on something so the most typical example within healthcare is bacteria travelling on skin scales. With every human being constantly shedding skin scales they can

carry bacteria on them and travel through an airborne route from one patient to another or from a member of staff to a patient.

- The third contaminant is fungal spores, probably the longest-lived outside of the body. Anecdotal evidence has shown that aspergillus spores were found in the Egyptian tombs, which were sealed for 3,000 years and were successfully cultured having spent 3,000 years in a sealed chamber. Fungal spores can travel within the air and compared to bacteria and viruses they tend to be larger, but you are still talking about particles that are between two and five microns typically in size. To put that in context, a human hair diameter is approximately 70 to 100 microns, so these are very small particles. Fungal spores can infect directly and travel for considerable distances in air with evidence suggesting spores can travel at least two miles from point of production.

5.6 For a particularly vulnerable patient who is neutropenic, it's not just about protecting them from the immediate environment of the hospital. For example, if there is construction work ongoing around the hospital environment and the wind is in the wrong direction then a concentration of particles could be introduced to that patient environment. Many fungal spores and indeed many bacteria are ubiquitous in nature, they are found commonly all over the place. We probably breathe in aspergillus spores on a daily basis, and they have no impact on us whatsoever. However for certain clinical groups they can be a greater problem, from asthma attacks or respiratory disorder and for a very small minority of severely neutropenic or immunosuppressed patients, they can evolve into invasive aspergillus which can be fatal.

5.7 Ventilation is used to extract, and preferably at the point of production or generation, any contamination that is done as a result of clinical activity or indeed non-clinical activity. For example, from the basics of a cooker hood extracting cooking fumes over the cooker it is extracted at the point of production rather than released into the general atmosphere, or within an operating theatre where point-of-

use extraction is not practical or achievable, it provides a general dilution effect to the air from any contamination that's generated in the space.

5.8 Ventilation can also be used to separate one area from another and generate clean air paths, so again linked to removing the contamination at the point of production or at least at a point where the contamination does not or is limited to travel through another person's breathing zone. For example, if it is an endoscopic procedure and you have a patient with potential tuberculosis, part of the endoscopic procedure is to pass the camera down into the lung area and the patient has to cough to pass the camera into there. You don't want the staff breathing in particles which that person expels as part of the cough if they have, or could have, TB. In this instance the recommendation and advice would be low-level extraction immediately behind the area where the patient is being treated. Any particulate that is expelled gets drawn away to low-level and extracted from the room, rather than passing through the staff breathing zone on its way to an extract grille in the ceiling.

5.9 Ventilation can also provide appropriate environmental room conditions, temperatures and in some cases humidity control, which is where ventilation can become air conditioning. Air conditioning is the control of the environmental air within a space by temperature and humidity. Recirculating air conditioning units you see mounted on walls or ceilings do not provide external fresh air but draw air from the room, heat it and cool it, and can adjust the humidity and put it back into the room. That can be necessary and essential for some clinical areas of activity, burns patients for example.

5.10 Humidity control is critically important because if you have a large wound site you would not want it to dry out or heal too quickly as it could cause subdermal scarring. Humidity control can be vital within certain clinical areas. In some previous versions of HTM humidity control was also critically important because of some of the anaesthetic agents that were used in sedation or anaesthesiology. These agents had the potential to be explosive or highly flammable and static electricity was a

concern where electrical discharge through static discharge could act as an igniter for an explosive anaesthetic agent. Those anaesthetic agents are no longer used, and therefore humidity control, generally, for the control of static electricity, is less of an issue now than it used to be. Ventilation requirements change and evolve as clinical practice changes and evolves and indeed some of the medicines, some of the agents that are used within that clinical practice also change. Ventilation technologies and engineering solutions also change and develop over time.

Parameters and types of ventilation systems

5.11 The terms “ventilation” and “air-conditioning” are often used interchangeably to describe the same type of equipment; however, a general explanation of the terms is given below.

5.12 Ventilation is a means of removing and replacing the air in a space. In its simplest form this may be achieved by simply opening windows and doors.

5.13 Mechanical ventilation systems basically 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. Ventilating equipment is generally used to remove smells, dilute contaminants and ensure fresh air enters the space.

5.14 Air-conditioning is the ability to heat, cool, dehumidify and filter air. For full air-conditioning, humidification may also be provided. Air-conditioning equipment may be required in order to provide close control or comfort conditions within the space. Owing to high capital and running costs, full air-conditioning should only be used in essential areas such as theatres, critical care units, manufacturing pharmacies and areas with particularly sensitive equipment.

5.15 Specialised Ventilation: In healthcare premises, certain activities will necessitate the provision of ventilation equipment with additional features in order to

achieve and maintain specific conditions. These may be required in order to assist in the treatment of patients or to maintain the health and safety of staff.

5.16 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, for example, laboratories, pharmaceutical manufacturing, mortuaries or woodworking equipment etc.

5.17 Extract ventilation is required in sanitary facilities, dirty utilities and rooms where odorous but non-toxic fumes are likely to be present. A single fan is generally provided to meet that need.

5.18 Natural ventilation is a term that generally refers to the natural movement of air through a building due to changes in air temperature and pressure between open doors and windows. Although it is difficult to maintain consistent air flow rates and ensure that minimum ventilation will be achieved at all times. This variability is normally acceptable in such areas as office accommodation, staff areas, seminar rooms and dining areas where open windows are available.

5.19 There are a number of parameters for healthcare ventilation systems. A system can have supply-only, extract-only, supply and extract ventilation and you can have natural ventilation, so it doesn’t have to be forced. Opening a window does provide natural ventilation to a space and you can engineer natural ventilation to achieve air-change rates and effective dilution within a space. However, natural ventilation is influenced by the size of opening, the facing of the opening and any prevailing wind direction and most critically outside influencing factors such as temperature differential. If it is very cold outside and very warm inside then you will get more natural infiltration of air through natural ventilation. If it is very warm outside

and warm inside, you will tend to get less natural ventilation because of the thermodynamics of air but you will get natural ventilation.

5.20 In certain circumstances natural ventilation may be the best option. I would not imagine anyone being comfortable with natural ventilation within a theatre setup but it has been done in the past. It could be used but it would depend on certain climatic conditions for it to work well. If using natural ventilation you would have to have a detailed understanding and assessment of the limitations and the factors that can influence it. In addition to natural ventilation “mixed-mode” ventilation can be used, which is a combination of natural ventilation and some forced ventilation, or you can have full forced mechanical ventilation supply and extract via fans, which is normally ducted. All three groups can be appropriate in some settings within healthcare.

5.21 The air change rate is used to describe the volume of air that goes into the room or is extracted from a room to give the number of times that the volume of air within that space is changed per hour. This is a tailored measurement that is governed by the room size or dimensions. Within previous versions of HTM the ventilation rates were specified as litres per second. The problem is that litres per second into a very small room will give a very high air-change rate. If you measure the velocity of the air and you know the cross-sectional area that that velocity is achieving, that will give you a volume of air. That can be defined in a litres per second or metres cubed per hour. An air change rate is derived directly from the litres per second or metres cubed per hour divided by the room volume, because you are getting air changes per hour. You cannot measure an air-change rate without measuring the volume-flow rate and the volume of the room. Air changes are used as a simplified method to identify the required dilution rate within a given space irrespective of its size.

5.22 There is a formula which was established as part of Lidwell's original research, which is that one air change, provided that it is distributed evenly across the whole room, is likely or will remove 63 percent of any airborne contamination. Any subsequent air change will remove 63 percent of any residual air contamination. If you had a room with 100 particles of contamination the first air change would clear 63 percent, leaving 37 percent within the space, the second air change would clear 63 percent of that remaining 37, provided no additional contamination was released into the room and provided that the air distribution covered the whole room volume. This formula that is widely used and accepted nationally and subject to the proviso that no additional contaminants are introduced into the room. If it was introduced in the right-hand corner of the ceiling and extracted in the right-hand corner at low level, it is unlikely to achieve full-room air change because the air will short circuit and take the path of least resistance. Air-change rates are a shorthand method for summarising ventilation rates, but they have to be governed or looked at to make sure that they relate to whole-room distribution or dilution/scrubbing. Lidwell's formula and research on air change contamination remains the basis of healthcare ventilation strategies.

5.23 When we look at air pressure this is used to denote air movement from one space to another. If something is at a positive pressure, the air provided into the room is greater than the air extracted or leaking from the room and therefore you get a positive pressure. If you have more extract than supply you suck the air out of the room, you don't necessarily provide air into the room so there's no supply air but air is drawn in through natural leakage, cracks under the doors and creates a negative pressure. Negative pressure is used to contain any airborne contaminant, that could be gaseous, that could be odour, or it could be particulate. Positive air pressure means that you provide that air into that space, and the air is pushed from clean to less clean spaces. It's a phrase that is used on numerous occasions throughout the HTM, and it's part of this desired airflow path, making sure that air moves from clean to less clean areas to control any potential contaminant risk.

5.24 When you are seeking to maintain within a space either a positive, neutral or negative pressure it is a specified level of pressure cascade or pascal (a pascal is a standard unit of measurement for pressure) that is used to determine a degree of positivity or negativity. Neutral pressure is intended that if there are no openings and the room is in a normal state, it will not share air to the surrounding area or from the surrounding area into the room. However, that can be impacted and will be impacted when doors are opened because you will get temperature differential and in exactly the same way as natural ventilation can occur, you will get potential air either coming into or out of the space.

5.25 The pressure that you maintain within a space is governed not only by the ventilation rate but also the air permeability of that structure. For example, you will never be able to pressurise a colander as it's full of holes, so it doesn't matter how much air you put in it, you are unlikely to ever achieve a pressure because it will balance naturally through all of the openings. The air permeability also ensures the desired clean air path. The air is drawn out from the area where you want it drawn out from and it doesn't leak out of other surrounding areas. It can be linked to areas such as fire strategy and smoke strategy as well to ensure that areas stay isolated from another area in the event of smoke transmission. So air permeability is the test method that we use to ensure that spaces can achieve a desired pressure cascade, be that positive or negative.

5.26 As you introduce air to a space or extract from a space you generate a pressure profile, either positive or negative. If there was no ventilation in a room it would be considered at neutral pressure. If you introduce supply air and don't have forced extract air you will generate a positive pressure within that room provided that room doesn't have too many leaks. If the door is open then it won't create a positive pressure because the air will stabilise between the point where it was introduced and the surrounding area. That's the interaction between pressure and air change, the amount of air that you put in and the amount of air you extract out, linked to the

integrity of the construction of the room, the air permeability, will determine the pressure cascade that can be achieved.

5.27 On looking at air filtration rate this is generally considered to be based upon a desired internal air quality, driven by the surrounding external air quality of the specific geographic area of the hospital. If the location of a hospital is inner city centre with large volumes of traffic, the external air quality is likely to be poorer than if you have a hospital out in the countryside. If you have a hospital located by a coast or subject to high salt levels, coastal environment, then that again can impact the level and quality of filtration that you have in your system to provide the required indoor air quality of a space.

5.28 There are times where the filtration is there to protect the equipment, including the air handling equipment. So the initial filter that is fitted, the pre-filter as it is normally called or the return-air filter on an extract system, is generally there to protect the mechanical engineering device from contamination and blockage. The final filters are then used to provide a finer grade of filtration to a desired air quality that the patient requires. In cases where a patient is neutropenic and susceptible to ubiquitous fungal spores in the air, you would filter to a higher grade standard. If you are manufacturing pharmaceuticals within an aseptic pharmacy suite then your concerns would be that the drugs are not contaminated by any air within the area, and that is where the use of High Efficiency Particulate Air (HEPA) filters or ultra-filters are brought into effect. They filter down to a far finer degree to keep particles out as much as practically possible and can be used in any setting where particulate size or concentration is critical.

5.29 The ventilation parameters are co-dependent and interlinked and within a healthcare setting they are fundamental in infection prevention control, fire strategy and smoke transmission. The dilution effect of air reduces the concentration of contaminants within the space, depending upon the patient, whether they are

infectious or at risk of infection. The pressure cascade is used to provide assurance that there is a positive pressured space so airborne contamination can't enter, or it's a negative pressure space so contamination can't leave through uncontrolled means.

5.30 If you changed one of the supply or extract air-change rates without adjusting the other proportionally, you would almost certainly have an impact on the pressure cascade because if you put less air in but drew more air out, you could turn an area from positive pressure to negative pressure.

5.31 When looking at a room that has both supply and extract ventilation and you adjust one and not the other, then you will definitely impact the pressure cascade of that room. It won't necessarily reverse it as it depends upon the scale of the change, but it will have a more definitive impact. The air-change rate is derived from either the supply or the extract. If a room has 10 air changes and you wanted positive pressure, and you had both supply and extract within the room, you could put in 10 supply air changes and extract out 8 air changes. That would give you a net positive pressure compared to adjacent areas. However, if you had 10 extract air changes and 8 supply air changes, you would still only have 10 air changes, but you would extract 10 air changes, 8 of them from the supply air that you'd introduced and two air change equivalents through natural leakage into the room. An air-change rate isn't supply plus extract, it's whichever one is the greater that gives you the air change for the room.

Setting performance parameters for specific healthcare environments/rooms

5.32 SHTM 03-01 clearly outlines the purpose of ventilation in healthcare premises or primary patient treatment in operating departments, high dependency units and isolation facilities. It is also installed to ensure compliance with quality assurance of processed items in pharmacy and sterile supply departments and to protect staff from harmful organisms and toxic substances, for example, in laboratories. It goes on to outline that ventilation' is also 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 control closely the environment and air movement of the space that it serves in order to contain, control and reduce hazards to patients and staff from airborne contaminants, dust and harmful micro-organisms.

5.33 The HTM 03-01 (2021) specifies some areas with recommended ventilation rates within chapter 8 and there is a table listed in Appendix 2 of the document to be used as a guidance for typical spaces. This table shows the air change rate, pressure cascade, filtration grade that's needed, temperature is specified and then there are some additional comments and advisory notes where supplementary guidance may need to be sought. All of these have a fundamental role in patient care and safety, as highlighted in Chapter 2 of Part A HTM 03-01. They were selected because they reflect the typical rooms that are detailed in Chapter 8 of Part A HTM 03-01 and are typical to what you will find in a vast majority of acute hospital settings. The whole of HTM 03-01 is written specifically for acute care medicine but it doesn't require an A&E department to be an acute care facility. If it's a surgical centre it would need to comply with 03-01 because of the operating theatres, critical care, and ward areas. For places like a dental practice, or GP, or mental health facility, or a care home, or one of the other myriad of healthcare providers, you need to assess the appropriateness of applying HTM 03-01 to the clinical risk profile. Some of them will be similar, some of them will be markedly different.

5.34 For example an operating theatre will typically require at least 22 air changes per hour, however the final air change rate is derived from the design and what is within the room. If you have a lot of equipment in that room that generates an awful lot of heat, such as robotics, CT (Computed Tomography) scanners, imaging devices then it may be that the air-change rate needs to be considerably higher. It is driven by the minimum air-change rate for infection control, which according to HTM 03-01 is at 22, but it may be that it requires 35 because of the heat gains from within the space.

5.35 If you have a clinical activity which is not defined within the HTM, what it should be possible to do is for the clinical team to look at similar patient environments and determine the correct minimum level of ventilation requirements. For example, there is no renal dialysis unit listed within chapter 8 of HTM, however, there is a listing for invasive treatment rooms. The hospitals will have rooms whereby, clinically, a comparison should be able to be made that if it is an invasive procedure that would typically be done in a treatment room then it would 10 air changes and 10 pascal positive air pressure for the right environment for a renal dialysis room. Ultimately that would be an infection prevention discussion between IPC, Clinicians, and Microbiologists with advice sought from engineers in a collaborative process, discussing what was going to be done in the room, any chemical agents or anaesthetising being used. All of these play a factor into the right level of ventilation for that space.

5.36 The decisions taken on setting these parameters would be driven by the clinical activity within that space. If you have a critical care area then you will have more vulnerable patients than those on a typical medical ward or a day-case ward or another type of patient environment. It's also about the length of time and duration that a patient, or indeed a member of staff, would be exposed to a potential risk. Within an Outpatient department the patient exposure is very limited due to the short duration in which patients are seen and treated. However an in-patient may be in for at least 24 hours, if not longer, so their potential exposure is over a much more extended period and therefore potentially requires different ventilation rates. This clinical assessment is typically managed by means of a standard operating procedure within the healthcare organisation for 'patient placement'. Evidence of this process is available in the patient placement SOP within QEUH document V1.5 dated May 2020, although no early versions have been provided. It's also about the staff exposure, for example those working within dentistry probably see a different patient every 20 minutes but the dentist and nurse are likely to be in the same room for 8 hours, exposed to a number of patients. If these patients all have COVID, then the level of risk to the individual staff working in there is that much higher. The levels

of contamination are potentially more concentrated depending upon the air-change rate, but also it's the duration of exposure. That's where legislation such as Control of Substances Hazardous to Health (COSHH) regulations and the work exposure limits, either instantaneous or over an eight-hour shift period, will determine what level of concentration you are trying to manage and that will derive any ventilation rates.

5.37 HTM03-01 (2007) Part A clearly states that the recommended air change rates for wards and single rooms is 6ACH and for isolation rooms and neutropenic wards is 10ACH and in part B the ventilation system should achieve not less than 75% of the design air-change rate. Therefore the minimum air change rate is 4.5ACH for wards and single none isolation bedrooms and 7.5ACH for isolation rooms and neutropenic wards. The draft SHTM03 (2009) agrees with this specification but adds a 10ACH recommendation for ITU/HDU. SHPN04 from 2008 specifies 10ACH for room, lobby and en suite for isolation units. When SHTM 03 Part A was officially released in 2013 the specifications were the same as the draft. In all subsequent versions of HTM03 and SHTM03 the air change recommendations stayed the same for these types of application although the in-use tolerance of 75% has been reduced to 80% since the current HTM 03-01 (2021) and Interim SHTM 03-01 (2021).

5.38 The air change rates specified for the UK have been in place and remained stable since 2007 at 6ACH for wards/single rooms and 10ACH for specialist ventilation facilities.

Key components in hospital ventilation system (mechanical or forced)

5.39 A ventilation system is made up a of a number of key components, an intake or discharge, an Air Handling Unit (AHU) or fan, a ductwork distribution system and

an intake/discharge terminal unit or grille. An air-handling unit is made up of a lot of separate components, all of which have a role to play. The order in which those components are positioned is critical to the efficiency of the unit and the condition of the air that you are trying to achieve.

5.40 The ventilation system starts with the outside air and from where you draw the air in from. It needs to be identified that the air being drawn in from outside isn't providing a source of potential contamination. Therefore even before you get to the air intake louvre, you don't want it drawing in air that's been exhausted immediately from another area. If you have an infectious disease unit and that's exhausting the air then you don't want a theatre air intake immediately beside it as this will draw in anything that's been removed from a potentially infectious area into a theatre air intake. The air intake area must also be free from vegetation, wildlife or anything else in the immediate area of an air intake because that will host fungal spores and bacteria and will act as a potential source of contamination. The air intake, which is normally a weather-proofed louvre preventing ingress of water, is fitted with a vermin screen to prevent large contamination entering in, such as feathers, vermin, rodents, birds. That then delivers the outside air into an intake plenum or ductwork section prior to the AHU which normally has an automatic shut-off damper, which ensures that if the air handling unit is shut down for any reason the damper will automatically close to make sure that external air pressure or wind does not blow through the unit.

5.41 Following on from this you have what is described as a fog or frost coil, which is an un-finned heating element designed to ensure that the air entering the air-handling unit does not carry an unnecessary level of moisture which could adversely affect the pre or primary filter. You then have a coarse-grade primary filter, which filters out large contaminant that's made it through the initial vermin screen but prevents and protect the equipment of the air-handling plant. This can also be fitted with an acoustic attenuator to cut down noise transmission from the air-handling unit back out into the atmosphere.

5.42 The next component is a fan unit, which traditionally would been belt and pulley, however under the current HTM, a direct-drive fan is fitted which draws the air into the air intake and directs it to the rest of the handling plant. Following this is a heat-recovery device whereby you recover the energy (either heating or cooling) that was taken from the exhaust air and you put it into to preheat or to precool the air. This facilitates the transfer of energy so you are not wasting all of the energy from the clinical treatment space, throwing it outside and treating raw outside air from external conditions. This is now governed by the European standards and international law, a requirement that air-handling units can't be provided without certain energy efficiency being achieved within the heat-recovery device (EU 1253 (ERP regulations) and EN 1886 (January 2008). The heat recovery device in healthcare settings can be one of three typical types, a cross flow air to air heat exchanger, a thermal wheel, or a run around coil arrangement.

5.43 Once air has passed through the heat recovery element, it then goes through a cooling coil. This will chill the air, but also, as a result of this it will naturally also increase the relative humidity of the air and condense moisture out from it. You will normally have an eliminator plate to stop moisture being carried in the air current beyond the drip tray, which is there to collect the moisture and safely drain it out of the air-handling unit. You then have a re-heater coil which reheats the air. If you've cooled it and you've increased the relative humidity and to control this you reheat and dry the air out. If you have to control the relative humidity, you can have a humidifier steam lance where you inject steam in to re-humidify the air without adjusting its temperature. It then goes through a final filter, which is the final finer-grade filter, another automatic shut off damper so it doesn't get backdrafts from the distribution ductwork, and you can close it off to work on the unit safely. You will then have a distribution attenuator which reduces noise transmission from the unit onto a ductwork distribution system, which delivers it to the area where you are providing air to.

5.44 If separate temperature controls within given areas are required then you can also have trimmer batteries, which can heat or cool to further condition the air if there is a requirement for separate environmental control temperatures within one specific space. The air will then get delivered through grilles into the room. If it's an Ultra Clean Ventilation (UCV) operating theatre, this would have a secondary ventilation recirculation HEPA, with current HTM guidelines stipulating that this should achieve 22 air changes per hour of outside 'fresh' air.

5.45 From the air being introduced to the room through the supply grilles, you would then have extract grilles, sometimes within the space or sometimes in adjacent spaces depending upon the pressure profile that you're trying to achieve. Those extract grilles go through ductwork back up to the air-handling plant and a coarse filter to take out any coarse particulate contamination that's been generated within the space, such as clothing, skin scales, etc. It will then go through an extract fan and another heat-recovery device, where the energy is transferred from the extract into the supply. Finally it goes through a further attenuator to an exhaust grille, which will be protected with a vermin screen to make sure rats, mice, foxes, birds cannot access into it against the flow of air, from where it is then discharged.

Ductwork materials and construction

5.46 The HTM standards details elements for ductwork installation and this is supplementary to the industry standards as outlined by Chartered Institution of Building Services Engineers (CIBSE) and the DWS 143 & 144 guidance standards. HTM includes for the following:

> "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."[1]

[1] A36962514 – HTM 03-01 Part A (2021) – Hearing Commencing 9 May 2022 – Bundle 2 - Page 426.

HBN 04-01 Supplement 1: Isolation facilities in acute settings

5.47 Ventilation – general requirements of isolation room ventilation systems

> “4.5 Ideally each suite should have its own dedicated supply and extract system. If two or more suites share a ventilation system there will be an inevitable increase in the complexity of the system and a corresponding reduction in reliability and serviceability. Further complications will occur when individual suites have to be isolated for deep cleaning following occupation.
>
> Routine maintenance of the ventilation system will result in complete closure of all suites that it serves. For these reasons it is strongly recommended that each suite should have its own ventilation system.
>
> 4.6 The object should be to keep the ventilation systems as simple as possible. Standby fans or motors are not required for either supply or extract. This is because the system as designed is robust enough to withstand fan failure without significantly compromising the level of protection. A flow sensor should be fitted to each system that will alarm on fan failure at a designated nurse station and the estates department.
>
> 4.7 Ductwork should be kept as direct and simple as possible. In order to facilitate duct cleaning, volume control devices and other obstructions in the distribution ducts should be avoided. Supply and extract flow rates should, where possible, be set by terminal and duct size design. In the unlikely event that volume control devices are required, iris dampers are the preferred type.
>
> 4.8 In a high-rise building a common supply and extract system may be the only feasible solution. In this case, run and standby fans would be required for the extract and a duplicate supply unit may be considered

necessary. The supply and extract branches to each isolation suite should be fitted with spring-close gastight dampers. This will permit individual suites to be shut down for cleaning and maintenance. The common supply and extract systems will need to be controlled to ensure a constant volume in each isolation suite branch regardless of the number in use. The overall design should ensure that short-circuiting cannot occur between isolation suites."[2]

[2] A34099878 – HBN 4 Supplement 1 (2005) - Bundle for Oral Hearing commencing 19 August 2024 – Bundle 16 - Page 326.

Room/suite permeability testing

5.48 Without solid ceilings permeability testing is unnecessary and meaningless. The documents that do mention solid ceiling also mention permeability testing. HNB04-01 (2005) is highly prescriptive

> "Validation – Isolation suite air permeability (leakage rate) The suite will be considered fit for purpose if at a test pressure of +20 and –20 Pascals it has an average leakage rate of not more than 1 l/s of air per 1 m3 of envelope volume"[3]

5.49 SHPN04 (2007) states that on commissioning or after works

> “The suite will be considered fit for purpose if at a test pressure of +20 and –20 Pascals it has an average leakage rate of not more than 1 l/s of air per 1m3 of envelope volume. The method of testing is set out below.”[4]

5.50 HBN04-01 (2013) modifies the method and states

> "Air permeability tests should be carried out by an independent testing company that is a member of ATTMA. Air sealers should not test their own work. These tests should be carried out before initial commissioning and as necessary thereafter following works of refurbishment or when there is any doubt as to the actual performance standard of the room. As a

[3] A34099878 – HBN 4 Supplement 1 (2005) - Bundle for Oral Hearing commencing 19 August 2024 – Bundle 16 - Page 337.
[4] A36372665 – SHPN 4 Supplement 1 (2008) – Hearing Commencing 26 February 2024 – Bundle 13 – Miscellaneous Volume 3 - Page 455.

minimum requirement, the air permeability should be no worse than that required by Approved Document L2A of the Building Regulations for the entire building. (This is a variable value with a minimum required air permeability of less than 10 m3.h–1.m–2 at a reference pressure of 50 pascals.)"[5]

5.51 In the latest HTM03-01 and SHTM03-01 the similar wording is used. The following areas will require permeability testing:

- “isolation suites of any type
- theatre suites
- any other area specified within the contract

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.

A full permeability test in accordance with the methodology given in Building Services Research and Information Association (BSRIA) BTS 3 will be carried out at practical completion to ensure that all service penetrations have been adequately sealed."[6]

[5] A37329297 – HBN 04-01 Supplement 1 (2013) - Hearing Commencing 9 May 2022 – Bundle 2 - Page 884.
[6] A36962514 – HTM 03-01 Part A (2021) – Hearing Commencing 9 May 2022 – Bundle 2 - Page 458; A37301627 – SHTM 03-01 Part A (2022) – Hearing Commencing 9 May 2022 – Bundle 1 - Page 943.

5.52 For isolation suites there has been guidance on permeability testing since 2005. Such testing would not be compatible with false ceilings. The updates guidance in the latest SHTM and HTM is very useful for future designs of hospitals.

6. QEUH - The Ventilation Strategy

6.1 Following a review of the ventilation system at the time of handover for Wards 2A RHC 4B and 4C the following issues with the ventilation strategy and the installed system have been identified.

Overview of design principles

6.2 Over 1500 chilled beams (Swegon Parasol ceiling mounted heating/cooling terminal unit) were installed in the QEUH and the RHC – these units provide fresh air as well as heating and cooling. Air enters the room via the chilled beam and is extracted through a door mounted grille in the en-suite bathroom, via a valve type terminal and is then ducted back through the ceiling void, to the riser before returning to the Air Handling Unit (AHU).

6.3 Chilled beams do not filter any particulates in the air.

The agreed specification

The design requirement from GGC taken from the NSGH ventilation strategy document (2009) Ventilation PPP bundle ward ventilation design strategy (page 1657) was that the summertime temperature limit was not to exceed 26 degrees. This exceeded guidance in SHTM 03 01 that stated that the summertime temperature was “not to exceed 28 degrees for more than 50 hours per year”.

6.4 SHTM 03-01 recommends air change rates for single rooms as 6ACH however thermal modelling based on this recommendation established that the requirement of 26°C could not be met, therefore the use of chilled beams was recommended as a low energy solution.

6.5 The M&E Clarification Log (2010) confirmed the use of chilled beams and a reduced air change rate of 2.5 ACH:

> Board Comment – “Ward Air change to be 6AC/HR, currently shown as 2.5AC/HR which is not in compliance with SHTM 03-01.”
>
> Brookfield Comments – “Brookfield proposal as outlined within the bid submission is to incorporate chilled beams as a low energy solution to control the environment which do not rely on large volumes of treated air or variable natural ventilation. All accommodation is single bedrooms and therefore the need for dilution of airborne microbiological contamination should be reduced (rooms could also be at slightly negative pressure to corridor).
>
> Providing 6 air changes is energy intensive and not necessary.”
>
> Agreed position – “The proposal was accepted on the basis of 40 litres per second per single room (8 litres per second per second) for one patient and four others.

6.6 The evidence suggests that GGC accepted a derogation to the guidance set out in SHTM 03-01 and suggests a focus on “the energy target/BREEAM rating” . The “8 litres per second” refers to the ventilation requirements set out in the Scottish Building Regulations (sets minimum standards for fresh air but not specifically for hospitals) – I have assumed that the ventilation strategy for single rooms was designed to comply with 3.14.5 C Scottish Building Standards not SHTM 03-01 guidance. I consider this assumption to be very likely correct as this was the position outlined in the GGC Project Board comment (as above). This strategic approach/prioritisation of temperature and energy control over clinical need is in my opinion a fundamental factor in the buildings design approach.

Issues with the ventilation strategy

6.7 The key issues with the ventilation system include:

- low air change rates (not compliant with SHTM 03-01 guidance)
- lack of HEPA filtration
- inadequate room pressure differentials
- in some wards, the use of chilled beams
- in some wards, spaces were not sealed
- air handling unit's (AHU) operating close to capacity and no standby/backup units
- the ventilation system was not validated

6.8 Details regarding why the existing installation could not be modified to overcome the issues listed above can be seen below:

Low air change rates and chilled beams

6.9 The Swegon Parasol Ceiling terminals (referred to as chilled beams) were limited in size and were designed to accommodate a fresh air supply of 40 l/s - in all wards where chilled beams had been installed the typical air change rate for a room was 2.5 – 3 air changes per hour (ACH).

6.10 The Swegon manufacturers' specifications suggest that the maximum fresh air supply that could be accommodated through the Parasol unit was 49 l/s – this small increase in air supply would not have had any significant impact and would not achieve 6 ACH. If the SHTM requirement of 6 ACH was required, then supplementary supply diffusers would also need to be installed in all single bedrooms to increase the additional fresh air.

6.11 SHTM 03 01(2013) advises careful consideration should be given to the use and location of chilled beams to the possible risk of cross infection – e.g. Ward 4C – haematology-oncology. Chilled beams also require access for cleaning which is disruptive as patients in high risk wards need to be moved out of the room.

HEPA filtration

6.12 At handover, there were no HEPA filters installed in the AHU's – is not clear why third level filtration was not provided for in the air handling units, when clearly certain patient groups require this level of filtration. I have assumed that the only ward that had HEPA filtration installed at handover was Ward 4B and in the patient bedrooms only - however the corridor is not HEPA filtered meaning there is a risk of contaminants getting into the room when the door to a patient's bedroom is opened. . I consider this assumption to be very likely correct given the absence of information to the contrary. It seems that the inclusion of HEPA filtration was seen an afterthought when the building was handed over, for example, Ward 4C was designed as a general ward and is relying on portable HEPA filters, however it has been suggested that these are not as effective, as air is still coming into the room unfiltered.

Room pressure differentials

6.13 A review of Ward 4B and Ward 4C has found deficiencies with the required room pressures.

6.14 I have assumed that bedrooms have been designed to operate under a nominal negative/neutral pressure to corridors (as per SHTM appendix 2 recommendations), however certain wards were required to provide a protective environment and should have been operating under positive pressure to reduce exposure to airborne pathogens – such as the Bone Marrow Transplant Unit in Ward B and the Haematology Ward in Ward 4C. I consider this assumption to be very likely correct given the absence of information to the contrary. There have been difficulties trying to achieve the required room pressures with the existing infrastructure and both still fall short of meeting the requirements[7].

Air handling units (AHU)

6.15 The air handling units were operating at close to capacity, in addition the size of the AHU's meant that the AHU's could not provide the required air volumes to

[7] Request for Information - Section 21 Notice - No 18 (Ventilation Systems)

achieve 6 ACH in single bedrooms. The limiting factors were attributed to the existing fans, motors and heating and cooling coils.

6.16 I have been unable to identify evidence of any provision for backup air handling plant, so when annual verification, maintenance need to take place or in the case of unplanned failures, the AHU would need be shut down. Shut down of the AHU would impact on the ability of the ward to provide the required airflow necessary for safe patient care.

Air permeability and pressure differentials

6.17 Some wards required some rooms to achieve a predictable and low level of leakage to provide safe air paths, for example the Bone Marrow Transplant Unit located in Ward 4B – however suspended ceiling tiles were installed in bedrooms and en-suites in this ward. This was acknowledged[8] as key design issue that affected the operation of the air system due to leakage into the ceiling void and particle transfer from the void into the room via loose fitting tiles or through the doorway when open due to drop in room pressure. Bedroom and en-suite ceilings had to be replaced with smooth Jointless impervious ceilings (plasterboard) which led to significant disruption and additional cost. It is not clear who signed off the original specification and how this was not picked up when works were on site.

[8] Request for Information - Section 21 Notice - No 18 (Ventilation Systems) RHC Ward 2A / 2B

7. QEUH/RHC design, installation, commissioning and validation (point of occupation)

What was/is the relevant standard for each clinical area and patient group?

7.1 SHTM 03-01 (2007) specifies key ventilation performance criteria in chapter 7 and Appendix 2 for many typical healthcare services or patient groups. In the current SHTM 03-01 (2021) this information has been expanded within chapter 8 and Appendix 2 to provide more comprehensive guidance, although it should be noted that specific ventilation performance criteria are also found in the relevant SHBN's for specific clinical activities. In addition, the SHTM is unable to provide specific performance criteria for every possible clinical activity or space and in these circumstances an assessment is needed to compare similar activities to establish a design standard. This assessment and process of agreeing the appropriate ventilation strategies for each clinical areas should be a joint exercise involving clinicians, IPC representatives, estates (Authorised Persons and Authorising Engineers (Ventilation)) and the design team. These performance criteria are typically recorded within the room data sheets or a comprehensive environmental matrix for the scheme.

Was that standard deviated from?

7.2 From the information reviewed I have concluded that the overall ventilation strategy for the building was non-compliant to the basic principles of healthcare ventilation as outlined in the SHTM standard 03-01 (2007) General ward areas were not designed to achieve the minimum standards of 6 air changes per hour and some

specialist areas were also not designed to achieve clinically appropriate standards. One example of this is detailed below:

Low air change rates (not compliant with SHTM 03-01 guidance)

General Wards

7.3 The SHTM 03-01 (2007) standard for air change rates in general wards and single wards states a requirement for at least 6 air changes per hour. This was never designed or achieved for any of the general wards. At design the working ACH was agreed to be 2.5ACH. In practice a range of between 2.5 and 3 ach is found in general wards in QEUH. The use of CBUs in patient rooms is contrary to both the latest versions of the HTM03-01 (clause 2.51) and in HTM 03-01 (2007) and SHTM03-01 (2009) there use was caveated by issues relating to Draughts, dew point risk, and maintenance issues (clauses 2.45 and 2.46) There potential use does not override the requirement for adequate dilution ventilation provision via air changes.

Ward 2A - Haematology and oncology and Teenage Cancer Trust (TCT)

7.4 Ward 2A is intended to house a range of child patients many of them immunosuppressed, immunocompromised and with neutropenia and thus requiring protective ventilation systems (HEPA filtered positive pressure).

7.5 In 2015 on handover the ward seems to have been built to the specification used for general wards of the QEUH. Patients were moved out the ward in 2018 and extensive ventilation works were carried out to improve the ward. As part of these works a review and report was produced by Innovated Design Solutions entitled

Queen Elizabeth University Hospital Adult & Children's Hospital Feasibility Study Regarding Increasing Ventilation Air Change Rates within Ward 2A Report (OCT 2018). Within the report a number of observations and recommendations were made including, an assessment that the original accommodation design philosophy was not intended for use by patients with immune response impairment/deficiency. On the contrary, the existing ventilation strategy would appear only likely to promote the risks associated with uncontrolled ingress of infectious aerosols into patient areas. Existing Bedroom supply air change rates were found to be in the region of 3ac/hr, which is significantly lower than would normally be expected, and not in accordance with recommendations defined within either SHTM 03-01, or HTM 03-01. The desired increase in air change rates, to achieve 6ac/hr whilst utilising existing installations, was deemed impractical. Notwithstanding this, in view of numerous deficiencies/inadequacies discovered with regards to existing system installations it was considered that significant system modification/replacement would be necessary. Works recommended within the report generally involve the complete separation of upper Ward 2A facilities from the existing centralised plant/system, with new dedicated air handling plant and distribution installed accordingly. The viability of creating dedicated Isolation Suites throughout the upper Ward 2A areas was considered, however, deemed to be impractical primarily due to the probable significant resultant reduction in accommodation. With a view to improving patient protection, they recommended consideration be given to the installation of completely new ventilation systems, providing a positive pressure within each Bedroom with air cascade into adjacent Corridors. In addition the report highlighted numerous significant deficiencies/inadequacies appertaining to the existing system installations, which were outlined within the report accordingly.

7.6 In 2019 the unit was commissioned, validated and re-opened. It had HEPA filtered bedrooms and corridors and all rooms had the specified 10ACH and + 10 Pa positive pressure from UK guidance. CBU and suspended ceilings were removed and all rooms were sealed. An air lock to the ward, a back-up AHU and pressure monitoring were also added.

Ward 2B- Paediatric Haematology and oncology - Day Care Unit

7.7 This ward is a day unit and has been designed as a general ward. Though treating patients who may be immunosuppressed the patients are still using public transport and going to public places so it is argued the ward did not require special ventilation.

7.8 However, in 2019 a ventilation up grade was performed in which an air lock was incorporated and HEPA filtered air was provided in the corridor.

Ward 4B - Adult Bone Marrow Transplant (BMT) - Neutropenic patient group

7.9 Ward 4B of the QEUH was built to house bone marrow transplant patient who need protective isolation due to their immunosuppression. In order to prevent exposure to obliquus airborne pathogens ventilation systems need to ensure the air supply is filtered to a high degree and there is no ingress of contaminated air from outside or surrounding areas. Special precautions will be needed if potentially aerosol generating building works are being undertaken close by.

7.10 This ward was not part of the original design of the hospital but was included in 2013 as a replacement for the existing Beatson Unit and an instruction to build a unit to the same standard was produced. No specific construction output specification or design brief was produced for the BMT unit, although reference was made to the construction output specification for the haematology-oncology ward.

7.11 The HTM03-01 document from 2007 clearly stated the ventilation needs of these patients. The requirements were rooms supplied with H12 filtered air with 10 air change an hour and a positive pressure of 10 Pa. The Beatson facility had the

same ACH, pressure differentials but also had sealed bedrooms, pressure alarms and an air lock entrance to the ward.

7.12 On the 2015 handover of the facilities there were the following deficiencies:

- air change rate of 6ACH was below the standard and specification
- rooms were not at the positive pressure value specified but ranged from 0-+4Pa
- HEPA filters were installed in the ceiling diffusers in patient bedrooms but not in the corridors or ancillary spaces.

7.13 In addition unlike the Beatson there were no pressure alarms, no air lock to the ward and the bedrooms had suspended ceiling which meant that the rooms were not sealed.

7.14 From 2015-2018 a series of upgrade works were carried out and patients returned to the ward in July 2018. In 2017 some improvements had been made positive pressure was now 5.5 Pa and the rooms were sealed, a pressure monitoring system was in place but the ward was still below specification

7.15 Currently (2024) the rooms now operate at +10Pa but still at 6ACH. An air lock has also been introduced to the ward.

Ward 4C - Haematology-oncology (10 beds) - Neutropenic patient group

7.16 Ward C was also intended to care for immunosuppressed patients with conditions such as leukaemia with the same ventilation requirements as specified in HTM03-01. The clinical output specification states:

7.17 All highly filtered air >90%, probably best HEPA with adequate number of positive pressure sealed HEPA filtered side rooms for neutropenic patients as in the Beatson West of Scotland Cancer Centre[9]

7.18 However, it appears that the ward was designed to the general specification of a general ward with the 2.5ACH performance standard, as above.

7.19 On handover the ward had no HEPA filtration, 2.5ACH, neutral pressure rooms which was not in compliance to the Construction Output Specification and HTM03-01.

7.20 Currently (2024) the ward is still at 2.5ACH, not HEPA filtered and rooms are still at neutral pressure and mobile HEPA units are being deployed to endeavour to improve the air quality, however it is understood that validation of performance information is not available for the efficacy of these units.

Ward 6A - Rheumatology patient group

7.21 Ward 6A – Designed for Rheumatology patients however patients from Ward 2A RHC moved there 26th September 2018

[9] Quote but source to be clarified.

7.22 Ward 6A was originally designed as a general ward and had 2.5ACH and CBU like all similar wards at QEUH. In Sep 2018 this was used to care for patients from 2A while building work was carried out.

7.23 In 2019 it was upgraded by placing portable HEPA filter units in three rooms (20,21, & 23). Installing Camfil recirculating scrubbers in the ceilings of en suites.

7.24 Level 5 of the QEUH was designed and constructed to the specification of a General Ward, including the ventilation system. At some point around August 2014 however, the decision was made to relocate the Infectious Disease Unit (IDU) from the Brownlee at Gartnaval General Hospital to wards 5C and 5D.

7.25 At handover of the new QEUH in 2015, the services being provided in the four generic wards on level 5 were:

- Ward 5A Diabetes
- Ward 5B Diabetes
- Ward 5C Communicable Diseases
- Ward 5D General Medical/ID Team

7.26 The general ventilation system on level 5 was designed to achieve 2.5ac/h and a nominally negative pressure relative to the corridor. This is below the minimum standards for a general in-patient ward which is 6 ACH. The ventilation parameters for a single bedroom in an Infectious Disease Unit. SHTM 03-01 recommends 10ac/h and -5Pa pressure for an ‘infectious disease isolation room’.

7.27 Specific concerns raised by clinical staff in 2014 with regards to the move of IDU included:

- IPC concern over the total number of lobbied isolation rooms available within the NSGH. In particular, the addition of both the Adult Bone Marrow Transplant unit and the Infectious Disease unit to the on-site specialties would increase need.
- IPC concern over the co-location of infectious disease patients with the most vulnerable patients in critical care, concluding however that “if the ID physicians have signed this off they must think the risk to others in critical care is low”.
- ID physicians concern that Isolation rooms would be located on a different floor, so the nursing expertise would not be aligned and patients would be nursed by a different cohort of nurses.

7.28 The Infectious Disease Unit on level 5 of the QEUH currently:

- is achieving air change rates between 2.7ac/h and 3.2ac/h
- is achieving a notionally negative pressure regime (from bedroom to corridor) ranging from 0 to -3.5Pa
- is being served by three AHUs operating at full capacity
- is not HEPA filtered
- does not have sealed rooms or doors
- does not have digital pressure monitoring and alarm systems
- has access to three negative pressure isolation rooms (with en-suites) in the critical care unit for isolation of airborne infections.

7.29 This ventilation strategy/performance is below the minimum standards that are specified within the SHTM standards and not considered appropriate.

7.30 Overall the ventilation strategy appears to have been influenced by a desire to achieve a certain BREEAM classification and utilised systems and design philosophies which did not adopt a patient centred approach or Infection Prevention and Control at its heart.

Lack of HEPA filtration

7.31 HEPA or EPA/UEPA filters are in simple terms a finer grade of filter which can remove or capture very small particles from an air supply. The size and efficacy (percentage of particles captured) is used to govern the grade of the filter. In microbiological terms these grades of filters can remove practically all significant levels of particles and due to the nature of viruses, bacteria, and fungal spores this grade of filtration is used to provide a clean air environment. It should be noted that these filters do not remove or capture gases or odours and are suitable for both supply and where necessary extract filtration.

7.32 If patients are identified as vulnerable to environmental airborne pathogens such as fungal spores it would be typical to provide this grade of filtration as part of an isolation facility, such as a PPVL, to provide protection from such potential contamination.

7.33 From the evidence reviewed[10] I have concluded that these grades of filter were not originally installed to areas of critically vulnerable patients were intended to be cared for and even when suitable filtration was installed the overall ventilation systems was not upgraded to a fully compliant level.

[10] Request for Information - Section 21 Notice - No 18 (Ventilation Systems)

Inadequate room pressure differentials

7.34 Pressure differential or room air pressure cascades are used to provide predictable air movements and protect critical environments from airborne contamination. A negative pressure differential between a room and surrounding areas will generally provide an air path into the space thus contributing to containing any airborne contamination within the room and minimising the risk of it travelling to surrounding areas (suitable for infectious or hazardous risks). A positive pressure differential between a room and the surrounding areas will generally prevent any airborne contamination from entering the protected space (suitable for immunosuppressed patients).

Air permeability in isolation rooms

7.35 HBN 04-01 Supplement 1 provides the design considerations and minimum performance and testing standards for isolation facilities. The standard refers to BSRIA's technical standard BTS 03: Air permeability of isolation rooms. The methodology detailed within the standard enables isolation facilities' air permeability levels to be validated as well as design air flowrates between adjacent rooms, pressure stabilisers and doors to be verified.

7.36 Isolation suites for the prevention of airborne infection can be categorised in two main groups: those used for the protection of immunocompromised patients and those used to contain airborne infection. Isolation suites can consist of several rooms, e.g. patient's room, entrance lobby, en suite bathroom. Pressure differentials between the rooms forming the isolation suite and adjacent areas (e.g. hospital corridor) are normally defined at design stage. Positively pressurised rooms are used to contain an immunocompromised patient and negatively pressurised rooms are used to contain an infectious patient. In the case of negative isolation rooms, protecting the patient from a secondary infection should be considered too. Some

designs include a positively pressurised ventilated lobby (PPVL) and a neutral room. The PPVL design can be potentially used for both immunocompromised and infectious patients, subject to suitable assessment and provision of supply air filtration (for immunocompromised patients).

7.37 In addition to the use of the isolation suite and the pressure differentials, designs include (or should include): ventilation rates (air change rate ACR), flows from one room to another and air flow rates through components such as doors, door grilles or pressure stabilisers. International guidance on the design of isolation rooms varies from one country to another and there are large differences in the recommended ACR, pressure differentials, internal design of the room, etc.

7.38 Achieving low levels of air permeability is essential; not only does the integrity of the walls offer protection during normal operation, but also in the event of fan failure, which can cause the room to operate at different pressurisation levels, walls become the first point of defence against airborne infection.

7.39 The limit recommended by BSRIA is 2.5 m3/h/m2 at 50 Pa, or lower. This is based on our testing experience, although much lower levels (1 m3/h/m2 at 50 Pa) have been obtained in isolation room mock-ups built and tested at BSRIA's laboratories. BSRIA's work on isolation rooms has demonstrated than an air permeability level of more than 2.5 m3/h/m2 at 50 Pa can be equivalent to having a leaky closed door at 10 Pa, where approximately 60l/s of contaminated air can travel to areas where Personal Protective Equipment (PPE) against airborne infection is not worn (e.g. hospital corridor). Ultimately, it will be the infection control team's decision whether this is an acceptable risk or not.

7.40 In addition to protecting against airborne infection, a low air permeability level assists during the commissioning of the rooms. During commissioning, it is frequent to find problems with the room not achieving the desired pressure. This leads to

further problems such as pressure stabilisers not opening. A room with a low air permeability level will achieve the design pressurisation levels with the design supply flowrate.

7.41 The BSRIA standard is used to quantify the air leakage of the overall isolation suite and the rooms that form it. The standard also offers a methodology to validate design flowrate through pressure stabilisers, doors and door grilles. The testing methodology is based on ATTMA standards for air permeability testing. The number of tests required is specific to each isolation suite and two testing examples are described in HBN4. Carrying out the air permeability tests takes approximately one day.

7.42 In conclusion, testing and achieving low air permeability levels in an isolation room will help the rooms achieve the design pressurisation levels and flowrate levels during the commissioning process and reduce the risk of infection between the room and adjacent areas during normal operation and in the event of fan failure.

The use of chilled beams

7.43 The use of chilled beams is not now recommended in clinical areas of hospitals due to the requirement for regular cleaning and the recirculating pattern of air movement they employ.

7.44 A chilled beam is a type of radiation/convection HVAC system designed principally to heat and cool large open plan spaces such as offices. As the beam (heat exchanger) chills the air around it, the air becomes denser and falls to the floor. It is replaced by warmer air moving up from below, causing a constant passive air movement called convection, which cools the space. In general terms chilled beams can be either passive which rely solely on convection, or active which can include a

small amount of forced fresh air supply ventilation to induce the circulation of room air through the unit (thus increasing its heating and cooling capacity).

7.45 The primary advantages of the chilled beam systems include:

- lower operating cost
- very quiet/low noise emitting
- highly energy efficient

7.46 Passive chilled beams do not provide fresh air dilution and are not considered appropriate within clinical care areas (as per HTM 03-01 (2021) clauses 5.18 to 5.24 inc. See below):

> "**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."[11]

[11] A36962514 – HTM 03-01 Part A (2021) – Hearing Commencing 9 May 2022 – Bundle 2 - Page 360 and 361.

7.47 In addition to the above issues and guidance the use of chilled beams will involve the creation of condensation from the air as it is cooled through psychometry and as such involves moisture which if not adequately drained and kept clean can provide a catalyst for microbiological proliferation.

Use of thermal wheels in areas requiring specialist ventilation

7.48 A thermal wheel, also known as a rotary heat exchanger, or rotary air-to-air enthalpy wheel, energy recovery wheel, or heat recovery wheel, is a type of energy recovery heat exchanger positioned within the supply and exhaust air streams of air-handling units, in order to recover the heat/coolth energy.

7.49 A thermal wheel consists of a circular honeycomb matrix of heat-absorbing material, which is slowly rotated within the supply and exhaust air streams of an air-handling system. As the thermal wheel rotates, heat is captured from the exhaust air stream in one half of the rotation and released to the fresh air stream in the other half of the rotation. Thus waste heat energy from the exhaust air stream is transferred to the matrix material and then from the matrix material to the fresh air stream. This increases the temperature of the supply air stream by an amount proportional to the temperature differential between air streams, or "thermal gradient" and depending upon the efficiency of the device. Heat exchange is most efficient when the streams flow in opposite directions, since this causes a favourable temperature gradient across the thickness of the wheel. The principle works in reverse, and "cooling" energy can be recovered to the supply air stream if desired and the temperature differential allows.

7.50 Thermal wheels can be used in healthcare applications as per HTM 03-01 (2021) clause 9.66, see below:

"**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."[12]

7.51 In a specific immunosuppressed patient area I would personally recommend either a plate heat exchanger as this has a lower potential risk of exhaust to supply air cross contamination or if in a highly infectious patient area a run around coil which has no risk of cross contamination.

Ventilation system resilience

7.52 A number of the critical ventilation systems are currently operating at or near their design capacity and this highlights two potential areas of concern.

7.53 The first is that when new the systems were commissioned, albeit not independently validated to achieve agreed, albeit non-compliant airflow performances. This level of performance is based on a new system with clean filters and minimal additional resistance from wear and tear or environmental

[12] A36962514 – HTM 03-01 Part A (2021) – Hearing Commencing 9 May 2022 – Bundle 2 - Page 419.

contamination. HTM 03-01 (2007) states that in packaged AHU's the system should ensure that an allowance has been made for 'dirty filter' conditions. In other words the system must be capable of delivering the required performance even when the system is nearing or in need of essential maintenance such as filter changes. This is reinforced within health building note (HBN) 00-07: Planning for a resilient healthcare estate which states under chapter 5 for Ventilation systems (starting at clause 5.55) Ventilation systems are installed throughout healthcare premises to fulfil a number of purposes, some of which have resilience implications. Hazards and threats that may be considered credible in a healthcare facility might include the spread of:

- airborne infections
- waterborne infections
- chemical or biological contaminants brought in on casualties
- a contaminant deliberately released in a healthcare facility[13]

7.54 Risk assessment may indicate the filtration of supply air either full-time or temporarily in times of heightened threat. Consideration should be given to the development of safe changing routines in the event that contamination has occurred.

7.55 The three resilience principles (robustness, redundancy and re-configurability) should be applied to designs to ensure that the ventilation system is:

- robust enough to withstand hazards and threats
- redundant in order to allow continued operation in the event of component failure and

[13] HBN 00-07 added to Bundle Instruction Template.

- reconfigurable in the event of damage – although in such a case, this may be limited to the provision of dampers to ensure that damaged areas are isolated and that pressure gradients can be maintained

7.56 In the majority of critical ventilation systems it is considered good practice to ensure provision at design stage of either back-up/run and stand-by resilience, or quick change/by-pass design arrangements for identified areas of single point failure. AHU's when new/validated running at full capacity provide no room for degradation overtime, although it is worth noting the in-use tolerance of ventilation performance at verification does allow for an 80% tolerance in performance for both airflows and room pressure differentials.

Design and installation conclusions

7.57 In my experience and opinion the overall ventilation design philosophy appears to have been driven by a desire to achieve a certain environmental performance rating (BREEAM), and a lack of understanding of critical clinical risks associated with the ventilation system. The design was agreed to significantly derogate from normal ventilation performance parameters and therefore provided a sub-optimal patient care environment from a ventilation perspective. The use of chilled beams in critical clinical care areas also influenced the sub-optimal airflow performances and added an avoidable risk to these highly vulnerable patient areas. The design was recognised as an issue after occupation as some rectification/improvement works were commissioned, however these failed to address all of the original design deficiencies and a number of the systems remain in a sub-optimal state as outlined in the following sections of this report.

8. Commissioning and Validation

Overview of commissioning process

8.1 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.

8.2 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.

8.3 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.

8.4 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.

8.5 The commissioning process is to make sure that all of the individual engineering elements work as they have been designed.

Ventilation system commissioning/validation report

8.6 The SHTM requires under clause 8.64 that - 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.[14]

8.7 Clause 8.65 goes on to state that - The report shall 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[15]

Overview of validation process

8.8 Following the commissioning process the systems will then be independently validated against the original ventilation strategy, acknowledging any accepted derogation, ensuring that all of the building engineering services interact with one another as they should. This is outlined in HTM 03-01 2021 in chapter 12 under the following clauses:

> "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

[14] A33662259 - SHTM 03-01 Part A (2014) – Hearing Commencing 9 May 2022 – Bundle 1 - Page 742.
[15] A33662259 - SHTM 03-01 Part A (2014) – Hearing Commencing 9 May 2022 – Bundle 1 - Page 742.

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, checking against the HTMs. 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.”[16] and it can be handed over and put into clinical use.

HTM 03-01 Part A extract of 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

[16] A36962514 – HTM 03-01 Part A (2021) – Hearing Commencing 9 May 2022 – Bundle 2 - Page 456.

- 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.” [17]

[17] A36962514 – HTM 03-01 Part A (2021) – Hearing Commencing 9 May 2022 – Bundle 2 - Page 459 and 460.

QEUH/RHC Commissioning

8.9 The commissioning of the initial installation at QEUH appears to have been undertaken for each individual element of the ventilation system, however, none of the systems which interact complimentary elements of the system were tested to assess the overall cause and effect. For example the ventilation system and fire alarm systems were not tested to ensure they operated as intended in all scenarios. This overall system performance testing would normally be undertaken as part of the independent validation process (see below).

8.10 In addition, the reports of the commissioning include information which would suggest the systems were not commissioned in their final finished condition as below.

8.11 QEUH Critical Care Ward Isolation Rooms AHU Supply Fans. Individual Air Handling Units (AHU) located in plantroom 21 provide supply air to Isolation Rooms on the 1st Floor of QEUH. The supply grilles are fitted with a Terminal HEPA box however the air balancing report records that there was no HEPA filter fitted when balancing of the system took place. Taken from Request for information Section 21 Notice No. 18 (Ventilation systems).

8.12 The commissioning process was undertaken by specialist contractors under the remit of the contract and no independent validation was completed. From the evidence reviewed it I have assumed that a formal ventilation system commissioning report was not produced/provided to the NHS Board".

QEUH/RHC Validation

8.13 Validation is important as it tests the whole system against the design and any derogations to demonstrate that the system is fit for purpose prior to use – it also sets the benchmark for future verifications. Following a review of Ward 4B and 4C it appears that no validation was completed prior to handover.

8.14 Without the formal confirmation through the validation process it would not normally be advisable to accept a critical healthcare ventilation system into use and the failure to appropriately undertake the validation process enabled the systems to operate in a sub-optimal state, potentially exposing patients to an elevated level of risk.

9. QEUH/RHC Operational and Maintenance

Ventilation system policy

9.1 The Greater Glasgow and Clyde (NHS) Health Board published an approved and ratified Ventilation Systems Policy in February 2020 which stated that:

- The policy sets out the detailed requirements for the maintenance and safe operation of all air conditioning and ventilation plant as stated in SHTM 03-01 Parts A & B. These will be maintained so that they do not present a risk to persons either in the vicinity of the plant, in areas served by the plant, or a statutory compliance risk to NHS Greater Glasgow & Clyde.

- The Policy requires that all ventilation and air conditioning equipment is installed, inspected, serviced and maintained in accordance with all Statutory

Instruments, NHS Guidelines and Scottish Health Technical Memorandums (SHTM's) to ensure that such equipment does not pose a health or operational risk to either, staff, patients or visitors.

- The policy includes a summary of key roles and outlines principle responsibilities of identified post holders. It also includes a broad definition of which ventilation systems are considered as 'critical' and be subject to annual performance verification.[18]

9.2 The document appears to be generic in nature and whilst it clearly states roles and responsibilities and duties to be undertaken, it would appear from the subsequent AE(V) audits that the policy was not appropriately complied to. The policy also makes no reference to the performance derogations or sub-optimal airflow performances and provides no system to manage or re-assess the impact or appropriateness of these derogations. A formal ratified system for the agreement and management of derogations is essential for the site (see section on areas for potential improvement below).

[18] Ventilation Systems Policy added to Bundle Instruction Template.

Provision of personnel and resources

9.3 From the evidence provided and findings from the AE(V) audit reports (extracts below) it would appear that the site was handed over and became operational without an appropriate planned preventative maintenance (PPM) programme in place. Site Estates staff were providing a reactive service and in many cases trying to address defects or snagging issues left from the construction process. It appears to have taken a number of years to establish/agree which systems should be classified as ‘critical’ and be subject to annual verification, and even then the failure to appropriately record or manage the agreed derogations on ventilation performance were not considered or in place. The level of resource availability for given roles was repeated highlighted as a concern and this remains a potential area of increased risk to the current day, (see section on areas for potential improvement below).

Authorised person (ventilation) provision

9.4 The need for AE’s and AP’s is generally well understood and defined within many of the current HTM guidance documents, however increasingly issues are arising due to staff/skills shortages that is seeing an evolving situation where the roles held by a small number of even single technical professional is exceeding practical limits of both skills/knowledge levels and time availability. As such the following is designed to provide an opinion on suitable limits for these roles, dependent upon influencing factors such as size or complexity of both the roles and healthcare setting.

Disciplines which may require an AE & AP

9.5 Some roles have been specifically outlined either within legislation or HTM's (or both), others are included below as they are known areas where a suitably qualified and experienced individual is either implied or required to provide assurance of compliance.

Technical Area	Status	Comment
Decontamination	HTM	Not present in all healthcare settings
Medical Gases	HTM	Not present in all healthcare settings
Ventilation (critical)	HTM	Not present in all healthcare settings
Water	Legal/HTM	Applies in all healthcare settings
Fire	Legal/HTM	Applies in all healthcare settings
Electrical (LV)	Legal/HTM	Applies in all healthcare settings
Electrical (HV)	Legal/HTM	Not present in all healthcare settings
Lifts/LOLLER	Legal/HTM	Not present in all healthcare settings
Pressure Systems	Legal/SHTM	Not present in all healthcare settings
Asbestos	Legal	Not present in all healthcare settings
Confined Spaces	Legal/SHTM	Not present in all healthcare settings
Environmental/Energy/Carbon Reduction	HTM	Emerging priority and applies in all healthcare settings

Classification of healthcare premises

9.6 As stated above not all healthcare sites will have all of the above technical areas, however the number of technical areas is not the only influencing factor in providing an effective AE/AP service provision. The size and complexity of the site has a significant impact on the remit and scope of the role. As such the following classifications have been used to inform the recommended role limits.

- Large acute or Teaching Hospital

- Medium multi-service or District General Hospital
- Small Multi-service or in-patient Community Hospital
- Large/Medium Primary Care non-residential site
- Specialist Hospital
- Large/Complex Mental health or Learning disability Hospital
- Medium/Small Mental Health or Rehabilitation Hospital
- Multi-site non-residential small sites (community premises)

Authorised person (AP) ventilation

9.7 The HTM 00 - Policies and Principles of Healthcare Engineering outlines the role of an Authorised Person and as such indicates the levels of specialist knowledge, skills, and experience required to be achieved and maintained to hold this role.

> Clause 3.18 The AP has the key operational responsibility for the specialist service. This person will be qualified and sufficiently experienced and skilled to fully operate the specialist service. They will be nominated by the AE, appointed by the healthcare organisation and be able to demonstrate:
>
> - their understanding through familiarisation with the system and attendance at an appropriate professional course
> - competency
> - a level of experience
> - evidence of knowledge and skills

Clause 3.19 An important element of this role is the maintenance of records, quality of service, and maintenance of system safety (integrity).

Clause 3.20 The AP will also be responsible for establishing and maintaining the validation of Competent Persons (CPs), who may be employees of the organisation or appointed contractors.

Clause 3.21 Larger sites may need more than one AP for a particular service. Administrative duties such as record keeping should be assigned to Specific AP's and recorded in the operational policies.[19]

To manage essential information, processes, and operational management contained in the specific guidance/HTM. To act as an on-site point of contact and knowledge for the HTM related issues, enabling organisations to manage these systems safely and economically.

Essential responsibilities of an AP's remit

- Apply the main applications for the specific HTM/Guidance and explain why the need exists.
- Apply management responsibilities in relation to the specific HTM/Guidance in accordance of the defined Authorised Person role in Department of Health guidance.
- Describe health and safety issues relating to the specific HTM/Guidance, including legal requirements relating to those issues and means of compliance.
- Describe how the specific HTM/Guidance can be used to minimise health associated risks.

[19] A37357440 – HTM 00 (2014) – Hearing Commencing 9 May 2022 – Bundle 2 – Page 110 and 111.

- Manage essential monitoring and maintenance procedures required for the safe and efficient operation of plant components.
- Use sources of guidance associated with the safe and efficient operation of plant components.
- Apply the main requirements of the specific HTM/Guidance and understand their relevance to the health of patients, visitors, and staff in accordance with HTM and HBN guidance.
- Manage and control works on the specific technical HTM/Guidance specialist in accordance with the Authorised Person role as defined in Department of Health guidance.

9.8 As stated above the number of AP roles an individual can reasonably be expected to hold is directly linked to the technical subject matter and the size/complexity of the site involved. As such the following table outlines a suggested minimum recommended numbers of individual post-holders (either lead or deputies) which are likely to be able to be practically maintained.

9.9 In addition to the stated role and responsibilities of an appointed Authorised Person it also needs to be acknowledged that these roles are not seen as a stand-alone role but as an additional activity to an existing primary job role or ‘day job’. It is not unusual to find that operational estates officers and engineers are expected to maintain a full range of operational duties, management roles, and associated tasks and in addition are expected to fulfil multiple AP roles. This is not a sustainable position and with an aging and reducing workforce capacity and skills base cannot be reasonably expected to be sustained.

	Large acute or Teaching Hospital	Medium multi-service or District General Hospital	Small Multi-service or in-patient Community Hospital	Large/Medium Primary Care non-residential site	Specialist Hospital	Large/Complex Mental health or Learning disability Hospital	Medium/Small Mental Health or Rehabilitation Hospital	Multi-site non-residential small sites (community premises)
Decontamination	**3**	**2**	**2**	**2**	**2**	**1**	**1**	**1**
Medical Gases	**3**	**2**	**2**	**2**	**2**	**1**	**1**	**1**
Ventilation	**2**	**2**	**2**	**2**	**2**	**1**	**1**	**1**
Water	**2**	**2**	**2**	**2**	**2**	**2**	**2**	**2**
Fire	**2**	**2**	**2**	**2**	**2**	**2**	**2**	**2**
Electrical (LV)	**3**	**2**	**2**	**2**	**2**	**2**	**2**	**2**
Electrical (HV)	**2**	**2**	**2**	**2**	**2**	**1**	**1**	**1**
Lifts/LOLLER	**2**	**2**	**2**	**2**	**2**	**1**	**1**	**1**
Pressure Systems	**2**	**2**	**2**	**2**	**2**	**1**	**1**	**1**
Asbestos	**2**	**2**	**2**	**2**	**2**	**2**	**2**	**2**
Confined Spaces	**2**	**2**	**2**	**2**	**2**	**1**	**1**	**1**
Environmental/Energy/ Carbon Reduction	**2**	**2**	**2**	**2**	**2**	**2**	**2**	**2**

Greyed out cells are not applicable at QEUH

9.10 Given the above numbers of post holders required it is likely that individuals will be required/expected to hold multiple AP roles, however the number of roles will be directly influenced both by the complexity of the role/sites and levels of knowledge/CPD needed to maintain appropriate competency. As such the following indicative limits are in the authors' opinion a sensible maximum to consider as appropriate:

9.11 For large acute or teaching hospitals it is recommended that a suitable number of disciplines or roles as an AP should be between 1 and a maximum of 3, with only 1 of these being a lead AP role.

9.12 If this approach is accepted as a reasonable method to ensure compliance whilst maintaining adequate resources then the result is likely to support a significant increase in the professional staffing levels required to operate a healthcare facility.

Provision of a ventilation safety group

9.13 Although the requirement for a specific ventilation safety group was not a requirement of the SHTM until the latest iteration (2021), given the critical nature of the clinical services at QEUH and the issues identified through the design and construction and early periods of operation a VSG would have been a suitable means to manage the ventilation systems, provide assurance or a means to escalate issues within the organisation.

9.14 A Ventilation Safety Group is intended to:

- Provide a means for the joint review of issues relating to the effective management and review/co-ordination of aspects of the performance of the sites ventilation systems including the development of strategies and approaches to manage risks associated with those ventilation systems.

- Accept ownership of and to be accountable for Ventilation Risk Management in accordance with all current legislation and guidance documentation.

- Develop a Ventilation Action Plan (VAP) which provides a risk-management approach to the safe operation of ventilation systems.

- Monitor and advise on ventilation across the site in line with the VAP and assist with understanding and mitigating risks associated with ventilation systems.

- Provide a forum for joint strategic discussion, considering actual and anticipated changes to the service provision.

Roles and function

9.15 The aim of the VSG is to ensure the safety of all ventilation systems used by/for patients, staff and visitors, and to minimise the risk of infection associated with airborne pathogens.

9.16 To implement the legal duties, the Duty Holder should appoint a VSG to undertake the commissioning, development, implementation and review of an operational procedure for the management of ventilation systems.

9.17 The VSG is therefore required to:

- Produce, review and implement a policy for the control of ventilation systems.
- Provide a framework for reviewing, agreeing and endorsing normal and emergency operating procedures and action plans.
- Ensure a regime of maintenance, inspection, testing, and cleaning has been implemented, and it’s performance monitored.
- Provide a forum for positive co-operation between all Trust departments.
- Have responsibility for the escalation of any significant issues to the IPC or H&S committees as appropriate to ensure patient and user safety.
- Ensure a thorough understanding of the risks by all staff and contractors.
- Ensure all staff and contractors carrying out work on ventilation systems are adequately competent.
- Ensure adequate records are kept and maintained.
- Review capital and small works projects to ensure installations are designed, installed and commissioned in line with relevant guidance.

Authority

9.18 The group should discharge under the authority of the Chief Executive and that authority delegated to the individual members of the Group both in the Scheme of Delegation, and from time to time by the Chief Executive as recorded in the minutes of the meetings.

Reporting

9.19 The VSG should report directly to the Board Health & Safety Committee and work closely with the Infection Prevention and Control (IPC) Group – dedicated members of the IPC Group and Health & safety Committee should provide a conduit for information between both groups.

Membership

- Director of Infection Prevention and Control (DIPC)
- Senior IPC nurse and other members of the IPC team as appropriate
- Consultant medical microbiologist
- Senior Operational Manager (Estates)
- Authorised Person AP (Ventilation); & a deputy
- Authorising Engineer AE (Ventilation)Estates Capital Project Representative
- Representative(s) from Health & Safety
- Representative(s) from critical clinical departments such as Surgery

9.20 The Chair of the group should be either the DIPC, or the Senior Operational Manager or their nominated deputies and is empowered to invite or co-opt additional members as and when necessary for the business of the VSG.

9.21 Members are asked to identify a named deputy to send to meetings if they are unable to attend themselves and provide apologies in advance. The named deputy must have full authority to act and make decisions on the full member's behalf and submit reports to the group.

Frequency of meetings

9.22 The VSG should meet every three months or more frequently should the need arise.

Review of terms of reference

9.23 The VSG should review its activity and performance annually, including attendance, and every three years review whether its founding principles are still relevant and whether this is the most effective means of delivering its purpose and recommend any changes it considers necessary for approval by its parent group the Trust Health & Safety Committee.

9.24 At each VSG it is considered necessary for the relevant AP(V) to produce and provide a Quarterly VSG Operational Update Report.

9.25 The concept of the report is to produce an overview summary of ventilation management and control systems on an operational site basis to members of the Ventilation Safety Group (VSG) to provide assurance that appropriate management

controls are in place to maintain the ventilation systems and minimise the risks to the organisation associated with the ventilation systems and comply to legal obligations.

Programme of critical ventilation and LEV system verifications

9.26 Provide a programme in a tabular form of the critical and LEV systems with dates of previous verification, summary of areas/identified issues raised including a risk rating assessment, a summary of remaining issues to address with risk rating, and the date of next scheduled verification.

Details of planned shutdowns required

9.27 Provide details of system planned shutdowns or servicing, including details of location, duration, and access arrangements.

Operational incidents (by exception)

9.28 Provide details of system issues (reported above) that require support or resources to address.

PPM’s and reactive works requests within quarter

9.29 Provide details of PPM’s generated and completed, and ventilation related reactive requests received and completed with details of any work still in progress. Also provide information to root causes for delayed completion such as access, etc.

Fire and smoke damper drop testing

9.30 Provide a statement of compliance or details of areas which are not fully recorded as being tested in line with organisations SOP/Policies. Provide a schedule of dampers which the VSG may want to consider escalating to the Fire Safety Group.

Air sampling test results (if undertaken)

9.31 Provide details of any active air sampling undertaken (total number of samples) and any notifiable or actionable readings by exception including location, level of count, and corrective actions taken to address and if available status of any re-sampling where required.

AE audit action plan remedial action progress

9.32 Provide a summary of the current AE Audit Action Plan identified remedial actions. Include number of red, amber or green remedial actions originally identified and current number of remaining remedial actions under each RAG rating.

A.O.B.

9.33 This formal quarterly status report is not currently in use, but consideration should be given to adopting this or a similar process to provide on-going assurance of compliance to all stakeholders.

GGC Provision of a ventilation safety group

9.34 I have been provided with no clear evidence of a ventilation safety group at QEUH, although many of the functions of a group are clearly present and have been confirmed during on-site discussions with staff, the form of a multidisciplinary format with collective responsibility, is not referenced in the current Ventilation Policy document (2022) or any of the independent audit reports.

Annual verification

9.35 Every ‘critical’ healthcare ventilation system should be subject to an annual performance verification process. The detail and scope of this verification process is outlined within the current health technical memorandum SHTM 03-01 and details all of the essential elements of the plant, system, and area served which must be completed to ensure the system and area remain appropriate and compliant, with the objective to ensure patient and staff safety.

9.36 The annual verification is intended to establish that:

- the system is still required
- the AHU conforms to the minimum standard
- the fire containment has not been breached
- the general condition of the ventilation system is adequate
- the fabric of the area served is satisfactory
- the system performance is adequate with respect to the functional requirement – this will require:
- a full measure of the supply and extract air-flow rates

- the calculation of room air-change rates if applicable
- the measurement of room differential pressures if applicable
- the measurement of room noise levels
- air-quality checks if appropriate
- a check on the control functions

9.37 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

9.38 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, if tiled, all tiles should be clipped down and sealed
- 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
- all service penetrations and access panels should be sealed to prevent uncontrolled air flow between rooms and service voids

- 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

9.39 Failure to achieve a suitable standard will render even the most sophisticated ventilation system ineffective.

9.40 All fire dampers should be tested as part of the annual verification.

9.41 LEV systems will be subject to an examination and test by a competent person at least every 14 months.

Verification standards

9.42 Unless otherwise specified below, the ventilation system should achieve not less than 75% of the design air-change rate given in Appendix 2 of HTM 03-01 Part A, or its original design parameters.

9.43 The pressure regime should achieve not less than 75% of the design value given in Appendix 2 of SHTM 03-01 Part A (2013), or its original design parameters; and the pressure gradient relationships with regards to surrounding areas must be maintained.

Authorised person(s) review and report process

9.44 Following the annual verification process a comprehensive written record should be produced, normally in the form of a report, to record the findings and

schedule any areas where failures exist and identify condition or areas which may be nearing the end of their anticipated safe working life.

9.45 Every verification report should be reviewed and assessed by the AP(V) and issues either addressed and resolved which should include a process to record what action was taken and when it was completed and 'signed off'. If the issue impacts clinical activity or patient safety then the issues MUST be raised with the Ventilation Safety Group for information and agreement of remedial actions. If resources or funding is required to address identified issues then this should be raised at the VSG who are then responsible for either agreeing funding/resource allocation, assessing and accepting the associated risks or escalating the issue to the QEUH Board through the approved escalation route within the terms of reference for the VSG.

Extract/summary of AE(V) Audit Report Summary Nov 2016[20]

9.46 A draft ventilation Standard Operating Procedure (SOP) was held on StaffNet. In addition to the SOP, a ventilation safety policy should be produced and ratified by the board.

9.47 Due to the size and ongoing change at the hospital the APs were not always able to find the time to carry out their duties. The provision of APs (V) should be reviewed by senior management taking into consideration other duties the APs are liable for.

9.48 CPs should be trained, assessed and appointed. Evidence of competency was held for two contractor CPs, letters of competency should be held for all contractor CPs.

[20] AE(V) Audit Report Nov 2016

9.49 Task risk assessments were not held for in-house tasks. These must be produced and communicated to the in-house CPs.

9.50 Permits to work were in use for the Lab Block but they were not in use across the rest of the estate. There were some minor errors on some of the permits to work issued which all APs should note.

9.51 The Document Register was populated for the Lab Block. This should be extended to include the Adult & Children's and the retained estate. The Document Register should include a list of all ventilation assets.

9.52 Planned maintenance was not carried out on the retained estate. The AHUs should be subject to planned maintenance, cleaning, quarterly inspections and annual inspections.

9.53 Chilled beams should be cleaned 6 monthly and split air condition systems should be cleaned 3 monthly.

9.54 The Lab Block AHUs were cleaned periodically but records were not retained. Cleaning records should be retained.

9.55 Not all critical systems were subject to annual verifications. Adult & Children's isolation rooms, critical care areas and MRI/CT suites should be verified annually. Retained estate neonatal and MRI/CT suites should be verified annually. When a critical system fails to meet the performance criteria set out in SHTM 03-01, Part B, the AP should notify the User (V)/Responsible Person and infection control in writing.

9.56 Most but not all LEVs had been subject to 14 monthly examinations under the COSHH Regulations. The mortuary dissection tables had not been examined and

performance tested. Some MGPS AGSS had been tested but records had not been retained. The test reports for the Lab Block LEV systems were retained by individual departments. The AP should check that all LEVs in the Lab Block have been examined and tested at least every 14 months.

Extract/summary of AE(V) Audit Report Summary Nov 2017[21]

9.57 Due to the size and on-going change at the hospital the APs were not always able to find the time to carry out their duties. The provision of APs (V) should be reviewed by senior management taking into consideration other duties the APs are liable for.

9.58 CPs should be trained, assessed and appointed. Evidence of competency was held for two contractor CPs, letters of competency should be held for all contractor CPs.

9.59 Task risk assessments were not held for in-house tasks. These must be produced and communicated to the in-house CPs.

9.60 The Document Register was populated for the Lab Block. This should be extended to include the Adult & Children's and the retained estate. The Document Register should include a list of all ventilation assets.

9.61 Chilled beams should be cleaned 6 monthly and split air condition systems should be cleaned 3 monthly.

[21] AE(V) Audit Report Summary Nov 2017

9.62 The Lab Block AHUs were cleaned periodically but records were not retained. Cleaning records should be retained.

9.63 Work should continue to verify all critical systems. When a critical system fails to meet the performance criteria set out in SHTM 03-01, Part B, the AP should notify the User (V)/Responsible Person and infection control in writing before it is brought back into service.

9.64 Most but not all local exhaust ventilation (LEVs) had been subject to 14 monthly examinations under the COSHH Regulations. The mortuary dissection tables had not been examined and performance tested.

9.65 Oil and combustible material should be removed from the Neonatal plant room ASAP.

9.66 Fire dampers must be tested for correct operation annually.

9.67 The use of authority for disconnection (permit to work) should be reintroduced to prevent unintentional loss of supplies to the theatres and critical equipment.

Extract/summary of AE(V) Audit Report Summary Dec 2018[22]

9.68 The report opened by stating that - Steady good progress has been made at QEUH under the direction of the compliance manager and interim site manager (operational estates). Some issues remain unresolved and are placing the board at risk:

[22] AE(V) Audit Report Summary Dec 2018

9.69 Fire dampers were not subject to annual testing.

9.70 Maintenance of ventilation systems is not planned and appears to be done on a reactive basis following planned inspections when faults are identified. The planned maintenance issued to NHS competent persons should be reviewed.

9.71 The schedule of ventilation assets should be extended to include LEV's, Split ACs, Cassette Units, FCUs, and ACBs.

9.72 The criticality of all ventilation systems should be reviewed with user groups to positively identify all systems that should be deemed critical. This should be recorded in the ventilation assets schedule.

9.73 Once identified, all critical systems should be subjected to performance verification at least annually and inspected every 3 months using the 40 point check or appropriate inspection template.

9.74 Split ACs, Cassette Units and FCUs should be subjected to 3m inspections and cleaning.

9.75 All Active Chilled Beams (ACBs) should be inspected on a 6m basis and cleaned as required.

Extract/summary of AE(V) Audit Report Summary Dec 2019[23]

9.76 This year's audit report opened by stating that - Another good year of progress was witnessed at QUEH Campus in terms of management of ventilation. Progress on the action plan was pleasing to see with 23/25 actions completed or in progress. Some areas that still need to be addressed are as follows:

9.77 Fire damper testing has not been carried out in the adult's and children's hospital. There has been good progress with a survey of the retained estates but the vast proportion are in the A&C.

9.78 The updated policy should be published and roles communicated accordingly following proposed structure changes. Once completed the AP's should be appointed formally.

9.79 Safety paperwork and 40 point checks are auditable and accountable documents. Care should be taken by both APs and CPs to ensure they are filled out correctly and in line with guidance.

9.80 If the Neurology AHUs on level 2 are to be retained works should be carried out to prolong the life and improve the standards. It is the opinion of the AE that the units are capable of being refurbished in situ and have a number of years of life remaining if action is taken within the next 12m.

9.81 It is strongly recommended that an AP(V) is trained and appointed for each shift to assist in the delivery of the safe system of work.

[23] AE(V) Audit Report Summary Dec 2019

9.82 Overall a good audit. Details of new actions are contained within this report.

Extract/summary of AE(V) Audit Report Summary Dec 2020[24]

9.83 This year's audit report opened by stating that - Another good year of progress was witnessed at QUEH Campus in terms of management of ventilation. Progress on the action plan was pleasing to see with 9/22 actions completed or in progress. Some areas that still need to be addressed are as follows:

9.84 Fire damper testing has not been carried out in the adults and children's hospital. There has been good progress with a survey of the retained estates but the vast proportion are in the A&C.

9.85 Safety paperwork and 40 point checks are auditable and accountable documents. Care should be taken by both APs and CPs to ensure they are filled out correctly and in line with guidance.

9.86 Efforts should continue to have AP(V)'s trained and appointed for each shift to assist in the delivery of the safe system of work.

9.87 APs should interrogate 40 point checks for accuracy and ensure issues identified are rectified in a suitable timeframe.

9.88 Statement made by the AE(V) in the conclusion of the Summary section of the audit was that "Overall a good audit. Details of new actions are contained within this report".

[24] AE(V) Audit Report Summary Dec 2020

Conclusion from AE(V) audit feedback

9.89 Over the five years of the audit reports which were reviewed a number of critically important patient safety and legal compliance issues remained consistently to be addressed or appropriately managed. The tone of the executive summary was in my opinion overly re-assuring and the risk rating of a number of the on-going or persistent issues was not escalated or highlighted to an appropriate level. The audit reports do highlight a number of serious issues and whilst it acknowledges progress, the speed and extent of improvement was poor. Each year the audit report stated that the ventilation systems were safe to continue in use, with the proviso that supervision of the AE(V) should continue. From the information of the identified sub-optimal compliance and nature of the potential risks present I would suggest very limited assurance of compliance could be taken from these audit findings.

Derogation management

9.90 The Issue of derogation or managing compliance to NHS standards is often a complex and potentially contentious issue with very long term implications. It can often involve legal issues, and the legal status of NHS specific guidance, and include a range of challenges.

9.91 The following protocol outlines a process for all aspects to be considered and stages to follow when assessing and managing any potential derogation and is intended for use on all technical disciplines. It should be noted that a derogation in one area may have implications to other areas and all aspects need to be adequately identified, assessed, and documented when determining if a derogation is appropriate. For the avoidance of doubt the following are my recommended approach and documents as currently no formal NHS protocols are in place.

Definition of a derogation

9.92 In the simplest of forms (the dictionary definition) a derogation is an exemption from or relaxation of a rule or law or standard. As it applies to NHS guidance this exemption must be appropriately recorded with all implications understood and accepted by all parties, and approved at an agreed appropriate level, and where applicable alternative and equivalent mitigation agreed for the risks or implications of the derogation.

9.93 The need to demonstrate a robust process for agreeing any derogation from Technical Guidance is a core component of the assurance process and as such must provide a clear auditable trail.

9.94 Derogations to guidance will potentially increase risks to the organisation and potentially clinical activity or patient safety and should only be considered in exceptional circumstances. A schedule of derogations will be required for any/all project(s). This schedule is not a simple list of derogations which can be stored in a project file. It is required to be comprehensive and stored where it can be easily referenced by all stakeholders and kept under regular review and monitored to ensure it remains safe and appropriate.

9.95 While it is recognised that derogation is required in some cases, this must be risk-assessed, agreed and documented in order that it may be considered within the appraisal and approval process.

9.96 Derogations must be properly authorised by the project’s senior responsible owner and informed and supported by appropriate technical, Infection Prevention & Control (IPC) and clinical advice (irrespective of a project’s internal or external approval processes).

NHS standards (mandatory, guidance, minimum standards, or simply best practice?)

9.97 Over the years the NHS has developed a comprehensive range of documents to provide standards and advice for those involved in the design, construction and operation of healthcare facilities. These include Health Building Notes (HBNs), Health Technical Memorandum (HTMs), Health Guidance Notes (HGNs), Health Facilities Notes (HFNs) and Fire Practice Notes (FPNs), to name just a few, with some of these standards now archived or superseded. It must also be noted that within the devolved administrations there are a number of documents which contain subtly differing guidance, although the manner to which these should be managed can be universally applied.

9.98 Debate over the status of all of these documents can be highly contentious and generally is not definitively defined, however the following elements need to be considered:

9.99 **Legal** - Anecdotal evidence is that any failures to follow these documents has been used in court proceedings to find against hospital Trusts. These are most likely to be in connection with Health and Safety Executive prosecutions or possibly civil or medical malpractice cases. The various Devolved Administrations agree that the documents produced are guidance documents. They become legal requirements when they form part of a contract, however, the guidance documents are generally considered as an Approved Code of Practice or at the very least good practice. This is summarised below from a general legal assessment of the status and use of these guidance standards.

9.100 ‘DoH guidance is relevant and is generally taken to be authoritative by the relevant authorities and the court, but this is not conclusive. However, if the guidance

isn’t followed, the Trust would be expected to justify why and to demonstrate what measures they took to satisfy the requirement of taking all reasonably practicable steps to protect people affected.

9.101 Also the Health and Social Care Act (2012), Health and Social Care Act (Regulated Activities) Regulations 2014, and the Care Quality Commission (Registration) Regulations 2009 are all used as the basis for CQC registration and certification. As such these regulations are used as the reference by the CQC for all healthcare providers (including the NHS).

9.102 Health and Social Care Act 2008 (Regulated Activities) Regulations 2014: Regulation 15 These Regulations outline 20 key criteria under which all healthcare providers must operate. The intention of this regulation is to make sure that the premises where care and treatment are delivered are clean, suitable for the intended purpose, maintained and where required, appropriately located, and that the equipment that is used to deliver care and treatment is clean, suitable for the intended purpose, maintained, stored securely and used properly. Providers retain legal responsibility under these regulations when they delegate responsibility through contracts or legal agreements to a third party, independent suppliers, professionals, supply chains or contractors. They must therefore make sure that they meet the regulation, as responsibility for any shortfall rests with the provider.

9.103 15(1)(c) suitable for the purpose for which they are being used, Premises must be fit for purpose in line with statutory requirements and should take account of national best practice. Any alterations to the premises or the equipment that is used to deliver care and treatment must be made in line with current legislation and guidance. Where the guidance cannot be met, the provider should have appropriate contingency plans and arrangements to mitigate the risks to people using the service.

9.104 Whilst the NHS guidance documents are not mandatory (unless specifically stated). They do however state that, any departures / derogations - including the measures implemented – should provide a degree of safety not less than that achieved by following the guidance set out in the various documents.

9.105 Overall in my professional opinion I believe that the SHTM standards should be treated as an Approved Code of Practice (ACOP) and have similar standing to that of L8 in the management of water systems.

9.106 **Minimum standard or best practice** – Often this is defined by the parties on either side of a debate around derogation. In practice the answer can be both, the guidance sets safe minimum standards which should not be relaxed where they impact patient safety or operational resilience including lifespan. However there isn't an alternative guidance document which could be described as best practice or 'compliance plus' standards, as the NHS guidance are generally considered by many as world leading, it is not unreasonable to describe them as best practice or even an Approved Code of Practice, at least in some circumstances.

Reasons or drivers to consider derogating

9.107 Typically there are many reasons cited to derogate from elements of even entire HTM's or HBN's, including but not limited to:

- refurbishment of existing buildings, facilities or services (including the limitations associated with existing footprints etc.)
- room allocation and sizes
- cost or budget allowance, (however cost should never be the sole consideration, as the budget should be set to reflect full compliance)
- scope of project

- omission of compliance issue at business case/design/construction stage, or
- we haven't done it before or had it agreed on a previous scheme

9.108 At times a derogation is a sensible and safe option to consider, however, the full implications of any such consideration must be carefully balanced and a full and detailed record made of the impact, risks, cost consequences, practical limitations of a scheme or site, and a formal review and approval process. This process may also identify other forms of mitigation or control measures and should also include a post project 'in use' assessment to ensure the decision was justified with the benefit of operational hindsight. For the avoidance of doubt it would be highly unusual to seek derogations on a 'new build' project.

What cannot be derogated

9.109 In HTMs 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.

9.110 The following describes the implications and use of these modal verbs in HTMs/HBNs:

- "Must" is used when indicating compliance with the law. These cannot be the subject of derogation.
- "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. These are elements which in extreme or specific circumstances could be considered for an area of derogation, however the organisation must be able to clearly demonstrate the circumstances/reasons for the derogation and if required

provide evidence of what measures they took to satisfy the requirement of taking all reasonably practicable steps to protect people affected.

- “May” is used for permission, i.e. to indicate a course of action permissible within the limits of the HTM/HBN. Again, these elements could be considered for an area of derogation, however the organisation must be able to clearly demonstrate the circumstances/reasons for the derogation and if required provide evidence of what measures they took to satisfy the requirement of taking all reasonably practicable steps to protect people affected.

The process of derogation

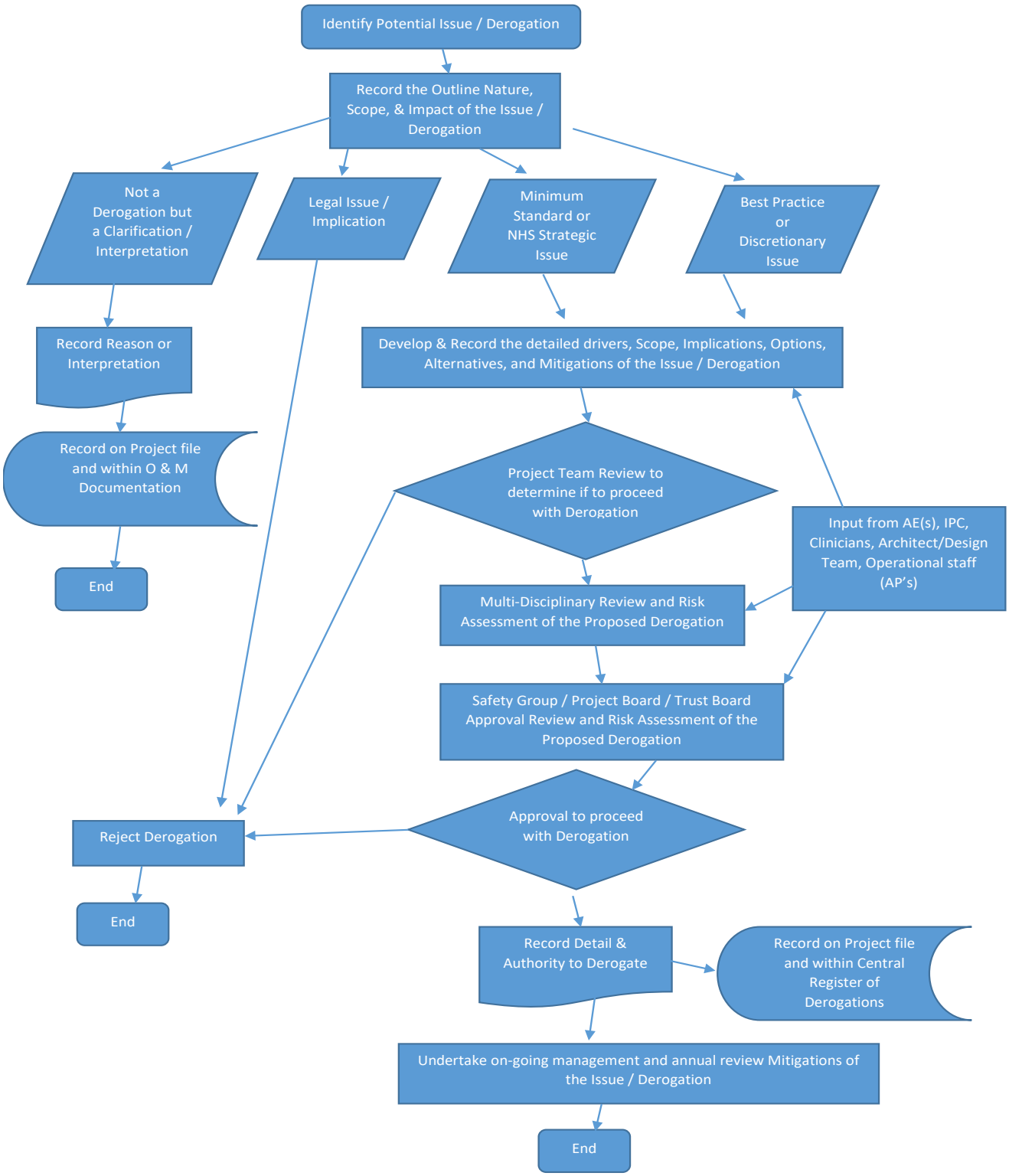
9.111 When considering a derogation, the initial question needs to be clearly established as to who has the authority to agree a derogation and who ultimately holds the responsibility for the decision.

9.112 Once a derogation has been identified as potentially being required or desired the issue needs to be very clearly defined by the requester as to the exact nature and extent of the potential derogation. This should include full details of the clause or area of derogation, the reason(s) for the inability to conform to the relevant standard, the predictable consequences of the derogation and what, if any mitigation is being proposed to minimise or remove the residual risk of non-conformance.

9.113 Following the request the project team should log the request and undertake a review to assess the request with input from the appropriate working safety group and Authorised Person(s) for the discipline(s) involved. If considered necessary the opinion/comment from the Authorising Engineer for the specific discipline should also be sought to ensure all aspects have been suitably identified and considered. For the avoidance of doubt the review must be comprehensive and include representation for all stakeholders including clinicians, IPC, Operational Estates & Facilities and the Project team, it must not be done in isolation by the project team.

9.114 Outlined below is my structure or flow diagram for the management process involved in the safe and appropriate management of derogations. This is not provided as the only or best approach to be adopted, however does represent my opinion on a suitable management process.

Derogation Flow Diagram



Essential considerations

9.115 The review process must consider a wide range of potential implications and consequences including but not limited to:

- patient, staff, or visitor safety
- patient, staff, or visitor comfort
- maintainability
- changes in guidance/best practice since publication of an HTM or HBN
- advances in technology since publication of an HTM or HBN
- clinical activity and clinical process/development or creep
- timescales (both in terms of project programme and lifespan of the development)
- practical limitations (e.g. space and existing building restrictions)
- life span and whole life costings
- energy consumptions and running costs
- cost (reduced capital costs must not be put ahead of whole life or revenue costs)

Risk assessment

9.116 Once all of these elements have been considered and the scope of the impact of the potential derogation agreed and risk based assessment should be completed to enable the ultimate decision to be made by the Designated Person for the respective system/service with a full understanding of the consequences of the approval or rejection decision.

Records

9.117 In my opinion a full and detailed schedule must be developed and retained for all proposed derogations or clarifications considered during a project or scheme. This schedule should be comprehensive and include as a minimum the following information (per derogation):

Reference No of Standard	For example HBN/HTM reference
Specific Clause Reference	
Derogation/Clarification	Details of what is being proposed for derogation including the exact extent and scope of the derogation requirement.
Derogation Reason/Driver	Details of the reason/explanation of why, extent/impact and details of any proposed alternative design solutions.
Derogation Proposed by	Name of individual or company proposing/requesting the derogation
Date	
Comments by Project team lead	Name of individual with details/commentary to evidence initial design review and a recommendation to approve or reject proposed derogation.
Date	
Comments by Authorised Person (AP)	Name of individual with details/commentary to evidence any recommendation to approve or reject proposed derogation.
Date	
Comments by Authorising Engineer (AE)	Name of individual with details/commentary to evidence any recommendation to approve or reject proposed derogation.
Date	
Working Safety Group (if applicable) comments/risk assessment	Details/commentary to evidence any recommendation to approve or reject proposed derogation.
Date	
Risk Assessment / Details of potential consequences	Details of any risks or potential consequences as a result of the proposed derogation

Mitigation / Control measures to address identified risk elements.	Details of any mitigation or supplementary control or management issues which could be used to reduce or address identified risks
Comments/Review Recommendations for Board Level Designated Person consideration	Consensus assessment of all stakeholders to the proposed derogation with if practical a recommendation to accept or reject.
Executive Board Level Designated Person assessment	Sign off by the DP or similar level board member to accept or reject derogation
Date	
Status	Approved or rejected, (including a time limit if appropriate).

9.118 For the avoidance of doubt the Duty Holder or Designated Person MUST make the final decision to accept or reject a request for derogation even where that decision is informed by advice from either external advisors or working multidisciplinary safety groups.

9.119 This schedule would form the basis of a live document register which should be accessible to all stakeholders for review purposes and information. Where considered necessary the schedule or register of derogations may also lead to the inclusion onto the organisations risk register to ensure approved derogations do not get overlooked or forgotten.

Recording file structure

9.120 All approved derogations must be kept in such a manner as to enable regular (at least annual) review to ensure the decisions taken remain appropriate for any potential usage changes. As such it is recommended that a filing structure or database system is developed to centrally record and manage derogations. One approach is to allocate a referencing system to any agreed derogation which incorporates the following details as a minimum:

- site reference
- building reference
- level or floor reference (this could be all floors if it applies to an entire building)
- guidance reference (HTM or HBN reference)
- date

9.121 This file structure or referencing system should enable specific elements, for example, any ventilation derogations (HTM 03-01) to be filtered or chosen as a condensed schedule to enable the respective working group to undertake an annual review exercise. The specific clause and derogation detail and reasoning would be stored under this searchable file structure.

On-Going management and review of agreed derogations

9.122 The majority of derogations tend to be considered in connection to capital investment projects, however there are also circumstances when operational derogations are required. These can relate to a relaxation of testing or inspection, due to resource shortages or other operational considerations such as access or external circumstances (like a global pandemic). Under these circumstances operational decisions are taken, however it is rare to find these incidents recorded as derogations whether temporary or permanent.

9.123 All derogations need to be kept under constant and on-going review to ensure that operational changes, clinical activity or condition surveys and investment planning is undertaken with the full knowledge that areas of the estate may not be fully compliant. An example of this could include an area converted to manage emergency admissions due to the pandemic becoming a more long-standing or permanent facility even after immediate pressures have passed. A non-compliant

heat recovery unit (which doesn't conform the HTM 03-01 standards for AHU's) intended as a short-term fix (say 18-month period) becomes a semi-permanent ventilation solution to the area. Or the use of temporary tent style isolation facilities become a permanent solution, when a more substantial permanent provision could be developed and installed to provide a safer and more robust solution. In emergency situations people can make sub-optimal decisions and these issues should be kept under review to ensure they remain appropriate, or with the benefit of hindsight lessons are learned to avoid repetition.

9.124 One option for this review process could be to incorporate the review into the standing agenda of the relevant working safety group. This would provide a forum for the majority if not all of the agreed derogations which would be held on a central register. It may also be appropriate to ensure that any agreed derogation is recorded on the Trust or divisional/departmental risk register as an accepted risk to ensure both operational and management staff are aware of the status and accepted associated risks.

Assessment of derogation management at QEUH

9.125 I have concluded that the process of managing/agreeing derogations of changes within the project at QEUH were restricted to a Project Board level, and outcomes would suggest that not all interested stakeholders were appropriately or fully consulted on all issues. The primary example would be the prioritisation of BREEAM status over that of air change rates.

Appendix 1 - Derogation recording form template (as used by A.Poplett and recommended to clients)

The following form is an example of the type of information required and details/signatures required to record an approved derogation. The format and layout can be adapted to suit individual organisations.

Element	**Detail / Comment**	**Signature**
HTM/HBN Reference No of Standard	For example HBN/HTM reference	
Specific Clause Reference		
Derogation/Clarification	Details of what is being proposed for derogation including the exact extent and scope of the derogation requirement.	
Derogation Reason/Driver	Details of the reason/explanation of why, extent/impact and details of any proposed alternative design solutions.	
Derogation Proposed by	Name of individual or company proposing/requesting the derogation	
Date		
Comments by Project team lead	Name of individual with details/commentary to evidence initial design review and a recommendation to approve or reject proposed derogation.	
Date		

Comments by Authorised Person (AP)	Name of individual with details/commentary to evidence any recommendation to approve or reject proposed derogation.	
Date		
Comments by Authorising Engineer (AE) (if considered necessary)	Name of individual with details/commentary to evidence any recommendation to approve or reject proposed derogation.	
Date		
Working Safety Group (if applicable) comments/risk assessment	Details/commentary to evidence any recommendation to approve or reject proposed derogation.	
Date		
Risk Assessment/ Details of potential consequences	Details of any risks or potential consequences as a result of the proposed derogation	
Mitigation/Control measures to address identified risk elements.	Details of any mitigation or supplementary control or management issues which could be used to reduce or address identified risks	
Comments/Review Recommendations for Board Level Designated Person consideration	Consensus assessment of all stakeholders to the proposed derogation with if practical a recommendation to accept or reject.	

Executive Board Level Designated Person assessment	Sign off by the DP or similar level board member to accept or reject derogation	
Date		
Status	Approved or rejected, (including a time limit if appropriate).	

10. Current condition and potential issues and risks

QEUH - Adult Hospital

Based on information from the Section 21 Notice Response (18 ventilation) the following information has been summarised:

HDU & ICU - Critical care & 10 isolation rooms

10.1 Patient Type - Infectious Diseases Patients with Airborne Infections such as TB {including MRTB), measles, chicken pox and MERs (Coronavirus). Also used for Isolation of Bone Marrow Transplant Patients requiring Intensive Care

10.2 HDU and ICU house both open plan bedded areas and isolation rooms.

10.3 6 open plan areas - There are no recorded physical changes made to either the ductwork or any components of the 6 ventilation systems serving HDU/ICU in the period 26 Jan 2015 to date.

10.4 The first verification of HDU/ICU systems was July 2019 when the report findings recorded that the Air Change Rate (ACR) and pressure cascades failed to meet the required standard for an ICU area. The findings recorded low Air Change Rate (ACR) and poor pressure cascades from clean to less clean areas and therefore several of the systems required re-balancing. Re-balancing was done by fan speed adjustment and repositioning of dampers in both supply and extract systems. The verification reports since 2019 demonstrate this work had been undertaken and improved both the air change rate and pressure cascades within the spaces. The initial verification reports, dated July 2019, also identified Ceiling Ventilation Grilles (CVG) were present in the area and recommended they be replaced with solid ceiling tiles. This is not a change to the ventilation system but would assist in increasing the pressure cascade regime within the spaces making it more likely to allow the airflow to go from clean to less clean. The 2020 verification

reports record these CVG's had been removed. There has been no HEPA filtration added to these systems since handover.

10.5 Whist some modifications and potential improvements have been undertaken it is understood that the open bay area remains non-compliant to the minimum air change rate of 10 ACH (confirmation from QEUH required). Confirmation is also required to ensure that by increasing the fan airflow performance the heating and cooling batteries and control functions remain capable of conditioning the increase airflow rates.

10.6 HDU/ICU Isolation Rooms - The isolation rooms were verified initially in 2019 (as above) and the verification reports from 2022 demonstrate satisfactory performance to the minimum recommendations of the SHTM 03-01 appendix 2 performance requirements.

Ward No. 4B - National Bone Marrow Transplant Unit

10.7 Patient Type - 24 beds for haematology patients undergoing bone marrow transplantation - patients are high risk and immunocompromised

10.8 Following concerns raised by clinicians and IPC team in June 2015 a number of phased modifications have been undertaken to the ward environment, including the increased airflow volumes by the upgrading of the primary supply fan motor and replacement of tiled ceiling grids to solid plasterboard ceilings. Works were completed and validated in November 2017 with patients being moved in to the ward in June 2018. In 2019 identified Ceiling Ventilation Grilles (CVG) were replaced with solid ceiling tiles.

10.9 Whist some modifications and potential improvements have been undertaken it is understood that the ward isolation rooms remain non-compliant to the minimum air change rate of 10 ACH. Confirmation is required to ensure that by increasing the fan airflow performance the heating and cooling batteries and control functions remain capable of conditioning the increase airflow rates.

Ward No. 4C Haematology-Oncology (10 beds) and Renal (18 beds)

10.10 Patient Type - Haematology-oncology patients who are immunocompromised

10.11 Ward 4C houses renal and renal oncology patients. The area is served by 3 Air Handling Units (AHUs) located in plantroom 124 on level 12 identified as 124 AHU 04, 124 AHU 05 and 124 AHU 06 and there have been no physical changes to the 3 ventilation units serving Ward 4C since handover (January 2015).

10.12 There is no HEPA filtration within the plant room AHUs or within the ductwork serving Ward 4C.

10.13 The ward has 18 rooms allocated for renal patients and 10 rooms for renal oncology patients.

10.14 January 2019, the ventilation system to the 10 oncology rooms was supplemented by floor standing HEPA filter air scrubbers. These scrubbers filter and recirculate air within the space with the intention of improving the air quality within the patient bedroom.

10.15 In January 2019 the Ceiling Ventilation Grilles were removed and replaced with a standard ceiling tile to reduce the risk of particulate moving from the corridor ceiling void into the corridor transfer area and rooms.

10.16 Between October and December 2020, a programme of works was undertaken to fit HEPA filtered air scrubbers within the ceiling voids of the en-suites in all 28 patient rooms of the ward. These units are not integrated within the existing ductwork system. These units recirculate air within the en-suite space through HEPA filtration improving the air quality within the space. There is no evidence provided to demonstrate the efficacy of these units and I would advise that this type of system should not be considered as a long-term solution or alternative to dilution ventilation. The positioning of the air intake and discharges and in room air movement needs to be carefully assessed with a methodology agreed for filter changing and testing.

Ward No. 5C and 5D - Infectious Diseases

10.17 Patient Type - Any patient with a recognised infectious disease - These wards will house patients with airborne infections such as TB, measles and chickenpox, including immunosuppressed HIV patients.

10.18 Ward 5C is served by 3 Air Handling Units (AHUs) located in plantroom 124 on level 12 identified as 124 AHU 04, 124 AHU 05 and 124 AHU 06 and there have been no physical changes to the 3 ventilation units serving Ward 5C since handover on 26 January 2015.

10.19 Ward 5D is served by 3 Air Handling Units (AHUs) located in plantroom 123 on level 12 identified as 123 AHU 04, 123 AHU 05 and 123 AHU 06 and there have been no physical changes to the 3 ventilation units serving Ward 5D since handover on 26 January 2015.

10.20 There is no HEPA filtration provision to either ward ventilation system and no requirement for it. The pressure differential cascades from the corridors into the rooms are all achieving the correct direction of airflow, however the acceptable tolerance of only 1Pa is considered very low/marginal and I would recommend a minimum verification level of -5Pa as a more appropriate target albeit with an 80% tolerance of in use performance (i.e. a minimum of -4Pa) as per SHTM 03-01.

Wards 7B, 7C and 7D - Respiratory

10.21 Patient Type - Patients with TB, Respiratory Disease and-Cystic Fibrosis.

10.22 Ward 7B is served by 3 AHUs in plantroom 121, located on level 12. There are 3 AHUs serving ward 7B which are identified as 121 AHU 04, 121 AHU 05 and 121 AHU 06. There have been no physical changes to the ventilation system serving ward 7B since handover on January 2015. There have been no alterations to the fan speeds. There has been no HEPA filtration, portable or fixed, added to any areas within the rooms or en-suites within Ward 7B. There is no HEPA filtration within the plant room AHUs or within the ductwork serving Ward 7B.

10.23 Ward 7C is served by 3 Air Handling Units (AHUs) located in plantroom 124 on level 12 identified as 124 AHU 04, 124 AHU 05 and 124 AHU 06 and there have been no physical changes to the 3 ventilation units serving Ward 7C since handover on January 2015. There have been alterations to the fan speeds serving Ward 7C. These alterations were a consequence of the required pressure changes on Wards 4C and 5C as 7C is served by the same group of AHU's.

10.24 On completion of the works to these wards the air flows to Ward 7C were rebalanced to their original state. There has been no HEPA filtration, portable or fixed, added to any areas within the rooms or en-suites within Ward 7C. There is no HEPA filtration within the plant room AHUs or within the ductwork serving Ward 7C.

10.25 Ward 7D is served by 3 Air Handling Units (AHUs) located in plantroom 123 on level 12 identified as 123 AHU 04, 123 AHU 05 and 123 AHU 06 and there has been no physical changes to the 3 ventilation units serving Ward 7D since handover on January 2015. The desired outcome of adjustments was for patient rooms to be negative pressure to the corridor, that is, air flow from corridor to room, with a target pressure differential of 1Pa or more.

10.26 The report issued on 23rd December 2018 for Ward 7D provides pressure cascade readings which indicated this had been achieved.

10.27 There has been no HEPA filtration, portable or fixed, added to any areas within the rooms or en-suites within Ward 7D. There is no HEPA filtration within the plant room AHUs or within the ductwork serving Ward 7D

10.28 There is no HEPA filtration provision to the ward ventilation systems and subject to a clinical/IPC risk assessment there is no requirement for it. The pressure differential cascades on ward 7D from the corridors into the rooms are achieving the correct direction of airflow, however the acceptable tolerance of only 1Pa is considered very low/marginal and I would recommend a minimum verification level of -5Pa as a more appropriate target albeit with an 80% tolerance of in use performance (i.e. a minimum of -4Pa) as per SHTM 03-01.

Royal Hospital for Children (RHC)

Ward No. 2A - Haematology and Oncology In-patient Ward/Teenage Cancer Trust Ward and National Bone Marrow Transplant Unit

10.29 Patient Type – Patients are high risk and Immunocompromised

10.30 At the point of handover ward 2A was served by AHU20A which delivered air to 3 floors of RHC including ward 2A providing air to the patient rooms via chilled beams while offices, corridors, and ancillary areas were supplied air by ceiling grilles. The air delivered by AHU20A was not HEPA filtered. There was no duty/standby arrangement for this AHU. AHU20B provided air via ceiling mounted grilles to 3 floors of RHC including to the ward 2A offices, ancillary rooms, prep room and MIBG suite. The air provided by AHU20B was not HEPA filtered and there was no duty/standby arrangement. The extraction ductwork on levels 1, 2 and 3 which included toilet extract systems, drew air through a thermal wheel within AHU20B allowing recovered heat to be transferred to the supply duct of AHU20B.

Ward 2B - Day Care Unit

10.31 Patient Type - Haematology-Oncology paediatric patients (Potential for weakened or low immunity tolerance)

10.32 Ward 2B is on level 2 of the RHC and from handover in January 2015 was served by air handling unit (AHU) 41 AHU24. This unit also provided air to level 1. In Ward 2B the air delivered from AHU24 supplied 10 chilled beams in day units and consulting rooms and 14 grilles supplied offices, corridors, and ancillary areas. The air delivered by AHU24 was not HEPA filtered. There was no duty/standby arrangement for this AHU.

Ward 2A & 2B Improvement Works Summary

10.33 Following extensive works undertaken between 2019 and 2022 a number of changes were made.

10.34 Wards 2A and 2B were disconnected from ductwork which had been providing ventilation to these wards as well as levels 1 and 3.

10.35 The ductwork was disconnected and capped at level 2 however the AHUs continue to serve levels 1 and 3.

10.36 Plantrooms 41 and 41A were remodelled to provide new ventilation systems for wards 2A and 2B.

10.37 A further plant room, 41B was created to accommodate additional units.

10.38 Listed below are descriptions of the new ventilation systems serving RHC Wards 2A and 2B.

a) A new supply ventilation system was installed in plantroom 41 identified as BMT AHU 01/02 Supply. This operates on a duty stand by arrangement and serves BMT Ward 2A and 2B. The air delivered from the unit is HEPA filtered. The air provided to ward 2B is via ceiling mounted grilles and chilled beams. The air provided to ward 2A is via ceiling mounted supply grilles in corridors, offices and support areas. The grilles in ward 2A also incorporate HEPA filters.

b) A new ventilation extract system was installed in plantroom 41B identified as BMT AHU 01/02 Extract. This operates on a duty stand by arrangement and serves BMT ward 2A and 2B. It provides extract ventilation from corridors, offices and support areas.

c) A new toilet extract system was installed in plantroom 41 identified as BMT TEF 01/02 Toilet Extract. This operates on a duty stand by arrangement and serves BMT ward 2A and 2B. It provides extract ventilation from WCs, dirty utility rooms and cleaners stores etc.

d) A new supply ventilation system was installed in plantroom 41B identified as AHU/HOTCT/01/02 Supply. This operates on a duty stand by arrangement and serves Ward 2A Haematology-oncology and Teenage Cancer Trust (HO/TCT) bedrooms. The air is delivered from the unit to Ward 2A HO/TCT bedrooms via ceiling mounted supply grilles which incorporate HEPA filters.

e) A new ventilation extract system was installed in plantroom 41B identified as AHU/HOTCT/01/02 Extract. This operates on a duty stand by arrangement and serves Ward 2A HO/TCT. It provides extract ventilation from corridors.

f) A new toilet extract system was installed in plantroom 41B identified as HOTCT TEF 01/02 Toilet Extract. This operates on a duty stand by arrangement and serves Ward 2A HO/TCT. It provides extract ventilation from WCs and patient en-suites.

g) A new supply ventilation system was installed in plantroom 22 identified as AHU/MIBG/ 01/02 Supply. This operates on a duty stand by arrangement and serves BMT MIBG suite. The air supplied from the unit is provided via ceiling mounted grilles with HEPA filtration

h) A new ventilation extract system was installed in level 5 ventilation plant compound identified as MIBG GEF 01/02 General Extract. This operates on a duty stand by arrangement and serves BMT MIBG suite.

i) A new ventilation extract system was installed in level 5 ventilation plant compound identified as MIBG TEF 01/02 Toilet Extract. This operates on a duty stand by arrangement and serves BMT MIBG suite.

j) A new ventilation extract system was installed in plantroom 41B identified as Hospital Street EF 01/02. This operates on a duty stand by arrangement and serves the hospital corridors external to BMT ward 2A.

k) A new ventilation extract system was installed in plantroom 41B identified as Hospital Street EF 03/04. This operates on a duty stand by arrangement and serves the hospital corridors external to HOTCT ward 2A.

10.39 The redesign of the ventilation systems serving RHC Wards 2A and 2B was to improve the overall performance of the ventilation systems serving the area. The installation of separate supply and extraction systems removed the risk of cross contamination from other zones and other levels.

10.40 The provision of duty/standby arrangements added resilience to the systems and allowed for planned maintenance of the AHUs to be undertaken without impacting the patient group.

10.41 The new design provides HEPA filtered air to Ward 2A and 2B and that the pressure cascade from clean to less clean areas is achieved.

10.42 The MIBG suite had previously been ventilated from AHU20B and therefore the air to the Prep room was not HEPA filtered. The MIBG suite is now provided with its own dedicated ventilation system providing HEPA filtered air and the extraction systems are separate from the main ward areas.

10.43 This updated/revised design approach is considered appropriate for the clinical group being cared for/treated.

Ward 1D - Paediatric Intensive Care Unit (PICU)

10.44 Patient Type – Potential need to care for Infectious Patients with Airborne Infections and potentially immunosuppressed patients who may also have potential transmittable infections.

10.45 PICU is identified as a Critical Care area and should meet the same criteria as Adult ICU i.e. provide a positively pressured space with 10 + air changes per hour. PICU is located on RHC level 1 and consists of single bed spaces, 4 bedded spaces, isolation rooms, office and support rooms. The area is served by two Air Handling Units (AHUs) in plant room 41, these being AHU14 and AHU46.

10.46 There have been no significant changes to these AHU’s since handover, other than a filter upgrade.

10.47 The first verification of PICU was July 2019 when the report findings recorded that the Air Change Rate (ACR) and pressure cascades failed to meet the required standard for an ICU area. The findings recorded low Air Change Rate (ACR) and poor pressure cascades from clean to less clean areas.

10.48 An option report in August 2019 outlined several proposals to resolve the findings identified in the verification reports. Estates and Infection Control agreed the

option to sequentially rebalance the whole unit. No physical changes were made to the ventilation system. Work included rebalancing of dampers on both supply and extract grilles as well as the removal of ceiling ventilation grilles and replacement with solid ceiling tiles. Derogations for reduced pressure cascades were agreed and subsequent verifications have demonstrated the works done were successful in achieving a compliant, although derogated, system.

10.49 There have been no HEPA filters fitted to the system and no portable HEPA systems used in PICU.

10.50 Sample verification reports (Jan 22) demonstrate suitable and generally satisfactory airflow performances to the minimum recommendations of the SHTM 03-01 appendix 2 performance requirements.

Conclusions from improvements works and current ventilation system compliance

10.51 From all of the information above (clauses 10.1 through 10.50) I have formed the following conclusions

10.52 Overall a significant amount of work has been undertaken to address some of the fundamental issues and concerns raised relating to the adequacy of the ventilation systems.

10.53 A number of the areas have now been improved to a level where they are compliant with the principles of the SHTM 03-01 standard, however some of the improvements have involved the installation or use of re-circulation air cleaning devices and the efficacy of these units and the methodology for the deployment and validation remains a significant concern.

10.54 Below are extracts from a recently published NHS England guide for the ‘Application of HEPA filter devices for air cleaning in healthcare spaces: guidance and standards’ dated 9 May, 2023.

Ventilation and device effectiveness

a) The Ventilation Safety Group should consider air flow strategies which achieve the most effective ventilation of occupied spaces. This requires that all factors such as air flow rate, mixing and distribution, dilution, thermal buoyancy and the impact of occupant movements and must be considered.

b) Airflow patterns and ventilation rates can be evaluated using measurements of air velocities, indoor air quality (IAQ) monitoring and visual methods such as smoke tracing. Computational Fluid Dynamics (CFD) modelling can also be a useful tool to assist the ventilation design engineer to assess airflow patterns in the rooms where HEPA filter devices are to be located. CFD, particle tracing and other forms of airflow assessment can be used to identify the optimal locations to place devices. CFD modelling requires specialist knowledge, and any simulations should be carried out by a competent person.

c) Airflow and particle/IAQ measurement, visualisation and CFD simulations can illustrate typical airflow patterns but unless carried out over a sustained period of time may not be able to capture all of the fluctuations that occur in real environments, particularly those that are naturally ventilated.

d) Air cleaner device performance depends on both the flow rate through the HEPA filter and the way the device distributes the air in a room, and both are important factors for ensuring devices are effective and properly positioned. Assessing how a device affects the air flow in a room using the approaches

described above can give greater assurance that the device is sufficiently sized for the room and is positioned to be able to distribute air properly. Although many devices are supplied as portable, they should be sized to the space where they are normally used. If a device is moved to a new location then it is recommended that a suitable risk assessment is undertaken by a competent person to ensure that the device is still likely to be effective.[25]

e) Maintenance including filter replacement should only be conducted only by a designated competent person.[26] SOPs must be in place for both replacing and safe disposal of used filters. Evidence suggests that the hazards posed by filters are small, but there could be potential risks from pathogens that have been trapped by the filter and hence risk assessments and guidance should be in place.

f) Filter changes should follow the manufacturer guidance regarding the process and internal cleaning of the device. Filters should not be changed in clinical areas due to the possible hazards of microorganism and dust dispersal during the procedure.

g) Those carrying out filter changes should wear appropriate PPE as agreed with their infection control team.

h) Disposal of used filters requires a suitable risk assessment for safe bagging, handling and appropriate waste disposal for the used filter as it is potentially contaminated with pathogenic microorganisms.

[25] A47362796 – NHS Estates Technical Bulletin, Application of HEPA filters – Hearing commencing 26 February 2024 - Bundle 13 – Miscellaneous Volume 10 - Page 313.
[26] A47362796 – NHS Estates Technical Bulletin, Application of HEPA filters – Hearing commencing 26 February 2024 - Bundle 13 – Miscellaneous Volume 10 – Page 315.

i) When new filters are installed they must be correctly seated as per manufacturer guidance to ensure there are no airflow leaks around the filter. Verification tests should be carried out after the new filter is installed

Annual checks

j) All devices should undergo at least annual checks to verify their continuing performance. These checks should include, but are not limited to, the following:

- visual inspection of external and internal electrical safety test
- check alarms simulate failures check filter run times and replace if necessary
- clean internals of the device.
- replacement and safe disposal of any filters
- check and document air flow rate measurements at different fan speeds against manufacturer's characteristic-specification
- check and document noise levels against manufacturer's characteristic specification
- apply visual confirmation of annual check[27]

[27] A47362796 – NHS Estates Technical Bulletin, Application of HEPA filters – Hearing commencing 26 February 2024 - Bundle 13 – Miscellaneous Volume 10 – Page 316 and 317.

11. Areas of potential improvement to minimise risk of future patient infections associated with ventilation provision.

11.1 The ventilation systems as designed installed and commissioned at QEUH were clearly not fully compliant to all of the relevant NHS standards at the time. The decision to install chilled beam systems and as a direct result lower room air change rates and the subsequent impact on potential contamination of patient spaces is clear. The extent of the resulting clinical and infection risk is outside of the scope of this report, however in my opinion the failure to involve all stakeholders and to ensure a multi-disciplinary review approach contributed to a sub-optimal final design.

11.2 Subsequent clinical occupations and movements also failed to identify, review or address the issues of ventilation provision and lead to clinical services being provided from noncompliant accommodation.

11.3 The principal areas of concern from a purely ventilation perspective can be summarised as follows:

- Poor assessment of areas which required specialist critical ventilation to be provided to ensure a safe and appropriate patient environment.
- Low air change rates and the use of chilled beams to achieve or prioritise BREEAM accreditation.
- Inconsistent provision of HEPA filtration to all appropriate clinical environments where contamination from external sources was a known risk issue.

- Lack of air permeability testing of designated patient isolation rooms (room air leakage).
- Poor commissioning process.
- Complete lack of independent validation of ventilation systems.
- Poor/inadequate management process for derogations.
- Poor pre-occupational operational maintenance practices – lack of comprehensive or suitable Planned Preventative Maintenance Plans (PPM's).
- Poor/inadequate assessment or provision of operational estates resources to manage and provide adequate assurance of ventilation system operational performance.
- Lack of suitable Ventilation Safety Group (VSG) to provide oversight and assurance of compliance of all aspects of ventilation performance.

What could be done to the QEUH/RHC ventilation systems for the whole site to meet the appropriate SHTM-03-01 standards without exception?

11.4 In practical terms the options available to address all of the above issues is limited, however as an initial assessment and prioritisation exercise (some of which may have already been undertaken) the following would be my recommendation:

11.5 A full multi-disciplinary assessment of each clinical speciality should be completed to identify current areas where ventilation plays a significant factor in patient safety. Each identified area should have the current performance parameters established via testing and an assessment made of plant/system condition and limitations, along with a clinical and IPC agreed minimum performance standards (informed from the current SHTM and best practice).

11.6 Following this assessment to establish minimum acceptable ventilation performances standards and current compliance there with a prioritised schedule of improvement works can be developed. These works would likely involve removal of current chilled beams from critical clinical areas and replacement of current ventilation plant and ductwork distribution systems with improved capacity and fully compliant systems, which would be both expensive and involve significant duration and clinical disruption.

11.7 It is entirely possible that following the assessment phase of review that it is impractical to modify existing facilities, and in such circumstances clinical activities may need to be suspended or stopped until suitable compliant facilities can be provided/identified. This may result in a reduction of clinical activity or bed numbers as a means to accommodate suitable ventilation or other essential building services.

11.8 All improvement works would need to be subject to fully compliant commissioning and independent validation reviews to ensure the works are effective in providing the agreed minimum performance standards.

11.9 The Ventilation Safety Group and Board need to agree a formal process to manage all derogations for all NHS standards (SHTM’s and SHBN’s), and develop a suitable process to agree, record, review and manage all essential derogations moving forwards, and include a suitable assessment process of these as an integral element of any planned clinical service developments or moves.

11.10 In some cases it may prove necessary to temporarily or even permanently to suspend clinical services whilst areas are modified to achieve agreed minimum standards. If practical limitations of plant space or current building structure prevent achievement of minimum standards then the clinical activities should be suspended until such time as a suitable and fully compliant facility can be provided.

11.11 The current provision of maintenance and estates management staff (AP(V)'s and CP(V)'s) needs to be reviewed and potentially increased to ensure adequate assurance can be provided to the Board of on-going progress on improvement works and operational compliance, including but not limited to the review of all annual verifications and timely corrective action to all identified issues.

11.12 Finally I would suggest that the Authorising Engineer (Ventilation) audit schedule should be increased from annual to 6 monthly to provide an external and independent assessment of progress and compliance until such time as the VSG and Board have complete assurance of the appropriateness of the ventilation services.

12. Other influencing factors

BREEAM

12.1 The project design and ultimately the 'agreed' performance specification appears to have been strongly influenced by the desire to achieve a certain BREEAM rating. The BREEAM assessment system is not specifically designed for healthcare buildings and should never be used as a primary performance driver where clinical or infection prevention and control needs could be jeopardised or compromised.

12.2 BREEAM for New Construction is a performance based assessment method and certification scheme for new buildings. The primary aim of BREEAM New Construction is to mitigate the life cycle impacts of new buildings on the environment in a robust and cost-effective manner. This is achieved through integration and use of the scheme by clients and their project teams at key stages in the design and

procurement process. This enables the client, through the BREEAM Assessor and the BRE Global certification process, to measure, evaluate and reflect the performance of their building against best practice in an independent and robust manner. This performance is quantified by a number of individual measures and associated criteria stretching across a range of environmental issues (see below), which is ultimately expressed as a single certified BREEAM rating.

12.3 BREEAM 2011 New Construction environmental sections and assessment issues

Energy

- reduction of CO2 emissions
- energy monitoring
- energy efficient external lighting
- low or zero carbon technologies
- energy efficient cold storage
- energy efficient transportation systems
- energy efficient laboratory systems
- energy efficient equipment (process)
- drying space

Water

- water consumption
- water monitoring

- water leak detection and prevention
- water efficient equipment (process)

Waste

- construction waste management
- recycled aggregates
- operational waste
- speculative floor and ceiling finishes

Transport

- public transport accessibility
- proximity to amenities
- cyclist amenities
- maximum car parking capacity
- travel plan

Materials

- life cycle impacts
- hard landscaping and boundary protection
- responsible sourcing of materials
- insulation

- designing for robustness

Land use and ecology

- site selection
- ecological value of site/protection of ecological features
- mitigating ecological impact
- enhancing site ecology
- long term impact on biodiversity

Pollution

- impact of refrigerants
- NOx emissions
- surface water run-off
- reduction of night time light pollution
- noise attenuation

Health and wellbeing

- visual comfort
- indoor air quality
- thermal comfort
- water quality

- acoustic performance
- safety and security

Management

- sustainable procurement
- responsible construction practices
- construction site impacts
- stakeholder participation
- service life planning and costing

Innovation

- new technology, process and practices

12.4 As outlined above the BREAM assessment process involves many areas of design performance and is intended to provide a basis for comparable performances across all buildings and facilities to provide a benchmarking performance indicator. This assessment approach is in my opinion appropriate for comparing building and facilities where similar activities or processes are undertaken, however healthcare is a highly specialised function and requires elements including ventilation to provide specific and safe environments for the facilities specific clinical function. In my opinion the current assessment criteria requires careful assessment and application and should not be used as a ‘out of the box’ single assessment process. The requirements of clinical process and environmental conditions linked to patient safety and appropriate treatment must always be considered as the primary key performance indicator.

12.5 In my opinion any healthcare facility design should be based upon clinical activity and patient/staff safety and once designed an assessment of comparable performance can be undertaken. However this assessment should never be used to influence or adjust design solutions that may compromise the primary function of a facility which is to ‘do no harm to patients’.

Cryptococcus overview

12.6 The following section provides a general overview and background to the Cryptococcus micro-organism and outline a number of consideration for estates maintenance provision to minimise and mitigate potential risk of infection.

12.7 Cryptococcus is a pathogenic yeast fungus whose spores are ubiquitous in the environment, normally found in air (including hospital ventilation systems), soil, decaying plant matter, and bird excrement. This makes it extremely difficult if not impossible to control at the point of source.

- the fungal spores produced by the fungi have an effective diameter of between (1 to 2μm)
- infection is mainly via inhalation although direct wound contamination is also possible.
- multiplication and growth are strongest in warm and/or damp environments

12.8 Whilst Cryptococcus rarely poses a threat to normal healthy people, it is recognised as a potential cause of severe illness and mortality in highly immunocompromised patients.

12.9 Cryptococcosis has a number of identified strains including neoformans, gattii, albidus, and uniguttulatus which have all been identified in cases of human infection, there are also a total of fourteen non-infectious species. For the purposes

of this briefing paper it is Cryptococcus neoformans that is referenced, as research suggests that this strain is the primary source for the majority of human infections.

Characteristics

12.10 Cryptococcus neoformans is a spherical yeast fungus, 3 μm in diameter when desiccated and 5 to 10μm in diameter when hydrated), that produces a capsule containing glucoronoxylomannan (GXM), extending the overall diameter to 25 μm or more.

12.11 The problem is the spores from the Cryptococcus are so small, like many other fungal spores such as ‘aspergillus’ etc, they can pass through the majority of filter grades with the exception of HEPA filters, and enable the spores to penetrate the alveoli within the lung more efficiently than other yeast organisms.

Mode of transmission

12.12 Humans and animals can get the infection after inhaling the microscopic fungal spores from the environment. Cryptococcus neoformans infections are not contagious (human to human), although some research suggests that people may be exposed to Cryptococcus in the environment when they are children. Most people who breathe it in never get sick from it. However, in people who have weakened immune systems, Cryptococcus can stay hidden in the body and cause infection later when the immune system becomes too weak to fight it off.

Incubation period

12.13 Unknown Cryptococcus neoformans can colonize in the host respiratory tract for months to years without causing any clinical symptoms

How common are Cryptococcus neoformans infections?

12.14 Cryptococcus infections are rare among people who have healthy immune systems; however, Cryptococcus can be a major cause of illness in people with HIV/AIDS or patients who have severely weakened immune systems (transplant/oncology).

Pathology

12.15 Infection with Cryptococcus neoformans is termed Cryptococcosis. Most infections with Cryptococcus neoformans occur in the lungs. However, fungal meningitis and encephalitis, especially as a secondary infection for severely immunocompromised patients, are often caused by Cryptococcus, making it a particularly dangerous fungus. Infections with this fungus are rare in those with fully functioning immune systems

12.16 Infection starts in lungs, disseminates via blood to meninges and then to other parts of the body. Cryptococcus can cause a systemic infection, including fatal meningitis known as meningoencephalitis in normal, diabetic and immunocompromised hosts. The infection from Cryptococcus neoformans in the brain can be fatal if untreated. CNS (central nervous system) infection may also be present as a brain abscess known as Cryptococcomas, subdural effusion, dementia, isolated cranial nerve lesion, spinal cord lesion, and ischemic stroke. If Cryptococcal meningitis occurs, mortality rate is between 10–30%.

Potential risk groups

- organ transplants
- oncology/Caner treatment
- patients on high dose steroids
- haematology
- I.C.U./P.I.C.U.
- S.C.I.D.S./B.M.T.
- HIV Positive patients
- laboratory facilities

Susceptibility to disinfectants

12.17 Cryptococcus neoformans is effectively killed by 70% ethyl alcohol and is susceptible to phenolic compounds, formaldehyde, glutaraldehyde, iodophors, and sodium hypochloride (1%)

Potential additional maintenance precautions

- Ensure all plantrooms and air handling unit air intake areas are clear and secured.
- All air intakes should be clear of debris and where practical the immediate surrounding area should be clear of vegetation and any accumulation of bird faeces should be cleaned at regular intervals.
- In all cases where bird ingress to plant areas is evident, it should be dealt with and cleaned up immediately upon discovery.

- Birds must be prevented from nesting or congregating close to any AHU intake. If anti-roosting netting has been recently installed, birds will be displaced and nest elsewhere, special attention should be given to ensure that they do not nest near AHU air intakes.
- All filters should be subject to routine inspection and changed when indicated by pressure drop.
- All anti-roost netting should be inspected as part of the existing quarterly inspection protocol for all critical ventilation AHU plant.
- The IPC team and estates team should establish a regular review meeting to identify clinical areas where patient susceptibility may be high and immunocompromised patients are treated. In extreme cases of known risk consideration should be given to provision of temporary or permanent HEPA filtered positive pressure ventilation systems, however this is not anticipated to be a routine requirement for the majority of healthcare environments.

Declaration

- I understand that my duty is to help the Inquiry on matters within my expertise and that this duty overrides any other obligation.
- I have stated the substance of all material instructions, on the basis of which the report is written. My evidence is my independent product, uninfluenced by external pressures.
- The opinions I have expressed are objective, unbiased and based on matters within my own expertise and I have not adopted the role of an advocate. I have made clear if a question or issues falls outwith my area of expertise.
- I have considered whether there is a conflict of interest and declared any potential conflict identified.

- I have given details of any literature or any other material relied on in making the report.
- I have set out the substance of all facts which are material to the opinion expressed in this report or upon which my opinions are based.
- I have said when there is a range of opinion on a relevant issue and summarised the range of opinions and I have formed my own independent view as to the appropriate point in that range applicable to this case and given reasons for that view.
- I have made clear which of the facts stated in the report are within my own knowledge. Those that are within my own knowledge I confirm to be true. The opinions I have expressed represent my true and complete professional opinions on the matters to which they refer.

…[redacted].

Date: 10/06/2024

Mr Andrew Poplett

13. Appendices

Appendix 1 – CV & Professional Qualifications

Detailed CV Statement - Andrew Poplett - IEng, MIHEEM, ACIBSE, AffIFE

13.1 I am an Authorising Engineer (AE) and currently employed as an independent healthcare consultant, where my role is to provide input/expertise to health facilities in relation to ventilation and water. . An AE acts as an independent professional adviser to the healthcare organisation. The AE should be appointed by the organisation with a brief to provide services in accordance with the relevant Health Technical Memorandum (HTM). The professional status and role required may vary in accordance with the specialist service being supported. The AE acts as assessor and makes recommendations for the appointment of Authorised Persons (APs), monitors the performance of the service, and provides an annual audit to the Designated Person (DP). To effectively carry out this role, particularly with regard to audit, the AE should remain independent of the operational structure of the healthcare organisation.

Experience and expertise

13.2 I started my career as an apprentice engineer in 1985, working for an installation building services company. During my six years with the company I undertook various aspects of design, contract supervision and installation work across a range of industrial and healthcare building services projects. I was later made redundant from this role, however was successful in gaining employment

within the NHS as an operational estates officer working at an acute district general hospital.

13.3 Within this role I began to specialise in ventilation within some of the critical units within that hospital as well as general estate management. Due to my role I moved between a number of NHS trusts, often as a result of trusts mergers. This led to me taking up the role of head of estates for a learning disabilities trust in Northumberland, which later merged to form the then largest mental health trust in England and I took up the role of head of property and planning. In 2010 an opportunity arose for me leave the NHS, which I chose to do and set myself up as an independent healthcare consultant. I now provide independent, impartial and bespoke consultancy services such as system auditing, personnel assessments and awareness training, compliance reviews and action planning to assist and guide clients through the maze of NHS, HSE guidelines, legislation and compliance. I act as an Authorising Engineer, and present my knowledge on subjects such as healthcare ventilation and water system management, service improvements and incident investigations.

13.4 During the last 14 years as a healthcare consultant, I have undertaken various support consultancy roles for a number of both private and NHS healthcare providers. Following the Health Technical Memoranda (HTM) 00 recognising the role of Authorising Engineer (AE) I began to practise as an AE for specialist ventilation and water, formally registering through IHEEM, which is the Institute of Healthcare Estates and Engineering Management. An Authorised Engineer is independent and appointed (normally by an NHS Trust or PFI Principle Service Provider) to take responsibility for effective management of safety guidance recommended by the Department of Health. Part of the AE role is to undertake an annual audit of the operation of facilities. The role and remit of an AE is the same in both the HTM and SHTM.

13.5 I have been peer-reviewed and operate now as a registered AE for both specialist ventilation and for water separately. The peer review process (by the Institute of Healthcare Engineering & Estate Management (IHEEM)) provides a level of assurance that the AE has been assessed by their peers to work and act in a manner and standard which meets the institutes code of practice and conforms to the requirements of the HTM. This role keeps me busy and I currently practice as an independent AE for around 35 to 40 healthcare organisations, principally NHS trusts, but I also act on behalf of trusts for a number of private healthcare providers through Private Finance Initiative (PFI) or Local Improvement Finance Trust (LIFT) arrangements.

13.6 I'm an incorporated engineer registered with the Engineering Council and a full member of IHEEM. I'm an associate member of the Chartered Institute of Building Services Engineers, (CIBSE) and an affiliate member of the Institute of Fire Engineering. I am currently a committee member of the Northeast Regional IHEEM Committee and Chair of the national IHEEM ventilation technical platform. I am also a founder member of the Specialist Ventilation in Healthcare Society (SVH), which is an independent society that was set up by Malcolm Thomas, the President, who is the lead author of the previous and current ventilation Health Technical Memoranda (HTM), such as HTM 2025, HTM 03-01 2007, and lead author on HTM 03-01 2021. The SVH Society was formed in November 2014 with the aim of bringing together those who were practicing or wished to become Authorising Engineers (Ventilation) (AE(V)) or who have a more general interest in Ventilation in the Healthcare setting. At this time I am only a member of the SVH and have no details on the membership but know it holds a register of practicing AEs and draws up competencies for prospective AEs. Those interested in ventilation for healthcare can also subscribe to association membership. A significant portion of the Society meetings is given over to discussing and clarifying interpretation of HTM 03-01 and other healthcare ventilation standards.

13.7 As a member of the SVH Society, I have been lead author and published various guidance or supplementary guidance documents on aspects of ventilation within a healthcare setting. I have also lead authored a couple of guidance notes and supplementary briefing notes for IHEEM's ventilation technical platform, and written numerous articles on ventilation-related issues and the management of ventilation for the Health Estates Journal, which is the magazine of IHEEM and healthcare engineering. Attached at Appendix 1is a summary overview of my work history and involvement with articles and guidance for the institutes and Societies to which I belong.

Employment history and resume of Andrew Poplett – IEng, MIHEEM, MSVHSoc, ACIBSE, AffIFE

Summary Employment History

Trained and qualified as a mechanical building services engineer (BTec HNC) (1985-89)

September 1985 to September 1991 : Haden Young Limited Newcastle upon Tyne

Worked as a specialist project engineer (commissioning & snagging) 1992 started work for the NHS as an operational Engineer

January 1992 to April 2000 – Newcastle General Hospital/Newcastle City Health NHS Trust

Following the completion and implementation of the Newcastle Services Review (NSR) became an Operational Engineer (Specialist Services) Newcastle General Hospital within the newly formed Newcastle City Health NHS Trust, where through internal promotion became Acting Estates Manager.

Lead engineer on Aspergillus “outbreak” in Newcastle (1998) helped develop containment precautions for Aspergillus control standards (NDSC Ireland)

April 2000 to March 2006 - Northgate & Prudhoe (NHS) Trust

In 2000 became Head of Estates for Northgate & Prudhoe NHS Trust

April 2006 to May 2009 - Northumberland Tyne & Wear (NHS) Trust

Due to a merger of three existing NHS Trust’s became Head of Property & Planning for Northumberland Tyne & Wear (NHS) Trust

May 2009 to present - Andrew Poplett Enterprises Ltd

Left NHS in 2009 to become an independent healthcare estates consultant and AE for specialist healthcare ventilation and water.

Over 35 years of experience in healthcare engineering

Chair of the IHEEM Ventilation Technical Platform, Member of IHEEM Regional Committee, & Member of the Water Technical Platform AE(W) Peer Review Panel.

Founder Member of the SVHSoc, Associate member of CIBSE, and Affiliate member of IFE

Lead author of the following Supplementary Guidance Notes

- IHEEM Ventilation Technical Platform (VTP)- Briefing Note - VTP/BN/001 - Potential Increased Risk of Aspergillus Infection due to COVID-19 & the Associated Essential Precautions & Control Measures to Consider

- IHEEM Ventilation Technical Platform (VTP)- Guidance Note - VTP/GN/001/V1.0 March 2021 - Design Output and Performance Specification Guidance for the Ventilation Strategy/Systems for Dental Care Facilities
- SVH Society - Updated Briefing & Guidance on Considerations for the Ventilation Aspects of Healthcare Facilities for Coronavirus – Revision Number 03-V5 8th June 2020
- SVH Society – Guidance Note - Air Handling Unit Condition and Risk Based Monitoring Briefing Document
- SVH Society - Guidance on Critical Ventilation System Risk Assessment Process and Factors
- SVH Society - Fire Damper Briefing Document
- SVH Society - Cryptococcus Briefing for AE(V)'s, AP(V)'s & Estates Professionals

Contributing author of the following Supplementary Guidance Notes

Health Technical Memorandum (2021) 03-01 Specialised ventilation for healthcare premises:

- 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.

HBN 16-01 Mortuaries - Facilities for mortuaries, including body stores and post mortem services.

National Guidelines for the Prevention of Nosocomial Invasive Aspergillosis During Construction/Renovation Activities via production of the Newcastle-upon-Tyne City Health Trust Estates Department – Operational Policy for Aspergillus Management EOP53 (Version 1 updated 2nd February 2000).

Author of the following Health Estate Journal (HEJ) Articles & IHEEM Presentations

Aspergillus fumigatus – a ubiquitous foe – October 2014

L8 – Consider the ventilation aspects – November 2014

Fire Safety – Importance of Regular Inspection stressed – January 2015

Who should appoint AE's & AP's – April 2019

The Estates Manager's Guide to Cryptococcus in Healthcare Ventilation - June 2019

When to seek derogation, and the best approach – September 2021

AE's & AP's – Jack of all trades but masters of none? March 2022

Appendix 2 – Bibliography and supporting documents/standards

Acts and regulations

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European regulations

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Health Technical Memoranda

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Health Technical Memorandum 04-01. Safe water in healthcare premises.

Health Technical Memorandum 05 series. Managing healthcare fire safety.

Health Technical Memorandum 06-01. Decontamination of flexible endoscopes.

Health Technical Memorandum 08-01. Acoustics.

Health Building Notes

Health Building Note 04-01. Adult in-patient facilities.

Health Building Note 04-01. Supplement 1 – Isolation facilities for infectious patients in acute settings.

Health Building Note 04-02. Critical care units

Other Publications

BESA (2013). DW 143: Guide to good practice: ductwork air leakage testing. B&ES Publications, Penrith. BESA (2016).

DW 144: Specification for sheet metal ductwork. B&ES Publications, Penrith. BESA (2020).

DW 145: Guide to good practice for the installation of fire and smoke dampers. B&ES Publications, Penrith. BESA (2020).

DW 172: Specification for kitchen ventilation systems. B&ES Publications, Penrith. BESA (2019).

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Appendix 3 – Glossary of Terms and Abbreviations

Abbreviation	Meaning	Comment
ac/h	Air changes per hour	A means of expressing a ventilation rate or performance
ACOP	Approved Code of Practice	
AE(V)	Authorising Engineer (ventilation)	
AHU	Air handling unit	
AP(V)	Authorised Person (ventilation)	
BESA	Building Engineering Services Association	
BMS	Building Management System	
BSRIA	Building Services Research and Information Association	
cfu	Colony forming unit	
CIBSE	Chartered Institution of Building Services Engineers	
COSHH	Control of Substances Hazardous To Health	
CP(V)	Competent Person (ventilation)	
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)	Also known as or formerly HEPA filters
ErP	Energy related products	
HBN	Health Building Note	
HEPA	High efficiency particulate air filter (H13 to H14)	
HIS	Healthcare Infection Society	
HTM	Health Technical Memoranda	
LEV	Local exhaust ventilation	
LSAPC	Light scattering airborne particle counter	
PPVL	Positive pressure ventilated lobby (isolation room)	
RH	Relative humidity	% RH Percentage relative humidity
UCV	Ultra clean ventilation	
ULPA	Ultra low particulate air filter (U15 to U17)	
VAV	Variable air volume	
VCD	Volume control damper	
VSG	Ventilation Safety Group	
WEL	Workplace exposure limit	


SCOTTISH
HOSPITALS
INQUIRY

SCOTTISH HOSPITALS INQUIRY

Ventilation Deficiencies at QEUH and RHC and their Potential Impacts

Prepared by Allan Bennett

Contents

1. Aim

1.1 In order to assist the Scottish Hospitals Inquiry, address its Terms of Reference items 1 and 7, I have been instructed to address the Key Questions below from a microbiological perspective:

- from the point at which there were patients within the Queen Elizabeth University Hospital and the Royal Hospital for Children (QEUH/RHC) were the ventilation systems in an unsafe condition, in the sense that it presented an additional risk of avoidable infection to patients?
- are the ventilation systems no longer in an unsafe condition in the sense that they now present no additional avoidable risk of infection?

2. Experience and Qualifications

2.1 I graduated from Glasgow University in 1983 with a 2.1 degree in Microbiology and then obtained an M.Sc. in Process Biotechnology from the University of Birmingham in 1984. I worked for three years at the National Engineering Laboratory in East Kilbride on biochemical engineering projects before joining Public Health Laboratory Service Centre for Applied Microbiology and Research (PHLS CAMR) at Porton Down in 1988. I subsequently worked at Porton Down for the Health Protection Agency, Public Health England and UKHSA until I retired in 2023.

2.2 Over the 35 years I worked at Porton Down my research interests have been around the airborne transmission of infection and its prevention. For the last 20 years, I have headed a research group of 10 to 20 scientists carrying out research in this area. During this time, I had my own research programme and obtained external funding from and delivered projects for NHS Estates, Home Office, EU, European Space Agency, WHO, and various research councils. I have over 140 research publications with over 5,000 citations.

2.3 As part of this group, I led a team carrying out independent testing of a wide range of equipment used in laboratories, healthcare and pharma. This included testing of filters, microbiological air samplers, air cleaners to agreed protocols and international standards. For part of that time, I also was involved with the annual testing of laboratory ventilation/filtration and that of specialist containment equipment within my organisation and in dstl[1] laboratories also at Porton Down. On occasion I carried out testing or assessment of containment systems for HSE as part of their investigations.

2.4 I have experience of leading investigations of the microbial contamination of air in dental surgeries, sewage treatment works, waste transfer stations and other industries. I also headed environmental sampling teams into anthrax cases associated with drumming. During the 2009/10 influenza pandemic, the 2020/22

[1] Defence science and technology laboratory.

COVID pandemic, the mPox outbreak 2022 I led teams measuring the concentration of influenza, SARS-CoV-2 and mPox in healthcare environments in air and on surfaces. The published results of these studies impacted on infection control guidance in the UK.

2.5 During the COVID pandemic I was a member of the UK Scientific Advisory Group for Emergencies (SAGE) Environment and Modelling Subgroup and contributed to a wide range of papers related to the impact of ventilation and other factors on the spread of SARS-CoV-2. I also was a member of The Scottish Dental Clinical Effectiveness Programme (SDCEP) Scottish Mitigation of Aerosol Generating Procedures in Dentistry – A Rapid Review Working Group and contributed to develop guidance on ventilation in dentistry.

2.6 From 2008- to 2020 I was involved as a subject matter expert in projects to replace the high containment facilities at Porton Down. This involved working with architects, designers and safety experts in order to design new facilities that would conform to regulations and be acceptable to regulators. I used this experience as a work package manager on the EU funded European Research Infrastructure on Highly Pathogenic Agents (ERINHA) project in which I worked with BSL4 facilities, international architects to provide guidance in the design of high containment facilities. I also worked on project with the European Space Agency and EU into the design of laboratories for the investigation of samples returned from Mars. I was a member of the editorial committee of the 4th edition of the WHO Laboratory Biosafety Manual and was co-head of a WHO Collaborating Centre in Applied Biosafety and Training from 2019-2023.

2.7 I am a member of the International Editorial Board of the Journal of Hospital Infection since 2017 and have peer reviewed over 70 scientific publications on the roles of the environment in infection control in healthcare to ensure they meet the scientific standards of the journal. I have contributed to teams investigating nosocomial infection outbreaks including the NI neonatal Pseudomonas outbreak, the global outbreak of *Mycobacteria chelonae* associated with cardiac surgery and sink associated anti-microbial resistant Gram negative bacterial infections.

2.8 My publication list can be accessed on Google Scholar (Allan Bennett - Google Scholar)

3. Limitations

3.1 I am an expert in the transmission of airborne microorganisms and in the prevention of their spread. I have no clinical expertise and no experience of day-to-day working in the hospital environment. I have knowledge of aerosol science but not fluid dynamics.

3.2 In October 2023, I visited some of the QEUH wards discussed in this report. I did not have access to all the wards described within this report.

3.3 I have knowledge of ventilation systems and concepts but I am not a ventilation professional authorised person or engineer.

3.4 I have carried out limited review of the scientific literature in some areas but I have not had the time or resources to carry out any full literature reviews.

3.5 The COVID-19 pandemic has had an impact on the use of ventilation to control transmission of airborne infection in public spaces and healthcare. Recommendations have been made in the UK and US to improve ventilation in public spaces. This report does not take any post COVID knowledge into consideration in considering any deficiencies in the QEUH/RHC ventilation systems.

4. Introduction to Ventilation and Airborne Infection Control

Basic Functions of Ventilation

4.1 The objective of this report is to investigate the impact of potential deficiencies in the ventilation systems in QEUH and RCH on patient safety. To do this an understanding of the basic functions of ventilation in a healthcare environment are

required as well as an understanding on the involvement of air in the transmission of microorganisms in the hospital environment.

4.2 The primary function of ventilation is to provide a comfortable environment by controlling temperature, humidity and reducing odours. Ventilation in hospitals is also intended to protect patients from exposure to microorganisms in the air which could lead to infections that could cause mortality and morbidity to patients undergoing treatment and to staff. Hospitals are unusual public spaces which house a wide variety of patients with different needs and susceptibilities to infection. Unlike most public spaces a hospital has a population of in-patients who are exposed to the hospital environment and breathing hospital air for 24 hours per day during their stay.

4.3 Since the COVID-19 pandemic there has been a great deal of interest in the role of ventilation to reduce the transmission of respiratory viruses. It is recognised that the period covered by this report is predominantly before COVID-19 and the change in practice and attitudes to ventilation and infection control caused by the impact of COVID. However, the COVID-19 outbreak is a demonstration on how the healthcare environment must be flexible in the face of changing health threats.

4.4 The QEUH is an example of fully sealed mechanically ventilated hospital with no natural ventilation in patient areas such as open windows. This means that all air in the facility is provided by the mechanical ventilation and extracted through the same system. This decision was taken at least partially due to concerns about odours from the neighbouring sewage treatment facility. It was proposed that the buildings were to be made airtight to reduce the infiltration of untreated air. It was originally proposed that mechanical ventilation systems were fitted with activated carbon filtration to remove odour from supply air,[2] but this proposal was not adopted in the final design due to concerns about energy usage and this was accepted by the Board.[3] [4]

[2] A33519492 – Design Solution Report July 2007 – to add to hearings bundle.
[3] A36939874 – Ecoteric Ltd - Ventilation review issued 181110 – to add to hearings bundle.
[4] A39094549 – Project Manager Instruction No. 659 issued 21.11.2011 – to add to hearings bundle.

4.5 Hospital ventilation uses three basic mechanisms to reduce transmission of infection, dilution, directional air flow and filtration. These mechanisms are introduced in the following sections:

Dilution of Air

4.6 The provision of a fresh air supply is intended to provide a comfortable environment and to remove contaminants from a hospital space by removing the contaminated air and replacing it with “clean air”; normally outdoor air which is filtered to remove gross contamination. The provision of temperature and humidity-controlled air will provide a comfortable environment within agreed set points. In the case of the QEUH, fresh air was supplied to patient areas through a mechanical ventilation system as such it is a sealed building with no opening windows in patient areas. The amount of dilution caused by a mechanical ventilation system is defined by the air change rate in units of air changes per hour (ACH). This is calculated by dividing the volume of air replaced within one hour by the volume of the ventilated area. In guidance documents for UK hospitals, an air change rate of 6ACH is recommended for wards and single rooms and 10 ACH for specialist facilities (all versions of HTM03-01, SHTM03-01). For mechanically ventilated systems, air change rates can be easily calculated and can be continually measured and monitored by modern building management systems which continually capture data from the ventilation system such as air flow rates, pressure differentials and temperatures. The building management system will be continually monitored by Estates staff.

4.7 In building codes provision of fresh air supply is often referred to in litres of fresh air provided per person per second with figures used such as 8l/p/s. For example, the Scottish Building Standards technical handbook from 2017 Section 3.14 states that “for occupiable rooms, where a mechanical air supply is provided at a rate of at least 8 litres/second of fresh air per occupant, based on sedentary

occupants and the absence of other requirements such as the removal of moisture."[5] However fresh air provision rate is not currently used as a specification in relevant healthcare guidance.

Directional Air Flow

4.8 Directional air flow is generally used to move air from a "clean" area into a "dirty" area from which air is extracted and discharged out of the hospital. In any building the air flows can be balanced in such a way as to create an area with a pressure higher or lower than the surrounding area. This can be utilised to prevent the ingress or egress of potentially contaminated air from one area to another. This can be done in various ways in hospitals, and this will be described in more detail later in this document, but the basic principle of operation is as follows.

4.9 If the patient housed in an area is determined to be infected with an infectious agent, such as *Mycobacterium tuberculosis* or SARS, which will pose a serious airborne infection risk to patients and staff, it is normal practice to house them in a negative pressure space where all air from the room will be extracted through the ventilation system thus preventing exposure of those in surrounding areas. If air is extracted and then discharged into a populated space, then additional filtration may be required to protect those exposed to the discharged air.

4.10 Some hospital patients will be immunocompromised due to their illness or immunosuppressed due to therapy. These patients are highly vulnerable to infections by opportunistic pathogens that will be harmless to the remaining hospital population and also infections caused by respiratory viruses. These agents may be common environmental agents or be human derived from other patients, staff or visitors. Depending on clinical assessment, it may be decided that these patients need to be housed in protective isolation. This normally means that they will be housed in rooms which will be held at positive pressure to the exterior environment, in other words, all

[5] A47128231 – Building Standards Technical Handbook 2017: non-domestic buildings, March 2017 – Bundle for Oral hearings commencing 19 August 2024 – Bundle 16 - Page 1210.

air from the room will be provided through the mechanical supply which will be filtered to a high standard often using HEPA filters.

4.11 The level of pressure differential used will be decided by the national guidance (SHTM03-01) and the magnitude required to avoid fluctuations from positive pressure to negative pressure. If pressure differentials are set too high this may cause damage to facilities. Systems should be monitored and alarmed if they go out of the specified pressure range.

Filtration

4.12 Filters are used to remove particulate from the air thus cleaning the air supply to areas of the hospital. Filters are graded by their efficacy at removing particles from the air to international standards and will vary in efficacy from coarse filters intended to remove gross contamination to HEPA (Highly Efficient Particulate Air) filters (up to 99.99%) intended to provide a near sterile air supply (Christopherson et al 2020).[6] While coarse filters will be widely used throughout the hospital, higher grade filters will mainly be used in specialist facilities including high level protective isolation.

4.13 Supply HEPA filters may be located in the AHU in the service floor, which ensures that the ventilation ducts are kept clean, or at the room junction. Extract HEPA filters, if required, will generally be placed in the room junction to prevent contamination of the extract ductwork.

4.14 The pressure differential across the filter will normally be monitored. An increase to the pressure differential will indicate that material deposited in the filter will be blocking the filter and thus increasing resistance. This will potentially increase energy use, reduce flow rate and damage filters. The use of HEPA filters will greatly increase the energy requirement needed to maintain air flow.

4.15 HEPA filters may also be incorporated with portable recirculating units to reduce aerosol build up in poorly ventilated spaces. While this may reduce aerosol

[6] A48356614 – David A. Christopherson, William C. Yao, Mingming Lu, R. Vijayakumar and Ahmad R. Sedaghat, 'High-Efficiency Particulate Air Filters in the Era of COVID-19: Function and Efficacy' (2020) – to add to hearings bundle.

concentrations within the space, they will not prevent the ingress of aerosol contamination into the space.

Practicalities

4.16 When a hospital is designed the ventilation systems capacity can be calculated by using the air change rate and room ward sizes to calculate the required air supply (or extract) to provide these air changes. The balances of flow required for directional ventilation and the resistance caused by filtration can also be used for the design. This information will be used by the engineer to calculate what size of fans and ducts are required to provide the calculated air flow. These systems are normally designed to be oversized to allow for reduction in fan performance over time to be taken into consideration and also to allow the potential for increased air flow in the future. However, guidance may allow some deviation from the recommendation in performance but not design. For example, HTM03-01 (2007) Part B states that ventilation should achieve not less than 75% of the design air-change rate.[7] However, if a ventilation system is designed to exactly meet requirements, then this may give problems at meeting ACH targets in the future if they increase or if additional filtration is installed. If it is undersized then any work to increase capacity will be disruptive and expensive as ductwork and fans may need to be replaced with larger units.

Isolation Rooms

4.17 Various designs of isolation rooms are used in hospitals for various patient groups. The following sections provide simple descriptions of the different categories of isolation room.

[7] A37344358 – HTM 03-01 Part B November 2007 – Hearing Commencing 9 May 2022 – Bundle 2 - Page 304.

Negative Pressure Isolation Room

4.18 Patients within a hospital may be there because they are being treated for a serious aerosol transmitted disease such as tuberculosis, suffering from a respiratory virus infection or similar. Hospitals also contain people to whom such an infection could be life threatening due to their immune status or frailty.

4.19 Therefore, patients with airborne transmissible respiratory infections need to be kept separate from uninfected cases and staff also need protection. This requires rapid identification and isolation of all suspected infectious cases. These patients are often housed in a separate isolation room designed so that all air within the room is extracted safely and the room is held at a negative pressure to the external area often with an anteroom which provides an extra layer of security and an area for the staff to change into protective equipment and disrobe on exit.

4.20 If there are a number of airborne transmissible infection cases on a ward, they may be grouped together on a specialist ward to minimise transmission to uninfected cases. Employers are also under a duty of care to their employees to ensure they are protected against these infections (COSHH 2002).[8] While ventilation will be part of this protection vaccination and the use of respiratory protective equipment will also be used to protect staff from exposure.

Positive Pressure Ventilation Lobby (PPVL)

4.21 A room with a positive pressure ventilated lobby (PPVL room) has air supplied into the anteroom which causes positive pressure that provides a barrier between the outside environment and the inside environment. Air from the supply flows both into the corridor and into the patient room. The air supply into the anteroom will be filtered to reduce any environmental contamination. This allows the patient to be supplied with clean filtered air which can be safely extracted away from the ward

[8] A48180004 – The Control of Substances Hazardous to Health Regulations 2002 – to add to hearings bundle.

area. While these rooms are normally used for immunocompromised patients, they have also been used to house infectious patients (Poovelikunnel et al 2020).[9]

Positive Pressure Isolation Room

4.22 Patients who are immunocompromised or immunosuppressed will be more prone to infection from other patients, staff or environmental sources. They will require to be held under protective isolation. This involves a whole series of measures including use of limited access to the patient, the wearing of protective clothing by all persons accessing the room, control of microbial contamination of food and water, enhanced cleaning as well as ventilation measures. The ventilation will be designed to ensure that the air being breathed in by these patients is as sterile as is possible. This will involve the air supplied to the patient being HEPA filtered, the room being held at positive pressure to the surrounding area and an adequate air change rate. Again, an anteroom is normally provided.

Chilled Beam Units

4.23 Chilled Beam Units (CBU) are widely used within the QEUH where they are used to provide temperature and humidity control from within the patient's rooms and other areas. They use water as a means of environmental control; cooling down warm air as it rises. They are marketed as an extremely energy efficient and cost-effective option for controlling the environment in a wide range of commercial applications. A chilled beam system can be either 'active' or 'passive'.

4.24 Active chilled beam technology is in use in hospitals globally, with their introduction largely driven by energy-saving advantages. Two disadvantages of chilled beam technology however are the production of condensation and issues with cleanliness/particulate build up. This will be discussed in subsequent sections.

[9] A48356789 – T.T. Poovelikunnel, A. Barakat, A. O'Hara, H.J. Humphreys, V. Newmann, A.F. Talento, 'Are positive-pressure ventilation lobby rooms effective for protective and source isolation?' (2020) - to add to hearings bundle.

5. Air Microbiology of Hospitals

5.1 I will now consider any link between deficiencies in the QEUH ventilation system and the risk of infection to patients and staff resulting from these deficiencies. To do this, the potential sources of airborne microorganisms in the hospital environment need to be considered.

5.2 All air outside controlled areas will contain microorganisms and we are exposed to airborne microorganisms whenever we breathe. Sources of microorganisms will be humans, resuspension of dust, outdoor environmental agents etc. Most of these microorganisms are harmless if inhaled by healthy individuals but patients with weakened immune systems will be at heightened risk if exposed to these microorganisms.

Transmission Routes and Sources

5.3 There are four main risks associated with exposure to airborne infectious agent found in hospitals. These are:

5.4 **Direct airborne transmission from person to person.** This occurs mainly with respiratory viruses such as SARS-CoV-2 and influenza and bacterial respiratory pathogens such as *Mycobacterium tuberculosis*. The infected person generates an aerosol of a respiratory transmitted agent due to some respiratory activity which contaminates a hospital space. The exposed person breathes in these agents thus causing infection then leading to disease. While it has long been thought that many respiratory viruses will be transmitted over short distances (i.e. less than 2m) there is some evidence of longer distance transmission with SARS-CoV-2 (Jones et al 2020, Duval et al 2022)[10] and other agents. This will depend on the amount of aerosol generated by the source, its particle size distribution, infectiousness of the agent, susceptibility of the host and the ventilation in the hospital. Duration of exposure will

[10] A48356950 – Nicholas R Jones, Zeshan U Qureshi, Robert J Temple, Jessica P J Larwood, Trisha Greenhalgh, Lydia Bourouiba, 'Two metres or one: what is the evidence for physical distancing in covid-19?' (2020) – to add to hearings bundle; A48357057 – Daphne Duval, Jennifer C Palmer, Isobel Tudge, Nicola Pearce-Smith, Emer O'Connell, Allan Bennett, Rachel Clark, 'Long distance airborne transmission of SARS-CoV-2: rapid systematic review' (2022) - to add to hearings bundle.

increase the risk of infection and so people housed in hospitals will be at more risk of infection than those only passing through an area. Therefore, a patient located in the vicinity of an infected person will generally be more exposed than a staff member or visitor.

5.5 For highly aerosol transmissible agents prompt diagnosis of the patient in the healthcare environment is required followed by some form of isolation to prevent transmission to patients and staff. Respiratory Protective Equipment (RPE) and, if available, vaccination will be required for staff.

5.6 **Contamination of surfaces by human derived aerosols or droplets.** In some cases, aerosols, droplets or skin flakes derived from an infected person may be deposited on surfaces which may contacted by patients. For example, a sneeze may generate particles that deposit on surfaces such as tables, food, medical equipment etc. which may be later ingested or come in contact with patients. Particles contaminating bedding may be re-aerosolised during bed change. This type of risk is lower than direct transmission but may be significant for agents such as poxviruses.

5.7 **Direct transmission from the environment.** Air may contain various opportunistic environmental pathogens which if inhaled by susceptible persons may lead to infection. This exposure will be common outside the hospital but may require to be controlled in the case of highly susceptible immunosuppressed or immunocompromised persons. Often these agents are fungal such as Mucor, Aspergillus, Cryptococcus, Pneumocystis and can commonly be found in outside air. High level filtration is used to protect immunosuppressed patients from exposure to these agents. Some of these agents such as Aspergillus can grow on water damaged surfaces within hospitals and be released into the air as spores.

5.8 Aerosolization of fungal opportunistic pathogens has been linked to building work and building demolition and this has been linked to many outbreaks of

Aspergillus mainly in immunosuppressed patients (Kanamori et al 2015).[11] If such work is carried out on a hospital site it may require additional protective measures to be taken such as the creation of temporary barriers to prevent ingress of contaminated dust, the use of portable HEPA filter units and the creation of temporary positive pressure areas. Other agents such as Legionella and non-tuberculosis mycobacteria may be transmitted due to the aerosolization of contaminated water in showers and other systems.

5.9 **Indirect transmission from the environment.** Aerosols and droplets containing opportunistic pathogens can be generated from the hospital environment. Sources can be sinks, leaking HVAC units, floor cleaners, condensation from CBU etc. These droplets can deposit on and contaminate surfaces such as tables, food, medical equipment etc which may be later ingested or come in contact with patients.

Impact of Aerosol Particle Size

5.10 The behaviour of particles in the air, including microorganisms, is governed by their particle size, density and shape and is defined by Stokes Law. Basically, this states that the deposition velocity of an aerosol particle is directly proportional to the particle diameter squared and to the particle density. So, the larger the particle the quicker it deposits from the air. As a rule of thumb, small aerosol particles (less than 10 microns diameter) can remain in the air for extended periods of time and during this time can spread spatially and potentially be inhaled by exposed persons at a distance from the infected person. Larger particles will remain in the air for shorter periods of time and will rapidly deposit on surfaces. Simply this means that ventilation (dilution and pressure differentials) will mainly impact on the transmission of agents on small particles (<10 microns) such as those disseminated from people infected with respiratory viruses and from fungal spores but not on transmission of larger particles. It also means that larger particles will generally only pose an

[11] A48357167 – Hajime Kanamori, William A. Rutala, Emily E. Sickbert-Bennett, David J. Weber, 'Review of Fungal Outbreaks and Infection Prevention in Healthcare Settings During Construction and Renovation' – to add to hearings bundle.

infection risk to those who are close to the source while small particles will have the potential to spread for significant distances. (Tellier et al 2019).[12]

5.11 However, large particles will tend to contain higher numbers of infectious agent than smaller particles. This is a cubic relationship i.e. a particle of double the diameter will have 8 times the volume and so 8 times the concentration of infectious agents.

5.12 The size of an aerosol particle will almost always be greater than that of the microbial agent it carries. For example, respiratory viruses will normally be surrounded by dried respiratory secretions and will not be present in a single naked virus form.

5.13 Filtration of liquids is often defined by particle size cut offs. This is **not** the case for particulate filtration. It is known that HEPA filters act by a combination of direct interception, impact inertia and diffusion (Christopherson et al 2020).[13] For HEPA filters a most penetrating particle size is defined for test purpose which is normally between 0.1 and 0.3 microns. All filters testing will be carried out at this most penetrating particle size as defined in standards for type testing or in situ testing.

Inhalation of Infectious Aerosols

5.14 Respiratory viruses and bacteria and opportunistic fungal pathogens will be transmitted through inhalation and deposition into the respiratory tract. The area of the respiratory tract the infectious particle deposits in will be governed by the particle size with only the smallest particle (< 5 microns) reaching the deep lung. However, larger particles can initiate infection in the upper respiratory tract and can potentially colonise the lung later in the course of the infection.

5.15 People at complete rest inhale approximately 6 Litres of air per minute and this can be used as a rule of thumb for potential exposure of a hospitalised person to

[12] A48519480 – Raymond Tellier, Yuguo Li, Benjamin J. Cowling, Julian W. Tang, 'Recognition of aerosol transmission of infectious agents: a commentary' (2019) – to add to hearings bundle.
[13] A48356614 – David A. Christopherson, William C. Yao, Mingming Lu, R. Vijayakumar and Ahmad R. Sedaghat, 'High-Efficiency Particulate Air Filters in the Era of COVID-19: Function and Efficacy' (2020) – to add to hearings bundle.

an infectious agent (Pleil et al 2021).[14] So, if an infectious agent is present in the air at a concentration of ca3 infectious units per 1000l a patient will inhale about 1 unit during one hour. Whether this gives rise to an infection will depend on the infectious dose of the agent and the vulnerability of the patient. An inpatient will be exposed to up to 8,640 Litres of air per day. A person undertaking light activities will inhale larger volumes of air.

Generation of Infectious Aerosols

Infected Persons

5.16 During a respiratory infection, patients can be infectious and generate aerosols of the infectious agent which can infect staff, patients and visitors exposed to these aerosols. Some infections such as tuberculosis, measles and RSV are thought to be mainly transmitted in this manner while other respiratory viruses such as influenza and SARS-CoV-2 are at least partly transmitted in this manner.

5.17 Traditionally, infectious aerosols were thought to be mainly generated through coughs and sneezes, but evidence form SARS-CoV-2 suggests that pre-symptomatic aerosol generation occurs. The kinetics of aerosol generation will greatly vary between agents and infected persons during the course of the infection with strong evidence emerging about the potential for superspreading persons or events. Infectious aerosol generation has been linked to “aerosol generating procedures” but this linkage is not strong for influenza (Thompson et al 2013)[15] and again a series of papers from the University of Bristol did not show this linkage (Brown et al 2021).[16] However, some procedures such as bronchoscopy and sputum

[14] A48359372 – Joachim D. Pleil, M. Ariel Greer Wallace, Michael D. Davis, Christopher M. Matty, ‘The physics of human breathing: flow, timing, volume, and pressure parameters for normal, on-demand, and ventilator respiration’ (2022) – to add to hearings bundle.
[15] A48359513 – Katy-Anne Thompson, John V. Pappachan, Allan M. Bennett, Himanshu Mittal, Susan Macken, Brian K. Dove and others, ‘Influenza aerosols in UK hospitals during the H1N1 (2009) pandemic – The Risk of Aerosol Generation during Medical Procedures (2013) – to add to hearings bundle.
[16] A48359747 – J. Brown, F.K.A. Gregson, A. Shrimpton, T.M. Cook, B.R. Bzdek, J.P. Reid, A.E. Pickering, ‘A quantitative evaluation of aerosol generation during tracheal intubation and extubation’ (2021) – to add to hearings bundle.

induction are likely to increase aerosol generation (Thomson et al 2013).[17] Generally once treatment with antibiotics or antivirals is initiated the level of aerosol generation will decline.

The environment

5.18 Environmental microbial aerosols will be generated in several different ways. Firstly, fungal spores are aerosolised from so called fruiting bodies and can travel long distances in the air. They tend to be generated in small particle sizes. The source can be external air or internal from surfaces that have been colonised by fungi often caused by water damage. Generally, the generation of aerosol particles from liquid sources tends to be associated with high energy processes as the generation of small particles from bodies of liquids or from solids needs energy to break down larger volumes into smaller ones. To generate aerosols from liquids surface tension needs to be broken. The smaller the particle size, the more energy required. To aerosolise microorganisms from water you need high energy processes that can be associated with showers or cooling towers. To aerosolise microorganisms from dust and skin flakes will require procedures to be undertaken such as bed changes or vigorous cleaning methods.

Microbiological Air Sampling

5.19 Microbiological air sampling is often used to gain information about the source of an airborne infection or to ensure that the air in an area is clean. Air sampling for viral pathogens has been widely carried out during the recent pandemic and often relies on specialist equipment and techniques to be used. However, in most hospitals including the QEUH microbial air sampling is carried out using conventional culture-based methods using impaction air samplers.

5.20 The sampler operates using a pump to pull air across an agar plate through either a sieve plate or a moving slit. Any particles within a size range defined by the aerosol physics will be accelerated into the agar surface and be deposited. If the

[17] A48359513 – Katy-Anne Thompson, John V. Pappachan, Allan M. Bennett, Himanshu Mittal, Susan Macken, Brian K. Dove and others, 'Influenza aerosols in UK hospitals during the H1N1 (2009) pandemic – The Risk of Aerosol Generation during Medical Procedures (2013) – to add to hearings bundle.

growth media is appropriate for the agent, then when the plate in incubated at the correct temperature for the correct time (normally seven days for fungi) colonies will form on the agar surface and the strain can be identified by colony morphology or by subsequent analysis using chemical or genetic techniques. By knowing the air flow and the duration of sampling the aerosol concentration can be calculated.

5.21 Successful microbial air sampling depends on having the correct sampler and media but also on the sampling being carried out in the right place at the right time and enough air being sampled. It is very difficult to rule out an aerosol source of infection as sampling often occurs after the potential infection has occurred and cannot be undertaken 24 hours a day and cannot sample the daily volume of patient air. However, finding the relevant agent in an air sample will always be highly significant unless it is present at a very low concentration.

5.22 A quicker method to monitor air quality is to use particle counters which can measure the concentration of particles within a defined size range. While this can be used as a real time method to determine air quality especially in HEPA filtered spaces and highlight potential defects it cannot give any information about microbial air concentration.

6. Patient placement and specialist ventilation at QEUH

6.1 It is important that patients are housed in wards and rooms that give them the best access to care. The decision on housing patients will be multifactorial but, in some cases, will be determined by the requirement for specialist ventilation, either to protect the patient and or other patients and staff. For patients requiring negative pressure isolation this decision will be made based on symptoms, clinical and travel history and the results of diagnostic tests. For patients requiring positive pressure isolation the decision will be made based on clinical history, treatment history and the results of tests such as white blood cell counts. Concerns have been raised by clinicians and infection control teams about how this was done during 2017 for both patients requiring positive and negative pressure isolation.[18] I am aware that in the 2020s a standard operating procedure (SOP) was developed to define the agreed practice for patient placement at the QEUH and is now on its fourth edition. Before that I have only been made aware of documents covering the placement of Tuberculosis, *C. difficile* and influenza patients. This chapter will discuss how the current SOP specifies how patient placement is done at the QEUH.

Wards and patient groups housed in QEUH and RHC

6.2 The wards and patient groups within QEUH and RHC referred to on this report are summarised in the table below.

QEUH - Adult Hospital - Patient Types		
Ward No.	Area	Patient Type
4B	National Bone Marrow Transplant Unit	24 beds for haematology patients undergoing bone marrow

[18] For example A38759270 - Action Plan arising in response to SBAR dated 3 October 2017, Item 3 – to add to hearings bundle.

		transplantation - patients are high risk and immunocompromised
4C	Haemato-Oncology (10 beds) and Renal (18 beds)	Haemato-oncology patients who are immunocompromised
5C and 5D	Infectious Diseases	Any patient with a recognised infectious disease - These wards will house patients with airborne infections such as TB, measles and chickenpox, including immunosuppressed HIV patients.
6A	Originally accommodated Rheumatology and was designated a general ward. Paediatric patients from Ward 2A in the children's hospital moved to this ward in November 2018	Immunocompromised paediatric patients were treated on this ward when accommodating RHC 2A patients

Royal Hospital for Children (RHC) - Patient Types

Ward No.	Area	Patient Type
2A	Haematology & Oncology In-patient Ward	Immunocompromised
	Teenage Cancer Trust Ward	Immunocompromised
	National Bone Marrow Transplant Unit	At handover 8 PPVL rooms were in place - patients are high risk and immunocompromised

Specialist ventilation rooms

6.3 A minority of patients in hospitals will need to be housed in specialist ventilation facilities either to protect them from infection or to protect other patients and staff from a transmissible infection. The current recommendations form the most up to date SOP for patient placement at the QEUH and RHC (issued Jan 2024) is shown below.

Type of Room	Patient allocation/suitability
PPVL with Lobby HEPA	Immunosuppressed patients, i.e. Haem-onc patients, should be prioritised for these rooms
	Immunosuppressed with chickenpox / measles
	Patients with Atypical Mycobacteria
	Patients with infections (non-airborne route)
Negative pressure	Chickenpox, Measles, Pathogens of High Consequence
	Tuberculosis (incl MDRTB and XDRTB) Prioritise airborne infection
BMT Rooms	Bone Marrow Transplant patients These are located in specialist units: QEUH 4B RHC 2A

6.4 The rooms are defined in the current SOP as follows:

6.5 Positive Pressure Ventilated Lobby (PPVL) Room (HEPA filtered air) (Verbatim from Jan 24 SOP)

> A PPVL room has a flow of air from the lobby which moves into the main room. The contaminated air is extracted via a vent in the en-suite toilet when one is available. In all instances in QEUH and RHC there is an additional extract in variable locations in the ceiling of the patient room. The lobby itself is positively pressurised to both the patient's room and the outer corridor providing a barrier between the patient within the room and the surrounding ward. This movement of air effectively prevents infection

spreading between the room and the surrounding ward. Some PPVL rooms have an air supply to the lobby via a filter (HEPA filter) providing some further protection for patients who are immunosuppressed within the room. It is important to keep the door to the main room and to the lobby closed when not in use to ensure that this flow of air is maintained. The pressure on the gauge from corridor to lobby should read +8 to +12 PA.[19]

6.6 Negatively Pressured Room (Verbatim from Jan 24 SOP)

A negative pressure room has a flow of air which moves from the corridor into the room preventing the escape of room air to the surrounding ward. The ventilation within the room is such that it dilutes any airborne pathogens which are circulating. The room provides a negative air flow/ 'cascade' from ward corridor to lobby, and lobby to isolation room, whilst allowing control of room temperature. The room is validated for 10 air changes per hour within an isolation room and a pressure differential of -8Pa to -10Pa in relation to the corridor. It is important to keep the door to the main room and the lobby closed when not in use to ensure that this flow of air is maintained.[20]

6.7 Bone Marrow Transplant (BMT) Room (Verbatim from Jan 24 SOP)

BMT rooms are reserved for use by those patients who are highly susceptible to infection, for example, those undergoing bone marrow transplant. The air supply to the room is via a filter (HEPA filter) to further provide protection to the vulnerable patient within the room from external airborne pathogens such as fungi. These rooms are currently only located within Ward 2A Children Hospital and also Ward 4B in the QEUH and are reserved for use by BMT patients.[21]

[19] A47611609 – NHS GGC Control of Infection Committee Standard Operating Procedure January 2024 - to add to hearings bundle.
[20] A47611609 – NHS GGC Control of Infection Committee Standard Operating Procedure January 2024 - to add to hearings bundle.
[21] A47611609 – NHS GGC Control of Infection Committee Standard Operating Procedure January 2024 - to add to hearings bundle.

Comment

6.8 There are numerous SOPs available for the placement of infectious cases with influenza, tuberculosis or *C. difficile* infection. However, I have not seen or been provided with any SOPs for placement of immunosuppressed patients from before 2022. The current patient placement SOP defines the design of PPVL and negative pressure rooms very strictly i.e. defined pressure differential but there are no ACH or pressure differentials defined for the BMT rooms.

Single Rooms

6.9 The QEUH was designed based on single rooms for patients apart from intensive care and accident and emergency. The provision of single rooms is regarded as beneficial to patients because of privacy, can allow the hospital flexibility and improves infection control by separating patients from others on the ward. However, there will still be the possibility of movement of air between rooms and from common areas to rooms. Most rooms with an en-suite toilet will be at slightly negative pressure to outside areas as air will be extracted from the en-suite. If the doors of the single rooms are closed this will reduce but not eliminate the potential for aerosols to move from outside into the single room as other fluctuations of air flow in the building (wind, elevators etc) and temperature differentials can cause flow reversals. If doors are kept open, then protection against airborne agents will be reduced.

7. Use of ventilation to reduce airborne infection – Evidence and Guidance

7.1 Ventilation has been recognised as a strategy to reduce infection in hospitals for at least 150 years**.** For example, the design of operating theatres has been developed on the basis of experiment and practice and has shown to reduce the rate of surgical site infections. The use of ventilation to reduce infection was a high priority before the antibiotic era and has recently been highlighted in the COVID-19 response (Morawska et al 2020).[22]

Research basis for hospital ventilation guidance

7.2 The evidence base behind the use of ventilation standards to improve patient outcome in hospitals is not easy to find. This is due to much of the work in this area being carried out at least 40 years ago but also to the difficulties in carrying out case control studies in this area. There are also the complications of different ward designs, different patient groups and difficulty of assessing the impact of ventilation as separate to other mitigations. Therefore, the evidence base largely consists of theoretical and environmental studies showing the effectiveness of ventilation in model systems and evidence of transmission of infection in healthcare caused by malfunctioning ventilation or lack of ventilation. It may be that the use of emerging sequencing methods will be capable of better determining evidence for spread of airborne infections in the future and the effectiveness of control measures.

Isolation Rooms

7.3 The recommendations for design of hospital ventilation including that of isolation rooms in the UK and globally are at least partially based on a series of papers describing work carried out by Owen Lidwell's group in the 1970s (Lidwell

[22] A48359878 – Lidia Morawska, Julian W. Tang, William Bahnfleth, Philomena M. Bluyssen, Atze Boerstra, Giorgio Buonanno and others, 'How can airborne transmission of COVID-19 indoors be minimised?' (2020) – to add to hearings bundle.

1972; Bagshawe et al 1978, Thomas 2022)[23] and Hambraeus' group in Sweden (e.g Hambraeus and Sanderson 1973)[24]. Lidwell's group used modelling backed up by the use of a range of aerosol particle tracers (e.g. *Staphylococcus aureus* and Potassium Iodide) to assess the ratio of airborne contamination within a room as compared to outside the room under a range of different airflow conditions and with and without anterooms.

7.4 The technique used involves generating a known quantity of aerosol particles of a similar size to microbial aerosols within an isolation room. Air samplers placed outside the room or in an adjacent room are used to sample any aerosol released. The ratio of total aerosol to released aerosol is calculated and expressed as a protection factor.

7.5 So, if an isolation room has a protection factor of 100 it means that if 100 aerosol particles are generated within a room then only 1 is released into the external environment.

7.6 Lidwell found that directional airflow could greatly reduce the transfer of aerosol particles from the isolation room to an adjacent room by about 10^3 and that the use of an airlock (unventilated) could add 10x to the level of protection. Having a positive pressure ventilated lobby seems to increase this factor to 10^6 to 10^7. This shows how effective properly functioning isolation rooms can be. They can be more efficient at reducing exposure to aerosols than HEPA filters. Throughout the Lidwell studies there is no measurement of pressure differential, but directional airflow volumes are used to define functioning systems. However, he notes that in

[23] A48360632 – O. M. Lidwell, 'The control by ventilation of airborne bacterial transfer between hospital patients, and its assessment by means of a particle tracer: II. Ventilation in subdivided isolation units' (1972) – to add to hearings bundle; A48360843 – K.D. Bagshawe, R Blowers, O.M. Lidwell, 'Isolating patients in hospital to control infection. Part III--Design and construction of isolation accommodation' (1978) - to add to hearings bundle; A48061462 – Malcolm Thomas, 'Guidance on Ventilation Revised and Updated' (2022) - to add to hearings bundle.
[24] A48361005 – A. Hambraeus and H.F. Sanderson, 'The control by ventilation of airborne bacterial transfer between hospital patients, and its assessment by means of a particle tracer: III. Studies with an airborne-particle tracer in an isolation ward for burned patients' (1972) - to add to hearings bundle.

investigations carried out in hospital isolation units he found 11/27 cases of flow reversal i.e. the rooms were not providing air flow in the required direction. Therefore, he finishes the paper by stating that it will "always be difficult to maintain the balance between flows … And if it is to be achieved some stabilizing factor, for example a relatively high pressure drop … must be included in the system. In addition, visual or other indicators of the flow directions are called for to ensure maintenance of the design conditions."(Lidwell 1972)

7.7 He also notes that "high airflows may result from small temperature differences" between rooms.

7.8 Hambreus and Sanderson (1972) carried out a study during an outbreak in a burns unit using a PPVL systems with a positive pressure patient's room found:

> "An estimate of the average transfer between rooms under conditions of normal activity and with correctly functioning ventilation showed that the isolation system was highly efficient, the proportion transferred being probably less than 1 in 10^5. However, the ventilation often did not function as designed and under these conditions the efficiency was reduced by a maximum of a factor of ten. These rates of transfer do not seem great enough to account for the high rate of cross-infection found in this unit."[25]

7.9 Both studies show that protection factors can be reduced when the people enter and exit the isolation rooms.

7.10 Correctly functioning isolation rooms have therefore been shown to be highly protective against aerosol particle transmission under a range of circumstances. Later in a study carried out by my research group Bennett et al (2002) we adapted

[25] A48361005 – A. Hambraeus and H.F. Sanderson, 'The control by ventilation of airborne bacterial transfer between hospital patients, and its assessment by means of a particle tracer: III. Studies with an airborne-particle tracer in an isolation ward for burned patients' (1972) - to add to hearings bundle.

Lidwell's methods to assess the effectiveness of containment laboratories and found that there was no relationship between pressure differential and protection but there was a direct relationship between inflow volume and protection for negative pressure rooms. However, Adams et al (2011) in an experimental study on negative pressure isolation rooms showed that protection increased with increasing negative pressure differential and decreased with increasing provider traffic.[26] They also showed that the provision of ante rooms limited particle escape. It appears that isolation rooms using a high enough directional volumetric flow can give a high degree of protection from airborne transmitted agents. The degree of protection appears to be related to the volumetric flow and not directly related to pressure differential. However, the pressure differential needs to be high enough to ensure the system is working correctly without pressure reversals and giving the correct amount of protection. Therefore pressure monitoring is required in isolation rooms to assure correct performance.

7.11 To summarise, it has been shown that directional airflow can be used to greatly reduce transfer of airborne particles from or into isolation rooms. In practise, to ensure that directional airflow is maintained in the correct direction, the pressure differential across the door need to be maintained at a high enough level to protect against flow reversals. This pressure differential should then be monitored to ensure correct operation.

7.12 In more recent years, model rooms have been set up in which air flows can be measured and movement of particulate and other tracers can be measured. These can be compared to CFD modelling which uses partial differential equations, grids and boundary layers to predict flows in model hospital rooms (for example King et al 2015).[27] While useful neither method can incorporate the full complexity of a hospital environment.

[26] A48701733 – Noah J. Adams, David L. Johnson, Robert A. Lynch, 'The effect of pressure differential and care provider movement on airborne infectious isolation room containment effectiveness' (2011) – to be added to bundle.
[27] A48361264 – M-F. King, C.J. Noakes, P.A. Sleigh, 'Modeling environmental contamination in hospital single-and four-bed rooms' (2015) – to be added to bundle.

7.13 Lidwell and Hambraeus' studies show that a correctly functioning pressure monitored isolation room (negative pressure, positive pressure or PPVL) can provide a high level of protection in preventing transfer of airborne particles such as airborne microorganisms.[28]

Evidence for outbreaks caused by ventilation deficiencies

Infectious patients

7.14 During the 1980s and 1990s outbreaks of nosocomial tuberculosis were occurring amongst HIV infected patients in hospitals globally. A factor in a number of these outbreaks was the improper use of isolation rooms. For example, Breathnach (1998) reports an outbreak of seven cases (two fatal) of MDR TB among HIV patients transmitted to an HIV ward from a patient in a single isolation room that was, unknown to staff, at positive pressure to the ward.[29] The author recommends "MDR-TB cases must be isolated in negative-pressure rooms. Hospital side rooms may be positive pressure as a fire safety measure; infection control teams must be aware of the airflows in all isolation rooms and must be consulted during the design of hospital buildings. Good communication between infection control teams and clinicians is important, and all medical and nursing staff must be aware of the principles of management of patients with proven or suspected tuberculosis and MDR-TB (Breathnach 1998)."[30] Similar cases of nosocomial transmission of tuberculosis were

[28] A48361005 – A. Hambraeus and H.F. Sanderson, 'The control by ventilation of airborne bacterial transfer between hospital patients, and its assessment by means of a particle tracer: III. Studies with an airborne-particle tracer in an isolation ward for burned patients' (1972) - to add to hearings bundle.
[29] A48378826 – A.S. Breathnach, A. de Ruiter, G.M.C. Holdsworth, N.T. Bateman, D.G.M. O'Sullivan, P.J. Rees and others, 'An outbreak of multi-drug-resistant tuberculosis in a London teaching hospital' (1998) – to add to hearings bundle.
[30] A48378826 – A.S. Breathnach, A. de Ruiter, G.M.C. Holdsworth, N.T. Bateman, D.G.M. O'Sullivan, P.J. Rees and others, 'An outbreak of multi-drug-resistant tuberculosis in a London teaching hospital' (1998) – to add to hearings bundle.

reported in the US (Kenyon et al 1997)[31], Spain (Rullen et al 1996)[32] also linked to lack of negative pressure isolation rooms and low air change rates. These outbreaks highlighted issues with carrying out aerosol generating procedures such as sputum induction in open wards, there were also issue with lack of isolation rooms with defined negative pressure and open doors (Jarvis 1993. Stroud et al (1995) and Maloney et al (1995)[33]. All the US papers report that the adoption of CDC guidelines for TB isolation (see below) stopped the outbreaks of MDR TB amongst AIDS patients.

7.15 There is good evidence that the placement of TB patients in single rooms without controlled negative pressure risks the transmission of tuberculosis to staff and patients on the same ward.

Protective Isolation

7.16 Protective isolation is a range of measures taken to reduce the exposure of the patient to microbial pathogens found in the environment. These measures include separation from other patients, control of microbial contamination in water and food, fungal prophylaxis and the use of positive pressure rooms supplied with HEPA filtered air. As with many hospital infection control practises, it can be difficult to separate the impact of each of these measures and most studies look at the

[31] A48408865 – Thomas A. Kenyon, Renee Ridzon, Roberta Luskin-Hawk, Carol Schultz, William S. Paul, Sarah E. Valway and others, 'A Nosocomial Outbreak of Multidrug-Resistant Tuberculosis' (1997) - to add to hearings bundle.
[32] A48361412 – John V. Rullán, Dionisio Herrera, Rosa Cano, Victoria Moreno, Pere Godoy, Enrique F. Pieró and others, 'Nosocomial Transmission of Multidrug-Resistant Mycobacterium Tuberculosis in Spain' (1996) – to add to hearings bundle.
[33] A48361505 – W.R. Jarvis, 'Nosocomial transmission of multidrug-resistant Mycobacterium tuberculosis' (1993) - to add to hearings bundle; A48408544 - Leonardo A. Stroud, Jerome I. Tokars, Michael H. Grieco, Jack T. Crawford, David H. Culvar, Brian R. Edlin and others, 'Evaluation of Infection Control Measures in Preventing the Nosocomial Transmission of Multi-drug-Resistant Mycobacterium tuberculosis in a New York City Hospital' (1995) – to add to hearings bundle; A48408772 - Susan Maloney, Michele L. Pearson, Marcia T. Gordon, Rachel Del Castillo, John F. Boyle, William R. Jarvis, 'Efficacy of Control Measures in Preventing Nosocomial Transmission of Multidrug-Resistant Tuberculosis to Patients and Health Care Workers' (1995) – to add to hearings bundle.

impact of bundles of measures on patient outcomes. A limited review of the literature found few studies looking at these factors as in many countries it may be hard to find a non-protective isolated control group and gain ethical approval for such a study.

7.17 Eckman et al (2005) showed in a review of 16 trials that the placement in HEPA protected areas of patients with haematological malignancies with severe neutropenia or patients with bone marrow transplants appears to be beneficial but the positive impact (R=0.86) was not significant.[34] There appears to be little evidence in the scientific literature on the benefits of HEPA filtration and positive pressure isolation rooms but this is not necessarily evidence that such measures are of no benefit. The reports of *Aspergillus* infection linked with building work shows how the exposure of immunosuppressed patients to environmental pathogens can have devastating results and how HEPA filters have been used to control outbreaks (Haiduven 2019; Hahn et al 2002, Kanamori et al 2015).[35]

Guidance (NHS UK and Scotland)

Introduction

7.18 The level and type of ventilation recommended in hospitals is laid out in a series of documents which have evolved over the years. These documents specify best practice for various parts of the hospital from general ward to operating

[34] A48519478 - Tim Eckmanns, Henning Rüden, Petra Gastmeier, 'The Influence of High-Efficiency Particulate Air Filtration on Mortality and Fungal Infection among Highly Immunosuppressed Patients: A Systematic Review' (2006) – to add to hearings bundle.
[35] A48579176 - Matthew Weissenbach, Donna Haiduven, Salah S. Qutaishat, 'Exploring the role of infection preventionists in antimicrobial stewardship programs through several lenses: A brief report' (2019); A48408687 - Theresa Hahn, K. Michael Cummings, Arthur M. Michalek, Brian J. Lipman, Brahm H. Segal, Philip L. McCarthy, 'Efficacy of High-Efficiency Particulate Air Filtration in Preventing Aspergillosis in Immunocompromised Patients with Hematologic Malignancies' (2002) – to add to hearings bundle; A48357167 – Hajime Kanamori, William A. Rutala, Emily E. Sickbert-Bennett, David J. Weber, 'Review of Fungal Outbreaks and Infection Prevention in Healthcare Settings During Construction and Renovation' – to add to hearings bundle.

theatres. They are the work of groups of experts and tend to rely on a limited evidence base and more on a practical assessment of best practice over the years. Nevertheless, they provide a framework for the design, construction, commissioning validation and maintenance of ventilation systems for the UK and Scotland that should ensure consistent practice throughout the country. While it may be difficult for existing hospitals to comply with this guidance it is expected that a new hospital would be built to meet existing guidance. If a new hospital was not complying with the current guidance documents, it would be expected that there would be a written explanation for the logic behind the decision.

7.19 In an article published in the Health Estates Journal in January 2022, Malcolm Thomas the lead author of the most recent editions of HTM03-01 and of several HBN explains the background, aims and status of these documents. He describes the importance of Owen Lidwell's methods and studies on ventilation in hospitals. He states that HTM03-01 is based "on good solid work many years ago … Where we have encountered problems, its generally been clear that guidance wasn't followed".

7.20 Also "ventilation rates noted in HTM03-01 are not opinion they have been proven to work in practice and over an extended period of hospital design and operation. History appears to show that this is the correct way of doing things".

7.21 He states that when explaining the need for HTM03-01 and the writing of a new edition "it has become very evident - especially with the PFI process - that lots of people designing hospitals and hospital systems in fact had no idea what the customer wanted". This showed the importance of complying with the guidance in these documents (Thomas 2022).[36]

[36] A48061462 – Malcolm Thomas, 'Guidance on Ventilation Revised and Updated' (2022) - to add to hearings bundle.

7.22 Scottish guidance documents such as SHTM03-01 are in most cases largely based on those provided in the wider UK. For example, the information on ventilation within the latest version of SHTM03-01 is almost identical to HTM03-01. The Scottish documents have up to this date been released later than the HTM documents they are largely based on. However, this allows an informed Scottish hospital estates and IC team to be aware of any changes coming. These documents have gone through a number of versions during the design, construction and operation of the QEUH. This evolution is described in detail in the Provisional Position Paper 12 Potentially Deficient Features of the ventilation system of the Queen Elizabeth University Hospital.

General Wards

7.23 For general wards guidance in all the HTM03-01 and SHTM03-01 editions from 2000 onward has recommended that general wards and single rooms are designed to have 6 air changers per hour. For single rooms, these documents have required that for General Wards room air pressure of 0 or -ve was required i.e. not positive pressure and no pressure monitoring is required. There are no requirements for specialised filtration for such wards. In the more recent versions of SHTM 03-01 (2022) the use of CBU in patient rooms is not recommended.[37]

7.24 The requirement for 6ACH in single rooms has been a longstanding specification in guidance for hospitals in the UK including Scotland.

Specialist Ventilation Areas

Use of HEPA filters

7.25 In many of the guidance documents I read, caution is called for with the use of HEPA filters outside some areas (UCV, labs, pharmaceutical areas) due to concerns about cost. In HTM03-01 (2007), HEPAs are mentioned in passing and advice on fitting and validation is given. In SHPN04 Supplement 1 Isolation Facilities in Acute Settings (2008) it states that:

> "The lobby air supply terminal should be of a type into which a HEPA filter can be fitted. While it is not envisaged that a HEPA filter will be routinely

[37] A37301627 – SHTM 03-01 Part A February 2022 - Hearing Commencing 9 May 2022 - Bundle 1 - Page 839.

> required, this arrangement will allow for subsequent fitting when appropriate with the least disturbance".[38]

7.26 No mention is made of sizing the fans and ducting to deal with any additional pressure drop causing resistance to flow.

7.27 In SHTM03-01 (2009) only available in draft form but provided to contractors as a mandatory contract document) it states:

> “HEPA filters are expensive so their use should be kept to a minimum. Applications requiring HEPA filters include the air supply to aseptic suites in manufacturing pharmacies, the discharges from microbiological safety cabinets and isolation facilities… 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".[39]

7.28 It is interesting that a risk assessment seems to being recommended on grounds of cost saving and not infection control.

7.29 The isolation facilities requirement is new for this edition of HTM03-01 and was included in the final released version of SHTM03-01 dated 2013.[40] Also in 2013 the HBN 04-01 Supplement 1. Isolation facilities for infectious patients in acute settings, it was stated that for PPVL rooms

[38] A36372665 – SHPN 4 Supplement 1 September 2008 – Hearing Commencing 26 February 2024 – Bundle 13 Volume 3 - Page 443.
[39] A33010802 – Draft for consultation SHTM 03-01 Part A Design and Validation, March 2009 - Bundle for Oral hearings commencing 19 August 2024 – Bundle 16 - Page 401.
[40] A35610757 – SHTM 03-01 Part A February 2013 - Hearing Commencing 9 May 2022 – Bundle 1 – Page 489.

> “In order to future-proof the system, the supply terminal in the lobby should be of a type that can accept a HEPA filter.”[41] (Consistent with HTM 03-01 2021)

7.30 In the most recent versions of HTM03 and SHTM03 from 2021 and 2022 respectively

> "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…
>
> 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."[42]

7.31 It seems surprising that there is not more emphasis on where and when HEPAs should be used i.e. supply filters for BMT units.

7.32 In my opinion, the advice on the use of high-grade filters in UK and Scottish guidance is patchy and not helpful for infection control or designers. CDC guidance in this area is clear on when HEPA filters will be required and readily available from the mid 1990s (see below).

[41] A37329297 – HBN 04-01 Supplement 1 (2013) – Hearing Commencing 9 May 2022 – Bundle 2 - Page 872.
[42] A36962514 – HTM 03-01 Part A (2021) – Hearing Commencing 9 May 2022 - Bundle 2 - Page 418; A37301627 – SHTM 03-01 Part A February 2022 - Hearing Commencing 9 May 2022 - Bundle 1 - Page 899.

Air Change Rates

7.33 HTM03-01 (2007) Part A clearly states that the recommended air change rates for wards and single rooms is 6ACH and for isolation rooms and neutropenic wards is 10ACH and in part B the ventilation system should achieve not less than 75% of the design air-change rate.[43] The draft SHTM03 (2009) agrees with this specification but adds a 10ACH recommendation for ITU/HDU.[44] SHPN04 from 2008 specifies 10ACH for room, lobby and en-suite for isolation units.[45] When SHTM 03 Part A was officially released in 2013 the specifications were the same as the draft.[46] In all subsequent versions of HTM03 and SHTM03 the air change recommendations stayed the same.

7.34 The air change rates specified in UK and Scottish guidance have been in place and remained stable since 2007 at 6ACH for wards/single rooms and 10ACH for specialist ventilation facilities.

Pressure Regimes

7.35 Prior to 2005 there were no specifications for pressure regimes in UK or Scottish guidance, but this changed, possibly due to the influence of the CDC guidance mentioned below. In HBN04-1 of 2005 a PPVL was defined as having a positive 10Pa from lobby to corridor, bedroom to lobby neutral and a negative pressure en suite.[47] The HTM03 Part A from 2007 suggests +10Pa for critical care

[43] A37344356 – HTM 03-01 Part A November 2007 - Hearing Commencing 9 May 2022 – Bundle 2 – Page 794; A37344358 – HTM 03-01 Part B November 2007 – Hearing Commencing 9 May 2022 – Bundle 2 - Page 304.
[44] A33010802 – Draft for consultation SHTM 03-01 Part A Design and Validation, March 2009 - Bundle for Oral hearings commencing 19 August 2024 – Bundle 16 - Page 483.
[45] A36372665 – SHPN 4 Supplement 1 September 2008 – Hearing Commencing 26 February 2024 – Bundle 13 Volume 3 - Pages 440 and 441.
[46] A35610757 – SHTM 03-01 Part A February 2013 - Hearing Commencing 9 May 2022 – Bundle 1 – Page 573.
[47] A34099878 – HBN 4 Supplement 1, February 2005 – Bundle for Oral hearings commencing 19 August 2024 – Bundle 16 – Page 325.

and neutropenic wards and -5Pa for isolation rooms.[48] Again, Part B suggests a lowest operational minimum of 75% i.e +7.5Pa and -3.75Pa.[49] The draft SHTM03 Part A agrees with the HTM but specifies ITU/HDU instead of critical care.[50] When finally published in 2013 the specification were kept but critical care area was defined instead of HDU/ITU.[51]

7.36 HBN04-01 of 2013 recommended a negative pressure of at least -5Pa for negative pressure isolation and a positive pressure of +8Pa to +12Pa with a pressure stabiliser set at +10Pa for PPVL.[52] In the most recent HTM03 and SHTM03 the recommendations from previous versions are kept.[53]

7.37 Recommendations for the pressure differentials of positive and negative pressure isolation have been consistent in guidance since 2005 with a recommended positive pressure differential of + 10Pa and negative pressure differential of -5Pa.

Pressure and Airflow Monitoring Systems

7.38 If pressure differentials are being used as an indication of correct operation of isolation facilities, they need to be monitored to ensure that they remain within specification and give assurance that isolation rooms are operating correctly. SHPN04 (2000) states “a local control and status indication panel for these single

[48] A37344356 – HTM 03-01 Part A November 2007 - Hearing Commencing 9 May 2022 – Bundle 2 – Page 794.
[49] A37344358 – HTM 03-01 Part B November 2007 – Hearing Commencing 9 May 2022 – Bundle 2 - Page 304.
[50] A33010802 – Draft for consultation SHTM 03-01 Part A Design and Validation, March 2009 - Bundle for Oral hearings commencing 19 August 2024 – Bundle 16 - Page 483.
[51] A35610757 – SHTM 03-01 Part A February 2013 - Hearing Commencing 9 May 2022 – Bundle 1 – Page 573.
[52] A37329297 – HBN 04-01 Supplement 1 – Hearing Commencing 9 May 2022 – Bundle 2 - Pages 870 and 871.
[53] A36962514 – HTM 03-01 Part A (2021) – Hearing Commencing 9 May 2022 - Bundle 2 - Pages 482 and 483; A37301627 – SHTM 03-01 Part A February 2022 - Hearing Commencing 9 May 2022 - Bundle 1 - Pages 970 and 971.

rooms will be required showing the pressurisation status of each room and allowing local control to alter the pressurisation of each room from positive to negative".[54]

7.39 In SHTM2025 (2001) alarms are recommended to indicate drop in flows under 80% of designed flow.[55] HBN04 from 2005 recommends alarms for supply or extract fan failures at the nurses' station and estates office.[56] SHFN30 from 2007 is very prescriptive for negative pressure isolation rooms stating

> "For negative pressure isolation rooms, there should be a readily visible monitor independent of the air supply/extract system. This is best achieved by monitoring the pressure differential between the patient room and corridor or lobby. This differential should preferably be monitored continuously, i.e. a pressure sensor linked to an alarm at the nurses' station should the pressure drop below a pre-set limit. The alarm should have a built-in delay of a few seconds so that it does not activate every time the door is opened. For negative pressure isolation rooms, there should be an interlock system such that supply ventilation is cut off if the extract ventilation fails. There should be a clear indication to users that the ventilation has failed".[57]

7.40 HTM03-01 (2007) only suggests alarms of air flows if they fall below 80% and across filters with "dirty filter" alarms in critical areas.[58] SHPN04 from 2008 only recommends flow failure alarms.[59]

[54] A33662211 – SHPN 04 May 2000 – Bundle for Oral hearings commencing 19 August 2024 – Pages 57 and 58.
[55] A33103375 – SHTM 2025 Part 2 of 4 June 2001 – Hearing Commencing 9 May 2022 – Bundle 1 - Page 88.
[56] A34099878 – HBN 4 Supplement 1, February 2005 – Bundle for Oral hearings commencing 19 August 2024 – Bundle 16 – Page 326.
[57] A33662182 – SHFN 30 Part 1 (June 2007) – Hearing Commencing 26 February 2024 – Bundle 13 – Page 622.
[58] A37344356 – HTM 03-01 Part A November 2007 – Hearing Commencing 9 May 2022 – Bundle 2 - Page 748.
[59] A36372665 – SHPN 4 Supplement 1 September 2008 – Hearing Commencing 26 February 2024 – Bundle 13 Volume 3 - Page 444.

7.41 The draft SHTM03 from 2009 and the published document of 2013 are similar to HTM03-01 (2007) and include the air flow alarms when air flow drops to 80% and filter pressure drop alarms.[60]

7.42 HBN04-01 (2013) clearly prescribes performance monitoring for both negative pressure and PPVL rooms stating;

> **Negative pressure room:** "The pressure differential between the patient room and corridor should be monitored continuously (for example, by using a differential pressure sensor). Failure to maintain a negative pressure should activate an alarm at a designated nurse station as well as in the estates department via a building management system. There should be a delay on the alarm to allow doors to be opened, resulting in a temporary zero pressure differential, to allow the transfer of a bed into and out of the room. Note that when the bed is moved into or out of the room, the patient is NOT in isolation. A Magnehelic pressure gauge should show the pressure differential between the patient room and the corridor. It should be mounted at eye level on the corridor wall adjacent to the entry door. The gauge should be clearly marked to identify the isolation room to which it refers."
>
> **PPVL room:** “A direct reading gauge showing the pressure in the lobby with respect to the corridor should be mounted at eye level on the corridor wall adjacent to the lobby entry door. The gauge and lobby entry door should be clearly marked to identify the isolation room to which they refer.” (p14) [61]

7.43 The latest editions of HTM03 and SHTM03 are identical and state.

[60] A33010802 – Draft for consultation SHTM 03-01 Part A Design and Validation, March 2009 - Bundle for Oral hearings commencing 19 August 2024 – Bundle 16 - Page 415; A35610757 – SHTM 03-01 Part A February 2013 - Hearing Commencing 9 May 2022 – Bundle 1 – Page 504.
[61] A37329297 – HBN 04-01 Supplement 1 – Hearing Commencing 9 May 2022 – Bundle 2 – Pages 871 and 872.

> “Supply and extract systems should include indicator lamps on the control panels to confirm the operational status of each system... "[62]

7.44 The basic requirements for an automatic control system include:

- control of the volumetric airflow
- control of the system or room pressure
- temperature/humidity control and indication
- devices to monitor and indicate the plant’s operating state
- alarms to indicate plant failure, low airflow, and filter state

7.45 "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.

7.46 The guidance for the monitoring rooms has varied between guidance documents over the years of this review but the principle of monitoring the specialist ventilation system performance parameters is retained.

Use of Chilled Beam Units (CBU)

7.47 The first mention of CBU in guidance was from HTM03 -01 Part A and B in 2007. It states in Part A

[62] A36962514 – HTM 03-01 Part A (2021) – Hearing Commencing 9 May 2022 - Bundle 2 - Page 372; A37301627 – SHTM 03-01 Part A February 2022 - Hearing Commencing 9 May 2022 - Bundle 1 - Page 851.

"The use of chilled beams for the provision of heating, cooling and ventilation is increasingly common in healthcare premises. Active chilled beams providing tempered, filtered air to the room can provide effective local control of environmental conditions. 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. Chilled beam units should be easily accessible for cleaning and maintenance."[63]

7.48 And in HTM03-01 Part B

"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."[64]

7.49 And from SHTM03-01(2014)

"The control settings should ensure that the external element of the beam are always above dewpoint"[65]

7.50 The SHTM03-01 draft of 2009 has similar text with more detail adding:

"Consideration should be given to the ease with which specific types of chilled beam units can be accessed for cleaning having regard to the

[63] A37344356 – HTM 03-01 Part A November 2007 – Hearing Commencing 9 May 2022 – Bundle 2 - Page 722.
[64] A37344358 – HTM 03-01 Part B November 2007 – Hearing Commencing 9 May 2022 – Bundle 2 - Page 308.
[65] A35610757 – SHTM 03-01 Part A February 2013 - Hearing Commencing 9 May 2022 – Bundle 1 – Page 459.

need to control the infection risk. The impact of maintenance requirements on room availability should also be considered. "[66]

7.51 Part B of SHTM03 2013 retains the HTM03 Part B wording for cleaning.[67]

7.52 By 2021 and 2022 the versions of HTM03-10 and SHTM03-01 have a different tone

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.

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...

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)… 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

[66] A33010802 – Draft for consultation SHTM 03-01 Part A Design and Validation, March 2009 - Bundle for Oral hearings commencing 19 August 2024 – Bundle 16 - Page 371.
[67] It's understood this is a reference to A33662241 – SHTM 03-01 Part B October 2011 - Hearing Commencing 9 May 2022 – Bundle 1 - Page 320.

> aspects of using chilled beams should be discussed and the decision to use them agreed in writing with the client."[68]

7.53 In my view there was a major change of attitude to CBUs between 2007 and 2021 possibly caused by issues surrounding QEUH and other hospitals. The requirement for Dew Point control of CBUs has been specified in guidance since 2007 as has the need for regular maintenance/cleaning and access for maintenance/cleaning.

Sealed Bedrooms/En-suites

7.54 HBN04-01 (2005) states that for isolation suites as a whole:

> “sealed, solid ceiling; windows to the exterior to be locked shut and sealed.”[69]

7.55 SHFN40 from 2007 states that ceilings for isolation rooms: “should have homogeneous plastered surface with flush-mounted recessed lights, ventilation grilles and other ceiling fixtures, where possible. Removable ceiling tiles in a grid layout are not advised for isolation rooms".[70]

7.56 HTM03-01 from 2007 does not appear to address sealability of bedrooms.

[68] A36962514 – HTM 03-01 Part A – Hearing Commencing 9 May 2022 - Bundle 2 - Pages 360 and 361; A37301627 – SHTM 03-01 Part A February 2022 - Hearing Commencing 9 May 2022 - Bundle 1 - Pages 839 and 840.
[69] A34099878 – HBN 4 Supplement 1, February 2005 – Bundle for Oral hearings commencing 19 August 2024 – Bundle 16 – Page 323.
[70] A33662182 – SHFN 30 Part 1 (June 2007) – Hearing Commencing 26 February 2024 – Bundle 13 – Page 621.

7.57 SHPN04 (2008) states that for isolation facilities ceiling to be sealed solid construction, external window to be sealed."[71] "an average leakage rate of not more than 1 l/s of air per 1m3 of envelope volume".[72] "A pressure stabiliser of the balanced blade type, set to operate at 10 Pascals, should be fitted above the door between the lobby and the bedroom".[73]

7.58 SHTM03-01 from 2013 states that windows in isolation facilities must be sealed.[74]

7.59 HBN04-01 (2013) is far more prescriptive and detailed.

> **Negative pressure room:** "A sealed solid integrated ceiling should be installed.
>
> • Windows to the exterior should be unopenable and well-sealed.
>
> • Service penetrations should be minimised to support the room being well-sealed.
>
> **PPVL room**: "To support the room being well-sealed, the detail of the construction joints between elements of the building and service penetrations will be critical to achieving the air leakage standard demanded. The joints should be carefully sealed as construction progresses and service penetrations minimised, as they will be

[71] A36372665 – SHPN 4 Supplement 1 September 2008 – Hearing Commencing 26 February 2024 – Bundle 13 Volume 3 - Page 449.
[72] A36372665 – SHPN 4 Supplement 1 September 2008 – Hearing Commencing 26 February 2024 – Bundle 13 Volume 3 - Page 455.
[73] A36372665 – SHPN 4 Supplement 1 September 2008 – Hearing Commencing 26 February 2024 – Bundle 13 Volume 3 - Page 444.
[74] A35610757 – SHTM 03-01 Part A February 2013 - Hearing Commencing 9 May 2022 – Bundle 1 – Page 520.

inaccessible once the inner finish is applied (see Appendix 2 on air leakage).[75]

7.60 The latest versions of HTM03 and SHTM03 state

"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." “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."[76]

NB. No explicit mention of sealed room or solid ceiling

7.61 The only two guidance documents that specify solid or sealed ceiling for isolation rooms are SHPN04 (2008) and HBN04-01(2005, 2013). Without sealed ceilings control of pressure in rooms will be problematic and there is the potential for transfer of air from a void which is uncleaned and can act as a reservoir for environmental microorganisms.

[75] A37329297 – HBN 04-01 Supplement 1 – Hearing Commencing 9 May 2022 – Bundle 2 – Pages 870 and 871.
[76] A36962514 – HTM 03-01 Part A (2021) – Hearing Commencing 9 May 2022 - Bundle 2 - Pages 378 and 444; A37301627 – SHTM 03-01 Part A February 2022 - Hearing Commencing 9 May 2022 - Bundle 1 - Pages 857 and 929.

Permeability Testing

7.62 Without solid ceilings permeability testing is unnecessary and meaningless. The documents that do mention solid ceiling also mention permeability testing. HNB04-01 (2005) is highly prescriptive:

> "Validation – Isolation suite air permeability (leakage rate) The suite will be considered fit for purpose if at a test pressure of +20 and –20 Pascals it has an average leakage rate of not more than 1 l/s of air per 1 m3 of envelope volume"[77]

7.63 SHPN04 (2008) states that on commissioning or after works:

> “The suite will be considered fit for purpose if at a test pressure of +20 and –20 Pascals it has an average leakage rate of not more than 1 l/s of air per 1m3 of envelope volume. The method of testing is set out below.”[78]

7.64 HBN04-01 (2013) modifies the method and states:

> "Air permeability tests should be carried out by an independent testing company that is a member of ATTMA (Air Tightness Testing & Measurement Association). Air sealers should not test their own work… These tests should be carried out before initial commissioning and as necessary thereafter following works of refurbishment or when there is any doubt as to the actual performance standard of the room. As a minimum requirement, the air permeability should be no worse than that

[77] A34099878 – HBN 4 Supplement 1, February 2005 – Bundle for Oral hearings commencing 19 August 2024 – Bundle 16 – Page 337.
[78] A36372665 – SHPN 4 Supplement 1 September 2008 – Hearing Commencing 26 February 2024 – Bundle 13 Volume 3 - Page 455.

required by Approved Document L2A of the Building Regulations for the entire building. (This is a variable value with a minimum required air permeability of less than 10 m3.h–1.m–2 at a reference pressure of 50 pascals.)"[79]

7.65 In the latest editions of HTM03-01 and SHTM03-01 the same wording is used (paraphrased)

The following areas will require permeability testing:

• isolation suites of any type;

• any other area specified within the contract

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).

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."[80]

7.66 For isolation suites there has been guidance on permeability testing since 2005. Such testing would not be compatible with unsealed false ceilings. The updated guidance in the latest versions of SHTM 03.01 and HTM03.01 give clear

[79] A37329297 – HBN 04-01 Supplement 1 – Hearing Commencing 9 May 2022 – Bundle 2 – Pages 884.
[80] A36962514 – HTM 03-01 Part A (2021) – Hearing Commencing 9 May 2022 - Bundle 2 - Page 458; A37301627 – SHTM 03-01 Part A February 2022 - Hearing Commencing 9 May 2022 - Bundle 1 - Page 943.

instructions for how sealed rooms can be verified during the commissioning of future designs of hospitals.

Back Up AHU

7.67 HBN04-01 (2005) states that

> "in a high-rise building a common supply and extract system may be the only feasible solution. In this case, run and standby fans would be required for the extract and a duplicate supply unit may be considered necessary. The supply and extract branches to each isolation suite should be fitted with spring-close gastight dampers. This will permit individual suites to be shut down for cleaning and maintenance".[81]

7.68 HTM03-01 (2007) states that for Mechanical ventilation systems:

> "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 backflow 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".[82]

[81] A34099878 – HBN 4 Supplement 1, February 2005 – Bundle for Oral hearings commencing 19 August 2024 – Bundle 16 – Page 326.
[82] A37344356 – HTM 03-01 Part A November 2007 – Hearing Commencing 9 May 2022 – Bundle 2 - Page 723.

Commissioning of ventilation system

7.69 It is important to ensure that any ventilation system meets the design performance specification agreed before hand over. All of the guidance documents already cited plainly set out the needs for commissioning before hand over. For example, from SHTM 2025 from 2001.

> "Performance tests
>
> - General ventilation systems –
> - The performance of the system should be measured and compared with information provided by the designer."[83]

7.70 SHFN30 from 2007 has explicit advice about the commissioning process:

> "Regular meetings with stakeholders referred to in paragraph 3.22 to discuss design, tendering, build and commissioning will ensure the facility is functionally suitable and fit for purpose. Regular communication during the construction and commissioning stages should also ensure that prevention and control of infection risks are highlighted and subsequently eliminated or mitigated."[84]
>
> "Common errors in design and construction (adapted from Carter and Barr, 1997) due to inept or non-existent risk management include: …ventilation systems which are not fully commissioned..."[85]

[83] A33103371 - Scottish Health Technical Memorandum 2025 (Part 3 of 4), Validation and verification, Ventilation in healthcare premises: June 2001 – Hearing Commencing 9 May 2022 – Bundle 1 – Page 189.
[84] A33662182 – SHFN 30 Part 1 (June 2007) – Hearing Commencing 26 February 2024 – Bundle 13 – Page 569.
[85] A33662182 – SHFN 30 Part 1 (June 2007) – Hearing Commencing 26 February 2024 – Bundle 13 – Page 574.

"Commission/equipping: Infection Control Teams must have input during this stage if costly and dangerous mistakes are to be avoided." [86]

"Technical commissioning of the building, services and equipment should include any areas that require inspection and testing to demonstrate compliance with prevention and control of infection standards, i.e. theatres, hydrotherapy pools, isolation/segregation rooms and clean rooms in pharmacy and Central Decontamination Units (CDUs). There is a legal requirement for compliance in CDUs and pharmacies."

"Commissioning of the building services is frequently curtailed to meet deadlines or put in the hands of inadequately qualified or experienced personnel. This is invariably to the detriment of user satisfaction, operational efficiency, HAI risk and running costs and should be avoided at all costs."[87]

“The work plan should allow for a phased approach to commissioning of systems. Once an area has been commissioned, it needs to be cleaned and sealed off. Equipment can then be cleaned and laid out providing access is strictly controlled prior to final handover.”[88]

"Microbiological monitoring and commissioning of specialised ventilation should be in accordance with guidance in SHTM 2025: ‘Ventilation in healthcare premises’. Ventilation systems should be designed to allow removal of filters without contaminating filtered air space.”[89]

7.71 And from HTM03-01 (2007) and from SHTM03-01 draft (2009) and the final version (2013)

[86] A33662182 – SHFN 30 Part 1 (June 2007) – Hearing Commencing 26 February 2024 – Bundle 13 – Page 591.
[87] A33662182 – SHFN 30 Part 1 (June 2007) – Hearing Commencing 26 February 2024 – Bundle 13 – Pages 595 and 596.
[88] A33662182 – SHFN 30 Part 1 (June 2007) – Hearing Commencing 26 February 2024 – Bundle 13 – Page 635.
[89] A33662182 – SHFN 30 Part 1 (June 2007) – Hearing Commencing 26 February 2024 – Bundle 13 – Page 643.

"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." [90]

(Air-handling and distribution system): "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%...

...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."

(Room air distribution): "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."

[90] A37344356 – HTM 03-01 Part A November 2007 – Hearing Commencing 9 May 2022 – Bundle 2 - Page 777; A33010802 – Draft for consultation SHTM 03-01 Part A Design and Validation, March 2009 - Bundle for Oral hearings commencing 19 August 2024 – Bundle 16 - Page 457; A35610757 – SHTM 03-01 Part A February 2013 - Hearing Commencing 9 May 2022 – Bundle 1 – Page 548.

(Specific performance standards): "The performance of the system should be measured and compared with information provided by the designer."[91]

(Bacteriological sampling, General ventilation systems: "Bacteriological sampling will not normally be required for either general or local exhaust ventilation (LEV) systems unless otherwise specified."[92] Sampling required in Operating theatres.

7.72 SHPN04 from 2008 is mainly derived from HPN04 from 2005 and again is explicit in commissioning requirements.

"[Air permeability] tests should be carried out at initial commissioning and as necessary thereafter following works of refurbishment or when there is any doubt as to the actual performance standard of the suite."

"System operating standard

The suite will be considered fit for purpose if, with the ventilation system operating and all doors closed, the following parameters are achieved:

• a positive pressure of between **10 and 12 Pascals** between the entry lobby and the corridor;

• the patient's room has an air change rate of at least **10 per hour**;

• the en-suite room is at a negative pressure with respect to the patient's room;

[91] A37344356 – HTM 03-01 Part A November 2007 – Hearing Commencing 9 May 2022 – Bundle 2 - Pages 781 and 782; A33010802 – Draft for consultation SHTM 03-01 Part A Design and Validation, March 2009 - Bundle for Oral hearings commencing 19 August 2024 – Bundle 16 - Pages 464 and 465; A35610757 – SHTM 03-01 Part A February 2013 - Hearing Commencing 9 May 2022 – Bundle 1 – Pages 555 and 556.
[92] A37344356 – HTM 03-01 Part A November 2007 – Hearing Commencing 9 May 2022 – Bundle 2 - Page 783; A33010802 – Draft for consultation SHTM 03-01 Part A Design and Validation, March 2009 - Bundle for Oral hearings commencing 19 August 2024 – Bundle 16 - Page 467; A35610757 – SHTM 03-01 Part A February 2013 - Hearing Commencing 9 May 2022 – Bundle 1 – Page 558.

• a failure of either the supply or extract fan will be indicated at a designated nurse station and the estates department.

The suite should be tested following initial commissioning and thereafter retested at least annually for conformity with this operating standard."[93]

7.73 Part B of SHTM03-01 published in 2011 states:

"Statutory requirements

COSHH

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.

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.

Certain substances have workplace exposure limits (WELs) set out in the Health and Safety Executive's 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

[93] A36372665 – SHPN 4 Supplement 1 September 2008 – Hearing Commencing 26 February 2024 – Bundle 13 Volume 3 – Pages 456 and 457.

amended)'. If specialised ventilation systems are provided in order to achieve these standards, they will be subject to the COSHH Regulations as above."[94]

7.74 In the latest versions of HTM03-01 and SHTM03-01, HTM 03-01 2021 makes a clearer distinction between commissioning and validation than in previous versions.

7.75 Section 11. 'Commissioning systems' provides 10 pages of detailed guidance.

(Air handling and distribution system): "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%."

(Order of commissioning): "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."

(Room air distribution): "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.

[94] A33662241 – SHTM 03-01 Part B October 2011 - Hearing Commencing 9 May 2022 – Bundle 1 - Page 297.

> "Note: When balancing combined supply/extract cascade ventilation systems (for example, operating suites, clean room 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."
>
> (Specific performance standards): "The performance of the system should be measured and compared with information provided by the designer"
>
> (Ventilation system commissioning records): "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."[95]

7.76 The requirement for commissioning has always been part of guidance for new hospital buildings. In particular, SHPN 04 Supplement 1: Isolation facilities in acute settings from 2008 explicitly states the commissioning requirements for protective isolation facilities.

Validation of ventilation systems

7.77 From HTM03-01 (2007)

> " 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.

[95] A36962514 – HTM 03-01 Part A – Hearing Commencing 9 May 2022 - Bundle 2 - Pages 451 to 455.

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.

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."[96]

"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.'

…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."[97]

[96] A37344356 – HTM 03-01 Part A November 2007 – Hearing Commencing 9 May 2022 – Bundle 2 - Pages 713 and 714.
[97] A37344356 – HTM 03-01 Part A November 2007 – Hearing Commencing 9 May 2022 – Bundle 2 - Page 777.

7.78 Part B stresses the need for competent persons to carry out the validation.

7.79 In SHTM03-01 draft from 2008 and the final version from 2013 the text is different and basically requires the provision of a validation report stating explicitly whether the ventilation system reaches the required standard.[98] HBN0401 from 2013 is short and to the point and states the requirements for Validation and annual revalidation includes filtration tests, air permeability tests, system operating standards (pressure differentials and ACH).[99]

7.80 And from the latest versions of HTM03-1 and SHTM03-01, Section 12 'Acceptance testing: validation' provides 16 pages of detailed guidance.

> "All new and refurbished ventilation systems should be independently validated prior to acceptance by the client... 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.'"
>
> "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."
>
> "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

[98] A35610757 – SHTM 03-01 Part A February 2013 - Hearing Commencing 9 May 2022 – Bundle 1 – Page 559.
[99] A37329297 – HBN 04-01 Supplement 1 – Hearing Commencing 9 May 2022 – Bundle 2 – Pages 884 and 885.

the acceptable standard of installation and performance when finally validated."

"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."

(Validation process): "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: [...]

• that the supply and extract airflow rates are in accordance with the design +10%; –0% and the system terminals are in balance...;

• 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..."

(Additional specialist tests): "Certain critical areas will require additional testing and validation in addition to the process given above"[100]

Annual verification

7.81 No mention of annual verification is made in documents until HTM03-01 from 2007 which states:

[100] A36962514 – HTM 03-01 Part A (2021) – Hearing Commencing 9 May 2022 - Bundle 2 - Pages 456 to 461; A37301627 – SHTM 03-01 Part A February 2022 - Hearing Commencing 9 May 2022 - Bundle 1 - Pages 941 to 946.

All ventilation systems should be subject to at least a simple visual inspection annually. 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.

"…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. The quarterly inspection should be as detailed [above]... 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."

..." – 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. An assessment should then be made as to whether the system overall is fit for purpose and operating in a satisfactory manner."

"…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. 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."[101]

7.82 And from Part B of SHTM03-01 from 2011

"Critical ventilation systems – verification standards

Unless otherwise specified below, the ventilation system should achieve not less than 75% of the design air-change rate given in Appendix 1 of Part A, or its original design parameters."[102]

7.83 Commissioning, validation and annual testing are necessary to ensure that any specialist ventilation systems are meeting the required performance criteria and to identify any remedial measures required. This is a statutory requirement in The Control of Substances Hazardous to Health Regulations 2002 (COSHH 2022).[103] The need for annual testing of critical ventilation systems has been stated in HTM03-01 since 2007.

[101] A37344358 – HTM 03-01 Part B November 2007 – Hearing Commencing 9 May 2022 – Bundle 2 - Pages 303 and 304.
[102] A33662241 – SHTM 03-01 Part B October 2011 - Hearing Commencing 9 May 2022 – Bundle 1 - Page 313.
[103] A48180004 – The Control of Substances Hazardous to Health Regulations 2002 – to add to hearings bundle

Other UK guidance

7.84 I have not carried out a review of UK clinical guidance which contains ventilation specific guidance but was personally aware of relevant NICE guidance described below which shows the relationship between clinical decision making and patient placement.

NICE tuberculosis guidance

7.85 The National Institute for Clinical Evidence (NICE) publishes evidence based recommendations for the treatment of tuberculosis (Tuberculosis (nice.org.uk)). Within these documents there are recommendations for infection control for hospitalised tuberculosis patients. The 2011 guidance recommends that all suspected tuberculosis patients are housed in a single room. Patients with respiratory tuberculosis should be separated from immunocompromised patients, either by admission to a single room on a separate ward, or in a negative pressure room on the same ward. Aerosol-generating procedures such as bronchoscopy, sputum induction or nebuliser treatment should be carried out in an appropriately engineered and ventilated area for all patients on an HIV ward, regardless of whether a diagnosis of TB has been considered all patients in whom TB is considered a possible diagnosis, in any setting. The process is shown in the figure below.[104]

[104] A47682743 – NICE Tuberculosis Guidance, March 2011 – Bundle for Oral hearings commencing 19 August 2024 – Bundle 16 - Pages 952 to 954.

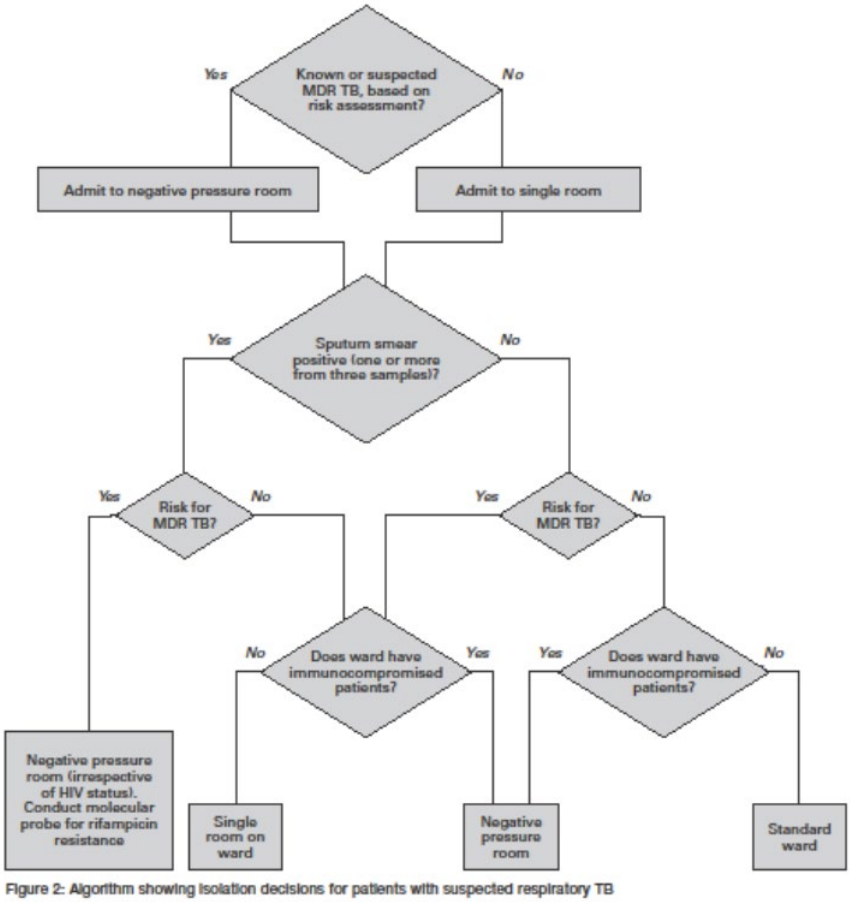

Figure 2: Algorithm showing isolation decisions for patients with suspected respiratory TB

7.86 The NICE guideline [NG33] was updated on 13 January 2016. And states that

> "In hospital settings, risk assess people with suspected infectious or confirmed pulmonary TB for multidrug-resistant TB (see the section on multidrug-resistant TB). Care for people deemed to be at low risk in a single room, as a minimum. For people deemed to be at high risk provide care in a negative pressure room and have specimens sent for rapid diagnostic tests, such as nucleic acid amplification tests."[105]

[105] A47682742 – NICE Tuberculosis Guidance, February 2024 – Bundle for Oral hearing commencing 19 August 2024 – Bundle 16 – Page 1264.

7.87 A negative pressure room is one where the air from the room is sucked out into dedicated ducting through a filter and into the outside air, at a distance from all other air intakes. The pressure should be 10 pascals below the ambient air pressure.

7.88 Do not admit people with suspected infectious or confirmed pulmonary TB to a ward containing people who are immunocompromised, such as transplant recipients, people with HIV and those on anti-tumour necrosis factor alpha or other biologics, unless they can be cared for in a negative pressure room on the same ward.

7.89 In people who may have TB, only carry out aerosol-generating procedures such as bronchoscopy, sputum induction or nebuliser treatment in an appropriately engineered and ventilated area (ideally a negative pressure room).

7.90 The requirement for negative pressure room isolation of suspected tuberculosis cases on wards with immunosuppressed patients i.e HIV and for high-risk patients has been in place for many years in evidence-based guidance from NICE.

International Guidance

7.91 Medicine is an international profession and advances in knowledge, practice and the evidence for their efficacy can be made in any country. The treatments of diseases and the knowledge surrounding transmission of infection is always changing. New treatments and therapies are constantly being developed and trialled. These advances will be disseminated firstly through conference lectures, scientific publications and then may be incorporated in guidance. For some patient groups and specialisms there may not be recommendations in current national guidance. The US CDC is especially influential in this area as is WHO and various international

professional organisations. CDC guidance may be regarded as “gold standard” but is normally evidence based and intended to set a benchmark for a country with a diverse healthcare system. There were two CDC documents published in the 1990s and revised in the 2000s which are pertinent to the QEUH. It is common for consultants to keep up to date with the medical literature and international practice in order to provide the best treatment for their patients for benchmarking and advice as was the case with the Beatson Unit. For a flagship hospital these facilities would be expected to take account of best international practice and be in advance of current practice. Before the construction of the hospital there was a set of guidance published by the US CDC in various editions (Chinn, R. Y., & Sehulster, L. 2003))[106] for environmental infection control in healthcare facilities which details best practice in ventilation along with consideration of evidence for efficacy. It includes clear diagrams of concepts of isolation room:

> **Airborne infection isolation** (AII) refers to the isolation of patients infected with organisms spread via airborne droplet nuclei 12 ACH is recommended for new construction as of 2001; (>6 ACH for construction before 2001), and is under negative pressure, such that the direction of the air flow is from the outside adjacent space (e.g., the corridor) into the room. The air in an AII room is preferably exhausted to the outside, but may be recirculated provided that the return air is filtered through a high-efficiency particulate air (HEPA) filter. The use of personal respiratory protection is also indicated for persons entering these rooms when caring for TB or smallpox patients and for staff who lack immunity to airborne viral diseases (e.g., measles or varicella zoster virus [VZV] infection).
>
> **Protective environment (PE)** is a specialized patient-care area, usually in a hospital, with a positive air flow relative to the corridor (i.e., air flows

[106] A48361954 – Lynne Sehulster and Raymond Y. W. Chinn, ‘Guidelines for Environmental Infection Control in Health-care Facilities: Recommendations of CDC and Healthcare Infection Control Practices Advisory Committee (HICPAC)’ (2003) – to add to hearings bundle.

from the room to the outside adjacent space). The combination of HEPA filtration, high numbers of air changes per hour (>12 ACH), and minimal leakage of air into the room creates an environment that can safely accommodate patients who have undergone allogeneic hematopoietic stem cell transplant (HSCT).

7.92 There are also recommendations on monitoring isolation rooms:

Negative Pressure Rooms: monitor air pressure periodically, preferably daily, with audible manometers or smoke tubes at the door (for existing AII rooms), or with a permanently installed visual monitoring mechanism.

Protective Environment: Maintain airflow patterns and monitor these on a daily basis by using permanently installed visual means of detecting airflow in new or renovated construction, or by using other visual methods (e.g., flutter strips or smoke tubes).

7.93 The advice on sealing and construction is as follows:

Protective Environment (PE) rooms: Ensure that rooms are well-sealed by

1) properly constructing windows, doors, and intake and exhaust ports;

2) maintaining ceilings that are smooth and free of fissures, open joints, and crevices;

3) sealing walls above and below the ceiling;

4) monitoring for leakage and making any necessary repairs (p10) Install self-closing devices on all room exit doors in PE rooms (p10)

Airborne Infection Isolation (AII) rooms: Ensure that rooms are well-sealed by properly constructed windows, doors, and air-intake and exhaust ports; when monitoring indicates air leakage, locate the leak and make necessary repairs9 and install self-closing devices on all AII room exit doors.

7.94 There was also well-established guidance for the management of *Mycobacterium tuberculosis* patients in healthcare facilities written for CDC (Jensen et al 2005).[107]

7.95 Both these documents were prepared by expert groups set up by CDC, regularly reviewed and the guidance was freely available from CDC websites. It would be expected that clinicians and expert control specialists would be aware of them. They contained guidance that later was adapted and incorporated in UK guidance. One of the contributors to the guidance, Andrew Streifel of the University of Minnesota was involved with the design of the Beatson bone marrow transplant unit.

Joint Accreditation Committee ISCT-EBMT (JACIE)

7.96 JACIE develops and maintain global standards for the provision of quality medical and laboratory practice in cellular therapy. Based on these standards, JACIE offers accreditation to transplant programmes to encourage health institutions and facilities to establish and maintain quality management systems impacting on all aspects of their activities and to engage in continuous improvement. The units in the

[107] A48363884 – Paul A. Jensen, Lauren A. Lambert, Michael F. Iademarco, Renee Ridzon, 'Guidelines for Preventing the Transmission of Mycobacterium Tuberculosis in Health-Care Settings, 2005' (2005) – to add to hearings bundle.

QEUH are JACIE accredited. The Bone Marrow Transplant standards are set by JACIE in the 6th edition standards and the relevant statement on specialist ventilation states:

> "B2.1 There shall be a designated inpatient unit of appropriate location and adequate space and design that minimizes airborne microbial contamination."[108]

7.97 A further explanation is given:

> "Clinical unit facilities may vary among centers. Variability may reasonably be based on a number of factors, including the number and/or type (autologous or allogeneic) of transplants performed, the patient case mix, the graft source, epidemiological factors influencing the prevalence of opportunistic infections, potential economic factors, and an increasing use of ambulatory facilities for transplantation. This standard is not meant to imply that every clinical unit must have laminar airflow available, but HEPA filtration with positive pressure is recommended for high risk patients. If non-HEPA filtered rooms are used for lower risk patients or if there is a shortage of HEPA filtered rooms, the SOP(s) on infection control, biosafety, and chemical and radiological safety should indicate how allocation of rooms is prioritized. Further, auditing of airborne microbial infections in non-HEPA rooms should be performed as part of the QM Program.[109]

7.98 While not prescriptive JACIE ventilation guidance indicates that the use of HEPA filtration and positive pressurisation is needed for high risk patients to comply

[108] A48097538 – FACT-JACIE International Standards for Hematopoietic Cellular Therapy Sixth Edition – To add to hearings bundle.
[109] A48097538 – FACT-JACIE International Standards for Hematopoietic Cellular Therapy Sixth Edition – To add to hearings bundle.

with JACIE standards and if not, a written protocol determining patient placement prioritization is required. Such a document has not yet been provided to the inquiry in my knowledge that covers the years before 2020.

Pre-existing specialist ventilation facilities in Glasgow

Beatson West of Scotland Oncology Centre

7.99 In 2013, it was decided that the Beatson West of Scotland Cancer Centre BMT Unit would move to the QEUH to be on a site with a full ITU and HDU support. The Beatson Centre BMT Unit had been designed with input from a US specialist ventilation expert, Andrew Streifel and UK expert, Peter Hoffman of HPA. The wards had an air change rate of 10 ACH and were operated at +10Pa to the corridor. The air supplied to the rooms and the corridor was HEPA filtered. Pressure differentials were monitored by digital display and there was an air lock to the ward to the rest of the hospital.[110]

[110] A38030454 – 04.04.2017 BMT Options Appraisal Report for the Acute Services Committee - To add to hearings bundle.

8. Deficiencies in QEUH/RHC wards compared to guidance

8.1 An assessment of the impact of the deficiencies described in this section will be discussed in Section 9.

Wards of interest

8.2 This report is restricted to the following wards all used to house in patients with immunosuppression at some time between 2015 and now.

- 2A Haematology & oncology and Teenage Cancer Trust (TCT)
- 4B Adult Bone Marrow Transplant (BMT) - Neutropenic patient group
- 4C Haemato-oncology (10 beds) - Neutropenic patient group
- 6A Originally Rheumatology but patients from Ward 2A RHC moved here 26th September 2018

8.3 However, consideration is also given to the deficiencies in ventilation of general wards and infectious disease wards (Wards 5C and D) .

Description of features of ventilation system (including commissioning and validation) in wards of interest.

General Wards

8.4 Guidance for air change rates in general wards and single wards from all editions of HTM03.01 and SHTM03.01 states a requirement for 6 air changes per hour for general wards and single rooms. This was never designed or achieved for any of the general wards. At design the working ACH was agreed to be 2.5ACH (A35761224).[111] [112] The use of CBUs in patient rooms is contrary to the latest versions of the HTM03-01 and SHTM03-01 but not to the versions in place when the hospital was built.

Ward 2A - Haematology & Oncology and Teenage Cancer Trust (TCT)

8.5 Ward 2A is intended to house a range of paediatric patients many of them immunosuppressed or immunocompromised and thus requiring protective isolation and was intended to replace wards at the Yorkhill site. This report will not cover the BMT rooms located on Ward 2A which will be discussed in a further paper.

8.6 The HTM03-01 document from 2007 and SHTM03-01 (2013) clearly stated the ventilation needs of these patients.[113] The requirements were rooms supplied with HEPA (H12) filtered air with 10 ACH and a positive pressure of 10 Pa. The

[111] A35761409 - The M&E Clarification Log (2010 ItP) – (FINAL) – Bundle of documents for Oral hearings commencing 19 August 2024 – Bundle 16 - Page 1664.
[112] A32993814 – NHSG Ventilation Strategy (December 2009) – Bundle for Oral hearings commencing 19 August 2024 – Bundle 16 - Page 1657 and Page 1658.
[113] A35610757 – SHTM 03-01 Part A February 2013 - Hearing Commencing 9 May 2022 – Bundle 1 – Page 473. A37344358 – HTM 03-01 Part B November 2007 – Hearing Commencing 9 May 2022 – Bundle 2 - Page 303.

Yorkhill facility had the same ACH, pressure differentials but also had sealed bedrooms, pressure alarms and an air lock entrance to the ward.[114]

8.7 The Clinical Output Specification for Haematology and Oncology from 2009 states “the ward should be accessed by entry through a double-door barrier system, which allows the entire ward area the benefit of low positive pressure ventilation” but there are no definitions of the magnitude of pressure differential, the required air change rate or any mention of filtration requirements.[115]

8.8 In June 2015 on handover, it became clear to clinical staff that the many of the rooms on the ward were operating to the specification used for general wards of the QEUH and not those required for this patient group. An SBAR dated October 2017 noted that “All other rooms on the unit, including those on the Teenage Cancer Corridor are:

- Single rooms with ensuite
- Have 3 ACH
- Neutral pressure
- Not HEPA filtered
- Have entrainment of air on to cooler beams resulting in collection of dust on grills
- The corridor is not HEPA filtered and is not positively pressure to the rest of the hospital.[116]

[114] A38030454 – 04.04.2017 BMT Options Appraisal Report for the Acute Services Committee - To add to hearings bundle.
[115] A35761962 – COS for NSGACL Haemat-Oncology NCH_iss1_rev (undated) - Bundle for Oral Hearings commencing 19 August 2024 – Bundle 16 - Page 1604.
[116] A38694862 – SBAR dated 30 October 2017 – Ward 2A Invasive Fungal Disease - Bundle for Oral hearing commencing 12 June 2023 – Bundle 4 - Page 114.

8.9 There were also concerns about high particle counts and the presence of fungi in air samples

> "Particle counts have been raised and fungal growth has occurred on a number of occasions in both HEPA and non-HEPA filtered rooms. These results have drawn attention to the ventilation of the rooms and have been instrumental in highlighting to the ICDs the underlying defects with the estate…"[117]

8.10 Patients were moved out of the ward in September 2018 into Ward 4B and 6A after three years of being housed in a substandard facility seemingly as a result of the evidence for ventilation deficiencies shown by air sampling and concerns about infections on the ward.

8.11 In a situational assessment report by Health Protection Scotland from June 2019 it is reported that on Ward 2A

> "Chilled beams were noted to have significant level of dust present in two separate rooms (Ward 2A) there was also discolouration to the edges of the ceiling around the supply. This is potentially due to water contamination and was under review by estates department. Dripping from the chilled beams had been observed by staff on a number of occasions. This was reported to estates and it has been identified that there were no dew point controls on the chilled beams. A dew point control has been fitted to the central system to alleviate the issue.[118]

[117] A38694862 – SBAR dated 30 October 2017 – Ward 2A Invasive Fungal Disease - Bundle for Oral Hearing commencing 12 June 2023 – Bundle 4 – Page 114.
[118] A32308315 – HPS Situational Assessment Wards 2A/B – June 2019 - To add to hearings bundle.

8.12 While the use of CBUs in patient rooms was not discouraged until the most recent versions of HTM03-01 and SHTM03-01 the use of dew point control was specified in the HTM03-01 and SHTM03-01 versions from 2007 and 2013 respectively.[119]

8.13 In September 2019 a tender was accepted from WGM Consulting Engineers which specified HEPA filtered bedrooms and corridors (H12/13) and all rooms had the specified 10ACH and + 10 Pa positive pressure specified in all editions of HTM03-01 and SHTM03-01. CBU, thermal wheels and suspended ceilings were to be removed and all rooms were sealed. An air lock, a back up AHU and pressure monitoring were also included in the specification.[120]

8.14 A validation report from February 2022 carried out by Sutton Service International shows that all the single bedrooms on ward 2A have >10ACH with a range from 13-18, the ACH in en-suites varies from 9-15ACH. All rooms were found to be in the specified range for positive pressure (+8 - +12Pa) ranging from +9.1 to +11.3Pa. Therefore, assuming filters testing and sealability testing has been undertaken these rooms on Ward 2A meet the specification set in all editions of HTM03-01 and SHTM03-01.

8.15 On my visit to QEUH in October 2023, Ward 2A appeared to have been built to a very high specification especially when compared to the adult units housing patients with similar conditions.

[119] A35610757 – SHTM 03-01 Part A February 2013 - Hearing Commencing 9 May 2022 – Bundle 1 – Page 473. A37344358 – HTM 03-01 Part B November 2007 – Hearing Commencing 9 May 2022 – Bundle 2 - Page 303.
[120] A41602092 – Report by WGM - 1215 QEUH Ward 2A Ventilation Upgrade Mechanical Services Specification Rev1 – 2019 - To add to hearings bundle.

Ward 4B Adult Bone Marrow Transplant (BMT) - Neutropenic patient group

8.16 Ward 4B of the QEUH is intended to house bone marrow transplant patient who require protective isolation due to their immunosuppression. This ward was not part of the original design of the hospital but was included in 2013 as a replacement for the existing Beatson Unit and a change control to build a unit to the same standard was produced[121] which specifies the use of HEPA filtration. The Beatson Unit had been designed with input from international and national experts in this field and was regarded as an exemplary facility. It had positive pressure HEPA filtered wards operated at a positive pressure of 10Pa and with 10ACH. The corridors were also HEPA filtered [122] The Bone Marrow Transplant (BMT) Unit transferred from the Beatson West of Scotland Cancer Centre to the QEUH, Ward 4B on 6th June 2015.

8.17 A month later, on the 6th July 2015, an SBAR from the Consultant Haematologist team, describe the environment in Ward 4B as "potentially unsafe accommodation, for this particular patient group" and expressed concern "that the safety of the environment for immune-compromised patients in terms of water and air quality cannot be guaranteed in the new accommodation on Ward 4B, QEUH."[123]

8.18 The HTM03-01 document from 2007 and SHTM03.01 from 2013 clearly stated the ventilation needs of these patients.[124] The requirements were that rooms supplied with H12 filtered air with 10 ACH and a positive pressure of 10 Pa.

[121] A36372603 – Change Control Procedure Form for Ward 4B, dated 9 July – Bundle for Oral Hearing commencing 19 August 2024 – Bundle 16 - Page 1699.
[122] A38030454 – 04.04.2017 BMT Options Appraisal Report for the Acute Services Committee - To add to hearings bundle.
[123] A40240682 - SBAR dated 06 July 2015 - Clinical Haematology and Allogenic Transplant Service - Environmental Risks – to add to hearings bundle.
[124] A35610757 – SHTM 03-01 Part A February 2013 Appendix 1: Table A1- Hearing Commencing 9 May 2022 – Bundle 1 – Page 473; A37344358 – HTM 03-01 Part B November 2007 – Hearing Commencing 9 May 2022 – Bundle 2 - Page 303.

8.19 On the June 2015 handover of the facilities there were the following deficiencies:

- Target air change rate of 6ACH was below the SHTM03-01 standard and specification of 10ACH.
- Rooms were not at the positive pressure value specified of +10Pa but ranged from neutral pressure to +4Pa.
- HEPA filters were fitted in diffusers in patient rooms but not in the corridors.[125]

8.20 In addition, unlike the Beatson there were no pressure alarms, no air lock to the ward and the bedrooms and bathrooms had suspended ceiling which meant that the rooms were not sealed. This means that there is a volume of air located in an uncontrolled, uncleaned, unsealed area which could infiltrate into the patient rooms. Particle counts for the patient rooms were found to exceed the levels expected for patient rooms and because of these deficiencies a decision was taken to return patients to the Beatson Unit in July 2015.[126]

8.21 From 2015-2018 a series of upgrade works were carried out and patients returned to the ward in July 2018. In 2017 some improvements had been made and in November 2017 H & V Commissioning Services carried out testing on the isolation rooms.[127] They measured the positive pressure differential in patient rooms as between 6.5 and 13. 9 Pa. Air change rates were measured at between 5.8 and 8.9 ACH. The rooms had had their suspended ceiling replaced with sealed ceiling and the rooms were tested for sealability by RSK Ltd and passed the criteria set in HBN

[125] A41683168 – 06.07.2015 BMT Briefing and Overview Note by Gary Jenkins - To add to hearings bundle; A43502680 – 07.07.2015 “BMT Document” – from Craig Williams to Jennifer Armstrong that considers the specification and identifies deficiencies with the BMT Unit – To add to hearings bundle.
[126] A41683168 – 06.07.2015 BMT Briefing and Overview Note by Gary Jenkins - To add to hearings bundle; A43502680 – 07.07.2015 “BMT Document” – from Craig Williams to Jennifer Armstrong that considers the specification and identifies deficiencies with the BMT Unit – To add to hearings bundle.
[127] A41683218 – 6-10.11.2017 QEUH Ventilation Report by H&V Commissioning Services Ltd - To add to hearings bundle.

04 Supplement 1 – Isolation Facilities in Acute Settings.[128] A pressure monitoring systems was in place but the ward was still below guidance specification for pressure differentials and air change rate in the majority of the isolation rooms. However, particle monitoring results were within the required specification and the patients were then returned to ward 4B in June 2018. However, there were still concerns that "air sampling has revealed low fungal counts including Aspergillus and Mucor. These counts were mainly in the corridor area rather than the HEPA filtered rooms. In view of this, keeping doors closed to rooms is essential."[129]

8.22 It is disappointing that despite significant remedial works ward 4B still does not meet the intention to replicate the standards shown in the Beatson facility which was built and commissioned in the 1990s and to perform to ventilation standards specified in HTM03-01 (2007) and SHTM03-01 (2013). It is also disappointing that the ventilation system used to protect these patients is currently far below that provided for paediatric patients in Ward 2A.

Ward 4C - Haemato-oncology (10 beds) - Neutropenic patient group

8.23 Ward 4C was also intended to house Renal and Haemato-oncology patients who were immunosuppressed patients with conditions such as leukaemia with the same ventilation requirements as specified in HTM03-01. The clinical output specification (ward 4B, undated) states:

> "Please note the haemato-oncology ward area has a very specific function and a considerably higher than average requirement for additional engineering support/infrastructure. There should be no opening windows,

[128] A41683249 – 22.07.2015 QEUH – Ward 4B Works (report by Brookfield Multiplex) - To add to hearings bundle; A41683247 – 10.2015 QEUH – Ward 4B Upgrade Works – report by Brookfield Multiplex - To add to hearings bundle.
[129] A38030413 – Proposal to Relocate Adult haemopoietic Stem Cell Transplant Service From Beatson West of Scotland Cancer Centre to QUEH – to add to hearings bundle.

no chilled beams. Space sealed and ventilated. Positive pressure to rest of the hospital and all highly filtered air >90%, probably best HEPA with adequate number of positive pressure sealed HEPA filtered side rooms for neutropenic patients as in the Beatson West of Scotland Cancer Centre."[130]

8.24 A briefing paper from January 2012 recommends the use of H13 (99.95%) efficient HEPA filters.[131]

8.25 It was intended to house these patients in Ward 4B but later in a change order, it was decided to provide ten rooms for haemato-oncology patients (Rooms 66 to 75) in Ward 4C to the same standard of the current haemato-oncology ward including the provision of HEPA filtration.[132]

8.26 It appears that the ward was designed to the general specification of a general ward with the 2.5 ACH derogation. On handover unlike the Beatson Unit specification required for these patients the ward had no HEPA filtration, 2.5ACH, neutral or slightly positive pressure rooms. There were also CBU installed and suspended ceilings in the rooms and ensuites. All this is contrary to the COS and requirements of HTM03-01 and SHTM03-01 (2009,2013).

8.27 A series of validation reports from Correct Air Solution show that in 2020 and 2022 the ten rooms intended for the most immunosuppressed patients (Rooms 66 to 75) operate at air change rates in the range of 2.8 to 3.3ACH and with most pressure differentials of 0.1 to 1.0 Pa).[133] This is well below the performance specified

[130] A36372545 – NHS Clinical Output Specification - To add to hearings bundle.
[131] A4363399 – Haemato-oncology Briefing Paper January 2012 - To add to hearings bundle.
[132] A36372603 - Change Control Procedure Form for Ward 4B, dated 9 July – Bundle for Oral Hearing commencing 19 August 2024 – Bundle 16 - Page 1699.
[133] A41790902 – Critical Ventilation Annual Verification & Inspection Report by Correct Air Solutions 16th & 17th January 2020 - To add to hearings bundle; A41791343 - Critical Ventilation Annual

originally, the specification of the Beatson and well- established guidance from HTM03-01 and SHTM03-01 and the change order. In my opinion, this level of unmonitored positive pressure will not protect against potential pressure reversals and thus the uncontrolled inflow of air from the rest of the ward. There is also no HEPA filtration of supply air to these rooms again contrary to guidance, COS and the change order. In fact, there seems to be no difference between these rooms and others on the ward for less immunosuppressed patients.
I am unaware of any clinical reason why these patients require less protection from microbial air contamination than those on Wards 2A and 4B.

8.28 An unusual feature of these wards was the installation of a recirculating Camfil HEPA filter unit in ceiling of the ensuites. I have assumed that these were installed in response to concerns about *Aspergillu*s growth on surfaces in the en-suite and to reduce particle counts in the en-suites as reported in a Risk Assessment in June 2021[134]. Since the en-suites are at negative pressure to the patient room this unit will not reduce contamination for the patient except for the limited time when they use the ensuite. I have assumed that they have been installed to allow air sampling and particle count data taken within the ensuite to be reduced below threshold as they would not greatly reduce patient exposure to any infectious agent in the air.

8.29 A series of SBARs (2019)[135], Action Plans as a result of HSE Intervention (2020)[136], Risk Assessments on Airborne Pathogens (2020, 2021)[137], ventilation

Verification & Inspection Report by Correct Air Solutions September 2022 - To add to hearings bundle.
[134] A41791142 – Risk Assessment Form Airborne Pathogens – 22nd June 2021 - To add to hearings bundle.
[135] A41791273 – SBAR – Ventilation Ward 4C – July 2019 - To add to hearings bundle.
[136] A41791079 – Action Plan in response to HSE Notification 18th December 2020 – To add to hearings bundle.
[137] A41791405 – Risk Assessment Form Airborne Pathogens – February 2020 - To add to hearings bundle; A41791142 – Risk Assessment Form Airborne Pathogens – 22nd June 2021 - To add to hearings bundle.

surveys[138] and ventilation upgrade proposals[139] have been written and distributed and yet ward 4C is still has the ventilation system of a general ward and there seems to be no plan to improve this except by continuing use of unvalidated mobile HEPA filtration units.

8.30 The SBAR from 2019 only recommends an increase to 6ACH and +6Pa, still below that specified in guidance. The most recent risk assessment (2021)[140] gives a risk rating of 9 which conforms to an estimate that currently on Ward 4C there may occur occasionally severe illness from airborne pathogen exposure on this ward. The ventilation surveys confirm the low ACH and only nominal pressure differential.

8.31 On my visit to the ward in October 2023, I noted that there was widespread use of HEPA filter units on the floor of the ward which were reported in a Risk Assessment in February 2020 introduced to reduce airborne contamination and to allow wards to pass particle count testing[141]. They would not prevent introduction of airborne environmental opportunistic pathogens like supply HEPA filters but potentially would reduce their levels post introduction and may be keeping particle counts within specification. However, their location at floor level on the ward may not impact on aerosol contamination levels close to the patients.

Ward 6A Originally Rheumatology but patients from Ward 2A RHC moved here 26 September 2018

[138] A41790902 – Critical Ventilation Annual Verification & Inspection Report by Correct Air Solutions 16th & 17th January 2020 - To add to hearings bundle; A41791343 - Critical Ventilation Annual Verification & Inspection Report by Correct Air Solutions September 2022 - To add to hearings bundle.
[139] A41791368 – QEUH Wards 4C, 5C, 6C & 7C Ventilation Proposal – 20th May 2022 - To add to hearings bundle.
[140] A41791142 – Risk Assessment Form Airborne Pathogens – 22nd June 2021 - To add to hearings bundle.
[141] A41791405 - Risk Assessment Form Airborne Pathogens – February 2020 - To add to hearings bundle.

8.32 Ward 6A was originally designed as a general ward and had a specified 2.5ACH with CBU, no HEPA filtration like all similar wards at QEUH. From Sep 2018 Ward 6A was used to house neutropenic patients from Ward 2A while building work was carried out to upgrade the accommodation and ventilation on this ward[142]. However, the ward specification was not increased so patients were being moved from one substandard ward to another and stayed there until transfer back to the refurbished Ward 2A in March 2022. (NHS Greater Glasgow & Clyde QEUH RHC Wards 2A & 2B Project Board 7 March 2022).

8.33 An SBAR from June 2019[143] makes the following observations:

- Air change rates were ca3ACH. Less than a third of recommended 10ACH
- CBU were in patient rooms with reported leaks and condensation.
- Nominal positive pressure in rooms was 2Pa (Correct Air Solution reported in September 2019 that the pressure differentials in the rooms on Ward 6 ranged from 0 to +0.7 Pa[144]
- Currently on 6A there is no HEPA filtration on the supply air. Portable HEPAs are in place in an effort to reduce airborne contamination, but this is not ensuring that HEPA filtered air only is breathed by patients. Contaminated air continues to enter the room and we are reliant on portable HEPA to clean the air.
- Air sampling in the bathrooms has detected pathogenic fungi such as *Aspergillus* and Mucoraceous mould.

[142] A41683195 – 09.07.2015 QEUH – Haemato-oncology Ward, Level 4, Briefing Note on Design of Unit - To add to hearings bundle.
[143] A41893682 – SBAR 6A – Ward 6A Environment – 26 August 2019 - To add to hearings bundle.
[144] A41893849 – Ward 6A Room to Corridor pressure profile – 12 September 2019 - To add to hearings bundle.

8.34 In 2019 the ward was upgraded by placing portable HEPA filter units in three rooms (20,21,23) and installing Camfil recirculating scrubbers in the ceilings of ensuite possibly to remove airborne spores originating from contaminated flooring/showers and to improve particle counts and flexible CBU fittings were replaced with push fit connectors. There is also widespread placement of HEPA units on rooms and corridors. (RFI response A41893863)[145].

8.35 The situation with ward 6A is very similar to that of Ward 4C and the comments from the previous section hold for Ward 6A. In fact, there seems to be no difference between these rooms and those on other wards for less immunosuppressed patients apart from the use of recirculating HEPA filters. I am unaware of any clinical reason why these patients required less protection from microbial air contamination than those on Wards 2A and 4B.

Ward 5C and D infectious diseases

8.36 In 2014 a decision was made to move the Brownlee Infectious disease unit from the Gartnavel to QEUH and locate it in ward 5C and D (Inquiry Note QEUH – Level 5 – Infectious Disease Unit).[146] This was designed as a general ward with 2.5ACH, CBU and minimal room negative pressure caused by en-suite. It was expected that any patients who needed to be isolated would be housed in other wards with isolation rooms such as critical care or renal. In 2016 ID physicians expressed concerns amongst “ongoing discussions about the basic engineering and lack of alarm systems” (Inquiry Note QEUH – Level 5 – Infectious Disease Unit).[147] In addition, the letter stated: “We are not clear if the HDU rooms have enough air exchanges to keep staff safe and we do have MDR-TB [Multiple Drug-Resistant

[145] A41893863 – RFI 10 Response 4.1 – 4.7 final - To add to hearings bundle.
[146] A39465106 – Timeline regarding move of the Infectious Disease unit to the QEUH. To add to hearings bundle.
[147] A39465106 – Letter dated 5 May 2016 from Infectious Disease consultants to Dr. Inkster raising concerns about management of dangerous pathogens in GG&C. To add to hearings bundle.

Tuberculosis] presenting commonly which is of particular concern".[148] In the SBAR Dr Inkster states that there are "no negative pressure rooms in QEUH".[149] She was expressing concerns about MDR TB patients being housed in PPVL.

8.37 In 2016 patients with an infectious disease such as pulmonary tuberculosis were to be geographically separated from immunosuppressed patients with an infection (largely those with HIV) in wards 5D and 5C, respectively. This complies with NICE guidance NG33. Operational measures were to be implemented in these wards which included the use of PPE and a 'two-hour rule'. That is, to control for reduced air changes, two hours were to be left before non-essential personnel could re-enter a room after any aerosol generating procedure. Also MDR TB and MERS cases were not to be treated in the ward.[150]

8.38 In November 2018, tests had indicated neutral to positive pressure in rooms where TB patients were being cared for, thus "spreading pathogens into the corridor and potentially other rooms".[151] In rooms where immunocompromised HIV patients were being cared for neutral to slightly negative pressure was detected, thus "sucking pathogens into their rooms from the corridor".[152]

8.39 By late December 2018, adjustments had been made to the ventilation in wards 5C and 5D and, despite an issue with the fire dampers in some rooms having become unexpectedly closed, H&V Commissioning verified that all rooms had achieved a notionally negative pressure following rebalancing. The report noted that

[148] A39465106 – Timeline regarding move of the Infectious Disease unit to the QEUH. To add to hearings bundle.
[149] A38694846 – SBAR dated May 2016 – Suitability of Isolation Rooms – Bundle for Oral hearing commencing 12 June 2023 – Bundle 4 - Page 49.
[150] A38694863 - SBAR dated 2 February 2017 – Isolation Rooms Critical Care – Bundle for Oral hearing commencing 12 June 2023 – Bundle 4 - Pages 91 and 92.
[151] A39465086 – Email dated 12 December 2018 from D Bell to A Harkness and others - To add to hearings bundle.
[152] A39465086 – Email dated 12 December 2018 from D Bell to A Harkness and others - To add to hearings bundle.

"the retro fit of door drop down seals would help with this control and stabilise pressures, as fitted on ward 4B".[153]

8.40 Currently, the Infectious Disease Unit on level 5 of the QEUH is achieving air change rates between 2.7ACH and 3.2ACH and is achieving a notionally negative pressure regime (from bedroom to corridor) ranging from 0 to -3.5Pa[154]. This is without any alarm systems[155] with no HEPA filtration[156] which requires 3 AHU working at full capacity.[157] There is access to three negative pressure isolation rooms (with ensuites) in the critical care unit for isolation of airborne infections.[158]

Impact of deficiencies in QEUH/RHC

8.41 Nosocomial infections in hospital patients are caused by multiple factors. The prevention of nosocomial infection involves a range of preventative measures often called bundles. In this section I will assess what the impact of the deficiencies in ventilation listed above have on the potential risk for patients and staff of contracting an airborne infection. I will examine the deficiencies separately for general patient wards, infectious disease wards and for immunocompromised patients.

[153] A41790834 – Ward 4C & 5C – Change Pressure Profile Results – 14th December 2018. To add to hearings bundle.
[154] A41790834 - Ward 4C & 5C – Change Pressure Profile Results – 14th December 2018. To add to hearings bundle; A44943716 – Ward 7D & 5D – Change Pressure Profile to Negative Wards. To add to hearings bundle; A41791368 – QEUH Wards 4C, 5C, 6C & 7C Ventilation Proposal – 20 May 2022. To add to hearings bundle.
[155] Note this is only the case for the ward rooms, see A35761949 – COS for NSGACL Generic Wards NSG_iss1_rev (undated) – Bundle for Oral hearings commencing 19 August 2024 – Bundle 16 - Page 1634. For HDU isolation rooms see A33642489 – QEUH Isolation Rooms meeting minutes 31 May 2016. To add to hearings bundle; A46157873 – Email from C Peters to M Bain dated 15 January 2020. To add to hearings bundle.
[156] A35761949 – COS for NSGACL Generic Wards NSG_iss1_rev (undated) – Bundle for Oral hearings commencing 19 August 2024 – Bundle 16 - Page 1634. The Inquiry team are not aware of any HEPA filters installed on the ward since handover.
[157] A41791368 – QEUH Wards 4C, 5C, 6C & 7C Ventilation Proposal – 20 May 2022. To add to hearings bundle.
[158] A46157873 – Email from C Peters to M Bain dated 15 January 2020. To add to hearings bundle.

General Wards

Reduced Air Change Rate

8.42 I understand that a recommendation was made by Brookfield to reduce the air change rates for the hospital for single rooms to 2.5ACH instead of the 6ACH defined in guidance and to use chilled beam units in order to maintain an acceptable climate (temperature and humidity) within the single rooms. From the M&E clarification log of 18.12.2009 the original proposal was

> Ward Air change to be 6AC/HR, currently shown as 2.5AC/HR which is not in compliance with SHTM 03 -0[159]

8.43 However, the Brookfield counter proposal states that

> "Brookfield's proposal as outlined within the bid submission is to incorporate chilled beams as a low energy solution to control the environment which do not rely on large volumes of treated air or variable natural ventilation. All accommodation is single bedrooms and therefore the need for dilution of airborne microbiological contamination should be reduced (rooms could also be at slightly negative pressure to corridor). Providing 6 air changes is energy intensive and not necessary."[160]

8.44 The response to this proposal from the Board was

[159] A35761409 – The M&E Clarification Log (2010 ItP) – (FINAL) – Bundle of documents for Oral hearings commencing 19 August 2024 – Bundle 16 - Page 1664.
[160] A35761409 – The M&E Clarification Log (2010 ItP) – (FINAL) – Bundle of documents for Oral hearings commencing 19 August 2024 – Bundle 16 - Pages 1664 and 1665.

> **Agreed** The proposal is accepted on the basis of 40 litres per second per single room (8 litres per second) for one patient and four others. Joint review to be carried out between the Board and Brookfield of the energy model to determine any impact on the energy target/BREEAM rating. Brookfield, however, remain responsible for achievement of the energy target/BREEAM, with £250,000 added to the contract sum in this regard. Negative pressure to be created in the design solution.[161]

8.45 Therefore, the rationale for the decision to reduce the ACH from 6 to 2.5 seems was energy efficiency and to contribute to complying with a BREEAM rating.

8.46 The stated rationale given by Brookfield is that the use of single rooms in the hospital would reduce infection risk (even though 6ACH is explicitly recommended in guidance for single rooms) and so justify the reduction in air change rate and that the use of the lower ACH and the CBU would improve energy efficiency and improve the BREEAM score. The use of CBU is explicitly forbidden for specialist ventilation facilities in the most up to date copy of SHTM03-01 (2020) but not in the issue current when the QEUH was designed and constructed.

8.47 The use of CBUs is discussed in a later section. So, the question is does reducing the air change rate to 2.5ACH from 6ACH and using CBUs create an increased infection risk if CBUs do not add an infection risk.

8.48 Patients in single rooms are less exposed to any potential aerosol hazards linked to other patients due to increased distance and closed doors providing a restriction to airflow and the spread of aerosols. However, the patients will still be exposed to visitors, nursing staff and support staff and doors will not always be

[161] A35761409 – The M&E Clarification Log (2010 ItP) – (FINAL) – Bundle of documents for Oral hearings commencing 19 August 2024 – Bundle 16 - Pages 1664 and 1665.

closed. This exposure will generally be more limited than on multi-occupancy wards but will still occur.

8.49 The difference in air changes between 6 and 2.5 means that any aerosol generated in the room will take longer to be removed. With 2.5ACH it would take 56 minutes to remove 90% of an airborne contaminant and 110 minutes to remove 99% of the contaminant. At 6ACH it would take 23 minutes to remove 90% of the contaminant and 46 minutes to remove 99% (adapted from Chinn and Sehulster 2003).[162] This is assuming good mixing and no deposition. However, if there is no airborne hazard or the exposure risk is minimal this would not greatly impact patient risk.

8.50 Single en-suite rooms are generally at slightly negative pressure due to extract of air from the en-suite. Therefore, air from the surrounding corridor/ward areas will tend to enter the single room. While having a closed door will reduce any transfer of aerosol particles it will not prevent it. While having two adjacent rooms at nominal negative pressure would seem to prevent transmission from one room to another pressure fluctuations caused by weather, temperature gradients (Lidwell et al 1972)[163], other air movements etc will allow significant movement of air from one room to the other and vice versa. For example, if a patient room has a higher set temperature air will expand and move into adjacent areas of lower temperature. Since rooms are not pressure monitored there is no guaranteed pressure differential or directional airflow.

8.51 While there may be an argument for reducing ACH in single rooms, I have not been provided with any written assessment carried out to address any adverse impacts on patients or staff on the reduction of the target ACH in the QEUH design from 6 to 2.5. As stated above when a decision is made that a new hospital is built to

[162] A48361954 – Lynne Sehulster and Raymond Y. W. Chinn, 'Guidelines for Environmental Infection Control in Health-care Facilities: Recommendations of CDC and Healthcare Infection Control Practices Advisory Committee (HICPAC)' (2003) – to add to hearings bundle.
[163] A48360632 – O. M. Lidwell, 'The control by ventilation of airborne bacterial transfer between hospital patients, and its assessment by means of a particle tracer: II. Ventilation in subdivided isolation units' (1972) – to add to hearings bundle.

a lower standard than recommended in guidance it would be expected that a derogation explaining the reason for the decision would be produced and agreed by all interested parties.

8.52 The reduced air change rate may have the greatest impact in times when there are cases of highly transmissible respiratory viruses on wards that can be partly transmitted in aerosols from and between patients, staff and visitors i.e. influenza, RSV and SARS-CoV-2. The lower air changes will increase the chances of airborne transmission between patients, between staff and between patients and staff. This can be ameliorated for staff by the use of high level RPE and vaccination (if available).

8.53 It seems likely that the reduced ACH would lead to an increase rate of transmission of respiratory viruses between patients, staff and visitors through airborne exposure on general wards. This would make the QEUH more vulnerable to seasonal respiratory virus outbreaks leading to increased staff absences and increased patient stays.

8.54 There were concerns expressed by infection control staff over the impact of reduced air change rates on the potential transmission of *Mycobacterium abscessus* amongst cystic fibrosis out patients.[164] A recent report (2018) of the Cystic Fibrosis Trust *Mycobacterium abscessus* Infection Control Working Group recommends, amongst other measures,

> "…current inpatient and outpatient facilities should be evaluated for their present air exchange and air flow and measures taken to optimise this wherever possible. Patients must be seen in well-ventilated rooms. Rooms must be left with the door closed, with at least an hour (amended

[164] A38694867 - SBAR dated June 2016 - Air changes in patient rooms QEUH – Bundle for Oral Hearing commencing 12 June 2023 – Bundle 4 – Page 52.

depending on knowledge of air flow/exchange) between patients to allow for dispersion of possible airborne contamination and then cleaned according to local infection control guidelines and that any future facilities should include the provision of enhanced ventilation for both inpatient and outpatient care and adequate ventilation in other areas."

8.55 This is another case where the reduced air change rate could lead to nosocomial infection and the provision of at least the recommended ACH would seem to be warranted.

8.56 An issue with reducing the required ACH in the design stage meant that the ventilation plant has been sized on the basis of the lower ACH leaving no possibility to significantly improve the ACH without replacing the plant and ductwork. To do this would requires closure of wards, disrupting the hospital with noisy and dirty building works and the associated cost and impact on infection control.

8.57 To summarise, lower air change rate on general wards than recommended by guidance would potentially increase the risk of transmission of respiratory infection between patients, staff and visitors especially in winter as compared to a standard ward. However, without further analysis the magnitude of increased risk cannot be quantified.

Use of Chilled Beam Unit (CBU)

8.58 As discussed in previous sections, CBU are widely used as an extremely energy efficient and cost-effective option for controlling the environment and are widely used within the QEUH. However, over the past decade, there have been concerns raised about their use in healthcare environments particularly by infection control physicians based on the experience at QEUH (Inkster et al 2020). They have

reported that condensation within the CBU encourages mould and bacterial growth posing an infection hazard even in small amounts. Entrained air from the room space carries particulate matter including fibres, skin squames and aerosols. Particulate matter passes over the fins of the coils and tends to collect and stick to the metal. As no filter is present, all recirculated air could carry the pathogens back into the room or deposit onto the beam. In the QEUH, lint from the bedsheets was found to be a source of fibre build-up. The risk is exacerbated if water drips through the accumulated dust into a clinical space. This occurred on several occasions at the QEUH, resulting in a "black rain" effect.[165]

8.59 The CBUs used with QEUH are Swegon Parasol heating/cooling comfort modules so are not strictly CBU. Basically, they operate by passing the air supply into the room over a convection circuit which will either chill or heat the air depending on the room setting from the control panel operated by patient or staff. The convection circuit is provided with water from both a chilled water and the heating system hot water.[166] The unit is designed so there will be some circulation of air back into the convection circuit for more efficient heating/colling. These units seem to be designed for use in offices, meeting rooms and other public spaces and do not seem to be designed for hospitals and seem to be an ingenious energy efficient way of controlling the spatial environment.

8.60 It is unclear what evidence was sought by the hospital design team for assurance that these units were safe to use in hospitals. Since over 1500 of the units were purchased, it would be expected that evidence would be sought over their performance *in situ*, their reliability and their previous use in healthcare environments before being approved for use. The contractor offered an opportunity for testing the devices in operation, in a mock up single bedroom, in the manufacturer's thermal laboratories, but it is not known whether the design team took this opportunity to

[165] A42855084, T. Inkster, C. Peters, H. Soulsby 'Potential Infection Control Risks Associated with chilled beam Technology: Experience from a UK Hospital' (2020) – To add to hearings bundle.
[166] A41745773 – Emails involving NHS GGC staff – Bundle for Oral hearings commencing 19 August 2024 – Bundle 12 – Page 1264.

assess the CBU in use before purchase.[167] It is well known that similar HVAC units can have problems with leaks and condensation.

8.61 The use of CBUs meant that an extra water supply needed to be provided in patient rooms as the CBU is connected to a hot and cold water circuit. Any failure of the connection to the water circuit would cause a water leak from the units which seem to be often situated directly above patient beds. Therefore, patients could be exposed to opportunistic pathogens in the water supply in case of connection failure. This seems to me to be a foreseeable risk and I would assume that comparative failure rate data would be available on connections and ones with acceptably low failure rates such as compression fittings would have been chosen. After a series of leakages from the original connectors used, they were replaced with compression fittings on Ward 6A but it is unknown whether more widespread replacement has occurred.[168]

8.62 The CBUs were fitted without dewpoint controls to avoid condensation even though this was specified in 2012.[169] This led to incidents where condensation led to dripping of contaminated water from units placed above patient's beds including a large-scale condensation event in June 2019 involving 106 rooms. Under what was perceived as extreme atmospheric conditions (for Glasgow), relatively high temperatures and humidity meant that the dew point exceeded this set point of 15°C and resulted in wide scale 'sweating' of the chilled beams. This was not an unforeseeable event as dew point control had been recognised as being required and an incident of high temperature and humidity would have been foreseen. Dew Point control was intended to be installed in the building management systems in

[167] A36939901 – New South Glasgow Hospitals: Specification Ventilation System November 2012 (Pages 39, 40, 53 & 54) – to add to hearings bundle.
[168] A41893723 – IMT Action List Ward 6A – to be added to bundle.
[169] A36939901 – New South Glasgow Hospitals: Specification Ventilation System November 2012 (Pages 39, 40, 53 & 54) – to add to hearings bundle.

2019 and if successful this should have reduced some of the exposure risk but not all from the use of CBU.[170]

8.63 The magnitude of the potential for microbial contamination of CBUs may not have been apparent when installed but what is their potential impact on patients? Having a reservoir of opportunistic pathogens in the ceiling of a patient room is obviously not a perfect situation in any hospital. There is a potential for the transfer of these agents from the CBU to the patients (drips, re-entrainment of dust into room air) and a potential for these agents to infect the patient through inhalation or contact. It is difficult to put a risk value on this exposure, but it is not zero and for immunosuppressed patients the consequence of infection could be serious.

8.64 The maintenance and cleaning burden of these units does not seem to have been recognised before installation. While guidance from HTM03-01 (2007) suggests that six monthly cleaning would be adequate this was not the experience at QEUH. Inkster et al (2020) identified several issues in hospitals that may impact on the use of CBUs such as lint from bedding being trapped by beams. She stated:

> "Cleaning is cumbersome and requires a six-week rotation due to visible build-up of dust, despite manufacturers suggesting six months to yearly. Access to clean (CBU) can be problematic when patients are occupying the room, as the chilled beam is situated directly above the patient's bed. High patient turnover makes chilled beam cleaning impracticable as part of the standard discharge clean".[171]

8.65 The Inquiry holds records of seven incidents (of varying scale) in which estates were called out where leaking and/or 'sweating' chilled beams occurred

[170] A43175917 – Email from I Storrar (NSS) to A Gallacher and C Purdon (GGC) regarding chilled beams (8 August 2019) – to add to hearings bundle.
[171] A42855084, T. Inkster, C. Peters, H. Soulsby 'Potential Infection Control Risks Associated with chilled beam Technology: Experience from a UK Hospital' (2020) – To add to hearings bundle.

between 2015 and 2019. These were dripping from chilled beams in Critical Care in 2015,[172] condensation and dampness in Ward 2A in 2017,[173] 14 rooms were affected by dripping dirty water from CBUs including Ward 2A in February 2018.[174] In the latter case it was blamed on internal rooms conditions. In 2019 there were reports of condensation from a CBU landing on a patient's foot in Ward 4C[175], report of problems in 6A in May 2019 and then in June 2019 water was reported dripping onto patient beds in nine rooms in 6A. This was caused by leaks in the connectors to the CBU and volumes of up to 10mls were collected in bowls in the ward. Estates were called out to all of them. There was reference to leaks occurring frequently in 2A and 6A and the likeliness that not all leaks were reported was also noted. Explanations for the incidents provided by the Estates team fell into three categories:

- flexible/push-fit connectors (leaking)
- boiler failure (leaking)
- condensation triggered by a) human error, b) internal and c) external conditions (with no dew point control to detect and/or prevent)

8.66 The decision to use CBU in patient rooms has led to the creation of a potential reservoir of opportunistic pathogens within patient rooms often located directly above patient beds. This has led to an increased workload to maintenance and cleaning staff as the cleaning regime has had to be increased from the expected six-monthly to six-weekly. Since many of the agents found by Inkster on CBU are water-associated it would be difficult to ascertain a connection between CBUs and

[172] A34466195 – Email chain from D Wilson, Brookfield Multiplex to D Hall, Currie and Brown and others – subject 'dripping chilled beams in Critical care' – Bundle for Oral hearings commencing 19 August 2024 – Bundle 12 - Pages 507 to 511.
[173] A37987226 – 05.08.2016 IMT Minutes – Bundle for Oral hearing commencing 12 June 2023 – Bundle 1 - Pages 22 to 26.
[174] A41745773 – Emails involving NHS GGC Staff – Bundle for Oral hearings commencing 19 August 2024 - Bundle 12 – Page 1251.
[175] A41745773 – Emails involving NHS GGC Staff – Bundle for Oral hearings commencing 19 August 2024 - Bundle 12 – Page 1252.

infections as distinct from general water systems. However, there is a risk of drips containing opportunistic pathogens landing on patient associated areas and potentially on patients. This has been documented at QEUH where drops landed on a patient's foot.[176] The potential for re-entrainment of material from these units is unknown.

8.67 The magnitude of the potential for microbial contamination of CBUs may not have been apparent when installed but their potential impact on patients is now clear. Having a reservoir of opportunistic pathogens in the ceiling of a patient room is not acceptable especially for vulnerable patients. With the documented failure rates, the microbial contamination identified by Inkster and the placement of these units, these risks are not insignificant and it would seem sensible that the use of CBUs at the QEUH is, when practical, discontinued with priority given to wards with the most vulnerable patients. Dew point controls need to be installed if this is still outstanding. It would also seem to be reasonable to replace any connectors known to have a high failure rate in patient rooms with more secure compression fittings.

Impact of Deficiencies in QEUH wards – infectious patients

8.68 The housing of patients with respiratory transmissible infection needs to protect staff and patients from airborne transmission of the pathogen from the patient. This is done by ensuring that all air from the patient room is discharged safely and does not enter adjacent patient areas and that any exposure to airborne pathogens is limited to those entering the isolation room.

[176] A41745773 – Emails involving NHS GGC Staff – Bundle for Oral hearings commencing 19 August 2024 -Bundle 12 – Page 1252.

Low air change rate

8.69 As stated in the previous section having a lower air change rate will increase the risk of transmission of airborne infectious disease. In wards housing patients with airborne transmissible infectious agents this will increase the risk of transmission from the infected patient to uninfected staff and patients. Within the single room having an air change of 2.5ACH instead of the recommended 10ACH will increase the exposure of those entering the patient room by four-fold. While the risk to staff and other visitors can be mitigated with the use of RPE it will still increase exposure risk especially as these mitigations may already be in place. If the patient is housed in a room without a measured pressure differential risk of transmission to patients outside the room will be increased by the lower air change rate in both rooms.

8.70 This risk can be mitigated by the use of negative pressure or PPVL rooms but the reduced ACH will increase the exposure of persons exposed to the infectious case in their room. This can be ameliorated by the use of high level respiratory protection but no RPE is 100% effective. The provision of low ACH has been postulated as a cause of a nosocomial outbreak of TB in the UK (Breathnach 1998)[177] and is likely to contribute to increased risk to patients housed on the ward.

Lack of negative pressure

8.71 The lack of negative pressure or nominal negative pressure in rooms containing patients with respiratory infections such as tuberculosis has been demonstrated as facilitating the spread of tuberculosis from the infected case in a

[177] A48378826 – A.S. Breathnach, A. de Ruiter, G.M.C. Holdsworth, N.T. Bateman, D.G.M. O'Sullivan, P.J. Rees and others, 'An outbreak of multi-drug-resistant tuberculosis in a London teaching hospital' (1998) – to add to hearings bundle.

single room to others housed in the same ward (Breathnach 1998).[178] This has most often been reported in HIV patients. It would be expected to be a possibility with other airborne infections such as COVID-19, measles etc. Therefore, staff and patients on the ward will be at heightened risk of infection especially the unvaccinated and immunocompromised.

Sub-guidance levels of negative pressure

8.72 The important aspect of a negative pressure room is the provision of a directional airflow into the room from other areas. In my opinion, if negative pressures are below standard but are monitored and pressure reversals do not occur then there should not be a significantly increased risk to those outside the room.

Use of PPVL

8.73 The use of PPVL rooms to house patients with transmissible respiratory infection should, if operating correctly, provide an adequate barrier to the release of microbial aerosol from the room to the adjacent ward giving a high level of protection as shown in work of Hambreus and Sanderson et al (1973).[179]

Lack of extract HEPA filtration

8.74 HEPA filtration of exhaust air from rooms containing patients with a transmissible respiratory infection is normally not required as any aerosol generated

[178] A48378826 – A.S. Breathnach, A. de Ruiter, G.M.C. Holdsworth, N.T. Bateman, D.G.M. O'Sullivan, P.J. Rees and others, 'An outbreak of multi-drug-resistant tuberculosis in a London teaching hospital' (1998) – to add to hearings bundle.
[179] A48361005 – A. Hambraeus and H.F. Sanderson, 'The control by ventilation of airborne bacterial transfer between hospital patients, and its assessment by means of a particle tracer: III. Studies with an airborne-particle tracer in an isolation ward for burned patients' (1972) - to add to hearings bundle.

will be diluted in the extract air and will normally be vented to the outside air. HEPA filtration would only be required if air is vented to inhabited areas where potentially infected people are exposed.

Use of CBUs

8.75 The use of CBUs on infectious disease wards will have the same impact as on general wards but will be an additional concern if the patient is immunosuppressed or on antibiotic therapy which makes them more susceptible to opportunistic pathogens.

Separation from immunosuppressed patients

8.76 It is essential that if correct negative pressure isolation cannot be achieved for patients with suspected airborne infection that they are not housed in the same wards as immunosuppressed patients such as those with HIV.

Impact of Deficiencies in QEUH wards – Neutropenic/Immunosuppressed patients i.e. those housed on wards 2A (before upgrade), 4B, 4C and 6A

8.77 Neutropenic patients are at a greatly increased risk of infection through exposure to opportunistic pathogens found in the air as well as to respiratory viruses. The reduced clearance of any infectious agents from the air of their room will increase their exposure and thus increase their risk of infection. The recommendation in all editions of HTM03-01 and SHTM03-01 for these patients is a positive pressure room at +10Pa with 10 ACH and HEPA filtered supply air. These ventilation values by themselves and together provide a highly protective environment for the patients in combination with other measures not considered here.

Air Change Rates less than guidance

8.78 The QEUH was originally designed to have an air change rate of 2.5ACH on all wards which is much lower than the recommended 10ACH required for specialist ventilation areas. This included wards intended for patients requiring specialist ventilation such as wards 2A, 4B, 4C and latterly ward 6A. The current air changes in these wards are ca10ACH for Ward 2A, ca6ACH for Ward 4B and 2.5-3ACH for Ward 4C and 6A. Apart from the renovated Ward 2A neutropenic patients are housed on wards with air change rates lower than recommended in guidance and on pre-existing facilities in GGC such as the Yorkhill site. The lower ventilation rates would reduce the clearance of any airborne pathogen found in this environment. This would increase patient exposure to any infectious agents in the air generated within their room from staff or visitors or the environment. For patients in rooms without positive pressure and HEPA filtration there will be increased risk from air contamination from outside their rooms. For such vulnerable patients this increased exposure risk is unacceptable in a new hospital. The knowledge that the wards had been designed with a low ACH must have caused concern in staff transferred from the Beatson facility, who were used to working in a facility with a ventilations system which, although built in the 1990s, met UK and Scottish guidance.

Lack of positive pressure

8.79 If a room has no positive pressure differential (Ward 6A and the original Ward 2A) or the positive pressure is only nominal (i.e. less than 1Pa as reported in ward 4C and 0 to 4Pa as reported in Ward 4B before upgrade) to the rest of the ward there is the potential for ingress of air from the ward into the patient room. This is especially true for Ward 6A as the en-suite extract would be expected to cause a slight negative pressure. Also, the potential for temperature differentials between rooms could cause movement from hotter areas to colder areas. Therefore, there will be no enhanced protection against any pathogenic agents found in the air of the

corridors outside the rooms generated from staff, other patients, or the environment. Therefore, the patients cannot be regarded in the true protective isolation recommended for their treatment in UK HTM03-01, SHTM03-01, clinical guidance, international guidance, JACIE and previous facilities operated by NHSGGC. The increased risk this posed to the patients cannot be easily measured as the protective impact of positive pressure rooms has not been quantified but, in my opinion, it would be the expectation of family, staff, patients and the general public that such vulnerable patients would be housed in rooms of the standard specified in guidance. JACIE states that a designated inpatient unit of appropriate location and adequate space and design that minimizes airborne microbial contamination. In my opinion this is not met in wards without positive pressure containment (and HEPA filtration).

Sub-optimal levels of positive pressure

8.80 The recommended positive pressure for a neutropenic patient ward is 10Pa. However, on some wards a lower positive pressure has been specified such as 6Pa[180]. As discussed previously the important factor to protecting the patient is maintaining a directional air flow from “clean” to “dirty “and ensuring there is no egress of potentially contaminated air. Having a reduced positive pressure, while not conforming with guidance may provide an adequate level of protection if the positive pressure is monitored and it can be shown in records that any pressure fluctuations do not cause reverse air flows. This required that pressure is both monitored and alarmed and remedial action is taken if pressure reversals occur.

[180] A41791273 – SBAR – Ventilation Ward 4C – July 2019 – To add to hearings bundle.

Lack of HEPA filtration

8.81 HEPA filtration of the air supply assures that the air supplied to the patient does not contain opportunistic pathogens that could potentially cause respiratory infection in severely immunocompromised patients. Professor Gibson states that the "It is inconceivable that a [Bone Marrow] transplant unit was built without HEPA filtration".[181] JACIE states that "There shall be a designated inpatient unit of appropriate location and adequate space and design that minimizes airborne microbial contamination" (JACIE 6th edition).[182] This is mainly done by the provision of a HEPA filtered air supply. The lack of HEPA filtration in the wards of the QEUH housing patients transferred from the Beatson must have caused serious concern in staff transferred from the Beatson facility who were used to working in a facility with a ventilations system which, although over 10 years old, met UK and Scottish guidance. The increased risk this posed to the patients cannot be easily measured as the protective impact of HEPA filtration has not been shown to be significant in the limited number of trials measured, but it would be the expectation of family, staff, patients and the public that such vulnerable patients would be housed in appropriate rooms with HEPA filtered air as specified in guidance.

Use of CBUs

8.82 The use of CBUs in rooms for patients on general wards has been discussed at length in a previous section. The risk to patients of the presence of a reservoir of opportunistic pathogens in a patient room is increased for immunosuppressed patients. These pathogens have an increased potential to infect these patients resulting in significant morbidity, and potentially, mortality. CBUs have no placed in wards with requirements for specialist ventilation for reasons of infection control and

[181] A43171285 – Email chain dated 3-5 June 2015 – Brenda Gibson and others – Bundle for Oral hearing commencing 12 June 2023 - Bundle 8 – Page 125.
[182] A48097538 – FACT-JACIE International Standards for Hematopoietic Cellular Therapy Sixth Edition – To add to hearings bundle.

practicality (enhanced cleaning in these rooms is problematic and disruptive. The increased understanding of their hazards and the changing guidance should lead to a phased replacement in areas requiring specialist ventilation.

Sealed Rooms

8.83 Guidance SHPN04 (2008) and HBN04-01(2005, 2013) specifies that isolation room should be of solid constructions with either solid ceilings or sealed joints. If the ceiling is not sealed there is the potential for the exchange of air from the void above the ceiling into the isolation room. Since the area above the ceiling will not be readily accessible it will not be cleaned, any leaks or dampness will not be detected, there would be potential for microbial growth in this area and for contaminated air in the void to enter the isolation rooms. It will also be impossible for the room to meet the required room permeability test standards. Another issue is that if the rooms are not sealed then it may be more difficult to control the pressure of the room (Rice et al 2001).[183]

Validation/Commissioning

8.84 Once the hospital is designed and constructed there needs to be a process to ensure that what has been built meets the agreed design. HTM03-01 (2007) states that "…critical ventilation systems should be inspected quarterly and verified at least annually".[184] This will involve measuring supply and extract air flows, air change rates, pressure differentials (when used) and testing HEPA filters (when installed).

[183] A48365200 – Nancy Rice, Andrew Streifel and Donald Vesley, An Evaluation of Hospital Special-Ventilation-Room Pressures – to add to hearings bundle.
[184] A37344358 – HTM 03-01 Part B November 2007 – Hearing Commencing 9 May 2022 – Bundle 2 - Page 303.

8.85 If these tests are not carried out during commissioning as seems to be the case in many parts of the QEUH and RHC then it cannot be demonstrated on handover that the critical ventilation systems are achieving their design values and thus that the wards have been correctly constructed according to the agreed design. It therefore cannot be demonstrated that the protective environment needed for the patient has been provided.

Impact of Mitigations to address deficiencies

Installed re-circulating units in ceilings

8.86 In wards 4C and 6A recirculating Camfil units were installed in en-suites to deal with concerns about Aspergillus growth and particle counts in the en-suite showers[185]. The use of these units would potentially reduce exposure to any airborne material in the ensuite but would have limited impact on airborne levels in the patient room as the ensuite is at negative pressure to the bedroom. It is unclear the rationale for their use as renovating the shower units and flooring to remove areas of potential Aspergillus contamination would be a more effective and economical way of reducing exposure of the patients.

Portable HEPA air cleaners

8.87 Portable air cleaners are currently widely used in the QEUH in wards 4C and 6A to improve air quality on wards without supply HEPA filtration and lower ACH than

[185] A41791142 – Risk Assessment Form Airborne Pathogens – 22nd June 2021 - To be added to hearings bundle; A41893682 – SBAR 6A – Ward 6A Environment – 26 August 2019 - To be added to hearings bundle; A41893726 – QEUH – Single Occupancy Bedroom Ward 6A Bedroom 1 with en-suite recirculation scrubber fan – Critical Ventilation Annual Verification & Inspection – 11 November 2019 – To add to hearings bundle.

recommended in guidance[186]. While these units have been independently tested and shown to be effective against aerosols generated with the laboratory (Beswick et al 2023, van Vossen et al 2023)[187] and in a COVID surge ward (Morris et al 2022)[188] there is currently no published evidence of efficacy in reducing nosocomial infection. Portable air cleaners do not prevent ingress of environmental pathogens from outside air but only work to reduce levels within the area by increasing the equivalent air changes within an area. Unlike HEPA filters in ventilation systems, they are not individually tested on commissioning or annually checked for performance so they cannot be assumed to be functioning correctly. Currently, in the QEUH they seem to be positioned on floor levels in corridors distant from the patient possibly due to noise concerns and it is possible their impact on the exposure of patients will be minimal for such patients. I have assumed that there is no information on the theoretical increase in ACH produced by these units so there is no indication of whether their contribution to cleaning air is significant or not. The use of such equipment should only be for emergency or short duration incidents, such as building work, they should not be used as a substitute for HEPA filtered supply air for immunosuppressed patients and to ensure that particle count tests are passed.

[186] A39234899 – IMT Expert Advisory Sub-Group Minutes – Cryptococcus – 22 February 2019 - To add to hearings bundle; A41893689 – Action List – Crypto Mit Table – 01 March 2019 - To add to hearings bundle; A41501465 – FW Responses to Parents Question 6A – email from Christine Peters to Fiona McQueen and Craig White – 11 December 2019 – To add to hearings bundle; A41791405 – Risk Assessment Form Airborne Pathogens – February 2020 - To add to hearings bundle.
[187] A48366345 – Alan Beswick, Jodi Brookes, Iwona Rosa, Claire Bailey, Charlotte Beynon, Stephen Stagg and Neil Bennett, 'Room-Based Assessment of Mobile Air Cleaning Devices Using a Bioaerosol Challenge' (2023) – to add to hearings bundle; A48366697 – J.M.B.M van der Vossen, A.P. Kreikamp, V. Hatt, A.M.T. Ouwens, D.J. Brasem, M. Heerikhuisen, R.C. Montijn, 'Establishment and application of test methodology demonstrating the functionality of air purification systems in reducing virus-loaded aerosol in indoor air' (2023) – to add to hearings bundle.
[188] A48366883 – Andrew Conway Morris, Katherine Sharrocks, Rachel Bousfield, Leanne Kermack, Mailis Maes, Ellen Higginson and others, 'The Removal of Airborne Severe Acute Respiratory Syndrome Coronavirus 2 (SARS-CoV-2) and Other Microbial Bioaerosols by Air Filtration on Coronavirus Disease 2019 (COVID-19) Surge Units (2021) – to add to hearings bundle.

9. Other issues

Prophylaxis

9.1 Immunosuppressed person are at a high risk of opportunistic infection. One protective measure that can be used to prevent infections in patients is the use of prophylactic antibiotics especially antifungals. However, many of these therapeutics have serious side effects which can impact on patients and cause serious symptoms in themselves. The use of prophylaxis is a clinical decision but should not be used to cover for deficiencies in ventilation systems especially if the prophylaxis used is likely to have serious side effects.

9.2 It is stated in Cryptococcus Incident Management Meeting Thursday 17 January 2019 that patients in wards 4C and 6A were prescribed prophylactic drugs due to concerns over air quality on these wards during the investigation of the Cryptococcus incident.[189]

9.3 An SBAR issued in July 2015 following the transfer of Bone Marrow Transplant patients from the Beatson to ward 4B of the QEUH expresses concern about the substandard accommodation and states that:

"…Antifungal prophylaxis measures had been taken for some patients prior to the concerns being raised and for others subsequently increased once the problem was identified."[190]

[189] A36690588 – 17.01.2019 IMT Cryptococcus Part 1 AM – Bundle for Oral hearing commencing 12 June 2023 – Bundle 1 – Page 268.
[190] A40240682 – SBAR undated – Clinical Haematology And Allogenic Transplant Service – Environmental Risks – Bundle for Oral hearing commencing 12 June 2023 – Bundle 4 – Page 11 and 12.

9.4 In a later report dated 26 June 2015 it is stated that:

> "The main risk poor air quality poses to patients is significant invasive fungal infection. It is impossible to quantify if there will be an increased risk incurred by moving back to the QEUH compared with the current provision at the Beatson West of Scotland Cancer Centre once the planned upgrade in air handling provision has been completed, given that there will be suboptimal air exchanges and no direct HEPA filtration of the corridor. Until the proposed changes have been made we cannot do air sampling or particle counts to look for fungal colonies. However, we can reduce the risk of invasive fungal infection by using well tolerated and effective anti-fungal prophylaxis such as posaconazole. With the measures that have been taken already, and further measures that are being planned, the air quality is almost certainly going to be adequate to protect patients, albeit the specification does not fully meet HPS standards."[191]

9.5 In an options appraisal for the BMT Unit on 4B dated April 2017

> "There is now very effective anti-fungal prophylaxis and sensitive screening tests, which can be used to manage risk in this patient population. A strategy of effective prophylaxis and confining patients to their rooms with the ward closed to all through traffic will minimise the risk of acquiring fungal infection whilst an inpatient."[192]

[191] A41683213 – 15.06.2016 Proposed Works June 16 – Report from Melanie McColgan to Jennifer Armstrong - To add to hearings bundle.
[192] A38030454 – 04.04.2017 BMT Options Appraisal Report for the Acute Services Committee - To add to hearings bundle.

9.6 An HPS SBAR from October 2017 gives an indication of the trigger for prophylaxis to be considered as the collection of >10 fungal spores per cubic metres[193]

9.7 I do not have the expertise to judge whether these prophylactic drugs would have any adverse effects on patients, but it would be my opinion that they should not be routinely used to protect patients from deficiencies in hospital ventilation systems.

Pigeons

9.8 Pigeons are known to harbour opportunistic pathogens. According to the most recent review "… the most commonly transmitted pathogens continue to be *Chlamydophila psittaci and Cryptococcus neoformans* (Haag-Wackernagel and Moch 2004).[194] Although feral pigeons pose sporadic health risks to humans, the risk is very low, even for humans involved in occupations that bring them into close contact with nesting sites. In sharp contrast, the immunocompromised patient may have a nearly 1000-fold greater risk of acquiring mycotic disease from feral pigeons and their excreta than does the general population". (Haag-Wackernagel and Moch 2004).[195] Pigeons and other birds are often known to be attracted to hospital sites such as QEUH and reports of dead birds and excreta in service floors and other areas have been common in the QEUH. This suggest that, while not proven, a potential transmission route from environmental air contaminated with bird dropping exists and this provides an enhanced case for HEPA filtration of supply air for immunocompromised patients who are at increased risk of infection and at a heightened risk of a serious outcome. These issues will be examined in more depth in forthcoming reports.

[193] A41683174 – 10.2017 SBAR by Health Protection Scotland (HPS) - To add to hearings bundle.
[194] A48379354 – D. Haag-Wackernagel and H. Moch, 'Health hazards posed by feral pigeons' (2004) – to add to hearings bundle.
[195] A48379354 – D. Haag-Wackernagel and H. Moch, 'Health hazards posed by feral pigeons' (2004) – to add to hearings bundle.

Thermal Wheels

9.9 Thermal wheels are a heat recovery system that allows heat from extract air to be returned to the supply air flow. This is thought to be a potential risk by allowing extracted contaminated air to return to patient areas. This should only be a concern when air from an airborne isolation room is returned to a general ward. The use of thermal wheels is addressed in the CDC Guidance for TB isolation (Jensen et al 2005) where it states that:

> "Heat wheels are often used to reduce the costs of operating ventilation systems. If such units are used with the system, a HEPA filter should also be used. As the wheel rotates, energy is transferred into or removed from the supply inlet air stream. The HEPA filter should be placed upstream from the heat wheel because of the potential for leakage across the seals separating the inlet and exhaust chambers and the theoretical possibility that droplet nuclei could be impacted on the wheel by the exhaust air and subsequently stripped off into the supply air."[196]

9.10 I assume that a well-maintained thermal wheel should pose limited risk to patients due to the limited likelihood of transferring potentially contaminated air from extract to supply and the dilution of any contamination in the fresh supply air.

[196] A48363884 – Paul A. Jensen, Lauren A. Lambert, Michael F. Iademarco, Renee Ridzon, 'Guidelines for Preventing the Transmission of Mycobacterium Tuberculosis in Health-Care Settings, 2005' (2005) – to add to hearings bundle.

Air Sampling Results

9.11 Microbiological air sampling is regularly carried out on wards containing patients with immunosuppression. The method of air sampling used in the QEUH was based on those used in other parts of NHSGGC (LP089 North Glasgow 2015) and it is assumed this was used for air sampling from 2015 to 2019. After then, the SOP developed for QEUH in 2019 is number LP539. It is a controlled document but the version I have seen is not a controlled copy. It includes particle counting using lase counters and describes a similar protocol for microbiological air sampling. Monthly monitoring is prescribed for Royal Hospital for Children, Ward 2A, Paediatric BMT Rooms and for QEUH 4B – Haematology ward (BMT).

9.12 This sampling should be able to identify if the presence of fungal pathogens exceeds trigger levels and thus identify ventilation issues. It should also allow an assessment to be carried out of potential patient exposure to opportunistic pathogens in the air. I have not been able to see any of these reports.

9.13 Particle counting of wards has been carried out widely and such results seem to have driven interventions to use re-circulating HEPA filter units in wards without adequate pressure cascades and supply HEPA filtration on Ward 4C and Ward 6A to reduce counts to acceptable levels.[197] While particle counts are a valuable tool at ensuring levels of air cleanliness the relationship between particle counts and microbial contamination is not direct and particle counts are not a measure of patient exposure to aerosols

[197] A41791142 – Risk Assessment Form Airborne Pathogens – 22nd June 2021 – to add to hearings bundle; A41893863 – RFI 10 Response 4.1 – 4.7 final – to add to hearings bundle.

Sewage Works

9.14 The QEUH is sited close to a major sewage works as was the previous Southern General Hospital. The adjacency has led to concerns about odours detected within the hospital, which led to considerations for the use of carbon filters for the air intakes. However, odours do not always indicate the presence of microorganisms in the air. It is unknown whether significant microbial aerosol contamination is generated from the sewage works, whether the high level intakes at the QEUH would entrain potentially contaminated air, whether this contamination could be present in ward areas and how these levels would relate to other sources of contamination. There is also a large re-cycling centre close to the site. This type of facility is known to generate high levels of fungal and bacterial pathogens (Kontro et al 2020).[198] The impact of proximity to these facilities will be reviewed in a forthcoming report.

Flexibility

9.15 A new build hospital will be expected to have a long operational life. For example, the expected working life of air handling units is 20 years (SHTM03-01 2014).[199] It will be used to treat patients in a safe and appropriate environment that will help to produce the best clinical outcomes. It should be designed with an eye on potential future developments by having a degree of flexibility in its design. As part of the design ventilation will be required to ensure a safe and comfortable environment for treatment and a higher level of specialist ventilation to allow safe isolation of infectious cases and protective isolation of patients undergoing treatment for immunosuppressing diseases or undergoing immunosuppressive therapy.

[198] A48367102 – Merja H. Kontro, Maija Kirsi, Sirpa K. Laitinen, 'Exposure to bacterial and fungal bioaerosols in facilities processing biodegradable waste' (2022) – to add to hearings bundle.
[199] A35610757 – SHTM 03-01 Part A February 2013 - Hearing Commencing 9 May 2022 – Bundle 1 – Page 473.

9.16 The current guidance documents are written and authorised by acknowledged experts and should be regarded as best practice and should be fully incorporated in the design of a new hospital and be at least a target for existing hospitals. No-one (staff, patients, public) would expect that a new hospital would not meet current guidance in any area without good reason. If a new hospital is not designed to meet guidance then there should be a written rationale for the derogation agreed by all interested parties included infection control specialists that clearly explain the rationale and why this will not impact in patient comfort and outcome.

9.17 The future requirements for hospital ventilation during its expected lifetime are unknown but they will be impacted by clinical practice, predicted rise in antibiotic resistance microorganisms and social factors such as sustainability. These are difficult to foresee but may require a degree of flexibility to be designed into the hospital to allow for increasing ventilation requirements. This may include designing ventilation systems to be under-capacity and allowing room for additional ventilation systems in service areas. This may seem to be an additional cost when building the hospital but will potentially have major cost savings over the life of the hospital by limiting costly post build renovations and building work.

10. Main Conclusions

Design

10.1 The UK and Scotland has clear and accepted guidance on ventilation in healthcare facilities that was in place during the design and construction period for the QEUH and RHC and known to the designers and the NHSGGC team.

10.2 The QEUH general wards were designed with a lower air change rate of 2.5 air changes per hour than the 6 air changes per hour recommended in guidance. The reduction in air change rate in the design proposed by Brookfield and accepted by the Board was taken to provide a more energy efficient hospital and to meet BREEAM targets but I have not seen any documentation that considers the impact on reduced air change rate on the transmission of infection within the hospital.

10.3 I have assumed from the documents I have seen that no consideration appears to have been given on the need for specialist ventilation in the original design of the hospital. This was either due to an assumption that such facilities were not required or an oversight in the design team.

10.4 There seemed to be a disconnect between the hospital design team and the cohort of experienced IC professionals with a knowledge of specialist ventilation systems located in the Glasgow area in Yorkhill and the Brownlee unit who I have assumed were not consulted during the design process. I consider this assumption to be likely given the limited information suggesting there was little if any collaboration between the design team and IC professionals during the design phase of the project who appear not have been consulted during the design process for specialist wards such as 2A and 4B.

10.5 When patients and clinical staff are being decanted from their previously used hospital to a new build hospital, they will be expecting an improvement in the facilities and practices that will at least duplicate those they are familiar with. If there are changes in the facilities this needs to have been explained to and agreed with the clinicians and potentially explained to the parents and families before the move. Any reduction in specification will be the cause of concern to staff, patients and parents and create stress among them unless a clear rationale is given. This was the case when patients were transferred from the Yorkhill site. Lack of this communication will lead patients and staff to focus any concerns about HAI on the facility issues.

Evidence for Protective Impact of Ventilation

10.6 Research studies show that a correctly functioning isolation room (negative pressure, positive pressure or PPVL) can provide a high level of protection in preventing transfer of airborne particles and airborne microorganisms.

10.7 It has been shown that directional airflow can be used to greatly reduce transfer of airborne particles from or into isolation rooms. In practice, to ensure that directional airflow is maintained in the correct direction, the pressure differential across the door needs to be maintained at a high enough level to protect against flow reversals. Therefore pressure differentials need to be monitored to ensure correct operation of isolation rooms.

10.8 There is good evidence that the placement of tuberculosis patients in single rooms without controlled negative pressure and low air change rates risks the transmission of tuberculosis to staff and patients on the same ward.

Compliance with Guidance

10.9 The air change rates specified in UK and Scottish guidance have been in place and remained stable since 2007 at 6ACH for wards/single rooms and 10ACH for specialist ventilation facilities and was in place during the design and construction of QEUH.

10.10 Recommendations for the pressure differentials of positive and negative pressure isolation have been consistent in guidance since 2005 with a recommended positive pressure of +10Pa and -5Pa respectively for these rooms.

10.11 In my opinion, the advice on the use of HEPA filters in HTM03-01 and SHTM03-01 is patchy and not helpful for infection control teams or designers of specialist ventilation rooms.

10.12 The current patient placement SOP from 2024 defines the design of PPVL and negative pressure rooms very strictly i.e. defined pressure differential but there are no ACH or pressure differentials defined for the BMT rooms.

10.13 It seems that there was a major change of attitude to CBUs between 2007 and 2021 possibly caused by issues surrounding QEUH and other hospitals. The requirement for dew point control of CBUs has been specified in guidance since 2007 as has the need for regular maintenance/cleaning and access for maintenance/cleaning. However, dew point controls were not installed leading to widespread condensation events in the QEUH.

10.14 For isolation suites there has been guidance on permeability testing since 2005. Such testing would not be compatible with false ceilings used in wards at QEUH/RHC.

10.15 The requirement for commissioning has always been part of guidance for new hospital buildings. In particular, SHPN 04 Supplement 1: Isolation facilities in acute settings from 2008, explicitly states the commissioning requirements for protective isolation facilities.

Impact of Ventilation Deficiencies

10.16 The lower air change rate on general wards than recommended in guidance in the QEUH and RHC would potentially increase the risk of transmission of respiratory infection in general wards between patients, staff and visitors especially in respiratory virus season as compared to a standard ward. However, without further analysis the magnitude of increased risk cannot be quantified.

10.17 When Ward 2A was opened in 2015 it was found to be built to the specification of a general ward, a specification far lower than the wards that housed patients at Yorkhill and the Clinical Output Specification. Nevertheless, it housed patients requiring specialist ventilation facilities until September 2018. On re-opening in 2022 after commissioning and validation the Ward 2A seems to be built to meet and in some ways exceed all requirements of UK and Scottish guidance.

10.18 It is disappointing despite significant remedial works that ward 4B still does not meet the intention to replicate the standards shown in the Beatson facility which was built and commissioned in the 1990s and to perform to ventilation standards specified in HTM03-01 (2007) and SHTM03-01 (2013). It is also disappointing that the operational specification of the ventilation system used to protect these patients is currently far below that of Ward 2A.

10.19 Ward 4C is operating at a lower specification than ward 4B. The most recent risk assessment (2021)[200] gives a risk rating of 9, which conforms to an estimate that currently on Ward 4C there may occur occasionally severe illness from airborne pathogen exposure on this ward. The ventilation surveys confirm the low ACH and only nominal pressure differential. I am unaware of any clinical reason why these patients require less protection from microbial air contamination than those on Wards 2A and 4B.

10.20 The situation with ward 6A is very similar to that of Ward 4C and the comments from the previous section hold for Ward 6A. In fact, there seems to be no difference between these rooms and those on other wards for less immunosuppressed patients. I am unaware of any clinical reason why these patients require less protection from microbial air contamination than those on Wards 2A and 4B.

10.21 In Wards 4C and 6A there is widespread use of portable HEPA filter units placed on the floor in corridors and within patient rooms. These have been used instead of supply HEPA filtration. The use of mobile HEPA filters in these wards cannot prevent the ingress of opportunistic pathogens from the outside air but can only reduce levels within the wards. I have not seen any information calculating the additional air changes provided by these units and evidence that the units placement makes them effective in protecting the patients in these wards.

10.22 JACIE ventilation guidance indicates that the use of high level filtration and positive pressurisation is needed for high risk patients to comply with JACIE standards and if not a written protocol determining patient placement prioritization is required. Such a document has not yet been provided to the Inquiry to my knowledge.

[200] A41791142 – Risk Assessment Form Airborne Pathogens – 22nd June 2021 – to add to hearings bundle

11. Declaration

- I understand that my duty is to help the Inquiry on matters within my expertise and that this duty overrides any other obligation.

- I have stated the substance of all material instructions, on the basis of which the report is written. My evidence is my independent product, uninfluenced by external pressures.

- The opinions I have expressed are objective, unbiased and based on matters within my own expertise and I have not adopted the role of an advocate. I have made clear if a question or issues falls outwith my area of expertise.

- I have considered whether there is a conflict of interest and declared any potential conflict identified.

- I have given details of any literature or any other material relied on in making the report.

- I have set out the substance of all facts which are material to the opinion expressed in this report or upon which my opinions are based.

- I have said when there is a range of opinion on a relevant issue and summarised the range of opinions and I have formed my own independent view as to the appropriate point in that range applicable to this case and given reasons for that view.

- I have made clear which of the facts stated in the report are within my own knowledge. Those that are within my own knowledge I confirm to be true. The opinions I have expressed represent my true and complete professional opinions on the matters to which they refer.

……

Mr Allan Bennett Date: 05/06/2024

12. Guidance Documents

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Glossary

ACH – Air changes per hour

AHU – Air Handling Unit

ATTMA - Air Tightness Testing & Measurement Association

BSRIA - Building Services Research and Information Association

CBU – Chilled Beam Unit

CDC – Centers for Disease Control (US)

CFD – Computational Fluid Dynamics

CIBSE – Chartered Institution of Building Service Engineers

COSHH – Control of Substances Hazardous to Health

HEPA filter - High efficiency particulate air filter

HDU – High Dependency Unit

HSE – Health and Safety Executive

HTM - Health Technical Memorandum

HVAC – Heating, ventilation, and air conditioning

ITU – Intensive Therapy Unit

JACIE - The Joint Accreditation Committee ISCT-Europe & EBMT

LEV – Local Exhaust Ventilation

MDR TB – Multi Drug Resistant Tuberculosis

NHSGGC – NHS Greater Glasgow and Clyde

NICE – National Institute for Clinical Excellence

PPVL room – Positive Pressure Ventilated Lobby room

RPE- Respiratory Protective Equipment

RSV – Respiratory Syncytial Virus

SHTM- Scottish Health Technical Memorandum

SOP- Standard Operating Procedure

VSG – Ventilation Safety Group


SCOTTISH
HOSPITALS
INQUIRY

SCOTTISH HOSPITALS INQUIRY

REVIEW OF CRYPTOCOCCUS CASE INVESTIGATIONS AT QEUH/RHC

Prepared by Allan Bennett

Contents

1. Scope

1.1 In the letter of instruction issued to me on the 19 June 2024[1] I have been asked to address three key questions (paraphrased):

- Risk assessment and infection link – to identify whether there is an association QEUH/RHC and the cases of *Cryptococcus neoformans*
- Whether these cases were remarkable?
- Was the methodology used by the subgroup to investigate the cases adequate and should subsequent cases be included?

2. Experience and Qualifications

2.1 I graduated from Glasgow University in 1983 with a 2.1 degree in Microbiology and then obtained a M.Sc in Process Biotechnology from the University of Birmingham in 1984. I worked for three years at the National Engineering Laboratory in East Kilbride on biochemical engineering projects before joining PHLS CAMR at Porton Down in 1988. I subsequently worked at Porton Down for the Health Protection Agency, Public Health England and UKHSA until I retired in 2023.

2.2 Over the 35 years I worked at Porton Down my research interests have been around the airborne transmission of infection and its prevention. For the last 20 years, I have headed a research group of 10-20 scientists carrying out research in this area. During this time, I had my own research programme and obtained external funding from and delivered projects for NHS Estates, Home Office, EU, European Space Agency, WHO, and various research councils. I have over 140 research publications with an h=35.

[1] **A49818107** – Allan Bennett letter of instruction in respect of Cryptococcus report 19.06.2024, Bundle 24, volume 3, document 1.

2.3 As part of this group, I led a team carrying out independent testing of a wide range of equipment used in laboratories, healthcare and pharma. This included testing of filters, microbiological air samplers, air cleaners to agreed protocols and international standards. For part of that time, I also was involved with the annual testing of laboratory ventilation/filtration and that of specialist containment equipment within my organisation and in dstl laboratories also at Porton Down. On occasion I carried out testing or assessment of containment systems for HSE as part of their investigations.

2.4 I have experience of leading investigations of the microbial contamination of air in dental surgeries, sewage treatment works, waste transfer stations and other industries. I also headed environmental sampling teams into anthrax cases associated with drumming. During the 2009/10 influenza pandemic, the 2020/22 COVID pandemic, the mPox outbreak 2022 I led teams measuring the concentration of influenza, SARS-CoV-2 and mPox in healthcare environments in air and on surfaces. The published results of these studies impacted on infection control guidance in the UK.

2.5 During the COVID pandemic I was a member of the SAGE Environment and Modelling Subgroup and contributed to a wide range of papers related to the impact of ventilation and other factors on the spread of SARS-CoV-2. I also was a member of SDCEP Mitigation of Aerosol Generating Procedures in Dentistry – A Rapid Review Working Group and contributed to develop guidance on ventilation in dentistry.

2.6 From 2008-2020 I was involved as a subject matter expert in projects to replace the high containment facilities at Porton Down. This involved working with architects, designers and safety experts in order to design new facilities that would conform to regulations and be acceptable to regulators. I used this experience as a work package manger on the EU funded ERINHA project in which I worked with BSL4 facilities, international architects to provide guidance in the design of high containment facilities. I also worked on project with the European Space Agency and EU into the design of laboratories for the investigation of samples returned from Mars. I was a member of the editorial committee of the 4th edition of the WHO Laboratory Biosafety Manual and was co-head of a WHO Collaborating Centre in Applied Biosafety and Training from 2019-2023.

2.7 I am a member of the International Editorial Board of the Journal of Hospital Infection and have reviewed over 70 publications on the roles of the environment in infection control in healthcare. I have contributed to teams investigating nosocomial infection outbreaks including the NI neonatal Pseudomonas outbreak, the global outbreak of *Mycobacteria chelonae* associated with cardiac surgery and sink associated CPE.

2.8 My publication list can be accessed on Google Scholar (Allan Bennett - Google Scholar)

3. Limitations

3.1 I am an expert in the transmission of airborne micro-organisms and in the prevention of their spread. I have no clinical expertise and no experience of day-to-day working in the hospital environment. I have knowledge of aerosol science but not fluid dynamics.

3.2 I have knowledge of ventilation systems and concepts but I am not a ventilation professional authorised person or engineer.

3.3 I have carried out limited review of the scientific literature in some areas but have not had the time or resources to carry out any full literature reviews.

3.4 I have no knowledge of therapeutic aspects in the control of fungal infections.

4. Approach

4.1 In this report I address the three questions from the letter of direction by reviewing the general background literature about Cryptococci including diagnostics, UK epidemiology, local epidemiology and incubation period. I then discuss how the investigation subgroup operated and the process to produce their report. I then critically review how the various hypotheses were addressed in the report. Finally, I summarise my responses to the key questions.

5. Background

A. Cases at QEUH/RHC

5.1 Two cases of *Cryptoccocus neoformans* (CN) infection were reported in Queen Elizabeth University Hospital (QEUH) and the Royal Hospital for Children (RHC) within a few weeks in [redacted] 2018[2]. In both cases the patient died shortly after the agent was detected. Since CN is considered an unusual agent of infection in the UK (Lamagni et al 2001)[3] a common source was postulated by the IMT. As the agent can be derived from pigeons (Haag-Wackernagel & Holger Moch 2004)[4] and a pigeon infestation in plant rooms on level 12 was concurrent with the diagnosis of these infections this linkage was subject to speculation and an investigation. As part of the investigation a subgroup of the Incident Management Team (IMT) was set up by NHS Greater Glasgow and Clyde (GGC) to investigate a number of hypotheses for the route of infection which is detailed within the minutes of the subgroup and in a report issued in April 2022[5]. In this report I will critically review the investigation and the report using the report and the minutes as my main source of information. I will also consider another three cases of Cryptococcal infection: CN infections in two patients who have had short stays at QEUH/RHC in 2018 and another Cryptococcal case identified in 2020.

B. Cryptococcus Diagnosis

5.2 Cryptococcus infection can be detected using simple lateral flow assays called Cryptococcus antigen tests (CRAG) which can be used in hospitals with serum and CSF samples (Nalintya et al 2016)[6]. However, to differentiate between species culture is regarded as a gold standard. In a recent review it is stated:

[2] **A36605178** - 20.12.2018 IMT Cryptococcus, Bundle 1, document 55, page 245
[3] **A49642999** – T. L. Lamagni, B. G. Evans, M. Shigematsu and E. M. Johnson, 'Emerging trends in the epidemiology of invasive mycoses in England and Wales' (1990-9), Bundle 14, volume 4.
[4] **A48379354** - Daniel Haag-Wackernagel and Holger Moch, 'Health hazards posed by feral pigeons' (2004), Bundle 14, volume 4.
[5] **A38662680** - Report prepared by Cryptococcus IMT Expert Advisory Sub-Group dated 5 April 2022, Bundle 24, volume 3. Also produced in earlier more extensively redacted form as document A39235063, Bundle 6, document 39.

[6] **A49776504**- Elizabeth Nalintya, Reuben Kiggundu, David Meya, 'Evolution of Cryptococcal Antigen Testing: What is new?' (2016), Bundle 14, volume 4.

> Fungal culture from blood, CSF, sputum, urine, BALF or other relevant clinical specimens is recommended in all patients suspected of cryptococcosis for genus and species identification. (Chang et al 2024)[7]

5.3 Therefore, it is expected that a Cryptococcal infection will be always confirmed by culture to allow CN to be differentiated from other Cryptococcal strains. This normally requires incubation of samples for 2-3 days on agar plates but some authors suggest longer incubation if anti-fungal therapy has been initiated (Maziarz et al 2016)[8]. Further differentiation of strains can be carried out by specialised techniques such as MALD-ToF or genetic sequencing (Misra et al 2023)[9].

C. Cryptococcus Epidemiology and Incidence in the UK

5.4 *Cryptococcus neoformans* is an opportunistic fungal pathogen derived from environmental sources that can cause serious infection mainly in immune-compromised hosts that can lead to fatality. Cryptococcal infections are rare in the UK and have been reported to be mainly limited to those with HIV and underlying immune disorders (Lamagni et al 2001)[10].

5.5 CN is one of the four highest priority fungal agents on the WHO fungal priority pathogens list to guide research, development and public health action (WHO 2022)[11] and this has led to a recent resurgence of interest in this pathogen.

5.6 Surveillance of the frequency of occurrence of a pathogen depends on the diagnostic method used, the likelihood of a diagnosis being attempted and the reporting of test results. Many diseases may be under reported due to lack of diagnostic method or samples not being sent to the diagnostic laboratory for the relevant test or test results not being centrally reported. There is a statutory duty to report notifiable diseases to UKHSA for national reporting but Cryptococcal infections are not listed as notifiable.

5.7 Lamagni et al (2001)[12] reported UK data on Cryptococcal infections reported to the PHLS Communicable Disease Surveillance Centre from 1990-99 and found only

[7] **A49776502** – C. C. Chang, T. S. Harrison, T. A. Bicanic, M Chayakulkeeree, T. C. Sorrell, A. Warris and others, 'Global guideline for the diagnosis and management of cryptococcosis: an initiative of the ECMM and ISHAM in cooperation with the ASM2' (2024), Bundle 14, volume 4.
[8] **A49776505** - Eileen K. Maziarz, John R. Perfect. 'Cryptococcosis' (2016), Bundle 14, volume 4.
[9] **A49776506** – Anisha Misra, Zachary A. Yetmar, Amber A. Milone, Lydia A. Ruefthaler, Nancy L. Wengenack, Paschalis Vergidis and Elitza S. Theel, 'The Brief Case: the Cryptic Cryptococcus' (2023), Bundle 14, volume 4.
[10] **A49642999** – T. L. Lamagni, B. G. Evans, M. Shigematsu and E. M. Johnson, 'Emerging trends in the epidemiology of invasive mycoses in England and Wales' (1990-9), Bundle 14, volume 4.
[11] **A49643002** - WHO, 'WHO fungal priority pathogens list to guide research, development and public health action' (2022), Bundle 24, volume 4.
[12] **A49642999** – T. L. Lamagni, B. G. Evans, M Shigematsu and E. M. Johnson, 'Emerging trends in the epidemiology of invasive mycoses in England and Wales' (1990-9), Bundle 24, volume 4.

15-41 annual cases which were mainly HIV associated with the highest incidence in London. Over the period reported the incidence in males varied from 0.31-1.38 per million and 0.04-0.41 per million in woman, incidence in children was lower (<0.1 per million for ages between 1-14). The authors suggest that Cryptococcal infection cases were under-reported in the UK. In a review from the UK in 2017, the authors estimated fewer than 100 cases of cryptococcal meningitis per annum based on information from the PHE Mycology Reference Laboratory in Bristol (Pegorie et al 2017)[13] but they caution that data is limited.

5.8 UKHSA Mycology Reference Laboratory data provided to the Inquiry shows a similar picture with the numbers of CN isolated at the laboratory varying between 28 and 38 between 2016 and 2023[14]. They also reported 39-54 positive CRAG tests carried out on serum and CSF samples. This data is not directly comparable to the Lamagni data as the published data for 1990-1999 is for reported Cryptococcal cases and the UKHSA data is for number of CN isolates identified. UKHSA state in their response to the enquiry that:

1. The UKHSA Mycology Reference Laboratory will not receive isolates from all patients with cryptococcal infection; for some patients there will be no isolates obtained and for others the local and regional mycology/microbiology laboratories will be able to deal with the samples without involving the reference laboratory. In some cases there may be multiple specimens received by the laboratory related to sequential sampling of the same patient with the same infection. Furthermore, the data within each dataset has been de-duplicated as far as possible, but not between data sets.

2. Cryptococcal antigen testing is a simple test that can often be conducted locally by non-specialised laboratories so positive results with this test reported by or known to UKHSA will be an underestimate of total cases in the UK. A positive result is highly suggestive of an infection with *Cryptococcus neoformans* or *Cryptococcus gattii* but cannot distinguish between them. It will not detect infection with *Naganishia* species. This test is frequently repeated on patients over time to monitor the response to treatment.

5.9 Therefore, the number of isolates reported by the reference laboratory may be an underestimate. However, it seems to be best practise that following a positive CRAG test, microbial culture should be carried out. QEUH/RHC seemed to do this and use the UKHSA mycology reference laboratory to carry out the isolation and identification. It is unknown whether culture is carried out in other laboratories within the UK and how many positive isolates are detected thus way and not reported to

[13] **A48089427** - Matthew Pegorie, David W. Denning, William Welfare, 'Estimating the burden of invasive and serious fungal disease in the United Kingdom' (2017); Bundle 24, volume 4.
[14] **A49629675** - UKHSA Rule 8 response, Bundle 24, volume 3, document 2, page 14.

UKHSA. It is disappointing that PHLS (UKHSA's predecessor) seems to have had a system to monitor case numbers unavailable to UKHSA.

D. Kennedy Report

5.10 Following the identification of the two cases of the two CN cases, Dr Kennedy of the Health Protection Unit of NHSGGC carried out a rapid epidemiological investigation of Cryptococcus cases in the NHSGGC Health Board Area from 2009-2018 and reported on the 10th of January 2019[15]. He identified 19 cases in this period. Cases were predominantly male (14/19, 74%), and median age was 53 (range 1 year to 80 years) and in the earlier years the cases were mainly in patients with HIV. 2018 had the highest number of cases mainly in patients with underlying haematological conditions (5), with cases clustered in the second half of the year. The second highest incidence was in 2010 with 4 cases. Some of the earlier cases were regarded as HCAI associated with venupuncture i.e injection site infection. No information was given on the diagnostic tests carried out and whether all cases were culture positive, what percentage were CN and whether some cases were only CRAG tested. No conclusions were made in the report on epidemiological linkages.

E. Theoretical Incidence in NHSGGC compared to UK

5.11 The UKHSA data from the reference laboratory from 2016-2023 reports 28-38 isolates per annum[16]. While this is likely to be an underestimate it also may represent multiple samples from the same patients. It also seems that all the QEUH/RHC samples were sent to the reference laboratory. As this is the best current data available, I use it to calculate an estimated incidence of CN infection in the UK.

5.12 If we take the UK population being 67 million from 2012 (ONS)[17] then the incidence of isolates of CN from the UKHSA reference laboratory in the UK was between 0.43 and 0.57 per million for the UK. NHSGGC covers a population of 1.3 million (NHSGGC)[18]. If we calculate the expected number of isolates in this population based on UK numbers, we get a rate of 0.56-0.74 per annum.

[15] **A38662680** - Review of cryptococcus spp cases diagnosed in NHS Greater Glasgow and Clyde laboratories, Bundle 24, volume 3, document 3, page 18.
[16] **A49629675** - UKHSA Rule 8 response, Bundle 24, volume 3, document 2, page 14.
[17] Office for National Statistics (ONS), released 21 December 2022, ONS website, statistical bulletin, <https://www.ons.gov.uk/peoplepopulationandcommunity/populationandmigration/populationestimates/bulletins/annualmidyearpopulationestimates/mid2021>
[18] Who we are - NHSGGC <https://www.nhsggc.scot/about-us/who-we-are/>

5.13 Using the maximum rate in Pegorie et al (2017)[19] of 100 cases of Cryptococcal meningitis per annum we get a UK incidence of less than 1.5 cases per million per annum and an expected annual case number of less than 1.94 in NHSGGC.

5.14 Therefore, the two cases investigated by the sub group, the four reported by QEUH/RHC and five by NHSGGC in 2018 exceed the expected annual case numbers using the UKHSA and Perogie figures. There can be many explanations for this:

- Randomness – This may reflect natural variation. I have not carried out any statistical analysis on this data.
- QEUH/RHC is more likely than the average hospital to send samples to the Mycology Reference laboratory.
- QEUH/RHC patient groups are more susceptible to CN infection
- There was something linked to QEUH/RHC that caused a higher rate than other healthcare areas which could be linked to environment or treatment
- Other NHS areas more likely to do in house culture for CN in other laboratories

F. Incubation Period

5.15 The time from initial exposure to a micro-organism until symptoms occur or diagnosis is called the incubation period. CDC on their website state:

> The incubation period of cryptococcosis is not well-established. Symptoms of cryptococcal infection typically appear weeks to months after breathing in spores. However, people can develop an infection many years after exposure, which is usually a form of reactivation when the person develops a weakened immune system. (CDC 2024)[20]

5.16 Garcia-Hermosa et al (1999)[21] have provided evidence that Cryptococcus infection can occur over 10 years post infection by identifying African strains in patients with no record of travel to Africa in the past ten years.

5.17 Meya and Williamson (2024) report[22] that studies have shown that 5% of healthy volunteers had antibodies to Cryptococci with higher levels amongst risk groups such as children living in inner city New York.

[19] **A48089427** - Matthew Pegorie, David W. Denning, William Welfare, 'Estimating the burden of invasive and serious fungal disease in the United Kingdom' (2017), Bundle 24, volume 4.
[20] [Clinical Overview of Cryptococcosis | Cryptococcosis | CDC <https://www.cdc.gov/cryptococcosis/hcp/clinical-overview/index.html>
[21] **A49642998** – D. Garcia-Hermoso, G. Janbon, F. Dromer, '' (1999), Bundle 24, volume 4.
[22] **A49643001** - David B. Meya, Peter R. Williamson, 'Cryptococcal Disease in Diverse Hosts' (2024), Bundle 24, volume 4.

5.18 In a recent review by Dao et al (2024)[23] it states:

> Latency and dormancy are also important aspects of cryptococcal pathogenesis. The fungus can remain dormant in the host due to both immune pressure and fungal factors, and in certain host environments, including granulomas, it can avoid immune detection. Reactivation of dormant cryptococci becomes a concern when the host's immune system becomes compromised, potentially leading to invasive disease

5.19 Therefore, due to dormancy and latency and an uncertain incubation period it is extremely difficult to identify incidents that lead to infections in Cryptococcus patients since the exposure could have occurred in a period of weeks to years before symptoms or diagnosis.

6. Incident Management Sub Group

A. Terms of Reference

6.1 The incident management subgroup was set up in February by the IMT[24] led by Dr John Hood with the following purpose[25]:

> "Provide expert advice and evidence to the Incident Management Team (IMT) on the current and any further hypotheses relating to the Cryptococcus Incident within QEUH/ RHC"

6.2 And its role and remit were as follows

- Review the current main hypotheses relating to the presence of Cryptococcus species within air samples at QUEH and RHC.
- Review the associated engineering and microbiology data informing the main hypotheses.
- Consider all potential sources through review of the full ventilation system, outdoor areas/ courtyards and the helipad.

[23] **A49776503** - Aiken Dao, Hannah Yejin Kim, Katherine Garnham, Sarah Kidd, Hatim Sati, John Perfect, Tania C Sorrell, Thomas Harrison, Volker Rickerts, Valeria Gigante, Ana Alastruey-Izquierdo, Jan-illem Alffenaar, C Orla Morrissey, Sharon C-A Chen and Justin Beardsley, 'Cryptococcosis—a systematic review to inform the World Health Organization Fungal Priority Pathogens List' (2024), Bundle 24, volume 4.
[24] **A39233720** - IMT Expert Advisory Sub-Group Minutes - Cryptococcus - 14 February 2019, Bundle 9 QEUH Cryptococcus Sub-Group Minutes - document 1, page 5.
[25] **A39234207** - IMT Expert Advisory Sub Group - Draft Terms of Reference - Bundle 9 - QEUH Cryptococcus Sub-Group Minutes – Document 37, Page 304.

- Develop and advise IMT on current hypotheses and any further hypotheses identified through review
- Advise on related control measures including airflow changes, HEPA filtration, enhanced cleaning and building management.

6.3 Susan Dodd of NSS in stated in her witness statement[26] that Dr Inkster as chair of the IMT did not sit on the sub group and the intention was that the final report would be issued to Dr Inkster as chair and the IMT would re-convene to consider the findings. The terms of remit did not include carrying out an epidemiological investigation of the CN cases only to identify the source of Cryptococci in air samples. This led to a focus on identifying Cryptococci in air samples and trying to identify mitigations not on investigating if the patients were exposed to the agent during their hospital stay between [redacted] 2018. The focus was on the present not the past. It was an advisory group reporting to the IMT. The Incident was declared closed on the 15th February 2019 and the IMT stood down[27] but the subgroup continued their meetings into 2020 and produced a final draft report on the 5th April 2022[28].

B. Membership

6.4 The group was chaired by Dr John Hood, Consultant Microbiologist and reported to and took direction from, the Incident Management Team through the IMT Chair.

6.5 The group was made up of the following participants (NHSGGC employees in bold)[29]

Dr John Hood (Chair)	**Consultant Microbiologist**
Tom Steele	**Facilities Director**
Colin Purdon	**Senior Estates Manager**
Ian Powrie	**Deputy General Manager - Estates**
Annette Rankin	Nurse Consultant, Health Protection Scotland

[26] **A49391416** – Witness Statement of Susan Dodd, Witness Bundle Volume 2, document 6, page 264.
[27] **A37750823** – HIIORT dated 15 February 2019, Bundle 24, volume 3, document 4, page 21.
[28] **A38662680** - Report prepared by Cryptococcus IMT Expert Advisory Sub-Group dated 5 April 2022, Bundle 24, volume 3, document 5. Also produced in earlier more extensively redacted form as document A39235063, Bundle 6, document 39.
[29] **A39234207** - IMT Expert Advisory Sub Group - Draft Terms of Reference - Bundle 9 - QEUH Cryptococcus Sub-Group Minutes – Document 37, Page 304.

Ian Storrar	Head of Engineering, Health Facilities Scotland
Dr Peter Hoffman	Public Health England (on advisory basis)
Dr Andrew Seaton	Consultant Physician Infectious Diseases (one meeting only)
Darryl Conner	**Authorised Engineer**
Tom Walsh	**Board Infection Control Manager**

6.6 Dr Seaton left the group after one meeting and was not replaced[30]. The membership of the group included 5 NHSGGC estates staff, 2 other NHSGGC staff and 3 external experts from HPS, HFS and PHE. This is not an independent group and was not intended to be an independent group but an internal investigation by NHSGGC staff aided by external experts. It is a group tasked with finding potential sources of Cryptococcus at QEUH/RHC and introducing mitigations intended to reduce any environmental infection risk. There were no fungal infection experts or epidemiologist on the group to investigate the potential source of these infections. It is also noticeable that infection control doctors with an interest in these infections such as Christine Peters were not included in the group.

C. Meetings and Minutes

6.7 The minutes of the group are available as a bundle and there was a minute taker for each meeting [31]. Concerns have been expressed by NSS that:

> Version control for minutes was confusing and there were examples of when minutes did not reflect discussion at the group meetings[32]

6.8 It is unknown whether minutes were signed off as a true record.

[30] **A39233718** – IMT Expert Advisory Sub-Group Minutes – Cryptococcus – 22 February 2019 - Bundle 9 - QEUH Cryptococcus Sub-Group Minutes – Document 2, Page 12
[31] **A47175206** - Scottish Hospitals Inquiry - Hearing Commencing 19 August 2024 - Bundle 9 - QEUH Cryptococcus Sub-Group Minutes
[32] **A48189468** – NSS Response to Question 2 of Request for Information dated 11 March 2024, Bundle 24, volume 3, document 7, page 117.

7.Report

7.1 The report I have been provided with was dated 5/4/2022 and titled a final draft[33]. This was over three years after the cases were identified and the IMT closed down. There is no circulation list given.

A. Rationale

7.2 The report does not contain an explanation of an aim or a scope. It is unclear the audience the report is aimed at. The IMT had been long been closed down by the time the report was dated so it was presumably written for consideration by the hospital senior management and infection control management. Due to the large amount of patient identifying information included I assume it was never meant for a wider audience. The report has an unusual structure and lacks a pithy executive summary and list of recommendations or conclusions. It is based on weighing up a number of hypotheses and giving them a probability assessment but at times it follows tangential paths.

B. Structure and Content

7.3 As stated above it is unclear who is the expected audience for the report. My critique of the report is on the basis of its clarity and how it deals with the hypotheses. This may be a little unfair as there appears to have been little administrative assistance for this task. The report does not read like a final version and does not appear to have gone through a final edit. The Table of contents is not correctly formatted, the summary of findings is 4 pages long and includes information you would expect to be in a discussions section. There is no Executive Summary. The report introduces papers throughout and individually summarises their contents them, often including full paragraphs in the text. There is an unnecessary amount of PII. There are no conclusions or recommendations section. It is not an easy read and I agree with the views of NSS stated below.

[33] **A38662680** - Report prepared by Cryptococcus IMT Expert Advisory Sub-Group dated 5 April 2022, Bundle 24, volume 3, document 5. Also produced in earlier more extensively redacted form as document A39235063, Bundle 6, document 39.

C. NSS Position

7.4 NSS expressed concerns with the report[34]. In general, they had concerns about the amount of patient information in the report, with the report structure and the lack of a methodology. They felt that some of their comments had not been addressed and there was no record of how comments had been dealt with. They also had concerns about how the report's conclusions had been presented to the NHSGGC board. From the RFI response from NSS

- A position paper had been developed for presentation to HSE which NSS were concerned did not reflect conclusions by the group. Papers then submitted to the NHSGGC board were found to contain incorrect statements about the work of the group and the conclusions associated with the hypotheses.
- There was no version control of the draft reports or documentation of Sub-Group members' comments and whether they had been accepted or declined, and the basis for the decisions. Within the report NHSGGC included data on cases that NSS had no knowledge of and actions that NHSGGC had taken out with the Sub-Group.

7.5 In Susan Dodds witness statement she states that[35]

> Myself, Annette (Rankine, HPS) and Ian (Storrar, HFS) submitted extensive comments and feedback on the report. Some related to the evidence being used to support statements. There was no understanding by me, or as far as I am aware by the rest of the group, as to how the evidence papers had been selected or the methods used to review them. Some of our feedback related to the writing style noting the report felt inconsistent and difficult to follow. Following discussion with ARHAI colleagues, we offered scientific support to undertake an evidence review using a robust methodology. NHSGGC did not accept our offer of scientific support at that stage. Over 70 comments were submitted in reference to the report and meetings were held to discuss comments. NHSGGC accepted the offer of ARHAI Scotland to undertake a literature review on 21 May 2021. Following discussion with senior members in NSS and NHSGGC, it was agreed that the report would be finalised as a NHSGGC report only and would not be endorsed by NSS.

Therefore, the report needs to be considered as an internal QEUH/RHC document.

[34] **A48189468** – NSS Response to Question 2 of Request for Information dated 11 March 2024, Bundle 24, volume 3, document 7, page 117.
[35] **A49391416** – Witness Statement of Susan Dodd, Witness Bundle Volume 2, document 6, page 264.

8. Critical Review of Hypothesis investigation

A. General

8.1 Before focussing on the sub group investigation of the individual hypotheses I will examine details of the patient journeys in QEUH/RHC to focus in on the likely window of possibility for a nosocomial infection to have occurred, then I will examine the air sampling data obtained by the IMT sub group to determine whether it indicates an environmental source for these infections and finally look at evidence of pigeon infestation during this time period.

i. Patient Journey

8.2 The report addressed two cases of *Cryptococcus neoformans* in patients in QEUH/RHC identified in late November/ early December 2018[36]. Patient A was diagnosed with a form of cancer in 2016. Patient A was admitted to Ward 4C in November 2018. Patient A was taken off an antifungal treatment protective against CN (Flucanazole)[37] and was found to test positive for CN in a sample taken 9 days later in late November. Patient B was an immunosuppressed paediatric patient who was admitted to Ward 2A of RHC in [redacted] 2018. Patient B was transferred to Ward 6A later that month, had a brief visit to PICU in [redacted] when Patient B was returned to Ward 6A. Patient B tested positive to a panfungal marker in [redacted] and then tested positive for CN.

8.3 The incubation period for CN is not well established and is stated as weeks to months by CDC with an additional possibility of reactivation after many years (CDC 2024). If we assume that the minimum incubation period of CN is 7 days, which is on the short side, then we can obtain a window for the time these infections could have been contracted during the patients stay in QEUH/RHC.

8.4 The potential period of infection of Patient A at QEUH/RHC is only 9 days in [redacted] 2018 while Patient B could have been infected over a [redacted] period from [redacted]. If there was a common source of infection for both patients, it was associated with a maximum 9-day period. Was there some activity during this period which could have increased the risk to the patients apart from being housed on Wards without positive pressure and HEPA filtration and a lower than

[36] **A38662680** - Report prepared by Cryptococcus IMT Expert Advisory Sub-Group dated 5 April 2022, Bundle 24, volume 3, document 5. Also produced in earlier more extensively redacted form as document A39235063, Bundle 6, document 39.

[37] **A38662680** - Report prepared by Cryptococcus IMT Expert Advisory Sub-Group dated 5 April 2022, Bundle 24, volume 3, document 5. Also produced in earlier more extensively redacted form as document A39235063, Bundle 6, document 39.

recommended air change rate? This period does not appear to have been investigated thoroughly by the expert group.

ii Air Sampling Results

8.5 The report contains a great deal of information from extensive air sampling undertaken after the CN cases were identified. In this report I will concentrate on data taken in December 2018 as this was the closest time period to the cases being identified.

8.6 It is clear from the reports of the air sampling results summarised in Table 1 that something was amiss on the 21st of December 2018. There were Cryptococcal strains recovered from over 50% of samples that were not overgrown. (If plates are overgrown Cryptococcus would not be detected even if it was present in the air samples) Even when overgrown plates were counted as negatives over 30% of plates had Cryptococci identified on them. This was not just in plantrooms but wards 4C, 6A and PICU. There were numerous overgrown samples which suggest high fungal burden or lack of care in incubating these samples and certainly this would reduce recovery/identification of Cryptococci. The lowest recovery (1/6) of Cryptococci was in the external air samples.

8.7 Subsequent air sampling during 2019 never recovered this high percentage of isolates. The average isolation of Cryptococcal strains from air samples taken in 2019 was 3%[38]. While it is possible that this was partially due to the introduction of portable HEPAs in wards 4C and 6A it seems likely that something unusual was happening in December 2018. Cryptococci were found in Wards 4C, 6A and the plant rooms providing the supply air to these rooms and not just Cryptococci but the same species, *C. diffluens*. So, the same strain was found in the Wards and the Plantrooms providing air to these wards. Every sample taken in the plantroom providing air to Ward 4C had a Cryptococcus isolate.

Area Sampled	Number of Plates with Cryptococcus isolates	Number of Overgrown Plates	Samples Taken
Plant Room 121	3 (1 *C.diffluens*)	18	24
Plant Room 122 (6A supply)	1 (*C. diffluens*)	2	4
Plant Room 124 (4C Supply	4 (3 C.*diffluens*)	0	4
4C	2 (all *C. diffluens*)	0	6
6A	3 (all *C.diffluens*)	2	6

[38] **A45379981** - Scottish Hospitals Inquiry - Hearing Commencing 19 August 2024 - Bundle 9 - QEUH Cryptococcus Sub-Group Minutes

PICU	2 (*all C. diffluens*)	0	3
Roof	1	3	6

Table 1. Air Sampling Data from 21st December 2018 (summarised from data in the Hood report and from IMT subgroup minute bundle p88)[39]

8.8 Were these levels of Cryptococcal isolation from air samples due to the pigeon eradication activities under way at the time noted in the GP environmental reports[40] or were they a blip or were they indicative of what was happening between September to December 2018. Routine air sampling results on Ward 4B taken during this period do not show evidence of elevated levels of airborne micro-organisms even the samples taken from the corridor which had supply air which was not HEPA filtered[41].

8.9 However, CN was never detected in any of the 3000 air samples wherever they were taken. John Hood states in the report[42] that the fungal reference laboratory of UKHSA said that CN is very difficult to detect in air samples but still the lack of an isolate in the 3000 air samples taken during the investigation seems significant.

iii Pigeon Infestation

8.10 Pigeon fouling at QEUH is a longstanding problem. In a report from GP environmental dated 02/04/2015[43] concerns were raised about pigeon fouling below the helipad area. In a report from GP environmental dated 24/3/2017[44] it was stated that:

> Pigeons have been accessing the plant rooms and walkways on the roof of the main hospital building. This has resulted in a heavy build-up of pigeon fouling on the ledges, beams, walls, floors and walkways of the plant rooms. The birds have free access to these areas as the roof area is exposed.

8.11 Another report from GP environmental from 8/1/2019[45] stated that:

> The sheer level of pigeon numbers are now posing a Significant Health and Safety Issue in many locations of the site involving walkways, plantrooms,

[39] **A39233902** – IMT Expert Advisory Sub-Group Minutes – Cryptococcus – 26 July 2019 - Bundle 9, QEUH Cryptococcus Sub-Group Minutes, document 15, page 88
[40] **A49631354** – Bundle 24 volume 1; **A49651673** - Bundle 24 volume 2
[41] **A49418979** – Air Sampling Results air sampling result from QEUH/RHC in October, November, December 2018 and January 2019, Bundle 24 volume 3, document 8, page 126
[42] **A38662680** - Report prepared by Cryptococcus IMT Expert Advisory Sub-Group dated 5 April 2022, Bundle 24, volume 3, page 47. Also produced in earlier more extensively redacted form as document A39235063, Bundle 6, document 39.
[43] **A49335803** – Bundle 24, volume 1, document 3, page 34
[44] **A49335848** - Bundle 24, volume 1, document 32, page 83
[45] **A49335867** – Bundle 24, volume 1, document 50, page 115

ledges round the hospital external structure of the Main Hospital Building, Neurological Institute, RCH, Laboratory Block, etc and within site loading bays.

8.12 From the IMT of 20th of December 2018[46]

A very large population of feral pigeons are present spread across various locations of the entire site. The most obvious breeding site being the hollow beams and partially enclosed beams/ledges below the Helipad.

8.13 It is clear that the QEUH had significant issues with pigeon infestation and fouling of environments. What is not clear is whether these issues were exceptional and whether they were dealt with adequately. I would imagine the battle against pigeon infestation is a continual one in many hospitals. However, I am not an expert in this area and cannot make an opinion on these issues. However, again the provision of adequate filtration for immunosuppressed patients would have prevented the potential for exposure to supply air contaminated with pigeon derived airborne material.

iv Review of Individual Hypotheses

8.14 I will now address each of the Hypotheses considered and compare my view to the IMT sub-group giving evidence for alterative ratings.

A. Hypothesis 1 PLANT ROOM AIR

View of Report – **UNFEASIBLE** due to lack of route for Plant Room air to reach patient room

My Opinion - **POSSIBLE**

8.15 It is assumed in the report's review of hypothesis one that there is only one way of Cryptococci entering the supply air steam and that is when the units are opened, and filters are removed. This is a little strange as that is the only time that air is not being pumped from the plant rooms into patient areas. I believe this is incorrect and there is a possible route from the plant room to the patient rooms. From the supply fan to the patient room the duct work will be at positive pressure to the plant room. This will prevent entry of plan room air into the duct as if there is a leak or opening air will move from the duct into the plant room. However, the air from the outside louver to the fan will be at negative pressure to the plant room and so plant room air will be able to enter the duct through any leaks or openings. While this air will be filtered, the F7 filter used in the supply air ducts for all wards barring 2A and 4C is only rated at ca90%,

[46] **A36605178** - 20.12.2018 IMT Cryptococcus, Bundle 1, document 55, page 245.

meaning that 10% of particulate will pass through it when it operates as intended. The F7 filters are not tested for efficiency *in situ* and thus it is possible that air can bypass the filter through an ill-fitting seal or that the filter could be damaged. The possibility of this route could have easily been checked using smoke pencils and other simple methods of directional flow visualisation. This does not appear to have been attempted even though a one inch hole was found on the AHU intake damper actuator spigot on the suction side of the fan and reported in the IMT subgroup minutes from 22 February 2019[47].

8.16 The magnitude of this leakage will be difficult to quantify but I do not think the possibility of a Plant Room source can be ruled out especially with the matched *C. diffluens* isolates found on the 21st of December in air samples from Plant rooms and wards they supply air to[48]. This finding has not been adequately addressed in the report. There is also a possibility that panels can be removed from ventilation systems before the fan and filter air supplies in the winter to prevent cut outs caused by the low temperature which would greatly increase the potential for plant room air to enter the supply air.

8.17 Therefore, I do not believe this route has been ruled out and remains a possibility

B. Hypothesis 2 – OUTSIDE AIR SOURCE

View of Report – **FEASIBLE**

My Opinion - **FEASIBLE**

8.18 The possibility of a “naturally occurring CN isolate” being introduced in the outside air not associated with pigeon associated material cannot be completely ruled out. However, compared to the Plant room and Ward areas, Cryptococci were seldom found in external air samples. This suggests that some mechanism could have been increasing the numbers of Cryptococci within the hospital environment during this time period possibly associated with pigeons. However, an external source cannot be ruled out.

C. Hypothesis 3 – LACK OF “PROTECTIVE ISOLATION”

View of Report - **POSSIBLE,** particularly in Case B, but less likely for Case A.

[47] **A39233718** – IMT Expert Advisory Sub-Group Mintes – Cryptococcus – 22 February 2019 - Bundle 9, document 2, page 12

[48] **A39233902** – IMT Expert Advisory Sub-Group Mintes – Cryptococcus – 26 July 2019 - Bundle 9, QEUH Cryptococcus Sub-Group Minutes, document 15, page 88

My opinion – **PROBABLE** (contributory) particularly in Case B, but less likely for Case A.

8.19 If external air or plant room air or air from uncontrolled areas of the hospital was the source of the CN then the lack of protective isolation was a contributory factor to these infections and since the chance of infection would be related to duration of stay then this is more probable for patient B. If we assume that the F7 filter is correctly fitted and operating at 90% efficiency and that the recommended HEPA was 99.95% then 10% of any CN in the air would penetrate the F7 compared to 0.05% through the HEPA. This means that if the patients contracted CN from these sources, then lack of the recommended HEPA filtration increased their potential exposure by 200 times.

D. Hypothesis 4 Cylinder Room in PICU (Paediatric Intensive Care Unit)

View of Report - is **POSSIBLE** but very unlikely for patient B and inexplicable for patient A.

My opinion – **VERY UNLIKEY** for patient B and inexplicable for patient A

8.20 I think it is highly unlikely that Patient A would be exposed to any air from this source as Patient A was housed in a PPVL room on PICU for a short period of time (4-5 days) and a PPVL room would provide an adequate level of protection from ingress of external air.

E. Hypothesis 5 – Helipad

View of Report – **REJECTED**

My opinion – **POSSIBLE**

8.21 The sub group rejected this hypothesis on the basis on a computer fluid dynamic (CFD) study contracted by NHSCGGC and carried out by Dr Althea de Souza of Quesada Solutions Ltd[49]. This report modelled the airflows into plant room air intakes under a range of wind speeds and directions. The CFD study was only undertaken for a limited number of scenarios based on weather data. Most of the modelling seemed to be undertaken at maximum wind speeds which are unusual. There was limited modelling at lower air speeds and some of this modelling seems to show potential for particulate from the helipad areas to drop into an air steam. The author states:

[49] **A39234098** - Report on the Computational Fluid Dynamics Simulation of the External Flow Around Queen Elizabeth University Hospital by Quesada Solutions Bundle 24, volume 3, document 9, page 130.

"The CFD simulations undertaken demonstrate that the air arriving at the AHU intake locations does not originate in the region beneath the helipad for any of the scenarios considered"

8.22 The simulation only incorporated the following scenarios (text from report)

"1. The flow under maximum prevailing wind conditions.

2. The addition of a momentum source to represent the downwash caused by a helicopter hovering on approach to the helipad. In addition, further simulations were considered to allow for the following variations:

• The most common wind speed of 1 m/s

• An intermediate wind speed of 5.5 m/s

• All three wind speeds with and without the rotor downwash present.

• Wind from the second most frequent direction at the maximum, intermediate and most common wind speeds (18.7, 5.5 and 1 m/s)

• Four rotor locations during approach: 22, 32, 47 and 117m horizontally from the center of the helipad."

8.23 The weather conditions at QEUH/RHC are far more variable than these scenarios which do not take account of other weather conditions such as temperature and stratification effects. So, while movement from the helicopter area to the Wards is ruled out for the scenarios in the report, it is uncertain how reflective these scenarios are of the range of weather conditions, wind speeds and directions found in QEUH/RHC.

8.24 Therefore, in my opinion, the possibility for movement of air from the pigeon contaminated areas below the Helipad cannot be REJECTED and could be a potential source of gross airborne contamination with pigeon derived materials under some weather conditions.

F. Hypothesis 6 - Specimen Transport System (POD)

View of Report – **UNLIKELY**

My opinion – **VERY UNLIKELY**

8.25 The low volume of air that could be provided by this system make it a very unlikely source especially as the air is introduced into areas remote from the patient rooms.

G. Hypothesis 7 - Dormancy/Reactivation (complex)

View of Report - **VERY POSSIBLE** for **BOTH** cases but likely to be **VERY DIFFICULT TO PROVE**

My Opinion – **VERY POSSIBLE** for Case A , **POSSIBLE** for Case B. Very difficult to **PROVE** or **DISPROVE**

8.26 The knowledge of CN infection is limited. Authoritative sources state that the incubation period can be from weeks to years. Data shows that French residents being treated with infections with African strains of Cryptococcus over 10 years of having been in Africa (Garcia-Hermoso et al 1999)[50]. There is other data showing that a significant percentage of non-symptomatic children in an urban area showed evidence of cryptococcus infection (Meya and Williamson 2024)[51]. Therefore, it is POSSIBLE that in both of the patients the original colonisations with CN occurred before the patients entered QEUH and CN was re-activated due to immunosuppression caused by their underlying conditions. Due to shorter stay and the older age of Case A this seems more likely.

8.26 It is also feasible that removal of antifungal treatments from the patients for clinical reasons caused the reactivation of infection leading to the outgrowth of a pre-existing infection.

H. Other Patients

8.27 There were three other cases of CN infection reported in patients with a connection with QEUH[52]. Patient H1 spent three days on Ward 8D in [redacted] 2017 and tested positive for CN in [redacted] 2018, Patient H2 spend two nights on Ward 11A in [redacted] 2018 and also tested positive for CN in [redacted] 2018.

8.28 A further patient C was admitted to QEUH in [redacted] 2020 and had positive serum samples positive for Cryptococcus using an antigen test in [redacted] 2020 while in Ward 6A[53]. Latex agglutination tests results reported by Professor Leonard were regarded as being negative[54]. However, four tests carried out by the UKHSA mycology reference laboratory were reported as being positive but culture negative for CN. The patient responded well to treatment. (Witness Statement of Questions and

[50] **A49642998** – D. Garcia-Hermoso, G. Janbon, F. Dromer, ‘’ (1999), Bundle 24, volume 4.
[51] **A49643001** - David B. Meya, Peter R. Williamson, ‘Cryptococcal Disease in Diverse Hosts’ (2024), Bundle 24, volume 4.
[52] **A39234581** - IMT Expert Advisory Sub-Group Mintes – Cryptococcus 26 November 2020 - Bundle 9 - QEUH Cryptococcus Sub-Group Minutes, document 33, page 286 and **A49619733** – Statement of Uncontroversial Facts Cryptococcus, Bundle 24, Volume 2, Document 205, page 201.
[53] **A48004322 -** Statement of Dr Sastry, Witness Bundle, volume 2, document 13, page 539.
[54] **A41890578** - 02.07.2020 IMT minutes Ward 6A, – Bundle 1, Document 94, page 431.

Responses Dr Jairam Sastry) I think that this case needs to be treated as a sporadic case especially as they tested negative for CN and there were no other cases reported during this period although it is concerning that there was reported to be pressure put on staff to write off this case as a false positive.

8.29 None of these cases had crossover with Case A or B at QEUH and both had only short stays in QEUH on different wards. Nevertheless having 4 positive CN cases in the QEUH/RHC and NHSGGC in 2018 represents 4 patients providing positive CN samples in a population of 1.3 million gives a case rate of 3.1 per million compared to 0.43 and 0.57 per million for the UK from the UKHSA data. This is between 5.4 and 7.2 times higher than would be expected.

9. Summary

9.1 I have been asked to address the following three key questions

a) Risk assessment and infection link – to address the scale of risk to patient safety

9.2 The connection between the QEUH environment and these cases of CN is unlikely to be proved or disproved at this distance of time. In my opinion if these patients had been housed in HEPA filtered positive pressure rooms the connection between the hospital environment and the patient could have been rapidly and quickly investigated and ruled out by demonstrating that the patient rooms conformed to best practise and guidance through validation. The lack of this assurance has, in my opinion, led to suspicion, loss of reputation and a great deal of effort in this investigation.

b) Whether these cases were remarkable

9.3 CN infections in the UK have been reported to be unusual and mainly associated with HIV cases. However, published data for the UK for Cryptococcal disease incidence is from the 1990s. Incidence of infection is not solely a reflection of actual incidence but is related to the availability and effectiveness of diagnostic provision. However, we can compare the four cases reported for 2018 to UKHSA data from 2016 to 2023. Having 4 positive CN cases associated with QEUH/RHC and NHSGGC represents 4 patients providing positive CN samples in a population of 1.3 million (using NHSGGC population) giving a case rate of 3.1 per million compared to 0.43 and 0.57 per million for the UK from the UKHSA data. This is between 5.4 and 7.2 times higher than would be expected. There can be many explanations for this:

- Randomness
- QEUH/RHC more likely to send samples to the reference laboratory
- QEUH/RHC patient groups more susceptible to CN infection
- There was something linked to QEUH/RHC that caused a higher rate than other healthcare areas which could be linked to environment or treatment
- Other NHS areas more likely to do in house culture for CN in other laboratories

9.4 I have not carried out any statistical analysis so cannot give any assessment of probabilities however the number of cases reported in QEUH/RHC during 2018 was remarkable and definitely warranted further investigation.

c) Was the methodology used by the subgroup to investigate the cases adequate and should subsequent cases be included

9.5 The subgroup was not directly tasked with investigating the cause of these cases but was asked to address a range of hypotheses provided by the IMT. The group was mainly made up of QEUH/RHC estates staff and did not contain epidemiologists or fungal disease specialists and did not carry out a formal investigation into the potential window of infection instead they investigated potential areas in the hospital estate that could have been the source of infection and attempted to make improvements. I have made some criticisms of the investigation which I felt ruled out some hypotheses too readily. I also feel that they did not investigate the concurrent isolation of a strain of *Cryptococcus diffluens* in air samples taken on 21st December 2018 from Wards 4C and 6A and the Plant Rooms supplying air to them. This would seem to demonstrate the potential for movement of Cryptococcal strains from plant room to wards.

9.6 I think that the IMT should have set up a different and possibly independent (additional) group including epidemiologists and fungal disease experts to carry an immediate rapid investigation into the possibility of a common factor in QEUH/RHC being a cause of these infections focussing on the potential infection window from September to November 2018.

10. Declaration

- I understand that my duty is to help the Inquiry on matters within my expertise and that this duty overrides any other obligation.

- I have stated the substance of all material instructions, on the basis of which the report is written. My evidence is my independent product, uninfluenced by external pressures.

- The opinions I have expressed are objective, unbiased and based on matters within my own expertise and I have not adopted the role of an advocate. I have made clear if a question or issues falls outwith my area of expertise.

- I have considered whether there is a conflict of interest and declared any potential conflict identified.

- I have given details of any literature or any other material relied on in making the report.

- I have set out the substance of all facts which are material to the opinion expressed in this report or upon which my opinions are based.

- I have said when there is a range of opinion on a relevant issue and summarised the range of opinions and I have formed my own independent view as to the appropriate point in that range applicable to this case and given reasons for that view.

- I have made clear which of the facts stated in the report are within my own knowledge. Those that are within my own knowledge I confirm to be true. The opinions I have expressed represent my true and complete professional opinions on the matters to which they refer.

Date: 21/08/2024

Mr Allan Bennett

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Glossary

AHU – Air Handling Unit

BALF – Bronchoalveolar lavage fluid

CDC – US Centers for Disease Control

CFD – Computer Fluid Dynamics

CN- Cryptococcus neoformans

CRAG- Cryptococcal antigen test

CSF – Cerebrospinal fluid

HCAI – Healthcare Acquired Infection

HEPA – High Efficiency Particulate Air

HFS – Health Facilities Scotland

HPS – Health Protection Scotland

IMT- Incident Management Team

NSS – National Services Scotland (Incorporating HPS and HFS)

ONS – Office of National Statistics

PHE – Public Health England (2013-2021)

PHLS – Public Health Laboratory Service (-2004)

PICU – Paediatric Intensive Care Unit

PPVL – Positive Pressure Ventilated Lobby

UKHSA – UK Health Security Agency (2021-)

SCOTTISH HOSPITAL INQUIRY

Addendum to Expert Report

Summarising the use of occupied bed days in calculating and comparing rates of infection at the Schiehallion unit between 2015 and 2022.

Prepared by Sid Mookerjee, BSc. MSc. MPH. FRSPH
Expert Witness

Data of submission: 16 October 2024
Final

1. Introduction

1.1. This report summarises the outcomes and learnings from the analysis undertaken in October 2024, whereby trends in the rate of environmental gram-negative and fungal blood stream infections at the Schiehallion were recalculated utilising occupied bed days activity data.

2. Methodology

2.1. In calculating the rate of infection per 1000 occupied days I have adopted the following datasets:

1. The Schiehallion cohort gram-negative and fungal blood stream infection figures as utilised in the Quantitative and Supplementary report were used for this analysis. See section 8.3.4 of the Quantitative report and section 2.8 of the Supplementary report for details regarding the methodology. Furthermore, I focused the analysis on blood stream infections taken on and tagged to ward 2A over the period 2015 to the decant, 2018, as we can be certain that the blood cultures taken on this ward were from patients who had in fact been admitted.
2. I utilised the NHS GGC bed days dataset, provided by NHS GGC in 2023 to SHI. Bed days data was aggregated by year for the period 2015 – 2022, using the ward names provided. Note that as noted in section 2.10 of the supplementary report, the issue around the same ward occurring under different names persists with the bed days dataset, as it did with the admission dataset.
3. Bed days data acquired via FOI requests from comparator hospitals, namely Oxford, Cardiff and Vale, Leeds and Great Ormond Street. On formatting the datasets from each hospital, key issues were noted as follows
    a. Great Ormond Street did not provide exact bed days numbers, rather provided a percentage proportion figure for paediatric haematology patients' bed days of the total hospital bed days.
    b. Cardiff and Vale noted that their bed days data - '*Only includes patients < 14 years. Any child over 14 years old diagnosed will be cared for on the Teenage Cancer Unit which comes under the Adult Haematology Directorate.',* which makes it different to up to and including 18 years of age cut off applied to the Schiehallion cohort.

c. Leeds noted that their bed days data was not specific to the paediatric haematology patient cohort.

4. Bed days data from Oxford hospital met the initial criteria set out in the FOI request, making up a single comparator unit with whom to compare the rates of infection per 1000 bed days at the Schiehallion. In my view it is not appropriate to have a single comparator dataset for reasons of data representativeness.

5. As noted in the Supplementary report there are key caveats pertaining to the use of bed days in calculate rates of infection in this patient cohort. These caveats are as follows:

5.1. *Owing to their specific medical requirements the Schiehallion cohort have frequent interaction with the hospital, and importantly with the environmental exposure in question – water and ventilation issues. This interaction was heterogeneous, i.e. a mix of inpatient stays (staying overnight in a bed), day stays and outpatient visits, which in its entirety makes up the cumulative risk of Schiehallion patients to acquire infections.*

5.2. Furthermore, as noted in the Supplementary report there are important considerations vis a vie the methodology that needs to be adopted to calculate bed days, which makes them less rigorous and more open to bias as compared to admission numbers, as noted below, and evident by the issues flagged in relation to the comparator bed days data:

Admission data comes from the EPR, and this goes for all hospitals who have provided data – NHS GGC and the comparators. This means that there is limited manual work required to collate the monthly and annual admission figures requested – essentially a tallying up of unique admissions from the EPR. This lends itself to limited inaccuracies and bias, and a high level of homogeneity in the methodology adopted by NHS GGC and comparator units in curating this data. On the other hand, bed occupancy data, requires in terms of the strictest methodology that someone calculates the occupancy rate at each ward in question, often requiring a visit to the wards in question at the same time everyday for the period

being reported on, and then finally aggregate the occupancy figures for the period into a single statistic, e.g. a month, a quarter, a year. This is very labour intensive, and to my knowledge current EPRs do not calculate these figures automatically – as it requires the EPR to have access to bed capacity by ward (which is subject to change over time) and occupancy at any given timepoint, and therefore the need for the manual element. The issue with this is that it introduces substantial bias and heterogeneity in methodology, both within a hospital site over time, as different actors might have collected, curated and saved this data at different points in time, and between hospital sites, in our case between QEUH/RHC and the comparator units, where there is a lack of confidence in the same methodology being followed, particularly as we did not state how we want the data to be collected in the FOIs nor could we curate this data ourselves. It is for this reason that I have made the decision to go with admission data when comparing rates of infections at Trusts across the country, where my focus has been to mitigate for bias, inaccuracy and heterogeneity of methodology adopted in curating datasets to the extent possible, seeing that I could not extract these datasets myself.

3. Results

3.1. The table below details figures specific to ward 2A - number of infections, bed days and rate of infections for the period 2015 – 2022, with the following graph illustrating the trend in the rate of infections for the period 2015 – 2018 (year of decant).

Year	Ward 2A infections	Ward 2A OBD	2A rate of infection / 1000 OBDs
2015	6	3434	1.75
2016	18	6450	2.79
2017	46	7344	6.26
2018	29	4225	6.86
2019	No patients	3	No bed days specific to 2A
2020	No patients	0	NA
2021	No patients	0	NA
2022	No infections	4299	0.00

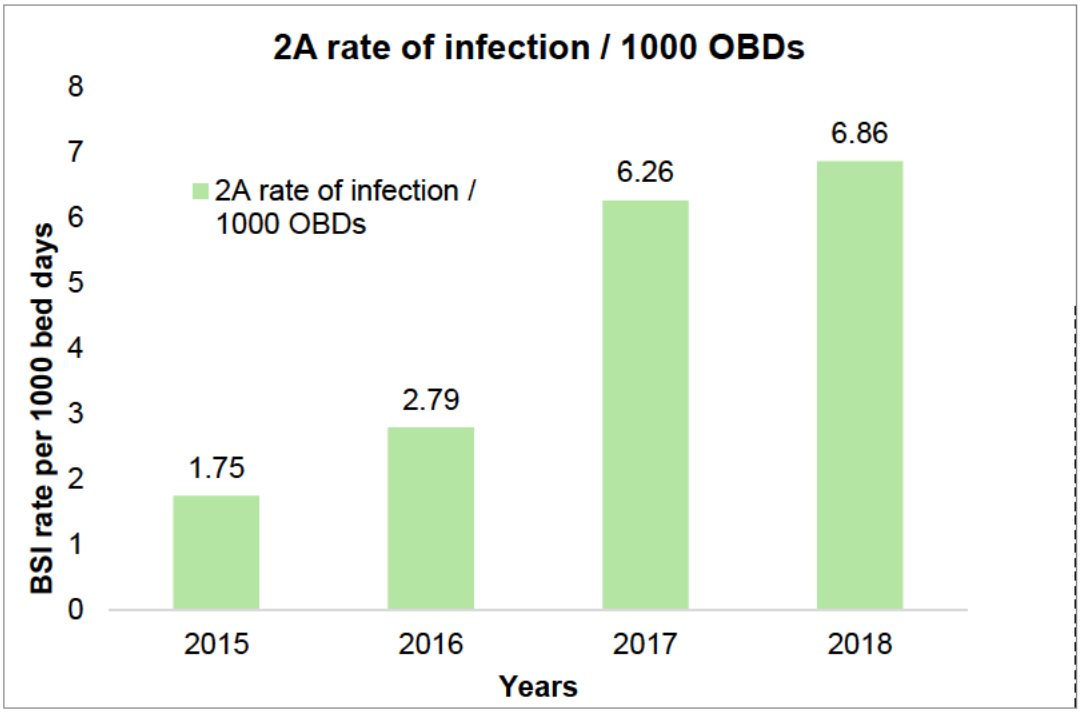


Figure 1: Trend in rate of infection per 1000 occupied bed days, 2015 – 2018.

4. Key findings

4.1. A summary of key findings are as follows:

1. Rate of infections (per 1000 bed days) at ward 2A over the period 2015 – 2018 (inclusive) follows a similar trend when compared to the rate of infection per 1000 admissions infographic (see graph below from the supplementary report, in particular the solid green line – Ward 2A infection rate / 1000 admissions)
2. The rate of infections per 1000 bed days commences at 1.75 per 1000 bed days in 2015, increasing to 2.79 in 2016, increasing yet again to 6.26 in 2017 and remaining at that level at 6.86 over 2018. An approximate four-fold increase in rate over the 2015 – 2018 period.
3. This trend is consistent when compared to the rate of infection per 1000 admission trend over the same period, 2015 – 2018, providing assurance with regards to the calculations performed.
4. I was unable to perform a comparative analysis as we did not have sufficient comparator institution data.

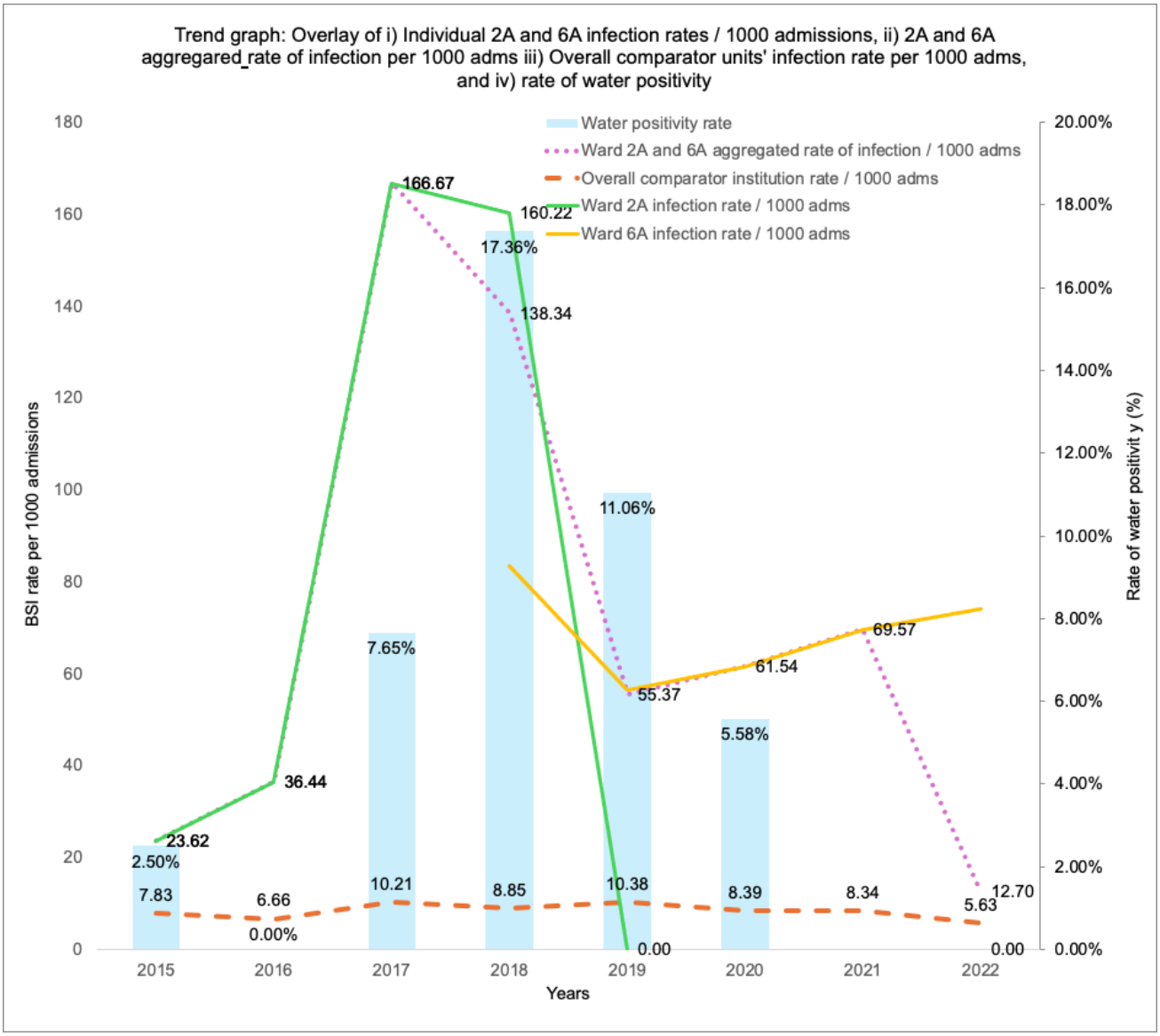


Figure 2: Trend graph for the period 2015 – 2022, taken from the Supplementary report.

SCOTTISH HOSPITALS INQUIRY

Addendum to Expert Report

Response to Professor A Leanord's oral evidence of 9 October 2024 relating to the antibiotic Meropenem and picks used in laboratory methodology

Prepared by Dr Sara Mumford MB. BS. MSc. FRCPath. SFFMLM.

and Linda Dempster RN. BSc. MA.

Expert Witnesses

Date of submission: 30th October 2024

1. Professor Leanord gave his oral evidence before the Inquiry on 9 October 2024. We have been asked to respond to the evidence he gave with respect to the antibiotic Meropenem and to picks used in laboratory methods following discussion of a sequencing report prepared by Professor Leanord and Derek Brown dated 18 January 2023[1].

2. Meropenem

2.1. Meropenem is an intravenous broad-spectrum antibiotic of the carbapenem group. It is active against gram-positive and gram-negative bacteria. Its mode of action is by interfering with the synthesis of cell wall components, leading to cell death. It is often reserved as a second- or third-line antibiotic due to its broad spectrum of activity and its efficacy. It is commonly used in immunosuppressed patients for these same reasons.

2.2. Bacteria which are naturally resistant to meropenem include *Stenotrophomonas maltophilia*, *Meticillin resistant Staphylococcus aureus*, *Enterococcus faecium*, some strains of *Pseudomonas sp* and some strains of *Streptococcus pneumoniae*. The mechanisms of resistance are either porin-mediated (where the antibiotic is prevented from entering the bacterial cell, or efflux pump-mediated where the bacteria is able to actively expel the antibiotic (e.g. *Pseudomonas aeruginosa* and *Acinteobacter sp*)

2.3. In recent years gram-negative bacteria which have the genetic ability to produce carbapenemases (enzymes which breaks down carbapenem antibiotics including Meropenem) have spread across the world and have been the cause of multiple hospital outbreaks of resistant bacteria. It is not suggested that these strains are implicated in the QEUH/RHC outbreaks of infection.

2.4. It is known that use of meropenem will cause resistance to develop. In one study[2] it was found that resistance can be identified in *Pseudomonas aeruginosa* in as little as 8 days after exposure to Meropenem. However, this does not necessarily mean that it will lead to infection with the resistant organism.

2.5. Professor Leanord identifies an increase in the use of antibiotics as a result of the high number of bacteraemias seen in the 2A patients.

2.6. We do not agree with Prof Leanord's assertion that the use of Meropenem is driving the rates of bacteraemia. The graph shown on page 121 of Ms Kathleen Harvey-Wood and Dr Christine Peters presentation[3], 'Environmental organisms, antibiotic use and Antibiotic Resistance' can be reworked using the data on the slide to show percentage resistance rates rather than numbers and that the overall resistance rates fluctuate

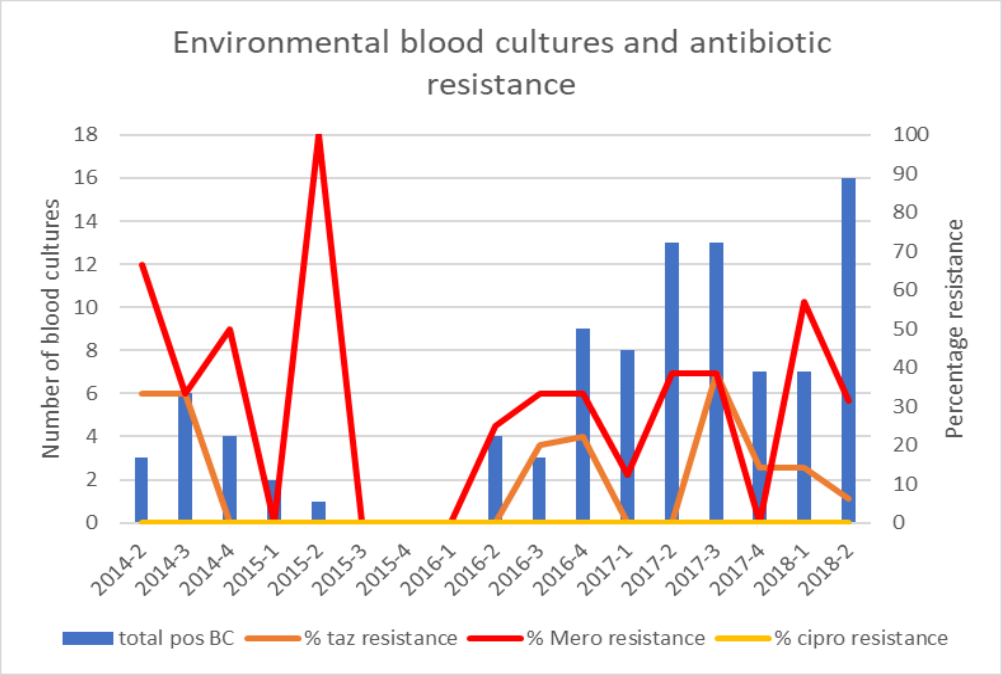
[1] **A42401483** – Report by Professor Alistair Leanord and Doctor Derek Brown Titled "Application of Whole Genome Sequencing to identify relationships among isolates of Cupriavidus app., Enterobacter spp., and Stenotrophomonas spp. Isolated from Clinical Samples and from water and drainage associated, sources within the healthcase environment." Dated 18 January 2023 - Bundles for Oral Hearing Commencing June 2023 – Bundle 6 - Page 1195

[2] Yusuf et al. Emergence of antimicrobial resistance to *Pseudomonas aeruginosa* in the intensive care unit: association with the duration of antibiotic exposure and mode of administration. Ann Intensive Care 2017 Jun 29; 7:72.

[3] **A46157936** – Bacteraemia rates and Resistance Paediatric Haemato-oncology 2014-2018 – Bundles for Oral Hearing Commencing August 2024 - Bundle 27 Volume 6 - Page 121.

throughout and are not significantly different to the rates seen in 2014 and early 2015 prior to the move to RHC.

Figure 1: Antibiotic resistance in environmental blood culture 2014-2018 (using data from K. Harvey-Wood's slide).



2.7. We do not have access to data on antimicrobial susceptibility for the individual environmental organisms causing bacteraemias, however, throughout our work looking at the infections at QEUH/RHC for the Inquiry, there has been no suggestion that the environmental organisms seen have had unusual resistance patterns or been multi-resistant. Therefore, given the relative stability of resistance rates in the group of bacteria, it is unlikely that the organisms causing infection have been selected out by the use of antibiotics.

2.8. We have been asked to comment specifically on the potential influence of Meropenem use on the acquisition of *Cupriavidus pauculus* infection. A study published in 2020[4] showed that only 8% of *Cupriavidus sp* isolates (of 39 tested) were susceptible to Meropenem (74% resistant). In Dr Inkster's publication on *Cupriavidus* spp in healthcare water systems[5], she found that only one of five organisms found in the study were susceptible to Meropenem.

2.9. In the light of this high level of resistance one could suggest that selection pressure by the use of Meropenem could contribute to *Cupriavidus* infection, however, this is highly

[4] Massip et al. *In vitro* activity of 20 antibiotics against *Cupriavidus* clinical strains. J*ournal of Antimicrobial Chemotherapy*, Volume 75, Issue 6, June 2020, Pages 1654–1658.
[5] **A39465156** - Inkster et al. Cupriavidus spp. and other waterborne organisms in healthcare water systems across the UK. Journal of Hospital Infection 123 (2022) 80-86.

unlikely given the very small number of infections seen in ward 2A patients and the rarity of clinical infections caused.

2.10. It is well recognised that patients undergoing chemotherapy can develop infection by a process called translocation through the inflamed gut wall. This can lead to bacteraemia and sepsis. The IMT's related to the environmental organism outbreaks have on occasion mentioned this as a possible route of infection. However, we have not seen any data on individual patients which would enable us to reach a conclusion on whether this has occurred.

2.11. Translocation could, however, be a source of infection which could be influenced by the use of Meropenem. When a patient is given any broad-spectrum antibiotic, one of the effects is to kill bacteria which reside harmlessly in the gut. The antibiotic will, however, only kill those bacteria which are susceptible to it, leaving the more resistant organisms behind. This effect is known to last for up to a year, reducing the diversity of organisms in the gut. This can result in future infections being caused by more resistant bacteria by mechanisms such as translocation.

2.12. In his evidence to the inquiry, Professor Leanord guessed that all of the resistant organisms during the period studied by Dr Harvey-Wood and Dr Peters were Stenotrophomonas. According to the data provided to us by NHS GGC[6] this is not the case and the maximum number of blood stream infections caused by *Stenotrophomonas sp* in any quarter was three.

3. Picks used in Laboratory Methodology

3.1. It would be helpful to describe, in simple general terms, the laboratory management of an environmental sample.

3.2. We know that the water at QEUH had a variety of organisms isolated from it and that widespread biofilm was present within the system. In order to gain a true picture of the microbiology of the water system, very extensive repeated sampling would be needed from a large number of outlets and other testing point throughout the system.

3.3. In order to identify all of the bacteria in the sample, a variety of media (agar plates with different nutrients added) would be required as different organisms need different factors to promote their growth. This could include culturing at different temperatures and in different concentrations of oxygen and carbon dioxide.

3.4. Taking a water sample as an example, one method is that a defined volume of water is put through a membrane filter, capturing the bacteria on the membrane, which is then placed on the agar plate and cultured overnight. It will then be possible to pick off individual colonies (each colony develops from a single bacterium) for further investigation. On the agar plate different organisms will have different appearances (size, colour, mucoid, dry etc) and this morphology can be used to choose different colonies to pick off and grow onto a purity plate. Purity in this context means that the aim is to have an agar plate on which is growing multiple colonies of identical bacteria.

[6] **A42219775** - QEUH Campus blood culture samples 1.1.15-31.12.22.

3.5. In a heavily contaminated sample and particularly where it is known that there is extensive biofilm and the likelihood of multiple strains of the same species, in our opinion it is good practice to not rely on morphology alone and to pick multiple examples of the same morphology to put on individual purity plates from where further identification can be done.

3.6. Colonies from the purity plates can be picked for identification to a species level using techniques such as Matrix-assisted laser desorption ionization-time of flight (MALDI-TOF) mass spectrometry and then further tests such as antibiotic sensitivity can be undertaken to distinguish, on a basic level, between strains. This will identify that strains of the same bacteria are different but will not confirm that they are the same.

3.7. If further differentiation of strains of the same species is required such as in an outbreak, whole genome sequencing can be used. Ideally all isolates should be stored for future investigation.

3.8. In his evidence to the Inquiry, Professor Leanord confirmed that his view was that a single colony should be picked from a purity plate to inoculate for whole genome sequencing. We support this view as a purity plate should be grown from a single bacterial colony as described above and all the bacteria on the purity plate should be identical.

3.9. However, Susanne Lee[7] and Dr Inkster[8] have put forward the view that 20-30 colonies need to be picked to ensure that all possible strains of the same species are identified. We believe that they are referring here to initial culture plates, again described above at 3.4, in order to ensure that the full diversity of the bacterial population is assessed even where morphologies are similar.

3.10. This would also chime with Professor Dancer's evidence to the inquiry[9] that if you don't find a link initially, keep looking. We would support this view in order to gain a full picture of the system microbiome for the benefit of patient safety

3.11. For clinical samples the above does not apply. Blood cultures should be sterile. Where bacteria grow in a blood culture it is usual for a single bacterial strain to be cultured but there are occasions where multiple bacteria may be isolated and even two strains of the same organism. Where more than one organism is grown, clinical information is needed to determine whether these are as the result of contamination of the blood culture or a genuine polymicrobial infection. Every organism grown in a blood culture should be identified as a routine and have antibiotic sensitivities carried out. As a result of the normal laboratory process, purity plates will be available and single colonies can be picked and stored for any future investigation.

[7] **A40732034** - Draft Meeting report prepared by Dr Susanne Lee dated 25 April 2018 - Bundle 8, page 134, para 3-9.
[8] **A50544753** - Dr T Inkster - Day 26 Transcript – 1 October 2024.
[9] **A50365535** - Prof S Dancer - Day 22 Transcript – 24 September 2024.

3.12. In our Expert Report to the inquiry[10] we challenged the Whole Genome Sequencing papers written by Professor Leanord[11] because there was no evidence of consistency in the methods used for culture, identification and picking of the organisms from each sample of water. There was also no methodology as to the number of colonies picked from the initial culture plates (see 3.4).

3.13. Our view on the Whole Genome Sequencing paper remains that it does not exclude a link between the water and drainage systems. The limitations due to the unknown number of strains picked from initial culture plates and the sources of the isolates tested result in an incomplete picture from which it is not possible to draw valid conclusions.

Dr Sara Mumford

Linda Dempster

[10] **A48460335** - Review of the Link between Patient infections and Identified Unsafe Features of the Water and Ventilation Systems at QEUH/RHC. Expert Report prepared for the Scottish Hospitals inquiry. Dr Sara Mumford and Linda Dempster – Bundles for Oral Hearing Commencing August 2024 – Bundle 21 Volume 1 – Page 96.

[11] **A42401483** – Report by Professor Alistair Leanord and Doctor Derek Brown Titled “Application of Whole Genome Sequencing to identify relationships among isolates of Cupriavidus app., Enterobacter spp., and Stenotrophomonas spp. Isolated from Clinical Samples and from water and drainage associated, sources within the healthcase environment.” Dated 18 January 2023 - Bundles for Oral Hearing Commencing June 2023 – Bundle 6 - Page 1195.

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 21 - Volume 1

Expert Reports by Sid Mookerjee, Sarah Mumford, Linda Dempster, Jimmy Walker, Andrew Poplett and Allan Bennett

A49142433