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

Bundle 21 – Volume 6

Direction 5 Process Questionnaires

SCOTTISH HOSPITALS INQUIRY

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Direction 5 Questions for Independent Expert Witnesses

25 June 2024

Dear Dr Walker,

On 21 January 2024 you produced a report for the Inquiry. This has been made available to Core Participants (CPs). On 13 December 2023 the Chair issued Direction 5 which set out at Appendix B a system by which CPs would be permitted to raise lines of questioning or questions with you and the other independent witnesses before the commencement of the Glasgow III hearing.

The CPs were told that within five weeks of the date upon which the Inquiry Team provided your report to them any CP who wished to propose questions for you about your report or to make comment on that report must send a note to the Secretary to the Inquiry setting out in concise numbered paragraphs with clear reference to the relevant parts of the report:

1. the specific questions that should be asked of the report's author and any comment that the CP wishes to make on the substance of the report;

2. whether these questions and/or comment will raise new matters or issues not covered in the report; or

3. where no new matters or issues are likely to be raised, reasons why the issue should be raised with the expert witness at that time.

The Inquiry Team has considered the responses received in respect of your report and consolidated them into 15 questions. These questions are set out in the Appendix to this letter. Please provide a supplementary report to the Inquiry Team as soon as possible and by 16 July 2024 at the latest in the form of concise answers to these questions. Your response will then be provided to CPs before the start of the Glasgow III hearing in the week of 19 August 2024.

Given the involvement of the counsel team in the hearing that deadline of 16 July 2024 cannot be extended.

Yours sincerely

Brandon Nolan
Solicitor to the Inquiry

Appendix

Supplementary Report by Dr James Walker for the Scottish Hospitals Inquiry

I have been asked a series of questions by the Inquiry Team and have been asked to respond to each question in turn.

1. Horne Taps: events prior to the decision to install, retain and maintain
Your report was concerned with events from point of occupancy in 2015, until 2023. However the Inquiry is aware that you had some involvement in the process, prior to those dates, by which Horne Optitherm Taps came to be present in the hospital from point of occupancy. In particular, you attended a meeting in June 2014 which resulted in the decision to retain these taps.

Please comment on the following events as having a material bearing on the decision to install, retain and maintain these taps:

- **Declaration of an outbreak of pseudomonas aeruginosa at the neonatal unit at Altnagelvin Hospital, Londonderry on 12 December 2011;**
- **Declaration of an outbreak of pseudomonas aeruginosa at the RJMS neonatal unit in Belfast on 17 January 2012;**
- **Linking of strain of pseudomonas aeruginosa between RJMS and a case in Craigavon Hospital;**
- **Presence of pseudomonas in other neonatal units in Northern Ireland between 17 and 31 January 2012;**
- **Request on 30 January 2012 by Minister for Health, Social Services and Public Safety to RIQA to establish an independent review into these incidents; and the resultant report published on 31 May 2012;**
- **Cross-NHS Scotland letter titled 'Water Sources and potential infection risk to patients in high-risk units', issued by Sir Harry Burns and Derek Feeley on 7 February 2012 and addressing potential infection risks and actions required; and the further letter CEL 08 (2013) by the same authors on 3 May 2013, drawing attention to revised SHTM 04-01 and to other guidance , and identifying action required.**

To what extent were you aware of these events at the time of the meeting in June 2014? To what extent did that meeting conclude with a decision or advice to: (a) ensure that all taps in all clinical areas in high-risk units are flushed daily (with records kept); and/or (b) to ensure that domestic staff have been trained in the correct decontamination procedures to minimise the risk of pseudomonas?

1.1. **Declaration of an outbreak of *Pseudomonas aeruginosa* in Northern Ireland:**

1.2. I was aware that there had been an outbreak of *P. aeruginosa* in neonatal units in Northern Ireland in which four neonates had died from *P. aeruginosa* bacteraemia. As described below I was an expert water microbiologist at Health Protection Agency when the outbreaks occurred in Northern Ireland and there was a request from NI for HPA experts to

provide assistance. Therefore, I was aware of the outbreaks when I attended the meetings in the Labs FM Block at the South Glasgow Hospital on the 5th June 2014.

1.3. At the time of the *P. aeruginosa* outbreaks in the neonatal units in Northern Ireland from January 2011 I was employed by Health Protection Agency as an expert in water microbiology.

1.4. I was involved in incident team meetings with other HPA experts with those involved in the outbreaks in Northern Ireland. During the incident meetings there were updates on the outbreaks in the different neonatal units.

1.5. In the HPA laboratories I worked with microbiological colleagues carrying out analysis of taps and plumbing components from the neonatal wards associated with the outbreaks. HPA reports were communicated to the Northern Ireland Adverse Incident Centre, senior HPA managers and Pat Troop (as the head of the RQIA independent review) [1] and published in scientific peer review manuscripts [2].

1.6. **Presence of pseudomonas in other neonatal units in Northern Ireland :**

1.7. The HPA investigation assessed thirty taps and eight flow straighteners for the presence of *P. aeruginosa.* The highest *P. aeruginosa* counts were from the flow straighteners, metal support collars and the tap bodies surrounding these two components.

1.8. Linking of strain of pseudomonas aeruginosa between RJMS and a case in Craigavon Hospital *:*

1.9. *P. aeruginosa* isolates were typed by Dr Jane Turton at PHE Colindale using variable number tandem repeat (VNTR) analysis. Representative *P. aeruginosa* tap isolates from two hospital neonatal units had VNTR profiles consistent with strains from the tap water and infected neonates which identified the taps as the possible source.

1.10. My understanding of the VNTR analysis was that *P. aeruginosa* isolates recovered from three taps at one hospital were indistinguishable from the strain found in both patients and tap water from that hospital. Isolates from tap biofilms received from another hospital were also indistinguishable from a patient strain. The interpretation of the data was that VNTR typing data matched the *P. aeruginosa* strains recovered from the environmental isolates to clinical isolates from the patients that died.

[1] RQIA, 'Independent Review of Incidents of *Pseudomonas Aeruginosa* Infection in Neonatal Units in Northern Ireland.'
[2] JT Walker and others, 'Investigation of Healthcare-Acquired Infections Associated with *P. Aeruginosa* Biofilms in Taps in Neonatal Units in Northern Ireland' (2014) 86 JHI 16.

1.11. **Request on 30 January 2012 by Minister for Health, Social Services and Public Safety to RIQA to establish an independent review into these incidents**

1.12. The RQIA report concluded:

1.12.1. "*This study (HPA tap study) has reached important conclusions as to the link between pseudomonas and the components called rosettes in the taps which were removed from the neonatal units. The study also reports that the strains of pseudomonas which led to infection of babies have been identified from the tap components which were analysed."* In addition

1.12.2. "*The authors of the report of the study recommend that further work should determine whether tap outlets used in neonatal units can be redesigned such that complex rosettes are not necessary and manufacturers should investigate the possibility of making the tap outlet removable for decontamination by autoclaving. The review team strongly endorse these recommendations*."

1.13. **Cross-NHS Scotland letters:**

1.14. It was my understanding that in response to the HPA Scotland published CEL 03 issued by Sir Harry Burns and Derek Feeley on 7 February 2012 addressing potential infection risks and actions required; and letter CEL 08 (May 2013) 3 May 2013, drawing attention to the revised SHTM 04-01 and identifying action required. CEL 03 and 08 letters were addressed for information to: Directors Nursing, Medical Directors, Directors Public Health, CsPHM (Health Protection), HAI Task Force, Health Protection Scotland and Health Facilities Scotland.

1.15. Following the findings of the HPA report the Department of Health convened a specialist group of experts, including myself, to draft an addendum to Health Technical Memorandum (HTM) 04-01 "Pseudomonas aeruginosa – advice for augmented care units" that was published in March 2013 [3]. This included the background as to the problem and providing advice to reduce the risk of patient exposure to *P. aeruginosa*.

1.15.1. HTM 04-01 addendum was concerned with controlling/ minimising the risk of morbidity and mortality due to *P. aeruginosa* associated with water outlets and provided advice on:

1.15.1.1. assessing the risk to patients when water systems become contaminated with *P. aeruginosa* or other opportunistic pathogens;

1.15.1.2. remedial actions to take when a water system becomes contaminated with *P. aeruginosa*;

[3] DH (England), 'Water Systems HTM 04-01: Addendum Pseudomonas Aeruginosa – Advice for Augmented Care Units.'

1.15.1.3. protocols for sampling, testing and monitoring water for P. aeruginosa; and

1.15.1.4. forming a Water Safety Group (WSG) and developing water safety plans (WSPs).

1.15.2. The addendum was also directed towards healthcare organisations providing patient care in augmented care settings and was specifically aimed at Estates and Facilities departments and infection prevention and control (IPC) teams. Patients in an augmented care setting were described as:

1.15.2.1. a. those patients who are severely immunosuppressed because of disease or treatment: this will include transplant patients and similar heavily immunosuppressed patients during high-risk periods in their therapy;

1.15.2.2. b. those cared for in units where organ support is necessary, for example critical care (adult paediatric and neonatal), renal, respiratory (may include cystic fibrosis units) or other intensive care situations;

1.15.2.3. c. those patients who have extensive breaches in their dermal integrity and require contact with water as part of their continuing care, such as in those units caring for burns.

1.16. Similarly, CEL 03 [4] issued in May addressed potential infection risks and actions required; and CEL 08 [5] (May 2013), drew attention to the revised SHTM 04-01 citing that:

1.16.1. all high risk units where patients may be at increased risk of pseudomonas and related infections are identified and control measures applied

1.16.2. best practice relating to the use of hand washing facilities is consistently and fully applied

1.16.3. all taps in all clinical areas in high risk units (manually or automatically) are flushed daily (and a record kept) to minimise the risk of pseudomonal contamination. Flushing should be for a period of one minute, first thing in the morning, at the maximum flow rate that does not give rise to any splashing beyond the basin

1.16.4. domestic staff have been trained in the correct decontamination procedures for sinks, basins and taps in ICUs and neonatal units to minimise the risk of pseudomonas

[4] H Burns and D Feeley, 'CEL 03 Water Sources and Potential Infection Risk to Patients in High Risk Units. 2012.' 03.
[5] H Burns and D Feeley, 'CEL 08 Water Sources and Potential Infection Risk to Patients in High Risk Units – Revised Guidance. 2013.' 08.

1.16.5. they have established a system of clear governance with accountability to the appropriate Executive Director

1.16.6. they are compliant with revised SHTM 04-01

1.17. My interpretation of CEL (2103) was that those in charge of the hospital water system had a duty of care to be compliant with the revised SHTM 04-01.

1.18. The SHTM 04-01 (July) 2014 (version 2) guidance was updated to take account of experience in using the guidance and recent developments affecting design and installation of domestic water services arising from the impact of the discovery of *P. aeruginosa* bacteria in water supplies, including re-titling "Water safety for healthcare premises". SHTM 04-01 cited (note 15 on page 65) that "Rosettes, flow straighteners and aerators have been found to be heavily colonised with biofilm but their removal can create turbulent flow at increased pressure resulting in splashing of surrounding surfaces and flooring. Current advice is that they should be removed but this should be subject to risk assessment". This advice reflected the publication of the Department of Health and acknowledged their efforts in producing the HTM 04-01 Part A. document

1.19. As described above I was aware of the *P. aeruginosa* outbreaks in the neonatal units in Northern Ireland and I was part of the authorship/drafting team of HTM Addendum and subsequent guidance produced by the DH (England) that was concerned with controlling/ minimising the risk of morbidity and mortality due to *P. aeruginosa* associated with water outlets.

1.20. To what extent were you aware of these events at the time of the meeting in June 2014? To what extent did that meeting conclude with a decision or advice to: (a) ensure that all taps in all clinical areas in high-risk units are flushed daily (with records kept); and/or (b) to ensure that domestic staff have been trained in the correct decontamination procedures to minimise the risk of pseudomonas?

1.21. Following my involvement and awareness of the outbreaks of *P. aeruginosa* in Northern Ireland I was invited as a PHE water microbiology expert to attend a meeting on the 5th June 2014 at the South Glasgow Hospital to present on the PHE findings and further PHE investigative research.

1.22. During the meeting I presented on the findings from the PHE investigation into the taps in Northern Ireland and presented the conclusions from the microbiology reports, updates that had been published (DH -England) within the HTM 0401 addendum and the subsequent peer reviewed scientific manuscript that had been published in the Journal of Hospital Infection [6]. My presentation described that :

[6] Walker and others (n 2).

1.22.1. Biofilms form in water systems on strainers, materials such as EPDM and complex plastic flow straighteners.

1.22.2. The presence of flow straighteners will exacerbate *P. aeruginosa* biofilm development and therefore flow straighteners should be avoided.

1.22.3. That this biofilm build up on the flow straighteners in Northern Ireland occurred within four months and identifies the last two metres as high risk.

1.23. Those representing Horne Engineering provided a presentation indicating that their taps required a solid body of water within the tap for if water continued to empty from the body of the tap, this would induce air providing scope for retrospective contamination.

1.23.1. My understanding was that those representing HE stated that Optitherm taps relied on a mesh insert made out of hexagonal holes to maintain surface temperature and hold back water within the tap body after shut-off.

1.24. I have not seen any scientific microbiological studies or data from Horne Engineering that the introduction of air, due to the absence of the mesh structure, would introduce microbial contamination into the tap bodies or that HE taps would control Legionella or Pseudomonas.

1.25. My understanding was that those persons representing NHS GGC concluded in the minutes that:

1.25.1. Risk management was the key – I do not recall that the risk management strategy was discussed in detail.

1.25.2. That six critical points (sic) were identified in the existing guidance and to be added to the forthcoming updated guidance. These were not recorded in the minutes I do not recall that the risk management strategy was discussed in detail.

1.25.3. Influences on outcomes included commissioning procedures, operational management, seasonal influences and personnel involved.

1.25.4. That as the taps installed within the new build development had complied with guidance current at the time of its specification and briefing and that the hospital was in the process of being commissioned, it should be regarded as being in the “retrospective” category, not “new build”. There was no need to apply additional flow control facilities or remove flow straighteners and any residual perceived or potential risks would form part of the routine management process.

1.26. I provided scientific expertise to the meeting on the 5th June 2014 and was not a party to the decisions and conclusions that were agreed and recorded by those representing Scottish hospitals.

1.27. My opinion is that the conclusions of the meeting on the 5th June 2014:

1.27.1.1. did not take account of the risk that had been identified with flow straighteners to patients in high risk units

1.27.1.2. did not follow the recently revised SHTM 04-01 that follow straighteners should be removed

1.27.1.3. did not take account of DH (England) addendum published to provide advice on the risks from P. aeruginosa

1.27.2. I do not recall the meeting discussing or concluding to (a) ensure that all taps in all clinical areas in high-risk units are flushed daily (with records kept).

1.27.3. Whilst there was a comment in the minutes that "Contamination was also likely if correct procedures were not followed in the cleaning regime adopted" I do not recall that there was a conclusion (b) to ensure that domestic staff have been trained in the correct decontamination procedures to minimise the risk of pseudomonas.

2. **Horne Taps: risk management**
In particular, please describe your understanding of the strategy that was adopted to minimise risk arising from the presence of these taps. Please see your comments at para 6.9.14 of your report.

2.1. My understanding of the meeting on 5th June 2014 which I attended as an independent representative of HPA was that NHS GGS decided to adopt the following strategy:

2.1.1. That as the taps installed within the new build development had complied with guidance current at the time of its specification and briefing and that the hospital was in the process of being commissioned, it should be regarded as being in the "retrospective" category, not "new build". There was no need to apply additional flow control facilities or remove flow straighteners and any residual perceived or potential risks would form part of the routine management process.

2.1.2. The minutes stated that "risk management of the taps" was the key to reducing the risk of P. aeruginosa growth and the risk to patients. However, I do not recall the details of this risk management strategy being discussed in detail.

2.1.3. That six critical points (sic) were identified (but not recorded in the minutes) in the existing guidance and to be added to the forthcoming updated guidance. I do not recall that the six critical points were explained or discussed at the meeting.

2.1.4. Influences on outcomes (sic *P. aeruginosa* growth and risk to patients) included, commissioning procedures, operational management, seasonal influences and personnel involved.

2.2. My understanding was that those representing Scottish Hospitals unanimously agreed:

2.2.1.1.1. Horne Engineering taps would be retained throughout the QEUH/RHC estate,

2.2.1.1.2. that the flow straighteners would not be removed

2.2.1.1.3. Risk management would form part of the routine management process**.**

2.2.1.2. I do not recollect that the risk management plan or the steps to achieve this were discussed in detail at the meeting.

2.2.1.3. In summary, my understanding was that NHS GGC decided to take a risk management approach to manage the risk of *P. aeruginosa* and the risk to patients without detail these strategies during the meeting.

2.3. In my opinion there are a number of documents that impacted on the risk management approach that was agreed and adopted by NHS GGC on June 5th 2014.

2.3.1. Cross-NHS Scotland letter (CEL 03) 2012 [7] . This letter advised the following immediate actions for Directors of Estates/Facilities.

2.3.1.1. Ensure site engineering and cleaning protocols are fully compliant with current guidance (including SHTM 04-01) and that manufacturers' instructions with regard to installation and maintenance have been followed

2.3.1.1.1. My understanding is that the manufacturer's instructions were not followed (DMA 2015/2017)

2.3.1.2. Ensure a coordinated approach between IPCTs and Estates/Facilities department on all water issues including through the establishment of a board/hospital water safety group

2.3.1.2.1. My understanding is that a coordinated approach between IPCTs and Estates/Facilities departments was lacking as IPCT staff had difficulty accessing results (Water meeting minutes October 2017) [8]

2.3.1.3. Ensure all taps are flushed in accordance with the attached best practice for handwash basins to minimise the risk of Pseudomonas aeruginosa contamination in high risk units

2.3.1.4. My understanding was that all taps were not flushed [9]

[7] Burns and Feeley (n 4) 03.
[8] NHS GGC, 'Board Water Safety Group Meeting Monday 16th October 2017 QEUH'.
[9] HIS, 'HIS Inspection Report – Safety and Cleanliness of Hospitals. QEUH RHC NHS GGC 2019'.

2.3.2. My understanding of CEL 03 was that site engineering and cleaning protocols had to be fully compliant with current guidance and that manufacturer's instructions had to be followed.

2.3.3. SHTM 04-01 Version 2 2014, published in July 2014 [10], notes that "This version (2.0) of SHTM 04-01 Part A has been updated to take account of latest guidance forthcoming regarding measures to prevent build-up of waterborne bacteria and biofilm such as Pseudomonas as it affects design and specification of domestic hot and cold water systems and components. (Notes 6, 15 and 17 and paragraphs 7.46, 9.54 and 10.1 particularly refer."

2.3.3.1. Note 15: "Rosettes, flow straighteners and aerators have been found to be heavily colonised with biofilm but their removal can create turbulent flow at increased pressure resulting in splashing of surrounding surfaces and flooring. Current advice is that they should be removed but this should be subject to risk assessment."

2.3.3.2. Note 17: "i. taps should be ideally removable and easily dismantled for cleaning and disinfection".

2.4. In my experience, Guidance documents take a considerable amount of time to be drafted and agreed and this version of SHTM 0401 must have been in final draft by the time of the 5th June meeting. SHTM 2014 was updated due to the fatalities that took place in Northern Ireland due to the presence of *P. aeruginosa* in tap components including flow straighteners and provided guidance for stakeholders. A number of NHS GGC would have been involved in redrafting the guidance.

2.5. The DH (England) had taken this risk to augmented care patients so seriously that it had rapidly published guidance "'Water sources and potential Pseudomonas aeruginosa contamination of taps and water systems: advice for augmented care units'" in March 2012 [11]. In March 2013 this was superseded by the addendum to HTM 0401 "Water systems Health Technical Memorandum 04-01: Addendum Pseudomonas aeruginosa – advice for augmented care units" [12]. The DH (England) used steering groups to draft its guidance which included members of the devolved nations including Scotland, Wales and Northern Ireland [13]. The DH (England) evidence and guidance was therefore available to experts across the UK for them to understand the risks posed to patients in the UK. This then enabled the devolved nations, including Scotland, to produce their own guidance to protect patients and led to the SHTM 04-01 including the statement "Current advice is that they (sic "flow straighteners") should be removed but this should be subject to risk assessment."

[10] HFS, 'Water Safety (SHTM 04-01) Part A: Design, Installation and Testing 2014'.
[11] DH (England) (n 3).
[12] DH (England) (n 3).
[13] DH (England), 'Health Technical Memorandum 04-01 Safe Water in Healthcare Premises Part A: Design, Installation and Commissioning. Https://Www.England.Nhs.Uk/Publication/Safe-Water-in-Healthcare-Premises-Htm-04-01/'.

2.6. It was my opinion that the strategy that was adopted by those representing Scottish Hospitals at the meeting on the 5th June 2014 was inappropriate in terms of the risk of patients to *P. aeruginosa*. This opinion is based on

2.6.1. my experience in researching the NI incident

2.6.2. the deaths of patients due to the association of *P. aeruginosa* and tap components such as the flow straightener in NI

2.6.3. guidance (HTM and SHTM 04-01) had been published since the outbreak in Northern Ireland which provided the evidence and background to the risk to patients in augmented care (high risk) units.

2.7. In addition NHS GGC were informed in the DMA report 2015 [14] Legionella Risk Assessment that thermostatic mixing valves (TMVs) should be serviced and have fail safe tests carried out routinely and strainers should be cleaned on a regular basis as per manufacturer's recommendations and in accordance with Written Scheme guidance." [15] [16].

2.8. Horne Engineering had arranged for maintenance training however no Estates personnel attended and the session was abandoned. As such NHS GGC staff were not trained in how to manage the risk of the taps.

2.9. I am not aware that NHS GGC were trained either in the servicing and maintenance or that clinical and nursing staff had been trained in operation of these complicated taps.

2.10. I was asked to make reference to my comments at para 6.9.14 of my report. This paragraph is as follows: "6.9.14. These taps should be demounted for servicing but according to the 2017 DMA report the required facilities had not yet been completed or commissioned. The lack of servicing facilities indicates that the Horne Optitherm Taps was not taking place in non-high risk clinical areas since the hospital had opened in 20 15 418 . DMA stated in the 2017 Legionella risks assessment that "we understand no servicing of any of these valves and the associated strainers in non-high risk areas has been carried out since the hospital opened and there has been a very limited programme in "high risk areas". According to the DMA Legionella Risk Assessment (2015) and the QEUH Written Scheme TMV taps should be serviced quarterly including cleaning / disinfection of strainers."

2.11. My understanding was that the necessary facilities required for the servicing and maintenance of the taps had not been completed or

[14] DMA, 'L8 Risk Assessment NHS GGC South Glasgow University Hospital. 2015.'
[15] HSE, 'HSG 274 Legionnaires' Disease - Technical Guidance Part 2: The Control of Legionella Bacteria in Hot and Cold Water Systems 2014'.
[16] Horne Engineering, 'Horne Opitherm Thermostatic Bib Tap Type TBT02 Installation, Commissioning, Operation and Maintenance Instructions'.

commissioned by NHS GGC. [17] Therefore there is a question as to how these taps could have been serviced.

2.12. In addition, only a very limited programme of servicing the valves and strainers in high risk areas had been carried out since the hospital opened to patients in 2015.

2.13. My opinion would be that such a lack of servicing of the valves and the strainers would have resulted in the accumulation of sediment and growth of microbial contamination of those components.

2.14. Horne Engineering recommend the following within their installation, commissioning, operating and maintenance instructions [18]: “4.1.3 The frequency of in-service testing depends upon the condition of the water passing through the tap. In-service testing must be carried out more frequently in hard water areas than in soft water areas. As a general guide, in-service testing should be carried out at least every twelve months and, where the water is hard, the interval may be less than six months. Experience of local conditions and the in-service testing record will dictate the frequency of in-service testing.”

2.14.1. Based on my understanding, Horne Engineering as the manufacturer of both the taps and the showers, recommended that in service testing should be carried out at least every twelve months. However, my interpretation of the DMA report was that this risk management strategy as recommended by the manufacturer had not been undertaken by NHS GGC since the hospital opened in non-high risk areas with only a very limited programme in “high risk areas”,

2.14.2. I have not seen any evidence that that manufacturer’s instructions were followed or that staff were trained in servicing and maintenance of the taps and components.

2.14.3. In my opinion such an approach would have resulted in the accumulation and growth of microbial contamination of the tap components.

2.15. The HSE guidance “Legionnaires’ disease Part 2: The control of legionella bacteria in hot and cold water systems” [19] recommend the following: “2.165 Where the risk assessment considers fitting TMVs appropriate, the strainers or filters should be inspected, cleaned, descaled and disinfected annually or on a frequency defined by the risk assessment, taking account of any manufacturers’ recommendations.”

[17] DMA, ‘Legionella Risk Assessment QEUH (Adult) Hospital and the Adjoining RHC 2017’.
[18] Horne Engineering (n 16).
[19] HSE (n 15) 274.

2.15.1. I have not seen any evidence that the guidance in HSG 274 was implemented at the QEUH / RHC .

2.15.2. Based on the evidence of the DMA report in 2017 the risk management systems that were agreed in Jun 2014 had not been undertaken and in my opinion this would have resulted in the microbial contamination of the tap components.

2.16. Intertek report 11 July 2018 (Bundle 6) [20] concluded that "The flow straighteners provided for the first round of sampling all showed significant levels of biofilm contamination. The levels were consistent throughout the sampling indicting that this is not localised".

2.16.1. My interpretation of the Intertek report (11 July 2018) was that the independent expert demonstrated that there was significant biofilm formation on the flow straighteners on taps from the QEUH/RHC and that this was extensive and systemic i.e. not just a localised issue. This data was published in a scientifically peer reviewed article in the scientific expert was an author and revealed widespread contamination of the water (including expansion vessels and outlets) and drainage system [21].

2.16.2. It is my opinion that as NHS GGC had not followed their own risk management process (agreed at the meeting on 5th June 2014) in managing the water system and also failed to follow national and local guidance (SHTM 04-01 and HSG 274) that the lack of servicing of the taps, strainers and TMV's led to the significant levels of biofilm contamination on the flow straighteners.

2.16.3. Horne Engineering taps are a complicated tap with two levers for operation. As described in my report this dual lever approach leads to additional risks if the taps are not operated appropriately, as per the manufacturer's instructions. [22] As referenced above Horne Engineering offered training to NHS GGC but that no maintenance staff attended the training briefing.

2.16.4. The Pseudomonas risk assessment (2015) [23] identified risk with these taps in that it would be unlikely for the cold lever to be operated by staff when washing their hands with Horne Engineering taps.

2.16.5. I have seen no evidence that NHS GGC took these additional risks into consideration when deciding to continue with the Horne Engineering taps at the QEUH.

2.16.6. In addition I have not seen any evidence that clinical/nursing staff at the QEUH / RHC have been trained in operating these

[20] SHI, 'DOCS Bundle 6 Miscellaneous Documents' 2023, 6.
[21] T Inkster and others, 'Investigation and Control of an Outbreak Due to a Contaminated Hospital Water System, Identified Following a Rare Case of *C. Pauculus* Bacteraemia.' [2021] JHI.
[22] Horne Engineering (n 16).
[23] DMA, 'Pseudomonas Report on Water Delivery System (Pre-Occupancy)'.

complicated taps to reduce microbial contamination and the risk to patients.

2.16.7. In conclusion, based on the evidence above my understanding of the strategy adopted to minimise risk from the taps is that:

2.16.7.1. There was a lack of understanding of the microbiological risks presented by these complicated taps.

2.16.7.2. NHS GGC unanimously agreed to install these high risk complicated taps in high risk areas even though they were aware of the risks to patients.

2.16.7.3. The risk management policy which had been agreed at the meeting on the 5th June 2014 was not implemented.

2.16.7.4. The facilities required to service the taps had not been completed or commissioned – so there was nowhere to service the taps appropriately.

2.16.7.5. Estates and facilities staff had not been trained to service or maintain the taps, TMV or associated strainers.

2.16.7.6. No taps had been serviced in non-high risk areas since the hospital opened.

2.16.7.7. Only a limited programme of maintenance had been carried out in the high risk areas since the hospital opened.

2.16.7.8. Manufacturer's instructions had not been followed.

2.16.7.9. Nursing and clinical staff had not been trained in the operation of these complicated taps which had two levers for operation.

2.16.7.10. Guidance issued in 2012 and 2013 (CEL 03 & 08) had not been followed

2.16.7.11. Guidance in the revised SHTM 04-01 had not been followed i.e. flow straighteners had not been removed.

2.16.7.12. Guidance in HSG 274 had not been followed.

2.16.7.13. Therefore, my understanding of the strategy that was adopted to minimise risk arising from the presence of these taps was that NHS GGC did not follow their own risk management strategy to reduce the risk of exposure to high risk patients when the taps were operated.

3. **Sampling: pre-2015 issues**:

- **Your comments at paras 6.10.3 [Legionella] and 6.27 [M.Chelonae] of your report;**
- **Allocation of responsibility for the sampling regime, and difficulties post-dating 2015 in gaining access to sampling results (see in particular 'South Water Safety Group' minutes).**
- **The letter CEL 08 issued by Sir Harry Burns and Derek Feeley on 3 May 2013, drawing attention to revised SHTM 04-01 and to other guidance, and identifying in particular that there should be annual reporting on compliance with requirements.**

3.1 Please comment on the culture around sampling, analysis and identification of bacteria at QEUH prior to 2015

3.1.1 The HSE provide guidance on commission of water systems in new buildings in its document HSG 274 on P23 at paragraphs 2.40 to 2.42. [24] The HSE indicate that "A new, correctly designed and installed water system should provide wholesome water at every outlet and where there are any problems, the design or installation defect should be identified and rectified". In addition on P49 in box 2.10 the HSE indicates that the "The Water safety Group (WSG) is a multidisciplinary group formed to undertake the commissioning, development, implementation and review of the Water Safety Plan. The aim of the WSG is to ensure the safety of all water used by patients/ residents, staff and visitors, to minimise the risk of infection associated with water, including legionella."

3.1.2 In Appendix 2.1 (P53) of the HSG 274 the HSE indicate that "It is a legal duty to carry out an assessment to identify and assess whether there is a risk posed by exposure to legionella from the hot and cold water system or any work associated with it.

3.1.3 The HSE ACOP indicates (P17), that "Where the risk cannot be prevented, a course of action must be devised to manage the risk by implementing effective control measures. The written scheme should be specific and tailored to the systems covered by the risk assessment."

3.1.4 The HSG 274 also indicates that:

3.1.5 Within the written scheme and risk assessment there should have been a plan for sampling the water system and how to deal with "out of specification" results.

[24] HSE (n 15).

3.1.6 The "Water Management Issues Technical Review [25] indicated that at the QEUH/RHC that:

3.1.6.1 There is no record of the pre commissioning checks as noted in SHTM 04-01 Part A.

3.1.6.2 There is no record available of the analysis of the water prior to treatment as required by the specification. [26]

3.1.6.3 In my opinion the lack of records would not be compliant with specification.

3.1.6.4 The review [27] also indicated that for a number of microbiological results that out of specification e.g. TVC were above 10 CFU/ml and that the results in (in Zutec) were extremely difficult to interpret and *E. coli* was detected with no evidence that the strain recovered was type tested for confirmation. It should be noted that the European Drinking Water Directive (98/83/EC), The Water Quality (Scotland) Regulations 2010 and Scottish Water By-Laws, do not permit any E. coli readings at the consumers outlets. There is no evidence to suggest that the E. coli found in the water system was escalated to NHS GGC Project Team, NHS GGC Infection Control, Health Protection Scotland or any other agency.

3.1.6.5 My opinion is that the microbiological results indicated that water prior to handover was not wholesome.

3.1.6.6 The presence of *E. coli* should have been escalated to NHS GCC or another agency. The lack of evidence of retesting and subsequent passes casts doubt on whether the water retested was wholesome.

3.1.6.7 There is evidence from the contractor that percentages of the Horne taps failed the initial disinfection tests, were disinfected and retested (a month-and-a-half) later (appendix 2 item 10) and failed the second test. There is no evidence within ZUTEC of any additional testing to resolve these

[25] HFS, 'Water Management Issues Technical Review NHSGGC – QEUH and RHC HFS – March 2019'.
[26] ZBP, 'COMMON MECHANICAL CLAUSES BP/TUV SUD ZBP-XX-XX-SP-520-307'.
[27] HFS, 'Water Management Issues Technical Review NHSGGC – QEUH and RHC HFS – March 2019' (n 25).

failures. Therefore the water may not have been wholesome.

3.1.6.8 I have seen no evidence of a water safety plan as requested in CEL 03 2012 or a sampling management plan of how many outlets were to be sampled including Horne taps in areas such as those identified as high risk?

3.1.6.9 The results within ZUTEC are extremely difficult to interpret with respect to whether a retest of the outlet has been carried out and successfully passed.

3.1.6.10 Whilst the majority of water samples tested passed I have seen no evidence that all the retested samples were wholesome.

3.1.7 From the Water Management Issues Technical Review it is my conclusion that there was limited evidence of NHS GGC Infection Control being involved in the handover process of the project (p38).

3.1.8 The NHS GGC Infection Control lead at the time provided confirmed that he was involved in reviewing the water testing methodology and the results for QEUH and RHC during commissioning and handover.

3.1.9 I have seen no evidence that the NHS Infection Control specialist was trained in water sampling and testing.

3.1.10 In addition, the involvement of the NHS GGC infection control was not reflective of the requirement for a water safety group as was instructed in CEL 03 2012 which would have implemented an appropriate culture around sampling.

3.1.11 Rankin [28] indicated that “Some samples yielded high TVCs. In response to the high levels of TVCs NHSGGC did not accept the handover of the hospital. As a consequence sanitisation of the water supply was undertaken prior to handover, with some impact and a reduction in TVCs in most areas, however there were reports indicating areas with higher than normally acceptable levels of TVCs”

3.1.12 As the water was not wholesome NHSGGC refused to accept the handover of the hospital.

[28] A Rankin, ‘Initial Report on the Findings of the NHS Greater Glasgow and Clyde: Queen Elizabeth University Hospital/Royal Hospital for Children Water Contamination Incident and Recommendations for NHS Scotland. Status: Final A45670795. Bundle Number 2 of Outstanding Documents for Linda Dempster – Glasgow 3’.

3.1.13 In my opinion this indicated that NHS GGC staff were sufficiently concerned about the increased risk to patients from microbially contaminated water. In addition, the sanitisation of the water confirms that those responsible for the water system accepted that the water was not wholesome and hence not safe for the patient groups.

3.1.14 Following commissioning and handover DMA Canyon undertook a Legionella Risk Assessment in April 2015 [29].

3.1.15 DMA [30] were advised the NHS sampling programme highlighted a number of out of specification Legionella and potable results i.e. the water was not wholesome.

3.1.16 A responsive programme of daily flushing and local disinfections was implemented in affected areas. The microbiological results after sampling and the method statement for disinfections were not submitted for comment or review to DMA.

3.1.17 In 2015 DMA identified high risk issues including (section 9):

3.1.17.1 no formal management structure,

3.1.17.2 no written scheme or communication protocols

3.1.17.3 individual calorifiers running at lower temperatures than the linked vessels and returns not achieving the design temperatures of 55°C.

3.1.17.4 the majority the cold water temperatures being more than 5°C higher than those recorded at the water tanks and with peak temperatures of 30°C being noted

3.1.17.5 significant communication issues between parties involved

3.1.17.6 No training records held for those managing Legionella

3.1.17.7 No competency records held for those managing Legionella

3.1.17.8 No training records held for those managing Legionella

3.1.17.9 No written scheme in place - it was stated that an informal written scheme is in place at present based

[29] SHI, 'DOCS Bundle 6 Miscellaneous Documents' (n 20) 6.
[30] SHI, 'DOCS Bundle 6 Miscellaneous Documents' (n 20) 6.

on SHTM 04-01 and had yet to be formulated into the Hospitals formal written scheme for on-going legionella control.

3.1.17.10 Twice weekly flushing is being carried out by NHS Estates staff in what have been deemed 'High Risk' clinical areas

3.1.18 My opinion from the DMA report is that the identification of the above high risk issues would hinder compliance with HSE and SHTM 04-01 guidance and did not provide an appropriate culture around sampling strategy.

3.1.19 DMA identified that Microbiological sampling was a "one-off sampling sweep carried out prior to patients being admitted to each department."

3.1.20 In my opinion the description of a "one-off sampling sweep" does not convey that there was a water safety group and water safety plan in place that understood the requirements of a comprehensive sampling plan to assess the QEUH/RHC water system.

3.1.21 It is my opinion that microbiological sampling of such a large hospital with high risk patients should have been planned as part of the written scheme and risk assessment written by a Water Safety Group (a multidisciplinary group formed to under as advised in HSG 274 and CEL 03) which should have been involved from the commissioning stage.

3.1.22 As such there appears to have been a lack of a robust culture around water sampling from the point at which the new building was commissioned including assurance that the system was fit for purpose. I have not seen any evidence to understand the rationale for how water testing took place and whether annual assurance was provided by the Board Water Safety Group to the NHS Board as requested in CEL 08 2013 [31].

3.1.23 Following the outbreak of *P. aeruginosa* in Northern Ireland 2011/2012, the Scottish Government issued CEL 03 in which Directors of Estates/Facilities were actioned to "Ensure a coordinated approach between IPCTs and Estates/Facilities department on all water issues including through the establishment of a board/hospital water safety group" and in 2013, CEL 08 was issued in which Boards must ensure that: all taps in all clinical areas in high risk units (manually or automatically) are flushed daily (and a record kept) to minimise the risk of pseudomonal contamination. Flushing should be for a period of one minute, first thing in the morning, at the

[31] Burns and Feeley (n 5).

maximum flow rate that does not give rise to any splashing beyond the basin.

3.1.24 It is my understanding from the DMA 2015 Report that only ”Twice weekly flushing is being carried out by NHS Estates staff in what have been deemed ‘High Risk’ clinical areas” and that this would not comply with the advice in the CEL 08 Letter in 2013 that was produced to ensure all taps in all clinical areas in high risk units (manually or automatically) are flushed daily (and a record kept) to minimise the risk of pseudomonal contamination.

3.1.25 My opinion is that the lack of flushing would have led to deadlegs and stagnation of water.

3.1.26 The HSE indicate (HSG 274, P6, pg16) that inadequate management, lack of training and poor communication have all been identified as contributory factors in outbreaks of legionnaires’ disease. This is particularly important where several people and teams are responsible for different aspects of the treatment or precautions. [32]

3.1.27 In my opinion the three areas that the HSE identify as being important to prevent outbreaks of Legionnaires’ disease i.e. inadequate management, lack of training and poor communication were apparent following handover of the QEUH/RHC to NHS GGC as identified by DMA (2015) which was had a negative impact on any culture around sampling.

3.1.28 My interpretation of the findings from the Legionella risk assessment in 2015 and 2017 are that prior to and following handover (2015/2015) that those involved in the management of Legionella did not have the necessary competence and training to carry out a microbiological sampling survey that would reflect the risk across the QEUH/RHC site.

3.1.29 In light of my comments at Section 6.10.3 of my report as follows: 6.10.3.

3.1.30 In my view the 2018 audit by the Authorising Engineer reflects a water system that is non-compliant with current guidance, nationally and locally, SHT ’s and that those responsible for the control of premises were not complying with their legal duties (HSE ACOP page 5 para 2). A complete lack of sampling for Legionella means that there is a complete lack of knowledge as to the risk of Legionella to the vulnerable patients in the hospital – monitoring can indicate whether you are achieving control and sampling for Legionella is a means of checking the system is under control (HSE ACOP page 5 para

[32] HSE (n 15).

2c). In addition, section 6.27 describes *M. chelonae* HAI where the hypothesis was that patients had been exposed to unfiltered water sources in the hospital indication that filters are not a panacea when the underlying problem is waterborne pathogens present in the water system.

3.1.31 My comments in section 6.10.3 of my report relate to the 2018 Authorising Engineer Report [33]. My understanding from this report was that "It was further pointed that no Legionella sampling is being undertaken while the POU filters are installed. " (p30) and that the risk was identified as being high risk i.e. requiring very urgent remedial action. In addition the AE recommend (p31) "that legionella sampling is reinstated in the POU filtered areas in order that an understanding of what is happening microbiologically in the hot and cold water can be had."

3.1.32 My interpretation of the AE 2018 report is that NHS GGC were not aware of the risks from Legionella as they had not been sampling in areas where filters were installed.

3.1.33 The AE stated (p31) "It is therefore recommended that a sampling protocol, covering what species should be monitored, how often, and from where, is agreed with the NHS GGC Infection Control team."

3.1.34 My interpretation from this recommendation is that estates department had not previously agreed and coordinated a sampling protocol, covering what species should be monitored, how often, and from where with NHS GGC Infection control team.

3.1.35 My understanding is that such a coordinated response was recommended in the CEL 03 letter in 2012 for *P. aeruginosa* and other related Gram negative water-borne organisms where "Directors of Estates/Facilities were required to Ensure a coordinated approach between IPCTs and Estates/Facilities department on all water issues including through the establishment of a board/hospital water safety group".

3.1.36 In addition my opinion would be that there was a lack of a water safety group and a lack of a water safety plan which would have accounted for the lack of a culture around sampling.

3.2 My understanding from HSE 274 is that hot and cold water samples should be taken from areas where the target control parameters are not met (i.e. where disinfectant levels are low or where temperatures are

[33] D Kelly, 'Legionella Control AE Audit – Queen Elizabeth University Hospital – July 2018'.

below 50 °C (55 °C in healthcare premises) for HWS or exceed 20 °C for cold water systems).

3.3 My interpretation of the DMA 2017 report is that "The return temperatures recorded at the calorifiers were consistently below 55°C." My understanding is that as a consequence of the hot water temperatures being identified consistently below 55°C that sampling for Legionella should have been taking place in targeted areas the QEUH/RHC to assess the risk to patients.

3.4 However, as discussed above the AE (W) report of 2018 [34] indicated that legionella sampling was not being carried out in the point of use filtered areas. The complete lack of sampling for Legionella could mean that the organism might be present in the water systems int hose areas with point of use filters. In my opinion this was a lack of culture around sampling and that guidance in the CEL 03 2012 letter was not being followed.

3.5 Whilst it may have been considered that the presence of point of use filters may have prevented the dispersal of Legionella bacteria it is my understanding that this risk to patients was not just from Legionella but also from other bacteria. Such a risk was highlighted at the QEUH where the hypothesis was that *M. chelonae* HAI patients had been exposed to unfiltered water sources in the hospital i.e. filters are not a panacea when the underlying problem is waterborne pathogens present in the water system that has not been managed according to guidance.

3.6 My interpretation from the IMT documents was that Mycobacteria had been isolated from 6A (three shower heads and a DSR being positive for mycobacterium) (p327) and also that a sample was positive for mycobacteria from an Arjo bath "even with a point of use filter on it". These filters were tested by the manufacturer and passed the filter integrity test.

3.7 It is my opinion that the filters had not failed and that as Mycobacteria was present in the water system then the patients had been exposed to unfiltered water. As the water sample from the filter was positive for Mycobacteria it is my opinion that the seal on the filter was leaking water that contaminated the filter. The hypothesis at the time were recorded in the SBAR (p196) [35]:

- Hypothesis 1 Patients exposed to unfiltered water outside of Ward 6a but within the hospital environment, for example in theatre, in school (RHC) or when visiting either of the main atriums with families.

- Hypothesis 2 Condensate/Fluid from the Chilled Beams was dropping directly onto the patients or their environment and this provided a source of bacteria which caused infection in the patients.

[34] Kelly (n 33).
[35] SHI, 'SHI - SBAR Bundle 4 – NHS NSS Situation, Background, Assessment, Recommendation (SBAR) Documentation for the Oral Hearing Com' 2023.

3.8 However, no link was identified between clinical isolates and results from environmental sampling i.e. chilled beams, air, water in Ward 6A except for the case of *M. chelonae* which was isolated from pre filtered water . (SBAR p196 Bundle 4)

3.9 My opinion is that despite the implementation of point of use filters that microbial control of water system had not been achieved and that where patients were expose to unfiltered water the patients in high risk units were still at risk of infection from a range of water borne pathogens including Mycobacteria [36].

3.10 Section 6.27 from my report: 6.27. Mycobacterium chelonae contamination of the water system.

3.10.1 In June 2019 it was recognized that a high number of cases of *M. chelonae* had been identified within a 12-month period. [37] (p193)

3.10.2 *M. chelonae* was isolated during water sampling from different areas (in two paediatric haemato-oncology inpatient wards and an operating theatre) in the hospital. The hypothesis was that patients had been exposed to unfiltered water sources in the hospital Whole genome sequencing confirmed that the isolate from one patient was closely related the environmental samples from water outlets .

3.10.3 6.27.3. In my view the high number of *M. chelonae* cases is unacceptable due to the presence of filters on the water outlets. These filters should have protected patients from exposure to *M. chelonae*.

3.10.4 6.27.4. In addition it is concerning that atypical mycobacterial species were detected when sampling using point of use filters.

3.10.5 In my opinion POU filters are absolute filters i.e. they prevent bacteria from passing through the filter and so patients are not exposed. By sampling through filters this would indicate that there was a lack understanding of the purpose of this sampling and what the results would demonstrate. Sampling through filters does not provide an assessment of the quality of the water system.

3.10.6 As discussed above patients were either exposed to unfiltered water due to i) leakage from poorly fitting filters resulting in exposure to unfiltered water. i) unfiltered water from taps that did not have filters.

[36] SHI, 'SHI - SBAR Bundle 4 – NHS NSS Situation, Background, Assessment, Recommendation (SBAR) Documentation for the Oral Hearing Com' (n 35).
[37] SHI, 'SHI - SBAR Bundle 4 – NHS NSS Situation, Background, Assessment, Recommendation (SBAR) Documentation for the Oral Hearing Com' (n 35) 4.

3.11 I was also asked to comment on the allocation of responsibility for the sampling regime, and difficulties post-dating 2015 in gaining access to sampling results (see in particular 'South Water Safety Group' minutes).

3.11.1 **Allocation of responsibility for the sampling regime:** In 2012 CEL 03 indicated that Directors of Estates/Facilities should "Ensure a coordinated approach between IPCTs and Estates/Facilities department on all water issues including through the establishment of a board/hospital water safety group". i.e. responsibility for sampling should be coordinated by the Estates facilities department.

3.11.2 DMA Legionella Risk Assessment 2015 recorded that there was no written scheme in place and no training or competency records and duties had not been assigned to named individuals or subcontractors.

3.11.3 In my opinion this would indicate that no one had been given responsibility for the sampling regime by the Directors of Estates/Facilities which may have reflected the lack of culture around sampling to ensure that the water was wholesome.

3.11.4 DMA legionella risk assessment 2018 indicated that the estates manager placed in the role of the Authorised Person (AP) water had not undergone any training in Legionella and had limited knowledge of the water system on site the requirements of L8, HSG 274 and SHTM 04-01.

3.11.5 My understanding is that DMA described Legionella onsite as being high risk, which reflected many of the high risk issues and risk previously identified in 2015 the lack of training of staff.

3.11.6 From my interpretation of the minutes of the NHS Greater Glasgow & Clyde Board Water Safety Group Meeting post 2015 [38] the General Manager for estates led the discussions on water sampling, protocols, water safety policy status and the water safety written schemes and in 2017 the General manager for estates was to work with the sector estates managers on the protocol for sampling on a site by site basis. Therefore, my opinion is that it was clear that sampling regime responsibility was with the General manager for estates.

[38] NHS GGC, 'Board Water Safety Group Meeting Tuesday 7th June 2016 at 9.30am. Object Conn'.

3.11.7 On the (12th) September 2016 [39] the Consultant Microbiologist noted the lack of testing at QEUH (as opposed to GRI) and raised concern regarding domestic services not flushing. My interpretation of the comment from the consultant microbiologist is that there was a lack of testing at the QEUH.

3.11.8 In the December 2016 NHS Greater Glasgow & Clyde Board Water Safety Group Meeting [40] the there were a number issues raised the General Manager, Estates including:

3.11.8.1 updated water asset lists are required from all sites by 31 January 2017,

3.11.8.2 referred to the updating of the risk assessments,

3.11.8.3 the current drawings are out of date and that in many cases GG&C got zero score for SCART, due to drawings being out of date.

3.12 My interpretation is that :

- asset lists were a requirement of HSG 274 published in 2014 and
- schematic drawings were a requirement of SHTM04-01 Part B
- therefore NHS GGC were non-compliant with HSG 274 and SHTM 04-01 Part A (section 5.3 record keeping).

3.13 My understanding is that without an updated water asset list and appropriate drawings then it would have been difficult for the estates department to undertake risk assessments and form a sampling regime to assess the risk to patients i.e. the sampling regime and risk was not being managed.

3.14 My interpretation of the water safety board minutes is that NHS estates and facilities were responsible for the sampling regime and that there was not an appropriate culture sampling regime in place.

3.15 **Difficulties post-dating 2015 in gaining access to sampling results**

3.16 In the Board Water Safety Group Meeting on 16th October 2017 [41] it was noted that infection control colleagues were looking at historical records and that the Associate Director of Facilities recorded that there was no reason to obtain access of historic records.

[39] NHS GGC BWSG, 'NHS Greater Glasgow & Clyde Board Water Safety Group Meeting 12th September 2016 at 9.30am. Objective Connect'.
[40] NHS GGC BWSG, 'Board Water Safety Group Meeting 20th December 2016. Object Conn'.
[41] NHS GGC, 'Board Water Safety Group Meeting Monday 16th October 2017 QEUH' (n 8).

3.17 In my opinion such comments would suggest that infection control colleagues were not being provided with the necessary data with which to carry out their professional duties.

3.18 In terms of access to sampling results in the March 2018 NHS GGC Board NHS Greater Glasgow & Clyde Board Water Safety Group Meeting [42] the General manager for estate made note of the sampling carried out and whilst it was not specific to QEUH there was guidance in place but "no evidence from the water groups that the sampling happens as there is no evidence of it in the minutes."

3.19 My interpretation is that the sampling regimes were not being managed appropriately as in some cases there was no evidence that it was taking place.

3.20 The case note review [43] (p1042) were informed that "some key staff involved in IPC at NHS GGC were denied access to water sampling/testing information despite multiple requests."

3.21 My interpretation is that infection control staff had problems accessing the microbiology data and therefore it is difficult to see how they could have carried out their professional duties without having access to this data.

3.22 **The letter CEL 08 issued by Sir Harry Burns and Derek Feeley on 3 May 2013, drawing attention to revised SHTM 04-01 and to other guidance, and identifying in particular that there should be annual reporting on compliance with requirements.**

3.23 In Scotland CEL 03 (2012) and CEL 08 (2013) were produced with actions for Directors of Estates/Facilities to:

3.23.1 Ensure that manufacturers' instructions with regard to installation and maintenance have been followed

3.23.2 Ensure a coordinated approach between IPCTs and Estates/Facilities department on all water issues including through the establishment of a board/hospital water safety group

3.23.3 Ensure all taps are flushed in accordance with the attached best practice for handwash basins to minimise the risk of Pseudomonas aeruginosa contamination in high risk units

3.23.4 Review existing microbiological data to determine whether there are areas which could pose an immediate pseudomonas

[42] NHS GGC BWSG, 'NHS Greater Glasgow & Clyde Board Water Safety Group Meeting Tuesday 6th March 2018 at 9.30am'.
[43] SHI, 'DOCS Bundle 6 Miscellaneous Documents' (n 20) 6.

risk and undertake a risk assessment in these areas as a priority, including sampling

3.24 In my opinion CEL 03 and 08 letter provided advice on the responsibilities and management of the water system. My opinion based on a number of reports including those from DMA is that the advice on sampling and flushing was not always managed from the time that patients occupied the QEUH. In the 2015 DMA report (p233) no one had been appointed as being responsible for flushing.

3.25 In addition, I have seen no evidence that staff were trained in these duties, there was a lack of risk assessments, written scheme, water safety group and a water safety plan.

3.26 For example, flushing issues were still being reported in 2022 in the Healthcare Improvement Scotland report (p29) [44] where "estates managers reported low compliance rates with some water flushing".

3.27 I have not seen any evidence of annual reports and therefore I am unable to comments on this.

3.28 In summary my impressions on the culture around sampling at the QEUH prior to 2015 are that as there were no risk assessments, no written scheme, no asset list and a lack of training of the staff. As such it is unlikely that there would have been a competent culture around sampling. I have seen no evidence of the standard methods in place prior to 2015 and no evidence of NHS GGC staff training for sampling.

3.29 However, DMA acknowledge that in 2015 a microbiological regimen was in place and that the sampling regime adequately reflected the complexity of the site. However, in my opinion the statement "it was a one off sweep carried out prior to patients being admitted" does not provide me with confidence that the sampling regime was adequate.

3.30 DMA indicated that sampling was carried out in accordance with the method statement (used by the main contractor prior to handover in order to ensure continuity of methodology) and the method statement had been reviewed and deemed as acceptable by NHS Microbiologists.

3.31 However, I have seen no evidence of training of those involved in water systems and sampling and therefore I have concerns about the diligence and robustness of the sampling regime and how it was carried out. I have seen no evidence of the water safety group or water safety plan or sampling plan in the time period pre 2015.

3.32 **In terms of analysis and identification of the bacteria**: the samples were forward to a UKAS accredited laboratory and therefore the laboratory would have undertaken the identification of the bacteria that were recovered on the agar plates using the methodologies prescribed in

[44] HIS, 'Healthcare Improvement Scotland. Inspection Report. QEUH Campus NHS GGC. 2022'.

their protocols. The laboratory would have been audited as per UKAS requirements. However, the laboratory may have been limited in the identification of bacteria and may not have retained isolates for matching to patient isolates at a later date.

4. **NHS GGC 'Summary of Incident' report of 22 February 2019**
You have referenced this document already in your report [fn 62]. Please comment on whether the testing system at QEUH was in accordance with the observation made at page 9 of 25 of that document *["Specific microorganisms which can be tested for include: Coliforms, Escherichia coli (including O157), Pseudomonas aeruginosa, Salmonella spp, Campylobacter spp and Environmental Mycobacteria. Testing for these is not conducted as standard within current guidance and typically occurs in response to a suspected or confirmed outbreak, or due to identification of a series of sequential cases."] The above statements relate to the commissioning stage.*

4.1. As discussed in my report (p32) there is a requirement that the water delivered to the hospital by Scottish water [45] is wholesome and that the water within the QEUH/RHC is wholesome as per the employers specification [46] and the contractors specification and building design strategy [47].

4.2. The Health and Safety at Work Act applies to the risk from Legionella bacteria and COSHH provides a framework to control the risk. [48] To comply with the legal duties dutyholders should identify and assess the risk i.e. produce a risk assessment and prepare a written scheme.

4.3. It is my understanding that the sampling plan would require to be comprehensive in terms of assessing the number of outlets in the hospital and risk profile of wards where high risk patients would be present.

4.4. To understand a water system and to determine that the water is wholesome requires trained and competent staff to establish a sampling programme that represents the number of water outlets in a hospital. Specialist staff who are trained in sampling should be employed and a UKAS accredited laboratory used to analyse the samples. A competent water safety group and water safety plan would be required to be put in place.

[45] DWQR, 'The Water Supply (Water Quality) (Scotland) Regulations 2001 (Superseded)' [2001] DWQR.
[46] NHS GGC, 'NHS GGC New South Glasgow Hospitals (NSGH) Project INVITATION TO PARTICIPATE IN COMPETITIVE DIALOGUE VOLUME 2/1 EMPLOYER'S REQUIREMENTS'.
[47] Brookfield, 'Design Strategies for the New South Glasgow Hospitals. SECTION 3.1: ARCHITECTURAL DESIGN STRATEGY 3.1 2009'.
[48] HSE, 'Legionnaires' Disease. The Control of Legionella Bacteria in Water Systems. ACOP 2013'.

4.5. From a microbiological perspective there should be an absence of *Clostridium perfingens* and Coliforms and there should be no abnormal change (i.e. the total colony count should be within set parameters) in the total colony count (number per ml) performed at either 22°C or 37°C.

4.6. My interpretation of the reports is that the sampling that was undertaken as part of the prehandover commissioning phase demonstrated that there were high levels of TVC i.e. the water was not wholesome.

4.7. NHS GGC were sufficiently concerned as to the microbiological risks of the water system that they refused to accept the handover of the hospital from the contractor [49].

4.8. In addition there was evidence from the contractor that percentages of the Horne taps failed the initial disinfection tests, were disinfected and retested (a month-and-a-half) later and failed the second test [50] (P25 of 201) i.e. the water sampled from the taps was not wholesome.

4.9. It is my opinion that the high TVC indicated that the water system in the QEUH/ RHC was not wholesome and presented a risk to patients.

4.10. It is my opinion that the lack of a risk assessment, water safety group, water safety plan and written scheme would have impacted on the management of the water system and the microbiology of the water system (DMA 2015) [51].

4.11. In my opinion the high TVC, may have been influenced by the failure to manage the water system e.g. bypass of the mains ultrafiltration system, failure of temperature control, presence of dead legs, stagnation due to early filling of the water system, debris present in water tanks, installation of open-ended pipework, presence of flexible hoses (DMA 2017) [52]. These risks would have contributed to the presence of TVC in the water system during the building/commissioning stages.

4.12. Whilst sanitation was carried out it was reported that there may still have been a number of areas with higher than normally acceptable levels of TVCs i.e. where the water not wholesome [53].

4.13. It is my opinion that the way the building was commissioned that the water in the building may not have been wholesome at the time of handover and that this was reflected in the high TVC.

[49] HPS, 'Summary of Incident and Findings of the NHSGGC: QUEH/RHC Water Contamination Incident and Recommendations for NHS Scotland. Final V2'.
[50] I Storrar and A Rankin, 'Report on the Findings of the NHS GGC: QEUH/RHC Water Contamination Incident and Recommendations for NHS Scotland 2018'.
[51] H Gbaguidi-Haore and others, 'A Bundle of Measures to Control an Outbreak of Pseudomonas Aeruginosa Associated with P-Trap Contamination' (2018) 39 ICHE 164, 6.
[52] SHI, 'DOCS Bundle 6 Miscellaneous Documents' (n 20) 6.
[53] HPS (n 49).

4.14. There are guidelines for monitoring waterborne pathogens such as Legionella which was tested for prior to handover.

4.15. Following the outbreak of *Pseudomonas aeruginosa* in Northern Ireland the DH (England) [54] published guidance that provided protocols for sampling, testing and monitoring water for *P. aeruginosa* within augmented care (high risk) units i.e. If test results are satisfactory (not detected), there is no need to repeat sampling for a period of six months.

4.16. The Note 16 in SHTM 04-01 Part B (2014) [55]: Testing of water for *P. aeruginosa* is only required if a very specific reason has been identified such as suspected or confirmed outbreak or a series of sequential cases, as guided by the Responsible Person (Pseudomonas).

4.17. Separate guidance for *P. aeruginosa* testing specifically in augmented care areas in Scotland was not introduced until 2018 which was four years later than that introduced in England.

4.18. It is my understanding that as there was no requirement to sample and test for *P. aeruginosa* in Scotland at that time then no testing was carried out as part of the commissioning and handover.

4.19. However, it is my opinion that considering the presence of high risk units in which patients were to be housed and the issuing of the CEL 03 (2012) and 08 (2013) letters then it would have been prudent to assess for a range of water borne pathogens and in particular *P. aeruginosa* in light of the Northern Ireland outbreak.

4.20. In addition the *P. aeruginosa* pre-occupancy report indicated that commissioning validation records for the taps were not fully available to the assessors [56]. In addition, some tap outlets with designated risk had water flowing directly into the drain, no flushing records available, taps with flow straighteners splashing out with the wash hand basin/ sink when outlets run. It was noted by the risk assessor that the cold water temperatures recorded by DMA vary considerably throughout the building with the majority being more than 5°C higher than those recorded at the water tanks and with peak temperatures of 30°C being noted i.e. the water system was a risk for the growth of Gram-negative waterborne pathogens such as *P. aeruginosa*.

4.21. Therefore whilst the microbiological testing system at QEUH may have been in accordance with the observation made at page 9 of 25 [57] there were issues due to the lack of a risk assessment and the lack of a written scheme, water safety group and water safety plan.

[54] DH (England) (n 3).
[55] HFS, 'Water Safety (SHTM 04-01) for Healthcare Premises Part B: Operational Management.' [2014] National Services Scotland.
[56] DMA, 'Pseudomonas Report on Water Delivery System (Pre-Occupancy)' (n 23).
[57] HPS (n 49).

4.22. In my opinion the lack of these documents and strategies demonstrated that the water system was not being managed according to the HSE or SHTM 04-01 guidance.

4.23. In addition the lack of the risk assessments and written scheme and training would question whether those managing and requesting sampling during the commissioning phase were sufficiently competent to understand the water testing requirements to deliver a safe water system at the QEUH and RHC.

5. **Testing: Gram-positive Bacteria**
Please comment on the absence of testing data for Gram Positive Bacteria. Please comment on the impact of IPC management by Water Safety Groups, should testing be incomplete.

5.1. My opinion and experience over 30 years of water microbiology is that Gram-positive bacteria associated with water systems is uncommon. This is supported by the peer reviewed published literature in the review "Rapid literature review of water associated HAI incidents in support of NHS GGC" produced by NHS NSS in 2018. [58]

5.2. As the majority of infections associated with water systems are Gram-negative then the majority of sampling would be undertaken for Gram-negative microorganisms.

5.3. Testing for Gram positives in water samples would be in response to specific cases where Gram-positive infections had been identified and water had been identified as a potential source.

5.4. My opinion is that as per guidance that the IPC representatives would manage this risk in the water safety group or associated meetings.

6. Testing: Gram-Negative Bacteria
(a) You address Gram Negative Bacteria throughout your report. In your view, were measures in relation to investigation, control and risk management at QEUH sufficient to address the risk of further outbreaks?

6.1. My report identifies many of the problems relating to the investigation, control and risk management of the water system at QEUH. The evidence provided by the inquiry would indicate that the investigations, control and risk management at QEUH were insufficient to address the risk of further outbreaks and some of that evidence is discussed below.

6.2. My opinion is that based on the evidence provided by the Inquiry that those in control of premises and those with health and safety responsibilities for the QEUH and RHC hospital water and wastewater systems did not comply with their legal duties as per HSG 274 [59] and SHTM 04-01 which resulted in the water system being contaminated with Gram-negative microorganisms. [60]

[58] Storrar and Rankin (n 50).
[59] HSE (n 15) 274.
[60] HFS, 'Water Safety (SHTM 04-01) Part A: Design, Installation and Testing 2014' (n 10).

6.3. This was evidenced in the DMA Legionella Risk Assessment of 2015 which identified high risk issues requiring remedial action as soon as possible by senior management prior to patient occupation in 2015. [61] These issues included the lack of a risk assessment and the absence of the written scheme for the control of Legionella. Problems were also identified with debris in the cold water storage tanks, hot water temperatures below 55°C and cold water as high as 30°C. The DMA report was very clear on the high risk problems of the water system and the risk to vulnerable patients with the hospital and that these should be remediated as soon as possible.

6.4. Two years later the next DMA Legionella Risk assessment in 2017 [62] addressed many of the same high risk issues including a lack of training of key senior staff and a lack of knowledge about the QEUH/RHC water system by the staff. The high risk problems identified in 2015 had not been addressed by senior management.

6.5. Independent microbiological reports by Intertek identified that the water system from the cold water storage tanks, expansion vessels through to the taps, showers, drains and ancillary equipment were microbially contaminated with a wide range of Gram-negative waterborne pathogens and biofilm. [63]

6.6. My opinion would be that these results demonstrated that there had been a lack of control and risk management of the water system.

6.7. Following the outbreak of *P. aeruginosa* in Northern Ireland in 2011/2012 the DH (England) had produced guidance related to flushing, sampling and the removal of flow straighteners in high risk areas.

6.8. In Scotland CEL 03 (2012) and (CEL 08 2013) were produced with action for Directors of Estates/Facilities to:

- Ensure that manufacturers' instructions with regard to installation and maintenance have been followed
- Ensure a coordinated approach between IPCTs and Estates/Facilities department on all water issues including through the establishment of a board/hospital water safety group
- Ensure all taps are flushed in accordance with the attached best practice for handwash basins to minimise the risk of Pseudomonas aeruginosa contamination in high risk units

6.9. In 2014 SHTM 04-01 Part A note 15 indicated that flow straighteners should be removed but this should be subject to risk assessment. However, in 2014 a decision was taken by those representing Scotland NHS,HFS, HPS and a number of Scottish hospitals to install taps with flow straighteners at the QEUH/RHC.

6.10. The DMA reports (2017) provided evidence that no servicing of any of these taps valves' (sic TMV), and the associated strainers in non-high risk areas has been carried out since the hospital opened in 2015 and there has been a very limited program of servicing in 'high risk' areas.

6.11. The Intertek reports demonstrated that the flow straighteners were significantly fouled which would have reflected the lack of control and risk management at the periphery of the water system

[61] SHI, 'DOCS Bundle 6 Miscellaneous Documents' (n 20).
[62] SHI, 'DOCS Bundle 6 Miscellaneous Documents' (n 20).
[63] SHI, 'DOCS Bundle 6 Miscellaneous Documents' (n 20).

6.12. In addition separate guidance for *P. aeruginosa* testing specifically in augmented care areas in Scotland was not introduced until 2018 which would indicate that the risk to patients in high risk units was not managed appropriately.

6.13. In my view following NHS GGC recognition that the HAI were related to water borne microorganisms an extensive number of enhanced control measures were implemented in relation to investigation, control and risk management at QEUH to control the risk to patients from the risk of water borne infections. [64]

6.14. (b) The Inquiry's attention has been drawn to a published paper in the Journal of Hospital Infection (Inkster et al. 2022, JHI 123:80) indicating a high incidence of detected presence of Gram Negative Bacteria at UK hospitals [99 out of 157 samples positive]. Are you aware of this paper?

6.15. Yes I am aware that this paper had been published. The paper demonstrates hospital water systems are not sterile and that Gram-negative microorganisms were present in hospital water systems. *Cupriavidus* spp. was detected by the authors in four of 10 hospitals tested, and all five isolates were from the periphery of the water system.

6.16. The above manuscript provides evidence that the water within hospitals is not sterile and that a wide range of Gram-negative microorganisms can be detected including *Cupriavidus* spp. at the periphery of the water system.

6.17. The paper cites ". The results indicate that the organism is also present in hospital water elsewhere in the UK, although both the numbers of affected outlets and concentrations of *Cupriavidus* spp. were significantly less than found during the Glasgow incident."

6.18. In my opinion, the latter statement provides evidence that the numbers and concentration of *Cupriavidus* spp. were higher in Scotland and that those responsible for the water systems had a duty of care to protect patients from these water borne pathogens.

6.19. However the 2015 and 2017 DMA Legionella risk assessments provide evidence that the duty of care had not been undertaken.

6.20. Do you have anything to add to your views on QEUH?

6.21. The above paper demonstrated that Gram-negative microorganisms are present in hospital water systems.

6.22. The HSE have identified contributing factors in outbreaks of waterborne infections where water systems were considered unsafe including inadequate management, lack of training and poor communication.

6.23. The evidence presented by the Inquiry demonstrated there was inadequate management, lack of risk assessments, written schemes, training and poor communication which resulted in the microbial contamination of the water system with a range of Gram-negative bacteria from the period when patients started to occupy the site in 2015 and through to 2018. Readily available guidance was not followed (HSG 274 and SHTM 04-01). As those high risk issues were not addressed for a significant period of time patients in

[64] Storrar and Rankin (n 50).

high risk units would have been at increased risk of exposure and potential infection from waterborne microorganisms.

7. **Contamination**
(a) At paragraph 2.3.4 of your report you observed that water supplies are not sterile. You go on throughout the report to make reference to 'contamination' or to water being 'contaminated'. Please explain what you mean when referring to those terms.

7.1. The statement for the above paragraph is as follows "2.3.4. Hospital water supplies are not sterile. However, waterborne infections can be prevented by careful design, implementation of control strategies, planned preventative maintenance schedules, due diligence, governance, training and education." [65]

7.2. As discussed in my report water delivered to hospitals must be wholesome. The water will still contain bacteria and there are prescribed tests that must be undertaken to prove that the water is wholesome.

7.3. Scottish water has been recognised to have high levels of sediment that when entering a hospital water system settles out and provides a carbon source for the growth of microorganisms that led to the extensive failure of copper piping in Scottish hospital in the 1980's. Independent scientific investigations implicated that the high level of sediment was used as a carbon source by waterborne bacteria resulting in biofilms that were associated with the failure of the copper piping in the hospitals. [66] The levels of detritus led to the conclusion that it was essential for healthcare premises pipework systems to be filtered to maintain hygienic conditions. [67]

7.4. To protect the pipework in Scottish hospitals SHTM Part E states that "all incoming cold water supplies destined for domestic use within NHS Scotland premises should be filtered".

7.5. However, the evidence provided in the 2015 Legionella risk assessment by the Inquiry indicated that during the commissioning stage an emergency bypass had been left in place that bypassed the ultrafiltration unit. [68]

7.6. It is my opinion that the QEUH/RHC hospital water system, from the cold water storage tanks, hot water calorifiers, expansion vessels, associated hot and cold pipework and flow straighteners were contaminated with a high level of sediment and detritus as result of the bypass hose.

[65] HSE (n 15).
[66] CW Keevil and others, 'Detection of Biofilms Associated with Pitting Corrosion of Copper in Scottish Hospitals' [1989] Biodeterioration Journal 99.
[67] HFS, 'Water Safety (SHTM 04-01) Part E. Alternative Materials and Filtration.'
[68] SHI, 'DOCS Bundle 6 Miscellaneous Documents' (n 20) 6.

7.7. After the bypass had been removed the water system was already contaminated by sediment and water borne bacteria.

7.8. My opinion is that this extensive contamination was presented in the Intertek microbiology reports [69].

7.9. As discussed in my report wholesome water contains a range of waterborne microorganisms. Water delivered to hospitals is deemed as wholesome. That is, the water supplied will contain microorganisms. However, where the water system in a building is not managed, does not have risk assessments or a written scheme then it is likely that conditions will prevail that will result in excessive growth of Gram-negative microorganisms. As the microorganisms are presented with conditions that are favourable for growth they will then use the high levels of sediment and detritus as a carbon source to microbially contaminate the water system and form biofilms on surfaces (such as the water tanks, expansion vessels, pipework and flow straighteners) as we evident in the Intertek reports [70]

7.10. The evidence presented by the Inquiry demonstrated there was inadequate management, lack of training and poor communication which resulted in the microbial contamination of the water system with a range of Gram-negative bacteria from the period when patients started to occupy the site in 2015 and through to 2018. As those high risk issues were not addressed for a significant period of time patients in high risk units would have been at increased risk of exposure and potential infection.

(b) When referring to bacterial contamination, are you in a position to say how many of the water organisms were typed? Are you aware of the rationale for doing so, and whether they were compared with the patients' isolates?

7.11. From the evidence presented I am aware that a number of water organisms were typed and compared to the patient strains but I am unable to say how many and can only work with the evidence that I have been provided with.

7.12. The rationale for doing so would be to compare patient and environmental isolates to determine if they matched.

7.13. Dr Mumford's report has discussed this area and indicated the first unusual infection recorded in February 2016, *Cupriavidus pauculus* blood stream infection and that the link was made with same organism in the sink in the aseptic pharmacy. Subsequent typing confirmed the two

[69] SHI, 'DOCS Bundle 6 Miscellaneous Documents' (n 20) 6.
[70] SHI, 'DOCS Bundle 6 Miscellaneous Documents' (n 20) 6.

organisms matched and measures were taken to rectify the pharmacy sink and plumbing.

7.14. Dr Mumford indicates that in some instances, not all processes may have been followed through to their conclusion when investigating BSI incidents associated with patients and examined with some reports incomplete.

7.15. Dr Mumford identified that there was poor communication between laboratory, clinical teams and the IPC team that led to inadequate flagging of cases of interest and a lack of follow up procedures including linking related organisms using typing methodology. In addition The CNR report71 was critical of the recording of environmental data which was found to be inconsistent and lacked organisation.

7.16. I am aware of the WGS report provide by Prof Leonard and I have made comments on the limitations of the sampling in that WGS report elsewhere in reply to other questions.

8. **Hospital-Acquired Infections (HAIs)**

In your report you make numerous references to HAIs, such as at paras 5.1.8 ["HAI associated with the built environment should not be accepted as an inevitable consequence of being admitted to a hospital to access lifesaving treatment"], 5.1.9 ["a safer built environment could be considered one in which HAI has been significantly reduced"] and 5.5.10 (quoting) ["Healthcare-associated infections related to the built environment are preventable, and strategies should be in place to provide effective and safe patient care"].

In general terms, please describe your view of the significance of the occurrence of an HAI. Is there an extent to which HAIs might be expected to occur? Does it automatically follow that the occurrence of an HAI will indicate a fault with the built environment?

8.1. **In general terms, please describe your view of the significance of the occurrence of an HAI.**

8.2. In my view and from my perspective as a water microbiologist the significance of the occurrence of an HAI associated with water would indicate that there has been exposure to waterborne bacteria within the hospital environment that has resulted in an HAI.

8.3. Waterborne HAI are avoidable and should not occur. [72]

8.4. Is there an extent to which HAIs might be expected to occur?

8.5. The HSE and the UK Governments have produced guidance over a number of years on the risks of HAI associated with water and have provided guidance on how to minimise those risks. There are a number of different aspects to HAI including the built environment and staff behaviour. The

[71] QEUH and RHC Case Note Review Overview Report. March 2021
[72] HSE (n 15).

implementation of risk assessments, written schemes and training are strategies by which the risk of HAI waterborne associated infections can be reduced. The HSE have identified that where there is inadequate management, lack of training and poor communication then it would be considered that there could be an increased risk from HAI (HSG 274 p6, paragraph 16).

8.6. Does it automatically follow that the occurrence of an HAI will indicate a fault with the built environment?

8.7. No, it does not automatically follow that the occurrence of an HAI will indicate a fault with the built environment. For example the WHO indicate that most HAI are preventable with hand hygiene practice preventing the onward transmission of infectious microorganisms being passed from a member of staff to a patient.

8.8. However, where there has been inadequate management, lack of training and poor communication in the risk management of a hospital water system, such as occurred at the QUEH/RHC, including education of staff in water hygiene and safety to alert them to the risks of contamination by water during everyday activities (see below). then HAI may indicate a fault with the built environment in terms of the water system.

8.9. I am unable to comment on other aspect of the built environment including ventilation.

8.10. In addition, patients in hospitals are potentially at risk of water borne HAI. For example those who are immunocompromised or who have an underlying condition, such as cystic fibrosis are more susceptible to opportunistic pathogens.

8.11. Guidance (HSE 274 and SHTM 04-01) including Government letters (CEL 03 and 08) have provided advice on risks to patients associated with waterborne microorganisms. As such those with responsibility for water system are required to prevent or control the risk from water borne microorganisms such as Legionella, Pseudomonas and other potentially pathogenic microorganisms from the water system, taps and other outlets. However, where there are failings in the management of the hospital water system then it is more likely that waterborne HAI will occur.

8.12. These failings were evident and identified in the risk assessments in 2015 and 2017 including no formal management structure, no written scheme for legionella, lack of training and competency records, gaps in the risk reduction systems and processes which were described as haphazard, no Authorised Person for water at QEUH and out of date schematics. I have not seen any evidence that the 2015 risk assessments were acted upon despite many of the issues being identified as high risk in 2017.

8.13. Infection Prevention and Control (IPC) is an established, evidence based and practical approach to prevent harm to patients, visitors and healthcare workers from avoidable infections.

8.14. To be effective and to reduce the impact of HAI from the built environment and particularly water, IPC must be a multi-disciplinary approach from clinical, estates and facilities and corporate teams together with users of healthcare facilities.

8.15. In my opinion, education of staff in water hygiene and safety is important to alert them to the risks of contamination by water during everyday

activities such as preparing drugs, filling water jugs and hand washing. This would include the risk of cleaning contaminated patient medical devices in clinical hand wash basins. Such actions would have led to the microbial contamination of drains.

8.16. I have not seen any evidence of this type of training for clinical staff at QEUH/RHC which may have assisted in minimising waterborne HAI and this lack of training was acknowledged during our visit and meetings at QEUH/RHC.

9. **Other physical components of the water system: general**
Having had the opportunity to reflect, are there are any other physical components of the water system at QEUH on which you would like to comment?

9.1. My comments arise not from any single physical component of the water system but more from the aspect of the lack of risk assessments, written scheme, absence of a management plan and the lack of a water safety group and water safety plan specifically to the QEUH/RHC that led to contamination of a wide range of physical components and hence risks to patients.

9.2. Problems were identified in the water system during the building and commissioning phase, when the building was handed over.

9.3. I have not seen any evidence that there was a comprehensive management of the risk from the water system as set out in national (HSE HSG 274) and local guidance (SHTM 04-01) from handover.

9.4. During the preoccupation phase the Legionella Risk assessment [73] identified and described a number of high risk issues associated with physical components and their operation, servicing and maintenance.

9.5. The high risk issues associated with equipment that were identified by DMA in 2015 were again identified in the Authorised Engineers report in May 2017 [74] and also in the DMA report in September 2017 [75] and there was no evidence that the points raised had been closed by NHS GGC.

9.6. To understand what physical components there are in a water system there needs to be an asset list – at the 6th March 2018 Water Safety Board meeting it was stated [76] that NHS GGC still did not have an accurate asset list including TMV's and were still debating whether taps and sinks were part of the asset list.

9.7. Using TMV's as an example, in the absence of an asset list it would be difficult to undertake a comprehensive sampling strategy and planned

[73] DMA, 'L8 Risk Assessment NHS GGC South Glasgow University Hospital. 2015.' (n 14).
[74] D Kelly, 'Legionella Control AE Audit – Queen Elizabeth University Hospital – 2017'.
[75] DMA, 'Legionella Risk Assessment QEUH (Adult) Hospital and the Adjoining RHC 2017' (n 17).
[76] NHS GGC BWSG, 'NHS Greater Glasgow & Clyde Board Water Safety Group Meeting Tuesday 6th March 2018 at 9.30am' (n 42).

preventative maintenance strategy to assess and reduce the risk to patients.

9.8. In terms of the taps that were fitted, NHS GGC were aware of the risks of fitting taps with flow straighteners and unanimously decided (at the NHS GGC meeting in June 2014) to fit those taps to the water system where high risk patients were present. The statement "Risk management was the key" was recorded at the meeting in June 2014 in terms of reducing the risk from Pseudomonas and other Gram-negative microorganisms. However, there is little or no evidence that the risks associated with the taps, flow straighteners and strainers were managed to reduce the risk to patients from 2014 to 2017. (DMA Legionella Risk Assessments 2015 and 2017).

9.9. Equipment supplied by third parties such as the stand alone water coolers also presented a risk in terms of waterborne pathogens and there appeared to be confusion as to whose responsibility it was for servicing and planned preventative maintenance. The 2015 Legionella Risk assessment (DMA) identified that "Water coolers and drinks machines should have regular servicing carried out (generally six monthly) as per manufacturers recommendations."

9.10. The poor standard of microbiological quality of the water sampled for these coolers became apparent in March 2017 [77] and it was indicated that "Mains coolers should be subject to regular quarterly maintenance and weekly cleaning."

9.11. I have seen no evidence that NHS GGC were managing that risk with water coolers following the identification of the risk in 2015.

9.12. Dishwashers had been identified as being fitted with flexible hoses in 2015 (DMA) and these were excluded in the specification. It was noted that microbiological samples taken were found to be positive and matched the fungi colonised on the patients [78]. In the IMT meeting in September 2017 (HOIC bundle) there was discussion as to whose responsibility it should be to clean the dishwashers.

9.13. I have seen no evidence that the dishwashers were serviced or previously cleaned or whether they were part of an asset list.

9.14. In my opinion there appears to have been issues as to who was responsible for what equipment and is an example of the poor communication and management that was in place.

9.15. The 2015 Legionella Risk Assessment [79] (p207) identified that "All other "at risk" systems should have a suitable L8 risk assessment carried out with an appropriate L8 monitoring regime implemented." An extensive list of other physical equipment is recorded in the RA indicating the risk

[77] Storrar and Rankin (n 50).
[78] Storrar and Rankin (n 50).
[79] DMA, 'L8 Risk Assessment NHS GGC South Glasgow University Hospital. 2015.' (n 14).

to patients from Legionella and other Gram-negative microorganisms was not assessed or controlled.

9.16. The 2017 Legionella Risk assessment [80] (p12&15) identified that these other risk systems throughout the hospital building may create a risk from Legionellosis.

9.17. There was a lack of evidence that the risk from these other physical components had been addressed despite being some being identified in 2015 as high risk for this site.

9.18. HSG 274 Part 3 The control of legionella bacteria in other risk systems provides advice and guidance for dutyholders, including employers, those in control of premises and those with health and safety responsibilities for others, will help them comply with their legal duties. This guidance would have covered the other physical components in the QEUH/RHC that should have been included in the risk assessment and written scheme. I have no evidence of the risk assessments or written scheme for the other physical components related to those examined during the Legionella risk assessments in 2015 and 2017.

9.19. The 2015 legionella risk assessment [81] identified that not all Duty Managers have completed Appointed Person training and in 2017 DMA identified that the Authorised Person had been in place for over 18 months without Authorised Person training.

9.20. NHS GGC had a duty of care to protect all patients from infection risks from bacteria or pathogens associated with the water by implementing risk assessments, written schemes, planned preventative maintenance, servicing of the physical equipment and training of staff responsible for the water system [82] [83].

9.21. The evidence from the risk assessments and independent microbiology laboratory [84] [85] would indicate that NHS GGC did not undertake this duty of care to protect patients from Legionella and other Gram-negative microorganisms in physical components of the water system.

10. Other physical components of the water system: drainage: potential deficiencies in the design of external components
In the Provisional Position Paper 11 on Water dated 12 April 2024 reference was made to the waste system being a potentially deficient feature of the drainage system at para 24.19.

[80] DMA, 'Legionella Risk Assessment QEUH (Adult) Hospital and the Adjoining RHC 2017' (n 17).
[81] DMA, 'L8 Risk Assessment NHS GGC South Glasgow University Hospital. 2015.' (n 14).
[82] HSE (n 48).
[83] HSE (n 48) 274.
[84] Intertek, 'Intertek Report Number ITSS-0718-0001W plus per Floor Contamination of Flow Straighteners Debris and Sponges 2018'.
[85] Intertek, 'ITSS- 0719-0001 Expansion Vessel Investigation Report for QUEH Glasgow. 2019'.

It has been suggested that there were significant issues with the 'design and build of the drainage system at the QEUH/RHC that presented a risk to patients and facilitated reflux of drain contents back up into sinks. These issues included: a lip at the connection with the sink which facilitated pooling and stagnation of water; the presence of excess sealant causing partial obstruction and the presence of material prone to corrosion. The issues with the drains were identified as a result of two Problem Assessment Groups (or "PAGs") which were held in May 2018 to discuss an increase in cases of Stenotrophomonas and Enterobacter infections on Ward 2A.'

10.1. Based on the documentation provided by the Inquiry the drainage system was designed to operate under gravity from basins sinks and showers with the soil and waste discharged long horizontal and vertical pipes to the ground floor via common vertical stack waste disposal pipes. The system was designed such that there would have been a water trap at the points of discharge to provide a water seal to prevent foul air from entering the ward environment.

10.2. As cited in my report the Mechanical and Electrical Services designer/Architect indicated which guidance document the sanitary ware should comply with but did not specify the type of hand wash basins to be installed. The specification cited concealed waste for back outlet basins (as per SHTM 64 [86]) and flush grated metal waste devices. [87] Therefore, consideration had been given to the type of hand wash basin to be fitted i.e. rear facing drain, the installation of the rear facing drains pipes as per guidance.

10.3. The connection to the drainage pipe work from the sink is via an aluminium spigot with a silicone gasket or washer. Following a clinical incident it was noted that the sink drains (Ward 2A) had a build-up of biofilm and the aluminium spigot was corroding. [88] (P111) The sealant that was previously described was actually the gasket [89] (p181). There is no evidence that the pipes and drains were not fitted according to the manufacturer's instructions.

10.4. In my opinion the damaged seals are likely to retain dampness and become colonised by mould and biofilm bacteria leading to contamination of the sink/basin/shower area and associated drains.

10.5. In my opinion the presence of a lip at the connection with the sink which facilitated pooling and stagnation of water would not be a good design feature as this would inherently result in the growth of microorganisms and biofilm in the stagnant water that would result in contamination of the basin.

[86] HFS, 'SHTM 64 SHTM Building Component Series Sanitary Assemblies' 64.
[87] Wallace Whittle TUV SUD, 'TUV SUD Specification Hot and Cold Water Systems Rev C April 2014. Document Ref: ZBP-XX-XX-SP-500-103'.
[88] SHI, 'SHI - IMT Minutes Bundle 1 of Documents for the Oral Hearing Com' 2023, 1.
[89] SHI, 'SHI - IMT Minutes Bundle 1 of Documents for the Oral Hearing Com' (n 88) 1.

10.6. At the 29th May IMT (Bundle 1 IMT documents p94 [90]) meeting there was concern that the drains could be a potential likely source of the *E.cloacae* and noted the black grime found within the drains of the sink. At the 4th June IMT (Bundle 1 IMT) it was discussed that here had been previous PAGs/IMTs held relating to Enterobacter and Stenotrophomonas which led to the drains being swabbed. At the 5th September IMT meeting the group was informed of the 3 cases of bacteraemia reported since 5th August 2018 which have been caused by Gram-negative organisms isolated from the drains. The build-up of grime noted in the drains despite having only been cleaned in the 4-6 weeks prior [91] (p149).

10.7. In addition, it was also noted at the 10th Sept 2018 IMT meeting[92] (p155) that the drain of the treatment room sink in ward 2A was heavily contaminated again having only been cleaned the week prior. Such findings would indicate that recolonisation of drains in 2A was occurring rapidly as a consequence of sufficient nutrients being disposed into the drain enabling microbial growth.

10.8. Such rapid regrowth of black slime and grime may occur where nutrients were being discarded into the basins that would provide nutrients for bacteria to grow. The more nutrients present in the drain then the quicker the bacterial growth and the more grime that will accumulate including patient and environmentally derived microorganisms.

10.9. In addition to the identification of a number of Gram-negative microorganisms present in the swabs from the drains, NHS GGC forwarded bottle traps to the independent microbiology laboratory Intertek for analysis [93]. The microbiological analysis of the drain was similar to that observed by NHS GGC. Whilst the lower part of the bottle trap was clear of visible debris, there was significant evidence of 10 mm solid contamination between the down pipe and the bottle trap. The debris consisted of a large piece of plastic film, clumps of hair and decaying organic matter. In addition the metal fitting was corroded and the rubber seal was found to be degraded. A swab of the area demonstrated the presence of significant biofilm ($210x10^6$ /cm^2 per swab).

10.10. My opinion of the Intertek drain study is that drains and seals were significantly fouled with biofilm and decaying organic matter. This material would have been used as nutrient source for the microorganisms.

10.11. The evidence from the HIS report [94] was that staff were cleaning medical devices (tracheostomies) in the basins which would have provided not only nutrients but potentially patient microorganisms.

[90] SHI, 'SHI - IMT Minutes Bundle 1 of Documents for the Oral Hearing Com' (n 88) 1.
[91] SHI, 'SHI - IMT Minutes Bundle 1 of Documents for the Oral Hearing Com' (n 88).
[92] SHI, 'SHI - IMT Minutes Bundle 1 of Documents for the Oral Hearing Com' (n 88) 1.
[93] Intertek, 'Intertek Report Number ITSS-0718-0001W plus per Floor Contamination of Flow Straighteners Debris and Sponges 2018' (n 84).
[94] HIS (n 44).

10.12. There was evidence of slow draining basins [95] (p232) which would have resulted in residual water from the drain contaminating the basin surfaces and potentially the point of use filters and this slow draining would also have led to splashing into the ward environment.

10.13. Such observations are important as in the HIS report 2019 [96] a member of medical staff was observed preparing an intravenous infusion in an area of the clean preparation room very close to a sink within splash contamination distance of this sink. Where a sink has a contaminated drain and that drain is slow draining then it is highly likely that splashing will occur in the immediate vicinity of the sink.

10.14. It was also noted that the drain of the treatment room sink in ward 2A was heavily contaminated again having only been cleaned the week prior to the IMT meeting[97] (p155). The recolonisation of a sink within one week would indicate that recolonisation of drains in 2A was occurring rapidly as a consequence of sufficient nutrients being available for microbial growth.

10.15. Theatre sink drains were also found to contain numerous plastic nail picks from scrubbing brushes gathered in the traps of the sinks which would have provide a nutrient source for biofilm growth. [98] (p228).

10.16. In my opinion, patient safety is not just about design, build and commissioning. Those managing a hospital water system have a duty of care to alert staff to the risks such that they too can reduce the risk to patients.

10.17. The education and training of staff in water hygiene and safety is important to alert them to the risks of contamination by water and drains during everyday activities such as preparing drugs, filling water jugs and hand washing. This would include education on the risks related to cleaning contaminated patient medical devices in clinical hand wash basins [99]. Such actions would have led to the microbial contamination of drains.

10.18. I have not seen any evidence of this type of training for clinical staff at QEUH/RHC which may have assisted in minimising waterborne drain associated HAI.

10.19. As the drain systems were connected it is likely that the bacteria were able to track along the drains to contaminate other parts of the ward or other wards. It should be taken into consideration that even the pouring of disinfectants will only have a transient effect as the biofilm will grow back along the drain piping.

[95] SHI, 'SHI - IMT Minutes Bundle 1 of Documents for the Oral Hearing Com' (n 88).
[96] HIS (n 9).
[97] SHI, 'SHI - IMT Minutes Bundle 1 of Documents for the Oral Hearing Com' (n 88) 1.
[98] SHI, 'SHI - IMT Minutes Bundle 1 of Documents for the Oral Hearing Com' (n 88) 1.
[99] HIS (n 44).

10.20. Additional problems were also occurring in patient shower rooms where large volumes of black moulds in showers were observed. [100] This mould would have been washed into the drain system causing contamination of the drain area and potential recontamination when the drain flow was slow or there was residual water on the shower floor.

10.1. **What were your observations during the course of your QEUH/RHC site visit in September 2023?**

10.1.1. My observations during my visit to the QEUH/RHC in September 2023 were that there was unnecessary clutter associated with hand wash basins and sinks including containers, wipes, eating and drinking utensils, patient water jugs, medical devices and toys cluttering the area around and within the splash zone of clinical hand basin and stainless steel sinks. In addition there was equipment and boxes blocking access to basins that would have led to underuse and stagnation of the water leading to the basins and sinks.

10.1.2. My opinion is that the extent of clutter that was observed reflected that the staff may not have received training in the risks of waterborne bacteria and basin hygiene and that his clutter increases the microbiological risk surrounding basins and to patients,

10.1.3. I observed a wide range of damaged sealant in and around basins as well as along joins (floors and walls) in showers.

10.1.4. My opinion is that the number of instances of damaged seals associated with basins and with floor/wall joints in showers was that this was not recognised as a risk of water and microbial entrapment that would increase the risk to patients.

10.2. How would the stated conditions give rise in particular to Stenotrophomonas and Enterobacter infections?

10.2.1. With Stenotrophomonas it is likely that the drains were contaminated from the water system. As discussed elsewhere I have seen little evidence of risk management of the water from handover through to 2017. Once contaminated the drains would have remained contaminated resulting in significant solid biofilm present between the wall of the bottle trap. It is my experience that even transient treatment with biocides would have little impact on the solid mass of biofilm that was present due to the lack of penetration.

10.2.2. *Enterobacteriaceae* is more likely to contaminate hospital sinks through inappropriate use e.g. disposal of patient body fluids into the drain. During the HIS inspection (2022) [101] staff were observed cleaning respiratory equipment (tracheostomies) in the clinical wash hand basin.

[100] SHI, 'Scottish Hospitals Inquiry Meeting Minutes Bundle Of Documents as Referenced in QEUH HOIC PPP'.
[101] HIS (n 44).

By cleaning patient medical equipment such as tracheostomies in a sink, there is a risk of contaminating the clinical wash hand basin and the drain with patient microorganisms.

10.2.3. As such the cleaning of used medical devices in basins will result in the contamination of the basin and the drain – with the drain becoming a long term repository of the microorganisms. When those contaminated basins are used they will result in splashing in and around the wash handbasin potentially with *Stenotrophomonas* and *Enterobacter*. As indicated above where there is unnecessary and excessive clutter (as I observed during my visit) in and around clinical wash hand basins then those items will potentially be contaminated with a range of drain associated microorganisms through that splashing.

10.2.4. The placement of equipment in the front of basins and sinks results in their infrequent use and potential stagnation of the water in hot and cold water pipes. Where equipment has been left lying on the ledges/shelf of sinks then it is likely that the bottom of the equipment will become contaminated with biofilm growth from the sinks. Items left within the splash zone of the sink will also become contaminated with drain associated microorganisms.

10.2.5. Hence, it is my opinion that the contamination of drains and subsequent splashing of contaminated drain water can increase the risk of HAI as a result of *Stenotrophomonas* and *Enterobacter* infections where splashes occur directly onto the patient or indirectly onto other medical equipment or ward equipment with which the patient would then come into contact.

10.3. Are there specific conditions that encourage the said bacterial species to proliferate more quickly?

10.3.1. As was indicated in the IMT report [102] (p155) the presence of grime in the drains was apparent after only 1 week. Where materials and liquids are disposed of into basins and drains then this provides nutrients for the growth of microorganisms. The rapid regrowth of black slime in one week would indicate that sufficient nutrients were being supplied to the drain for microorganisms including bacteria to grow in the drain. The washing of medical devices (using the example of the tracheostomies) and disposal of patient body fluids would lead to the sink area and drain being contaminated with a high nutrient source and infectious microorganism from the patient.

10.3.2. My opinion is that the more nutrients present in the drain then the quicker the bacterial growth and the more grime that will accumulate including microorganisms.

10.3.3. I have not seen any evidence of this type of training for clinical staff at QEUH/RHC which may have assisted in minimising waterborne

[102] SHI, 'SHI - IMT Minutes Bundle 1 of Documents for the Oral Hearing Com' (n 88) 1.

drain associated HAI and this was acknowledged during out visit to the QEUH/RHC.

11. **Other physical components of the water system: specific features**

11.1. **(a) At para 5.24 of your report you made reference to u-bends. Are you aware of whether u-bends were used at QEUH?**

11.2. During my visits it evident that all the drain equipment were behind access panels that we did not access. On reviewing the images from my visits I have only been able to observe a bottle trap in the photographs (Figure 1).

11.3. Figure 1 demonstrating bottle trap as observed at the QEUH (supplied by J Walker 2024).

11.4. All drains in basins and sinks require a water trap to prevent foul odours from permeating from the drain into the surrounding ward or single patient room. This can be achieved by either using u-bends where the pipe is in the shape of a u-bend, such that the water is retained in the trough of the u-bend.

11.5. With bottle traps a container like an upside down bottle is attached to the waste pipe, where the waste pipe sits in the fluid contained in the bottle thus preventing foul odours from entering in the ward space or patient room. The bottle also traps materials that have been placed into the drain to prevent them entering the rest of the waste system. Bottle traps are often used in tight spaces where traditional u-bends may not fit.

11.6. Both the u-bend and the bottle trap work in a similar nature but retaining water to prevent foul odours from the drain from entering the ward or patient environment. As discussed in Q10, where water, patient medical equipment or body fluids and other fluids are disposed of into drain, then the drain will become contaminated with range of waterborne, patient and environmental microorganisms.

11.7. The presence of bottle traps rather than u-bends does not change my view that the traps were contaminated and that transient biocide treatment would not remove the dense biofilms that were observed in the Intertek studies.

(b) At para 6.3.16 of your report you stated your view that dump valves at QEUH were not operational "i.e. not connected to the BMS". Are there other means by which dump valves can work?

11.8. Dump valves were strategically placed at a number of points on the domestic cold water system in the lower floors of the QEUH and RHC. The purpose of the valves is to prevent stagnation by periodically flushing water, reduce biofilm formation by flushing away loosely attached biofilm and temperature control where the valves operate to flush and return the cold water to 20°C.

11.9. However, during the 2015 Legionella risk assessment [103] it was noted that cold water temperatures were in excess of 20°C with peak temperatures of 30°C being recorded. The independent risk assessors were advised by Estates of ongoing commissioning problems on the cold water dump valve system and that the system was not working as intended i.e. the dump valves were not discharging the water as the system had been designed and built to do as the sensors were positioned incorrectly. As the valves were not operating as intended this would have led to stagnation, biofilm formation and increased temperature. Importantly the growth of microorganism would have seeded the water system upstream.

11.10. Where the sensors were positioned incorrectly and the dump valves were not discharging automatically as intended it may have been feasible to operate the dump valves manually to reduce the water temperature back to 20°C. I have seen no evidence that the dump valves were operated manually.

11.11. (c) At para 6.4.6 of your report you make reference to deadlegs "…of excessive length up to 2.9-3m…". Attention has been drawn to SHTM 04-01 Part A 2008, which provides that "…the complete length of the spur should not exceed 3m." [at section 9.49]. Please comment on this.

11.12. In the NSS Health Facilities Scotland Water Management Issues Technical Review NHS Greater Glasgow and Clyde – Queen Elizabeth University Hospital and Royal Hospital for Children 2019 the following statement was written "With respect to the return on the hot water pipe work, this has not been installed to the requirements of SHTM 04-01. The installed hot water pipe loop is created in the corridor or ceiling void and then a spur drops down behind the removable panel to the outlet. This method of installation creates a dead leg to the outlet. Both SHTM 04- 01 and HSG 274 part 2 (2014) show the hot water circulation pipe work branching as close as practically possible to the outlet so that dead legs and stagnation are avoided. SHTM 04-01 part A notes:- Paragraph 8.6 All pipework should be insulated, except for any exposed final

[103] DMA, 'L8 Risk Assessment NHS GGC South Glasgow University Hospital. 2015.' (n 14).

connections to sanitary appliances, and should be arranged to eliminate or minimise dead-legs".

11.13. The issue of excessive dead leg length was raised in the Supervisors report number 19, October 2012 Item 4.3.5 pipework "We have identified locations where the dead legs on hot water pipe runs are excessive and greater than the specified distance of 3m. We are working with the Contractor to review and identify all areas and to ensure this is not repeated in the future installations." (Figure 2)

11.14. The photographs supplied from the Capita Symonds report No. 20 2012 [104] provided evidence that the length of the spur from the return loop to the end of that single pipe was over 3m in length.

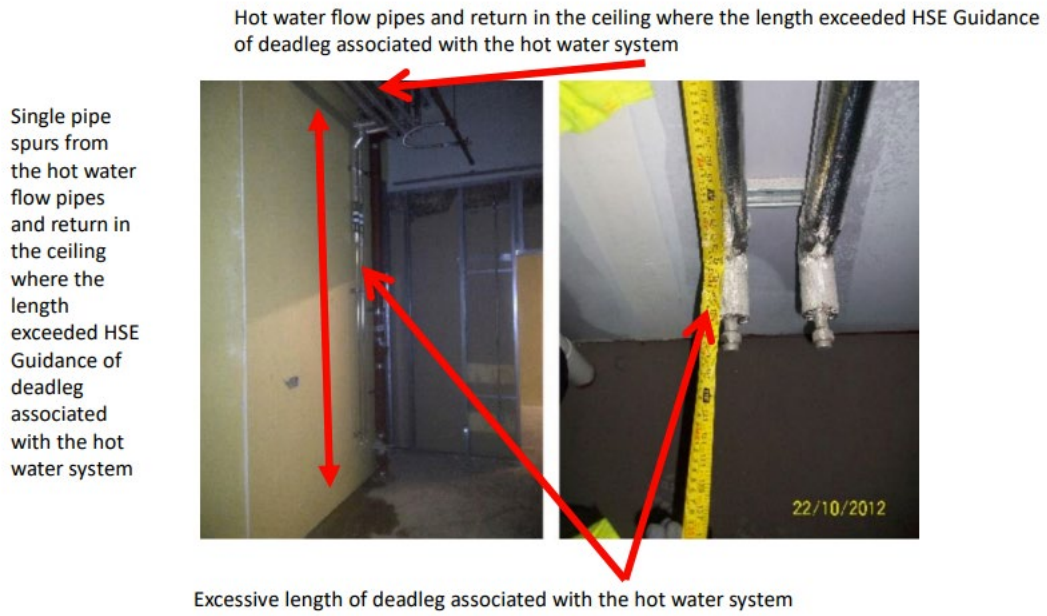


Figure 2. Excessive length of deadleg associated with hot water system.

11.15. The statements in SHTM 2008 are as follows "Generally, the downstream dead-leg should not exceed 2 m, and the complete length of the spur should not exceed 3 m. The length is measured from the centre line of the circulation pipework to the point of discharge along the centre line of the pipework."

11.16. From the images provided above, there was no equipment such as basins or sinks attached to these deadlegs. At the time of the notification by the contractor only the actual spur was reduced to less than 3m. When the basins were fitted it is likely that the length as measured from

[104] Capita Symonds, 'Report No. 20 NEW SOUTH GLASGOW HOSPITAL ADULT AND CHILDREN'S HOSPITAL AND THE ENERGY CENTRE NEC 3 SUPERVISORS REPORT NO. 20 NOVEMBER 2012'.

the centre line of the circulating hot water pipework to the point of discharge i.e. at the tap outlet would have exceeded 3m.

11.17. The NSS Health Facilities Scotland Water Management Issues Technical Review NHS Greater Glasgow and Clyde – Queen Elizabeth University Hospital and Royal Hospital for Children 2019 [105] then stated that "It should be noted that the version of SHTM 04-01 current during the design and installation stages of the contract advises in Paragraph 8.6 that for cold water systems "All pipework should be insulated, except for any exposed final connections to sanitary appliances, and should be arranged to eliminate or minimise dead-legs." For hot water systems paragraph 9.49 advises "Generally, the downstream dead-leg should not exceed 2m, and the complete length of the spur without circulation should not exceed 3m".

11.18. If I am interpreting the NSS HFS [106] report correctly then the downstream deadleg of the hot water system should not have exceeded 2m and thus the deadlegs that were dropped from the ceiling exceeded this length.

11.19. The Legionella risk assessment [107] was completed in April 2015 and therefore the guidance current at the time would have been the SHTM 2014 Part A [108] in which it is stated that "Generally, the complete length of spurs without circulation should be as kept to a minimum with circulation pipework taken right up to the point of use. This means the recirculation loop should pass as physically close to the outlet tap as possible which minimises stagnation, biofilm formation and temperature control.

11.20. HSE 274 [109] states that where the risk cannot be prevented then effective control measures in the written scheme should be specific and tailored to the systems covered by the risk assessment. One of the precautions included is "ensuring water cannot stagnate anywhere in the system by regular movement of water in all sections of the systems and by keeping pipe lengths as short as possible, and/or removing redundant pipework and deadlegs".

11.21. In my opinion the spurs had not been kept as short as possible as was advised in national guidance.

11.22. The 2015 legionella risk assessment [110] identified that not all Duty Managers have completed Appointed Person training and in 2017 [111] it

[105] HFS, 'Water Management Issues Technical Review NHSGGC – QEUH and RHC HFS – March 2019' (n 25).
[106] HFS, 'Water Management Issues Technical Review NHSGGC – QEUH and RHC HFS – March 2019' (n 25).
[107] SHI, 'DOCS Bundle 6 Miscellaneous Documents' (n 20) 6.
[108] HFS, 'Water Safety (SHTM 04-01) Part A: Design, Installation and Testing 2014' (n 10) 04–01.
[109] HSE (n 15).
[110] SHI, 'DOCS Bundle 6 Miscellaneous Documents' (n 20) 6.
[111] DMA, 'Legionella Risk Assessment QEUH (Adult) Hospital and the Adjoining RHC 2017' (n 17).

was identified that the Authorised Person had been in place for over 18 months training.

11.23. I have not seen any evidence that those responsible for the water system (Authorised Person) and reducing the length of deadlegs were trained in Legionella risk assessment at the time of the risk assessments in 2015 and 2017.

11.24. The evidence from the Inquiry indicates that the authorised person was trained in June 2018 and that
training of Senior staff as Water Responsible Persons was undertaken Aug-Oct 2018 [112]. This would indicate that that the authorised person and the water responsible persons who were in place were not trained to manage the water systems as per HSE or SHTM guidance prior to June 2018.

11.25. NHS GGC had duty of care to ensure that staff were trained and that deadlegs were kept as short as possible.

11.26. **(d) At para 4.33.2 of your report you noted that "A RAID server was not supplied under the contract.". It has been suggested that a RAID server may in fact have been supplied. Are you able to comment on that? If it were correct, would it change any of your views?**

11.27. A RAID server is a data storage technology that combines multiple physical discs drive components into one or more logical components to improve data security and performance. The supply of this RAID server for data storage does not change my view on the lack of evidence on the management of the water system at the QEUH / RHC as based on the evidence supplied by the Inquiry.

(e) At para 6.20.10 of your report you make reference to 'SHTM Part A' providing that "Strainers can be a source of Legionella and Pseudomonas bacteria and should be removed after commissioning has been satisfactorily completed". It has been suggested that the applicable guidance would have been SHTM 04-01 Part A 2008, which at section 9.56 provided that "Strainers can be a source of Legionella bacteria and should be included in routine cleaning, maintenance and disinfection procedures (see Chapter 7, Part B).". Please comment on this. Does it change any of your views?

11.28. SHTM 04-01 2008 states the microbiological risk from strainers and that they should be retained and that they should be included in routine cleaning, maintenance and disinfection procedures. [113].

[112] SHI, '1(Iii) 1(Iv) & 2(i) Material Changes, Explanation and Advice Section 21 Notice No. 8.'
[113] 'SHTM 04-101 2008'.

11.29. In terms of the strainers at the time that they were fitted, NHS GGC were aware of the risks to fit stainers and the requirement of (SHTM 04-01 2008) for servicing and maintenance.

11.30. The 2015 Legionella risk assessment stated (p111) that “thermostatic mixing valves (TMVs) should be serviced and have fail safe tests carried out routinely and strainers should be cleaned on a regular basis as per manufacturer’s recommendations and in accordance with Written Scheme guidance.” On P239, quarterly servicing was recommended in high risk areas as recommended by HSG 274 as was following the manufacturer’s instructions [114].

11.31. The tap manufacturer’s instructions [115] stated that “As a general guide, in-service testing should be carried out at least every twelve months which would involve cleaning and replacement of the strainers. I have not seen evidence that this servicing was carried out.

11.32. The 2017 Legionella risk assessment stated on P11 that “We understand no servicing of any of these valves', and the associated strainers in non-high risk areas has been carried out since the hospital opened and there has been a very limited program of servicing in 'high risk' areas.” [116] DMA were not able to confirm whether the strainers on supplies in high risk areas had ever been removed for cleaning/disinfection (p32).

11.33. In addition, these taps should be demounted for servicing but according to the 2017 DMA report (p32) the required facilities to undertake servicing of the taps and strainers had not yet been completed or commissioned.

11.34. DMA also reported that “We understand no servicing of any of these valves', and the associated strainers in non-high risk areas has been carried out since the hospital opened.

11.35. Evidence from the independent microbiology study was that extensive and significant systemic microbial contamination and biofilm formation associated with tap components would indicate that these components presented a microbial risk to patients and that they had not been serviced and maintained as per SHTM and HSE guidance by those responsible for the water system [117] [118].

11.36. Therefore, whilst SHTM 04-01 Part A 2008, (section 9.56) provided that "Strainers can be a source of Legionella bacteria and should be included in routine cleaning, maintenance and disinfection procedures (see Chapter 7, Part B)." it does not change my view that that strainers were not maintained nor serviced and I have no seen evidence that the valves

[114] HSE (n 15).
[115] Horne Engineering (n 16).
[116] DMA, ‘Legionella Risk Assessment QEUH (Adult) Hospital and the Adjoining RHC 2017’ (n 17).
[117] Intertek, ‘Intertek Report Number ITSS-0718-0001W plus per Floor Contamination of Flow Straighteners Debris and Sponges 2018’ (n 84).
[118] Intertek, ‘Intertek ITSS-1018-0001 Intertek Diffuser Report Outlet Fitting Biofilm Timeline’.

and strainers in non-high risk areas had been serviced since the hospital was commissioned and handed over in 2015. Indeed there appears to only have been a limited programme of servicing in high risk areas.

11.37. NHS GGC had a legal duty of care to ensure that strainers were inspected, cleaned, descaled and disinfected. I have not seen evidence that there was a risk assessment or a written scheme or that the strainers were serviced or the risk controlled as indicated the 2017 legionella risk assessment.

11.38. (f) Water tanks. It has been suggested that the two raw water tanks are of 125k litres capacity [your para 4.8.1 indicates 100k litres]. Are you able to comment on this? Would it change any of your views?

11.39. During the legionella risk assessment in 2015 it was stated that the raw water tanks were 100K litres [119]. What was evident from the risk assessment was that raw water tanks were identified as being high risk (p16) with sediment and debris already visible in the raw water tanks (p273). This sediment and debris would have acted as nutrient source for bacteria and biofilm proliferation. Raw Water CWST 1A inlet was isolated (and had been for a considerable period of time) with the outlet remaining live and which may contribute to stagnation, and film formation on the water as well as any out of specification microbiological results. (P22) There was heat gain in the raw water storage tanks which when combined with the debris, sediment and stagnation would have resulted in biofilm formation.

11.40. During the 2017 risk assessment there was also some evidence of biofilm forming on baffles at mains inlets, possibly due to splashing etc. Baffles should be inspected periodically (e.g. monthly) and cleaned as and when required. [120]The risk assessment also indicated that there were storage temperature issues with all the cold water storage vessels indicating favourable conditions for growth of microorganisms.

11.41. In both the 2015 and 2017 Legionella risk assessments washers were identified in the bulk tank 2B indicating that the annual inspection and maintenance schedule had not been carried out.

11.42. In addition it was highlighted that the link between the tanks 1A/1B and 2A/2B was closed at the time of the survey.

11.43. HSG 274 states that “to avoid stagnation, where multiple cold water storage tanks are fitted, they should be connected to ensure each tank fills uniformly and water is drawn off through each of the tanks.” (p20) It also states that there should be an annual inspection of the cold water storage tanks (p25).

11.44. That the two raw water tanks are of 125k litres capacity and not 100k does not change my views that NHS GGC had a duty of care to ensure that the raw water tanks were managed to reduce the risk from Legionella and other Gram-

[119] DMA, ‘L8 Risk Assessment NHS GGC South Glasgow University Hospital. 2015.’ (n 14).
[120] DMA, ‘Legionella Risk Assessment QEUH (Adult) Hospital and the Adjoining RHC 2017’ (n 17).

negative microorganisms. I have seen no evidence from the 2015 [121] and 2017 [122] Legionella risk assessments [123] that i) the raw water storage tank were being managed according to guidance to minimise the growth of Legionella and other Gram-negative microorganisms, ii) there was risk assessment or that iii) or that the Authorised Person was trained.

g. Similarly, it has been suggested that the filtered water storage tanks are of 243,750 litres capacity [your para 4.12.3 indicates 225k litres]. Are you able to comment on this? Would it change any of your views?

11.45. It has been stated that the filtered water storage tanks are of 243,750 litres and not the 225,000 litres that was stated in my report.

11.46. The DMA 2015 Legionella risk assessment [124] indicated that i) There have been issues reported with filtration units failing leading to filtered Water tanks draining down such that levels were extremely low; ii) small debris including washers in filtered Water Tank 2B; iii) that the volume of debris within the water tanks appeared to be more than would be expected considering the filtered Water tanks are fed via 0.5 micron filter sets; iv) whether there was suitable backflow protection from the other non-domestic outlets; v) a bypass had been in place from the Hardgate towns supply that bypassed the raw cold water storage and filtration sets; and vi) sediment was visible in bulk tanks A2, B1 and B2.

11.47. In 2017 the Legionella risk assessment [125] indicated that i) The link between the tanks 1A/1B and 2A/2B was closed at the time of the survey and estates staff were unsure why; ii) the debris and washers from the 2015 Legionella risk assessment were still present in bulk water tank 2B; iii) storage temperatures combined with heavier water mark (biofilm) indicated poor turnover; iv) doubts on whether the filtration system was working due to the level of debris and biofilm marks at the water line.

11.48. The filtered water storage tank would have been contaminated via the bypass in 2015 however, HSG 274 indicates that an annual inspection should be carried out.

11.49. Whether the bulk water tanks were 243,750 litres and not 225,000 litres does not change my views that the filtered water tanks were not managed appropriately. NHS GGC had a duty of care to ensure that the bulk water tanks were managed to reduce the risk from Legionella and other Gram-negative microorganisms.

11.50. I have seen no evidence from the 2015 and 2017 Legionella risk assessments [126] that i) the filtered water storage tank were being

[121] SHI, 'DOCS Bundle 6 Miscellaneous Documents' (n 20).
[122] SHI, 'DOCS Bundle 6 Miscellaneous Documents' (n 20).
[123] SHI, 'DOCS Bundle 6 Miscellaneous Documents' (n 20) 6.
[124] SHI, 'DOCS Bundle 6 Miscellaneous Documents' (n 20).
[125] SHI, 'Scottish Hospitals Inquiry Meeting Minutes Bundle Of Documents as Referenced in QEUH HOIC PPP' (n 100) 6.
[126] SHI, 'DOCS Bundle 6 Miscellaneous Documents' (n 20).

managed according to guidance to minimise the growth of Legionella and other Gram-negative microorganisms, ii) there was risk assessment or that iii) or that the Authorised Person was trained.

12. Chlorine dosing

In the Provisional Position Paper 11 on Water dated 12 April 2024 reference was made at 10.33 to continuous dosing being introduced in 2018/2019 in relation to out of specification sampling results as follows:

"GGC have advised the Inquiry that from November 2018 to January 2019, a Continuous Chlorine Dioxide dosing system was installed in the QEUH and RHC. It is not known if this fixed the concern."

In terms of long-term chemical dosing of a water distribution system are you in the position to comment on:

12.1. whether continuous chlorine dioxide dosing can cause detriment to the integrity of the pipework and more generally the water system long term;

12.2. I am neither a metallurgist nor a chemist but will answer from my perspective as water microbiologist and my experience of ClO_2 as water scientist and the evidence with which I have been provided. I discuss the limitation of ClO_2 in a number of questions in this response.

12.3. The use of chlorine dioxide has been established for many years and the use of this oxidising biocide is well established and described in HSG 274 (p35) [127]. A number of scientific manuscripts have been published data demonstrating the use of this product for the control of Legionella bacteria in hospital water systems [128] [129] [130] [131].

12.4. Scientific publications have demonstrated that ClO_2 has a significant impact on plastic and metal (including copper, stainless and steel materials) and that severe damage occurs due to the strong oxidizing power of CLO_2 in terms of surface chemical modification of metals and progressive cracking of plastics. [132]

12.5. As a consequence of the known detrimental impact of chlorine dioxide on non-metallic and metal components in hospital water systems the HSE

[127] HSE (n 15).
[128] I Marchesi and others, 'Monochloramine and Chlorine Dioxide for Controlling Legionella Pneumophila Contamination: Biocide Levels and Disinfection by-Product Formation in Hospital Water Networks' (2013) 11 JWH 738.
[129] Z Zhang and others, 'Legionella Control by Chlorine Dioxide in Hospital Water Systems' (2009) 101 JAWWA 117.
[130] S Vincenti and others, 'Environmental Surveillance of *Legionella* Spp. Colonization in the Water System of a Large Academic Hospital: Analysis of the Four-Year Results on the Effectiveness of the Chlorine Dioxide Disinfection Method' (2019) 657 The Science of the Total Environment 248.
[131] A Muzzi and others, 'Prevention of Nosocomial Legionellosis by Best Water Management: Comparison of Three Decontamination Methods' (2020) 105 JHI 766.
[132] A Vertova and others, 'Chlorine Dioxide Degradation Issues on Metal and Plastic Water Pipes Tested in Parallel in a Semi-Closed System' (2019) 16 Int J Environ Res Pub Hlth 4582.

advise that “Excessive levels of chlorine dioxide should be avoided since they can encourage the corrosion of copper and steel pipework and high levels of chlorine dioxide can degrade certain types of polyethylene pipework particularly at elevated temperatures.”

12.6. Therefore, my opinion is that continuous dosing of this strong oxidising agent, chlorine dioxide, will have a negative impact the integrity of the water system pipework in the longer term.

12.7. The chlorine dioxide manufacturer should advise on the implementation of a monitoring programme to assess the long term impact on the use of their product on the different materials used within the water in the QEUH/RHC over a number a of years to assess the corrosion rates taking place. My advice would be to engage a specialist metallurgist and chemist with experience in this area.

12.8. **bacterial resistance within the water system**

12.9. ClO_2 is a biocide that has strong oxidising properties that are able to penetrate and inactivate bacteria and is able to penetrate and disperse biofilms. Bacterial resistance within water systems may occur in a number of different ways.

12.10. For chlorine and chlorine dioxide biocides to be effective they must be transported to where the bacteria are present in the water system at a concentration and for a contact time period that will inactivate the microorganisms including bacteria.

12.11. The presence of organic carbon including sediment, detritus, bacteria and biofilm will degrade the concentration of chlorine dioxide in water systems. It is likely that in the QEUH/RHC where the ultrafiltration system was bypassed that the whole water system would have been contaminated with debris (organic carbon). As a consequence, the presence of organic carbon would have interacted with the biocide resulting in a lowering of the active biocide concentration. This action would have reduced the efficacy of the biocideal product to control the bacteria contaminating the water system [133].

12.12. Where the biocide was ineffective then organic carbon would be used as a microbial nutrient enabling the microorganisms to proliferate.

12.13. Corrosion products (as was evident in the expansion vessels at the QEUH/RHC) have been shown to result in a more significant decrease in the concentration of ClO_2 in a distribution system than the total organic carbon present in finished water. [134]

12.14. ClO_2 is generally dosed at the cold water tanks. As the biocide encounters bacteria and biofilms the oxidising capacity of the biocide decreases such that there is less concentration as the water is moved through the water system and the bacterial kill is less efficient.

[133] Intertek, ‘Intertek Report Number ITSS-0718-0001W plus per Floor Contamination of Flow Straighteners Debris and Sponges 2018’ (n 84).
[134] Intertek, ‘ITSS- 0719-0001 Expansion Vessel Investigation Report for QUEH Glasgow. 2019’ (n 85).

12.15. Limitations of products such as ClO_2 are that they suffer from volatility in hot water systems such that they have to be delivered in the cold water system. Due to the volatility and gassing off in the hot water system then it can be challenging to control microorganisms and Gram-negative bacteria in the hot water system.

12.16. ClO_2 is relatively slow to penetrate biofilms [135] and therefore control of biofilm in the already contaminated QEUH/RHC hospital water system would take a considerable amount of time.

12.17. The biofilm that is released, particularly during shock dosing has been shown to be deposited and accumulate at the distal outlets creating an increased risk to patients.

12.18. Where point of use filters have been fitted the accumulation of biofilm and debris on the upstream section may result in reduced flow of the water through the filter.

12.19. As a consequence of biocide degradation and volatility in the hot water it is likely that that there will be insufficient biocide concentration to maintain bacterial control in the hot water pipes at the distal outlets.

12.20. Marchesi *et al*., compared pre-flush (before the tap is flushed) and post-flush samples, and demonstrated that there was a significant higher frequency and count of Legionella in pre-flush positive samples using chlorine dioxide, suggesting that there would be an increased risk to patients, staff and visitors when they open the tap [136]. As such it would be challenging for a biocide to control the extensive and systemic microbial contamination at outlets as was found at the QEUH/RHC. [137]

12.21. Other studies [138] have demonstrated that chlorine dioxide decreased the positivity of all distal outlets (sinks and showers) for *Legionella* from 60% to ≤ 10% after the ClO_2 treatment. According to this study ≤10% of all outlets presented a risk to patients staff and visitors.

12.22. Microorganisms such as non-tuberculous mycobacteria are resistant to disinfectants due to the structure of their bacterial cell of which results in their persistence in drinking water distribution systems. [139] *M. avium* and *M. intracellulare* are many times more resistant to chlorine, chloramine, chlorine dioxide, and ozone than are other water-borne microorganisms.

12.23. As a result of this resistance, disinfection of water systems results in the selection of mycobacteria and presents a risk to patients who are exposed to this NTM positive unfiltered water.

12.24. Antibiotic resistant bacteria have mechanisms of developing resistance to many different types of antibiotics. However, the same cannot be said for resistance to biocides. In terms of biocides resistance is explained as “tolerance” to the presence of the biocide. With oxidising biocides it is often claimed that bacteria that have been recovered from samples where the biocide has been present are termed resistance. This is not the case. In fact it is more likely:

[135] S Behnke and Anne K Camper, ‘Chlorine Dioxide Disinfection of Single and Dual Species Biofilms, Detached Biofilm and Planktonic Cells’ (2012) 28 Biofoul 635.
[136] Marchesi and others (n 128).
[137] Intertek, ‘Intertek Report Number ITSS-0718-0001W plus per Floor Contamination of Flow Straighteners Debris and Sponges 2018’ (n 84).
[138] Zhang and others (n 129).
[139] Joseph O Falkinham, ‘Nontuberculous Mycobacteria in the Environment’ (2022) 137 Tuberculosis.

12.24.1. with oxidising biocides that the concentration of the biocide has been quenched or degraded such that there is not a sufficient concentration of the biocide to inactivate the microorganisms.

12.24.2. the biocide has not been in contact with the microorganisms for a long enough contact time period and thus the microorganisms are not inactivated

12.24.3. the biocide is unable to penetrate structures such as biofilms such that not all the cells in biofilm layers are inactivated

12.24.4. the presence of deadlegs will results in the biocide not being transferred to niche environments where the microorganisms have an established biofilm – such as the cold supply on the Horne engineering tap that is not used frequently

12.24.5. any taps that are infrequently used will have developed biofilm e.g. at the flow straighteners and hence the biocide will not be at a sufficient concentration for a sufficient period of time to completely inactivate the cells as was demonstrated in the Intertek study.

12.24.6. Regular flushing of taps will ensure that biocide is delivered to the last two metres of the pipe work which will increase the likelihood of the biocide achieving microbial reduction - where flushing has not always been carried out (as per CEL 03 and 08) then it is less likely that the microorganisms in the last two metres will be inactivated.

12.24.7. However in a water system such as the QEUH/RHC the efficacy of any biocide would have been challenged due to the systemic contamination (organic carbon, debris and biofilm) that had been demonstrated by the independent laboratory. Such systemic microbial contamination would have quenched and degraded the biocide concentration to the extent that it would not have inactivated the heavily colonised components.

12.24.8. Examples of the above challenges were evident in wards in November 2021 [140] when it was claimed that disinfectant resistant biofilm forming taxa were not affected by the chlorine dioxide treatment.

12.25. This was not the case. The bacteria were not resistant. There were structural and management issues identified in the water system by NHS GGC as follows:

12.25.1. pipe work(redundant deadlegs?) in six rooms in 2A that were biofouled with the same biofilm forming organisms detected in water samples (notably *Sphingomonas paucimobilis* and *Cupriavidus pauculus*)

12.25.2. old cartridges on old taps that were biofouled (colonised by these same organisms, with high TVCs)

12.25.3. and insufficient flushing to achieve biocide concentrations in the last few metres

12.26. My opinion was that there was insufficient understanding of water sampling, biofilm, pipe contamination, impact of deadlegs and appropriate flushing. It does not appear to me that those managing the water system understood what they were faced with in 2021.

12.27. It was only once the pipes were removed, taps replaced and appropriate flushing regimens implemented (in addition to supplementary

[140] Chaput, '8 February 2022 Presentation by Dominique Chaput, Healthcare Scientist, Scottish Microbiology Reference Laboratories (1)'.

Hydrogen peroxide/silver ion treatment) that the contamination of the samples were shown to have a reduced microbial load.

12.28. My opinion is that in 2021 the water system was still challenging to manage due to the lack of understanding and management of the water system as demonstrated by the microbiology challenges that were evident when chlorine dioxide was administered and the further changes that had to be undertaken to reduce the risk to high risk patients.

12.29. How other system risk control measures might be adversely affected?

12.30. Other physical risk control measures in the QEUH include temperature control and point of use filtration system.

12.31. As discussed above the concentration of ClO_2 in the water system and its efficacy against bacteria and biofilms is impacted by a number of factors which may result in patients being at risk from exposure to waterborne pathogens that have not been inactivated.

12.32. Therefore, due to the degradation of the biocide concentration it is paramount that the temperature control and water system management systems are in place and effective whilst ClO_2 biocide is administered to the QEUH/RHC water system. The legionella risk assessments in 2015 and 2017 demonstrated that there were examples where the hot water was less than 55°C and that the cold water was greater than 20°C [141] [142]. In addition there was a lack of servicing and planned preventative management and systemic microbial contamination through the water system through to the distal outlets. [143] [144]

12.33. The implementation of ClO_2 in the QEUH is not a panacea and will not provide 100% assurance that the water system is safe for patients.

12.34. Many control strategies were implemented at the QEUH/RHC following the identification that the water system was systemically contaminated by a wide range of Gram-negative microorganisms and NTM . [145] ClO_2 was found to result in a reduction of the Gram-negative bacteria but Mycobacteria was isolated from a number of points including three shower heads in ward 6A. [146] (p31)

12.35. Due to the recognition that the water system was contaminated with waterborne pathogens point of use filters were used extensively to protect

[141] DMA, 'L8 Risk Assessment NHS GGC South Glasgow University Hospital. 2015.' (n 14).
[142] DMA, 'Legionella Risk Assessment QEUH (Adult) Hospital and the Adjoining RHC 2017' (n 17).
[143] Intertek, 'Intertek Report Number ITSS-0718-0001W plus per Floor Contamination of Flow Straighteners Debris and Sponges 2018' (n 84).
[144] Intertek, 'ITSS- 0719-0001 Expansion Vessel Investigation Report for QUEH Glasgow. 2019' (n 85).
[145] SHI, '1(Iii) 1(Iv) & 2(i) Material Changes, Explanation and Advice Section 21 Notice No. 8.' (n 112).
[146] SHI, 'SHI - IMT Minutes Bundle 1 of Documents for the Oral Hearing Com' (n 88) 1.

patients from being exposed to microbially contaminated water in the QEUH and RHC.

12.36. The use of microbial retention filters will only protect patients from the water coming out of that tap. POU filters are not a long lasting solution as they only remove the bacteria from the water passing through the filter at that point in the water system.

12.37. Where the water system is still microbially contaminated whether it is the water tanks, expansion vessels or taps then where filters have not been fitted then patients will still be at risk. Therefore even where filters are fitted the water system has to be managed accordingly to reduce the risk to patients.

12.38. However, any debris, sediment and biofilm disturbed by shock dosing chlorine dioxide will be flushed to the last two metres and will deposit in the point of use filters. This will result the reduction of the flow through the filters. Whilst this does not impact on the efficiency of the point of use filter to retain bacteria it reduces the water flow to the extent that it impacts on usability and may result in the removal of filters by patients – this would of course result in the patients being exposed to the microorganisms present in the water.

12.39. The cases of mycobacteria infection in ward 6A [147] (p127) where point of use filters were fitted would indicate that the patients had been exposed to unfiltered water and that water unfiltered posed a risk to patients. In addition, as previously indicated non-tuberculous mycobacteria are more tolerant to the presence of oxidising biocides.

12.40. In addition water samples through point of use filters were positive water samples for Mycobacteria it is feasible that the filter connections to the taps may have been leaking leading to exposure of patients to Mycobacteria.

12.41. Whilst continuous dosing of chlorine dioxide and point of use filters may reduce the risk of patient exposure to water borne pathogens the drains at the QEUH/RHC were identified as a risk due to the positive results for a wide range of environmental microorganisms that were associated with the infections at the QEUH/RHC.

12.42. Significant slime build up in drains was evident in June 2019. ClO_2 had been in use and evidently was not controlling the build-up in drains. As discussed in other questions a number of drains were found to contain extensive and significant biofilm, debris, hair and foreign bodies (plastics). [148] (p19) The concentrations of ClO_2 in the water system would not have been effective against the thick residues that were identified in the drains. As a consequence there would still have been a risk to patients from the drain microorganisms even whilst continuous dosing was undertaken.

[147] SHI, 'SHI - SBAR Bundle 3 – NHS NSS: Documentation for the Oral Hearing Com' 2023.
[148] Intertek, 'Intertek Report Number ITSS-0718-0001W plus per Floor Contamination of Flow Straighteners Debris and Sponges 2018' (n 84).

Guidance: other sources

13. In the Provisional Position Paper 11 on Water dated 12 April 2024 reference was made to sources of guidance at Section 4.1.

Please comment on these suggested sources. Were you familiar with the said guidance, do you consider them to be of significance and do they affect your views?

13.1. (BS 8580-2:2022) [Risk Assessments for Pseudomonas Aeruginosa and Other Waterborne Pathogens Code of Practice – published in January 2022 – BSI, 'BS 8580-2 2022 - Risk Assessments for Pseudomonas Aeruginosa and Other Waterborne Pathogens. Code of Practice details - Objective ECM (scotland.gov.uk)

13.1.1. Yes I am familiar with this document. BS 8580-2 2022 focusses on the risk of *P. aeruginosa* in water systems in healthcare properties, the use of risk assessments which form the core of the development and implementation of a water safety plan. The document takes into account;

13.1.1.1. the engineering factors which can lead to their growth and transmission (including those related to the design and engineering of water systems and associated equipment).

13.1.1.2. the way that water systems are used, the individual types of use, the susceptibility of users and those in the vicinity of the systems and equipment being used, as well as a range of other environmental factors and, where relevant, clinical factors.

13.1.1.3. that a multidisciplinary risk assessment team approach is the most effective approach to reducing the risk to patients.

13.1.2. BS 8580-2 2022 assists both risk assessors and users, duty holders, owner/managers and water safety group members to understand the microbial hazards (pathogens) associated with different systems, potential hazardous events and other factors which lead to their presence and to provide information and support to WSGs on how to prioritize actions and minimize the risks.

13.1.3. However, following the outbreak of P. aeruginosa in Northern Ireland in 2011/2012 the Cross-NHS Scotland letters CEL 03 (2012) and CEL 08 (2013) drew attention to revised SHTM 04-01 and to other guidance , and identifying action required.

13.1.4. This document BS8580-02 does not change my view from the evidence presented by the Inquiry. I have not seen evidence that those responsible for the QEUH/RHC water system managed the risks according to national and local guidance to reduce the risk to patients at handover. For example, NHS GGC were aware of the risk from flow straighteners in taps, however they decided to fit taps with flow straighteners within the QEUH/RHC. The risk was not subsequently managed leading to patient risks from exposure to waterborne pathogens when the outlets were used. I have also not seen evidence that nursing / clinical staff were trained in the risks presented by water systems, equipment being used (taps) and the susceptibility of users (disposal of body fluids and cleaning of medical devices in the basins).

13.2. **SHFN 01-02 [on cleaning], version 5 (2016) ('The NHS Scotland National Cleaning Services Specification'). 474 SHFN 01-02 v5.0 Jun 2016 details - Objective ECM (scotland.gov.uk)**

13.2.1. No, I was not familiar with the detail of SHFN 01-02. SHFN 01-02 emphasises the need to have a cleaning specification that allows NHS Boards to accurately and effectively risk assess specific tasks to determine the frequency of cleaning based upon the risk to the patient and also public perception. SHFN 01-02 includes specific generic risk assessments pertaining to the near patient environment to reduce the risk of HAI.

13.2.2. SHFN 01-02 includes advice on running sanitary fixtures and fittings, sinks, wash hand basins and baths and showers (p80-83) i.e. All tap and shower outlets must have water run as per local water management policy following.

13.2.3. Following the outbreak of *P. aeruginosa* in Northern Ireland in 2011/2012 the Cross-NHS Scotland letters CEL 03 (2012) which cited immediate actions such as:

13.2.3.1. Directors of Estates/Facilities: Ensure all taps are flushed in accordance with the attached best practice for handwash basins to minimise the risk of Pseudomonas aeruginosa contamination in high risk units

13.2.4. To reduce the risk of waterborne infection from P. aeruginosa in Scotland CEL 08 (2013) cited that Boards must ensure that:

13.2.4.1. All taps in all clinical areas in high risk units (manually or automatically) are flushed daily (and a record kept) to minimise the risk of pseudomonal contamination. Flushing should be for a period of one minute, first thing in the morning, at the maximum flow rate that does not give rise to any splashing beyond the basin

13.2.4.2. domestic staff have been trained in the correct decontamination procedures for sinks, basins and taps in ICUs and neonatal units to minimise the risk of pseudomonas

13.2.4.3. they are compliant with revised SHTM-04-01

13.2.5. The evidence provided by the Inquiry in the "2019 Healthcare Improvement Scotland Inspection Report – Safety and Cleanliness of Hospitals" identified the following:

13.2.5.1. staff were not clear about who was responsible for carrying out water flushing on the unused or less frequently used water outlets.

13.2.5.2. Nursing staff told us they sometimes run the water, but there was no sign-off sheet to record this

13.2.5.3. Domestic staff told us they sometimes run showers when they had not been used by patients. However, they could not confirm what water outlets had been run or when.

13.2.5.4. baths that had not been identified by staff as infrequently used water outlets that would need flushing.

13.2.5.5. a bath that had not been working for 3 years

13.2.5.6. Staff were unaware that ensuite showers, unused because of the patient's health condition, would require regular flushing

13.2.5.7. One ward had a closed patient room due to a leaking ensuite shower. Staff were unclear about how long it had been like this and if any flushing regime was in place to mitigate any potential risks

13.2.5.8. The majority of staff we spoke with were unclear about their roles in the flushing regimes.

13.2.6. From the evidence provided in the HIS report (2019) I have not seen evidence that the Directors of Estates/Facilities or the Boards followed the advice issued in 2012 by the chief Medical Officer and Director General in 2012 and 2013 to reduce the risk to patients from waterborne P. aeruginosa and other Gram-negative microorganisms that had contaminated the QEUH/RHC water system.

13.3. At 4.1 - NSS suggested - SHFN 30 guidance documents Parts A, B, and C, 2007 [on built environment issues] Scottish Health Facilities Note 30 Part 1 - Infection Control in the Built Environment: Design and Planning - June 2007 details - Objective ECM (scotland.gov.uk).

13.3.1. No, I was not familiar with SHFN 30 in detail. SHFN 30 2007 highlights the need for rigorous examination of proposals for new build healthcare facilities, extensions to healthcare facilities, and refurbishment of healthcare facilities in relation to prevention and control of infection to reduce Healthcare Associated Infections (HAIs). Areas that are discussed include;

13.3.1.1. “Special consideration should be given to specialised areas such as control of Legionella and cites (SHTM) 2040: HSE guidance note L8 ‘Legionnaires Disease: Approved code of practice and guidance’”

13.3.1.2. “The evidence from the Inquiry indicates that the management of the water system at the QEUH / RHC that at the time of the legionella risk assessment (2015) there was no formal management structure, written scheme or communication protocols and there were significant communication issues between parties involved.”

13.3.1.3. “Due to the difficulty of cleaning of baths after each patient, showers are generally more acceptable to both patients and infection control personnel. However, showers have been implicated in outbreaks of infection due to Legionella spp. (Tobin et al, 1980). Such problems, however, can be minimised by proper planned maintenance.”

13.3.2. The evidence from the legionella risk assessments (2015 and 2017) would indicate that were a lack of cleaning, disinfection and maintenance of showers and components such as filter strainers. There was no evidence that the QEUH/RHC risk of legionella from showers had been minimised either 2015 or 2017.

13.3.3. There was no evidence in 2015 or 2017 that the legionella risk in other units e.g. hydrotherapy which was described as high had been carried out by NHS GGC

13.3.3.1. “ Taps should be easy to turn on and off without contaminating the hands. Infrared taps are an alternative but these are expensive and can pose problems with cleaning and flushing (Bushell, 2000).”

13.3.3.2. There was a lack of evidence that staff were trained in the use of the complicated Horne taps fitted at the QEUH/RHC which may have exacerbated the risk to patients.

13.3.4. The dimensions of a clinical sink must be large enough to contain splashes however, during my visits to the QUEH/RHC it was clear that a considerable amount of splashing was occurring around the clinical wash hand basin. Whilt this can be difficult to control there was a lack of splash guards installed to prevent splashing of the surrounding area. There was a considerable number of containers on basins and sinks, equipment and supplies close by that would have been splashed when the basins and sinks were used which would have increased the risk to patients.

*13.3.4.1. "*maintenance - environment is important to ensure that areas are intact, functioning properly and in a state such that they can be cleaned properly. 11.170 The maintenance of the environment is important to ensure that areas are intact, functioning properly and in a state such that they can be cleaned properly."

13.3.5. During my visit to the QEUH in 2023 there were a number of areas where there had been a lack of maintenance of environment which was evident by the damage to sealant behind clinical wash hand basins and the linoleum in the shower rooms and this had been noted in my report – such damage leads to water being retained and the growth of microorganisms which could be a risk to patients.

13.3.5.1. "Outbreaks - Some sampling may have to be performed in response to an investigation of an outbreak of infection"

13.3.6. The CNR report indicated that "Overall, we were unable to conclude that the organisation had a systematic approach to environmental sampling in the context of either a specific, unusual infection or an outbreak of a more commonly seen infection." This would indicate that water or drain sampling was not always followed up following the identification of an infection in a patient.

*13.3.6.1. "*Planned preventative maintenance: planned maintenance system should be set up to start at the same time as handover or occupancy. A record of Planned Preventative Maintenance needs to be kept*".*

13.3.7. The legionella risk assessments in 2015 and 2017 indicated that devices as thermostatic mixer taps were not being serviced and facilities for carrying this out had not been provided. There was also a lack of servicing of supplied by third parties such water coolers. As such the risk from Legionella and other Gram-negative microorganisms was not being minimised.

*13.3.7.1. "*Plant and services should be located behind panels that should be easily accessed with quick release fixings."

13.3.8. The legionella risk assessment (2015) indicated that access for ongoing monitoring, maintenance and servicing would be problematic as the domestic pipework ran above the ceiling (p35) and that there was no access to the TMV network in a number of the other specialists units (p41).

13.3.9. There is limited evidence that the recommendations in SHFN 30 for the rigorous examination of proposals for new build healthcare

facilities, extensions to healthcare facilities, and refurbishment of healthcare facilities in relation to prevention and control of infection to reduce Healthcare Associated Infections (HAIs) were addressed at the QEUH/RHC.

14. Guidance: general

At paras 4.2.1-2 of your report you make an observation that it is difficult to identify whether the correct standards were in place at the time of construction. Attention has been drawn to paragraph 5.1.1.9 of the Employer's Requirements, which states: *"All references in these Employer's Requirements to NHS Facilities Scotland Requirements, building and engineering standards, Building Regulations, legislation, Statutory Requirements, Codes of Practice, Department of Health publications, NHS Publications and other published guidance shall be deemed to mean those in place at the date of signing the construction contract. Any date reference in Table 2 or Table 3, therefore, may be replaced/read as that in place at the date of signing the construction contract."*. Do you have any comment to make on that paragraph? Does it address your concerns at paras 4.2.1 and 4.2.2? Does it change any of the view expressed in your report?

14.1. There is an extensive list of documents presented in table 5.1.2. of the employer's Requirements. [149]

14.2. However, as has already been pointed out in other reports [150] (p11) a number of the standards/publications/guidance documents that were referred in the employers requirements were not applicable in Scotland, had been superseded or were known to about to be updated including;

14.2.1. HTM 04-01 which is only applicable in England.

14.2.2. SHTM 2027 should not have been cited as it was superseded by SHTM 04-01 (published August 2011)

14.2.3. SHTM 2040 should not have been cited as it was superseded by SHTM 04-01 (published August 2011)HTM 02 refers to medical gases (and therefore would not provide guidance on the safe operation of water systems)

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

14.3. The paragraph 5.1.1.9 of the Employer's Requirements does not address my concerns as a number of the documents cited at the time were incorrect or outdated as identified by HPS NSS.

[149] NHS GGC, 'NHS GGC New South Glasgow Hospitals (NSGH) Project INVITATION TO PARTICIPATE IN COMPETITIVE DIALOGUE VOLUME 2/1 EMPLOYER'S REQUIREMENTS' (n 46).
[150] Storrar and Rankin (n 50).

14.4. The clarification in paragraph 5.1.1.9 of the Employer's Requirements does not change any of the view expressed in my report.

15. Miscellaneous

Please comment on the following points which arise from your report.

(a) At para 7.5.1 you stated that "Whilst *L. pneumophila* serogroup 1 was rarely detected in the retained estates, *L. pneumophila* serogroup 2-14 were detected frequently.". It has been suggested that the testing results do not show this, and that this is a mis-reading or mis-statement of an observation of Dr Chaput to the effect that *"Across the retained buildings, Lp.1 was almost absent, whereas Lp.2- 14 and L. species were detected more frequently."*

15.1. The statement that *L. pneumophila* serogroup 1 was ***almost absent*** acknowledges that *L. pneumophila* serogroup 1 was detected. The water samples that were taken were either positive for the presence of *L. pneumophila* serogroup 1 or they were not. From a microbiological perspective the HSE indicate that "in healthcare, the primary concern is protecting susceptible patients, so any detection of legionella should be investigated and, if necessary, the system resampled to aid interpretation of the results in line with the monitoring strategy and risk assessment"

15.2. The term "almost absent" is not one that I am familiar with in scientific publications.

15.3. I would still agree with my wording that "*L. pneumophila* serogroup 1 was rarely detected in the retained estates." (Figure 3) as they were detected periodically.

15.4. In terms of the data for *L. pneumophila* serogroup 2-14 the evidence presented from the Inquiry [151] I would agree with the statement that *L. pneumophila* serogroup 2-14 and Legionella species were detected more frequently.

15.5. The results demonstrated that *L. pneumophila* serogroup 2-14 and Legionella spp. were frequently detected (Figure 3) and that a number of the positive tests were frequently and consistently out of specification over the time period in question.

15.6. The results in Figure 4 also demonstrate that where the results are coloured orange that the results were >1000 cfu/l. The HSE indicate that "The system should be resampled and an immediate review of the control measures and risk assessment carried out to identify any remedial actions, including possible disinfection of the system". Such high counts in the water

[151] DL Chaput, 'Microbiological Testing (2015-2020) of Water and Environmental Samples from the QEUH (Adults) and RHC, Overview of Sample Numbers and Test Results.' [2023] NHS GGC.

in the retained estates would have presented a risk to patients who were exposed to water.

15.7. The results that are presented indicate that these high counts persisted in the retained estates from 2015 through into 2018. The presence of such high counts over such a long time period would indicate that the risk was not managed as per HSG 274 or SHTM 04-01.

15.8. I have seen no evidence of the location from where these out of specification samples were taken e.g. whether they were from high risk units.

15.9. Figure 3. Legionella species and serogroup that were identified as being out of specification across the QEUH campus.

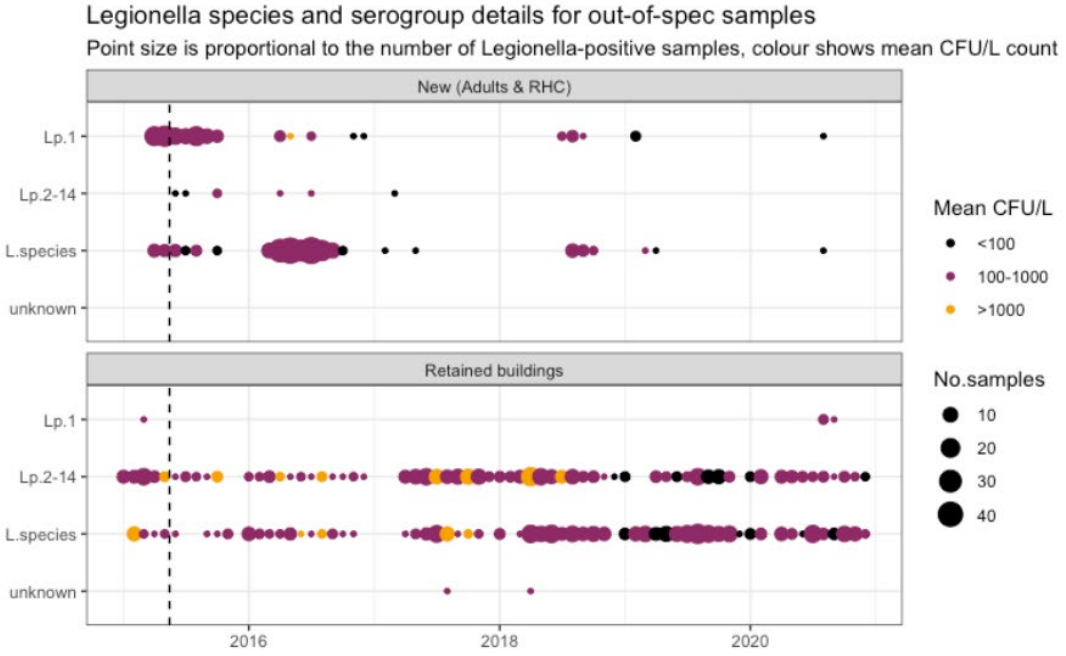


Figure 3. Legionella species and serogroup details for out of spec samples across the QEUH campus.

15.10. Figure 4. Number of out of specification Legionella species per month across the QEUH campus.

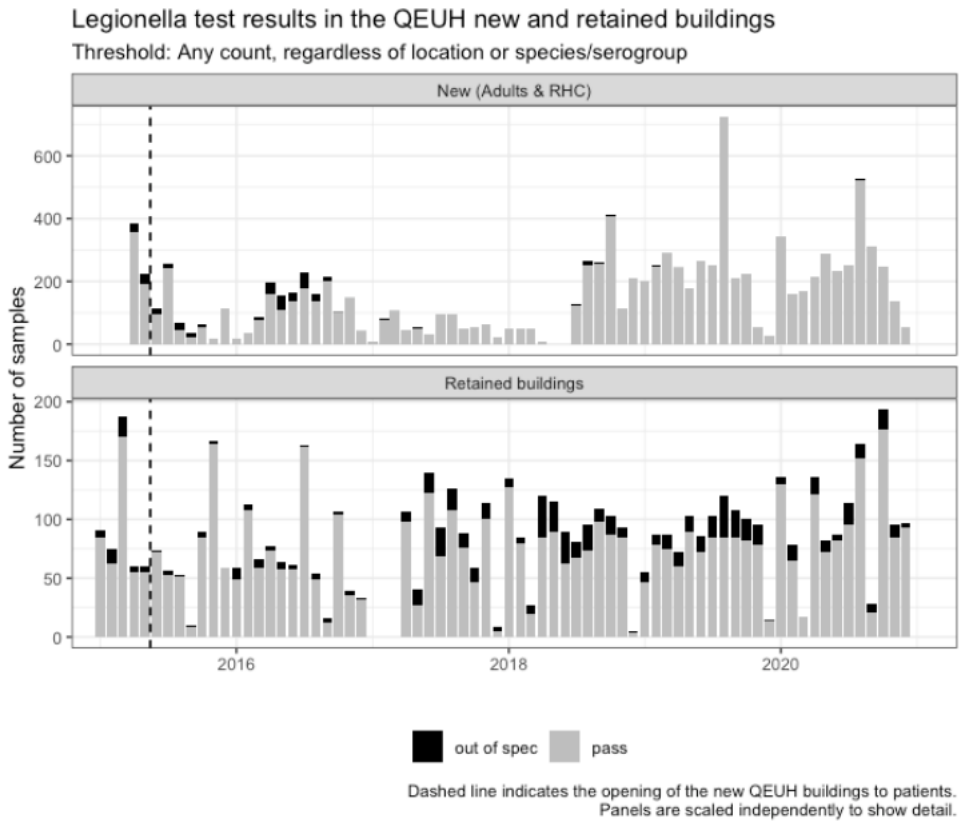


Figure 2. Number of Legionella tests out of spec per month across the QEUH campus (new versus retained buildings). Panels are scaled independently to show detail.

15.11. (b) At para 2.1.16 you stated that "In some cases the patient strains matched the water isolate providing evidence of a link between the water and the patient infection." It is suggested that this is not borne out by supporting evidence.

15.12. The evidence provided by the inquiry on the matching of water isolates to patient isolates at the QEUH indicates: "that the isolate from one patient was closely related to environmental samples from water outlets, supporting nosocomial acquisition". This statement was published in the manuscript in the Journal of Hospital Infection in 2021 entitled "Investigation of two cases of *Mycobacterium chelonae* infection in haemato-oncology patients using whole genome sequencing and a potential link to the hospital water supply"

15.13. The manuscript went on to suggest that "These WGS results suggest that the isolate from one patient (Patient 2) was closely related to environmental isolates from water outlets. Epidemiologically this fitted, with the patient linked in time and place to these outlets."

15.14. The authors then go on to add that "Whilst no link with Patient 1 was established, no contemporaneous water results were available from the time this patient developed infection, so a water source in the hospital cannot be excluded completely."

15.15. My interpretation of this latter statement is that the experts who published this paper could not exclude the water as a source of the second infection.

15.16. In another publication related to patient and environmental strains at the QEUH in the Journal of Hospital Infection in 2021 entitled "Investigation and control of an outbreak due to a contaminated hospital water system, identified following a rare case of *Cupriavidus pauculus* bacteraemia" the authors indicated that;

15.17. "A patient lookback exercise was undertaken and a patient with a *C. pauculus* bacteraemia who had received total parenteral nutrition (TPN) from the unit was identified. Typing of the isolates was undertaken by the antimicrobial resistance and healthcare associated infection (AMRHAI) reference laboratory and on pulsed-field gel electrophoresis (PFGE) the patient isolate matched the water".

15.18. Therefore in the above manuscripts there is definitive scientific evidence of links between some patient strains and isolates from the water

15.19. In the evidence presented to the inquiry [152] there was an extensive volume of material changes and work carried out on the water system including the addition of point of use filters for water outlets; augmented chlorine dioxide treatment of the entire water supply; replacement of Horne taps; replacement of shower heads; removal of water coolers; servicing of TMV/strainers: cleaning of water tanks; increased water sampling: removal of water coolers: replacement of expansion vessels; additional ultrafiltration plant in the basement; POU Filters fitted in theatres and Imaging areas: decontamination of the healthcare environment including drains. The changes that were implemented for infection prevention practices were in addition to the changes to and management of the water system.

15.20. The volume, extent and number of changes to the water system, wards and drain environment that took place were in the recognition of the extensive and systemic microbial contamination of the water system as was eloquently described in the Intertek independent microbiology reports [153] [154].

15.21. The CNR were critical in the inconsistencies in the data that it received from NHSGGC and the use of typing methods to link different bacterial isolates. [155] An inability to see an overview of infections, typing and environmental data due to poor record keeping would prevent the clarity needed to identify the environmental risks. Nevertheless, the CNR report

[152] SHI, '1(Iii) 1(Iv) & 2(i) Material Changes, Explanation and Advice Section 21 Notice No. 8.' (n 112).
[153] Intertek, 'Intertek Report Number ITSS-0718-0001W plus per Floor Contamination of Flow Straighteners Debris and Sponges 2018' (n 84).
[154] Intertek, 'ITSS- 0719-0001 Expansion Vessel Investigation Report for QUEH Glasgow. 2019' (n 85).
[155] S Stevens, G Evans and MH Wilcox, 'Queen Elizabeth University Hospital and Royal Hospital for Children Case Note Review Overview Report March 2021.'

identified that 70% of bacteraemia could possibly relate to the hospital environment and that 30% probably did.

15.22. It is beyond doubt that a positive typing result (between the patient and an environmental isolate) supports the hypothesis of environmental transmission.

15.23. However the lack of a match to an environmental isolate does not exclude the likelihood of that transmission having taken place. Indeed it has been cited that no contemporaneous water results were available from the water system at the time that some of the patients the developed their infections [156].

15.24. In my opinion, this is a major limitation as per my comments on the whole genome sequencing study below.

15.25. In addition, water and biofilm sampling has an important role to play and detection of microorganisms will be dependent on how a sample is taken e.g. pre or post flush or a swab. Where contamination is likely to occur in the last two metres a pre-flush sample is more likely to isolate the microorganisms than a post flush sample. Once samples have been taken and microorganisms grown on the agar plate there will be variability in the colonies that have grown. Whilst it is not unusual for only one colony to be selected for typing from the hundreds of microbial colonies present on an agar plate it has been recommended by national water experts that 30 colonies would have to be picked to statistically determine there is no match between the patient and water strain. [157]

15.26. From the evidence presented by the enquiry the whole genome sequencing study undertaken to identify relationships between clinical and water strains from the QEUH/RHC recognised a number of limitations in the study [158]:

15.26.1. There was no standardised methodology recorded for either taking samples, labelling or culturing organisms from the water and drainage samples.

15.26.2. The water and drainage samples were taken over several years and by an unknown number of people i.e. there was limited contemporaneous water samples i.e. available from the time patients developed infections.

15.26.3. “Isolates that were collected from environmental swabs (drains, wash hand basins, shower stalls etc) were not routinely saved and we have a paucity of isolates from these sources.” The use of the word “paucity” by the authors would indicate that they had very few of the

[156] T Inkster and others, ‘Investigation of Two Cases of *M. Chelonae* Infection in Haemato-Oncology Patients Using WGS and a Potential Link to the Hospital Water Supply’ (2021) 114 JHI 111.
[157] S Lee, ‘Draft Meeting Report 25/4/2018 NHS Greater Glasgow & Clyde’.
[158] A Leonord and D Brown, ‘Application of WGS to Identify Relationships among Isolates of Cupriavidus Spp., Enterobacter Spp., and Stenotrophomonas Spp. Isolated from Clinical Samples and from Water and Drainage Associated Sources within the Healthcare Environment.’

isolates from the water or drain samples from when patients were infected (location time and place) at the QEUH/RHC.

15.26.4. "only single colonies were taken and stored from clinical and potable water/environmental samples".

15.27. Recognition of the limitations by the authors and the unknown elements of the study add uncertainty and reduces the confidence with which the report can be viewed when making judgements on the link between infections in patients and the water/drainage system as an environmental source of infection.

15.28. As a consequence, absence of evidence is not evidence of absence and with the limitations in the WGS study, therefore the methods used in the WGS report cannot be used to exclude any link. The microorganisms in the water and drains at the QEH/RHC cannot be excluded from matching to the patient samples.

15.29. Therefore, I have not changed my view that in some cases the patient strains matched the water isolate providing evidence of a link between the water and the patient infection.

15.30. (c) At para 7.11.18 you stated (in respect of the return to wards 2A and 2B) that "Independent analysis by Intertek (as at s.7.11.11 above) provided evidence that the outlets were microbially re-contaminated following one week of use." It is suggested that this is not borne out by supporting evidence.

15.31. The report by the independent microbiology laboratory provided microbiological analysis of a variety of flow straighteners including unused, after one weeks use and after one month's use in the QEUH/RHC [159].

15.32. There are two sets of data presented including biofilm assessment and microbial load. The results for biofilm assessment indicate that no biofilm formation had occurred after one week.

15.33. However, what is important is that the results for the microbial load provide evidence of up to >3.0 x 10^4 cfu per straightener (i.e. 20 x the colonisation of unused flow straighteners which had a count of 242 TVC/straightener. This twenty fold increase in the microbial load was stated in the manuscript published. [160]

15.34. Bacteria isolated from flow straighteners included *S. maltophilia*, *Chryseobacerium* sp, *Sphingomonas paucimobilis*, *C. pauculus*, *Acidovorax temperans*, *Caulobacter* spp. and *Microbacterium laevaniformans**. (* from flow straighteners removed after one month - there did not appear to be any microbial identification from the flow straighteners analysed after one week)

15.35. As such the results conclusively demonstrate that;

[159] Intertek, 'Intertek Report Number ITSS-0718-0001W plus per Floor Contamination of Flow Straighteners Debris and Sponges 2018' (n 84).
[160] Inkster and others (n 21).

15.35.1. flow straighteners that had been present in taps within the QEUH/RHC for one week were microbially contaminated.

15.35.2. microbial contamination of the flow straighteners presented a risk to patients

15.35.3. the risk to patients from fitting flow straighteners in taps within the QEUH/RHC water system in 2018 was not managed by NHS GGC who were aware of this particular microbial problem in 2012 [161].

15.35.4. (d) It is suggested that para 7.12.3 of your report, which records that *"Legionella, coliforms, E.coli or cupriavidus were detected from 9 March 2022 to 15 March 2023"*, is wrong and that none of these were detected over this period.

15.35.5. The sentence should have read " No Legionella, coliforms, cupriavidus or E.coli detected"

15.35.6. It should be clarified that it appears that many of these water samples were taken through point of use filters. Point of use filters are absolute filters i.e. they prevent microorganisms present in the water system from exiting the outlet at the point of use filter and remove the risk of waterborne pathogens present in the water system to patients.

15.35.7. Taking water samples and presenting the data in this way does not provide any evidence as to the safety of the water system as it only assesses whether the point of use filters are effective (previous tests by the manufacturer demonstrated that filter integrity was intact when NHS GCC had concerns about whether point of use filters had failed).

15.35.8. Where water samples taken through point of use filters are positive it indicates that either:

- the sample was contaminated at the time of sampling
- or there has been contamination of the filter from the environment including the drain.

15.35.9. The detection of *P. aeruginosa* and *Mycobacteria* from a water sample that was taken through a filter is concerning.

15.35.10. Other hospitals have demonstrated that the external housing of the point of tap water end filters can be contaminated with patient wastewater and that contamination of the point of use filter housing can occur probably as a result of the contamination with patient wastewater. [162]

[161] Burns and Feeley (n 4).
[162] Garvey, CW Bradley and Pauline Jumaa, 'The Risks of Contamination from Tap End Filters.' (2016) 94 JHI 282.

15.35.11. In the healthcare infection Scotland inspection report in June 2022 [163] it was identified that "However, in one area, we observed staff cleaning respiratory equipment (tracheostomies) in the clinical wash hand basin. By doing this, there is a risk of contaminating the clinical wash hand basin."

15.35.12. The education of staff in water hygiene and water safety is important to alert them to the risks and to inform them of the dangers of contamination through activities such as preparing drugs, filling water jugs, hand washing and inappropriately cleaning used medical devices in clinical hand wash basins.

15.35.13. I have not seen any evidence of this type of training for clinical staff at QEUH/RHC and this was acknowledged during our visit to the QEUH/RHC.

15.35.14. There are only a very limited number of water samples taken in the absence of filters. See P 5, TVC37CFU counts and on the graph on P7 it is indicative that a number of the sample are out of specification in February and March 2023. The lack of the number of samples taken in the absence of filters is concerning as there does not appear to be sufficient data to understand the recontamination of the water.

15.35.15. In addition the summary on page 10 is rather misleading. The total data has been aggregated and analysed a percentage of the total over the entire time period. Such analysis is misleading in the context that the majority of the samples were taken during the disinfection stage and prior to when the ward was reopened to patients (p5). By analysing each organism as percentage of the total in this way the percentage for each organism looks extremely small.

15.35.16. For example the analysis should concentrate on the number of microorganisms in the time frame in which it is taken to assess the risk at the period in time. In Dec 2022, Feb 2023 and Mar 2023 a number of water samples in 2A/2B TVC 22°C were out of specification in the absence of a filter. Similar results are recorded for TVC37°C (p5) in March 20223 in the absence of a filter. Such results would warrant investigation and there is no reference to these results or how they were dealt with in terms of risk to patients.

15.35.17. It should also be noted that water samples taken from the water system in the absence of point of use filters from March 2022 to March 2023 indicated the continued presence of atypical Mycobacteria. As a consequence patients in high risk wards where point of use filters are not present would still be at risk from exposure to unfiltered water. [164]

(e) At paragraph 2.2.16 of your report you made reference to systemic microbial and biofilm contamination of the water system, stating that

[163] HIS (n 44).
[164] Inkster and others (n 156).

"Microorganisms identified in the water and biofilms in the QEUH and RHC had been identified in published literature as being associated with HAI". **Please explain your understanding of the sampling and testing regime for identifying and typing such cases to which you refer? Would it have been possible for that regime to identify specific matches?**

15.35.18. My understanding of the sampling and testing regime for identifying and typing such cases is as follows and is taken from the documents provided by the enquiry. For example for the *C. pauculus* bacteraemia cases it is described that extensive water testing from various points within the water system was undertaken including taps, showerheads, flow straighteners and drains were also swabbed 165 (p1236).

15.35.19. "Water testing: approved methods and trained staff were used to take the samples. Appropriate microbiological methods were used for analysing water and swab samples including the process, the growth medium for the different type of microorganisms, appropriate growth temperatures. Identification tests used included selecting oxidase positive and Gram-negative microorganisms and further identification using matrix assisted laser desorption ionization-time of flight (MALDI-TOF) mass spectrometry."

15.35.20. "Taps and showerheads: were sent to the local microbiology laboratory where taps were dismantled and each component separately sampled. The thermostatic mixer valve (TMV) (n=1) was sampled with a swab that was then plated on to appropriated media and selected colonies identified using MALDI-TOF mass spectrometry."

15.35.21. "Flow straighteners: microbiological analysis and bioburden assessment undertaken by an Intertek. Water was added to the flow straightener and plated onto agar media to assess TVCs and *P. aeruginosa*. Colonies were identified using MALDI-TOF mass spectrometry. Biofilm presence was assessed."

15.35.22. "Drains: during the incident these were swabbed in situ and components were also removed and sent for analysis using appropriate agar and incubated. Drain traps were visually inspected, and a biofilm test undertaken."

15.35.23. It was stated in the publication that "A patient lookback exercise was undertaken and a patient with a *C. pauculus* bacteraemia. Typing of the isolates using pulsed-field gel electrophoresis (PFGE) matched the water to the patient isolate". In my opinion this would indicate that microorganisms identified in the water and biofilms in the QEUH and RHC were associated with HAI.

15.35.24. In the investigation of two cases of *Mycobacterium chelonae* infection in haemato-oncology patients extensive water testing of outlets (pre- and post-flush) was undertaken in wards and departments where patients

[165] SHI, 'DOCS Bundle 6 Miscellaneous Documents' (n 20).

had been nursed. The WGS results suggested that the isolate from one patient (Patient 2) was closely related to environmental isolates from water outlets [166] (p1236). In my opinion this would indicate that microorganisms identified in the water and biofilms in the QEUH and RHC were associated with HAI.

15.35.25. As demonstrated in the cases of the *C. pauculus* (historical case) and *M. chelonae* it is possible for extensive sampling and analysis to identify specific matches of the patient and environmental isolates.

15.35.26. It is my experience from studies that I have been involved in, that these technologies, i.e. PFGE, WGS and other typing technologies to confirm matches between patient and environmental isolates [167] [168] [169].

15.35.27. Therefore, in terms of this specific question it is possible for sampling and testing regimes to identify specific matches.

15.35.28. It was noted in the QEUH/RHC *C. pauculus* outbreak that typing of all patient isolates were unique and not related to one another, thus ruling out patient to patient transmission demonstrating a wide heterogeneity and therefore there must have been another source.

15.35.29. There are of course limitations with every study that lessens the likelihood of matching a patient isolate to an environmental isolate.

15.35.30. For example a number of limitations were identified in the study on *C. pauculus* (Inkster *et al*., JHI 2021) [170] including the large number of water samples (1878) taken that resulted in a huge strain on laboratory resources, such that not all water samples were sent for typing.

15.35.31. The laboratory did not select multiple colonies from each agar plate for typing and it has been recommended by national water experts that 30 colonies would have to be picked to statistically determine there is no match between the patient and water strain. [171]

15.35.32. Several *C. pauculus* isolates could not be typed due to DNA degradation and therefore could not be matched to the patient isolate.

15.35.33. In the *M. chelonae* paper (Inkster *et al*., JHI 2021) [172] it was stated that no contemporaneous water results were available from the time (patient 1) developed infection and the concluded that a water source in the QEUH / RHC could not be completely.

[166] SHI, 'DOCS Bundle 6 Miscellaneous Documents' (n 20).
[167] Walker and others (n 2).
[168] F Halstead and others, '*P Aeruginosa* Infection in Augmented Care: The Molecular Ecology and Transmission Dynamics in Four Large UK Hospitals' [2021] JHI.
[169] Meera Chand and others, 'Insidious Risk of Severe *M Chimaera* Infection in Cardiac Surgery Patients' (2017) 64 CID 335.
[170] SHI, 'DOCS Bundle 6 Miscellaneous Documents' (n 20) 6.
[171] Lee (n 157).
[172] Inkster and others (n 156).

15.35.34. It should be noted that it is also important in how water samples are taken with preflush (first sample from the tap) samples more likely to be positive for microorganism that have grown either in the water or as a biofilm in the tap and associated components close to the outlet. Therefore if post flush samples are taken (i.e. after the tap has operated the likelihood of detection microorganisms associated with the tap will be lessened.

15.35.35. Whilst Whole Genome Sequencing can be used to identify linked cases in an outbreak of infection, it may not always link a patient strain to one that has been detected in the environment and as such should not be used to exclude acquisition of infection from a water system to patient owing to the limitations of microbiological testing i.e. absence of evidence is not evidence of absence.

15.35.36. The NHS GGC WGS report 173 (p1195) also recognised the limitations of the work in matching or excluding any direct connection between patient isolates and the water and drainage isolates. In the NHS GGC report it stated that:

15.35.36.1. there was no standardised methods recorded for either taking samples, labelling or culturing organisms from the water and drainage samples.

15.35.36.2. the samples were taken over several years and by an unknown number of people and not at the time of the patients infection with associated location.

15.35.36.3. there was no standard method for picking colonies from the agar culture plates and the paper states that “only single colonies were taken and stored from clinical and potable water/environmental samples”. Therefore it was not known if all of the organisms isolated were identified and stored.

15.35.36.4. There was no standardised methodology recorded for how the organisms were stored and labelled and which organisms were chosen to be saved.

15.35.37. These limitations of the NHS GGC WGS study reduce the confidence in the study to exclude a link as would any studies derived from the same stored samples or interpretation of the WGS study by others that does not address the limitations.

15.35.38. The December 2018 HPS report[174] states that the environmental Gram-negative blood stream infections in the first quarter of 2018 were all considered to be linked to the water system as organisms of the same species had been isolated from water samples taken within 2A/2B.

15.35.39. In addition, the CNR panel of experts identified that 70% of Gram-negatives could possibly relate to the hospital environment with “30% probably” relating to the hospital environment which supports the hypothesis that the bacteraemia’s were potentially associated with the water system. This hypothesis by the CNR does not support the findings of the NHS GGC

[173] SHI, ‘DOCS Bundle 6 Miscellaneous Documents’ (n 20).
[174] Summary of Incident and Findings of NHS GGC QEUH/RHC. HPS, 20 December 2018

WGS study where matches between the patient and environment were not identified.

(f) At paragraph 5.1.15 of your report you stated that *"the water systems associated with chilled beam heaters are known as a closed water system where there is no environmental exposure directly from the water within the chilled beam."* To what extent does this this statement envisage leaks occurring in such systems? Are you in a position to comment on the occurrence of such leaks at QEUH?

15.35.40. Chilled beam technology was in use in at the QEUH/RHC to deliver fresh air to the patient bedroom and was integrated into the suspended ceiling systems. The air movement creates low pressure and draws air back in from the room over the cooling coils and provide thermal comfort.

15.35.41. During the construction and commissioning phase there is a reference to the "Low Temperature Hot Water and Chilled Water system were flushed, chemically cleaned, flushed again before corrosion inhibitor added." [175] (p194)

15.35.42. The chilled beam coolers were included in the Legionella risk assessment in 2015 where they were cited in the other risk systems and whilst considered a low risk for legionella they were also included in the risk assessment and should have been part of the planned preventative maintenance programme.

15.35.43. The chilled beam system was supplied by water from the trade water tank. During the 2015 legionella risk assessment it was identified that i) the RHS side of the Trades tank was valved off due to a reported inlet valve issue (tank was full of water and there were signs of stagnation in the bottom of the tank) and ii) "Closed Chilled Systems Minimise aerosol creation during maintenance procedures. Maintain in accordance with manufacturers/installers instructions."

15.35.44. In the 2017 Legionella risk assessment the trades tanks (x2) were identified as being high risk (14) again as the RHS was isolated and full of water with signs of stagnation and had been offline since the construction phase – in my opinion this risk had obviously not addressed in the intervening period. The RA indicated that "estates were unsure if the trades system was being monitored.

15.35.45. I have seen no evidence that the trade tanks were monitored, serviced or maintained following handover of the QEUH/RHC to NHS GGC.

15.35.46. Two issues were identified with the chilled beam coolers i) condensate dripping from the coolers and ii) leaks from the chilled beam closed water system. These have been cited in numerous reports (IMT, Bundle 1/SBARS, Bundle 4) and in a peer review published manuscript (Inkster *et al*., JHI 2020).

[175] Storrar and Rankin (n 50).

15.35.47. During the IMT meeting (August 2019) [176] (p339) it was identified that, there was a heavy growth (counts >100) of *Pseudomonas oleovorans* from the beam water system and from swabs from the leakage, external to the beam. *P. aeruginosa* was also detected. *Pseudomonas* spp should not be present within the sealed water system of the chilled beams.

15.35.48. In Bundle 4 (SBAR p166) it was recorded that "This chilled beam water system has not been subject to the water quality management system through the water governance structures of the organisation."

15.35.49. In my opinion such evidence from NHS GGC indicates that appropriate maintenance of the chilled beam system was not being carried out. The chilled beam system is a closed system, from which the water should not leak and to which patients should not be exposed.

15.35.50. In my opinion the detection of *P. oleovorans* and *P. aeruginosa* in the water in the chilled beam system and associated leaks may have increased the risk to patients with the QEUH/RHC to these Gram-negative microorganisms.

15.35.51. In my opinion the presence of these waterborne pathogens in the chilled beam closed water system should have been controlled through servicing and maintenance.

(g) At paragraph 2.1.19 of your report you stated that there are "high counts and heavy biofilm contamination in the last two metres [before the taps]". Please comment on the significance of this remark as it relates to current practice at QEUH. In particular, what effect might this be expected to have upon testing strategy?

15.35.52. The actual paragraph at 2.1.19 is as follows "High counts and heavy biofilm contamination in the last two metres including pipework and tap components (Horne Optitherm taps) related to frequency of use, temperature control of water to the outlets that pose a risk through exposure of unfiltered water".

15.35.53. In the context in which the paragraph was written the last two metres includes the taps and associated components such as strainers, thermostatic mixer taps and flow straighteners.

15.35.54. As was demonstrated through the *P. aeruginosa* outbreaks in Northern Ireland the last two metres, including the taps can be high risk for patients due to the growth of microorganisms including Gram-negative bacteria such as *P. aeruginosa* *Cupriavidus* spp.

15.35.55. In my experience water stagnation, heat loss in the hot water, heat gain in the cold water, cold water deadlegs, presence of plumbing materials that encourage

[176] SHI, 'SHI - IMT Minutes Bundle 1 of Documents for the Oral Hearing Com' (n 88) 1.

microbial growth including strainers, thermostatic mixer valves and flow straighteners result in conditions that encourage microbial growth [177].

15.35.56. Several letters were produced in Scotland in 2012 [178] and 2013 [179] to alert Boards, Chief Executives, Infection Prevention and Control Teams and Directors of Estates/Facilities of the best practice for hand wash basins to minimise the risk of *P. aeruginosa* contamination in high risk units in Scotland. This advice included not disposing of body fluids in the sinks and not to wash patient equipment in hand wash basins as well as ensuring that taps and thermostatic mixing valves (manual and automated) have been commissioned (including programming auto flushing cycles), and routinely validated, as per the manufacturer's instructions.

15.35.57. The SHTM (2014) indicated that "Current advice is that they (flow straighteners) should be removed but this should be subject to risk assessment."

15.35.58. However, in June 2014, NHS GGC decided to install taps with flow straighteners, which had previously been demonstrated as particular risk for the growth of *P. aeruginosa*. However it was noted in the minutes that the risk should be assessed.

15.35.59. The last two metres of the water system at the QEUH / RHC had a number of features which increased the risk of microbial growth and the presence of Gram-negative microorganisms including long deadlegs, complicated taps and a lack of maintenance of the taps and associated components. The Legionella and the Pseudomonas risk assessments in 2015 both identified a number of these unsafe features which would lead to high counts and heavy biofilm contamination in the last two metres. According to the 2017 DMA legionella risk assessment these issues were not addressed .

15.35.59.1. As the QEUH/ RHC was based on single patient rooms there was an extensive number of basins and outlets which would lead to underuse, stagnation of water, hot water below the required temperatures and heat gain in the cold water.

15.35.59.2. The was no local hot flow and return to individual outlets (P7 DMA Pseudomonas RA 2015 [180]) – as such the spur from the hot water flow and return was cited as being 2.9m in length this would become a deadleg when the tap is not operated. Spurs of this length would rapidly result in heat loss resulting in temperatures that would encourage the growth of Gram-negative microorganisms. Due to the risks from *P. aeruginosa* growth the CEL 03 (2012) letter issued the advice that the taps (hot and cold) in high risk units (manually or automatically) should be run at maximum flow first thing every morning for a period of two minutes and for a record to be kept of when they were flushed. I have not seen any evidence that this was undertaken.

[177] Walker and others (n 2).
[178] Burns and Feeley (n 4).
[179] Burns and Feeley (n 5) 0.
[180] DMA, 'Pseudomonas Report on Water Delivery System (Pre-Occupancy)' (n 23).

15.35.59.3. Hot water temperatures frequently recorded below 55°C at the supply to TMV/TMTs. (p34 DMA Legionella RA 2015 [181]) which was identified as high risk and these temperatures would have decreased in the hot water deadleg in the last two metres.

15.35.59.4. During the DMA Pseudomonas RA (2015) it was identified that "the cold water temperatures recorded by DMA varied considerably throughout the building with the majority of the cold water temperatures more than 5°C higher than those recorded at the water tanks and with peak temperatures of 30°C being noted. In my opinion such high cold water temperatures would encourage the growth of microorganisms and the risk of microbial growth would be increased in the last two metres of the pipework where the water would be stagnant when the outlet was not being used.

15.35.59.5. DMA were advised by Mercury Engineering and Estates that all materials fitted during the construction are WRAs approved and do not support bacterial growth (DMA Pseudomonas report 2015 p9). However the evidence from the microbiological investigations from Intertek are that microorganisms were recovered from these WRAS approved materials in the last two metres (Bunde 6 p632).

15.35.59.6. From the evidence that I have seen, microbial growth and biofilms were present on the WRAS materials in the last two metres, where stagnant conditions (when the tap is not being used) and inappropriate temperatures prevailed (Bundle 6 p632). In my opinion the microbial growth was a result of a lack of planned preventative management of the water system.

15.35.59.7. The Pseudomonas risk assessment (DMA 2015) pointed out that "The cold "outlet" at Horne TMV taps may have reduced usage as mixed hot outlet used preferentially for hand washing purposes could create a small low flow zone with the tap body." Basically the cold outlet becomes a deadleg as it is underused.

15.35.59.8. I have seen no evidence that training was provided for using the taps and operating the cold lever. The lack of operation of the cold lever would have increased the risk of microbial growth in these taps due to the cold outlet being stagnant.

15.35.59.9. There is a statement in the Pseudomonas risk assessment that "In particular Horne TMV taps were designed specifically with Legionella and Pseudomonas control in mind."

15.35.59.10. I have not seen any evidence, in terms of scientific studies or otherwise, from the manufacturer (Horne Engineering) that these taps, used in the last two metres, would control Legionella or Pseudomonas and therefore in my professional opinion, this statement is misleading.

15.35.59.11. The 2015 Pseudomonas risk assessment also included the proposed actions to control the risk, who should carry out this action and by when (Figure

[181] DMA, 'L8 Risk Assessment NHS GGC South Glasgow University Hospital. 2015.' (n 14).

5). It was clear that the 6 monthly service of the Thermostatic mixer tap i.e. the Horne tap should be carried out by the Estates Department by September 2015.

Proposed actions to control the problem List the actions required. If action by others is required, you must send them a copy	**By Whom**	**Start date**	**Action due date**
Routine maintenance measures In line with Boards Water Safety System Policy and site specific written scheme:			
• Develop site specific written scheme	**Estates**	**Sept 2014**	**Dec 2014**
• 3 Monthly: Carry out TMT operation test & visual inspection of outlet flow control device.	**Estates**	**May 2015**	**May 2015**
• 6 Monthly: Service exchange TMT maintenance procedure including: o Visual inspection and manual clean of components. o Full mechanical service & inspection. o Functional testing. o Thermal sanitisation.	**Estates**	**Sept 2015**	**Sept 2015**

Figure 5. information from the DMA Pseudomonas risk assessment.

15.35.59.12. In the 2017 Legionella risk assessment there was no evidence that the facilities for servicing and maintaining the taps had been completed and commissioned. In my opinion it would have been difficult to undertake the servicing and maintenance if the facilities were not available.

15.35.59.13. It was also noted that no servicing of the TMT and strainers had been carried out in non-high-risk and only a limited service programme of taps in high risk areas since the hospital had opened. In my opinion the lack of servicing and maintenance would have increased the risk of microbial and biofilm growth with the components in the last two metres.

15.35.59.14. Other risks within the last two metres included the risk of contamination of the tap outlet from the ward environment due to human behaviours that may lead to contamination of the outlet including disposing of body fluids and washing medical equipment in the basins.

15.35.59.15. I have not seen any evidence of this type of training for clinical staff at QEUH/RHC.

15.35.59.16. Flushing of taps had been highlighted in the Cel 03 (2012) and 08 (2013) letters as a measure to reduce the risk of *P. aeruginosa* and the low compliance rates would have increased that risk.

15.35.59.17. I have not seen any evidence of this type of training for clinical staff at the QEUH/RHC.

15.35.59.18. The microbiological analysis of the tap components by Intertek (Bundle 6 p634) confirmed that components such as the flow straighteners in the last two metres of the pipework were heavily contaminated by microorganisms that that biofilm was also present.

15.35.59.19. Therefore, prior to occupancy the Legionella (2015 and 2017) and Pseudomonas (2015) risk assessments highlighted issues that would have increased the risk microbial proliferation in the last two metres of the pipework.

15.35.59.20. In my opinion this risk would have been increased due to the lack of flushing - particular issues with flushing observe in the Healthcare Inspection Report (2019)

15.35.59.21. The Healthcare Inspection Report (2022) identified inappropriate cleaning of medical devices (tracheostomies), which in my opinion, would lead to microbial contamination of the basin, drain and filter housing.

15.35.59.22. As was demonstrated by the Intertek reports in addition to the microbial contamination at the last two metres, multiple components of the water system (e.g. water tanks, expansion vessels [182]) were positive for water borne pathogens indicating that the water system was systemically contaminated and that it was not just a local problem.

15.35.59.23. However one of the strategies for dealing with microbially contaminated water outlets at the QEUH/RHC was to undertake localised biocide treatment.

15.35.59.24. Water samples would then be taken and the outlet declared safe after a number of negative tests had been undertaken.

15.35.59.25. Following the localised biocide treatment and negative testing the tap would have been returned to service. However, as the Intertek data had shown the water system contamination was not localised and as such microbially contaminated water upstream would have contaminated the last two metres within a relatively short time period.

15.35.59.26. The Intertek data (P 5) [183] indicated that flow straighteners that had been present in the water system for one week had a microbial loading and that those in place for more than one month were heavily colonised with Gram negative microorganisms including *C. pauculus*.

15.35.59.27. The evidence from the inquiry would indicate that any outlets that had undergone localised biocide treatment due to out of specification counts would likely have been recontaminated after a time period of one week to 1-2 months use due to upstream microbial contamination of the water system components that had not been decontaminated.

15.35.59.28. In my opinion the sampling testing strategy should have taken into account the rapid recolonisation of the outlets.

15.35.59.29. In order to reduce the exposure of patients to waterborne pathogens present in the last two metres point of use filters were fitted to the outlets. These bacterial retention filters prevent the release of waterborne pathogens from the water system but they do not address upstream contamination of the water system.

15.35.59.30. The way the water testing was carried out would also have influenced the counts from the water system.

15.35.59.31. Water samples taken from water outlets can either be preflush (the first sample when the tap is opened) or post flush which is taken after the tap has been operated for a certain period of time.

[182] Intertek, 'ITSS- 0719-0001 Expansion Vessel Investigation Report for QUEH Glasgow. 2019' (n 85).
[183] Intertek, 'Intertek Report Number ITSS-0718-0001W plus per Floor Contamination of Flow Straighteners Debris and Sponges 2018' (n 84).

15.35.59.32. The preflush would provide an indication of the microbial quality of the water in the last two metres of the pipework (including the strainers, tap and flow straightener) whereas the post flush would provide an indication of the microbial quality of the water downstream of the last two metres i.e. further back in the water system.

15.35.59.33. Therefore, both pre and post flush sampling would have to be carried out to assess microbial contamination of the water system.

15.35.59.34. One approach taken at the QEUH has been taking water samples through point of use water samples to assess the microbial quality of the water system.

15.35.59.35. In my opinion such a testing and sampling strategy (through filters) does not provide an indication of the water system as the point of use filters deliver water that is safe and as such was not addressing the root cause of the contamination of the upstream water system.

15.35.59.36. At the QEUH the taking of water samples through point of use filters detected Mycobacteria. The manufacturer assessed the filters and could find no fault with filters.

15.35.59.37. My opinion is that such positive microbial results through a point of use filter can then only be due to contamination of the water sample as the sample is taken, for example, it is possible that there was leakage through the seal of the point of use filter to the tap and that the filter had become contaminated in this way.

15.35.59.38. In my opinion I would agree with the NHS GGC hypothesis that the NTM infections of patients can only have occurred i) where the external housing of the point of use filter had become contaminated or ii) the patients had been exposed to unfiltered water elsewhere in the hospital where point of use filters were not fitted.

15.35.59.39. The other control strategy that will impact on the microbial contamination of the last two metres was the continuous dosing of the water system with chlorine dioxide.

15.35.59.40. As discussed elsewhere the dosing of chlorine dioxide was introduced into the QEUH/RHC to combat the systemic microbial colonisation of the water system. However, biocide used can be is impacted by a number of factors. ClO2 is added to the cold water tanks however as this oxidising biocide passes through the water system the concentration present will be degraded by the amount of organic carbon present in the water system including sediment and detritus (identified in the water tanks), corrosion products (detected in the calorifiers and expansion vessels) and Gram-negative bacteria and biofilm as was demonstrated by Intertek to be present systemically (Bundle 6 p645 and [184]) through the water system and at the last two metres.

15.35.59.41. The Intertek study (Bundle 6 p650) carried out in September 2019 demonstrated that flow straighteners removed from the QEUH/RHC had significantly less bacteria than those previously examined in June 2018.

[184] Intertek, 'ITSS- 0719-0001 Expansion Vessel Investigation Report for QUEH Glasgow. 2019' (n 85).

15.35.59.42. My opinion is that compared to the previous heavy fouling on the flow straighteners that these results do demonstrate an improvement in the microbial control of the water system.

15.35.59.43. However, in my opinion, there are some interesting aspects to the results that need to be commented on when considering the last two metres of the water system and sampling and testing strategy as per the current practice and control strategies at the QEUH.

15.35.59.44. The conclusions from the Intertek study were as follows:

- No Biofilm was detected during this analysis
- No visual soiling was detected during this analysis
- Comparing the results from this testing against previous samples tested has shown a significant improvement against the parameters tested.
- The results for this testing had an average cfu/flow straightener result of 325 cfu per flow straightener

15.35.59.45. From my own particular expertise, from many years of analysing water system components, my interpretation of the conclusions on the microbial control in the last two metres would be as follows:

- No biofilm detected: this result is based on the sensitivity of the assay that was used (of which there are no details). Had these components been examined using microscopy techniques [185] then biofilm would have been observed on the surfaces of the components.

- No visual soiling was observed - I have been unable to determine how this visuals soiling was undertaken but assuming it was undertaken by what the operator observed by the naked eye then this would not have been quantitative nor sensitive nor specific for microbial growth on the surface of the components.

- When comparing the results against previous samples there was a significant reduction in the microbial counts. However, it is my opinion that the average result of 325 cfu per flow straightener may be misleading. The results range from <100-9.0 10^4 cfu per straightener which would give average of 8.1 x 10^3 cfu per flow straightener.

- In my opinion, it was interesting that the three highest counts were omitted when the analysis was carried as the operator decided that these high counts were significantly different from the others and therefore should not be included in the analysis - I have not been able to understand why the three highest counts would be omitted?

- I have been unable to determine whether any microbial identification was carried out on the microorganisms that were recovered and therefore cannot determine whether any waterborne pathogens such as *C. pauculus* were present (as per the previous examination).

[185] Walker and others (n 2).

- My own interpretation and conclusion of the Intertek study on the flow straighteners is that:

    - Biofilm is still developing albeit at a slower pace
    - The microbial load was significantly reduced compared to flow straighteners examined previously indicating that growth on the flow straighteners is being controlled to a certain degree.
    - That the outliers represent flow straighteners that despite the presence of control strategies could present a risk to patients due to the accumulation of microbial load that will develop over a longer time period.

15.35.59.46. Therefore, in terms of the importance and significance of the last two metres and current sampling strategy at QEUH/RHC is that those managing the water system at the QEUH need to be aware that there are continuing microbial risks from the last two metres. In the last two metres biocidal control is not a panacea and the risk of microbial growth at that point has to be managed accordingly through the current sampling and testing strategy.

15.35.59.47. In particular, the effect these outcomes might have on the testing strategy is whether;

- Water samples should be taken through point of use filters – these samples provide no information on the safety of the water system.
- Preflush and post flush samples to be taken from the outlets in the absence of point of use filters.
- Rather than concentrate on the number of samples taken and the percentage that are out of specification, concentrate on those samples that are out of specification, the units and risk to patients where samples have been taken and take action accordingly.
- There should be less reliance on total viable counts and concentrate on the different type of water borne pathogens present in the water sample that has been taken and take action accordingly.

(h) To what extent, in your view, does non-use of POU filters at the QEUH and RHC at present pose a risk for higher risk groups including CF patients, ITU and other immune compromised groups? Would further measures be warranted?

15.35.59.48. The risk of the water system to the high risk patient groups in different locations needs to be risk assessed and this can be undertaken through microbiological sampling to assess the type and number of different bacteria in the water system. This will determine the risk to patients in those locations.

15.35.59.49. High risk groups including CF patients, ITU and other immune compromised groups will be at greater risk of infection than patients in non-high risk units. However, high risk patients may be located in different parts of the hospital for different reasons including in non-high risk units and hence their specific environment (including the water) still needs to be risk assessed to reduce that patients risks of water borne infections.

15.35.59.50. Consideration should also be given to patients with Hickman Lines who will be at risk from infection related to *Klebsiella pneumoniae* or *Enterobacter* cloacae form splashing from basins and drains.

15.35.59.51. POU filters are typically used where a risk from waterborne microorganisms has been identified. Being absolute bacterial retention filters they prevent exposure of waterborne microorganisms into the patient environment when the tap is operated.

15.35.59.52. The decision whether to fit POU filters where higher risk groups including CF patients are located must be risk assessed. However, this risk assessment must take into consideration the quality of the water from all sources as well as the microbial contamination of the drain.

15.35.59.53. A considerable amount of work has been undertaken to implement control strategies of the microbial contamination that had been identified at the QEUH / RHC 186

15.35.59.54. The data provided by the Inquiry presents the results (2015-2020) for the whole new (adults and RHC) and is not broken down by category of location. Therefore, I have not seen the microbiological data from the wards where higher risk groups including CF patients, ITU and other immune compromised are located and so I am unable to comment on the current risk.

15.35.59.55. In addition, the tests over the period 2015-2020 (p3) [187] did not provide additional information on whether a point-of-use (POU) filter was fitted and if so, whether the sample was taken through the POU filter or after its removal, whether the sample was collected before or after outlet flushing, whether it was a repeat sampling following an earlier out-of-spec result, etc and as such there are some limitations to interpreting the data and understanding the risk to the patients in the adult ITU.

15.35.59.56. Only by assessing the microbiological data from the water sources and drains would one be able to assess the current risk to high risk patients located in those areas.

15.35.59.57. The use of POU filters would reduce the risk from the water system however there are other risks associated with basins, drains, splashing, clutter and contamination of the drains with body fluids and used medical devices, which have been discussed elsewhere.

15.35.59.58. The risk from the biofilm in the sink areas was recognised at the reason for decanting the patient group from 2A/2B and 4B. [188]

15.35.59.59. In my opinion the sampling and testing strategy of the water, tap components and the basin environment should be used to determine the risk to patients in high risk areas where point of use filters are not used.

15.35.59.60. I have seen no evidence that clinical staff are trained in the risk of water management within the clinical area and these concerns were evident in the Healthcare Inspection Scotland reports (2022).

[186] NHS GGC, '1(Iii) 1(Iv) & 2(i) Material Changes, Explanation and Advice. OC'.
[187] Chaput (n 151).
[188] NHS GGC, 'Water Review Meeting – Draft Meeting Note 18th September 2018 Objective Connect'.

15.35.59.61. In my opinion further measures that could be warranted (if not already caried out) to reduce the risk to high risk patients in areas where point of filtration is not currently installed;

- Surveillance of bacteraemia's, that may be suspected as being due to environmental Gram-negative waterborne bacteria (and drain associated bacteria), should be undertaken using look back exercises for a period of up to 2 years, as these incidents may reoccur after considerable long periods of time.
- Compilation of an asset list to record all the equipment that may be associated with water and its uses in the high risk units where point of use filters are not used.
- The implementation of planned preventative maintenance strategy including servicing and validation of components and any equipment that uses water as per national and local guidance.
- Continual dosing with chlorine dioxide will assist in the reduction of risk from waterborne infections in the adult ITU
- Sampling the water system
  - In the absence of point of use filters (even where fitted)
  - Pre and post flushing water samples should be taken (it is important that the true preflush should be taken first thing in the morning prior to the outlet used for example in the morning) and carrying out microbiological testing according to local guidelines
- Sampling of showers (not through point of use filters if these are fitted), hoses and TMVs.
- Sampling of drains should also be carried out to assesses the risk from drain associated microorganisms.
- Assessing the risk of splashing
- Reducing the presence of spurs or deadlegs from the hot flow and return – the longer the spur the more difficult it will be to maintain temperature control as the hot water temperatures will decrease when the tap is not being operated.
- Removing taps with flow straighteners as these components increase the risk as biofilm development will occur on the flow straighteners
- Removing Horne Engineering taps with dual levers (hot and cold) where the lever that operates the flow of cold water will be infrequently used and will create a deadleg
- Implementation of remote monitoring and increasing the number of temperatures monitoring points on the hot and cold water system to ensure that appropriate temperatures are being achieved as per guidance
- Staff training to address staff behaviour including inappropriate use of the clinical handwash basin for disposing of body fluids and washing used medical devices [189]
- Staff training to ensure flushing is carried out and that staff responsibility is identified [190]

[189] HIS (n 44).
[190] HIS (n 44).

- Staff training to reduce inappropriate use of clinical hand wash basins and to ensure that sink flushing is undertaken such that staff are aware of the risks
- Reducing the amount cluttering of unnecessary equipment and items including medical equipment in and around the clinical wash hand basin.
- Implementation of splash screens to reduce the splash from sinks into the surrounding environment
- Servicing and maintenance of hand wash basin and shower drains
- Inspection reports and maintenance of degraded sealant surrounding wash hand basins to prevent moisture entrapment that will results in biofilm formation
- Inspection reports and maintenance of shower linoleum to repair damage where floor and wall seals have degraded to prevent moisture entrapment and microbial growth of Gram-negative microorganisms and fungal contaminants.
- Implementation of a fully functioning water safety group and water safety plan.

(i) **In relation to the adult ITU, please comment on that unit not ever having had POU filters in place. Please comment on any risk, or otherwise, posed by the use of unfiltered water.**

15.35.59.62. I have discussed a number of the risks to high risk patients in adult ITU above in Question 15h and where appropriate recommended further measures that could be warranted to reduce the risk to high risk patients from the use of unfiltered water.

15.35.59.63. The use of control strategies such as the installation of point of use filters would be in response to out of specification water microbiology results. This was the scenario in wards 2A, 2B and 4B where Gram-negative organisms (different strains) and fungal growth was identified in tap outlets (flow straighteners particularly) and shower heads in RHC/QEUH. The hypothesis is that the outlets were the source and so point of use filters were fitted.

15.35.59.64. I have not had access to the microbiology data from the adult ITU and so I am unable to comment on the current risk to patients in that area.

15.35.59.65. In my opinion based on the evidence presented by the inquiry including the legionella risk assessments (2015 [191] and 2017 [192]), pseudomonas risk assessment [193] (lack of risk assessments, written scheme and planned preventative maintenance) and then the water system was not managed appropriately following handover.

15.35.59.66. Intertek assessed the microbiology results [194] and concluded that;

[191] DMA, 'L8 Risk Assessment NHS GGC South Glasgow University Hospital. 2015.' (n 14).
[192] DMA, 'Legionella Risk Assessment QEUH (Adult) Hospital and the Adjoining RHC 2017' (n 17).
[193] DMA, 'Pseudomonas Report on Water Delivery System (Pre-Occupancy)' (n 23).
[194] Intertek, 'Intertek Report Number ITSS-0718-0001W plus per Floor Contamination of Flow Straighteners Debris and Sponges 2018' (n 84).

15.35.59.67. Samples from the cold water storage tanks were positive for *Cupriavidus* spp. which in my opinion indicates that the cold water system would have seeded the rest of the cold water system as well as the hot water calorifiers.

15.35.59.68. Between 20-60% of the water samples examined from the water system including water tanks and water samples from floors 1-11, basement and basement tank were positive for *Cupriavidus*. In my opinion this would indicate that all the areas sampled were colonised by *Cupriavidus*.

15.35.59.69. Therefore, it was apparent that the microbiological contamination of the water was not confined to wards 2A, 2B and 4B and it is highly likely that the water from the outlets in the adult ITU would have been similarly contaminated and the high risk patients in the adult ITU will have been exposed to the water borne microorganisms when exposed to water from the water system.

15.35.59.70. 75% of the expansion vessels were positive for *Cupriavidus* spp. indicating a high level of contamination and a high potential to contaminate the hot water systems supplied by those expansion vessels.

15.35.59.71. From the analysis of the pre (33% positive) and post flush (44% positive) samples, the microbial contamination by *Cupriavidus* spp. was not localised but was widespread through the entire water system. Preflush represents those microorganisms present in the tap and last two metres with post flush representing contamination from further upstream in the water system.

15.35.59.72. A summary of the microbiology data is available in the published peer review manuscript [195] that described that over 60 species of Gram-negative bacteria, fungi (including Aspergillus spp.) and atypical mycobacteria were recovered from the water and system components.

15.35.59.73. In my opinion the *Cupriavidus* spp. and the other microorganisms that extensively contaminated the water system and involved both hospitals and was therefore not just a localized problem [196].

15.35.59.74. In my opinion these microbiological results indicate that there would have been a risk posed by the use of unfiltered water in the adult ITU where high risk patients were located.

15.35.59.75. Contamination of drains should also be assessed in non-use of POU filters units at the QEUH and RHC

i. " To what extent might the effect of biocide treatment affect your answer?"

15.35.59.76. In my opinion the use of a biocide including chlorine dioxide dosing has limitations in any water system and its application is not a panacea to microbial control. I have discussed these limitation elsewhere in this response.

15.35.59.77. As discussed in other responses chlorine dioxide is added to the cold water tanks and is pulled through the cold water system and to the hot water calorifiers and to the downstream outlets. The concentration of chlorine dioxide will be reduced in the hot water systems as the biocide gasses off. The ability of chlorine dioxide to inactivate microorganisms will depend on the concentration of

[195] Inkster and others (n 21).
[196] Inkster and others (n 21).

organic carbon (sediment, detritus, organic carbon and microorganisms / biofilm) in the water system. The presence of organic carbon reduces the concentration of chlorine dioxide as it passes through the water system. The concentration that is dosed into the cold water tank will be reduced as the biocide passes through the water system such that the concentration that is present downstream of water tanks may not be sufficient to inactivate microorganisms at the periphery of the water system e.g. in the last two metres.

15.35.59.78. The use of ClO_2 is relatively slow to penetrate biofilms [197] [198] and therefore control of biofilm in an already contaminated hospital water system as the QEUH/RHC can take a considerable amount of time to reduce microbial the extensive microbial burden

15.35.59.79. The difficulties in achieving microbial control were exemplified by the microbiological results from NHS GGC dated 8th February 2022. [199]

15.35.59.80. The data that I have been provided with by the Inquiry following chlorine dioxide treatment details microbial tests taken from the newly refurbished wards indicated that:

15.35.59.81. Chlorine dioxide treatment in 2A/2B did not significantly decrease TVCs with 2A/2B having considerably higher TVCs than the floors below and above.

15.35.59.82. These are disinfectant-tolerant biofilm-forming taxa and were not affected by chlorine dioxide treatment that were protected by in contaminated pipe sections..

15.35.59.83. When the pipe sections were removed from 6 rooms in ward 2A they showed the same biofilm forming organisms detected in water samples (notably *Sphingomonas paucimobilis* and *Cupriavidus pauculus*).

15.35.59.84. Almost all out-of-spec samples were from old Markwik taps.

15.35.59.85. Installation of new Markwik taps have significantly lowered the CFU counts.

15.35.59.86. The pipe and tap results would indicate the presence of biofilm that the chlorine dioxide was not inactivating i.e. the concentration of ClO_2 was not sufficient to inactivate the bacteria.

15.35.59.87. As a consequence of the presence of the waterborne pathogens notably *Sphingomonas paucimobilis* and *Cupriavidus pauculus* that had previously been associated with HAI a number of other preventable measures were implemented including.

15.35.59.87.1. Increased flushing to more closely mimic an occupied ward

15.35.59.87.2. Cleaning schedule to clinical standards

15.35.59.87.3. Hydrogen peroxide / silver ion treatment (2000 ppm H_2O_2) of entire ward 2A/2B on Dec 13

[197] Am Jang and others, 'Measurement of Chlorine Dioxide Penetration in Dairy Process Pipe Biofilms during Disinfection' (2006) 72 Applied microbiology and biotechnology 368.
[198] Behnke and Camper (n 135).
[199] Chaput (n 140).

15.35.59.87.4. All Markwik 21+ taps replaced on Jan 10-12

15.35.59.88. In my opinion these results demonstrate that:

15.35.59.88.1. the application of a biocide is a not a panacea i.e. not a universal control strategy as the microorganisms in the last two metres were not inactivated.

15.35.59.88.2. That the contaminated pipework (spurs or deadlegs) and taps that were removed were contaminated with biofilm and that this had not been managed.

15.35.59.88.3. That flushing was not being carried out effectively as per the guidance.

15.35.59.88.4. That the microbial growth in the water system, biofilm growth and risk to patients was not fully understood at this stage of the refurbishment.

15.35.59.89. In summary this lack of control of the microbial contamination and water borne pathogens including *S. paucimobilis* and *C. pauculus* would have been replicated in the other areas of the hospital including adult ITU where high risk patients were located.

15.35.59.90. There was a conclusion that “TVCs and GNBs in 2A/2B now similar to other floors, and broadly similar to 6A. My understanding is that all the samples for 6A were taken through point of use filters. However, these samples were not testing the water system but contamination either through the sampling process or contamination of the housing of the filters.

15.35.59.91. My opinion is that this conclusion is misleading and uninformed as the work on 6A provides no microbiological evidence of the status of the microbial contamination of the actual water system in 6A. Considering that some of the counts are above 100 CFU/ml would indicate that the contamination was coming from elsewhere and may reflect staff use of the hand wash basins and the contamination in the drains. Such results do not provide me with confidence that that water system itself was being microbiologically assessed.

(j) Please comment on whether it is possible that small clusters of environmental infections could occur across multiple sites, should biofilm be disrupted in the tank? What effect might that have when it comes to establishing an epidemiological link?

15.35.59.92. The question is whether it is possible that small clusters of environmental infections could occur across multiple sites should biofilm be disrupted in the tank? The evidence from the inquiry (DMA Legionella risk assessment 2015) would indicate that there was sediment and debris present in the cold water storage tanks at the handover phase prior to patient occupation. These same problems were identified in the 2017 DMA Legionella risk assessment. In the absence of planned preventative maintenance, microbial growth occurred within the tanks, due to the large surface area to volume ratio provided by the surface exposed to the water.

15.35.59.93. Biofilm would have sloughed off the walls, seeding the water in the tank that would have been pulled through to the downstream water components. The 2015 and 2017 risk assessments identified that when the calorifiers were at full

temperature the return hot water temperatures were only reaching 50°C. Where poor recirculation was taking place or deadlegs were present this temperature would have decreased further to temperatures favouring microbial growth. Peak cold water temperatures of 30°C were noted (2015 legionella and Pseudomonas risk assessment) which would encourage microbial growth.

15.35.59.94. The microbiological evidence conclusively demonstrates that there was systemic microbial contamination across the QEUH/RHC including the water tanks, different floors, expansion vessels and tap fittings.

15.35.59.95. My opinion is that with systemic microbial and biofilm contamination across the water system then patients would have been exposed to these microorganism when the taps were operated and basins used.

15.35.59.96. Microbial surveillance and look back exercises over 1, 2 or even 3 would assist in determining whether small clusters of environmental infections occurred across multiple sites when biofilm was disrupted in the tanks.

15.35.59.97. What effect might that have when it comes to establishing an epidemiological link?

15.35.59.98. I can only discuss this from my perspective as a research water microbiologist. I have no clinical, medical or epidemiological expertise in matching or typing strains though I have been involved in projects where this technology has been used and have worked with experts with those skill sets.

15.35.59.99. Therefore, In terms of establishing a link I will restrict my response to my area of expertise in sampling and detection of the microorganisms from the water system. When a waterborne HAI has been suspected it is important that water samples are taken from the location where the patient has been identified as soon as possible using prescribed standing operating procedures (SOP). This would include identifying all the sources of water to which the patient has been exposed either from the water system or from standalone equipment such as water coolers or water dispensers. A range of different samples would need to be taken including water samples (pre and post flushing), swabs of moist surfaces or drains, tap and shower outlets (and hoses). This may also involve removing plumbing components to enable them to be dismantled for microbial and biofilm assessment [200]. The samples that have been taken would be analysed as per the SOP using standardised microbiological techniques in a UKAS accredited laboratory.

15.35.59.100. In terms of establishing an epidemiological link microbiological isolates would be identified using prescribed methods and compared to patient isolates. The greater the number of environmental colony isolates that can assessed from each culture plate then the more likely that a match will be identified. It has been suggested by Dr S. Lee that 30 different colonies should be selected and typed from each culture plate to statistically ensure that a particular strain was not missed.

[200] Walker and others (n 2).

15.35.59.101. At the QEUH the WGS results suggest that the isolate from one patient (Patient 2) was closely related to environmental isolates from water outlets which fitted with the patient linked in time and place to these outlets. [201]

15.35.59.102. During a patient lookback exercise of a patient with a *C. pauculus* bacteraemia typing of the isolates using pulsed-field gel electrophoresis (PFGE) matched the patient isolate to the isolate.

15.35.59.103. The Case Note Review [202] established a relationship between the environmental risk and the observed infections and concluded that a link between the environment and infection was most likely in 32% of cases. The CNR report [203] was also critical of the recording of environmental data which was found to be inconsistent and lacked organisation at the QEUH/RHC.

15.35.59.104. I have described above the extensive amount of sampling and analysis that is required as soon as a patient is identified with a potential environmental HAI to increase the likelihood of identifying a link or match to the patient strain.

15.35.59.105. Professor Leanord and Dr Brown [204] used WGS to identify relationships among isolates of *Cupriavidus* spp*., Enterobacter* spp*.,* and *Stenotrophomonas* spp*.* from clinical samples and from water and drainage systems. They acknowledged that there were a number of limitations to the way that the environmental samples were taken, stored, assessed and environmental colonies analysed to determine related to the patient isolates including:

a. no standardised methodology recorded for taking samples, labelling or culturing organisms from the water and drainage samples.
b. samples taken over several years and by an unknown number of people.
c. lack of contemporaneous sampling in time and location with the patient infection
d. no standardised methodology for picking colonies
e. only single colonies of each individual colonial appearance (morphology) were picked
f. no standardised methodology recorded for how the organisms were stored and labelled and which organisms were chosen to be saved.
g. My opinion would be that the high number of unknowns in the QEUH/RHC WGS study would add uncertainty and reduce the confidence of establishing a link between infections in patients and the water/drainage system as an environmental source of infection.

[201] Inkster and others (n 156).
[202] Stevens, Evans and Wilcox (n 155).
[203] QEUH and RHC Case Note Review Overview Report. March 2021
[204] Leonord and Brown (n 158).

16. I remain clear that my duty is to assist the Inquiry in an impartial manner.

17. I have no connection, personal or otherwise, to any core participant in the inquiry other than that I have declared in this response or my earlier report dated 21st January 2024.

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

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

20. I acknowledge the duty to set out all material facts, assumptions, methodology or other matters upon which my views and opinions are based, including such matters as may detract from the opinion formed, and that I have complied with that duty in this response and my earlier report dated 21st January 2024.

21. I acknowledge the duty to address only areas within my own areas of expertise and that we have made it clear when a particular question or issue falls outside our expertise. and that we have complied with that duty in this response and my earlier report dated 21st January 2024.

22. I acknowledge, understand and accept the obligation to state if my opinion is not properly researched because insufficient data are available and to give an indication that the opinion is no more than provisional, and have done so in this response and my earlier report dated 21st January 2024 where appropriate.

23. I acknowledge, understand and accept the obligation to indicate if any opinion I have expressed is qualified, or subject to revision, and have done so in this response and my earlier report dated [date] where appropriate.

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

Yours sincerely,

Dr James Walker

5th August 2024

Direction 5 Questions for Independent Expert Witnesses

5 August 2024

Dear Mr. Bennett,

On 5 June 2024 you produced a report for the Inquiry. This has been made available to Core Participants (CPs). On 13 December 2023 the Chair issued Direction 5 which set out at Appendix B a system by which CPs would be permitted to raise lines of questioning or questions with you and the other independent witnesses before the commencement of the Glasgow III hearing.

The CPs were told that within five weeks of the date upon which the Inquiry Team provided your report to them any CP who wished to propose questions for you about your report or to make comment on that report must send a note to the Secretary to the Inquiry setting out in concise numbered paragraphs with clear reference to the relevant parts of the report:

1. the specific questions that should be asked of the report's author and any comment that the CP wishes to make on the substance of the report;

2. whether these questions and/or comment will raise new matters or issues not covered in the report; or

3. where no new matters or issues are likely to be raised, reasons why the issue should be raised with the expert witness at that time.

The Inquiry Team has considered the responses received in respect of your report and consolidated them into nineteen questions. These questions are set out in the Appendix to this letter. Please provide a supplementary report to the Inquiry Team as soon as possible and by Monday 12 August 2024 at the latest in the form of concise answers to these questions. Your response will then be provided to CPs before the start of the Glasgow III hearing in the week of 19 August 2024.

Given

the involvement of the counsel team in the hearing that deadline of 12 August 2024 cannot be extended.

Yours sincerely

Brandon Nolan
Solicitor to the Inquiry

Appendix

Supplementary Report by Allan Bennett for the Scottish Hospitals Inquiry

I have been asked a series of questions by the Inquiry Team and have been asked to respond to each question in turn.

1. In relation to paragraph 7.3 of your report, how should PPVL rooms be used in units for HCID (High Consequence Infectious Diseases)?

    - PPVL rooms are not recommended in Scottish or UK guidance for the housing of patients with a HCID or suspected HCID (see below)

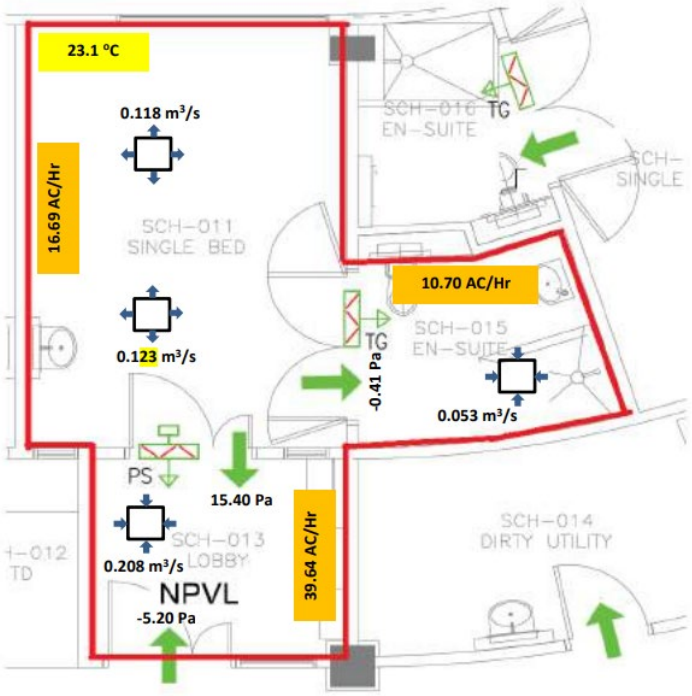
- High consequence infectious diseases (HCID) - GOV.UK (www.gov.uk)
- High Consequence Infectious Diseases (HCID) - NHSGGC

2. In relation to paragraph 7.8 of your report, how different, if at all, is the PPVL room in the Hambreus study from the PPVL design in the SHTM?

    - The PPVL set up in the Hambreus study was in a Swedish burns isolation unit during the early 1970s. In their study they did not measure pressure differentials between the rooms so a direct comparison to modern PPVL is difficult. The PPVL rooms in the study had an air change rate of 4ach. In SHTM03-01 Part A (2022) the only design features stated for PPVL is as follows “Bedroom air change: ≥10 per hour Lobby pressure: +10 Pa to corridor”. Therefore, there is not a direct comparison. It seems likely that the PPVL used currently in the UK are of a higher specification to Hambreus’s rooms. However, the basic operational set up is equivalent.

3. In relation to paragraph 8.14 of your report, describe room No.23's functionality, i.e. is the room positive pressure to corridor but negative pressure to lobby?

    - I do not mention any individual rooms in this section of the report. I have checked Sutton Service validation report for RHC Ward 2A - Bed 23 Negatively Pressurised Ventilation Lobby (NPVL). This room is designed to have a negative pressure ventilated lobby. The lobby has a measured air change rate of 39.6 ACH and a negative pressure (-5.2Pa) to the corridor. The patient room is at positive pressure to the lobby (15.4Pa) with a high air change rate of 16.7. The pressure differential between the room and the corridor is 9.7 Pa. See diagram below



Therefore, during normal operation this room provides a protective environment for the patient while preventing the egress of potentially contaminated air to the other wards.

4. If so, can you confirm that this room behaves differently from both a negative pressure room and a PPVL (requiring separate explanation and monitoring)?

    - Yes. Its design is non-standard and its performance is different. I would imagine that this room is designed to house an immunosuppressed patient who has a serious airborne infection. The room is designed to both protect the patient from environmental pathogens and to prevent spread of the airborne infection to other patients on the wards. The different operation of this room would need careful explanation to staff including those monitoring its performance. For a room designed in this way the opening of doors should be limited and both lobby doors should never be opened at the same time.

5. In relation to paragraph 8.30 of your report, do the NICE recommendations fail to identify additional risk in comparison with national standards?

    - There are many NICE recommendations. I need the specific NICE document to be specified before I will be able to comment.

6. In relation to paragraph 8.30 of your report, to what extent would a failure to identify that many fungal species are not covered by posaconazole prophylaxis

impact on the level or risk that exists for the high-risk patients (e.g. intrinsic resistance in Fusarium)?

- This is outside my area of expertise. I am not a clinician.

7. In relation to paragraph 8.63 of your report, to what extent, if any, do the identified risks of CBUs apply to all patients in general ward rooms (taking account of procedures and possible occupation by vulnerable patient groups)?

   - The risks of contamination from CBUs for patients will depend on the type of patient, the type of procedure undertaken on the patient and the length of stay of the patient. Patients who spend short times in these rooms and have minimally invasive procedures will be at low risk. However, patients spending longer times in these rooms, patients being treated with antibiotics and those with open wounds could be at higher risk due to the potential for infection with opportunistic pathogens shown to be present on CBU.

8. Have you considered the NHSGGC Workplace Health Safety and Welfare Policy, July 2018 (available at: https://www.nhsggc.org.uk/media/234150/nhsggc-health-safety-policy-workplace-hs-and-welfare-ver-4.pdf) with regard to health care worker safety and whether the QEUH ventilation accords with the statements therein?

   - Thanks for making me aware of this document. The document seems cover the NHSGGC estate and not just QEUH/RHC and many of the statements are written in a general fashion which makes it hard to judge whether or not they are met. I think my colleague Andrew Poplett is better placed to comment on issues of testing and maintenance.

9. In relation to paragraph 7.2 of your report, how did the limited evidence base impact your conclusions?

   - While the papers that demonstrate the effectiveness of isolation rooms are mainly from the 1970s, their conclusion that correctly operating isolation rooms providing directional airflow can give a high degree of protection against microbial aerosols still holds as they are based on basic physical laws. However, different designs of rooms may impact on the magnitude of protection afforded. Where the evidence is limited is in controlled studies showing the benefits of isolation rooms on patient outcomes. I think this is made clear in how I wrote my conclusions.

10. In relation to paragraph 7.2 of your report, why are you confident in the conclusions you reached based on limited evidence?

    - See above. I am confident that correctly operating isolation rooms will provide a high degree of protection against airborne micro-organisms being released from negative pressure rooms and from airborne micro-organisms entering positive pressure rooms. PPVL will protect against both.

11. In relation to paragraph 7.2 of your report, did you give consideration to whether the environment as a whole presented an additional risk to patients beyond what would be expected in a comparable hospital environment?

    - No. I focussed my report on ventilation only.

12. What additional analysis requires to be done to address the question of whether reduced ACH leads to an increased risk of infection?

    - During the COVID -19 pandemic a great deal of work was carried out looking at the impact of ventilation on the transmission of this infection using mathematical modelling such as Islam et al (2024). A similar approach by Edwards et al (2023) has been used to assess the impact of ventilation on the transmission of airborne agents in hospitals. These approaches are theoretical and depend on a series of assumptions but give an insight on the potential impact of changing ACH. Another analysis would be comparing the incidence of respiratory infections in comparable hospital wards with different ventilation strategies. This would need careful design to ensure wards are similar and other variables are controlled.

    - Edwards, A. J., Benson, L., Guo, Z., López-García, M., Noakes, C. J., Peckham, D., & King, M. F. (2023). A mathematical model for assessing transient airborne infection risks in a multi-zone hospital ward. *Building and Environment*, *238*, 110344.A mathematical model for assessing transient airborne infection risks in a multi-zone hospital ward - ScienceDirect

    - Islam, M. T., Chen, Y., Seong, D., Verhougstraete, M., & Son, Y. J. (2024). Effects of recirculation and air change per hour on COVID-19 transmission in indoor settings: A CFD study with varying HVAC parameters. *Heliyon*. https://www.cell.com/heliyon/fulltext/S2405-8440(24)11123-1

13. In relation to paragraph 9.7 of your report, what is the basis of your opinion, as a non-clinician, that prophylaxis should not be used?

    - The decision whether to use a prophylaxis will be taken by balancing the benefit to the patient against the negative impacts of any potential side effects. I think if there is a choice between using a prophylaxis with serious side effects to protect against an airborne pathogen or housing a patient in a protective environment to give a similar level of protection the latter would be better for the patient.

14. To what extent were the four BMT rooms in Ward 2A, at handover, achieving the outcomes or being capable of the function or purpose for which they were intended?

    - The rooms referred to as rooms 17,18,19 and 20 seem to have been designed as PPVL rooms before being converted to positive pressure isolation rooms. In Para 8.5 I explain that these rooms are out of scope of my report and will be dealt with in another report. However, if correctly designed and operated, PPVL should be able to offer a high level of protection for the patient against the ingress of airborne environmental opportunistic pathogens. However, I have not seen any commissioning reports from handover that demonstrates that these rooms are operating correctly i.e measurements of

ACH, pressure differentials, sealability and filter testing. If no commissioning was undertaken there would be no way to demonstrate they are capable of their function and purpose.

15. What is your view as to whether these four rooms, at handover, conformed to relevant statutory regulation and other applicable, guidance and good practice?

- See above. The guidance for PPVL rooms was minimal in SHTM03-01 (2013) only specifying ACH and pressure differential. However, in my opinion the lack of commissioning shows lack of conformation to regulation, guidance and best practise such as SHTM03-01.

16. How does the QEUH/RHC's use of antimicrobial prophylaxis compare with other hospitals in the UK?

- I don't know. This is outside my area of expertise and I have no knowledge of the use of antimicrobial prophylaxis in other UK hospitals.

17. If there is a difference in approach between the use of antimicrobial prophylaxis between QEUH/RHC and other hospitals in the UK, why do you think that is?

- Again, I don't know if there is any difference in approach. However, I know from NHSGGC and HPS documents that antimicrobial prophylaxis at QEUH/RHC was used due to concerns about sub-standard accommodation and poor air quality see paragraphs 9.2-9.6 in my report

18. What are the implications for patient care of the prolonged use of prophylaxis on child patients?

- This is not my area of expertise. I am not a clinician. I would think there needs to be a balance between risk and benefits of treatment which would be decided by the clinician on a case by case basis.

19. To what extent, if any, should parents of child patients be informed by QEUH/RHC clinicians that prophylaxis use poses a risk to their child's health?

- This is not my area of expertise. I am not a clinician

1. I remain clear that my duty is to assist the Inquiry in an impartial manner.

2. I have no connection, personal or otherwise, to any core participant in the inquiry other than that I have declared in this response or my earlier report dated [date].

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

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

5. I acknowledge the duty to set out all material facts, assumptions, methodology or other matters upon which my views and opinions are based, including such matters as may detract from the opinion formed, and that I have complied with that duty in this response and my earlier report dated [date].

6. I acknowledge the duty to address only areas within my own areas of expertise and that we have made it clear when a particular question or issue falls outside our expertise. and that we have complied with that duty in this response and my earlier report dated [date].

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

8. I acknowledge, understand and accept the obligation to indicate if any opinion I have expressed is qualified, or subject to revision, and have done so in this response and my earlier report dated [date] where appropriate.

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

You [redacted]

Allan Bennett

12 August 2024

Direction 5 Questions for Independent Expert Witnesses

Mr Sid Mookerjee

19 July 2024

Dear Mr Mookerjee,

On 9 May 2024 you produced a report for the Inquiry. This has been made available to Core Participants (CPs). On 13 December 2023 the Chair issued Direction 5 which set out at Appendix B a system by which CPs would be permitted to raise lines of questioning or questions with you and the other independent witnesses before the commencement of the Glasgow III hearing.

The CPs were told that within five weeks of the date upon which the Inquiry Team provided your report to them any CP who wished to propose questions for you about your report or to make comment on that report must send a note to the Secretary to the Inquiry setting out in concise numbered paragraphs with clear reference to the relevant parts of the report:

1. the specific questions that should be asked of the report's author and any comment that the CP wishes to make on the substance of the report;

2. whether these questions and/or comment will raise new matters or issues not covered in the report; or

3. where no new matters or issues are likely to be raised, reasons why the issue should be raised with the expert witness at that time.

The Inquiry Team has considered the responses received in respect of your report and consolidated the relevant questions into fifteen questions. These questions are set out in the Appendix to this letter. Please provide a supplementary report to the Inquiry Team as soon as possible and by Friday 2 August 2024 at the latest in the form of concise answers to these questions. Your response will then be provided to CPs before the start of the Glasgow III hearing in the week of 19 August 2024.

Given the involvement of the counsel team in the hearing that deadline of 2 August 2024 cannot be extended.

Yours sincerely

Brandon Nolan
Solicitor to the Inquiry

Appendix

I have been asked a series of questions by the Inquiry Team and have been asked to respond to each question in turn.

I have been provided with Direction 5 Responses from:

- GGC
- NSS
- Professor Cuddihy and
- Drs Peters and Inkster
- Multiplex

Your Supplementary Report.

Prior to the deadline for submission of Direction 5 responses to my initial report ("the Quantitative Report") NHS GGC and Dr Peters and Dr Redding provided additional information and asked specific questions about the choice of data used in that report.

I have been asked to produce a Supplementary Report following a paper prepared by Counsel to the Inquiry setting out what that report should cover (**FM Note - Request for a Supplementary Report from Sid Mookerjee - 12 July 2024**). I have separately produced that report.

In answering the following questions where I consider that the question is answered in my Supplementary Report I have responded to that question by a simple reference to the relevant paragraph.

Formal Questions (please respond in this document)

1. **How do you respond to the following statement by NHS GGC regarding your approach in relation to water positivity?**

   "[12] In considering the organisms causing infections attributable to the water environment, the expert has amalgamated data for blood cultures from which yeasts were isolated. In the case of QEUH/ RHC, this represents approximately 10% of isolations. The proportion of fungal isolates in the four comparator hospitals is not described. As the majority of yeast infections in haemato-oncology patients arise from their commensal flora, this inclusion will overestimate positive blood cultures associated with the environment.

   [13] The expert has correlated water data with rates of positivity for certain key pathogens found in the water. Water positivity rates are almost exclusively due to isolation of Cupriavidus and fungal isolates. Cupriavidus occurs almost universally in water. There were, however, only two cases of infection with Cupriavidus noted from the total of infections considered. Further, no filamentous fungal infection is known to have occurred in the paediatric population over the period. The approach taken by the expert to the correlation of water data with water positivity rates is unclear.

[14i] It is not clear why the expert focused upon Legionella spp., Pseudomonas spp., Cupriavidus spp., Serratia spp., Stenotrophomonas spp., and fungi. The selection of taxa appears to be at odds with the purpose of the report (to assess whether there is a link between water testing results and blood stream infections), given that: (i) there were no Legionella spp. in the BSI data (pp. 23-24); (ii) Serratia spp. were extremely rare in the water data; (iii) several bacterial species listed in the BSI data were also present in the water data, but have been excluded (e.g. Delftia acidovorans, Sphingomonas paucimobilis); and (iv) the heterogeneous kingdom-level grouping 'fungi' is included, despite the fact that there is almost no overlap in detected fungal species between the BSI and water data.

[15] The expert calculates what he calls a 'rate of water positivity' by agglomerating a large, varied, complex data set and reducing it to a single number per year. Fundamentally, this approach does not account for differences in the types of water tests carried out over this period. By generating a single number per year and comparing its trend over time, the expert is assuming or implying that the same 'thing' is being counted throughout this period and therefore that the values are comparable which is not the case.

[16] Routine testing specifically for Gram negative bacteria (GNB) and fungi was only introduced in 2018. Fungi would not have been reported in 2015-2017 because fungal water testing was not carried out. Any GNBs detected over this earlier period were incidental non-target findings, usually from the Pseudomonas test, and the recording of non-target results was not required nor consistent among the different testing laboratories. Those earlier GNB results are therefore not comparable to the results from GNB-specific tests carried out from 2018 onwards.

[17] The summary water testing documents provided to the expert explain how water testing at the QEUH/RHC changed over the period 2015-2020, and these changes are also obvious from the raw data sheets the expert used to generate these numbers (e.g. the 2015-2017 data sheets have no columns for fungal results).

[18] The expert states in paragraph 10.5 that the computed water positivity rates for 2015 and 2016 are likely to be underestimates. However, the expert then proceeds to use these apparent underestimates as the start point for the water positivity trend analysis, stating that there was a 'rising trend' of water positivity. Trend analysis is extremely sensitive to the start and end points, and using known underestimates as the start points biases the trend upwards (i.e. the rates can only go up once the values are no longer underestimated). Furthermore, the expert has chosen to exclude the 2020 data point, which further biases the trend upward. "

1.1. **In response to [12]:** In line with Key Question (4), namely '*Is there a link, and if so in what way and to what extent, between patient infections and identified unsafe features of the water and ventilation systems?*', the objectives as laid out in Quantitative report paragraph 4.1 was to calculate a rate of infection for the Schiehallion cohort, compare it to peer organisations' (comparator) rate over the same period, and understand the 'level of

association or relationship' that existed between water contamination and the Schiehallion rate of infection. In comparing the Schiehallion rate of infection to that of comparator organisations, I compared like for like, i.e. environmental bacteria and fungi as defined in paragraph 5.1.7 of the Quantitative report, weighted for the activity in admissions specific to the paediatric haematology oncology patient cohort. Comparing the Schiehallion to other large Trusts over a set period of eight years allows for a high level of confidence in the representativeness of the dataset and the outcome derived.

1.2. **In response to [13]:** The methodology adopted in analysing the water sampling data provided by NHS GGC is outlined in detail in section 5.4 and 7 of the Quantitative report with further clarifications offered in paragraph 2.38 to 2.40 of the Supplementary report. Furthermore, please see paragraph 2.41 of the Supplementary report which makes specific reference and offers clarification regarding the calculation of the correlation coefficient statistic.

1.3. **In response to [14i]:** See response to [13] provided in paragraph 1.2 above.

1.4. **In response to [15]:** Please note that the annual water positivity figure is the proportion of all water samples taken in that year which were positive. See paragraph 5.4.10 of the Quantitative report, namely '*Each of the organism columns noted in section 5.4.3. denoting a positive count was coded as a positive (n=1). The definition used - water sample positive is a positive count from a water sample of any magnitude / count.*'

1.5. **In response to [16, 17 and 18]:** Please see my response regarding the changes in water sampling methodology and how I approached it in paragraphs 2.42 to 2.44 of the Supplementary report.

2. How do you respond to the following statements by NHS GGC regarding your approach in relation to statistical analysis?

[19] The expert recognises that establishing causality is complex (para 5.5.2). Two points follow from this to be recognised: (i) causality cannot be inferred from a strong correlation; and (ii) correlation can only ever show association. Correlation is not a suitable approach if the question relates to the influence or effect of one variable on another (rather than a simple association).

[20] It is also questionable whether the agglomerated yearly BSI rates and water positivity rates that the expert computed are even suitable for a correlation analysis, given that both are values that were measured repeatedly over time and given the small number of data points involved.

[21] In seeking to explore any association between infection rates and water positivity, the expert makes reference to the Pearson correlation coefficient analysis (para 10.2). The expert's approach to conducting a Pearson correlation analysis is unclear. Using the expert's own computed values for BSI and water positivity rates, Pearson correlation analysis shows the following:

a) There is no clear linear relationship between these variables when plotted together;

b) They do not obviously cluster around a straight trend line superimposed on the plot;

c) Computing the Pearson coefficient (R) without the 2020 data replicates the value reported by Mr Mookerjee (0.66, which he rounds to 0.7);

d) When the 2020 data point is included, the R value is lower (R = 0.54);

e) Confidence intervals give 'the range of values which we can be confident includes the true value' and these are not provided in the report. Here, the 95% confidence intervals for the R values were -0.53 to 0.98 without the 2020 data and -0.48 to 0.94 with the 2020 data. These intervals are both large and cross zero, meaning that we cannot confidently state that any correlation exists between these variables. The 'true' value could be zero or even negative (a negative correlation coefficient would indicate that as water positivity rate increased, BSI rate decreased, or vice versa);

f) Furthermore, hypothesis testing clearly shows that this is not a significant correlation. Without the 2020 data, the p-value of the correlation is 0.22, which means that with five data points, as in this analysis, there is a 22% chance of obtaining an R value of 0.66 or higher if these data were completely random. With the 2020 data included, this percentage is 26%. Neither correlation would be considered significant by any reasonable metric.

[22] While the expert appears to have correctly computed the R value, he makes no mention of computing confidence intervals or p-values to assess whether the stated correlation is at all likely to be true, i.e. statistically significant (unlikely to have occurred through random chance alone). These metrics both clearly show that there is no correlation between the expert's calculated BSI and water positivity rates, which is the opposite of what the expert has concluded.

[23] There is a concern about using "admissions" in the calculation of infection rate in any event: an admission could be for a duration of one day for a low risk patient or 100 days for a high risk neutropenic patient receiving a bone marrow transplant and so does not give an accurate picture of risk. "Admissions" is a weak denominator and it would be more appropriate to calculate infection rate by central line days.

2.1. **In response to [19]:**The Quantitative paper's aim was to, i) calculate the rate of infection at the Schiehallion by focusing on the physical space demarcated by wards 2A, 2B, 4B and 6A, ii) compare this rate, in a like for like analysis, to other peer-organisations over the period 2015 – 2022, and finally iii) to understand the level of association that existed between rates of infections and water positivity at the Schiehallion by way of utilising Bradford Hill's postulates, and the epidemiological tool of correlation-coefficients. The Quantitative report did not delve into matters of causality. Please see paragraph 6.1 of the Quantitative report for

details on how the correlation tool was employed '*..understanding the association/correlation between variables of interest'.*

2.2. **In response to [20]:** Please see paragraph 2.28 and 2.29 of the Supplementary report for details on water sampling data and my opinion on its rigour. Furthermore, see paragraph 2.42 to 2.44 of the Supplementary report on how changes in water sampling methodology were approached.

2.3. **In response to [21]:** The correlation-coefficient noted in the Quantitative report paragraph 7.7 is 0.7, which suggested a 'moderate – very strong' correlation between the trends in rate of infection and water positivity for the period 2015 – 2019. Furthermore, please see paragraph 2.67 of the Supplementary for details on the re-calculated correlation-coefficient, and paragraph 2.41 of the Supplementary report on my reasons for excluding water sampling data for the year 2020 from the correlation-coefficient analysis.

2.4. **In response to [22]:** Since we are utilising real world data from the Schiehallion regarding rates of infections and water positivity, and not intending on using either statistic to infer something about a larger population, there is no need for confidence intervals around the statistics I have calculated in the Quantitative and Supplementary reports.

2.5. **In response to [23]:** Please see paragraph 2.16 and 2.17 of the Supplementary report where I clarify my reasonings for utilising admissions rather than bed-days in calculating rates of infection.

3. **At Question D of their response NHS NSS have asked a specific question:**

"*In the report's summary of findings (paras. 9 and 10), there is no express reference to significance testing. Significance/hypothesis testing e.g. calculation of p-values and confidence intervals can demonstrate that the results from analyses are not the result of random variation. It is not possible confidently to interpret the key findings without acknowledgement of and controlling for the effects of chance/random variation. This is particularly relevant to incidence rate ratios (paras. 9.2- 9.7), linear trends and time series analysis (paras. 9.9- 9.11, paras. 10.6- 10.8), and correlation coefficients (paras. 10.2- 10.3). Can Mr Mookerjee please explain what significance testing was undertaken?"*

What is your answer to this question?

3.1. Please see paragraph 2.1 of this report where I include a note on confidence intervals.

4. **How do you respond to the following statement by NHS GGC regarding BSI data?**

[24] The data quoted on BSI (data provided by NHSGGC) have different values than those provided by NHSGGC. It is not clear why there are discrepancies between the data provided and the data in the report.

Although NHS GGC have provided no specification at this time please can you check your values against those provided by NHS GGC and respond.

4.1. Please see paragraphs 2.2 – 2.4 of the Supplementary report for clarifications on the methodology followed in analysing the BSI data provided by NHS GGC.

5. **GGC have made the following statement regarding whole genome sequencing in their response:** *"*

[25] In relation to whole genome sequencing, the expert states that "the robustness of reliance on the absence of an exact match is very much dependent on the comprehensiveness (including the frequency) of water testing" (para 13.6). From 2018 onwards, QEUH/ RHC was subject to more water surveillance than any other hospital within any other NHS board. "

Are you aware of this? Does it affect your conclusions and if so how?

5.1. The statement referenced by NHS GGC is only part of the considerations noted in Appendix 1 of the Quantitative report where I note my views on whole genome sequencing (WGS). I did not include WGS data, for the reasons stated in said section, in my analysis and therefore this does not affect my conclusions.

6. **NHS NSS have made this statement at paragraph 3 of their response:**

"3. *The Glossary of terms at section 3 defines 'Temporality' as "In epidemiology, temporality refers to the overlap in time between the exposure and the outcome." This may be too narrow a definition. NSS notes that there may be a relationship between the exposure and the outcome without there necessarily being an overlap. For example, there may be a lag between the exposure and the outcome."*

How do you respond to this observation and is there any further conclusion that can be drawn from the data by taking this approach?

6.1. In the Quantitative report, the level of association was sought by employing the correlation-coefficient statistic. The analysis did not delve into 'time to positivity' analysis, i.e. the time from exposure to when the patient exhibited signs and symptoms from an environmental pathogen, where I agree with NHS NSS, the lag between exposure and outcome would need to be considered. I calculated annual aggregated figures for infections and water, with a focus on the longitudinal temporality or overlap between these two variables over the years 2015 – 2019.

7. **NHS NSS have made this statement at paragraph 7 of their response:**

   7. Para. 8.1.1 refers to the "QEUH and RHC dataset of blood stream infections supplied by NHS GGC, covering the period 2015-2022". NSS notes that this dataset appears to include negative as well as positive infection results, so it may be more accurate to use the term "dataset of blood culture samples".

   How do you respond to this observation and is there any further conclusion that can be drawn from the data by taking this approach?

   7.1. I agree, 'dataset of blood culture samples' is a more apt term for the dataset supplied by NHS GGC.

8. **NHS NSS have made this statement at paragraph 11 of their response:**

   11. At para 11 of its response NSS observes that "The chart at para. 9.10 includes linear trend analysis. NSS would be cautious about using such analysis on a small number of data points, particularly where there is such variation amongst the data points".

   Do you agree or disagree with this observation and, if so, why?

   8.1. The trend line is the line of best fit, i.e. it considers all data points over the period 2015 – 2022, and plots the 'direction of travel', i.e. are rates going up, down or remaining static. The annual data points considered are aggregates of all infections and water positivity for that year, and therefore are based on a large amount of data over a period of eight years in the case of infections, and 5 years in the case of water.

9. NHS NSS have responded to your Appendix 3 that relates to the HPS 2019. The NSS Response is at paragraphs 12 to 15 of their response. What is your response to the points made by in these paragraphs?

   9.1. **In response to paragraph 14 of the NSS response:** I refer here to paragraph 13.2.4 of the Quantitative report, specifically ' *Note that the Public Health Scotland website confirms that the ISD(S)1 dataset offers one speciality code under haematology – J4 100, and two for oncology - AD 17 and H2 96, see screenshots below , with no paediatric haematology nor oncology specific codes.,* 'and to the table inserted below outlining the ISD(1) codes under which admission data is grouped. I do not see a code for paediatric haematology-oncology. I am therefore still unclear on the exact source of the paediatric haematology-oncology activity data.

ISD(1) Public Health Scotland	
specialty	spec_name
A1	General Medicine
A2	Cardiology
A3	Clinical Genetics
A6	Infectious Diseases
A7	Dermatology
A8	Endocrinology & Diabetes
A9	Gastroenterology
AB	Geriatric Medicine
AD	Medical Oncology
AG	Renal Medicine
AH	Neurology
AM	Palliative Medicine
AP	Rehabilitation Medicine
AQ	Respiratory Medicine
AR	Rheumatology
AV	Clinical Neurophysiology
AW	Allergy
C1	General Surgery
C3	Anaesthetics
C4	Cardiothoracic Surgery
C5	Ear, Nose & Throat (ENT)
C6	Neurosurgery
C7	Ophthalmology
C8	Trauma and Orthopaedic Surgery
C9	Plastic Surgery
CB	Urology
CC	Intensive Care Medicine
H1	Clinical Radiology
H2	Clinical Oncology
J4	Haematology
J5	Immunology

9.2. **In response to paragraph 15 of the NSS response:** Thank you for the clarification regarding the source of the data. Please note my reservation noted in the same paragraph on the inclusion of day cases and outpatient stays in the total bed occupancy figure.

10. At Question E of their response NHS NSS have asked a specific question:

"E. Can Mr Mookerjee please provide further explanation of the inclusion and exclusion criteria for the infection rate and water positivity rate correlation analyses (paras. 10.2 and 10.3)? He states that the water positivity data from 2020 was excluded from the analyses due to the consequences of access to clinical areas during the pandemic (para. 10.5). Did he have any information to suggest that the 2020 data is biased and should be excluded? There were 1469 samples taken in 2020. This is in contrast to the much lower number of samples in 2015 (n=80) and 2016 (n=47) - both years were included in the analysis. NSS notes that the inclusion of the 2020 data may change the correlation coefficient and a key finding. NSS also notes that the interpretation of the Pearson's correlation coefficient in para. 10.3 states water positivity increases over the period 2015 to 2019. The purpose of a correlation analysis is to determine the association between water positivity

and infection rates and it does not provide evidence for an increasing or decreasing trend over time"

Please provide the further explanation sought.

10.1. Please see paragraphs 2.2 to 2.4 of the Supplementary for clarifications regarding the inclusion and exclusion criteria applied to the infection variable. Furthermore, please see paragraph 2.41 of the Supplementary report for clarifications on the exclusion of water sampling for the year 2020.

11. At Question H of their response NHS NSS have asked a specific question: :

"H *Mr Mookerjee does not expressly refer to the principle of confounding in the report. Whilst it is appreciated that multivariate analyses were unlikely to have been possible for this review, acknowledgement of this epidemiological issue, and how it was considered, is critical to interpretation. This issue is particularly important to consider in the interpretation of the Incidence Rate Ratio comparing the NHSGGC rate with the comparator organisations (paras. 9.5-9.7). Please can he explain what additional analytical work he undertook to assess the comparability of the cohorts?"*

Please provide the further explanation sought.

11.1. Please see paragraphs 2.53 to 2.57 of the Supplementary report where I address the comparability between NHS GGC and peer-organisations and my opinion on points of bias.

12. Multiplex have raised the following issues in their Response (paras 2.1 to 2.2) regarding the size of the comparator institutions referenced in your report.

(i) (This is) the number of beds which Multiplex understands are available in each hospital:
Great Ormond Street Hospital – 389
Cardiff and Vale Childrens Hospital – 179
Leeds Teaching Hospital – 1,103, 286 children
Oxford – 1,300, 100 children
QEUH/RHC – 1631, 256 children

(ii) The QEUH/RHC is significantly larger and thus more susceptible to contamination. Multiplex therefore has reservations as to whether the hospitals referred to are appropriate comparators.

To what extent is this a legitimate criticism of the methodology chosen?

To what extent is the size of the comparator children's hospitals and associated adult hospitals relevant in the context of the study you carried out?

Should the comparison have been made with the total admissions for the whole hospital rather than just the Schiehallion Unit or the RHC?

12.1. Please see paragraphs 2.53 to 2.57 of the Supplementary report where I address the comparability between NHS GGC and peer-organisations and my opinion on points of bias. Furthermore, please see paragraph 2.49. of the Supplementary report for my view on using total admissions to calculate the Schiehallion rate of infection.

13. **Dr Peters and Dr Inkster have specific comments about the data supplied by NHS GGC:**

"Was Glasgow data gather based solely on ward location or was it based by Consultant looking after the patient? In our experience to pick up the at risk group it is a more sensitive methodology to search for cases associated with a consultant. This will pick up patients who may have developed bacteraemia on another ward but still had links to the QEUH water system including the wards 2A, 6A."

The Inquiry Team note that in the GGC blood cultures data spreadsheets QEUH Campus Blood Culture Samples 1 January 2023 to 31 August 2023 that was supplied to you included Consultant names for each entry. Do you have any comment to make on the observation by Dr Peters and Dr Inkster?

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

14. **From paragraph 4 on the second page of their response Dr Peters and Dr Inkster note that:** *"There appear to be discrepancies in the number of organisms between this report, the case note review (who despite the same methodology and a shorter time have counted more cases for some pathogens) and the data analysed by Dr Christine Peters and Kathleen Harvey Wood. We feel this may be due to some ward codes being omitted from the data extraction. It would be important to check whether the following codes were applied when data was being extracted from tpath (Telepath) ;*

CH4BMT/CHCDU/CHD2B/CH2A/CH2ASC/CH2BDC/CH2BDS/CH2BSC

For example, Dr Peters can identify additional cases:
19 Stenotrophomonas (cf 14)
8 Pseudomonas (cf 5)
2 Pantoea (cf 1)

Please address these specific issues either here or in your Supplementary Report.

14.1. Please see paragraphs 2.2 to 2.4 of the Supplementary report where I clarify the methodology followed in curating the infection dataset. Importantly, NHS GGC provided me with the bacteraemia dataset, and I did not have the opportunity to extract this dataset myself.

Declaration:

1. I remain clear that my duty is to assist the Inquiry in an impartial manner.

2. I have no connection, personal or otherwise, to any core participant in the inquiry other than that I have declared in this response or my earlier report dated 9 May 2024.

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

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

5. I acknowledge the duty to set out all material facts, assumptions, methodology or other matters upon which my views and opinions are based, including such matters as may detract from the opinion formed, and that I have complied with that duty in this response and my earlier report dated 9 May 2024.

6. I acknowledge the duty to address only areas within my own areas of expertise and that we have made it clear when a particular question or issue falls outside our expertise. and that we have complied with that duty in this response and my earlier report dated 9 May 2024.

7. I acknowledge, understand and accept the obligation to state if my opinion is not properly researched because insufficient data are available and to give an indication that the opinion is no more than provisional, and have done so in this response and my earlier report dated 9 May 2024 where appropriate.

8. I acknowledge, understand and accept the obligation to indicate if any opinion I have expressed is qualified, or subject to revision, and have done so in this response and my earlier report dated 9 May 2024 where appropriate.

9. I acknowledge, understand and accept that I should at the earliest opportunity after completing the report, indicate if, for any reason, including as a result of discussions with other experts, my views have been altered or the report

requires any correction or qualification, and if so, in what area, and we shall comply with that duty.

Yours sincerely

Sid Mookerjee

11 August 2024

Direction 5 Questions for Independent Expert Witnesses

Dr Sara Mumford and Ms Linda Dempster

22 July 2024

Dear Dr Mumford and Ms Dempster,

On 24 May 2024 you produced a report for the Inquiry. This has been made available to Core Participants (CPs). On 13 December 2023 the Chair issued Direction 5 which set out at Appendix B a system by which CPs would be permitted to raise lines of questioning or questions with you and the other independent witnesses before the commencement of the Glasgow III hearing.

The CPs were told that within five weeks of the date upon which the Inquiry Team provided your report to them any CP who wished to propose questions for you about your report or to make comment on that report must send a note to the Secretary to the Inquiry setting out in concise numbered paragraphs with clear reference to the relevant parts of the report:

1. the specific questions that should be asked of the report's author and any comment that the CP wishes to make on the substance of the report;

2. whether these questions and/or comment will raise new matters or issues not covered in the report; or

3. where no new matters or issues are likely to be raised, reasons why the issue should be raised with the expert witness at that time.

The Inquiry Team has considered the responses received in respect of your report and consolidated them into **33** questions. These questions are set out in the Appendix to this letter. Please provide a supplementary report to the Inquiry Team as soon as possible and by Friday 2 August 2024 at the latest in the form of concise answers to these questions. Your response will then be provided to CPs before the start of the Glasgow III hearing in the week of 19 August 2024.

Given the involvement of the counsel team in the hearing that deadline of 2 August 2024 cannot be extended.

Yours sincerely

Brandon Nolan
Solicitor to the Inquiry

Appendix

Supplementary Report by Dr Sara Mumford and Ms Linda Dempster for the Scottish Hospitals Inquiry

We produced an expert report dated 24 May 2024 ("the Qualitative Report"). We have now been supplied with Direction 5 responses from the following Core Participants:

1. NHS Greater Glasgow & Clyde
2. NHS National Services Scotland
3. Multiplex Construction Europe Ltd
4. Currie & Brown UK Ltd
5. IBI Group (UK) Ltd
6. Dr Teresa Inkster
7. Dr Christine Peters
8. Prof. John and Molly Cuddihy

We have now been asked a series of questions by the Inquiry Team and have been asked to respond to each question in turn.

1. It has been suggested that because your report and therefore your opinion relies substantially upon the opinion of others (including Dr Walker, Mr Bennett, Mr Poplett and Mr Mookerjee) your report is not (a) independent and (b) is undermined by any errors or omissions in those reports. How do you respond to that criticism?

1.1. As infection prevention specialists we recognise the need to seek expert opinions of other subject matter experts. In the course of our writing of the report we also considered other published reports and peer reviewed papers, as is common practice within this field, to assist us in coming to our conclusions.

1.2. We do not believe that this prevented us from writing an independent report nor that our report is diminished in any way by including the opinions of others as set out in paragraph 1.5 of the report.

2. At paragraph 4.15 of your Qualitative Report you state "The existence of a link between infections and the water system appeared to have been accepted when the patients from wards 2A and 2B were moved to ward 6A and 4B(BMT) in QEUH so that 2A and 2B could be refurbished. This major refurbishment work was extended to include the ventilation system and patients returned to wards 2A and 2B in March 2022." This seems to be an important conclusion and is controversial. Why have you reached this conclusion and what evidence have you seen of this acceptance?

2.1. In this context we refer to the water system as the whole system from the intake of water from external supply to the release of drainage water to the municipal system.

2.2. The Incident Management team investigating a cluster of gram-negative blood stream infections on Ward 2A identified an issue with the wash hand basin drains in patient bedrooms. At the meeting of 5 September 2018, the minutes state that 'TI [Theresa Inkster] informed the group of the 3 cases of bacteraemia which have been caused by gram negative organisms isolated from the drains'.[1]

2.3. Actions from this meeting included a programme of photographing and swabbing drains on four RHC wards including 2A and 2B, identifying a product for sink cleaning and establishing a water testing programme for ward 2A

2.4. Further IMT meetings took place including on 14 September[2] when five cases of blood stream infection had been identified in total and contingency arrangements were discussed. Phase one of these contingencies included all new cases being diverted to Edinburgh, existing cases being managed at their local hospitals and new admissions to the Schiehallion unit being on a case by case basis. The second phase of contingency was identified as decanting the ward in order to investigate what was happening in the environment and identify a permanent solution. This recommendation was made to the Executive Group however it was not approved at this time on the basis that they wished to wait for a drainage expert had given a preliminary scope on the required work[3].

2.5. On 18 September, the IMT[4] was informed by Grant Archibald (Chief Officer – acute) that a water review meeting[5] the previous day had agreed that a decant should take place and by the following day a decision had been made to decant the majority of patients from 2A to ward 6A in QEUH and the Bone Marrow Transplant patients to ward 4B, the adult BMT unit. This meeting was attended by the Chief Executive. We apologise for mis-attributing this decision to the water technical group.

2.6. Although the decant was finally agreed for a drain survey to be carried out by an external contractor, this appears to be a direct consequence of the increased number of infections and concerns that the environment is the source of the infections.

2.7. The chronology associated with the ongoing contamination of the water system is described in paragraphs 9.1 to 9.41 of our report. In his paper,

[1] IMT minutes - 5 September 2018. Bundle 1 for Oral Hearings Commencing 12 June 2023, Page 149.

[2] IMT minutes - 14 September 2018. Bundle 1 for Oral Hearings Commencing 12 June 2023, Page 164.

[3] IMT minutes - 17 September 2018. Bundle 1 for Oral Hearings Commencing 12 June 2023, Page 169.

[4] IMT minutes - 19 September 2018 Bundle 1 for Oral Hearings Commencing 12 June 2023, Page 180.

[5] Water Review Meeting - Draft Meeting note - 18 September 2018. Bundle 19 for Oral Hearings Commencing 19 August 2024, Page 614.

Dr Walker[6] has laid out the high level of persistent contamination of the water system at QEUH/RHC since the hospitals were occupied in 2015 and that this resulted in an unacceptably high risk of infection in patients.

3. In your report you discuss of the water system. What do you mean by "contamination" and what information or testing might be obtained by operators of a hospital water system in order to justify describing it as contaminated in that way?

3.1. Contamination in this context is the presence of microorganisms in the water supply in excess of that deemed acceptable by guidance current at the time of sampling. Contamination may be local, ie related to a particular outlet or group of outlets serving a clinical area, or more widespread, affecting the supply to a number of clinical areas.

3.2. In Scotland, guidance is contained within Scottish Health Technical Memorandum (SHTM) 04-01. Current recommendations for routine testing include Total Viable Counts (TVC) and Legionella at least quarterly. Since 2018, Health Protection Scotland has advised testing for Pseudomonas at least six monthly in augmented care areas. Other testing should be carried out on a risk-based basis.

3.3. When reviewing how widespread contamination may be, water testing should be undertaken at various points throughout the system, from mains intake through to local outlets.

3.4. If there were concern about a particular system or cluster of infections, then testing looking at the whole range of organisms present in the water supply could be carried out.

3.5. Raised TVC or high level of a micro-organism of interest should result in risk assessment and remedial actions followed by more frequent testing until the contamination is under control.

4. NHS GGC have drawn attention to the fact Dr Chaput's reports do not conclude, either implicitly or explicitly, that the domestic water system of the hospital was "contaminated" and challenge you to produce evidence to support your conclusion that the system was so "contaminated". . How do you respond to that criticism?

4.1. The contamination of the water system has been well documented both in published peer review papers including that by Theresa Inkster et al[7],

[6] Review of the design, build, commissioning and maintenance of the water and drainage systems within the Queen Elizabeth University Hospital and Royal Hospital for Children to determine whether they had an adverse impact on the risk of healthcare associated infection on patients. Dr Jimmy Walker 2024. Bundle 21 for Oral Hearings Commencing 19 August 2024, Volume 1, Page 179.
[7] T.Inkster, C.Peters, T.Wafer,D,Holloway, T.Makin. Investigation and control of an outbreak due to a contaminated hospital water system, identified following a rare case of *Cupriavidus pauculus*. Journal of Hospital Infection 2021;111:53-64. Bundle 6 for Oral Hearings Commencing 12 June 2023, Page 1236.

external reports including the HPS/HFS report authored by Storrar and Rankin[8], and QEUH/RHC IMT minutes[9].

4.2. We were asked to address Key Question (4): Is there a link, and if so in what way and to what extent, between patient infections and identified unsafe features of the water and ventilation systems. Providing further proof that the water system was contaminated was out with our instruction from the Chair of the Inquiry

5. NHS GGC have drawn attention to the fact that within the 2015 (Bundle 6, Page 122) and 2017 (Bundle 6, Page 416) DMA Canyon Reports it is noted that there was a near absence of Legionella in the new buildings at the QEUH/RHC at the time of those reports. In light of all that was then found would that suggest that widespread microbial contamination was not then an issue? If not, why not?

5.1. The DMA Canyon Reports are risk assessments. The reports both identify numerous (64 in the 2017 report) level 2 remedial actions required to be completed as soon as reasonably practicable. Many of these actions were in respect of water temperatures not being maintained with the cold water reaching up to 30 degrees in some areas. This would enable any legionella present to multiple more easily as temperature control is the main control mechanism for this organism in water systems.

5.2. It is known that in August 2015 *L. pneumophila* serogroup 1 was found in samples at level greater than 1000cfu/l.[10]

5.3. DMA Canyon also found debris in tanks in 2015 which was still there in 2017 and a tank containing stagnant water which could potentially be a source of bacterial pathogens.

5.4. The report concentrates on the legionella risk and does not look at the wider contamination risk due to other bacteria and fungi, except in so far as the issues with the water system infer a higher risk of contamination with other micro-organisms.

6. If contrary to the view taken by Dr Walker and others the Chair was to conclude that in 2015 the hospital domestic system could not properly be described as "contaminated" how would impact on your conclusions?

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[8] Report on the findings of the NHS Greater Glasgow and Clyde: Queen Elizabeth University Hospital/Royal Hospital for Children water contamination incident and recommendations for NHS Scotland. Storrar I and Rankin A. Bundle 19 for Oral Hearings Commencing 19 August 2024, Page 174.

[9] IMT minutes - 2 March 2018 to 21 June 2018. Bundle 1 for Oral Hearings Commencing 12 June 2023, Page 54 to 136.

[10] Report on the findings of the NHS Greater Glasgow and Clyde: Queen Elizabeth University Hospital/Royal Hospital for Children water contamination incident and recommendations for NHS Scotland. Storrar I and Rankin A. Bundle 19 for Oral Hearings Commencing 19 August 2024, Page 174.

6.1. In 2014, prior to handover, water testing results showed high total viable counts after commissioning such that NHS GGC requested decontamination of the system prior to hand over of the building.

6.2. However, if the chair were to conclude that in 2015 the system could not be described as contaminated, this would not change the conclusions in our report which relate to the period 2016 onwards, when there is supporting evidence of a range of environmental pathogens being isolated from the water system, build up of biofilm in flow straighteners and drains, and a series of infections in immunocompromised patient due to organisms normally associated with environmental sources.

7. It has been noted by Multiplex that at paragraph 9.58 you have referred in your footnotes to SHTM 03-01 (2014) and that the version applicable to the Building Contract for the QEUH/RHC is SHTM 03-01 Part A dated March 2009. Please review your conclusions in respect of the ventilation system of the hospital and set out here any changes in your conclusions that would arise by reliance on the 2009 version of SHTM 03-01 rather than the 2014 version. If you make no changes explain why that is.

7.1. As stated at paragraph 9.59 of our report, the gold standard of air changes has long been established with the minimum standards first published in 1994[11].

7.2. The latest version of SHTM 03-01 recognises the new technologies and different requirements for air handling in areas used for different purposes but the requirements around protective isolation have not changed save for the addition of a specification for PPVL rooms. The PPVL rooms in the Schiehallion unit did not meet the specification for protective neutropenic isolation in any case.

7.3. The conclusions in our report are based on expertise gained over many years of practice in Infection Prevention and Control and the updated SHTM does not alter our findings.

7.4. It should also be noted that the 2009 version was released as draft and then finalised and published in 2014.

8. At paragraph 9.78 of your Qualitative Report you discuss chilled beams. Currie and Brown note that the note of caution about the use of chilled beam units in specialist ventilation areas was not introduced until SHTM 03-01 was updated in February 2022, long after the construction of QEUH was completed. Please review your conclusions in respect of the ventilation system of the hospital and set our here any changes to your conclusions that would arise from a recognition of this change to guidance after the fact.

[11] Health Technical Memorandum (HTM) 2025 Ventilation in Healthcare premises: Design considerations, NHS Estates 1994 – To be included in Bundle 27 (page TBC) for Oral Hearings Commencing 19 August 2024.

8.1. Our conclusions are based on our expertise in infection prevention and control.

8.2. In our view the failure to take into account other reasons, including infection control considerations and odour control, apart from temperature control when choosing chilled beams followed by the implementation of the derogation across all rooms irrespective of prospective use of the rooms, created an unacceptable level of risk for the most vulnerable patients. This view is not changed by the earlier SHTM.

9. What would be the impact on your conclusions if the Chair was to find that at all times NHS GGC complied with the surveillance requirements as set out in the National Infection Prevention and Control Manual and may well have exceeded them?

9.1. The National Infection Prevention and Control Manual advises that routine water testing is not currently mandated in NHS Scotland, however it is recommended for *Pseudomonas aeruginosa* in line with HPS guidance[12] and compliance with the HSE Code of Practice[13] for legionella testing is required.

9.2. The HPS guidance also suggests increasing the frequency of testing if clinical infections are seen although prior to 2018 there was no recommendation for routine testing.

9.3. If the Chair were to find that NHS GGC had complied with the guidelines and even exceeded them this would be unlikely to change our conclusions as the requirements of the guidance are not exhaustive and we would expect testing to have been increased to a level in excess of the guidance in the face of an increase in infections suspected to be associated with water and the environment.

10. Dr Inkster challenges your statement at paragraph 4.8 of your Qualitative Report that you had "seen no evidence that there was any overarching surveillance of environmental organisms despite the frequency with which they were occurring." She states that surveillance was put in place for Serratia after the NICU outbreak in 2015 to which Stenotrophomonas Pseudomonas and Acinetobacter were added in May 2016 and that Cupriavidus was added after the aseptic pharmacy incident in 2016. What is meant by "overarching surveillance"?

10.1. The environmental organisms causing infections in vulnerable patients were varied and it is our view that it would have been helpful to keep and

[12] Pseudomonas aeruginosa routine water sampling in augmented care areas for NHS Scotland. September 2018, Health Protection Scotland. Bundle 18, Volume 2 for Oral Hearings Commencing 19 August 2024, Page 98.
[13] Legionnaire's disease; the control of legionella bacteria in water systems: Approved Code of Practice and guidance on regulations. – To be included in Bundle 27 (page TBC) for Oral Hearings Commencing 19 August 2024.

electronic database of all infections with environmental organisms once it became clear that there was a recurring issue.

10.2. The advantage of an electronic database would have been to provide a searchable resource into which all information on infections and water testing results could have been inputted, enabling relevant information to be stored in the same place and easily accessible to the IPC team and ICDs

11. Is your view that the surveillance established in May 2016 was insufficient based on both what was known at the time and the guidance in appendix 13 of the NIPCM at the time?

11.1. The surveillance established in 2016 was helpful, however it was reactive rather than proactive. In our view, a proactive surveillance of environmental organisms may have acted as an early warning system and allowed correlation of different organisms which may have remained otherwise unconnected.

11.2. The guidance in the NIPCM was restricted in that it was the standard list of alert organisms and did not include environmental organisms.

12. Do you agree or disagree with the view expressed that in 2016-2017 the infection triggers in place in the QEUH/RCH were too sensitive? (single case of bacteraemia, 2 infections other than BSI in 2 weeks, 3 colonisations in 2 weeks, general increase in environmental Gram negatives for the above-mentioned organisms)?

12.1. We understand from Dr Inkster's response to our report[14] that she put the triggers in place and they were questioned whilst she was off sick in 2017.

12.2. Our view is that the triggers are helpful and not over sensitive. Waiting for a second infection before reacting or investigating, delays any interventions required to protect other patients.

13. It has been suggested that paragraph 4.14 of your Qualitative Report and the narrative section at paragraph 9.35 are inaccurate as it fails to include all cases of Mycobacterium chelonae infections specifically those in June and October 2018. Professor Cuddihy has observed that there is an error in the Oversight Board timeline in respect of these infections. At a recent consultation with the Inquiry Team you mentioned that this narrative in your Qualitative Report had its origins in the data set of infections you had been provided with by NHS GGC. How did you prepare this part of your report and how can you explain how it comes to be the case that this significant infection is missed from your narrative? Does this information have any impact on your conclusions and what would that impact be?

[14] Response to Expert report from Theresa Inkster. Bundle 21, Volume 4 for Oral Hearings Commencing 19 August 2024, Page 89.

13.1. The evidence we have seen regarding *M. chelonae* is inconsistent and we apologise for not being clearer in our report.

13.2. The blood culture data[15] provided by NHS GGC was requested as all blood cultures from the beginning of 2015 to the end of 2022 for QEUH and RHC. This spreadsheet contains only one case of *M. chelonae* – A [redacted] child who had a blood culture sample taken on ward 2A on 29 January 2016. There is no PAG or IMT related to this case.

13.3. The next mention of *M. chelonae* is IMT minutes dated 19 June 2019[16]. This minute refers to a new case of *M. chelonae* infection and notes another the previous year. The new case is noted to be a skin infection.

13.4. The Case Note Review[17] refers to three cases of *M. chelonae* infection. Two with bacteraemia and one with a skin infection. However, only one of these cases (in 2016) appears in the blood culture data supplied by NHS GGC.

13.5. In the IMT dated 25 June 2019[18], the *M. chelonae* cases are discussed further and the 2018 case identified as having been diagnosed through a blood culture taken on 16 May 2018.

13.6. This IMT also goes on to discuss the two cases as an unusual occurrence and states that there have been no paediatric cases in the previous 10 years, failing to take the 2016 case into account.

13.7. Also discussed at the IMT on 25 June 2019 were water testing results from three shower heads being positive for mycobacteria

13.8. At the IMT on 3 July 2019[19], it was confirmed that whole genome sequencing had shown that a sample of *M. chelonae* from a shower on 6A was closely related to that of the most recent patient with a difference of only 13 SNPs

13.9. The conclusion from this IMT was that the working assumption for a route of exposure was patients/staff having access to unfiltered water throughout different areas of the hospital.

13.10. We are unable to explain why the second patient with *M. chelonae* infection, widely stated to be a bacteraemia, does not appear in the blood culture data supplied

[15] QEUH Campus blood culture samples 1.1.15-31.12.22.
[16] IMT Gram negative Blood ward 6A - 19 June 2019. Bundle 1 for Oral Hearings Commencing 12 June 2023, Page 320.
[17] QEUH and RHC Case Note Review Overview Report. March 2021. Bundle 6 for Oral Hearings Commencing 12 June 2023, Page 975.
[18] IMT Gram negative Blood ward 6A - 25 June 2019. Bundle 1 for Oral Hearings Commencing 12 June 2023, Page 325.
[19] IMT Gram Negative Blood ward 6A - 3 July 2019. Bundle 1 for Oral Hearings Commencing 12 June 2023, Page 330.

13.11. Dr Mumford met with Professor Leanord and Elaine McCormick on 21 December 2022 to discuss the requirements of the data to be supplied. This fields required had already been sent to NHS GGC at this point. It was made clear at that meeting that the data should be a download of data from the Telepath laboratory information management system (LIMS) and not manipulated in any way other than to be moved into an Excel spreadsheet and anonymised.

14. At paragraph 7.11 of your Qualitative Report you state that you "did not have access to the Electronic Communication of Surveillance in Scotland (ECOSS) system or the Central Line Associated Blood Stream Infection (CLABSI) surveillance system used in previous analyses". Why was this access was not obtained?

14.1. We have based our analysis on the blood culture database provided by NHS GGC and the reports of others who have used these systems. We did not feel that repeating the work of others would add value to the report as we had access to the primary source data[20].

14.2. The blood culture data[21] provided by NHS GGC was requested as all blood cultures from the beginning of 2015 to the end of 2022 for QEUH and RHC.

15. You discuss Whole Genome Sequencing from paragraph 9.130 of your Qualitative Report. To what extent do you consider the value of WGS or the prospect of positive connections between blood testing samples and environmental samples being made would be affected by actions such as the changing of showerheads or the quality of record keeping specifying which outlets were test?

15.1. If WGS is to be undertaken to investigate an outbreak and positively link the environment with infections it is important to ensure that environmental samples are taken in as contemporaneous manner as possible compared with the timing of the development of infection. Patients take varying times from contact with the infecting organism to have clinical symptoms.

15.2. Contemporaneous sampling is rarely possible for the initial samples of an outbreak as there is inevitably a delay in identifying the outbreak.

15.3. If actions are taken in response to an infection such as changing showerheads, removing a potential source, prior to water testing then it becomes much harder to isolate the relevant organism which may have been harbouring in biofilm in the showerhead.

[20] Expert report prepared by S Mumford and L Dempster paragraph 7.11. Bundle 21 for Oral Hearings Commencing 19 August 2024, Volume 1, Page 95.

[21] QEUH Campus blood culture samples 1.1.15-31.12.22.

15.4. Record keeping is essential in order to relate water testing results to patient infections. Patient movements should be tracked so that their placement can be identified at any point during their admission.

15.5. In many healthcare facilities rooms are identified with barcodes and this should be used as a unique identifier for any water testing undertaken in the room, alongside a descriptor of the sample source.

15.6. Without complete records of both patient and sample origin, matching cultures from environmental samples with patient cultures becomes complicated and inaccurate

16. By reference to your experience of water testing in other large hospitals and what level of sampling and testing was being carried out elsewhere in 2015/2016 what volume of water testing should have been carried out for a unit such as the Schiehallion Unit at that time? In the absence of specific HAIs or HAICs what pathogens should then have been tested for?

16.1. The level of testing during 2015/16 following handover would have been based on the local risk assessments of the water system to ensure compliance with the relevant guidance at the time. Scottish Health Technical Memorandum 04-01 Water safety for Healthcare Premises part G and HSE ACOP L8/HSG 274 are relevant here, as is BSI 7592:2008.

16.2. As a minimum, water should have been tested for total viable counts and Legionella. Outlets tested would be laid out in the water safety plan for the building. Routine Pseudomonas testing was not recommended in Scotland at this time.

16.3. Positive findings should increase the frequency and focus of testing.

17. Do you have any opinion as to whether national guidance should encourage routine water testing in high risk areas?

17.1. In our opinion it would be beneficial for the relevant bodies to undertake a review of national guidance on routine water testing in high risk areas to assess the evidence for testing for a wider range of potential pathogens and the frequency and extent of testing.

17.2. Reflecting on the reports in the literature of outbreaks associated with water in high risk areas, it would also be beneficial to consider whether testing should be mandated.

18. How do you respond to the criticism made by NHS GGC that your definition of "environmental pathogens" includes enteric bacteria and gram negative bacteria and fungal taxa for which there are few or no case reports of

human disease and is not consistent with the report from the American Academy of Microbiology that you cite at paragraph 7.3 of the Qualitative Report?

18.1. Whilst the above report was cited we included the organisms listed in the CNR and HPS guidance for consistency. The list has additional organisms isolated in blood cultures specimens taken from Schiehallion Unit patients which are also widely accepted as water-borne and/or environmental organisms over and above those in the HPS guidance.

18.2. These include *Aeromonas sp, Brevundimonas sp, Delftia acidovorans, Raoultella sp, Rhizobium sp, Roseomonas sp and Sphingomonas sp.*

18.3. The report is based on this cohort of patients and it is therefore, entirely reasonable to include these organisms.

19. Your approach has been to see use Schiehallion patient cohort as proxy for wider hospital population when considering the risks posed by the water and ventilation systems of the hospital. Given that the Schiehallion patient cohort is the most vulnerable group does that render the comparison inappropriate?

19.1. As the most vulnerable group of patients in the hospital, it is vital to protect these patients from healthcare associated infections and protection for these patients should be the gold standard to achieve. Any successful system-wide changes put in place to protect these patients will also protect all other patients.

19.2. Patients from this cohort may, on occasion be admitted to other areas of the hospital and will be vulnerable to infection wherever they are within the site.

20. How do you respond to the observation by NHS NSS that whilst they accept Statistical Process Control charts have limitations, this format was used in the HPS review of NHS GGC paediatric haemato-oncology data from October 2018 (Bundle 7, Page 214) as the report "was not written for the purpose of showing increased risk. The IMT had already established an increase in the number of cases. The purpose of the report, as commissioned by the Scottish Government, was to review several sources of information that were being presented to the Scottish Government." Does that impact on your critique of the report or its use by HPS or by others?

20.1. We note that HPS view that the report was not written to demonstrate increased risk as the IMT had already established an increase in the number of cases.

20.2. This does not impact on our critique of the report as we believe that expressing the data in a different format would have alerted other agencies, including the Scottish Government, to the increase in

environmental gram-negative cases and minimise the possibility of false reassurance.

21. It has been suggested that the fact that you lack experience and expertise in the Scottish IPC system and the operation of large health boards such that you do not have expertise in how infection, prevention and control, the structure of IPC staff and systems of surveillance and monitoring in Scotland such that you are not qualified to give opinion evidence on these issues?

21.1. In our expert opinion, safe IPC practice applies regardless of country. Both authors have extensive experience in a wide range of settings, including large NHS Trusts, covering acute and community settings. In addition, we have wide experience at system, regional and national level with Ms Dempster having held the role of Head of IPC at NHS England

21.2. We also have wide experience of working within governance systems at these levels and Board level experience of over 15 years.

21.3. Whilst there may be nuances of the Scottish system which we are not as familiar with, the essential components of team structure, IPC practice, surveillance and monitoring are universal in their nature and can easily be transferred from one system to another.

22. Dr Peters has asked a specific question about the operation of the Scottish IPC system. Are you aware of the limitations in ECOSS data validation and also the permissions required by HPS/ARHAI to analyse data for trends? What understanding do you have of the role and limits of the rights that ARHAI have to monitor trends compared to the NHS boards who "own" the data; as Dr Peters put it.

22.1. We are not aware of the limitations of the ECOSS data validation and permissions required by HPS/ARHAI. However, as we did not use ECOSS data in the preparation of the report, instead relying on source data from NHS GGC, this is a moot point.

22.2. We would expect NHS boards to have processes in place to undertake surveillance and analyse trends in order to be able to safely manage patients.

23. NHS NSS have noted that at paragraph 9.4 of your Qualitative Report you have referred to four definitions of healthcare infection incidents in the NIPCM when there are in fact six. What impact does the existence of six, rather than four, definitions have on your conclusions?

23.1. The NIPCM does indeed have two other definitions: 1. An exceptional infection episode single case of rare infection that has severe outcomes for an individual AND has major implications for others (patients, staff and/or visitors), the organisation or wider public health for example, high consequence infectious disease (HCID) OR other rare infections such as

XDR-TB, botulism, polio, rabies, or diphtheria, and 2. A healthcare infection exposure incident Exposure of patients, staff, public to a possible infectious agent as a result of a healthcare system failure or a near miss e.g. ventilation, water or decontamination incidents.

23.2. We have noted this and apologise for the omission, however in the context of our report it does not change our conclusion.

24. NHS NSS have produced an Electronic Outbreak Reporting Tool (Bundle 21, Volume 4, Page 28) which they describe in detail at paragraph 18 of their response. It has been added to your Objective Connect space and will be added to an Inquiry Hearing Bundle. What impact do you consider that such a tool would have, if used, on the effectiveness of the processes and practices of reporting and investigating HAIs within the QUEH/RHC?

24.1. This is a comprehensive tool that permits the electronic outbreak reporting. It is based upon the existing definitions in chapter 3 of the NIPCM[22]. We do not believe it will change processes or practices as these are already based upon the NIPCM. From the documentation provided we are not able to comment on how easy this process is to undertake in real time for each incident or the time needed to complete the tool. From the information provided this looks like a reporting tool rather than an aid to operational investigation of an IPC incident.

24.2. In order to be useful to the team investigating an outbreak a tool such as this needs to be searchable and flexible enough to enable the extract of information to analyse trends and create reports. Any tool that does not have this functionality is unhelpful to a busy operational IPC team.

25. What evidence do you have for your statement at paragraph 9.133 of your Qualitative Report that "there has been no standardised methodology recorded for either taking samples, labelling or culturing organisms from the water and drainage samples" and would your opinion be affected by the fact that NHSGGC laboratories are UKAS accredited? Is this impacted by Dr Inkster's evidence at paragraph 4.2 of her response about record keeping?

25.1. This comment relates to the content of the paper under discussion[23] in this paragraph which contains no information on methodology for sampling, labelling or culturing the organisms.

[22] NIPCM. Bundle 19 for Oral Hearings Commencing 19 August 2024, Page 440.
[23] Application of whole genome sequencing to identify relationships among isolates of *Cupriavidus* spp.,*Enterobacter* spp., and *Stenotrophomonas* spp. isolated from clinical samples and from water and drainage associated sources within the healthcare environment. A Leanord, D Brown, v9 18.1.23. Bundle 6 for Oral Hearings Commencing 12 June 2023, Page 1195.

25.2. UKAS accreditation recognises that laboratories have processes in place to reach the required standards. However, these processes may have changed over time and there is no recognition of this in the paper.

25.3. We support Dr Inkster's comment at paragraph 4.2 of her response that an electronic system would make record keeping ad analysis easier and less prone to transcription errors

26. It has been noted by NHS NSS and Dr Inkster that whilst at paragraphs 3.13 and 3.17 of your Qualitative Report you make reference to "post infection review" formal Post Infection Reviews are exclusive to NHS England and they are not carried out in Scotland. In your report you state that such reviews should take place. Why is that?

26.1. We have used the term post infection review as a generic term. We would expect any healthcare system to undertake a review of a healthcare associated blood stream infection. This may also be called a case review or a root cause analysis.

26.2. It is important to undertake such reviews to understand the cause of the infection, any avoidable factors and to establish best practice and shared learning from the infection. This is fundamental to infection prevention and control.

27. NHS GGC have challenged your statement at paragraph 3.30 of the Qualitative Report that "the lack of an open culture that supports the reporting of cases/ incidents in an honest manner leads to a failure in recognising the learning and ensuring that those lessons are learnt and shared within the organisation, ultimately resulting in the same errors occurring" and express the view that this challenges the honesty and integrity of NHS GGC staff. Explain how it is that you feel able to make this statement in your report?

27.1. This comment is a generalisation and not intended to be specific to any particular group of staff or organisation.

28. Dr Inkster has challenged your narrative that the February 2016 case of Cupriavidus pauculus took five months to investigate. Please consider her observations at paragraphs 3.1 to 3.3 of her Direction 5 response and set out any changes to your conclusions that arise from her evidence.

28.1. Dr Inkster has explained at paragraphs 3.1 to 3.3 of her response that she was asked for advice regarding the raised TVCs in the aseptic pharmacy on 23 February 2016 and control measures including increased flushing of outlets and descaling of taps were instigated. At a later date a little used sink was removed.

28.2. The patient case was identified retrospectively. The PAG relating to the blood stream infection which presented on 10 February 2016 was held on 17 June 2016, four months later.

28.3. We apologise for miscounting the months between infection and PAG, however, this does not change our conclusions with regards to this case

29. How would you respond to a suggestion that in respect of your observation at paragraph 11.24 of your Qualitative Report that "the move to ward 6A was an additional risk for this cohort of patients" that the move was required in order to allow estates work to be carried out and that patients could not viably have remained in place while this happened. Is this your understand of the reason for the move and what is your source for your understanding?

29.1. We acknowledge that the move to 6A was necessary due to the estates work required on 2A to bring the water system and ventilation up to a safe standard

29.2. However, as laid out in paragraphs 9.36 and 9.37 of our report, high particle counts led to concern about air quality of such severity that patients were given antifungal prophylaxis, *M. chelonae* was isolated from a number of outlets on 6A and the risk of infection was thought to be high enough to send patients to Edinburgh rather than admit to 6A

29.3. Concerns were raised in SBAR prior to the move that 6A had unacceptable levels of infection risk

29.4. Taken together these facts support our statement that the move to ward 6A was an additional risk for this cohort of patients

30. In what circumstances should memberships of IMTs investigating potential environmentally linked HAIs be widened beyond IPC clinicians, treating clinicians and estates or buildings staff?

30.1. The National Infection Prevention and Control Manual (NIPCM) gives clear guidance on the role of the IMT and that the membership will vary depending upon the nature of the incident.

30.2. Additional members may need to be invited to the IMT depending on the nature of the outbreak and the actions required to control it. Facilities management are likely to be needed where additional cleaning is required, occupational health clinicians may be required to advise on staff screening and treatment and communications team may be required to provide their expertise. If the outbreak has potential to spread more widely than the initial clinical area, a wider cross section of clinical staff may be required to share information and ensure readiness in other parts of the hospital. Water or ventilation specialists may be required to advise for outbreaks related to the built environment and

decontamination expertise may be required if an outbreak related to medical equipment is suspected.

30.3. It may also be necessary to invite external experts for complex situations or rare infections

31. To what extent should matters related to Infection Prevention and Control be reported to high level board meetings of NHS organisations where the constitution of such a bodies would require those meetings and the papers for the meeting to be public?

31.1. NHS organisations will have established governance arrangements to ensure that relevant information is escalated to the Board of an organisation.

31.2. Patient identifiable information should not be included in papers. Information presented should be factual and high level although in sufficient detail for the Board to gain assurance that issues are being managed appropriately or for the Board to make informed decisions about escalated items. Some escalated items may be of a sensitive nature and best heard in a private Board meeting.

31.3. Infection Prevention and Control should be a key area of assurance for the Board with performance and both existing and emerging risks identified.

32. To what extent is public perception or organisational reputation relevant to the Infection Prevention and Control?

32.1. Infection prevention and control can be a highly emotive subject for the public, particularly when potentially preventable infections cause severe harm or even death.

32.2. IPC issues can have a significant impact on an organisation's reputation. In our experience, being open and honest with the public is essential in order to gain trust and allay the inevitable fears of patients and their families.

33. **The Inquiry Team has instructed Mr Mookerjee to carry out further analysis of the data he was provided with prior to producing his Quantitative Report and to also analyse data subsequently provided by NHS GGC. You have now been supplied with a copy of his Supplementary Report. In what way do the criticisms made of his earlier work, his response and the further analysis he has now carried out impact on the opinions you expressed in your Qualitative Report?**

33.1. In his supplementary report Mr Mookerjee has clarified his use of the data provided by NHS GGC and the comparator units. We note that he has not included Non-tuberculous Mycobacteria (atypical mycobacteria) in his data set and further note that only one case of this infection was included in the data set provided by NHS GGC as outlined in our Direction 5 response. We also note that he has clarified that the data used related to patients under the age of 19 only.

33.2. Mr Mookerjee discusses the additional admissions data set provided by NHS GGC and how that has affected the impact of his analysis. Despite restricting the data analysed to inpatient (overnight) admissions to ward 2A RHC and subsequently 6A QEUH, in his supplementary report, Mr Mookerjee has demonstrated a significant difference in the infection rates per 1000 admissions between the Schiehallion unit and the four English comparator units. At the peak in 2017 the ward 2A rate of infection was more than 16 times the average rate for the comparator units.

33.3. This picture is in line with our comments in chapter 9 of our report, particularly 9.174. Based on this supplementary report we find no reason to amend the opinions expressed in our report.

Declaration by Dr Sara Mumford:

1. I remain clear that my duty is to assist the Inquiry in an impartial manner.

2. I have no connection, personal or otherwise, to any core participant in the inquiry other than that I have declared in this response or my earlier report dated 24 May 2024.

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

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

5. I acknowledge the duty to set out all material facts, assumptions, methodology or other matters upon which my views and opinions are based, including such matters as may detract from the opinion formed, and that I have complied with that duty in this response and my earlier report dated 24 May 2024.

6. I acknowledge the duty to address only areas within my own areas of expertise and that we have made it clear when a particular question or issue falls outside our expertise. and that we have complied with that duty in this response and my earlier report dated 24 May 2024.

7. I acknowledge, understand and accept the obligation to state if my opinion is not properly researched because insufficient data are available and to give an indication that the opinion is no more than provisional, and have done so in this response and my earlier report dated 24 May 2024 where appropriate.

8. I acknowledge, understand and accept the obligation to indicate if any opinion I have expressed is qualified, or subject to revision, and have done so in this response and my earlier report dated 24 May 2024 where appropriate.

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

Yours sincerely

[redacted]

Dr Sara Mumford

11 August 2024

Declaration by Linda Dempster:

1. I remain clear that my duty is to assist the Inquiry in an impartial manner.

2. I have no connection, personal or otherwise, to any core participant in the inquiry other than that I have declared in this response or my earlier report dated 24 May 2024.

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

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

5. I acknowledge the duty to set out all material facts, assumptions, methodology or other matters upon which my views and opinions are based, including such matters as may detract from the opinion formed, and that I have complied with that duty in this response and my earlier report dated 24 May 2024.

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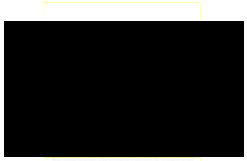
Yours sincerely



Ms Linda Dempster

11 August 2024

Direction 5 Questions for Independent Expert Witnesses

Andrew Poplett

5 August 2024

Dear Mr Poplett,

On 10 June 2024 you produced a report for the Inquiry. This has been made available to Core Participants (CPs). On 13 December 2023 the Chair issued Direction 5 which set out at Appendix B a system by which CPs would be permitted to raise lines of questioning or questions with you and the other independent witnesses before the commencement of the Glasgow III hearing.

The CPs were told that within five weeks of the date upon which the Inquiry Team provided your report to them any CP who wished to propose questions for you about your report or to make comment on that report must send a note to the Secretary to the Inquiry setting out in concise numbered paragraphs with clear reference to the relevant parts of the report:

1. the specific questions that should be asked of the report's author and any comment that the CP wishes to make on the substance of the report;

2. whether these questions and/or comment will raise new matters or issues not covered in the report; or

3. where no new matters or issues are likely to be raised, reasons why the issue should be raised with the expert witness at that time.

The Inquiry Team has considered the responses received in respect of your report and consolidated them into 24 questions. These questions are set out in the Appendix to this letter. Please provide a supplementary report to the Inquiry Team as soon as possible and by Friday 16 August 2024 at the latest in the form of concise answers to these questions. Responses will then be given to CPs.

Given the involvement of the counsel team in the hearing that deadline of 16 August 2024 cannot be extended.

Yours sincerely

Brandon Nolan
Solicitor to the Inquiry

Appendix

Supplementary Report by Andrew Poplett for the Scottish Hospitals Inquiry

I have been asked a series of questions by the Inquiry Team and have been asked to respond to each question in turn.

1. In relation to paragraph 1.4.2 of your report, what sample of documents were reviewed?

1.1. Given the large quantity of documents provided a random sample of reports for repeated actions or issues were used (not every copy of every document). So as an example TMV servicing or TMV in service testing records I reviewed 6 records at random to see if issues existed and did not review every document. The same approach was adopted for the review of handwritten scans of the CLO2 documents.

2. In relation to paragraph 1.4.2 of your report, how did you choose this sample?

2.1. As stated above I chose documents from the evidence files at random

3. In relation to paragraph 2.6.3 of your report, does this conclusion that the water plan/policy was appropriate in QEUH apply to RHC?

3.1. The water policy states within section 1 application of the Policy that it applies to all sites within the organisation, so yes my conclusion applies to both sites.

4. In relation to paragraphs 5.11.25 and 5.11.26 of your report, can you clarify if the guidance for drains goes beyond the remit described in SHTM 04-01?

4.1. The current remit of the SHTM 04-01 documents focuses on the supply element of domestic water systems and drainage is not covered to the same level of detail. In my opinion the drainage systems, both in terms of design and operational maintenance issues represent a significant potential source of contamination and potential transmission of waterborne pathogens and as such should be covered within the overall standards for domestic water. I would stress this is my opinion however you can’t have supply water without considering waste / drainage.

5. In relation to paragraphs 5.11.25 and 5.11.26 of your report, what research evidence was referred to in relation to the above?

5.1. The researched referenced within my report relates to clinical and IPC areas and is not an engineering area, my conclusions are based on my own continued professional development in areas where I have attended seminars on the subject matter and read articles over recent years

relating to the subject principally reported or hosted through the Healthcare Infection Society, of which I am a member.

6. In relation to paragraphs 7.94 and 9.16 of your report, can you state the evidence or guidance that you rely upon in suggesting these steps ought to be taken in paras 7.94 and 9.16?

6.1. The conclusion that these steps are required is based on the guidance and requirements of HSG 274 and SHTM 04-01 in relation to the need for a risk assessment to be completed and reviewed / maintained to ensure it remains accurate and appropriate. BS 8580 and BS 8680 provide further support for the on-going management of risk assessments and water safety plans to ensure they remain current and appropriate. To ensure a comprehensive and fully informed review it should be conducted and considered by a multi-disciplinary group and should not be seen as an estates only responsibility, again re-enforced through the operation of an effective water safety group under SHTM 04-01.

7. In relation to paragraph 2.2.1 of your report, reference is made to "the pre-occupation risk assessment". Is what is being referred to the April 2015 DMA Canyon report?

7.1. Yes

8. In relation to paragraph 2.2.1 of your report, when should a pre-occupation risk assessment be carried out for a project of this kind with a number of identified high risks?

8.1. Ideally a preliminary risk assessment should be conducted at the design stage to gain assurance that the planned design approach minimises and adequately manages the risks from waterborne pathogens. From my experience this is seldom if ever done, however it could assist in the prevention of 'building in risks' to new systems. If a preliminary design review water risk assessment is undertaken it should again involve a multi-disciplinary group to review the design and identify and agree that he operational requirements are being provided in the safety possible manner and identify any operational or maintenance considerations at the design stage to ensure all parties are able to contribute to making an informed decision on design acceptance.

9. In relation to paragraph 2.4.2 of your report, what, if any, are the current safety implications for high risk patient groups caused by the identified gaps in TMV/TMT maintenance?

9.1. The issue identified with the lack of provision of TMV/TMT stabilisation testing represents a technical failure in process and whilst it may represent an increased risk in terms of potential scalding or potentially a slight increase risk of microbial activity it is in my opinion a relatively low risk issue if all other elements are correctly followed.

10. In relation to paragraph 2.6.5 of your report, why did you conclude that the water safety policy was adequate at the current time in the absence of the patient safety risk profile?

10.1. As stated above in question/answer 6.1 the review of the current risk assessment should include the potential of changing clinical profiles of patients as well as the physical nature of the water and waste installations and how and when (how frequently) those systems are used. All of the factors impact the potential risk of the systems.

11. In relation to paragraph 4.2.4 of your report, what improvement works are being alluded to?

11.1. The works referenced relate to the series of modifications and improvement measures (both permanent and temporary) which have taken place since opening. Examples of these changes are shown below, taken from the DMA Canyon Risk Assessment of January 2019.

11.2. 'The construction phase ended in January 2015 with phased occupancy of patient areas beginning in April 2015 and full working occupancy achieved in July 2015. There have been departmental changes and small scale works in the intervening period (e.g. ward use changes and the required service alterations) though no significant water system alterations have been notified to DMA prior to this report being commissioned.'

11.3. 'In late 2018 Wards 2A & 2B in the Children's Hospital was closed to allow for extensive alterations to be made to the local water system, running hot flow and return services as close as is practical to the outlets, changing taps and WHBs, trough sinks removed from anterooms within the isolation rooms in 2A and other rooms repurposed to suit ward operations.'

12. In relation to paragraph 5.4.1 of your report, does document "2310 RHC TMV Servicing Clinic 6" refer to actions in 2023?

12.1. Yes, although this is a example and is not intended to imply that other records are present or complete/correct.

13. In relation to paragraph 5.4.1 of your report, what areas were TMVs serviced and when did they start servicing them?

13.1. This is not a question that I am in a position to answer as I have not seen or reviewed every TMV servicing record. What can be established is that from the information reviewed the stabilisation tests for new or adjusted TMV's was not recorded as being completed, and where TMV's were recorded as having failed a test the audit trail of corrective action and re-testing is unclear.

14. In relation to paragraph 5.11.43 of your report, do you have information regarding sluice drainage adequacy in terms of standards with regard to angle and diameter?

14.1. No, this is not an area I have reviewed and would not consider myself to have expert knowledge of.

15. In relation to paragraph 7.4.6 of your report, which areas were the actions taken for and is this comprehensive enough for the patients at high risk?

15.1. This is not a question I am able to answer, given it relates to the operational responses to the issues raised by an audit in 2017.

16. In relation to 7.4.6 of your report, to what extent can the water management system provide reassurance in the absence of any evidence about the actual state of the system?

16.1. Based on the findings of the audit report in May 2017 I would conclude that limited assurance could be taken that the management of the water systems was appropriate / adequate.

17. In relation to paragraph 7.4.12 of your report, how adequate is the infection control assessment in the yearly audit relating to delineation of key areas of risk?

17.1. The AE(W) audit does not appear to include direct involvement of IPC staff in the audit process. Whilst this is not unusual it is an area for improvement (in my opinion) IPC are involved in the water safety group, however the extent and detail to which the audit actively involves IPC representation is in my opinion poor.

18. In relation to paragraph 7.4.12 of your report, at what stage in a project should a water safety group be established?

18.1. A project based WSG is not necessarily essential, if the main WSG are involved at all stages of the project from inception, through design, delivery and validation. However it is often the case as particularly on a complex and large estate site that the main WSG may want to establish a project based team to engage with the project process to ensure any new development or modification is appropriately designed and managed through to its operational stage. If a dedicated Project WSG is established it should report on progress and status back to the main WSG throughout the project process. Any proposed derogations should be approved and managed at the appropriate level of the organisation and for water related issues that should include the main WSG consultation and approval prior to formal acceptance / sign-off.

19. In relation to paragraph 7.4.12 of your report, what level of organisational governance would you suggest should have been in place to ensure the project handover included the appropriate Board structures of water governance?

19.1. A process of formal validation and handover should be in place with the main WSG given the opportunity / responsibility of final sign off for the acceptance of a project.

20. In relation to paragraph 7.5.2 of your report, why is the DMA Canyon assessment not considered "external assurance"?

20.1. The DMA Canyon risk assessment is an external assessment however is designed to report the condition or status in relationship to risk. It does not necessarily provide a fully independent review of all aspects and does not provide advice or support in terms of addressing the overall level of compliance, which the role of an AE is required to fulfil to the WSG. That said I would consider the DMA Canyon risk assessment as comprehensive from a technical perspective.

21. In relation to paragraph 7.6.6 of your report, when did the level of training and awareness reach the appropriate and required standard?

21.1. The current Water Policy states that all levels of management with responsibilities for water will individually participate in appropriate periodic training to establish and maintain personal knowledge and a level of expertise allowing the efficient discharge responsibilities related to the Policy. This includes the Duty Holder and Corporate Management Team.

21.2. The lack of formally appointed and trained individuals was initially recognised in 2017 during the Legionella Management and Compliance Audit – Domestic Water Systems by Legionella Control Ltd. It was also noted in the Water Management Issues Technical Review by Health Facilities Scotland – March 2019 that ‘Since handover, no formal appoint was available for any of the positions noted in Section 6 of SHTM 04-01 Part B.’

21.3. In the AE(W) Audit of 2023 that ‘The details of the training records are available in the WSP in section 3. The board wide water skills register is available on Smart Sheet. Access to Smartsheet was not available at the time of the audit as there was a problem with the Smartsheet software and this was outside of the control of NHS GGC. The written scheme details completed AP training for the QEUH and full details, including dates of the training will be found in the Smartsheet system. It was stated at the time of the audit that the CP training may require updating. It is recommended that the requirement for CP training for the QEUH staff is evaluated and that appropriate training, if required, is delivered to the appropriate staff members. There was a note beneath table 3.1 of the QEUH written scheme advising that relevant training records and appointment letters are electronically filed on the QEUH shared drive within folder “Water Quality Training and Appointments”. Training records were produced for the auditor during this audit process’.

21.4. The February 2022 Audit by Pro Lp Consulting Ltd Authorising Engineer Water Systems Management and Compliance Audit of NHS Water System' made no specific reference to management structures or training records, however recommended a review of the water risk assessments.

21.5. It is assumed that the focus of staff training has been centred on estates staff and members of staff with specific responsibilities for the management of water systems.

21.6. From all of the above information I would assume that the stated position of training and competency requirements has been in place since 2021, with the most recent audit indicating an adequate level of compliance, although the issue of access to software systems may need to be addressed.

22. In relation to paragraph 7.8.2 of your report, should the patient migration have taken place given the number of issues identified in the DMA Canyon reports?

22.1. Based purely on water issues only I would not have recommended patient occupation with the level and nature of water issues identified. However patient occupation is always a very complex process and multiple issues are taken into consideration during the planning of initial occupation. That said the level and nature of the water issues was in my opinion sufficient to recommend against occupation until issues were addressed or mitigated against.

23. In relation to paragraph 7.9.1 of your report, are you comparing a 9-year-old building to similarly aged buildings that have been managed in an appropriate manner since opening, or to the status of old NHS estate buildings?

23.1. The age of a building does not directly affect the status of its water systems. The management structure and maintenance practices are suitable for all buildings, with some degree of additional maintenance or management required for buildings with legacy issues.

23.2. The nature of water management is an on-going continuing process and can never be considered as complete or finished whilst the building is in operation. This is especially true for a highly dynamic environment such as a hospital.

24. In relation to paragraph 9.1.2 of your report, are there any levels of assessment that the AE(W) needs to undertake to ensure high risk water provision can be pronounced as "satisfactory" or can the current level of scrutiny be regarded as adequate?

24.1. As stated above the current level of control and management is adequate and as such satisfactory, however as the use of the building is

in constant change, either due to changes in technology, microbiology, patient conditions and severity, the management and assurance does require constant vigilance.

Declaration:

1. I remain clear that my duty is to assist the Inquiry in an impartial manner.

2. I have no connection, personal or otherwise, to any core participant in the inquiry other than that I have declared in this response or my earlier report dated 10 June 2024.

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

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

5. I acknowledge the duty to set out all material facts, assumptions, methodology or other matters upon which my views and opinions are based, including such matters as may detract from the opinion formed, and that I have complied with that duty in this response and my earlier report dated 10 June 2024.

6. I acknowledge the duty to address only areas within my own areas of expertise and that we have made it clear when a particular question or issue falls outside our expertise. and that we have complied with that duty in this response and my earlier report dated 10 June 2024.

7. I acknowledge, understand and accept the obligation to state if my opinion is not properly researched because insufficient data are available and to give an indication that the opinion is no more than provisional, and have done so in this response and my earlier report dated 10 June 2024 where appropriate.

8. I acknowledge, understand and accept the obligation to indicate if any opinion I have expressed is qualified, or subject to revision, and have done so in this response and my earlier report dated 10 June 2024 where appropriate.

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

Yours sincerely

Andrew Poplett

18th August 2024

Direction 5 Questions for Independent Expert Witnesses

Andrew Poplett

5 August 2024

Dear Mr Poplett,

On 10 June 2024 you produced a report for the Inquiry. This has been made available to Core Participants (CPs). On 13 December 2023 the Chair issued Direction 5 which set out at Appendix B a system by which CPs would be permitted to raise lines of questioning or questions with you and the other independent witnesses before the commencement of the Glasgow III hearing.

The CPs were told that within five weeks of the date upon which the Inquiry Team provided your report to them any CP who wished to propose questions for you about your report or to make comment on that report must send a note to the Secretary to the Inquiry setting out in concise numbered paragraphs with clear reference to the relevant parts of the report:

1. the specific questions that should be asked of the report's author and any comment that the CP wishes to make on the substance of the report;

2. whether these questions and/or comment will raise new matters or issues not covered in the report; or

3. where no new matters or issues are likely to be raised, reasons why the issue should be raised with the expert witness at that time.

The Inquiry Team has considered the responses received in respect of your report and consolidated them into 21 questions. These questions are set out in the Appendix to this letter. Please provide a supplementary report to the Inquiry Team as soon as possible and by Friday 16 August 2024 at the latest in the form of concise answers to these questions. Responses will then be given to CPs.

Given the involvement of the counsel team in the hearing that deadline of 16 August 2024 cannot be extended.

Yours sincerely

Brandon Nolan
Solicitor to the Inquiry

Appendix

Supplementary Report by Andrew Poplett for the Scottish Hospitals Inquiry.

I have been asked a series of questions by the Inquiry Team and have been asked to respond to each question in turn.

1. In relation to paragraph 1.7 of your report, what impact, if any, is there on risk to patients by placing HIV patients on a ward with TB patients?

1.1. Whilst this question is primarily a clinical / infection transmission issue and not strictly an engineering issue, in relation to my report (clause 1.7) I would respond as follows.

1.2. The mixing of potentially vulnerable patients groups with others who have infections that have an element of airborne transmittable diseases would be unusual and carry an element of increased risk. If the ventilation systems of the ward area concerned had been designed to provide a protective environment, such as the use of PPVL isolation rooms then this may be possible without significant risk, however in my opinion and experience any such system would need to have had comprehensive validation of its efficacy and performance prior to any such arrangements.

2. In relation to paragraph 1.10 of your report, what information from Clinical teams was provided relating to the ventilation specification?

2.1. My assumption relating to the management or agreeing of variations/derogations was informed from the Bundle 16 Ventilation PPP information, which shows the original clinical output specifications, (Pg 1595) which in the case of Haematology specifically excluded the use of chilled beams and highlighted the need for appropriate ventilation provision or in other cases where it clearly stated the need to comply to the then current SHTM standards of 6ACH.

2.2. Within the same bundle of information (Pg 1657) the NSGH Ward Ventilation Strategy outlined the proposal to deviate from these standards. A fact that was recorded on the M&E Clarification Log (Pg 1662) as being agreed. At no point in the evidence provided is there any indication that this derogation was taken back to IPC or clinical leads to assess and endorse the change, and it appears to have been taken at a Project Board level.

3. In relation to paragraph 5.5 of your report, to what extent, if any, can bacterial pathogens generated from non-human sources (e.g water dispersal) have a bearing on the bio burden in a clinical space?

3.1. Whilst this question is primarily a clinical / infection transmission issue and not strictly an engineering issue, in relation to my report (clause 1.7) I would respond as follows.

3.2. Whilst the people occupying a clinical space do represent a significant potential source of airborne micro-biological burden, from the shedding of skin scales, breathing, etc… It is also the case that the environment can add contamination to the air within a clinical space. The extent and level of this potential contamination is driven by the available sources, dust/dirt from outside, to water sources and potential of aerosolisation of water droplets from drains, toilets, wash hand basins, and showers. If water or waste water is enabled to be agitated or sprayed then it will likely result in an increased risk of airborne micro-organisms. Ventilation by means of filtration and dilution is used to control or limit concentrations of these risks.

4. In relation to paragraph 5.36 of your report, to what extent, if any, does patient placement policy require accurate information about the types of accommodation available, IPCT assessment of infection risk, and clinical determinations of the immune status of patients in order to be effective?

4.1. In my opinion it is critical to have a thorough understanding of the clinical environments available across the accommodation to enable clinical and IPC teams to make informed decisions relating to patient placement / admission. If clinical / patient demands means that patients have to be admitted or cared for in sub-optimal environments then supplementary precautions or monitoring may be required to mitigate the associated risks. This is one driver for the creation of multidisciplinary ventilation safety groups to enable fully informed discussions and decisions to be taken.

5. In relation to paragraph 6.16 of your report, have you seen any evidence of an SOP and/or risk assessments which deal with the occasions when the AHUs are turned off?

5.1. As a basic requirement of the health and safety at work act I would expect that every maintenance activity should have a detailed risk assessment and method statement present for every maintenance activity. Where this work is planned, such as in the case of all planned preventative maintenance tasks, these should be present and subject to routine auditing for accuracy and ensure operatives are following them. In the case of breakdowns or failures these may be dynamic risk assessments and not necessarily recorded, but should still be undertaken by the operatives involved. No details of these SOP’s or advice notes have been provided to the best of my knowledge.

6. In relation to paragraph 6.17 of your report, how does the ingress of dust and spores from a ceiling space impact on the risk of infection for immune supressed patients?

6.1. Whilst this question is primarily a clinical / infection transmission issue and not strictly an engineering issue, in relation to my report (clause 1.7) I would respond as follows.

6.2. Dust and fungal spores can exist/survive for many years and if left undisturbed do not present a significant risk to most people, however if patients are immune-suppressed or vulnerable to infections then these sources of dust/spores can have very serious clinical consequences. It is therefore specified within the SHTMs and SHBNs to ensure solid ceilings are present and not loose fitting suspended ceiling tiles.

7. In relation to paragraph 7.6 of your report, have you seen any IPC sign off for the HAI SCRIBE for the ward 2A works?

7.1. I have not seen any specific evidence that the re-design / improvement works on ward 2A were subject to specific IPC or clinical sign off / approval, however given the nature of the works undertaken I would expect that some degree of consultation and involvement took place.

7.2. The redesign of the ventilation systems serving RHC Wards 2A and 2B was to improve the overall performance of the ventilation systems serving the area. The installation of separate supply and extraction systems removed the risk of cross contamination from other zones and other levels. The provision of duty/standby arrangements added resilience to the systems and allowed for planned maintenance of the AHUs to be undertaken without impacting the patient group.

8. In relation to paragraph 7.36 of your report, to what extent, if at all, can PPVL rooms be used for a specialist IDU unit?

8.1. The type and design of patient isolation facilities is typically informed by the type or category of infectious disease being treated / cared for. The general options are for positive pressure protective facilities (for immune suppressed patients), negative pressure isolation facilities (for infectious patients0 or PPVL’s which can provide an option for both categories of patients. PPVL type rooms are generally considered appropriate for most categories of pathogen, however category 4 (HCID) High Consequence Infectious Diseases may need more specialist facilities and should consider more than just the airborne transmission route in isolation so involve separation of water and waste systems in addition to ventilation systems.

9. In relation to paragraph 7.36 of your report, to what extent, if at all, can PPVL rooms be used for a specialist BMT units?

9.1. PPVL type isolation facilities can be used for Immune suppressed patients such as BMT patients, however the grade of supply air filtration also needs to be considered and not just the air change rates or pressure cascades/differentials.

10. In relation to paragraph 7.39 of your report, what, if any, issues arise with the PPVL neutral pressure design?

10.1. As with any design solution the practicalities of space and room layouts are critical to the efficacy of any isolation facility. HBN 04-01 supplement 1 outlines the full range of considerations and limitations involved. Note this standard has very recently been reviewed and updated (published July 24).

11. In relation to paragraph 9.46 of your report, have you seen the 2015 ventilation audit referred to in the AE(V) Audit Report Nov 2016?

11.1. Yes, a copy of the AE(V) Audit report of the 9th & 0th December 2015 was provided withint he documentation and it highlights a number of areas for improvement including areas of none conformance to the requirements of SHTM 03-01.

12. In relation to paragraph 9.46 of your report, to what extent, if any, did the 2016 ventiation audit identify non-compliance with SHTM 03-01 in relation to the ventilation system?

12.1. The 2016 AE(V) Audit report identified a number of issues of none conformity to the SHTM 03-01 standards as outlined within paragraphs 9.46 to 9.56 inclusive.

13. In relation to paragraph 9.46 of your report, to what extent, if any, did the 2016 ventilation audit fail to provide any reason for the withdrawal of the action to provide a standby handling unit for Ward 4B?

13.1. The AE(V) Audit report appears to cover operational issues only and does not extend to cover on-going or planned project or improvement works. It does make reference for the need to expand and ensure all critical systems are suitably verified and the resilience of the critical ventilation systems should be covered within the respective original validation and subsequent verification reports / reviews.

14. In relation to paragraph 9.46 of your report, to what extent, if any, did the 2016 ventilation audit fail to identify an infection control risk assessment for the filter issues in NICU AHU?

14.1. As outlined above the AE(V) Audit report appears to cover operational issues only and does not extend to cover none estates related activities such as IPC or clinical risk assessment.

15. In relation to paragraph 10.6 of your report, what did the assessment of the relevant room include (for example, ACH)?

15.1. The verification reports record a number of elements including AHU performance readings (filter pressure drops), measurement of room air change rates, differential pressure cascades and physical condition of the room. A summary of the areas covered is below;

- Are windows hermetically sealed?
- Are the ceilings in the Lobby, Isolation Room & WC complete and sealed
- Are there any significant faults in the fabric of the rooms within the Isolation Room envelope?
- Are room light fittings correctly sealed?
- Do all doors close completely and hold against the room pressure?
- Are the pressure stabilisers operating correctly and silently?
- Are all supply and extract air terminals and pressure stabilisers visibly clean?
- Measure and record the room temperature
- Measure and record the air flow at all supply and extract terminals
- A Negative pressure of greater than or equal to -10Pa is achieved between the room and the corridor – Clients specification.
- The patients room has at least 10AC/HR;
- The en-suite has a at least 10AC/HR;
- The en-suite is at a negative pressure with respect to the patients room;
- Measure and record the noise levels in the principal rooms of the suite.
- Do the noise levels fall below the limits set out in table 2 of Health Technical Memorandum 03-01, Part B

16. In relation to paragraph 10.43 of your report, what ACH do you consider appropriate for the en-suites?

16.1. Within a PPVL designed isolation room the en-suite air change rate is determined by the patient bedroom size in relation to the size of the en-suite. Typically this will be at least 10 ACH, but can be higher subject to individual room dimensions.

17. In relation to paragraph 3.7 of your report, what, if any, wider mitigations were taken into account in your analysis?

17.1. The only other issue experienced during my assessment of information and subsequent conclusions was that I had limited time and availability of resources (not a consequence of the Inquiry but due to other work commitments). There is also a considerable amount of information provided and this has not always been easy to sift through to identify the key elements required. I have used my best endeavours to ensure all information was identified and assessed in drawing my assumptions and conclusions.

18. What is the basis for your conclusions reached in paragraphs 9.1 and 9.89?

18.1. The basis of my conclusion from paragraph 9.1 (covered in paragraph 9.2) was that the Policy document clearly stated that full compliance to

the SHTM was the basis of the document and made no reference to the derogations from this standard in the design of the facility.

18.2. In paragraph 9.89, in my opinion, a number of the issues identified as none conformities had a potentially significant risk to patient safety and legal compliance and as such should have been escalated to the highest level of the organisation.

19. In relation to paragraphs 9.1 and 9.89 of your report, why do you consider the executive summary to be "overly reassuring"?

19.1. As stated above, in paragraph 9.89, in my opinion, a number of the issues identified as none conformities had a potentially significant risk to patient safety and legal compliance and as such should have been escalated to the highest level of the organisation. This failure to escalate may have contributed to the time taken to address a number of the issues raised.

20. In relation to paragraph 9.1 and 9.89 of your report, what is your basis for stating that issues were not escalated?

20.1. Given the potential patient safety and legal compliance issues I have not seen any evidence of escalation of these issues to the Infection Control Committee, health board or even HSE, all of which should have been considered.

21. In relation to paragraph 9.1 and 9.89 of your report, what is your basis for stating that the speed and extent of improvement was poor?

21.1. As stated above a number of the issues identified as none conformities had a potentially significant risk to patient safety and legal compliance and as such should have been escalated to the highest level of the organisation, with the subsequent prioritisation to address being immediate and not left for a number of subsequent years of audit reviews. Typically I would expect a director lead task and finish group or similar to be established to ensure the issues were addressed as a matter of extreme urgency with such a group involving all relevant parties and regular (at least monthly) monitoring and reporting on progress.

Declaration:

1. I remain clear that my duty is to assist the Inquiry in an impartial manner.

2. I have no connection, personal or otherwise, to any core participant in the inquiry other than that I have declared in this response or my earlier report dated [date].

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

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

5. I acknowledge the duty to set out all material facts, assumptions, methodology or other matters upon which my views and opinions are based, including such matters as may detract from the opinion formed, and that I have complied with that duty in this response and my earlier report dated 10 June 2024.

6. I acknowledge the duty to address only areas within my own areas of expertise and that we have made it clear when a particular question or issue falls outside our expertise. and that we have complied with that duty in this response and my earlier report dated 10 June 2024.

7. I acknowledge, understand and accept the obligation to state if my opinion is not properly researched because insufficient data are available and to give an indication that the opinion is no more than provisional, and have done so in this response and my earlier report dated 10 June 2024 where appropriate.

8. I acknowledge, understand and accept the obligation to indicate if any opinion I have expressed is qualified, or subject to revision, and have done so in this response and my earlier report dated 10 June 2024 where appropriate.

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

Yours sincerely

Andrew Poplett

17th August 2024

Direction 5 Questions for Independent Expert Witnesses

30 September 2024

Dear Mr. Bennett,

On 2 September 2024 you produced a report for the Inquiry. This has been made available to Core Participants (CPs). On 13 December 2023 the Chair issued Direction 5 which set out at Appendix B a system by which CPs would be permitted to raise lines of questioning or questions with you and the other independent witnesses before the commencement of the Glasgow III hearing.

The CPs were told that within two weeks of the date upon which the Inquiry Team provided your report to them any CP who wished to propose questions for you about your report or to make comment on that report must send a note to the Secretary to the Inquiry setting out in concise numbered paragraphs with clear reference to the relevant parts of the report:

1. the specific questions that should be asked of the report's author and any comment that the CP wishes to make on the substance of the report;

2. whether these questions and/or comment will raise new matters or issues not covered in the report; or

3. where no new matters or issues are likely to be raised, reasons why the issue should be raised with the expert witness at that time.

The Inquiry Team has considered the responses received in respect of your report and consolidated them into nineteen questions. These questions are set out in the Appendix to this letter. Please provide a supplementary report to the Inquiry Team as soon as possible and by Friday 11 October 2024 at the latest in the form of concise answers to these questions. Your response will then be provided to CPs before you given evidence during the Glasgow III hearing on 31 October and 1 November 2024.

Given the involvement of the counsel team in the hearing that deadline of 11 October 2024 cannot be extended.

Yours sincerely

Brandon Nolan
Solicitor to the Inquiry

Appendix

Supplementary Report by Allan Bennett for the Scottish Hospitals Inquiry

I have been asked a series of questions by the Inquiry Team and have been asked to respond to each question in turn.

1. In relation to paragraph 5.3 of your report, to what extent is CRAG positive adequate evidence of the organism even without culture positivity? Have you considered that lack of culture positivity does not exclude the diagnosis?

1.1. In my report I did not go into detail into the interpretation of diagnostic tests. I am not an expert in Cryptococcal diagnostics but with many micro-organisms it is possible to get contradictory results with different diagnostic methods. The CRAG test measures levels of antigen so will pick up the presence of a component of the Cryptococcus cell. It is possible that this test will detect up the presence of Cryptococcus cells that will be inactivated or unculturable and cell wall components. It is highly possible that if samples are taken post anti-fungal therapy has been initiated CRAG tests will be positive and culture tests negative. It is also possible that due to technical issues or limits of detection culture may not be effective.

I am not aware of any studies that measure the effectiveness of CRAG testing against culture. I also assume that CRAG testing only detects Cryptococcal antigens and is not a definitive test for *Cryptococcus neoformans* so culture will be required for confirmation unless a direct PCR assay has been developed.

2. In relation to paragraphs 5.9 and 5.11 of your report, were you aware that cryptococcus isolates are grown in the QEUH/RHC lab, identified locally and sent to Bristol only for secondary testing? Does that have any impact on your views?

2.1 I was not clear on this from the information I received, I assumed that any species identification was carried out at the Bristol laboratory and have not seen any details of any testing carried out at QEUH such as SOPs or result reports. It would be good to have had this information as it would allow a better understanding of number of cases and the likelihood cases would be detected.

3. In relation to the explanations provided at paragraph 5.14 of your report, for possible reasons the cases reported exceeding the expected annual case numbers using the UKHSA and Perogie figures, could you consider the following comments:

- Randomness producing a 5-7 fold increase is unlikely. Has any statistical analysis been applied regarding the likelihood of all excess cases having a link to one building?
- The QEUH/RHC data is based on in-house diagnostics, with the lab in Bristol not picking up any cases.
- It seems unlikely that the susceptibility profile would alter 5-7 fold in one year uniquely across Glasgow. There would require to be a plausible susceptibility factor shared by the four cases that is different from previous years and other populations. None have been suggested.
- CN culture does not require special equipment or agar plates.

Please confirm:

a) whether any or all of these points were initially considered, and
b) do you agree or disagree with the points made?

c) Does anything in your response to these points change the conclusions reached at paragraph 5.14

3.1 I state throughout my report that I have not carried out any statistical analysis as is not my area of expertise. It is possible that there may be factors behind spikes in disease incidence that are unknown if there is randomness. The calculation of exceedance values for hospital acquired infections is a speciality of Andre Charlett's group at UKHSA. I am surprised that no formal epidemiological investigation was carried out of these cases including statistical analysis. Unfortunately, I don't have a great deal of clarity of Cryptococcal case incidence and likelihood of diagnosis at the QEUH, other hospitals and national level which greatly impacts on any conclusions I can make.

4. Following the evidence of Darryl Conner to the Inquiry, could cleaning up pigeon mess from floors by spraying could have created an aerosolisation event? What impact, if any, could such spraying combined with issues for example, inadequate door seals, or the presence of a gap around the spigot, have had on the potential risk of increase in ingress of infectious spores into the AUH? Could any of this have increased the concentration delivered to patients and, thus, increased the probability of infection?

   4.1 In general the input of energy is required to generate an aerosol of a pathogenic agent from liquid or solids. The potential for aerosolization of spraying of pigeon excreta will be related to the force of the spray. The more energy inputted the more likelihood of aerosolization and the smaller the aerosol particle likely to be formed. Therefore, it is possible to state there is potential for aerosolization from spray cleaning and that would likely increase the concentration of pathogenic agents in the air in the areas being cleaned. If, as mentioned in the report, parts of the supply air systems were at negative pressure to the plant room and there were holes or inadequate sealing there is the potential for this aerosol to enter the supply air.

5. In respect of paragraph 8.9 of your report, why is the failure to identify Cryptococcus neoformans in 3000 air samples significant? Do plantrooms provide the perfect environment for excess amounts of aerosolised cryptococcus given the lack of UV light and water ingress? If so, why and what flows from that? Does this alter the conclusions reached by you?

   5.1. The lack of identification of *Cryptococcus neoformans* in 3000 air samples in which other Cryptococci were detected is suggestive that the agent was not in the air at detectable concentrations during the sampling periods. However, information on the behaviour of Cryptococci in the air and the effectiveness of air sampling methods is lacking. It may be that for unknown reasons it is difficult to detect CN from the air.

   The levels of Cryptococci in the air will mainly be governed by the source. Environmental factors such as UV and moisture may impact on the survival of a microbial agent in the air and thus its detection in air samples but the impact of these factors on Cryptococci is unknown.

   In relation to the cases, it must be remembered that air sampling was undertaken about a month after any potential infection window.

6. With regards to paragraph 8.24 of your report in respect of weather conditions, has consideration been given to any data on the weather conditions in late November 2018?

Have any records of helicopter landings in that 9 day window period been obtained and considered?

6.1. There is detailed weather data available from Glasgow airport which I studied (https://meteostat.net/en/station/03140?t=2024-09-18/2024-09-25). However, during the 9 day window wind speeds and directions fluctuate and so no conclusions could be taken. I have not had access to helicopter landing records. Due to the long window of infection no correlations can be made.

7. In respect of paragraph 8.29 of your report;

a) When considering the rates of infection, what account was taken of RHC being a tertiary referral centre? Does this impact your assessment at paragraph 8.29 of Cryptococcus neoformans being between 5.4 and 7.2 times more likely at the QEUH/RHC?

b) What consideration has been given to the probability of acquisition of infection in the periods that the individuals have spent out-with the hospital setting?

7.1a) I'm not entirely sure what is meant by a tertiary referral unit. My figures assume that the hospital is the most likely location for patients with vulnerabilities to CN in the greater Glasgow area. Obviously, if all child patients with high levels of neutropenia in a wider area are exclusively treated in RHC not just those in the GGC area then this would mean that there would be a slight reduction in the 5.4 and 7.2 figures.

b) I cover the potential for acquisition of CN out with the hospital setting in my response to Hypothesis 7 i.e

"Therefore, it is POSSIBLE that in both of the patients the original colonisations with CN occurred before the patients entered QEUH and CN was re-activated due to immunosuppression caused by their underlying conditions. Due to shorter stay and the older age of Case A this seems more likely."

8. In respect of paragraph 9.2 of your report, please confirm the basis for the assertion that 'had patients being housed in HEPA filtered positive pressure rooms, the connection between the hospital environment and the patient could have been investigated and ruled out'.

8.1. The point I was making was that if patients had been housed in HEPA filtered positive pressure rooms that had been demonstrated as being working correctly through annual validation it could be shown there would be no potential route from the external environment to the patients as they would only have been supplied with clean HEPA filtered air. This would provide them with a very high degree of protection from infection through environmental air even if the outside environment and service floor was highly contaminated.

9. Refer to paragraph 8.15 of your report. Does the one inch hole to allow a mechanical drive spindle to be operated to drive the damper mechanism to a closed or opened position provide a potential route for contaminated air within the plant room to be drawn into the ventilation system?

9.1. Yes, if the inside of the supply air duct is at negative pressure to the plant room at that point. However, the magnitude of the leak would need to be calculated to show if the leak is significant.

10 Can you consider bundle 9, page 13, where Mr Steele advised that action was taken to smoke test and verify there was no infiltration. Does this impact your comment that 'this does not appear to have been carried out' at paragraph 8.15 of your report?

10.1 Thank you for drawing this to my attention. It does impact on my comment. However, I have not seen any reports on the smoke testing so cannot comment on the methodology and whether it was carried out for each relevant supply air duct in every plant room. If I can be provided the reports containing this information it may allow to me to modify my conclusions.

11. . At 8.16 you suggest that 'panels can be removed from ventilation systems before the fan and filter air supplies in the winter to prevent cut outs caused by the low temperature which would greatly increase the potential for plant room air to enter the supply air'. Having regard to bundle 9, page 12, if the units had not been opened since September 2018, was this still a possibility, and if so, how so?

11.1. I have been informed that it not uncommon to remove panels from the ventilation systems in the event of a low temperature shutdown. I do not state that this happened in the QEUH only that it is a possibility. I don't know whether it is possible that panels can be removed without it being documented.

12. There is a Mycology Reference Centre in Manchester. Is it possible that further laboratories may have been used for sending isolates? If so, was this considered when reaching the conclusions set out in paragraph 5.7? If so, do you consider that the data used may be an underestimate, and if so, could this impact the conclusions of the report. Please explain your answer.

12.1. There appears to be no official reporting of CN cases within the UK. Therefore, benchmarking is difficult. I used the number of isolates provided to the UKHSA mycology reference laboratory as an indicator of incidence. However, you point out there is another centre providing similar service in Manchester. However, since all QEUH samples were sent to UKHSA and since carrying out a Google search from "mycology reference laboratory" and "mycology reference laboratory cryptococcus" bring up the UKHSA laboratory I would assume the majority of isolates would be sent there. It is my understanding that the Manchester laboratory is mainly concerned with Aspergillus and is not a formal reference laboratory. However, if they receive a significant number of yearly patient positive samples then UK Cryptococcal rates may be higher.

13. In regard to paragraph 8.13 of your report, did you take into account that relapse of a latent infection may happen after years of acquiring the infection? How does this impact, if at all, on the conclusions reached in your report, particularly with regards to patients A and B?

13.1. Yes. See paragraphs 5.15-5.19, 8.3 and 8.26 and Response 7b above. I took this possibility into account in my conclusions.

14. With regard to paragraphs 8.6-8.9 of your report, what is the significance, if any, of Cryptococcus neoformans never being detected in any of the over 3,000 samples taken?

14.1. Air sampling is not an exact science. When I train people to carry out air sampling, I always say the most important factor is not the air sampler or detection method you use but when and where you carried out the sampling. As sampling was not undertaken during the potential window of infection we do not know whether *Cryptococcus neoformans* was present in the air during this period.

However, not finding the agent in 3,000 samples taken after the cases were identified is suggestive the agent was not present in detectable levels especially as other Cryptococci were detected. If I remember correctly 500l of air were sampled each time so a total of 1,500 cubic metre of air was sampled from December 2018 to summer 2019 which is a very large volume of air.

15. Please explain your calculations at 8.19 . Is it necessary to use a baseline value in order to reach these conclusions? Does this impact the conclusions reached?

15.1. Filters are defined in terms of efficiency in removing particles from the air. This is normally demonstrated in standard laboratory tests and in situ tests of HEPA filters. As stated in the report, a F7 has a 90% efficiency if operating correctly and the HEPA has a proven >99.95 efficiency as it is regularly tested *in situ*. If these filters are challenged by a baseline level of 10,000 infectious particles then 1,000 particles will penetrate the F7 filter and enter the supply air to the wards. If a HEPA is used less than 5 particles would enter the supply air. Obviously if there are no infectious particles in the supply air the use of filters would not make a difference to the patient exposure which is why my conclusion is that the lack of protective environment would be contributory.

1. I remain clear that my duty is to assist the Inquiry in an impartial manner.

2. I have no connection, personal or otherwise, to any core participant in the inquiry other than that I have declared in this response or my earlier report dated [date].

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

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

5. I acknowledge the duty to set out all material facts, assumptions, methodology or other matters upon which my views and opinions are based, including such matters as may detract from the opinion formed, and that I have complied with that duty in this response and my earlier report dated [date].

6. I acknowledge the duty to address only areas within my own areas of expertise and that we have made it clear when a particular question or issue falls outside our expertise. and that we have complied with that duty in this response and my earlier report dated [date].

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

8. I acknowledge, understand and accept the obligation to indicate if any opinion I have expressed is qualified, or subject to revision, and have done so in this response and my earlier report dated [date] where appropriate.

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

Yours sincerely

Allan Bennett

9th October 2024

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

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