Scottish Hospitals Inquiry
Witness Statement of
Donald Inverarity

Background

1. My name is Donald James Inverarity. I have been asked to provide a statement detailing my involvement with the Royal Hospital for Children and Young People and Department of Neurosciences (RHCYP / DCN) Project (the Project).

Professional Experience

2. I am currently employed as a Consultant Medical Microbiologist by NHS Lothian (NHSL) and started in this post on 1 October 2014. I am also currently the Lead Infection Prevention and Control Doctor (LIPCD) for NHS Lothian and began that role in October 2015. I was an Honorary Senior Clinical Lecturer, Division of Pathway Medicine with the University of Edinburgh (2015 – 2020). Prior to joining NHSL I was the Infection Prevention and Control Doctor (IPCD) at Monklands Hospital (2009 – 2014) and LIPCD for NHS Lanarkshire (2013-2014).

3. My areas of expertise in microbiology include:

    - Clinical liaison (including several years as a trainee physician treating patients with infectious diseases);
    - Tropical Medicine;
    - Diagnosis and management of Infections of People Who Inject Drugs;
    - Pneumococcal disease diagnosis and management and comparative genomics of *Streptococcus pneumoniae*;
    - Intensive Care microbiology;
    - Infection Control (particularly in relation to advising on Healthcare-associated infections (HAI) risk from water systems and ventilation systems in healthcare settings such as resolving water contamination with *Legionella species* or *Pseudomonas aeruginosa* bacteria);

- Antimicrobial stewardship. This is defined in the British National Formulary as, “an organisational or healthcare system-wide approach to promoting and monitoring judicious use of antimicrobials to preserve their future effectiveness.”

4. As a consultant medical microbiologist, I am part of the senior management team of the medical microbiology laboratory service for NHS Lothian. The role of a consultant medical microbiologist is a specialist role as a senior decision maker involved in the accurate diagnosis of human infections (through utilisation of a wide range of laboratory tests) and also has a clinical aspect through being able to advise on optimal antimicrobial management and broader infection management of patients. This is contextualised to the individual medical needs of such infected patients. It also involves participation in laboratory management, to maintain a quality laboratory service that meets the standards set out by the United Kingdom Accreditation Service (UKAS) for clinical microbiology laboratories. To function as a consultant medical microbiologist, I have undergone higher specialty training in medical microbiology and virology and passed the Fellowship exams of the Royal College of Pathologists in order to appear on the specialist register of the General Medical Council. To continue to function in this role I undergo annual appraisal and revalidation every 5 years.

5. Specialty training in medical microbiology and virology involves understanding and being able to apply principles of infection control and incident management to control and resolve infection outbreaks. With regards to the built healthcare environment and healthcare water systems, this would include understanding how healthcare water systems can be contaminated with *Legionella species* of bacteria or the bacteria *Pseudomonas aeruginosa* and an understanding of some of the basic principles to apply to mitigate risk and to resolve the contamination. With regards to healthcare ventilation there should be an understanding as to how an operating theatre ventilation system works to reduce post operative wound infection incidence. The context of such training though is generally to provide insight and leadership into what measures to take when faced with clusters of human infections caused by micro-organisms that may have originated from exposure during the delivery of healthcare, recognising that some such micro-organisms may have arisen from the healthcare environment. Micro-

organisms that do not cause human disease or are recovered from areas which are not the human body are generally considered “out of scope” for a medical microbiologist as the training does not cover all aspects of environmental microbiology, ecology, veterinary microbiology or food microbiology. The laboratory tests that a medical microbiologist is familiar with and the standard methods (UK Standards for Microbiology Investigations or UK SMIs) that are followed in medical microbiology laboratories are tailored to optimal detection of micro-organisms from human body fluids or human tissues. Sampling of non-human items for micro-organisms would generally not be undertaken in NHS medical microbiology laboratories unless there was a clearly validated, reproduceable method by which to perform such testing and when reported, the result would need to explicitly state the UKAS accreditation status of the laboratory and whether the test was considered to be a UKAS accredited test for that laboratory.

6. As an IPCD, I am expected to demonstrate participation in continuous professional development annually in learning related to infection prevention and control which may include aspects of infection risk from the built environment. As LIPCD I work with a team of other medical microbiologists (either consultants who are medically trained or who are consultant clinical scientists) who have also undertaken further training in aspects of infection control after completion of specialist training in medical microbiology and/or virology, specialist infection prevention and control nurses (IPCNs), administrative staff and scientific staff. The LIPCD role brings with it a leadership aspect working, in NHSL, with the Associate Nurse Director for infection prevention and control in providing senior decision maker level advice to the infection control team and to other senior clinical and healthcare management colleagues in NHSL including executive board members (particularly the HAI Executive Lead), leadership during infection incident or outbreak management as well as local and national infection control policy development and implementation.

Qualifications

7. I graduated from the University of Edinburgh in 1995 with a Bachelor of Medicine

and Bachelor of Surgery (MBChB) degree, having also gained a Bachelor of Science in Pharmacology degree (First Class Honours) (BSc) in 1992. I received a Masters of Science degree in Infection and Health in the Tropics (MSc) in 2000 from the University of London (London School of Hygiene & Tropical Medicine) and a Doctor of Philosophy degree (PhD) from the University of Glasgow (2009). I gained my Certificate of Completion of Training in Medical Microbiology and Virology in 2005 and joined the General Medical Council (GMC) Specialist Register in 2005.

8. I passed the required exams to become a Member of the Royal College of Pathologists (MRCPath) in 2005 and was awarded a Fellow of the Royal College of Pathologists (FRCPath) in 2008. I was also awarded a Fellow of the Royal College of Physicians of Edinburgh (FRCP (Ed)) in 2012 having passed the exams to be a Member of the Royal College of Physicians in 1998.

9. Relevant postgraduate infection control training and courses include:

- Public Health Laboratory Service (PHLS) Colindale, Laboratory of Healthcare Associated Infection and Hospital Infection Society, Hospital Infection Control Course, 21st-25th February 2005. (PHLS provided a network of public health and reference laboratory functions in England and Wales at the end of the 20th century and beginning of the 21st century. PHLS became part of Public Health England (PHE) in 2013 and PHE has more recently been replaced by another organisation known as the UK Health Security Agency (UKHSA). With regards to the healthcare built environment, this course introduced me to the concepts by which healthcare specialist ventilation systems are built and maintained in order to minimise risk from airborne micro-organisms.

- Eastwood Park Training and Conference Centre, Falfield, Gloucestershire Health Protection Agency and Hospital Infection Society, Engineering Aspects of Infection Control Course, 17th-21st May 2010. This course is considered additional learning to foundations taught in the PHLS Colindale course noted above. It is a 5 day residential course exploring healthcare ventilation in much greater detail, covering the principles behind ventilation

systems for isolation rooms, operating theatres and pharmacy cleanrooms. Training in ventilation systems was delivered by Dr Peter Hoffman and Mr Malcolm Thomas. The extant technical guidance for healthcare ventilation in use at this time was HTM 2025. Healthcare water quality was discussed but in the context of decontamination of endoscopes. This particular course is tailored to the needs of infection prevention and control nurses and consultants and registrars training in medical microbiology.

- Cadham Consultancy Ltd and Malcolm Thomas: Specialised Ventilation Systems in Healthcare Practical Information and Guidance Workshop. Ventilation in Hospitals – its role in Infection Control, Royal Hotel Bridge of Allan, Stirling. 22nd-23rd May 2013. This course was undertaken by me as an update following the pandemic of swine flu. My employer, NHS Lanarkshire, was planning an upgrade of air handling units to all its operating theatres as well as designing a new intensive care unit at the time for Monklands Hospital and Mr Malcolm Thomas was employed as an external ventilation specialist. This course was more technically demanding and less tailored to the needs of IPCT staff. Many attending were NHS estates staff with an engineering background involved in maintaining healthcare ventilation systems and the course involved being able to determine air flows and pressure cascades in operating theatres, for example. Some of the content of Scottish Health Technical Memoranda (SHTM) 03-01 was alluded to as Malcolm Thomas was a key author but the extant ventilation guidance being discussed and applied was HTM 2025 and SHTM 2025.

- Healthcare Infection Society Spring Meeting, 14th May 2019, at the Royal College of Physicians, London. “Worries with the (hospital) water: problems, practices and pragmatic solutions.” This training day covered many aspects of risk assessment and risk mitigation for healthcare water contamination events due to *Legionella species* and *Pseudomonas aeruginosa*. It was practical and much of the learning presented from Birmingham regarding *P aeruginosa* water contamination and the use of point of use filters we were able to quickly implement as we were managing a very similar situation at the Department of Clinical Neurosciences building on the Western General Hospital (WGH) campus in Edinburgh. I was able to network with my

microbiologist colleague Dr Teresa Inkster and informally gained some insights into the water quality issues being experienced at the Queen Elizabeth University Hospital (QEUH) in Glasgow. All the above learning proved very useful to be able to understand the implications and infection risks of the water microbiology results relating to RHCYP/DCN which were beginning to be shared with me by that stage of 2019.

- Healthcare Infection Society Spring Meeting 20th June 2023. "How do you build a safe hospital? IPC considerations for the built environment." I was an invited speaker at this national training event and asked to teach on the subject of "Infection Control, Competing Priorities, New Technologies and Building Safe Healthcare Buildings." Other speakers spoke about their experiences as infection control staff and estates officers in Northern Ireland, Scotland and England regarding building safe and unsafe healthcare water systems and healthcare ventilation requirements.

10. I am (or have recently been) a member of the following groups:

- Scottish Microbiology Association (SMA) Council member 2019-2022. The SMA is a multidisciplinary group comprised of biomedical scientists, laboratory managers, clinical scientists, medics, vets, IPCNs and academics all working in the area of microbiology in Scotland. It holds two weekend conferences each year for members to meet socially and academically with speakers teaching on subjects relevant to working as a microbiologist in Scotland. The Spring 2022 weekend conference featured Dr Mike Weinbren speaking about healthcare water systems and risk of infection and Professor Malcolm Richardson speaking about fungi in healthcare water systems.

- Scottish Microbiology and Virology Network Infection Prevention and Control Doctors (SMVN IPCD) subgroup. I have been a member since this group formed in 2020. The SMVN recognised that IPCDs in Scotland would benefit from more than an informal group to be able to communicate with each other about issues affecting them and now hosts the IPCD subgroup enabling all IPCDs in Scotland to formally meet together to address current

issues on a quarterly basis. This group has been instrumental in scoping out the role of IPCDs within built environment projects as well as responding to several groups asking for expert opinion regarding draft documents on a variety of issues such as hospital water quality, high consequence infectious disease preparedness, IPCD job descriptions and IPCD recruitment and retention issues. It has provided a group that can be approached for IPCD opinion by national bodies such as Scottish Government, Antimicrobial Resistance and Healthcare Associated Infection (ARHAI), NHS Scotland Assure rather than targeting individual members.

- Scottish Health Protection Network High Consequence Infectious Disease (HCID) Group representing Scottish IPCDs since 2019. This group is actively seeking to improve resilience, co-ordination, capacity and resource allocation during the response within Scotland to the importation of High Consequence Infectious Diseases such as Ebola or Middle Eastern Respiratory Syndrome. Isolation room design and capacity and healthcare ventilation systems designed for source isolation of infectious patients are fundamental to this work. It provides insight into the current optimal design of such facilities as well as how they would be used.

- National Infection Prevention and Control (NIPC) Steering Group represented Scottish IPCDs and SMVN (2016 – 2019). I resigned from this group in August 2019 due to a personal concern that I had a conflict of interest when asked to be a member of NHSL's RHCYP/DCN Executive Steering Group. I had a contractual obligation to advise the Executive Directors in NHSL regarding infection control matters and interpret and contextualise infection control advice discussed at the RHCYP DCN Oversight Board. The RHCYP DCN Oversight Board had representation from NHS National Services Scotland (NSS) and represented views of NSS staff, who were also members of the NIPC Steering Group, which I did not share. In particular, my views differed regarding assessment and interpretation of microbiologically safe water and the role of a clinical microbiologist in the competent interpretation of environmental water microbiology results and the need for standardisation and quantification of laboratory methodologies to perform water culture for organisms other than

Legionella species and *Pseudomonas aeruginosa*. There were proposals at NIPC Steering Group during 2019 to change aspects of national policy with regards to assessment and monitoring of microbiological water safety. Neither did I agree with suggestions that, during a time of national shortage of medical microbiologists, medical microbiologists should deprioritise their involvement in advising on optimal infection management of patients with complex, difficult to treat infection, increase their programmed activities as IPCDs, undertake further training in aspects of plumbing and ventilation engineering and then dedicate time each week to meetings discussing optimal performance of taps, showers and air handling units and their compliance with technical standards as compliance officers when there are other disciplines, such as authorising engineers, better qualified and more appropriately trained to perform such a role. My views were being influenced by events and investigations at the RHCYP DCN so, I felt I could no longer represent the SMVN and IPCDs on this national body (where my role was to assess or agree changes in national policy in relation to infection control issues) with objectivity and without personal bias.

- Scottish Microbiology and Virology Network (I previously represented NHS Lanarkshire microbiologists until 2014).

- I was NHS Lanarkshire's Lead Microbiologist on their Antimicrobial Management Team until 2014.

- NSS Centre of Excellence (now named NHS Scotland Assure) workstream member scoping needs for Environmental Microbiology Laboratory Services 2019-2020. I was invited to contribute to this group by the consultant microbiologist at Public Health Scotland, Dr Michael Lockhart, given the experiences I had during 2019 as a clinical microbiologist being faced with water quality issues that were associated with healthcare infections and insights into how provision of microbiological assessment of water testing could be improved to assist such incident investigations.

- ARHAI Scotland Clinical Assurance Oversight and Advisory Group where I

represent the Scottish IPCDs. I joined this group at the request of ARHAI Scotland for an SMVN IPCD Subgroup representative in early 2023. It is a governance group that allows stakeholders such as IPCDs, IPCNs and ICMs to feed back to ARHAI Scotland concerns they have about the service delivered to them by ARHAI Scotland.

Experience in Healthcare Construction Projects

11. I have experience of healthcare construction projects. When I was IPCD at Monklands Hospital I was involved with the design and commissioning of the refurbished adult haematology unit in 2010 and the design of a new adult ITU in 2013/2014. I was also involved in the early stages of an operating theatres refurbishment project working with Malcolm Thomas, the author of SHTM 03-01, but then left to join NHSL in October 2014.

12. In general, the involvement of a consultant microbiologist or an IPCD in a project will often be very bespoke to the particular project and what clinical areas are being planned and built and what risk of infection to users can be anticipated from the design. For instance, a project building an outpatient unit for mental health services will predictably require little IPCD involvement as the risk of acquiring an infection for patients and staff in such a facility is very low. However, for a suite of operating theatres, intensive care unit or a bone marrow transplant unit, there will be numerous infection risks to identify and mitigate and issues to discuss by nature of the complexity of the building systems involved and susceptibility of the patients to infections. There will be numerous points for clarification and discussion and potentially escalation or derogation during design and significant involvement in ensuring critical services (which could result in infections if malfunctioning) such as water systems and ventilation systems are running optimally before patient occupation. IPCD and IPCT involvement is also not generally uniform throughout a project but tends to be most required in the design stages and the safety checks pre-occupation with less involvement during the construction phase when there is a building site rather than a completed healthcare building.

13. I consider my role as an IPCD primarily to be a stakeholder with clinical infection

training who can identify potential clinical risk of infection to the designers and users of the facility through understanding how micro-organisms can cause infection, where they are likely to be found and grow, how activities within the facility might increase or decrease the risk of exposure for facility users, measures that can be taken to mitigate infection risk and an understanding of potential consequence of any infection through training in diagnosis and management of infection. I would emphasise that I don't consider the IPCD role to be one of a compliance officer cross checking engineering specifications in technical guidance or that of a clerk of works on a building project. The ability to assess technical engineering information and translate it into potential clinical consequences is a skill we acquire that is sometimes required by IPCT staff to spot where a deviation may subsequently manifest as an infection risk but compliance checking and identification of areas where there may be a need to seek derogation from guidance is not fundamentally the role of IPCT in my view.

14. My familiarity with technical guidance such as SHTMs is primarily to have insight into how human infection risk can be increased or decreased through engineering, plumbing and architecture and I have no specific qualification in engineering or plumbing or environmental microbiology. Assessment of compliance against engineering standards is, in my view, more appropriately determined by authorising engineers who have the required breadth of understanding of extant technical guidance, statutory regulations as well as relevant qualifications to assess engineering performance more comprehensively. Authorising Engineers working in a healthcare context usually also have some insight into what designs or malfunctions will pose risk to patients, visitors or staff.

15. The risk of acquiring an infection after an exposure to micro-organisms during a healthcare episode is only one aspect of clinical risk. There are other clinical risks that the built environment may create for patients – for example a risk of tripping and sustaining a fracture or risk of scalding from hot water. Nevertheless, there are often misconceptions that the infection control team (by nature of having a clinical background) will advise on all aspects of clinical risk (some of which may be very specialty specific) or that the IPCT will represent and speak for the clinical services who will use a facility or that the IPCT have authority to approve

derogations from technical guidance on behalf of the health board. This often arises through not having appropriate stakeholder involvement in decision making meetings.

16. I am not aware of any formal preparation of IPCDs for involvement in the processes of building projects. It is therefore an activity that generates much trepidation amongst many newly qualified consultants who find themselves in an IPCD role. My experience was fortunately gained from shadowing more experienced consultant colleagues in the early stage of my consultant career and observe these activities being performed as well as through self-directed learning. In 2011 the Infection Prevention Society issued a draft document (to help IPC practitioners demonstrate competence in their work **(A47150199 – Journal of Infection - Bundle 13 - Volume 8, Page 115)**. Under "Clinical Practice" point 5 in relation to the built environment it states "advise on the design, construction, modification of facilities to prevent and control infection in the built environment." (**Page 125)**. The competence is predominantly around using skills to prevent and control infection in the built environment and monitoring for infection once the building is occupied by patients, rather than advise on all aspects of risk during design, construction and modification of facilities.

17. Of note demonstration of such competence was proposed as primarily through self-directed learning and reflection on any personal knowledge gaps and could be achieved through "self-study, undertaking learning programmes and/or academic qualifications or seeking learning opportunities in the workplace such as mentoring and job shadowing." (**Page 120**). It was not prescriptive about specific courses or qualifications that would be expected to be obtained to qualify an individual for their role and so for IPCDs there is no set curriculum to follow specifically with regards to built environment issues. IPS updated their competencies framework in 2021 (**A47150205 – Competencies Framework for Infection Prevention and Control Practitioners – dated 21 June 2021 – Bundle 13 - Volume 8 - Page 10**) and (**A47150214 – Education Framework for Infection Prevention and Control Practitioner (IPC) Workforce – dated 05 October 2023 – Bundle 13 - Volume 8 - Page 17),** but the remit of IPCT with regards to the built environment remains about identification of infection risk and

optimisation of infection risk mitigation strategies such as cleaning, waste management and equipment decontamination and not a compliance function with regards to technical performance of engineering systems (**A42215058 – IPC Standards for Health and Adult Social Care settings– dated 16 May 2022 – Bundle 13 - Volume 8 - Page 64)** and **(A47150199 – Journal of Infection Prevention – Outcome competencies for practitioners in infection prevention and control – dated 2011 – Bundle 13 - Volume 8 - Page 115)**. Some health boards may easily find themselves with consultants undertaking an IPCD role with little to no experience of large building projects, although they will have insight into the infection prevention and control principles to apply. Some health boards have little or no IPCD capacity at all, far less an IPCD with extensive understanding of infection risks of healthcare facilities. **(A47225939 – Healthcare Built Environment – NES infection prevention and control education team – Bundle 13 - Volume 8 - Page 2110).**

Role on a Day to Day basis

Up to March 2019

18. Currently my day to day role bears little resemblance to what I did on a day to day basis in general microbiology up to March 2019.

19. Pre 2019 I had the following roles:

- LIPCD for NHSL
- Site IPCD for WGH
- IPCD for primary care/Health and Social Care Partnerships
- Site IPCD for RIE
- Clinical liaison activities for microbiology (1 Programmed Activity (PA) per week) which involved reviewing patients at the bedside on ward rounds.
- On call nights and weekends for microbiology 1:8 (i.e. roughly 1 night in every 8 days averaged over a year.)
- Provision of specialist microbiology input to WGH ITU, WGH oncology,

Royal Victoria Hospital building (on WGH campus)

- Year 4 teaching of University of Edinburgh medical students
- Deputy for the Director of the Scottish Mycobacteria Reference Laboratory

20. Day to day work in the above roles included: (i) general microbiology, e.g. results authorisation, overseeing laboratory work, dealing with specific outbreaks of infection and clinical liaison; (ii) teaching and trainee clinical supervision; and (iii) local IPCT guideline development and advice.

21. During the Covid pandemic the majority of my role, when not dealing with IPCT issues relating to water and ventilation systems, was in the implementation and development of ever changing Covid guidance, outbreak and incident management and providing expert advice to hospital site management and Executive Directors but that has since eased off.

<u>Post Spring 2019</u>

22. Post Spring 2019 I retained the following roles but with much less time allocated to the day to day work because of the additional activities I began to undertake (noted in the following paragraph):

- LIPCD for NHSL;
- Site IPCD for WGH and primary care/HSCPs;
- Clinical liaison activities for microbiology 1 PA per week;
- On call nights and weekends for microbiology 1:8;
- Provision of microbiology input to WGH ITU, WGH oncology, RVH building at WGH.

23. The additional activities that I was required to support are listed below. Those that directly addressed issues being uncovered at RHCYP DCN are prefixed by RHCYP.

- NHSL Water Safety Group - 2 hr monthly (previously quarterly 2 hr)

- NHSL Ventilation Governance Group - 2 hr monthly (new meeting)
- Decontamination Governance Group - 2 hr monthly (not previously invited)
- RHCYP site Operational Water Safety Group Meeting - 2 hr monthly (new meeting)
- RHCYP Executive Steering Group -1 hr every 2 weeks (new meeting)
- RHCYP Water Remedials Meeting *(This was a task and finish group intended to resolve non-conformances detected within the water system. It developed into the site Operational Water Safety Group and reported to the RHCYP Executive Steering Group (ESG))* - 1 hr per week (new meeting)
- RHCYP Ventilation Remedials Meeting (*This was a task and finish group intended to resolve non-conformances detected within the ventilation system. Outputs from this group were reported to the RHCYP ESG)* - 1 hr per week (new meeting)
- Emerging Infection Preparedness Group - 1 hr per month (new meeting)
- IPCD Building Project Input on SJH A&E Refurbishment, WGH ITU Refurbishment, WGH Cancer Assessment Unit Refurbishment, East Lothian Community Hospital Commissioning – Variable but about 2 hr weekly (new involvement)

Role in the RHCYP/DCN Project

Pre 2019

24. I was not involved with the original design of the RHCYP + DCN, was not part of the NHSL RHCYP DCN Project Team and did not attend Project Meetings. It was an established Project when I joined NHSL in October 2014 and there was already representation from Infection Prevention Control Team (IPCT) by way of the lead HAI Scribe Nurse, Janette Richards (now Rae) with additional input from Dr Pota Kalima (Consultant Medical Microbiologist) who had performed the role of IPCD for the existing Royal Hospital for Sick Children (RHSC) at Sciennes for many years. I did not take up any specific infection control duties in NHS Lothian until a year later in October 2015 so during the period of October 2014 to October 2015 I had no need to be aware of any background or specifics to the project although I could see that excavation work to dig foundations had begun. Once I

undertook the role of LIPCD in October 2015 I took more of an interest in the project and began to be asked my views if Dr Kalima was unavailable. These were views about infection risk from aesthetic issues relating to fixtures and fittings being planned rather than infrastructure and engineering issues relating to critical systems. Dr Kalima and myself were in regular contact as we shared (and continue to share) an office at the Western General Hospital but I don't recall any need for either of us to discuss aspects of the RHCYP DCN project during 2015.

25. My understanding of the situation with regards to the project in 2014/15 was that the construction phase had begun and that the design stage had been completed prior to this. Dr Kalima had been involved in discussions regarding isolation room provision in the hospital and ventilation strategy in critical care and the haematology/oncology ward and those discussions took account of best practice principles and guidance that was current at the time. Dr Kalima was the most appropriate consultant microbiologist in NHSL to be involved in the initial design stage as he had around 15 years' experience as a consultant medical microbiologist in NHSL and had been advising on infection control issues at the Royal Hospital for Sick Children (RHSC) throughout that period and was highly respected by the clinical staff in paediatrics. He had also undertaken additional postgraduate training in issues of infection control in the built environment at Eastwood Park, Falfield. Consequently, the project team were able to utilise his knowledge of microbiology, infection control and the built environment during design as well as his extensive understanding from personal experience of how these would need contextualised to a paediatric hospital. It was not his full time job though and was fitted in around his other consultant microbiologist duties.

26. It is very unusual for health boards to dedicate a consultant full time to an IPCD role or an IPCD full time to a building project. This is more about workforce capacity though, as it is very difficult to provide additional consultant microbiologist staff to cover the regular microbiology workload that would be left through such a project secondment. It is also not attractive for the consultants who can become deskilled in laboratory microbiology and infection management. The model of consultant medical microbiologist involvement in an IPCD capacity only providing limited time to a new building project (or refurbishment) was therefore not unusual across health boards in Scotland. For the project team to

be able to tap into the knowledge and experience of the most qualified staff it would inevitably end up as an additional task amongst other established duties rather than a dedicated role. NHSL was unusual in having a HAI Scribe nurse i.e. a dedicated IPCN who had additional experience of building projects, their stages and processes and relevant guidance to be able to provide more skilled and focussed involvement in project teams. There wasn't workforce capacity to mirror that with dedicated IPCD involvement. It is still unusual to be able to provide an individual in an IPCD role to be able to support building projects as their primary responsibility. Workforce capacity in medical microbiology has deteriorated since 2014 in Scotland.

27. My role and responsibilities in relation to the Project changed over time. Pre 2019, my involvement was sporadic and ad hoc and related to a variety of IPC issues. For example, the first time I was involved in the Project was in March 2016, when I was asked whether fish tanks would be a risk for Healthcare Acquired Infection (HAI) in the new building. As detailed below, my first involvement in any discussion about ventilation was in August 2016 in relation to Positive Pressure Ventilation Lobby (PPVL) isolation room ventilation strategy in Lochranza (the paediatric haematology and oncology ward) where I disagreed with the proposal to have all 5 isolation rooms for protective isolation of neutropenic patients supplied by a single air handling unit. I had subsequent involvement in ventilation issues in September 2016 in relation to operating theatres and separately in relation to Radiology and CT scanners.

28. In NHSL IPCT, the staffing and skill mix model that had been developed for all infrastructure, building and refurbishment projects was that one of the IPCNs (Janette Rae) had been trained with particular specialist experience and understanding of SHTMs and Health Building Notes etc. and had a specific role to inform stakeholders (who would be completing a HAI Scribe assessment) of HAI risks. To a large degree, this was done without input from others in the wider IPCT (Infection Prevention Control Team) but their input and involvement would be requested when felt to be needed and issues would be raised with consultant medical microbiologists or other senior IPCNs. In 2015 the IPCT was comprised of an infection control manager role (Head of Service), a Lead IPCN role, 4 Geographical lead IPCNs with a remit for quadrants of the health board, 2

healthcare scientists, a HAI Scribe specialist IPCN, 3 administrative staff and about 17 IPCNs (not all working full time). There were two consultant microbiologists performing an IPCD role for St Johns Hospital (SJH) and RHSC with one programmed activity (4 hour time sessions per week) each for those sites and myself with 2.5 programmed activities (10 hours per week) in the lead IPCD role. It was an established model of working when I arrived at NHSL.

29. The role of IPCD is not a full time role and the number of programmed activities per week in a consultant job plan for IPCDs is not uniform across health boards. It is generally between 1 and 4 programmed activities for all infection control activities including infection surveillance and incident management. Large building projects will at points in the design and commissioning stages require much of that time allocation which can be to the detriment of time required for other infection control or laboratory based activities. As a result, it is unusual for an IPCD to have sufficient time in their week to be considered a full time, formal member of the project team and attend all necessary project meetings. Participation in such project meetings often requires an element of planning for the IPCD to provide added value to discussions and not waste their time when there is nothing for them to contribute.

30. The role of HAI Scribe IPCN allowed a dedicated staff member with an appropriate skill mix in infection control and familiarity with the HAI Scribe process (which I explain in detail at paragraph 67 onwards below) to interact with the Project Team and be more responsive to their questions. It is not an ideal model as having the added skills of the IPCD brings a wider perspective to discussions and avoids a “single point of failure” but full IPCD involvement in every project team is too resource intense in terms of IPCD available time to be deliverable, particularly if there is more than one capital project to assist. In my experience, the IPCD will usually be responsive to addressing specific questions from a project team within a set timeframe but that is reliant on the project team engaging with the IPCD and having awareness that the issue in question has a component that would benefit from IPCD input. There is risk that for some issues, recognition of the benefit and added value of an IPCD perspective may be missed. Similarly increasing the time that an IPCD can dedicate to such projects then compromises their time to maintain essential skills outwith infection

control which reduces their job satisfaction.

31. When I started the role of LIPCD in 2015, I was supported by one consultant microbiologist colleague who undertook IPCD activities for St Johns hospital (SJH) and one consultant microbiologist colleague (Dr Pota Kalima) who undertook the IPCD activities for the Royal Hospital for Sick Children (RHSC) at Sciennes. Site infection control doctor responsibilities at the Royal Infirmary of Edinburgh (RIE) and Western General Hospital (WGH) would fall to me along with other infection control activities such as surveillance programmes. I would be assisted with incident management activities by other consultant microbiologists if it was in a clinical specialty that they had a particular interest in (such as intensive care or obstetrics) or if the incident related to viral infection I was supported by a team of 4 virology consultants who would take the lead for incident management for influenza or norovirus outbreaks. By mid 2019, through further successful consultant recruitment, and some departmental re-organisation, we were able to have 4 microbiology consultants as site IPCDs at SJH, RHSC, RIE and WGH which allowed me to focus attention on issues with the RHCYP DCN building and oversee the other mandatory IPCT activities such as infection surveillance across the health board.

32. After my appointment as LIPCD in Oct 2015 (following a period of a vacancy where NHS Lothian had no lead infection control doctor in post after the resignation of my predecessor, Dr Elzbieta Czarniak, as lead IPCD in March 2015) and the appointment of Lindsay Guthrie as Lead Nurse for Infection Control ,who started on 1st June 2015 (after the resignation of her predecessor Natalie Oakes from the Lead Nurse for Infection Control in early 2015), there was *ad hoc* input to the RHCYP DCN project from either of us as required. I believe our predecessors had less involvement with regards to issues of the built environment. Janette Rae, as the HAI Scribe IPCN, was line managed by Mrs Guthrie. Ms Rae would seek a second opinion on her interpretation of matters relating to the built environment if she was unsure, from her own training and experience, from myself or others such as Mrs Guthrie within the wider IPCT; or I would be asked a direct question from one of the Project Team seeking my view. That view would be given but often I would not be informed of the outcome and whether that had changed an approach in the Project or not. Decisions regarding

any action to take based on IPCT advice given would sit with the Project Team.

33. I was content that Janette Rae, in her role as HAI Scribe IPCN, was the appropriate representative from IPCT. Janette Rae was an experienced IPCN who had developed a particular understanding of the infection control nursing issues encountered during new building and refurbishment projects. She was clear that she considered herself a nurse and matters of engineering were outwith her expertise. In relation to ventilation issues, Janette Rae in my experience, would make reference to SHTM 03-01 or seek a second opinion from colleagues in Health Facilities Scotland if there was a particular scenario not covered by SHTM 03-01 or a point where differences in interpretation of SHTM 03-01 had arisen. When she considered issues were outwith her competency, she would consult others for a second opinion or steer. She consulted with me, Lindsay Guthrie, Health Facilities Scotland (HFS) or Health Protection Scotland (HPS) as required. NHSL also had technical advisors, Mott MacDonald, who I understand were there to advise on technical issues such as engineering and the applicable Guidance. I am not aware of comprehensive guidance that outlines which disciplines should all be present during discussions about design of ventilation systems. My experience is that it is most productive if it is a multidisciplinary discussion with the involvement of the independent authorising engineer for ventilation, the project team, design team, estates team, IPCT and informed representation by the future clinical users of the facility being built all involved in the discussion.

34. My experience is that there is great variation amongst consultants of other clinical specialties with regards to their understanding of infection risk from the healthcare environment. It varies between specialty and varies with the age and experience of the colleague. For instance, surgical consultants and anaesthetic consultants often have a good understanding of the principles behind ventilation of operating theatres, consultant colleagues working in cancer services may have a greater understanding of isolation rooms for protective isolation of immunocompromised patients and consultant colleagues who routinely manage highly infectious patients may understand the principles of source isolation through having to deliver care in such rooms. Generally, the principles of how to design and build a safe healthcare facility are not taught in specialty training but

are acquired through working in a specialist unit (with specialist ventilation or isolation rooms) or through being involved in relocating services when something has gone wrong and the environment for delivering care has been compromised such as microbiological contamination of water or ventilation system failure. Often there are misconceptions that need corrected and unawareness of standards set in technical guidance or even the existence of such technical guidance.

35. It is often the case that in design meetings there are very good intentions proposed but ideas which do not align with statutory requirements or best practice. There is sometimes a need for well-intentioned enthusiasm to be tempered by pragmatism and the voice of someone in the multidisciplinary project team who is able to explain what is not legal, not safe, not practical, not workable or not affordable. This can be the project manager, technical advisors, independent authorising engineer, contracted design team or IPCT staff for example. My experience of clinical colleagues and indeed many IPCT colleagues is that they are not aware of NHS Capital Planning processes unless they have had prior experience of involvement in a building project. As a consequence of the Covid 19 pandemic, there was a substantial increase in awareness of all staff groups regarding ventilation provision, air quality and the roles of droplets and aerosols in the transmission of respiratory viral infection in clinical areas, the concepts of mechanical and natural ventilation and air changes per hour but there was not such awareness prior to early 2020. How water quality issues arise and the contribution of healthcare staff to either exacerbate them or improve them generally is not well understood in my experience and often it is not appreciated that some of the control measures required to prevent microbiological contamination of healthcare water are legal requirements.

36. Janette Rae represented IPCT on the RHCYP DCN as the main point of contact for the Project Team and was the HAI Scribe IPCN from around 2014. This was a role within IPCT that I had not come across when working in other health boards in Scotland. Where I had previously worked, the IPCN involved in a multidisciplinary completion of HAI Scribe would be an experienced IPCN but whose role was not specific to involvement in building projects. Janette Rae retired around December 2018 and after a short period of succession planning

and upskilling, Sarah Jane Sutherland was appointed to the role that Janette Rae had performed as “HAI Scribe IPCN.”

37. The role of IPCT in healthcare construction projects needs careful consideration and I have set out my views on that below.

From March 2019 onwards

38. My roles and responsibilities in relation to the Project changed significantly from around March 2019, when it became apparent that IPCT needed more information on the validation of the ventilation systems and water quality. On my return from a week of annual leave (4th to 10th March), I discussed with Professor Alex McMahon (as HAI Executive Lead) my concerns face to face that I had not seen ventilation validation data for RHCYP DCN prior to handover of the building which was announced to NHSL staff on 27th February 2019. This discussion took place on 13th March 2019 at the end of an incident management meeting about *Pseudomonas aeruginosa* water contamination at the Western General Hospital. Professor McMahon instructed me to e-mail him and outline my concerns which I did on 13th March **(A34010959 – Email from Lindsay Guthrie to Annette Rankin regarding a Sunday Hearld Article on ventilation issues QEUH RHCYP - Bundle 5 - Page 35)**. Professor McMahon escalated this among other Executive Directors also on 13th March (I discuss this email chain in more detail at paragraph 104 below).

39. During the period December 2018 to 12th March 2019 there was heightened concern regarding water safety and ventilation safety and compliance with best practice in all NHSL buildings including RHCYP DCN. On 25th February 2019 I had e-mail correspondence with the Director of Facilities, George Curley, and the Deputy Director of Facilities, Brian Douglas regarding the content of the NSS report, “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” which had been issued on 22nd Feb 2019 (**A47150204 – Glasgow report on water incident at QEUH – dated 12 March 2019 – Bundle 13 – Volume 8 - Page 158**). During that correspondence a draft of a paper to be presented at the NHSL Healthcare

Governance meeting on 12th March was shared with me It included a copy of the letter **(A35270542 – Letter from SG Health & Social Care and CE NHS Scotland to NHS CEs setting out a set of actions about an ongoing incident (Cryptococcus infections) in QEUH – dated 25 January 2019 – Bundle 4 - Page 8)** dated 25th January from Scottish Government to NHS Scotland Chief Executives and Directors of Facilities seeking assurance regarding compliance with SHTM 03-01 for ventilation systems and subsequent correspondence from NHSL in response. This was the context in which I raised concern that I, as the LIPCD, had not had sight of any critical system ventilation validation data for RHCYP DCN with the HAI Executive lead on 13th March 2019.

40. It was and continues to be established best practice that commissioning of operating theatres involves a step to assess the microbiological air quality **(A47150195 – Microbiological Commissioning and Monitoring of operating theatre suites – Hoffman et al – dated 2002 – Bundle 13 - Volume 8 - Page 173)**. As the consultant medical microbiologist with most experience of interpretation of this data in NHSL I was expecting to see such information to be able to assess this parameter of whether the theatres were providing a safe environment for surgery. Likewise, I was expecting to see data regarding air quality in the HEPA filtered isolation rooms in the building. In my role of IPCD and a senior member of the IPCT I was expecting to see a validation report (as per SHTM 03 01 section 8.64 and 8.65) for each operating theatre to be assured that they were meeting the parameters described in SHTM 03-01 Appendix 1 for air change rates and pressure cascades. I was expecting to see water culture results for *Legionella species* from sampling taken throughout the building (as per SHTM 04-01) and *Pseudomonas aeruginosa* results water culture results from augmented care areas (as per HTM 04-01) and assurance that water met all the microbiological criteria to meet a drinkable standard.

41. I was requested by various Executive Directors in NHSL to participate in discussions and planning regarding RHCYP DCN and was effectively seconded from the majority of my clinical microbiology activities to give the majority of my time to address issues arising at RHCYP DCN and other high profile infection control incidents happening concurrently e.g. *Pseudomonas aeruginosa* infections in neurosurgical patients and critical care patients at Western General

Hospital (WGH) and post-operative invasive fungal infections in cardiothoracic surgery at Royal Infirmary of Edinburgh.

Governance

42. Initially an Incident Management Team (IMT) for RHCYP DCN was formed and first met on Monday 8th July 2019 which later transitioned into an ESG. The IMT was formed by the Executive Directors as a forum to discuss and address the non-conforming issues being identified at RHCYP DCN but I wasn't involved in the formation of the group membership or deciding its remit – I was only asked to attend to provide infection control specialist input. The ESG comprised:

- Susan Goldsmith, Director of Finance – Chair
- Tim Davison, Chief Executive
- Tracey Gillies, Medical Director
- Alex McMahon, Nurse Director (took over as Chair from 28 October 2019)
- Jacquie Campbell, Chief Operating Officer
- Janis Butler, Director of Human Resources
- Judith Mackay, Director of Communications
- Iain Graham, Director of Capital Planning and Projects
- Brian Currie, Project Director
- George Curley, Director of Facilities
- Donald Inverarity, Lead IPCD and Consultant Microbiologist
- Lindsay Guthrie, Lead Infection and Prevention Control Nurse
- Sorrel Cosens, Programme Manager.

43. Mary Morgan, who was appointed as the RHCYP DCN Strategic Programme Director by Scottish Government in September 2019, also attended the ESG and others from time to time. Lindsay Guthrie and I were present at the ESG meetings to provide representation from IPCT. We were not necessarily the ultimate decision–makers in the meetings, that was Chief Executive and Executive Directors, but we were consulted as subject matter experts. From that point onwards, I was heavily involved at the request of the NHSL Executive Team in respect of advising on infection control risks in the built environment.

44. There were also specialist sub-groups for the RHCYP DCN building set up including a Water Safety Group (Tracey Gillies was the Executive Lead) and a Ventilation Safety Group (Alex McMahon was the Executive Lead), which both Lindsay Guthrie and I attended. The work generated by these groups became almost a fulltime job and from around September 2019 onwards, NHSL released funds to provide consultant microbiologist backfill so NHSL could employ a locum consultant to do more of the day-to-day consultant microbiology work that I would have otherwise been doing. I continued to advise in relation to infection control in the built environment at RHCYP DCN until the last ESG meeting post full occupation of the building which was held on 22nd March 2021. Since then, I have continued to advise NHSL generally on built environment infection control issues in existing buildings and on other new build capital projects.

45. As above, pre 2019 my role in the Project was *ad hoc* and I had communications with the Project Team both directly and indirectly via Janette Rae, the HAI Scribe IPCN. In the Project Team, I had communicated with: Ronnie Henderson (Commissioning Manager Hard Facilities Management), Brian Currie (Project Director), Ashley Hull (Commissioning Manager), Janice MacKenzie (Clinical Director), Jackie Sansbury (Head of Commissioning) and I would also communicate with George Curley as Director of Estates and Facilities about the RHCYP DCN project.

46. Post 2019, in relation to water and ventilation issues at the new RHCYP DCN building and also water quality issues at the old DCN at the Western General Hospital, I had discussions with the NHSL Project Team and other external parties including: Westfield Caledonian water safety experts (John Bryson), Dennis Kelly the NHSL Authorising Engineer for water; John Rayner and Jamie Minhinnick as the Authorising Engineers for ventilation (Turners Engineering) who represented NHSL; Hoare Lea; Bouygues; IHSL; Wallace Whittle (Stewart McKechnie), Multiplex; Mott MacDonald; HFS (Eddie McLaughlin and Ian Storrar); HPS (Annette Rankin and Laura Imrie). I also attended as a witness some of the assessments of ventilation performance with the Institute of Occupational Medicine (IOM) staff (Paul Jameson) after June 2019.

47. I reported to Professor Alex McMahon in his role as the HAI Executive Lead and

Director of Nursing and Tracey Gillies, Medical Director who was lead for water issues at RHCYP DCN. She was also HAI Executive lead before that passed to Alex McMahon but also as Medical Director she was the Executive who managed me as a medic. There were frequent and direct communications between the three of us and Lindsay Guthrie. I also reported to the Executive Director members of the ESG as detailed above.

48. I sat on Lothian Infection Control Advisory Committee (LICAC) which was chaired by the Director of Public Health, Dr Alison McCallum. This committee predated my arrival in NHSL in 2014. It did not oversee issues at RHCYP DCN but they could be discussed there with the Director of Public Health.

49. I sat on the Pan Lothian Infection Control Committee (PLICC), which held quarterly meetings. It pre-existed the issues with the Project and while the issues with the Project will likely have been reported there, it would have been for interest rather than oversight.

50. After January 2020 I was also a Member of NHSL COVID Silver Command Group and NHSL COVID Gold Command Group. These committees did not provide oversight of RHCYP DCN but did address Covid impacts at RHSC and DCN (while it was at WGH) and across the whole of NHSL. Questions about the RHCYP DCN building and whether it was at a point which it could be used to ease Covid pressures in any way would arise.

51. The forums available to me where IPCT could raise a patient safety concern around the RHCYP/ DCN Project were:

- Directly to HAI Executive Lead, Tracey Gillies initially then Professor Alex McMahon (2019 onwards)
- Directly to Medical Director Tracey Gillies (line manager)
- Pan Lothian Infection Control Committee chaired by HAI Executive Lead
- Lothian Infection Control Advisory Committee chaired by Director of Public Health
- RHCYP DCN Executive Steering Group (from July 2019)

52. I also liaised with my consultant microbiologist colleagues to seek their views and provide feedback and support as my deputy at meetings if I was on leave.

Role Of Infection Prevention Control in the Built Environment

53. The role of IPCT members in healthcare projects and the built environment is not clear in the NHS in United Kingdom and has been unanswered for a long time. I found a useful paper published in the Journal of Hospital Infection in 2004 called **(A46883669 - The Future of the UK infection control doctor: report of a one-day Association of Medical Microbiologists organized workshop – dated 3 September 2004 – Bundle 13 - Volume 8 - Page 201)** and there is absolutely nothing to suggest any specific IPCD role in respect of the built environment in the UK at that point in time. The Vale of Leven Inquiry was disparaging of its IPCD but there has been no clear guidance or understanding as to the remit of IPCD in Scotland before or since then. If there can be clarity for health boards as to the remit of (i) Authorising Engineers (AE) for Water, Ventilation and Decontamination and (ii) IPC nurses and doctors, then that would be helpful particularly in relation to who is best placed to establish compliance against technical guidance.

54. SHTMs such as SHTM 01-01 do not accurately describe the role of IPCD as they consider it to be the same as a clinical microbiologist but they are not necessarily interchangeable roles – a consultant clinical microbiologist can undertake the role of an IPCD but an IPCD can also have the background of a consultant virologist or consultant infectious disease physician for instance and may not have the same laboratory expertise as a consultant microbiologist but have different skill sets within infection medicine. SHTM 01-01 also presumes the infection control doctor has skills in decontamination without any clarity as to what that skill set entails. With regards to SHTM 00 **(A33662233 – Scottish Health Technical Memorandum 00, Best Practice guidance for healthcare engineering, Policies and Principles dated February 2013 – Bundle 13 - Volume 3 – Page 325)** I believe the roles of the authorising engineers are too vague. SHTM 00 says that the authorising engineer role is *"to provide services in accordance with SHTM guidance"* (section 4.18) and only cross references a role in compliance

with other SHTMs whereas my experience of working with authorising engineers is that the role also considers other relevant subject matter such as building standards, health and safety executive legislation or relevant guidance from other learned organisations. Section 4.19 says the AE will *"monitor the performance of the service"* and alludes to a role in audit and compliance assessment but isn't explicit enough in my view.

55. Within SHTM 00 (p91-94) the only mention of infection control is in a table listing commonly encountered estates issues where "infection control infection involvement?" is listed against every scenario. I think this needs revision as it is generating many unnecessary requests for IPCT involvement in areas where there is little requirement for infection control (examples from SHTM 00 being, "extreme weather" or "fire" or "explosions" or "paging systems") and creating the perception that infection control must sanction all estates activities. I think clarity is also required for national bodies too as it is not unusual for guidance documents to be issued from them which task IPCT members with activities that don't align with their skill mix, experience or competence with little or no reference to the authorising engineer role (who may be more experienced, competent and able to perform the task). My experience is that IPCT members will have their most effective impact in establishing patient safety when working in a multidisciplinary group along with the project team, facilities staff, authorising engineers and clinical teams who will use a facility, as no individual team has all the knowledge and experience to assess practicality and safety wholistically. Scottish Government has attempted to create role descriptors for members of the IPCT but these have not been popular or accepted within the IPCT community in Scotland so far.

56. It is not uncommon in more recent NSS documents for IPCT members to be tasked with activities outwith their training (e.g. related to engineering compliance assessments) which could be more competently and more knowledgeably performed by Authorising Engineers or other professional groups. One example was the NSS HFS Lessons Learned and Recommendations Report on Cowlairs CDU Incident Nov 2018 **(A47150197 – Lessons Learned & Recommendations report on Cowlairs CDU Incident Nov 2018 – dated 06 September 2019 – Bundle 13 - Volume 8 - Page 204)** issued regarding a review of a failure of a

decontamination unit in Glasgow and purported to identify lessons learned, one of which advised particular “focus” on the training of IPCDs and medical microbiologists (**Page 210**). This was in relation to recommissioning a cleanroom within the decontamination unit with the inference that there had been a training issue of the medical microbiologists involved during the incident. There was no representation of either IPCDs or medical microbiologists during the writing of the document or its review, before publication, so no opportunity to explain that the tasks the medical microbiologists were being expected to be proficient at may legitimately be outwith their training or that the tasks may be better delivered by an Authorising Engineer for Decontamination. This is one of the reasons why the SMVN IPCD subgroup was formed to be able to give IPCDs more of a voice to correct misconceptions regarding their role and to highlight that the skill set required to deliver an infection prevention and control service comprehensively is more than can be delivered by IPCNs or IPCDs alone.

57. In Scotland although there are a few IPCDs with extensive experience and understanding of clinical risk from building water and ventilation systems, many have only generic understanding of the infection control principles involved as outlined in the FRC Path curriculum. These skills and experience are not evenly distributed across all health boards. The expectations put on IPCDs are often aligned to what a smaller group of more experienced and trained individuals can deliver rather than recognising that many IPCDs cannot necessarily perform at that level and have not had extensive access to either the training or the experience of projects where technical guidance has not been followed, novel technologies have been installed, critical system maintenance has been suboptimal or where known microbiological hazards have been identified within buildings resulting in patient infections.

58. Consultant Medical Microbiologists are usually medically qualified (although some have clinical scientist rather than medical training) and are skilled in the laboratory diagnosis and “end of the bed” diagnosis of infections of all forms and in all ages of patient in any specialty be that medical, surgical, paediatrics, obstetrics or any other specialty. That involves a repertoire of clinical history and patient examination skills appropriate to an experienced ward based doctor as well as a wide understanding of prescribing antimicrobials and laboratory skills

equivalent to microbiology based biomedical scientists. It involves understanding laboratory methods, quality structures and laboratory management and also involves understanding infection control principles and infection incident management. Most consultants will develop specialist interests and may pursue further postgraduate training in such areas as teaching, quality improvement, antimicrobial stewardship, laboratory management skills. Within infection control one such area is infection control relating to healthcare buildings and their water and ventilation systems. It is not mandatory to undertake such training and not all consultant medical microbiologists will have had such training.

59. In Scotland, membership of the SMVN IPCD subgroup is constantly changing so it is difficult to give figures for how many individuals are in that role. The expectation is that every health board should have at least one IPCD. The present reality is that some health boards do not have an IPCD and some island health boards share their IPCD with another mainland health board. For some mainland health boards, it has been recognised that the workload is too great for one individual to deliver with a model of some individuals taking on particular aspects of the IPCD remit such as water issues or ventilation issues or antimicrobial stewardship. There is no framework against which such doctors can benchmark themselves as to whether they have undertaken training to make them proficient in these tasks and no list of appropriate training activities to cross check against. Consequently, training needs are usually self-identified as part of a personal development plan within the annual consultant appraisal process and any personal assessment of whether the IPCD feels that they have had adequate training or not becomes a private discussion between them and their appraiser. That then can help to formulate the perceived training need and a process of how that can be escalated by them and their line manager or HAI Executive lead. So IPCDs across Scotland will often be in very different parts of the spectrum of post completion of specialist training learning for any matter and not just infection control aspects of the built environment.

60. I started to specialise in infection control in the built environment, mostly as a result of the circumstances I found myself in. My knowledge and interest stemmed from the healthcare refurbishment projects or repairs I was involved in at Monklands Hospital as an IPCD there. I worked for a short time with Malcolm

Thomas, author of SHTM 03-01 (**A32353809 – SHTM 03-01 Part A dated 1 February 2014 – Bundle 1 - Page 2490**), who was contracted as external advisor to the Monklands operating theatres refurbishment project and gave advice on ventilation systems. However, I would flag that this all pre-dated publication of SHTM 03-01 and was based on SHTM 2025, (**A33103351 – SHTM 2025 Part 1 dated June 2001 – Bundle 1 - Page 3208**) which did not contain the same level of detail as found in Appendix 1, Table A of SHTM 03-01 regarding air change rates and pressure cascades required for particular areas.

61. Lindsay Guthrie and I gained a phenomenal amount of practical knowledge on ventilation in the built environment and SHTM 03-01 and water quality and SHTM 04-01 from the RHCYP DCN project. However, the learning and knowledge that we have gained is as a result of the circumstances we found ourselves in, i.e. sitting through lengthy and detailed meetings with ventilation engineers and the Authorising Engineers for ventilation or discussions about water systems and their components with the Authorising Engineer for water and Estates staff. By 2019, this was not all learning arising from the RHCYP DCN project though as there were significant incidents being investigated at both the Royal Infirmary of Edinburgh and Western General Hospital campuses where ventilation systems and water systems were being systematically assessed as possible sources for microbiological hazards that were causing patient infections prior to March 2019. HFS and HPS were aware of the incidents and were invited to participate in the IMTs. It is not usual for IPCT members to have such a detailed understanding of mechanical ventilation systems or healthcare water systems or to navigate IMTs of such complexity and both incidents had substantial input and support from NHSL's Executive Directors. These IMTs at The Royal Infirmary Edinburgh (RIE) and The Western General Hospital (WGH) were ongoing active issues when concerns about RHCYP DCN systems were being discussed in 2019.

62. There are professional groups and bodies who have an interest in developing a clearer remit for IPCT in the built environment. I am part of Scottish Microbiology and Virology network Infection Prevention and Control Doctor subgroup and we wrote a paper for the Scottish Government from our perspective as to what the role of the infection control doctor is becoming and how the IPCD role may help to minimise clinical risks related to the built environment. This was shared with

Scottish Government as part of the IPCT workforce planning exercise that was being undertaken in 2021/2022. The increasing role of IPCDs in built environment issues is specifically addressed in section 2.7 of the paper which SMVN IPCD subgroup produced in March 2021 titled “The Infection Prevention and Control Doctor in Scotland – report on current position.” **(A47150209 – The Infection and Prevention Control Doctor in Scotland – dated 29 March 2021 – Bundle 13 - Volume 8 - Page 224).**

63. There is often (but not always) a mismatch in perception between what IPCD consider their role to be; what IPCN consider their role to be; and what Project Managers consider the IPCD and IPCN role to be. Bringing clarity here would be welcomed. IPCDs and IPCNs bring different perspectives from a nursing and medical perspective as to what is and what is not a safe patient environment with regards to the possibility of acquiring an infection during the delivery of healthcare. Often the role of IPCT is incorrectly perceived to be one of assessing compliance with various guidance documents and approving and “signing off” documents on behalf of the Health Board but IPCT members generally do not have the authorisation to “sign off“ on documents which ultimately sits with the Project Sponsor in an Executive role for capital projects.

64. This is particularly important because newer microbiology consultant appointees over the last 10 – 15 years have far less infection control exposure and experience. My sense is that there is some reticence to get involved due to their lack of experience and fear of doing something wrong. The challenges with infection control in the built environment at both the QEUH and RHCYP DCN has only intensified that. The result is that we are losing experienced IPCN and IPCDs en masse in Scotland and there are few newly qualified staff with sufficient experience of the built environment issues specifically. Many have retired, some have changed career and left the health service after the demands on them from the Covid pandemic or for other personal reasons such as illness or family, some have dropped their IPCT work to focus on other less demanding areas of their specialty and several have moved from working in health boards to work for NHS Scotland Assure, ARHAI or Scottish Government HAI policy unit.

65. In general, IPCNs and IPCDs do not receive much training on infection control in

the built environment as part of their basic training. There are training courses run by the Healthcare Infection Society such as the Engineering Aspects of Infection Control held twice a year Eastwood Park Training Centre, Falfield, Gloustershire (discussed above at paragraph 9) which is a highly rated UK course for learning about ventilation and water systems but it's not mandatory and not everyone does it or is interested in it and there is often a waiting list of places. The result is that there are only a small pool of people in the UK with relevant experience and that pool seems to be getting smaller.

66. I discuss the role of IPCT and its impact on this Project specifically below.

HAI Scribe

67. The risk of acquiring an infection while attending a healthcare facility in Scotland is generally assessed by the HAI Scribe process which stands for Healthcare Associated Infection System for Controlling Risk In The Built Environment. It was issued in NHS Scotland by National Services Scotland (Health Facilities Scotland) after a pilot in the early 2000s and features now in Scottish Health Facilities Note (SHFN) 30 Parts A, B and C. Its use in Scotland became mandatory with the issuing of CEL (2007) 18 and reiterated in DL (2015) 19 and DL (2019) 23. The current version 3 of HAI Scribe was issued in 2014/2015. It is important to appreciate that a set of circumstances that leads to an HAI in one healthcare setting may not do so in another healthcare setting and may not do so in the same setting on the same day if the set of circumstances is altered even marginally. The permutations of circumstances that can occur in one ward far less the whole building over a year are enormous so the prediction of possible infection risk is never all encompassing.

68. The HAI Scribe document itself makes the point that its intent is to "minimise risk of infection" – it is not intended to cover all dimensions of clinical risk and it cannot eradicate infection risk from a building. It is only intended to, as far as can be reasonably achieved, anticipate infection risk and either design it out or mitigate against it. The HAI Scribe document itself is really a checklist of questions that categorises into sections recognised hazards that lead to infection, if all is not optimal or following best practice. It is not applied only once but is to

be used during 4 stages of the pre-occupation life of the building and these are:

Development Stage 1:	Initial briefing and proposed site for development
Development Stage 2:	Design and planning
Development Stage 3:	Construction and refurbishment work
Development Stage 4:	Pre handover check, ongoing maintenance and feedback.

69. The anticipation of the infection risk changes as the stages progress. All stages require an element of “horizon scanning” and prediction based on knowledge of current best practice in infection control. Much like completion of a picture on a jigsaw, understanding of the hazards bespoke to the design or building becomes clearer as the building is completed as they move from being hypothetical issues to being demonstrable issues. It isn’t until system performance assessments have been performed (at validation in stage 4) that a clearer picture is available regarding the water and ventilation systems by which to assess the hazards and mitigate risk before a point when patients and staff may be exposed. Not all questions in the checklists are relevant for every building or can be answered accurately at every development stage of the project. The perspectives of an infection prevention and control nurse and infection prevention and control doctor with experience of assessing and identifying infection risk from building systems are important and they can be considered key stakeholders but they do not complete the document alone. Completion is intended to be multidisciplinary and would optimally involve the contractor doing the building, owner of the building if not NHS, clinical teams or site management teams who will use the building and have knowledge of the needs of the services it will host, estates team with engineering and plumbing expertise, and may involve domestic services representative to assess anything that may impair their cleaning processes too. The project team in a large project would be the co-ordinators of its completion and in smaller refurbishment projects it would be the NHS Estates team for the health board. In the later stages such as Stage 4 there will also be a dependence on information being generated by water testing laboratories and assessment of the ventilation system by the independent authorising engineer to fully assess if they are SHTM compliant and “fit for purpose.” The Authorising Engineers may also be considered stakeholders themselves in the HAI Scribe if the nature of the

project involves significant revision work on a water system or ventilation system or commissioning of new systems in new buildings and so HAI Scribe can't easily be completed at short notice.

70. I was not present during the meeting regarding the HAI Scribe stage 4 that generated the document scanned **(A35230420** - **SHFN 30 Part B form on Development stage 4 Review of completed project - dated 1 June 2019 – Bundle 5 - Page 95)**. I had been invited to attend but was on annual leave that day. My colleague, Lindsay Guthrie, Lead IPCN, is the best person to speak to the HAI Scribes in the Project. Sarah Jane Sutherland, who became lead HAI Scribe nurse after Jeanette Rae retired, was also involved.

71. The HAI Scribe process that should be followed is set out clearly in SHFN 30 Part B and C. Stage 4 should be completed after verification and snagging is completed or near completion but before handover, see Part B at 1.6. (**A33662208 – 416 SHFN 30 Part B v3 dated October 2014 – Bundle 13 - Volume 3 - Page 471)**

72. My understanding is that at no point did Lindsay Guthrie or Sarah Jane Sutherland approve the stage 4 HAI Scribe before 9th July 2019. Indeed, they refused to sign it because they did not have the information needed to assess whether the ventilation and water systems were "fit for purpose". This was an unusual stance to take and as such it had been discussed with me by Mrs Guthrie but none of us were comfortable that we could truthfully sign a document that explicitly asks whether the ventilation system and water system do not pose a risk of spreading infection when we did not have sight of data that had demonstrated that they didn't. SHFN 30 Part B section 4.26 **(Page 533)** asks "Is the ventilation system designed in accordance with the requirements of SHTM 03-01 Ventilation in Healthcare Premises?" and section 4.27 asks "Is the ventilation system designed so that it does not contribute to the spread of infection within the healthcare facility?" **(Page 533)** Section 4.37 asks "Are water systems designed installed and maintained in accordance with current guidance SHTM 04-01 series Water Safety"? (**Page 534)** We could not answer "Yes" to any of these. To answer them we agreed we needed to see validation reports for the operating theatres ventilation systems and isolation rooms ventilation

systems as well as microbiological evidence that the water system was of a drinkable quality, free of *Legionella* species bacteria and free of *Pseudomonas aeruginosa* bacteria in augmented care areas.

73. As discussed above, Mrs Guthrie and I were both heavily involved in two other concurrent IMTs where ventilation and water systems were being considered as a source of microbiological hazard where patients had acquired significant infections in other hospitals in NHS Lothian and we were also aware from the NSS report regarding water quality issues at QEUH of the experiences there too. We were aware that if these systems were not functioning optimally and safely the probability was that patients would eventually come to harm. The decision not to sign the HAI Scribe stage 4 at that stage was done collectively within the senior IPCT and I was consulted and agreed. I don't recall us being aware that the practical completion certificate would be signed off without the HAI Scribe Stage 4 being signed. The stage 4 HAI Scribe was not signed off until just prior to occupation and was done with the agreement of the Oversight Board (OSB).

Lochranza Unit (haemato-oncology)

First Issue: Resilience of Ventilation Strategy to Supply the Isolation Rooms (August 2016)

74. There were two separate ventilation issues in relation to the Lochranza unit. The first was to do with the resilience of the proposed ventilation strategy of running 5 isolation rooms from one air handling unit (AHU). In around August 2016, Janette Rae raised a concern in this regard **(A41295527 – Email Re: for comments (Email correspondence between Janette Rae and Donald Inverarity) - dated 22 August 2016 – Bundle 13 - Volume 8 - Page 233)**, resulting in a meeting with the Project Team, IHSL, Multiplex, Wallace Whittle & Mott MacDonald to discuss the ventilation. I was not at the meeting but was aware of the issue and was provided with a copy of the August 2016 Situation Background Assessment Recommendation (SBAR) that was subsequently produced by Janette Rae following the meeting **(A41295528 – 2016 08 22 Ventilation – dated 22 August 2016 – Bundle 13 - Volume 7 - Page 40)** and I

provided comment. An SBAR is a communication tool used in NHSL that provides a succinct summary of written information to interested persons and is an acronym for Situation, Background, Assessment, Recommendations and usually consists of a paragraph or two under each heading.

75. Janette Rae suggested to the Project Team that they should consult with HFS about the issue of 5 isolation rooms being served by one AHU as it primarily is an issue about best practice regarding ventilation system design, compliance with an HBN (HBN 04-01 Supplement 1) and resilience of a clinical service. Being able to articulate the risk of infection would depend on the final ventilation system design but there were clear concerns being expressed that a ventilation system was being installed which increased the risk of infection transmission rather than minimised it if it had been compliant with HBN 04-01 Supplement 1. Other deviations with regards to SHTM 03-01 compliance with regards to ventilation in Lochranza were not known by IPCT at that time. IPCT's expectation was that the Project Team, would seek the view of a ventilation engineer and consult with the NHSL Authorising Engineer for ventilation (An SBAR written by Janette Rae identifies John Rayner of Turner FM as NHSL's Authorising Engineer for Ventilation in August 2016) and/or directly with HFS. It would be an unusual expectation for an IPCN to be co-ordinating discussions about a point of clarification with regards to compliance with technical ventilation engineering guidance as that's one of the roles of the project team and a question better answered by an AE for ventilation.

76. Janette Rae prepared an SBAR outlining IPCT concerns. It sets out that there were to be isolation rooms throughout the new build that would have gowning lobbies and en-suites with shower facilities, i.e. PPVL isolation rooms (positive pressure ventilation lobbied rooms). The ventilation in terms of air change rate (10 ac/hr) and pressure regime in the room is detailed in the SBAR and is noted as being compliant with SHTM 03-01 and Health Building Note 04-01, Supplement 1, Isolation facilities for infectious patients in acute settings. The concern that was being flagged, is that there should have been a ratio of one air handling unit serving (AHU) supplying air to one isolation room, whereas what was proposed was one AHU to serve all 5 isolation rooms in Lochranza.

77. We were concerned as to what would happen if the AHU were to fail, which would result in 5 isolation rooms losing their supply air and pressure cascades which would compromise the protective isolation environment for neutropenic immunocompromised children. The strategy of having all isolation rooms fed by one AHU was discussed but not acceptable to IPCT as there was no redundancy in the design and nowhere else in the building that would provide a protective isolation environment to keep neutropenic patients safe co-located with the haematology and oncology medical and nursing teams in the event of a failure of the AHU or during periods of necessary AHU maintenance.

78. From a patient risk perspective, the children being treated in the isolation rooms could not be easily moved. They can be extremely vulnerable to the risk of infection. They require a protective isolation environment. We had to consider a contingency plan for 5 vulnerable patients if the single AHU serving all 5 rooms failed. There was no contingency in the ventilation strategy for that scenario. It was a scenario that was avoidable if each lobby, isolation room, and toilet/shower room (i.e. each PPVL isolation suite of lobby, bedroom and shower/toilet room) had its own AHU as outlined in HBN 04-01 Supplement 1 section 2.37. **(A37329297 – Health Building Note 04-01 Supplement 1 – Isolation facilities for infectious patients in acute settings – Department of Health 2013 ED – Bundle 1 - Page 1219)** This is also “strongly recommended” in section 4.5 of the Scottish document published in 2008 titled, “Scottish Health Planning Note 04 Inpatient accommodation: Options for Choice Supplement 1: Isolation Facilities in Acute Settings,” **(A36372665 – H5 – SHPN 4 Supplement 1 (2) – Bundle 13 - Volume 3, Page 425)** which predated HBN 04-01 Supplement 1 (published in 2013). I am unclear how this situation arose as my view of it was requested on receipt of the SBAR after the issue had been identified by Janette. To deviate from key guidance in this way I would have expected that the issue would have been raised with NHSL by the ventilation system designer and construction company and opportunity given for the project ventilation group (with input by IPCT and Authorising Engineer for Ventilation) to discuss its implications and seek approval of a derogation if it was considered suitable before the non-compliant ventilation system was installed. I would not have considered it a suitable design though had I been asked about it at an earlier stage.

79. To clarify further, these isolation rooms would be present to provide protective isolation for post chemotherapy neutropenic patients susceptible to infection or for containment (source isolation) of any child with an infectious disease (e.g. chicken pox) and an underlying cancer. As such, they would be frequently used and the safety of the patient inside or the patients and staff outside depends heavily on the reliability and performance of the supply mechanical ventilation, with respects to the number of air changes, pressure cascades, quality of filtered air and crucially no interruption to any of those aspects. Best practice, according to HBN 04-01 Supplement 1 (2013), **(A37329297 – Health Building Note 04-01 Supplement 1 – Isolation facilities for infectious patients in acute settings – Department of Health 2013 ED – Bundle 1 - Page 1219)** which Janette Rae had been trying to convey was that one isolation room is served by one AHU. HBN 04-01 Suppl1 concedes that more than one isolation room could be served from one AHU but actively discourages such an arrangement. The 1:1 ratio minimises the clinical risks but is more expensive to deliver and needs more plant room space for all the Air Handling Units (AHUs) and ceiling void space for ductwork and is more expensive to run and maintain. In the event of a critical failure of an AHU or the need for annual maintenance there is redundancy and resilience in the system such that for a short period of hours to days a room can be closed to clinical use and patient care maintained in the other unaffected PPVL isolation rooms so only one room is impacted rather than them all simultaneously.

80. The proposed supply ventilation to the PPVL rooms though in Lochranza was designed such that all of them were supplied by one AHU. This would be cheaper to run and maintain but there was absolutely no redundancy or resilience in the design to safely continue to care for neutropenic children in the event of AHU failure or when they needed switched off for a period of annual maintenance or filter changes. This was a red flag to me. I had been heavily involved in providing microbiological clinical liaison to the adult haematology unit while working at Monklands Hospital and knew that neutropenic patients can be incredibly unwell and can’t just be moved to a new location at short notice. This could easily compromise their outcomes and avoidably and unnecessarily risk exposure to micro-organisms that could lead to fatal infections. My understanding of the design of the RHCYP DCN building at that time was that there was no other

suitable similar location where patients could be moved to on the site that would be anywhere near co-located with the specialist staff with best expertise to care for them. There were substantial clinical risks to patients and uninterrupted service delivery which would not be hypothetical but real as the AHU would need to be shut down at least once a year. These were issues which, in my view, were not satisfactorily resolved prior to the decision to delay opening RHCYP DCN. It was only after that date that the performance of the proposed solution of a back up air supply to the isolation rooms in the event of AHU failure was demonstrated and found to be inadequate to sustain the protective environment for patients required in the isolation rooms. In my view, the issue was only resolved satisfactorily once the installed Lochranza ventilation had been revised and a new HBN 0401 Supplement 1 compliant system installed.

Second Issue: (February 2017)

81. I have been asked to look at an email chain in February 2017 between Dorothy Hanley, service lead for Redesign and Commissioning for NHSL, and some of my IPCT colleagues, including Janette Rae and consultant medical microbiologist Pota Kalima. I was not included in that email chain and was not aware of it at the time **(A42980258 - Email chain - Dorothy Hanley and Janice Mackenzie meet with Haem & Onc team for consultation - dated 13 February 2017 – Bundle 13 - Volume 8 - Page 235).**

82. It refers to a meeting to take place to discuss a deviation from SHTM 03-01 in relation to ventilation for single rooms in the Lochranza ward, including the balance of potential risks to patients. I understand that was in relation to ventilation settings in non-isolation rooms. It appears from the email chain that a date was agreed for the meeting on the afternoon of 23 February 2017 but I did not attend it. I do not know who attended as I was not present. From the email chain, it appears as though Pota Kalima, Janette Rae, Dorothy Hanley, Mark Brougham, Ann Cairney and Ronnie Henderson were invited to the meeting. I do not know what was discussed at the meeting or what was decided regarding the supply ventilation to Lochranza ward. I understand that it was to risk assess and discuss strategies to compensate for impacts on optimal care of paediatric cancer patients as the supply ventilation system was already installed.

September 2019

83. When Lindsay Guthrie and I were consulted by other members of the RHCYP DCN Executive Steering Group regarding our views of the ventilation strategy in Lochranza ward in August and September 2019, my understanding was that the air change rate in the single occupancy spaces, other than the isolation PPVL rooms, in Lochranza ward had been designed and installed to 4 ac/hr, rather than the recommended 10 ac/hr for neutropenic patients as set out in table A of SHTM 03-01. In the circumstances, i.e. where the non-compliant ventilation system had already been installed, my view was that as long as the demand for protective isolation by neutropenic patients did not exceed 5 patients at one time (who could be managed safely in the PPVL isolation rooms) then there may not be an adverse impact. The majority of children receiving inpatient haematology or oncology management in Edinburgh are not neutropenic and therefore would not need the specialist environment for care of neutropenic patients. Edinburgh is not a paediatric bone marrow transplant centre for instance whereas the children's hospital in Glasgow is and provides inpatient management for more immunocompromised children. Discussions relating to this risk assessment are in the initial draft SBAR within the e-mail trail from 9 September 2019 **(A47150202 – First Draft of risk assessment relating to addressing HAI risks in RHCYP clinical areas taking account of ventilation and its delivery – dated 30 August 2019 – Bundle 13 - Volume 8 - Page 239)**.

84. It is important to understand that neutropenia is not a disease. It describes a period (usually transitory but may persist in terms of days, weeks or months) when the neutrophil count in peripheral blood drops below 0.5×10^{9} cells per litre, most often as a consequence of receiving chemotherapy drugs to destroy cancer cells in the body but particularly cancer cells in bone marrow. Not all patients who are neutropenic are susceptible to infection to the same degree as often the severity of immunosuppression depends on which chemotherapy regimen they have been exposed to and not the fact they are neutropenic *per se*. It is also influenced by the duration of the period of neutropenia. The neutropenia is a marker indicating that a period of greater infection susceptibility has been entered and more careful monitoring for infection is required. Traditionally such

patients have been placed in “protective isolation” i.e. a room on their own to minimise contact with other people and any micro-organisms others are carrying or shedding that they might be exposed to. During the period of neutropenia there may also be susceptibility to environmental micro-organisms so traditionally attempts have been made to provide an environment that is as clean as possible with attention given to what sort of foods are consumed, water quality and air quality and use of antimicrobial prophylaxis to try to prevent infection with antibiotics and antifungal drugs. The air quality issue is primarily to avoid exposure to fungal spores which are ubiquitous in the air that everyone breathes as during the period of neutropenia there is particular susceptibility of some patients to fungal opportunistic pathogens. *Aspergillus species* are moulds which cause the infection Invasive Aspergillosis and are particularly feared in haematology patients as it is a condition that is difficult to diagnose, difficult to treat successfully and requires the use of antifungal drugs which have lots of side effects and drug interactions. Another fungal pathogen to which such patients are susceptible is *Pneumocystis jiroveccii* which causes pneumonia and is also very difficult to treat successfully, can be fatal and requires the use of drugs with significant side effects and interactions.

85. It is hard to advise on the risks and impacts that not providing an environment of 10Pa positive pressure and 10 Air changes per hour would have as the infection risk is now very individual to particular patients and their degree of immunosuppression and an assessment of the clinical risk of acquisition of infection is often best done by the clinical team looking after the patient who understand which cancer they are treating and which chemotherapy regimen is being used. Many neutropenic patients (paediatric and adult) are now managed at home with no protective isolation and until 2022, the adult haematology and oncology wards at the Western General Hospital had no such isolation facilities and did not experience excess mortality among their patients over several decades of using those facilities. Neither did RHSC at Sciennes have such facilities. I am not an expert in this area and not fully versed in the evidence base for the ventilation parameters stipulated in SHTM 03-01 for wards managing neutropenic patients but I am aware of guidance issued by the Centre for Disease Control (CDC) in the USA which has advised use of greater than 12 air changes per hour for such areas which references papers from the late 20th

century and early 21st century to support this. See **(A47205320 - Guidelines for Environmental Infection Control in Health-Care Facilities – dated July 2019 – Bundle 13 - Volume 8 - Page 1867).**

86. I'm not in a position to describe the corporate risks to NHSL from non-compliance with SHTM 03-01 or impacts on other aspects of the delivery of cancer care.

87. Once the Critical Care ventilation issue became to light in the Summer of 2019 and it was clear that remedial works would be required there, IPCT took the opportunity to suggest a review and improvement of the ventilation system in the Lochranza ward so that it fully complied with SHTM 03-01. This is set out in the SBAR from Tracey Gillies to ESG on 3 Sept 2019 **(A42980429 - Haematology Oncology Provision in the RHCYP briefing - dated 3 September 2019 – Bundle 13 - Volume 8 - Page 256)**. It was considered an opportunity to improve resilience and capacity to manage neutropenic patients based on increasing demand for paediatric cancer inpatient beds in NHSL. This was partly driven by events at the QEUH in Glasgow whereby the time spent in Glasgow for treatment by Lothian paediatric cancer patients was being minimised, with consequently more pressure on Lothian inpatient beds for neutropenic children, and realignment of referral patterns from other health boards. I understand that some paediatric cancer patients from Glasgow were also receiving care in Lothian around that time. It also aligned with the refurbishment already in progress which was installing an updated ventilation strategy for the adult haematology ward at WGH.

Radiology

88. In September 2016, there was an issue in relation to air change rates in CT (Computed Tomography scanner) rooms. The issue related to scanning the heads of neurosurgical patients who were also being treated in intensive care and may have been on ventilators. That poses particular problems and I discussed the best approach with ITU consultants at WGH who were familiar with transferring patients for such scans and scanning while the patient is attached to a mechanical ventilator to allow them to breathe. They described that current practice at the time was that they did use medical gases (sometimes anaesthetic gases) during CT scans. Janette Rae then discussed that with Iain Storrar of HFS

to agree a sensible approach. It was agreed that the air change rates should be increased from 8 ac/hr to 15 ac/hr in CT rooms where that activity would be undertaken **(A34443759 – RE CT Air Change Rates – dated 29 September 2016 – Bundle 13 – Volume 8 – Page 258)**.

Multi-bedded rooms - Pressure Issue

89. In July 2017, an issue arose in relation to bedroom ventilation design in multi bedded rooms throughout the hospital in relation to the pressure of the rooms. In summary, whether you need positive pressure or negative pressure is the difference between trying to create a protective bubble around the patients who are profoundly susceptible to infection (which requires positive pressure); or source isolation where you need to isolate the patients who are highly infectious to keep the organisms that they're shedding from spreading outside their room (which requires balanced but preferably negative pressure between room and corridor). If patients are infectious particularly with pathogens that are spread by an airborne route (such as respiratory viruses) then a positive pressure environment could actively facilitate spread and transmission to other patients, staff and visitors rather than contain it to a room. Multi-bedded bays can be used to cohort patients with the same infection but that is never the first choice. Best practice would be to first isolate patients who have such infections in mechanically ventilated isolation rooms until all such capacity runs out, then single bedrooms would be used until all such capacity runs out and only then consider cohorting patients together in a multi-occupancy room and even then only if there was certainty that they were infected with or recovering from the same pathogen.

90. I was not consulted at the time but have since read the risk assessment dated 5 July 2017 **(A40981178 – Record of General Risk Assessment_ combinedrev300118 – Bundle 6 – Page 14)** assessed by Janice Mackenzie (Project Clinical Director), Dorothy Hanley and Fiona Halcrow, Project Manage**r**. The SBAR sets out that, at that time, the bedroom ventilation design in the multi bedded rooms throughout the hospital did not meet the recommendations of SHTM 03-01 because the design had the multi bedded rooms as being positive pressure. In SHTM 03-01 (2014) Appendix 1 (**A32353809 – SHTM 03-01 Part A**

dated 1 February 2014 – Bundle 1 - Page 2628) the criteria for a general ward is not positive pressure. Clinical areas which should be at positive pressure in Appendix 1 are indicated as +ve or +10 Pascals and general ward areas do not feature as pressurised areas. The design of not being at positive pressure assists with preventing air from leaving the room to corridor and this is beneficial when trying to contain spread of common viral infections encountered in hospital such as norovirus or influenza. It was considered that in order to allow cohorting of patients with the same air-borne infections the multi-bedded rooms required to be balanced or negative pressure to corridor. There were risk assessments carried out for all wards that included multi-occupancy rooms, including critical care. At the time, it was considered by the project team that the multi-occupancy rooms in critical care should have balanced pressure. This was, I believe, based on the agreed design for paediatric critical care ventilation that predated the publication of SHTM 03-01 when the previous ventilation guidance document SHTM 2025 (**A33103351 – SHTM 2025 Part 1 dated 1 June 2001 – Bundle 1 - Page 3208**) was not explicit regarding ventilation parameters for critical care units. However, that design was not in line with SHTM 03-01, which required all rooms in critical care to have 10 pascals positive pressure.

91. As noted, I was not consulted at the time but can try to put the thinking in to context. At the old hospital in Sciennes, there was no mechanical ventilation for most bedspaces. Clinicians and IPCT were familiar with outbreaks of pathogens like the respiratory virus, Respiratory Syncytial Virus (RSV), which causes bronchiolitis, on wards and is very common amongst children admitted to hospital during winter. They were very keen to have a negative pressure cascade so that air flows into the bedroom from the corridor and not from the bedroom into the corridor to help prevent spread of respiratory viruses from room to corridor. That school of thought is completely justifiable and is just a different way of approaching mitigating the risk of spread of respiratory viruses than is set out in SHTM 03-01. However, the pressure cascade is not the only feature of critical care ventilation design that mitigates against spread of infection and it shouldn't be considered without considering the roles of other mitigating measures such as the air change rate, the distance between rooms, positioning of doors and the positioning of air extraction points within rooms which were later considered in our discussions regarding an SHTM 03-01 compliant critical care design in July

2019.

92. The types of clinical activities in critical care are very different to general wards. For example, invasive procedures such as chest drain insertion can be needed in emergencies and, on rare occasions, a room in critical care needs to be on par with, or at least closer to, the parameters for an operating theatre rather than a general ward. That is because occasionally an ITU bed space can of necessity function as an operating theatre if a patient requires immediate surgical intervention and it is not feasible to transfer them to an operating theatre until they are more stable. In my view, that's why you need conditions with air changes and positive pressure, which effectively replicate operating theatre conditions or treatment room conditions. However, as noted, the concern of colleagues coming from Sciennes was a more common scenario of RSV outbreaks which was a legitimate concern but based on having worked for many years in a cramped environment without mechanical supply or extract ventilation.

93. I understand the 4 bedded ventilation risk assessment was reviewed in January 2018 **(A40981178 – Record of General Risk Assessment ventilation_ combinedrev300118 – dated 30 January 2018 – Bundle 6 – Page 14)** but again I did not have any input into that. I discuss below at paragraphs 164 onwards how the decision to have balanced pressure for to multi-bed rooms in critical care was discussed, reviewed and ultimately changed at meetings on 10 & 11 July 2019.

Theatres

94. On 9 January 2019 Jackie Sansbury, NHSL Project Team, emailed me **(A40979123 – Email – FW Theatre Ventilation - Bundle 2 - Page 1394)** attaching an example (for theatre 30) of a commissioning checklist to clarify whether it would serve the purpose of independent validation. It was Jackie Sansbury who had re-initiated this discussion, following up an original discussion initiated by Jackie Sansbury on 23 August 2018 and I had replied with my views on 24 August 2018 **(A41295523 - Email Independent verification of theatres and isolation room ventilation - dated 24 August 2018 – Bundle 13 - Volume 8 - Page 460)**.

95. There was growing concern about the clinical and corporate risks associated with suboptimal ventilation. I was concerned that we had no data regarding whether the ventilation performance in theatres and isolation rooms was acceptable. From my perspective, to avoid HAI risk, theatres and isolation rooms were the priority areas that required independent validation. The need for microbiological assessment of air quality in an operating theatre as part of its commissioning has been best practice for many years and certainly since 2002 when the working party of the Hospital Infection Society issued guidance regarding how and when to do it **(A47150195 – Microbiological Commissioning and Monitoring of operating theatre suites – Hoffman et al – dated 2002 – Bundle 13 - Volume 8 - Page 173)**. It is also covered in SHTM 03-01 (2014) section 8.59-8.155 (**A32353809 – SHTM 03-01 Part A dated 1 February 2014 – Bundle 1, Pages 2613 to 2624**). My expectation was that a company with experience of building operating theatres in the United Kingdom would be aware of these guidance documents that are essentially describing safety checks of the air quality within the operating theatre being acceptable before using it for surgery. If not followed there would be substantial clinical risk of poorer surgical outcomes. In my view not following this guidance as written should not be an option. My experience has been that the fact there are different methods to performing the microbiological assessment of air quality in a conventional theatre and an ultraclean theatre is not always understood by non microbiologists and there is often a need to be explicitly clear which test to perform in which theatre to avoid unnecessary testing or delayed results. I had some awareness from microbiology colleagues in Glasgow that there had been issues with PPVL isolation room functioning at QEUH identified after the building was opened from e-mails sent around the informal group of IPCDs in 2016 **(A47150212 – Ventilation Query - Teresa Inkster – dated 20 May 2016 – Bundle 13 - Volume 8 - Page 463)** and then a conversation with colleagues in Glasgow and did not want to see that happen at RHCYP DCN.

96. I considered independent validation required to be arranged pre-handover. I would say, roughly, that the issue of independent validation was first raised by Janette Rae in an e-mail to Ashley Hull on 29 December 2016 along with a copy of SHTM 03-01 Part B outlining the expectation (please see paras 125 onwards

below where I discuss the requirements of validation more generally). I was copied in to the e-mail. Janette Rae had discussed this with me. I was next contacted by Jackie Sansbury on 23 August 2018 and replied 24 August 2018 outlining the need for independent validation and the expectation of what would be received. The issue was then raised again in January 2019 with Ronnie Henderson and Jackie Sansbury **(A40979123 - Email FW - Theatre Validation - 10 May 2019 – Bundle 2 – Page 1395)**. At this point in time though it was not possible to deliver independent validation of the operating theatres ventilation performance as the building of the operating theatres had not been completed.

97. Ronnie Henderson advised in his email of 11 January 2019 **(A40980996 – Email chain – RE: Theatre Ventilation, 10 - Bundle 2 - Page 1394)** that MPX would by handover have carried out all the tests and validation required in the SHTM and would record that they had done so. The first half of the e-mail read as though it would not be necessary to arrange such further validation as it was being arranged by Multiplex and IPCT took this at face value. We were being advised that we would be provided with ventilation validation documents that complied with SHTM 03-01 prior to handover and so we understood we would be able to review such information prior to handover to assess HAI risk and complete the Stage 4 HAI Scribe section about ventilation suitability.

98. However, it was announced to NHSL staff on 27th February 2019 that handover had taken place and IPCT had not had any sight of any validation data far less read validation reports. Our understanding was to expect that there would only be minor snagging issues to resolve and if anything more significant arose there would be opportunity for further correction and validation between handover and occupation to assess and correct items of concern. It was a compromise. We had stated several times what we wanted to see was an independent validation report but we were being advised that this would not be the case. My expectation was that such a validation report would be recently written by an independent ventilation engineer such as an authorising engineer for ventilation and be unambiguous, easy to read, detailed (as per SHTM 03-01 section 8.64 **A32353809 – SHTM 03-01 Part A dated 1 February 2014 – Bundle 1 - Page 2614**) and as such contain data that indicated current performance of the ventilation system serving each operating theatre i.e. provide baseline

measurements of air changes per hour and pressure cascades to be able to compare with future measurements, should the performance of the air handling units deteriorate, and end with, “a clear statement as to whether the ventilation system achieved or did not achieve the required standard” as per SHTM 03-01 section 8.65. It is not a document written by infection control as it is entirely a compliance assessment of the performance of the ventilation engineering against current technical guidance.

99. As far as I can recall, the email discussion did not go any further at this point in time. I do not know if it was continued in Commissioning meetings as I was not invited to them. IPCT were waiting on the validation data we had requested.

100. It is important to note that this period coincides with media coverage of deaths from cryptococcosis at QEUH, possibly linked to ventilation, so we were also awaiting whether further guidance would be issued in relation to this which might influence what we would need to comply with. NSS and HFS interim guidance ‘Managing the Risk of Contamination of Ventilation Systems by Fungi from Bird Droppings v1.0 was issued in March 2019 **(A43168692 – Bird Droppings Guidance V 1.0 – dated March 2019 – Bundle 13 - Volume 8 - Page 468)**. There was also information about preventing cryptococcosis from ventilation systems produced by the Specialised Ventilation for Healthcare Society (SVHSoc) in April 2019 **(A33625562 – SVHSoc Briefing Document on Cryptococcus - dated Feb 2019 – Bundle 13 - Volume 8 - Page 472)**.

101. There was a parallel discussion about how to validate ventilation for an intra-operative MRI scanner and microbiological air sampling in early February (4-11) 2019. Through Sarah Jane Sutherland, I had offered to meet with the Project Team to discuss the role microbiological air sampling as part of theatre commissioning but was advised on 11 February that it wouldn’t be necessary for me to meet **(A47150200 – RE Air testing MRI intra-operative scanning room – dated 11 February 2019 – Bundle 13 - Volume 8 - Page 476)**. There were ongoing discussions about aspects of assessment of air quality and ventilation performance, see **(A47150210 – Ultraclean laminar flow ventilation in DCN new theatres – new RHSC and DCN – dated 15 April 2019 – Bundle 13 – Volume 8 - Page 478)** and **(A47150203 – RE Ultraclean laminar flow**

ventilation in DCN new theatres – new RHSC and DCN – dated 15 April 2019 – Bundle 13 - Volume 8 - Page 483).

102. In relation to the emails from Ronnie Henderson of 10 May 2019 and 13 May 2019 I was being asked my opinion as to whether the Multiplex report for theatre 30 would suffice as the independent validation report for theatre ventilation as the format was quite different to the example I had provided of a theatre validation report issued to NHSL for a recently built operating theatre at St Johns Hospital (**A40980996 – Email from Donald Inverarity to Ian Laurenson et al regarding Theatre Validation at RHSC and DCN – dated 10 May 2019 – Bundle 6 - Page 6)** and **(A40981038 – Email from Kerryann Little to Tracey Gillies acknowledging the response provided on Theatre Validation at RHSC and DCN - dated 13 May 2019 – Bundle 6 - Page 8)** and **(A40988868 – Email from Ronnie Henderson to Donald Inverarity regarding Theatre Validation at RHSC and DCN - dated 13 May 2019 – Bundle 6 - Page 11)**. The reasons I did not consider the Multiplex reports would satisfy the requirements in SHTM 03-01 sections 8.64 and 8.65 **A32353809 – SHTM 03-01 Part A dated 1 February 2014 – Bundle 1 - Page 2614)** for independent validation of the ventilation systems are as follows:

- Not independent;
- Not in an easy to read format - it was a checklist not a validation report;
- Items marked yes had to be taken on trust - there was no evidence I had access to which verified the statements;
- No Data about theatre air changes rates or pressure cascades;
- Dated October 2018 and significant works had been ongoing in theatre suite since that time so not reflective of current state.
- In the comments it made reference to commissioning certificates as evidence rather than measurements of current performance.
- It wasn't signed so it was unclear whether the theatre was considered to meet "the required standard" or not.

103. My understanding was that the reason sample reports were only sought in May when we had been raising concerns for several months was that many of the

areas with critical ventilation systems e.g. theatres had not finished being built and so could not undergo a validation exercise.

104. I considered that the technical standards required to be met with a wide safety margin because ventilation systems deteriorate over time. AHU life span is considered to be around 20 years so it would need reserve capacity to maintain performance for such a period of time without potentially creating clinical risk of HAI and poor patient outcomes. There is a need to have reserve capacity to overcome filters silting up over time. There is also a need to minimise down time for servicing and maintenance as that creates service disruption and delays access to surgery.

105. As at 15 March 2019, when I first escalated my concerns to Professor Alex McMahon (**A34010959 – Email from Lindsay Guthrie to Annette Rankin regarding a Sunday Herald Article on ventilation issues at QEUH and RHCYP 5 August 2019 – Bundle 5 - Page 30**) and that information we would need to understand potential infection risks and progress with the HAI Scribe process at RHCYP DCN was not available, I had not had sight of any ventilation system validation reports. At this point, my involvement with the Project had only been sporadic and I was only consulted on an ad hoc basis. I hadn't been invited to or attended any commissioning meetings. At around this point in March 2019, we were beginning to have awareness of non-compliant issues but the full nature and scale was not known and so it was not easy to anticipate risk of HAI or other clinical risks. As information began to be shared about the experiences with building systems at QEUH we started to see some potential parallels that could lead to HAI risk if occupied by vulnerable patients with regards to: water contamination with recognised bacterial hazards in some areas; water that was not of a drinkable standard in others; deviations in ventilation and room design in critical ventilation systems, (primarily the PPVL isolation rooms in Lochranza); and the neurosurgical operating theatres.

106. We were also concerned about the future impact a major flood which occurred during the summer of 2018 may have on air quality within the building given the subsequent risk of mould and fungal exposures, particularly given media attention regarding cases of cryptococcal infections (a fungal infection) at QEUH.

Retention of water damaged building materials in walls for example can lead to mould growing behind the walls and release of fungal spore into the environment and so removal of water damaged material and rebuilding of walls was required. These were fully addressed and resolved by the time of occupation but did not appear to be complete when we performed an inspection visit in March 2019.

20 March 2019 – IPCT Walkround

107. There was an IPCT inspection visit or "walkround" with some of the Project Team which took place at the new site on 20 March 2019. There is an email from Ronnie Henderson of 21 March 2019 **(A40988839 - Email from Ronnie Henderson to Donald Inverarity providing a summary of main points of discussion and evidence following a site visit of 20 March 2019 addressing concerns raised by IPC – dated 21 March 2019 – Bundle 5 - Page 44)** reporting on the IPCT walkround. In retrospect, there were probably several purposes to this walkround, one of which was to gather information relevant to completing a Stage 4 HAI Scribe but we were not planning to complete it there and then. I think different people had different expectations as to what it was about. My expectation was that I was there to support the Executive Director of Nursing/HAI lead, Professor Alex McMahon, to see first-hand what issues IPCT had been raising and whether they had been addressed or resolved and gauge what remaining work was required and whether that could compromise the planned date of occupation.

108. Ronnie Henderson's email **(A40988839 - Email from Ronnie Henderson to Donald Inverarity providing a summary of main points of discussion and evidence following a site visit of 20 March 2019 addressing concerns raised by IPC - Bundle 5 - Page 44)**, notes that the following people attended: Janice MacKenzie; Ronnie Henderson; Alex McMahon; Sarah Jane Sutherland; David Gordon (Bouygues); and, me.

109. We visited areas that had been affected by flood damage in summer 2018 to see the extent of the repairs and extent of removal of water damaged building materials. We were able to visit a neurosurgery operating theatre and see the intra-operative MRI room. We were shown in a plant room and shown vermin

control measures to assess their adequacy in response to guidance from HPS about controlling pigeons and their excrement. We visited a PPVL isolation room in Lochranza and were able to see the solution to the lobby ceiling void drip tray ventilation issues that had been a concern during second half of 2018.

110. During the visit we were advised that independent validation of the theatres would be performed once construction was completed. It was confirmed that there were some commissioning and validation reports for theatres and isolation rooms but on the visit it became clear that some of the theatre areas were still building sites and construction was still in progress so it was unclear how the historical reports reflected current performance.

111. We identified and visited a water outlet that had a persisting contamination issue with *Pseudomonas aeruginosa* and for the first time IPCT were able to clarify the purpose of the room which was to be a 4 bedded room in the paediatric respiratory ward. This was a concern as children with chronic lung diseases are particularly prone to developing *P aeruginosa* lung colonisation or infection and there was potential for them to be exposed to and inhale this bacteria if the water contamination issue was not resolved.

112. On visiting the neurosurgery operating theatre, we established that all the neurosurgery theatres had been designed as ultraclean theatres and had installed laminar flow canopies. This was an unconventional design for neurosurgery and raised some concern about whether surgery could be performed in a conventional mode and how both modes would be validated. Many neurosurgical tumour resection procedures last many, many hours and there was perceived risk that brain tissue could be dried out if laminar flow ventilation was used in such operations.

113. Additionally, the neurosurgical theatre had an adjoining MRI room for intra-operative MRI scans and this raised concerns as to how to commission the ventilation in that room and how transfers from the theatre to scanner could take place without compromising the sterile field of the operation. There was nothing written yet in national guidance that covered how to assess air quality for such a new design of operating theatre and we were unable to seek advice from other

health boards as we could not identify another board with an existing intra-operative MRI scanner facility. Discussions about the design and ventilation provision of the facility had predominantly been with members of the neurosurgical team and it may have been that the difficulties that would be encountered in establishing microbiological air quality and safe performance of both the theatre and the MRI scanner in the context of use by a patient with an open skull may not have been anticipated until it had been built. There had been IPCT input in discussions regarding the intra-operative MRI scanner in October 2017 but they were around how the surgical team and radiology team would be segregated and routes they should take to enter and exit the facility and what level of personal protective equipment (scrubs and gowns) the radiology team would need and not about ventilation **(A34443491 – RE Urgent advice required – dated 04 October 2017 – Bundle 13 - Volume 8 - Page 2162)**. The involvement of someone with experience of ventilation in such a setting (Authorising Engineer or Microbiologist) would have been a helpful additional resource to consult but I'm not aware of anything that mandates such involvement.

114. From IPCT perspective, I concluded that the building was not yet sufficiently complete to undertake a Stage 4 HAI Scribe but my understanding was that the building had already been handed over to NHSL.

115. In my view, independent validation of the ventilation system had not been agreed at this point because Multiplex were not independent of the construction process. They may have been able to supply commissioning data but that was unlikely to be unbiased. The Project Team were aware of the type of report we wished to see having been given an example from previous theatre commissioning at St John's Hospital. We wished to see what style of report Multiplex would provide and whether it included any data that would allow us to assess even provisionally whether the theatres were safe to operate in. At this point we had no data regarding the theatre performance with which to do that and were aware that some of the theatres had not been completed, as we had seen that first hand on the walkround, so we were aware that validation reports would be impossible to write as theatre performance can only be assessed once building work is complete. The IPC team were taking their steer from my view at this point.

116. The only document provided by Multiplex had been a checklist about theatre 30, which had no useful data and was dated October 2018. We knew there was still construction work happening in theatres so that document, as well as having no useful data in it, was not contemporary on which to base any judgement of current or future safety.

Settlement Agreement 1 – February 2019

117. I was not aware of Settlement Agreement 1 (SA1) (**A32469163 – Settlement Agreement and Supplemental Agreement relating to the Project Agreement for the provision of RHSC and DCN between Lothian HB and IHS Lothian – 22 February 2019, Bundle 4 - Page 11**) or its contents until after it had been signed. I first found out NHSL had taken possession of the building on 27 February 2019 when an announcement was made to all NHSL staff.

118. I have discussed above that there was a risk assessment in relation to balanced pressure in multi-bed rooms, which included multi-bedded rooms in critical care **(A40981178 – Record of General Risk Assessment ventilation_copmbinedrev300118 – dated 30 January 2018 – Bundle 6 - Page 14)**. I am not aware of IPCT having carried out a formal risk assessment for a derogation to 4ac/hr for multi-occupancy or single rooms in general wards or rooms in critical care prior to SA1 being entered in to. However, in relation to single rooms and multi-occupancy rooms in general ward areas (i.e. not in critical care), if the project team presented to IPCT that these areas were receiving 4 ac/hr mechanical plus 2 ac/hr natural ventilation they would be considered compliant with SHTM 03-01 as it would be 6 ac/hr by mixed mode ventilation in a general ward area and therefore wouldn't need any risk assessment.

119. I have previously reviewed e-mails from Janette Rae that relate to air change rates in general ward areas and I did not find anything in writing to suggest that, as the IPCT representative, she was involved in consenting to such a derogation (see e-mail trail to Tracey Gillies and Alex McMahon sent 9 July 2019) **(A41295517 – Email from Tracey Gillies to Audrey Trotter – request to print out email (6) attachments as relevant to discussion about whether HPS**

and HFS had been involved in the earlier stages of RHCYP – dated 14 August - Bundle 7, Volume 1 - Page 203). There is also an e-mail exchange on 20 January 2017 where she highlights that in HTM 03-01 the required environmental conditions in such a 4 bedded room would be 6 ac/hr **(A47150211 – FW Other matters – dated 20 January 2017 – Bundle 13 - Volume 8 - Page 2165)**. I don't know the mechanism by which the change from 6 ac/hr to 4 ac/hr was approved or who was involved or if it was done before or after the ventilation systems had been installed.

120. In my view, if there was considered a need to derogate from guidance that is considered best practice then consideration should be given as to whether that approach may adversely increase any clinical risk. The risk of the proposed new environmental conditions facilitating the acquisition of an infection through the delivery of healthcare is only one aspect of clinical risk that should be considered along with other considerations about impacts on fire protection, room temperature control etc. Because there would be potential for easier transmission of respiratory viruses with fewer than 6 ac/hr I would have expected some risk assessment by IPCT to be done that would involve understanding the nature of the patient group and their probability of being admitted with respiratory viruses or susceptibility to acquiring respiratory viruses if exposed (and the possible consequences to them of that) and, whether aerosol generating procedures would be undertaken in the room for example.

121. Lindsay Guthrie and I performed a retrospective risk assessment much later in the autumn of 2019 **(A32653315 – SBAR General ventilation IPC risk assessment – dated 29 August 2019 – Bundle 13 - Volume 8 - Page 2169)** with ventilation performance data provided by IOM and assessed the impact the reduced air change rate of 4 ac/hr provided by mechanical ventilation might have on the risk of infection transmission for multi-occupancy rooms and single beds in general wards and outpatient areas. This acknowledged that 4 air changes per hour is substantially higher than the majority of bed spaces within the pre-existing NHSL estate which has natural ventilation provision via windows only from buildings that pre-date 2014 and SHTM 03-01. Therefore, achieving 4 ac/hr was not considered unsafe as it represented improvement compared to ventilation provision at RHSC at Sciennes which had natural ventilation in general wards.

Additionally, at this stage in autumn 2019, IPCT were being advised that in addition to 4 ac/hr mechanical ventilation there would also be an additional 2 ac/hr provided if windows were open in such general ward areas and so meet the 6 ac/hr stipulated in SHTM 03-01 by provision of mixed mode (mechanical and natural) ventilation.

122. We knew that low air changes were a concern for containment of respiratory viruses in the existing RHSC at Sciennes. To perform such a risk assessment, there would need to be knowledge of how the ventilation system performs but also knowledge of what patient group would occupy the area and what range of medical or surgical interventions would be performed. The risk of HAI is not uniform nor solely determined by the room ventilation parameters. Knowledge of what patient groups (and their susceptibility to infection) would be in which areas and which procedures would be being performed was not information that was comprehensively available to IPCT at the time of SA1.

123. We were also aware verbally of other new build healthcare facilities that were open to patients which had 4 ac/hr or less. Under most circumstances, 4 air changes per hour mechanical ventilation in general wards would not likely compromise patient safety and care but it would impact on the risk of infection transmission if someone on the ward was shedding respiratory viruses who was not isolated, be that staff, visitors or patients.

124. It would not be appropriate to have 4 air changes per hour mechanical and 2 air changes per hour natural ventilation instead of the required 10 mechanical air changes per hour in either multi-bed or single bedrooms in critical care as a modern critical care unit should not be designed with opening windows. The critical care unit should be at 10 Pascals positive pressure and opening windows would render it at atmospheric pressure not positive pressure. Health Building Note 04-02 published in 2013 relates to the design of critical care units and it states in section 6.7 that, “ceilings and windows should be sealed.” This is to allow pressurisation of the room. **(A37329307 – Health Building Note 04-02 – Critical Care Units – Department of Health – dated 2013 – Bundle 1 – Page 2853)**.

125. I do not agree that SA1 represented an important missed opportunity to spot and address further issues with non-compliant ventilation before the end of the construction phase. It would represent missed opportunity to detect non-compliant aspects of ventilation design. I understand that the ventilation system had been installed for some time before SA1 was signed so the issue wasn't that the specification was incorrect and not detected, it had progressed from a specification to being installed. Other aspects of construction work for instance in the theatres were not complete by the time of signing SA1 so it would not be possible to fully assess how their ventilation systems performed. Non-compliant and unsuitable ventilation performance is determined once the room being ventilated is completely built and the ventilation system is installed and running. There may have been earlier opportunities to identify that some aspects of the design would become a concern. For instance, that Air Handling Units and supply air ductwork did not have capacity to deliver parameters of ventilation set in SHTM 03-01 but that is an issue of ventilation engineering non-compliance and outwith the remit of IPCT. It was not the case that all ventilation non-conformance with SHTM 03-01 was missed prior to the signing of SA1. For example, Ronnie Henderson had alerted IPCT and HFS in October 2018 to an issue regarding placement of heater batteries in the ceiling void of the lobbies of PPVL isolation rooms in Lochranza ward **(A47150206 – RE Isolation Room Heater Batteries – dated 06 December 2018 – Bundle 13 - Volume 8 - Page 2201)**. This had the potential to cause water pooling beneath them. We were asked for our view regarding the solution that Multiplex proposed of placing water drip trays beneath them, but this concerned us. The infection hazard was that it could create stagnant water within the ceiling void of the isolation room with the risk that immunocompromised children would potentially be at unnecessary risk of breathing aerosols of any environmental bacteria or mould that grew in the stagnant water or that water damage from a drip tray overflowing would form damp areas in the ceiling void with risk of fungal growth and fungal spores being inhaled by vulnerable children defeating the purpose of the ventilation system that was there to provide ultraclean air and minimise risk of inhaled fungal spores. The location of the heater batteries did not conform with SHTM 03-01 as outlined in Ronnie Henderson's initial summary when he escalated the issue **(A47150198 – Issues Relating to location of Heater Batteries – Bundle 13 - Volume 8 - Page 2205)**. Discussions about this matter continued to December

2018 **(A47150207 – RE Isolation Room Heater Batteries – dated 06 December 2018 – Bundle 13 - Volume 8 - Page 2208)** when it was agreed the heater batteries (used in control of the ambient temperature within the bedroom) would not be used but radiant heater panels in the ceiling would be used instead. The installed heater batteries were not being removed though, just made redundant and not used to avoid condensate forming. It was still a non-conforming ventilation system design, but it had been identified and escalated by the project team prior to the signing of SA1.

Commissioning and Validation

126. It is an important point to understand the distinction between and the timing of commissioning and validation. The applicable guidance at the time was SHTM 03-01(2014) Part A **(A32353809 – SHTM 03-01 Part A dated 1 February 2014 – Bundle 1 - Page 2490)** and section 8 page 114 (**Bundle 1 - Page 2603)** of the guidance deals with the commissioning and validation of specialised ventilation systems. On page 114 Commissioning is defined as follows:

> *"Commissioning - Commissioning is the process of advancing a system from physical completion to an operating condition. It will normally be carried out by specialist commissioning contractors working in conjunction with equipment suppliers. Commissioning will normally be the responsibility of the main or mechanical services contractor."*

127. Validation is defined on page 114 **(Page 2603**) as follows:

> *"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."*

Note:

…

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 independent Authorised Person appointed by the NHS Board.

It is anticipated that training in the validation of specialised healthcare ventilation systems for independent Authorised Persons will become available during the life of this SHTM."

On page 125 (**Bundle 1 - Page 2614**) the guidance states:

"Ventilation system commissioning/validation report

8.64 Following commissioning and/or validation a full report detailing the findings should be produced. The system will only be acceptable to the client if at the time of validation it is considered fit for purpose and will only require routine maintenance in order to remain so for its projected life.

8.65 The report 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."

128. In line with Guidance, Multiplex undertook the commissioning of the ventilation system, including independent tester sign off by Arcadis. However, the information provided to me did not have the level of detail and assurance I needed to conclude that the system reached the required standard. For me to assess infection risk in an operating theatre, as a minimum, I would need to know:

- the air change rate per hour in the theatre and adjoining rooms. This involves a calculation which is outwith my expertise to perform and requires knowledge of the volume of the room being assessed not just air flow measurements.
- The air pressure in Pascals in the theatre and adjoining rooms

- Information about the airflows. In a conventional theatre there must be turbulent air demonstrated above the surgical site. The direction of air flow must be from the cleanest area to least clean/disposal areas.
- In addition to these ventilation checks I would include a visual inspection to be assured, for example, that there are not avoidable horizontal surfaces for dust to gather, that wall and floor surfaces are intact and sealed to allow cleaning, that air extract grilles are correctly positioned to avoid extraction of air that has only just entered and bypassed the room, that scrub sinks do not splash, that doors close properly to maintain pressure cascades.

Although I was not part of the decision, my understanding is that IOM were appointed by NHSL (with input from HFS) as suitably qualified, independent, Authorised Persons to carry out the validation of the critical and specialised ventilation systems at RHCYP & DCN. They provided the validation reports and it was through those that the issues with the air change rates in critical care were first discovered by NHS Lothian.

IPCT Role in Validation

129. With reference to SHTM 03-01, page 114 para 8.65 (**A32353809 – SHTM 03-01 Part A dated 1 February 2014 – Bundle 1 - Page 2614**) quoted above, my understanding is that the IPCT role is that we only need to be provided with a copy of a self-explanatory validation report that outlines either a fully compliant and "fit for purpose" ventilation system or that there is non-compliance with guidance affecting any particular area of the hospital. IPCT would then seek to understand what patient groups use that area and what interventional procedures may be performed there. IPCT can then assess whether the non-compliance may cause clinical risk for the patients or staff using the area. IPCT will either be content that the facility is suitable or seek to mitigate against any particular HAI risk that might be anticipated.

130. In terms of SHTM 03-01, independent validation should take place before a Stage 4 HAI Scribe as it informs how the question about ventilation being fit for purpose can be answered. This should be done before hand over of the building.

131. The risks of independent validation in terms of SHTM 03-01 not taking place

timeously are: (i) HAI risk from accepting sub optimally performing systems; and (ii) other corporate risks such as financial, reputational and service disruption.

Validation of all critical systems

132. In early 2019, I was not aware that the requirement for independent validation, in terms of SHTM 03-01, applied to all critical systems and not just theatres. The ventilation system training I had and my previous experiences had mainly focussed on assessing infection risk from critical ventilation systems serving operating theatres and isolation rooms and I was aware of the need for annual verification of local exhaust ventilation systems in laboratories. Much of that previous experience and training had been before SHTM 03-01 had been published though in 2014. My understanding of the term “critical ventilation” in healthcare is that it refers to any clinical area that is fully or partially dependent on mechanical supply or extract ventilation (or both) to maintain an optimally safe environment for the delivery of clinical activities such as operating theatres, isolation rooms, endoscopy suites, containment level 3 laboratories for example. The ventilation system is “critical” to the provision of a safe environment. It should not be confused with the term “critical care” (synonymous with “intensive care”) which refers to a clinical area where the patients being managed are critically ill and have a significant probability of dying without complex life-saving interventions. Confusion often arises because all critical care areas are supplied by critical ventilation systems but not all critical ventilation systems deliver air to critical care areas.

133. I agree it is clear in on page 114 of SHTM 03-01 Part A **(A32353809 – Part A 1 February 2014 – Bundle 1 – Page 2603)** that it should apply to all critical systems. From the perspective of preventing HAI, it would be wider than just theatres as it would also involve isolation rooms. It would make sense to independently validate all critical ventilation systems given their fundamental role in providing and maintaining safe clinical environments.

134. Page 114 of SHTM 03-01 indicates that it is the role of the Independent Authorised Person to ensure that the relevant parts of SHTM 03-01 were interpreted correctly and validation was completed in all the required areas. At

the end of the validation process, defined on page 114 of SHTM 03-01 as assessment of "fitness of purpose as a whole," the health board should be assured that the ventilation system is optimally functioning to deliver the safest clinical environment (in terms of parameters such as pressure cascades, air changes, air filtration) that it can and that all measures to mitigate against predictable ventilation related hazards (which would include fire risk as well as possible microbiological hazards) have been taken. To me, that indicates it should be an independent Authorising Engineer for Ventilation to determine compliance with design best practice and engineering parameters, which is ultimately what IOM did. It is not a recognised role of an infection control doctor.

Period following independent validation (July 2019)

135. My first awareness of IOM's test results in the Critical Care unit was it being reported verbally at one of the RHCYP DCN systems update meetings in the run up to the decision whether to occupy the building or not. I certainly had awareness of it on 1 July 2019. I don't recall if it was mentioned at the 4pm ventilation discussion on Friday 28 June 2019 but for most of that day we were only aware of operating theatre ventilation issues.

136. My immediate involvement in the days following the Critical Care air change issues coming to light was explaining the potential patient safety implications in critical care (particularly risk of HAI through respiratory virus transmission) of the IOM performance data to NHSL Executive Directors and Project Team colleagues. On 2 July 2019, I contacted my IPCD colleague Dr Teresa Inkster in NHS Greater Glasgow & Clyde (NHS GG&C) to discuss if there were similarities between what IOM had found at RHCYP DCN and what had been discovered regarding ventilation systems at QEUH. On 4 July 2019, I was asked to attend a meeting to be held on 5 July and chaired by the NHSL Chief Executive, Tim Davison, and attended the meeting on 5 July. I had further e-mail discussion with Dr Inkster on 5 July.

137. On 2 July 2019, I attended a meeting with Tim Davison, Iain Graham, Brian Currie, Tracey Gillies, Lindsay Guthrie, Pota Kalima, Eddie Doyle, Jacquie Campbell, and Fiona Mitchell. The purpose of this meeting was to assess the

Critical Care ventilation issue and possible solutions. This meeting was held at 17:30. At 16:30 IHSL and their contractors had presented calculations relating to 3 options A, B and C to alter the ventilation supply to critical care in order to increase air change rates in some areas. 3 options were presented as follows **(A47150196 – Air change enhancement options – dated 02 July 2019 – Bundle 13 - Volume 8 - Page 2211)**.

138. All of the options involved starving a 4 bedded bay and a single room of their mechanical supply air and re-directing that supply air to the remaining rooms to enhance their air change rates in varying combinations. In option A, four bedded bays were hoped to achieve 5 ac/hr and single rooms were hoped to achieve 7 ac/hr. In option B, more air would be supplied to single rooms which it was hoped would achieve 6 ac/hr and the 4 bedded bays would achieve 4 ac/hr. In option C, the 4 bedded rooms would be given priority for the supply air and it was hoped they would achieve 8 ac/hr while the single rooms would achieve 4 ac/hr.

139. I do not recall in any detail what risks were discussed relative to each course of action but clinical risks to patients, service delivery and business continuity risks and corporate legal risks of accepting the proposals were discussed. I do not recall why the meeting was not minuted. I do not have a record of it. I only have a copy of the options being discussed. Lindsay Guthrie took some handwritten notes at the meeting.

140. I recall the conclusion of the meeting was that HFS were to be consulted for their interpretation of the data and advice. Other UK experts in healthcare ventilation were also mentioned as potential people to contact for advice such as Dr Peter Hoffman at Public Health England, Colindale. No option was decided upon at the meeting. The IHSL calculations were to be checked.

141. My view/input on the options tabled was that none of them were good options and all of them had substantial compromises. They were theoretical, unverified calculations and there was no assurance that they were correct or that rebalancing in this way was achievable. None were compliant with SHTM 03-01 as none of them could achieve 10 ac/hr. All of them involved the ITU losing 5 bed spaces and created compromised rooms which already had ITU equipment

installed. None of them addressed the room pressure issues and none would achieve 10 Pa positive pressure. Logistically it would be difficult to perform the proposed ventilation system rebalancing work in an occupied ITU as it would inevitably disrupt the delivery of care to critically ill children. All 3 options had inequity between bed spaces with regards to supply ventilation provision. In each, only a proportion could meet SHTM 03-01 requirements of a general ward bedspace and several would not but none met criteria for ITU. Bedspaces receiving only 4 ac/hr would, according to Appendix 1 of SHTM 03-01, be similar in ventilation provision to a ward single room toilet which intuitively was just wrong for a bed occupied by the most critically ill children in the hospital.

142. In terms of other discussions I had about this issue on the same day, 2 July 20I9, I had an e-mail discussion with Dr Tracey Gillies regarding Appendix 1 of SHTM 03-01 and recommended air changes for rooms **(A40984693 – Summary of critical care ventilation (Email from Donald Inverarity to Tracey Gillies) - dated 2 July 2019 – Bundle 13 - Volume 8 - Page 2212)**. I updated my microbiologist colleague Dr Pota Kalima regarding IOM data relating to PITU ventilation performance ahead of a ventilation meeting at 16:30 which he would attend with me. I spoke with microbiology colleagues looking for contact details for Dr Peter Hoffman in PHE Colindale. I had regular contact with Lindsay Guthrie through the day as we kept each other updated. I attended the twice daily RHCYP DCN ventilation meetings at 12:00 and 16:30. I had a telephone discussion with Dr Teresa Inkster during the morning and further e-mail contact with her in the early afternoon.

143. I have been referred to an email of 2 July 2019 from Jacquie Campbell summarising discussions from that day (**A35827796 – Email from Jacquie Campbell to Iain Graham et al, summarising the key topics of discussion – dated 2 July 2019 – Bundle 7 - Volume 1 - Page 33**). Jacquie Campbell notes in this email that I advised all the air exchange rates in the new build are nonetheless better than the existing site at RHSC, Sciennes. My understanding of the conditions at Sciennes, as at July 2019, was that very little of the ward areas had mechanical supply ventilation. As it was opened in the 19th century, most areas only had natural ventilation from opening windows. There had been a Healthcare Environment Inspectorate inspection in October 2018 and window

cleanliness had been discussed and it was established that some of the windows didn't open. The room hosting some bedspaces of the high dependency unit in the critical care area had once been a library and still had a mezzanine floor and stairs to it. The haematology/oncology ward was ward 2 and although it had some segregated bedspaces, they didn't all have lobbies and did not have supply ventilation. When we were undertaking preparation work ahead of the first wave of Covid in January 2020 we identified that ward 6 (Surgical Admissions Unit) had some mechanical supply ventilation and single rooms. ITU had 2 switchable pressure rooms for isolation and so did the HDU **(A47172277 – Survey of Isolation Facilities – dated 09 January 2020 – Bundle 13 - Volume 8 - Page 2217)**.

144. Continued occupation of clinical spaces at RHSC, Sciennes was far from ideal architecturally and not aligned to the delivery of 21st century healthcare. Many areas were of a "Nightingale" ward design and there were very few single rooms in which to isolate infectious children. As a result, children with transmissible infections (such as some lung pathogens in Cystic Fibrosis) might be located in single rooms anywhere in the building with an available single room and not necessarily co-located with the nursing skill mix and medical staff with the most expertise of looking after them. Preventing the transmission of respiratory viruses was difficult (although ward design and ventilation was only a component of that) and cohorting of infectious patients happened much more often than we would have liked as the number of patients with the infection exceeded the single room capacity. There were no isolation rooms that met any modern design or performance with regards to ventilation. However, the staff were very familiar with the issues of their wards and hospital and were proficient at working around them such that patient outcomes were optimal. Infection rates for infections where there was mandatory surveillance were very low. The deficiencies of the RHSC site were common knowledge among staff who worked on the site and the senior staff who managed it. It was one of the primary reasons for building a new children's hospital.

145. On 3 July 2019, one of the options being considered was whether the move could go ahead as planned, with the exception of the Intensive Care Unit only. By this time, I, along with Lindsay Guthrie, had been invited to participate in the

discussions at the Incident Management Team/Executive Steering Group as the most senior members of the IPCT to advise the Executive Directors on the potential infection consequences and outcome to patients using the areas in their present configuration and design. The ultimate decision was not ours to make and that rested with the Executive Team members.

146. I was becoming more concerned that proceeding with the move without the Paediatric Intensive Care Unit may not be a feasible or a safe option if there was an open Accident and Emergency department or emergency surgery being performed in operating theatres. These areas have interdependencies as very ill patients in these areas would most likely need to go directly to intensive care and not a ward. It often wouldn't be safe to attempt to transfer unstable patients to other hospital sites and without an operational intensive care unit there may not be easy access to appropriate facilities even to stabilise them prior to transfer for longer term intensive care management.

147. There would there have been an HAI risk to patient safety and care in proceeding with the planned move and carrying out remedial works to the ICU with patients *in situ* in other parts of the building. The delivery of patient care adjacent to building sites is well recognised as leading to Healthcare Associated Infection (HAIs) in both immunocompetent and immunocompromised patients. That is why the HAI Scribe process was developed to try to identify and minimise such risk.

148. The clinical risks in proceeding with the move as planned but without ICU were risks of misalignment of the needs of critically ill children and access to the support they need in the shortest possible time. Managing critically ill patients adjacent to an active building site has many predictable consequences. With regards to HAI, the incidence of ventilator acquired pneumonia would likely increase and potentially due to environmental bacteria. The incidence of intravenous device infections would also be at risk of increasing too along with other invasive device infections in even more crucial locations such as intraventricular devices accessing cerebrospinal fluid etc. It is much harder to maintain a suitably clean environment for delivery of clinical care when there is building work in the vicinity due to dust generation. Dust settling on equipment is a predictable issue which can directly or indirectly lead to higher incidence of

post-operative wound infections. The HAI risks though are perhaps not as great as other potential clinical risks from inadvertent electrical failures or ventilation system failures or compromised access to life saving equipment during emergencies. Additionally, at this point in time, it was highly likely that the hospital would not initially have all its operating theatres functional – surgical capacity in a major incident with paediatric trauma casualties or adult head injuries would potentially be compromised. Critical care nursing and medicine are not universally held skills and visibility and co-location of such patients with skilled teams is critical to their welfare and optimal outcomes. Likewise, the equipment required to look after them is highly specialised and would be unlikely to be located elsewhere in the building.

149. In my view, keeping the existing RHSC site in full operation was the safest option until rectification works at RHCYP DCN could be planned, implemented, completed and checked. Moving paediatric A&E across without an ICU risked adverse outcomes and had, at that point, lots of unknown risks and unknown consequences. There was a very stark reality that delayed or impeded access to intensive care might result in children dying. Trying to rectify the intensive care ventilation system while using the area as an active intensive care unit had some predictable risks, unknown consequences and would be logistically very difficult to arrange and run and would take much longer to complete than if the unit was unoccupied. Reversing the move and continuing to keep services delivered from the RHSC site was not ideal, as many areas were wound down, packed and ready to move but the clinical and HAI risks at RHSC were known and known to be manageable and staff were familiar with it. It was the safest option available at that time in my view. This personal view was made based on information and discussions I was privy to during the weeks leading up to the decision not to occupy. My views about the move and my interpretation of potential future HAI risk had been requested by Professor Alex McMahon during June 2019 and shared with other Executive Directors, IPCT and Project Team for consideration, see **(A47172502 – HAI SCRIBE RHCYP Risks and Mitigations – dated 17 June 2019 – Bundle 13 - Volume 8 - Page 2218)**. As more information became available, my views were still being requested by the NHSL Executive Directors to inform the Chief Executive, see **(A40984626 – RE Summary email or critical care ventilation – dated 01 July 2019 – Bundle 13 - Volume 8 - Page 2223)**

and **(A47172339 – RE question – dated 08 July 2019 – Bundle 13 - Volume 8 - Page 2108)**. Throughout the week prior to the decision not to occupy RHCYP DCN being taken, my views were being taken into consideration when requested at daily update meetings with the Executive Directors, Chief Executive and Project Team and in the weeks following regarding interpretation of HAI risk and corrective actions required to resolve the issues that were being identified **(A40988883 – RE Summary email or critical care ventilation – dated 01 July 2019 – Bundle 13 - Volume 8 - Page 2376)**.

150. It is important to recognise that IPCT were very keen to have DCN moved off the WGH site to Little France as soon as it was safe to do so. Since February 2019, NHSL was trying to resolve issues of *Pseudomonas aeruginosa* water contamination that was manifesting throughout the DCN building. Additionally, since June 2019 NHSL had discovered *P aeruginosa* water contamination issues in the WGH adult Intensive Care Unit which were also proving hard to resolve. If DCN services moved to the Little France site it would be a safer area for the neurosurgical patients to be managed than WGH DCN and the number of WGH ICU beds was due to be reduced (as the majority of WGH ICU patients were neurosurgical and their ICU support would follow them to be provided at the RIE adult ICU). This would have reduced patient numbers in WGH ICU as we were concerned about the risk from water contamination to them and by having fewer patients it would have facilitated access for the estates team to more comprehensively address the microbiological hazard by replacing the affected plumbing that was inaccessible without structural disruption to areas that were in use such as penetrating behind walls.

151. By not moving DCN we had ongoing legitimate concerns about the safety of neurosurgical patients. Some had developed post operative ventriculitis (which is a difficult to treat infection of the ventricles within the brain which invariably requires difficult to administer intrathecal antibiotics and revision surgeries to remove infected cerebrospinal fluid shunts with the risk of worsening hydrocephalus and deterioration in neurological function). We desperately wanted to decommission the DCN building at WGH to stop the risk of *Pseudomonas aeruginosa* exposures and post operative infections there. In the first week of July 2019 though a move of DCN from the WGH campus was not

feasible as we did not yet have confidence that the newly completed neurosurgical operative theatres were functioning optimally and we did not yet know if there was *Pseudomonas aeruginosa* contamination of water within the new neurosurgical wards. The new adult DCN wards and operating theatres were not dependent on the paediatric ITU being operational so there were discussions at the Executive Steering Group about the feasibility of phased migration of services with DCN being one of the first to move across and I was part of those discussions as a member of the Executive Steering Group.

Communication with NHS GG&C

152. I have been referred to an email dated 5 July 2019 from me to NHSL colleagues regarding contact from Teresa Inkster at NHS GG&C **(A40986380 – FW – QEUH building related HAI issues from GG&C ICD perspective – dated 05 July 2019 – Bundle 13 – Volume 8 – Page 2226).** Dr Inkster and I had trained together in microbiology at the same time in Glasgow. She was based at the Western Infirmary and I was based at Glasgow Royal Infirmary and we would meet at training events. We became consultants within a couple of years of each other. When I worked in NHS Lanarkshire there was a service level agreement with NHS GG&C and several microbiology tests performed on NHS Lanarkshire patients were tested in NHS GG&C and occasionally I would be discussing results with GG&C consultants like Dr Inkster. Contact was intermittent and remained so when I moved to NHSL.

153. At that time there was an informal ‘network’ of the IPCDs in Scotland such that we had each other’s e-mail contact details and it wasn’t too unusual for an IPCD in one health board to contact IPCDs in other boards to check if an issue they were experiencing was being experienced in other boards and compare ways of dealing with the same problem. Dr Inkster and Dr Christine Peters at NHS GG&C had used this route themselves to ask questions of the Scottish IPCDs regarding isolation room design and performance and suitability for High Consequence Infectious Disease (HCID) infections in 2016. Face to face contact sometimes would happen at national events run by Scottish Antimicrobial Prescribing Group or SMVN. I had met Dr Inkster earlier in London at the HIS Spring Meeting in May 2019 which was devoted to discussing *Pseudomonas aeruginosa* in

healthcare water and we naturally discussed issues she had been experiencing with water quality in QEUH as at the time these issues were only beginning to emerge in the public domain.

154. I don't recall having any further direct contact until July 2019 although some details of the HAI problems at QEUH were emerging via the media, word of mouth and some information from HPS. By then I was aware that QEUH and RHCYP DCN were both built by the same company and Dr Inkster had acquired substantial awareness of HAIs which might be linked to design of some of the QEUH building systems. Because patient safety was potentially at stake if RHCYP DCN was occupied it was natural to contact her to gain awareness of where she had identified non-conformance that might lead to HAI risk in QEUH to be able to quickly check if we had any of the same design issues in RHCYP DCN, while there was opportunity to intervene and protect patients. The opportunity was because the RHCYP DCN building had not been occupied yet with patients. The information we received about HAI risks and building system non-conformance coming from Glasgow was exceedingly valuable and helpful in targeting our actions when time was short but it is not my view that issues at RHCYP DCN would not have been detected or unaddressed without it. IOM were already detecting multiple areas of concern with the critical and non critical ventilation systems and Westfield Caledonian and Callidus had already begun to identify areas of risk within the water system. The decision to delay the occupation of RHCYP DCN was being informed by provisional data from these sources as well as information about the possible consequences that were being experienced at QEUH in Glasgow.

155. The process of sharing experiences as described above was open to all IPCDs in Scotland and not just between Dr Inkster and myself. Following some e-mail exchange and a telephone conversation together on 2 and 3 July 2019 there was further communication between us on 5 July that I recall specifically was about RHCYP DCN. It wasn't an ongoing discussion. It didn't need to be as following the discussions we had on 2, 3 and 5 July 2019 all the key issues had been communicated. I had further contact with Dr Inkster by e-mail in October 2019 about a decontamination issue that had occurred in NHS GG&C that was unrelated to either QEUH or RHCYP DCN.

156. It was extremely useful to have that shared insight into what technology or design was being considered problematic at QEUH and which HAI risks might arise from them. Much of it was not relevant to RHCYP DCN but some of it was crucial. Without that direct contact with Dr Inkster, I would have had no awareness of these issues as it was not information accessible in the public or professional domain. It facilitated being able to quickly distinguish between what issues could be considered hypothetical risks for HAI and what in her experience were genuine areas to be concerned about that would need rectification. Such information wasn't being volunteered by any other agency we had contact with at the time in as much detail or microbiological insight.

157. The information from Dr Inkster was shared by me with members of the Executive Steering Group who had a particular remit for addressing water system and ventilation system issues. Her insights into the HAI risk from thermal wheels in ventilation systems for heat recovery heavily influenced discussions about the RHCYP DCN operating theatres. We identified there were thermal wheels installed in some critical ventilation systems where we wanted a zero tolerance approach towards the mixing of clean air and fouled air. In the revised designs I think plate heat exchangers were installed which did not have the same potential of air streams mixing.

158. Dr Inkster's positive experience of the Markwik 21 design of tap along with our own experiences of controlling *Pseudomonas aeruginosa* at WGH and the experiences of colleagues in Birmingham resulted in us adopting that tap design in the areas where we detected *P aeruginosa* in the augmented care areas of the RHCYP DCN water system. We were able to quickly establish that there were no chilled beams for comfort cooling installed in RHCYP DCN. Her suggestions to contact HFS and Dr Peter Hoffmann at Public Health England Colindale (PHE Colindale) for help were being actively followed up. Guidance about thermal wheels and chilled beams now features in the 2022 revision of SHTM 03-01 and Dr Inkster has published papers regarding designing bone marrow transplant units and intensive care units based on her experiences.

159. I have been referred to an email from me to Tracey Gillies on 5 July 2019

(**A40986421 – Email from Donald Inverarity to Tracey Gillies et al advising Tracey's note on the shortfall in the standard of air changes in the paediatric critical care ares looks measured and addresses the points covered – dated 5 July – Bundle 7 - Volume 1 – Page 125)** commenting on a draft internal briefing prepared by Tracey Gillies. The intended recipient of the final internal briefing was the NHSL Chief Executive, Tim Davison. It is noted that IPCT staff did not believe safe patient care could be provided even with an interim solution, which was reflective of my view. IPCT considered that an interim solution would compromise patient safety and care because there was still risk that transmission of air borne pathogens could occur and not be controlled by the ventilation, e.g. measles, influenza, chickenpox, drug resistant pulmonary tuberculosis along with the other clinical and HAI risks that I have outlined earlier in this statement.

160. The interim solution would still not conform with SHTM 03-01 and be considered non-compliant. There was uncertainty as to when or how interim work could be completed. Once an ICU is occupied and running it is very difficult to safely perform the kind of invasive rectification works that would be required without risk to patient outcomes and HAI from excessive dust generation or excessive noise generation or excessive vibration. There were also interdependencies between sub-optimally functioning systems to consider. For instance, A&E could not open as a trauma centre without a functioning ICU and functioning operating theatres and at this stage we were aware none of the operating theatres were functioning correctly when first assessed by IOM and neither was critical care ventilation. At best, NHSL hoped that four of the operating theatres might be functional by 9 July 2019. If the interim solution was implemented there would be very little resilience if an AHU failed or required maintenance or if a mass casualty trauma major incident occurred particularly if it involved children. There would likely be unintended impacts on paediatric hospitals elsewhere in Scotland if planned capacity had to be reduced at RHCYP DCN and risk Lothian patients being managed in other health boards which is added stress and inconvenience to parents at a very traumatic time if their child is critically ill.

Decision to Delay

161. I have been referred to an email from me to Tracey Gillies and Alex McMahon on 09 July 2019 (**A41295517 – Email from Tracey Gillies to Audrey Trotter – request to print out email (6) attachments as relevant to discussion about whether HPS and HFS had been involved in the earlier stages of RHCYP – dated 14 August - Bundle 7 - Volume 1 – Page 203)** in which I make reference to IPCT advising the project team of the need for theatre validation since December 2016 (with supporting emails attached). The December 2016 communication I'm referring to **(A41263314 – Email Theatres new build – dated 29 December 2016 – Bundle 13 – Volume 8 – Page 499)** was with Ashley Hull who was part of the Project Team. There was further communication with Ashley Hull in May 2019 about microbiological assessment of air quality in operating theatres, see **(A47172271 – Theatres Air sampling – dated 24 May 2019 – Bundle 13 – Volume 8 – Page 548)** and **(A47172352 – RE Air Sampling Theatres – dated 16 June 2019 – Bundle 13 – Volume 8 – Page 551)**.

162. In the same email, I also refer to communication in 2018. This relates to the communication with Jackie Sansbury in August 2018 discussed and January 2019, discussed above at paras 93 and 95 above.

163. I also make reference to Janette Rae's advice to install air handling units in isolation rooms on a 1:1 ratio which is discussed in detail at paragraph 76 above. When we undertook the remedial works, we ensured that the clinical team was involved for the following reasons:

i. My role is primarily to explain and anticipate HAI risk but this plan risked the provision of safe care to neutropenic patients predictably for periods of AHU maintenance or filter change or for an undefined time instantly in the event of AHU failure. The implications of provision of service continuity and contingency planning are not my remit for any other service other than some aspects of the running of the microbiology laboratories.

ii. My experience of working with haematology teams was that they are very dedicated to their patients and very knowledgeable regarding the possible impacts of environment on neutropenic patients and will often default to being

risk averse. This proposed plan had substantial future clinical risk so I was seeking assurance that the clinicians (who would eventually be running their service from that ward and were key stakeholders) were aware of the implications of the design to their service continuity and potentially patient outcomes.

164. Communicating effectively with colleagues and working collaboratively with colleagues are professional standards required of doctors by the General Medical Council. The awareness of potential clinical risk from a building to paediatric haematology patients, given the media coverage of events relating to QEUH in Glasgow was substantial for both staff and the public. Colleagues working in paediatric haematology therefore were keen to be involved in plans for Lochranza to ensure it was as safe as possible and also to be able to field questions from their patients. Referral and admission patterns for their specialty had also been changing too since the original design stage and there was a will to keep abreast of that in what would be provided going forward. It's not that there hadn't been effective engagement with the clinical teams in the design stage in the past, it was about ensuring what was installed in a revised design met current and not historical requirements as the landscape with regards to what was being considered as safe paediatric haematology service provision in Scotland was changing significantly and quickly over 2018 and 2019 and was, in part, due to events relating to QEUH.

Meeting on 10 and 11 July 2019

165. On 10 and 11 July 2019, I attended a meeting with Critical Care clinicians, IPC Nurses, microbiologists, and members of the Project Team to discuss the Critical Care ventilation issue (**A40988924 – Summary of RHCYP Critical Care Ventilation discussions – dated 10 and 11 July 2019 – Bundle 13 – Volume 8 – Page 554)**. At this meeting, it is noted that previously a decision had been made in relation to the 4 bedded areas to allow patients with the same air-borne infection to be cohorted and following consultation with the clinical team and IPCT representatives at the time the decision was made that these areas should have air pressure which was balanced or slightly negative to the neighbouring spaces, see **(A40981178 – Record of General Risk Assessment**

ventilation_combinedrev300118 – Bundle 6 – Page 14). The SHTM 03-01 states that critical care areas should have 10 air changes and 10PA (positive pressure) and I understand that recommendation to apply to both 4 bedded areas and single rooms in the critical care department. As noted at paragraph 90 above, I had no involvement in that earlier decision but can further explain the possible reasoning behind it and the reason to change from it.

166. It should be understood that a paediatric intensive care unit is not the same as an adult intensive care unit. Children are not just small adults when ill. From an intensive care perspective, it is more difficult to insert life saving devices as they are much smaller, dosing of drugs is more complicated based on weight, they are much less able to communicate what is wrong with them, they deteriorate much quicker than adults physiologically, when septic for instance, and are less able to regulate body temperature. This is why HBN 04-02 notes a different criteria for bedspaces in a paediatric ICU than an adult ICU as in a paediatric ICU the bedspace temperature control must be controllable locally at the bedspace, as ill children require a higher ambient room temperature than adults as they lose body heat more readily due to their smaller size (HBN 04-02 section 4.9). The case mix of patients in a paediatric ICU has a higher proportion of children with congenital diseases, many of whom are there because they require long term mechanical ventilators to breathe and have tracheostomies so may be more susceptible to micro-organisms in water when exposed to water for personal hygiene, and more susceptible to airborne respiratory viruses if exposed as their lungs may not be physiologically normal. They may also have impaired immunological systems and be less able to fight off infections. They also require much more hands on care by staff and parents for airway positioning in cots or beds and personal hygiene with greater risk of transmission of micro-organisms by hands. Devices are more commonly dislodged in infants through unpredictable movement or contaminated by sucking them or soiling them. Additionally, they are also more likely to be asymptomatic carriers of bacteria (*such as Streptococcus pneumoniae* or *Streptococcus pyogenes/* Group A Strep) or viruses (such as RSV or SARS CoV2) in their throats which can be highly transmissible in an ICU. As such, optimising ventilation system dependent control measures to prevent micro-organisms spread by a droplet or airborne route is very important in a paediatric intensive care unit, particularly for the winter

months when the presence of these microbiological and virological hazards in the ICU environment is common and predictable.

167. Maintaining good quality water is also very important. From the perspective of intensive care bedspaces, all bedspaces should be considered as the same with regards to being able to mitigate or minimise these risks. For many diverse clinical and operational reasons, patients may move bedspaces often during their admission and it makes no sense to have some bedspaces perform better than others as that would mean some areas in the unit were effectively safer than others. I would be wary of singling out one dimension of the intensive care environment (for instance the ventilation system) and focussing on one dimension of that (for instance, the air change rate or the room pressure). There are many other aspects of a ventilation system that influence whether there is an optimal environment for vulnerable patients and trying to focus on the risk or benefit of any single aspect is likely misleading as they interplay with each other in a live ward and with other non ventilation parameters. For example, the position of air extraction grilles and rate of air extraction within a room may influence the pressure in the room and the probability that airborne microbiological hazards remain in the room for long. Spread of microbiological hazards is influenced by simultaneous dilution with wholesome air being pumped in and removal by mechanical extraction before they have a chance to leave the room by an open door. Closing doors reduces risk of suspended droplets leaving the room. Gravity will pull most air suspended droplets to the floors or horizontal surfaces before they travel any great distance so having distances between doors of rooms at much greater than two metres assists the removal of any droplets that escape into a corridor by gravity before they can enter another room. Having air extraction grilles within corridors also assists that process of removing anything that may have escaped a room before it enters another room (assuming that somehow it could also overcome the 10 Pascal pressure gradient pushing it back into the corridor at the doorway).

168. I have explained in paragraph 123 that windows shouldn’t be openable in a pressurised ward area (such as intensive care) as it removes the pressurisation and that an intensive care environment benefits from being positive pressure in paragraph 92 to replicate conditions in a treatment room or operating theatre. If

there are no opening windows, apart from some small amounts of air leaving through doors, the bulk of the air needs to leave through mechanical extraction and replacement with fresh/wholesome newly delivered air which is a process of dilution for any microbiological or virological hazard in the air. If the air change rates are low and the ICU is filling up with admissions of children with complications of RSV infection (for example during periods of high community prevalence) and those children in ICU are excreting virus into the air through breathing and aerosols being generated by high flow oxygen delivery for example, it won't take long before there is increasingly higher probability of being exposed to RSV in the air as a non-infected patient or staff member than if the air change rate had been higher.

169. It is preferable to manage or cohort patients with respiratory viruses in a room at balanced or slight negative pressure (see Specialised Ventilation for Healthcare Society Guidance on the Considerations for the ventilation aspects of healthcare facilities for coronavirus from 2020) but it is feasible to be able to cohort patients with respiratory viruses in a room together that is pressurised to 10 Pascals but that hinges on other factors too such as a high air change rate, the distances between bedspaces being much greater than two metres, having air extraction points within the room and a high extraction rate, preferably near to where the patient's head will be at each bedspace where most contaminated aerosols will be generated, having doors shut, having distances of over two metres between rooms, having air extraction points in the corridors and ensuring staff are using respiratory protective equipment optimally. This was all demonstrated in intensive care units during the first wave of the Covid 19 pandemic but was all perhaps more theoretical in early 2019 and would not have been widely appreciated when the original Paediatric Intensive Care Unit (PICU) design was being discussed and agreed in 2013/2014. It is covered in documents produced by the Specialised Ventilation for Healthcare Society (SVHSoc) in early 2020. See **(A47172280 – Specialised Ventilation for Healthcare – dated 27 April 2020 – Bundle 13 – Volume 8 – Page 557) and (A47172257 – Updated Briefing and Guidance on Considerations for the Ventilation Aspects of Healthcare Facilities for Coronavirus – dated 24 March 2020 – Bundle 13 – Volume 8 – Page 575).** The positive pressure environment as explained in paragraph 92 is, I believe, to minimise risk of post procedure infection when invasive devices are

being placed or any surgical procedures performed in the ITU at the bedspace. The optimal environmental conditions needed to minimise risk of post procedure infection (positive pressure) and the optimal conditions needed to minimise spread of respiratory viruses leaving the room (balanced or negative pressure) need somehow to be reconciled in the same multipurpose intensive care bedspace. SHTM 03-01 approaches this in my view by advocating positive pressure at 10 Pascals but with a higher air change rate than a general ward at 10 ac/hr.

170. My contribution to the meeting on 10 and 11 July 2019 was that I was there with members of the Project Team to answer the critical care teams' concerns about the findings of the IOM discoveries about the performance of the PICU ventilation and to discuss the need to enhance the ventilation to align it as much as possible with what was set out in SHTM 03-01. I was also there to discuss what a new design might look like and address concerns that critical care colleagues had regarding that with regards to the ability to prevent transmission of infection but particularly Respiratory Syncytial Virus (RSV). RSV is a respiratory virus and is very common in children under five years old during winter months and creates predictable pressure on capacity to isolate infected children to prevent transmission in hospital. It also causes the condition bronchiolitis which can cause respiratory failure by itself or exacerbate chronic lung diseases in children (such as asthma) leading to acute respiratory failure and hypoxia needing high amounts of oxygen and sometimes intubation and management on a ventilator in intensive care. At times of peak community prevalence of RSV, paediatric ITU will often be managing several children each day with RSV related respiratory failure and with a high number of infected children in the unit, the risk of onward transmission to unaffected children co-located there with other needs for intensive care management increases. If capacity to segregate infected from non infected patients is exceeded, then cohorting of the RSV infected children together in the same area is the usual next step.

171. The outcome of the discussions by end of 11 July 2019 was that there was agreement by all involved (IPCT, Project Team and Paediatric ITU team) to move to an SHTM 03-01 compliant design for PITU and concerns that this might facilitate transmission of respiratory viruses had been explored and addressed

and the features of a compliant design that would mitigate against that had been understood by all involved. Simultaneous to these discussions on 10 and 11 July 2019 in Edinburgh I had contacted NHSL colleagues in infection control (Lindsay Guthrie and Sarah Jane Sutherland) and microbiology (Dr Jennifer Poyner and Dr Michelle Etherson) who were attending the Health Protection Agency and Hospital Infection Society, Engineering Aspects of Infection Control Course at Eastwood Park, Falfield with the very questions and concerns being raised by the intensive care staff and me about infection risk from either a positive pressure ICU bedspace or a balanced or negative bedspace to have them raised with and discussed with national experts in healthcare ventilation (Peter Hoffman particularly from PHE). Their response on 11 July 2019 by e-mail was reassuring that the conclusion we had come to was not considered wrong.

172. Janice MacKenzie communicated the outcomes of these meetings on 12 July 2019 to IPCT, microbiology, project team and PICU stakeholders indicating that the conclusions would be fed back to HFS **(A47172712 – Critical Care Ventilation – dated 12 July 2019 - Bundle 13 - Volume 8 - Page 586)**. There had been discussion at the RHCYP DCN IMT meeting at 4pm on 11 July 2019 about the critical care ventilation and the decision to start to design an STMH 03-01 compliant unit with 10 ac/hr and 10 Pascals positive pressure so the NHSL Executive Directors and other IMT members were aware of this progress on 11 July 2019, see (**A47172285 – SHTM 03-01 Critical care – dated 11 July 2019 – Bundle 13 - Volume 8 - Page 591)** and **(A47172483 – FW SHTM 03-01 Critical care – dated 11 July 2019 – Bundle 13 - Volume 8 - Page 593).**

173. I considered compliance with SHTM 03-01 to be a necessary part of the remedial design. Had I been involved in the original design discussions and been made aware that the designers and contractors intended to build a critical care unit that did not conform to guidance, I would have raised compliance with extant guidance as an issue. However, it is my understanding that the initial critical care design stage was undertaken and a final plan reached with the clinical team, infection control and microbiology stakeholders when SHTM 2025 was the extant guidance for ventilation systems and it does not include any parameters in terms of air changes or pressure cascades for ventilation in a critical care unit. The final agreement about the design was just around the time when SHTM 03-01 was

released.

174. I have been referred to an email dated 11 July 2019 from Janice Mackenzie circulated of which I was one recipient **(A41263402 – Email from Janice MacKenzie to Brian Currie et al which provides an update from tow meetings with the Critical Care Clinician Team with Donald and other colleagues from the IPCT – dated 11 July 2019 – Bundle 7, Volume 1 – Page 316)**. I consider that satisfying the requirements of SHTM 03-01 would provide a safe ventilation design.

175. Even if there was a fully compliant ventilation system in the critical care unit, there would still have been remedial issues such as the rebalancing of the theatres to address. 'Rebalancing' of the operating theatre ventilation is a term that might be better explained by a ventilation engineer that performs it, but my rudimentary understanding is that it is a fine-tuning process of optimisation of supply and extract ventilation delivery, pressure cascades and airflows to optimise the safety of the clinical environment (such as an operating theatre) from a ventilation perspective. Opening could either have been done with patients *in situ* (which in my view would not be the preferred option); or there could have been a shorter delay to the planned opening of the hospital in order to rebalance the theatres. It is important though to understand that the opening of a hospital very much depends on the interdependencies between departments and streamlined migration of patients and staff, as I explain in more detail below.

176. I have been asked to comment on an email of Tracey Gillies, Medical Director, dated 5 July 2019 which I reviewed **(A40986421 – Email from Donald Inverarity to Tracey Gillies et al advising Tracey's note on the shortfall in the standard of air changes in paediatric critical care ares looks measured and addresses the points covered – dated 5 July 2019 – Bundle 7, Volume 1 – Page 125)**. Here, Tracey Gillies is referring to the process of rebalancing theatres in her bullet point "Ventilation in 10 theatres, a detailed technical assurance matrix of measurements of the ventilation has been requested for each theatre. In the light of the issues identified by IOM, engineers have been working to rectify these issues and provide the level of assurance required that each theatre is delivering against the design parameters" The process of

rebalancing of theatres had begun prior to 5 July 2019. It had been discussed with the Project Team and with Executive Directors during that week. There had been a consensus view taken that if four theatres could be rebalanced and optimised then it might be possible to safely run essential emergency surgical services from RHCYP DCN. If I recall correctly by 5 July 2019 four theatres had been made operational.

177. It looked feasible to open the DCN parts of the building with minimal delay because there was not an inter-dependency with the PICU. Adult neurosurgical and neurological patients requiring ICU were always planned to go to the adult ICU in RIE, the neuro imaging suite did not have any issues that would have prevented occupation and it looked feasible that neurosurgical theatres could be rebalanced, independently validated and ready for use in a fairly short time scale. There appeared to be minimal work required on water outlets with raised TVCs or *P aeruginosa* and localised water risk mitigation measures could have been employed. Not being able to occupy DCN, when the Health Secretary's announcement was made on 5 July 2019 that none of the building was to be occupied until all building systems had been independently verified and partial occupation was not possible, was a significant blow as the existing facilities on WGH site were deteriorating and there were significant issues with water contamination in WGH DCN and WGH ITU and the decision to delay DCN occupation meant services had to continue in a very compromised environment with real risk of post-operative HAIs. Even being able to open the neuro-imaging suite would have helped mitigate other non-infection risks being experienced by NHSL.

178. Partial occupation was not a decision being made without due consideration as it creates a new set of clinical risks such as access to support from other services in an emergency such as cardiac arrest, staff access to food and staff wellbeing, whether staffing levels are sufficient if services are split across two sites, risks of patients inadvertently being injured if building work is in progress. There are always IPCT concerns about delivering care near an active building site because of dust that is generated and inhalation of fungal spores. There are more hazards than would normally be expected in a clinical environment and so it becomes more of a challenge to keep patients and staff safe but it is not uncommon in the

NHS to need to continue to deliver care in areas near refurbishment activities.

179. Likewise, there was far less assessment and corrective work required to have areas operational for Child and Adolescent Mental Health Services (CAMHS) to run from as CAMHS areas do not require critical ventilation systems and this could have been considered as part of a phased occupation before the more acute paediatric services could occupy. There would still be the same potential new issues of access to help in a clinical emergency, staffing levels, staff welfare and risk of injury if a building site area was accessed by mistake.

180. The risk profile changed over the course of the week before 9 July 2019, as more information emerged from the work IOM was doing to identify ventilation issues and the work engineers were doing to resolve the issues simultaneously. Firstly, all healthcare buildings will potentially compromise patient safety and care in the wrong set of circumstances and that needs to be acknowledged. I was concerned that there were also non-conformances with all the operating theatres. That had been identified by IOM before the issue with PICU ventilation. However, IOM along with other ventilation engineers had been working tirelessly to correct and rebalance some theatres.

181. If the hospital had opened on 9 July 2019, it would have done so with reduced surgical capacity as only a proportion of operating theatres would have been functional. The ESG was hoping at best to have 4 functional operating theatres by 9 July 2019. There were many other “snagging issues” that needed addressed and although perhaps no single issue from them was a show-stopper, in combination it would have been hard to provide an optimal service to paediatric patients and their parents. That may not have translated into harm but would certainly have been inconvenient. I can only really speak to whether there may have been harm from hospital acquired infection but the potential harms that can happen when there is building work or repair work happening on a ward are wider than just infection risk. Many areas were fit for opening but often had interdependencies with areas which were not. The issue with non functioning theatres was predominantly affecting paediatric surgery but also affected adult neurosurgery. Neurosurgery has an absolute requirement for ready access to an emergency operating theatre to intervene for some conditions such as rising

intracranial pressure after trauma or bleeding where delay may be fatal or spinal decompression where delay may lead to permanent paralysis.

182. However, many of the issues that might have compromised patient safety were not infection issues. Staffing was being discussed at ESG as a major issue as the specialist paediatric teams were just not large enough to sustain working across two sites for very long. It became clear that all paediatric inpatient services would need to either come across to RHCYP DCN at Little France or stay at RHSC Sciennes because of that.

183. ESG were concerned regarding the resilience of what had been delivered. For instance, in Lochranza, there was capacity to manage neutropenic patients safely in what was provided but only for a maximum of 5 patients at a time in the PPVL rooms. With events in NHS GG&C paediatric haematology and cancer services where there had been a move of the childrens' haematology/oncology ward to the adult hospital, reports of excessive blood stream infections from Gram negative bacteria that might relate to water quality at QEUH campus, deaths from cryptococcosis that were suspected as having a link to ventilation systems and plant room cleanliness at QEUH campus, there were unintended impacts on NHSL and concerns were emerging that the number of bedspaces suitable for patients now requiring protective isolation for neutropenic management might be outstripped by demand due to NHSL providing some mutual aid and caring for paediatric cancer patients from Glasgow These events in Glasgow were changing awareness of clinical risk from attending paediatric services throughout Scotland by patients, their families and staff. Public opinion was clear that it would not accept a ventilation system as suitable in a new hospital that had been designed and installed in ways that had clear deviation from current guidance as that guidance was to be considered safe and anything else was viewed as unsafe by the media.

184. As an IPCT, we were concerned regarding where we could safely manage a child presenting with a High Consequence Infectious Disease (HCID), particularly one that was airborne. This was prior to the emergence of SARSCoV2 and Covid 19 in China and more focused on patients potentially having Middle Eastern Respiratory Syndrome (MERS) or Ebola virus as there had been a large Ebola

outbreak in West Africa and colleagues in NHS Lanarkshire and NHS GG&C had had to initially manage a complex case of Ebola infection in an adult. The facilities that we were dealing with in July 2019 at RHCYP DCN did not assure us that these diseases could be optimally contained for long on the site. There were no negative pressure isolation rooms for instance. This didn't necessarily make the hospital unsafe such that it shouldn't open, just unprepared and lacking resilience in some situations which were more than just hypothetical possibilities. This issue was more around capacity to provide safe services (particularly critical care and A&E services), in the face of changing disease patterns that had not been anticipated, with minimal disruption to the hospital if someone who was highly infectious presented and needed to be segregated from other patients quickly. It was also being influenced by a changing perception of clinical risk by world events. During the period July to December 2019, it was not much more than a hypothetical concern but as news reports emerged from Wuhan, China and then closer countries like Italy where health services were being overwhelmed by a new highly contagious respiratory viral infection it became much more of a concern. It was a real issue of preparedness to maintain safe service delivery and avoid HCID transmission episodes that needed addressed by March 2020.

Issues as at July 2019

185. I have been asked to provide my view on how serious the issues were around the following, and whether they should have prevented the hospital from opening in July 2019:

The air handling units

186. I'm not a ventilation engineer and not best placed to comprehensively answer this question. My view relates to their performance and whether any aspect of performance might create an environment where a patient may acquire a HAI. The IOM independent validation had identified AHU issues which posed a fire risk and AHUs were running at a higher speed than expected suggesting they could not meet the demand placed on them and their lifespan may be reduced as well as there being access issues which would hamper maintenance. One issue IOM

identified which did alarm me was that there were surplus drip trays in the AHU suggesting that there could be at some point stagnant water in the airstream which would increase the risk that bacteria which might grow in stagnant water such as *Legionella* could then be aerosolised and potentially inhaled if air bypassed filters.

187. Much of what I learned about the issues of the AHUs were identified in September 2019 when there were multidisciplinary inspections of the AHUs with IHSL, Project Team (Brian Currie, Ronnie Henderson), NHSL Estates (George Curley), Authorising Engineer Ventilation for NHSL (John Rayner), Mott MacDonald (Ian Brodie), David Gordon (Bouygues) and IPCT (myself and Lindsay Guthrie) present **(A41355176 – AHU 02-06 Inspection dated 27 September 2019 – Bundle 13 – Volume 8 – Page 596)**. We witnessed design failings that would allow air to bypass filters in the units which would potentially compromise air quality being delivered to clinical areas such as operating theatres which might increase the risk of post-operative infections. There were issues of resilience and unanswered questions as to what would happen during periods of maintenance and how much delivery of service would be impacted. I was generally being guided by the view of the authorising engineer for ventilation and other ventilation engineers in Mott MacDonald and estates team in NHSL that the AHUs were not of standard expected in a healthcare facility far less providing air for critical ventilation systems in a healthcare facility. But, prior to 9 July 2019 many of the AHU issues were not yet identified.

<u>Ventilation in Critical Care</u>

188. The air changes per hour at all bedspaces (except the PPVL isolation rooms) was lower than what would be optimal for performing many of the invasive procedures involved on a daily basis in an intensive care unit and could have compromised patients undergoing the procedures and increased their risk of infection e.g. device infections, blood stream infections, nosocomial pneumonia all of which could have fatal consequences for children already critically ill for other reasons.

189. Likewise, the low air change rates would have hampered dilution and removal of

airborne pathogens such as respiratory viruses which are a predictable microbiological hazard in ITU and would risk staff and other patients catching infections like influenza from ill patients. As the air change rates weren't uniform across all bedspaces, the risk of occupational exposure would be greater in some bedspaces than others. It didn't align with Health and Safety Executive hierarchy of controls as mitigation of the airborne hazard would be very dependent on respiratory PPE being used optimally whereas HSE hierarchy of controls advocate that the hazard should be engineered out as a higher priority before use of PPE. The hierarchy of controls advise that before resorting to PPE to protect staff from a hazard there should be steps to elimination (physically remove the hazard), substitution (replace the hazard), engineering controls (isolate people from the hazard) and administrative controls (change the way people work). **(A47172252 – Using personal protective equipment (PPE) to control risks at work – Bundle 13 – Volume 8 – Page 600).**

190. As all the isolation rooms were of the PPVL design we were not assured we had optimal facilities for some uncommon (but predictable) situations e.g. a critically ill child with drug resistant tuberculosis or MERS for example with respiratory failure. This was partly based on a document that had been shared with me by Dr Teresa Inkster in Glasgow that was written in relation to the PPVL isolation rooms at QEUH, by Ian Storrar of HFS, **(A32310951 – QEUH Isolation Rooms report 2016 – dated 29 June 2016 – Bundle 13 – Volume 8 – Page 601)** and NICE guidance for management of tuberculosis, that advocates a negative pressure isolation room as being the optimal environment for placement of patients with drug resistant tuberculosis (section 1.5.1.4) **(A47172398 – NICE Tubercolosis – dated 12 September 2019 – Bundle 13 – Volume 8 – Page 609)**.

191. Concerns about PPVL room suitability in this circumstance is that the contaminated exhaust air requires to be HEPA filtered before discharge when isolating an airborne HCID and PPVL rooms don't have this in their design unless explicitly requested so it might not be included. Also because the lobby is at positive pressure there is a hypothetical risk of contaminants generated by doffing PPE being directed into the corridor which doesn't exist with a negative pressure isolation room configuration.

192. I agree that the findings in the ventilation provision to critical care were of sufficient magnitude to justify not opening. A fully functioning ICU would be critical to virtually all acute paediatric inpatient services in RHCYP DCN and because it is so critical there are rarely safe opportunities to undertake substantial repair work while it is occupied.

Ventilation in the Lochranza Ward

193. The issue of ventilation in Lochranza is not straight forward and that relates more to patient case mix and projected demand. Not all cancer patients require protective isolation for neutropenia. The original provision of Lochranza did provide accommodation that could have provided suitable protective isolation for post chemotherapy neutropenic children. NHSL was not intending to provide a bone marrow transplant unit so the degree of susceptibility to infection in the patient group in Edinburgh was not on a par with the immediately post Bone Marrow Transplant patients at QEUH in Glasgow. The two units should not be compared for that reason.

194. The issue in RHCYP DCN was not that there weren't bedspaces with suitable ventilation for neutropenic patients as there were 5: the issue was that changing demands and availability of paediatric cancer beds was changing (some of which as a consequence of events in NHS GG&C) and there was a real concern that the future need would outstrip what had been installed in the building.

195. There was one significant concern which had not been resolved and related to objections made in 2016 as all the isolation rooms in Lochranza did indeed run from one AHU and so there was no resilience for times of AHU maintenance or critical failure. Either all isolation rooms would be operational or all would be offline and that created substantial inability to sustain protective isolation during such periods with no other suitable location to place affected children where suitable room design and staff skill mix were co-located. This scenario is actually outlined in HBN 04-01 Suppl 1 in section 2.37 as one to avoid during design. Additionally, although we were told there had been built a means to divert air from supplying top floor offices to supply the Lochranza isolation rooms in event of AHU failure this was a very unconventional solution and was predicted to

substantially compromise the function of the rooms through delivering lower air change rates and compromised pressure cascades and worryingly this appeared to have never been tested. It was not clear to me why the concerns that were first raised in 2016 had not led to a revised ventilation strategy by July 2019 although I now believe it was because of the additional cost and space required to provide one AHU per isolation room.

196. Even though the ventilation provision Lochranza meant the majority of bedspaces were non-compliant with SHTM 03-01 criteria for a neutropenic ward, it didn't in my view merit delaying occupation overall as it was an improvement to what was being provided for cancer patients at RHSC, Sciennes (ward 2 at RHSC only had 6 'cubicles' for neutropenic patients but they did not provide HEPA filtered air or a positive pressure cascade to corridor). The Lochranza ventilation strategy for isolation rooms was however non-compliant with HBN 04-01 Suppl 1 during periods of maintenance, and lacked resilience and the decision to delay occupation provided a window of opportunity to resolve these issues.

Ventilation in General Wards

197. The key issue here was whether the rooms were at balanced or slight negative pressure to corridor. If the rooms had been at positive pressure to corridor then there would have been possible risk of spread of airborne infection to other rooms (although this would also be influenced by the distance between doors and what the pressure gradient was and locations of air extraction in corridors). In a paediatric context that could be chickenpox, measles, influenza, or other respiratory viruses. I believe that had been addressed by July 2019. This is based on the principle outlined in paragraph 150 by the Specialised Ventilation for Healthcare Society (SVHSoc) that prevention of spread of respiratory viruses is best achieved in an area that is at balanced or slight negative pressure to its corridor.

198. I don't believe the ventilation performance in general ward areas on 9 July 2019 merited preventing the hospital from opening. The risk though was not universally the same. The respiratory team managing cystic fibrosis patients did ask IPCT what the impact 4 ac/hr may have on transmission of bacteria which commonly

colonise lungs of this patient group **(A40988924 – Summary of RHCYP Critical Care Ventilation discussions – dated 10 and 11 July 2019 – Bundle 13 – Volume 8 – Page 554)** but as we were not experiencing such transmission in less well ventilated facilities in RHSC and there were functioning PPVL isolation rooms with 10 ac/hr, this was considered a manageable risk rather than a show-stopper to occupation. Although not aligned to SHTM 03-01 it was an improvement on what was provided at the RHSC Sciennes site.

Remedial Works

Critical Care

199. In relation to my involvement with the design development of the Critical Care remedial works solution, I was representing the infection control service along with Lindsay Guthrie in the multiagency team formulating what became known as High Value Change 107 (HVC 107) relating to Paediatric Critical Care and Haematology ward ventilation to make them SHTM 03-01 compliant. I attended the RHCYP DCN Ventilation Meetings which were tasked by the RHCYP DCN ESG to address issues of ventilation performance at RHCYP DCN from their start in 2019 and then was involved in each of the different workstreams addressing different areas of non-compliant ventilation systems. Updates from these workstreams were fed back to the RHCYP DCN ESG by Brian Currie. I attended the HVC 107 Meetings from their start in December 2019 and when Imtech Hoare Lea were appointed as the design team I attended meetings with them.

200. In the Critical Care remedial project, the initial plan had been to ensure all the isolation rooms performed optimally as PPVL isolation rooms but as 2020 progressed there was more awareness that this might not be the most resilient configuration and it was agreed to alter one of the existing PPVL isolation rooms to be a negative pressure isolation room. This was the preference of colleagues in Paediatric Infectious Diseases as well as the virology and microbiology consultants who covered paediatric issues as it would provide more optimal isolation for any child requiring respiratory support because of drug resistant tuberculosis or MERS for example (see paragraph 189). I don't believe that the choice of design of all isolation rooms as PPVL rooms rather than negative

pressure isolation rooms was one that had been discussed with the paediatric infectious disease service initially as they had questions regarding how PPVL rooms worked for protective and source isolation which they addressed to the project team in July 2019.

201. It was identified during 2020 that there were some changes that could be made to create a negative pressure cascade with HEPA filtered extract air or extraction at height which would safely create a negative pressure isolation room and provide this additional resilience without having to alter the built architecture of a pre-existing PPVL room. There were several reasons why there was a wish to have more assurance regarding containment of HCID at that time:

    - There were no negative pressure isolation rooms anywhere in NHSL.
    - The first wave of Covid 19 was beginning to spread outwith China in January 2020 and Covid 19 was classed, at the time, as an HCID akin to MERS and upscaling of isolation facilities in preparation for a mass influx of patients of all ages to intensive care was a national healthcare priority.

202. Both myself and Lindsay Guthrie were core members of the multiagency team who worked together to agree a design and implement High Value Change 107 and design, install and commission SHTM 03-01 compliant ventilation performance for Paediatric Critical Care **(A34012543 – RE RHCYP DCN – Little France – High Value Change 107 – Vent works to PCC and HP – dated 03 December 2019 – Bundle 13 – Volume 8 – Page 716)**. I believe that the design was finalised around June 2020 although the project team would likely have more detail regarding this exact date and approved initially at the RHCYP DCN ESG and then the RHCYP DCN Oversight Board which was composed of NHSL, NSS and Scottish Government Representatives.

203. We attended the planning meetings with the Project Team and Hoare Lea and Mott MacDonald and the NHSL Authorising Engineer for ventilation to plan how and where to install replacement and supplementary AHUs to enable the PICU ventilation to be upgraded and the conversion of one PPVL isolation room to be a negative pressure isolation room.

204. We were part of the multidisciplinary team who inspected the “exemplar” AHU after it had undergone all the corrective repairs and then subsequent AHUs as they also underwent corrective work. We were involved in planning corrective repairs, rebalancing and witnessing the performance of operating theatres and isolation rooms. A final report was produced by IPCT in early March 2021 for the project team and ESG that outlined all the risk assessments that IPCT had undertaken on aspects of the ventilation system and that IPCT were satisfied all the HAI risks had been addressed to our satisfaction and at that point we signed the HAI Scribe Stage 4 documents. This report was informed by reports produced by IOM and the NHSL Authorising Engineer for RHCYP DCN (John Rayner) regarding the performance of the ventilation systems in February and March 2021 **(A47091309 – 20211203 NHS Lothian Infection Prevention Control Team Review of Suitability of the Performance of Redesigned Ventilation Systems in RHCYP DCN – dated 03 December 2021 – Bundle 13 - Volume 7 – Page 152)**. I was not involved in the ultimate decision to open the hospital. Although I was a member of the RHCYP DCN ESG, I did not attend the Oversight Board meetings and the ultimate decision to open was made by the oversight board.

<u>Other Remedial Works</u>

205. We were asked for IPCT input on various other issues by the Project Team and RHCYP DCN ESG as follows.

- How to improve preparedness of A&E for respiratory virus containment changing cubicle curtains to doors, identify an area of A&E suitable to contain airborne HCID and help in the design of its ventilation and advise on suitability and rebalancing of the ventilation of the A&E resus rooms.

- We were asked to risk assess every clinical area in the hospital as to whether the ventilation provided aligned with the need to safely perform the planned activities in the rooms, and we concluded that it would not be considered unsafe if due thought was given to appropriate patient placement. **(A40981178 – Record of General Risk Assessment ventilation_combinedrev300118 – Bundle 6. Page 14) and (A47172292 –**

SBAR Assessment Outpatient and therapy areas Ventilation Room Review RHCYP DCN – dated 12 November 2019 – Bundle 13 – Volume 8 – Page 721).

- We were involved in assessing the suitability of repairs after the flooding event in summer 2018 and were able to view their outcome on the walkround visit in March 2019 and were satisfied.

- We were asked to risk assess significant water damage to the walls in dental chair rooms in outpatients on discovery that there had been leakage from incorrect plumbing of the supply water to the dental chairs, and this resulted in an incident management team being formed to ensure the issue was resolved while minimising disruption and patient risk of exposure to mould. The IMT did not close until there was satisfaction that the work was completed. No HAIs arose from this. See **(A47172700 – Dental RHCYP – dated 19 February 2021 – Bundle 13 – Volume 8 – Page 724)** and **(A47172447 – NHS Lothian – Infection Prevention and Control – dated 13 January 2021 – Bundle 13 – Volume 8 – Page 2109).**

- We were asked for views on the suitability of rectification plans to address the issue of over-pressurisation of the operating theatre corridor that was preventing fire door closure. This issue has not yet been resolved to IPCT or NHSL's satisfaction.

<u>IPCT involvement in issues with water systems at RHCYP / DCN</u>

206. To provide some context to the IPCT involvement in issues with the water systems at RHCYP DCN, it is of note that NHSL was actively managing two unrelated but complex *P aeruginosa* water contamination issues on the WGH site around the same time in the first half of 2019. There had been adverse media coverage about the issues at WGH and they were not resolving quickly. Additionally, information was being released via the media, HPS, and word of mouth about the nature of water contamination issues at QEUH in Glasgow and the alleged connection between unresolved high Total Viable Counts (TVCs) at commissioning and later HAIs with water associated bacteria had been made

public.

207. My initial concerns about water quality in the RHCYP DCN building were raised with the Project Team, Ronnie Henderson (NHSL Director of Facilities) and Brian Currie (Deputy Director of Facilities), in February 2019 in response to being alerted by Ronnie Henderson of water commissioning results which were detecting growth of indicator organisms. Of significant concern for a new building that was unoccupied was detecting of a *Legionella species* at 25cful/1000ml from a kitchen area and detection of *Pseudomonas aeruginosa* in areas that might be augmented care areas.

208. SHTM 04-01 Part B section 6.6 states that the infection control doctor has responsibility for water quality once it leaves the tap. In SHTM 04-01 Part B Section 6.3 and 6.7 it also advises that where there are *Legionella* or *Pseudomonas aeruginosa* issues with the water that a consultant medical microbiologist should be contacted for advice as a key decision maker. So as the microbiologist who attends the water safety group, I should have an awareness of where there are microbiological hazards affecting a healthcare water system and be involved in the planning of corrective work and hazard mitigation measures. The nature of the hazard mitigation measures will be influenced by the vulnerability of anyone likely to be exposed to developing an infection. Multiplex had issued the Project Team with some water results that indicated that *Legionella* had been detected and *Pseudomonas aeruginosa* had been detected. Although the *Legionella* count was low, it should not be present. Its presence indicates that *Legionella* control measures which are required by law by the Health and Safety Executive had failed to prevent the growth of *Legionella*.

209. With the information provided we didn't know the extent of the problem as the number of water outlets tested in the building was quite small (only 12 water outlets had been tested and 1 was positive and in a building the size of RHCYP DCN I would have expected more outlets tested to fully assess the water system). We didn't know what *Legionella* control measures were in place and we didn't know why they had failed. *Legionella,* once in a water system, invariably is difficult to remove and requires targeted actions like intensive flushing and/or chemical or thermal disinfection to eradicate it. It does not usually go away itself.

It usually gets worse and begins to affect more outlets at higher concentrations if left unaddressed. The presence of *Pseudomonas aeruginosa* is also difficult to resolve and requires similar control measures. NHSL IPCT and Estates teams had gained extensive experience of measures need to mitigate the risk of *Pseudomonas aeruginosa* in the DCN building and ITU at the Western General Hospital where there were ongoing IMTs and much replumbing had been required but those were in old buildings.

210. This however was an entirely new water system which already had evidence of water outlets with bacterial contamination with organisms that were recognized hazards. This suggested that there may be water temperature issues, flow issues or contaminated components within the system that would need to be addressed. We also had not been told where in the building the *Pseudomonas aeruginosa* was detected so it was impossible to adequately assess risk to any vulnerable patient groups who might be placed in the affected rooms as we had not been told where the affected rooms were or the type of patients who would occupy them. We didn't know if the *Pseudomonas aeruginosa* issues were widespread across the building or just localised. Without measures to remove the hazard though it would invariably spread in the system and get worse too.

211. There were parallels with what was beginning to be described about the QEUH water system which were a concern to me **(A47172335 – RE RHCYP DCN Edinburgh – Water Quality – dated 21 February 2019 – Bundle 13 – Volume 8 – Page 725)**. Although some water testing had been performed, it was suggesting the water system might not be in good condition and this had clear implications for patient safety in the future if true, so we needed to know more about what was causing these hazards and through further testing define the nature and the extent of the issues and resolve them. The concern was not so much that there hadn't been assessment of risk, it was because there was the presence of recognised microbiological hazards and a strong suspicion that Health and Safety Executive (HSE) requirements for control of Legionella were not being met. I was not alone in my conclusions as they were shared by my microbiology consultant colleagues, and it transpired they were shared too by Bouygues who had already directly raised their concern with IHSL prior to my being notified by the Project Team. **(A47172311 – RHCYP and DCN Edinburgh**

– Water Quality – dated 19 February 2019 – Bundle 13 – Volume 8 – Page 762) and **(A47172329 – RE RHCYP & DCN Edinburgh – Water Quality – dated 13 February 2019 – Bundle 13 – Volume 8 – Page 765)**

212. I then updated Professor Alex McMahon as HAI executive lead on 13 March 2019 (I was on annual leave from 2 to 10 March) **(A34010959 – Email from Linsday Guthrie to Anette Rankin regarding a Sunday Herald Article on ventilation issues at QEUH RHCYP – dated 5 August 2019 – Bundle 5 – Page 35)**, as discussed at paragraph 104 above.

213. It was announced on 27 February 2019 by e-mail to NHSL staff that NHSL had taken ownership of the RHCYP DCN building. This was a surprise to IPCT members who had involvement in the Project and we had not known that it was coming. Professor Alex McMahon was also chairing the IMT in relation to water contamination with *Pseudomonas aeruginosa* in WGH DCN at the time and he escalated concerns to other Executive Directors. As uncertainties remained unresolved through June 2019 there was wider communication with Ronnie Henderson, Brian Currie, Janice Mackenzie, George Curley, Susan Goldsmith, and Tracey Gillies.

214. During the first six months of 2019 the main issue was that the data in relation to the out of range water test results was very limited. It was received in a piecemeal fashion and it was not clear what location in the RHCYP DCN the data related to. I recall that there was data received on 21 February and 17 May 2019 but there were no ward locations given for the affected outlets, just a file showing water results with out of range *P aeruginosa* results (many >100 colony forming units(cfu)) and raised TVC counts (some >1000 cfu). With regards to *P aeruginosa* in water, there was draft HPS guidance in circulation from December 2018 that set out what interventions to take to resolve the hazard based on what level (in colony forming units) was detected. *P aeruginosa* should be completely absent from water in augmented care areas but it wasn't clear which parts of the hospital were affected so we did not know if they were augmented care areas.

215. Generally, in a newly installed water system the expectation would be that the water would be free of *P aeruginosa* and other bacteria that are used as indicator

organisms (i.e. markers that the water quality is poor) such as *Escherichia coli* (or other Gram negative bacteria in the Enterobacteriales group more commonly called coliforms) and *Legionella species.* Any detection of these bacteria would be considered 'out of range' as there should be none. For other specific bacteria which are not used as indicator organisms there are no set parameters in the United Kingdom that would determine an acceptable level from an unacceptable level or a 'normal range' of values to compare against to determine if they are 'out of range'. This includes Total Viable Count (TVC) measurements where there is no longer an agreed normal range to identify acceptable from unacceptable. For water that may be ingested, there were historical criteria set by the World Health Organisation but these are no longer used and are considered by some to be too strict. They were also used primarily to determine if water was of an acceptable quality for drinking whereas in a healthcare building water may be used for personal hygiene (bathing and showering) or some clinical purposes (mouth care and wound care) and cleaning and there are no criteria that would indicate if such water was poor quality or not. That creates clinical risk though as if a patient is bathing or showering with healing surgical wounds exposed to water with a high burden of micro-organisms or damaged lungs and at risk of inhaling micro-organisms or has a skin penetrating medical device like an intravenous catheter then the micro-organisms in the water have any easy route by which to enter the body and cause deep infections.

216. In February 2019 the water testing was being performed as part of a commissioning exercise initially to pass maintenance responsibility for water management over to Bouygues Energies and Services who had identified the same concerns about water quality. It was being performed I believe more from the perspective of assessing a water system from a plumbing perspective to complete an aspect of building commissioning in a public building. But this was to be a functioning hospital for children and a high proportion of those would be susceptible to infection from the organisms being identified in the water if they were exposed and exposure to the water would be inevitable during an inpatient admission. The future clinical risk of paediatric infections associated with what was being uncovered did not seem to be fully recognised by all involved. It was recognised by the NHSL project team and IPCT but there was insufficient information being shared with them to assess the extent of the problems, the

cause of the problems or plan how to mitigate them.

217. My understanding was that NHSL did not have responsibility for maintaining the water system. A key issue was that with the water system now filled with water, if there was stagnation and tepid water the micro-organisms present would be growing and seeding around the building and as it was now a dynamic water system there would be water movement and movement of micro-organisms too along with the water. As time progressed it would become harder to resolve. To reiterate, NHSL Estates, IPCT and Executive Directors were at this same time intensively involved in trying to resolve the *P aeruginosa* water contamination issues on the WGH campus in the existing DCN building and were acutely aware of the potential consequences from an HAI perspective if the RHCYP DCN water quality situation was not addressed comprehensively.

218. The locations of other outlets with water quality issues were not known until 19 June 2019 when that information was released to Brian Currie by IHSL, but until then the location of the affected water outlets and therefore the nature of the patients to be treated in those locations was not known. These two crucial parts of the assessment of potential risk of water related HAI did not align until the first week of July 2019 (as explained below).

219. The causes of the 'out of range' water results were likely to be a combination of:

(i) inadequate water flowing throughout in the building and outlet flushing to replicate a live building once the water system had been filled
(ii) Swarf and other particulate debris left within the water system and taps
(iii) Uncertainty regarding water temperature controls being consistent. There had been a gas leak and issues with calorifiers being switched off in April 2019
(iv) Uncertainty whether pipework had been appropriately protected from contamination during construction
(v) Lack of system wide chemical disinfection of the water system before handover.

220. Although some of the above causative factors might have been addressed during

completion of system commissioning it is important to realise that a microbiologically contaminated and filled water system in an unoccupied building is not a static hazard. With each day, the micro-organisms will grow and spread and so if they are not promptly removed by effective flushing and disinfection the hazard burden increases and the ability to effectively decontaminate the system decreases over time as the extent of contaminated pipework and the concentration of micro-organisms increases. What starts as a small and localised issue doesn't stay small and localised if not promptly and effectively addressed by removal of the predisposing factors and cleaning out the contamination either physically by flushing or by thermal or chemical disinfection. NHSL wanted to avoid a bigger problem and bigger clinical risk manifesting in the future. It is true that the water system commissioning had not been completed prior to handover but it was also, in places, demonstrating microbiological contamination. Although a flushing regimen was being performed this now had to be ramped up to replicate water turn over in an occupied hospital and there needed to be more investigatory water testing performed so it wasn't just that the commissioning process needed to be completed.

221. In my view, these issues would have posed a risk to patient safety and care, in particular: (i) *P aeruginosa* in augmented care clinical areas; and (ii) raised TVCs – although the impact of this is unknown but data was beginning to emerge from QEUH of possible severe consequences. As noted, the presence of high TVCs (a marker that there is significant microbiological contamination of the water) in a healthcare building where that water may be used for bathing or hand hygiene has risk of contaminating wounds or invasive devices (such as Hickman lines) with an aqueous suspension of micro-organisms and a risk that infection will then develop. Intuitively, the lower the concentration of micro-organisms in the water (a lower TVC) the lower that risk becomes. It could be considered an avoidable risk if there is assurance that TVCs were low for instance. HPS had been reviewing evidence and mechanisms of transmission for outbreaks of water related micro-organisms and they circulated a draft of this for discussion in April 2019 **(A47172358 – Rapid Review of Healthcare Associated Infection Risks and Outbreaks Associated with Healthcare Water Systems – dated April 2019 – Bundle 13 – Volume 8 – Page 767)**. Additionally the HPS report '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" which we had seen in February 2019 **(A42362411 - Summary of Incident and Findings of the NHSGGC QEUH RHC water contamination incident and recommendations for NHS Scotland – dated 20 December 2018 – Bundle 13 – Volume 8 – Page 796)**, inferred that there was a relationship between raised TVCs in the water system detected prior to occupation and the incidence of bloodstream infections with organisms related to water in the paediatric bone marrow transplant unit, Schiehallion.

222. Callidus were contracted by NHSL Project Team to undertake a compliance audit of *Legionella* controls. This was initiated by the Project Team and IPCT were not involved in that decision. It was prepared following site visits by Callidus on 21 and 22 March and 25 and 26 April 2019. The Callidus report was issued in May 2019 and identified several areas of concern. This report however was not shared with IPCT and other members of ESG until after 9 July 2019. The report notes that Callidus had identified several issues in the water system that would predispose to the growth of Legionella species and the water testing in February 2019 had identified growth of Legionella species in one outlet so it appeared that the root causes of this were still present when Callidus did their review. I was surprised that the Callidus report hadn't been flagged earlier to me as microbiologist on the water safety group or to the Executive Directors earlier as it notes on page 19 that a Legionella Risk Assessment for the building had been performed in February 2019 and the overall risk rating was determined as high. Callidus too gave Legionella control a red rating as they could not obtain evidence that there was an adequate flushing regimen in place (page 27). **(A34053106 – Callidus – Compliance report (Final) – dated 01 May 2019 – Bundle 13 – Volume 8 – Page 1005)**.

223. Westfield Caledonian were contracted by NHSL to perform an assessment of the whole water system and independently perform microbiological water testing. I believe this was arranged by the NHSL Director of Facilities (George Curley). This began on 1 July and was not completed until 12 July so the results of this were not available to IPCT until after 9 July 2019 (which had been the date that the hospital was due to open to patients.) **(A40982080 – Email from Anna**

Munro to Lindsay Guthrie et al re HAI SCRIBE RHCYP Risks and Mitigations - dated 12 June 2019 – Bundle 13 - Volume 8 – Page 821). This had been discussed and planned at the RHCYP DCN IMT meeting where NHSL Estates, Project Team, IPCT and Executive Directors were in attendance. Neither IPCT nor microbiology contract water testing from commercial laboratories directly in NHSL.

224. Without comprehensive data to inform a risk assessment (because commissioning water data provided by IHSL was very scant), IPCT (based on experience of trying to resolve significant water system contamination due to *P aeruginosa* at the WGH with the assistance of Westfield Caledonian) took a risk averse stance with regards to water issues at RHCYP DCN. The NHSL Authorising Engineer for Water (Dennis Kelly of Pro Lp Consulting Ltd) and Director of Estates (George Curley) were also involved.

225. I was concerned that there was an unsafe water system at the RHCYP + DCN. We had been told there were recognised microbiological hazards in the water (particularly *Legionella* species and *Pseudomonas aeruginosa*) but had uncertainty regarding the extent or locations. We had no assurance they had been appropriately eradicated. There were too many unknowns to consider it safe when we first had awareness in 2019. It wasn't until 19 June 2019 that actual water result locations were received by the Project Team from IHSL, who then forwarded the results to me and Lindsay Guthrie, to be able to begin to understand what the actual issues were and where they were in the building.

NSS Reports

226. With reference to an email from Annette Rankin to Ian Storrar **(A34012673 – Email from Annette Rankin to Ian Storrar regarding the 2015 HAI standards - dated 28 August 2019 – Bundle 7 - Volume 3 – Page 287)** and an email from Donald Inverarity to Sorrel Cosens and others (**A41352302 – Email from Donald Inverarity to Sorrel Cosens with comments on the report of the NSS - dated 5 September 2019 – Bundle 7 - Volume 3 – Page 345)**, there were several different water reports that originated from NSS which I have been asked by the

Inquiry to review and give an opinion regarding in the period between 23 August and 5 September which I have done in the following paragraphs.

227. Regarding, **(A42362411 - Summary of Incident and Findings of the NHSGGC QEUH RHC water contamination incident and recommendations for NHS Scotland – dated 20 December 2018 – Bundle 13 - Volume 8 - Page 796)**, we received on 20 August 2019 from SMVN (although had been published online in February 2019). The NHSL response is within **(A47172460 – HPS Water Report – made available to NHS Lothian via Scottish Microbiology and Virology Network – dated 20 December 2018 – Bundle 13 - Volume 8 - Page 827)**.

228. The significance of the NSS/HPS report to the RHCYP DCN building is that it was released in February 2019 at the time when we first were seeing water results with raised TVCs, *Pseudomonas aeruginosa* and *Legionella species* detected in water testing that IHSL had undertaken. In the hypothesis section on p14/15 HPS proposed that microbial contamination at installation could have been enabled to flourish in the filled water system due to lack of flushing and allowed to establish biofilms in the system. We were concerned that the same scenario would manifest at RHCYP DCN if there wasn't intervention to increase water throughput in the system by increasing the flushing frequency and begin disinfection of the affected outlets.

229. An interim report from "Water Solutions Group" into RHCYP DCN which had been commissioned by NSS along with a selection of environmental microbiological reports issued by a company called Intertek. The significance of this report is that it was commissioned by NSS (HFS and HPS) to investigate the water system at RHCYP DCN. The same company had been involved in the investigation of water safety at QEUH. When the system was assessed microbiologically for conventional markers of water safety it identified that:

- *Legionella species* were not detected in the water at any location page 5
- TVC counts "in some areas were slightly elevated but would not be considered excessive" page 5
- No detection of *Pseudomonas aeruginosa from* 60 outlets tested page 9

- "there is no indication from the microbiological results to suggest that the water system is not fit for use" page 6. **(A34053098 - 20190718 Water Safety Consultant Report (T Wafer) dated 18 July 2019 – Bundle 13 - Volume 8 - Page 879)**

230. There were several concerning issues about compliance with a duty structure, documentation, information management, training and other matters relating to water safety governance and quality management but it did not identify any major issues with the microbiological state of the water system itself when using methodology for a conventional assessment of the water quality. Strainers in many of the wash hand basins demonstrated that they had metal filings and general debris caught in them. Bearing in mind the building was not yet open this likely occurred during its construction and the aftermath of that but if left in place would easily facilitate growth of micro-organisms and a loss of water quality through rising TVCs. It raised questions about why it had not been detected earlier during the commissioning process. This can be seen in the following documents **(A34053122 – 20190813 Fwd Draft water and ventilation reports – dated 13 August 2019 – Bundle 13 – Volume 8 – Page 839)** and **(A34053098 – 20190718 Water Safety Consultant Report (T Wafer) - dated 18 July 2019 – Bundle 13 – Volume 8 – Page 879)**

231. A further report from NSS was received in September 2019: Royal Hospital for Children and Young People and Department of Clinical Neurosciences NHSL response to actions identified in the NSS National Services Scotland – Review of: Water, Ventilation, Drainage and Plumbing Systems v2 **(A47172417 – NHS Lothian response to actions identified in the NSS review of: Water, Ventilation, Drainage and Plumbing Systems – dated September 2019 – Bundle 13 – Volume 8 – Page 894)**.

232. This was an updated version of a draft that was circulated on 9 August 2019, see **(A47172405 – NHS National Services Scotland Review of: Water, Ventilation, Drainage and Plumbing Systems – dated September 2019 – Bundle 13 – Volume 8 – Page 904)**

233. This replaced an earlier draft and confidential version that was issued to NHSL

on 6 August, see **(A47172508 – Fw Draft RAG Report of the NSS Review of the NHSL RHCYP and DCN – dated 6 August 2019 – Bundle 13 – Volume 8 – Page 925).**

234. These reports initially gave red, amber or green ratings based on perceived risk severity. It was understandable that a red rating was given to matters relating to water system management and compliance with Health and Safety Executive legislation regarding Legionella controls or Scottish Water Bylaws. But a red rating was given to "Pseudomonas being found in taps in critical care areas" which had never been described or found in the NSS commissioned Water Solutions Group investigation or any other investigation to date. It was baseless. There was also a red rating given for "widespread fungal contamination" and the basis for this statement was also very unclear. Assessment of water for fungi is not a conventional means of assessing water quality. It had been found in water at QEUH (where there had been much media attention about deaths from fungal infections) and so was being interpreted as a significant clinical risk but nothing had been shared which demonstrated to us in NHSL that it was anything other than a normal feature of the ecology of a building water system. There was no requirement we knew of that the water should be free of fungi or what level of fungal growth was to be considered acceptable or unacceptable.

235. The NSS report seemed to have drawn two very different conclusions to the Water Solutions Group based on the same microbiological data and given them red ratings for high clinical risk. The various drafts of the NSS reports were all concluding there were serious concerns about significant clinical risk from the microbiological state of the RHCYP DCN water system whereas the Water Solutions Group report did not. The draft NSS report was then revised and re-issued as version D0.20 without the RAG rating and now conceding that, "testing identified no widespread contamination of the water system." It still erroneously stated that *Pseudomonas* was found in critical care taps as a main finding (page 16). It also noted that because of the finding of fungal contamination of the water, it merited system wide disinfection and retesting for fungi (page 17) which rather than being advised by standards and guidance, was an opinion. By the final version 2.0 the location of *Pseudomonas aeruginosa* detection in paediatric medical inpatient and DCN inpatient wards and not critical care had been

corrected but the instruction to undertake system wide disinfection and retesting for fungi remained which in my view was not deliverable. A system wide disinfection was indicated before occupation but not because of the detection of fungi in my view. This raised questions for me about the NSS interpretation of the microbiological data that they were using to formulate their actions for NHSL and their understanding of what was and what wasn't deliverable regarding laboratory testing of water.

236. To clarify, it is the Draft Versions of reports and the RAG ratings within them (6 and 9 August 2019), along with the "Water Solutions Group" paper and email exchange 14 August that the email exchange with Tracey Gillies on 23 and 28 August 2019 (**A34012673 – Email from Annette Ranking to Ian Storrar regarding the 2015 HAI standards - dated 28 August 2019 – Bundle 7 - Volume 3 - Page 287)** relate to.

NHSL commissioned assessments of the RHCYP DCN Water System

237. As detailed above, there were also two water reports commissioned by NHSL during July 2019 produced by:

- Westfield Caledonian (e-mail contains the actual water test results) **(A47172495 – FW RHCYP DCN Water Safety Assessment – dated 17 July 2019 – Bundle 13 – Volume 8 – Page 938**) and **(A34053095 – NHS Lothian Report on Water Safety Assessment at RHCYP & DCN – dated 1 July 2019 – Bundle 7 - Volume 1 - Page 10)**

238. Lindsay Guthrie and I wrote a paper outlining the implications of this report from our infection prevention and control perspective with regards to HAI risk from water, see **(A47172450 – IPCT response to Westfield Caledonian Water Safety Report – dated 19 July 2019 – Bundle 13 - Volume 8 - Page 974)**.

239. There was then additional feedback from Dennis Kelly (Authorising Engineer for Water), who added to this updated version to aid interpretation of the risks being flagged for the RHCYP DCN Executive Steering Group, see **(A34053090 – IPCT response to Westfield Water Report v2 – dated 24 July 2019 – Bundle 13 -**

Volume 7 - Page 144).

240. The Callidus Report (also discussed in paragraph 221) **(A34053106 – Callidus – Compliance report (Final) – dated 01 May 2019 – Bundle 13 – Volume 8 – Page 979)**.

241. IPCT did not have sight of the report from Callidus until it was issued via the ESG in July although it relates to inspections in March 2019 and was issued in May 2019. This raised our concern that *Legionella* controls in the building were not optimal.

Interpretation of the microbiological water testing results made available by September 2019

242. In relation to water, not all of the items with a red rating in the NSS draft report **(A47172508 – Fw Draft RAG Report of the NSS Review of the NHSL RHCYP and DCN – dated 6 August 2019 – Bundle 13 – Volume 8 – Page 925)** were contested by me (and consequently the RHCYP DCN ESG) and for some, plans were already in place or being formulated to allow rectification. Two items did however cause me significant concern. Firstly, a statement that *Pseudomonas aeruginosa* water contamination was present in the critical care area. This was factually incorrect. Commissioning water testing results from IHSL that we had seen had identified an outlet with >100cfu/100ml *P aeruginosa* in 3c1.1.-046. (this is a room reference using IHSL nomenclature for rooms in the building and was identified as in Dalhousie which would be the paediatric respiratory ward which would be in the category of an augmented care area for *P aeruginosa* risk in water, but it was not a critical care area). Critical Care had not been sampled. The more extensive testing for *P aeruginosa* performed by Westfield Caledonian for NHSL identified several outlets with *P aeruginosa* contamination but all the water outlets in PICU and Neonatal (area 1-B1) had been tested during the period 1 to 11 July 2019) and found to be completely free of *P aeruginosa*.

243. Secondly, the statement that there was widespread fungal contamination of the water system because:

- It inferred that detection of fungi in healthcare water was an abnormal finding. There was no data provided to justify this conclusion. Some laboratory results were shared which showed taxonomical naming of fungi being performed in a laboratory in Bremen, Germany but no data regarding quantitative counts of fungi present or interpretative framework being used to distinguish ‘normal’ from ‘abnormal’ in relation to fungal counts in healthcare water was provided.
- It inferred that NHSL should take a “zero tolerance” approach to fungi in healthcare water. This would indicate a change in national policy regarding acceptable water quality in healthcare which hadn’t been approved through NSS governance routes that reviewed changes in policy and was not something that all other health boards were being expected to implement.
- It was advocating that the red rating would not change until repeat testing for fungi in water was performed after system disinfection. This was not deliverable by NHSL as the water testing for fungi methodology had not been shared and we had not been given any steer as to whether there were any commercial water testing laboratories within the UK who could offer this as a United Kingdom Accreditation Service (UKAS) accredited laboratory test. This was testing that NHSL microbiology did not have the equipment, staff training or expertise or laboratory accreditation to perform.

244. I was also concerned that the report issued on 9 August 2019 outlined an entire section explaining how the findings were to be considered as based in interpretation of standards and guidance. In my view many of them were not based in standards and guidance but were ‘expert opinion’ with no explanation as to what criteria made the advisor an expert and no assessment as to whether the expert advice was biased or not. In section 1.3.7 of the report, NHSL is advised to take account of “lessons learned” from elsewhere without description as to what the lessons were or whether or not they were unbiased conclusions or biased speculation.

245. I can explain why, given my prior concerns around bacteria in the water system, there is a suggestion here that some micro-organisms may not pose a risk to patient safety and care. Healthcare facilities are not sterile environments and neither are they expected to be. Water systems within healthcare facilities are not

sterile either and many different types of micro-organisms can be found in healthcare water coming from the mains water supply but usually beneath the level of detection by microbiological culture. All water systems form dynamic ecological systems and may contain microscopic levels of biofilm containing micro-organisms including bacteria and fungi. So in any healthcare water system the following would be true:

- There will be a range of bacteria and fungi present at low levels.
- Those organisms can be considered as opportunistic pathogens i.e. not all of the micro-organisms present would necessarily pose a threat to patient safety all of the time. This is a dynamic situation though and bespoke to individual patients based on whether there is a route of entry into the body, patient's immune system and ability to fight off infection and the infectious dose of micro-organism the patient was exposed to.
- The presence of pre-defined "indicator" organisms would raise a red flag that patient safety may be compromised.

246. As a public building, a hospital would be expected to provide water that met a drinkable standard. It is not practical to test for all potential micro-organisms that could be encountered in water so particular representative bacteria (for which there are agreed thresholds to distinguish acceptable from unacceptable levels) are chosen from which water quality is inferred – in the context of commissioning a new healthcare water system these are total coliforms, *E coli*, *Legionella species*, *Pseudomonas aeruginosa* and testing for Total Viable Counts (TVC) incubated at two different temperatures (22 and 37 degrees Celsius). These organisms are internationally agreed by the World Health Organisation (although the WHO interpretative criteria for TVC testing is no longer mandated.)

247. My concerns regarding detection of bacteria in the water related to the clear detection of one of these indicator organisms e.g. *P aeruginosa* and several TVCs which were too high to quantify (i.e. >1000cfu/ml) which suggested that water quality was not optimal pre-occupation in some locations. Without intervention, these levels would inevitably increase as the micro-organism grow, divide and multiply and potentially spread to other areas of the water system, settle and create contamination there too. This was not necessarily a complete

bar to occupation as the microbiological hazard that such water outlets posed could be mitigated effectively in the short term while rectification work was undertaken e.g. using point of use water filters.

248. Additionally, the comprehensive independent site wide water testing performed by Westfield Caledonian was indicating that of around 770 water outlets tested, *P aeruginosa* was detected in only about 40 and the vast majority of water outlets were not raising any concerns at all from the microbiological water test results and several of the outlets which were flagging as having poorer quality water were not in areas where patients would have any exposure to the water. Westfield Caledonian also demonstrated that there was no growth of *Legionella* species from the water system in July 2019 and although there were legitimate concerns regarding not being able to demonstrate compliant documentation with regards to *Legionella* controls and risk assessment, that had not translated into its sustained presence yet.

249. I did not agree that detecting other micro-organisms solely by a qualitative method (i.e. the test can only tell if it is detected or not detected but no indication as to how much is present or what threshold determines safe from unsafe) informs current or future risk of HAI. WHO advocate that if other micro-organisms were to be considered as indicator organisms the testing should be supported by a verification and validation process that would determine safe from unsafe levels at least in the context of ingestion of the micro-organisms. See **(A47172465 – Guidelines for drinking-water quality – dated 24 April 2017 – Bundle 13 – Volume 8 – Page 1015)**.

250. The criteria that, “any potential pathogenic contamination found should be eradicated before patients and staff move in,” would substantially delay occupation as it could be unachievable. There would always be the potential for pathogenic micro-organisms in the water as it is not sterile and such a zero tolerance approach to micro-organisms in healthcare water far from being a “lesson learned” was at odds with my reading of water system ecology where certain micro-organisms were not tolerated but only once they had breached a threshold based on a quantitative culture method. Virtually any micro-organism may be pathogenic if a patient is particularly susceptible. The ability to cause

infection is not solely a feature of the organism but also of the susceptibility of the person exposed and the infective dose i.e. how much the person was exposed to. The infective dose varies substantially between organisms –some bacteria require very few organisms to cause disease while others require thousands or more.

251. The accepted thresholds at which microbiological samples would pose a risk to patient safety and care relate to specific micro-organisms in specific situations in healthcare in the UK. The thresholds currently used in a hospital context are outlined (Tables 3-9) by Public Health England (PHE) in **(A47172694 – Examining food, water and environmental samples from healthcare environments – dated February 2020 – Bundle 13 - Volume 8 - Page 1640)**.

252. There is also PHE guidance regarding managing the detection of Legionella in a healthcare facility. These align with what is outlined in SHTM 04-01 Parts B and C. **(A47172318 – Responding to the detection of legionella in healthcare premises – dated December 2015 – Bundle 13 - Volume 8 - Page 1687)**.

253. In Scotland, the thresholds for dealing with *P aeruginosa* in water are less clear than in the English HTM04-01. In 2018 and 2019 there were draft documents circulated by HPS for comment in Scotland but no definitive guidance about microbiological assessment of water by culture for *P aeruginosa* has been issued in Scotland since then. Water coming out of water outlets in augmented care areas should be kept free of *P aeruginosa*. **(A47172391 – Psuedomonas aeruginosa routine water sampling in augmented care areas for NHS Scotland – dated September 2018 – Bundle 13 – Volume 8 - Page 1708)**. The term augmented care is defined in draft guidance from HPS in 2018 as:

- Bone Marrow Transplant Units, Haemato-Oncology and Neonatal Units, and any other care areas where patients are severely immunosuppressed through disease or treatment.
- Critical and intensive care units (neonatal, paediatric and adult), renal units, and respiratory units (including Cystic Fibrosis patient care units). Burns units and other care areas where patients have extensive breaches in their dermal integrity.

254. With regards to fungi in water, there is no accepted threshold that distinguishes safe from unsafe levels in the UK. Fungal colony growth would be detected through TVC testing so if there was a substantial issue with fungal contamination, it would manifest as high TVC counts and that should then trigger a review as to why the TVCs were high. If TVCs are below 100cfu then by inference, fungal counts must be below 100 cfu also.

255. DEFRA have proposed that threshold level for numbers of fungi that can cause altered taste or smell of water may be around 102-103 cfu per 100ml water, see **(A47172717 – A Review of Fungi in Drinking Water and the Implications for Human Health – dated April 2011 – Bundle 13 - Volume 8 - Page 1713)**.

256. Fungal assessment of drinking water is performed in Sweden but not routinely. The limit of acceptability for the occurrence of fungi in water is 100cfu per 100ml water according to the Swedish regulatory authority, see **(A47172603 – Fungal contaminants in drinking water regulation – dated 13 June 2017 – Bundle 13 - Volume 8 - Page 1820)**.

257. Data that was eventually shared with NHSL by NSS in January 2020 listed the cfu per sample of fungi that had been detected to inform the report issued by "The Water Solutions Group" and this showed that only one outlet tested (from a shower) breached a 100cfu/100ml water threshold yet NSS considered this as representing "widespread fungal contamination" of the water system. Only 60 outlets were tested and only 2 others had fungal counts that exceeded 10cfu/100ml, see **(A47172296 – Edinburgh Sampling – dated 26 July 2019 – Bundle 13 - Volume 8 - Page 1864)**.

258. PHE used to run food and water testing proficiency quality assurance schemes for microbiology laboratories undertaking microbiological assessment of water. There was a scheme for Hospital water and Mycobacteria in water although I'm not sure if these EQA schemes still run.

259. Food and water proficiency testing schemes: scheme guide - GOV.UK (www.gov.uk) Their scheme for *Mycobacteria species* in water was not

accredited but that for hospital water was. I'm not very familiar with them as I don't work in a water testing laboratory.

260. WHO addresses how to determine risk of infection from ingestion of micro-organisms in healthcare from water in the following document from 2017 in Chapter 7. Often risk of infection from ingestion is extrapolated to represent all risk of infection acquisition situations in healthcare and it may not be appropriate to do that. **(A47172465 – Guidelines for drinking-water quality – dated 24 April 2017 – Bundle 13 - Volume 8 - Page 1015)**.

261. I am not aware of any reliable means of assessing clinical risk of HAI from washing or bathing in tap water contaminated with micro-organisms that is used as this would be a factor of many variables such as the amount of micro-organism in the water, a route of transmission into the body e.g. open wound or device puncture site and host immunity of the exposed patient.

Reflections on IPCT involvement

262. I do not think there were sufficient opportunities for the complete set of relevant skills or experience that was present in IPCT to be involved with, and provide clinical input to, the Project at all stages. Initially, input from me as Infection Control Doctor was *ad hoc* at the request of existing Project team members. That began to change from summer 2018 onwards because of the nature of some of the ventilation issues being encountered (e.g. discussion over the design of the lobbies in the Lochranza isolation rooms) and the imminent retirement of Janette Rae. From March 2019, we were much more heavily involved but by then we were uncovering many issues that concerned us, some of which might have been avoidable through earlier involvement in the design stage such as the ventilation strategy to neurosurgical theatres.

263. I think IPCT used the opportunities we had to be involved with the Project as they came up but only Janette Rae had dedicated time to be fully involved. The rest of us had our regular workload to deliver and initially no back fill of our posts to free us up. A project of this scale really needs the IPCT stakeholders to have agreed, dedicated, funded time to be involved to the depth that is required. It became a

full time job and for many months that was on top of our existing full time job responsibilities and commitments although colleagues did try their best to free us up to dedicate time to RHCYP DCN issues. There were several, prolonged, high profile or complex HAI incidents in NHSL at RIE and WGH described above being experienced that required our skills as the leads for IPCT in the period summer 2018 to summer 2019. This was before the Covid 19 pandemic. The pandemic made the human resource availability to address issues of the built environment much worse even when the projects were related to improving ventilation provision in clinical areas to minimise risk of SARS CoV2 exposure and Covid 19 outbreaks. It continues to be a problem through the ongoing loss of experienced IPCNs and IPCDs as described in paragraph 279 below.

264. From January 2020, IPCT resource was by necessity focussed on preparing for the first wave of Covid 19 with the awareness that we were only 2 weeks behind other European countries who were being swamped by this new disease. But Lindsay Guthrie and I were still having to balance involvement in ESG meetings, walkrounds and inspections, ventilation and water meetings and risk assessments for RHCYP DCN as the pandemic hit the UK and that continued up until RHCYP DCN was fully opened and occupied. The expectation of IPCT involvement by the Oversight Board exceeded IPCT human resource and skill mix to fully engage at times.

265. In my view IPCT members with further specialist training in the infection control implications of critical building systems (such as ventilation performance and assessment and water quality) should be involved as stakeholders at the design stage when there were discussions with clinical teams. Traditionally IPCT involvement has been more related to discussions about whether fixtures and fittings might harbour micro-organisms and whether they are able to be cleaned with disinfectants. The design stage is the point when it is easier to highlight where a clinician’s wish may not be deliverable or permissible due to the framework of guidance that would need to be complied with or would risk creating a clinical environment that doesn’t reflect best practice while there is opportunity to steer plans back towards a safe outcome. Or it may present opportunity to highlight to a designer that too great an emphasis was being put on energy recovery for instance and creating a non-compliant design or that there was

misunderstanding of the clinical purpose of the area. Of note though, many of the design discussions with clinical teams and the plans that were formulated with regard to RHCYP DCN occurred before 2014 and before there was very explicit guidance regarding ventilation parameters and performance for areas like intensive care and there was IPCT involvement. The issue may have been to do with designs not being sufficiently reviewed to comply with updated, current guidance or changing clinical needs before building and installation commenced, though I have been advised that the Project Agreement did specify compliance with SHTM 03-01.

266. Ideally though having an Authorising Engineer for Ventilation or Water either present or reviewing the outcomes of design discussions adds another important perspective as to whether what is being proposed is compliant or not with current standards or any standards that are being revised and updated of which IPCT may not yet be aware or to identify non-compliance that creates risk to the project outcome but not necessarily an infection risk. Many clinicians have no knowledge of healthcare ventilation or water systems and their safe functioning or the technical guidance behind designing and maintaining them. That said, clinicians and IPCT should be able to rely on engineers designing a healthcare building in line with current Guidance. I have noticed that if the designers and engineering team have experience of working on previous successful healthcare projects then discussions go much more smoothly and an experienced project manager with a background in healthcare is a clear asset. I have worked with teams with little or no healthcare experience and not only is much time wasted explaining mandatory processes like HAI Scribe there is no memory of when things have gone wrong in the past and so similar errors are repeated unnecessarily.

267. A clearer competence assessment of contractors for healthcare projects would be beneficial before they begin and waste clinicians time and generate unnecessary additional costs. This shouldn't be an IPCT function though. Any proposed non-compliances with Guidance should be flagged up by the engineers at the design stage for input from relevant other stakeholders such as IPCT. IPCT can then consider, along with the clinicians in that particular department, whether the proposed non-compliance would compromise patient safety and

whether, or not, any risk from a non-compliance can be appropriately mitigated. The design stage definitely needs multi stakeholder participation that involves the design team, project team, clinicians who will use the facility, IPCT and Authorising Engineer input too in order to be most effective but that can be prohibitively time consuming for comprehensive IPCT and clinician input. It is dangerous though for people who will not be using the area to assume that they know how it will be used as invariably they have misconceptions and that can then translate into an incorrect design from which it may be difficult and costly to step back from.

268. In summary, an explanation of how a clinical area will be used best comes from the clinical team who will be using it. The infection control team can then explain the potential infection risks that could be encountered, highlighting known risks from other projects or current infection control guidance. The design team then take this information and create a design that designs out the known and identified risks and doesn't inadvertently design in clinical risks to the best of their ability. The project team co-ordinates the process, assessing that what is built aligns with best practice and current technical guidance, through liaising with the construction company or subcontractors, with the independent support of authorising engineers and identifies areas for clarification and may escalate those to NHS Scotland Assure to adjudicate.

269. There could have been more scrutiny during critical system commissioning but a variety of NHS stakeholders were unaware of this happening or the implications of any information being generated. Had IPCT had more visibility of that data and process then there might have been earlier opportunity to explain the relevance of the data to timely completion of the Stage 4 HAI Scribe – which was not signed off in July 2019. That said, SHFN 30 Part A and Part B are comprehensive NSS documents that explain the multidisciplinary nature and timing of the HAI Scribe assessment process and it is clear that IPCT are not the lead agency but provide an advisory role (Part B section 2.9 p18). Ideally it should be the estates team or project team that take the lead role in HAI Scribe completion with input from IPCT. Clear and visible record keeping throughout the project of why decisions have been made, and based on what available information, would help with continuity when project team members change which they inevitably do for

various reasons during a long, protracted project.

270. There was a change as to the level of IPCT involvement sought by the project team from around June/July 2019 as the implications of the extent of the non-compliances in ventilation and water systems became more apparent. Between March and July 2019, it did feel like IPCT involvement was more valued by the NHSL Executive Directors than the Project Team. IPCT were perhaps perceived as holding things up and at risk of derailing the project timelines. Once the IMT, subsequently renamed as the ESG, was set up and the water and ventilation workstreams began from July 2019, I had more of a feeling that we were all working together with a common goal.

271. I have been asked whether the Critical Care issue could have been avoided had IPCT been more involved at any particular stage and, if so, to describe how and when. In this particular Project, the answer is probably no because nobody in NHSL knew there was an error in the Environmental Matrix. I also understand the engineers designing the hospital, TUV SUD / Wallace Whittle, consider all rooms in critical care (other than isolation rooms) only require 6 ac/hr in order to comply with Guidance SHTM 03-01. For that reason, it seems unlikely that they would have ever proposed a derogation from 10 ac/hr and sought IPCT input given they did not think critical care required 10 ac/hr in the first place. I believe it was the reduction in air change rate from 10 to 4 ac/hr that was the key deviation that was making the clinical environment unsafe in critical care but other design deviations like the installation of opening windows were also a concern.

272. In subsequent capital projects for NHSL, experienced IPCNs and IPCD have participated in multidisciplinary room data sheet review meetings at the design stage to utilise both perspectives and wider skill mix. Had that model occurred in the design stage of the RHCYP/DCN project then I believe issues where room ventilation provision doesn't align with room purpose would have been more likely to be detected and corrected prior to building. However, as above, that does not mean the specific issue regarding the air change rate in critical care (or other engineering issues) could or should have been picked up in the Project had IPCT been more involved, because of the engineer's belief that 6 ac/hr was compliant with SHTM 03-01. It should not be for IPCT or clinicians to go through

each and every RDS (or an Environmental Matrix) to check for non-compliances. That is just not their role or always within their professional expertise, and nor should it be. IPCT practitioners won't know off the top of their head what each space in a building should have in terms of air change rates and would themselves need to consult with Guidance and/or HFS/HPS (now NHS Scotland Assure) on technical issues.

273. Clinicians generally do not know how to design and build ventilation systems but they do know how to use the areas that are served and can communicate that to the designer. Since the Covid 19 pandemic awareness of safe room ventilation parameters has increased among clinical teams but it is quickly forgotten when teams have a high turnover of staff. Teams that have had their service disrupted by a ventilation system failure or RIDDOR event from a ventilation issue will tend to have more awareness of room ventilation design and parameters. In my view, the Guidance should be the starting point for everyone on the Project. If any party, be it the designer, contractor or a clinician, wishes to propose a derogation from Guidance, that should be flagged with IPCT (both IPCN and IPCD disciplines) for discussion but IPCT are not the decision maker who "approve," rather they provide an assessment of risk of infection from what is proposed in the same way that the fire officer would provide an assessment of fire risk. It is up to the project team to co-ordinate such discussions and include the project sponsor and collectively agree the way forward with regards to derogation. The earlier this is done the better.

274. Generally though, as I've said before, clinical teams may not often know the design guidance or what is considered best practice but they will be enthusiastic about doing something differently, that they perceive to be quality improvement, without necessarily realising that it can't be done without appreciable corporate risk from non-compliance with design guidance or building standards for instance. A common example we experience are well intentioned plans to refurbish offices or bathrooms to become areas to perform clinical activity which may have an invasive component like insertion of a device through skin or minor surgery without appreciating that the area isn't large enough or doesn't have anywhere to wash hands or doesn't have sufficient supply fresh air for the number of people who will be in the room. Essentially it is identifying that the new

purpose doesn't align with the old environment and the environment needs changed too. IPCT can then be perceived as delaying progress when all we are doing is trying to prevent poor outcomes or harms and explain that if there is predictable infection risk then there is also corporate risk to address. With regards to the signing of SA1 and handover of the building I do think that if IPCT had been consulted it would have been flagged that due process as outlined in HAI Scribe was not being followed as completion of the HAI Scribe process is now such a fundamental part of the IPCT job. It would not have corrected the issues but may have reduced adverse impact on NHSL.

275. I do not think that the Critical Care issue could have been avoided had IPCT taken a different approach during discussions in respect of general wards and Haematology/Oncology ventilation provision. When there was IPCT awareness of the reduction of mechanical supply to general wards it was in the context of there being additional natural supply from opening windows and so it was perceived that there would still be the advised 6 air changes overall (4 mechanical and 2 natural) and it would still function as a general ward. With Lochranza ward, IPCT were asked to advise how the installed ward ventilation system could be aligned to clinical needs of neutropenic patients once it was realised that the 4 bedded rooms and single rooms met the criteria of a general ward and only the PPVL isolation rooms met criteria for neutropenic patients. That was a manageable infection risk because not all the inpatients on that ward required the protective measures of a neutropenic patient and fortuitously the 5 isolation rooms provided appropriate ventilation for that purpose. Lochranza could still function as a haematology/oncology ward. I believe critical care was also past a point when the extensive changes needed to comply with SHTM 03-01 could be implemented, at the point of discovery of the non-compliance in Lochranza, as I understand that the AHUs were not powerful enough to deliver the optimal 10 air changes per hour to all clinical areas of the critical care unit. The difference with PICU was that all bedspaces were expected to meet the same criteria of 10 ac/hr to be considered optimally safe for the activities that would take place in them but only the PPVL isolation rooms were designed to that standard. The remainder (and majority) of bedspaces, as built, had greater risk of exposures to respiratory viruses for patients and staff during periods when the number of admissions with respiratory viral infections leading to respiratory failure exceeded 4 (the number

of isolation rooms). This avoidable hazard had been designing into the unit by nature of the low air change rates to 4 bedded rooms and single rooms. The design that involved a component of natural ventilation in single rooms was also non-compliant with best practice in the health building note for designing critical care units HBN 04-02 and not just SHTM 03-01. It suggests to me that the designer did not understand that the environment required all bedspaces in PICU (critical care) to have higher ventilation delivery, through mechanical supply, than a general ward and that a general ward and an intensive care unit have different functions and different environmental conditions. Bedspaces in an intensive care unit are served by a critical ventilation system in its entirety and a general ward is not. It would be difficult to derogate from that position and still consider all the bedspaces to be suitable for the full range of critical care activities. What had been built from the ventilation strategy appeared to be a 4 bedded intensive care unit (composed entirely of 4 PPVL isolation rooms) within a 20 bedded general ward footprint. NHSL was anticipating a fully functional 24 bedded critical care area. The PICU design was changed to align with the ventilation strategy (and windows) of a general ward without challenge because NHSL were unaware that it had been changed until after it was already installed.

276. I do not have any concerns about the extent to which issues with building systems in general were addressed and resolved prior to the hospital opening to patients in 2021. There was much more comprehensive testing and assessment of the performance of systems before patients were allowed to occupy it.

Future Role of IPCT

277. I refer to my comments at paragraphs 68 above. I have been asked how IPCT involvement can be improved and encouraged for future projects for the rebuilding of healthcare environments. I would reiterate that there simply aren't enough experienced staff (nursing or medical) with generic IPCT skills plus additional specialist training in the issues around the built environment to perform at the level that seems to now be expected by NHS Scotland Assure.

278. The NHS Scotland Assure Key Stage Assurance Review (KSAR) Workbook for instance requires the health boards who are submitting a project for review to

demonstrate IPCT involvement. For an IPCD this would require submission of:

- Evidence of qualifications held (without stipulating what qualifications are required)
- Previous experience supporting new build projects (making it hard for built environment projects to be taken on by newly appointed consultant microbiologists in an IPCD role)
- Produce evidence such as risk assessments of reviews of derogations and satisfaction that there is no impact on patient safety (it doesn't recognise that IPCT staff are only qualified to comment on infection risk rather than the entirety of patient safety and this activity takes substantial time to deliver comprehensively)
- Perform walk round audits during the construction phase (it's unclear what the perceived added benefit is of having a doctor and nurse do this role, which is essentially that of a clerk of works, when nurse staffing may be too low to provide safe nurse staffing on wards and there may be insufficient microbiologists to provide anything other than essential microbiology laboratory and clinical liaison services)
- Provide evidence that fixtures and fittings do not represent infection risks. (Traditionally this was previously all that was generally expected of IPCT in a building project and aligns best with the training and skills that IPCNs will bring to a project.)

279. In general, the time required to do this for one project is substantial and hard to deliver if the IPCD only has one or two programmed activities per week in their job plan (which also must be used to deliver all other aspects of the IPCD role that don't involve the built environment). If there is more than one project in progress at any time (as there is in NHS Lothian) then there just aren't staff who meet the required criteria to be involved or staff who can offer the time involved. In 2023, I have been asked to contribute to 20 different building projects within NHS Lothian many of which are refurbishments and a smaller number of capital projects with at least 3 that have been passing through the KSAR process requiring my input as our LIPCD with four less consultants providing IPCD sessions than were in post in 2022. In addition, NHS Scotland Assure regularly

request IPCD input to review their new literature reviews or draft guidance documents which are time consuming activities. These are done through good will but rarely seem to lead to changes in policy or guidance. An example of the resource impacts of this is a request to review information to inform national policy on respiratory protective equipment in November 2023 where IPCDs were issued with over 900 pages of information to process and give informed comments on.

280. The attrition in IPCT, microbiology and the broader group of experienced NHS staff through retirement and dissatisfaction post pandemic is alarming and continues each month. IPCT needs to be much better resourced and incentivised across the UK and there needs to be much more accessible training so that the disconnect between expectation and actual training, skill mix and competence doesn't persist. The role of IPCD needs to be much better defined and clear differentiation made as to what is the role and competence of a medical microbiologist alone, what is the role and competence of an IPCD (who is not necessarily a medical microbiologist) and where that IPCD role stops and what is better delivered by the role of an Authorising Engineer or a clerk of works, particularly in relation to issues of technical compliance which are much more clearly aligned with the skill mix of the authorising engineers.

281. Part of this problem is that "IPC" has been used in a generic sense but there are very few IPCTs who are particularly experienced in the built environment. Most IPCTs do not have the experience because they've never been involved in designing or commissioning a hospital before. There is disparity across the country of health boards' access to experienced IPCT staff or even qualified IPCT staff which is getting worse. At least one Scottish mainland health board had no IPCD at the end of 2023 and some island boards share the resource with a mainland board. I do not think that all IPCTs should necessarily have someone who specialises in the built environment, that is not feasible. As above, the focus should not be on training IPCT staff for involvement in assessing compliance with technical standards but more about the role of a clerk of works, the Authorising Engineers and that of specialist technical bodies such at NHS Scotland Assure. IPCT would continue to have a role in assessing risk of infection for their health board and require a more rudimentary understanding of principles to apply in a

multistakeholder discussion. Strangely a historical version of Scottish Health Facilities Note 30: version 3 " Infection Control in the Built Environment: Design and Planning" (published 2007) **(A33662182 - Scottish Health Facilities Note 30 Part 1 - Infection Control in the Built Environment Design and Planning – dated June 2007 – Bundle 13 - Volume 3 - Page 553)** was much less ambiguous regarding the role of IPCT in building projects with clear examples and lists of tasks to cover and a clearer description of IPCT role and skills in a Project Team and roles at different stages of the project than the current version from 2014 which now attributes many of these roles to the Project Team without them being explicitly within the remit of IPCT members.

282. It is a dangerous mistake to expect from IPCT the knowledge and skills that align with that of an Authorising Engineer or to attribute to medical microbiologists' knowledge and skills that relate to environmental or public health microbiology or microbial ecologists and expect them to perform faultlessly in an area they are not trained in. Compliance issues are in my opinion the remit of an experienced clerk of works and the Authorising Engineers. It may be that had the Authorising Engineers for water and ventilation been fully informed of what was happening they could have identified the ramifications earlier and flagged them with the project team and IPCT. The Authorising Engineers would identify a non-compliance and the IPCT should assess the risk it poses to patient safety from infection. If further input is required, then the Project Team can flag it with NHS Scotland Assure. Both need to work together to achieve a comprehensive risk assessment. Neither has the complete skill mix to do it alone. Perhaps the answer is also that Authorising Engineers should participate in the design stage and the role of a clerk of works needs to be explored. I understand though that NHSL did have Mott MacDonald attending meetings in a technical advisory role.

NHS Scotland Assure Role

283. I do not think that NHS Scotland Assure and the corresponding Key Stage Assurance Reviews will substantially assist in improving health boards' IPCTs involvement in new build projects. Quite simply there aren't enough people in IPCT teams to be involved to the level that NHS Scotland Assure expect or to retrain to demonstrate competences that are now expected for involvement in

such projects. Ironically, NHS Scotland Assure has generated some of that problem as experienced IPCNs have left health boards to fill posts in NHS Scotland Assure. My experience so far of NHS Scotland Assure is that it has increased my workload (through issuing of numerous draft documents for review by IPCDs, IPCNs and ICMs) not diminished it and it takes an excessive amount of time to receive a comprehensive answer that addresses the specific points of a question if a question is submitted. I have experienced that the Key Stage Assurance Review process delays projects unnecessarily.

284. To ensure IPCN and IPCD involvement is guaranteed to a sufficient degree for each building project, each health board would need to significantly expand their IPCN and IPCD capacity and have sufficient time allocated to them to be adequately trained and then time allocated for each building project either as part of their job description or with backfill to cover their other duties for the duration of the project. Another way would be standardise the designs for healthcare buildings and agree room data sheets so that at least at the design stage there is already a “once for Scotland” agreed design for all commonly encountered clinical areas. A dedicated IPCN and IPCD both need to be core members of the Project Team as they have different skill sets that they bring to assessment of HAI risk.

285. IPCNs generally come into infection prevention and control with experience and training of delivering care to patients (personal hygiene, environmental cleanliness assessment, optimal invasive device care and management) and often have had a senior nursing role in the running of a ward or and are familiar with processes for procurement, audits and inspections, liaison with domestic services and estates colleagues for repairs or cleaning as well as understanding the complex logistics of keeping wards running when needing to contain infections. IPCDs usually come to the role with some aspect of laboratory training and are more able to provide correct interpretation of laboratory results, arrange further testing of micro-organisms, liaise with reference laboratories or other infection related specialties (such as public health), have experience as prescribers and are more familiar with antimicrobial safe prescribing and antimicrobial stewardship, are involved in diagnosis and management of complex infections on a daily basis and are more likely to be tasked with leading incident

management teams and co-ordinating outbreak investigations for example.

286. There also needs to be clear understanding of what the role of an IPCT representative is and ensure the person doing that role can demonstrate competence and training to do so as an independent practitioner but also be clear that rubber stamping compliance with technical engineering guidance is not the IPCT role. The IPCT role is, in my opinion, to explain whether a design or actual building could facilitate transmission of infection and explain what measures need to be taken to prevent or mitigate that hazard.

Guidance

287. One further issue that may have contributed to the issues is the nature and interpretation of Guidance. Clearly, healthcare Guidance can be misinterpreted by people not familiar with the delivery of healthcare. In my view, it is fairly clear from SHTM 03-01, appendix 1, Table A that all bedspaces of critical care require 10 ac/hr although that interpretation was not shared by those who designed and installed the original ventilation to PICU. The presence of internal inconsistencies in some SHTMs or cross referencing to other guidance documents that lead back to the document you started with is not helpful in removing potential ambiguity.

288. But there are other aspects of the Guidance that can be open to different interpretations where guidance in Scotland has lagged behind that in other parts of the UK, for example differences between SHTM 04-01 and HTM 04-01 with regards to resolving *Pseudomonas aeruginosa* issues in healthcare water.

289. The Guidance is not fully comprehensive in that it does not cover every possible scenario for ventilation. For example, even with positive pressure isolated lobby single rooms (PPVL), there are caveats. A PPVL is able to provide either source or protective isolation. With a PPVL isolation room, you can provide protective isolation to a patient because there's a positive pressure air barrier between the bedroom and corridor and the air can be filtered to be ultra clean so the environment in the bedroom is protecting the patient form breathing in anything outside the room. But equally there's a negative cascade in the room because you're pumping air into the room and pulling it out through the en-suite toilet.

290. However, the PPVL room design is still not considered the safest for high consequence infectious disease and if you did have someone with HCID there are some caveats like the exhaust air from the toilet needs to be HEPA filtered or discharged at a certain height form the building so you don't discharge pathogens to the outside atmosphere and be at risk of them being drawn in to a window a few metres or so down the corridor and inhaled.

291. In Scotland, since 2008, the default design is a PPVL isolation room (as per SHPN 04 Suppl 1) but there isn't actually a design for a negative pressure isolation room in the Guidance. The English equivalent of this document is HBN 04-01 Suppl 1 which was updated and published in 2013 but there is still not prescriptive design guidance for a negative pressure isolation room in that either. I think this is relevant because NHSL decided during the remedial works phase (i.e. post July 2019) that for future proofing we should change one of the isolation rooms in the PICU to a negative pressure room. There was no Guidance in Scotland we could use. The design that we did end up using was based partly on Australian Guidance. So, while the Guidance is extremely important, strict adherence would not be workable. There needs to be scope to respond to different clinical scenarios, which will be specific to particular health boards and the patients they are likely to encounter.

292. To the best of my knowledge, the hospital was safe to accept patients at each of its eventual phased openings.

Declaration

293. I believe that the facts stated in this witness statement are true. I understand that this statement may form part of the evidence before the Inquiry and be published on the Inquiry's website.