SCOTTISH HOSPITALS INQUIRY

Provisional Position Paper 5

The History of Infection Concerns (HOIC) for the Queen Elizabeth University Hospital Campus

Purpose of the Paper

As Lord Brodie explained at the official launch of the Scottish Hospitals Inquiry on 3 August 2020, the Inquiry was set up against a background of concerns over patient safety at the QEUH campus. He explained that patient safety, and the need for there to be public confidence that the QEUH did not compromise patient safety, would be at the heart of the Inquiry's work. The purpose of this paper is to set out the Inquiry's present understanding of that history of concern about patient safety: the history of concern that led to the Inquiry being instituted in the first place and any evidence of further or ongoing concern beyond that point.

This paper sets out in a chronological narrative the Inquiry's present understanding of the various issues and events said to indicate a concern that aspects of the built environment within the QEUH have caused, or created a risk of, infection to patients. The Inquiry's key questions are concerned with assessing whether there was or continues to be an objectively valid basis for the concern. But first the Inquiry must identify what the concern actually is. That is the purpose served by this paper.

The paper sets out the Inquiry's understanding of events and issues that have been said to indicate concerns about the following three matters: first, concerns about the incidence of infection within the QEUH campus, secondly, concerns about the safety of key aspects of the built environment (notably the water, drainage and ventilation systems) and, finally, concerns that there might be links between infections and the concerns about the built environment.

This 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 workstreams. It should be seen as being a work in progress. It may be added to as the Inquiry's understanding of things develops. In due course, Lord Brodie may be asked to make factual findings on matters covered by the finalised paper. CPs are therefore being given the opportunity to comment upon the paper. They should direct themselves to five matters:

(1) Whether the narrative is accepted as an accurate history of what occurred (and if not where the narrative is challenged and why);

(2) Whether CPs are aware of other matters that ought to be part of the narrative;

(3) An indication of whether CPs were aware of the events at the time that they occurred, and if not when they became aware;

(4) Whether any of the concerns about safety of the building systems are accepted by CPs as valid (and if not why not); and

(5) An indication by CPs of which if any of the suggested links between infection and built environment are accepted (and the basis upon which such links are accepted, or refuted as the case may be).

Contents

List of acronyms and abbreviations

Acronym/ Abbreviation	Definition
A	Aspergillus
AARG	Advice, Assurance & Review Group
AB	Acinetobacter baumanii
AC	Achromobacter spp
ACFG	Area Clinical Forum Group (?)
ACH	Air Change per Hour
AECOM	Architecture, Engineering, Construction, Operations, and Management
AHU	Air Handling Unit
AICC	Acute Infection Control Committee
ARHAI	Antimicrobial Resistance & Healthcare Associated Infection
ARU	Acute Receiving Unit
BBAL	Blind Bronchoalveolar Lavage
BICC	Board Infection Control Committee
BMT	Bone Marrow Transplant
BSI	Blood Stream Infections
BWSG	Board Water Safety Group
CA	Cryptococcus albidus
CCGC	Clinical and Care Governance Committee
CD	Chlorine Dioxide
CDU	Clinical Decision Unit
CEO	Chief Executive Officer
CF	Cystic Fibrosis
CFD	Computational Fluid Dynamics
CH	Chryseomonas
CHWB	Clinical Hand Wash Basins
CICD	Co-ordinating Infection Control Doctor
CLABSI	Central Line Acquired Blood Stream Infection
CN	Cryptococcus neoformans
CNO	Chief Nursing Officer
CNR	Case Note Review
CNR OR	Case Note Review Overview Report
CPE (Klebsiella)	Carbapenemase-producing enterobacteria (Klebsiella)
CPs	Core Participants
CU	Cupriavidus
CVL	Central Venous Line
DA	Delftia acidovorans
DSR	Domestic Service Room
E.coli	Escherichia coli

Acronym/ Abbreviation	Definition
EA	Enterobacter aeromonas
EC	Enterobacter cloaecae
ECOSS	Electronic Communication of Surveillance in Scotland
EM	Elizabethkingia miricola
F&E	Facilities and Estates
GGC	Glasgow and Greater Clyde NHS Health Board
GNB	Gram-negative bacteria
GOSH	Great Ormond Street Hospital
GPB	Gram-positive bacteria
GRI	Glasgow Royal Infirmary
HAI	Healthcare Associated Infection
HaN	Hospital at Night
HEPA	High Efficiency Particulate Air
HFS	Health Facilities Scotland
HH	Hand Hygiene
HIIAT	Hospital Infection Incident Assessment Tool
HPS	Health Protection Scotland
ICD	Infection Control Doctor
ICNET	Clinical Surveillance Software
ICU	Intensive Care Unit
IMT	Incident Management Team
IPCN	Infection Prevention Control Nurse
IPCT	Infection Prevention Control Team
IPS	Integrated Plumbing System
IR	Independent Review
LIMS	Microbiology Laboratory Information System
MA	Mycobacterium Abscessus
MB	Microbiologist
MC	Mycobacterium chelonae
MD	Medical Director
MDT	Multidisciplinary Team
NICU	Neonatal Intensive Care Unit
NIPCM	National Infection Prevention and Control Manual
NNU	Neo Natal Unit
OB	Oversight Board
PAG	Problem Assessment Group
Pan	Pantoea
PanS	Pantoea septica
PICU	Paediatric Intensive Care Unit
PMI	Project Manager Instruction
PO	Pseudomonas oleovorans

Acronym/ Abbreviation	Definition
PPVL	Positive Pressure Ventilation Lobby
Ps	Pseudomonas spp
PsA	Pseudomonas aeruginosa
PsP	Pseudomonas putida
QEUH	Queen Elizabeth University Hospital
RCA	Root Cause Analysis
RHC	Royal Hospital for Children
SBAR	Situation, Background, Assessment, Recommendation
SCN	Senior Charge Nurse
SCWSG	South Clyde Water Safety Group
SGHD	Scottish Government Health Directorate
SHTM	Scottish Health Technical Memorandum
SICPs	Standard Infection Control Precautions
SLWG	Short Life Working Group
SM	Serratia Marcescens
SOP	Standard Operating Procedure
SPC	Statistical Process Control (Charts)
spp	species (plural)
STM	Stenotrophomonas Maltophilia
SU	Schiehallion Unit
TBPs	Transmission Based Precautions
TCT	Teenage Cancer Trust
TCV	Temperature Control Valve
TVC	Total Viable Count

1. Episodes of concern that took place or commenced prior to handover or patient migration

1.1 Timeline

1.1.1 The hospital was handed over on 26.1.15. Patients were moved to the hospital from 27.4.15 to 1.5.15 in the case of adults and from 10.6.15 in the case of children.

1.2 Ventilation system concerns:

1.2.1 At various points in 2014/15, the lead ICD raised concerns about ventilation particularly in relation to the Adult BMT unit, the Paediatric BMT Unit and the Infectious Disease Unit.

1.3 Water system concern: taps

1.3.1 In March 2014, GGC sought guidance from HPS about the taps which had been procured for the new hospitals. The taps were not compliant with NHS Guidance (SHTM 04-01). Nor were they compliant with guidance which had recently been issued by HPS (*Guidance for neo natal units (NNUs) (levels 1,2 and 3) adult and paediatric intensive care units (ICUs) in Scotland to minimise the risk of pseudomonas aeruginosa infection from water*).

1.3.2 The cause of the non-compliance was the incorporation of 'flow regulators' in the design. The revised guidance was published because of the implication of flow regulators in a Pseudomonas outbreak in Northern Ireland in 2012, which resulted in neonatal deaths and prompted a review of policy in this area.

1.3.3 HPS produced an SBAR, dated 9 April 2014, which set out various ways to address the problem, and recommended in that SBAR that GGC either install the procured taps without the flow regulators in high-risk areas, or,

alternatively, instruct the contractor to install new compliant taps (i.e., not including a flow regulator in the design) in high-risk areas.

1.3.4 The Horne taps which were ultimately installed on all clinical wash hand basins across the QEUH and RHC were fitted with flow regulators, contrary to the advice within the HPS SBAR.

1.3.5 The taps which were installed were not compatible with the use of silver hydrogen peroxide, which was to be used in the commissioning process to sanitise the water system.

1.4 Water system concern: water testing results

1.4.1.1 In December 2014 and January 2015, the contractor arranged for testing of the water system. The results showed high Total Viable Counts (TVCs) and E. coli in the water. Water outlets with high TVCs were disinfected with silver hydrogen peroxide. Some water samples still failed the test after dosing had occurred. There is no evidence that further testing was undertaken. The Lead ICD reviewed the initial water results and water testing methodology, but there is no evidence that the final water testing results were presented to or reviewed by the lead ICD.

1.4.1.2 Between the end of January and June 2015, a flushing regime was instituted by GGC F&E staff, as well as agency staff, to ensure turnover of water prior to patient occupation.

1.4.1.3 Between April and December 2015 NHS GGC conducted testing of water outlets for Legionella only (in line with national requirements). The testing was carried out by two F&E managers with no training in taking samples. Sampling was taken from 500-600 sentinel points throughout the campus. The April test results showed positive results for Legionella species in certain areas. Between April and December 2015, some water samples were positive for legionella spp and had high TVCs. Where

positive samples were found, the area/outlet was disinfected until 3 consecutive samples were negative.

1.4.1.4 There is a suggestion (by some MB/ICDs) that Stenotrophomonas Maltophilia (STM) was isolated in water samples before or around the time that the hospital opened. That suggestion is supported by HPS, who reported that Cupriavidus, Pseudomonas and Stenotrophomonas Maltophilia isolates were identified in water samples in October 2015.

1.4.1.5 There is a suggestion by certain MBs/ICDs that concerns were raised about 'the water system' prior to the hospital opening.

1.4.1.6 That concern appears to be echoed in the report of the Independent Review, which records: "*the early occupation of the hospitals in 2015 accompanied concerns about…missing information particularly about water quality and management, and infection risk*".

1.4.1.7 There is a suggestion that GGC refused to accept handover of the hospital until sanitisation of the water supply was undertaken, standing concerns about the high level of TVCs. It is not known what action was taken in relation to this.

1.5 Water system concern: DMA Canyon report

1.5.1 DMA Canyon are a water specialist consultant. DMA produced a report, entitled "Legionella L8 Risk Assessment 2015 (pre-occupancy)", dated 29 April 2015. The report was received by NHS GGC in early-May 2015.

1.5.2 The report identified several significant concerns with the water system at that point including temperature control of the water system; installation of flexi-hoses and the associated risks of bacterial growth, and the lack of effective management, notably regarding communication and control of contractor activity at the point of handover. There was no formal

management structure, written scheme or protocols in relation to the management of the water system.

1.5.3 The report made a number of recommendations relating to the water system. In particular, the report recommended: (i) adjustments to water temperature control; (ii) the removal of 'dead legs' in the system, and (iii) the removal of debris from the water storage tanks.

1.5.4 The DMA report records that a sampling programme (testing for TVC, E. coli, coliforms and Legionella) was being conducted and that daily flushing and local disinfections were underway where positive results were found. Neither the sample results, nor the disinfection process was provided to DMA to review.

1.5.5 It does not appear to be disputed by NHS GGC that the DMA Canyon report was received in early-May 2015. It is not clear who within GGC saw or knew of the report's conclusions following its receipt; the author of the OB Timeline indicates that they understood GGC to say that the report had not been shared with "the senior management team or the F&E team or with IPCT".

1.5.6 The recommendations made within the report were not actioned prior to 2018. It is not clear why that occurred. The report (and possibly others) is said to have "surfaced" when papers were being provided to HPS/HFS. The report was not disclosed publicly until November 2019.

1.6 Other concerns: risks posed by demolition works

1.6.1 Prior to patient migration, concerns were repeatedly raised about the risks posed by treating immunocompromised patients at the new hospital due to the ongoing demolition and building work.

2. Episodes of concern that took place or commenced in 2015 after patient migration

2.1 Timeline: patient migration April-June 2015

2.1.1 Patient migration commenced with the Southern General Hospital Outpatient department move to the new campus on 27 April 2015. Migration of patients from the Western Infirmary, Victoria Infirmary, Mansion House Unit, and Gartnavel General Hospital commenced on the same date. On 1 May 2015, the Inpatient departments of the Southern General Hospital moved to the new campus.

2.1.2 On 10 June 2015, the Royal Hospital for Sick Children at Yorkhill moved in to the new RHC campus.

2.1.3 By 14 June 2015, the move by all units and hospitals to the new campus was complete.

2.2 Ventilation concerns by MB/ICDs

2.2.1 In June 2015, concerns were raised by the lead ICD about the absence of HEPA filtration and that the absence of such would be “potentially unsafe” as regards children presently cared for in facilities with HEPA filtration. Concerns were also raised about the absence of HEPA filtration in transplant rooms.

2.2.2 On 6 July 2015, the Acute Infection Control Committee (AICC) minutes record discussion “*around HEPA filters and the need to ensure air pressures are correct as the MB had reported there were some issues around slightly positive air pressures*”. One Microbiologist (MB) advised “*there are issues with ventilation in QEUH in a couple of areas and one room in particular*”.

2.2.3 There appears to be a dispute about the accuracy of the minute of the AICC meeting of 6 July 2015, and some dispute about the nature and extent of the issues which were raised.

2.3 ICD resignation (9 July 2015)

2.3.1 On 9 July 2015, the ICD with responsibility for the adult BMT Unit resigned. She explained that she had “major concerns regarding the specialised ventilated areas within QEUH and RHSC and the impact on patient safety”. ICDs had concerns about the availability of information relevant to the safety of the as-built ventilation and water systems.

2.4 **Ventilation in Ward 4B (adult BMT)**

2.4.1 In June 2015] the adult BMT had ‘high particle counts’ so the Unit was moved back to the Beatson in July 2015 whilst extensive refurbishment took place. The particle readings indicated that the isolation rooms intended for adult haemato-oncology patients (including potential BMT patients) were unsatisfactory and showed potential risk of infection by the airborne route. The readings demonstrated an increase in fungal counts, including Aspergillus.

2.4.2 The Ward 4B protective isolation rooms did not achieve the required air pressure differentials or air change per hour (ACH) rates required by the specification (and NHS Design Guidance).

2.4.3 By around July 2015, clinical staff were of the view that the adult BMT unit was not fit for purpose.

2.4.4 On 27 July 2015, the Board Infection Control Committee (BICC) minutes record that BMT patients have been transferred to the Beatson as the unit was not built to the correct specification. The main contractor had agreed to fund the rebuild for this area (Ward 4B). At the same meeting, concerns were again expressed about the continued treatment of

immunocompromised patients due to the scheduled demolition of the surgical block in September 2015.

2.4.5 Non-transplant patients remained at the Beatson for several weeks. BMT patients remained at the Beatson for over 2 years before returning.

2.5 PMI 424 (July 2015)

2.5.1 GGC issued a Project Manager Instruction, PMI 424, to Multiplex in July 2015, which required Multiplex to implement an air change rate of 10-12 changes per hour, and achieve a pressure differential of +5 to +10 pascals in Ward 4B. The pressure differential is not in line with NHS Design Guidance, which requires a pressure differential of +10 pascals.

2.6 Initial infection outbreaks in retained estate (? late-2015)

2.6.1 Several ‘infection matters’ and the first ‘outbreaks’ of infection took place in buildings of the ‘retained estate’ of the hospital site, in the Neonatal Intensive Care Unit and the Neurological Sciences building.

2.7 Serratia Marcescens (SM) in NICU (July-Dec 2015)

2.7.1 Between July and November 2015, a total of 13 cases of Serratia Marcescens (SM) occurred in patients in NICU. The infections were reported to HPS, following the death of an infant with sepsis caused by SM on 31 October 2015, and against a background of an increasing number of cases over the previous months.

2.8 Work carried out on Ward 4B BMT

2.8.1 On 5 October 2015, the BICC meeting minutes record that the rooms in the ‘adult Tower’ had been completed, with the exception of two rooms. Alternative routes into the QEUH for immunocompromised patients were being found during the period of demolition of the surgical block. A

significant flood had occurred in the neuro theatre, which was closed for approximately 6 weeks, but was now in use following satisfactory air monitoring results.

2.8.2 On 30 November 2015, the BICC meeting minutes record that adult BMT patients were due to transfer to the QEUH on 19 December 2015. The co-ordinating ICD (CICD) advised that there was no national standard for testing BMT rooms. It is not clear what testing, if any, had taken place in the refurbished Ward 4B. The planned return of patients was postponed.

2.8.3 The mechanical ventilation system to Ward 4B of the adult hospital was upgraded in December 2015. The works included: installing metal frame plasterboard ceilings (MF ceilings) to reduce air permeability; applying sealant to various areas and replacing sealed lighting units. The measures were designed to improve the pressure differential between the rooms and the corridors on the ward. HEPA filtration was also installed.

2.8.4 Advice was received by way of SBAR from HPS and from Public Health England on the Adult BMT unit in December 2015.

2.9 PMI 471 (December 2015)

2.9.1 Following receipt of the HPS SBAR, GGC issued a PMI (PMI 471) to Multiplex to carry out further work on the ventilation systems in Ward 4B. The PMI required Multiplex to achieve 6 air changes per hour; room pressures of +2.5 to +8 pascals; the corridor to be HEPA filtered, and the entrance to the ward to be air locked using double door at the front entrance.

2.10 Pseudomonas aeruginosa (PsA) in PICU (December 2015)

2.10.1 On 24 December 2015, an IMT meeting took place following the isolation of Pseudomonas aeruginosa (PsA) in the respiratory specimens of two patients in Ward 1D, the Paediatric Intensive Care Unit (PICU). The

samples were taken on 17 December 2015. According to the OB Timeline, the samples identified two different strains of PsA.

2.10.2 This is the first infection of concern recorded in the OB Timeline. In light of the infections, a “water safety checklist” was completed. An SBAR on the cases was issued to the Senior Charge Nurse (SCN). An ‘action plan’ was agreed in respect of these cases.

2.11 Clinician concerns in 2015

2.11.1 On 9 November 2015, two consultation MBs wrote to the medical director of GGC/the QEUH to raise certain concerns. The concerns they raised included: (i) lack of involvement on the part of the ICT in relation to the design of the hospital; (ii) in relation to the adult BMT unit, the absence of environmental monitoring prior to patients moving in and the non-availability of information regarding specification and validation reports; (iii) a concern that despite monitoring of the air in the children’s BMT unit disclosing evidence of fungal spores and there being holes in the ceiling of rooms, children were moved in and transplants proceeded. The two clinicians said they did not consider that their concerns were being addressed.

2.12 GNB infections in Ward 2A (? 2015)

The Case Note Review retrospectively identified that, during 2015, there were 2 instances of GNB infection (1 patient with blood stream infection caused by Klebsiella and 1 patient with a blood stream infection caused by Pseudomonas) in paediatric haemato-oncology patients, which do not appear to have been investigated at the time.

3. Episodes of concern that took place or commenced in 2016

3.1 Timeline: ongoing work by contractors (January- December 2016)

3.1.1 Throughout 2016, work to address the issues being identified with the hospital continued.

3.2 Ongoing work on Ward 4B (adult BMT) (January 2016)

3.2.1 On 25 January 2016, the BICC meeting minutes record that discussions about the specifications for the adult BMT Unit were ongoing, but ‘all ventilation issues’ were now complete. The key issue was the HEPA filtration of corridors, and the compliance of what was in place with the ‘guidance’.

3.3 Patients move from Beatson to Ward 4B

3.3.1 At a date currently unknown (possibly early 2016), patients moved from the Beatson to Ward 4B.

3.4 Cupriavidus (CU) (unknown location) and the connection to an aseptic sink (January 2016)

3.4.1 In January 2016, a patient tested positive for Cupriavidus pauculus (CU). An investigation determined that the patient had received parenteral nutrition which had been reconstituted in the aseptic pharmacy. A sample taken from a tap on a wash hand basin in the aseptic pharmacy also isolated CU. Typing of both isolates were found to be the same. The wash hand basin was subsequently removed.

3.4.2 There is a suggestion (by certain MB/ICDs) that the investigation was prompted by a raised TVC in a sample taken from the aseptic pharmacy unit, with the patient case being retrospectively identified. The MB/ICDs considered that the matching of the typing demonstrated a link between

water and the case of CU in the patient. An article published in February 2021 indicates that high TVCs were found in two sinks.

3.4.3 There is doubt about the location of the patient and whether or not they were in ward 2A.

3.4.4 This is the first of two instances of infection which NHS GGC appear to accept are linked to the hospital environment (the second being an instance of Mycobacterium chelonae in 2019).

3.5 Flow straighteners and Pseudomonas (February 2016)

3.5.1 On 2 February 2016, the Board Water Safety Group (BWSG) meeting minutes record a discussion between the Lead ICD and GGC Senior Estates Manager of 'water and environmental issues'. Discussion had taken place about the risk of Pseudomonas with the use of flow regulators. HPS advice was recorded as being to remove, sanitise, and return the flow straightener to the tap and to replace the plastic components every three months, or alternatively to keep the flow straighteners in place with sampling to be undertaken in high-risk areas.

3.6 Acinetobacter baumanii (AB) in PICU (June 2016)

3.6.1 In June 2016, two patients tested positive for Acinetobacter baumanii (AB) in Ward 1D (PICU). Both patients had undergone cardiac surgery. The hypothesis at least at the time of the OB Timeline was that the time was that cross-transmission had occurred (patient to patient).

3.7 Klebsiella in Ward 2A (June- November 2016)

3.7.1 Between June and November 2016, there were 9 episodes of Klebsiella infection, affecting 8 patients in Ward 2A. No investigation into these infections took place at the time and thus no IMT.

3.8 An increase in Aspergillus (A) cases in Ward 2A (August 2016)

3.8.1 On 25 July a patient in Ward 2A tested positive for Aspergillus (A). A second paediatric haematology patient was identified as a probable case was identified on 4 August, although this was subsequently found not to be Aspergillus infection. There is a suggestion of one of the patients also having had Pseudomonas.

3.8.2 Neither patient was in a BMT room. A Problem Assessment Group (PAG) meeting took place on 4 August, followed by an Incident Management Team (IMT) meeting on 5 August 2016. The infections were reported externally to HPS on 5 August 2016.

3.8.3 The potentially contributing factors to the infection were identified as: (i) tears in the ventilation ductwork; (ii) the construction/demolition work on site, which was creating dust, and (iii) condensation forming on the chilled beams, this issue having been raised with the main contractor as abnormal. There was also a suggestion of a water leak.

3.8.4 Whilst air samples from the chilled beams had been collected and shown to be negative, samples taken from an air handling unit showed fungus, and the IMT indicates that no air sampling programme was in place. The continued absence of HEPA filtration was noted.

3.8.5 An increased programme of cleaning, and cleaning of the chilled beams was implemented in response to the infection. High risk patients were prescribed prophylaxis (the IMT refers to AmBisome or Posaconazole).

3.8.6 In addition to the above, there is a suggestion that there were 2 cases of A in QEUH Critical Care in June 2016; and that water ingress was suspected as a cause.

3.9 Portable HEPA filters in Ward 2A (? 2016)

3.9.1 Following the infection of a patient within Ward 2A with Aspergillus, portable HEPA filters were to be placed in the unit. Whilst the air in Ward 2A was filtered, it was not HEPA filtered. The placement of the HEPA filtration units within the ward, and the timescale in which they were provided, is unknown.

3.10 Ongoing work in paediatric BMT rooms (September 2016)

3.10.1 On 5 September 2016, the AICC meeting minutes record that the Adult BMT and Paediatric BMT rooms fell below the standards implemented in other units. Work was ongoing in the paediatric BMT unit to achieve the required specification.

3.11 Serratia Marcescens (SM) in PICU (Sept/Oct 16)

3.11.1 In September/October 2016, 6 patients were reported to have SM in PICU. One patient with a positive result had transferred from Neonatal Intensive Care Unit (NICU). An IMT was held on 27 September, which recommended the implementation of Standard Infection Control Precautions (SICPs).

3.11.2 The environment was screened as negative for SM and Pseudomonas. Water sampling results were undertaken, but the results are unknown. The practice of washing equipment in sinks was thought to be a potential source of contamination in the environment.

3.12 Retrospectively identified GNB infections in Ward 2A (? 2016)

3.12.1 During 2016, there were a total of 26 instances of bacteraemia amongst the haemato-oncology patients in Ward 2A (including the 9 cases of Klebsiella identified above).

3.12.2 None of these infections appear to have been investigated at the time (although one of two cases of Elizabethkingia which occurred in 2016 appears to have been considered in February 2017 when two further patient infections had occurred). These infections were retrospectively identified by the CNR.

4. Episodes of concern that took place or commenced in 2017

4.1 Ongoing work by contractors (January- December 2017)

4.1.1 Throughout 2017, work to address the issues being identified within the hospital continued.

4.2 Serratia Marcescens (SM) in PICU (February 2017)

4.3 In February 2017, an unknown number of patients in NICU/Ward 1D developed SM infection. The focus of the response was on domestic cleaning, especially “pendants”. Chlorine cleaning of the bed spaces took place. The isolates were typed, and timelines were created.

4.4 Elizabethkingia miricola (EM) in Ward 2A (September 2016- February 2017)

4.4.1 Three cases of EM were isolated from patient line cultures between September 2016 and February 2017. All were unique strains.

4.4.2 A PAG took place on 3 March 2017. The action plan prompted a focus on the environment. There was a suspicion of a connection to the water supply or to condensation from chilled beams. F&E undertook a review of vent cleaning and maintenance, as well as sampling of vents, chilled beams and water outlets. All samples were negative. The IPC Nurse carried out a visual inspection of the environment. The incident was closed on 27 March 2017.

4.5 Increasing number of unusual bacteraemias (July 2016- February 2017)

4.5.1 Between July 2016 and February 2017, there was a gradually increasing upwards trend in bacteraemia rates amongst paediatric-haematology patients. Multiple organisms were identified.

4.5.2 It does not appear that any further steps were taken by GGC in response to the trend of increasing numbers of unusual bacteraemias amongst this patient cohort. The precise numbers and types of organisms responsible are unknown.

4.6 Concern emerging about increased bacteraemia rates (March 2017)

4.6.1 In March 2017, concern began to emerge within GGC about increased bacteraemia rates in paediatric haemato-oncology patients. The first Problem Assessment Group (PAG) for a Gram-Negative environmental bacterium (GNB) was convened.

4.7 Water sampling begins (March 2017)

4.7.1 Water sampling was undertaken in Ward 2A from March 2017.

4.8 Unsuitability of QEUH isolation rooms (March 2017)

4.8.1 On 6 March 2017, the AICC meeting minutes record that the QEUH isolation rooms had been found to be unsuitable for airborne infectious disease patients. A report on the facilities was provided by HFS. The rooms were out of use: any patients were to be transferred to GRI or Monklands.

4.9 Aspergillus (A) in Ward 2A (March/April 2017)

4.9.1 In March 2017, three patients in Ward 2A contracted Aspergillus infection. Following the HIIAT red report, the infections were reported to HPS. IMTs took place between 7 March and 28 April 2017, when the incident was closed.

4.9.2 A number of investigations into the outbreak took place, some of which considered the environment as a potential source of infection: the IPC team reviewed the level of dust from ongoing works on site; a leak into the ceiling void was identified and found to be causing mouldy ceiling tiles; an inspection of cooling beams (which leaked periodically) took place; air and water sampling was carried out (results were negative), and hand hygiene audits (85% score) were carried out.

4.9.3 The control measures which were put in place included the removal of mouldy tiles and ceiling void repair; a full terminal clean of the ward; anti-fungal prophylaxis being given to all patients; ongoing surveillance by clinical teams “to alert IPCT as lab testing unreliable”, and the development of a water damage policy by ICD and Facilities & Estates (F&E).

4.10 Serratia Marcescens (SM) in PICU (March 2017)

4.11 The SM incident in PICU, which began in February 2017, continued into March 2017. At least 3 cases occurred in March 2017.

4.12 CLABSI working group set up (May 2017)

4.12.1 In May 2017, a working group on CLABSI (Central Line Acquired Blood Stream Infection) met for the first time to develop measures to attempt to reduce the rate of infection. It appears that the group was formed in response to concerns about the increasing rate of unusual bacteraemias in Ward 2A between July 2016-early 2017.

4.12.2 By June 2017, the initial rate of CLABSI had doubled.

4.12.3 The measures were ultimately successful: the median rate of line acquired infection reduced from 6.33 in June 2017 to 1.34 in December 2019.

4.13 Ongoing work in Ward 2A (May 2017)

4.14 On 8 May 2017, the AICC meeting minutes record that work was underway in Ward 2A to change the pressure in two isolation rooms from ‘negative’ to ‘positive’ pressure (incorrectly described as positive to negative in minutes).

4.15 Change to NIPCM to include 4 environmental organisms (June 2017)

4.15.1 In June 2017, the National Infection Prevention and Control Manual (NIPCM) was updated to include 4 environmental organisms: Pseudomonas aeruginosa (PsA), Acenitobacter baumanni (AB), Stenotrophomonas maltophilia (STM) and Serratia marcescens (SM). Alert organisms for gram-negative bacteria (GNB) and gram-positive bacteria (GPB) were added to Appendix 13.

4.15.2 On 3 July 2017, the AICC meeting minutes recorded that no changes were required within GGC as IPCT already included the extra organisms as alerts within the system. Whilst no guidance was provided in the NIPCM on how to manage the organisms or implement surveillance, the ICD had developed triggers for these organisms based on ‘available scientific literature’. An SBAR was issued by GGC to IPCTs advising of the update to the list in August 2017.

4.16 Stenotrophomonas maltophilia (STM) in Ward 2A (July 2017)

4.16.1 There were a number of identified cases of Stenotrophomonas Maltophilia (STM) in 2017. The overall number is unclear. There were two cases in July 2017. The OB timeline indicates that MB/ICDs considered SPC charts to show a marked increase in cases beyond these 2. It has been

suggested that there were two cases in the early part of 2017. It has also been suggested that inquiry by MB/ICD staff at the time of the two July cases showed either a further 5 cases having occurred in recent months or showed a total of 5 cases (as having occurred after a long period of none).

4.16.2 The CNR OR indicates that they were aware of something in the order of 6~~12~~ cases in 2017 among the cohort of patients that they were considering.

In November 2019, an SBAR addressing STM cases in 2017 was prepared by a GGC clinician. It was said to have been prepared as part of an IMT process. The SBAR indicates that that process involved a retrospective review of STM cases in 2017.

4.16.3 Control measures put in place as a result of the infections included: terminal clean of the 2 rooms occupied by the affected patients; ongoing review of line care (CLABSI group); additional staff and parent education, and a 'review of the environment' led by the Lead Nurse for IPC, Senior Charge Nurse and Domestic Manager.

4.16.4 A PAG was convened on 26 July 2017. The MB dealing with this incident sought information on recent cases. That produced the information that there had been a further 5 cases (or a total of 5 cases).

4.16.5 The MB requested water testing in July 2017. This was eventually carried out in September 2017. GGC is understood to consider that this testing demonstrates there is no link between cases of STM and the built hospital environment.

4.16.6 The CNR concluded, without indicating which years in particular their finding covered, that the frequency of STM was "higher than would be expected". They appeared also to consider that there was a clustering in time and of place as regards STM cases. They considered that the chances of this having occurred by chance was small. Again without

indicating which particular years their findings covered, the CNR concluded that 14 cases of STM were “most likely” to have been “associated with the environment".

4.17 Infections affecting the Cystic Fibrosis Population: July & September 2017

4.17.1 On 20 July an IMT took place to discuss cases of Mycobacterium Abscessus (MA) within the CF patient population. According to the OB Timeline, a meeting of the BICC took place on 31 July 2017, and the minutes record a number of cases of MA. Genome sequencing results confirmed these were linked. IPC were unclear of route of transmission and HPS were involved.

4.17.2 A further meeting took place on 22 September 2017 to consider cases of Exophilia among the CF population. Among the issues discussed was a requirement to check and clean ventilation in the area including the chilled beams.

4.18 Klebsiella in Ward 2A (July- December 2017)

4.18.1 Between July and December 2017, there were 9 episodes of Klebsiella infection, affecting 7 patients. It is unclear what investigation of these was made at the time. An IMT (which appears to be wrongly) dated 13.2.17 indicates some consideration of 11 Klebsiella infections between August and December 2017 in relation to infections in the Philipshill ward which is part of the adult hospital, but is in a building separate to the main QEUH building. The CNR OR states that “there was no investigation into an increasing number of Klebsiella bacteraemias encountered between 2016 and 2018”.

4.19 Fungal counts in Ward 2A

4.20 High fungal counts were recorded in cubicles within Ward 2A, and the TCT area. Following the cleaning of the affected areas, re-sampling confirmed acceptable results.

4.21 Pseudomonas spp (Ps): in PICU (August 2017); and in Ward 100D QEUH (November 2017)

4.21.1 In August 2017, two cases of Ps were identified in NICU: one patient with a Ps positive blood culture and the other patient with a colonisation. There was an 'epidemiological link' between the two. A PAG was held on 2 August 2017. The control measures which were implemented in response included a full terminal clean of the unit, completion of a 'water checklist' with practice issues identified and reported to the SCN, and ongoing monitoring.

4.21.2 On 3 November 2017, an IMT was held in relation to cases Ps on Ward 100D.

4.22 DMA Canyon Report (September 2017)

4.22.1 According to the OB Timeline, in September 2017, work on a report by DMA Canyon dated from the same month began. It is unclear what report that was or what work was involved.

4.23 Cupriavidus (CU) in Ward 2A (September 2017)

4.23.1 A patient in Ward 2A tested positive for Cupriavidus pauculus (CU) in September 2017, 17 months after a patient had tested positive for CU which had been matched to an isolate in a water sample taken from a sink in the aseptic pharmacy (i.e., a confirmed environmental link between the environment and patient infection).

4.23.2 This was the second instance of patient infection with CU. This case was similarly linked to the isolation of CU bacteria in a clinical handwash basin within Ward 2A, which could not be removed but which was disinfected at the time, although it is unknown whether typing of the isolates confirmed a match. This suggests that water sampling investigations into the source of this infection took place, although these are not documented in the OB Timeline and the HPS reporting suggests that no sampling took place.

4.24 Step 1 whistle blowing procedures (September 2017)

4.24.1 In September 2017, three consultant MBs raised Step 1 of GGC's whistle blowing procedures. The concerns they had included patient placement, issues with ventilation, a lack of information about commissioning and validation, issues with the water system and concerns about water testing. They were asked to submit an SBAR setting out the issues of concern.

4.24.2 This was not the first time the concerns had been raised. Whilst the format (SBAR) was new, the concerns about emerging environmental risks arising from the hospitals design and construction had been raised since before the formal handover of the new building.

4.25 SBAR (October 2017)

4.25.1 The matters of concern raised in the SBAR related to the facilities in the QEUH and RHC, as well as the structure of the IPCT service within NHS GGC.

4.25.2 In particular, the five main concerns raised were:

4.25.3 Building design, including ventilation concerns about isolation rooms for patients with infectious diseases, apparent flaws in the construction of the hospital and the effect of those flaws on accommodating particular patients;

4.25.4 Specific building problems and infections in Ward 2A of RHC;

4.25.5 Water quality (taps having temperature control valves (TCVs), concerns about water testing and reporting of results, and the fact that ICDs required to request water testing relating to Ward 4B of the adult hospital in light of recent water test failures and the vulnerable patient population;

4.25.6 Standards of cleaning; and

4.25.7 The skill set and leadership of the Board Infection Control Team.

4.25.8 Additional concerns were raised about plumbing in the neurosurgical block and decontamination of respiratory equipment.

4.25.9 The likely patient impacts predicted in the SBAR of September 2017 went on to occur in the manner in which the medical microbiologists predicted.

4.26 GGC Action Plan to address SBAR (October 2017)

4.26.1 On 4 October 2017, a meeting took place to discuss the concerns. A 27-point action plan was developed to address the concerns, which was 'ratified' by the CCGC on 5 December and noted by the Board on 20 February 2018. Work to address the action plan is extensive and was still ongoing in 2021 (as recorded in the OB Timeline).

4.26.2 The extent to which the action plan represents an agreed course of action amongst the MBs is disputed. It is suggested in the OB Timeline that certain MBs maintain that they had raised concerns with their consultant colleagues in relation to the number of infections, including unusual infections at RCH.

4.26.3 HPS were requested to provide support to GGC whilst the action plan was compiled.

4.27 Serratia Marcescens (SM) in PICU (October 2017)

4.27.1 In October 2017, at least 4 patients were colonised with SM in PICU. A PAG was held on 6 October 2017. The control measures put in place included a terminal clean of the affected patient bay, and a hand hygiene audit. No further action was to be taken unless new cases were identified.

4.28 Ongoing concern around ventilation in QEUH/RHC (October 2017)

4.28.1 In a meeting of the BICC on 9 October 2017, the minutes record the receipt of emails concerning "*the ventilation and negative pressure rooms in QEUH and RHC*" and a meeting held by the Medical Director (MD) a week previously to progress matters on those issues (it is unclear whether this is a reference to the Stage 1 whistle blowing/SBAR by three consultant MBs).

4.29 Aspergillus (A) in Ward 2A (October 2017)

4.29.1 A single patient identified with an Aspergillus infection following a Bronchoscope procedure on 23 October 2017. A PAG was held on 27 October 2017. HPS were advised of the infection on the same date. The patient had been prescribed anti-fungal prophylaxis since 20 October 2017 (although the minutes of the AICC meeting of 6 November 2017 doubt whether the patient had anti-fungal prophylaxis).

4.29.2 The control measures which were put in place included the risk assessment of all Ward 2A patients by the clinical team before anti-fungal prophylaxis was prescribed; twice weeks IPCN visits to the ward to monitor the environment, cleaning and practice, and ongoing cleaning of the ward with chlorine-based detergent.

4.30 Acinetobacter baumanii (AB) in various locations of RHC (October-November 2017)

4.30.1 A number of cases of Acinetobacter baumanii (AB) occurred in various locations of the RHC/QEUH in September/October and November 2017.

4.30.2 In October 2017, a new case of AB was identified in Ward 3A. It was identified as being of the same strain as two previously colonised cases on the ward (identified in September) at that time. A fourth case, a patient colonised with AB since 2016, who returned to the ward after the new HAI occurred, also had the same strain of AB. Control measures put in place were SIPC measures and monitoring of Ward 3A for onward transmission (the theory appears to have been patient to patient transmission).

4.30.3 In November 2017, two new cases of AB colonisation occurred, one in Ward 1E and the other in PICU. A third patient with AB colonisation was also in PICU (believed to be one of the cases from Ward 3A in October 2017). There was a time and place link for all three cases: the same bed bay (location unknown). Two of the cases from October 2017 were also associated with the same bed bay.

4.30.4 The control measures put in place were: ‘TBPs around bed spaces’; hand hygiene audit and environmental sampling undertaken (results unknown), and ongoing IPCT investigations and monitoring. There is no suggestion of consideration of an environmental link.

4.31 Ongoing work in Ward 2A (November 2017)

4.31.1 By November 2017, 4 of the PPVL rooms in Ward 2A had been converted to positive pressure rooms. At a meeting of the AICC on 6 November 2017, the minutes record that significant expenditure would be required to convert the rest of the rooms to positive pressure rooms.

4.32 Ongoing CLABSI work (November 2017)

4.32.1 The CLABSI working group had caused infection rates to decrease through a series of changes including staff practice; new equipment (including the Curos port protector tip), and ensuring staff adhered to decontamination/line care.

4.32.2 From December 2017, every CLABSI was to be subject to 'rigorous review' utilising what is described as Event Cause Analysis methodology within 72 hours of a reported case.

4.33 Conclusion of work by contractors (December 2017)

4.33.1 By December 2017, the works ongoing by contractors in the hospital since handover were said to be completed.

4.34 Retrospective view of GNB infections in Ward 2A (? 2017)

4.34.1 During 2017, there were a total of 51 episodes of infection amongst the haemato-oncology patients in Ward 2A considered by the CNR. This included: 6 instances of Stenotrophomonas (including the 2 instances identified above); 10 instances of Klebsiella (including the 9 cases identified above); and 8 instances of Enterobacter. It also included 6 instances of Acinetobacter; 3 instances of Pseudomonas, and 1 case of Serratia marcescens. Infections caused by these latter three bacilli were identified in patients in other areas of the RHC/QEUH during 2017, in respect of which PAG/IMTs took place.

4.34.2 The infections also included the case of Cupriavidus in September 2017, an unusual organism which had previously been identified in a water sample from a sink in an aseptic pharmacy in January 2016, and which prompted widespread testing of the water system when it was found again in a patient in January 2018.

4.34.3 A total of 27 different species of organism caused bacteraemias in 2017, more than in any other year between 2015 and 2019.

4.34.4 With the following exceptions, none of these infections appear to have been investigated at the time. They were retrospectively identified as having occurred by the CNR.

4.34.5 The exceptions are a PAG which took place following the identification of 2 cases of Elizabethkingia in February 2017; a PAG which took place in September 2017 following the identification of 2 cases of Stenotrophomonas (and the death of one of those patients); and a PAG which took place in March 2017 to consider the increase in unusual Gram-negative bacteraemias in the Schiehallion Unit between mid-2017 and February 2017. No further action appears to have been taken to investigate the infections or to consider an environmental link.

4.34.6 The IR described the infections occurring during 2017 as "*an emerging picture of very unusual organisms causing blood stream infections"*.

4.35 Water sampling results consistently negative (2017)

4.35.1 Between 7 March 2017 and 17 November 2017, 151 water samples were collected. All tested negative for Elizabethkingia; coliforms; Pseudomonas spp; Legionella, and Stenotrophomonas maltophilia within the water system.

5. Episodes of concern that took place or commenced in 2018

5.1 HPS Report on ventilation in Ward 2B (January 2018)

5.1.1 In January 2018, HPS issued a report entitled "*Ward 2B NHS GG&C SBAR Final HPS/HFS January 2018*". The report advised GGC on the appropriate design to provide protective isolation to hematopoietic stem

cell transplantation (HSCT) patients, namely HEPA filtered, positively pressured patient rooms with a pressure cascade system, designed to comply with SHTM 03-01 Ventilation for healthcare premises Part A-Design and validation (2009). The use of PPVL rooms for immunocompromised patients was considered unsuitable by HPS/HFS.

5.2 DMA Canyon Report 2017 finalised (31 Jan 2018)

5.2.1 By 31 January 2018, a report by DMA Canyon for 2017 is said to have been completed and finalised. In response to the report, F&E is said to have formulated a work plan to action the recommendations.

5.3 Pseudomonas aeruginosa (PsA) in PICU (January 2018)

5.3.1 In January 2018, 2 cases of PsA were identified in PICU. Those cases were said to be linked in place and time to another two cases on the unit (long-term colonisation). The cases were at opposite ends of the ward, and typing was said to have confirmed different strains so there was no evidence of cross-transmission.

5.3.2 In response, water and environmental sampling was undertaken. The results are said to have been negative. A review of the cleaning practice of sinks and drains was undertaken.

5.4 Klebsiella in Ward 2A (January- May 2018)

5.4.1 Between January and May 2018, there were 5 patients identified with a blood stream infection caused by Klebsiella in Ward 2A. These infections were not investigated at the time.

5.5 Step 2 whistle blowing procedures activated (February 2018)

5.5.1 In February 2018, two consultant MBs raised Step 2 whistle blowing procedures due to their concerns that the issues raised in September 2017

were not being addressed. Around this time, GGC was looking to recruit external advice in relation to its ventilation systems. The MBs who instigated the whistle blow were, in May 2018, advised by the clinician appointed to investigate it that there was no increase in levels of infection rates.

5.6 Various Gram-Negative Bacteria in Ward 2A (26 January-1 March 2018)

5.6.1 At the end of January 2018, a patient on Ward 2A contracted a blood stream infection caused by Cupriavidus (CU) bacteria.

5.6.2 Throughout February and March 2018, further bacteraemias occurred in Ward 2A. By 1 March 2018, in addition to the CU case, one case of Pseudomonas (Ps) and 2 cases of Stenotrophomonas maltophilia (STM) had been isolated. By March 2018, a further 4 cases of STM had occurred, in patients in various locations of the hospital: 1 patient in Ward 2A; 1 patient in PICU; 1 patient in Ward 2B for line care, and 1 patient in Ward 3C (renal ward).

5.6.3 In addition to the bacteraemias, in March 2018, two patients in Ward 2A had pyrexia (high temperature) as a result of possible fungal growth. Further potential cases were identified in Ward 3C, and IPCT commenced an investigation.

5.7 Water testing results confirm contamination (March 2018)

5.7.1 As a result of the identification of CU, an unusual bacterium which had previously been identified in the water supply on two previous occasions, an investigation into a possible environmental source was commenced. The investigation involved water sampling in the aseptic pharmacy (the site of the previous CU case in January 2016). The results of that are said to have been negative.

5.7.2 Water sampling was carried out in other locations in Wards 2A, 2B and 4A. The main water supply was tested, as well as various outlets: taps (including, in particular, flow straighteners) and shower heads.

5.7.3 The main water supply tested negative for isolates. However, there were positive tests for various GNB (different strains) and fungal growth in various locations in the QEUH/RHC, including Ward 2A, 2B and 4B. The MBs prepared a report setting out the investigation findings.

5.8 Water Incident Management Team (IMT) commences (March 2018)

5.8.1 IMTs in relation to the 'water incident' were held between 2 – 27 March.

5.8.2 The hypothesis was that the outlets were the source of infection, particularly when flow straighteners had been linked to other outbreaks as they are prone to biofilm growth.

5.8.3 The IMT minute of 6 March 2018 records that concerns raised by the clinical team about risks from the environment in Ward 2A were communicated 'higher up' and externally to HPS over two years previously. Members of the IMT were dissatisfied with the response by senior management and 'outside of GGC'.

5.8.4 The IMT minute of 23 March records the possibility of contamination of the water system points at the time of commissioning of the hospital.

5.9 GGC request support from HPS (March 2018)

5.9.1 Following the discovery of microbiological contamination of water outlets, GGC requested support from HPS and HFS on 16 March 2018. Included within the papers provided to HFS was a copy of the DMA Canyon 2015 report. The recommendations of the 2015 DMA report were similar to those in the 2017 DMA report, and were included in the work plan created by F&E to action the latter.

5.9.2 In addition to seeking support from HPS/HFS, GGC also engaged the support of the Scottish Government, Public Health England and water experts.

5.10 National Framework: stage 3 (26 March 2018)

5.10.1 On 26 March 2018, the Chief Nursing Officer invoked the National Framework, which offers additional support to Health Boards in responding to HAI incidents/outbreaks and to ensure assistance from HPS. Stage 3 of the framework required HPS to lead an investigation and to provide board support.

5.11 Remedial steps taken vis water supply (March 2018)

5.11.1 As a consequence of the discovery of microbiological contamination in the water outlets, a number of remedial steps were taken by GGC in March 2018:

5.11.2 Water dosing was performed, but was successful only in reducing (as opposed to removing) the organism counts, so taps were replaced and sanitised;

5.11.3 Point of use filters (POUFs) were fitted to taps in areas with high-risk patients (not throughout the entire hospital), with the filters to be changed every 25 days and taps to be tested weekly;

5.11.4 Sinks in the Prep and Treatment rooms are said to have been removed;

5.11.5 Patient contact with the water supply was limited, through the provision of mobile wash hand basins and bottled/sterile water for washing and drinking;

5.11.6 CU and STM were added to the IPCT alert organism software system;

5.11.7 Patients were to be prescribed Ciprofloxacin prophylaxis and additional line protection measures were introduced;

5.11.8 An increased hand hygiene and cleaning regime was implemented, and

5.11.9 A Technical Water Group (TWG) was created to find ‘long term solutions’ to the problem.

5.12 IMT closed (March? 2018)

5.12.1 The IMT was closed at the end of March 2018. On 13 April 2018, a full IMT report was produced detailing the incident and the actions which were taken as a consequence of it. The final case count was 1 instance of CU; 1 instance of Ps, and 5 cases of STM. A debrief meeting in relation to the IMT took place on 15 May 2018.

5.12.2 This initial cohort of infections formed the basis for the investigation by HPS, which resulted in their initial report in May 2018.

5.13 Technical Water Group (April 2018)

5.13.1 A Technical Water Group (TWG) was established in March/April 2018. The first meeting of the TWG took place on 6 April 2018, and meetings continued throughout April 2018.

5.13.2 The TWG directed a programme of water sampling to investigate the extent of the water contamination. Discussions were held with the tap manufacturer (Horne) who advised that issues with Pseudomonas in flow straighteners were known, but not other organisms, and that the flow straighteners would require to be decontaminated and replaced as required.

5.13.3 External advice was sought from a water expert, Susanne Lee, and a further expert, Tom Makin.

5.13.4 The TWG considered reviewing information on water temperature to identify trends, but were advised that the majority of water temperature data had been lost due to a system failure. The existing records were not extensive.

5.14 Susanne Lee's Report on water supply 25 April 2018)

5.14.1 GGC commissioned advice and received reporting from Dr Susanne Lee, a consultant clinical scientist. She considered issues in relation to the water system. She is understood to have concluded that it is likely that the system was contaminated before handover and that fluctuations in the water temperature experienced since opening of the hospital were also a likely contributing factor; and that fungus in the water system was likely due to the dust levels around the site during construction and demolitions.

5.14.2 Dr Lee considered the question of whether evidence that environmental strains did not match patient isolates permitted a conclusion that water could be ruled out as a potential source of infection. She said, "It is likely that water was the source and cannot be ruled out because the [isolates] do not match."

5.15 Further testing of water system (April 2018)

5.15.1 Following POUF being fitted in areas with high-risk patients, further testing of the water system uncovered a more systemic problem: widespread contamination of the water system across the hospital.

5.15.2 In order to understand where the bacteria were located within the water supply, samples were taken from all parts of the water system. Results showed that all floors had some contamination, indicating that the problem was widespread.

5.15.3 Positive results were also returned from water coolers (maintained by a third party), which were disinfected.

5.16 TWG considers longer term solutions for de-contamination (April 2018)

5.16.1 The TWG discussed the formation of biofilm and how long it takes to develop: opinions varied from a short period to up to a year.

5.16.2 The TWG discussed long term solutions to de-contaminate the water system. Options included: shock dosing; thermal cleaning and chemical cleaning (including Chlorine Dioxide (CD)). Whichever option was selected would require a full risk assessment and consideration of what would cause minimum disruption to patients.

5.16.3 The TWG were agreed that POUF would only be fitted to high-risk areas rather than the whole campus.

5.17 Acinetobacter baumanii (AB) in PICU (April/May 2018)

5.17.1 In April 2018, three patients were identified as being colonised with AB in PICU. In May 2018, a further two colonised patients were identified. PAG/IMT meetings took place in relation to the incident between 11 May and 6 June 2018. The IMT retrospectively identified a further case colonised in February 2018, bringing the total to 6 cases. The earlier patient remained in the unit.

5.17.2 Two of the patients were in adjacent bed spaces, and a domestic audit identified cleaning concerns. All isolates were sent for typing. IPCT raised concerns over ‘TBP’ adherence, and a review of TBPs in the unit was undertaken. IPCT continued to monitor for new cases.

5.17.3 The hypothesis appears to have been that cross-transmission between patients had occurred.

5.18 TWG: map the extent of the contamination (May 2018)

5.18.1 By 16 May 2018, the TWG had instructed over 2000 water samples to be taken and mapped to floor plans of the hospital and within schematic diagrams. The conclusion was that there was a biofilm build up in the water system which required to be eradicated and which would require preventative measures to be put in place to prevent re-occurrence.

5.18.2 By May 2018, the BICC, AICC and CCGC were all aware that the problem with water contamination was extensive and involved both RHC and QEUH.

5.19 TWG: Tom Makin advice (?date)

5.19.1 Dr Tom Makin, Senior Consultant with Legionella Control International, provided advice to the TWG, at a meeting on [ ]. The advice was that Chlorine Dioxide (CD) was the best option to strip biofilm from the water system.

5.20 Intertek report (? 2018 date unknown)

5.20.1 GGC commissioned a report from Intertek. They undertook examination of flow straighteners within the hospital and tested for various microbiological pathogens.

5.21 TWG: formulate a plan for decontamination of water supply (May 2018)

5.21.1 The TWG continued to meet during May 2018. Relying on the advice of Tom Makin, the group had determined by May 2018 that chemical cleaning with Chlorine Dioxide (CD) was the best choice to strip the biofilm

from the water system. The plan was to start with continual dosing of the water supply, followed by a shock dose and then to revert back to continual dosing.

5.21.2 Flow straighteners on taps were to be replaced on a 3 monthly basis and taps were to be steam cleaned and put back with POUFs in place. Until taps were replaced, caution was required to ensure that the taps did not "re-seed" the system. Only taps in Wards 2A and 4B were to be replaced- the rest of the QEUH/RHC was to be monitored.

5.22 HPS Initial Summary Report (31 May 2018)

5.22.1 On 31 May 2018, Annette Rankin, Nurse Consultant Infection Control at HPS produced an initial report on the 'water contamination incident' at the QEUH/RHC (the HPS Initial Report).

5.22.2 The report identified 3 organisms of concern (CU; Ps and STM), which caused infections in a cohort of 7 patients between January and March 2018. The report records that the clinical aspect of the incident was closed, given that no new cases had been identified since 3 April 2018.

5.22.3 The report records that HPS, HFS and GGC had initiated a detailed investigation into the contaminated water system within the hospitals, and that the results from ongoing water testing appeared to confirm that '*regressional seeding of contamination*' continued to occur and supported '*the theory that a whole system remedial approach is required*.' Water sampling had revealed not only the 3 organisms associated with the incident, but '*numerous additional gram-negative bacilli and fungal species*.'

5.23 Various gram-negative bacteria (GNB) in Ward 2A (May-June 2018)

5.23.1 Between 28 April and June 2018, there were a total of 17 cases of patient infection with GNB bacteria in Ward 2A, with some patients displaying

multiple organisms. A total of 23 organisms were isolated in patients' samples:

5.23.2 A single case of Pantoea (Pan) was identified in May 2018;

5.23.3 Two cases of Acinetobacter baumanii (AB) were identified in June 2018;

5.23.4 A single case of Cupriavidus (CU) was identified in June 2018;

5.23.5 Nine cases of Stenotrophomonas maltophilia (STM) were identified in May/June 2018;

5.23.6 Six cases of Enterobacter cloaecae (EC) were identified in June 2018 (including one patient that was infected twice and 2 isolates in separate patients on the same day), and

5.23.7 Four cases of Pseudomonas (Ps) were identified in June 2018.

5.24 'Water Incident' PAG/IMT re-commences (18 May- 21 June)

5.24.1 Following an initial PAG on 18 May, IMTs were held between 29 May and 21 June in relation to the ongoing water incident.

5.25 IMT: investigations and water testing results (May/June 2018)

5.25.1 The IMT carried out a number of investigations and testing.

5.25.2 Drain swabs revealed a variety of GNB of different strains, including all of the GNB organisms contracted by patients (the 23 cases listed above), as well as Sphingomonas, Klebsiella oxytoca, and Elizabeth~~a~~kingia.

5.25.3 Visual inspection revealed black grime in the drains of the hospital (both QEUH and RHC). Dissection of a sink waste pipe showed exposed metal parts with biofilm present.

5.25.4 A review of the cleaning regime in Ward 2A was undertaken and additional resource was allocated following certain issues being identified.

5.25.5 Ongoing analysis was being carried out by HPS to assess whether the number and level of infections was unusual. GGC continued to consult HPS and other water experts during this time. Two water experts (Susanne Lees and Tom Makin) had visited the site to advise on long term solutions to the 'water incident', including the use of Chlorine Dioxide (CD) to dose and decontaminate the water system.

5.26 IMT hypothesis: drains thought to be the cause (June 2018)

5.26.1 In June 2018, the hypothesis of the IMT was that the drains were the source of patient infection. The water supply was believed to be 'clean'. Biofilm may have formed in the drains, resulting in 'aerolisation' of the biofilm (and contamination of the sink area) when the taps were turned on.

5.26.2 The IMT hypothesis is difficult to reconcile with the conclusions of TWG, who had determined that there was widespread contamination of the water system on the basis of the 2000 samples which had been taken and mapped.

5.27 IMT: Remedial steps taken (May/June 2018)

5.27.1 The number of visitors to the ward was restricted, and parent information was provided to prevent the build-up of clutter in patient rooms.

5.27.2 The following remedial steps were taken to address the perceived problem with the drains: drains were cleaned and then decontaminated with Hydrogen Peroxide Vapour in Wards 2A, 2B, 7A, 7D, PICU and elsewhere on site; waste pipes and sink drains were replaced, and enhanced hand hygiene measures, involving the use of alcohol gel after washing, was introduced.

5.28 IMT 15 June 2018: cases of Mycobacterium chelonae

5.28.1 At an IMT to discuss the water system incident, a clinician raised a concern about a mycobacteria infection. This was a very unusual infection. Although it had been queried as an environmental case and reported to HPS and SGHD no water testing was reported as having been done. It was also reported that a patient from the Beatson had the same sort of infection. That patient had not been an inpatient at RHC or QEUH but they had attended the latter for clinics.

5.29 Patient treatment impacted

5.29.1 During the decontamination of the drains, patient chemotherapy and BMTs were delayed/stopped altogether. Admissions to the ward were restricted. Patients were prescribed prophylactic Ciproflaxacin.

5.30 Concerns by clinicians

5.30.1 During May and June 2018, ongoing meetings took place with clinicians who expressed their concern that the IMT was not in control of the environment as there had been ongoing issues since the ward opened.

5.31 TWG: remedial work carried out to water system (June/July 2018)

5.31.1 The TWG identified a replacement tap (Marwick with Bio Guard) for high-risk areas, which required the flow straightener to be replaced every 3 months.

5.31.2 Raw and bulk water tanks and one section of the filtration plant were sanitised in June 2018, with the rest to be completed in July. Debris found in a tank, which looked like sponges, was sent for analysis.

5.31.3 The cleaning of drains and replacement of flow straighteners in high-risk areas was ongoing. Water coolers had been removed from Wards 2A and 2B.

5.31.4 HFS had been informed of the debris found in drains, which was a potential ‘national issue’. Whilst cleaning of drains was against national policy, it was agreed that this should continue in high-risk areas.

5.32 TWG: water sampling results (July 2018)

5.32.1 Flow regulators that were sampled were said to show counts [of isolates?] but no biofilm.

5.33 Implementation of DMA Canyon report recommendations (July 2018)

5.33.1 A work plan to address the recommendations of the 2 DMA Canyon reports (2015 and 2017) was understood to have been completed in July 2018. The actions were allocated to members of the F&E team and work was understood to have commenced [in July 2018?].

5.33.2 All actions to address the recommendations of the DMA Canyon reports were reported to the OB as having been completed by December 2018.

5.33.3 Members of the F&E team were said to have received formal training as an Authorised Person for water in May/June 2018. Prior to that point, the individuals did not hold that certification.

5.34 Water system: placed on IPC ‘risk register’ (‘summer’ 2018)

5.34.1 At some point during the summer of 2018 (date unknown), the water system was placed on the IPC risk register.

5.35 Klebsiella in Acute Spinal Injuries Unit (July 2018)

5.35.1 During June/July 2018, 3 cases of Carbapenemase-producing enterobacteria (CPE) Klebsiella occurred in patients in the spinal injuries' unit of the QEUH. The infections were reported to HPS.

5.36 Enterobacter cloacea in Ward 2A (July- August 2018)

5.36.1 During July and August 2018, a further two instances of patient infection with Enterobacter cloacae occurred. No investigation appears to have taken place in relation to these infections, which were retrospectively identified by the CNR.

5.37 TWG: investigations and plan for decontamination develops (August 2018)

5.37.1 The TWG continued to consider the options to treat the contaminated water system. Shock dosing of the system would be difficult to deliver given the extent of disruption to the hospital, so the plan was to be for continual dosing, with increasing amounts of CD being injected into the system and the results monitored over a 3-month period. If the results were not within limits, a risk assessment would be required.

5.37.2 Testing of flow straighteners showed that biofilm had built up after a month.

5.37.3 Water testing of the tank room showed that water was mostly negative post-filtration, but the raw water tanks had positive results from drain connections which were not capped or sanitised. Bulk storage tanks also had positive results- which were attributed to environmental conditions- namely the presence of cockroaches, fungal odour, room not ventilated, water ingress and dried algae present on the floor**.** The area was to be disinfected, repainted with anti-fungal paint, repairs made and pest control called in, with testing to be done once work had been completed.

5.38 HFS/HPS Draft report (August 2018)

5.38.1 In August 2018, HFS/HPS produced a draft report on their findings of the investigation into the contaminated water system, entitled “Technical Review Water Management Issues NHS GGC QEUH and RHC”. The report was produced by Mr Storrar of HFS and Ms Rankin of HPS.

5.38.2 The main focus of the report was on the technical aspects of the water systems within QEUH, and explaining and exploring possible mechanisms of contamination of the system. The report concluded that contamination of the water system in the hospital had occurred, either (i) during the construction phase and through lack of adequate maintenance, leading to build up of biofilm and consequently the proliferation of GNB, or (ii) that biofilm had built up in the tap flow straighteners and regressed back into the water system. HFS recommended that GGC implement the recommendations set out in the DMA reports.

5.38.3 At some point the focus by HPS (as seen in the initial report produced in May 2018) upon CU, STM and Ps had been broadened to include “*all gram-negative bacteria which had been identified within the water/drains*”.

5.38.4 According to the August 2018 report, between 29.1.18 and 31.5.18, 17 patient infection cases had been identified in Wards 2A/2B. Little specification of these is provided. It is difficult to reconcile the infection numbers reported by GGC with the HPS report. The report records that there had been no new reported cases since 31.5.18. It may be that HPS were unaware of the infections which occurred in June 2018 (i.e., after 31 May 2018).

5.38.5 HPS reported that “exact link” between “patient cases and the water system” was said not to have been made. It is unclear what the authors intended to suggest here, and the report proceeds to hypothesise a link between “environmental and person contamination” and *Enterobacter* within the drains.

5.38.6 There was widespread contamination of the hot and cold water systems within QEUH, the hypothesis being that this had occurred at one or more times during installation. Although, ventilation systems were considered during a literature review, the report identifies no investigation of, or consideration being given to, the QEUH ventilation systems at this point.

5.39 Ongoing problems with contaminated drains in Ward 2A (August 2018)

5.39.1 On 29 August 2018, thick black and yellow grime was visible in the drains of Ward 2A, following the cleaning regime which had been implemented only 4-6 weeks prior.

5.39.2 Swabs taken from the drains revealed: coliforms; Delta acidovarons; Chryseomonas indologenes; Cupriavidus, Pseudomonas aeruginosa and Klebsiella oxytoca.

5.40 Further Gram-Negative Bacteria (GNB) cases in Ward 2A (September 2018)

5.40.1 Between 5 August and 5 September 2018, a further 3 instances of patient infection with GNB occurred in Ward 2A. All three of those cases were caused by gram negative organisms which had been isolated from the drains. It appears that the three patient infections were caused by: Chryseomonas indologenes, Stenotrophomonas maltophilia, Klebsiella oxytoca, and Enterobacter cloacae.

5.40.2 Two out of three of the cases matched swabs taken from the drains.

5.40.3 During September 2018, a further four patients contracted GNB infection, including one case of Serratia marcescens (SM) and one case of Stenotrophomonas maltophilia (STM) (the other two patients are described as having unspecified ‘GNB’ infection).

5.41 IMT re-commences (September 2018)

5.41.1 An IMT was convened on 5 September 2018.

5.41.2 Prior to September 2018, IPCT had initially been visiting Ward 2A daily, but those visits had reduced to twice weekly, following the implementation of environmental and equipment cleaning regimes. There were less people and clutter on the ward and both environmental and domestic audits had scored well.

5.41.3 In light of the drain swab testing results and patient infections, the IMT carried out further investigation of drains and trough sinks within the hospital. The investigations revealed that only some drains and trough sinks were affected. The issue was thought to be confined to the RHC only (and not the QEUH).

5.41.4 HPS had previously advised that drains should not be subject to regular cleaning, so cleaning had ceased. Further guidance was awaited from HPS.

5.41.5 The hypothesis was that there were more GNB cases than usual, that the TWG were doing a lot of work to investigate the source of the infections, but that despite that the IMT was no closer to identifying the source of the infections which were occurring. The feeling was that the wards ought to close.

5.41.6 At least at Board level, the assumption was that the cases in September 2018 were associated with the drains and not the water supply.

5.42 TWG: investigations and de-contamination plan progresses (September 2018)

5.42.1 Air sampling in the tank room found fungi. A leak was found in one tank and one manhole cover, which was repaired. HEPA filters had been installed.

5.42.2 A timeline was agreed for the CD system. Shock dosing of the water supply was ruled out after discussion with clinicians due to smell, effects on pipework and the need to decant the hospital. The TWG noted that it might take 3 years for CD to be effective, but as the pipework was new it would not provide any resistance to CD so the effect may be quicker. Taps may need to be removed and cleaned separately.

5.42.3 Discussion was held on the need for work in Ward 2A/2B with regard to pipework, drains and ventilation. The potential cause of the issues was discussed and whether they were being caused by water/drains/ventilation, a combination or simple hand washing. A decant of the ward would allow full investigation to take place. It was noted that only haemato-oncology (and not BMT) patients were affected even though biofilm was found in both areas.

5.43 Concern around levels of dust and ventilation (September 2018)

5.43.1 In addition to the very significant concerns around the water and drainage system, the IMT also had concerns about the general build-up of dust despite increased cleaning, particularly around vents and chilled beams. The fact that the rate of air change per hour (ACH) was only 3 in the RHC (as opposed to 6 in the QEUH) might explain the levels of dust present. Air sampling had been undertaken on chilled beams, the results of which were reported to be negative.

5.43.2 HPS was reviewing ‘ventilation’ in Wards 2A/2B.

5.44 Control measures to address concerns (September 2018)

5.44.1 The IMT recommended the reinstatement of weekly cleaning of sinks and shower drains. Patient pathways were recorded to/from theatres with a view to identifying sinks/drains in those areas for review. A drain survey and a ventilation survey were commissioned.

5.44.2 On 17 September 2018, an Executive Management meeting rejected the idea of decanting the patients from Ward 2A until the results of a drain survey were known. Clinicians were concerned about the decision, and a paper was sent to the Director for Women and Children requesting that the decant go ahead.

5.44.3 The drain survey did not reveal any issues with the drains.

5.45 Decision to close ward (18 September 2018)

5.45.1 Patient admissions to Ward 2A had continued throughout the water incident, but were restricted and judged on a case by case basis.

5.45.2 On 18 September 2018, the TWG made the decision to decant BMT patients in Ward 2A to Ward 4B in the QEUH.

5.46 Preparation of Ward 4B and 6A for decant (September 2018)

5.46.1 Ward 4B and 6A in the adult hospital were inspected by F&E and IPCT and made ready for patients.

5.46.2 Steps taken included: repairs being made; full deep cleans (including of the drains and vents) and POUF being fitted to taps and showers.

5.47 Closure of wards 2A/B (26 Sept 2018)

5.47.1 On 26 September 2018, Wards 2A/2B were closed. BMT patients were transferred to Ward 4B in the QEUH (adult BMT unit). All other patients were moved to Ward 6A QEUH.

5.48 IMT continues (October 2018)

5.48.1 The IMT meetings continued during October 2018. The IMT continued to assess the environment.

5.48.2 Consideration was given to whether it was possible to create a ‘waterless ITU’ in the BMT setting, but this was not thought to be possible.

5.48.3 Consideration was given to changing the roles of the prep and treatment rooms.

5.49 TWG: ventilation survey (October 2018)

5.49.1 The TWG received a report on the survey of the drainage and ventilation system.

5.49.2 The ventilation system report showed that the system did not have as much capacity as initially thought. The report highlighted problems with pressure and air changes. Air changes were recorded during commissioning but not air pressure. A derogation was made from 6 to 3 ACH, and this was applied everywhere apart from BMT areas. The Project Board did not pick this up. The ward was currently at negative pressure to the rest of the hospital, which was not suitable for immunocompromised patients.

5.49.3 In addition, dirty and clean extractor fans were connected, which means that dirty air could be re-circulated, potentially ‘causing the problem with bacteria’.

5.49.4 Extensive work would be required to address these deficiencies. A specialist ventilation expert was to be engaged to complete a design feasibility study, which would delay the move back to Wards 2A/B.

5.50 TWG: communication with IMT (October 2018)

5.50.1 The TWG provided the IMT with an outline scope of the work to be undertaken in Wards 2A/2B to address the contamination of the water system. The water supply was to be dosed with Chlorine Dioxide CD), taps and wash hand basins were to be changed, and elements of plumbing were to be replaced.

5.51 Internal changes: procedure and personnel (October 2018)

5.51.1 On 1 October 2018, a new director of F&E took up post.

5.51.2 As a result of the 'water incident', the Compliance team began to review and develop the Standard Operating Procedures (SOPs) for sector estates offices to ensure consistence and appropriate quality of work in key areas. This coincided with a review of the Water Policy. This work continued throughout 2019.

5.51.3 A new SOP was issued by GGC entitled "*Environmental Organisms in High-Risk Areas*". The SOP refers to Appendix 13 of NIPCM and appears to replace a SOP which was circulated but then withdrawn in August/September 2017.

5.51.4 A register of assets was received from the main contractor in late 2018, some 3 years after maintenance schedules were requested. The F&E constructed more appropriate maintenance schedules for all hospital systems in the following 2-3 months.

5.52 Pseudomonas aeruginosa (PsA) in Theatre 6, RHC (October/November 2018)

5.52.1 In late-October 2018, a PAG was held, followed by an IMT to investigate 5 cases of PsA isolated from patients who had all had appendectomies in the same theatre during October 2018.

5.52.2 Sampling of drains identified PsA growth in the anaesthetic trough in the theatre.

5.52.3 All drains throughout theatre were cleaned. An excessive amount of debris, including nail picks, was found in u-bend traps of the drains.

5.52.4 The IMT was closed on 14 November in the absence of any further cases.

5.52.5 At a later date (January 2019), GGC were proceeding on the basis that there was no evidence of a link between the anaesthetic trough and the patient infections, with the cases instead being attributed to a 'normal background level of PsA'.

5.53 'Water incident' IMTs ongoing (November 2018)

5.53.1 The IMT meetings continued throughout November 2018. Following the decant of patients to Wards 6A/4B, there had been a marked reduction in bacteraemia.

5.53.2 Work was underway in Wards 2A/2B. The design of the ventilation system for all patient rooms (except BMT rooms) stipulated that the rooms were to be neutral/slightly negative pressure. Ventilation in all rooms (other than BMT rooms) ought to be positive pressure. An option appraisal was requested from a specialist ventilation engineer on what is required 'to rectify and bring the system up to standard'.

5.53.3 The IMT was closed on 30 November 2019.

5.54 Refurbishment of Ward 2A (November/December 2018)

5.54.1 On 10 December 2018, the minutes of the ACFG meeting record that the investigation into the 'water issues' in Ward 2A "*uncovered a ventilation issue which may require significant infrastructure work and prolong the*

current decant arrangements". It is assumed that this is a reference to the fact that patient rooms were neutral/slightly negative pressure, as opposed to the standard of positive pressure, described in the IMT minutes from November 2018.

5.54.2 By 11 December 2018, the installation of the Chlorine Dioxide (CD) dosing plant was complete, with a further 12 localised dosing sites to be installed. Ongoing reviews of the efficacy of the dosing were to be undertaken. HPS/HFS 'and external advisors continue to investigate' the 'cause' of the issues with the water supply.

5.54.3 Further remedial work being undertaken in Wards 2A/2B included: replacement of basins, taps, and drainage outlets, as well as additional work to replace the flooring, décor, entry systems, lighting and ventilation. Work was required to replace one of the air handling units, which would mean that the ward would be out of use for 'some months'.

5.55 Chlorine Dioxide (CD) dosing of water supply in RHC/QEUH (November/December 2018)

5.55.1 On 22 November 2018, continuous dosing of the water supply to the RHC with Chlorine Dioxide (CD) began. CD dosing continues to the present day.

5.55.2 In December 2018, continuous dosing of the water supply to the QEUH with chlorine dioxide (CD) began. CD dosing continues to the present day.

5.56 TWG: water samples in Ward 2A following initial dosing with CD (December 2018)

5.56.1 The first set of water samples were returned with good results: no legionella was returned, and all results were within parameters. Samples had been taken from the tank room, sentinel points at the start and end of

the ward, and shower points. The TWG considered that this indicated that it has been the taps that held the biofilm.

5.56.2 Water samples later in the month indicated fungi, although not in Ward 2A/2B, which appeared to have increased from the first samples, but fungi can be difficult to overcome, and CD would take longer to take effect.

5.57 Completion of DMA Canyon recommendations (December 2018)

5.57.1 By 16 December 2018, the actions to implement the recommendations of the 2015 and 2017 DMA Canyon reports were said to have been completed.

5.58 HPS 'summary report' (December 2018)

5.58.1 On 20 December 2018, HPS produced a report entitled "*Summary of Incident and Findings of NHS GGC QEUH/RHC*" (HPS Summary report). The report is a summary of the investigations carried out by HPS during the period between 29 January 2018 and 26 September 2018.

5.58.2 The report is largely a summary of the HPS element of the Draft report which was produced by HPS and HFS in August 2018. The HPS Summary report was produced in light of concerns expressed by GGC about the length of the former report.

5.58.3 The report's recommendations refer to those made in the August 2018 HFS/HPS report: namely to implement the recommendations of the 2015 and 2017 DMA Canyon reports.

5.58.4 The HPS Summary Report advised that by this stage (26 September 2018) GGC had reported to it 23 cases of BSI relative to 11 different organisms potentially linked to water contamination covering the period 29 January 2018 to 26 September 2018. Appendix 1 of the Summary report includes a timeline of cases. It is difficult to reconcile this timeline with the

cases which are reported by GGC. The timeline does not appear to include the patient infection with CU bacteraemia, as well as patient infections with STM and Ps in June and September 2018.

5.58.5 The report stated that testing had confirmed widespread contamination of the water system. The report described the 23 cases as "*probable linked cases of bloodstream infections associated with wards 2A/2B RHC*". Under reference to infections detected/reported in/up to April 2018, HPS said that "*all cases [were] considered to be linked to the water system*". Between April and June 10 cases (5 Enterobacter, 3 mixed GN, 2 STM) had been reported. These organisms were also said to be present in drain samples within 2A/B. In addition to the organisms linked to water and to infections, there was "*evidence of fungal growth in the water system*".

5.58.6 Impacts from infections linked to the environment could be stated: "*This incident has resulted in a number of children requiring additional intervention and some delays in chemotherapy treatment, however, there was no associated mortality*."

5.58.7 No cases of infection had been reported since the decant of children to 6A on 26.9.18.

5.58.8 The HPS Summary Report was published in February 2019.

5.59 Retrospective view of GNB infections in Ward 2A/6A (2018)

5.59.1 During 2018, a total of 48 episodes of blood stream infection caused by bacteria associated with the environment (either GNB or M. chelonea) occurred in haemato-oncology patients in Ward 2A and latterly 6A. This total number of infections was retrospectively arrived at by the CNR following a review of patient blood results and other data. Some but not all of these infections were identified and investigated at the time at which they occurred.

5.59.2 The infections included: 10 episodes of infection caused by Enterobacter; 7 caused by Klebsiella; 6 caused by Pseudomonas, and 12 caused by Stenotrophomonas.

5.59.3 The episodes of infection also included 2 cases of Mycobacterium chelonae (MC). It is unclear what if any investigation of these was made at the time (although 1 case was said to have been retrospectively identified in June 2019 when a further case of MC occurred which was said to have prompted further comprehensive water sampling as a result of the rare nature of the organism.)

5.60 'Hospital microbiology and pharmacy report' (? 2018)

5.60.1 A report from a 'hospital microbiology and pharmacy group' [date and title unknown] analysed the rate of paediatric bacteraemia between June 2014 and 2018. The report observed that whilst there was an initial decrease in bacteraemias occurring in paediatric haemato-oncology patients following the move to RHC in June 2015, that was followed by a rise in Gram-positive bacteraemia commonly associated with CVL infection, and then a 'steady rise' in Gram-negative bacteraemias. The microbes being identified were of many types, and often bacteraemia results showed multiple results in the same sample. The most likely explanation was that the pattern of infection could be linked to environmentally derived sources.

5.61 Descriptive analysis of five year trends in bacteraemia

5.61.1 On 1 October 2018, a consultant clinician within GGC produced a report that set out analysis of trends of bacteraemia rates for the patient cohort within the RHC for certain Gram negative organisms. The report was based on descriptive epidemiological analysis. The period covered was five years, so that it compared trends before and after the move to RHC.

5.61.2 The report concluded that there had been a clear increase in selected GN infections in 2017 and 2018 compared to previous years, and that there

was also an increase in 2016 with the magnitude less clear. The report stated: “The other obvious change over the time period is the increase in the number of blood cultures for multiple organisms. Again, consideration should be given to potential causes for this change.”

5.61.3 A further report was done by the same clinician in July 2019.

5.62 Innovated Design Solutions reporting: October/November 2018

5.62.1 GGC commissioned an investigation into aspects of the ventilation system within the hospital from Innovated Design Solutions.

5.63 Cryptococcus neoformans (CN) in Ward 6A (December 2018)

5.63.1 On 18 December 2018, a PAG took place following the identification of the second of two cases of Cryptococcus neoformans (CN) on 17 December 2018. An IMT was set up on 20 December 2018. The cases are described as ‘isolated’ and occurred in one paediatric patient and one adult patient. Each patient had a different ‘type’ of CN.

5.63.2 CN is a fungal infection. The fungi is found in soil and pigeon droppings. It is a rare organism.

6. Episodes of concern that took place or commenced in 2019

6.1 Investigation of Cryptococcus NeoformansCN (CN) identified in air samples in Ward 6A (January 2019)

6.1.1 On 16 January 2019, air sampling was said to have found Cryptococcus albidus (CA) in Ward 6A. No CN was said to have been identified in air samples. Out of 1,800 samples taken (over a period that is unclear), 10 were said to have identified CA and none to have identified CN.

6.1.2 Around this time there were various hypotheses around the source of the two cases of CN within the hospital. Contamination of the air from pigeon droppings was among these hypotheses. The potential source of the fungi was thought to be the plant room on the roof of the adult hospital, as pigeon droppings were found there. Pest control were called to remove the droppings[pigeons?] and the area was said to have cleaned.

6.1.3 Air sampling results from the plant room was said not to support the hypothesis that the plant room was the source of infection. But there was concern about the validity of the sampling results. There was a suggestion that the air samples were taken after the pigeons had been removed and the plant room had been cleaned.

6.1.4 As a consequence of the infections and associated investigations, high risk patients were prescribed antifungal prophylaxis.

6.1.5 On 8 January 2019, a senior clinician raised a concern with senior management within GGC around the safety of ward 6A and the use of prophylaxis.

6.2 Mucor in adult hospital (January 2019)

6.2.1 In January 2019, a patient in the adult hospital died with a diagnosis of multi-system disorder. A rare Mucor organism was isolated from the patient during their final illness.

6.2.2 There is a suggestion that there were 2 cases of Mucor in patients between 21 January and 18 February 2019.

6.3 External expert advice on ventilation advice (? Early 2019)

6.3.1 GGC took advice from external consultants on the ventilation system around this time.

6.4 Queseda Solutions Ltd Report (?January 2019)

6.4.1 The F&E team commissioned an independent company, Queseda Solutions Ltd, to undertake Computational Fluid Dynamics (CFD) simulations to test the hypothesis that the ventilation system was contaminated by droppings from pigeons roosting below the hospital helipad on the South West tower being drawn into the ducts of the system.

6.4.2 The report determined that the air arriving at the four Air Handling Unit (AHU) air intake points on each of the four towers of the adult hospital, and those on the children's hospital, did not originate from the region beneath the helipad. It was therefore unlikely that debris or particles from the helipad area was being carried into the hospital ventilation system.

6.5 The Cryptococcus Incident Management Team Expert Advisory Sub-Group

6.5.1 The CN incident had first been reported to HPS on 20 December 2018. The incident had been declared over on 15 February 2019. The last IMT took place on that date. The IMT was stood down on 20 February 2019. Among the actions of the IMT was to commission a review by experts of all possible hypothesis regarding routes of transmission.

6.5.2 It is not known when the Sub-Group first or finally reported. A "draft final" report was produced on 5 April 2022.

6.6 Establishment of Independent Review (January 2019)

6.6.1 Following the deaths of the three patients identified above (2 cryptococcus deaths and 1 Mucor death), the Independent Review was established.

6.7 Mould in shower rooms in Ward 6A (January 2019)

6.7.1 During the course of the investigation into the source of the CN, a further issue was identified relating to the sealant in some of the shower rooms in Ward 6A, which had developed a large volume of black mould. The cause of the mould was thought to be water hitting a defective join and causing water damage to the surrounding areas, which were supposed to be waterproof, but which were not.

6.7.2 In order to perform remedial work to those areas, some patients were moved to Ward 4B with other moved to the Clinical Decision Unit (CDU) in RHC.

6.8 Patients decanted from Ward 6A (22 January 2018)

6.8.1 Paediatric haemato-oncology patients were transferred out of Ward 6A due to concerns relating to Cryptococcus and the sealant used in the ensuite shower rooms. Patients were returned to Ward 6A on 11 February 2019.

6.9 Provision of HEPA filters in Ward 6A (January 2019)

6.9.1 Following the completion of the shower room repairs in Ward 6A, the air sampling results confirmed that the air quality was ‘optimal’. HEPA filters were placed in all rooms, corridors and treatment rooms in Ward 6A ‘as a precaution’.

6.10 Short Life Expert Advisory Group convened (January 2019)

6.10.1 A Short Life Expert Advisory Group was convened in January 2019 to investigate the source of the CN infections. The group consisted of representatives from GGC, HPS, HFS and ‘UK experts on ventilation’.

6.11 ‘Ongoing work’ to create isolation rooms which meet requisite standard [in Ward 6A?] (January 2019)

6.11.1 The IMT minutes for the CN incident refer to "*ongoing work to create more protection isolation rooms which are sealed, under positive pressure and with HEPA filtered air*".

6.12 DMA Risk Assessment Report 2018 (January 2019)

6.12.1 In January 2018, the 2018 DMA Risk Assessment Report was said to have been finalised, and a work plan was created to address the recommendations which it made.

6.13 TWG: testing results and ongoing refurbishment of Wards 2A/2B (January 2019)

6.13.1 Upgrading of the ventilation system in Ward 2A which was required to bring the ventilation up to standard for immunocompromised patients was estimated to take a further 12 months to complete.

6.13.2 Water testing results for Ward 2A/2B showed some out of spec, some very low-level counts (deemed acceptable), some fungal counts and 4 CU counts. Pre CD dosing counts had been much higher. One consultant room in Ward 2B and treatment rooms continued to show higher counts. The playroom wash hand basin and sink showed positive results on cold water. The TWG agreed to address the issues, retest and if there was still an issue to increase CD dosing level.

6.13.3 By late-January 2019, CD dosing was embedded in RHC and the cold-water system for the rest of the campus. It was to be introduced next to the hot water system in the QEUH.

6.13.4 Across the [whole?] campus, 240 water samples were taken with only 30 said to be showing issues. It was said that both hot and cold systems were being tested to indicate where the issues were and to allow those areas to be targeted.

6.14 TWG: water testing results and POUFs (February 2019)

6.14.1 In early February 2019, out of a total of 142 water tests, 12 were positive for fungal yeast. In late-February, ‘good results’ were seen, but there were 3 positive legionella samples which may have been attributable to biofilm being removed.

6.14.2 Water sampling results showed Ward 2A had CU in certain rooms. This ward had received the most exposure to CD but was the only one showing CU. CD dosage was to be increased for this area.

6.14.3 A TVC (total viable count) protocol document was agreed setting out when POUFs could be removed: after 4 weeks of consecutive clear tests, then moving to monthly and then quarterly for 3 continuous acceptable results to confirm control values are maintained long term. Monthly checks were to remain in high-risk areas for Legionella and Pseudomonas.

6.15 GNB in PICU (January/February 2019)

6.15.1 Between 5 January and 3 February 2019, a total of 5 cases of GNB were identified in patients in PICU: 2 Pseudomonas (Ps); 2 Acinetobactor baumanni (AB), and 1 Serratia marcescens (SM).

6.15.2 A PAG took place on 7 February 2019, which identified ‘environmental issues’.

6.16 Klebsiella in Ward 6A (? 2019)

6.16.1 During 2019, there were 2 instances of patient infection with Klebsiella spp. The timing of the infections is unknown. Despite the fact that Klebsiella spp was added to the list of alert organisms in 2018, neither of these infections had a case created on ICNet, raising concern that the alert was not active.

6.17 Internal reviews and the External Independent Review (February/March 2019)

6.17.1 At the Board meeting on 19 February 2019, the CEO announced that 3 work streams were to be commissioned as a result of the 'recent issues' at the QEUH/RHC. The workstreams included a 'review of the Estates, Facilities and environmental issues at the QEUH and RHC'.

6.17.2 The Board was also advised that the Cabinet Secretary had announced an independent external review of the QEUH and RHC.

6.18 HPS/HFS Report (March 2019)

6.18.1 The HPS/HFS Report, entitled "*Technical Review Water Management Issues NHS GGC QEUH and RHC*" is finalised but it is unclear whether it was published. The March 2019 report appears to comprise the HFS contribution to the Draft report, which was produced in August 2018, i.e., the technical aspects of the contamination of the water systems within the QEUH.

6.18.2 The report does not say whether any further information regarding the incidence of infections had been provided to HPS/HFS. On the basis that the report is said to be based on information provided up to 25.7.18 by GGC it is assumed not.

6.18.3 The HFS report confirmed widespread problems with the water system, on the basis of extensive sampling of water and drains. The report advised that NHS GGC had found ~~considered that~~ organisms within the water system and had~~were~~ linked these to bloodstream infections associated with ward 2A. Extensive sampling of the water system and sink drains disclosed the widespread presence of these organisms. It had taken a significant amount of time to establish the extent of the contamination because the GGC laboratory had been "*swamped with requests for rest*

results and the sheer volume of results and data was problematic to manage".

6.18.4 Although this observation is more relative to other Inquiry papers, it should be noted that HFS concluded that contamination of the water system was thought to have occurred at one or more times during installation, and that best practice had not been followed in design, installation, handover, operation or maintenance of the water system. Indication – in the form of test results – of "system-wide contamination" had been present in 2015. The presence of flow regulators on the Horne taps had allowed certain bacteria to grow, particularly Cupriavidus and Pseudomonas. The contamination of the tap body and components was widespread; and biofilm may have caused retrograde contamination back into the water system.

6.18.5 The report concluded that by July 2018 sufficient remediation work had been done to describe the level of risk to patients as "reduced".

6.19 TWG: testing results and ongoing de-contamination of water supply (March 2019)

6.19.1 Water test results from March showed only one sample was positive for legionella from over 200 counts. Complaints had been received about the odour and taste of the water, which may be attributable to biofilm breakdown.

6.19.2 Water sampling showed 16 fungal results, but the TWG considered that CD dosing would eliminate this over time. High TVCs had been recorded in the ARU.

6.19.3 General results for RHC were good, apart from certain areas in Ward 2A: Hospital at Night (HaN) room tested positive for Enterobacter in cold water system and TCT rooms 3 and 6 routinely recorded fungal counts and Cupriavidus pauculis respectively. 2 water coolers, dead legs and a little

used wash hand basin had been removed from the HaN room and automatic flushing of water outlets was installed.

6.20 Remedial work in Ward 2A (March 2019)

6.20.1 The taps and sinks in Ward 2A were changed.

6.20.2 The POUF on taps in Haematology were to be kept in place for the long term as fungi was identified there.

6.20.3 Discussions continued as to whether the taps should be removed [and replaced?] in other critical care areas.

6.21 Enterobacter cloacae isolated in water samples (27 March 2019)

6.21.1 On 27 March 2019, Enterobacter spp was identified in a water sample from an anaesthetic kitchen and a basement water tank.

6.22 Completion of CD dosing on both sites (March 2019)

6.22.1 Installation of continuous (low level) chlorine dioxide (CD) water treatment system across both hospital sites in hot and cold-water systems was complete by March 2019. There had been no cases of bacteraemia associated with water since September 2018.

6.23 Implementation of 2018 DMA report (April 2019)

6.23.1 In April 2019, the work plan to address the recommendations made in the 2018 DMA report was said to have been completed, and implementation by the F&E team began.

6.24 Cryptococcus: air sampling results (April 2019)

6.24.1 Over 800 air samples had been taken in relation to Cryptococcus neoformans, however, Cryptococcus was said not to have been identified in air sampling since the end of January 2019. Air sampling continued.

6.25 GNB in Ward 6A (April/May 2019)

6.25.1 During April and May 2019, there were 4 cases of GNB in Ward 6A: 2 cases of Stenotrophomonas maltophilia (STM); 1 case of Pantoea septica (PanS), and 1 case of Enterobacter cloacae (EC).

6.25.2 On 3 June 2019, a PAG took place to review the 4 infections. Water samples had been collected from Ward 6A, and the provisional results found no GNB, but full results were awaited (full results were ultimately reported to be negative).

6.25.3 Further investigations are said to have included the construction of patient timelines to identify areas of the hospital that patients had visited, and to test those locations and to visually inspect the drains for grime and test if grime present.

6.25.4 Ward 6A was determined to be safe for new admissions. Some high fungal counts had been recorded on the ward, but no water or moisture sources had been found to explain the high counts.

6.26 Acinetobacter baumanii (AB) in PICU (April 2019)

6.26.1 On 16 April 2019, a PAG took place in relation to two instances of infection with Acinetobacter baumanni, identified in patients in PICU on 21 February and 9 March 2019. One patient had died, but AB was not listed on the death certificate. The PAG concluded that there was no link between the two cases. Surveillance monitoring by IPCT was ongoing.

6.27 Acenitobacter baumanni in Ward 4D and 4A (March-May 2019)

6.27.1 Between March and May 2019, a total of four patients in ward 4A and 4D QEUH tested positive for AB. The index case tested positive on admission to the Ward. The infections were reported to HPS. The hypothesis was that cross-transmission had occurred, due to a failure of SICP measures.

6.28 External advice on refurbishment of Ward 2A (May 2019)

6.28.1 On about 8 May 2019, GGC received advice regarding the ventilation system on Ward 2A. It said that the as-fitted system was in line with what might be seen in a modern general ward but that "it falls short of what would be considered appropriate for a modern facility designed to meet the needs of immune-compromised patients."

6.29 Further cases of environmental bacteria in Ward 6A (June 2019)

6.29.1 In June 2019, a patient tested positive for Enterobacter cloaecae (EC), and a separate patient tested positive for Mycobacteria chelonae (MC) on the chest wall around the CVL site.

6.29.2 MC is a very rare pathogen, with only 4 adult cases and no paediatric cases being reported by GGC in the ten years prior to 2019. There had been a case of MC during the 'water incident' in Ward 2A in May 2018. The patient that contracted MC had no contact with unfiltered water.

6.29.3 An IMT was set up to consider the six infections which had occurred since April 2019.

6.29.4 The investigation considered the areas of the hospital that the patient had visited outwith Ward 6A, as well as Ward 6A. Visual inspection of the drains and trough sinks in the theatre which the patient had visited were found to be clean, but there was visible grime in the hand wash basins in the anaesthetic room, and the clean and dirty prep rooms. The drains from the theatre grew unique strains of 'steno' [STM?], Enterobacter and other

organisms. The drains in Ward 6A were dosed with Hysan disinfectant regularly and were found to have no grime.

6.30 MC isolated in the water supply in Ward 6A (June 2019)

6.30.1 Water samples from theatres and Ward 6A were collected. The results revealed that, with POUF removed, the water was positive for MC in several areas, including three shower heads and Domestic Service Rooms (DSR).

6.30.2 Overall, there was a significant reduction in GNB noted in the water samples. With the filters removed, the samples showed fungal growth in the water. The theatre water samples were negative.

6.30.3 The hypothesis was that the patient that contracted MC had contact with unfiltered water. Certain areas within A&E, outpatients and theatres did not have POUF fitted to clinical hand wash basins.

6.31 Typing confirms MC isolate from patient line site and water supply match (June 2019)

6.31.1 In June 2019, typing of the isolates extracted from water samples and the patient colonised by Mycobacterium chelonae were confirmed to be a match. This appears to be the second instance of infection which GGC appear to accept can be definitively linked to the hospital environment.

6.32 TWG: investigation of MC source (June 2019)

6.32.1 In late-June 2019, the TWG were advised of the identification of STM and MC in water samples in Ward 6A. The TWG agreed that water samples from both filtered and non-filtered outlets, as well as areas of the hospital visited by the patients affected, ought to be taken and analysed. A small increase in the CD dosing was proposed. Whilst a large dose to be added to the bulk water storage tanks was possible, it would render the water

undrinkable and may damage the pipework. That step was only to be taken if the water system was confirmed to be the source.

6.32.2 If the CD dosing was killing off bacteria in the water system, it may be breaking up the biofilm, and allowing more resistant bacteria (including M. chelonae) to grow. It could take 3 or 4 years for the water testing results to be clear.

6.33 Fungal growth in water tanks and sprinkler tap room (June 2019)

6.33.1 Fungi continued to be identified in water tanks, but there was a suspicion that cross-contamination may be occurring during the sampling process. The sprinkler tap room smelled musty, and air sampling results showed fungus. The area was to be cleaned and sanitised, and the water tanks repaired and sealed to the floor.

6.34 Corrosion of water system (June 2019)

6.34.1 A review of all water system apparatus demonstrated that items made of cast metal, or which had paint treatment, showed signs of corrosion and biofilm. The affected products required to be replaced. HFS were asked to provide advice.

6.34.2 DMA Canyon were later commissioned to carry out a survey of all cast iron and paint treated products in the water system.

6.35 Mould in Ward 2A (June 2019)

6.35.1 High levels of mould and lead leachate had been found in integrated plumbing system (IPS) panels and water samples respectively in Ward 2A. This was thought to have been exacerbated by the automatic flushing of outlets, which was discontinued as a consequence.

6.36 Enterobacter spp isolated in patient rooms on Ward 6A (24 June 2019)

6.36.1 Enterobacter cloacae was isolated from toilets in 3 patient rooms in ward 6A on 24 June 2019.

6.36.2 The ward samples were obtained within 12 days of two patients with Enterobacter cloacae bacteraemia, although there was no co-location with the rooms in which these patients had been nursed.

6.37 Remedial steps vis a vis water supply (June 2019)

6.37.1 The dosage of Chlorine Dioxide (CD) in the water system was to be increased. POUFs were to be fitted in theatres, interventional radiography and OPDs. Water sampling in Ward 6A was to continue, with and without POUF fitted. Handwashing was to be followed by gel sanitisation. Drains in theatre were cleaned.

6.37.2 Replacement taps in high-risk areas had been identified and authorised, and the programme of replacement would take 12 months to complete.

6.38 Reflection on significance of rare organism (MC) (June 2019)

6.38.1 MC was added to the IPCT alert organism list.

6.38.2 Previous water sample results were to be checked for MC.

6.38.3 HPS were asked to research what other instances other health boards have of MC in order that GGC could compare its own figures.

6.39 Concern and investigation of leaking chilled beams (June 2019)

6.39.1 During the MC investigation, concerns were noted about mould which was evident on ceiling tiles in Ward 6A, following recent leaks from chilled

beams in the ventilation system. Leaks were thought to have been caused by a boiler failure and leaking pipe with ingress to the ceiling void.

6.39.2 The chilled beams were to be sampled. F&E were to review all leaks within Ward 6A within the month prior to identify any commonality with patients.

6.40 HPS Report (June 2019)

6.40.1 HPS produced a report, entitled "*Situational Assessment Wards 2A/B RHC NHS GGC*", in June 2019. It is not clear from the terms of the report when it was commissioned or what the purpose of the report is. It appears that the report is based on data for a 5-year period between June 2013 and June 2018. The report records that 'observational assessment walk rounds' of Wards 2A/B took place on 18-22 June, 2 July and 8 August 2018, making the findings significantly out of date by the time the report was produced (June 2019).

6.40.2 The June 2019 report appears to have been based on two sources of data on infection. The first was the Healthcare Infection Incident Assessment Tool (HIIAT) reporting relative to wards 2A/B from GGC. Based – it would appear – on the HIIAT data set and the investigation around/prompted by that, HPS said the following: around May 2017, in response to noted increase in line infections, a CVL quality improvement group had been formed; a reduction in CLABSI figures had followed "outwith the BSIs identified as part of the water incident". This indicates that although issues about CVL care might have made a contribution to overall rates of infection it did not provide a complete answer. The investigations of HPS and GGC had identified a higher-than-expected level of healthcare associated incidents linked to wards 2A/B.

6.40.3 The second data set on which HPS relied was extracted from the Electronic Communication of Surveillance in Scotland (ECOSS) system. Analysis of this data indicated that "*the overall incidence of Gram-negative, Gram-positive and environmental bacteria blood cultures*

increased in [what was described as] the 2A/2B Group after the move to RHC".

6.40.4 Overall, the HPS report appears to support the link suggested in the other reporting of HFS/HPS between infections and the water system. The report says: "*Based on the ward reviews and the epidemiological data presented in this report it is hypothesised that the increased number of HIIAT reports could all be linked to environmental factors and are not considered to be indicative of poor or compromised practice*."

6.40.5 Whereas earlier HPS/HFS reports focused on concerns to do with water systems, this report postulated a contribution from the ventilation system: "*It could be hypothesised that ventilation may have been a contributory factor in several incidents*". The report said that this could not be confirmed pending a "*full ventilation review*".

6.41 2 further GNBs in Ward 6A (July 2019)

6.41.1 By July 2019, two further instances of GNB infection (Pseudomonas putida (PsP)) had occurred in patients located in Ward 6A, taking the total of GNB patient infections to 8. Both were considered to be HAI.

6.41.2 An IMT meeting took place on 3 July 2019. The hypothesis was that it was unclear whether the GNB infections reflected the normal background rate or were related to the environment. For the MC cases, the hypothesis was that patients/staff had access to unfiltered water in another area of the hospital.

6.42 Control measures in light of further instances of GNB infection (July 2019)

6.42.1 Water sampling in Ward 6A continued, and a sink with a filter in the 'arjo bathroom' was found to be positive for MC. The arjo bath was removed as a consequence.

6.42.2 POUFs were to be fitted at all locations along patient pathways, and drain cleaning was also to take place at all patient locations. Sinks in the DSR in Ward 6A which were not compatible with POUF were to be replaced as a preventative measure, following discussions with the manufacturer to see if a POUF could be retrofitted.

6.42.3 The TWG was investigating whether to use a higher dose of Chlorine Dioxide (CD) to shock dose the water supply.

6.42.4 Water testing was to continue for the entire ward over the course of the next month to give an 'overview of all water outlets in the whole ward'.

6.43 TWG: water samples positive for MC (July 2019)

6.43.1 In July 2019, pre-filter water samples in Ward 6A continued to test positive for Mycobacterium chelonae. The theory for the re-appearance of MC was that it was resistant to chlorine, that the introduction of chlorine dosing had killed off the other types of organisms, letting this more unusual bacteria grow. The dose of Chlorine Dioxide (CD) in the water system was to be increased from the rate of 0.5ppm to 0.7ppm. An increase to 1.2ppm was considered, but this was not considered feasible based on 'engineering challenges and potential impact on services'.

6.44 Descriptive analysis of trends in bacteraemia rates for selected gram negative organisms (July 2019)

6.44.1 The clinician who provided the report on bacteraemia trends on 1.10.18, provided a further report in July 2019. He explained that his report was a response to the increase in rates among haemato-oncology patients within the RHC. He reported an improvement in rates since his first report.

6.44.2 Once again, the report was descriptive in nature and advised that causality could not be assumed. However, the report hypothesised a contribution to

the improvement in rates from the following: the decanting of patients from 2A/B, chlorine dioxide (CD) dosing, education and other measures to ensure high practice standards, and the introduction of point of use filters.

6.45 4 further GNB positive patients in Ward 6A (August 2019)

6.45.1 Between 3 July and 1 August 8 August 2019, a further 4 patients with a link to Ward 6A tested positive for at least one type of GNB, as follows: 1 case of Chryseomonas (CH) who also developed Pseudomonas a week later; 1 case of Enterobacter cloaecae (EC) and Elizabethkingia miricola (EM); 1 case of Stenotrophomonas, and 1 patient with Enterobacter aeromonas (EA) who previously had Pseudomonas (Ps). The last patient was an inpatient at Raigmore in Inverness, but was linked to Ward 6A due to post-transplant care at the RHC.

6.45.2 The total number of instances of infection since April 2019 now totalled 11, with the Raigmore case a possible further case (12).

6.46 IMT meetings continue (August 2019)

6.46.1 IMT meetings took place on 1, 8, 14 and 23 August.

6.46.2 Water testing was carried out throughout August 2019. Tests were performed on taps with POUFs in Ward 6A and elsewhere, and the results were negative. A water sample from a plant room (not know if pre-or post-filter sample) tested positive for Klebsiella and Psuedomonas Putida.

6.47 TWG: water samples positive for Ps and coliforms (August 2019)

6.47.1 Water samples from the main water tank room tested positive for Pseudomonas (Ps) and coliforms, as well as for mould and yeast. The ‘ongoing issues’ with mould and yeast in the basement plant room required to be investigated, including by air sampling.

6.48 Focus on ventilation (August 2019)

6.48.1 During August 2019, focus shifted to the chilled beams in the ventilation system and the fact that they suffered from leaks and condensation.

6.48.2 Discussions between GGC and HPS took place on where samples on chilled beams should be taken from.

6.49 Isolates identified in sampling of chilled beams (August 2019)

6.49.1 Samples show Pseudomonas oleovorans (PO) and Pseudomonas aeruginosa (PA) in the cold water. It is unclear whether this was part of the investigation into the chilled beam system or a reference to the water system.

6.49.2 Swabs of the grills on the beams showed small growths of Acinetobacter, Klebsiella and Pantoae species.

6.49.3 Air samples from patient room ensuites showed small counts of Aspergillus.

6.50 Clinician concern about chilled beams (August 2019)

6.50.1 Clinicians express their concerns that immunocompromised patients were in rooms with chilled beams, but all rooms in the hospital were the same apart from Ward 4B. Possible options discussed included: use of beds in Ward 4B; a further decant, and use of a temporary mobile unit.

6.50.2 There was disagreement amongst MBs about the reliability of swabbing and whether the level and nature of GNB infections being seen was unusual.

6.50.3 The hypothesis for the ongoing GNB infections was that the patients had either had contact with unfiltered water or that the chilled beams were either leaking or dripping condensation onto patients.

6.51 Restriction of admissions to ward 6A (2 August 2019)

6.51.1 As a consequence of the level of concern over the GNB infections, admissions to ward 6A were restricted from 2 August 2019 and new patients were diverted to other health boards.

6.52 Remedial work to address contamination of chilled beams/ventilation of rooms (August 2019)

6.52.1 A number of control measures were put in place. Biocide was introduced to the chilled beam system, and subsequent testing was negative. The cleaning of grills on the chilled beam system was increased from 3 monthly to every month/6 weekly. F&E were instructed to draw up a ‘dedicated action plan’ for chilled beams in Ward 6A to address how issues/services were to be managed.

6.52.2 HEPA filtration units were to be installed within the ceiling void of patients’ ensuite bathrooms.

6.53 Additional control measures in place (August 2019)

6.53.1 Clinicians spoke to the Medical Director regarding alternative accommodation for the patients in Ward 6A. A review was to be done to see which patients could be moved to Ward 4B.

6.53.2 All patients were receiving ciprofloxacin prophylactically.

6.53.3 The dosage of Chlorine Dioxide (CD) within the water supply was to be increased.

6.53.4 The sink in the DSR was to be removed as it had no POUF and this could not be retrofitted.

6.54 3 further cases of GNB in Ward 6A (September 2019)

6.55 Three further instances of GNB infection occurred in patients during September 2019: a patient admitted on 2 September had a positive culture for multiple GNB organisms the next day; on 22 September 1 patient tested positive on admission for Achromobacter spp (AC), and on 29 September 1 patient tested positive for Stenotrophomonas maltophilia (STM). The total cases were now 14 cases and 1 possible case.

6.56 Ongoing IMT (September 2019)

6.56.1 The IMT continued to meet throughout September 2019.

6.56.2 Environmental sampling in Ward 6A and “Beatson” [MD- Ward 4B?] was said to be negative.

6.56.3 Typing of the GNB organisms collected from sampling and those found in patients revealed that the isolates were different and unique.

6.57 MBs SBAR (August/September 2019)

6.57.1 At the IMT on 6 September 2019, MBs submitted an SBAR (dated 26 August 2019) outlining a number of concerns about Ward 6A, including air changes and pressure; use of HEPA filtration; infection risks from chilled beam technology; existence of pathogenic fungi; exposure to unfiltered water; risk from toilet plume; ceilings not solid; lack of play area; door entry; sinks, and prep room.

6.58 F&E visit to GOSH (September 2019)

6.58.1 F&E visited Great Ormond Street Hospital to look at their water and ventilation systems and were to produce a report on their findings.

6.59 Options paper on alternative accommodation for patients (September 2019)

6.59.1 Clinicians prepared an options paper identifying alternative accommodation which patients could be moved to if required. That paper was submitted to the Executive committee, MD and CEO of GGC. It would be used if further problems occurred.

6.60 Discussion about the epidemiology of the infections (September 2019)

6.60.1 A number of epidemiology reports are said to have been produced by certain MBs within GGC and by HPS on the numbers and types of infections being found in the patient cohort, as compared to other hospitals. That particular group of MBs were said by the OB Timeline to have concluded that the environment was safe but there was debate over the methodology used and whether the measures used were appropriate.

6.61 Control measures put in place (September 2019)

6.61.1 The remedial work outlined in the IMTs in August was completed, with the exception of the installation of the HEPA filters, which was due to take place within 6 weeks.

6.62 Changes to IPC procedures and SOPs (September 2019)

6.62.1 From September 2019 onwards, a full microbiological analysis and root cause analysis (RCA) was to be performed on all cases.

6.62.2 A SOP was developed for obtaining regular water, environmental and chilled beams sampling. HPS were to have input into this.

6.62.3 Central line infection triggers were to be put in place so if reached then action could be taken.

6.62.4 Consideration was to be given to the appropriate threshold for an IMT to be triggered: either 2 cases of the same infection in a 2-week period (proposed by GGC) or 2 infections regardless of type (proposed by HPS).

6.63 DMA Canyon 2018 report implemented (September 2019)

6.63.1 By September 2019, the work to address the recommendations of the 2018 DMA report was said to have been completed.

6.64 TWG: water sampling results (September 2019)

6.64.1 Water samples which had showed positive results were reviewed. There had been an initial increase in positive samples, followed by a steady decrease over the following weeks. The samples (unknown location) were showing yeast and moulds. Initial samples had shown coliforms and E. coli, but no Legionella of Pseudomonas.

6.65 Specialist subgroup formed to consider ventilation in PICU (September 2019)

6.65.1 A specialist subgroup was formed to consider ventilation in PICU. The group included clinicians, IPCT, F&E and the ventilation Authorised Engineer. The PICU was ‘non-compliant’ as it had a lower number of isolation rooms than required. Following an options appraisal, the group recommended that a derogation be signed off and agreed to allow the unit to operate in its current set up.

6.66 Delftia acidovorans (DA) in Ward 6A (October 2019)

6.66.1 1 patient who had a line inserted on 24 September returned for treatment on 1 October and tested positive for Delftia acidovorans (DA). The total number of cases was now 15 with 1 possible case.

6.67 Ongoing IMT (October 2019- 14 November 2019)

6.67.1 IMTs continued throughout October and into November 2019, finally closing on 14 November 2019. No further cases of GNB infection were said to have been identified following the case of DA in early-October. Scottish Government (SG) representatives attended the first IMT in October due to concerns about the lifting of the ongoing ward restrictions.

6.68 Water sampling continues (October 2019)

6.68.1 Water sampling continued to be undertaken, and the results were reported by the TWG. August sampling results showed both very low and very high levels of coliforms, but sequence testing was negative. September results showed DA and STM, but retest results were awaited.

6.68.2 There was a new hypothesis in the IMT as a result of RCA methodology that infections may be from Smart Site Hubs which allow needleless injections of medication into the patient line. As a consequence, Smart Site Hubs were to be tested, and to be replaced when contamination spotted, as opposed to weekly.

6.69 TWG: water sampling results (October 2019)

6.69.1 Testing of flow straighteners for the previous 3 months showed no Pseudomonas or biofilm formation. The chlorine dioxide (CD) dosing appeared to be keeping the flow straighteners clean. Periodic testing should continue to allow any changes to be identified and actioned.

6.69.2 Testing of the basement tanks post-filter showed Delftia in one tank and room: Pseudomonas in the drain points, and high TVCs in certain lines of the raw water tank.

6.69.3 Out of 142 samples taken from the campus, only 1 showed bacteria. The samples over August and September continued to become clearer and clearer.

6.70 GGC seek external support from HPS (October 2019)

6.70.1 In October 2019, GGC requested support from HPS to review the data being used to inform the risk assessment and decision making in relation to Wards 6A and 4B at QEUH.

6.71 HPS Epidemiological Analysis (Oct 2019)

6.71.1 The request resulted in the HPS report, entitled "*Review of NHSGG&C paediatric haemato-oncology data*" in October 2019.

6.71.2 The October 2019 report states its key objective was to assess GGC's datasets and to investigate the suspected increase in environmental Gram-negative blood cultures in the paediatric haemato-oncology patient population. The review compared different sources of data on positive blood samples from haemato-oncology patients. Blood samples were divided into four groups- Gram-negative; Gram-positive; environmental bacteria and environmental bacteria including enteric bacteria (those found in the gut). Analysis covered the period between July 2013 and September 2019. The patient cohort appears to have been "patients less than 18 years of age cared for in the paediatric haematology oncology speciality in NHSGG&C (including new and existing patients)".

6.71.3 On the incidence of infection within QEUH, precisely what should be taken from the HPS epidemiological investigation requires further investigation. But overall, HPS summarise their findings as indicating variation in

expected infection rates for the cohort of patients. Statistical Upper Warning Limits were exceeded for Gram-negative cases in August 2017, March 2018, May 2018 and September 2019; for “environmental group” cases in March and June 2018 and March 2019; and in Gram-positive cases in July 2016 and May, November and December 2017. It is not clear what should be taken from the comparison between QEUH and other sites.

6.71.4 The report concluded that the analysis did not provide evidence of a single point of exposure causing blood stream infections. It is not clear what this was intended to indicate. Analysis of some different types of bacteria showed some changes, but given the small numbers in each group, the significance of the changes was not fully understood and should be part of the ongoing monitoring.

6.71.5 The report recommended that GGC should consider lifting the restrictions on admissions as based on HPS review of the data there was no evidence to support their continuation.

6.71.6 There is a suggestion that the HPS October 2019 report ‘validated the study’ carried out by the ‘hospital microbiology and pharmacy group’ in 2018, although this study is not referenced in the report itself.

6.72 IMT closed (14 November 2019)

6.72.1 On 14 November, the ongoing IMT in relation to the infections in Ward 6A was closed.

6.72.2 The new procedure for cases was agreed as: RCA to be done for all cases; PAG to be set up if there were 2 GNB cases in 30 days or upper warning limits on SPC charts were met; escalation to IMT would be based on Board’s standard outbreak procedures; if immediate source was not identified, external advice will be sought early; findings of PAG to be reported to Clinical Review Group, a ‘data collection form’ developed with

the assistance of HPS, was to be used by a MDT to collect the relevant data.

6.73 Water results are 'pristine' (November 2019)

6.73.1 Water results were reported as being 'pristine' with very low TVCs.

6.73.2 Increased water testing continued, for the purpose of providing reassurance to patients and families.

6.74 Ward 6A re-opens to new patients (21 Nov 2019)

6.74.1 In light of the conclusions of the HPS October 2019 report, HPS gave their formal agreement to lift restrictions on admissions to Ward 6A. A SBAR was prepared by a GGC staff on 14 November 2019. Ward 6A re-opened to admissions on 21 November 2019.

6.75 HPS Report published (29 November 2019)

6.75.1 On 26 November 2019, HPS published its report: Review of NHS GGC Paediatric Haematology Oncology Data.

6.76 Ventilation in PICU upgraded (October/November 2019)

6.76.1 In October/November 2019, work to upgrade the ventilation in all 4 bedded rooms in PICU was said to be completed. Only a few cubicles were still to be completed.

6.77 Escalation to level 4 Framework (22 Nov 2019)

6.77.1 On 22 November 2019, the Scottish Government's Health and Social Care Management Board escalated NHS GGC to 'Stage 4' of its escalation ladder and a new Oversight Board, led by the CNO, Professor Fiona McQueen, was established.

6.77.2 Stage 4 represents a level where there are "*significant risks to delivery, quality, financial performance or safety, and senior level external transformational support [is] required*".

6.77.3 The OB was set up to address two specific sets of issues that led to escalation to Stage 4: (i) infection and prevention and control and associated governance associated with the QEUH, and (ii) communications and engagement with affected families.

6.77.4 The OB's aim was to "*review and address the set of critical issues relating to the operation of infection prevention and control (IPC), governance and communication and engagement with respect to the Royal Hospital for Children (RHC) and the Queen Elizabeth University Hospital (QEUH) and the handing of infection incidence affecting children, young people and their families within the paediatric haemato-oncology service of NHS GGC*".

6.77.5 The OB consisted of a group of experts and representatives drawn from other Health Boards, the Scottish Government and the affected families themselves. It was chaired by Scotland's Chief Nursing Officer, Professor Fiona MacQueen. The work of the OB was split into three subgroups: "Infection Prevention and Control and Governance"; "Technical Issues", and "Communication and Engagement".

6.77.6 The IPC and Governance subgroup was tasked with examining whether appropriate IPC and IPC governance was in place across NHS GGC in relation to the incidence of infections affecting children, young people and their families within the paediatric haemato-oncology service of GGC, and "*to recommend how to strengthen current approaches to mitigate avoidable infection harms*".

6.77.7 The Technical Issues Subgroup was focused on the 'technical operations' of the hospitals in question, "*with a particular focus on key infrastructure issues, including the Board's approach to water safety*".

6.77.8 The Communication and Engagement Subgroup was to consider "*effective communication with the children, young people and families of the paediatric haemato-oncology service of NHS GGC, as well as whether a wider, robust, consistent and reliable person-centred approach to engagement has been evident*".

6.78 Multiple cases of GNB in PICU (November/December 2019)

6.78.1 On 5 November 2019, a PAG was held following the identification of 3 cases of Acinetobacter baumanii (AB) in PICU during a 12-day period in October 2019. Two patients were in the same bed bay, so cross-transmission was suspected.

6.78.2 On 12 November 2019, a PAG was held following 2 cases of Pseudomonas aeruginosa (PsA) in PICU, the first was thought to be community acquired (identified on 21 September 2019), and the second was a HAI (identified on 7 November 2019).

6.78.3 On 19 November 2019, an IMT took place to assess if the 2 PsA infections were HAI or not. The medical history of the patients led to both cases being classified as HAI. Patient 1 had been transferred from NHS Ayrshire and Arran and no samples had been taken prior to transfer, so it was unclear where the infection was acquired by that patient. Typing results for the two patients did not match, however, both patients had treatment on an ECMO machine on 21 September and 7 November respectively. ECMO has disposable circuits and is sterilised weekly and after each patient use. The water in the machine is tested after each patient and the results are negative. Both patients had also used a hemofiltration unit which uses disposable circuits. It is not clear whether this had been tested.

6.78.4 The ECMO machine was out of use pending results of water samples being obtained. Water samples were also to be taken from NICU and Theatre 8 as patient 2 was in both of those locations.

6.78.5 No ‘domestic or water checklist issues’ were highlighted.

6.78.6 On 21 November 2019, a PAG took place following the identification of a further case of PsA, this time by a bronchoscope investigation to gain a sample from lower airways (blind bronchoalveolar lavage (BBAL)). The patient had been transferred from NHS Ayrshire and Arran in late-September. Water samples taken on 14 November 2019 were negative, and no domestic or water checklist issues were identified.

6.78.7 On 24 November 2019, a patient in PICU tested positive for Serratia marcescens (SM). The patient sadly died on 25 November and as the cause of death was unknown, it had been reported to the Procurator Fiscal. The patient had been transferred from NHS Highland.

6.78.8 On 27 November 2019, an IMT was convened to review the single case of SM, as well as the 3 cases of AB and 3 cases of PsA which had been identified since October 2019. Water sampled taken with POUFs removed were negative. The only connection between cases identified so far is that 2 of the PsA patients were treated in theatre 8. Theatre 8 had tested negative for isolates. Environmental sampling of frequently touched surfaces was underway.

6.78.9 On 10 December 2019, a second case of SM was reported from a BBAL sample. The typing was different from any seen in the hospital so far. The patient had been transferred from NHS Ayrshire and Arran. The clinical team considered that the case was not HAI.

6.78.10 A fourth case of AB was identified in a BBAL sample on 23 December 2019. Environmental samples (including drains) taken on 11 and 19 December were negative. The hypothesis was that this was a sporadic

case, as there was no overlap in time and place or equipment with the earlier cases. No AB had been isolated in environment, water, Theatre 8 or in the specific rooms tested. No further IMT was arranged, but one was to be held if any further cases occurred to activate the trigger. F&E were to survey PICU to check for leaks and dampness. Water samples of all outlets in 4 bedded areas and room 17 to be undertaken.

6.79 Prospective and retrospective investigation (December 2019)

6.79.1 SG directed GGC to investigate the last three incidents (i.e., all instances of GNB in PICU since October 2019) together prospectively and retrospectively using the HPS definition (2 GNB positive results in 30 days).

6.79.2 The initial hypothesis was possible water transmission for PsA in Theatre 8, and possible water transmission of SM. AB was thought to be cross-transmission between patients.

6.79.3 Water samples were taken from PICU, Theatre 8 and NICU. All were negative for isolates.

6.79.4 Weekly swabbing of POUFs, drains, CHWBs and water sampling for GNB was to continue for a four-week period. Monthly water sampling for Mycobacterium was to continue. Drains were to be dosed with Hysan weekly.

6.79.5 All water sample tests in Theatre 8 were negative. All water sources were tested against PsA, SM and AB including inside filters, trough sinks and HH sinks in peripheral rooms. As a result, the water hypothesis for transmission of PsA in Theatre 8 was closed.

6.79.6 An environmental screen picked up a number of organisms in drains including SM in a trough sink adjacent to the bed space of the patient with SM. Whilst the water hypothesis was closed, there was a new hypothesis

about colonisation from the drains as a positive sample was found in the room that the patient was nursed in.

6.79.7 No further IMTs took place in relation to this incident.

6.80 HSE Improvement Notice (Dec 2019)

6.80.1 It is understood that around 20 December 2019, the HSE served a notification of contravention and improvement notice on the chief executive officer of GGC. This was received on 24 December 2019 and published on the NHS Scotland website.

6.81 Retrospective view of episodes of infection in Ward 6A (? 2019)

6.81.1 During 2019, there were a total of 28 episodes of patient blood stream infection with bacteria commonly linked with the environment in the Schiehallion Unit patient cohort, according to the CNR. This included 4 episodes of infection caused by Stenotrophomonas; 4 caused by Pseudomonas, and 8 caused by Enterobacter.

6.81.2 It appears that some but not all of these infections were identified and investigated at the time at which they occurred.

7. Episodes of concern and assessments of concern from 2020 to date

7.1 Ongoing water sampling (January 2020-)

7.1.1 Regular water sampling is reported as having been ongoing across the hospital site. F&E were taking 142 samples (2 samples from each of 71 designated points throughout QEUH and RHC). The results are recorded on a ‘sample matrix’.

7.1.2 Between January 2020 and April 2020, a total of 1111 samples were collected. If a sample is ‘out of spec’, for Legionella or TVCs, it is added to a further spreadsheet and actions are taken to address it. The identification of other bacteria in water samples (apart from Legionella and TVCs) are passed to ICD for review.

7.1.3 There was a total of 39 ‘out of spec’ samples between January and April 2020 (although 83 samples had not yet been reported).

7.2 Case Note Review (CNR): announced (28 January 2020)

7.2.1 On 28 January 2020, as part of the work of the OB, the Cabinet Secretary for Health and Sport announced in Parliament the plans for a Case Note Review CNR).

7.2.2 The CNR team were to review the case notes of Haemato-oncology paediatric patients in the RHC and QEUH from 2015-2019 who have had a Gram-negative environmental pathogen bacteraemia (and selected other organisms) identified in laboratory tests.

7.3 CNR: commenced (24 February 2020)

7.3.1 The work of the Expert Panel carrying out the CNR commenced on 24 February 2020.

7.3.2 The purpose of the CNR was to undertake a review of the medical records of all children diagnosed with a qualifying infection, cared for at the RHC between 1.5.15 and 31.12.19, to establish the number of immunocompromised children likely to have been put at risk because of the hospital environment, and to assess how any infections may have influenced their health outcomes.

7.3.3 The selection criteria for cases to be included in the review was: all patients cared for in the Paediatric Haemato-oncology service at the RHC

who had at least one positive blood culture of a Gram-negative bacterium associated with the environment (Group 1) or at least one positive culture of an atypical Mycobacterium spp (acid-fast environmental bacteria) (Group 2). One patient that did not meet these criteria, but who experienced severe infection with a Gram-negative environmental bacterium (without proven bacteraemia) was included at the request of the family (Group 3).

7.3.4 The initial cohort consisted of 85 patients (although the number of infection episodes was higher as some patients had multiple episodes). Of those 85 patients: 81 patients were in Group 1; 3 patients (2 with bacteraemia and 1 with a skin infection) were in Group 2, and 1 patient was in Group 3 (that patient also had an infection with Aspergillus).

7.3.5 Patients were identified using the combined dataset used by HPS in preparing their report of October 2019, with the data extract being extended to December 2019, comprising: HPS Electronic Communication of Surveillance in Scotland (ECOSS) data; GGC Central Line Associated Blood stream Infection (CLABSI) surveillance system data; GGC's ECOSS data, and GGC's microbiology laboratory information system (LIMS).

7.3.6 The CNR attempted to assess the likelihood of the hospital environment being the source of each patient's bacteraemia, using information provided by GGC in the form of patient, clinical, infection prevention and control, microbiology, local investigations (including Datix and IMTs where available and hospital environmental data.

7.3.7 Episodes of infection were to be categorised into four levels of likelihood that the hospital environment was the source of the bacteraemia: Unrelated; Possible; Probable or Definite. For the hospital environment to be classified as a Definite source, not only was 'time, place and person' data required to confirm the opportunity for the infection to be derived, but bacterial typing data was required to match the patient blood culture

isolate to the same microorganism recovered from water or surface samples.

7.3.8 For cases to be considered as Unrelated, there had to be 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 a strong alternative hypothesis about the origin of the bacteraemia.

7.3.9 The CNR considered the question of how to distinguish whether the hospital environment was a Possible as opposed to Probable source. For a Probable finding, the CNR required that the information available supported the view that the environment was the likely source (on the grounds of probability) using a standard IPC assessment of the available data/information. Clustering of cases caused by a bacterial species was a key factor in reaching a Probable conclusion, as well as: multiple opportunities for contamination of intravascular catheters; bacteria that are uncommon causes of bacteraemia, and repeated recovery of the same bacterial species from hospital environment samples around the time of the bacteraemia occurring (particularly if taken close to where the patient was managed).

7.3.10 The CNR observed that the ability to identify a bacteraemia as linked to the hospital environment may depend on how commonly/systematically the environment was sampled, as well as whether the samples were targeted specifically at a particular microbe or more generally. Not finding a bacterium in the hospital environment did not exclude the possibility that the environment was the source of patient infection.

7.4 Independent Review Report published (June 2020)

7.4.1 The Independent Review Report was published in June 2020.

7.4.2 The IR identified multiple failures in relation to key buildings systems (water and ventilation) during the design, build, commissioning, and

maintenance stages of the project. In so far as relevant to the instance and occurrence

7.4.3 of infections, the detail has been included in this timeline.

7.4.4 The report considered that the hospitals "*now have in place the modern safety features and systems that we would expect of a hospital of this type. The general population of patients, staff and visitors can have confidence that the QEUH and RHC offers a setting for high quality healthcare*".

7.5 SHI: TOR published (15 June 2020)

7.5.1 On 15 June 2020, the TOR were published for the Independent Inquiry into the construction of the QEUH, Glasgow and the Royal Hospital for Children and Young People and Department of Clinical Neurosciences (RHCYP/DCN), Edinburgh.

7.6 Article on chilled beams August 2020

7.6.1 On 15 August 2020, the Journal of Hospital Infection published an article by T Inkster et al entitled *Potential infection control risks associated with chilled beam technology: experience from a UK hospital*. Among other things, the paper reported that surface swabs from chilled beams in the QEUH had grown multiple organisms including fungi, enteric organisms and environmental Gram-negative bacteria.

7.7 Oversight Board Interim Report (Dec 2020)

7.7.1 The QEUH/NHS GGC Oversight Board published its Interim Report on 21 December 2020.

7.7.2 The interim report set out some of the initial findings and recommendations of the OB on the following matters: the processes, systems and approach to improvement of Infection, Prevention & Control

(IPC); communication and engagement with patients and families; an update on the work of the CNR, and an update on the work of the Technical Review group.

7.7.3 The interim report narrates the background of concern about instances of infection in the hospital, by adopting the narrative provided by HPS in their Summary report published in February 2019: a handful of infections occurring in 2016 and 2017, followed by 23 infections caused by 11 different organisms in 2018, followed by water testing which revealed contamination of the water system and drains.

7.7.4 The interim report also records that concerns about the potential environmental risks of the building, and the link to emerging infections, had been raised consistently by several clinicians since completion and handover of the building. Some clinicians felt that their particular concerns about the water and ventilation systems, and the potential impact on vulnerable patients, had not been addressed.

2021

7.8 Article on the 2018 “water incident” (February 2021)

7.8.1 On 2 February 2021, an article was published in the Journal of Hospital Infection by T Inkster, C Peters, T Wafer (of the Water Solutions Group), D Holloway (of Intertek) and T Makin (of Makin and Makin Consultancy). The article described events connected to an outbreak of infections within the QEUH/RHC between February and September 2018. The article reported that no fatalities had occurred as a result of the incident.

7.8.2 The article said that water testing had revealed widespread contamination of the water and drainage system. Outlets were said to be heavily contaminated.

7.8.3 The authors said: “The exact route of transmission is not possible to determine but all our patients had Hickman lines, thus direct contact with water via showering or splashing seems likely.”

7.8.4 The authors also said: “Due to the extent of the contamination in our hospitals it is likely to take years for control to be achieved and point of use filters remain in situ.”

7.9 CNR: completed (January 2021)

7.9.1 The review of cases and episodes within the Case Note Review was completed in January 2021.

7.10 CNR Report (published March 2021)

7.10.1 The CNR Overview Report was published in March 2021.

7.10.2 Review of all available patient data led the Expert Panel to conclude that 84 haemato-oncology paediatric patients suffered a total of 118 episodes of infection during the period between 15 May 2015 and 31 December 2019. One patient, with a single episode of bacteraemia caused by Moraxella catarrhalis, was excluded from the initial cohort of 85 patients, as that bacterium is not considered to be environmental and spreads predominantly by person-to-person droplet contamination.

7.10.3 The findings of the Expert Panel on frequency of infection by organism (species level) are contained in Table 4.3 of the Report (Appendix 1).

7.10.4 The CNR concluded that the frequency of GNB caused bacteraemias appeared to be higher than expected, particularly for the infections caused by Enterobacter spp and Stenotrophomonas spp. The pattern was less clear for Klebsiella spp and Pseudomonas spp, which were the second and third most common GNB causing blood stream infections. The second notable point was the clustering of infections in time, as well as in place

(by virtue of the patients being treated together in Wards 2A/B and latterly 6A/4B). Whilst neither of those conclusions proved that the bacteraemias had hospital environment sources, the observations were consistent with that hypothesis.

7.10.5 The CNR noted that, following retrospective review of a large database of logs and documents provided by GGC relating to the maintenance of the clinical environment with a focus on Wards 2A/2B/6A/4B, there were a large number of requisitions for Estates and Facilities department interventions, particularly in relation to plumbing and drainage. The problems included blocked toilets or drains; leaking showers and taps; and the management and maintenance of chilled beams following reports about leaks or condensation, or both, and where additional cleaning was required for control of dust. The CNR were unable to ascertain exactly what planned programme of planned inspection and preventative maintenance existed or was actually undertaken, particularly regarding the chilled beam system.

7.10.6 The CNR considered that their ability to link the hospital environment with the patients' infections was affected by the fact that hard surface samples were infrequent, and when taken at all, were not taken in a systematic way. Overall, the CNR was unable to conclude that GGC had a systematic approach to hard surface environmental sampling, either in the context of a specific unusual infection or during an outbreak of a more commonly seen infection.

7.10.7 In relation to water sampling, the CNR noted that both HFS and the Independent Review had each confirmed that there were serious issues about the design and commissioning of the water system. The CNR found that there was a lack of a robust water testing strategy from the point at which the new hospital building was commissioned, including assurance that the system was fit for purpose. There did not appear to be a systematic water sampling process in place, or a consistent water system related response to clusters of infections caused by (often unusual or

uncommon) Gram-negative bacteria. The lack of a clear step change in GGC's approach to water sampling, testing, reporting and strategy in the face of increasing concern that the bacteraemias in the Schiehallion Unit patient cohort was of concern to the CNR. Water sampling data which the CNR were provided with frequently did not specify the precise location from where the sample was obtained, and/or precisely which bacteria were sought and identified in the laboratory. Searching once or only occasionally for a specific bacterium, and from only a limited number of sites, limited the confidence that a bacterium of concern was not contamination a water point/system and was the source of the patient infection. The CNR could not confidently exclude the water system as potential point sources for bacteraemias caused by GNB that are known to be associated with such environments.

7.10.8 The Expert Panel concluded that out of the 118 infection episodes: 1 they were unable to determine; 8 (7%) were unrelated to the environment; 76 (64%) were possibly related to the environment, and 33 (28%) were probably related to the environment. Overall, the CNR concluded that just under one third (31%) of the total number of patient infection episodes were 'most likely' linked to the hospital environment. In the 'most likely' group, there was a striking excess of Stenotrophomonas infection (14 episodes out of a total of 44).

7.10.9 The absence of systematic testing results for either hard surfaces or water samples impacted the ability of the CNR to assess environmental link between patient and infections and the hospital systems, and particularly to identify the infections as definitely linked, standing the tight criteria of microbiological typing to confirm a match between the blood sample and environmental isolate.

7.10.10 The CNR also addressed the impacts of blood stream infections on patient outcomes, as well as considering communication with patients and families.

7.10.11 The CNR also made a number of further observations about areas of concern identified in the review. These included: substantial and varied concerns about the availability of data and its quality across multiple systems; the management, investigation and reporting of infection outbreaks; microbiology and IPC information systems; the completeness of clinical records; the accuracy of patient location records; Adverse Event reporting; the adequacy of Morbidity and Mortality reports; Central Venous Line care; and the use of antimicrobial prophylaxis and the impact of the organisational response on clinical care.

7.10.12 In relation to the management, investigation and reporting of infection outbreaks, the CNR reviewed the PAG and IMT reports covering incidents between 2016 and 2019 (none being available for 2015) and concluded that not all outbreaks which may appear relevant retrospectively were investigated at the time, and not all incidents/outbreaks progressed to IMT status. As an example, the CNR records that no investigation into an increasing number of Klebsiella infections took place between 2016 and 2018, despite a total of 22 patient infections occurring, with 9 episodes occurring between June and November 2016; 9 episodes occurring between July and December 2017; and 5 episodes between January and May 2018. The CNR expressed concern that earlier opportunities to investigate the problems may have been missed because of too great an emphasis on ‘standard’ outbreak definitions.

7.11 OB Final Report (March 2021)

7.11.1 In March 2021, the OB published their final report, entitled “*The Queen Elizabeth University Hospital/NHS Greater Glasgow and Clyde Oversight Board Final Report*” (OB Final Report). The purpose of the OB Final Report was to set out the “findings, conclusions and recommendations” arising from OB’s programme of work from its establishment in Dec 2019-March 2021.

7.11.2 The OB Final Report narrates the context of the escalation of GGC to Stage 4 of the Framework: "*a background of a series of infection issues affecting children and young people in the paediatric haemato-oncology service at the QEUH and RHC over a number of years, combined with rising concerns about the source(s) of those infections and how they were being handled*".

7.11.3 One of the key aspects of the OB's work was to examine IPC and IPC governance within GGC in relation to the incidence of infection amongst the paediatric haemato-oncology patient cohort, with a view to assessing whether current IPC processes were fit for purpose. In other words, the OB was considering IPC national standards and good practice with a view to answering the question of whether within GGC "*the current approaches that are in place to mitigate avoidable harms, with respect to infection prevention and control, are sufficient to deliver safe, effective and person-centred care*". The OB appear to have approached this task by commissioning the compilation of a detailed chronology of the 'issues and incidents' which occurred between 2015-2019 within a specific patient cohort, to appraise what happened in IPC terms with potentially relevant infections during that period.

7.11.4 The OB Final Report included, at Annex F, a timeline of "infections and governance", which was commissioned as a special report by the OB, and which purports to provide a timeline of incidents in which a Gram-negative or other unusual bacteria were identified in blood cultures of patients located in Wards 2A/2B RHC, and latterly in Wards 4B/6A QEUH ("the OB Timeline").

7.11.5 The OB Timeline was compiled from written evidence provided by GGC, as well as from interviews with members of GGC staff . The written evidence which is said to have been taken into account includes: (i) minutes of the Incident Management Team (IMT)/Problem Assessment Group (PAG) meetings which were set up to investigate each incident; (ii) minutes and papers of the GGC Board and various associated committee

meetings which demonstrate the escalation of the incidents; (iii) papers provided by Facilities & Estates (F&E) team in relation to water risk assessments, audit and compliance documents; (iv) minutes of meetings of the Technical Water Group (TWG), established in April 2018, and the other GGC water groups which relate to the QEUH/RHC (Board Water Safety Group (BWSG) and South Clyde Water Safety Group (SCWSG)); (v) three reports produced by HPS/HFS (published in February 2019; March 2019 and October 2019 respectively), and (vi) two reports by DMA Canyon, entitled "Legionella L8 Risk Assessment 2015 (pre-occupancy)" and "Legionella L8 Risk Assessment 2017" dated 2015 and 2017 respectively.

7.11.6 Whilst the OB Timeline is said to be the product of a '*paper based review of documentation supplied by GGC*' and not the product of detailed or extensive interviews with staff members, it is said to take into account interviews with the GGC Infection Prevention Control Team (IPCT) to understand how *'incidents associated with GNB and fungi'* were reported to 'the Board, HPS and Scottish Government' and with F&E to '*understand the procedures around water risk assessments, audit and compliance of water systems and water testing'*.

7.11.7 The OB Timeline expressly records that the only infections and colonisations which are included relate to the paediatric patient population of the Schiehallion Unit. The Timeline does not include instances of infection in the adult hospital, or within the adult hospital population, with the exception of infection incidents in SU patients when that group of patients were moved to Wards 6A and 4B of the QEUH.

7.11.8 In its Interim report, the OB had said that among the questions that it would be addressing was this one: "To what extent can the source of the infections be linked to the environment and is the current environmental risk?"

7.11.9 In relation to the first part of this question, the OB Final Report concluded that "*in the absence of definitive sources, the strong possibility of a link has been- in the Oversight Board's view- undeniable*". In the context of GGC saying that an "exact source" of infection had not been proved "beyond doubt", the OB said that it had been "evident" that the source of infections had related to water; and it rejected the suggestion that the HPS reporting in November 2019 supported the view that what was happening as regards infection patterns was not unusual compared to other hospitals.

7.11.10 It is not clear what if any answer the OB came to on the second part of the question: current environmental risk. It did however note "*there continue to be unusual environmental bacteria incidents at different points in the site*". The source for that statement is unclear.

7.11.11 Following publication of the final report, GGC remained in Stage 4 of the National Performance Framework.

7.12 QEUH Advice, Assurance & Review Group (AARG) (March 2021?)

7.13 Article on two cases of Mycobacterium chelonae ("MC") (May 2021)

7.13.1 On 1 May 2021, an article was published in the Journal of Hospital Infection by T Inkster et al. The article was entitled "*Investigation of two cases of [MC] infection in haemato-oncology patients using whole-genome sequencing and a potential link to the hospital water supply*."

7.13.2 Of the two cases under consideration, the authors concluded that in one case the patient's MC infection was "closely related to environmental isolates from water outlets." Of the other case, the authors noted that as no contemporaneous water results were available, "a water source in the hospital [as the source of the infection] cannot be excluded completely."

7.13.3 The authors also noted: “Water systems which are being treated with disinfectants may be of particular risk as they remove competing organisms and enable atypical [MC] to proliferate.”

2022

7.14 Re-opening of Wards 2A/B (9 March 2022)

7.14.1 On 9 March 2022, Wards 2A/B RHC were due to reopen after extensive refurbishment. The refurbishment works included replacement of the ventilation system, with the installation of 11 new air handling units.

7.14.2 The Inquiry continues to investigate the basis upon which decision makers decided to reopen the ward and to consider in particular what assurance had been provided to decision makers as regards patient safety.

7.15 Final Draft Report from the Cryptococcus Incident Management Team Expert Advisory Sub-group

7.15.1 A report was issued by the CN Sub-group on 5 April 2022. It considered 7 hypotheses as regards the question of how patients within the QEUH/RHC had become infected with CN.

7.15.2 The first was whether CN spores had got into the relevant Air Handling Unit during a filter change. This was deemed to be unfeasible. Reference was made to sampling of the plant room in question which was said not to have identified CN spores. Reference was also made to sampling of air (referred to in the report as “outside air”) on different levels of the QEUH and in a different building in which evidence of SN spores was found.

7.15.3 The second hypothesis was that the absence of HEPA filtration on certain wards may have permitted CN spores to get into the air circulating in the wards. Noting the presence of CN spores in the so-called “outside air”, this hypothesis was said to be possible.

7.15.4 The third was a lack of protective isolation. This was a reference to an absence of HEPA filtration in certain areas and to issues with air control. In particular, reference was made to the following: on Ward 4B, the presence of HEPA filtration but a lack of air control; on Ward 4C, an absence of HEPA filtration (but good air control); on Ward 6A an absence of HEPA filtration and poor air control . The third hypothesis was considered possible, particularly for the patient who had spent time on Ward 6A but less so for the one who had not.

7.15.5 The fourth hypothesis concerned the cylinder room in PICU. This was considered possible but very unlikely for one patient and inexplicable for the other.

7.15.6 The fifth involved a contribution from the helipad. This was rejected as unlikely.

7.15.7 The sixth involved the pneumatic tube system. This was deemed unlikely.

7.15.8 The seventh hypothesis was that the patients themselves had brought their CN infections into the hospital: i.e. the infections had been dormant until their immune systems had been sufficiently compromised [from illness and treatment it is assumed]. The report said this of the seventh hypothesis: “VERY POSSIBLE for BOTH cases but likely to be VERY DIFFICULT TO PROVE.”

7.16 De-escalation within the National Performance Framework

7.16.1 On [around 13 June 2022] the decision was taken to move GGC to stage 2 of the National Performance Framework. The Cabinet Secretary for Health said that this was a positive step forward and highlighted the significant progress made by GGC to meet all recommendations made in previous reviews.

7.16.2 The Inquiry continues to engather and investigate the evidence understood to that statement. In particular, the Inquiry continues to engather and investigate evidence bearing on the question of whether key building systems present no risk to patient safety.

7.16.3 HIS undertook inspections and reported on 7-8 and 20 June 2022.

Annex to the History of Infection Concerns Paper

Overview of the Infection Control Team, Infection Reporting and the Microbiologists/ICDs

The following is intended to be a brief overview of the structure of Infection Prevention and Control Team in NHS GGC and the procedure for reporting infections, incidents and outbreaks.

1. The Infection Prevention and Control Team in NHS GGC

1.1. Within NHS GGC there is an Infection Prevention and Control Team (IPCT) which consists of an Executive Level Director, and Associate Nurse Director, a Nurse Consultant, a Business Manager, a Local Board Hand Hygiene Coordinator and Administrators.

1.2. There are then local IPCTs which sit within each sector of NHS GGC, which are: Clyde, North, South (adults) (covers QEUH), South (paediatrics)(covers RHC), Health and Social Care Partnerships (HSCPs).

1.3. The local IPCTs consist of a Lead IPC Nurse and a combination of Senior Infection Control Nurses and Infection Control Nurses (ICNs). There is also a dedicated Surveillance Team which supports the IPCT.

1.4. The IPCT is also supported by Infection Control Doctors. There is a Lead Infection Control Doctor (ICD) supported by Sector ICDs who cover the sectors as noted above. The primary role of the IPCT is the prevention of Healthcare Associated Infections (HAI).

1.5. All ICDs within NHS GGC are Consultant Microbiologists. As such, they all have a clinical role as a Microbiologist with sessions dedicated to Infection Control.

2. ICD Reporting Structure

2.1. The sector ICDs work closely with the ICNs and Surveillance Team to deal with any infection control issues in their particular sectors. The sector ICDs report to the Lead ICD, who, in turn reports to the Director of Infection Prevention and Control, (formerly known as the Infection Control Manager (ICM)). The Director of IPC reports directly to the HAI Executive Lead, who is a Medical Director sitting on the Board.

2.2. The Lead ICD, Director of IPC and the Associate Nurse Director of IPC make up the IPC Senior Management Team (SMT) and attend Acute Infection Control Meetings (AICC), Board Infection Control Meetings (BICC) and Clinical and Care Governance Meetings.

2.3. Sector ICDs attend a monthly IC SMT meeting along with the Lead ICD, Director of IPC, Lead surveillance Nurse and sometimes a Public Health Consultant. The purpose of these meetings is to report issues within the sector, and receive updated from the SMT about any national or local policy changes.

3. Infection reporting and Outbreaks and Incidents

3.1. The National Infection Prevention and Control Manual (NIPCM) which is produced by Antimicrobial Research and Healthcare Associated Infection (ARHAI) (previously Health Protection Scotland (HPS)) outlines a nationally agreed minimum list of Alert Organisms or Conditions which, if detected, require further investigation by the IPCT.

3.2. ICNs will generally deal with any alerts initially and escalate to the ICDs if they require any further input or advice. The ICD or antimicrobial pharmacist would provide advice on the appropriate antibiotics for example.

3.3. There is a surveillance system in place called Infection Control NET (ICNET). This has been in place since 2014 and links information from different

departments in the hospital meaning there is real time information on every patient and their history. If they have one of the alert organisms or conditions then this will appear directly from the lab on ICNET and will alert members of the IPCT so that they can take action.

3.4. Chapter 3 of the NIPCM was published in 2015 and provides a definition of an incident or outbreak, a tool to assess the incident or outbreak, a list of those who should be considered to attend an Incident management Team (IMT) meeting and the agenda for those meetings.

3.5. If there is a suspected incident/outbreak, then the ICD may choose to convene a Problem Assessment Group (PAG) which undertakes an initial assessment of the situation. The PAG considers whether it is necessary to convene an IMT and this would be done using the Healthcare Infection Incident Assessment Tool (HIIAT) which is contained within Appendix 14 of the NIPCM.

3.6. The HIIAT scores incidents and outbreaks as Green, Amber or Red. If the score is Amber or Red, this is entered on the Healthcare Associated Infection Reporting Template (HAIRT) is presented to the AICC, BICC and the Care and Clinical Governance Committee.

3.7. If an incident is assessed as Green then this is submitted to ARHAI for information purposes only.

3.8. If an incident is Amber or Red then the IPCT must complete a Healthcare Infection, Incident and Outbreak Reporting Template (HIIORT).

3.9. If Amber then the HIIAT is reviewed and reported at least twice weekly or as agreed between the IMT and ARHAI.

If Red, the HIIAT is reviewed and reported daily or as agreed between the ARHAI and the IMT.


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