Appendix 1

Documentation provided to the Scottish Hospitals Inquiry

Requests for Information (RFI)

RFI Ref No	Description	Date received	Applicati on of Section 21 Notice	No of Docs Submitted	Date(s) Submitted
1	Documentation on: water; ventilation; governance; project management; effects of issue on patients and their families	01/02/2021	-	7,380	19/03/21 – 15/12/21
2	Written & pictorial evidence for relevant QEUH & RHC Wards	25/06/2021	-	2 2 16	30/08/2021 08/09/2021 21/09/2021
3	Development of QEUH & RHC, Schiehallion unit and comment on Timeline	09/02/2022	-	4	03/08/21 08/03/21
4	Comment on standalone issues with the hospital environment	28/02/2022	-	3	04/04/2022
5	Organograms and reporting structures for IPC, Microbiology & Schiehallion Unit	04/03/2022	-	20	12/05/202
6	Provision of Communication Narratives	10/04/2022	-	2,583	13/05/22 – 10/02/23
7	Relating to: Problem Assessment Group & IMTs; Whistleblowing Policy; Reports produced by and for NHSGGC; Correspondence; Minutes/summaries of meetings; Miscellaneous	11/04/2022	-	847	25/03/22 31/08/22
8	Relating to the Water System and Filtration	03/08/2022	-	6 1	26/08/2022 28/10/2022
9	Relating to Water System and Disinfection	13/09/2022	-	8 1	12/10/2022 16/11/2022
10	Relating to all perceived problems, defects and issues with the ventilation system	04/11/2022	S21 – 1	356 68 17 61	Q1 - 05/11/2022 Q2 - 02/12/2022 Q3 - 09/12/2022 Q4 - 16/12/2022
11	Documents pertaining to Problem Assessment Group (PAG) and Infection Management Team (IMT) Meetings between 2015 and Present	21/09/2022	S21 – 2	199 100	16/12/2022 06/01/2023
12	Documents relating to the Water Distribution System, from the outset of the initial design, build and installation phase to handover	05/12/2022	S21 – 3	114	13/01/2023

13	QEUH Scoring, Design and Contractual Documentation	20/12/2022	S21 – 4	1	27/01/2023
14	Data for all positive blood cultures for 2015 to present including demographic data (across the whole Queen Elizabeth University Hospital and Royal Hospital for Children in Glasgow)	09/01/2023	S21 – 5	1	20/01/2023
15	SBARS held by NHS GGC in addition to the SBARs submitted in response to RFI 7 2.24	13/02/2023	S21 – 6	2 42	28/02/2023 19/04/2023
16	Emails and documents referred to within witness statements	14/03/2023	S21 – 7	34 2	31/03/2023 04/04/2023
17	Chronological Narrative of Water Investigations, Expert Input and principal witnesses	24/04/2023	S21 – 8	136	30/06/2023
18	Chronological Narrative of Ventilation Investigations, Expert Input and principal witnesses	Original 05/05/2023 Revised 14/07/2023	S21 – 9	Work in Progress	
19	SOPs, Policies and Data requested by Expert Panel following the visit, Further documentation and some points for clarification	12/05/2023	S21 – 10	16 12	22/05/2023 26/05/2023
-	Preliminary request: AICC Minutes			605	27/08/20 – 30/08/20
-	Preliminary request: BICC Minutes			597	31/09/20
Total				13,238	

Positioning Papers:

- NHS GGC submitted a Positioning Paper following the evidential hearing in September to November 2021, to the SHI 14/12/2022
- NHS GGC submitted a second Positioning Paper on matters relating to the issue of infection, to the SHI 5/04/2023
- NHS GGC provided a response to the SHI Provisional Positioning Paper 5 History of Infection Concerns (PPP5 – HOIC) – 21/04/2023

Opening & Closing Statements:

- NHS GGC submitted an Opening Statement to the SHI on 06/09/2021
- NHS GGC submitted a Closing Statement in response to the Glasgow 1 Hearings 2021 on 17/12/2021
- NHS GGC submitted a Closing Statement in response to the April and May 2023 Hearings relating to the Royal Hospital for Children and Young People/ Department of Clinical Neurosciences

Appendix 2

Meetings, Visits & Tutorials

Meetings:

There have been numerous meetings attended by NHS GGC Senior Counsel, the solicitors from the NHS Central Legal Office and the NHS GGC Programme Management Office to assist the SHI Team.

Facilitation of visits to the Queen Elizabeth University Hospital and Royal Hospital for Children:

A total of three sites visits to QEUH and RHC for Inquiry Counsel and staff have been facilitated by NHS GGC as set out in the table below.

The list of attendees does not include the various NHS GGC staff who facilitated these visits.

The most recent visit by the Scottish Hospitals Inquiry Expert Panel also included the facilitation of four round table discussions on the following topics:

- Clinical (9 NHS GGC Members of staff attended)
- Infection Prevention & Control & Microbiology (10 NHS GGC Members of staff attended)
- Estates & Facilities (9 NHS GGC Members of staff attended)
- Corporate (11 NHS GGC Members of staff attended)

With the recent appointment of further Expert Advisors to the SHI Expert Panel, as advised NHS GGC will facilitate a further visit to the QEUH and RHC on request.

Date	Group	Attendees
23/06/2021	Inquiry Counsel & Staff	Lord Brodie David Anderson Jesse Hevor Victoria Arnott Kim Milligan Karen Munro
20/08/2021	Inquiry Counsel & Staff	Alistair Duncan KC Samantha Rore Mairi MacNeil Kenny Warren Wilma Johnston-Graham Aileen Black
20/03/2023 21/03/2023	Expert Panel Members	Dr Sara Mumford Linda Dempster Dr Jimmy Walker

NHS GGC provided a tutorial to Inquiry Counsel and staff on18/05/2022 on the following topics:

- Infection Prevention & Control
 - Delivered by Sandra Devine, Director of Infection Prevention & Control
- Whole Genome Sequencing Introduction & Overview

Delivered by Prof Alistair Leanord, Consultant Microbiologist

Appendix 3

NHS GGC Recent & Prospective Witnesses

Witnesses from NHS GGC who have provided evidence at the June 2023 Hearing:

Witness name	Position	Action
Professor Brenda Gibson	Consultant Paediatric Haematologist, NHS GGC	Oral evidence & Statement
Dr Shahzya Chaudhury	Consultant Paediatric Haematologist, NHS GGC	Oral evidence & Statement
Emma Somerville	Senior Charge Nurse, NHS GGC	Oral evidence & Statement
Angela Howat	Neuro-oncology Clinical Nurse Specialist (formerly Senior Charge Nurse), NHS GGC	Oral evidence & Statement
Dr Dermot Murphy	Consultant Paediatric Oncologist, NHS GGC	Oral evidence & Statement
Jamie Redfern	Director of Women and Children's Services (formerly General Manager for Paediatrics and Neonates), NHS GGC	Oral evidence & Statement
Jennifer Rodgers MBE	Deputy Nurse Director for Corporate and Community Services (formerly Chief Nurse for Paediatrics and Neonates), NHS GGC	Oral evidence & Statement
Melanie Hutton	General Manager for Paediatrics and Neonates (formerly, Clinical Service Manager and Lead Nurse), NHS GGC	Oral evidence & Statement
Dr Anna Maria Ewins	Associate Specialist in Paediatric Oncology, NHS GGC	Stood Down Statement & Supplementary Statement
Dr Jairam Sastry	Consultant Paediatric Oncologist, NHS GGC	Stood Down Statement & Supplementary Statement
Mr Andrew Murray	Executive Medical Director, NHS Forth Valley	Stood Down Statement
Dr Alistair Hart	Consultant Haematologist, NHS GGC	Stood Down Statement

Kathleen Tomson	Lead Nurse (2018-2020), NHS GGC	Statement
Sarah-Jane McMillan	Clinical Nurse Educator (formerly Senior Staff Nurse) NHS GGC	Statement
Dr Milind Ronghe	Consultant Paediatric Oncologist, NHS GGC	Statement
Gael Rolls	Senior Charge Nurse PICU (2015 - 2019), NHS GGC	Statement
Dr Johnathan Coutts	Consultant Neonatologist, NHS GGC	Statement

NHS GGC Draft Positioning Paper on Infection dated April 2023

SCOTTISH HOSPITALS INQUIRY

POSITIONING PAPER 2 ON BEHALF OF NHS GREATER GLASGOW AND CLYDE

Executive summary

- 1. The September-November 2021 hearings of the Scottish Hospitals Inquiry focused on evidence of experiences and perceptions of patients and families over the period of their treatment at Queen Elizabeth University Hospital at Glasgow, predominantly within the Royal Hospital for Children. A significant feature of the testimony of patients and families centred around their experience of suffering infection over the course of their treatment and their understanding that their infections may have been caused or contributed to by the built environment of the hospital itself.
- 2. Included in the remit of the Inquiry is to "determine how issues relating to adequacy of ventilation, water contamination and other matters adversely impacting on patient safety and care occurred" and "if these issues could have been prevented." In particular, the Inquiry Team has sought the position of NHS GGC on the question of whether the built environment at the QEUH was in an "unsafe state," and, if so, whether any link between infections and the built environment can be said to exist.
- 3. It is the position of NHS GGC that the built environment of the QEUH did not, on a proper reading of the available evidence, expose patients to any increased risk to their health, safety or wellbeing. Further, with the exception of two discrete cases of paediatric infection, there is no evidence before the Inquiry to properly suggest a link between infections suffered and anything arising from the built environment. In particular, there is no evidence to demonstrate any increased rate of infections within the QEUH from microorganisms related to the built environment.

Questions posed by Counsel to the Inquiry

- 4. It is our understanding that the Inquiry considers that there are 3 questions in relation to infections that require to be considered:
 - (a) "Was the built environment in an unsafe state in that it presented the opportunity for pathogens to come into contact with patients?"
 - (b) "If the built environment was in an unsafe state is there a link between infections suffered and the unsafe state of the built environment?"
 - (c) "If the built environment was in an unsafe state has it now been addressed?"
- 5. In addition, the Inquiry wishes to understand NHS GGC's position on whether there is a causal connection between the infections and the hospital built environment. In

particular, "whether it is the Board's position that unless one can categorically confirm connection e.g. Stevie-Jo Kirkpatrick, then there is no basis to conclude that there may nevertheless be likely/very likely to have been a connection."

 In order to properly address these points, there are relevant factors that must be borne in mind, which will also change the nature of the question that requires to be answered. However, before doing so there are key concepts on how infections occur that must be understood.

Background

7. An infection is the presence of live and multiplying micro-organisms, evident clinically, in a part of the body where the micro-organisms should not be present (or present in those numbers). For an infection to occur, that micro-organism must have come from somewhere (a source), had a path to get to that person (transmission route) and a way to get into the body (opportunity/susceptibility). The development of any infection is therefore multifactorial.

Source

8. The micro-organism can either come from the same person (endogenous) or from somewhere else (exogenous) such as the environment, food and other people. It should be noted that the human body has more bacteria than human cells (40 trillion bacteria cf. 37 trillion human cells)¹ and so an individual's own body represents the largest source of micro-organisms to which they are exposed.

Transmission

- 9. If it is an exogenous infection (i.e. one caused by a micro-organism that is not part of the person's own flora) then there must have been a route by which it reached the person. The most common route is by direct contact with the source (another person, food, soil etc.), but depending on the type of micro-organism it may be spread through another medium from the source such as by air (e.g. *Aspergillus fumigatus*), droplets (e.g. *Coronavirus*), or water (e.g. *Escherichia coli*).
- 10. It should be noted that transmission may not be directly from the originating source of the micro-organisms to the point of infection, but can be through several steps including becoming part of the community of micro-organisms that have colonised the body (commensal flora) for a period before the opportunity to cause an infection arises.

¹ Presentation by Prof. A Leanord to Inquiry team on 29 June 2022.

Opportunity/Susceptibility

- 11. The human body has a number of mechanisms to prevent infection. Firstly, there are barriers such as the skin, mucous membranes and stomach acid, all of which prevent potentially infective micro-organisms from entering the body. Secondly, the body's immune system attacks and kills micro-organisms that do enter the body preventing an infection developing. Any defect in these mechanisms, such as a wound, creates susceptibility and will provide an opportunity for an infection to develop.
- 12. This is particularly the case in a hospital setting as patients are more susceptible to infection than the general public for several reasons. They have invasive devices, which are necessary for their treatment, that breach their natural barriers (e.g. a venous cannula for the administration of intravenous fluids). Also as they are unwell, hospital patients are less able to mount an effective immune response in general and even less so for patients who are immunosuppressed. In these circumstances, it is by no means unusual for a hospital patient to acquire an infection. In particular, paediatric haemato-oncology patients, who are immunocompromised, are unfortunately particularly vulnerable to infection.
- 13. A point to note is that, whilst the commensal flora act as a barrier to exogenous infections, they can cause an endogenous infection as a result of this susceptibility/opportunity (opportunistic infection).

Healthcare associated infections

- 14. People are not sterile. Buildings are not sterile environments. Healthcare buildings such as hospitals, although subject to significantly higher cleaning standards than other premises (e.g. office or domestic premises) are not sterile. Hospitals have a large volume of people (staff, patients and visitors). Hospital surfaces, which are subject to cleaning regimes, are not sterile. Hospital water and air, which are filtered, are not sterile.
- 15. Patients do get infections as they are susceptible (as noted above). As hospitals are not sterile, they inevitably can be and will be a source of infection. However, determining whether the hospital is, in fact, the source is not straightforward and even if it is, this does not mean that the particular infection was avoidable. This will be explored later in this Paper.
- 16. As it is difficult to determine whether the hospital (or healthcare setting) may be the source in any particular case, in order to be able to carry out surveillance, assumptions must be made. The term originally used was nosocomial², but this has since been replaced

² Derived from the Greek *nosokomos* meaning "one that tends the sick".

by the terms hospital acquired infection (HAI) and healthcare associated infection (HCAI). These terms are defined and set out below, per the slides previously provided to the Inquiry. As can be seen the defining characteristic is the timescale in which the infection develops and that neither definition indicates causation.

17. Once a micro-organism enters a susceptible body, it will multiply and this process takes time for there to be a sufficient amount of growth before a clinical infection has developed. This incubation period, meaning the time duration between exposure to the pathogen and the appearance of disease symptoms, varies significantly depending on the particular micro-organism. Although the definition of HAI sets the cut-off as 48 hours from admission, the incubation period for the infection is often uncertain and can be significantly longer: for example, the incubation period for *Cryptococcus neoformans* infections can be up to 102 days and can be much longer when latency and dormancy is taken into account.³ Also these definitions include periods when the patient may have been exposed outwith the healthcare setting, for example whilst at home or in the community. Therefore, these definitions are not helpful in attributing causation; this is not surprising as the definitions are deliberately conservative, and are designed to inform a precautionary approach to infection control.

Hospital Acquired Infections BSI

Positive blood culture obtained from a patient who has been hospitalised for ≥48 hours. If the patient was transferred from another hospital, the duration of in-patient stay is calculated from the date of the first hospital admission.

If the patient was a neonate / baby who has never left hospital since being born.

OR

The patient was discharged from hospital in the 48 hours prior to the positive blood culture being taken.

OR

A patient who receives regular haemodialysis as an out-patient.

OR

Contaminant if the blood aspirated in hospital.

OR

If infection source / entry point is surgical site infection (SSI). [This will be attributed to hospital of surgical procedure]

³ Report from the Cryptococcus Incident Management Team Expert Advisory Sub-Group by Dr John Hood.

Healthcare Associated BSI

Positive blood culture obtained from a patient within 48 hours of admission to hospital and fulfils one or more of the following criteria:

Was hospitalised overnight in the 30 days prior to the positive blood culture being taken.

OR

Resides in a nursing, long-term care facility or residential home.

OR

IV, or intra-articular medication in the 30 days prior to the positive blood culture being taken, but excluding IV illicit drug use.

OR

Had the use of a registered medical device in the 30 days prior to the positive blood culture being taken, e.g. intermittent self-catheterisation or Percutaneous Endoscopic Gastrostomy (PEG) tube with or without the direct involvement of a healthcare worker (excludes haemodialysis lines see HAI). OR

Underwent any medical procedure which broke mucous or skin barrier, i.e. biopsies or dental extraction in the 30 days prior to the positive blood culture being taken.

OR

Underwent care for a medical condition by a healthcare worker in the community which involved contact with non-intact skin, mucous membranes or the use of an invasive device in the 30 days prior to the positive blood culture being taken, e.g. podiatry or dressing of chronic ulcers, catheter change or insertion.

The approach of infection control and prevention (IPC) Teams

18. As noted above, if a patient develops an infection, determining if the interaction with the hospital or healthcare setting was, in fact, the source is not straightforward: whether that be from other people in the hospital (such as staff or visitors); a moveable item (such as a toy, a newspaper, or a scalpel); or the built environment (such as a shower head or tap outlet). The approach of the IPC Team is based on these defined HAI and HCAI surveillance parameters as governed by the National Infection Prevention and Control Manual ("NIPCM"), in which it will be assumed the hospital is the source until this can be ruled out. Mitigation measures are often implemented before the results of any investigations into the source of the infection are known. This approach is necessary in order to ensure infection rates are as low as reasonably practicable. IPC Teams therefore essentially operate on a reverse burden of proof, the standard of which is high, as noted above. The Case Note Review, as is to be expected from IPC practitioners, adopted a reverse burden of proof as is set out in their report at section 3.6.6.⁴

⁴ At page 44 of the Overview Report: "For cases that we considered to be Unrelated to the hospital environment, we agreed either that key issues such as a (relative) lack of opportunity to acquire bacteria from the hospital environment over a period of time consistent with the development of bacteraemia, and/or strong alternative hypotheses about the origin of the bacteraemia, had to be present."

19. Accordingly, having regard to the surveillance parameters applied by IPC practitioners, particular care must be taken when considering the views expressed by them when seeking to determine whether the source of any particular infection may have been attributable to a hospital built environment.

Questions Posed by the Inquiry

20. Turning to the questions that the Inquiry has posed, and taking each in turn, there are a number of aspects that must be considered.

(a) Was the built environment in an unsafe state in that it presented the opportunity for pathogens to come into contact with patients?

- 21. What is "unsafe" or "an unsafe state"?
- 22. As described above, the built environment is not sterile and therefore the microorganisms in the built environment will come into contact with patients. As a consequence, in any acute hospital setting there will always be an unavoidable background rate of infection; this issue is considered in detail at paras 39- 45 below. Further, with any building that is in use there will be localised operational or maintenance issues that require to be addressed. To that extent, it may always be said of any hospital environment that its built environment is "unsafe".
- 23. What is assumed, therefore, is that the question which is posed is intended to ascertain whether it is accepted that the built environment of the hospital was "unsafe" in the sense that there existed at the relevant time systemic or widespread issues relating to the built environment which, as a consequence, resulted in an increased level of exposure to micro-organisms, and manifested in an increased rate of infections from environmental micro-organisms found in the built environment. Given the remit of the Inquiry to explore the extent to which ventilation and water issues impacted adversely on patient safety, these issues are the principal focus in considering the question of whether the built environment was "unsafe" in the sense that we understand the term to be meant.

Technical approach

24. There are broadly two approaches that can be taken to attempt to answer this question from a technical perspective. The first approach is whether the design met the relevant technical standards or guidance, but this approach relies on the assumption than non-compliance is the same as being "unsafe" which may not be supported by evidence. The second approach is whether testing of the systems provides evidence of any widespread issues.

Ventilation

- 25. There has been no factual evidence placed before the Inquiry thus far of any suggested link between ventilation and any known case of infection. Very little evidence has been led thus far on patient experience related to ventilation: the evidence led at the September- November 2021 hearings on the experience and perceptions of patients and families referenced concerns about ventilation at the QEUH in the briefest of terms, with concern about sources of infection associated with water being the predominant theme. Similarly, the Case Note Review and the Oversight Board Report focus primarily on issues surrounding water safety and infection. However, specific concerns were raised by the whistle-blowers as to the adequacy of ventilation in the QEUH, with particular focus on its role in the infection with *Cryptococcus neoformans* of two patients who died whilst being treated at the QEUH.
- 26. There is an absence of standards or guidance on the testing of air quality in hospitals. Thus, in relation to ventilation, the question of whether or not the design met the relevant technical standards or guidance is the only question which is applicable. The Inquiry has heard evidence in relation to guidance pertaining to ventilation systems, notably the guidance as set out in SHTM 03-01.⁵ It is important to note that, in terms of its status, SHTM 03:01 is peer produced guidance which is there to support, rather than replace, appropriate management and engineering expertise, and compliance with its guidance is not mandatory.⁶ Whilst it is accepted that ventilation on wards within QEUH did not comply with SHTM standards, there remains, however, a question about the practical effect of that non-compliance, if any, from the perspective of infection prevention and control and patient safety.
- 27. In that regard, it is important to note that, in evidence, microbiologist Professor Humphries questioned the evidential basis for the standards as set out in SHTM 03-01 from a microbiological perspective. In particular, he questioned in evidence what scientific basis exists for the rate of air changes being as they are in the guidance and advised the Inquiry that there is no precise science that he is aware of which sets rates of air changes per hour as they appear in SHTM. Whilst acknowledging the importance of ventilation in preventing infection, he took a more holistic view in relation to infection prevention and control and emphasised that ventilation is just one aspect in what should be a series of measures in place to prevent infection, including the use of prophylaxis. In addition, he noted that the relevant standards appear to have been derived from research carried out by Dr Owen Lidwell in 1972, at a time when hospital wards tended to be configured as

⁵ Scottish Health Technical Memorandum: Ventilation for Healthcare Premises 03:01.

⁶ Edward McLaughlin, HFS engineer; statement May 2022 hearing.

Nightingale wards and long before the more recent prevalence of single bedrooms on wards, which is preferred from an infection prevention and control perspective.⁷

- 28. Therefore, where there is a deviation from the guidance as set out in SHTM 03:01, it is far from evident that any such deviation would render the hospital "unsafe". There is no evidence to support why SHTM proposed minimum ventilation requirements are as they are, and there is nothing to suggest that particular rates of air changes themselves have any direct impact upon rates of infection. This has been examined specifically in relation to Ward 4C by Dr Samir Agrawal⁸, who concluded that although the ventilation system serving Ward 4C does not meet the SHTM 03-01 there is no evidence of a material increase in the risk of airborne infection as a result, a position which is supported by the low rates of documented airborne infections.⁹
- 29. In relation to the two patients who suffered infection with *Cryptococcus neoformans*, ventilation arrangements at the QEUH were subject to intensive and thorough scrutiny, in order to explore any and all hypotheses which could be considered to show a link between the patients' infections and the ventilation within wards 4C and 6A where these patients had been treated within the QEUH. The Cryptococcus IMT Expert Sub-Advisory Group was established and chaired by Dr John Hood, consultant microbiologist. Following extensive work, the group concluded that it was highly unlikely that the 2 affected patients had been infected with *Cryptococcus neoformans* as a result of the hospital environment: from around 3000 air samples which had been identified. Genotyping of the infection of the 2 patients in question showed that their cases were different genotypes. In particular, the hypothesis that *Cryptococcus* spores had been able to enter the air handling unit during a filter change in the plant room, and thereafter travel down duct work to wards 4C and 6A, was deemed to be unfeasible, not least because no filter changes had occurred during the index period of infection.¹⁰
- 30. Thus, there is no evidence that the ventilation arrangements in the QEUH could be described as causing or contributing to the built environment at the QEUH being fairly categorised as in an "unsafe state."

Water

31. The position in relation to water systems is, perhaps, more complex to illustrate from the perspective of NHS GGC, particularly given the focus and reported findings of the Case Note Review. The Inquiry has not yet heard evidence in relation to water systems. The

⁷ Professor Hilary Humphries statement and parole evidence to Inquiry, May 2022 hearing.

⁸ Consultant haematologist at St Bartholomew's Hospital, London.

⁹ Expert Report 18 May 2021.

¹⁰ Report from the Cryptococcus Incident Management Team Expert Advisory Sub-Group by Dr John Hood.

design of water systems is intended to limit the growth of micro-organisms, and there are specific requirements on water quality. In relation to the water system it is important to note that the design and commissioning was the responsibility of the contractor, Multiplex, and was checked by the Project Supervisor, Capita. Again, in adopting a technical approach to the question of whether water systems at the QEUH might be classified as "unsafe", and the two aspects of such an approach, consideration may be directed to (a) whether the system was compliant with any set standards or guidance, and (b) whether testing of the system has, in fact, revealed any widespread issues. Both approaches can be utilised here, however any failure to control microbial growth would require to be evidenced through testing. As such the second approach is the preferred approach.

- 32. The requirements on water testing principally relates to standards of "wholesomeness" at the time of commissioning and monitoring in certain areas of the hospital for particular organisms.¹¹ Requirements and guidance on water testing are limited to only a few organisms (namely coliforms, *E. Coli, Legionella* and *Pseudomonas*) and total viable counts (TVCs). In relation to TVCs, the guidance does not provide any acceptable limits.¹² Full details on the requirements and guidance on water testing, which NHS GGC has exceeded in relation to the QEUH since its opening in 2015, is provided in the report by Dr Dominique Chaput.¹³
- 33. There is no guidance on whether the presence of other micro-organisms in hospital water systems is acceptable. This means that where hospital water is tested for a different micro-organism, such as *Cupriavidus pauculus* and it is found, there is no guidance that would permit the result to be interpreted to show whether or not the water was "unsafe". Water systems, whether in hospitals, office buildings or domestic premises, are not routinely tested to ascertain the range of micro-organisms that are present.¹⁴ As water is not intended to be sterile, it would follow that it should be expected that water-borne micro-organisms would be present and this has been shown to be the case in other

¹¹ The Public Water Supplies (Scotland) Regulations 2014, SHTM 04-01, and Pseudomonas aeruginosa routine water sampling in augmented care areas for NHS Scotland (Health Protection Scotland, 2018 draft).

¹² In November 2022, HTM 04-01, the applicable standard for safety of healthcare water systems in England and Wales and the equivalent of Scotland's SHTM 04-01, was scrutinised in an Inquiry by the Coroner for Cambridgeshire and Peterborough, following the deaths of 2 hospital patients from mycobacteria infection. Amongst his findings, the Coroner made a recommendation to the Secretary of State for Health and Social Care that HTM 04-01 that required urgent review and amendment as it contains guidance only on the identification and control of legionella and pseudomonas and no other micro-organisms. See <u>Karen Starling and Anne Martinez</u> - <u>Prevention of future deaths report - 2022-0368 (judiciary.uk)</u>

¹³ Summary of legislation and guidance for routine microbiological water tests carried out at QEUH Adults and RHC by Dr Dominique Chaput, dated 9 December 2022.

¹⁴ ARHAI Report NHSScotland's Approach to Microbiological Water Testing dated July 2022.

hospitals.¹⁵ Therefore, no conclusion as to whether or not the water system was "unsafe" can be drawn merely from the presence of such micro-organisms.

- 34. However, the established guidance on testing can be used as a marker of water quality as a substitute for whether or not the water system is "unsafe". Testing carried out from 2015 onwards does not demonstrate that there is any noteworthy issue with water quality.¹⁶
- 35. If it is considered that seeking to answer this question from a technical perspective is not sufficient, an alternative approach can be taken, although that too is also not without its challenges.

Clinical approach

- 36. An alternative approach to ascertaining whether the built environment was "unsafe" is to look at whether any effect can be demonstrated, i.e. determine whether any harm (infections) have arisen. As described above, patients will get infections, and it is inevitable that some of these will have been due to micro-organisms acquired from the hospital built environment. This is particularly the case with immunocompromised patients. By way of example, a review of data from five London hospitals during 2009-2011 found that in 112 children with cancer there were 149 significant blood stream infection episodes involving 266 significant bloodstream isolates.¹⁷ This averages as more than one significant blood stream infection episode.
- 37. The key question therefore is not whether there have been infections that are linked to the built environment, but rather whether there is an increased rate of infections from micro-organisms related to the built environment.¹⁸ In theory, if there is an "unsafe state" then that should increase the level of exposure to micro-organisms and manifest in an increased rate of infections from environmental micro-organisms found in the built environment.
- 38. Infections are multifactorial. Whilst the questions that the Inquiry is seeking to answer focus on the source, differences in transmission and susceptibility/opportunity factors are

¹⁵ *Cupriavidus* spp. and other waterborne organisms in healthcare water systems across the UK<u>; T Inskter et al;</u> Journal of Hospital Infection 123 (2022) 80-86. It is also present in drinking water in Glasgow – <u>Khan et al. 2016</u>, <u>Chemosphere 152:132</u>, and <u>Khan et al. 2016</u>, <u>Environmental Processes 3:541</u>.

¹⁶ Microbiological testing of Water and Environmental Samples from QEUH 2015- 2020: Overview of sample numbers and test results; and Water Testing Summary for whole of QEUH campus 2015- 2020, both dated 3 March 2023 by Dr Dominique Chaput.

¹⁷ Calton EA et al. Pediatr Blood Cancer 2014;61(7):1239-1245.

¹⁸ It is the rate of infection, not the number of infections as is noted in the Closing Submissions by Counsel to the Inquiry at paras 192-193, that is relevant as a large hospital will have a higher number of infections and the QEUH is one of the largest acute hospital campuses in Europe.

just as significant (if not more so). Many of the patients and families who gave evidence at the evidential hearing in 2021 described having a central line. A central line breaches the body's primary barrier to infection (the skin), the entry point is a wound and the line itself is a foreign body directly into major blood vessels upon which bacteria can grow and travel. Changes in the type of device, the surgical technique of insertion, subsequent manipulation and care of that line can all impact the likelihood of the patient developing an infection regardless of the source.¹⁹ If an increased rate of infection from microorganisms related to the hospital environment can be shown, this does not of itself demonstrate that the built environment is "unsafe". It would be only an indicator that the built environment may be "unsafe" and further investigation would be required to establish the position as there may be a number of confounding factors present. For example, if a person, whether patient, staff or visiting family member, is unknowingly colonised by a micro-organism, they may show no signs of infection themselves. Contact between that person with a patient or patients within the hospital environment may then result in transmission of micro-organisms, causing infection. This may, in turn, result in an increase in rate of infection related to the hospital environment as a whole, without any issue with the built environment itself being a factor per se and without anything to suggest the hospital built environment could properly be described as "unsafe." The fundamental question is whether an increased rate of infections related to the built environment can be shown: if no increased rate can be demonstrated, that would be an indicator that the built environment is not "unsafe".

- 39. In order to evidence whether or not there is an increased rate of infection from microorganisms related to the built environment at the QEUH and RHC, this requires a comparison of infection rates against other hospitals to be carried out. There are a number of challenges with carrying out such an exercise. The main challenges are:
 - It is not straightforward to define what would constitute "environmental organisms" as very few organisms are found solely in environmental sources.²⁰
 - Infection rates will vary if the patient populations being compared are different. Factors such as the case-mix of patients and levels of deprivation are relevant. Patients from the Greater Glasgow area are generally more socially deprived and therefore have poorer health outcomes compared to the population as a whole due to factors such as smoking, alcohol, drug use etc. It would therefore follow that areas with high levels of ill health may also have higher rates of HCAIs. Also, in respect of a number of care services, such as paediatric cancers, QEUH and RHC

¹⁹ This was the subject of a significant quality improvement work from 2017- 2019, led by Chief Nurse for Paediatrics, Jennifer Rodgers, and has led to dramatic reduction in the central line associated blood stream infection (CLABSI) rate. See CLABSI QI presentation for ICG Subgroup (June 2021).

²⁰ It should be noted that the classification used by HPS/ARHAI in their Review of NHSGG&C paediatric haematooncology data (dated October 2019) was in fact "provided by the NHS GGC lead Infection Control Doctor" i.e. Dr Inkster, and her views are not necessarily shared by other microbiologists in NHS GGC.

are a tertiary centre and will therefore have the most complex and sick patients in Scotland. Again, a higher rate of HCAIs may be expected.

- 40. Notwithstanding these challenges, where comparative data exists or can be obtained, this can be a useful indicator. In particular, given that a higher rate at the QEUH and RHC might be expected for the reasons above, if these comparisons show that infections rates at QEUH and RHC are, in fact, in line with the rest of Scotland this would be a strong indicator that the built environment is not unsafe. The QEUH consists of five teaching hospitals combined into one: despite its sheer size, and its complex patient mix, infection rates at the QEUH compare favourably to national rates.
- 41. ARHAI collect infection data from all Health Boards in Scotland and have published quarterly reports on the rates of infection for certain organisms since at least Q4 2014.²¹ These reports define an expected "normal variation" and demonstrate that from Q4 2014 to Q2 2022 NHS GGC has been within the expected "normal variation" throughout, except for one occasion.²² The published data is for NHS GGC as a whole and not specific to the QEUH and RHC. NHS GGC asked ARHAI for specific information on the performance of QEUH and RHC and the response from ARHAI confirmed that the rates were still within these parameters.²³
- 42. ARHAI also carry out a periodic national point prevalence survey of HAIs across all of NHS Scotland. The last survey was conducted during September to November 2016. The overall prevalence of HAIs during this survey in the QEUH was 4% and in the RHC 3.6%, both lower than the national rate of 4.5%.²⁴
- 43. The ARHAI Review of NHS GGC paediatric haemato-oncology data²⁵ carried out a comparison with other health boards and found that the rate of positive blood cultures for the RHC during the period of June 2015 to September 2019 was lower for Grampositive organisms and that there was no difference for Gram-negative organisms or environmental organisms. The rate was higher for environmental plus enteric organisms, but this is due to a higher rate of enteric (i.e. gut) organisms and <u>not</u> environmental organisms. This may reflect the higher complexity of patients at the RHC who may be more prone to developing infections from their gut flora.

²¹ Available online at <u>https://www.hps.scot.nhs.uk/publications/</u>. The incidence rates provided are for meticillin sensitive *Staphlycoccus aureus* and meticillin resistant *Staphlycoccus aureus, Staphlycoccus aureus* bacteraemias, *Clostridium difficile* infection, and *Escherichia coli* bacteraemias. It should be noted that the methodology used to generate the funnel plots "are based on the same calculations as the control limits in SPC charts" - <u>https://learn.nes.nhs.scot/2470</u>.

²² Clostridioides difficile infection rate in Q2 2019.

²³ Appendix 1 - Summary of Patient Safety Indicators by Sandra Devine.

²⁴ Appendix 1 - Summary of Patient Safety Indicators by Sandra Devine.

²⁵ Report dated October 2019. See also Appendix 1 - Summary of Patient Safety Indicators by Sandra Devine.

- 44. The Case Note Review does not provide any comparative data on infection rates. The only comparison noted in the Case Note Review is in relation to adverse events and the Paediatric Trigger Tool. In this regard the Case Note Review concluded that "NHS GGC is comparable with reports from other tertiary care hospitals."²⁶
- 45. None of these comparison exercises indicate that, during the period with which the Inquiry is concerned, there was an increased rate of overall infection, or of infection from micro-organisms related to the built environment at the QEUH or RHC. Indeed, the ARHAI comparisons with other health boards found that infection rates at the QEUH and RHC are as good, if not better, than those of other NHS boards. The NHS GGC Director of IPC, Sandra Devine, has collated the information from the varying sources of these indicators, which is attached to this Paper at Appendix 1. Considering the patient population served by both hospitals, a very reasonable inference may be drawn from these findings that the built environment at the QEUH and RHC was not in an unsafe state during the period with which the Inquiry is concerned and, in fact, continues to be safe.

(b) If the built environment was in an unsafe state is there a link between infections suffered and the unsafe state of the built environment?

- 46. This question seeks to establish whether there is a causal connection between infections and an "unsafe" built environment. If infections are to be expected, the mere presence of such infections does not demonstrate per se that the built environment is "unsafe" or that there is a link.
- 47. In particular, as noted above, where there is no guidance or standards on the presence or absence of the particular types of micro-organisms that caused these infections it cannot be concluded that the built environment is "unsafe". Indeed, if an organism is known to be found in water, and the water is tested and the organism is found that leads to the question, so what? Furthermore, as noted above, there is no evidence of an increased rate of infection at the QEUH, a factor which would be required in order to evidence an "unsafe state". Accordingly, it is reasonable to conclude that the built environment is not "unsafe".
- 48. Should the alternative position be taken i.e. that for some, as yet unidentified reason it is considered that the built environment was in an "unsafe" state, establishing a link between that state and infections suffered is very difficult as any and all potential sources of exposure must be taken into account. The identification of an organism from a blood culture only identifies the species (e.g. *Staphylococcus aureus*) and not the actual causative organism itself. It is important to note that there is scope for error in this identification. Conventional identification methods, as used in a diagnostic laboratory, are significantly less accurate compared to whole genome sequencing e.g. 17 out of 155 (11%)

²⁶ Sections 3.4.5 and 8.6.2 of the Case Note Review Overview Report. See also commentary in 2 Report p.6.

of isolates identified as *Cupriavidus* spp. by the diagnostic laboratory were found to be different organisms on whole genome sequencing.²⁷ Taking an analogy of a shop being broken into and items being stolen, this is the equivalent of identifying that it was a human (*Homo sapiens*) who committed the offence. It does not identify which human it was and, in particular, does not assist if the alleged offence was committed in an area where humans are typically to be found (in the same way that many environmental organisms are ubiquitous e.g. *Cupriavidus* spp.).²⁸

- 49. The built environment is only one of the possible sources of micro-organisms to which patients are exposed, and it does not even represent the largest pool of micro-organisms (that being the patients themselves). Furthermore, in current medical practice patients are no longer confined to hospital for treatment, but have shorter periods as an in-patient with continuing treatment on a day case or out-patient basis. Even where a patient may be an in-patient for an extended period, patients are often allowed out of hospital "on pass". In the event of an infection occurring, however, it is only the hospital built environment in respect of which testing is carried out; none of the other possible sources are tested. As noted above, as incubation periods vary significantly and as the transmission of the micro-organism may not be direct (e.g. from outside the hospital, on the hands of a visitor, or that it has become part of the patient's own flora for a period prior to infection), identifying when, and the circumstances in which, a patient was exposed to a particular organism is not straightforward, in particular in the absence of comprehensive testing.²⁹
- 50. Taking all these factors into account, it is considered that, save in the two discrete cases to which reference has already been made, it would be difficult to conclude with any degree of confidence that an infection was causally linked to the built environment; in fact, quite the contrary.
- 51. Further, if there are circumstances in respect of an individual patient which could result in such a conclusion being made, given that, for the reasons previously stated, there will always be some infections caused by the built environment as it is not sterile, it is even more challenging to conclude that the infection was the result of an "unsafe state of the built environment". To put it another way, how can it be said that but for the "unsafe state of the built environment" the patient would not have developed the infection when the built environment will always be a potential source?

²⁷ 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, by Prof. A Leanord and D Brown, dated 18 Jan 2023. This was also shown to be the case in the publication by T Inskter et al (see footnote 15) where 4 out of 9 isolates identified by conventional methods as *Cupriavidus* spp. were found to be *Xenophilus aerolatus*.

²⁸ This is because the purpose of identifying the causative organism is so that appropriate treatment can be administered, not to identify the source of the infection.

²⁹ E.g. Report from the Cryptococcus Incident Management Team Expert Advisory Sub-Group by Dr John Hood.

52. It is against this background that Whole Genome Sequencing (WGS) is of critical importance to the issue of causation being considered by the Inquiry. WGS is a relatively novel tool, but is already recognised as the gold standard for the identification of microorganisms, and the analysis of possible outbreaks of infection. Reverting to the analogy given earlier, WGS provides the genetic fingerprint of the human who broke into the shop, which would allow the individual to be identified. In relation to the infections at the QEUH with which the Inquiry is concerned, comprehensive investigation, applying WGS, has been undertaken by Professor Alistair Leanord and Professor Tom Evans, in which the most common Gram-negative infections identified were examined, and it was found that no link could be shown between the built environment and those infections except for a single case of *Cupriavidus pauculus* in 2016.³⁰ It is considered that, in these circumstances, it cannot on any reasonable view be said that a single linked case of *Cupriavidus pauculus* (plus a single linked case of *Mycobacterium chelonae*) constitutes a built environment which was in an "unsafe state", in particular as these organisms are known to be present in drinking water in any event.³¹

(c) If the built environment was in an unsafe state has it now been addressed?

- 53. The findings narrated above, and the inferences to be drawn from them, would suggest that this question is redundant, but if a different view were to be taken, what constitutes an "unsafe" or safe state would need to be clearly defined, together with guidance on how that is to be assessed in order for this to be determined. No such definition or guidance currently exists.
- 54. Notwithstanding the findings above, consistent with the approach of IPC, NHS GGC has undertaken significant works to improve the environment at the QEUH and RHC. This has included a refurbishment of RHC wards 2A/B and an upgrading of the filtration on wards 4C and 6A from F7 level to F9 level. The improvement works are detailed in the responses provided to various RFIs.
- 55. Further, in relation to water treatment and testing, since 2018, the routine water sampling plan at the QEUH has been expanded and has coincided with the installation of the chlorine dioxide dosing system to eliminate bacteria in water. From 2018, all routine water testing now currently carried out across the QEUH adult hospital and RHC exceeds

³⁰ See footnote 27 regarding the Report by Prof. A Leanord. Reports by Prof. T Evans all dated 5 March 2023: Report on *Stenotrophomonas* Infection at Queen Elizabeth Hospital University Glasgow; Report on *Enterobacter* Infection At Queen Elizabeth Hospital University Glasgow; Report on *Cupriavidus* Infection at Queen Elizabeth Hospital University Glasgow. Separately as part of the IMT investigations, only one other case was also identified as being linked to the built environment, that being the case of Stevie-Jo Kirkpatrick who tested positive for *Mycobacterium chelonae* in 2019.

³¹ <u>https://www.sciencedirect.com/topics/agricultural-and-biological-sciences/mycobacterium-chelonae</u>. See also footnote 15 above.

requirements and recommendations set out in national guidance (where such guidance exists) in terms of testing frequency, locations tested (general as well as high risk), types of tests performed and thresholds to trigger action. Much of the routine testing carried out at these sites is bespoke to NHS GGC as there are no formal requirements and recommendations applicable to these tests.³²

(d) Whether it is NHS GGC's position that unless one can categorically confirm connection e.g. Stevie-Jo Kirkpatrick, then there is no basis to conclude that there may nevertheless be likely/very likely to have been a connection?

- 56. It is not NHS GGC's position that unless WGS confirms a link that there is *no* basis to conclude that an infection may be linked to the built environment. Every case will depend on its own facts and circumstances. However, for the reasons detailed above (which are non-exhaustive) without WGS (or another highly discriminative method of typing) it would be difficult to reach such a conclusion with any degree of confidence. This is particularly the case in the circumstances that arose in the RHC in 2018, where instead of there being multiple infections by a single species (akin to a standard outbreak), there were infections from multiple different genera and species.³³ In this regard, the ARHAI Report stated that the "data presented in this report do not provide evidence of single point of exposure".³⁴
- 57. Further, as noted above, even if it could be concluded, on the balance of probabilities, that a particular infection was linked to the hospital, it is accepted that such infections will always occur in hospital environments from time to time. In any hospital there will be a recognised "background rate" of infection. This renders it particularly difficult to then conclude that, where such a connection between a particular infection and the built environment is found to have existed, that an inference may be drawn that the built environment of the hospital was therefore in an "unsafe state" at the material time.
- 58. In relation to the importance of WGS in identifying the source of any infection, one of the arguments that has been made against it is that species of micro-organisms that exist in the environment are genetically diverse and therefore if no link is found then that can simply mean sampling failed to pick it up and is not evidence that there is no link.³⁵ It is true that species of micro-organisms in the external environment are genetically diverse (the level of diversity will depend on the micro-organism); however to say that this is the same in a hospital built environment is no more than an assumption as there is little published scientific literature which demonstrates the level of genetic diversity that exists

³² Summary of legislation and guidance for routine microbiological water tests carried out at QEUH Adults and RHC by Dr Dominique Chaput, dated 19 Dec 2022.

³³ The significance of this issue is a matter which has been considered by Prof. Al Leanord and about which he is able to provide further comment.

³⁴ HPS Review of NHS GGC paediatric haemato-oncology data, dated October 2019.

³⁵ This being the position of Dr Inkster and Dr Peters, but also the position expressed by the Case Note Review Overview Report at p.96.

within hospital built environments. Using a considerably more extensive data set than was available at the time of the Case Note Review, the work undertaken by Professor Alistair Leanord and Professor Tom Evans would indicate that there is, in fact, a more limited degree of genetic diversity within an individual hospital than might be expected to be seen in the community. Therefore if, using an appropriate data set, WGS demonstrates no link between a patient's infection and a micro-organism obtained from the built environment through sampling, then it is more likely than not that any such infection was unconnected to the hospital built environment. When considered against the analysis by Professors Leanord and Evans of this extensive data set, the proposition that a link could nonetheless exist, despite not having been demonstrated by WGS, would seem to be one of speculation rather than scientific foundation. Taking the argument that is being made against WGS to its natural conclusion, the suggestion would appear to be that, as sampling would never be able to definitively show the absence of a link, that WGS, as a consequence, has no value: that clearly cannot be right, in particular where extensive sampling has taken place.

- 59. In relation to the approach taken by the Case Note Review the following observations are made in addition to those already made earlier. Insofar as the issue of sampling is concerned (upon which the Case Note Review placed considerable reliance), it is important to recognise its obvious limitations, namely that the only potential source that was sampled following the discovery of an infection was the hospital built environment. Any other sources such as the patient, their visitors, staff and the patient's home environment (all of which represent larger pools of micro-organisms that the patient is exposed to) were not sampled, and it is considered that the absence of these potential sources having been considered, must inevitably undermine significantly any conclusion reached on the source of the micro-organisms.
- 60. For example, the genus *Klebsiella*, amongst other sources, is often present in surface waters used for human consumption or for recreational purposes and can survive in water distribution systems despite chlorination.³⁶ *Klebsiella* spp. is also is a normal commensal of the human intestinal tract.³⁷ *Klebsiella pneumoniae* has commonly been found as a coloniser in human stools and "is strongly linked to subsequent infection" as patients who are colonised are 4 to 6.9 times more likely to develop an infection compared to non-colonised patients.³⁸ In healthy individuals, there is a high clonal diversity of strains carried.³⁹ It is the second most prevalent Gram negative infection in the UK. *Klebsiella* was only isolated in 3 samples from 10,311 samples (of which 6,183 looked specifically for

³⁶ <u>https://onlinelibrary.wiley.com/doi/10.1002/tox.2540030512</u>.

³⁷ https://www.gov.uk/government/collections/klebsiella-species-guidance-data-and-analysis

³⁸ <u>Martin RM et al. Msphere. 2016 Sep-Oct;1(5):e00261-16</u> and <u>Gorrie et al. Clin Infect Dis. 2017 Jul 15;65(2):208-</u> 215.

³⁹ Lepuschitz S et al Front Microbiol. 2020 Nov 24;11:58108.

Gram negative organisms) taken from the water in the QEUH and RHC between 2015 and 2020.⁴⁰

- 61. In total, 30 infections of *Klebsiella* were examined by the Case Note Review and it was concluded that 10 were "Most Likely" to be associated with the environment and 18 were in other categories.⁴¹ Given (i) the vastly greater numbers of *Klebsiella* spp. organisms that form part of the normal gut flora compared to what may be present in the water system; (ii) that any presence of *Klebsiella* spp in the water system is of doubtful clinical significance;⁴² and (iii) that it has been shown that colonisation is significantly more likely to be the source, it is difficult to conclude that the most likely source was the water and not the patient themselves without such a link being demonstrated by WGS. It is not clear how the Case Note Review reached that conclusion in those 10 cases.
- 62. Finally, although the Case Note Review reaches conclusions as to the likelihood that infections were linked to the hospital environment, the Case Note Review does not define the criteria used to categorise the cases in relation to likelihood.⁴³ In the absence of such definition, it is difficult to attach any weight to the conclusions reached by the Review, in particular when taken together with the other observations and criticisms which have already been made elsewhere in this Paper.⁴⁴

Conclusion

63. It is the position of NHS GGC that, when the available evidence is set apart from theories and hypotheses as to the safety of the QEUH campus, notably those put forward by the "whistle-blowers", the suggestion that the built environment of the QEUH is "unsafe" in the sense that it poses, or has at any time ever posed, an increased risk of infection to its patients does not withstand scrutiny. The Board took advice from the Lead Infection Control Doctor, and external organisations, predominantly ARHAI, at all times in responding to all hypotheses which were put forward in relation to infection prevention and control and has conducted more extensive surveillance than any other NHS Board as a result. Each hypothesis advanced by the "whistle-blowers" as to the risks to patient

⁴⁰ Microbiological testing of environmental samples from the Queen Elizabeth University Hospital and Royal Hospital for Children, 2015-2020 by Dr Dominique Chaput, dated 3 March 2023.
⁴¹ At p.70 Table 5.4.

⁴² <u>https://onlinelibrary.wiley.com/doi/10.1002/tox.2540030512</u>. Note the abstract states "There is no evidence that waterborne *Klebsiella* play any significant part in the epidemiology of these hospital-acquired infections. *Klebsiella* in water supplies should therefore not to be considered a hazard to human health."

⁴³ These are not provided in the Case Note Review Overview Report. As NHS GGC does not have access to the individual reports for each case it is unknown whether these are provided for in those. Furthermore, the conclusions reached by the Case Note Review appear to be based on the subjective opinion of the authors (see p.56) and this opinion is heavily caveated (e.g. "it is not possible to state this with certainty" and "Neither phenomena prove that some of the bacteraemias had hospital environment sources, but the observations are consistent with this hypothesis").

⁴⁴ NHS GGC has provided separately a detailed response to the Case Note Review, which was submitted to the Inquiry in response to RFI 1 on 1 March 2021.

safety posed by the QEUH built environment have, on thorough and proper investigation, been demonstrated to be unsubstantiated.

64. As will be clear, there is no evidence to demonstrate any increased rate of infections within QEUH from micro-organisms related to the built environment. When looked at properly and scientifically, the evidence demonstrates that the QEUH and RHC campus provides a safe environment for its patients.

Peter Gray KC

and

Emma Toner, Advocate

5 April 2023.

Appendix 1 - Summary of Patient Safety Indicators by Sandra Devine

Introduction

The question posed on a number of occasions throughout all of the reviews has been did the estates issues in QEUH/RHC, impact on the safety of the patients who received clinical care within these buildings? The sequencing of organisms within clinical cases/environment is explored in reports elsewhere, however, this paper aims to describe what indicators we have that can provide some assurance that patient outcomes on this campus were as expected or in some instances better than expected. Although not as definitive as we would wish for, these indicators are used across NHS Scotland and could be considered collectively as a proxy for whole system performance. Certainly, at the very least, it places QEUH/RHC performance in terms of patient outcomes within the context of NHS Scotland as a whole.

In the background section it is proposed that several factors should be considered when we try to analyse how QEUH/RHC performs in the context of the significant challenges faced by this complex health care system and the current case mix in QEUH i.e. those most at risk of infection due to their vulnerability from across Scotland and how, despite this, these hospitals perform well when compared to other less complex systems when reviewing the limited data that we have available to us. In the absence of comparative data, this paper attempts to demonstrate the systems and processes in place and local outcomes if available.

Background

The Queen Elizabeth University Hospital, Glasgow, opened in April 2015. The campus has 1,860 beds with a full range of healthcare specialities, including a major emergency department/trauma centre. In addition to the 14-floor hospital building, the Royal Hospital for Children is situated on the campus. The hospital campus also retains a number of other services in adjacent facilities. This includes maternity services, the Institute of Neurological Sciences and the Langland's Building for medicine of the elderly and rehabilitation.

Regional/National Services QEUH (Main Stack)

The QEUH/RHC has a number of specialist services and deal with some of the most vulnerable patients in the west of Scotland. The following are housed in the main building:

- Renal inpatient services (only site in GGC with in-patient renal beds)
- Adult Bone Marrow Transplantation Regional Service
- Chimeric Antigen Receptor T (CAR-T) National Service
- Adult cystic fibrosis services Regional Service
- Infectious Diseases Regional Service
- Haematology Oncology Services
- 88 Critical Care Beds (42 beds in Edinburgh Royal Infirmary)

Regional/National Services RHC

The Royal Hospital for Children, Glasgow is one of the largest paediatric care centres in the UK and provides a wide range of complex medical, surgical, cardiac and mental health services to children across Scotland and indeed the UK.

- RHC is the Major Trauma Centre for children in the West Coast of Scotland. Regional Service.
- The Scottish Paediatric Cardiac Service (SPCS) is based at the Royal Hospital for Children (RHC) and is the tertiary referral centre for children and young adults with heart conditions. National Service.
- RHC provides a national tertiary service for children and young people with airway problems throughout Scotland. National Service.
- The Paediatric Neurosciences Unit provides a comprehensive array of diagnostic and support services for children and young people from all over the West of Scotland. Regional Service
- Paediatric Intensive Care Unit is one of the largest in the UK, bed numbers are double that of the Royal Hospital for Children and Young People in Edinburgh.

Social Deprivation

Below is a map produced by Scottish Index of Deprivation (2020) which clearly demonstrates areas of high deprivation (red) across the Scottish central belt. Public Health Scotland describes the impact of deprivation on health in that:

People who live in poorer areas in Scotland are more likely to die early from disease and have more years of ill health.

The Scottish Burden of Disease Study (2016) Deprivation Report shows that

- poorer areas have double the rate of illness or early death than richer areas
- people in Scotland's richest areas are more likely to live in ill health than die early due to ill health, and the number of years of life affected are much smaller

Comparing rates of illness across boards has always been problematic in Scotland because it has a diverse socio-economic spread. Patients from Greater Glasgow are more socially deprived and therefore have poorer health outcomes due to factors such as smoking, alcohol, drug use etc. Compared to the population as a whole. Illness in itself requires contact with healthcare and we know that anyone who received medical care is at greater risk of infection, it would therefore follow that areas with high levels of ill health may also have higher rates of healthcare associated infections.



Ref :Scottish Index of Multiple Deprivation 2020

✓ KEY							
All Deciles							
Most deprived 10% 2nd 3rd 4th 5th							
6th 7th 8th 9th Least deprived 10%							

Clinical Governance Review of Patient Safety and Clinical Indicators on the QEUH Campus

In order to ensure an assessment of clinical quality and safety provided at the QEUH Campus, a review of patient safety and clinical data and information was commissioned by the Board's Clinical and Care Governance Committee in 2021.

The report that is embedded below provides a summary of data and information relating to the Queen Elizabeth University Hospital campus. It brings together and considers information that is processed through the existing governance arrangements for services at the campus.

The report includes information and data covering the following:

- Clinical governance arrangements and the oversight of clinical quality
- Infection control data
- Hospital Standardised Mortality Ratio (HSMR)
- Scottish National Audit Programme (SNAP)
- Clinical Quality Publications

- Patient and carer feedback QEUH and RHC
- Incident reporting
- National Services

Item 06 - QEUH Update (combined).

This review would suggest that there is no indication that QEUH or RHC were exceptions in terms of the information available.

Infection Prevention and Control (IPC) Specific Indications and Systems

1. National Point Prevalence Survey of Healthcare Associated Infection (HAI) & Antimicrobial Prescribing (AMP) 2016 <u>National Point (nhs.scot)</u> (extract)

Healthcare associated infections (HAI) are a major public health concern and a significant cause of morbidity and mortality globally. The European Centre for Disease Prevention and Control (ECDC) estimates that 3.2 million patients develop a HAI every year in Europe. In 2011, it was estimated that one in twenty Scottish inpatients had an infection associated with healthcare delivered in a Scottish hospital. The inpatient cost of HAI originating in Scottish acute care hospitals was estimated to be £137 million a year with an additional 318,172 bed days required in order to care for patients with HAI; the equivalent of a large teaching hospital occupied for one year. A significant proportion of HAI are considered avoidable and prevention of these infections provides an opportunity to improve patient outcome and reduce unnecessary costs within healthcare systems.

Nationally it is considered that a robust and current evidence base that is specific to Scottish hospital settings is necessary to inform the development of local and national strategies to reduce HAI and contain antimicrobial resistance (AMR). National point prevalence surveys (PPS) are undertaken every five years in Scotland in order to take stock of the current epidemiological situation and to review local and national policy.

This study surveys every patient within the NHS Scotland in every ward for every type of hospital-acquired infection. This type of surveillance is resource intensive which is why it can only be carried out once every 5 years but does give information on where to target resources nationally to have the most impact.

The study aims to:

- a) Measure the specific types and overall prevalence of HAI.
- b) Measure the overall prevalence of antimicrobial prescribing and types of antimicrobials prescribed, as well as compliance with Scottish Antimicrobial Prescribing Group (SAPG) hospital-based empirical prescribing and surgical prophylaxis prescribing indicators.
- c) Describe the organisation of IPC and antimicrobial stewardship programmes.
- d) Identify priority areas for future interventions to prevent and control HAI, for antimicrobial stewardship and for future targeted incidence surveillance of HAI.

e) Contribute to the European Centre for Disease Prevention and Control (ECDC) prevalence survey and inform the European strategy to reduce HAI and antimicrobial resistance.

The overall prevalence of hospital-acquired infections in QEUH during this survey (2016) was 4%. The National rate was 4.5%. QEUH has some of the most vulnerable and complex patients in Scotland and, despite this, the rate was lower than the national average.

The Children's Hospitals throughout Scotland are sufficiently different that comparisons are less meaningful (Royal Hospital for Children Glasgow: 3.6%; Royal Aberdeen Children's Hospital: 0%; and Royal Hospital for Sick Children Edinburgh: 7.7% - ref Prevalence of HAI in Scottish acute inpatients 2016).

The anticipated 2021 survey was not undertaken due to the COVID 19 pandemic therefore, more recent data is not available for comparison. At this moment, it is unclear when this survey will be repeated.

2. Annual Operational Plan (AOP) targets - Standards on Healthcare Associated Infections and Indicators on Antibiotic DL (2022) 13 (Previously DL (2015)19 & DL(2019)23)

In October 2019, a letter was sent to NHS Scotland Boards on the required antibiotic use indicators and healthcare associated infection (HAI) targets (DL(2019)23). The standards and indicators were set as:

- a) A 10% reduction of antibiotic use in Primary Care (excluding dental) by 2022.
- b) The use of WHO Access antibiotics (NHSE list) ≥60% of total antibiotic use in acute hospitals by 2022.
- c) The use of intravenous antibiotics in secondary care defined as DDD / 1000 population / day will be no higher in 2022 than it was in 2018.
- d) Gram-negative bacteraemia (healthcare associated E. coli bacteraemia) (ECB): A reduction of 50% in healthcare associated infections by 2023/24, with an initial reduction of 25% by 2021/22.
- e) *Staphylococcus aureus* bacteraemia (SAB): Reduction of 10% in the national rate of healthcare associated SAB from by 2022.
- f) *Clostridioides difficile* infection (CDI): Reduction of 10% in the national rate of healthcare associated Clostridioides difficile infection, with (CDI) by 2022.

Percentage reductions in SABs, CDI and ECB were measured against individual NHS Scotland Boards' current levels, rather than taking a "best in class" approach as previously. The Directors Letter referenced above extended the time to achieve these standards to March 2023. Addendum 1 demonstrates the NHS GGC performance since the targets were introduced.

3. ARHAI Hospital Level Review of AOP in RHC/QEUH

In 2019, NHSGGC requested an external review of how QEUH and RHC performed against these targets when compared to similar types of hospitals; below is the response from Health Protection Scotland (HPS) (now ARHAI).

Hospital attributed cases of Clostridioides difficile infection (CDI), Escherichia coli bacteraemia (ECB) and Staphylococcus aureus bacteraemia (SAB) for 2016, 2017 and 2018 (Q1 to Q3) were compared to peer hospitals with similar patient population using funnel plot analysis. The Queen Elizabeth University Hospital (QEUH) and the Royal Hospital for Children (RHC) were not highlighted as an exception (rate above the 95% confidence limit) in any of the plots for 2016, 2017 and 2018 (Q1 to Q3).¹

4. HPS (ARHAI) Report November 2019²

The report summary and conclusions note:

- Approximately a third of cases of positive blood culture of environmental organisms had a polymicrobial episode.
- The data presented in this report do not provide evidence of <u>single point of exposure</u> and there is a need to continually monitor the risk in this patient population.
- All patients within this cohort are at risk from developing gram-negative bacterium due to their co morbidities and treatment plan.
- NHS GGC should consider current control measures around restriction on services for newly diagnosed patients, as there is no evidence from the HPS review of the data that supports the continued restriction of services.

Overall rates - The report notes that in comparison with other Health Boards:

- The incidence of positive blood cultures was lower for Gram-positive group throughout the time period. This includes the entire 2015-19 time period and the specific periods in question both Oct 2017 Sept 2019 plus Oct 2018 Sept 2019.
- There is an increase in gram negatives from 2017 2019. This is primarily driven by increase in enterics (enteric organisms are bacteria that exist in the intestines of animals and

The denominator was hospital level 'total occupied bed days (TOBDs)' using ISD1 data.

¹ The peer hospitals for QEUH were Aberdeen Royal Infirmary (ARI), Forth Valley Hospital (FVH), Glasgow Royal Infirmary (GRI), Ninewells Hospital (NWH), Royal Alexandra Hospital (RAH), Royal Infirmary of Edinburgh (RIE), University Hospital Crosshouse (UHC) and Western General Hospital (WGH).

The peer hospitals for RHC were Royal Aberdeen Children's Hospital and Royal Hospital for Sick Children. ECB and SAB cases were hospital attributed assigned through enhanced surveillance ECOSS webtool. For CDI cases were categorised through linkage with Scottish Morbidity records (SMR01) for a patient with CDI onset on day 3 or later following a hospital admission on day one.

Funnel plot analysis was based on an over-dispersed Poisson regression model.

² <u>HPS Website - Review of NHSGG&C paediatric haemato-oncology data (scot.nhs.uk)</u>

humans) rather than environmental organisms. Overall there is no difference in environmental organisms but there is an increase in environmental plus enterics. (? Population differences as not directly comparable or due to complex case mix, however logic would suggest that the more vulnerable the population the higher the risk of infection and both population and complex case mix were present in the cohort of children cared for in RHC).

Summary of data Presented in HPS (ARHAI) Report 2019 - Review of NHSGG&C paediatri	С
haemato- oncology data.	

	Gram Pos	Gram Negs	Environmental	Environmental & Enteric
June 2015	LOWER	No Difference	No Difference	HIGHER
– Sept 2019	RR 0.76 (0.70-	RR 1.18 (0.96-	RR 1.42 (0.94-	RR 1.86 (1.42-2.47)
(since	0.83)	1.42)	2.16)	P< 0.001
move to	P< 0.001	P= 0.07	P= 0.11	
Oct 2017	LOWER	HIGHER	No Difference	HIGHER
– Sept	RR 0.74 (0.66-	RR 1.31 (1.00-	RR 1.36 (0.77-	RR 1.70 (1.17-2.53)
2019	0.84)	1.73)	2.52)	P< 0.005
(2 yr	P< 0.001	P= 0.05	P= 0.39	
pendaj				
Oct 2018	LOWER	No Difference*	No Difference *	No Difference *RR
– Sept	RR 0.77 (0.64-	RR 1.23 (0.85-	RR 0.93 (0.41-	1.26 (0.74-2.18)
2019	0.93)	1.8)	2.23)	P= 1
(Last yr)	P< 0.005	P= 0.3	P= 1	

*Caution re small numbers

Note

The HPS report published in November 2019 <u>HPS Website - Review of NHSGG&C paediatric haemato-oncology data (scot.nhs.uk)</u> noted that 'In the last year following the move to QEUH (October 2018 to September 2019) there was no difference in the rate for Gram-negative group ... , environmental including the enteric group ... or environmental group ... however the rate was lower for the Gram-positive group ... '. This means that NHSGGC has equivalent or lower infections rates than the other sites in Scotland despite having a more complex case mix.

5. Report from the Cryptococcus Incident Management Team Expert Advisory Sub-Group

Cryptococcus neoformans is a fungus that lives in the environment throughout the world. People can become infected with *C. neoformans* after breathing in the microscopic fungus, although most people who are exposed to the fungus never get sick from it. *C. neoformans* infections are rare in people who are otherwise healthy; most cases occur in people who have weakened immune systems, particularly those who have advanced HIV/AIDS (CDC).

Since the opening of RHC/QEUH there have been two cases of *Cryptococcus neoformans* both in November/December 2019. This site provides healthcare for some of the most profoundly immunocompromised patients in the West of Scotland. There have been no cases before or since 2019 and over 3000 air, samples from the site have been analysed. None of the air samples have isolated this organism.

The report's rationale as to why it considered latency to be the most likely hypothesis is summarised below:

The very significant issue of dormancy and reactivation. The most probable hypothesis as concluded in the report from the sub group was that the patients acquired the *Cryptococcus neoformans* prior to their admission to the QEUH/RHC and the infection lay dormant until their immune system was sufficiently compromised by their co-existing conditions. The literature review supports this hypothesis. However, as reported in many other cases within the literature, due to the length of time that may have elapsed since first exposed and the complexity of how reactivation occurs, this is very difficult to prove.

Reasons why this was concluded:

Haemato-oncology patients with particular lymphoreticular malignancies (as both patients had) are not the only patients at risk of infections with *C. neoformans.* There are a wide variety of other diseases that predispose to this infection noting that the QEUH/RHC is the biggest acute hospital in Scotland and will contain many patients who are/were at risk. If there is a fundamental issue, with the building why didn't other patients acquire *C. neoformans* either before or since? Infection caused by *Cryptococcus neoformans* is a rare disease in adults and even rarer in children. Commoner in males than females - twice as common in males than females). Please also note that no cases of adult males in this cluster, or in the past 7 years. Why not, if adult males are most at risk?

Nosocomial (hospital-acquired cases) cases are very very rare (worldwide). Only one other cluster of *C. neoformans* infection in hospitalized patients has been reported in the literature. In Arkansas in 2013, six patients in a community hospital developed blood stream and respiratory infections. Bird habitats at the hospital and staff who had contact with birds were investigated, but no definitive source was established, and environmental sampling was negative. Isolates from the clinical cases appeared genetically diverse, as three separate MLST (multilocus sequence typing) types were identified.

Please note that the Genomics of the above 2 cases and 2 others from the community (in Greater Glasgow & Clyde, around the same time) showed 4 completely different Genotypes.

There were no environmental isolates of *C. neoformans* found, within or near, QEUH/RHC in some 3000 air samples.

The adult case was cared for in ward 4c. Ward 4C has a cohort of renal beds and carries out in the region of 140 Renal Transplants per year. Note that there has never yet been any cases of *Cryptococcus neoformans* infections in any of these patients. Again, why not? as this group of patients are at risk of contracting *C. neoformans* infections.

As stated in the introduction to this section, the aim of healthcare ventilation is to mitigate the risk of airborne pathogens but it can never eliminate this risk. The sections on aspergillus, specifically the findings of the HIS review and the report by Dr J Hood on *C. neoformans* demonstrate that the procedures and processes that are in place are safe and that in the case of *C. neoformans* the report from Dr Hood dismisses the possibility that the air within QEUH was a source in this incident.

6. Summary

The question posed at the beginning of this paper was "did the estates issues in QEUH/RHC impact on the safety of the patients who received clinical care within these buildings?". This paper is a summary of what we can say with regards to patient safety using the indicators that are available. The data presented show that QEUH had lower rates of hospital acquired infection than other hospitals in Scotland, that WGS has not supported links to the environment (water and air) that our population is vulnerable due both to deprivation and the resulting ill health associated with deprivation. The context of health provision must also be considered in that GGC provides new, innovative, national services that often require more creative, complex, aggressive or invasive techniques to cure patents of disease that unfortunately often has, as an unintended consequence, an increased risk of infection.

The ARHAI definition of High Risk (of infection) units are³:

- Heamatology
- Oncology
- BMT
- Stem cell transplant units
- Neonatal Units
- Paediatric ICUs
- Adults ICUs
- Any other care areas where patients are severely immunocompromised through disease or treatments*.

QEUH Campus has <u>all</u> of the services above and the following services where patients are considered to be immucompromised:

³ www.nipcm.hps.scot.nhs.uk/media/1680/2019-08-water-incidents-info-sheet-v1.pdf

* Renal Inpatient Beds, Cystic fibrosis in patients (adults and children), ID in- patient and it is also the West of Scotland Trauma Centre (adults and children).

All of this information should be considered collectively and should provide a global overview of patient outcomes.

Addendum 1

There have been several significant changes to the reporting and presentation of CDI, ECB and SAB in the timeframes and an explanation of this is included in the graphs below. This demonstrates reduction in key infections over a prolonged period of time with continuous improvement demonstrated.

Staphylococcus aureus bacteraemia (SAB)

The line graph below (fig.1) displays the total number of SAB cases each quarter from December 2005 (n=230) to December 2019 (n=91). This equates to a 60% reduction in cases over 12 years. The linear trendline in the graph also shows the decrease in case numbers to date. From Quarter 1 2020 only healthcare associated infection (HCAI) cases are displayed and the dotted orange line is the HCAI standard aim of a reduction of 10% of HCAI cases to be achieved by March 2023 (based on individual NHS Board status at March 2019). We have estimated this to be 69 HCAI cases or less per quarter.



Fig.1 S.aureus bacteraemia cases in NHSGGC Q4-2005 to Q4-2022

Figure 2 displays the rate of SAB with corresponding bed days. The numerator of cases changed as explained above (all cases then healthcare associated cases only), however the bed day rate methodology also changed with reporting from Q2 2017. From 2005 until this point, occupied bed day data used different national definitions for the individual reporting of SAB (Acute Occupied Bed Days) and CDI (Acute and Non-acute Occupied Bed Days). The inclusion of E.coli bacteraemia surveillance in 2017 provided a revised and standardised approach by using the same occupied bed day data for all three measures (OBD). Community onset cases would now be reported separately from Healthcare Associated cases using the denominator rate of cases per 100,000 health board population. Bed day and population data is provided by ISD (a division of National Services Scotland).Dual reporting of rates was undertaken from this period and retrospective HCAI rates were published by Health Protections Scotland (now ARHAI).

HEAT target reductions for SAB were established in 2007, initially with a 35% reduction in cases, however a defined reduction rate of 26 cases per 100,000 acute occupied bed days was to be achieved by March 2013, and then a further reduction to 24 cases per 100,000

AOBDs. In October 2019, three HCAI standards were introduced for implementation in 2020. For SAB, this was a reduction of 10% in Healthcare Associated cases by March 2022. This is currently extended until March 2023.



Fig.2 S.aureus bacteraemia rate per 100,000 bed days in NHSGGC Q4-2005 to Q3-2022 (Q4 data not available at time of report compilation)

Clostridioides difficile Infection (CDI)

Reporting methodology for CDI has also changed, with data on cases aged 65 and over first reported in Q4 2006. Inclusion of cases in ages 15 to 64 were reported from Q2 2009 onwards, however different occupied bed day data were used for both age groups. CDI cases from out with the hospital setting were also included (GPs, care homes, hospices etc.)

From the first quarter of 2007 (n=472) to the end of 2019 (n=81), there has been a reduction of 83% in CDI cases. The dotted trendline in Figure 3 highlights this significant reduction.

As with SAB, from 2020 only HCAI cases are included, with the current 10% reduction aim to be attained by March 2023. This equates to 51 cases or less per quarter.



Fig.3 C.difficile cases in NHSGGC Q1-2007 to Q4-2022

Figure 4 displays the variations in national reporting since 2007. It should be noted that NHSGGC have been on or below HEAT/HCAI standard aim over this period.



Fig.4 C.difficile rate per 100,000 bed days in NHSGGC Q1-2007 to Q3-2022 (Q4 data not available at time of report compilation)

Escherichia coli bacteraemia (ECB)

National enhanced surveillance of *E.coli* bacteraemia commenced in Q3 2016 and healthcare associated cases account for just over half of all NHSGGC cases to date (3496 compared to 3225 community associated cases). Many ECB cases are not amenable to quality improvement

reduction measures e.g. hepatobiliary, therefore there has been a slower reduction of cases in the past six years.



Fig.5 E.coli bacteraemia cases in NHSGGC Q3-2017 to Q4-2022

The HCAI standard for ECB is a reduction of 25% in Healthcare Associated cases by March 2022. This is currently extended until March 2023. This remains a challenging aim for NHS Scotland as a whole.



Fig.6 E.coli bacteraemia rate per 100,000 bed days in NHSGGC Q3-2016 to Q3-2022 (Q4 data not available at time of report compilation)

Appendix 5

NHS GGC response to SHI Provisional Positioning Paper 5 – History of Infection Concerns (PPP5 – HOIC) dated April 2023

SCOTTISH HOSPITALS INQUIRY

RESPONSE TO PROVISIONAL POSITION PAPER 5 OF THE INQUIRY

ON BEHALF OF

GREATER GLASGOW HEALTH BOARD

- 1. Greater Glasgow Health Board ('NHSGGC') welcomes the opportunity to comment on Provisional Position Paper 5 ('PPP') of the Inquiry, circulated on 20 March 2023, and notes that, as matters stand, the Paper is a work in progress which may be added to as the Inquiry's understanding of matters develops. In its response, NHSGGC seeks to address the 5 questions as posed by the Inquiry in the PPP and to offer clarity on those matters which it disputes and its reasons for doing so.
- 2. It is noted that the principal purpose of the PPP is to set out the Inquiry's understanding of events and issues that have been said to indicate concerns about: (i) the incidence of infection within the QEUH campus; (ii) the safety of key aspects of the built environment (notably the water, drainage and ventilation systems); and (iii) the possibility of links between infections and concerns about the built environment. Whilst it is stated that the narrative sets out the Inquiry's present understanding in relation to these matters, there is little or no analysis put forward as to the substance of any of these concerns.
- 3. In particular, it is common for patients to get infections especially if they are immunocompromised and not all infections are preventable. The PPP does not set out why the "episodes of concern" are outwith what would ordinarily be expected in a hospital environment.
- 4. With reference to those concerns, NHSGGC does not accept that, on the basis of the evidence currently available, any aspect of the water, drainage or ventilation systems in the new QEUH and RHC buildings ('QEUH') has posed a risk to the safety of patients beyond that which may reasonably be expected in any comparable hospital environment. As hospitals are not sterile environments, in any hospital there will be infections that may be linked to the hospital environment. With the exception of two discrete cases of

paediatric infection in 2016 and 2019, NHSGGC does not accept any suggestion that there was any direct transmission link between the built environment and any infection suffered by a patient within the QEUH in relation to the "episodes of concern".

5. The PPP notes that the paper "is based upon publicly available and other prominent reporting and it also takes into account certain of the Inquiry's investigations across its various work streams." However, the paper does not, on the face of it, appear to have taken into account information submitted by NHSGGC.

Whether the narrative is accepted as an accurate history of what occurred

- 6. NHSGGC acknowledges that this PPP is a work in progress and will be adapted as the Inquiry's understanding develops. However, at this stage, NHSGGC wishes to emphasise that it considers that the timeline does not give the full picture of its response to the "episodes of concern". In particular, there are gaps in the contextual information presented in the narrative regarding the investigation of what are referred to as "episodes of concern" which may create a false impression that NHSGGC did not respond appropriately to these concerns. To that extent, the narrative is not an accurate summary of events.
- 7. NHSGGC accepts the narrative in relation to the incidence of infections which patients suffered whilst being treated at the QEUH. However, the narrative is not accepted insofar as it sets out any link, whether explicitly or implicitly, between those infections and the water, drainage or ventilation systems at the QEUH. Whilst there is always some degree of risk from any built environment, the suggestion in the narrative that patients were exposed to an increased risk to their safety by any aspect of those systems at the QEUH, is not accepted by NHSGGC. The basis for NHSGGC's position on these matters is set out in full below.
- 8. It is clear from the narrative that reliance has been placed upon the timeline which was created by the Oversight Board. NHSGGC does not accept that the timeline created by the Oversight Board was created with full reference to proper source materials. NHSGGC does

not consider the Oversight Board timeline to be either accurate or reliable. In consequence, where the narrative has adopted the terms of the Oversight Board's timeline, there are often inaccuracies and incomplete information.

Whether other matters ought to be part of the narrative

- 9. The draft narrative as set out in the PPP provides a chronology of certain "episodes of concern". As a general comment, it would assist NHSGGC's verification of the chronology for reference to be made in the narrative to the sources of information or evidence which underpin the issues of concern as put forward in the PPP, in order that those sources of evidence upon which the Inquiry seeks to rely at this stage can be readily identified.
- 10. As indicated, NHSGGC does not accept that the narrative in its present form is reflective of the true picture of NHSGGC's response to the "episodes of concern". By way of example, reference is made throughout the PPP to meetings that took place following certain "episodes of concern". However, the meetings referenced are only a small number of the meetings that actually took place. Such meetings included meetings at Board level, together with AICC, BICC, AOMG, PAG and WRG meetings. Many of these meetings were attended by clinical specialists and external advisors.
- 11. Critically, the PPP does not set out the actions that were agreed and implemented as a result of those meetings. For example, it does not detail the input of clinical specialists in identifying, validating and implementing a strategy to manage potential infections. Those strategies included testing and cleaning. The adopted strategies were often devised with input from external bodies such as HPS. Further, the PPP does not detail NHSGGC's investigations in respect of the cause of infections at the QEUH which disavowed any direct transmission link to the built environment in relation to the "episodes of concern". Without this further detail, NHSGGC considers that the timeline provides no more than a partial picture in respect of the "episodes of concern".
- 12. As a result, NHSGGC considers that the timeline does not accurately reflect the investigation process and remedial work that was instigated as a result of the "episodes of concern".

Whether NHSGGC Health Board was aware of the events as set out in the narrative at the time they occurred

- 13. As summarised above, NHSGGC accepts the narrative insofar as it identifies the instances of infections. However, NHSGGC considers that it only provides a partial picture of NHSGGC's response to those infections. NHSGGC considers that, without that further detail, the PPP presents an incomplete and, accordingly, inaccurate chronology, both of the actions taken by NHSGGC as well as the time at which it became aware of the various issues raised in the PPP. NHSGGC will provide a chronology of events by issue, including NHSGGC's actions in relation to those issues. The chronology is not intended to be exhaustive but is intended to show where the chronology in the PPP requires further development.
- 14. The PPP primarily addresses certain "episodes of concern" that arose after the QEUH was handed over to NHSGGC on 26 January 2015. However, there are references in the PPP to matters that took place prior to handover. In particular, it is notable that reference is made to concerns raised by the Lead ICD about ventilation in 2014/2015. The nature of those concerns is not set out in the PPP.
- 15. The systems were designed with input of clinical specialists. A clinical output specification was prepared that was then captured in Employers' Requirements by the Lead Consultant, Currie and Brown. Those requirements were subject to peer review. The requirements then informed the design of the QEUH/RHC by the main contractor.
- 16. Clinical specialists were involved throughout the process. NHSGGC considers that that context must be provided in order to give a full chronology of NHSGGC's actions in relation to risk of infection from ventilation and water systems, otherwise it would appear from the PPP that the first clinical specialist involvement was in 2014/2015. That is not the case. The role of each of the entities involved in the design, build and commissioning phases, together with the clinical specialists who informed the design, needs to be understood in order to give the full picture of any concerns raised prior to handover and the validity of those concerns. As such, NHSGGC considers that the PPP is not, as currently drafted,

accurate. NHSGGC cannot therefore comment in this response on the accuracy of the PPP in respect of the times at which NHSGGC became aware of the "episodes of concern".

Whether any of the concerns about safety of the building systems are accepted as valid

- 17. Given the remit of the Inquiry to explore the extent to which ventilation and water issues impacted adversely on patient safety, these issues are the principal focus in considering the question of whether any concerns about the safety of the building systems can be accepted as valid.
- 18. At the heart of the consideration of safety of the building systems at the QEUH, as is clear from the PPP and the Inquiry's terms of reference, is the question of whether any aspect of the building systems caused QEUH patients to be exposed to increased risk of infection. With that in mind, NHSGGC seeks to highlight 2 points at the outset.
- 19. First, it is important for the Inquiry to distinguish facts from impressions and to have regard to evidence rather than speculation. Secondly, it should be acknowledged that no building is, or can be, an entirely sterile environment and hospitals are no exception. Hospital patients do get infections, particularly when such patients are immunocompromised. As hospitals are not sterile, they inevitably can be, and will be, a source of infection, even despite thorough infection prevention and control measures. Micro-organisms in the built environment will come into contact with patients and, as a consequence, in any acute hospital setting, there will always be an unavoidable background rate of infection. Indeed the background rate of infection would also be attributable to factors outwith the built environment, of itself, ought not to amount to an enhanced concern about the safety of the building systems.
- 20. Against this background, in addressing the question of whether there is validity to any perceptions or concerns about the safety of the building, the Inquiry is invited to consider2 questions in relation to both ventilation and water systems, namely: (i) whether the design met the relevant standard or guidance, where available at the time; and (ii)

whether testing of the system provided evidence of any widespread issues in the sense of having exposed patients to a risk of infection beyond that which may reasonably be expected in any comparable hospital environment.

Ventilation

21. There has been no factual evidence placed before the Inquiry thus far of any suggested link between ventilation and any known case of infection at the hospital. Further, whilst the PPP sets out a history of ventilation concerns, and makes reference to patients having suffered from airborne infections, there is no material referenced to demonstrate definitively, or even legitimately to imply, a causal link between the ventilation system and any cases of infection.

Standards/ guidance

- 22. The Inquiry has heard evidence in relation to guidance pertaining to ventilation systems, notably the guidance as set out in SHTM 03-01.¹ It is important to note that, in terms of its status, SHTM 03-01 is peer produced guidance which is there to support, rather than replace, appropriate management and engineering expertise, and compliance with its guidance is not mandatory.² It is accepted that general ventilation on wards within QEUH did not comply with SHTM standards in respect of the number of air changes per hour. However, the general ventilation on wards exceeded the guidance in relation to filtration. There remains, however, a question about the practical effect of that non-compliance, if any, from the perspective of infection prevention and control and patient safety.
- 23. Further, it is important to note that, in evidence, microbiologist Professor Humphries questioned the evidential basis for the standards as set out in SHTM 03-01 from a microbiological perspective. In particular, he questioned in evidence what scientific basis exists for the rate of air changes being as they are in the guidance and advised the Inquiry that there is no precise science of which he is aware that sets rates of air changes per hour as they appear in SHTM. Whilst acknowledging the importance of ventilation in preventing

¹ Scottish Health Technical Memorandum: Ventilation for Healthcare Premises 03:01.

² Edward McLaughlin, HFS engineer; statement May 2022 hearing.

infection, he took a more holistic view in relation to infection prevention and control and emphasised that ventilation is just one aspect in what should be a series of measures in place to prevent infection, including the use of prophylaxis. In addition, he noted that the relevant standards appear to have derived from research carried out by Dr Owen Lidwell in 1972, at a time when hospital wards tended to be configured as Nightingale wards and long before the more recent prevalence of single bedrooms on wards, which is how the QEUH is configured, and which is preferred from an infection prevention and control perspective.³

- 24. Reference is made in the PPP to the absence of HEPA filtration on wards throughout the QEUH. HEPA filtration was not a requirement. A safe environment could be achieved through other means, such as rooms at positive pressure in comparison to the corridor; this was confirmed by HPS in 2015.⁴
- 25. It is far from evident that any deviation from the guidance as set out in SHTM 03:01 would amount to a valid concern about the safety of the building. There is no evidence to support why SHTM proposed minimum ventilation requirements are as they are, and there is nothing to suggest that rates of air changes themselves have any direct impact upon rates of infection. This has been examined specifically in relation to Ward 4C by Dr Samir Agrawal⁵ who concluded that, although the ventilation system serving Ward 4C does not meet the SHTM 03-01, there is no evidence of a material increase in the risk of airborne infection as a result, a position which is supported by the low rates of documented airborne infections.⁶ The Inquiry is invited to have regard to his report.

Testing of system

26. The design, commissioning and testing of the ventilation system was undertaken by the Main Contractor, Multiplex. There are no standards or guidance on the testing of air quality in hospitals. There are, therefore, no properly considered parameters against

³ Professor Hilary Humphries statement and parole evidence to Inquiry, May 2022 hearing.

⁴ HPS SBAR December 2015.

⁵ Consultant haematologist at St Bartholomew's Hospital, London.

⁶ Expert Report 18 May 2021.

which the Inquiry can meaningfully assess whether concerns about ventilation systems have any validity in relation to the question of safety of the QEUH building.

- 27. However, as is highlighted in the PPP, specific concerns were raised by "certain MBs/ICDs" as to the adequacy of ventilation in the QEUH, with particular focus on its role in the infection with *Cryptococcus neoformans* of two patients who died whilst being treated at the QEUH. Following these concerns, ventilation arrangements at the QEUH were subject to intensive and thorough scrutiny, in order to explore any and all hypotheses which could be considered to show a link between the patients' infections and the ventilation within wards 4C and 6A where these patients had been treated within the QEUH.
- 28. The Cryptococcus IMT Expert Sub-Advisory Group was established and chaired by Dr John Hood, consultant microbiologist. Following extensive work, the group concluded that it was highly unlikely that the 2 affected patients had been infected with *Cryptococcus neoformans* as a result of the hospital built environment: from around 3000 air samples which had been taken from within or near QEUH at that time, no *Cryptococcus neoformans* spores had been identified. Genotyping of the infection of the 2 patients in question showed that their cases were different genotypes. In particular, the hypothesis that *Cryptococcus* spores had been able to enter the air handling unit during a filter change in the plant room, and thereafter travel down duct work to wards 4C and 6A, was deemed to be unfeasible, not least because no filter changes had occurred during their inpatient stay.⁷ The Inquiry is invited to have regard to the report of Dr John Hood which gives a detailed description of the sampling regime undertaken in the investigation of these *Cryptococcus neoformans* cases.
- 29. On this basis, it is the position of NHSGGC that any concerns about the ventilation arrangements in the QEUH lack validity in relation to the question of increased risk to patient safety when the matter is properly considered.

<u>Water</u>

⁷ Report from the Cryptococcus Incident Management Team Expert Advisory Sub-Group by Dr John Hood

30. The Inquiry has not yet heard evidence in relation to water systems. The design of water systems is intended to limit the growth of micro-organisms and there are specific requirements on water quality in relation to the water system. It is important to note that the design and commissioning was the responsibility of the contractor, Multiplex. The design was to comply with Employer's Requirements, subject to agreed derogations, which were prepared by the Lead Consultant, Currie and Brown, following input from clinical specialists.

Standards/ guidance

- 31. The requirements on water testing principally relates to standards of "wholesomeness" at the time of commissioning and monitoring in certain areas of the hospital for particular organisms.⁸ Requirements and guidance on water testing are limited to only a few organisms (namely coliforms, *E. Coli, Legionella* and *Pseudomonas*) and total viable counts (TVCs). In relation to TVCs, the guidance does not provide any acceptable limits.
- 32. There is no guidance on whether the presence of other micro-organisms in hospital water systems is acceptable. This means that, where hospital water is tested for a different micro-organism, such as *Cupriavidus pauculus*, and it is found, there is no guidance that would permit the result to be interpreted to show whether or not the water was "unsafe". Water systems, whether in hospitals, office buildings or domestic premises, are not routinely tested to ascertain the range of micro-organisms that are present.⁹ As water is not intended to be sterile, it would follow that it should be expected that water-borne micro-organisms would be present and this has been shown to be the case in other hospitals.¹⁰ Therefore, no conclusion as to whether or not the water system was "unsafe" can be drawn merely from the presence of such micro-organisms.

⁸ The Public Water Supplies (Scotland) Regulations 2014, SHTM 04-01, and Pseudomonas aeruginosa routine water sampling in augmented care areas for NHS Scotland (Health Protection Scotland, 2018 draft). ⁹ ARHAI Report NHSScotland's Approach to Microbiological Water Testing dated July 2022.

¹⁰ *Cupriavidus* spp. and other waterborne organisms in healthcare water systems across the UK; T Inkster et al; Journal of Hospital Infection 123 (2022) 80-86. It is also present in drinking water in Glasgow – Khan et al. 2016, Chemosphere 152:132, and Khan et al. 2016, Environmental Processes 3:541.

Testing of system

- 33. However, the established guidance on testing can be used as a marker of water quality in considering the question of the safety of the water system. Testing carried out from 2015 onwards does not demonstrate that there is any noteworthy issue with water quality across the QEUH campus. NHSGGC has exceeded the requirements as set out in the available guidance on water testing in relation to the QEUH since its opening in 2015. The Inquiry is invited to refer to the reports of Dr Dominique Chaput in this regard. ¹¹
- 34. Further, in relation to water treatment and testing, since 2018, the routine water sampling plan at the QEUH has been expanded and has coincided with the installation of the chlorine dioxide dosing system to reduce bacteria in water. From 2018, all routine water testing now currently carried out across the QEUH exceeds requirements and recommendations set out in national guidance (where such guidance exists) in terms of testing frequency, locations tested (general as well as high risk), types of tests performed and thresholds to trigger action. Much of the routine testing carried out at these sites is bespoke to QEUH itself as there continues to be no formal requirements and recommendations applicable to these tests. As above, reference should be made to the reports from Dr Dominique Chaput.¹²

Case Note Review

35. The PPP places reliance on the Case Note Review and its findings in relation to the likelihood of infections being linked to the built hospital environment. It is not accepted by NHSGGC that anything contained in the Case Note Review can properly justify any adverse inference about the safety of the water, drainage or ventilation systems at the

¹¹ Summary of legislation and guidance for microbiological water tests carried out at QEUH and RHC, dated 9 Dec 2022; Microbiological testing of Water and Environmental Samples from QEUH 2015- 2020: Overview of sample numbers and test results; and Water Testing Summary for whole of QEUH campus 2015- 2020, both dated 3 March 2023; all by Dr Dominque Chaput

¹² Summary of legislation and guidance for microbiological water tests carried out at QEUH and RHC, dated 9 Dec 2022; Microbiological testing of Water and Environmental Samples from QEUH 2015- 2020: Overview of sample numbers and test results; and Water Testing Summary for whole of QEUH campus 2015- 2020, both dated 3 March 2023; all by Dr Dominque Chaput

QEUH. NHSGGC has challenged the methodology of the Case Note Review and the basis upon which it reached its findings in a number of respects.¹³

- 36. In particular, the Case Note Review did not take account of Whole Genome Sequencing (WGS) which is of critical importance to the issue of causation of infection being considered by the Inquiry. WGS is a relatively novel tool, but is already recognised as the gold standard for the identification of micro-organisms, and the analysis of possible outbreaks of infection.
- 37. In relation to the infections at the QEUH in the period with which the Inquiry is concerned, comprehensive investigation, applying WGS and using a considerably more extensive data set than was available at the time of the Case Note Review, was undertaken in which the most common Gram-negative infections identified were examined, and it was found that no direct transmission link could be shown between the built environment and those infections except for a single case of *Cupriavidus pauculus* in 2016. The Inquiry is invited to have regard to the reports of Professor Alistair Leanord and Professor Tom Evans in this regard.

Comparative data

38. There is no evidence to indicate an increased rate of infections from micro-organisms related to the built environment at the QEUH over the period with which the Inquiry is concerned. As above, a background rate of infection within a hospital can always be expected. In considering whether an increased rate can be demonstrated, comparative data can be a useful indicator. Despite the sheer size of the campus, complexity of patient group and other demographic factors, comparisons show that infection rates at the QEUH are, in fact, in line with the rest of Scotland and, indeed, were during the period with which the Inquiry is concerned.

¹³ NHSGGC's response to the CNR report was submitted to the Inquiry under RFI 1 6

- 39. The Advisory Committee on Antimicrobial Resistance and Healthcare Associated Infection (ARHAI) (formerly Health Protection Scotland) collects infection data from all Health Boards in Scotland and has published quarterly reports on the rates of infection for certain organisms since at least Q4 2014.¹⁴ These reports define an expected "normal variation" and demonstrate that from Q4 2014 to Q2 2022 NHSGGC has been within the expected "normal variation" throughout, except for one occasion.¹⁵ The published data relates to NHSGGC as a whole, and is not specific to the QEUH. NHSGGC asked ARHAI for specific information on the performance of QEUH and the response from ARHAI confirmed that the rates were still within these parameters.¹⁶
- 40. ARHAI also carry out a periodic national point prevalence survey of HAIs across all of NHS Scotland. The last survey was conducted during September to November 2016. The overall prevalence of HAIs during this survey in the QEUH was 4% and in the RHC 3.6%, both lower than the national rate of 4.5%.¹⁷
- 41. The ARHAI Review of NHSGGC paediatric haemato-oncology data ¹⁸ carried out a comparison with other health boards and found that the rate of positive blood cultures for the RHC during the period of June 2015 to September 2019 was lower for Grampositive organisms and that there was no difference for Gram-negative organisms or environmental organisms. The rate was higher for environmental plus enteric organisms, but this is due to a higher rate of enteric (i.e. gut) organisms and <u>not</u> environmental organisms. This may reflect the higher complexity of patients at the RHC who are more prone to developing infections from their gut flora.
- 42. Accordingly, none of these comparison exercises indicates that, during the period with which the Inquiry is concerned, there was an increased rate of overall infection, or of

¹⁴ Available online at <u>https://www.hps.scot.nhs.uk/publications/</u>. The incidence rates provided are for meticillin sensitive *Staphlycoccus aureus* and meticillin resistant *Staphlycoccus aureus*, *Staphlycoccus aureus* bacteraemias, *Clostridium difficile* infection, and *Escherichia coli* bacteraemias. It should be noted that the methodology used to generate the funnel plots "are based on the same calculations as the control limits in SPC charts" - <u>https://learn.nes.nhs.scot/2470</u>.

¹⁵ *Clostridioides difficile* infection rate in Q2 2019.

¹⁶ Appendix 1 - Summary of Patient Safety Indicators by Sandra Devine.

¹⁷ Appendix 1 - Summary of Patient Safety Indicators by Sandra Devine.

¹⁸ Report dated October 2019. See also Appendix 1 - Summary of Patient Safety Indicators by Sandra Devine.

infection from micro-organisms related to the built environment, at the QEUH. Indeed, the ARHAI comparisons with other health boards found that infection rates at the QEUH are as good, if not better, than those of other NHS boards. NHSGGC collated the information from the varying sources of these indicators, which is attached to this Paper at Appendix 1. Considering the patient population served by both hospitals, a very reasonable inference may be drawn from these findings that the built environment at the QEUH was not in an unsafe state during the period with which the Inquiry is concerned and, in fact, continues to be safe.

- 43. It should be noted that the Case Note Review did not provide any comparative data on infection rates. The only comparison noted in the Case Note Review was in relation to adverse events and the Paediatric Trigger Tool. In this regard, the Case Note Review concluded that "NHSGGC is comparable with reports from other tertiary care hospitals."¹⁹
- 44. On the basis of all of these factors, NHSGGC does not accept that concerns about the safety of the water, drainage or ventilation systems at QEUH have any validity, on any proper reading of the available evidence.

Whether any of the suggested links between infection and the built environment are accepted

45. At para 3.4.1, the PPP narrates that, in January 2016, a patient tested positive for *Cupriavidus pauculus*. Further, it is narrated at para 6.31.1 that, in July 2019, a patient tested positive for infection with *Mycobacterium chelonae*. NHSGGC accepts that these 2 instances of infection were linked to the hospital environment, following typing which demonstrated a positive link between water and patient samples. With the exception of these 2 cases, NHSGGC does not accept that there is any direct transmission link between any case of infection and the water, drainage or ventilation systems at the QEUH.

¹⁹ Sections 3.4.5 and 8.6.2 of the Case Note Review Overview Report

46. As above, NHSGGC does not accept that any concerns about the safety of the QEUH water, drainage or ventilation systems have validity in relation to any bearing upon infection risk to patients. That being so, NHSGGC does not accept that any infections within the QEUH, with the exception of the 2 cases referred to, have any direct transmission link to the built hospital environment. In particular, NHSGGC does not accept that any infections have occurred within the QEUH as a result of any aspect of the water, drainage or ventilation systems posing, or ever having posed, an increased risk of infection to the QEUH patients.

Other matters

- 47. As referred to in paragraph 13 above, NHSGGC will provide a chronology of events which will include corrections to the timeline in the PPP and to highlight where relevant information has already been provided. NHSGGC has set out examples of inaccuracies in the PPP below.
- 48. It is stated throughout the PPP that "concerns were raised by ICDs and MBs." It would appear that these references in the narrative have been adopted from the timeline produced by the Oversight Board, the content of which is not accepted by NHSGGC as reliable or accurate, as stated above. It should be noted that, within the remit of the Infection Control Doctor, is to lead investigations into infections where they occur, including directing sampling, and to chair Incident Management Teams (IMTs). Throughout the operation of the various IMTs set up to investigate infection and their potential link with the hospital environment, all sampling for environmental organisms was reactive sampling, directed as a result of the relevant IMT and at the direction of the Chair of the IMT.
- 49. It is stated in the PPP at para 6.80.1 that the HSE served an improvement notice upon NHSGGC in December 2019. For context, it should be noted that the notice relates to the standard of ventilation on ward 4C. Further, NHSGGC has appealed against the notice and appeal proceedings are currently sisted before the Employment Tribunal.

- 50. At paras 7.6.1, 7.8.1²⁰ and 7.13.1, the PPP makes reference to a total of 3 journal articles, from August 2020, February 2021 and May 2021. Whilst the PPP does not state what conclusion is to be drawn from any of these articles, it should be noted that all 3 were authored by the "certain MBs/ICDs", one of whom is on the editorial board of the journal, who had raised concerns about the safety of building systems at the QEUH. Their relevance as independent or objective pieces of analysis requires to be viewed in that context.
- 51. The PPP states that the taps which were installed on all clinical wash hand basins across the QEUH and RHC were fitted with flow regulators, contrary to advice within the HPS SBAR. That statement does not reflect the true position in relation to these fittings. It should be noted that, upon the issue coming to light, NHSGGC requested a meeting with HPS to review the position. A meeting took place on 5 June 2014 and was attended by representatives of NHSGGC, HPS, HFS, Horne Engineering Ltd and Public Health England including Dr Jimmy Walker (a member of the Inquiry's expert panel). It was unanimously agreed by the representatives at the meeting, including HPS, that, as the taps installed within the new build development had complied with guidance current at the time of its specification and briefing, and as the hospital was in the process of being commissioned, it should be regarded as being in the "retrospective" category, not "new build". It was agreed that there was no need for NHSGGC to apply additional flow control facilities or remove flow straighteners within QEUH and RHC and that any residual perceived or potential risks would form part of the routine management process.
- 52. The PPP reflects a fundamental misunderstanding as to the formal investigation requirements in relation to *Klebsiella* infections. Paras 2.12, 3.7.1 and 5.4.1 make reference to cases of *Klebsiella* not having been investigated within the QEUH. At the time of the infections referred to, there was no requirement for infections of these types to be investigated, nor is there any such requirement to date. At para 6.16.1, reference is made to *Klebsiella spp* having been added to the list of alert organisms in 2018. This statement is incorrect: sensitive *Klebsiella* is not, and has not been, an alert organism within the National Infection Prevention and Control Manual and there is no requirement for

²⁰ Also referenced at para 3.4.2 of PPP

infections with such micro-organisms to be reviewed. *Klebsiella* is a normal commensal of the human intestinal tract. It is the second most prevalent Gram negative infection in the UK. *Klebsiella* was only isolated in 3 samples from 10,311 samples (of which 6,183 looked specifically for Gram negative organisms) taken from the water in the QEUH between 2015 and 2020.

- 53. In relation to para 1.5 of the PPP, the DMA Canyon report was received in 2015 by the former estates manager within NHSGGC. The findings of the report gave rise to the creation of an action plan by the estates manager, the delivery of which was delegated to two members of the estates team. At no time was the existence of the DMA Canyon Report concealed by the estates manager or NHSGGC, and, on its existence and contents being made known for the first time to more senior management in July 2018, it was immediately shared with a number of organisations including HPS, and the Lead ICD in her capacity as Chair of the IMT.
- 54. With reference to para 2.7.1, it should be noted that, over the period of those infections, 200 environmental swabs were taken within NICU, all of which were negative. In any event, the NICU is part of the retained estate and not part of the newly built hospitals. The NICU's water system is separate to that of the QEUH.
- 55. With reference to para 4.16.1, it should be noted that *Stenotrophomonas maltophilia* was only added to the National Infection Prevention and Control Manual alert organism list in June 2017. Further, the figure of 12 reported cases of *Stenotrophomonas maltophilia* in 2017 is not correct: the Case Note Review Table 4.2 shows 6 reported cases in 2017.
- 56. With reference to para 4.30.4, it should be noted that the results of environmental sampling were negative and, in particular, did not isolate *Acinetobacter baumanii*.
- 57. With reference to para 5.35.1, it should be noted that the spinal injuries unit is part of the retained estate and has a different water system from the new building.

58. The heading at para 6.1 of "CN identified in air samples in Ward 6A (January 2019)" is incorrect as it is known that no *Cryptococcus neoformans* was found in any of the extensive air sampling carried out in Ward 6A.

Conclusion

- 59. It is the position of NHSGGC that, when the available evidence is set apart from theories and hypotheses as to the safety of the QEUH, notably those put forward by the "certain MBs/ICDs", the suggestion that the built environment of the QEUH is unsafe in the sense that it poses, or has at any time ever posed, an increased risk of infection to its patients, does not withstand scrutiny. The Board took advice from the Lead Infection Control Doctor, and external organisations, predominantly HPS, at all times in responding to all hypotheses which were put forward in relation to infection prevention and control and has conducted more extensive surveillance than any other NHS Board as a result. Each hypothesis advanced by the microbiologists, ICDs, and the IMT as to the risks to patient safety posed by the QEUH built environment has, on thorough and proper investigation, been demonstrated to be unsubstantiated.
- 60. As will be clear, there is no evidence to demonstrate any increased rate of infections within the QEUH from micro-organisms related to the built environment. When looked at properly and scientifically, the evidence demonstrates that the QEUH is a safe environment for its patients.

Peter Gray KC, Emma Toner, Advocate and Andrew McWhirter, Advocate

21 April 2023