Scottish Hospitals Inquiry
Witness Statement of
Lindsay Guthrie

Introduction

1. My name is Lindsay Jane Guthrie.

2. 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).

Qualifications and professional experience

3. I am a registered general nurse with the Nursing and Midwifery Council (NMC). I attended the North Lothian College of Nursing and completed my General Nurse training 1991 to 1994 (allowing me entry to the NMC register as Registered General Nurse from 23 January 1995). I have the following post graduate qualifications: Post Graduate Diploma (Distinction) Infection Prevention & Control - University of Highlands & Islands (completed in 2008, awarded 2010); Post Graduate Diploma Healthcare Quality Improvement – University of Dundee (completed 2018, awarded 2019); Healthcare Infection Society – Engineering Aspects of Infection Control (RCPath accredited CPD course July 2019) (Falfield Course) and The Built Environment (Infection Prevention & Control) – SQA Level 11 CPD Module (Distinction) University of Highlands & Islands (awarded 2022).

4. I am also a member of the Infection Prevention Society and Hospital Infection Society, previously I was the Deputy Chair and Chair of NHS Scotland Senior Infection Control Nurses Network (2019-2020; 2010-2021) and I am currently the Chair of NHS Scotland Infection Control Managers Network (2022-present).

5. Below is a summary of my career history:

- Student nurse Oct 1991 to Dec 1994 – North Lothian College of Nursing
- January to April 1995 - NHS Lothian Department of Clinical Neuroscience Theatres Western General Hospital – Neurosurgery - D grade staff nurse
- April to September 1995 – NHS Lothian St Johns Hospital Theatres – plastic surgery, gynaecology, obstetrics, endoscopy, general surgery, orthopaedic surgery, urology - D Grade staff nurse
- October 1995 to 1996 – NHS Lothian Outpatient Theatres Western General Hospital – specialising in General Surgery, Urology, Endo-urology - D Grade staff nurse
- 1996 to 1998 - NHS Lothian Department of Clinical Neurosciences Theatres Western General Hospital – E grade staff nurse
- 1998 to 2005 - NHS Lothian Out Patient Theatres - E grade staff nurse
- January 2005 to September 2010 - G Grade, then H Grade, Clinical Nurse Specialist Infection Prevention and Control (IPC) NHS Lothian (Royal Infirmary of Edinburgh and Western General Hospital) – all aspects of clinical infection prevention and control, education, audit and policy, including specific remit for Decontamination of Reusable Medical Devices and IPC response to the Glennie Technical Requirements. This post required completion of a formal post graduate academic qualification (master's level) in Infection Prevention and Control in addition to role specific training and education which was provided whilst in post. Similar to other specialist nursing posts, formal post graduate training and education was a requirement for the Infection Prevention Control Nurse (IPCN) post in all NHS Scotland health boards.
- September 2010 to August 2013 - Associate Inspector - Healthcare Environment Inspectorate Healthcare Improvement Scotland 2010 - external scrutiny of NHS Hospital compliance with Healthcare Associated Infection (HAI) Standards, registration, inspection, complaints and enforcement role for Independent Hospitals

- August 2013 to June 2015 - Senior Nurse Health Protection – NHS Lanarkshire – professional lead for Health Protection Nursing, communicable disease control, surveillance and incident management
- June 2015 to January 2021- Lead Nurse Infection Prevention & Control – NHS Lothian - professional lead for IPC Nurses, subject matter lead advising NHS Lothian on operational and strategic aspects of IPC and HAI. All aspects of clinical IPC; built environment; decontamination; audit, surveillance and monitoring; education and policy development, incident management. Representing NHS Lothian and wider IPC network on national working groups (Health Protection Scotland (HPS), Antimicrobial Resistance and Healthcare Associated Infection Scotland (ARHAI), NHS Education for Scotland (NES)) and contributing to development of national guidance. Supporting and advising the then Infection Prevention and Control Head of Service who was not an IPC subject matter specialist (similar to some other health boards in Scotland). The Head of Service fulfilled the requirements for the Infection Control Manager required by (**A47086948 – HDL 2005 (8) – dated 18 March 2006 – Bundle 13 – Vol 7 – Page 6)**. This is a Scottish Government directive which sets out the main responsibilities for Chief Executives and Infection Control Managers, and the governance arrangements expected for Infection Control in Health Boards. The post holder had overall responsibility for management processes and risk assessment relating to infection control. They were a very experienced registered Nurse, with extensive clinical experience in both the NHS, the British Army, and specialist qualifications in Burns Nursing and Nursing Education, but did not hold any post registration qualification in Infection Control.
- October 2019 to March 2020 - Acting Head of Service Infection Prevention & Control (in addition to lead nurse role), NHS Lothian - covering periods of long-term sickness absence of the Head of Service – overall responsibility for management processes and risk assessment relating to infection control (including the issue of antibiotic resistant infections and antimicrobial prescribing), medical devices

decontamination, medical devices management, and cleaning services as per HDL 2005(8)

- 2021 to present - Associate Director Infection Prevention & Control – NHS Lothian (continuous employment as the subject matter lead for IPC in NHS Lothian since 2015 (lead nurse)) - overall responsibility for management process and risk assessment relating to infection control, decontamination, cleaning as per HDL 2005(8). Providing strategic leadership and advice as a clinical subject matter lead for NHS Lothian with designated responsibility and accountability for HAI/IPC in NHS Lothian. Professional leadership for IPC nursing service.
- As an Infection Prevention and Control Nurse, between 2005 and 2010, I had limited experience of dealing directly with the IPC implications of a hospital building design. This was principally limited to advising on the fit and finish of surfaces, fixtures and fittings of small-scale refurbishment or reactive maintenance projects in line with published technical guidance. Prior to 2019 I had no practical experience of the process for commissioning new water or ventilation systems as I had never been involved in a project where such systems were installed. I had a working understanding of critical ventilation systems in the operating theatre environment (air change rates, pressure cascades) in line with Scottish Heath Technical Memorandum (SHTM) 2025 and latterly SHTM 03-01 from both my clinical roles in theatre and my previous IPC roles supporting theatre services and medical device Decontamination. This knowledge was acquired on the job and through self-directed learning.
- As Lead IPC Nurse between 2015 and 2019, my role involved the assimilation and interpolation of a wide range of national guidance, policy, technical documents, safety alerts or Scottish Government Directives, with reference to Infection Prevention and Control and advising the Head of Service IPC, and indirectly NHS Lothian Board of any required action or risk. I undertook these duties in consultation with others including the Lead Infection Control Doctor where required or appropriate. I therefore developed a broad understanding of basic

technical principles contained in various SHTM and the ability to ask critical questions of technical subject matter experts to inform a view on clinical infection risk associated with non-compliance with these documents. In 2019 my understanding of the design and management of water distribution systems developed in response to the outbreak of *Pseudomonas aeruginosa* in The Department of Clinical Neurosciences (DCN) at the Western General Hospital (WGH) site.

- In addition to my post, NHS Lothian Infection Prevention and Control team current has 21 infection control nurses employed in posts ranging Band 6 to Band 8a. All are registered nurses; some hold dual training or registration (for example, they are registered adult and sick children's nurses or mental handicap nurses). They have come from a range of different clinical backgrounds and experiences including critical care, infectious diseases, acute medicine, theatres, paediatrics, orthopaedics, medicine of the elderly, community nursing and residential nursing homes. Some have previous managerial experience. All are required to complete post graduate training to achieve a formal qualification in Infection Prevention and Control in addition to role specific training and development. The composition of the IPC team in NHS Lothian is broadly similar to that of other territorial health boards across the NHS in Scotland.

6. During the period of the Project, I held the following roles in NHS Lothian:
    - Clinical Nurse Specialist Infection Prevention and Control (2005 to 2010)
    - Lead Nurse Infection Prevention and Control (2015 to 2021)
    - Acting Head of Service Infection Prevention and Control (concurrently with Lead Nurse role) (October 2019 to March 2020)
    - Associate Director Infection Prevention and Control (Jan 2021 to Present)

7. My main duties involve:

- Through clinical expertise and leadership, translate policy directives and initiatives in relation to infection prevention and control into operational procedures and implementation plans.
- Through professional leadership and influencing skills, play a key role in shaping the development of practice in relation to infection prevention and control, supporting patient safety through the reduction in healthcare associated infection.
- Provide line management to NHS Lothian Infection Prevention and Control Nurses
- Contribute to the development of local, national and international knowledge of HAI through contribution to research and specialist publications.
- To provide strategic leadership and management of Infection Prevention and Control within NHS Lothian and the responsibilities set out in HDL 2005 (8)
- Accountable for an annual programme of work and work autonomously within a framework of annually agreed objectives.
- Accountable for all decision-making relating to the agreed work programme.
- Expected to anticipate problems, changing needs and emerging issues, identifying and initiating actions required.
- Independently advise partner organisations in relation to healthcare associated infection.

Role in the Project

8. I was aware of the initial discussions for the Project concept and design prior to 2010. I was not directly involved in the Project at that time as the Royal Hospital for Sick Children was not part of my clinical 'patch'. At that time, the Project was not progressed significantly prior to my leaving NHS Lothian in 2010.

9. NHS Lothian established the HAI Scribe Lead Nurse post in February 2014 as a seconded role. Prior to this date IPC nurse support for any building work, including the planned reprovision of the Royal Hospital for Sick Children, was usually assigned to whichever IPCN held clinical remit for the service (that is, the IPCN who 'covered' RHSC provided advice on the building Project). It is my understanding that staffing levels in the IPC team in 2014 were sufficient to provide a dedicated post for this build Project in the short term. The post holder seconded into the role was an experienced and qualified Band 7 IPCN who was employed in a substantive capacity as a Band 7 Geographical Lead IPCN (for example, a team lead). They did not have any additional built environment specific qualifications or experience to other IPCN in the team but were interested in the subject area. This was a new role created specifically to support capital projects (initially limited to the RHCYP/DCN Project, but quickly a more extensive remit to include other major capital projects), unique to NHS Lothian, and the post was occupied by a single post holder until their retiral in 2018. The job involved providing the same type of advice and input that others in the Infection Prevention and Control Team (IPCT) had provided in relation to major refurbishment or building work, but this post provided a single point of contact and consistency of advice for defined projects. Supporting these types of projects is time consuming. The HAI Scribe post allowed other IPCNs employed in NHS Lothian to focus on the core clinical aspects of their role. Formal job evaluation was submitted to the Workforce Organisational Change Committee to make this a substantive post in February 2015. Job evaluation is formal organisation policy and process that allows new posts or service change requests to be considered by Human Resources, Finance, senior management and Staff Partnership representatives to ensure the proposed change meets a defined service need, fairness and equity in pay for work undertaken, and to ensure compliance with equal pay legislation. Posts endorsed through this process are allocated a recurring funding source. The new post was aligned to the existing IPC team structure during the period of secondment, and subsequently allowed the permanent appointment of a Band 7 Geographical Lead IPCN to the secondee's substantive post. To the best of my knowledge, NHS Lothian was the only Board in Scotland to have this type of post as a substantive role

rather than a project specific secondment. NHS Lothian had a number of refurbishment, expansion or new construction projects in development over the period 2014 to 2019 including East Lothian Community Hospital and the Royal Hospital for Children and Young People. The creation of the post recognised the increased expectation for IPC involvement in projects in line with the directive of Scottish Health Planning Note 30 (SHPN 30) HAI risk in the Built Environment (2014, previous version issued 2005). The role had not previously existed because historically the Built Environment was not a defined priority area for IPCT. The key areas of focus for teams aligned with Scottish Government Scottish Antimicrobial Resistance and Healthcare Associated Infection – Strategy Group (SARHAI) are HAI policy or plans. IPCT were expected to support implementation and comply with any and all guidance issued by Health Facilities Scotland or any other Scottish Government directive, including the Scottish Health Facilities Note 30: Infection Control in the Built Environment (SHFN 30), as a mandatory requirement for capital projects. **(A33662182 - Scottish Health Facilities Note 30 Part 1: Infection Control in the Built Environment – Design and Planning – Bundle 13 – Volume 3 – Page 553)** It highlighted the multidisciplinary nature of project teams and advised that all members of the Project team understand principles of prevention and control of infection. There was less expectation at that time for IPC teams (nurses and doctors) to contribute to design and technical aspects of planning and construction. The HAI Scribe role was designed to be held by an experienced IPCN but did not require the post holder to have or undertake any additional or specific training or education in relation to the healthcare-built environment. It required a working understanding of SHFN 30 and other technical guidance. The knowledge, skill and competence to do the role was core to the role of any qualified IPCN. Janette Rae (formerly Richards) was seconded, then appointed to the role between 2014 and her retiral in 2018. I cannot comment on why other Health Boards did not have a similar role, but this may be related to local arrangements for project specific IPC roles, the absence of any planned major refurbishment or new build projects in other Boards, or because this was not a defined priority delivery area for the Board IPCT at that time. There are advantages and disadvantages of a dedicated post.

10. On my return to NHS Lothian in 2015 my role included leading on all aspects of communicating and implementing national policy and other directives, clinical IPC advice, local policy development, HAI Education strategy, audit and surveillance, risk assessment and incident management, IPC in the healthcare built environment and IPC workforce development as detailed above. See paragraph 5 in relation to my role relating to aspects of SHTM.

11. On return to NHS Lothian in 2015, I was the professional and subject matter lead with responsibility and accountability for IPC and HAI. Part of my role was to provide professional (subject matter) oversight of the HAI Scribe Lead Nurse. In practice, this was achieved in real time through regular discussion, email, or progress reports in meetings. The post holder reported directly to the Head of Service IPC for line management and appraisal purposes. This was an existing arrangement that was established at the time of Janette Rae's original secondment and prior to me coming into post in June 2015. The IPCT had been without a Lead IPCN for approximately 6 months before this. This reporting arrangement was retained by the Head of Service along with some others (the Band 7 Clinical Scientist, and all administrative posts). It provided the Head of Service with direct oversight and evaluation of the HAI Scribe role but was also intended to provide workload balance and distribution of functional managerial responsibility (such as carrying out appraisals, managing sickness absence, coaching) for myself and the Head of Service. I provided direct line management for four Geographical Lead Band 7 nurses. I had weekly one to one meetings with the Head of Service which provided opportunity to discuss progress, or any concerns relating to performance of any IPC staff. In June 2015, the Project was (to the best of my knowledge) well advanced and had moved into the construction phase (ground works, foundations, infrastructure) I reported directly to the Head of Service Infection Control for all aspects of my own line management (for example, sickness absence, performance and appraisal) and professional support and management as a registered nurse. As the Head of Service did not hold a subject matter qualification in IPC, my role as Lead Nurse was to provide senior subject matter expertise and leadership for the IPCT and Clinical

teams, and to provide, through the Head of Service, reports to NHS Lothian Board advising them of performance against mandatory targets, HAI or IPC issues and risks.

12. Any issues or concerns arising from any built environment project were escalated to me as IPC subject matter lead for the IPCT and professional lead for HAI Scribe Lead Nurse on ad hoc basis as required. The HAI Scribe Lead Nurse was a qualified and experienced IPCN, and I was confident that they were able to advise and support projects independently based on my understanding of the IPCN role and requirements of SHFN 30. This did not include providing detailed technical expertise of hospital design, critical system design or engineering. My expectation of the IPC role was to provide advice or a view on any clinical infection risks associated with the design, or during construction (risks to adjacent areas and working clinical areas). There was regular opportunity for the HAI Scribe Lead Nurse to discuss any emerging issues, questions where IPC opinion was required in the absence of formal guidance, or where any disagreement or difference of opinion was raised. I did not attend project meetings or provide regular commentary or input into the design or construction of the Project. This was the principal purpose and function of the HAI Scribe Nurse post. Input, or advice, or both, in relation to specific issues or concerns was usually provided in conjunction with Dr Donald Inverarity (Lead Infection Control Doctor) (Lead ICD) or input from a Consultant Microbiologist. My direct involvement in relation to the Project in the period June 2015 to December 2018 was therefore to some extent ‘at arms length’, other than when asked to provide advice or commentary on specific questions (as noted above) or where Janette Rae specifically requested senior support in relation to these. This could take the form of us both contributing to email, discussion, telephone call or short meetings with other individuals in relation to specific questions or topics. I do not believe the practices employed in NHS Lothian at this time were materially different to those of other IPC teams in other Health Boards. This is based on my understanding of the role of the IPC defined in national guidance (SHFN 30) at this time, and the very broad requirements of the Healthcare Improvement Scotland Standards for Healthcare Associated Infection

(versions issued in 2008 and 2015). Health Boards were independently assessed against these standards, with reports published and available to Scottish Government and the wider public. Specifically, in relation to the built environment, the standards required evidence of compliance with national directives (for example, the CEL letter referred to in paragraph 9) and provision of a safe environment for care. Delivery against these standards was NHS Lothian's responsibility, and not solely an IPCT responsibility.

13. I received periodic updates from the HAI Scribe Lead Nurse at departmental meetings – mostly verbal, some written. The purpose of these updates was to provide overall progress and reporting by exception any areas of specific concern for IPC. This was primarily an operational update and provided at the monthly IPC Business Meeting which I chaired. We also had a monthly Senior Management Team meeting chaired by the Head of Service for IPC and attended by all Band 7 nurses including the HAI Scribe Lead Nurse and myself. This provided another regular forum for any exceptions to be reported or discussed in real time. I would discuss or provide advice on areas of infection control (subject matter) specifically. The Head of Service would be made aware of any areas of contention, or dispute, or both, which may require further discussion, or senior management input, or both, and for oversight (in line with their responsibility for overall management of process and risk assessment). As the Head of Service retained line management and one to one oversight of the HAI Scribe Lead Nurse for most of the period between June 2015 (when I returned to Lothian) and December 2018 on the retirement of HAI Scribe Lead, there was also opportunity for the HAI Scribe Lead Nurse to raise any specific points for discussion. As a small team we had a close working relationship, with regular (daily, weekly) and open discussion and communication. The work and workload of the HAI Scribe Nurse in all building projects including RHCYP/ DCN was primarily directed by the stage of the Project, the frequency and type of input the project teams were requesting, or the actions set out in the HAI Scribe documents (stages 1-4). For example, during development of 1:200; 1:100 or 1:50 plans there may be more frequent meetings until a final design is agreed by all parties. Stage 4 Scribe requires room review (on site). The HAI Scribe advisor also retained some clinical IPC

remit supporting Marie Curie Hospices under service level agreement to maintain their wider clinical skills and support registered nurse revalidation.

14. On the retirement of Janette Rae, the HAI Scribe Lead Adviser post (previously titled HAI Scribe Lead Nurse) was advertised July 2018. The post and job description remained unchanged, but the job title was amended to reduce confusion about the difference in Lead IPC Nurse (my post), Geographical Lead IPC Nurses and the HAI Scribe Lead Nurse post, and route for communication and escalation. The post had to be re-advertised due to lack of interest, or suitable candidates, or both. I led the interview panel in 2018 and appointed an internal applicant, Sarah Jane Sutherland, as replacement to this post. Sarah Jane took up post in December 2018. It was agreed that professional oversight and line management responsibility for the role would both sit under my direct supervision. This change in line management was discussed and agreed with the Head of Service in recognition of the increasing complexity and potential IPC issues being recognised in other building projects across Scotland, delays and queries relating to the RHCYP Project, and acknowledging that Sarah Jane would require more active subject matter support and development in a newly promoted post. It also took account of impending periods of planned sickness absence for the Head of Service. This aligned to my responsibilities as Lead Nurse for IPC rather than a purely line management or oversight role. This positively reflected the changing and emerging focus for IPC and the Built Environment. Similar to many IPCNs in Lothian and across Scotland, Sarah Jane had extensive experience of supporting day to day reactive building work and small and medium scale refurbishment projects using HAI Scribe as part of her IPC role but did not have any experience of major capital or construction projects. Construction projects are often a ‘never’ or ‘once in a career’ experiences for the majority of IPCNs. Sarah Jane had had not received any formal training on construction projects, critical systems, or engineering. To the best of my knowledge, no such education or training existed for IPC nurses or doctors at that time (as further explained in paragraph 5).

15. The HAI Scribe Nurse post was created as a secondment in 2014 initially to support the RHCYP Project. The one Whole Time Equivalent (WTE) post holder, Janette Rae, then concurrently was asked to support another new hospital construction project (East Lothian Community hospital) and a range of other capital improvement projects on hospital and community sites across the whole NHS Lothian Board area (East, Mid, West Lothian, and Edinburgh City). The workload demand with each project was dynamic and, at times, overlapping or conflicting deadlines for review of documents, meeting attendance or other project related activities would have occurred. Prioritisation of IPC support would be made to the area of greatest need. There was no formal review of IPC capacity or capital planning workload demand between 2015 and 2018 but we were increasingly aware that the number of larger projects, or capital projects, or both, and volume of work was not sustainable for a single post holder. I did discuss this with the Head of Service as part of a one to one meeting, and there was already a process in place for Geographical Lead IPCNs to cover all HAI scribes for small and medium scale refurbishment work within their area of work.

16. My involvement in the Project increased significantly from December 2018 until migration of all services to the new hospital in 2021. This involvement was in part due to phased retirement of Janette Rae (IPCN) in the latter part of 2018, the delay in securing a successor to this post, ongoing discussions about commissioning, handover and HAI Scribe requirements for the RHCYP/DCN, emerging information and consideration of potential risks associated with built environment design and function, and to support Sarah Jane Sutherland (as a newly promoted, newly appointed role). The leadership and senior decision-making component of my role was also increasingly important over this period in light of the scrutiny being placed on the Queen Elizabeth University Hospital (QEUH) building Project, and emerging information about water, ventilation, and design issues.

17. Over this period, I was a core participant in discussion which:

    a) a sought commissioning and other data to inform the completion of the HAI Scribe stage 4

b) b. was in response to the evolving situation at the QEUH and potential issues and risks associated with the hospital environment
c) c. was in response to significant clinical incidents in NHS Lothian (Pseudomonas outbreak at the DCN, Western General Hospital and Cardiothoracic Mould infections at the Royal Infirmary of Edinburgh (RIE)) which Dr Donald Inverarity and myself were concurrently providing senior and expert IPC support and leadership, and our own emerging understanding of infection risks in the healthcare built environment.

18. I was asked by Professor Alex McMahon (HAI Executive Lead) via Fiona Cameron (Head of Service IPC), my line manager, to prioritise and provide full time support to the Project from mid June 2019. I did not receive any 'back fill' into my post and provided support concurrently with my existing Lead Nurse duties, and later both the Lead Nurse and Acting Head of Service roles. In conjunction with Dr Donald Inverarity (Lead ICD), I provided day to day review, risk assessment and subject matter advice to NHS Lothian senior management in response to the emerging information provided by the Project team, external companies, Health Protection Scotland, and Health Facilities Scotland.

General Infection Prevention and Control Involvement in RHCYP/DCN Project

19. As detailed above, until 2019 I had an indirect role only in the Project through professional oversight of the HAI Scribe Lead Nurse. I was consulted on a reactive and ad hoc basis in relation to specific questions or problems highlighted by exception.

20. The IPCT were principally represented on the Project by the HAI Scribe Lead Advisor Janette Rae who was appointed into a seconded role for all capital works in February 2014. She was a qualified and experienced IPCN. Janette

also held dual registration as a registered general nurse (adults) and registered sick children's nurse.

21. IPC specialists are expected to be core members of a project team in any major refurbishment or construction project. The roles and responsibilities for all stakeholders including IPCT are set out in SHFN 30 Part A and Part B (Health Facilities Scotland: 2014). It is important to note that responsibilities for aspects of infection prevention and control apply to all members of the Project team and is not the sole domain of the IPCT as subject matter experts. The IPCT is required to be involved at all stages of the Project from design and planning, through construction and commissioning and handover.

22. A named IPCN, Janette Rae, was available to the RHCYP/DCN Project team from February 2014 as the principal contact. She attended some design and Project meetings and latterly the construction from 2015 until her retiral in 2018. Prior to this, I am aware that Jean Harper and Carol Horsburgh were consulted and had some input into the very early stages of the Project. These IPCNs had specific clinical remit for the existing RHSC as part of their clinical 'patch' at some point between 2010 and 2014. Prior to the creation of a dedicated role for Janette Richards in 2014, this was the normal process for teams seeking IPCN involvement in any HAI Scribe work including capital projects.

23. As I was not part of the Project Team, I was not aware that there was an overarching Programme Board for this Project and, to the best of my knowledge, there was no IPC representation at any other senior management group or committee where this Project was considered or reviewed other than the workstreams which reported into the Project team. Although the Pan Lothian Infection Control Committee included oversight of building plans and project updates over this period, these related more to non-capital projects, and were assigned to Estates representatives to provide an update rather than Capital Planning or Project team leads.

24. The HAI Scribe Lead Nurse was not a core member of the Pan Lothian Infection Control Committee and was not required to submit any papers. I

have no recall of the Project ever being discussed at this committee up until April 2019, and no reference is made in minutes to this.

25. I had a formal role in providing IPCN oversight for this Project from October 2018 onwards during Janette Rae's phased retiral (for example site review with Dr Olson, Consultant Microbiologist and Dr Donald Inverarity to review the Heater Battery arrangements in Critical Care in December 2018) and after Sarah Jane Sutherland took up the post in December 2018. Although Sarah was an experienced IPCN who had used HAI Scribe for estates work and refurbishment projects, she had no experience of capital or construction projects, and this was her first promoted post. Therefore, although she provided day to day input from January 2019 onwards her level of autonomy in the role was very limited.

26. I also provided subject matter advice to Fiona Cameron, the Head of Service IPC in relation to issues and risks from the Project (for example, following the flooding incident in early 2018). I discussed and escalated requests to the Head of Service where water and ventilation commissioning information had not been met, referenced in (**A47086952 – 20190412 PLICC Minutes – dated 12 April 2019 – Bundle 13 – Vol 7 – Page 20)** and requested that she seek clarity on whether emerging or known issues in the QEUH Project were replicated in RHCYP (for example chilled beams). This provided her with a level of assurance and oversight of IPC activity, and informed discussion or escalation to the HAI Executive lead or others.

27. In relation to informal role, roles, or regularity of informal communication, or discussions, or both, from my perspective this can split into two periods during my time as Lead Nurse: 1) June 2015 to December 2018 and 2) October and November 2018 onwards.

28. For the first period, I attended regular meetings with the HAI Scribe Lead Nurse including our monthly IPC business (whole team) meeting which I chaired, and the monthly IPC senior management team meetings chaired by Fiona Cameron (Head of Service IPC). The purpose of the business meeting was, and is, to review the IPC team's actions and progress against the agreed

IPC workplan including active capital projects supported by the IPCT and HAI Scribe Lead Nurse, to provide feedback from other internal and external meetings, and to share information and support learning from issues or incidents. It is attended by the IPC nurses, surveillance staff, administrative staff and, when capacity allows, the Lead ICD. The Head of Service did not attend the business meeting given the operational focus of the meeting. The Senior Management Team meeting was only attended by senior members of the IPC team who held line management responsibility. It was chaired by the Head of Service IPC. The focus of this meeting was on staffing, finance, workforce development, and any other more service/strategically focused discussion or actions. These meetings were both regularly attended by the HAI Scribe Lead Nurse, we were intermittently provided with a very brief update on the progress of various capital projects, or less frequently, any emerging issues by the HAI Scribe Lead Nurse. These meetings were not designed or intended to serve a formal governance role for the RHCYP or other capital planning projects, as IPC consideration was only one part of the overall Project and the IPCT did not have project or programme management responsibility for this. It was my expectation that formal reporting on progress or risks, including any IPC issues or risks, associated with the RHCYP would have been provided by the Project Director or Project Manager through the wider Capital Planning structure. This is in line with my understanding of the roles and responsibilities set out in sections 2.6 and 2.7 of SHFN 30 Part B.

29. Any informal discussion/support and advice to the HAI Scribe Lead Nurse as required – frequency varied – daily, weekly, monthly. There would be periodic email communication seeking advice or input on specific issues – for example CT room air changes, ventilation design arrangements, flooding. Specific advice was frequently provided by Dr Donald Inverarity as Lead ICD as part of wider discussions. I was copied into email communications between HAI Scribe lead nurse and Project team for awareness and oversight on an ad hoc basis.

30. The second period from October/ November 2018, Janette Rae was moving into her phased retirement and had begun a process of hand over of all live

projects. In October 2018 she advised the RHCYP Project team to copy me into all correspondence regarding heater batteries noting she was retiring. We had not appointed a successor to her post at this stage.

31. The senior IPCT received a written handover from Janette Rae on 5 November 2018 as part of preparation for her retirement (**A47086947 – Region update – dated 22 October 2018 – Bundle 13 – Vol 7 – Page 29)**. Although this provided limited detail it notes commissioning for the Project was delayed from the intended date of October 2018, noting that a move in date likely to be 'late spring' and that room reviews had recommenced. The room reviews formed part of the HAI Scribe Stage 4 process.

32. For all escalated issues – HAI Scribe completion, handover, water and ventilation commissioning, correspondence with Dr Donald Inverarity, Project team, I became point of contact/lead for the IPCT. Both Sarah Sutherland and I were included in discussion/communication – Sarah undertook some independent activity (room reviews, meeting attendance, correspondence) but escalation/dialogue with Head of Service/Executive Team and others was via myself and Dr Donald Inverarity.

33. There was a significant increase in dialogue between the IPCT and the Project team from late 2018 onwards. The IPCT had been advised in early November 2018 via a Board wide 'everyone' email that Project handover had been pushed out from the revised date of October 2018 to allow 'independent assessor' work to be completed with anticipated hand over in 'late spring'. The IPCT did not request or schedule any HAI Stage 4 Scribe meetings at this stage, as further information was required from the Independent Assessor (any work completed or information received after completion of a HAI Scribe review may invalidate the findings of that review) and because a final hand over and completion date was not known or confirmed at that time.

34. The frequency and intensity of the email discussions between the IPCT, members of the Project Team and other senior managers also increased relative to commissioning of water and ventilation systems, room reviews and

planning for the HAI Scribe stage 4. This coincided with wider discussions about emerging information from QEUH incident and concurrent incidents in NHS Lothian from early 2019 onwards relating to water quality and patient infections (*Pseudomonas aeruginosa* infections in DCN patients at Western General Hospital and Cardiothoracic mould infections at the Royal Infirmary of Edinburgh). Information about the emerging issues in QEUH were shared in confidence directly between the Infection Control Managers Fiona Cameron from NHSL and Tom Walsh from NHS Greater Glasgow and Clyde (for example, SBAR report (summarising the situation, background, assessment and recommendations) which was shared with me on 14 December 2018 following discussion on this point at the IPCT senior management meeting). None of the documents or information shared divulged patient specific or patient identifiable information. There was ongoing discussion in the Scottish Parliament prompting Lothian Health Protection Team to contact Dr Donald Inverarity by email on 15 February 2019 (and shared with me) in relation to a query from the parliamentary inquiry on Health Hazards in the Healthcare Environment. The NHS Lothian Director of Facilities had also prepared an internal briefing paper in February 2019 in relation to building management, risk and assurance citing ongoing dialogue with Scottish Government in relation to both water and ventilation. In early 2019 there was direct correspondence and discussion between representatives of HPS (now ARHAI) – Annette Rankin (Nurse Consultant), Ian Storrar, (Principle Engineer) - and myself and Dr Donald Inverarity in early 2019 in relation to both water quality and water safety as part of the DCN *Pseudomonas aeruginosa* Incident Management Team, and ventilation in relation to the Cardiothoracic mould infection issue at RIE.

35. In both of the NHS Lothian incidents noted above, the potential role of both water and ventilation systems was either known or being actively investigated. Through our roles as Lead Infection Control Nurse and Doctor, and our ongoing dialogue with the Project team about commissioning and Project completion, Dr Donald Inverarity and I were very keen to ensure that that we had confidence about the water quality in the new DCN building given the

issues we had with the water system in the old DCN building at Western General Hospital.

36. I have been asked by the Inquiry to provide brief details of forums available through which I or, separately, IPC may raise patient safety concerns around the RHCYP/DCN Project and individuals or groups outside of IPC that I liaised with, or reported to, as part of the RHCYP/DCN Project. As Lead Nurse for Infection Prevention and Control, there were a limited number of forums open to me and wider IPC colleagues to raise or discuss patient safety concerns around the RHCYP/DCN Project. Infection Control risks would usually be discussed with wider stakeholders through site infection control committees or the Pan Lothian Infection Control Committee. Capital projects including the RCHYP Project were not a regular agenda item at these meetings. The IPCT were not members of the Project Programme Board and did not attend Capital Planning or Finance meetings. The nature of any concern, the risk associated with it, the phase of the Project and the expected action or outcome would usually determine where, by, and with whom concerns were raised. Escalation of concern by the IPCT would usually be to the Project team directly, or by email to senior managers/responsible Directors.

37. During the planning and construction phase, infection control and patient safety risks associated with the Project related primarily to either the design, compliance with published guidance or the potential impact of construction on adjacent clinical areas at RIE. I was not employed in NHS Lothian between 2010 and 2015 so can offer limited commentary on the processes followed at that time. It would be my expectation that any design detail with potential to impact on any aspect of patient safety was discussed and managed by the Project team. This is in line with the roles and responsibilities of section 2.6 of SHFN 30 Part B which was extant guidance at this time. Outside of the regular Project meetings including the design and commissioning workstreams, I am not aware of any regular committee or other forum within NHS Lothian where the IPCT specifically had opportunity to raise concerns about the design or construction of the RHCYP/DCN. I am aware that questions or advice on developing a compliant and safe design were shared

directly between the IPCT (Janette Rae) and the Project team, for example in September 2016 in relation to ventilation air change rates in CT scanning. Health Facilities Scotland principal architect and engineering leads were also contacted for expert advice and input. It was my expectation that the Project team would seek a solution to address any potential patient safety issues flagged in this way rather than requiring wider escalation. From an IPCT perspective, this is the type of issue that was highlighted for awareness via email to myself, Dr Donald Inverarity or the Head of Service and/or discussed at IPC business or senior management meetings.

38. Towards the end of the Project (2018-2021) there was discussion at the Pan Lothian Infection Control Committee (PLICC) in April 2019 in relation to the handover of the Project and completion of Stage 4 HAI Scribes. Prior to this date, I can find no evidence of discussion or formal reports submitted to PLICC in relation to this or other capital projects. The terms of reference for PLICC at this time referred to oversight of 'building/estates development plans' but responsibility for reporting against this item was assigned to the Facilities team rather than the Capital Planning or project teams. The HAI Scribe Lead Nurse was a not core member of PLICC and did not attend this meeting. The Director of Facilities or the deputy was usually in attendance. Capital projects/project teams were not directly represented at this meeting. Individuals or groups outside of the IPCT that I communicated directly with in relation to the Project include:
    - Informally – IPC colleagues in NHS Greater Glasgow & Clyde in late 2018 to 2019
    - Executive Management Team (HAI Executive lead, Executive Medical Director, Chief Executive/Deputy Chief Executive, Director of Facilities, Programme Director) – on a daily, weekly basis from Spring 2019 onwards
    - HPS (latterly ARHAI) – for wider water/ventilation queries from late 2018, for RHCYP Project specifically, from June 2019 onwards
    - HFS - for wider water/ventilation queries from late 2018, for RHCYP Project specifically, from June 2019 onwards

- Mary Morgan/other members of the Oversight Board – through the RHCYP Incident Management Team (IMT) /Lothian Executive Steering Group from July 2019 onwards
- IHSL – through regular, weekly meetings from July 2019 onwards
- Multiplex – through regular weekly meetings from July 2019 onwards
- TUV SUD – through meetings held from July 2019 onwards
- Mott MacDonald – through regular, weekly meetings from July 2019 onwards
- Bouygues – through regular weekly meetings from July 2019 onwards
- Westfield Caledonian – in response to specific water testing requests or reports from 2019 onwards
- Institute of Occupational Medicine (IOM) – through the commissioning phase late spring 2019 onwards
- Authorising Engineers (Water, Ventilation) – from late spring 2019 onwards
- Clinical teams/ Clinical Management Team RHCYP – from early 2019 onwards

39. From June 2019 onwards, the principal forum for Dr Donald Inverarity or myself to escalate any issues or concerns was via the NHS Lothian RHCYP Incident Management Team (IMT) meeting, which subsequently became the Executive Steering Group of which I was a core member.

40. In the period between at least March 2018 and July 2019, the NHS Lothian IPCT were aware of emerging concerns in relation to the QEUH RHC Project in NHS Greater Glasgow and Clyde and were seeking to actively understand, in more detail and in real time, any potential issues and types of issues that had been identified with the building design (specifically water and ventilation systems) and how this was translating into patient risk. We were also looking to take any relevant learning about water and ventilation systems to inform our management of the *Pseudomonas aeruginosa* incident in DCN at the WGH in early 2019, and the Cardiothoracic mould incident at RIE from March 2019. Information and learning from Glasgow was not being proactively

shared with us as an IPCT by HPS or HFS at that time. Annette Rankin (Nurse Consultant HPS) and Ian Storrar (Principal Engineer HFS) attended or were consulted as part of the WGH and RIE Incident Management Team (IMT).

41. I was aware from discussions Dr Donald Inverarity had had with colleagues in NHS Greater Glasgow & Clyde as far back as 2016 that there had been potential concerns regarding ventilation room design or performance in the QEUH building which had been, as I understand it, raised in discussion at professional microbiology meetings. I understood that those discussions were with Dr Teresa Inkster (Consultant Microbiologist) and Dr Christine Peters (Consultant Microbiologist).

42. There was mainstream media coverage of some of these emerging issues which we were aware of from at least March 2018 (**A47086949– Water Concerns BBC News – dated 20 March 2018 – Bundle 13 – Vol 7 – Page 34)**. We were seeking information in the context of professional and peer to peer discussion between members of the Microbiology and IPCTs in NHS GGC and NHS Lothian. We were reliant on this as a means of gaining real time insight and understanding of the issues. No information, guidance or alerts were issued to NHS Lothian by HPS or HFS in this period. Although the RHCYP Project was not at the point of completion or handover, NHS Lothian, and specifically the IPCT were being asked to actively respond to questions about IPC risk and this Project by March 2018. We had received a Freedom of Information request on 22 March 2018 seeking information relating to the RHYCP Project and infection control documents, reports and correspondence with Health Facilities Scotland with regards ventilation and air change rates. In or around late November or early December 2018, the Head of Service IPC received from Mr Tom Walsh who was Infection Control Manager GGC at the time, in confidence a copy of the SBAR dated 13 November 2018 prepared by GGC in relation to a range of infections considered linked to the water at QEUH. The senior IPC nursing team discussed the issues relating to water safety being raised in the media, the progress with the RHCYP Project and potential implications of the ongoing infections at QEUH at our IPC Senior

Management Team meeting on 18 December 2018. With the agreement of Mr Walsh, and on the proviso that I did not subsequently share this document, I was provided with a copy of that SBAR in confidence by the Head of Service's personal assistant Morven Jamieson.

43. I was also aware through peer-to-peer discussions and occasional telephone calls with Pamela Joannidis (NHS GGC Nurse Consultant for IPC) of the types of investigation explored by GGC in relation to these infections, and specifically in relation to both water exposure and ventilation systems over the course of 2018 but I am unable to provide precise dates and times for these discussions.

44. In early January 2019 NHS Lothian was being asked to respond to potential concerns raised by our Infection Control Committee public partner regarding pigeon access to ventilation plant rooms and potential infection risks which were also being covered in national media (the BBC) at this time. I was made aware indirectly in conversation with the Director of Facilities that these, and other issues were being formally discussed at a meeting chaired by Paul Gray (Chief Executive NHS Scotland) on or around 22 January 2019. I cannot recall or find records of any formal communication with HPS (now ARHAI) or HFS in relation to Cryptococcus or managing the risk of pigeons in healthcare premises until a guidance document was eventually issued by HPS (now ARHAI) later in March 2019.

45. After issues relating to the design, installation and performance of critical ventilation systems at RYCHP DCN were identified in early July 2019, I can see from my handwritten notes at the time that NHS Lothian were still seeking information in real time from NHS GGC in relation to the issues at QEUH. On 1 July 2019, I noted an action for myself to contact Pamela Joannidis to confirm the air change rate in their critical care area and to understand what was being retrofitted to critical ventilation systems in QEUH, and where. These notes are contained in (**A47085953 – Q119 20190701 LG Handwritten Notes – dated 01 July 2019 – Bundle 13 – Vol 7 – Page 35).**

46. On 2 July 2019, Dr Donald Inverarity was authorised by Dr Teresa Inkster to share SBAR reports circulated in NHS GGC in 2016 and 2018 in relation to ventilation design and suitability for isolation rooms and containment of airborne infection with myself and Dr Pota Kalima (Consultant Microbiologist and ICD for RHCYP). We considered this useful intelligence in informing our risk assessment of the information provided in the IOM ventilation commissioning reports. This information was not available to us via HPS or HFS.

47. From these peer-to-peer conversations we learned in more detail issues relating to heater battery design, isolation room design (relevant to the Project), issues relating to the use of point of use filters as a local control measure (this was relevant to the DCN *Pseudomonas aeruginosa* outbreak). This approach of Board peer to peer discussion and sharing of knowledge is a normal part of how IPCT work across NHS Scotland on an ongoing basis.

General Infection Prevention and Control (IPC) involvement during commissioning and construction phases of the Project

48. I have been asked to provide an overview of IPC's involvement, and my role, in ventilation design, construction and commissioning in the following clinical areas with reference to the time period:

Critical Care:

- 2009 to Feb 2014 – IPC involvement in capital projects during the design phase was expected as part of the HAI Scribe stage 1 and stage 2 processes (initial brief and proposed site for development; design and planning which was mandated by CEL 18 (2007)). This would have been provided by Jean Harper and Carol Horsburgh (Infection Control Nurses in NHS Lothian) in the very early stages of project scoping and project design. Their role was to advise the Project team on principles of infection prevention and control and contribute to risk assessment and advice for susceptible patient groups. This is in

line with section 2.9 of SHFN 30 Part B. I am confident that the advice anyone from the IPCT provided at this time would have reflected extant guidance (SHTM 2025) prior to the publication of SHTM 03-01. SHTM 2025 provided limited guidance for ventilation parameters outside of those expected in operating theatres. I cannot comment further on the development of plans or an environmental matrix during this period. I was not employed in NHS Lothian between September 2010 and June 2015. In 2014, Janette Rae was appointed as the IPC contact for the Project from February 2014 (see response and paragraph 20).

- June 2015 to Nov 2018 – I had a minimal active role in advising the Project and provided ad hoc advice to specific queries raised by Janette Rae or the Head of Service IPC only. During this period, I was included in a question about air change rates in CT scanning, and air sampling as part of commissioning. Please see responses in paragraphs 19 to 35.
- During the period February 2014 to Oct 2018, Janette Richards (later Rae) was available to the Project Team as the principal IPC contact and the HAI Scribe lead nurse. The IPC role was advisory to the Project through the HAI Scribe Lead Nurse. With reference to design - email correspondence that I was either copied into at the time, or aware of through discussion with Fiona Cameron (the Head of Service IPC), Dr Donald Inverarity or Janette Rae shows that the HAI Scribe Lead Nurse directed the Project team to SHTM/HTM 03-01 guidance on more than one occasion, and to HFS (Ian Storrar Principal Engineer, Susan Grant Principal Architect) for technical advice on design or performance in relation to CT air changes (more detail below)
- I was copied to an email from Janette Richards (later Rae) (HAI Scribe Lead Nurse) on 23rd Jan 2017 (**A47086954 – Email Other matters - dated 19 March 2018 – Bundle 13 – Vol 7 – Page 37**). Ronnie Henderson on behalf of the Project team sought guidance on ventilation parameters required for 4 bed rooms – although this does not explicitly reference which part of the hospital this related to. I

cannot recall being approached with any specific question about ventilation design other than CT scanning rooms between 2017 and June 2019.

- I was made aware of dialogue between Dr Donald Inverarity, Janette Rae and the Project team in August 2018 requesting independent validation and verification of the theatres and isolation room ventilation. This request was in line with the requirements of STHM 03-01 but also provided for the Project team, with the context by this time of known and emerging issues from the QEUH relating to both design and performance of these critical ventilation systems and the importance of seeking evidence and assurance that the RHCYP/ DCN building was not affected by similar issues given shared design and construction contractors. The reference to the QEUH was important in reinforcing the seriousness and potential implications of not having this information in terms of corporate liability but more importantly in informing and mitigating any clinical infection risk for patients who would be cared for in the new building.

Haematology/Oncology (“the Lochranza Ward”):

- June 2015 to June 2019– I had no active or formal involvement in the ventilation design or construction phase. I can find no record of being asked to comment or note any derogation or risk assessment specific to air change rate or pressure cascades other than the provision of multiple isolation rooms from a single air handling unit (AHU) in August 2016.

General single rooms:

- Pre 2019 – I had no formal involvement as noted above. From late June 2019/early July 2019 I was actively involved in the review of ventilation system commissioning, validation and risk assessment for all clinical and non-clinical areas in RHYCP/ DCN.

General Multi-bedded rooms

- Pre 2019 – I had no formal involvement. From late June 2019 my involvement was as noted in the point above.

From mid-June 2019:

- I attended a meeting on 19 June 2019 with senior members of the Project team (Janice Mackenzie, Brian Currie) and the RHCYP senior management team (Dr Edward Doyle, Fiona Mitchell) at the request of the deputy Chief Executive to discuss issues ahead of the planned move. Ventilation commissioning reports were not available at that time
- From on or around 28 June 2019, along with Dr Donald Inverarity I attended twice daily meetings with the senior Project team and executive team to review emerging information from independent commissioning of critical ventilation systems undertaken by IOM.
- In early July 2019 I was provided with copies of ventilation commissioning data from external contractors for review and comment – in conjunction with Dr Donald Inverarity, this was discussed at the twice daily meetings noted above.
- These meetings were also variously attended by representatives from Multiplex (Darren Pike, Colin Grindlay), Bouygues (Richard Hair), Wallace Weir, Craig Simpson (HCP) as well as IOM, NHS Lothian Executive Nursing and Medical Directors, Estates Director, senior Project team and RHCYP senior management team.
- By 1 July 2019 it was apparent there were some significant issues emerging from the IOM review in relation to theatre ventilation performance and critical care ventilation capability and performance.
- By 11 July 2019, NHS Lothian was advised in a letter from Jim Miller, Director Procurement Commissioning and Facilities at NSS (HPS/HFS) of the scope of their intended technical review that had been commissioned by Scottish Government. This included review of ventilation systems.
- From July 2019 onwards, I attended regular meetings with the RHCYP Project team, architects, authorising engineers, technical designers

and members of NHS Lothian Executive Team to discuss, agree and confirm actions and solutions for the areas of non-conformance identified by the independent commissioning reports. Representatives from HPS (Annette Rankin) and HFS (Ian Storrar) were invited to attend and comment on the emerging information and proposed actions. There were a variety of meetings in relation to both critical and non-critical ventilation systems with specific objectives at that time. The membership of each meeting reflected the purpose of the group.
In relation to the ventilation design solution for critical care and aspects of ventilation system improvement, rebalancing and recommissioning in theatres and other critical systems.

HAI-Scribe Process

49. The HAI-SCRIBE is a mandatory process to be followed for all work including planned and reactive maintenance, refurbishment, medium and large-scale projects and full construction. This requirement was issued through Health Department Letters (HDL) by Scottish Government to NHS Boards in 2015 and reiterated in 2019.

50. The HAI Scribe process covers the whole life of the Project. There are 4 stages with specific documentation to be completed by the Project team for each:

    Stage 1: Initial brief and Proposed site for development
    Stage 2: Design and planning stage
    Stage 3: Construction and refurbishment
    Stage 4: Pre-handover check

51. Scottish Health Facilities Note 30 Part B section 2.9 defines the main responsibilities of Infection Prevention and Control specialists to be:
    - advising the Project Team on the principles of infection prevention and control of infection as applied to the built environment

- contributing to risk assessment and providing advice on infection risk to susceptible patients
- contributing to advice and guidance on control measures to be implemented
- advising Project Manager/Estates Manager as to the need to stop work where infection prevention and control measures have not been adequately implemented or have failed
- providing education on infection prevention and control measures to relevant staff involved in the Project where required
- determining with the Project Team and Health & Safety representatives a suitable and sufficient dust monitoring methodology for each project
- assisting in the review of all HAI-SCRIBE assessments within agreed timescale.

52. The IPCT would expect to be invited as part of the Project team to review the completed build project as part of the Pre-Handover check (commonly referred to as the Stage 4 Scribe). This involves an on-site review of the physical environment and confirms that key requirements set out by Scottish Health Facilities Note 30 Part A for the fit, finish and function of the building has been achieved. This assessment also encompasses some comment on compliance with relevant technical and design guidance (for example, SHTM 04-01 Water safety for healthcare premises, SHTM 03-01 Ventilation for Healthcare Premises, SHTM 64 SHTM Building Component Series Sanitary Assemblies) and the suitability of the design/materials to comply with cleaning and wider requirements of national infection control policy. It also requires those completing the document to have both knowledge and sight of other project information such as commissioning data.

53. Our role as infection prevention and control nurses, or infection control doctors is to comment on any clinical infection or wider IPC risk associated with the design or fit out or finish of the building, and how we understand the space will be used by clinical staff, and the risk profile of the patient population. It may also include contributing to a risk assessment where

derogation from guidance is required or desired to ensure any hazards or risks associated with these are recognised and that adequate mitigation is put in place. It also helps the Board understand the level of any residual risk associated with the derogation and whether this is acceptable to them.

54. The IPCT are a stakeholder in the HAI Scribe process. The 'ownership' and coordination of the process for commissioning and handover including completion of the HAI Scribe is the responsibility of the Project team as defined by sections 2.4-2.7 of SHFN 30 Part B: HAI-SCRIBE Implementation strategy and assessment process. I cannot confirm who, if anyone, within the Project team was formally assigned as the HAI Scribe Project manager. The practical arrangements for HAI Scribe review were usually confirmed by Janice Mackenzie, Ronnie Henderson, Dorothy Hanley, or Ashley Hull. There is a common (and persisting) misconception which the IPCT have encountered before, during and since the RHCYP Project that HAI Scribe is an 'infection control' process and that we lead the process and are responsible for 'signing off' work. The successful completion of the Project and assurance that all infection risks have been identified and adequately mitigated for requires all relevant stakeholders to confirm they are content, for example, confirmation from the Authorising Engineer (Ventilation).

55. It is my experience that, in reality, the attendance at these Stage 4 HAI Scribe and review meetings is frequently limited to members of the Project team and IPCT only. This is not appropriate as the IPCT cannot represent all stakeholder views. For example, the HAI Stage 4 question set includes questions about ease of domestic cleaning and suitability for clinical care and service provision. These points need to be confirmed by domestic services and clinical teams responsible for the delivery of domestic cleaning and clinical care. SHFN 30 Part B: Questions 4.25 -4.42 relate to engineering services (water, ventilation, lighting, vacuum units) and seek to confirm compliance of design, operation and access for technical maintenance. The IPCT are not qualified in aspects of healthcare engineering design or maintenance. Therefore, confirmation and assurance should be provided by the relevant Duty Holder (Authorised Person, Authorised Engineer etc).

56. It was (and remains) normal practice for members of the IPCT to annotate a copy of the Stage 4 document during physical review to reflect any comments, snagging or additional actions required from an IPC perspective which we then retain. A copy of our notes are then shared by email with the Project team while they collate any and all comments and contributions from other stakeholders.

57. The Stage 4 HAI Scribe reviews that I participated in (May 2019) were annotated by me to reflect the fact that we were not provided with evidence or confirmation to satisfy the questions regarding engineering services design or performance compliance. The document template used in NHS Lothian at that time was a Word based version of SHFN 30 (Part C) 2014 HAI Scribe question sets and checklists – P38-42 Pre-Handover check, ongoing maintenance and feedback Stage 4 which is only provided to NHS Boards as a PDF document.

58. A final copy of the Project document which is signed by all relevant stakeholders confirming they are content with the physical review and information provided should be retained by the Project team. This may be provided by means of an electronic rather than physical signature.

Ventilation

59. The concerns expressed prior to 2019 re ventilation that I was aware of mainly relate to design and functionality of ventilation systems and applied mostly during the design and construction phase. Most of these discussions centred on compliance with technical guidance rather than being framed as patient safety concerns specifically – these were implied as being associated with a non-compliant design. Some of the concerns raised I was aware of but not directly involved in at the time the concern was raised, and some I became more aware of in late 2018 as part of Janette Rae's handover.

60. In August 2016, Janette Rae had included me in correspondence relating to Air Handling Units (AHU) provision for isolation rooms as the design proposal included serving multiple rooms in paediatric oncology (latterly Lochranza) (**A41263185 – Email DI LG JR Lochranza ventilation for comments – dated 22 August 2016 – Bundle 13 – Vol 7 – Page 38)**. The consensus view of the IPCT was that more resilience for planned and unplanned shutdown of ventilation was required, specifically for oncology. A SBAR summarising the IPCT position was developed by Janette Rae and shared in September 2016 (**A41295528 –2016 08 22 Ventilation – dated 22 August 2016 – Bundle 13 – Vol 7 – Page 40)**. The risk associated with this issue would be the loss of protection for very vulnerable children and young people if the ventilation to one or more isolation rooms was shut down for any period of time. These issues were raised with the Project team and shared with the IPC Head of Service, Dr Kalima site ICD, Dr Donald Inverarity as Lead ICD and myself as Lead IPCN. I am not aware where this was discussed outside of the Project meeting, and I cannot comment on how the issue was resolved or where the governance arrangements surrounding this decision to accept this arrangement or not. The SBAR prepared by Janette Rae dated 14 September 2016 **(A34443762 – NHS Lothian SBAR Ventilation – dated 14 September 2016 – Bundle 13 – Vol 7 – Page 41)** noted that:

"Multiplex (previously Brookfield Multiplex) have agreed that they will provide a re-route facility that if one air handling unit e.g. in Haematology/Oncology fails it will be backed up by an air handling unit that supplies only one room in another part of the facility, until the faulty air handling unit is repaired or until maintenance has been carried out".

On that basis, my assumption would be that this solution had been engineered as described at the time. It appears there was a meeting on 3 November 2016 with IHSL, MPX, Motts and the AE for NHSL, John Reiner, at which Janette Richards (later Rae) was present where the isolation suite ventilation design philosophy and strategy appears to be discussed (**A47086951 – IHS Lothian Meeting RHSC DCN Isolation Rooms – dated 03 November 2016 – Bundle 13 – Vol 7 – Page 43)**. I do not recall Janette

discussing that meeting with me. The IPCT were not members of the Project Programme Board. We provided an advisory service into the Project, our role was not to approve or endorse any wider project decisions in line with section 2.9 of SHPN 30 Part B. The IOM commissioning reports dated 2 to 9 July 2019 confirmed the presence of several isolation rooms with shared air handling units which was contrary to HBN 04-01 supplement 1 para 2.37. This suggests to me that either the required re-route solution was not enacted, or a decision was made not to pursue this option.

61. In Autumn 2016, there was a separate dialogue relating to the design of the ventilation in CT scanning, which included external stakeholder advice from HFS (Ian Storrar – Principal Engineer). The IPCT consensus was in line with the advice provided by HFS to provide 15 ac/hr. The patient risk associated with sub optimal ventilation in this context would be post procedure infections. The infection risk would be associated with patients undergoing complex surgeries which expose brain, bone and other tissue to room air which may have a higher concentration of microbiological contaminants during intraoperative CT scanning or CT assisted procedures i.e., in a room which did not offer optimal air quality. This risk is different to the risk to patients receiving a diagnostic CT scan in the absence of an invasive or surgical procedure. A higher room air change rate is associated with a higher rate of dilution and extraction of any potential microbial contamination (bacteria, mould) in that room air. A positive pressure differential of at least 5 Pascals (5 Pa) between the interventional room and surrounding spaces is also desirable. This helps to push ‘dirty air’ away from the wound site and outwards from the procedure room. This pressure also helps prevent ingress and egress of contaminated air between adjoining rooms. In operating theatres, higher pressure differentials are advised with pressure stabilisers at junctions between spaces (SHTM 03-01 Part A). Pressure stabilisers are designed to help manage and control the flow of air between rooms. These allow air at different pressures to pass in one direction only (from clean to less clean). They help to mitigate the risk of loss of room pressure when doors are opened in the suite. The consequences of brain infections can be very serious, may require prolonged antimicrobial treatment, and be associated

with poorer patient outcomes or death. These risks were raised with the Project team, clinical team, HFS through the SBAR (**A47088790 – Email from Janette Richards to Donald Inverarity regarding air changes – dated 16 September 2016 – Bundle 13 – Vol 7 – Page 45)** and email correspondence, (**A47088789 – Air Changes JR Email 2018 (Email from Janette Richards regarding air changes – dated 19 March 2018 – Bundle 13 – Vol 7 – Page 54)** and copied to microbiology, Dr Donald Inverarity as Lead ICD and myself as Lead IPCN. The CT room ventilation design was resolved in line with the guidance from HFS and the IPCT.

62. I was made aware in 2018 during collation of information for a Freedom of Information request (see paragraph 42) of correspondence between Janette Rae and Ronnie Henderson from January 2017. Ronnie Henderson was seeking to confirm the definition of a 4 bedded room, and whether this would be deemed as a 'general ward area' for the purpose of ventilation design, and whether a 4 bedded room should have the same ventilation configuration as a single bedroom for the purposes of infection control/patient isolation. No further detail was provided in the email trail about what type of patient care/ ward area this correspondence related to. Janette advised that the ventilation parameters set out in SHTM 03-01 for a general ward area should be followed. She also explained that if a number of patients with the same infection were cared for in a 4 bedded room (a 'cohort') then the provision of extract ventilation in toilets and showers which would likely render the bedded space as balanced or slightly negative pressure to the corridor and was desirable. Dr Donald Inverarity was also copied to the correspondence between Janette and Ronnie Henderson. The patient risk that might be associated with this bed and ventilation arrangement would depend on the type of ward and patient care delivered there. In a high-risk ward such as critical care or paediatric haematology/oncology such as Lochranza, the patients in the ward are considered more susceptible to acquiring infection because of possible immunosuppression associated with their underlying disease or treatment. These patients frequently have other risk factors for developing infection, such as the presence of invasive devices (central lines, peripheral cannula, invasive monitoring) or immune system immaturity and

not having received all routine childhood immunisations based on age at the time of admission to hospital.

63. In July of 2018, the IPCT and Project team sought advice from HFS (Ian Storrar) and HPS (Annette Rankin) in relation to rectification work, risk of environmental moulds and discussion on air quality monitoring following a significant flood of water at the RHCYP in 2018 which resulted in significant water damaged to clinical areas across several floors.

64. In December 2018, we were involved in discussion with Ronnie Henderson in relation to isolation room heater battery arrangements and a proposed solution to run additional pipes within the ceiling void. This was followed up with a site visit by myself, Dr Donald Inverarity, and Dr Olson (Consultant Microbiologist) jointly with Ronnie Henderson. Although this wasn't specifically a risk to the ventilation system, the proposed solution did include potential to create further access points in the solid ceilings provided as part of the overall ventilation design. It also raised questions of water safety, and we were also keen to understand any similarities to a solution provided at the QEUH which was associated with mould growth and potential risks.

65. On 2 April 2019, I became aware, through reading notes of a meeting I had not been able to attend, of water leaks from air conditioning units in the MRI unit in DCN theatres. This was new information to me, Dr Donald Inverarity and Sarah Jane Sutherland who had attended some meetings and had noted a point about snagging which Sarah Jane Sutherland planned to discuss with Janice Mackenzie, RHCYP Project Clinical Director, in more detail ahead of planning for the Stage 4 Scribe reviews. This incident caused concern as we were already aware that Legionella had been detected in water in the building, we had the potential legacy of the flood damage from 2018, and this represented a further potential hazard for patients and staff where the IPCT were not actively advised of at the time of the issue being identified. This contributed to an overall lack of confidence and assurance that the information we had been provided with to that point was adequate in helping us understand the scale, scope and impact of any environmental issues or the

potential impact on patient or staff safety following planned transfer of services.

66. I do not recall, and cannot locate any emails, files or minutes which highlight any other specific escalations from the IPCT to the RHCYP/ DCN Project team regarding ventilation design or function until 2019.

67. The IPCT made repeated requests in discussion and by email to the Project team for information to inform the Stage 4 HAI Scribe sign off in 2018 and 2019 as the Project was scheduled or reported to be near to complete and handover. This included advice that independent confirmation of ventilation systems was advised as part of hand over. Some of these requests and the rationale and supporting technical directive were previously communicated by the IPCT to the Project team at various points from 2016 onwards.

68. IPCT were made aware through email chain from Brian Currie of 11 March 2019 (**A47088787 – Email regarding Infection Control and Ventilation issues from Sunday Herald article on Glasgow QEH/RHCYP – dated 18 March 2019 – Bundle 13 – Vol 7 – Page 65)** that there was 'sub optimal air change rates' in side rooms and 4 bedded rooms but this did not specify further which wards were affected.

69. The first time I was aware that critical care did not achieve 10 ac/hr was from information provided to us (Dr Donald Inverarity & myself along with others in the IMT that had been convened to consider all issues) on 1 July 2019 and receipt of the IOM report on 2 July 2019.

70. As more information emerged from QEUH we were able to probe specific elements of design (for example, heater batteries) to offer a view on potential IPC risks and the significance of patient safety considerations increased. Similarly, our experience with Cardiothoracic surgery mould infections had highlighted significant questions about ventilation design, maintenance, performance, and validation.

Independent validation of ventilation systems

71. I have been asked to refer to an email from me to Ronnie Henderson of 17 May 2019 (**A40988859 – 20190524 RE RHSC Ventilation – dated 24 May 2019 – Bundle 6 – Page 152).**

72. I did have concerns with the ventilation and/or water systems at this point in time. My concerns were primarily that the IPCT had not been provided with adequate information or responses to specific questions about compliant design, commissioning and validation raised by any of the IPCT (but principally through myself, Sarah Jane Sutherland or Dr Donald Inverarity) in relation to both ventilation and water systems over a period of some months. With specific reference to ventilation, the IPCT had requested through a variety of conversations, meeting forums and emails that independent commissioning and validation of the critical ventilation systems should be undertaken, and the results from this shared with us. This was necessary to provide assurance that these systems were installed and functioning correctly and would mitigate risk of infection to patients. We had also asked if there were any derogations from design guidance, so that we might be able to provide a view on any clinical IPC risk relative to this once the hospital was occupied. We had also asked for further clarification on ventilation contamination issues identified as part of the Settlement Agreement between NHS Lothian and IHSL dated 22 February 2019 (SA1) (part of the 81 residual risks reported at the April 2019 Pan Lothian Infection Control Committee). These questions were principally posed to Ronnie Henderson as the Hard FM Commissioning manager but were raised with Brian Currie (Programme Director) and Janice Mackenzie (Clinical Director). In addition to the requirement to complete the Stage 4 HAI Scribe and demonstrate assurance against design guidance, we were cognisant of the potential for issues at QEUH which had been shared with us by colleagues in NHS GGC (see paragraph 34) to affect the RHCYP DCN. If similar hazards or risks did exist, we were keen to ensure that adequate control or mitigation was achieved prior to patient occupation to avoid the risk of preventable patient infections

which could be linked to the hospital environment. It became clear that some of the information was not yet available (until IOM commenced independent commissioning in late June 2019) or that information held was not contemporary (i.e., further work had been undertaken within the system which invalidated previous information).

73. I was also concerned that the IPCT had only learned via a general communication to all staff 26 February 2019 (**A47088785 – Update on new Royal Hospital (Email from Carol Horsburgh regarding update on RHCYP – dated 26 February 2019 – Bundle 13 – Vol 7 – Page 75)** that the Project had been 'handed over' and accepted by NHS Lothian. It was my understanding from that communication that this meant that construction was complete, and plans would be enacted to begin transfer of patient services. At that time, I was concerned that the Project was considered to have concluded without the HAI Scribe Stage 4 process being completed.

74. Given the number of issues and potential hazards already known to the IPCT (flood, heater batteries, air conditioning units in MRI, water samples positive for Legionella, Pseudomonas and raised Total Viable Counts (TVC) of other microorganisms), our own understanding of environmental hazard and infection risk arising from the Western General Hospital Pseudomonas IMT and the Royal Infirmary of Edinburgh Cardiothoracic mould IMT, and some possible parallels with issues identified at the QEUH, I was not comfortable that either the IPCT or the Project team had sufficient oversight and understanding of risk and mitigation required as part of a single structured review process.

75. Specifically in relation to ventilation, at that time most of our concerns focused on critical ventilation systems, and particularly theatres and MRI where there had been issues during construction or recent months (the flood, air conditioning leaks).

76. As a service, we had highlighted concerns about mould risks following a leak that affected areas including MRI in July 2018. An SBAR (**A47095870 –**

201807 06 SBAR RHCYP DCN – dated 06 July 2018 – Bundle 13 – Vol 7 – Page 77) was prepared by Janette Rae and shared with members of the Project team at the time (**A47095685 – RHCYP SBAR Flood – dated 06 July 2018 – Bundle 13 – Vol 7 – Page 80)** and (**A47096126 – RE RHC and YP Hospital – dated 05 July 2018 – Bundle 13 – Vol 7 – Page 91)**. Ian Storrar (Principal Engineer at HFS) was also included in this communication. We flagged again in early April 2019 (**A47096239 – Re REHSC DCN Queries – dated 09 April 2019 – Bundle 13 – Vol 7 – Page 94)** following reports of a further small leak, that questions about further air sampling that had not been satisfactorily resolved and no further information had been received in relation to this. Questions had also been raised in relation to theatre design and inclusion of ultraclean ventilation (UCV) in the new DCN theatres and the ability to use this in conventional theatre or UCV setting in March 2019. We had highlighted in walk round some considerations for the safe use of the UCV theatres from a practice perspective (for example, setting up instrument trays underneath the UCV canopy and not at the margin).

77. Dr Donald Inverarity had also again raised specific questions about the information provided about theatre ventilation in the RHCYP/DCN in May of 2019 (**A47088786 – HAI Scribe Stage 4 Reviews RHSCDCN – dated 03 May 2019 – Bundle 13 – Vol 7 – Page 96)** and (**A47088791 – DI Theatre Validation – dated 13 May 2019 – Bundle 13 – Vol 7 – Page 99)**. This noted a lack of detail and information that would allow either the IPCT or anyone else in NHS Lothian to take meaningful assurance of compliance or functionality of the system. This information was required to complete the HAI Scribe Stage 4 in relation to questions 4.25 to 4.34. The independent commissioning and validation reports that were expected to be provided to address these questions would provide more information about compliance, suitability and functionality than is summarised in the questions noted within the HAI Scribes stage 4 template. This information would be considered alongside any permitted design derogations or other issues identified during construction.

78. Dr Donald Inverarity and I had discussed ventilation and potential risk at length as we had already involved both HPS and HFS in March 2019 about queries about theatre ventilation at the RIE as part of the cardiothoracic mould IMT. We also understood some of the concerns about ventilation more generally that had arisen at QEUH through our peer-to-peer discussions over a long period of time (see paragraph 34) which related to several parts of the ventilation system. A summary of these prepared by Dr Teresa Inkster was shared with permission by Dr Donald Inverarity on 5 July 2019 to be considered along with the IOM commissioning reports. The NHS GGC summary highlighted issues relating to heater battery units, chilled beams, pressure differentials reversed, potential entrainment of contaminated air through thermal wheels, isolation room design. Throughout late 2018 until 1 July 2019 (when IOM commissioning information was becoming available) I remained concerned that similar issues may be discovered at RHCYP given that the same contractors had been involved in the design and construction of both facilities, and in the absence of documentation to confirm satisfactory design, installation and performance.

79. Project documents were not accessible to the wider IPCT as these were held on a separate system which required access rights and training in its use. I do not know if Janette Rae had access to this system. I did not request access to the system. As subject matter expert advisors I did not expect the IPCT to be able to access all project documents, nor would we have time to navigate all such records. It was my expectation that relevant data, reports and documents defined in technical guidance such as SHTM 04-01 Water safety for healthcare premises or SHTM 03-01 Ventilation for Healthcare Premises would be shared in way that we as clinicians would be able to access and interpret with ease.

80. My understanding of SHTM 03-01 is that independent commissioning and validation was required for all critical ventilation systems including theatres, critical care, LEV – as defined in SHTM 03-01 Part A (2014 version). SHTM 03-01 Part A: Design and Validation (2014 version) in section 1.26 defines departments which require ‘special ventilation’. This includes ‘intensive

treatment unit' (ITU) which is an older, alternative term for critical care units. Section 7.2 also sets out a requirement for specialised ventilation in a range of areas which includes operating theatres, all critical care and high dependency units and isolation facilities, including oncology units and those delivering chemotherapy. These sections provide the definitions of where 'critical ventilation' systems would be installed. Section 8 of this guidance sets out the definitions for commissioning and validation of ventilation systems. Commissioning of all systems is essential as this provides information on the fitness and performance of the system moving from installation to full operational state. The general note in section 8 advises that in house staff are not likely to possess the required skill, knowledge, or equipment to complete this. Independent expert contractors would therefore usually be advised. Section 8.15 advises that for critical systems, independent validation of the performance of the system may be advised.

81. An independent validation is required to be arranged in advance of project completion and before patient occupation. Although the requirement for independent commissioning and validation is not explicitly stated in sections 4.26 to section 4.34 of the HAI Scribe stage 4 template, it is implicit through the questions asked confirming that the design, quality of installation, and functionality is relative to the risk profile of the area it is installed in and capable of controlling pathogens through means of 'dilution or entrainment'. To achieve these criteria, the system should be designed, installed, commissioned, and validated in line with SHMT 03-01. This should be reflected in the HAI Scribe Stage 4 process to give assurance that a compliant system had been provided and was operating correctly prior to patient occupation.

82. There are clear statements that an independent validation is a requirement in SHTM 03-01 Part A of the guidance (see paragraph 80 above). There had already been request for this by Dr Donald Inverarity in prior emails to the Project team and in discussion at various points from as early as 2016 and reiterated in 2019.

83. I emailed Ronnie Henderson on 17th May 2019 (**A47090715 –Email RH LG RHSC Ventilation – dated 17 May 2019 – Bundle 13 – Vol 7 – Page 115)** following a face-to-face discussion with him and others following one of the HAI Stage 4 reviews on the same day. In this email I restated that:

> "We (the IPCT) do think that it would be useful to have independent validation by an authorising engineer, recognising there is a cost associated with this".

My use of language in this email to the Project team was intended to be measured and collaborative, rather than being seen to instruct the Project team to arrange commissioning or being construed as critical of them in not providing commissioning information. This is because there was some tension developing in the relationship between the Project team, estates, and IPC by this stage in the Project. I had highlighted in the face-to-face discussion my ongoing concerns the IPCT had about not having sight of more detailed information on either water testing, water quality, or ventilation design and performance, and the lack of independent validation. In my email, I also referenced the other issues around water safety and ventilation that had been part of email and other discussion in the preceding weeks. I was given verbal assurance by Ronnie Henderson that most of the 81 items identified as part of the SA1 had little or no HAI component, and that all of those which carried residual risk had been captured on the Project risk register. The IPCT had not been directly part of discussions relating to SA1 and had learned of this, and the remaining risks from a verbal report by the NHS Lothian Director of Facilities at the Pan Lothian Infection Control Committee on 12 April 2019. I had not received any documents setting out the risks identified or information in detail of what actions had been taken. A meeting had been scheduled on 5 June with the IPCT and wider members of the Project team to review and discuss these residual risks.

84. The Project team present at the meeting on 17 May 2019 were aware that there had been discussion at the infection control committee in April 2019 (**A47086952 – 20190412 PLICC Minutes – dated 12 April 2019 – Bundle 13**

– Vol 7 – Page 12) about the Project but that they were not present and voiced some concern that they had not been invited to participate in this discussion. The minutes reflect a number of points relating to derogated air change rates, potential mould contamination following reported leaks, availability of water sampling and problems with theatre flooring as well as the 86 (later confirmed as 81) non-conformances accepted at SA1.

85. By advising that independent commissioning and validation of the ventilation system would be 'useful', I was seeking to be conciliatory and influence this action in a collegiate manner rather than create a perception that I was 'instructing' the Project team (which was not my role) which I felt may further impact on the working relationship we had with them at that time.

General Overview of HAI Scribe Process

86. The process to undertake hand over and commissioning review was phased and required several separate visits with a separate Scribe document produced for each department or area being reviewed. This was agreed with the Project team and confirmed in email from Sarah Sutherland on 3rd April 2019 (**A47088988 - RE RHSC DCN HAI Scribe Phasing – dated 03 April 2019 – Bundle 13 – Vol 7 – Page 102)**.

87. The Scribe document from 26 April with IPC notes from the review of the ward areas including Lochranza and critical care (**A35230420 - HAI SCRIBE Stage 4 – Inpatient Wards and PICU - dated 3 May 2019 – Bundle 13 – Vol 7 – Page 104)** is annotated to reflect verbal information we were provided with by members of the Project team during the physical review. There are asterisks on points where additional information was required (specifically ventilation and water).

88. At the meeting on 26 April 2019, I discussed with the Project team (Ronnie Henderson, Fiona Halcrow, Dorothy Hanley) the outstanding information relating to water commissioning and testing, and ventilation commissioning

and testing (which had been requested in the preceding weeks) and made clear that I would not sign the document to confirm that the IPCT were assured all criteria had been met or witnessed. This in effect meant that the Project team did not have IPC 'sign off' to complete this part of the process.

89. I emailed Dr Donald Inverarity on 29 April 2019 **(A40980763 – Email 29th April FW RHS - dated 29 April – Bundle 13 – Vol 7 – Page 110)** highlighting that Sarah and I had carried out a Scribe review on the previous Friday (26 April 2019) and that we had not 'signed off' due to the outstanding requests for information and assurance. I wanted to discuss in more detail some of the ongoing questions we had in relation to water and ventilation. Dr Donald Inverarity had not been available to join us on the 26 April 2019.

90. The covering email to the Project team on 3 May 2019 by Sarah Sutherland made clear that the two HAI Scribes from our reviews on 26 April and 2 May 2019 were not 'signed off' by the IPCT.

91. I emailed Janice Mackenzie and other members of the Project team on 13 May 2019 **(A47088786 – RE HAI Scribe Stage 4 Reviews RHSCDCN - dated 29 April – Bundle 13 – Vol 7 – Page 96)** clarifying what further information was required by us to help inform completion of the stage 4 Scribe process.

92. This email also highlighted that we would not be in a position to finally 'sign off' the Scribe ahead of a planned meeting with the Project team and others on 5 June 2019. This had been arranged to allow the IPCT to understand in more detail a number of 'non-conformances' that the Board had accepted as part of the Project handover in relation to SA1 earlier in the year.

93. The non-conformances were first brought to the attention of the IPCT in a verbal update from George Curley the Director of Facilities at the Infection Control Committee of 12 April 2019 (**A47086952 – 20190412 PLICC Minutes – dated 12 April 2019 – Bundle 13 – Vol 7 – Page 20)**. We were keen to

understand and advise on any residual IPC risk associated with these non-conformances.

94. I emailed Ronnie Henderson on the evening of 17 May 2019 **(A47090715 – Email RH LG RHSC Ventilation - dated 17 May 2019 – Bundle 13 – Vol 7 – Page 115)** following on from the Stage 4 Scribe review of theatres and Imaging earlier that day. This email refers to theatre ventilation validation which he advised had been scheduled for 24 May. In the absence of this validation information and assurance at 17 May 2019 the HAI Scribe for theatres and imaging was therefore not considered 'signed off'. A subsequent email from Ronnie Henderson to IPCT on 24 May advised that the scheduled testing in theatres had been postponed until 28 May.

95. The HAI-Scribe process should be multidisciplinary, recognising that IPCT are clinical staff with specific remit for clinical infection control advice and must work within their professional regulatory requirements (i.e., act within limits of skill, knowledge and competence). Our staff do not hold any formal training or qualification in construction, plumbing or mechanical engineering.

96. Some of the more technical questions relating to engineering services should have the relevant Authorising Engineer confirmation.

97. The evidence IPCT would require to see would be:

    - the commissioning records – ventilation design and performance compliance to SHTM 03-01
    - water sampling records to demonstrate compliance for L8 and SHTM 04-01 sampling requirements
    - specific risk assessments, operational procedures etc relevant to any approved derogation against design guidance, the rationale for derogation and any identified risk/issue.

98. This evidence should be required by the Project team, not just the IPC team. The IPC team can only advise on the aspects of microbiological or clinical

safety or risk associated with engineering systems. The Project Team should be assured on the performance of water distribution systems and that engineering controls are adequate in maintaining water quality (for example, temperature control on flow and return legs of water systems, water pressure).

99. If there was not a structured review with input from relevant stakeholders including IPC, there may be further unidentified hazards and risks associated with design, construction, quality or performance of the built environment which could be associated with avoidable infections for vulnerable patients, staff or the wider public.

100. There is a risk that where even the most basic of standards are not met at the time of patient occupation (for example, incomplete sealant round shower floor to wall junctions) this may lead to rapid damage and deterioration of the new hospital environment (for example, through water ingress during normal use). In some cases, this could reduce the expected lifespan of materials or fittings.

101. Where surfaces are not intact, sealed, impervious and capable of being cleaned, this can be associated with a microbiological hazard and nosocomial infection risk (for example, development of mould in patient care areas leading to mould spore exposure and infections which can be severe and life threatening).

102. This type of snagging/defects log can be associated with service disruption caused by access to achieve remedial repair or rectification. Depending on the nature of the work and the type of clinical area, achieving effective mitigation of risk to protect adjacent occupied service and patient care areas can be complex (e.g. erection of temporary PVC walls (hoard fast) or sealed dust barriers, use of HEPA cubes) This work may also incur significant additional and avoidable financial costs.

103. There are corporate risks associated with statutory non-compliance and wider contractual, financial, reputational risks. Failure to identify issues prior to handover with limited ability to retrospectively seek action or compensation from contractors.

104. SHFN 30 Part A section 4.105 states “Upon completion of construction, the facility must be brought into use; the complexity of the task involved generally means that a Commissioning Manager and Commissioning Team will be needed. Senior managers, infection prevention and control teams, specialist teams and users should be fully involved in the process.”

105. As detailed above, the Scribe review should be completed, and counter signed by all relevant stakeholders including the clinical team. The Project manager has overall responsibility for coordinating, leading and completing HAI Scribe stages 2, 3 and 4 (SHFN 30 Part B section 2.7). In my view, it would also be appropriate to request the input of the relevant Authorising Engineers to check and endorse commissioning and validation information as they have the qualifications, training, and competence to advise on technical aspects of design, function and safety which are not likely to be held by individuals within the Project team, including the IPCT. This is in line with SHTM 03-01 Part A section 8 definitions and note. This acknowledges that the expertise to validate critical systems is not likely to be available ‘in house’.

106. The Project team retain overall ownership and responsibility for the document and process. The process for signing-off on the Stage 4 HAI-SCRIBE is an area which lacked clarity at the time and subsequently. It is my perception from many years of using the HAI Scribe document in a number of settings and both small and large scale projects, and from feedback from other members of the IPCT that I manage, that the Scribe was viewed as an infection control document rather than a project document, and that the ‘sign off’ was expected to rest solely with the IPCT.

Stage 4 HAI Scribe Process Review

107. My role in the HAI-Scribe process is as detailed in the above paragraph19.

108. The HAI Stage 4 scribe document covered all in patient wards including critical care and Lochranza (haemato-oncology). I was not aware at the time of the HAI Scribe review meeting on 26 April 2019 that multi bed bays in critical care had been inadvertently included in derogation of air changes rates. Sarah Jane Sutherland and I were advised verbally by Ronnie Henderson during the HAI Scribe stage 4 review of Lochranza ward, Paediatric Intensive Care (PICU) and DCN Acute Care that derogation had been approved for single rooms to achieve 4 air changes/hr from mechanical ventilation in the ward for single rooms and that this had been risk assessed, however no documentation to confirm this position was seen during the review.. I understood that this applied to single rooms rather than isolation rooms (PPVL rooms) in the general ward areas which included DCN Acute Care and excluded PICU.

109. Sarah Jane Sutherland had also shared information with Dr Donald Inverarity, myself and other members of the IPCT on 4 April 2019 (**A47088988 - RE RHSC DCN HAI Scribe Phasing – dated 03 April 2019 – Bundle 13 – Vol 7 – Page 102)**, stating that Janice Mackenzie, Clinical Director for the Project had advised all single rooms in DCN would be considered the same as single rooms in Paediatrics from a design and performance perspective. She had also been advised that:

> "any issues we thought should have been picked by the project teams own room reviews and specifications/requirements should have been addressed during HAI Scribe Stage 2".

I had only recently been made aware at Pan Lothian Infection Control Committee on 12 April 2019 that a number of non-compliances had been agreed as a derogation as part of SA1, but at that stage had not been provided with any detail of what those were. Independent ventilation

commissioning information for the critical system in Critical Care and Theatres had been requested by the IPCT most recently as 18 March 2019 in email correspondence between the Programme Director, Professor Alex McMahon (HAI Executive Lead), Dr Donald Inverarity and others in the IPCT (see item for paragraph 68). We had been advised verbally, and through email communication that this information was available, and all results were satisfactory, but no one in the IPCT or Microbiologists had seen this information at 26 April 2019.

110. At the time of the Stage 4 HAI-Scribe reviews at RHCYP, as lead nurse I was accountable for the provision of IPC clinical subject matter expertise, senior leadership and IPC oversight of a complex situation to ensure that both the Project team and the Board could be assured that any IPC risks specific to the Project had been adequately described, to extrapolate and advise on any potential learning or themes emerging from both local infection control incident management teams, but also reflecting emerging learning from the QEUH Project detailed in paragraph 40. This included aspects of water system and water quality with links to a range of unusual patient infections (as per the NHS GGC SBAR shared in confidence with me on 18 December 2018), issues relating to use of Point of Use filters on taps (impact on water flow, splashing) which had been shared with us during our management of the WGH *Pseudomonas aeruginosa* incident in March 2019, and issues with non-compliant ventilation design and performance affecting different parts of the QEUH hospital which had been highlighted through peer to peer discussions, and to some extent the HFS guidance from March 2019 on Managing the Risk of Contamination of Ventilation Systems by Fungi from Bird Droppings.

111. I was also responsible for the provision of training, support and development of the newly promoted and appointed HAI Scribe lead nurse as the professional nursing lead for the IPCT.

112. As noted above, the HAI Scribe stage 4 documents were not completed (‘signed off’). I was responsible for contributing to the Scribe process as one of several stakeholders.

113. The department specific Stage 4 Scribes for RHCYP DCN were never completely confirmed as being ‘signed off’ by the IPCT by the time the Cabinet Secretary formally instructed NHS Lothian on 4 July 2019 that migration of patient services should not proceed.

114. The HAI-Scribe Stage 4 process is physical review of the building and relevant data or documentation with relevant stakeholders. This should be after all construction work is considered complete, a builders’ clean completed and all commissioning work completed with results available. A final domestic services clean (terminal clean) may or may not be complete by the time the Stage 4 review is carried out, but will be complete by the time patient services move in.

115. The review is a combination of:
    - visual checks to assess fit and finish, integrity and quality of workmanship and materials, any potential operational issues. These checks can be very detailed (for example, no defects in hard surfaces, ceiling tiles/ceiling grids intact & flush, ensure all silicone seals robust and intact around all sinks & showers) as well as more general observations (for example, access for cleaning, placement of hand gel dispensers) and ‘compliance’ checks with key guidance where this can be observed
    - review of documentation/evidence to confirm commissioning & validation results are satisfactory and compliant with STHM 03-01, SHTM 04-01 etc – and that there are no clinical risks associated with performance
    - an understanding of any approved derogations - these are usually more associated with refurbishment rather than new construction – for example, non-compliant bed spacing, ability to fit fully compliant design within existing footprint
    - supporting risk assessments or procedures which set out actions to mitigate risk associated with these derogations or design limitations.

116. The HAI Stage 4 review of ventilation systems and water systems are made against the requirements of SHTM 03-01 and SHTM 04-01 respectively and not the Project contractual specification as per questions 4.26; 4.31 and 4.37 of SHFN 30 Part B HAI Scribe Implementation strategy, Development stage 4: review of a completed project. If the design, installation, commissioning or performance of these systems does not conform to these documents, it would be expected that this was noted as formal derogation with risk assessment during Stages 2 and 3 HAI Scribe review.

117. A Stage 4 Scribe review was undertaken by the IPCT on:

- 26 April (in patient wards including oncology and critical care)
- 2 May (Outpatients)
- 17 May (Theatres & Imaging)

118. Managing the process and document control is the responsibility of the Project Manager/Project team and they are best placed to advise on the timing of the Stage 4 review once all construction and commissioning work is complete. There is always some negotiation to identify suitable dates and times to bring together the relevant stakeholders. For IPCT these requests are balanced against existing clinical and work programme priorities and seek to minimise any delay to the Project.

119. The biggest risk of the Stage 4 HAI-SCRIBE not being completed prior to handover of the build and ultimately occupation by patients is lack of information or assurance that the building is safe or suitable for occupation by staff or patients. It is important to have evidence and assurance that critical systems function effectively and within required parameters.

120. I have been referred to a note on the HAI Scribe document against section 4.26 **(A35230420 - HAI Scribe stage 4 – Inpatient wards and PICU - dated 3 May 2019 – Bundle 13 – Vol 7 – Page 107)** stating that the derogation to 4 air changes has been risk assessed and approved. The handwritten notes on the Scribe reflect verbal information and assurance provided to me during the

review. Please refer to response in paragraph 121. I had no further understanding of what or where approval had been given for the reported design derogation and was not provided with any risk assessment documents. I have been asked by the Inquiry Team why this information was accepted if no such document was provided. The verbal information provided to me is noted on the Scribe document. I had no reason to disbelieve the information provided to me by members of the Project team who had been involved in the Project over its lifetime and therefore had a detailed and explicit understanding of the key stages and decision points within the Project. I recall advising Ronnie Henderson and Dorothy Hanley in discussion at the end of the HAI Stage 4 Scribe review meeting that professionally, I could not in good faith 'sign off' these points without being provided with the evidence to support them. As evidenced by subsequent email correspondence with Dr Donald Inverarity on 29 April 2019, the components of water and ventilation in the HAI Scribe were not 'signed off'. This is further evident in my email to Ronnie Henderson on 17 May 2019, where myself and Dr Donald Inverarity were still requesting to see copies of all commissioning and validation documentation relating to both ventilation and water systems, and to understand the implications of the residual risks accepted at SA1. The HAI Scribe Stage 4 reviews remained incomplete as at July 2019 when a decision was taken to delay opening the hospital.

121. No evidence was provided to me by the Stage 4 HAI Scribe review team in relation to assurance that the reduced ac/h in general wards and the Lochranza Ward had been "risk assessed and approved". The handwritten note on the Scribe template is from verbal information provided by the Project team. As far as I'm aware, the Project team were not anticipating reduce ac/h rates in critical care areas. I assumed that the risk assessment would relate to general ward areas (i.e. a change of 6 air changes to 4 air changes) as this had been stated by Brian Currie Programme Director in his email of 14 March 2019 (see paragraph 58) and would be the air change rate indicated for general ward bed rooms and single rooms as per SHTM 03-01 Part A Version 2 (2014) Appendix 1: Recommended air-change rates. My expectation was

that both Lochranza and Critical Care were achieving 10 air changes/hr in line with SHTM 03-01 Part A Version 2 (2014) Appendix 1.

122. Neither the Project team or the IPCT had sufficient information or oversight of this information to state with confidence that any hazards and risks associated with the hospital environment had been adequately mitigated.

123. To the best of my knowledge, nobody in the IPCT or the Project Team was aware at the time of the Stage 4 HAI Scribe review that the Lochranza or Critical Care design was non-compliant with SHTM 03-01.

124. All Stage 4 HAI Scribes remained incomplete by the time a decision was made to defer relocation of patient services in July 2019 (not 'signed off' by IPCT). This round of Stage 4 reviews was superseded once further remedial, design and construction work was planned and progressed.

125. The email response of 14 March 2019 from Brian Currie to our concerns noted under point 5 that some 4 bed and single rooms achieved only 4 air changes rather than 6 ac/hr as required by SHTM 03-01 Part A Version 2 (2014) Appendix 1. There was no further information provided at that time about the location of these rooms or the type of patient care that would be provided. The response made reference to a risk assessment in relation to suboptimal air change rates but I was never provided with a copy of this risk assessment, and I cannot comment on either the content or who might have contributed to this.

126. I was copied into an email thread on 18 March 2019 which contained a detailed summary of IPC involvement in the Project provided by Brian Currie on 14 March 2019. This was produced in response to a press inquiry which asked about the IPC role in the Project following reports into the QEUH Project. When I was made aware of the email, I raised concern to the IPC Head of Service and in turn the HAI Executive lead that I did not think the response was an accurate reflection of our role and that statements which implied full assurance had been made which I did not believe could be

substantiated. I had discussed this with Dr Donald Inverarity and I am aware he raised concerns by separate cover to the HAI Executive lead following one of the Western General Hospital Pseudomonas incident meetings which were running concurrent to this issue.

127. In March 2019, it was my view that critical care areas required 10 ac/hr 10pa positive pressure as per SHTM 03-01 Version 2 (2014) Appendix 1.

128. In March 2019, it was my view that the Lochranza Ward, a neutropenic patient ward, required 10 ac/hr 10 pa positive pressure as per SHTM 03-01 Version 2 (2014) Appendix. Although not all patients in Lochranza would be considered neutropenic, the ventilation requirements were required to provide resilience and assurance for all patient care.

129. I was first aware that some 4 bedrooms had been accepted with 4 air changes as part of an FOI request earlier in 2018, and then subsequently that 'some 4 bed and single rooms' only achieved 4 ac/hr from Brian Currie's email thread on 18 March 2019. At this point, I had no understanding which rooms or which part of the hospital this applied to.

130. I assumed that because the derogation was from 6 ac/hr to 4 ac/hr that this applied in general ward areas (in line with the specification for general wards laid out in SHTM 03-01 Version 2 (2014) Appendix 1). It was my expectation that all of critical care would be provided with 10ac/hr with 10PA positive pressure. Therefore, any derogation in critical care I would have expected to see expressed as derogation from 10ac/hr to 4 ac/hr. I would have expected IPC input into this decision, as the implications for infection control, patient safety and occupational health exposure risks associated with sub optimal ventilation in critical care would be greater than those risks in general ward environment. These risks relate to the vulnerability of the patient population and acquisition of infection due to their underlying illness or as a consequence of their treatment, the types of colonisation or infection that patients may have in these areas, and the role of room air change rates and pressure differentials in mitigating risks to patients, staff and visitors associated with

aerosol generating procedures such as intubation, tracheostomy procedures which are more frequently carried out in critical care areas.

131. Formal documentation which provided some confirmation of ventilation derogation design from 6 ac/hr to 4 ac/hr was provided to IPCT on 5 June 2019 by Janice Mackenzie in the Residual Risks Log generated at Project hand over **(A47090713 – 080519 RHCYP DCN Residual Risks – dated 08 May 2019 – Bundle 13 – Vol 7 – Page 121)**.

132. This risk log was shared in advance of the planned meeting on the same day to discuss the 'non compliances' accepted by NHS Lothian at Project handover which IPCT first learned about at Infection Control Committee on 12 April 2019 from George Curley the Director of Facilities.

133. The residual risks log notes issues about 'ventilation contamination' but in the worksheet titled deleted items there were items relating to "Bedroom ventilation pressure regime and air change rate in rooms for neutropenic patients" recording that only 7 rooms were suitable for the most vulnerable patients, and for both 4 bed ventilation and single bedrooms ventilation rates that:

> "The Board has compromised on the air change rate requirements in the SHTM 03-01 (6 ac/hr requested in the SHTM, and only 4 ac/hr being provided). There is therefore a potential reduction in the air quality, albeit well in excess of building standards. The Board has also accepted that only 14 of the 20 4 bedrooms have the correct pressure regime."

Again, given this is 6ac/hr to 4 ac/hr I would not have expected this derogation to apply to rooms in critical care, which have a starting point of 10 ac/hr.

134. There was a ventilation meeting by teleconference on Friday 28 June 2019. I cannot locate minutes of this meeting, but I have information provided to Dr Donald Inverarity and myself by Brian Currie by email on 28 June 2019

(A47090716 – Email from Brian Currie regarding RHCYP and DCN ventilation – dated 28 June 2019 – Bundle 13 – Vol 7 – Page 126) and my hand written notes from the meeting later that day **(A47090714 –LG Handwritten notes – dated 28 June 2019 – Bundle 13 – Vol 7 – Page 132)**. The IOM commissioning exercise had started and was initially focused on theatre ventilation and isolation rooms and issues were arising. From my written notes the main issues related to pressure cascades, air change rates, balancing, and Ultraclean ventilation (UCV). It was agreed that, by the end of Monday, 1 July 2019, information on theatres and isolation rooms was to be made available, and if these issues were 'fixable or not' to allow a decision to made about partial or full occupation of the site. My notes also record that 'HDU not performing'. This refers to High Dependency Unit (critical care).

135. This meeting on 1 July 2019 was the first time I had received confirmation that the critical care ventilation was neither designed, nor performing to the parameters set out in SHTM 03-01 Part A Appendix 1. I cannot locate minutes of this meeting, but I have handwritten notes from the meeting, noting no derogation was provided in the original design (**A47085953 – Q119 20190701 LG Handwritten Notes – dated 01 July 2019 – Bundle 13 – Vol 7 – Page 35)**.

136. The IPCT (Dr Donald Inverarity and myself) did not have a copy of the environmental matrix or any other design or commissioning information provided at the time of the ward Stage 4 HAI Scribe review (26 April 2019). The IPCT had not yet seen any non-compliances or derogations that were accepted at Project hand over. These were due for discussion on 5 June 2019.

137. Where I am aware or was copied into correspondence about ventilation design or performance for specific areas of the RHCYP/DCN, Janette Rae and others in IPCT were consistent in advising the Project team that ventilation design and performance should align to SHTM 03-01 requirements and to seek advice from HFS architects or engineers where available guidance lacked clarity (ref to emails regarding CT Scanning rooms). The

same advice and approach was adopted by Janette and other members of the IPCT with regards ventilation queries arising from other capital projects over this period (East Lothian Community Hospital, Haematology Unit refurbishment WGH). It therefore appears implausible to me 1) that anyone in the IPCT had advised or endorsed a position of non-compliant ventilation design for high-risk clinical areas, and 2) that there was any wider awareness of this within the senior IPC team.

138. Nobody from the IPCT was actively involved in the process of agreeing SA 1. It is likely that previous discussions and contributions from the IPCT (and specifically Janette Rae as the dedicated IPC project resource) in relation to the known derogations such as the provision of 4 ac/hr rather than 6 ac/hr in some single rooms were reflected by the Project Team involved in these negotiations. I would surmise that had independent water and ventilation commissioning and validation reports, the environmental matrix and details of the '81 non-conformances' discussed as part of the SA1 process been made available to the IPCT in advance of the formal handover, it is highly likely that we would have highlighted the non-conformances and potential clinical infection risks associated with these. The context in which these issues should have been viewed had changed over the lifetime of the RHCYP Project. The awareness of the IPCT and others of the complexity and scale of issues emerging from QEUH, and how this was thought to be manifesting as clinical infections in vulnerable patients was not widely available to us until the latter part of 2018, and after water and ventilation systems had already been designed and installed.

139. The only email correspondence and point of clarity relating to Lochranza ventilation escalated to me directly was in August 2016 when a question was raised about ventilation design and provision of multiple isolation rooms from a single air handling unit. Janette Rae, Dr Donald Inverarity and I all agreed this would likely be associated with some clinical infection risk and offer a lack of resilience of isolation capacity in the event of planned or unplanned AHU shut down. A short SBAR report (summarising the situation, background, assessment and recommendations) was prepared and submitted by Janette

Rae and submitted on this, and the issue of CT ventilation design on 14 September 2016**(A34443762 – NHS Lothian SBAR Ventilation – dated 14 September 2016 – Bundle 13 – Vol 7 – Page 41)**. This is a standard reporting format used extensively across NHS Scotland.

140. Any confirmation of ventilation design suitability or performance would be derived from the commissioning and validation information which had been requested on numerous occasions but not provided at the time of HAI Scribe review. This validation information was not provided until late June 2019 or early July 2019 through the IOM validation exercise.

141. At the time of the HAI Scribe review (26 April 2019) the IPCT were still waiting for information on the Residual Risk log advised at the Pan Lothian Infection Control Committee meeting on 12 April 2019. This information was not made available until the meeting on 5 June 2019.

142. None of the information received by the time of the Scribe review suggested that reduced air changes related specifically to Critical Care or Lochranza. From our perspective we expected these areas to have been designed to provide 10 ac/hr not 6 ach/hr. At the time of the HAI Scribe review, all information shared with the IPCT described a reduction in 4 bedded rooms and single rooms ventilation from 6 ac/hr to 4 ach/hr, which we assumed related to general wards only given the starting point of 6ac/hr.

Infection Prevention and Control (IPC) involvement in issues with water systems

143. I was aware from discussion with Dr Donald Inverarity and subsequently on being copied into an email thread on 18 March 2019 that water quality issues had been identified (including the presence of Legionella and *Pseudomonas aeruginosa* in some samples) in around late February 2019. This was around the time of Project hand over in terms of SA1 with post completion works still

to be undertaken. I was aware that more information had been requested by Dr Donald Inverarity at this time but not been received.

144. Ronnie Henderson shared water results with us on 29 April 2019 but we requested that this be formatted to ensure that results could be viewed chronologically and to understand what action and interventions had been completed and when. A template used in the ongoing Pseudomonas incident at the Western General Hospital was provided to the Project team.

145. I had contacted the Project Team (ref email sent to Janice Mackenzie 13 May 2019) seeking information on which areas were to be defined augmented care areas and more information on the locations and intended clinical use of areas where *Pseudomonas aeruginosa* had been identified during water sampling.

146. On receipt of the Project risk log from Janice Mackenzie on 5 June 2019, IPCT saw confirmation that 'failed samples' had been returned for TVC, Pseudomonas and Legionella prior to hand over. Brian Currie provided the IPCT with the Water Sampling Results Schedule on 19 June 2019. There was email discussion between the senior management team, IPCT and Project Team in response to this information. The Board were also preparing a response to the HPS Request for NHS Scotland water testing survey at this time. There were overlapping email discussions in relation to these two issues in June 2019. The Board Water Safety Group met on 20 June but did not specifically consider these points at this time.

147. From the information provided and resulting email discussion, we were not able to clearly identify the locations where positive results had been identified as results were presented by a location reference number rather than any meaningful explanation of location and intended use. There was insufficient and incomplete information available to the IPCT and Microbiology to make any sort of informed risk assessment in relation to these results (and implications for patient safety after occupation). No information was provided in relation to remedial actions taken in response to the water testing results.

148. I summarised ongoing and unresolved concerns in relation to water in email to the Executive Management Team on 26th June 2019.

149. In the absence of robust and contemporaneous information on water quality at the time of planned patient occupation, it is my opinion that we could not provide assurance to clinical teams or the Board that the water was safe for use all patient groups, specifically those in 'augmented care areas'. There is no fixed definition of augmented care provided in SHTM 04-01. The IPCT advise the definitions provided by HPS in their 2018 Interim Guidance for Management of *Pseudomonas aeruginosa* in Augmented Care document. This includes critical care units and Haemato-oncology units (therefore Lochranza ward). Following the *Pseudomonas aeruginosa* incident in DCN at the WGH in early 2019, NHS Lothian also considered Neurosurgery to be an augmented care unit. I shared this definition with Ronnie Henderson on 28 June 2019 **(A40983461 – RHCYP DCN Little France – dated 28 June 2019 – Bundle 13 – Vol 7 – Page 138)**. The definitions of augmented care areas had previously been shared with members of the Project team by email in August 2018.

150. We were aware of issues relating to Legionella*, Pseudomonas aeruginosa* and raised levels of micro-organisms (referred to as Total Viable Counts (TVC) in 1000mls of sample) in water sampling carried out between late 2018 and the first part of 2019. These samples were taken across the new building, but a lack of clarity as to where all of these positive outlets were, the actions taken in response to the findings or that additional consecutive water testing had confirmed that these water quality issues had successfully been resolved.

151. As we were already actively managing a situation where we had identified *Pseudomonas aeruginosa* in the water supply in the existing DCN building and ITU at the Western General Hospital I was particularly anxious that we had full assurance on water quality and water management prior to moving Neurosurgical patients to the new hospital. The move to the new hospital was recognised by the Incident Management Team (IMT) managing this issue as

one of the ‘control measures’ to eliminate or mitigate risk of serious infections in this patient population.

152. There was insufficient information available on Legionella sampling therefore it was not possible to confirm that NHS Lothian met statutory compliance or if there was any risk to patients, staff or the wider public from water systems.

153. The infection risks for patients associated with exposure to water in hospital relate mostly to personal hygiene or aspects of clinical care rather than ingestion of water. They can also include risk of inhalation of Legionella through showering or water sources. Staff and the wider public may also be a risk of exposure to Legionella from hospital water if monitoring and control measures are not robust and adequate.

154. Patients with invasive devices (vascular access devices, urinary catheters, invasive monitoring) wounds (surgical, burns), immature immune systems (for example, neonates) or any immunosuppression associated with disease or treatment (for example, oncology, cystic fibrosis, chemotherapy) are particularly vulnerable to infection.

155. There was correspondence between the Project team and IPCT in August of 2018 to advise on which areas of the new hospital would be considered ‘augmented care’. This was specific to surveillance testing requirements set out in interim HPS guidance.

156. The response provided did not include DCN as an augmented care areas because the query pre-dated the *P. aeruginosa* incident in DCN in Feb 2019. One of the actions agreed by the IMT was to include DCN in the definition of an augmented care area in light of the vulnerability of the patient group and presence of invasive monitoring devices akin to those used in a critical care area.

157. The Project team supplied the IPCT with information on water sampling on 29 April 2019. This comprised a series of individual PDF reports.

158. There was subsequently some dialogue back and forwards between IPCT and Ronnie Henderson in relation to how this data were presented, and a request to understand in more detail the actual ward locations of sample (and whether these were 'augmented care'), the numerical values (the number of colony forming units in the sample) of any 'failed' outlet and any historical data relating to testing, previous positives and evidence of consecutive sampling on completion of any corrective actions taken.

159. On 19 June 2019, Brian Currie (Project Director for RHCYP/DCN) shared a spreadsheet of water data which was discussed at NHS Lothian Water Safety Group on 20 June 2019. This group had representation from Estates, the executive Team, IPCT, Microbiology and the Authorising Engineer (Water).

160. I summarised the discussion held in response to this data in an email to Brian Currie on 27 June 2019. This set out specific questions in relation to formatting of information, the scope of sampling already completed and a request that further sampling be undertaken to provide more contemporary data. It also set out a number of actions to be taken for prospective surveillance sampling and communication with microbiology, IPCT and others to ensure any issues identified were assessed and mitigated timeously.

161. At a later date (after the opening had been delayed) the IPCT learned of the Callidus report which related to a Health & Safety review commissioned by NHS Lothian in February 2019. This report had identified concerns relating to Legionella control and made some recommendations for action.

162. Following the various communications in relation to water quality, both in person and by email, Westfield Caledonian were commissioned by NHS Lothian to carry out water sampling for *Pseudomonas aeruginosa* in augmented care areas. This took place between the 1 and 12 July 2019. Culture and reporting of water samples for Legionella takes 10 days for a final authorised result to be made available.

163. From 580 samples *Pseudomonas aeruginosa* was isolated in 56 locations, but the sampling survey did not demonstrate widespread contamination of the water system. It did highlight some contamination of parts within the water system. The findings of this report were considered by myself and Dr Donald Inverarity on the 19 July 2019 and we prepared a summary risk assessment paper for the Executive Team as part of the regular Board governance. The Authorising Engineer (Water) provided his assessment to this document on 22nd July 2019 **(A34053090 – 20190724 IPCT Response to Westfield – dated 24 July 2019 – Bundle 13 – Vol 7 – Page 144)**.

164. A report on Health and Safety compliance and assurance had also been commissioned in February of 2019 by NHS Lothian (the Callidus report) and published in May 2019. The review highlighted a number of health and safety non-conformances. This included concerns that Legionella risk assessments had not been completed and the review by Callidus in February had identified "various areas of Legionella risk" and overall, this was given a high (red) risk status in the report.

165. This report was only shared with Dr Donald Inverarity and I on 22 July 2019, but some reference had been made in passing from I think approximately mid-June 2019 onwards. This report was considered at the same meeting as the IPC review of the Westfield Caledonian report.

166. From April 2019, there was dialogue between the IPCT and Project team specifically in relation to commissioning activity and water sampling required by SHTM 04-01. For the reasons outlined above, there was insufficient information available to me or others in the IPCT to say with certainty that the hospital water system was or was not suitable for patient care.

167. In light of the ongoing IMT into infections from *Pseudomonas aeruginosa* in DCN at the Western General Hospital, we required further assurance that we were moving vulnerable patients from an area where we had both a good understanding of water quality and assurance of control measures to an area with limited understanding of water quality and limited assurance on the

adequacy of control. This would have been a retrograde step in terms of patient safety for this patient group.

168. The HAI Executive Lead, Executive Medical Director, Estates Director, RHCYP Clinical Director and Programme Director, Head of Service IPC were aware of these concerns through ongoing discussion and meetings relating to RHCYP and wider IMT/water quality issues.

169. The Authorising Engineer (Water) was also aware of discussion and contributed to the advice provided to the Project team from at least 20 June 2019 onwards.

170. I have been asked to refer to an email from me to Dr Donald Inverarity, Tracey Gillies, and George Curley of 05 July 2019 **(A40986510 – Email from Lindsay Guthrie to Donald Inverarity et al advising uncomfortable to say that the water sampling passed or imply that commissioning was fully in line with the SHTM – 5 July 2019 – Bundle 7 – Vol 1, Page126).** Within the email I state that I am "a bit uncomfortable to say that the water sampling passed or imply that commissioning was fully in line with the SHTM." I communicated this in more detail as the email was a draft response to be included as part of a formal response from NHS Lothian Chief Executive to the letter received from Malcolm Wright (Chief Executive of NHS Scotland) on 4 July 2019. I was anxious to ensure that anything we were reporting was factually accurate and could be substantiated by formal documentation or through a defined process or governance structure. I did not believe that proposed statement that "assurance sampling for commission purposes has passed" to be factually accurate based on the information available to me at 5 July 2019.

171. At this time, we had had no oversight of commissioning activity as set out in SHTM 04-01 Part A section 16 (Commissioning) whether this had successfully been completed and the Authorising Engineer (Water) had not independently reviewed this. No information had been shared with me or others in the IPCT.

172. We had not yet received the results of water sampling requested by the Water Safety Group from the discussions around 19 June 2019 meeting and at meeting of 28 June 2019. Water sampling took place 1 to 12 July 2019. The information we had was not up to date and could not be used to provide assurance of water quality,

173. None of the previous sampling results had been shared contemporaneously with Microbiology or the IPCT. Where remedial work including system disinfection had been completed following positive samples, we had no information then, or at 5 July 2019, which would allow the IPCT to confirm that the actions taken were compliant with national guidance for augmented care areas (HPS guidance), SHTM 04-01 Parts A or in line with Written Scheme of Control for Legionella.

Decision to delay opening of the Hospital.

174. The decision not to proceed with hospital opening was made by the then Cabinet Secretary on the 4 July 2019. Through attendance at the twice daily meetings held from mid June 2019 I was asked to provide a clinical IPC view on aspects of ventilation and water safety emerging from the various commissioning and validation exercises which were taking place at that time. By 1 July 2019 there was already an understanding within NHS Lothian that issues relating to ventilation in particular would almost certainly preclude the safe opening of the hospital on 9 July 2019 and that phased or partial opening was not feasible. This is because it was recognised that a paediatric hospital could not run safely without access to critical care services on the same site, and that any corrective or enhancement work undertaken within Critical Care would require the decant of patients to eliminate or mitigate any risks to patients associated with that work. This would be complex and very disruptive for patients, parents, and staff. I understand that a briefing was given to Scottish Government by the Chief Executive on 2 July 2019 to this effect. I agreed with this approach as the safest option to allow a full understanding of

all defects or non-conformances and development of detailed plans to address these.

175. At the time of the decision not to open the hospital on 4 July 2019, there was insufficient information available about water quality and water safety (and specifically in relation to DCN areas) from the ongoing water sampling, and there was further work required to address defects in DCN theatre ventilation. There was also a recognition that partial occupation of the site was not desirable from a staffing and security perspective, and that any corrective works required within the paediatric areas could impact on DCN patients. For these reasons, there was consensus that it was not feasible to move DCN services at that time.

Remedial Works

176. From June 2019, I was a core member of twice daily incident calls and a core member of the Executive Steering Group which met weekly. Along with Dr Donald Inverarity, we were responsible for providing IPC advice and risk assessment relating to emerging information from the IOM reports, and then subsequently the HFS review.

177. Initially, and before the full extent of non-conformances in the critical care ventilation system were known, I contributed to an outline HAI Scribe to support what we understood at that time to be quite limited improvement work within the existing system to be undertaken after transfer of paediatric services onto site. This was drafted on 3 July 2019.

178. In conjunction with Dr Donald Inverarity, I attended the technical design workshops and provided IPC advice and assessment of design solution for critical care. With Dr Donald Inverarity, I co-authored a number of IPC risk assessment and review of external reports received (e.g. IOM, HFS) including advice on the impact of design ventilation in managing HAI risk which included paediatric critical care **(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 – Vol 7 – Page 152).

179. I was an active participant in the design workshops which included scrutinising the technical design, technical conformance with SHTM 03-01, advising any clinical or IPC risks or considerations highlighted in guidance, IPC policy or emerging review from QEUH, development of HAI Scribes, completion of Stage 4 review.

180. In conjunction with Dr Donald Inverarity, I reviewed the commissioning and validation of the new system on completion and before patient services were transferred on site.

181. From 1 July 2019 onwards, I attended daily and weekly meetings with IHSL, Multiplex, NHS Lothian, and others to review and work through an action log for all ventilation remedial work for the RHCYP DCN building. This also included visual inspection of the air handling units, duct sections and plant room before and after the planned work. HFS were present during physical inspections.

182. I was at the residential PHE/HIS Engineering Aspects of Infection Control Course ('Falfield course') from Sunday 7 July 2019 until Friday 12 July 2019. My attendance at this course had been agreed and arranged earlier in the year and was not specifically related to events at the RHCYP. The rationale for attendance was partly in response to the increased focus of the importance of healthcare ventilation systems and their potential role in patient infections. This course was led by Dr Peter Hoffman of Public Health England (later consulted as an external expert by NHS Lothian) and Mr Malcolm Thomas (also later consulted by NHS Lothian as an external expert advisor). At this course, also attended by Sarah Jane Sutherland, Dr Michelle Etherson and Dr Jennifer Poyner (Microbiology Specialist Trainees) from NHS Lothian, we were able to raise queries in real time with these experts from regular communication by phone/email/text with Dr Donald Inverarity.

183. I was an active participant in the ventilation meetings in relation to high, medium, and low Value Change ventilation work and solutions for isolation room bypass arrangements, theatre ventilation, Emergency Department capacity to isolate and manage a child or young person with a high consequence infectious disease (for example Ebola).

184. I participated in meetings about Fire Remedial work, specifically where this impacted on ventilation arrangements and where HAI Scribe was required.

185. Towards the completion of all remedial work (medium and high value change, Critical care redesign, theatres) and prior to final handover in 2021, Dr Donald Inverarity and I reviewed and confirmed the ventilation design and performance (environmental matrix) for every clinical and non-clinical room in RHCYP/DCN building. This was supported by Graeme Greer, Ross Southwell, and Kelly Bain of Mott MacDonald. The environmental matrix detailing SHTM 03-01 or CIBSE requirements, and measured performance was confirmed line by line (supply, extract, air change rate, air pressure) for all clinical and clinical support rooms (for example sluices, offices) on the site. This process took several meetings, lasting several hours over several weeks. It was a very time-consuming process and required significant concentration. Dr Donald Inverarity and I were also heavily involved in directing and supporting the NHS Lothian COVID pandemic response from early 2020 onwards. This therefore represented a significant demand on our time and impacted on other important clinically focused work. I have been asked if I consider this a realistic or appropriate use of IPC time in future projects. I do not think this is an appropriate or effective use of clinical subject matter expert time. The principal objective in this exercise was one of confirming compliant design and validation of performance against technical guidance. It did not require specific clinical infection control skill or knowledge. The input or advice of infection prevention and control specialists should only be required if derogation from design guidance is sought or where performance is not within the expected parameters. Our role in that scenario would be to advise on any clinical infection risk associated with the issue identified. However, the input of

other staff would also be required as there may be other clinical or safety considerations (for example fire safety, health and safety)

186. I was involved in witnessing Helicopter test landings in 2020 to understand the potential impact and risk on ward areas (garden areas, opening windows and ventilation intake valves).

187. I was involved in all aspects of water remedial work, including ARJO bath decontamination, tap decontamination, water risk assessment. With Dr Donald Inverarity, I co-authored a number of risk assessments, papers and reports for the Executive Team and Oversight board.

188. In relation to all other issues my involvement with the design development of solutions is as the same process as above for critical care. I actively participated in: all the reviews of IOM reports; daily/weekly meetings to review Issues Log; reviewing the proposed design; advising on compliance with SHTM 03-01; advising on clinical risk associated with design and function; witnessing commissioning and validation and Stage 4 HAI scribe prior to transfer of patient services. With Dr Donald Inverarity, I specifically, co-authored a risk assessment in relation to air change rates and pressure differentials in the Lochranza Ward.

189. I am confident that Dr Donald Inverarity and I were asked to comment on all remedial work and that our comments and advice were acted on. I am satisfied that all remedial work undertaken was fully compliant with standards and technical guidance, noting that HFS and ARHAI (previously HPS) retained oversight and input into all of these activities either directly through attendance at meetings, or through the Scottish Government Oversight Board.

Reflections on Infection Prevention and Control (IPC) involvement

190. The IPCT comprises both IPC specialist nurses (IPCN), and Consultant Microbiologists or Consultant Clinical Scientists who provide the role of Infection Control Doctor (ICD).

191. There was opportunity for IPCN involvement throughout the initial phases of the design and construction phases of the Project. The HAI Scribe lead nurse regularly attended project meetings, and site reviews, and to the best of my knowledge, this was, on the whole, a constructive and useful working relationship over this period.

192. The advice of the IPCN was sought (and provided) on a number of specific questions during design and construction.

193. I am not wholly confident that other technical or subject matter experts e.g., the Authorising Engineers, were adequately consulted to provide specialist input into aspects of both design and derogation.

194. In my view, some of the questions posed to the HAI Scribe Nurse were not commensurate with the skill, knowledge or expertise of a registered nurse. I am confident from emails shared with me, and discussion for this and other projects that Janette Richards (latterly Rae) recognised this, and actively sought the advice of HFS Principal Architects or Engineers for technical issues in the RHCYP and other projects **(A47091311 – Email from Janette Richards to Kamil Kolodziejczyk regarding comments on Zone 2 Level 3 M&E RDD Ventilation – dated 04 June 2015 – Bundle 13 – Vol 7 – Page 156)**.

195. It is my impression that the ICD role was not explicitly considered at all stages of the Project by either the project team or others. Requests for input and advice to Consultant Microbiologists/ICDs were sporadic and often made without background information or context, which could help provide a meaningful response.

196. It is my view that some of the questions posed to the ICD would have been more readily addressed by technical/engineering experts as these relate to aspects of technical design or functionality rather than clinical risk. I am aware that the Lead ICD did suggest seeking external advice on more than one occasion.

197. I cannot say with confidence that opportunity to contribute or attend meetings equates with the opportunity to provide clinical input or advice, which was accepted by the designers, or Project team. By this I mean that in some stages of the Project, it is clear that the HAI Scribe Lead Nurse attended meetings, but it is less clear if their views or advice were always accepted and acted upon by those at the meeting. For example, this is one of the points that I highlighted to the Head of Service IPC in March 2019 in response to Brian Currie's email summarising IPC involvement in the Project. It would not be correct to equate IPC attendance at a meeting with IPCT endorsement of all actions discussed at those meetings. Please see response in paragraph 197.

198. I cannot say with confidence that advice or assessment provided by the IPCT was always documented accurately in meeting minutes or other project documentation. Please also see the email from Dr Donald Inverarity from 3 September 2019 summarising IPCT involvement in the Project specific to ventilation **(A47091306 – Email from Tracey Gillies including 6 email attachments related to HPS and PFS involvement in early stages of RHCYP – dated 03 September 2019 – Bundle 13 – Vol 7 – Page 160)**. This notes that there was a lack of clarity about the actions taken despite the documented views of the IPCT in relation to the ratio of air handling units to isolation rooms.

199. In the period up to Spring 2019, IPC input was focused solely on the practical aspects of project delivery rather than any strategic involvement with a Programme Board or other senior oversight groups.

200. I do not think there was sufficient consultation with the IPCT in the Project at the time of practical completion and Project handover. It is possible that this was because SA1 was a legal/contractual process taken for commercial reasons rather than a practical project issue which necessitated clinical IPC involvement. I have since been advised that there were significant post completion works attached to SA1 such that HAI scribe and the validation process were not possible at the time of SA1. I do not believe that the role of the IPCT is best directed towards line by line review of the Environmental

Matrix in any stage of the Project. In line with sections 1.11 and 1.12 of SHFN 30 Part B October 2014, the identification of risk relies on a multi-professional team with the necessary skills and a background understanding of the principles of prevention and control of infection in the built healthcare environment. The provision of a compliant design brief and being able to demonstrate due diligence in decision making is a Project team responsibility. The IPCT have a role to play as expert advisors on aspects of clinical infection risk associated with design, and not as compliance officers to confirm that a compliant design has been achieved.

201. However, it is my view that inclusion of (consultation with) the IPCT at this stage would be in line with roles and responsibilities of the IPCT in the Project as set out in SHFN 30 Part B section 2.9. A contemporary risk assessment and input of IPCT advising on aspects of clinical risk associated with known defects or non-conformances in the RHCYP Project, the potential parallels with the QUEH Project and acknowledging the unavailability of up to date commissioning and validation information did not take place until June 2019, some four or five months after Project handover. From an HAI Scribe stage 4 perspective (Pre-Handover check) historical information or assessments would not be considered valid if further construction, rectification or modification had subsequently taken place.

202. I am confident that the IPCT were given sufficient opportunity to be involved in the review of emerging information relating to the building and critical systems from late Spring 2019 until the building fully occupied in 2022.

203. We met on a daily, weekly and monthly basis with members of IHSL, Bouygues, external expert advisors, NHS Lothian clinical leads and Executive management. We also spoke frequently with representatives of HFS and ARHAI.

204. IPC used opportunities as much as possible, however the ability to engage in active discussion and design review, and attend meetings, during the pre-June 2019 period was to some extent limited by the capacity of one Whole

Time Equivalent (WTE) nurse (Janette Rae) to support multiple capital projects (HAI Scribe Lead Adviser).

205. The HAI Scribe Lead Adviser's remit included two new hospital construction projects (East Lothian Community Hospital and RHCYP/DCN) in 2017/2018. Janette also retained a small clinical remit for infection prevention and control to ensure that she could remain current in her specialist clinical skills and knowledge and adequately meet professional revalidation requirements so her actual available time for HAI Scribe work was around 0.8 WTE. I think that support for the RHCYP project was achievable within the available capacity of the post holder. I do not think that a single post holder with 0.8 WTE capacity was sufficient to support multiple capital projects including major the construction of East Lothian Community Hospital as well as a range of other major and medium size refurbishment projects. Single post holders also represent a business resilience and continuity risk (single point of failure risk).

206. Where ICD or microbiologist input was sought, their capacity to attend meetings or respond to queries was also likely limited by the capacity in their job plans and clinical workload at the time. Reviewing project documents, architectural plans, meeting minutes, and other project documents is time consuming and requires concentration. Where specific questions or issues were raised, the IPC took time through direct discussion and email to contribute or advise. I have been asked if I think there are advantages to having project input from ICD who concurrently hold a clinical workload versus an external ICD, or one who does not have a clinical workload. The purpose (currently) of the ICD input is to provide commentary on the clinical infection risk associated with the functionality of systems within the built environment. This is achieved by applying their specialist knowledge of microbiology and the reservoirs, virulence, transmission routes for a wide range of organisms, and the presentation, diagnosis, and treatment of infection. Not all ICD are medical doctors. Some are Consultant Clinical Scientists, who are specialists in clinical diagnostics and clinical infection management but will not have held direct patient care roles. Both Consultant Microbiologists and Consultant Clinical Scientists can provide specialist clinical microbiology advice in relation

to the clinical risk of infection associated with organisms which may be present in the healthcare environment.

207. However, to the best of my knowledge, environmental or Public Health microbiology is not a core component of a clinical microbiologist, or currently, the combined infection training. Environmental microbiology is a specialist area of practice in its own right, similar to Food Microbiology or Veterinary Microbiology for example. A Microbiologist with specialist training in environmental or public health microbiology may be able to offer a different and more comprehensive view on the hazards and risks associated with specific environmental organisms which may not frequently be encountered by clinical microbiologists and IPCT.

208. Currently, specific training on aspects of ventilation, water microbiology or engineering design or construction (for example) are not core components of the infection specialty training. Concurrent clinical workload is therefore not wholly relevant to the expertise required to advise on these aspects of hospital design or function. Therefore, there could be no barrier or disadvantage to having an external Consultant Microbiologist (not ICD) who has the requisite qualifications, training, and competence to advise on aspects of infection hazard and risk associated with building or critical service design providing advice to a design and construction project. I would not view this role as materially different to that of an Authorising Engineer (Ventilation) or a mechanical ventilation design engineer contracted to provide specialist skills and input to key stages in the Project. The disadvantage of such a role may be in relation to incomplete understanding and accessing local context, contacts, systems and processes (for example laboratory records). I am not clear how a microbiologist could hold an ICD role without other clinical duties. It is my understanding that to demonstrate ongoing clinical competence/revalidation for professional registration there would have to be clinical sessions allocated in their job plans.

209. In my view, the IPCT should have been actively consulted leading up to, and at the time of Project handover in terms of SA1 in February 2019. This

appears to have been a critical time in the Project where assessment of clinical and infection control risk could have been strengthened. I would advise SHTM 03-01 compliance during design and construction, however, given that the ventilation system had already been installed in February 2019, had I been consulted at this time on this specific issue, I would likely have agreed to derogation from 6 ac/hr to 4 ac/hr in general ward environments on the basis mechanical ventilation was superior to the ventilation provided in existing RHSC; scale, cost and disruption to rectify this post construction; the paucity of evidence for 6 versus 4 ac/hr and that compliant PPVL isolation rooms were provided for source and protective isolation of infectious/high risk children and young people.

210. I also think that the roles of the IPCN and ICD could have been more explicitly considered as this may have brought different, but highly complementary expertise to the Project. By this, I think that the mechanism to consult with the ICD was through the HAI Scribe Lead Nurse, rather than directly from the Project team. A more formal recognition of the different roles that the IPCN and ICD/Microbiologist have particularly in relation to SHTM 03-01 and SHTM 04-01 would have been helpful as well as a clear and consistent approach of involving the ICD at key stages in the Project. This aligns the ethos of engaging the Infection Control Team as per SHTFN 30 Part B and with section 6.6 of SHTM 04-01 Water safety for healthcare premises Part B: Operational management and section 2.11 of SHTM 03-01 Part B: Ventilation for healthcare premises: Operational management and performance verification.

211. I think IPC involvement was valued to some extent during the Project design and construction. Where the IPC advice or approach did not concur with the wider project or clinical team position or created a perceived challenge to project cost or timeline, it is my perception that the IPC involvement was then sometimes viewed as disruptive or unhelpful and was on occasion disregarded.

212. For example, a concern was raised by the IPCT in August 2016 with regards the AHU design for isolation rooms and specifically the impact for paediatric oncology (Lochranza ward). The SBAR report produced by Janette Rae at the time outlined (correctly) the expected SHTM 03-01 specification for isolation room air change rate and pressure differential. It went on to highlight the IPCT had concerns about multiple isolation rooms in paediatric cancer services being served off a single AHU.

213. The SBAR notes the design proposal was based on cost and lack of space, and a concern raised from the construction team that "the IPCT will change their requirements". The meeting where this issue was being considered was attended by design and project staff and the then Authorised Engineer (Ventilation).

214. The issue of technical compliance or optimal design (an AHU for each isolation room) should be considered by the technical experts and the Project team as a whole. The issue of clinical suitability and clinical infection risk is something that both the clinical team and the IPCT would specifically comment on (i.e., resilience for maintenance, impact on patient source isolation, loss of protective isolation for vulnerable children). The design 'requirements' therefore were not specified by IPCT, they were specified by SHTM 03-01. The implications for clinical risk were:

    - The SBAR suggests to me that there was a failure of both the Project and construction team to acknowledge or recognise the wider aspects of clinical risk associated with the solution.

    - The SBAR makes clear that collectively; the IPCT did not find the proposal acceptable and requested this point be accurately minuted in project records having already been raised at the previous meeting.

215. Although Janette Richards (latterly Rae) was noted as in attendance at a meeting to discuss ventilation design with IHSL, Multiplex and members of the NHS Lothian Project team on 14 September 2016 (shortly after the SBAR on

the Isolation Room AHU proposal was circulated) and at a follow up meeting on 3 November 2016 (**A47086951 –IHS Lothian Meeting RHSC DCN Isolation Rooms– dated 03 November 2016 – Bundle 13 – Vol 7 – Page 43)**, no contribution from her and no consideration or record of discussion on any aspect of clinical risk or risk assessment is recorded in the meetings. No other clinical staff were present at that meeting, though I note the AE for ventilation, John Reiner, was present. Janette was a confident and experienced IPC nurse who was never reticent in actively contributing to discussion or to provide challenge in a situation where she perceived there to be a clinical infection risk. Despite her regular attendance at meetings, there is limited documented evidence in minutes of her contribution on this matter.

216. A further example of this was the ongoing dialogue about Computerised Tomography (CT) scanner room air change rate specification in 2018, with clinical members of the Project team continuing to challenge the IPC view, which had already been supported by HFS in writing and shared with members of these teams.

217. Janette escalated both of these issues to myself and Dr Donald Inverarity, and we supported her position, confirming this to the Project team. Whilst this demonstrates that the local escalation, oversight and governance arrangements for the IPCT was in the whole working satisfactorily, our endorsement of Janette's advice did not necessarily influence the outcome of the discussion so not necessarily effective as part of a process to provide assurance. The CT room ventilation specification was resolved in line with HFS and IPCT advice. The advice regards provision of multiple isolation rooms from a single air handling unit was not.

218. During the latter part of 2018, and between January and early June 2019 there appeared to be a lack of understanding or willingness by the Project Team to engage effectively with the IPCT and provide information and commissioning data requested by us as in the context of the emerging concerns from QEUH and as part of project completion and 'sign off' of the

HAI Stage 4 Scribe. No specific rationale was provided by the Project team for not providing or being able to provide some of this information.

219. These requests were not spurious but based on best practice or requirements of various technical documents including SHTM 04-01 and SHTM 03-01. The information requested was to evidence and provide assurance that there were no clinical or IPC risks associated with the design or construction of the hospital, particularly with reference to water and ventilation systems, and ultimately the Board could be fully assured by the Project team (including IPCT) that the building was safe and ready for occupation.

220. It was my impression that because of repeated delays in bringing the Project to completion, the Project team were perhaps frustrated by the questions and challenges we were raising and perceived these to be a possible threat and further delay to successful migration of patient services.

221. When the new HAI Scribe Lead Nurse took up post in January 2019 and requested to meet with members of the Project team to go over or update room reviews this request was met with a certain level of resistance by Janice Mackenzie, Ronnie Henderson, and Dorothy Hanley. The Project team were adamant in discussion with Sarah Sutherland that this work was already completed and ‘signed off’ by Janette Rae and did not need to be repeated. No HAI Stage 4 scribes had been completed by the end of December 2018 and was advised as incomplete in discussion with Janette Rae at the time of her retiral.

222. Quite aside from the need to ensure that the IPCN with primary responsibility for the Project had opportunity to familiarise herself with the design and building, it was important that the Stage 4 HAI Scribe reflected a contemporaneous assessment of fittings, function and finish. Sarah Jane Sutherland was still within a familiarisation/development period in her new role between January and April 2019. In this period, I was very conscious of environmental hazards and risks associated with the QEUH Project, our own experience of incidents at both Western General Hospital and Royal Infirmary

of Edinburgh which had a proven or potential environmental component, and the increased scrutiny on all matters relating to water, ventilation and IPC in the built environment by HPS, HFS and Scottish Government. For these reasons, Sarah Jane Sutherland worked with less autonomy in this period than Janette Rae may have done, and Dr Donald Inverarity and I took a more active role in support of Sarah and seeking information from the Project team.

223. It's not clear if the Project team recognised that ongoing construction on site over 2018 and early 2019 and action taken in response to other problems that had transpired over this time (for example the flood in 2018) impacted on the IPC assessment of risk and in being able to provide assurance/'sign off' to that effect in the HAI Scribe stage 4.

224. It is also not clear that there was recognition or acknowledgement of the wider context the IPCT and NHS Lothian found themselves at the time.

225. Issues and concerns relating to the QEUH including quality of design and construction, and possible patient infections were known to the Project team (Brian Currie provided a response to a media request in March 2019 (see paragraph 68) re this but there appeared to be some disconnect that this should prompt actively checking and confirmation that similar issues were not likely to be found at RHCYP/DCN. Much of the information that would allow us to do this would have been contained in the commissioning data we were already requesting, and this point was reiterated by myself and Dr Donald Inverarity to individuals and collective members of the Project team several times.

226. We also highlighted through our discussions and the ongoing incidents at Western General Hospital and Royal Infirmary of Edinburgh which we were managing concurrently with input from the Executive Medical and Nurse Directors. These had highlighted that the hospital-built environment, particularly that mechanical ventilation and hospital water systems were critical aspects of a safe patient environment. Having visibility of water sampling results which were presented in a way which allowed full oversight

of sampling locations, historical results and numerical values of ‘failed’ water tests were crucial to informing a risk assessment and immediate actions.

227. I have been asked if the Critical Care issue could have been avoided had been more involved at any particular stage of the Project. Assuming this refers to the non-compliant design to provide 4 air change/hr rather than 10ac/hr. To the best of my knowledge, the IPCT were not aware at any stage of design, construction or handover up to the point of the IOM reports were received on 2nd July 2019 that there was any non-conformance with critical care ventilation. There was regular IPC attendance at Project meetings and support provided throughout the period from 2014 until and inclusive of SA1. When asked to provide a view on ventilation design, the IPCT advice was to follow SHTM 03-01 Part A. I therefore don’t think that the IPCT could have influenced this matter by further consultation or offering different advice. We were not able to influence the issue because we were not aware of it in the first place.

228. The issues in critical care appear to relate to the process for design approval, consultation, communication, and derogation rather than a lack of IPC involvement. As far as I’m aware, the Project team were not aware of the any non-conformance within critical care prior to the involvement of IOM.

229. The first time I was made aware of derogation in air change rates for 4 bedded areas from 6ac/hr to 4ach/r (which I took to mean general wards) was in a response provided to a freedom of information request passed to IPCT in April 2018 from the Project lead. At that time, I could find no other information providing background, rationale or evidence to support this derogation or records that it had been discussed with Janette Rae as the HAI Scribe lead nurse.

230. From that communication, it was my impression that the decision to proceed on with 4 air changes in 14 x multi bed wards had already been made. I am not clear what, if any, discussion had taken place with IPCT in the preceding period.

231. The only other point that IPCT were asked to comment on in general wards related to room pressure rather than air change rates for 4 bedded rooms. A need to clarify the exact location or intended clinical purpose in these areas was highlighted to the Project team, but I am not aware that this additional information was shared with IPCT.

232. The next time I was aware that 4 bed and single room ventilation was non-compliant with SHTM 03-01 in terms of 6ac/hr to 4ac/hr was in an email thread from Brian Currie in March 2019 (see paragraph 68). This was after project handover in terms of SA1 but before completion of the post completion works, HAI Scribe stage 4 reviews and patient occupation. The exact location of these 4 bed and single rooms was again not made clear to IPCT at that time but I assumed it was in general wards rather than critical care given the starting point of 6ac/hr. Please see paragraph 138 in relation to IPC involvement at SA1.

233. To the best of my knowledge there was no direct discussion with the IPCT that I was aware of, or documentation shared with us which advised that a derogation for ventilation design in Lochranza was proposed other than the issue relating to the provision of up to 5 isolation rooms from a single air handling unit as outlined above. It was our assumption that this ward would meet ventilation design specification for a ‘Neutropenic patient ward’ as per SHTM 03-01 Part A Appendix 1 in the absence of any information provided to the contrary.

234. In all the correspondence, I was copied into, or had access to after Janette Rae retired, I am confident that the IPCT advice over the lifetime of the Project was that compliance with SHTM 03-01 Appendix 1 should be met. This is evidenced by correspondence with HPS and HFS about CT scanning rooms, and concerns raised regarding isolation room AHU provision.

235. I was not aware until 5 June 2019, when Janice Mackenzie shared the Residual Risk Log from project handover, that ventilation (“air pressure and

air change rates for neutropenic patients") in Lochranza had not been provided in line with SHTM 03-01.

236. From around the summer of 2019 onwards when myself and Dr Donald Inverarity became more involved in the Project, there was more oversight and a more detailed understanding on the part of IPC of the design, condition and performance of the building systems installed there was a robust, systematic and comprehensive risk assessment of both technical issues and solutions, and the impact on patient safety and clinical care. This included but was not limited to consideration of infection control risk associated with the built environment and clinical care.

237. The scale of work required to achieve compliant and suitable critical ventilation systems would not have been achievable in a fully occupied and operational hospital.

Role of Infection Prevention and Control (IPC) in future projects

238. I have been asked how IPC involvement be improved and encouraged for future projects for the build of healthcare environments. In order to answer this question, it is important to set out the context of the current workload and workforce capacity & capability of IPCTs across NHS Scotland.

239. There are already insufficient numbers of qualified IPCN and ICD to meet the demand of existing (pre pandemic) clinical work and priorities, and the workforce has already been required to absorb significant and enduring workload associated with the healthcare-built environment. Most if not all Territorial Boards have vacancies for both IPC nurses and microbiologists.

240. The workload demand from the built environment is not solely restricted to new build projects. IPCT are required by National Infection Prevention and Control policy to lead and/or actively support incident and outbreak investigation and management relating to water quality issues, infections with

potential environmental links, and any potential ‘exposure’ or near miss event. These form part of the day-to-day workload of IPCT, are frequently complex and time consuming to manage.

241. The HAI Scribe process extends to all planned and unplanned estates work from simple repairs (for example, repairing a floor, sink replacement) to extensive refurbishment or reprovision. IPCNs and ICDs are regularly involved in assessing risk and advising on mitigation and risk control relating to remedial and planned work in the healthcare-built environment. Most, but not all, of this work will be carried out in or adjacent to areas being actively used for clinical care or other critical clinical services (such as sterile instrument reprocessing). This also requires an element of ongoing ‘site’ review of control measures to provide assurance & mitigation of risk (for example, confirming presence and integrity of dust control barriers). Control measures and frequency of review correlates to the level of patient risk areas.

242. It is normal for IPCT in a large Board to have multiple HAI Scribe works in progress at any one time. This work is time consuming (high volume of work, variable complexity, ongoing follow up).

243. There is also an emerging and increasing demand from health and social care providers such as GP and Primary care providers to support both incident management and building/infrastructure improvement.

244. Concurrently, there has been the exponential & material change in the expected role of the IPCT in relation to all aspects of the built environment, specifically technical aspects of building design, water, ventilation drainage, medical gas and electrical systems over the past few years as part of normal service delivery and operational management. This workload has increased following the issues identified at the QEUH and RHCYP building projects and the creation of NHS Scotland Assure.

245. No additional resource or funding has been provided to support any new or additional IPC workload.

246. During the COVID Pandemic, and as part of wider IPC workforce review, IPCTs have been asked to pick up clinical IPC support for adult Care Homes. Additional funding and resource was provided by Scottish Government to deliver this, but there has been limited success to date in recruiting to a permanent specialist workforce.

247. The COVID pandemic has also highlighted a number of gaps across non-hospital healthcare settings and disciplines where IPC clinical support and expertise would be required or desirable. These additional demands have not been met in full and no additional resource has been identified to deliver against additional workload identified. I do not believe that the level of IPCN or ICD involvement in building projects now expected by NHS Scotland Assure, and therefore by default, territorial NHS Boards can be met from existing workforce without additional funding and resource allocation. This includes not only funding for additional posts, but also to cover additional costs associated with academic and subject specific training required to develop and demonstrate competence in this area.

248. NHS Scotland Assure advised NHS Boards on a number of occasions in 2022 at Key Stage Assurance Review (KSAR) feedback or learning events that they did not consider that a single post holder has sufficient capacity to provide IPC project support across multiple projects. They advised one dedicated WTE (or near to) IPCN should be assigned for each project. No specific guidance has been provided on the expected ICD resource to support these types of projects. Currently KSAR reviews are only conducted in new construction or major refurbishment projects. The reference to WTE capacity required is therefore specific to this type of large scale project. KSAR workbooks do not specify the allocation of IPC resource required **(A47091308 – Quality in the Healthcare Built Environment Compliance Service– dated 02 December 2022 – Bundle 13 – Vol 7 – Page 230)**.

249. IPCT are unable to meet this expectation given the current workforce challenges as outlined above. This is a further and very significant demand on

a small, and dwindling workforce. Allocation of the limited qualified IPCN and ICD resource at Board level to support building projects available means that aspects of essential clinical work will not be met.

250. NHS Scotland Assure require as part of the KSAR review process that IPCT should provide the evidence or assurance of “necessary expertise and leadership, skills, knowledge and experience” in supporting capital projects. However, no definition of the skill, knowledge or experience has been defined by either NHS Scotland Assure or NHS Education for Scotland (NES). NES published a Healthcare Built Environment Knowledge and Skills framework in 2022 **(A47091310 – NHS Preventing and reducing infection and other risks in the healthcare built environment – dated 02 December 2022 – Bundle 13 – Vol 7 – Page 248)**. I developed a local implementation plan in response to this document. NES have endorsed this as an example of good practice. The NES framework highlights that academic qualification or formal training in relevant topics alone (for example, ventilation) is not the only skill or competence required to support complex projects. It also sets out expectations for competencies in leadership, risk identification and risk management and aspects of accountability and governance.

251. Aspects of plumbing, engineering, building design and construction do not form part of undergraduate nursing or medical studies. Outside of a general awareness and understanding of mandatory policy and technical guidance, these do not currently explicitly form part of IPC specialist postgraduate education or training. From a workforce development and resilience perspective, the priority is to have staff complete the core clinical IPC qualification and consolidate this learning into practice.

252. Therefore, the expertise, skill, leadership and experience to support complex projects cannot be provided by new or relatively inexperienced IPCNs. These skills and knowledge will take time to develop. For qualified IPCN, there will be further consolidation, development and learning required to provide sufficient capacity and resilience within Board IPC teams to support large scale or complex projects.

253. IPCN and ICDs have historically used their knowledge of microbiology, clinical procedures, healthcare processes, published evidence and peer reviewed articles to inform clinical infection risk assessment relating to the healthcare environment. Knowledge and understanding of various SHTM and other technical guidance was gained ‘on the job’ and through self-directed learning.

254. Commentary or advice relating to technical design, engineering systems or functionality has always been out of scope for the IPCT role. This was, and should continue to be a responsibility for Authorised Engineers and other suitably qualified and experienced technical experts.

255. A small number of accredited courses are available for Healthcare Engineering and Infection Control in the Built environment (which includes aspects of hospital design and water safety). Places on these courses are limited. Some are residential. All are relatively expensive (£560 to £1,800 each (excluding travel and other expenses)).

256. No additional financial uplift has been provided to NHS Boards to support continuing learning and development in this field. These additional costs have been absorbed from within existing budgets at present, often offset against staff vacancies.

257. NHS Education for Scotland (NES) have been commissioned to develop education and training resources to support IPCT but these are not due for delivery until 2024.

258. There is growing concern amongst many IPCN that the current expectation from NHS Boards, NHS Scotland Assure and Scottish Government in relation to the IPC role and the built environment conflicts with Nursing and Midwifery Council (NMC) Code of Practice in the absence of additional education training or development. The NMC code of practice requires that individuals have, and are supported to, “maintain the knowledge and skills you need for

safe and effective practice". All registered nurses must "Recognise and work within the limits of your competence".

259. Scottish Government published an IPC workforce strategic plan in December 2022. This document highlights the existing crisis in IPC workforce capacity and sets out strategic aims to develop workforce, improve recruitment, development retention and succession planning for IPC specialists. This strategic plan does propose the creation of new non-clinical specialist posts (for example, healthcare scientists) to support healthcare built environment projects. This is an area which warrants further consideration.

260. The current focus on IPC and the expectation of the role for the built environment has been raised during staff meetings, appraisal and exit interviews as a role that IPC nurses are not comfortable to undertake as it does not readily align to their clinical or specialist training or experience, is cited as a reason for IPCNs leaving the speciality or for not wishing to pursue promoted posts.

261. At present, and following the QEUH and RHCYP, issues and inception of NHS Scotland Assure, Board IPCTs are increasingly being asked to attend lengthy meetings to review and confirm standard information or design specification in the absence of derogation from published design guidance and where there is little or no discernible impact on infection prevention and control, for example room data sheet reviews. This has a significant impact on ability to meet other clinical workload needs.

262. Significant amount of specialist IPCT time is currently spent reinforcing information, which is already provided in extant guidance (for example SHFN 30 Part A or SHTM 04-01) and requires little or no subject matter interpretation to apply as part of a compliant design.

263. The input and expertise of Authorising Engineers and other technical or subject matter advisors on matters of technical design, specification or functionality could be more effectively utilised.

264. Basic IPC considerations could be more effectively considered in construction projects if design and project teams had better education, information, design or technical guidance, which includes many of the fundamental elements of IPC. In this way, a wider range of staff would be able to ensure that IPC requirements were already being reflected in these processes.

265. I believe that IPCTs are increasingly being used as quality control officers within projects, with an expectation of attendance at arbitrary meetings to satisfy an NHS Scotland Assure defined process.

266. More effective use of expert IPC advisors could be achieved if there was a greater focus and definition of when IPC input is rather than expecting default contribution in all aspects at all stages of the Project. IPC advisors can advise on clinical infection risks but are not necessarily best placed to advise on infection risks associated with technical aspects of design. Therefore, asking IPCN or ICD to advise or endorse a specific technical design is not commensurate with their skill knowledge or training, and therefore not the best use of their (limited) time. Questions may arise because of an absence of, or gap or conflict in, existing design or technical guidance, or as part of a necessary or desirable derogation from guidance. In these scenarios a multiprofessional risk assessment which includes specialist IPC subject matter input is required to understand potential microbiological or clinical hazards or risks for patients, staff or the wider public. I would anticipate that IPC experts at NHS Scotland Assure could take a more active role in providing specialist advice in these types of scenarios.

267. It would also be helpful to define the roles of IPCNs and ICDs in building projects. Although these are complementary roles, these staff have different training, experience, skill, and roles, which are not always interchangeable as 'IPCT'. In many situations the input of both professionals is desirable. Nurses selecting IPC as a career option will often come to this with (and are encouraged to have) many years of post-registration clinical practice which may include providing nursing care in one or more highly specialist areas (for

example critical care, theatres, acute medicine) or gaining dual registration as in both adult nursing and other branches of nursing or midwifery for example mental health, paediatric nursing). Some will come with experience of managing a ward or department which includes staff and budgetary management. Nurses will usually bring practical experience of working with a wide range of different functions and teams across the whole healthcare system (for example liaising with Estates teams to for reactive maintenance, procurement of clinical supplies, quality assuring environmental cleaning activities). Nursing staff employed as IPCNs are required to complete a specialist qualification specifically in Infection Prevention and Control (master's level) in addition to role specific training completed on the job. Medical staff will have completed foundation and core medical training, working with across a range of general or specialist clinical areas and with a wide range of other clinical disciplines (physiotherapists, pharmacists etc). They will then complete a specialty training programme in medical microbiology or combined infection training (since 2015). Specialty infection programmes focus on laboratory and clinical aspects of microbiology and infection treatment. Infection prevention and control is only one relatively small part of this programme.

NHS Scotland Assure

268. I have been asked if NHS Scotland Assure and corresponding Key Stage Assurance reviews will assist in involving IPC in new builds of healthcare environments. I think these new processes will provide limited benefit for Board level IPC teams based on the current approach.

269. The KSAR review process has primarily added a layer of external scrutiny over projects although we have been advised NHS Scotland Assure do not have a formal scrutiny function.

270. The scope of IPC 'involvement' has become too wide and lacking in definition or purpose. As outlined above, the attendance of IPC at meetings and IPC review of project documentation is now expected at all stages of the process even where there is no clearly defined need or benefit in doing so. This detracts from capacity to deliver other clinically relevant or important areas of work for Microbiology and IPC teams.

271. There appears to be limited stratification by risk of the methodology advised for projects. Whilst the scope of KSAR review is limited to new build/major construction projects at present, the methodology could in the future be applied to all capital projects– for example infrastructure work, or new health centres. The Scottish Government IPC workforce plan currently proposes an expansion of IPC remit across care homes and social care. It is not clear if other premises such as local authority education and health hubs, care homes, day centres will be expected to follow NHS Guidance or NHS Assure processes. The potential hazards and risks to patients or service users from the health or social care environments are not uniform. The need for input from IPC is not equal across all projects.

272. It is not clear why some aspects of the quality assurance or quality control of new build design or construction should focus on IPC review rather than a technical compliance review and build quality review process, that is, building control rather than infection control process.

273. I am concerned that these new processes have simply created an unrealistic workload demand on board IPCTs which is not matched with capacity or capability. In larger Boards like NHS Lothian, where there may be multiple capital projects running in parallel, there is a risk that the NHS Scotland Assure processes are in effect setting Boards up for failure from the outset if successful completion of the KSAR process is contingent on IPC input at all stages and in all projects.

274. There was no effective consultation with either the Infection Control Managers Network, ICD network or through Board Capital Planning teams or Chief Executives prior to the launch of the KSAR review. I raised this, and a number of other concerns and observations about the proposed process in an internal communication to members of the NHS Lothian Executive team on 16 March 2022 **(A47091312 – Email regarding NHS Assure key stage assurance review – dated 16 March 2022 – Bundle 13 – Vol 7 – Page 319)** and **(A47091307 – Email from Ian Graham to Lindsay Guthrie regarding NHS Assure - Key Stage Assurance review – dated 17 June 2022 – Bundle 13 – Vol 7 – Page 327)**. Since the launch of the KSAR review process, NHS Scotland Assure have run a number of engagement events. I raised the concerns outlined in my email at the events I attended. I have highlighted the current gaps in IPC training and competence my service currently has through the application of the NES Built Environment Knowledge and Skills Framework.

275. I believe that currently, there would be a greater value in NHS Scotland Assure updating or producing new and comprehensive technical and design standards for the NHS and addressing known gaps or inconsistencies in guidance. This would have a positive impact on improving safe design and may obviate the need for local risk assessment and solution generation where evidence of guidance is lacking.

276. Where there are complex technical and IPC questions, these could be answered by the NHS Scotland Assure expert advisors, and a ‘bank’ of

answers maintained to ensure a consistent response on the same/similar questions across all Health Boards. Currently, these assessments appear to sit with multiple IPC teams with varying levels of expert knowledge and experience in the built environment, so there will be variation and lack of consistency in approach at Health Board level. To date, the benefit of having expert IPC advisors within NHS Assure has yielded limited benefit for Board IPCT or Project Teams in response to questions generated by live projects.

277. I agree there is a need for more research and evidence to inform our understanding of environmental hazards in the healthcare-built environment. Many of the standards where non-compliance has created an 'infection control concern' – for example nominal derogation of 6 air changes to 4 mechanical air changes in a general ward, are not necessarily based on robust evidence or scientific data. As written, the ventilation strategy of 4 air changes (mechanical) and 2 air changes (natural) in general ward and Lochranza ward single rooms was compliant with SHTM 03-01 Part A Appendix 1. In relation to Critical Care and other high risk clinical areas, there is scientific plausibility that an increased mechanical (consistent and reliable) rate of air change rate dilution and extraction, in conjunction with the controls on directional air flow will more effectively assist the containment of transmissible infection, for example respiratory viruses, and safe management of aerosol generating procedures. The risks to patients, staff and the wider public associated with sub optimal ventilation in these settings is not uniform.

278. We are all exposed to a wide range of organisms in water, air, and the environment where we live, socialise and work every day. When these organisms are isolated in the water, air or the wider environment in healthcare buildings the clinical significance and risk associated with these findings may be uncertain. Where these organisms are isolated from clinical samples it can be challenging to establish definitively if the source exposure is from the healthcare environment or not. Many of these organisms have long incubation periods which mean that standard Healthcare Associated Infection (HAI) surveillance definitions for hospital acquisition are difficult to meaningfully apply (usually a HAI is one which presents or is diagnosed >48 hours after

admission to hospital).There are no accredited laboratory sampling methodologies available for environmental sampling, and many NHS board microbiology laboratories do not have the facilities or environmental/public health microbiology expertise to process environmental samples. Therefore, independent laboratory environmental sample results may have to be interpreted against NHS Board laboratory clinical results with caution. There is currently no clinical guidance provided on how to interpret the clinical significance of finding some/many of these organisms in water, safe parameters, or actions required should specific organisms be identified in water or other water system samples.

279. I think the definitions and criteria for where expert IPC involvement is necessary and useful needs to be stratified to define clearly where the responsibilities for non IPC staff lie in ensuring generic principles of infection prevention and control are applied to project decision making, design and construction, as regards the need for clinical IPC experts to advise on the specific aspects of hospital design, performance or maintenance which may impact on the risk of proliferation or exposure to harmful pathogens and the risk of infection transmission.

280. Priority should be given to update and address the known existing gaps and inconsistencies in technical and design guidance. This would be a role for national experts such as NHS Scotland Assure. The availability of high quality, consistent and evidence-based guidance would assist design teams, engineers, and project teams to ensure design and construction addressed and mitigated for many IPC risks.

281. Given the current challenges around IPC expert capacity and capability, there are economies of scale, which could be achieved by having NHS Scotland Assure, National Procurement, HFS and ARHAI as national advisors providing advice on a single exemplar design specification for hospital new build projects. For example, several NHS Health Boards are building new National Treatment Centres, which will all treat elective day case patients and short stay surgical patients. It appears illogical and inefficient to have each

Board develop and have approved through NHS Assure KSAR review processes a safe and compliant design and technical specification which requires the input of individual Board IPCT and different design, engineering and construction teams.

282. I am unclear why ventilation or water systems design and procurement would not be subject to national procurement assessment and contract. The design specification and performance criteria could be assessed and verified as part of a national contract award. Similarly, assessment criteria for competent designers and building contractors should be developed and provided at a national level. I am not clear what skill, knowledge or competence would be required by (or would be available from) staff at Board level to assess and endorse this level of contractor competence. As a registered nurse and clinical IPC expert, I do not believe this is within my existing skill, knowledge, or competence to advise.

Reflections

283. To the best of my knowledge, the hospital was safe to accept patients at each of its eventual phased openings. From March 2021, I considered the hospital to be safe to accept patients. This was based on the extensive and detailed review of all aspects of the built environment including critical systems (water, ventilation, electrical, drainage, fire) and the fit and finish to the standard defined in SHFN30 Part A.

284. Independent commissioning was completed, reports were shared and reviewed in considerable detail by the IPCT, clinical, project and technical advisors. HAI Scribe stage 4 reviews were completed and signed off by all core participants. The actions taken by NHS Lothian were scrutinised in detail by HPS (ARHAI), HFS and the Scottish Government's Oversight Board.

Declaration

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.