SCOTTISH HOSPITALS INQUIRY

Bundle of documents for the Oral hearing commencing on 12 June 2023

Bundle 6 – Miscellaneous documents

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PATIENTS FIRST AND ALWAYS

HPN Control of Infection Steering Group
Tuesday 13 June 2017
12.30pm – 1.45pm
Level 3 Conference Room, GWS 008, RHC

PRESENT:	Tricia	Friel	TF	Lead Nurse (Chair)
	Katie	Anderson	KA	Infection Control
	Allison	Armstrong	AA	SCN
	Janice	Hackett	JH	Minute Secretary
	Lorraine	Harper	JH2	Age Appropriate Care
	Jim	Harrigan	JH3	Audiology
	Angela	Howat	AH	SCN
	Melanie	Hutton	MH	Lead Nurse
	Elinor	Johnson	EJ	Physio Service Lead
	Sheenagh	Leighton	SL	Deputy Site Facilities Manager
	Kalsoom	Mohammed	KM	SCN
	Ailsa	Shivas	AS	SCN
	Kathleen	Thomson	KT	Senior Nurse Quality Improvement
1. APOLOGIES:	Aileen	Begley	AB	Pharmacy
	Marjorie	Clark	MC	SCN
	Helen	Cupchunas	HC	SCN
	Melville	Dixon	MD	Orthotics
	Susie	Dodd	SD	Lead Nurse Infection Control
	Elaine	Johnstone	EJ2	Lead Nurse
	Morag	Liddell	ML	SCN
	Mandy	Meechan	MM	Lead Nurse
	Catriona	Riddell	CR	SCN
	Lynne	Robertson	LR	Clinical Service Manager
	Jen	Rodgers	JR	Chief Nurse
	Fiona	Scott	FS	SCN
	Eleanor	Selkirk	ES	SCN
	Emma	Sommerville	ES2	SCN

ACTION

2. MINUTE FROM PREVIOUS MEETING

The minute from the meeting on 9 May was approved by the group.

3. MATTERS ARISING

Picked up in agenda.

4. LEAD NURSE IC UPDATE

Policy Updates
KA advised that Cleanliness Champions are being replaced by Scottish Infection Prevention and Control Education Pathway (SIPCEP) which consist of 3 levels; foundation, intermediate, improvement. These will be rolled out by NES at the end of the month.

ACTION

The Policy Group have agreed to make the Respiratory Care Plan into a one page checklist. This was circulated round the group and will be finalised within the next couple of weeks.

SCNs are encouraged to avoid always carrying out SICPs audits when wards/departments are at their quietest.

HEI Findings
Key issues from the HEI visit at QEUH were:

- Staff knowledge in relation to blood and body fluid spillages – staff need to know where to find this information
- Hand Hygiene – staff need to be aware of the 6 stages and the 5 moments
- Waste – staff need to ensure waste holds are kept locked and waste is segregated and stored appropriately. SL advised that since the report a porter is now checking waste bags. New posters are up in the waste rooms advising the "do's" and "don'ts" in relation to waste. She asked the group to remind their staff that all waste should be locked away with trackers attached.
- PPE removal – PPE should be removed after each task
- Ensure single patient toiletries are not multi use
- Ensure patient equipment is clean and checklist is up to date
- Ensure exceptions are recorded within domestic cleaning and that domestic staff have access to rooms to clean
- Ensure mattresses are checked and contaminated ones are disposed of
- SCNs should undertake SCIPs audits when their areas are busy

AS advised that some beds brought into wards from corridors have not had their undercarriage cleaned and can be dusty as they can be lying in the corridor for days. SCNs are not aware of this until checking them once they are on the ward. SL stated she has no staff available to clean the undercarriages but will try to get this done in future. It was noted that there are storage problems in the new hospital therefore beds are left in the corridors. SCNs should contact Facilities or the Duty Manager if beds are brought onto their wards and are dusty.

KT queried if orthopaedic beds could be cleaned using a tagging system which that is used for the trolleys to see if this makes a difference. SL agreed to try this on one bed.

Decontamination Issues
No update.

Person Centred
The What Matters to You Day took place last week and has continued into this week. Staff, patients and parents were asked questions in relation to CVCs and isolation. TF asked the group to state what mattered to them.

LH – CVC's
EJ – the follow through on domestic issues
KM – ensuring that documentation is completed after the insertion of a CVC on the ward and ensuring it is clean.

ACTION

AA – domestic issues (high dusting and under beds)
MH – ensure PVC documentation is completed and good audits are achieved with both PVCs and CVCs. Would like the entrance to the hospital to be cleaner.
AS – domestic and cleaning issues
JH3 – domestic issues as department is carpeted
KT – would like assurance that water is good enough for cleaning rather than detergent as Theatres look dirty.

KT would like support from Infection Control regarding information for staff wearing uniforms outwith the hospital.

Action: JR to discuss with Chief Nurse from adult services.

The group agreed that Infection Control walk rounds are helpful.

Theme of the Month Trends
KA advised that IPCNs have asked staff the key principles associated with transferring a patient who is in isolation. It was noted that whilst use of PPE in previous 'Theme of the month observations' was good, some staff were still seen walking up and down the ward corridor in aprons and a lot were unsure when to put PPE on and take off. Staff have been updated on practice.

There is a programme for Theme of the Month Trends but these are subject to change depending on what's happening in the hospital.

5. CPE SCREENING

SD will attend the next SCN meeting for discussion and the launch of CPE screening.

6. CAS IPC LINK NURSE

This has currently been put on hold until further information is obtained relating to the future of the link nurse programme. The June IPC CAS link nurse meeting has been cancelled and will be reconvened in August in the hope that further information will be available. SD stated that the twice yearly SCIPs audits which some SCNs have allocated to the CAS link nurses are still required to be carried out.

7. SAB REVIEW

KA advised there have been 4 community acquired SABs and 1 HAI related to line infection. The quarterly report will be available at the end of June.

8. CURRENT OUTBREAK/INCIDENTS

KA advised that the outbreak of Chicken Pox has settled down. Staff were advised to check their immunity status.

The current outbreak of Norovirus in Ward 2A is being monitored and the ward remains open.

ACTION

9. ROOF GARDEN

The draft Roof Garden Policy was circulated to the group for final comments. The group were happy to approve this from an Infection Control point of view. It will now be taken forward by Coral Brady after Health and Safety issues are looked at.

10. FFP3 MASK TESTING

Mask testing is ongoing and an adequate amount of staff have been trained.

11. IPCAT AND SCIPS AUDITS

Audits were circulated to the group for information:

ED – very positive audit
1A – excellent audit which scored 100%
2A – good audit scoring 96% although there are still certain areas for improvement with staff knowledge and facilities issues.
2B – audit scored 97%. This audit fell down on staff knowledge.
3B – audit scored 96% and is overall a good report

12. AOCB

EJ advised that the domestic in the Therapy Hub is on sick leave and only the bins are being emptied. SL advised she has no staff to cover this.

MH advised EJ to put her concerns in an email to Lynne Robertson, CSM to escalate.

SL emphasised she is very short staffed.

13. DATE AND TIME OF NEXT MEETING

The next meeting will be held on 11 July 2017, 12.30pm – 2pm, Level 3 Conference Room, GWS 008, RHC.

SBAR

Review of prescribing in Haemato-oncology patients
Royal Hospital for Children (RHC)
Glasgow

Situation

A review of the current prescribing practice in paediatric Haemato-oncology patients in RHC, Glasgow was requested by the Chair of the GG&C Oversight Board, the Chief Nursing Officer.

Background

The current issues within RHC are well understood so the details below pertain specifically to lack of clarity on precautionary, or prophylactic, antibiotic and antifungal treatment which has created uncertainty for patients and families.

Paediatric Haemato-oncology patients are at a high risk from sepsis, from their disease, their treatments and the presence of a central venous catheter. This can be bacterial or fungal sepsis.

Currently, paediatric Haemato-oncology patients are inpatients in ward 6A, decanted from wards 2A/B in RHC to the adult hospital. Many patients have central venous catheter devices to deliver treatment. Recent practice has been to prescibe oral ciprofloxacin on a continuous basis, for the duration of Systemic Anti Cancer Treatment (SACT) via the central venous catheter, as a precaution. Antifungal treatments are also currently used when appropriate patients are inpatients.

Haemato-oncologists have provided confirmation that they are reassured regarding the safety of the water and the environment in 6A, based on evidence from a range of sources and the longstanding improvement approach to Infection Control. Advice received from Infectious Diseases and Infection Control specialists in October specifically recommended that ciprofloxacin was no longer required as a precaution for every patient with a central venous catheter. Implementing this change in practice immediately was challenging given the heterogeneity of the patients in terms of the stage of their illness and other clinical features.

It was also agreed at that meeting that antisepsis (Taurolock commercial flush solution) against Gram negative infection in central venous catheter patients should be looked at and instituted, if felt to be best practice, as an adjunct to current practice.

Antifungal treatment is given according to a protocol which has clear clinical criteria and evidence base for their use and this will still be the case when ward 6A patients return to the refurbished ward 2A/B in spring 2020.

Assessment

The prescribing of ciprofloxacin by Haemato-oncologists has been actively considered by both that group of consultants and Infectious Diseases and Infection Control specialists and it was agreed in October that precautionary use for all ward 6A patients was no longer required as it had only ever been intended as a short term option, as Infection Control evidence was being gathered. That agreement is now able to be implemented given the degree of reassurance the accrued evidence offers alongside the enhanced safeguards this group of patients require due to their increased clinical risk.

The clinicians have also been assessing the evidence for Taurolock as they look for best practice in central venous catheter management and anticipate that being introduced in the very near future. It would obviate the need for any precautionary antibiotics to be prescribed in this group.

Antifungal prescribing is based on clear criteria and requires to be continued when clinicians assess patients meet those criteria. The guidelines for antifungal prescribing are currently being reviewed, to ensure alignment with latest evidence.

There is a demonstrable culture of engagement by prescribing clinicians with Infection Control and Infectious Disease specialists, and a strong Quality Improvement approach to ensure best practice for patients.

Recommendation

Recommendations are as follows:

The Haemato-oncology clinicians should be recommended to meet regularly with Infectious Diseases and Infection Control colleagues to review that their prescribing of antibiotics and antifungals is case-by-case, clinically appropriate and in keeping with agreed guidance, and to review any adverse events through their prescribing, either in their regular weekly departmental meetings or separate governance group.

A protocol for the use of Taurolock should be developed through NHS GG&C clinical and governance processes and implemented as an intervention for which there is a growing evidence base, with expanding use in vulnerable populations with central venous catheters. As with all interventions this should be kept under review to ensure it is best practice.

Families and patients should be informed

- The clinicians looking after patients in ward 6A are in complete agreement that the water and environment are safe
- Any prescribing of antibiotics such as ciprofloxacin is because the consultant has risk assessed that patient on an individual basis
- There is no policy to prescribe all patients precautionary antibiotics because of environmental safety concerns

- Antifungals are prescribed for patients according to a protocol, irrespective of location or current concerns
- All prescribing will be reviewed as appropriate by an oversight group with all consultants, meeting regularly
- As a team, the consultants are always looking for best practice to improve safety for their vulnerable patients and, as an example, are looking at an antiseptic product for central venous catheters

Andrew Murray
Medical Director, NHS Forth Valley
Co-chair, Managed Service Network for Children and Young People with Cancer
12/12/19

Scottish Government
Riaghaltas na h-Alba
gov.scot

OVERSIGHT BOARD – NHS GREATER GLASGOW AND CLYDE

Date and time: 13th December 2019, 14.00 – 15.30
Venue: Flemming A, Atlantic Quay 5, 150 Broomielaw, Glasgow, G2 8LU
Attendees: see Annex A
Meeting 3 – Minute

1.	**Welcome, introductions and apologies** Chair welcomed attendees to the third meeting of the Oversight Board for NHS Greater Glasgow & Clyde and noted apologies (see Annex A).
2.	**Minutes** The Chair asked attendees for comments on the minutes from the previous meeting that took place on the 3rd December. Revisions were suggested and accepted and the amended minute is embedded here for reference. Meeting 2 Minutes ACTION: • CM to update minutes.
3.	**Matters arising** No matters arising were noted.
4.	**Terms of Reference, Governance and Membership:** • **Redrafted ToR for discussion** • **Governance structure diagram** The Chair asked for comments on the revised Terms of Reference. KM proposed that Marion Bain's (MB) role be referenced which prompted discussion on the Independent Case Review. In relation to this, the Chair noted that: • MB has been appointed as HAI Executive Lead for NHSGGC, accountable and responsible to the Chief Executive of NHSGGC and the Chief Nursing Officer. • MB will be invited to attend the Oversight Board and provide regular updates on her review of cases. • The review will focus on the individual clinical cases and also the wider context; a process for reviewing cases will be developed and support provided from a policy team. • The parameters of the work are still be agreed, however, Chair confirmed that it will include an epidemiological review and enable the voices of patients and families to be heard throughout the process. The role of CW's sub-group was discussed in supporting the families affected to input into the OB, taking into account the ethical considerations. MM noted that Jim Beattie is already working within NHS GGC to review cases, which may be helpful for MB.

	DM asked that under purpose and role of group, the first bullet point is changed to 'seek assurance that appropriate governance is in place to increase public confidence'. Attendees reflected on references to NHSGGC staff within the ToR and considered whether an additional point would be required around appropriate support for them. It was agreed that the 'approach' section of the ToR should be adapted to include an additional reference to NHSGGC staff. DM asked that the ToR are adapted to note that AT and DM, as ACF and APF Chairs respectively, are listed as being 'in attendance' within the membership section. Chair noted that a third sub-group is being established to focus on technical issues in relation to facilities and estates. Members discussed and agreed that once the technical sub-group is established, additional expertise will be required on the OB to provide appropriate levels of assurance. The Chair reminded members that the 'background' section of the Terms of Reference is based on wording that is in the public record and cannot be changed. Attendees reviewed and agreed the updated governance structure diagram. ACTION: • CM to revise Terms of Reference
5.	**Update from chair** The Chair provided an update on developments since the previous meeting on 3 December: • The Cabinet Secretary's statement to Parliament on Tuesday 10th December; • Dr Eleri Davies, Consultant Medical Microbiologist and Director of Infection Prevention and Control at Public Health Wales, will bring independent expertise and support the work of MB in the Independent Review; • A Programme Management Office (PMO) is being established within NHS GGC to centralise and co-ordinate requests and information flows. Discussions are taking place between Elaine Vanhegan (NHS GGC) and Jason Birch (Scottish Government) to develop a system for managing requests. Angela O'Neill has been appointed to work within NHS GGC to provide support to the OB and Independent Review. The Chair introduced Dr Andrew Murray's SBAR on prescribing to Haemato-oncology patients within the Royal Hospital for Children (RHC), and asked for comment. CW suggested that it would be useful to get a steer on whether, in light of environmental concerns, recommendations around what to provide to patients and families were implemented. AT felt it would be helpful to consider governance in more detail around decision making and the audit trail, with a more overt consideration of the role of pharmacists in prescribing. MM

	suggested that further assurance is required as to whether good practice is being implemented and evidenced through patient records. The SBAR was accepted by the OB and it was agreed actions be remitted to the Communications & Engagement subgroup and the Infection Prevention & Control and governance subgroup. ACTION: • Subgroups to provide a report for the OB on current prescribing practice in NHSGGC and how it is evidenced
7.	**Progress and next steps on key issues:** **a. Infection prevention and control** **b. Governance** **c. Communications and engagement, with a focus on family members** The Terms of Reference and minutes of initial meetings for the Communications & Engagement sub-group and the Infection Prevention & Control and Governance (IPCG) sub-group were circulated as papers in advance of the meeting. Attendees did not have comments and the Chair asked for any material comments to be sent to a member of the Scottish Government policy team following the meeting. KW fed back to the OB on the initial meeting of the IPCG sub-group, in light of apologies from the Chair. KW noted that the meeting was action focused and members discussed the methodology that they will be adopting to fulfil their objectives. A draft timeline is in development and the sub-group will follow a 'board to floor' approach. The sub-group aims to next meet on the 30th December. CW provided a report of the initial meeting of the Communications & Engagement sub-group and noted that further meetings have been arranged to take place fortnightly until April. CW noted that he has written to 400 families that have had involvement with the haemato-oncology units within NHSGGC to ask for their views on what has worked well and what could be improved in their interactions with NHSGGC and with CW; responses will be considered at the next meeting. CW highlighted the importance of creating the conditions for all family representatives to feel confident and supported to share their experience. The Chair of the OB noted that the answers that families are looking for may come from a variety of sources, including the public inquiry. The Chair asked sub-groups to begin setting out a work programme as part of a robust programme management process. Sub-groups were asked to discuss this at their next meeting. SA has been asked to provide a draft work programme. The Chair asked attendees to consider how patients and families will feed into the work of the OB, and stated that she would welcome family members around the table. CW will ask the Communications & Engagement sub-group for their views on this.

	Attendees recognised that issues relating to information governance must be considered now for the work of the OB as well as for MB role. It was agreed that SG will take this forward as an action through discussions with MB and with advice from HIS. The Chair noted a third sub-group is to be established, to be chaired by Alan Morrison (SG). ACTIONS: • Communications & Engagement sub-group to ascertain views on how family representatives can best feed into work of OB • Sub-groups to develop a work programme with support from SA • PR to consider issues relating to information governance in discussion with MB and taking advice from HIS.
	AOB KW noted that the Scottish Government is continuing to add staff resource to support the work of the OB and subgroups.
6.	**Timeline and next steps** The next meeting of the Oversight Board will take place on the 19th December. The Chair suggested the OB meets fortnightly from the New Year to enable sub-groups opportunity to meet and feed into the work of the OB. The Communications & Engagement sub-group already has dates until April. This will be used to inform the dates of the OB meetings and attempts will be made to find an opportunity to meet at the same time each week.

Annex A: List of Attendees

Fiona McQueen	Chief Nursing Officer, CNOD, Scottish Government
Keith Morris	HAI/AMR Professional Medical Advisor, CNOD, Scottish Government
Laura Imrie	Lead Consultant for Healthcare Associated Infection (HAI), Antimicrobial Resistance and Infection Prevention and Control, HPS
Sandra Aitkenhead	CNOD, Scottish Government (secondee)
Craig White	Divisional Clinical Lead, Healthcare Quality and Improvement Directorate
Lesley Shepherd	Professional Advisor, CNOD, Scottish Government
Kirsty Walker	CNOD, Scottish Government
Calum Henderson	CNOD, Scottish Government
Claire McGrath (secretariat)	CNOD, Scottish Government
In attendance	
Dorothy McErlean	APF Chair Employee Director, NHS GGC
Audrey Thompson	ACF Chair Lead Pharmacist Prescribing Services, NHS GGC
Mags Mcguire	Executive Nurse Director, NHS GGC

Apologies:
Irene Barkby - Executive Director of Nurses, Midwives and Allied Health Professionals & HAI Exec Lead, NHS Lanarkshire
Andrew Murray – Medical Director, NHS Forth Valley
Hazel Borland - Executive Director of Nursing, Midwifery and Allied Health Professionals & Healthcare Associated Infection Executive Lead, NHS Ayrshire and Arran
Angela O'Neill – NHS GGC
Phil Raines – CNOD, Scottish Government

Annex B: Action Log

Action	Date of Action	Action Officer	Date for Completion	Status
Draft outcomes to share with OB members.	27 November 2019	CNOD, CM to co-ordinate	To be presented at meeting 3 (13/12/19)	ONGOING To be redrafted after 13 December
Approach Lynsey Cleland and Andrew Moore to join subgroups	27 November 2019	FMc	3 December 2019	COMPLETE Confirmed 28 November 2019
Approach Evonne Curran to join infection prevention and control & governance subgroup	27 November 2019	LS	3 December 2019	COMPLETE Confirmed 29 November 2019
Approach Andrew Murray to join OB	27 November 2019	CM / KW	3 December 2019	COMPLETE Confirmed 29 November 2019
Draft timeline and key milestones to share with OB members.	27 November 2019	CNOD, CMc to co-ordinate	To be presented at meeting 3 (13/12/19)	ONGOING To be redrafted after 13 December
Support chairs to establish subgroups	27 November 2019	CM	Subgroups to be formed with meetings in diary by 6/12/19	ONGOING Initial meetings of C&E and IPC&G subgroups have taken place, technical subgroup is now being established
Update Terms of Reference	3 December 2019 27 November 2019	KW / CM	13 December 2019	ONGOING To be redrafted after 13 December
DM and CW to discuss communications with NHSGGC staff	3 December 2019	CW		

Amend minutes of meeting 1 as agreed	3 December 2019	KW	13 December	COMPLETE
Redraft governance diagram.	3 December 2019	KW	13 December	COMPLETE
Amend minutes of meeting 2 as agreed	13 December 2019	CM	19 December	ONGOING
Development of draft work programme for OB and subgroups	13 December 2019	SA, CW & IB		ONGOING
Report on current prescribing practice in NHSGGC and how it is evidenced	13 December 2019	CW & JB		ONGOING
Ascertain views on how family representatives can best feed into work of OB	13 December 2019	CW		ONGOING
Consider information governance	13 December 2019	PR		ONGOING

MEETING TO DISCUSS BMT UNIT RHC
Monday 7 September 4.45pm

In attendance: Jennifer Armstrong
Alan Mathers
Billy Hunter
Jamie Redfern
Grant Archibald (by telephone)
Brenda Gibson
Craig Williams

Apologies: David Loudon

This meeting was brought together to identify progress in resolving BMT room estates issues and determine position regarding starting new cases. JA acknowledged the clinical frustration about progress and the need to plan for patients in system.

The meeting was informed by the Agenda set by JA and a stepwise debate took place around:

- Spec of RHC service/building/air flows, etc.
- Comparison between RHSC spec and the new departments spec. The air flow/extraction and room pressures were described with detailed descriptions between the systems employed in both set ups.
- Data from sealed rooms and microbiology testing to date.
- Clinical progress of patients already in ward suite system (favourable).

The testing suggests that the sealed rooms are providing the appropriate level of 10Pa positive pressure. The seals are regarded as being good for a year (minimum) and will be subject to 6 monthly inspection. Any adverse change in pressure testing will prompt early assessment (frequency of this regular testing TBC).

As a further enhancement Brookfield have identified a way of further enhancing air flows to provide a safety net quote of c. £35K per room possibly taking 4-6 weeks (TBC). How such work would be achieved whilst patients were being treated was to be clarified and would require detailed assessment.

Actions:

Directorate will supply SOP for room management.

Facilities to improve cleaning regime in room and corridor (with Chlorine based cleaners?)

Estates to contract with Brookfield:

1. Extended Sealing Programme to 4 rooms (minimum) but possibly all rooms.
2. Agree with Brookfield a plan to enhance air flow management (c. 35K per room) and develop a plan to implement this with minimal risk of disruption of current and future cases.

Estates will confirm the pressure tests performed 6 hourly for last week in 2 recently sealed rooms and that these tests showed a +pressure c. 10 Pa with 0.5 tolerance.

They will compare RHC specifications compared with current: i.e. same or enhanced spec in new RHC.

Craig will review microbiology testing (results awaited Wednesday)

Clinical

[redacted]

From: McNamee, Sandra
To: Archibald, Grant
Cc: Armstrong, Jennifer; Redfern, Jamie; Williams, Craig; Louden, Alana; Walsh, Tom; Williams, Craig
Subject: RE: Paediatric BMT
Date: 11 September 2015 09:42:00

Hi Grant
I have had a chat with Jennifer. If we could reassure Teresa that the rooms have been tested, sealed and signed off by David this may help with the decision making process. I will also ask Teresa to put into context the significance of the particle counts - if they are higher that previously reported then this could indicate that there is still some problem with the build if however they are lower then I will ask her to review in light of the information from David and the risk to the patient of not being able to access treatment.
kind regards
Sandra

Sandra McNamee
Associate Nurse Director
Infection Prevention & Control
[redacted]

-----Original Message-----
From: Archibald, Grant
Sent: 11 September 2015 09:09
To: McNamee, Sandra
Cc: Armstrong, Jennifer; Redfern, Jamie; Williams, Craig; Louden, Alana
Subject: Paediatric BMT

Dear Sandra

I have reviewed ICT team correspondence Jamie forwarded to me last night. In it the ICT doctors appear to be saying they have not had a hand over from senior ICT team regarding this facility and lack data to inform their decision making. I understood data had been provided over the last few days and so was available.

Jamie advised Tom and Craig were on leave. Is this still the case? If so in their absence i need your senior opinion regarding what further data (if any)are required, if the rooms are safe to use or is there any action that could make them safe for use by Monday when we have a patient booked for admission

There are references in the emails to the importance of this matter. That is an issue upon which everyone appears to agree. We have a patient we require to provide care for. As a result a definitive, senior ICT opinion is essential and required by noon today.

Grant Archibald
Chief Officer

From: Redfern, Jamie
To: Archibald, Grant
Subject: RE: MEETING TO DISCUSS BMT UNIT RHC
Date: 11 September 2015 11:40:45

Yes I had said to them Grant that I wanted to meet with them and based on what they said I mentioned they would need to meet with you later.
Hope that was okay
Ill feed back immediately after the meet by email and be available on telephone
Jamie

From: Archibald, Grant
Sent: 11 September 2015 11:23
To: Redfern, Jamie
Subject: Fwd: MEETING TO DISCUSS BMT UNIT RHC

Jamie

I have to attend the OPAH feedback at QEUB at 1200.

Grant Archibald
Chief Officer

Begin forwarded message:

From: "McNamee, Sandra" [redacted]
Date: 11 September 2015 10:47:23 am BST
To: "Kane, Mary Anne" [redacted] "Matheson, Fiona" [redacted] "Redfern, Jamie" [redacted] "Armstrong, Jennifer" [redacted] "Archibald, Grant" [redacted] "Loudon, David" [redacted] "Williams, Craig" [redacted] "Walsh, Tom" [redacted]
Cc: "Hunter, William" [redacted] "Joannidis, Pamela" [redacted] "Inkster, Teresa [redacted]" [redacted]
Subject: RE: MEETING TO DISCUSS BMT UNIT RHC

Hi
I have just been informed that there are fungal spores on the plates - the results will presented at the 12md meeting with Jamie and the clinical team.
kind regards
Sandra

Sandra McNamee
Associate Nurse Director
Infection Prevention & Control
[redacted]

From: Kane, Mary Anne
Sent: 11 September 2015 10:31
To: Matheson, Fiona; Redfern, Jamie; McNamee, Sandra; Armstrong, Jennifer; Archibald, Grant; Loudon, David; Williams, Craig; Walsh, Tom
Cc: Hunter, William
Subject: RE: MEETING TO DISCUSS BMT UNIT RHC

The content of Billy's response has been approved by David Loudon and myself and confirms that from a engineering controls perspective everything has been completed in accordance with the Building and tTesting guidance - Billy has referenced these in the attached response under the RHSVer2 document
Regards
Mary Anne

From: Matheson, Fiona
Sent: 11 September 2015 10:24
To: Redfern, Jamie; McNamee, Sandra; Armstrong, Jennifer; Archibald, Grant; Loudon, David; Kane, Mary Anne; Williams, Craig; Walsh, Tom
Cc: Matheson, Fiona; Hunter, William
Subject: MEETING TO DISCUSS BMT UNIT RHC
Importance: High

Sent on behalf of Billy Hunter

Dear All

Can I please pass on the Facilities response to the points that were raised in relation to RHC Ward 2A, further to Monday 7th September meeting. I can confirm that each point has been referenced against appropriate SHTM and HBN.

Regards
Billy

PS I've signed up to improving our email culture

[redacted]

[redacted]

[redacted]

[redacted]

[redacted]

[Click here to Call](#) [Click here to Chat](#)

From: Inkster, Teresa [redacted]
Sent: 20 July 2022 16:38
To: Inkster, Teresa [redacted]
Subject: FW: BMT service at Royal Hospital for Children

From: Inkster Teresa [redacted] [redacted]
Sent: 11 September 2015 15:59
To: Mathers, Alan <[redacted] Williams Craig [redacted] [redacted] [redacted]
Cc: Gibson, Brenda [redacted] Redfern, Jamie [redacted] Jones, Brian [redacted] Devine, Sandra [redacted]
Subject: RE: BMT service at Royal Hospital for Children

Dear Alan,

Thanks for your email . I appreciate that this is a difficult risk assessment. Whilst I cannot comment

on the haematological risk, from my perspective, based on available evidence as discussed this morning, I am unable to state that the rooms are microbiologically safe.

Antifungal prophylaxis is not 100% effective. Furthermore the efficacy of prophylaxis would be reduced in an environment with an increased fungal burden . The prevention of invasive fungal disease in SCT patients is achieved through a combination of both antifungal chemoprophylaxis and the provision of a clean air environment.

I hope this advice is useful and I would be happy to discuss further.

Please find attached a spreadsheet and lab reports of fungi grown from June onwards. We are awaiting mycology reports from fungi grown in August/September .

Kind Regards
Teresa

Dr Teresa Inkster
Consultant Microbiologist and Infection Control Doctor
Dept of Microbiology
Queen Elizabeth University Hospital
Glasgow
[redacted]

From: Mathers, Alan [redacted]
Sent: 11 September 2015 14:53
To: Williams Craig [redacted] Inkster Teresa [redacted]
Cc: Gibson, Brenda; Redfern James [redacted]
Subject: BMT service at Royal Hospital for Children

Dear Teresa,

Thanks for input today.
Appreciate that you were catapulted into a difficult situation.

"We" (ie local team) have to weigh up a whole range of risks as you appreciate from, in particular the acute patient situation. There is inherent mortality risk and this escalates with time passing and in addition the donor is being worked up and there is a risk that we lose them. So: risk assessment continues to evolve.

Would you be able to send a list of the fungi grown and the site and provide a view as to how effective anti-fungal prophylaxis would be (there is a Double prophylaxis option too)?

The use of another place in Glasgow (such as Beatson) is considered untenable for the patient foremost in our thoughts due to lack of Paediatric Intensive care.

A meeting on Monday will be convened and so info for then would be very helpful.

Appreciate if you can reply to all.

Kind regards

Alan

Dr Alan M Mathers
Chief of Medicine Women and Children
Consultant Obstetrician and Gynaecologist
Greater Glasgow and Clyde Health Board
[redacted]

From: Inkster Teresa (NHS GREATER GLASGOW & CLYDE - SGA20)
To: Mathers, Alan; Williams, Craig
Cc: Gibson, Brenda; Redfern, Jamie; McNamee, Sandra
Subject: RE: BMT service at Royal Hospital for Children
Date: 11 September 2015 16:26:28
Attachments: Mycology_interim_reports[1].pdf

Please find attached further mycology reports from air sampling in August - these were just sent to me this afternoon
Kind Regards
Teresa

Dr Teresa Inkster
Consultant Microbiologist and Infection Control Doctor
Dept of Microbiology
Queen Elizabeth University Hospital
Glasgow
[redacted]

From: Mathers, Alan [redacted]
Sent: 11 September 2015 14:53
To: Williams Craig [redacted] Inkster Teresa [redacted]
Cc: Gibson, Brenda; Redfern James [redacted]
Subject: BMT service at Royal Hospital for Children

Dear Teresa,

Thanks for input today.
Appreciate that you were catapulted into a difficult situation.

"We" (ie local team) have to weigh up a whole range of risks as you appreciate from, in particular the acute patient situation. There is inherent mortality risk and this escalates with time passing and in addition the donor is being worked up and there is a risk that we lose them. So: risk assessment continues to evolve.

Would you be able to send a list of the fungi grown and the site and provide a view as to how effective anti-fungal prophylaxis would be (there is a Double prophylaxis option too)?

The use of another place in Glasgow (such as Beatson) is considered untenable for the patient foremost in our thoughts due to lack of Paediatric Intensive care.

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Kind regards

Alan

Dr Alan M Mathers
Chief of Medicine Women and Children
Consultant Obstetrician and Gynaecologist
Greater Glasgow and Clyde Health Board
[redacted]

From: Devine, Sandra
To: Redfern, Jamie
Cc: Armstrong, Jennifer; Mathers, Alan; Archibald Grant [redacted] Jones, Brian; Inkster Teresa [redacted] Walsh, Tom; Williams Craig [redacted]
Subject: Re: BMT RHC
Date: 11 September 2015 16:59:28

Hi I have spoken to Brian Jones who has advised me that at this point there is no advantage to re sampling. Brian will call Alan directly to explain the rationale for this advice. Thanks. Sandra

Sent from my BlackBerry 10 smartphone on the EE network.

From: Redfern, Jamie
Sent: Friday, 11 September 2015 16:30
To: McNamee, Sandra
Cc: Armstrong, Jennifer; Mathers, Alan; Archibald, Grant
Subject: BMT RHC

Hi Sandra

I have just spoken to Jennifer A and she has asked that infection control be instructed to carry out further particle and fungi tests on cubicle 18 and 19 in RHC ward 2a over the weekend. She is also keen that we get the reported results on these tests as quickly as possible [redacted] Can you please put the processes in place to make this happen and confirm to all ccd into this email when actioned. Thanks

Jamie

PS: I will try to follow this email up by phone call to you

From: Redfern, Jamie
To: Archibald, Grant
Subject: Re: BMT service at Royal Hospital for Children
Date: 14 September 2015 08:33:55

Hi Grant
Didn't hear anything.
Yes will brief you as updated.
Cheers
Jamie

Sent from my Samsung device

-------- Original message --------
From: "Archibald, Grant" [redacted]
Date: 14/09/2015 8:32 AM (GMT+00:00)
To: "Redfern, Jamie" [redacted]
Subject: Re: BMT service at Royal Hospital for Children

Jamie

Did you hear anything over weekend or if you get a progress report this am please brief me

Sent from my iPad

On 11 Sep 2015, at 18:21, "Redfern, Jamie" [redacted] wrote:

> Cheers Grant
>
> Sent from my Samsung device
>
> -------- Original message --------
> From: "Archibald, Grant" [redacted]
> Date: 11/09/2015 6:20 PM (GMT+00:00)
> To: "Redfern, Jamie" [redacted]
> Subject: Re: BMT service at Royal Hospital for Children
>
> Jamie
>
> Saw this and Alan's email. I will monitor over weekend also
>
> Grant
>
> Sent from my iPad
>
> On 11 Sep 2015, at 17:17, "Redfern, Jamie" [redacted] wrote:
>
> > Fyi Grant
> > Important obv to reconcile against my prev email.
> > You will see that infection control are resisting Jen A's instruction.
> > I'm on email all thru weekend so if I pick anything up between now and Monday I will forward on.
> > Have a nice weekend
> > Jamie
> >
> > Sent from my Samsung device
> >
> > -------- Original message --------
> > From: "Mathers, Alan" [redacted]
> > Date: 11/09/2015 4:31 PM (GMT+00:00)
> > To: "Inkster, Teresa (NHSmail)" [redacted] "Williams, Craig" [redacted]
> > Cc: "Gibson, Brenda" [redacted] "Redfern, Jamie" [redacted] "Jones, Brian" [redacted], "McNamee, Sandra" [redacted]
> > Subject: Re: BMT service at Royal Hospital for Children
> >
> > Thanks : very helpful
> >
> > Sent from my BlackBerry 10 smartphone on the EE network.
> >
> > **From:** Inkster Teresa (NHS GREATER GLASGOW & CLYDE - SGA20)
> > **Sent:** Friday, 11 September 2015 15:58
> > **To:** Mathers, Alan; Williams, Craig
> > **Cc:** Gibson, Brenda; Redfern, Jamie; Jones, Brian; McNamee, Sandra
> > **Subject:** RE: BMT service at Royal Hospital for Children
> >
> > Dear Alan,
> >
> > Thanks for your email . I appreciate that this is a difficult risk assessment. Whilst I cannot comment on the haematological risk, from my perspective, based on available evidence as discussed this morning, I am unable to state that the rooms are microbiologically safe.
> >
> > Antifungal prophylaxis is not 100% effective. Furthermore the efficacy of prophylaxis would be reduced in an environment with an increased fungal burden . The prevention of invasive fungal disease in SCT patients is achieved through a combination of both antifungal chemoprophylaxis and the provision of a clean air environment.
> >
> > I hope this advice is useful and I would be happy to discuss further.

Please find attached a spreadsheet and lab reports of fungi grown from June onwards. We are awaiting mycology reports from fungi grown in August/September .

Kind Regards
Teresa

Dr Teresa Inkster
Consultant Microbiologist and Infection Control Doctor
Dept of Microbiology
Queen Elizabeth University Hospital
Glasgow
[redacted]

From: Mathers, Alan [redacted]
Sent: 11 September 2015 14:53
To: Williams Craig [redacted] Inkster Teresa [redacted]
Cc: Gibson, Brenda; Redfern James [redacted]
Subject: BMT service at Royal Hospital for Children

Dear Teresa,

Thanks for input today.
Appreciate that you were catapulted into a difficult situation.

"We" (ie local team) have to weigh up a whole range of risks as you appreciate from, in particular the acute patient situation. There is inherent mortality risk and this escalates with time passing and in addition the donor is being worked up and there is a risk that we lose them. So: risk assessment continues to evolve.

Would you be able to send a list of the fungi grown and the site and provide a view as to how effective anti-fungal prophylaxis would be (there is a Double prophylaxis option too)?

The use of another place in Glasgow (such as Beatson) is considered untenable for the patient foremost in our thoughts due to lack of Paediatric Intensive care.

A meeting on Monday will be convened and so info for then would be very helpful.

Appreciate if you can reply to all.

Kind regards

Alan

Dr Alan M Mathers
Chief of Medicine Women and Children
Consultant Obstetrician and Gynaecologist
Greater Glasgow and Clyde Health Board
[redacted]

From: McNamee, Sandra
To: Armstrong, Jennifer; Mathers, Alan; Redfern, Jamie
Cc: Archibald, Grant; Williams, Craig; Walsh, Tom
Subject: Re: BMT RHC
Date: 14 September 2015 07:24:50

Good morning. I spoke to Brian Jones on Friday night and he confirmed sampling of the unit would take place on Saturday with some results available on Thursday. Billy Hunter actioned our recommendations regarding modifying some of the cleaning SOPS and implementing the changes suggested last thursday friday. Sandra
Sent from my BlackBerry 10 smartphone on the EE network.

From: Armstrong, Jennifer
Sent: Monday, 14 September 2015 06:58
To: Mathers, Alan; Redfern, Jamie; McNamee, Sandra
Cc: Archibald, Grant
Subject: Re: BMT RHC

Just for clarity, what I asked for is that the estates team and the infection control team work together over the weekend to urgently address the issues identified in the unit. They would then put in place any additional measures to mitigate the risks. I was keen that we engender a sense of urgency to address the problem. However I note further meeting today so hopefully there may be some progress and review of all the data with a risk assessment of different courses of action.
J

Sent from my BlackBerry 10 smartphone on the EE network.

From: Mathers, Alan
Sent: Friday, 11 September 2015 17:52
To: Redfern, Jamie; McNamee, Sandra
Cc: Armstrong, Jennifer; Archibald, Grant
Subject: RE: BMT RHC

Dear Jamie,

Just spoke with Brian Jones, listened and have advised him to organise further testing over weekend irrespective of any pre-conceived perceived doubts about value.
He quoted different lethality of some of the Fungi described earlier in day but isn't hopeful for a bacteriology clean bill of health (no pun at all intended).

Interim results from plates placed on Saturday would be available Wednesday / Thursday.

Kind regards

Alan

From: Redfern, Jamie
Sent: 11 September 2015 16:30
To: McNamee, Sandra
Cc: Armstrong, Jennifer; Mathers, Alan; Archibald, Grant
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Hi Sandra

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Jamie

PS: I will try to follow this email up by phone call to you

From: McNamee, Sandra
To: Mathers, Alan; Archibald, Grant; Armstrong, Jennifer
Cc: Redfern, Jamie; Archibald, Grant; Williams, Craig; Inkster, Teresa (NHSmail)
Subject: Re: BMT RHC
Date: 14 September 2015 08:24:44

Hi to be fair, additional information regarding the type of fungal spores became available between these conversations. Sandra
Sent from my BlackBerry 10 smartphone on the EE network.

From: Mathers, Alan
Sent: Monday, 14 September 2015 08:17
To: Archibald, Grant; Armstrong, Jennifer
Cc: Redfern, Jamie; McNamee, Sandra; Archibald, Grant
Subject: Re: BMT RHC

Dear All
I am doing a theatre list this morning at GRI and will be over for an already packed afternoon at RCH around 2pm providing theatre goes to plan.
I sense that none of the local measures that could be / are being put in place will militate against the risk that the majority bacteriological advice is providing and there is a matter of determining whose opinion trumps others: every time the advisory circle increases and different people are round the table there is more heat than light.

I was quoted very different risks from bacteriological about some of the organisms last Friday and obviously the context of how they might reach the patient is critical.
Kind regards

Alan

Sent from my BlackBerry 10 smartphone on the EE network.

From: Archibald, Grant
Sent: Monday, 14 September 2015 07:57
To: Armstrong, Jennifer
Cc: Mathers, Alan; Redfern, Jamie; McNamee, Sandra; Archibald, Grant
Subject: Re: BMT RHC

In on site now and this an if discussions are required

Grant Archibald
Chief Officer

On 14 Sep 2015, at 6:58 am, Armstrong, Jennifer [redacted] wrote:

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Topical Question Time

14:14

Royal Hospital for Children (Water Contamination)

1. **Anas Sarwar (Glasgow) (Lab):** To ask the Scottish Government whether it will provide an update on the response to, and the impact of, the contamination of water at the cancer ward at the Royal hospital for children in Glasgow. (S5T-00987)

The Cabinet Secretary for Health and Sport (Shona Robison): I welcome the opportunity to update members on the work that NHS Greater Glasgow and Clyde and the incident management team are doing to address that issue.

I am sure that the overriding concern of all of us is the wellbeing of the children and families in the affected areas. I have spoken today with the board's chair and chief executive, who were clear that no patient is giving any cause for concern as a result of bacterial infections associated with the incident. However, the board, with support from Health Protection Scotland, is taking appropriate precautionary measures to ensure that any infection is contained and addressed. Following identification of the bacteria, testing of water from the water tank that supplies both the Queen Elizabeth university hospital and the Royal hospital for children has been negative. A range of control measures has been put in place, which include some taps and shower heads being taken out of use for chemical disinfection, and point-of-use filters are in the process of being installed. Filters are due to be in place by close of play today, and sampling will be undertaken to ensure that the water is deemed safe.

I have asked Health Protection Scotland to co-ordinate a thorough investigation as a matter of urgency to review all those matters and to make any recommendations for the national health service. I will ensure that that review is reported to Parliament.

Anas Sarwar: The news of contamination of the water supply at the cancer ward at the Royal hospital for children in Glasgow has caused worry and concern for parents of very sick children. I have spoken directly with affected parents, who are angry, distressed and understandably concerned. Parents tell me that they learn more about the problem from a newspaper than from any communication from the health board. They also tell me that the issue has been running for three weeks.

The Deputy Presiding Officer (Christine Grahame): Come on, please. Ask the question.

Anas Sarwar: However, the issue has come into the public domain only in the past few days. It is clear that there is an issue with transparency.

Will the cabinet secretary advise when she was first made aware of the issue and what communications with NHS Greater Glasgow and Clyde she has had prior to today? Can she say why it took a press inquiry for the health board to go public and why there has not been better communication with patients and parents?

Shona Robison: I absolutely understand the worry and concern of parents. I have been assured by the health board that it has been keeping parents informed, but if Anas Sarwar is saying that that is not the case, I will certainly follow that up. The board has said that it has had extensive communication with parents, who will understandably be anxious.

I was first made aware of the issue on 11 March, I think. Scottish Government officials were made aware of it prior to that, and Health Protection Scotland has been helping the board to address the issues of concern that have been highlighted.

One of the bacteria involved is very rare, so it is quite a complex matter to try to get to the bottom of the issue. Obviously, the welfare and safety of the children has been the priority, which is why procedures are being followed to ensure that there are alternative cleaning facilities while filters are being fitted to taps and shower heads, for example. If the water testing is negative after the filters have all been fitted by the end of today, it is hoped that the water supply will be back up and running by tomorrow evening. However, that depends on having a negative result from the water testing.

The Deputy Presiding Officer: Anas Sarwar's supplementary should be brief, please.

Anas Sarwar: The hospital is Scotland's flagship hospital, but parents have spoken about a lack of hot water for nearly three weeks. That has meant child cancer patients being unable even to bathe. Some have been forced to take a taxi to other sites so that they can wash. They are cancer patients—

The Deputy Presiding Officer: No. You have had three questions. You should ask a brief supplementary question now.

Anas Sarwar: —who are at a greater risk of infection. With respect, Presiding Officer, these are issues that have been raised by concerned parents. That is three weeks of people not having the ability to wash their children. That is three weeks of no transparency.

The Deputy Presiding Officer: No, Mr Sarwar. I said that you should ask a supplementary. Please ask the question.

Anas Sarwar: That is three weeks in which there has been no urgent resolution. Will the cabinet secretary investigate the matter further and apologise directly to the patients and their parents?

Shona Robison: Of course I apologise to the parents and the children for the inconvenience that they have experienced, but I am sure that everybody will understand that the most important thing is safety. If the shower heads and taps are being tested and investigated, that has to take its course.

These are complex issues that need to be fully investigated. As I said, one of the bacteria is rare. I assure Anas Sarwar and, indeed, the parents and the children affected that absolutely everything has been done to get to the bottom of the matter. The focus is now on fitting filters in the immunocompromised wards, which will be done by the end of today.

As I have said, if the tests are negative, the water supply will be switched back on. I have also said that Health Protection Scotland will be looking into all related matters. If recommendations can be made to improve the situation, that will happen.

Annie Wells (Glasgow) (Con): The reports are very worrying, and I welcome the news that none of the children involved is currently giving cause for concern. As the cabinet secretary has stated, tests have also been carried out at the Queen Elizabeth university hospital, where concerns have previously been raised—

The Deputy Presiding Officer: Will you please ask a question?

Annie Wells: —about contamination of patient equipment and the cladding of the building. How will the cabinet secretary reassure patients and those living in Glasgow that the hospitals are fit for purpose?

Shona Robison: First, the incident is completely unrelated to the cladding on the building. The hospitals are state-of-the-art facilities. They are not alone in sometimes having bacterial infections break out. When the bacterium is rare, identifying its source is particularly complex. Everybody has been putting their shoulders to the wheel in order to get to the bottom of the incident. I hope that all members will support the board, Health Protection Scotland and the incident management team in their efforts to do so. The focus is on the safety of the children in the hospital; that should be our main priority, too.

The Deputy Presiding Officer: I call Fulton MacGregor. Make it a question, Mr MacGregor—I am losing patience.

Fulton MacGregor (Coatbridge and Chryston) (SNP): Will the cabinet secretary confirm that there has been no infection as a result of the incident at the Queen Elizabeth university hospital? Has NHS Greater Glasgow and Clyde taken full advice on handling the incident from Health Protection Scotland and Health Facilities Scotland?

Shona Robison: No adults in the hospital have been infected. Health Protection Scotland and Health Facilities Scotland have provided support, and the board has been working flat out to get to the bottom of the incident. It took immediate action once it realised that a bacterial infection was present. It has done everything possible to get to the bottom of the matter as quickly as it could, and it has received expert advice and support in order to do that.

These are complex issues to deal with, and we should get behind those who are trying to resolve the matter and support them in their efforts in doing so.

James Kelly (Glasgow) (Lab): On a point of order, Presiding Officer. I raise the issue of the scheduling of the urgent question and the topical question. As we have just seen from the exchanges, Anas Sarwar raised a very serious matter. Members were not allowed to properly develop the urgent issue, because of the restriction—

The Deputy Presiding Officer: Thank you, Mr Kelly. As you know, that is matter for the business managers. Both topics were very serious. Mr Sarwar asked three questions. I did not mind his first question at all—[*Interruption*.] Please sit down, Mr Kelly. That is not a point of order. The timetabling of today's business was set by the business managers. We have to start stage 3 of the Forestry and Land Management (Scotland) Bill. I have given a little extra time. Members know the timetabling for stage 3, which must go ahead. Please sit down, Mr Kelly; I have dealt with the matter.

NHS Greater Glasgow and Clyde

Acute Division

Women and Children Directorate

Hospital Paediatrics and Neonatology

Ward 2a Issues

1 Introduction

This paper has been prepared for the Director of Women and Children's consideration and follows recent re emerging infection control issues with Ward 2a/ 2b of the Royal Hospital for Children, Glasgow.

It reviews the various options for a full decant of both wards and makes a preferred recommendation if this is to happen.

The paper does not present the arguments or justification for decant as this is covered in a separate paper to Director.

2 Options for Decant

There are various options to consider if there is to be a full decant of Ward 2a / 2b?

These are summarised as relocation to:

- Paediatric ward (s) in the RHC?
- Adult ward (s) in the QEUH?
- Mobile unit on the QEUH campus?
- Adult ward in another hospital (Beatson Oncology Unit - BOU)
- Alternative paediatric service (s) in Scotland
- Alternative paediatric service (s) out with Scotland

3 The criteria to consider when deciding what option?

There are various criteria to consider when deciding what is the best option to consider. These are summarised as follows:

- Impact on paediatric Bone Marrow Transplant (BMT) service
- Impact on general Haematology Oncology service
- Impact on the paediatric hospital at night service
- Impact on Clinical teams who work closely with Haematology Oncology
- Impact on support services who work closely with Haematology Oncology
- Impact on adult services
- Impact on clinical staff working across paediatric haematology oncology service
- Impact on patients and families using the paediatric haematology oncology service

- Time it will take to establish the decant area and implement the change

4. Working principles

There are some key principles involved in the decision making for a full decant. These are summarised as follows:

- Location of the decant area in consideration to the paediatric hospital
- Infection control safety of the decant area
- Avoiding diseconomies of scale by having multiple decant areas

5 Matching options against Criteria

Table 1 provides a matrix summary of options against criteria if a full decant of both wards is to happen.

Table 1	Paediatric Ward (s) in the RHC	Adult Ward (s) in the QEUH	Mobile Unit on the QEUH campus	Adult Ward (s) in another Site (BOU)	Alternative Paediatric Unit in Scotland	Alternative Paediatric Unit (s) out with Scotland
Impact on the BMT service	Facilities for BMT can't be provide elsewhere in the RHC	Ward 4b can support paediatric BMT service	A mobile unit with correct specification could support BMT service	BOU could support paediatric BMT service	No paediatric unit in Scotland can support BMT service	Alternative UK providers could support the BMT service
Impact on the Haematology Oncology Service	No significant impact for inpatient services. Query whether ward 2b could be located in a single RHC Ward	There would need to be a separate 28 bed ward provided for service (in addition to Ward 4b – BMT)	No significant impact for inpatient or day care services if proper specification commissioned	Adequate space available but no on site access to paediatric theatres, intensive care or radiology services	No paediatric unit in Scotland has the capacity to support full decant without impact on wider local acute service	Unlikely there will be a full decant of patients to an alternative UK provider. There would need to be patient dispersal across various hospitals
Impact on the Paediatric Hospital at Night Service	No impact	Issue about covering more than one ward in adult site. Plus geography to cover	Would depend on where mobile unit was situated but geography would be an	HaN would not be able to provide on-site support. Telephone advice only	N/A	N/A

			issue.			
Impact on other paediatric Clinical Teams who work with Haematology Oncology	No impact in working with haem-onc team. There would be significant upheaval for some specialties in a new ward has to be identified	See comments for HaN	See comments for HaN	See comments for HaN	N/A	N/A
Impact on Support Services who work with Haematology Oncology	No impact with exception of pharmacy	See comments for HaN	See comments for HaN	See comments for HaN	N/A	N/A
Impact on Adult Services	N/A	Significant impact on winter plan for QEUH. Also clinical impact on patients and how managed off site at Gartnavel	N/A	No impact – decant space available in BOU	N/A	N/A
Impact on Clinical Staff working in Haematology Oncology	How do we maintain adequate staffing levels if multiple decant areas required across BMT, haem onc inpatient and day case services	How do we maintain adequate staffing levels if multiple decant areas required across BMT, haem onc inpatient and day case services	No impact	No impact	N/A unless there was request to deploy RHC staff to support transfer of activity	N/A unless there was request to deploy RHC staff to support transfer of activity
Impact on patients and families	See footnote 1	See Footnote 1	See Footnote 1	See footnote 1	See footnote 1. Also travel implication	See footnote 1 Also travel implication for children

					for children and families to consider	and families to consider
Time to make decant area available	See footnote 2	See footnote 2	12 week time line at the earliest to get mobile unit on site	No immediate impact	See footnote 2	See footnote 2

Footnotes

1) No matter what option is considered there is going to be significant anxiety amongst patient and families if a full decant is to be implemented. This needs to be matched against the concerns they will have with a do nothing approach. Patients and families may have greater anxiety about being transferred to an adult hospital and out with RHC. This needs to be considered against the infection control risks in remaining on the RHC site.

2) Most of the options are going to take some time to plan. BOU aside there is no immediate decant areas sitting unused. The mobile unit cannot be fast tracked beyond a 12 week installation period

6. Decision Making

If there is to be a full decant of both ward 2a/2b then the following questions needs to be considered.

- Can another area in the RHC be used? Or is the same problem faced in ward 2a / 2b going to be replicated?
- If the BMT service is to be retained then space in ward 4b needs to be freed up. The paediatric service is likely to need 2-3 immediate beds with this being maintained over duration of the decant. What is the impact of this on the adult BMT service.
- It is not physically possible to fit all ward 2a and 2b activity into Ward 4b. A combination of ward 4b for BMT and generic 28 bedded ward in the QEUH stack would provide adequate space. The split would present a staffing challenge to the paediatric haematology oncology unit due to physical diseconomies of scale covering two sites.
- Any use of space in the QEUH is going to need carefully thought out pathways to paediatric radiology, theatres and intensive care. There is also going to be additional pressures placed on the paediatric hospital at night service especially if decant extends into winter months.
- The use of any decant facility requires urgent discussion with pharmacy.
- Impact on wider paediatric and / or adult services will be considerable assuming the BOU is ruled out. There is no spare capacity sitting unused in the system and as such it is likely that freeing up a paediatric and /or adult ward will have impact on elective and emergency admission plans.
- BOU site is ruled out because of various gaps in paediatric provision most notably intensive care.

- Plans to relocate all or a proportion of patients out to another Scottish and /or UK unit are unlikely because of complexity to plan and impact on patients / families distance to travel.

If elsewhere in the RHC is thought to provide a safe infection control environment to the existing problem then the priority for decant should be in the RHC. However, if this is not possible then decant provision should be provided in the QEUH. There is no option to use the BOU; nor plan for the transfer out of patients from Board area. The BMT should be retained on site with use of Ward 4b as a priority.

Jamie Redfern

General Manager HPN

Draft 1.1 17/9/2018

[redacted]

From: Gibson, Brenda
Sent: 08 January 2019 22:16
To: Armstrong, Jennifer; INKSTER, Teresa (NHS GREATER GLASGOW & CLYDE); Redfern, Jamie

Follow Up Flag: Flag for follow up
Flag Status: Completed

Dear Jennifer,

[redacted]

As a consultant body we are now very concerned about the safety of our environment. We have not experienced water associated environmental organisms in blood cultures since our decant , [redacted]. We are concerned that we may have moved to an even less safe environment . We are being asked to nurse patients in rooms with portable HEPA filters and to prophylax vulnerable patients . The latter is not without risk . Only AmBisome and Posaconazole can be used . We have already experienced [redacted] serious anaphylactic reactions in patients receiving AmBisome requiring adrenaline . We are being told that prophylaxis will have to last for a year. The prolonged use of Posaconazole is not without the risk of hepatotoxicity. Are all new patients to be told that the environment carries a risk to their child which will require prophylaxis , and that in itself may carry a risk? Is that a true statement?

Securing the safety of our current environment requires action across the Directorates. In sending this e mail I am not bypassing Jamie or Kevin , but they can only control Women and Childrens Directorate. We are disappointed that air sampling in the ward is having to be repeated because that sampled before Christmas was not treated as a priority and the results may not be meaningful. This is the remit of the Diagnostics Directorate. We have two rooms on the ward out of action because of water damage with mould on the wall , which have not been dealt with because of reported difficulties in identifying a contractor over the holiday period. This responsibility lies with Estates and Facilities Directorate. Promised statements from the Press Office have not materialised and we are prophylaxing children without any agreement on what information should be given to the parents. It is hard to believe that the gravity of this situation is really appreciated by those charged with resolving it.

We need to be assured that someone to whom all Directors are answerable is managing this situation , co ordinating the necessary work and guaranteeing that timelines are met. We also need to be assured of the safety of the environment for our children and the safety of long term prophylaxis.

We have a Unit meeting at 8.30 am this Friday on ward 6A QEUH and we ask if you would be willing to use this opportunity to meet with us. If you are not the appropriate person at the Board , please let me know who is.

B.W.

Brenda

Chief Nursing Officer Directorate
Fiona McQueen, Chief Nursing Officer

Scottish Government
Riaghaltas na h-Alba
gov.scot

[redacted]

HAI Executive Leads
Copied to: Chief Executive Officers and
Infection Control Managers
NHSScotland

11 February 2019

Dear Colleagues

HAI-related incidents, outbreaks and data exceedance: Assessment, and reporting requirements and communication expectations

Assessment and reporting

The purpose of this letter is to reiterate the mandatory requirements of assessment and reporting of infection incidents, outbreaks and data exceedance.

The Healthcare Infection Incident Assessment Tool (HIIAT) should be used to assess every healthcare infection incident as stated in the National IPC Manual (NIPCM): http://www.nipcm.scot.nhs.uk/chapter-3-healthcare-infection-incidents-outbreaks-and-data-exceedance/

As you will be aware, timely assessment of a possible incident, outbreak or data exceedance supports implementation of appropriate control measures to prevent ongoing transmission. An early and effective response to an actual or potential healthcare incident/outbreak is crucial. Your local Board infection control and health protection teams should be aware of and refer to the national minimum list of alert organisms/conditions in Appendix 13 of the NIPCM. Guidance outlines that typically, two or more linked cases should trigger local teams to investigate a possible incident/outbreak and the necessity to call a Problem Assessment Group (PAG). Any incident/outbreak initially assessed HIIAT amber or red must be reported to Health Protection Scotland (HPS) and a Healthcare Infection, Incident and Outbreak Reporting Template (HIIORT) completed within 24 hours as stated in the NIPCM.

Communication

Within the incidents/outbreaks resources section of the NIPCM, there are checks regarding communications with patients, family and staff:
http://www.nipcm.scot.nhs.uk/resources/incidents-and-outbreaks/

It is a requirement for all infection incidents/outbreaks that the Incident management Team (IMT):

- Communicate with all patients affected and where appropriate their families;
- Communicate with all other patients and where appropriate families who may be affected or concerned e.g. those in the same ward/unit as patient(s) affected;
- Prepare a press statement (holding or release) for all HIIAT amber or red assessed outbreaks/incidents. If a proactive media communication is planned then this should be undertaken in consultation with HPS and Scottish Government communication team colleagues.

I would be grateful if you could cascade this letter to your HAI Executive Leads and Infection Control Managers for onward distribution as appropriate.

Yours sincerely

[redacted]

Professor Ann Holmes
Chief Midwifery Advisor and Associate Chief Nursing Officer

National Health Service (Patient Safety)

The Presiding Officer (Ken Macintosh): The next item of business is a statement by Jeane Freeman on patient safety in the NHS in Scotland. The cabinet secretary will take questions at the end of her statement, so I encourage all members who wish to ask a question to press their request-to-speak buttons as soon as possible.

14:20

The Cabinet Secretary for Health and Sport (Jeane Freeman): The recent loss of life in which a healthcare associated infection was a contributory factor is a stark reminder of how vital infection prevention and control measures are. I am sure that I speak for everyone in the chamber when I offer my sincere sympathies and condolences to the families and friends who have lost loved ones.

I know from speaking with NHS staff that they, too, are profoundly affected by the loss of their patients. Every day, our front-line NHS staff work to prevent and control, as much as is possible, healthcare associated infections. They have my thanks—and the thanks, I am sure, of everyone in the chamber—for the vital role that they play and the responsibility that they take.

The step change in the approach to managing infections in Scotland stems from the Clostridium difficile outbreak in 2007-08 at the Vale of Leven hospital. At that time, C diff and MRSA were the biggest infection threats to patients. Identification of the outbreak did not happen quickly enough to stop the spread of infection, and many of the cases were only identified as being part of a major outbreak through retrospective analysis. The subsequent inquiry and efforts of the Scottish Government and the NHS led to the introduction of a national inspection and scrutiny programme of healthcare facilities, and the development of a national infection prevention and control manual, with clear and wide-ranging procedures for healthcare professionals to follow. We also set up the world-leading Scottish patient safety programme, which has contributed to significant and sustained improvement in a range of areas, including healthcare associated infection.

Those approaches have delivered real results. In people who are the most at risk—those who are over the age of 65—C diff infections have reduced by 85 per cent, from 6,325 cases in 2008 to 917 cases in 2017. However, although infection incidents on the scale of the Vale of Leven are now markedly rarer, it remains vital that we continue to learn from them and take whatever further steps are necessary to make sure that our NHS is as safe as possible.

Last year, there was a water contamination incident in the Royal hospital for children in Glasgow. The previous cabinet secretary asked Health Protection Scotland to examine the issues and I published its report, “Summary of Incident and Findings of the NHS Greater Glasgow and Clyde: Queen Elizabeth University Hospital/Royal Hospital for Children water contamination incident and recommendations for NHS Scotland” on Friday. The report makes a number of recommendations, and today I give members my commitment that the recommendations will be addressed.

The report will be passed to the independent review group for it to consider as part of its work to review the design, commissioning, construction, handover and maintenance of the Queen Elizabeth university hospital and how such matters contribute to effective infection prevention and control. My officials are in the concluding stage of appointing two co-chairs of the review. The potential co-chairs have asked for time to consider what would be required of them, in order to ensure that they can fulfil their responsibilities.

I fully appreciate that members will be keen to see the work begin as a matter of urgency—I am, too. However, I am also adamant that we take the time that we need to appoint the right clinical experts to lead this critically important work. The focus is on the Queen Elizabeth university hospital, but the lessons are for NHS Scotland. We need to ensure that our physical infrastructure is designed, built and maintained to maximise infection prevention and control. I expect to be able to advise Parliament shortly on the review’s co-chairs, and then its remit and membership, in line with Professor Britton’s recommendations.

Since the water contamination incident, NHS Greater Glasgow and Clyde has given notification of a number of other infection outbreaks. Such notifications happen as a result of the clear procedures that were agreed after the Vale of Leven tragedy and set out in the “National Infection Control and Prevention Manual”, which is evidence of a monitoring and control system that acts much earlier to identify and control infection and protect patient safety.

Some infections, such as the Staphylococcus aureus bloodstream infections at the Princess Royal maternity unit, are common in the general population but can impact acutely on patients who are very unwell and likely to have a lower immunity. Other infections, such as the Stenotrophomonas maltophilia infection at the Royal Alexandra hospital, are rare. However, no matter whether the infection is rare or not, it is crucial that staff identify it early, deal with it and

prevent it from spreading. In all infection outbreaks, immediate additional measures are put in place to ensure that hygiene and infection prevention is absolutely as good as we need it to be.

Given the serious nature of these incidents, my officials have daily phone calls with Health Protection Scotland so that I can be updated, and the healthcare incident infection assessment tool—HIIAT—reports are delivered following multidisciplinary incident management team updates.

As members know, following the Cryptococcus infection at the Queen Elizabeth university hospital, I asked the healthcare environment inspectorate to undertake an unannounced inspection of the hospital. The report on that inspection will be published by Healthcare Improvement Scotland on 8 March. We will publish our response to it at that time, and it, too, will feed into the work of the expert review.

All those steps are important and it matters that, while the independent review undertakes its work, we make any immediate improvements that are necessary and identified by the reports. I want to make sure that the clinical voice is heard with regard to clinicians' work environment, so that they can continue to deliver safe, effective and person-centred care to their patients.

The Health and Care (Staffing) (Scotland) Bill, which will reach stage 3 in the chamber in the coming months, follows Lord MacLean's recommendation from the Vale of Leven inquiry that we should act to ensure that the staffing and skills mix is appropriate for each ward and that, where that is not the case, an escalation process is in place to respond. The bill provides an opportunity to enable a rigorous evidence-based approach to decision making on staffing, taking account of service users' health needs, including in infection prevention and control.

It is important, too, that we recognise the role and voice of all our front-line staff in NHS Scotland. Porters, domestic and housekeeping staff, catering staff, receptionists and maintenance staff all have a critical role to play in effective patient safety. I will be giving further thought to how we can ensure that, across all our health boards, the voices and expertise of those staff members are integral to the work on infection prevention and control.

Scotland's response to healthcare associated infections is wide ranging, and a number of expert agencies are involved. Health protection Scotland is responsible for undertaking surveillance and horizon scanning for emerging threats and seeking advice from United Kingdom and international organisations where required. When HPS is made aware of threats, it produces guidance for NHS Scotland to prevent on-going transmission of infections. The Healthcare environment inspectorate leads on independent inspections of every NHS acute and community hospital in Scotland. Since 2009, HEI has published 261 hospital inspections as well as thematic inspections of theatres and invasive devices.

The Scottish Government has underpinned those efforts by launching the mandatory national infection prevention and control manual in 2012, using a once-for-Scotland approach. The manual provides a framework for staff to apply effective infection prevention and control practice and it sets out the process that health boards must follow to manage incidents and outbreaks. We have led the world with the national infection prevention and control approach. It has been adopted by NHS Wales and there are calls for it to be adopted across the UK.

In the past decade, Scotland has made significant progress on infection prevention and control. Spurred by the tragedy of the loss of 34 lives in the Vale of Leven, where C diff was a contributory factor, NHS Scotland is now in a position to identify incidents and outbreaks much earlier and take immediate action.

Infections are present in everyday life. We cannot avoid all infections, but we must ensure that our systems include horizon scanning for emerging infection threats and ensuring preparedness and resilience. I assure Parliament and, through members, the public that a culture of improvement and safety is woven through our national health service and that I am committed to ensuring that our hospitals remain some of the safest healthcare facilities in the world.

Miles Briggs (Lothian) (Con): I thank the cabinet secretary for advance sight of her statement. We pass on the thoughts of members on the Conservative benches to the families involved.

Public confidence has been shaken in the light of recent events in Glasgow. It is now critical that we see leadership and action to ensure that our hospital estate is safe and that all measures are put in place to meet the best infection control standards. I agree that the review will suggest lessons and recommendations for other hospitals—including the new Edinburgh sick kids hospital—on infection control measures and building standards that go above and beyond those that are currently in place.

How will ministers make sure that health boards take forward any and all recommendations, and will the cabinet secretary commit to the publication of any interim findings and recommendations?

Jeane Freeman: I understand that public confidence has been shaken, which, in part, is why I made the statement. I wanted to remind us all of the significant improvements that have been made in infection prevention and control across Scotland, and the steps that have already been taken to ensure that we do not repeat what happened at the Vale of Leven hospital, so that we do not have any outbreak that is not identified until it has progressed quite considerably.

That said, I am not suggesting, by any stretch of the imagination, that therefore everything is fine. When there are infection outbreaks, that suggests to me that there is more that we need to do. I completely commit making public the interim recommendations—if there are any—and our response to them. We will also publish not only the HEI report but my response to it and the actions that I will take on Cryptococcus. I cannot give the details of the overarching review until we appoint the co-chairs, because it will be for them to determine how long they think that it might take. However, I hope that they will agree a remit, a timeframe and an approach that we can publish, within which we will be able to see where there might be milestones and where recommendations will come forward that we can act on. I will certainly share that information with the Health and Sport Committee, but I am also happy to share it more widely with members when we get to that point.

Monica Lennon (Central Scotland) (Lab): I thank the cabinet secretary for advance sight of her statement. The thoughts of Scottish Labour remain with the families of the patients who have died.

What has occurred is no reflection on the hardworking staff in the hospitals affected by these infections. However, it is clear that NHS Greater Glasgow and Clyde has suffered reputational damage. A culture of secrecy has clouded the health board's communications and I think that we all agree that that has had an impact on public confidence. Staff and patients who raised concerns about cleanliness, infection control, building maintenance, workforce pressures and more felt that their concerns were not acted on, which is bitterly disappointing.

In the interests of transparency, will the cabinet secretary update Parliament on how many patients have been affected by the infections referred to in her statement or any other rare infections, how many patients have died, how many have received treatment, and how many cases relating to hospital-acquired infections have been referred to the procurator fiscal in the past 12 months?

Jeane Freeman: In order to be absolutely certain that I provide Monica Lennon with the accurate detail, if she and other members are content, I will write to her later today with the answers to all those specific questions, including the PF question—as far as we know that information. I will make sure that that detail is shared with the other party spokespersons on health, so that they have that information too.

Ms Lennon knows that, in previous statements in the Parliament, I have recognised that our health board communications across NHS Scotland are at times not as good as I want them to be. I take the view that if we have information we should give it to people and that there is nothing worse than a vacuum that people fill with their understandable worries and anxieties. That is not an approach that I want our health boards to adopt.

We are working with our health boards to ensure that communications are as transparent and detailed as they can make them, bearing in mind that they have an absolute duty under their Caldicott guardian and other responsibilities not to release any information that could lead to the identification of individual patients. That duty curtails the boards to some extent, but it might not always curtail them to the extent to which they believe themselves to be curtailed.

I am also aware of concerns that have been raised in the past in NHS Greater Glasgow and Clyde. I now have information on some of those concerns, which I will ensure is passed on to the independent review. I know that the individuals who have raised such matters with me will make sure of that, too. I have given a commitment that I will make sure that that information is passed on so that the review has the benefit of historical information as well as the evidence that it may choose to take.

Alison Johnstone (Lothian) (Green): In her statement, the cabinet secretary recognised that all NHS staff, from clinicians to those who are involved in catering and maintenance, have a critical role to play in effective patient safety. I appreciate that she said that she will give thought to how we can make sure that all those voices are heard, but given the pressure on staff who work in the NHS, what assurances can she provide that staff will be given sufficient time for the expert training and mentoring that they need, so that we can ensure patient safety?

Jeane Freeman: That issue will be dealt with partly through the Health and Care (Staffing) (Scotland) Bill, which is working its way through the Parliament. We are very keen to ensure that that bill is also applicable in our social care settings, where safety and infection prevention and control are as important as they are in our acute settings.

I want to make sure that, as part of the standard work that a board should undertake on infection prevention and control, which includes all the processes that I outlined, we are assured that important voices such as those of maintenance, housekeeping and catering staff are integral to the overall approach that a board takes in a hospital setting and elsewhere to infection prevention and control. Rather than being seen as additional, their involvement should be considered to be as central as the involvement of nursing and medical staff. That is a case of making sure that the individuals who would be part of those discussions have the time to bring to bear the expertise that they bring from the roles that they play. When additional training or support is needed, I will expect boards to make that available.

As Ms Johnstone knows, I regularly meet the chairs of our health boards to seek their assurance on the areas that I consider to be of the utmost importance, and there can be nothing of higher importance than patient safety. In addition, the chief executive of NHS Scotland regularly meets the board chief executives. All those discussions are aligned with the Government's key priorities. We regularly have the opportunity to get such assurances and to act when we believe that what needs to be done is not being done.

Alex Cole-Hamilton (Edinburgh Western) (LD): The investigation into the water contamination incident at the Royal hospital for children in Glasgow was instructed by the cabinet secretary's predecessor on 20 March last year in response to a question from Anas Sarwar. The report on the investigation was concluded and given to the Government in December, but the Government released it only this weekend. What was the reason for the delay? Why did the investigation take so long? Why did the Government choose not to release that information to the Parliament and the general public until two months after it received it? If there are learning points for all of us and we are to work together to combat and control infection, surely time is of the essence.

Jeane Freeman: I am grateful to Mr Cole-Hamilton for that question. If he has read the report, I am sure that he will understand that it took time for HPS to identify the exact source of the water contamination and to take the necessary steps to address that in what was an ever-changing situation in the hospital. HPS had to do that before it could produce conclusions and recommendations that it was confident about and could be assured that it had looked widely for expert advice and support on to allow it to get to that point.

There were two parts to my decision to publish the report last week although I had been made aware of it on 21 December. I took the view that publishing the report in the week before Christmas was not necessarily the most helpful thing to do and would be considered in a critical light. I then took the view that I had to be sure that HPS could see how the report fitted into the work of the wider independent review. There was no intention not to publish it; it was about making sure that the report could be aligned with the independent review. I am sure that members understand that I had hoped to be able to say today who would lead the expert independent review into Queen Elizabeth university hospital. However, for the reasons that I outlined, I am not able to do that.

All those reasons contributed to the reasons why we took longer than we would otherwise have wanted to take to publish the report. There was no intention to conceal anything, as is evidenced by the fact that we have published the report and the fact that I have committed to implement its recommendations, notwithstanding the independent review. It is important that the information is available, understood and acted on.

The Presiding Officer: I am conscious that the minister is giving detailed answers. I welcome that, but we have 10 more questions to get through.

Emma Harper (South Scotland) (SNP): Will the cabinet secretary confirm how the Scottish Government's approach to safe staffing will ensure patient safety as well as the delivery of high-quality, safe care across our hospitals and emergency services?

Jeane Freeman: The legislation on safe staffing is designed to ensure that there is a consistent approach across Scotland to understanding the workload demands of meeting the healthcare needs of any patient cohort at any time and the skills mix that is required to address those demands. Inside that is infection prevention and control, which, as Ms Harper knows from her own experience, varies between different patient cohorts depending on the presenting healthcare need.

Notwithstanding the fact that colleagues will have identified ways in which the legislation could be improved, we all agree that it will provide consistency of assurance and methodology, so that workload is understood in the context of the presenting healthcare needs of patients and the skills mix is understood so that we have the right staff in the right place and a way of escalating if staff feel that they require additional support that is not being delivered to them.

Brian Whittle (South Scotland) (Con): Health Improvement Scotland has no regulatory powers to enforce the implementation of recommendations. For the confidence of staff and patients, and given the seriousness of the

situation, will the cabinet secretary commit the Scottish Government to implementing all the HIS recommendations when it publishes the HIS report?

Jeane Freeman: Yes, I will. The question of regulatory powers and the various bodies involved—health facilities Scotland, HPS and HEI—will be part of the review. As I said, the focus is on the Queen Elizabeth university hospital, but the lessons are for NHS Scotland on what more we might do to ensure that there is a more joined-up approach to what needs to happen. It will be for the review to determine whether more regulatory powers are needed. If they are, the review will produce recommendations.

Sandra White (Glasgow Kelvin) (SNP): The cabinet secretary mentioned the Scottish patient safety programme, which is helping to reduce hospital mortality and reduce avoidable harm at every stage of care. Will the cabinet secretary provide an update on hospital standardised mortality ratio figures for Scotland?

Jeane Freeman: The hospital standardised mortality ratio has shown a significant decline, decreasing by 13.2 per cent in the four years from January to March 2014 to July to September 2018. That is all helped by the Scottish patient safety programme, which is one of the key drivers of that reduction. We need to continue the improvement in the ratio, which has been in a steady decline since the introduction of the measures that I outlined.

David Stewart (Highlands and Islands) (Lab): What lessons have been learned about patient safety with regard to new-build hospitals, specifically concerning the handover and maintenance of buildings?

Jeane Freeman: Some lessons are immediate—some, in the HPS report that was published last week, have already been picked up by NHS Lothian for the new children's hospital for Lothian—and others are being worked through by our directors of estates with the chief executive of NHS Scotland, together with health protection Scotland and health facilities Scotland, to see what more can be drawn at this point from the HPS report and whether there is anything further to draw from the HEI report. That is what I meant when I said that, although the independent review is very important and its work will be of significance, there are recommendations that we can take forward at this point. Once the HEI report has been published, I will be happy to set out those recommendations that are specifically for buildings, so that members can see what we are doing to act on them.

Rona Mackay (Strathkelvin and Bearsden) (SNP): The Scottish patient safety programme has contributed to a significant reduction in harm and mortality in our NHS. Will the cabinet secretary outline how that internationally renowned programme can continue to provide public assurance about the quality and safety of care that the public expects?

Jeane Freeman: Healthcare Improvement Scotland is the primary driver of the Scottish patient safety programme. It provides assurance with regard to its inspections and reviews, which are reported and published, and can be used and seen by others. Some of the data that we produce about overall general infection rates are also reassuring about the continuing decline of Clostridium difficile, MRSA and so on. Members can see, for their individual health boards, other work that we discuss with Health Improvement Scotland, including on surgical site infections and other aspects of the Scottish patient safety programme, but there might be merit in pulling that together for the health service across Scotland. Again, I will be happy to look at whether that is worth doing.

Annie Wells (Glasgow) (Con): As the cabinet secretary has pointed out, front-line staff have a critical role to play in patient safety. Despite that, figures show that there was an 11.5 per cent cut in maintenance and estate workers across Scotland in the two years to September 2018. In NHS Greater Glasgow and Clyde, the numbers have reduced by nearly 19 per cent since 2009. What action will be taken to address that drastic reduction?

Jeane Freeman: Ms Wells is correct about the level of vacancies that are being carried in maintenance and, in some instances, in domestic staff. I am very alert to that and have already asked for explanations from boards about what exactly they are doing.

Annie Wells will know that boards are required, in addition, to produce an annual operating plan that shows how they will use their resource. This year, that will be within an overall three-year financial planning cycle, but there will be more detail in the first year. We have been really clear about how we will sign off that annual operating plan, and I will be looking to ensure that capacity—by which I mean staffing—is not being reduced in areas that are critical to infection prevention and control, in which I include all the areas that I have mentioned. Once the plans signed off, they will be published, so the member will be able to see what specific action we are taking.

Ruth Maguire (Cunninghame South) (SNP): I am sure that, across the chamber, we agree that all staff are essential to ensuring patient safety. What impact could a no-deal Brexit have on NHS staffing levels and patient safety?

Jeane Freeman: Ruth Maguire will know that our current estimate is that just under 6 per cent of the current health and social care workforce are non-United Kingdom European Union nationals, and that we have a significant number of non-UK EU nationals in our health service. The figures are greater than that in some parts of the country and in some job roles. Our planning for our workforce needs in areas that Ms Wells identified and other areas has to take account of the fact that we might not, in the current climate of uncertainty, be able to retain all of that workforce.

There are practical steps that we can take, which we hope to be able to set out soon for members in order that we can make good on our words, the intentions of which are genuine. We value all those staff very much and we want them to stay.

An additional issue is how we can attract into our health service people from EU countries from which people have traditionally come here to work. Ruth Maguire will be aware of the 80 per cent reduction this year from last year in the number of nurses from the European Union coming to work in the UK: non-UK EU nationals are not registering.

There are serious issues relating to Brexit, and serious uncertainty and anxiety are being experienced by people who work in our health and social care services. We are doing what we can to reassure them that they continue to be welcomed and valued in our service.

Mary Fee (West Scotland) (Lab): Last week, the cabinet secretary responded to a question from my colleague Neil Bibby on infection control at the Royal Alexandra hospital in Paisley. She said that she shared his concerns about gaps in the domestic cleaning rotas. In light of that case and other tragic cases in NHS Greater Glasgow and Clyde, does the cabinet secretary have any plans to review and update the "National Infection Prevention and Control Manual", which was published in 2012? If so, when?

Jeane Freeman: That matter will be part of what the independent review will consider. The review will consider our existing measures, including that mandatory manual. In addition, I have asked our national clinical director and HIS to review our current measures to see whether we can make other improvements to particular steps, in the light of current knowledge.

I do not yet know the answer to the question. I am mindful of the point that Mary Fee has made about domestic staff, which Mr Bibby has made and which Ms Wells made again. I do not think that I need anything to be reviewed before I can act to make it clear to boards that I do not think that it is acceptable to carry such levels of vacancies in maintenance, domestic and housekeeping staff. Those staff are central—as central as any other bit of the workforce—to infection prevention and control. We can act on that now, while we consider whether our current procedures require updating and review as a consequence of our recent experience.

David Torrance (Kirkcaldy) (SNP): Can the cabinet secretary confirm whether measures are in place to ensure that health boards promptly and effectively implement recommendations that are made by independent reviews?

Jeane Freeman: When a review is undertaken by Healthcare Improvement Scotland, it has in place a process for going back and checking that its recommendations and associated actions are completed. HIS also takes a view on whether actions that a board suggests it should take are adequate to meet the recommendations that HIS has made.

If a review is external and the recommendations are to the Scottish Government, obviously members have a means by which they can check the Government's responses to those recommendations and how we are taking them forward. In addition, we have, as I said earlier, regular meetings with board chief executives, directors of estates, directors of human resources and directors of finance. I also meet chairs of health boards in order to pursue specific recommendations board by board or across the whole health service.

Anas Sarwar (Glasgow) (Lab): I welcome the cabinet secretary's comments. However, clinicians and patients have expressed concerns about NHS Greater Glasgow and Clyde's statement that was issued on Friday, in which it seemed to imply that the cabinet secretary's independent review had limited scope and in which it announced three reviews of its own.

Will the cabinet secretary please confirm that the review that she announced has a broad scope that will include the Queen Elizabeth university hospital's maintenance and upkeep since it opened? Will she outline what the three reviews that NHS Greater Glasgow and Clyde proposes to undertake will cover? Will she guarantee that they will not undercut the work of her independent review?

Jeane Freeman: I am grateful to Mr Sarwar for raising the issue. It is disappointing that the board does not appear to have understood what I have—exceptionally clearly—said. I repeat and absolutely confirm that the scope of the independent review that I have commissioned is exactly as was described in the answer to a written question that was lodged. The review will go back to the design and take us right through.

To comply with the Britton report's recommendations, it will be for the review's independent chairs to work the scope that I have commissioned into a remit, and to decide where they will bring in expert advice, whom they will seek evidence from, how they will seek evidence, how long that will take and whether—on the basis of their work plan—there is an opportunity to make interim recommendations. I will ask the chairs to give permission for all that to be made public. I have no doubt that they will be happy to do that. I take that responsibility.

My understanding—I will make a point of double checking, so that I can confirm it to Mr Sarwar and others who are interested—is that one of NHS Greater Glasgow and Clyde's immediate reviews is of whether it should take additional maintenance and infection prevention and control measures now, at its estate at the Queen Elizabeth university hospital. Another review is about ensuring that infection prevention and control steps are being taken in the right places as people flow through the hospital. As I said, I will ensure that we have the clear detail on that, which I will pass to Mr Sarwar and Opposition spokespeople so that they are clear on the subject.

NHS Greater Glasgow and Clyde's reviews absolutely should not undercut the independent review: they should feed into it. The independent review can take a view on the board's reviews and their conclusions.

Greater Glasgow and Clyde NHS Board

[redacted]

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Private and Confidential

Date: 4th July 2019
Our Ref: JB/GD

Professor John Cuddihy FRSA

[redacted]

Enquiries to: John Brown
Direct Line:
E-mail: [redacted]

Dear John

Firstly, I must apologise for the delay in replying to your concerns about the infection control process in general and Molly's care in particular. As you know, I asked our Chief Executive to look at the issues you raised in detail and provide both of us with a detailed briefing. Unfortunately, this has taken longer than either of us would have liked due to the circumstances surrounding Molly's care.

Hopefully, the following paragraphs will provide you with some assurance that the NHS Board has taken your concerns seriously and responded appropriately.

In respect of Molly's care, I appreciate that this must have been an extremely distressing and

[redacted]

[redacted]

When we last talked about Molly's care you also shared your concerns about the NHS approach to infection control in general. I've received a detailed briefing on this and thought it important I share this with you.

In terms of the infection control processes in general, the infection control team track all of the alert organisms and conditions listed in the NHS Scotland National Infection Prevention Control Manual routinely using an electronic surveillance system which links directly to our laboratory systems. This is, however, only one type of surveillance. In each laboratory, Consultant Microbiologists and Infection Control Doctors are alerted by the laboratory systems and staff to any rare, exceptional or unusual microorganisms that present through analysis of samples and this initiates further testing and investigation. In some cases, on the instruction of the microbiology consultant, these samples are sent to one of the Scottish or UK reference laboratories for further detailed investigation and typing. At a national level, whilst one individual NHS Board may not always know if there were other rare or exceptional cases in Scotland or indeed the UK, central agencies such as Health Protection Scotland and Public Health England are alerted to unusual organisms and share this information across the country if appropriate. Therefore, you can be reassured that single occurrences of rare infections are not overlooked.

Finally, I want to say how impressed I was to hear about the fundraising Molly and her friend [redacted] are doing in support of the Schiehallion Unit. I had a word with the Chair of the NHS Greater Glasgow and Clyde Endowments Committee, and he has said that the Endowments Committee would welcome an approach from Professor Gibson and Dr Kidson for funding to support the new social/common room for children aged between 8-12.

I've also spoken to our Nurse Director, Dr Margaret McGuire, who would be interested in meeting Molly and [redacted] to discuss them telling their story to the Board. At every Board meeting, the Nurse Director presents a short patient story video to help remind the Board why we're here and ensure everyone remains focused on our patients. If Molly and [redacted] would be interested in taking part in a video to be shown at a future Board meeting please let me know and I'll arrange this.

I hope that this response has provided you with some reassurance but please do not hesitate to contact me should you require any further information.

Yours sincerely

[redacted]

JOHN BROWN CBE
Chairman

From: "Redfern, Jamie" [redacted]
Subject: RE: [ExternaltoGGC]Molly Cuddihy
Date: 18 July 2019 at 16:53:57 BST
To: 'John Cuddihy' [redacted]

Dear Professor Cuddihy

I acknowledge receipt of this email and will respond further within the timescale you mention once having spoken to various colleagues involved in the latest infection control incident.

Jamie

-----Original Message-----
From: John Cuddihy [redacted]
Sent: 17 July 2019 19:10
To: Redfern, Jamie
Subject: [ExternaltoGGC]Molly Cuddihy
Importance: High

Good Afternoon

My reason for this email is to express my utter disgust and anger at the manner in which you and indeed the hospital management have failed to inform my family and in particular my daughter Molly of the most recent incident in the Royal Hospital for Young People and more specifically the suspected case of mycobacterium contracted by one of the patients.

Indeed, having “volunteered” to be the single point of contact between the hospital and myself in matters, materially affecting my daughter, you have failed to do that which you agreed. In addition, following our meeting, recorded in the formal minutes you accepted that communication was key in addressing the fear, anguish and pain being suffered through-out this last 18 months by both patient and families affected. You gave a commitment that you would learn from the mistakes of the past and keep us informed.

This, as you know, has not been the case. Having attended the hospital clinic for treatment and consultancy with Dr Sastry, my wife and daughter were advised of the news that another vulnerable young person had contracted this terrible bacteria within ward 6A, a ward you assured me was a safe environment.

We fully recognise and respect patient confidentiality however the fact that this latest bacterial out-break was so inextricably linked to my daughters ongoing condition and

continued treatment, you should be ashamed of yourself for keeping this critical information from us.

I am aware that you were called that day whilst my daughter and wife were in the hospital ward, but still you had neither the compassion or common decency to make contact with us, leaving me to conclude that you and indeed the hospital have matters you wish to hide.

Further, I am aware that you gave an undertaking to make contact with me on the day that this latest bacterial out-break was made known within an internal governance meeting, specifically when advised to do so by those present.

I have afforded you some time since we were advised of this latest development out of respect however this does not seem to have been forthcoming nor has any respect been reciprocated.

In all the circumstances you have engaged in a wilful act so reckless as to show an utter disregard for the consequences. Shame on you!

Be advised that my daughter continues to be treated far beyond the original timescales set out by the medical team as her white blood count has not recovered sufficiently as a result of her contracting the hospital acquired infection. Whilst I appreciate that further tests were required to take place to confirm whether both bacteria were from the same source, you have treated us with utter contempt by not formally making contact.

I await any comment you may have and will do so for a period of one week from the date of this email.

John Cuddihy

****

From: "Redfern, Jamie" [redacted]

Date: 25 July 2019 at 11:31:26 BST

To: 'John Cuddihy' [redacted]

Subject: FW: [ExternaltoGGC]Molly Cuddihy

Dear Professor Cuddihy

Further to my email of 18th July 2019, which acknowledged receipt of your email, I have discussed with senior colleagues and can now provide an update to the points of concern you raised in your email to me dated 17th July 2019.

It is important to stress that we believe that we have been open about what we have known, and what we have been seeking clarification and scientific data on. However, we acknowledge that this may have complicated effective and timely communication, but this should not be misconstrued as obfuscation on our part. Both myself and Dr Inkster have been on annual leave and this has been a further factor.

Unfortunately I do not agree with your suggestion that there has been any “cover up” of anything specific to your daughter’s case or the wider infection control matters still under surveillance in paediatric Haematology Oncology services provided from the Royal Hospital for Children, Glasgow. This position is clearly reflected in the establishment of an Incident Management Team (IMT) to review the latest evidence as is normal best practice.

The minutes of these IMT meetings through June and July 2019 clearly list an action to update you.

It is important to be clear that whoever is nominated to carry out this

action and when it takes place, is at the instruction of the IMT Chair. Normally this action would be undertaken by Dr Inkster and or myself or the named consultant of any specific child. However, in this case there were mitigating circumstances that need to be considered when reviewing how this action has been progressed.

- We were waiting on some bacteriological typing results pertinent to what we might say in such discussion with you and your family.
- We needed to be very careful around patient confidentiality and avoid any criticism around breach in this regard. This is pertinent to the second case involved.
- We were keen not to cross the ongoing communication between our Chairman and yourself which we were aware was ongoing in respect of Molly's treatment.

It had been my expectation that this matter would be completed in my absence on leave. I apologise that this did not happen.

Dr Inkster is expected back at work later this week. All relevant typing results have been received and the strains are not identical. Communications with the other family have been progressed. There have been no other cases.

There is a further IMT scheduled for Friday 26 July 2019 and I will ensure that at this meeting your concerns, as raised in your email, are formally noted to inform future communication.

It may be advisable to convene a meeting with myself and Dr Inkster to go over the specifics of Molly's case in relation to what information we have and can disclose about the second case. If you are agreeable to this please let me know and I will get this arranged.

Yours sincerely

Jamie Redfern

-----Original Message-----
From: Redfern, Jamie
Sent: 18 July 2019 16:54
To: 'John Cuddihy'
Subject: RE: [ExternaltoGGC]Molly Cuddihy

Dear Professor Cuddihy

I acknowledge receipt of this email and will respond further within the timescale you mention once having spoken to various colleagues involved in the latest infection control incident.

Jamie

-----Original Message-----
From: John Cuddihy [redacted]
Sent: 17 July 2019 19:10
To: Redfern, Jamie
Subject: [ExternaltoGGC]Molly Cuddihy
Importance: High

Good Afternoon

My reason for this email is to express my utter disgust and anger at the manner in which you and indeed the hospital management have failed to inform my family and in particular my daughter Molly of the most recent incident in the Royal Hospital for Young People and more specifically the suspected case of mycobacterium contracted by one of the patients.

Indeed, having “volunteered” to be the single point of contact between the hospital and myself in matters, materially affecting my daughter, you have failed to do that which you agreed. In addition, following our

meeting, recorded in the formal minutes you accepted that communication was key in addressing the fear, anguish and pain being suffered through-out this last 18 months by both patient and families affected. You gave a commitment that you would learn from the mistakes of the past and keep us informed.

This, as you know, has not been the case. Having attended the hospital clinic for treatment and consultancy with Dr Sastry, my wife and daughter were advised of the news that another vulnerable young person had contracted this terrible bacteria within ward 6A, a ward you assured me was a safe environment.

We fully recognise and respect patient confidentiality however the fact that this latest bacterial out-break was so inextricably linked to my daughters ongoing condition and continued treatment, you should be ashamed of yourself for keeping this critical information from us.

I am aware that you were called that day whilst my daughter and wife were in the hospital ward, but still you had neither the compassion or common decency to make contact with us, leaving me to conclude that you and indeed the hospital have matters you wish to hide.

Further, I am aware that you gave an undertaking to make contact with me on the day that this latest bacterial out-break was made known within an internal governance meeting, specifically when advised to do so by those present.

I have afforded you some time since we were advised of this latest development out of respect however this does not seem to have been forthcoming nor has any respect been reciprocated.

In all the circumstances you have engaged in a wilful act so reckless as to show an utter disregard for the consequences. Shame on you!

Be advised that my daughter continues to be treated far beyond the

original timescales set out by the medical team as her white blood count has not recovered sufficiently as a result of her contracting the hospital acquired infection. Whilst I appreciate that further tests were required to take place to confirm whether both bacteria were from the same source, you have treated us with utter contempt by not formally making contact.

I await any comment you may have and will do so for a period of one week from the date of this email.

John Cuddihy

[redacted]

[redacted]

From: "Duncan, Gillian" [redacted]
Subject: Re: Private and Confidential - NHS Greater Glasgow and Clyde
Date: 6 August 2019 at 09:20:12 BST
To: 'John Cuddihy' [redacted]

Dear John

Thank you for your email to John Brown. John is on leave at the moment but I am acknowledging receipt on his behalf and I will bring this to his attention on his return.

Kind regards.

Gillian

Gillian Duncan [redacted]

From: John Cuddihy [redacted] **Sent:** 05 August 2019 03:23 **To:** Brown, John **Subject:** [ExternaltoGGC]Fwd: [ExternaltoGGC]Re: Private and Confidential - NHS Greater Glasgow and Clyde

Good Afternoon John

May I first of all thank you for the letter that you sent to me and thereafter, extend an apology for the delay in responding as I have been overseas for extended periods on business.

I am extremely grateful to you for taking the time and effort to commission a report into my daughter Mollys case and for updating me on your findings relative to her medical condition and her contracting the hospital acquired infection, mycobacterium chelonae.

[redacted]

[redacted] However, the development of the HAI has placed Dr Sastry in an unenviable position, balancing the risk of doing against the risk of not doing, a position that he should not have ever been in! Indeed, I am sure you will agree Molly should not have to be in this position!

Whilst I very much appreciate your update relative to the processes and procedures surrounding hospital acquired infections, my overriding concern has and continues to be, a lack of clinical knowledge around this bacteria. Indeed it was my understanding that, whilst accepting all you say relative to the reporting mechanisms, Molly's case was never formally reported to the Board, although it had been to the organisations you mentioned. I wonder if you would be good enough to clarity that this was the case.

[redacted]

During this time, we were also made aware of other issues of bacteria within ward 6A, something I am sure you will be acutely aware of. However, sadly, despite minutes from two separate IMT meetings instructing that I be informed as to the latest development, I was not. Instead, Molly and my wife found out whilst attending as an out-patient. As you can imagine this did not go down well at all with my wife and daughter being extremely upset with this development within a ward that we were assured was safe. In this regard I wrote to Jamie Redfern expressing my extreme disappointment and anger about his failure to make contact and advise us of developments.. I have requested a meeting with both Jamie and Dr Teresa Inkster which I hope will take place in the coming week.

I do appreciate that the issues within the Childrens ward are subject to numerous enquiries, each of which will consider evidence from an amalgam of sources and feed back with conclusions and recommendations. I would not wish to pre-empt those enquiries/investigation and as such will await the outcomes. However, please note that I will be looking to provide evidence to each of those investigations but will do so directly to those leading them.

May I also thank you for the kind words concerning the fundraising by Molly and [redacted]. They have certainly managed to get their message out there and despite the trauma they have both experienced, they wish to assist in any way they can, not simply with financial resource but also implement change in the lives of critically ill young people.

The ‘Ball' is a 750 sell out with sponsorship from a host a household brands, each wishing to support this worthy cause. We have also embarked on a media strategy to maximise impact, garnering support from some ‘big names’ touched by their story and that of the Schiehallion. We are currently awaiting contact with Jamie Redfern to discuss the proposals concerning the common room along with Professor Gibson who has been advised of the Glasgow and Clyde Endowments Committee, kind offer. Professor Gibson will progress this in early

course. Please note also that Molly has been canvassing those children from the ward to provide stories of support from the TCT funded staff; Ronan Kelly, who has been an out standing ‘critical’ friend to the young people, particulary when they have been at their most vulnerable. It is our intention to request a meeting with the Board of the Robertson Trust who currently fund this position. We would wish to present to them the importance and significant value of this post and to canvass their support for a similar post for 8-12 year olds, requesting they give consideration to the covering of revenue costs for the next 3-5 years.

Molly and [redacted] would be delighted to ‘tell their story’ to the Board and as such grateful if you could progress on their behalf.

Thanks again John for doing that which you committed to do and for your openness, honesty, transparency and above all leadership. It means so much to us all and whilst we may not have an answer yet as to ‘HOW’ this bacteria occurred, you have provided support, confidence, communication and developed trust that has been sadly lacking from elsewhere in the hospital.

Thank you and best wishes

John

SEP SEP

Begin forwarded message:

From: "Duncan, Gillian" [redacted]
Subject: RE: [ExternaltoGGC]Re: Private and Confidential - NHS Greater Glasgow and Clyde

Date: 18 July 2019 at 12:10:29 GMT+4:30
To: 'John Cuddihy' [redacted]

Thanks, John, I will pass this on to the Chairman when he is in the office today.

Kind regards.

Gillian

Gillian Duncan | [redacted]

From: John Cuddihy [redacted] **Sent:** 17 July 2019 19:22 **To:** Duncan, Gillian **Subject:** [ExternaltoGGC]Re: Private and Confidential - NHS Greater Glasgow and Clyde

Good Evening Gillian

May I first of all apologise for the delay in responding to your email and indeed to the letter sent by your Chairman John Brown.

I have been overseas on business having recently returned and now addressing those matters outstanding.

I am grateful to your Chairman for taking on my concerns and commissioning the various strands to those within the hospital in order that he could address those concerns. I am acutely aware of the demands on all those involved, especially the medical team who have and continue to do such wonderful things for those vulnerable young patients. I am extremely grateful to all of those involved.

If I may, I will respond separately relative to the matters contained within the letter but in the meantime would be grateful if you could pass

on my sincere thanks to your Chairman.

Best wishes

John

SEP SEP SEP

On 17 Jul 2019, at 19:15, John Cuddihy [redacted] wrote:

[redacted]

**********NHSGG&C
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Note of Meeting about IMT of Tuesday, 20th August 2019

Boardroom, Glasgow Royal Infirmary

Present:

Prof. Linda De Caestecker (Chair)
Dr Jennifer Armstrong
Dr Mags McGuire
Mr Jonathan Best
Dr Chris Deighan
Mr Tom Steele
Mr Jamie Redfern
Dr Ian Kennedy
Ms Sandra Devine
Dr Rachel Green
Ms Jennifer Rodgers
Dr Alan Mathers
Mr Graeme Forrester (Board Administration)

Apologies:

Dr Teresa Inkster

Background

Prof. de Caestecker opened by outlining the purpose of the meeting as considering recent experience of IMT meetings, the appropriateness of using this mechanism to manage the complex issues which are ongoing in the Queen Elizabeth University Hospital, and identifying learning from experience which might be beneficially applied to re-setting the IMT process. Prof de Caestecker reminded the meeting that national guidance states that the DPH has a role in reviewing the functioning of an IMT if there are any concerns

Issues of concern

Prof. de Caestecker invited those present to give feedback on their experience of IMT meetings. Two themes of feedback were raised: practical issues relating to membership, room, role of IMT Chair; and behavioural issues in recent IMT meetings. The group also highlighted the need for an IMT to work within a safe and confidential environment in order to manage the situation and protect patient confidentiality. However it was reported by staff that recent press leaks have led to a climate of fear and intimidation as staff are concerned that if they disagree with others at the meeting, they might be criticised in the press. This has resulted in a lack of openness at the meeting which can affect decision making. It was also felt unhelpful when information is tabled at the meeting, thus not enabling everyone to review it properly to inform decision making.

Regarding practical issues, those present raised concerns regarding the number of people who are present at IMT meetings, and the uncertainty as to who might attend and the 'coming-and-going' of people once the meeting is underway. Also raised were issues of the nature of rooms which are available for IMT meetings often not facilitating productive discussion, or making inclusion and engagement of all those who are present challenging.

It was noted that guidance for IMTs provides for 'required' attendees and 'discretional' attendees, who may change depending upon the nature of the issue. It was noted that one role of the Chair

would be to identify who should attend, and who is required for any particular discussion within an IMT.

Regarding behavioural issues in recent IMT meetings, those present raised concerns regarding the nature of communication within the IMT ('confrontational', 'uncomfortable dialogue', 'off-the-scale bad', 'totally disrespectful', 'inappropriate language'), and feelings of defensiveness and vulnerability experienced during the meeting, noting particularly a 'toxicity' and lack of identification as a team, as well as feelings of blame being attributed. It had been reported that some people felt unable to speak up at the IMT because of this culture.

Potential way forward

Those present discussed ideas for re-setting the IMT process in respect of the ongoing issues and thereafter identifying learning which could be applied more broadly.

It was recognised that chairing of such a meeting can be very difficult especially if the person chairing has considerable input to make to the discussions as well as managing the conduct of the meeting. Consideration was given to the identification of an independent chairperson for the IMT, though still someone from NHS GGC. The role requires someone with relevant knowledge, experience and skills from a non-involved section of the organisation, recognising a need for clinical and managerial experience and noting that taking forward actions from an IMT needed a capacity to engage and influence others. It was noted that effective Chairing of a complex meeting would not be possible if the Chair is also engaged in presenting information, and that independence would facilitate challenge and consideration of all views expressed.

Consideration was given to the benefits of holding a small-group pre-meeting to ensure that the Chair is fully informed of the circumstances, is prepared for Chairing the IMT, and can consider discretional attendees.

Consideration was given to the benefit of an agreed escalation process. This may include the identification of an appropriate oversight group which would have an overview of the functioning of any issue-related IMTs, with discussion of the potential of the Acute Infection Control Committee, the Clinical Governance Committee, and the creation of a 'real-time' oversight group

Consideration was given to the benefit of adopting a defined mechanism for measuring risk to ensure all potential actions are risk assessed fully.

Actions

1. In respect of chairing of the ongoing IMT process, an experienced CPHM or ICD from another area should be identified to take on role of chair of this particular IMT.

2. Sandra Devine is revising the IPC Incident and Outbreak SOPs and this will include clarity of roles and responsibilities of members and chair of an IMT. Further consideration will also be given to identification of relevant "independent" (independent to the running of the investigation) Chairs for the most complex IMTs. This would need to be discussed with SG in relation to ensure it is consistent with national guidance for IMTs

3. There should be a pre-meeting before very complex IMTs especially if there are results or reports available that have not been circulated to the whole IMT to allow key members to review this prior to the meeting. This would enable a transparent review of all the information and a proper risk assessment to discuss at the full meeting

4. An escalation process will be developed which will support the IMT where there is a recommendation from the IMT which may have significant implications for service delivery, e.g. closure of a regional or national service, significant disruption to multiple patient services or significant financial resource.
5. The diagnostics COM should consider how best to support individuals whose behaviours have been described at this meeting.
6. Senior staff should be prepared to and be supported to challenge inappropriate behaviours at meetings to ensure their effectiveness as well as providing feedback following meetings.
7. Jonathan Best will discuss with colleagues ensuring that there is an appropriate room available for the IMT for every meeting.
8. There will be a programme of training on the role and conduct of IMTs for relevant staff

In January 2018 my daughter [redacted] and initially treated within Ward 2A, Schiehallion, Royal Hospital for Young People under the care of Dr Sastry.

Whilst being treated within ward 2A, Molly contracted a Hospital Acquired Infection, mycobacterium cholonae, the circumstances of which have been the subject of investigation by Infection Management Board under the chair of Dr Teresa Inkster and reported to Scottish Government and Health Protection Scotland. Additionally, I have had dialogue and communication with the Chair of the NHSGGC Board Chair, John Brown CBE who initiated a review of the circumstances.

Over the last 16 months Molly has required to take significant antibiotics, all of which have impacted negatively on her health including damage to her kidneys. It is the case that little is known about the bacteria and as such any developing information may have a direct impact on my daughter's treatment.

During discussions and meetings relative to the environment in which Molly has been treated it was agreed that a single point of contact would be identified to ensure that I and through me, Molly, would be kept informed of matters that materially affected her care.

In this regard Jamie Redfern was identified as the single point of contact.

In June of this year, my wife and daughter were in hospital during which time they were advised by the medical team of another potential incident involving the bacteria mycobacterium Cholonae within ward 6A, the ward in which my daughter had been displaced to. This caused significant anguish as we had been advised that this environment was safe!

I advised my family that we would be informed, as agreed, as to the details of this incident and the wider impact and implications for Molly, with due regard to the other patients' confidentiality.

Indeed, I understand that the minutes of the infection control management meeting held in respect of this recent outbreak, reflected an 'action' for myself to be contacted and updated.

However, despite waiting several weeks for contact to be made, nothing was forthcoming resulting in my contacting Jamie Redfern expressing my extreme disappointment and anger regarding the foregoing. I thereafter met with both Jamie Redfern and Dr Teresa Inkster during which time they advised that they had been told by senior management not to contact me. I understand that the minutes of the July meeting reflected that the previous action had been discharged with the narrative that I had been updated regarding events. I am in no doubt that both Jamie Redfern and Teresa Inkster acted in good faith, believing that someone else in senior management would update me.

It is the case that I was not informed, save for the brief details by clinicians. I am sure you as Chief Executive will agree that should such a wilful act have taken place, there must have been a compelling reason for doing so. To deprive me and indeed my daughter of information that may impact on her critical care is not a cultural within which she is valued and respected.

Indeed, to deprive her of information that may or not transpire to be of material benefit is to not only fracture trust between patient and the hospital but to leave one to conclude that there are matters to hide, which instil significant fear and alarm in an already vulnerable and critical ill young person.

In this regard, I would ask you as Chief Executive to ascertain who made the decision to deprive myself and my daughter of this information and on what basis this decision was made.

I would also ask that you ascertain who provided information that the 'action' was discharged and that I had been updated with regards to this information. Again, I would wish to know the motive behind this decision.

As Chief Executive I would wish to know what you intend to do about this and how you will re-build this fractured trust, instil a belief in my daughter that she is being considered and respected, and that she will be treated within a safe environment, free from further risk to her health, safety and wellbeing.

I look forward to hearing from you.

Yours sincerely

John Cuddihy FRSA
Professor.

Greater Glasgow and Clyde NHS Board

[redacted]

[redacted]

www.nhsggc.org.uk

Private and Confidential
Professor John Cuddihy FRSA

[redacted]

Date: 27th September 2019
Our Ref: JG/LLPA

[redacted]

Dear Professor Cuddihy

Thank you for your email of 30 August 2019 which enclosed a letter raising a number of points with respect to your daughter, Molly's, treatment during her stay on Ward 2A of the Royal Hospital for Children, and recently on Ward 6A of the Queen Elizabeth University Hospital. I apologise for the delay in my response to you.

Firstly, I would like to acknowledge that I realise that Molly, you and the rest of your family have experienced a very difficult time given her illness. Despite all your concerns, I would like to try and impress upon you that we care deeply about our patients, and I am very sorry that the impression we have given you has not always been a positive one. I do not underestimate the importance of patients and their relatives having faith and confidence in our hospitals and staff, and I very much hope that this letter will go some way in restoring this.

I note your concern regarding the Myobacterium Chelonae infection that Molly contracted in May 2018. In June 2019 a separate case of Myobacterium Chelonae was suspected. I understand your frustration regarding our communication with you and Molly about a second child with this bacteria. I have now reviewed the position in this regard. From the outset I would like to assure you that there was no wilful intent in withholding any information.

During June and July 2019, the Infection Management Team (IMT) was still trying to understand the nature and typing of the bacteria of the second child. The IMT is a dynamic group of clinical experts, supported by managers, who review and understand the nature of an incident of infection and agree clinical management. It is normal practice for an IMT to review data and linkages over a period of time. It was felt that communication with you regarding this, should wait until such time that the typing results of the second child's bacteria were available, and hence an understanding of any linkage to Molly's bacterial typing could be excluded. It was also imperative that we maintained confidentiality until the second child and their parents were informed of the possible infection type. As you will now be aware, Molly's infection and this other patient's bacterium were found not to be related

However, on reviewing our communication with you from IMT meetings, I consider that unfortunately there does appear to have been a lack of clarity which we fully accept and I apologise for unreservedly.

Please let me reassure you that the clinical treatment of Molly is our primary objective, and communication regarding this will continue to be via her clinical team.

I would also like to thank you for taking the time to feedback via letters and discussions. We are committed to improving our management of such events and have now instigated, following every IMT, face to face, written and verbal updates to all families in Wards 6A and 4B. These are personally delivered by Mr Jamie Redfern, General Manager, and Ms Jennifer Rodgers, Chief Nurse, following an IMT. On the majority of occasions they have also supported the patient's Consultant or Professor Gibson during their face-to-face interactions with every patient and their parents. The feedback from this approach has been well received by the parents concerned.

I hope this letter has been helpful. If you have any further questions, please do not hesitate to contact me.

Yours sincerely

[redacted]

Jane Grant
Chief Executive
NHS Greater Glasgow and Clyde

List of issues raised by the families of children treated on the haemato-oncology wards at Queen Elizabeth University Hospital and Royal Hospital for Children with the Cabinet Secretary for Health and Sport

Response from NHS Greater Glasgow and Clyde

Following meetings parents had with the Cabinet Secretary for Health and Sport about infection issues in the Queen Elizabeth University Hospital (QEUH) and Royal Hospital for Children (RHC), a number of questions have been posed, and NHS Greater Glasgow and Clyde (NHSGGC) welcomes the opportunity to answer these fully and transparently.

The remainder of this document will address each individual question posed to us in detail. Before we do so, we wish to be clear that the safety and wellbeing of our patients and their families has, and remains, our key priority, and we are very sorry that some of those in our care have had worries about the hospital environment, at what is an already difficult time.

If, as a result of the points being addressed, any individuals have additional questions specific to their child's care and treatment, they are welcome to contact Jennifer Haynes in the Board's Headquarters, who will ensure their concerns are addressed. Jennifer's contact details are: [redacted]

The Cabinet Secretary for Health and Sport has also appointed Professor Craig White, Divisional Clinical Lead from the Scottish Government to lead and direct the work required to ensure that the voices of the families affected are heard and that the information they have asked for and entitled to receive is provided as a matter of priority. Professor White can be contacted at [redacted]

The families raised the following specific points:

Issues with the environment

1. Is the ventilation and water system currently safe?

Yes, and we would seek to reassure all our patients and their families of this.

a. Ventilation

With regards to the ventilation, there was a concern regarding the number of air changes and the air pressure within rooms where patients who were immunocompromised (which can happen as a result of cancer treatment and other treatment) were being cared for.

An upgrade was carried out in four paediatric Bone Marrow Transplant isolation rooms in 2015. Ward 6A currently has portable HEPA filters (High Efficiency Particulate Air – a type of high quality air filter) in all patient rooms and the corridor, providing additional and ongoing air cleaning. We have not identified any link between infections and ventilation.

Our priority is patient safety and we are investing £2 million to upgrade the ventilation system in Wards 2A and B to provide optimal, state of the art facilities for all our young haemato-oncology patients. This is to ensure we are taking every possible measure to reduce the likelihood of infection for this group of patients, who have an increased risk due to their treatments. We very much hope this will reassure the patients and the families in our care how seriously we are taking these issues.

b. Water

When the hospital first opened in 2015, there was no indication that there was a problem with the water in the RHC. We later had a spike in infections in 2018 (in ward 2A) and on testing the environment and water, we found organisms which can potentially cause infection in the water supply. To address this, we put extensive measures in place, including the installation of a water treatment system, as well as filters on water outlets. The water was then re-assessed by an independent authorising engineer, who described it as 'wholesome'. The Public Water Supplies (Scotland) Regulations 2014 outline in legislation the requirements that are to be met for public water supplies to be regarded as 'wholesome'. This means the water in both the RHC and QEUH is safe.

2. **Is the hospital a safe place for the children - as the families are too scared to take them in for fear of infection and want to keep them at home.**

Yes, we can reassure both patients and parents that the hospital is safe, and we are sorry for the concern caused. Whilst we continue to investigate the issues and take action, every precaution has been put in place to ensure we care for our patients safely and fully.

Patient safety is the main priority for our organisation, and this is regulated and monitored in a number of ways, from individual clinical specialty and ward meetings, right up to formal committees of the Board.

We closely monitor clinical outcomes (which are measurable changes in health as a result of care given), and complete tests of the environment, including sampling of air and water tests, as well as wider water quality analysis throughout the site. In addition, doctors, nurses and estates staff undertake regular inspections of the environment for monitoring purposes, and from this, any issues are identified and addressed.

We are very sorry that families have been scared about the risk of infection, and we are committed to ensure that our staff provide all necessary supporting information and opportunity for discussion to anyone experiencing concerns about safety, or fears for their children.

3. **Can reassurance be provided that all the clinical environment is safe?**

As with the above question, yes, we can reassure parents that the hospital is safe, and we have taken every measure to ensure that each patient is cared for in the best and safest way.

4. **There needs to be a check to ensure that the water from the showers drains away properly and doesn't leak back into the rooms**

We are sorry this has caused concern, as the shower floors were designed so that water drains away appropriately. There are no problems with Ward 6A showers. If there ever was an issue with an individual shower (which was not a design issue), then this would be immediately reported to estates colleagues and the drainage issue would be fixed.

As part of the work underway in Ward 2A, we will be doing a refit of the en-suite bathrooms including floor and wall coverings, to ensure that this is not a subject of concern going forward. The work to refit the en-suite facilities will include a revised detail and new materials which should reduce the need for the same level of regular repair, and minimise disruption to day-to-day ward operations.

5. **A copy of the HPS water contamination report should be shared with the families.**

   This is available online at the following web address:

   https://www.hps.scot.nhs.uk/web-resources-container/summary-of-incident-and-findings-of-the-nhs-greater-glasgow-and-clyde-queen-elizabeth-university-hospitalroyal-hospital-for-children-water-contamination-incident-and-recommendations-for-nhsscotland/

   If any patient or family member would like us to send them a paper copy of this, we would be happy to do so (please contact Jennifer Haynes on [redacted]

6. **There needs to be a complete holistic look into the environment in the wards to ensure they are clean and safe.**

   We agree with this comment, and we would seek to assure families that a complete review of the ward environment involving infection prevention and control staff, senior ward charge nurses and estates and facilities staff takes place every week to monitor cleanliness and the general estates environment. If any issues are identified, then these are quickly remedied.

   In addition to the above described weekly walk round, infection prevention and control colleagues, along with estates staff, are on the ward regularly to ensure vigilance and ongoing review the environment. Any issues raised are immediately resolved between the nursing and estates and facilities teams.

7. **Why are the remediation works to the wards taking so long and why are there problems in the decant wards? Are the works so far just a sticking plaster?**

   This is a major piece of work currently underway in Ward 2A/2B. There was extensive planning, design and procurement work undertaken in order to commence this work, which began in April 2019, in order to ensure we were creating the right conditions for the physical work to start. As is normal, there was a lead in time before the physical work started, which it did in October 2019.

   There are a number of significant technical challenges to remove the existing ventilation systems and install the enhanced system. Whilst we appreciate the concern about the time taken, these are major works, and it is important we ensure the work is carried out to a high standard. At the moment, we would anticipate this work to be complete by March 2020, which given the level of work, is a reasonable and realistic timeframe.

   All works being undertaken are being done as a preventative measure to minimise the risk of infection, and to ensure absolute vigilance in our approach to the prevention and control of infection.

8. **The works in ward 6A need to be investigated with details then provided on progress.**

   In Ward 6A we have completed a number of actions to improve environmental controls within the ward, including the use of mobile HEPA filters (see response to Question 1) and the imminent installation of fixed HEPA filters in the en-suite areas. We have also increased the cleaning and maintenance of the chilled beams, which regulate the daily air temperature within the rooms, and have committed to a cleaning programme every six weeks. This is significantly in excess of the annual cleaning regime recommended by the manufacturer, and we have put this in place to be extra thorough.

The Chief Nurse and General Manager for Hospital Paediatrics regularly visit parents and patients within the ward, and would be pleased to answer any questions. We have also set up a closed Facebook page to ensure that the families of other haemato-oncology patients are also updated. If there are any other ways that families would find it helpful for us to communicate with them, we would welcome any suggestions that they would find beneficial.

9. **The extent of the works and the length of time until they are completed in wards 2A and 2B needs to be checked thoroughly with all details provided.**

   Please see our response to Question 7 and 8.

10. **Why are the rooms not cleaned properly so the families have to clean the rooms themselves and have to bring in their own bedding?**

    No families should ever have to clean hospital rooms, nor bring in their own bedding, and we are therefore extremely sorry where this has happened.

    Sometimes family members may want to do activities, such as clean the hospital room, but this should only be if they wish to do, and absolutely not because they feel they have to.

    Ward 6A has its own domestic staff and a domestic supervisor to ensure it is kept clean. There is a daily meeting between clinical and domestic staff to monitor cleaning levels. The aim is to ensure that cleaning takes place frequently and to a high standard, and we would encourage any families concerned about this to speak to the nurse in charge of their child's care.

    No patient is asked or expected to bring in their own bedding, however, if a child or young person wishes to bring in their own bedding, then we will support this. This is to help make the bedroom child-friendly and personal to the patient, in keeping with person-centred care and what matters to children.

    Parents who sleep over are also provided with a bed and bedding. If this is a concern that individual parents have, we would encourage them to get in touch with us so we can make further enquiries, as this is not an issue they should have to contend with.

11. **Why are there so few facilities on ward 6A, including the facility to make tea and coffee, warm up food in a microwave, play area for the children, space for the parents to talk and discuss very difficult issues. In addition the available food is poor and expensive on site which compounds the problems.**

    When a decision was made to decant Wards 2A and 2B in September 2018, an assessment was made at that time about the best clinical option that would see young patients remain on site with access to paediatric intensive care and specialist services. This recognised that there would be compromise in terms of social spaces for children, families and staff.

    The short term solution was for parents to use either the kitchen facilities (including microwave and kettle) in the RHC or the microwaves within the QEUH.

    Both the play assistant and the Teenage Cancer Trust Activities Co-ordinator are based in Ward 6A and arrange individual and group activities for the patients. They also ensure that the children have age-appropriate toys.

    As this is an issue of ongoing concern for families, we are currently creating some parent and child facilities in the ward, including a playroom and a parents' kitchen / social space. We would welcome any ideas patients or parents may have that they would find helpful in this regard.

12. Are there enough cleaners on the wards?

Yes, there are sufficient numbers of cleaners, and if there are any gaps (for example, due to sickness absence), then this is immediately managed to ensure appropriate cover. Ward 6A has its own domestic staff and a domestic supervisor to ensure standards of cleanliness are maintained. There is a daily meeting between clinical and domestic staff to monitor cleaning levels.

As described previously in this document, a complete review of the ward environment, involving infection prevention and control staff, senior ward charge nurses, the domestic services manager and estates and facilities staff, takes place every week to monitor cleanliness and the general estates environment. If any issues are identified, then there are quickly remedied.

13. Why were parents told that ward 6A would have a play room for children when it did not?

We are sorry that parents were told that Ward 6A would have a play room, when it did not, as we appreciate that this would have had a negative impact on experience.

We set up a play space and this was approved by infection prevention and control colleagues, however, when the incident occurred, it was agreed that this should be removed.

Both the play assistant and the Teenage Cancer Trust Activities Co-ordinator are based in Ward 6A and arrange individual and group activities for the patients. They also ensure that the children have age-appropriate toys.

As this is an issue of ongoing concern for families, we are creating some parent and child facilities in Ward 6A, including a playroom and parent space with kitchen facilities. We would anticipate that to be ready in early November 2019.

14. There is a lack of room for fold down beds for parents, the blinds don't work, the TVs also don't work. The lack of natural light in particular effects the children when they do go outside.

We are sorry that these issues have impacted negatively on care experience, particularly as we recognise that patients and their families spend a great deal of time in their rooms. These issues relate to previous concerns raised about Ward 2A and 2B, which is undergoing an upgrade, and issues with the TVs and blinds will be addressed as part of this. This will be completed for the ward reopening in March 2020. We are committed to take action whenever we receive feedback about anything that impacts negatively on care experiences, and encourage anyone with any concerns or suggestions for improvement in this area to make these known to staff.

15. Why did the Board not consider all these vital issues, relating to the lack of facilities when decanting the patients – in particular did they consider the effects on the mental health of the patients and their families?

When a decision was made to decant Ward 2A and 2B in September 2018, our absolute priority was where the best and safest place was to deliver care to our patients. We are sorry that patients and families have been worried about this, as we would have been keen to allay their concerns.

At the time of the decision, an assessment was made about the best option that would see young patients remain on site with access to paediatric intensive care and specialist services.

This recognised that there would be compromise in terms of social spaces for children, families and staff, but that this was necessary in order to be able to deliver the best care. We are sorry that we did not explain this as well as we could have to families.

All of these issues were considered at the time, but we hope we have explained that patient safety was of the highest clinical priority, as it is now.

The new family room will have a 'What matters to me' board that families can use, which we hope will act as a good communication tool in ensuring our staff know what is important to families.

16. Why aren't there enough electrical plugs in the rooms for all the medical equipment?

Our staff have advised the Director of Estates and Facilities that there are enough electrical plugs with rooms for all the medical equipment that is needed to provide safe, effective and person-centred care. More electrical plugs can be fitted if these are required. We would appreciate any questions or suggestions for improvements that can be made to ensure that concerns about the number of electrical plugs are addressed.

17. Why don't the batteries work in the mobile drip stands?

In order to keep batteries fully charged we recommend that they are connected to the electrical supply when they are not mobile or being used. We expect this to be monitored by staff so that the batteries do not run out. We also expect that any concerns about the functioning of batteries to be reported so that they can be replaced, and encourage anyone with any concern at any time about battery performance to raise this with staff in order that action can be taken in response.

18. Why do the trolleys have defective wheels?

It is not acceptable for any equipment involved in the provision of care to be defective. We expect any such defects to be reported in order that these can be repaired. If any patient or family member has any concern about whether trolley wheels (or any piece of equipment) is defective, please report this to a member of staff so that action can be taken in response to this.

All equipment defects or failures, if reported, are repaired through routine maintenance. We are sorry for the concern that has been caused by any defects in equipment that have been noted as not having been repaired.

19. Have the Board considered the practical difficulties in terms of patients using safe toilet facilities, without contaminated water, given the difficulties in moving with drip stands etc?

We think this question may relate to Wards 2A and 2B prior to the move when we put in place temporary measures whilst we dealt with investigations into water safety. Wards 2A and 2B are currently undergoing a full refit prior to reopening in April 2020. The toilet, sinks and showers within Ward 6A had filters added to the water outlets as a precautionary measure to be sure we were minimising the risk of infection wherever possible.

As previously described, patient safety is our priority, and has been our primary consideration throughout all of this.

20. How can the water be usable now in ward 2A/2B given that there are still restrictions in the floors directly above and below?

No patients are currently in Wards 2A and 2B.

The water in the hospital is safe to drink. Our on-site water plant ensures all water coming into the hospital has a low dose of chlorine dioxide, which keeps it clean and safe. In addition, any patient cared for high risk areas have point of use water filters in place as an extra precaution.

The safety of the water was then confirmed to be safe by the external Authorising Engineer, a specialist engineer who acts, and is employed, independently of NHS Greater Glasgow and Clyde. The Authorising Engineer has rated the water supply as 'wholesome', meaning it is safe.

We are sorry for the concerns that have been caused. Signs at the sinks within the single bed rooms advise that the sinks are for handwashing only. This forms part of our infection prevention and control standards. Patients and their families are discouraged from drinking water in the rooms as these sinks should be dedicated to handwashing only.

If any patient or family member has any concerns about the use of water, they should speak to the nurse in charge.

21. What happens next if the QEUH campus is not safe and what is the backup plan?

The QEUH campus is safe. We would like to assure all our patients and their relatives that the hospitals on this site are safe, and that we strive to deliver safe care at all times.

We continually monitor and test to ensure the safety and integrity of the water and ventilation systems.

22. What if the water system is found to be unsafe - is a plan B being considered at the moment?

As previously described, the water in the RHC and QEUH is safe. This has been confirmed by the Authorising Engineer, a specialist engineer who acts, and is employed, independently of NHS Greater Glasgow and Clyde. We will always consider all options and resilience plans, but we hope we have reassured that the position is that there is no issue with the water. Please see our response to Question 20.

23. Is the QEUH campus itself safe?

Yes. Please see our response to Question 21.

24. Is the overall water supply across the QEUH campus safe - in particular, McDonald House and the local residents use the same water supply so do they have the same problems?

The domestic water supply to the local population and to Ronald McDonald House is the responsibility of Scottish Water.

The water supply to the hospitals is safe – please see our response to Question 20.

25. The Healthcare Improvement Scotland HEI inspection in March and 2018 didn't go to the oncology wards or ward 6 – what was the reason?

When Healthcare Improvement Scotland undertake an independent HEI inspection, this is part of their role. They will visit a number of wards and areas, but not necessarily all wards within a hospital site. During an inspection, they will then carry out a range of checks to ensure hospitals are meeting national standards, guidance and best practice. Healthcare Improvement Scotland have been asked by Professor White from the Scottish Government to provide details on their process for deciding which wards to visit.

More information about Healthcare Improvement Scotland inspections, is available at : http://www.healthcareimprovementscotland.org/our_work/inspecting_and_regulating_care/nhs_hospitals_and_services.aspx

26. The families want to liaise directly with Healthcare Improvement Scotland on these issues.

Professor White from the Scottish Government will provide details of a named contact at Healthcare Improvement Scotland for any families who have further questions on their decisions and approach.

27. Why is the day care room at the other end of the ward – which is in itself an infection risk

When considering the decant to Ward 6A, infection prevention and control experts, with clinical teams and estates staff, agreed that the best area for the day care waiting room would be the former adults' day room, which would maintain the waiting area within the day care area. Other options were examined, but this was considered the safest and best choice due to the practicalities and available options, in a way that does not elevate the risk of infection in an unacceptable way. Putting the day care elsewhere in the ward would have meant no proper reception area for the families.

28. When specifically were the water filters put into the theatres?

The filters were installed in the theatres in June 2019 as a preventative control measure to make sure that the full patient pathway had sinks with filters.

Before June 2019, point of use filters (i.e. filters on water outlets) were not installed in theatres on the advice of infection prevention and control colleagues, because patients in theatre were not in direct contact with water.

As part of the current Incident Management Team investigation in June 2019, the decision was taken to install point of use filters as an extra precaution at every stage along the patients' clinical pathway within the RHC, including the theatres.

29. Is the cladding on the buildings where wards 2A/2B and ward 6A are located safe?

Yes. All cladding meets current safety standards, and is therefore safe.

30. Why was one of the kitchens on ward 6A shut recently – it was suggested this was down to fungus being found.

This particular staff kitchen was shut because a leak (not fungus) was noticed within the staff kitchen on 27th September 2019. The leak was as result of a faulty tap connector on a recently fitted tap. The leak has been repaired, and the kitchen is now in use again.

Issues connected to medical care

31. Are there sufficient infection prevention and control prevention measures in place?

Yes. NHSGGC have an infection prevention and control team, who provide strategic coordination and direction to ensure our programme of work reflects the National Infection prevention and control standards and requirements. We also have local infection prevention and control teams assigned to each sector of the Health Board, to provide local support, guidance, advice and action. For more information, please visit:

https://www.nhsggc.org.uk/your-health/infection-prevention-and-control/

The current incident with Ward 6A is being investigated by an Incident Management Team (IMT), which, as described earlier, is a team of experts, including infection prevention and control nurses and doctors, clinical staff, estates and facilities teams and Health Protection Scotland, who are national experts in this field. One of the responsibilities of an IMT is to confirm that all infection prevention and control measures are being applied effectively and are sufficient. This has been closely scrutinised, and the IMT continues to meet regularly.

32. Are children getting drugs they don't need?

In light of the current situation with infections, it was recommended by the IMT that prophylaxis (preventative treatment) against infections was considered. There are many scenarios when children and adults are given prophylactic treatment.

If any individual patients or parents have concerns about medications, we would encourage them to speak to the Consultant in charge of their care in the first instance.

33. An explanation of the outbreak monitoring process, and the involvement of HPS should be provided to the families.

Outbreak monitoring is the ongoing assessment of results of tests or changes we make to stop new infections from happening.

As described earlier (see response to Question 31), the current incident is being investigated by an IMT. HPS representatives are members of the IMT, and attend all IMT meetings. In addition they provide expert advice and support. NHSGGC has published information on its website on this national process:

www.nhsggc.org.uk/your-health/infection-prevention-and-control/.

This sets out that the responsibilities of an IMT are to:

- Develop theories and suggestions for testing as to which cross-transmission pathways and clinical procedures may be involved in causing the infections, to try and find the cause.
- Determine whether there are any additional cases that need to be considered, and what control measures (i.e. actions to help control the likelihood of risk) may be necessary.
- Confirm that all incident control measures are being applied effectively and are sufficient.

34. Is there an infection risk because of the smell from the nearby sewers in the QEUH campus? In particular there is a smell in the isolation ward and reassurance is sought that they are safe.

We have no evidence to say that the smell being referred to is likely to be a safety risk. At the planning stages of the new QEUH and RHC hospitals, which are on the same site as a previous hospital, an environmental impact assessment was carried out. This included a review of the air quality and considered whether there would be any detriment associated with being located next to a sewage plant. No clinical or microbiological issue was identified.

The Independent Review team have also looked into this issue as part of their independent review of the hospitals. They have stated:

> *Following the inquiry's formal Call for Evidence in June, members of the public asked for the facility to be taken into consideration by the investigation team. The site is a concern for members of the public because of the quite potent smell which is noticeable at the QEUH.*
>
> *A number of hospitals have been sited close to major wastewater treatment sites across Scotland over the years. This includes the former Southern General Hospital on which the QEUH now sits. The Shieldhall wastewater treatment site dates back to 1901.*
>
> *Dr Montgomery said: "Clearly there are concerns relating to its proximity to the QEUH. If we are to fully address public confidence issues we would be remiss not to explore any health links associated with the site as part of our review. Smell alone will not cause an infection risk but we felt that we should look into this and any associated issues. To date, nothing of concern has been uncovered."*

35. Why were patients given medication, for infections, which is only supposed to be used for a week?

Some medication is used to reduce the risk of developing certain types of infection. In light of the current situation with infections, and as described in response to Question 32, it was recommended by the IMT that medication to reduce the risk of infection be considered. We are sorry that questions about the use of such medicines, including how long this was recommended for, were not adequately addressed for some families.

This is something that continues to be monitored. If any patient or family member has any questions or concerns about any aspect of clinical care/use of medicines, suggestions to improve the current approaches to the provision of information, or unanswered questions about this, these should be directed to the Consultant in charge of the care being provided. The IMT continues to review the position.

36. Why were patients given prophylaxis without consent of the parents?

We expect all families to be informed and fully involved in discussions regarding all medication and any treatment changes. The named Consultant is responsible for ensuring ongoing discussion with the parents about the care of their child, and we are committed to reviewing the concerns of any family where they felt they were not involved in discussions or decisions about their child's care. As described in previous responses, the use of medication to reduce the risk of infection is not unusual, and not all infections are preventable, but as with any medication, it should be clear why it is being prescribed.

We welcome the opportunity to look into this for any parent who has concerns about how this essential element of care planning has been delivered.

37. Why if all the infection prevention and control measures are in place are the patients still being given prophylaxis?

Please see our response to Questions 32 and 35.

38. Are the clinicians all able to access the same, correct, information?

Yes. Clinicians are active participants in the IMT, along with colleagues from Health Protection Scotland, where the data is presented and assessed.

Because not all clinicians can attend all meetings, as they are in clinics or looking after patients, those who attend feed back to those not present. The Chief Nurse and General Manager provide verbal updates to the clinical teams following IMT meetings. Any actions or matters arising are passed over to each new shift via ward safety briefs (which are verbal meetings). Special meetings with all clinicians were organised to ensure all had a chance to discuss progress.

39. Why are the staff washing their hands in contaminated water?

As described above, the water quality has been assessed and is clean and safe. There has been extensive work and action undertaken to fix the issues identified with the water; the water has been through a general filtration process, water treatment and a point of use filter at the sink. As noted in response to precious questions, the water has been deemed as 'wholesome' by an independent expert. It is therefore not the case that staff are washing their hands in contaminated water.

40. Why are families being told that their child has not got an infection only for them to be subsequently treated for the infection?

There are occasions when families would be informed that their child has not got an infection and would then receive treatment. This could be if information became available to suggest the presence of an infection at a later stage, or if a decision was made to commence medication to reduce the risk of infection developing. As referenced earlier, the IMT also recommended that prophylaxis against infections was considered (see Question 32).

Any parents who have unresolved concerns about treatment, the reasons for this and how this relates to information they have been given should raise this with the Consultant responsible for the provision of care.

41. Do families have sufficient access to relevant medical records? - in particular as diagnosis has been changed or even denied on a few occasions.

We will support any family who wishes to discuss access to relevant medical records and, in cases where there are questions about diagnosis, take all necessary steps to discuss and respond to any questions about this. This should be raised with the Consultant in charge of care in the first instance.

42. There needs to be external scrutiny of the Board.

There are currently a number of internal and external reviews of the QEUH and RHC ongoing. As well as our own internal reviews, there is the Independent Review commissioned by the Cabinet Secretary of Health and Sport (more details of which can be found at https://www.queenelizabethhospitalreview.scot/), an investigation by the Health and Safety Executive and the recently announced Public Inquiry. We are fully contributing to all of these reviews.

43. What are the long term effects on health given the delay in treatment caused by the infections?

All patients are individual, and going through different illnesses and treatment. For this reason, this question needs to be answered on a case by case basis with the relevant Consultant in charge. We are happy to help facilitate this for any parent with concerns about delays in treatment (or any other issue regarding the care provided).

44. Why were toys, particularly those from a local charity not allowed on the ward and who made the decision?

Sometimes soft toys are not allowed on the ward as they can be more difficult to keep clean. The play service provides toys for children and staff are committed to ensuring that the provision of appropriate toys is supported and that conversations take place in a way that addresses any concerns regarding infection, while taking account of the importance of this as a part of an individual child's plan of care.

45. Where will the children go if the wards are not safe? For example are the only other suitable hospitals in Newcastle, Manchester and London? (for bone marrow treatment.)

There are no concerns for Bone Marrow Transplant (BMT) patients within NHSGGC. The BMT patients are currently in a dedicated BMT unit, and have not been part of this incident. They continue to receive their care at the RHC, QEUH and Beatson West of Scotland Cancer Centre.

46. Have the Board considered issues such as patients having to travel to different wards to use the toilets because of the risk posed by contaminated water.

It is not necessary for patients to visit other wards to use the toilets. We would welcome further detail on any situation if this has been advised, so that we can ensure that this is reviewed, and action taken to make sure that accurate information is being provided.

47. Has the Board considered the mental health effects on the families and in particular the children, who through a lack of facilities are in effect institutionalised.

Yes. We are committed to doing everything possible to ensuring that these issues are considered as part of care planning and co-ordination. Clinical psychologists are available to any families who has concerns about the impact of the care environment on the psychological health and wellbeing of children and their families.

48. Why is there an issue with patients getting chemotherapy overnight? Are the correct clear details being provided?

There are no restrictions on patients getting chemotherapy overnight. Concerns about this issue should be discussed with the Consultant in charge of care.

49. Where do the patients go if they have a spike in temperature?

For patients who are no longer staying in the ward, from Monday to Friday day time hours, parents should call the day care unit and patients would be brought there. Out of hours access would be via the Emergency Department, or parents can call NHS24 for advice.

Parents can also call the ward their child was in for advice at any time, who in turn can let the Emergency Department know they are going to attend, if that is what the advice is.

50. Is there an argument for moving the Schiehallion patients to Edinburgh and retrospectively fit Glasgow in the meantime?

High risk patients are assessed on a case by case basis. Those who are clinically assessed by the haemato-oncology consultants and infection prevention and control doctors, may be admitted to either Ward 4B in the RHC, or another centre. Other patients are safe to be cared for in Ward 6A, outpatients and day care at the RHC.

Issues with communication

51. The families need to know exactly what is happening – as at the moment they have no details or understanding of the remedial works.

We realise how important it is to keep families informed and are committed, based on feedback, to continuously improve how we do this. The parents of all inpatients directly affected have been provided with regular verbal updates on the work underway within Ward 6A. As described earlier, we have also set up a closed Facebook page to ensure that the families of other haemato-oncology patients are also updated.

Please also see our response to Question 8 in relation to this point.

52. Why was advice given by staff that patients were perfectly safe in terms of infection risks from the environment but then contradicted by other staff who said that the environment, and water, was not safe? This led on occasion to the position changing overnight and patients being moved at very short notice.

We are very sorry for confusion and distress caused by differences in the information that was provided or when changes in information have not been fully explained.

The hospital is safe. Since late 2018, we have put in place a number of additional preventative control measures to mitigate further the risk of infection in this vulnerable group from the environment. This has meant a number of patient moves over eighteen months. We apologise again for the inconvenience, distress and concern this will have undoubtedly caused. Patient safety is always our main priority and we remain committed to continuously improving our communication, support and provision of information to patients and families on the basis of feedback. In a situation like this, we are constantly monitoring and investigating the position. That means we regularly receive updated information and it is a changing picture.

53. Who has the information that the wards are safe? – where does it come from and why is there so much contradiction?

We have local infection prevention and control and infection data that is collected as a matter of routine, which shows trends and highlights issues across the hospital, and in individual specialties. It has been a changing picture rather than contradictory, but we are sorry that this has caused confusion.

54. Why are the families not being told everything about their children's treatment, in terms of what medication is required and what might be the side effects.

It is our expectation that patients and parents are fully informed, and we apologise for all instances when this has not been patients and families experience. We are committed to reviewing and learning from all instances where this has not been the case; and to ensuring that everyone is clear on the importance of supporting discussion with the Consultant in charge of care provision. If you would like to tell us more about this, we would welcome your feedback and any questions so we can ensure you have all the information you need and want.

55. Why are staff members told to not tell the facts and the truth of the situation?

Staff should always be truthful in their discussions with patients and families. Staff have not been told not to talk to families, and have been encouraged to share information about what they know. If they cannot answer questions, they are asked to pass these questions onto relevant colleagues, for instance senior management and infection prevention and control colleagues, in order that points of concern can be addressed.

As described earlier, the Chief Nurse and General Manager of the hospital regularly visit the ward to provide an update to families, and to give written updates, and we also have a closed Facebook page for parents to provide regular updates and answer questions.

56. Why did families first hear in the STV news about the 6 children moving?

We make every effort to keep families informed in a timely manner, and we are therefore sorry parents found out this information from STV. We ensure that parents directly affected are informed of any press statement prior to issue, however, we are unfortunately unable to control when the media will start to report on issues that they are informed about by other sources.

57. Why did the NHSGGC management not explain the situation and instead offered no communication – they appear to be concerned about legal action.

We have sought to prioritise the information and support needs of patients and families throughout this situation. We are sorry that there has been an appearance that concern about legal action has compromised our commitment to explain and ensure timely, sensitive and appropriate communication.

Throughout the past eighteen months we have made a number of public statements and regularly updated families on the actions taken. We are committed to continuously improving our approach to providing information, responding to questions or concerns and providing any support that may be required.

58. Why is the Board so defensive?

We are sincerely sorry that any actions taken have been experienced as defensive. The IMT are continuing with their investigations; there are a number of areas where questions remain and where we do not yet have the full answers. It is important that when questions are asked that we do not know the answers to, that this is explained openly, supportively and sensitively.

The Chairman and Chief Executive have committed to meeting every family that wishes to do so to discuss any concerns, and they have written to all families to offer this.

59. Why are the staff prevented from telling the truth – why do they have their hands tied?

Please see our response to Question 57.

60. Why did the Board issue a press release stating that the water was safe to drink when the families were clearly told that it wasn't safe to drink? Why did the Board lie?

Although the water is safe to drink, water from basins in patient rooms should not be used, as they are for handwashing only; this is advice from infection prevention and control colleagues. If this has caused any confusion, then we sincerely apologise.

As previously described, the water is safe to drink, and this has been confirmed by the Authorising Engineer, a specialist engineer who acts, and is employed, independently of NHS Greater Glasgow and Clyde.

We understand, however, that there may have been confusion because of the signs at the sinks within the single bed rooms, which advise patients that they are for hand washing use only. Patients and their families are discouraged from drinking water in the rooms as sinks are dedicated to hand washing.

As there was no parent kitchen currently in Ward 6A, we provided patients with bottled water. This was not connected to the quality of the water supply, but due to the fact that there was no facility for the parents access tap water.

61. All the staff, including the clinical staff need to be praised for their hard work and providing fantastic care – they should not be singled out for criticism.

We greatly value our fantastic staff and completely recognise that recent events have been difficult and stressful for them.

The health and wellbeing of our staff is hugely important, and we have therefore put in place additional support for any member of staff who wishes to access it.

The senior management team of the children's hospital regularly praise the work of the clinical and support team and ensure that they get the recognition they deserve.

62. Why is the Board not speaking to the families and complying with the Duty of Candour Legislation?

Organisational Duty of Candour legislation has very clear and defined criteria of what needs to be considered in relation to an incident that may require activation of the procedures outlined in this legislation. Regardless of whether an issue or incident meets the criteria outlined by this legislation, all regulated healthcare professionals have a professional duty of candour and NHSGGC is committed to ensuring that our actions are always informed by the principles of openness and honesty; we understand that this is key to creating trust in situations such as those that have rightly concerned families.

We are therefore very sorry for the perception that we have not been candid, as this was absolutely not our intention and we will learn from this. We have asked Professor White from the Scottish Government to review all individual care incidents to provide us with advice on the approach that has been taken to decision-making in respect of the application of the organisational Duty of Candour legislation, reflecting our commitment to ensure that we are continuously improving the way we respond to incidents where we need to consider whether the organisational Duty of Candour applies.

63. Reassurance was sought that the patients won't be stuck in a ward which doesn't provide oncology care and therefore the relevant protocols.

We can assure you that we will always care for patients in an appropriate setting. Patients will always be looked after by staff who are specifically trained for work with children who have cancer. They may have to be cared for in another ward for a number of reasons, but in that ward they will still receive specialist care by staff who are appropriately trained.

64. A public apology is also needed from NHS GGC to clinicians and staff who have being doing their jobs very well. This would start to build trust. There needs to be real engagement with the staff as they feel vulnerable.

We are very grateful to our excellent staff and we are sorry that our views of how well staff have been doing their jobs has been doubted. We completely agree that this is essential to supporting our staff and minimising any feelings of vulnerability they might experience. We recognise this is a difficult time for staff as well as parents.

Our Chairman and Chief Executive met staff on the ward on October 2019, 8 October 2019, and 23 October 2019. Our Medical Director and Deputy Medical Director also spoke with staff on Ward 6A, as well as Ward 4B. We are working with clinical and nursing staff to address the issues raised in these meetings, and in a meeting with the Deputy Chief Medical Officer for the Scottish Government.

As described in response to Question 62, the health and wellbeing of our staff is important and we have therefore put in place additional support for any member of staff who needs it. The senior management team of the children's hospital regularly praise the work of the clinical team, particularly the nursing staff, and ensure that they get the recognition they deserve.

65. Why did the children get moved into an unsuitable adult ward?

Please see our responses to questions 11, 15 and 65.

Children have not been moved to any area that we would regard as unsuitable. We have always endeavoured to take all necessary measures to ensure continuity of care, in the best and safest way possible.

Issues raised that will potentially fall within the remit of the Public Inquiry or are within the remit of the Independent Review

66. Is there a risk because the QEUH campus (including the RHC) was built next to the main sewage plant?

No. Please see our response to Question 34.

67. Why were patients admitted to wards 2A and 2B after meeting minutes established that the ventilation was not fit for purpose prior to the ward opening?

Please see our response to Question 1.

68. Why are all the problems happening in a new hospital?

The design, commissioning, build and maintenance of the RHC and QEUH are the subject of a number of internal and external reviews to examine these issues. These reviews will provide answers to questions such as this one.

69. Can the Terms of Reference of the Public Inquiry have child/patient experience at the heart of it?

Whilst the Terms of Reference of the Public Inquiry is not for NHSGGC to determine, we would agree that this issue should be a key feature. Professor White from the Scottish Government will liaise with officials supporting the establishment of the Public Inquiry to make them aware of this suggestion.

70. Confirmation that a decision will be taken by the chair of the inquiry (following appointment) as to persons who will be required to attend or otherwise provide evidence to the inquiry, for example the First Minister (who was Cabinet Secretary for Health and Sport at the time of the QEUH's construction) and former Chief Executives/ senior staff.

These are matters that will be determined by the Public Inquiry in accordance with the arrangements in place for establishing processes and procedures that will support this work.

From:	Ives J (Josephine)
To:	Cabinet Secretary for Health and Sport
Cc:	McQueen F (Fiona); Dunk R (Rachael); Birch J (Jason); Burgess E (Elizabeth); Ives J (Josephine); Allan L (Lara); Shepherd L (Lesley); Morris K (Keith); Hutchison D (David); Ingebrigtsen R (Ross); Henderson C (Calum); Lloyd E (Elizabeth); White C (Craig); Minister for Public Health, Sport and Wellbeing; Minister for Mental Health; Wright WA (Billy); DG Health & Social Care
Subject:	Off:Sen - Reopening of Ward 6A, QEUH
Date:	18 November 2019 18:47:43
Attachments:	Briefing - Re-opening of Ward 6A - 18 November.docx Annex A - Review of NHSGGC paediatric haemato-oncology data final version v1.5.pdf Annex B - IMT actions.pdf

Official: Sensitive

PO/ Cabinet Secretary,

Please find attached briefing seeking the Cabinet Secretary's view on reopening Ward 6A to new admissions.

Kind regards,
Jo

Jo Ives | Team Leader – HCAI/AMR | Chief Nursing Officer's Directorate [redacted]

Descriptive analysis of five year trends in bacteraemia rates for selected gram negative organisms

Introduction

As part of the investigation into the increase in gram negative bacteraemia in the Royal Hospital for Children, Glasgow, the trend in selected gram negative bacteraemia in RHC and the old RHSC (Yorkhill) over a 5 year period has been examined. Microbiological and environmental investigations have linked cases to water and drainage systems. Epidemiological information, in conjunction with other investigations, can assist in guiding further investigations and control measures, and is important for determining when the incident is closed, and in providing background information for any future surveillance.

Notes

- This report contains only descriptive epidemiology. Analytical epidemiology to quantify change in trends are on going and will be separately.
- These types of analysis cannot demonstrate causality – that is, they are for hypothesis generation, not hypothesis testing.
- During the time period examined there was significant service change with the move to the new RHC on the South Glasgow campus, as such it is not possible to directly compare count data. To allow comparison, rates per 1000 occupied bed days have been calculated. Changes in bed days are discussed later in this report.
- Gram negatives are a heterogeneous group, with variable ecology and pathology. However, given the small numbers for most of the bacteria, trend analysis requires aggregation. Further consideration would have to be given to how rates for these organisms can be monitored for future surveillance.
- Due to the changes in service, small counts, and challenges in disaggregating by specialty, data are presented at hospital level. Further consideration could be given to how best to carry out subgroup analysis, given these challenges.

Method

The ECOSS system was queried to obtain data on positive blood cultures for selected gram negative organisms reported from the GLA:SGH or GLA:GRI laboratories, age <16, date of report from July 2013 to June 2018. The list of gram negatives was provided by the NHS GGC lead Infection Control Doctor. This list is based on organisms identified in recent investigations. To increase sensitivity, data were pulled from ECOSS on basis of genus, rather than species.

Following extraction, the following exclusions were applied:

- Results from neonatal, maternity and pathology removed
- Results from areas not part of RHSC/RHC

During initial screening, laboratory GLA:RAH was also included, however as no relevant results noted, this parameter was removed from the query.

CHI numbers were replaced with new unique ID, and patient identifiers deleted.

Two separate counts were calculated, based on methodologies described by PHE and CDC:

- Organism count: Number of positive blood cultures per calendar month. Results within 14 days of a previous positive for the **same** organism in the same patient excluded.
- Case count: Number of positive blood cultures per calendar month results within 14 days of previous positive for **any** organism in the same patient excluded (ie only one positive per patient per 14 days)

In both cases the date of result was counted as day one.

Rates were then calculated as cases per 1000 bed days. Bed day data used were those produced by NHS GGC acute service information team.

Results

RHC gram-negatives

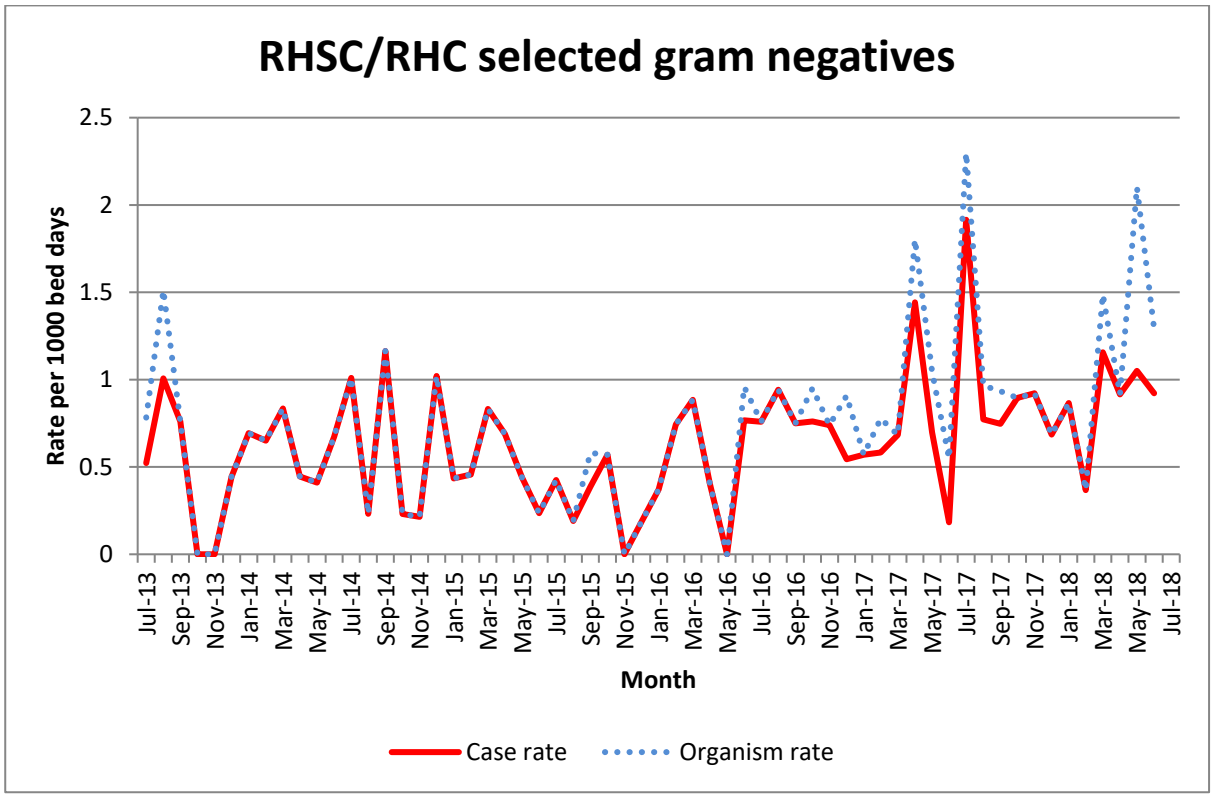


Figure 1 Organism and case rates for 61 month period. July 18 data was available after initial data extraction and has not been included in other analyses. Rate per 1000 bed days used to allow comparison between RHSC and RHC sites.

Other than a spike around August/September 2013, the rate of gram negative organisms at the Yorkhill RHSC had a fairly stable pattern, particularly between January 14 and May 15, fluctuating around the mean on a month to month basis (Range 0.21 to 1.16 cases per 1000 bed days).

Following move to the new RHC in June 2015 the case rate is lower than it was previously for 12 months, until quarter two 2016, when the case rate increases again. Despite this increase, the month-to month variation in rate is the smallest for any part of the time period examined. It is also inside the variation seen in the 14/15 stable period. The mean level at this point is higher than the old hospital. Formal testing is required to demonstrate if there is significant difference in the rates at this time.

From 2017 there are a series of spikes –

- April 17 – which is followed by a decrease through May and June 17, reaching the lowest monthly rate in 12 months.
- June 17 – the highest monthly rate for both case and organism count. Significant work on reducing CLABSI rate and general improvement in infection control practice have occurred following the detection of these increases in 2017.
- March 18 + May 18– RHC water incident. Case rate is similar to the peaks in rate during the 14/15 period, but without any troughs. However organism rate is much higher. These peaks are associated in time with the clusters of *Stenotrophomonas* and *Enterbacter.*

The organism rate is equal to the case rate in the majority of months. Prior to June 16 the two rates differ in only 3/36 months. This compares to 13/26 months from June 16 onwards. This indicates patients who have multiple identified organisms from a single blood culture. Potential reasons for this:

- Patients having multiple bacteraemia simultaneously.
- Some of the organisms are not causing systemic infection, but are line colonisations or local infection and detected as blood cultures are taken through contaminated line
- Change in lab practice in identifying multiple organisms.

Given the immunosupression of this patient cohort, multiple bacteraemias in a single patient is a much more plausible scenario than for other patient populations. However the other options cannot be excluded on basis of these data, and may contribute to the difference between organism rate and case rate.

Relying solely on the organism rate could be misleading. As an example – May 2018 the organism count is 12, however the case count is only 6. A further example is found with results for *Elizabethkingia, where* nearly 63% of these are from a single patient

Organisms

Based on the organism count, the following table details the frequency of the most common organisms. The four most common organisms follow a similar pattern, with stable counts for the first three years, with large increases in year 17/18. In some cases there is an indication that this increase is starting in 16/17. With *Serratia,* the peak is in 16/17, with a subsequent decrease in 17/18. The 5th most common organism, *Klebsiella oxytoca,* has been stable throughout the period. *Acinetobacter spp.* have higher

numbers in both 16/17 and 17/18, though there is variety in species, with *A. Baumannii* predominating in 16/17, and *A. Ursingii* in 17/18.

The "other" category is an aggregate of all other organisms, where the counts are too small to provide meaningful trend data. Due the heterogeneity in this group, interpretation should be cautious, though they do appear to peak in 16/17, and then decrease in 17/18.

Given the small numbers, looking at more detailed trends in individual species is problematic, as they all have counts average less than one per month. However these counts are not evenly distributed. As an example rates per 1000 bed days of *K. pneumonia*, the most common organism included in the data, in the chart below (figure 2). The rate is generally higher in most recent years, in particular there are few months with zero counts. A similar pattern can be seen for *E. cloacae* and *S. maltophilia* (as well as the clusters mentioned above).

Importantly, only identified organisms are accessible via ECOSS. Some results may have been reported as non-specific gram negative or oxidase negative gram negatives. If there has been a change in lab practice resulting in a higher proportion of organisms being identified, then this would impact on the infection rates. A request has been made for these data to allow consideration of this issue.

		13/14	14/15	15/16	16/17	17/18	Total
Klebsiella	*pneumoniae*	8	8	9	11	20	56
Enterobacter	*cloacae*	<5	<5	<5	6	14	32
Stenotrophomonas	*maltophilia*	<5	<5	<5	5	13	25
Pseudomonas	*aeruginosa*	<5	<5	<5	<5	8	18
Serratia	*marcescens*	<5	<5	<5	6	<5	15
Klebsiella	*oxytoca*	<5	<5	<5	<5	<5	15
Acinetobacter	*spp*	<5	<5	<5	<5	5	12
Other		*	*	*	19	13	50

Figure 2 Table of counts of most common bacteria. Cells with counts less than 5 have been suppressed. To prevent cross-tab disclosure, additional cells have been suppressed for the "other" category.

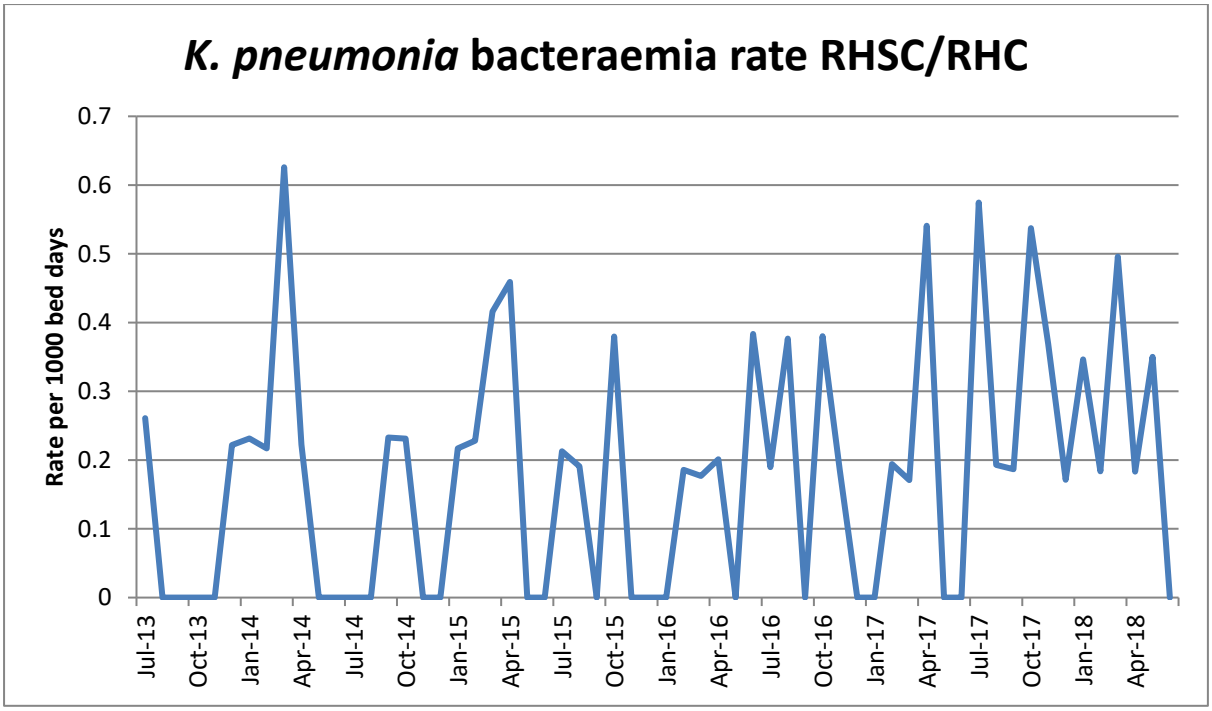


Figure 3 *Klebsiella pneumonia* rates over time, demonstrating change from mid-2016 onwards

Denominator

To allow comparison across time periods, bed days have been used as the denominator. There have been significant shifts in bed days for both RHC as a whole, as well as the haematology-oncology services. The shifts, though, occur at different times.

Figure 4 shows these changes over time, comparing the total bed days recorded for medical oncology and haematology compared to the rest of the hospital. To allow comparison the bed day numbers have been indexed, with 100=average monthly bed days in 2014 (2014 chosen due the relative stability in bed days).

With the move to the new hospital, there is a large increase in bed days for the hospital as a whole, which settles down to approximately 20% higher than the old hospital. Haematology/oncology bed days drift downwards at the time of the opening of the new hospital, demonstrating the controlled temporary restriction on activity during the move to the new hospital. The activity, as measured by bed days, does increase in the same proportion as the rest of RHC, but not until quarter 3 2016.

Given that infections from the selected organisms occur predominantly amongst the haematology-oncology population, the different pattern in change in bed days can cause artefact in the infection rates. This would explain the decrease in rate immediately after the opening of the new hospital, and a proportion of the increase in 2016, though it can only explain part of the increase.

it is also important to note two other factors: the bed day data is recorded by specialty, and not be ward, so does not represent specifically activity on Schiehallian/Ward 2A. Secondly, a large proportion of activity is on a daycase and outpatient basis, so not captured in the bed day data.

There has been an increase in daycase activity in recent years, and further consideration should be given to adjustment of the rate on the basis of the totality of haematology and oncology activity.

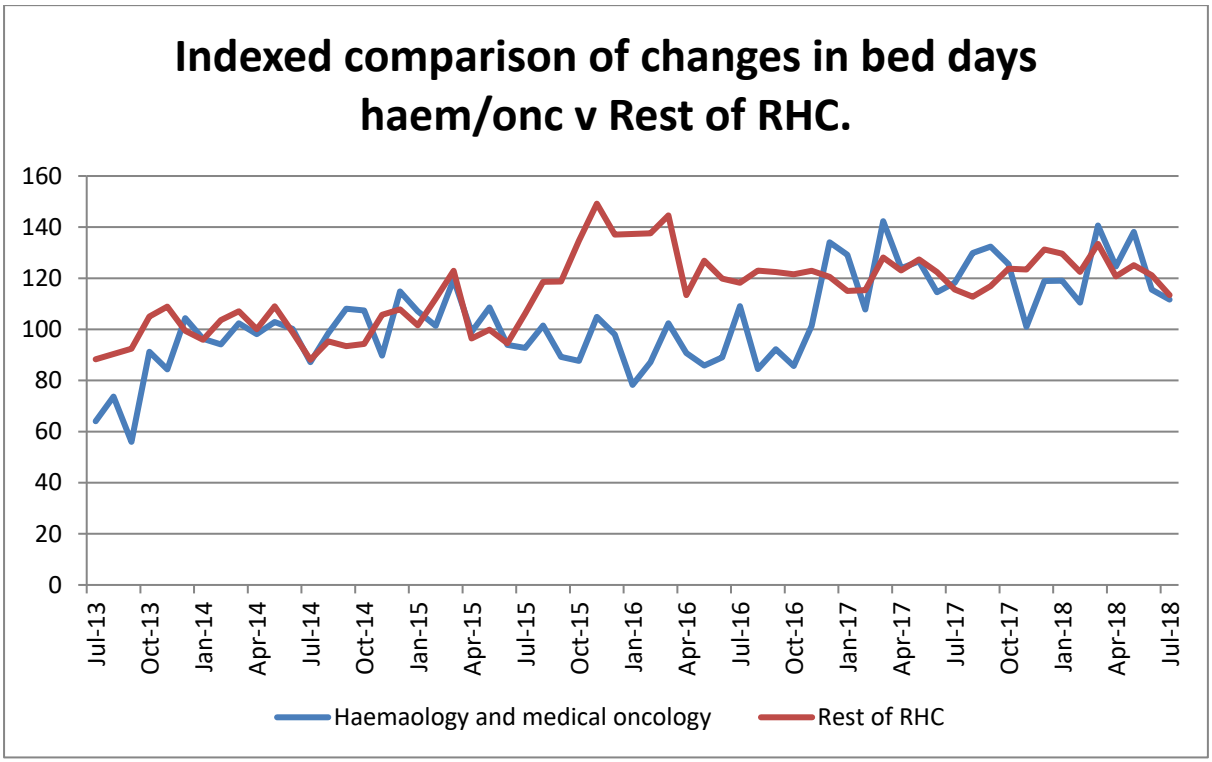


Figure 4 To allow comparison between the service and the rest of the hospital, changes are relative to index value. 100=mean monthly bed days Jan-Dec 14.

Comparators

Four comparators were chosen:

1. Ecoli bacteraemia at RHSC/RHC (one of most common gram negative bacteraemia in RHC)
2. Selected gram negatives at SGH/QEUH (to compare rates in adult hospital on same site)
3. Selected gram negatives at GRI (to compare rates on another site)
4. SAB rates at RHC (as general marker of bacteraemia and infection prevention practice)

Comparators 1-3 use same method as described for RHC selected gram negatives (with exception of limited organism for comparator 1, and using 17 or over as age criterion for comparators 2 and 3). Comparator 4 used routinely available data.

Charts for these comparators are appended at the end of this document.

Results

1. There is no clear trend in *E. Coli* bacteraemia rates, with significant month to month variability

2 and 3. There may be a slight trend upwards at both sites, but in general neither GRI nor QEUH demonstrate similar patterns to that seen at RHSC/RHC. For QEUH in particular, given the level of service reconfiguration involved in the opening of the hospital, it is likely that any change is secondary to change in service delivery on the South Glasgow site.

4. SAB rates in this chart are based on the local enhanced SAB surveillance counts, with rates calculated using the same bed day denominators as the

Summary and next steps

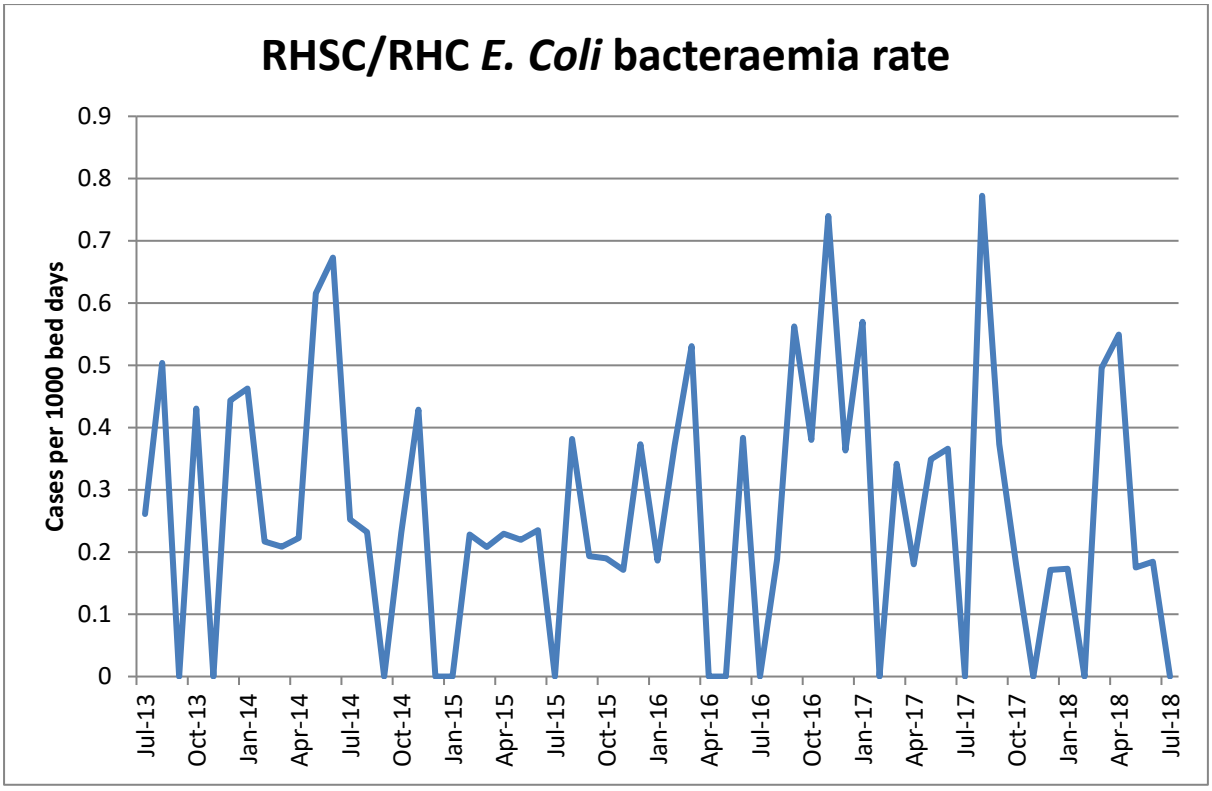
The data demonstrate a clear increase in the selected gram negatives in 2017 and 2018 compared to previous years, with a number of spikes in the rate of infection, which have been associated with certain clusters for which outbreak response and quality improvement activities have been under taken. There is also an increase in 2016, though further work is required to define the magnitude and asses if this is a "true" increase in infection rate, or is explained, at least in part, by changes that are not related to changes in the underlying risk. The other obvious change over the time period is the increase in the number of blood cultures positive for multiple organisms. Again, consideration should be given to potential causes of this change.

Further actions:

- Formal analysis to define trends in data, including testing of aberration detection
- Consider how best to analyse data to minimise denominator artefact
- Include oxidase negative/non-specific gram negatives in analysis

Once these additional analyses are completed, the IMT should consider:

- What is the true baseline rate of gram negative bacteraemia
- Potential causal factors for changes in level or trend, or for deviation from that baseline.


RHSC/RHC E. Coli bacteraemia rate
Cases per 1000 bed days
0.9
0.8
0.7
0.6
0.5
0.4
0.3
0.2
0.1
0
Jul-13
Oct-13
Jan-14
Apr-14
Jul-14
Oct-14
Jan-15
Apr-15
Jul-15
Oct-15
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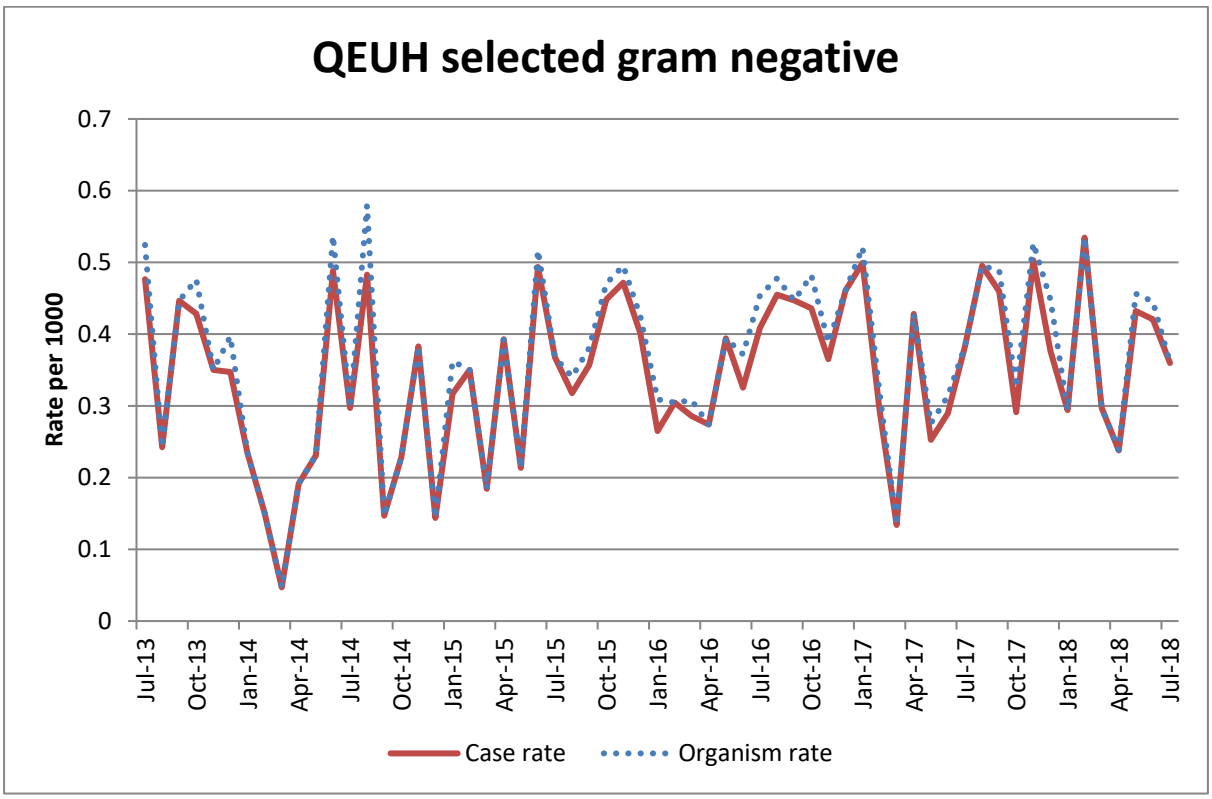
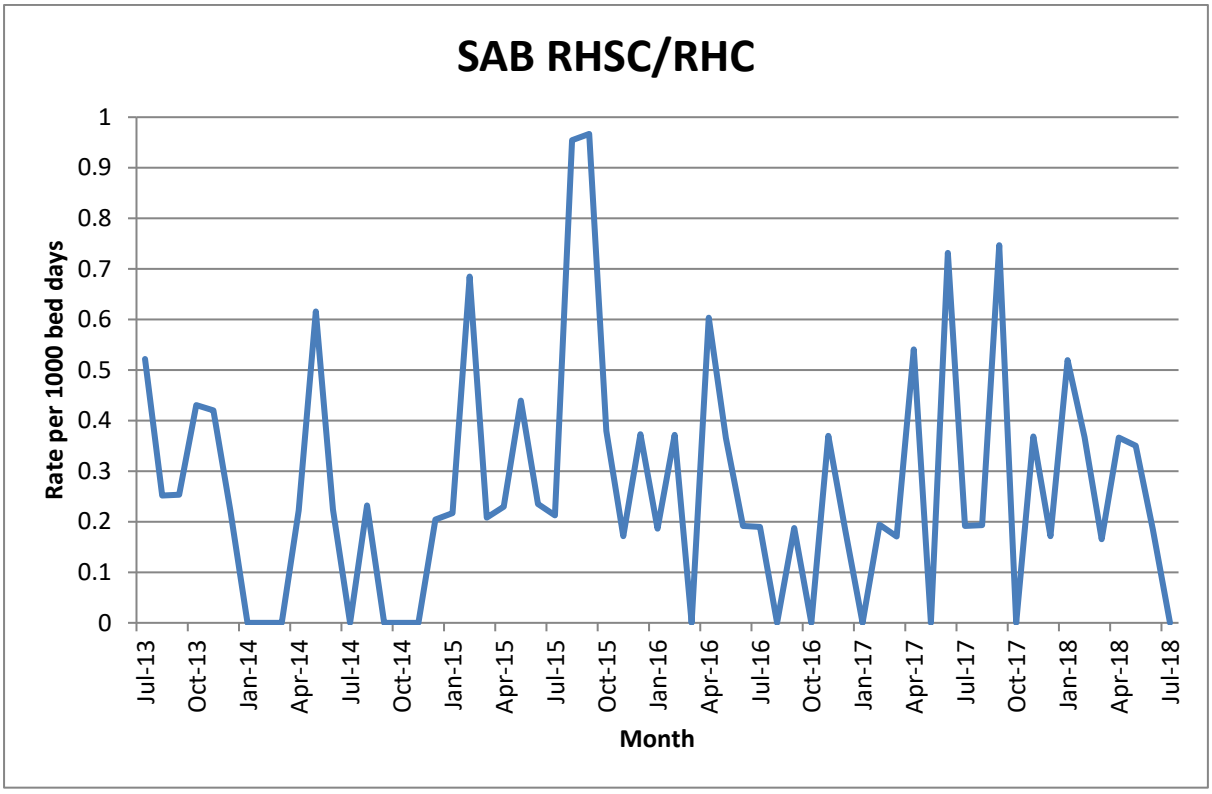
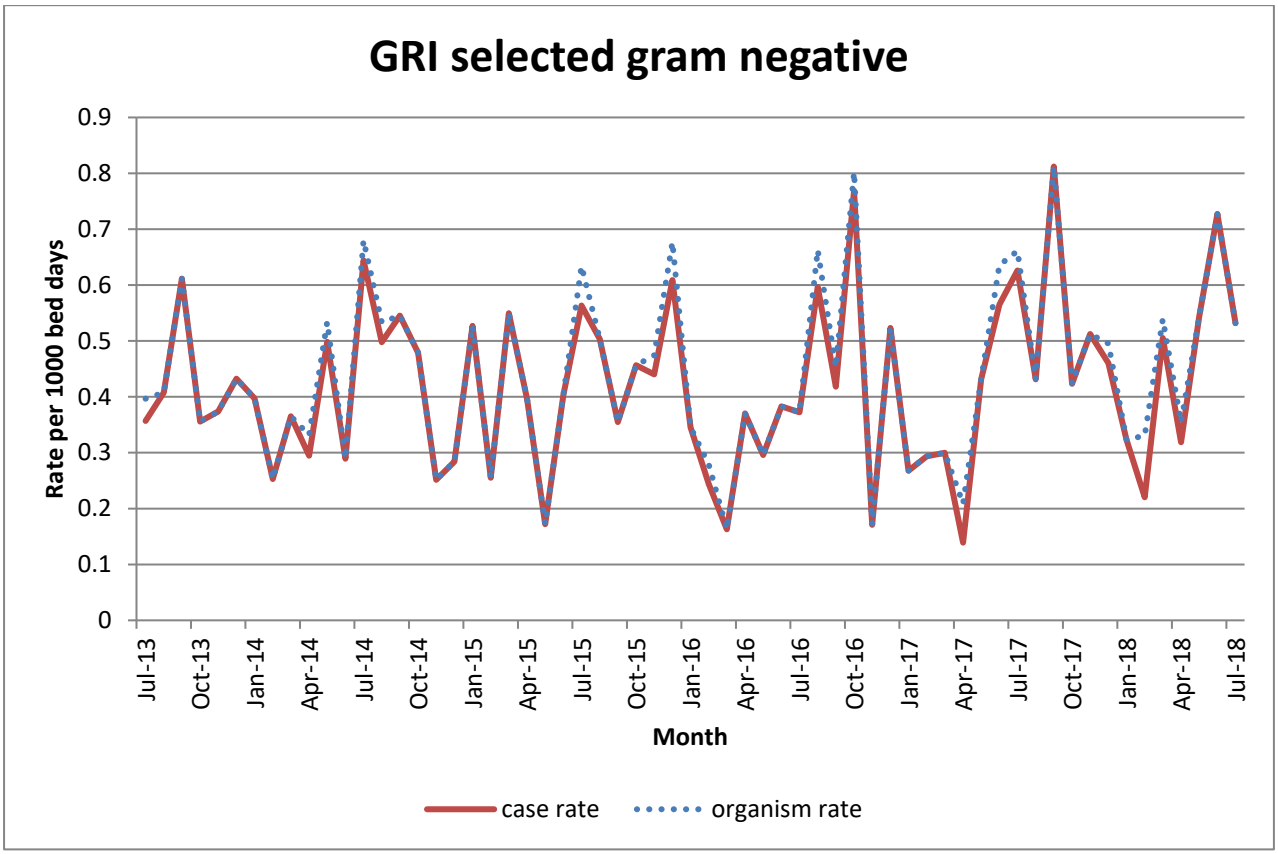
Apr-17
Jul-17
Oct-17
Jan-18
Apr-18
Jul-18


QEUH selected gram negative
Rate per 1000
0.7
0.6
0.5
0.4
0.3
0.2
0.1
0
Jul-13
Oct-13
Jan-14
Apr-14
Jul-14
Oct-14
Jan-15
Apr-15
Jul-15
Oct-15
Jan-16
Apr-16
Jul-16
Oct-16
Jan-17
Apr-17
Jul-17
Oct-17
Jan-18
Apr-18
Jul-18
Case rate
Organism rate


SAB RHSC/RHC
Rate per 1000 bed days
1
0.9
0.8
0.7
0.6
0.5
0.4
0.3
0.2
0.1
0
Jul-13
Oct-13
Jan-14
Apr-14
Jul-14
Oct-14
Jan-15
Apr-15
Jul-15
Oct-15
Jan-16
Apr-16
Jul-16
Oct-16
Jan-17
Apr-17
Jul-17
Oct-17
Jan-18
Apr-18
Jul-18
Month


GRI selected gram negative
Rate per 1000 bed days
0.9
0.8
0.7
0.6
0.5
0.4
0.3
0.2
0.1
0
Jul-13
Oct-13
Jan-14
Apr-14
Jul-14
Oct-14
Jan-15
Apr-15
Jul-15
Oct-15
Jan-16
Apr-16
Jul-16
Oct-16
Jan-17
Apr-17
Jul-17
Oct-17
Jan-18
Apr-18
Jul-18
Month
case rate
organism rate

Descriptive analysis of trends in bacteraemia rates for selected gram negative organisms

Contents

Introduction

As part of the response to the increased gram negative bacteraemia in the haematology and oncology patients at Royal Hospital for Children, Glasgow (Haem/onc; RHC), Public Health Protection Unit drafted a descriptive epidemiology report on the incidence of selected gram negative bacteraemia. The draft was shared with the chair of the IMT in October 2018. Given the time elapsed since that draft report, and in light of the recent cluster of gram negative infections, the report has been updated. The first section of this document is the updated report, and the previous report is included as an annex. The original report and the update should be read together. A list of the organisms initially suggested for review is included in the appendix.

Notes on questions raised from previous report

Analytical epidemiology

Following completion of the initial report, statistical support was sought for the possibility of formal analytical work. The conclusion of that discussion was that an interrupted time series design may be suitable, however, the lack of *a priori* breakpoints in the period between the move to the new hospital and the decant to ward 6A limit the usefulness of this method. In the alternative, the data has been presented as counts, with activity displayed on different axis on same chart, both with 3 month rolling average also marked.

Denominator

The potential for denominator artefact was raised in the previous report. Considering haem/onc separately to the rest of RHC (see below) assists with this, as does suggestion of displaying count and denominator data on different axes. Additionally, to account for underestimation of denominator, a combined "activity" denominator has been used in the updated report (bed days+day cases+total outpatient appointments [including DNAs]), with the exception of figure 1, where the previous bed days denominator has been used to allow direct comparison with the previous report.

A question has been raised about alternative denominators, such as number of blood cultures taken, or number of positive blood cultures from patients with sepsis diagnosis. Neither of these however is suitable. A denominator needs to be able to account for person-time at risk, for example bed days, or line days. Although not without their own drawbacks, bed days and other activity data are the best routinely collected data which account for person-time.

Oxidase negative/non-specific gram negatives

The previous report raised the question of possibility of earlier results being reported as "oxidase negative GNB", or otherwise being described as without specific speciation and therefore not accessible via ECOSS. However, feedback from microbiology indicates that the number of such cases is extremely small, and has not changed over the period examined. Therefore these organisms are unlikely to have any significant impact on the results.

Lab practice

A question was raised in the previous as to whether any portion of the increase, in particular the increase in number of tests where multiple organisms were identified, could be due to changes in lab practices. Microbiology staff have confirmed that the identification modalities (MALDI-ToF and

Viteck) have not changed during the time period examined, and it has also been stated that any samples showing gram negatives would have been investigated, and that this had not changed. Confirmation that there has been no other changes to lab practices and procedures is required.

Specialty specific results

The initial report was limited to review of cases at hospital (RHSC/RHC) level. There reasons for reporting at hospital level were:

- Practical: the imeadiate availability of the data, without requiring further segmentation
- Impact of changes to individual services/wards as potential confounder is lessened when examining hospital as a whole
- issues of water quality were considered to be potentially site-wide.
- To have data that is comparable to for example SAB data, or to other hospital sites
- Very small numbers makes looking at trends difficult

The updated report, whilst updating the principal chart and table from the earlier version, also presents results from patients in the haematology and oncology services separately.

ECOSS data quality

ECOSS captures data from diagnostic and reference laboratories, and is a national tool for monitoring organisms, infections and microbial intoxications that are of clinical or public health importance. There are inherent limitations in any such surveillance system, including completeness, quality of underlying data, and operation of the surveillance system. Blood cultures are the most reliable results in ECOSS, and there is strong confidence in accuracy of the data. Concurrence in count data between ECOSS and other local reports supports this.

There is a limitation in that only samples tested in an NHS GGC lab were included in the current study. I f the sample was processed in a lab in another board area, it would not be available for inclusion in this report.

Method

The same method of extracting the data from ECOSS and calculating counts used in the previous report was used in the update, and so is not repeated here. Because of the removal of patient identifiers, it is not possible to ascertain if cases were identified in more than one phase of data extraction, however it is possible to spot recurrence within each phase.

To allow separate analysis of haem/onc patients, each case was assigned to a specialty based on the following data points included in the ECOSS reports –

1. Ward sample was taken
2. Diagnosis/clinical history recorded on lab request
3. Requesting consultant.

If it was not possible to identify a specialty from information contained in the ECOSS report, then speciality was confirmed using electronic patient records.

Unless otherwise stated, ‘Years’ refers to the period July – June(inclusive)

Results

Chart and table up dates

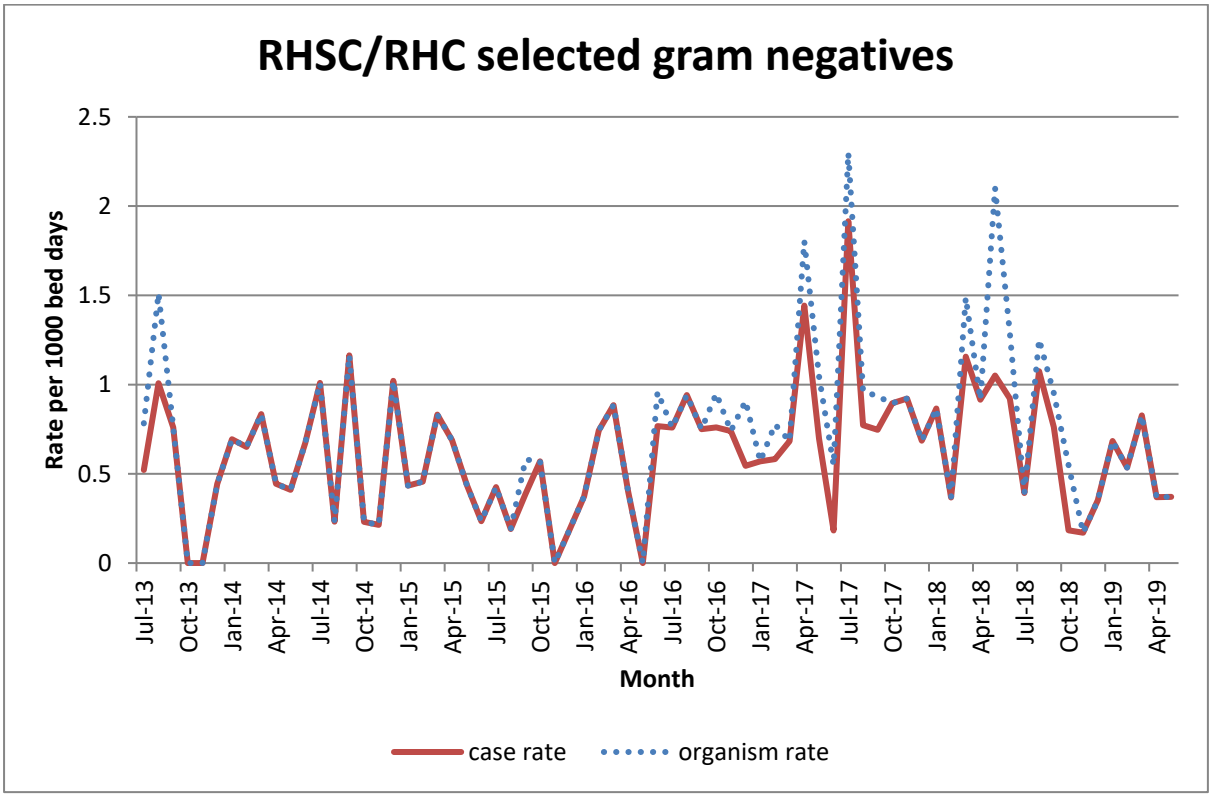
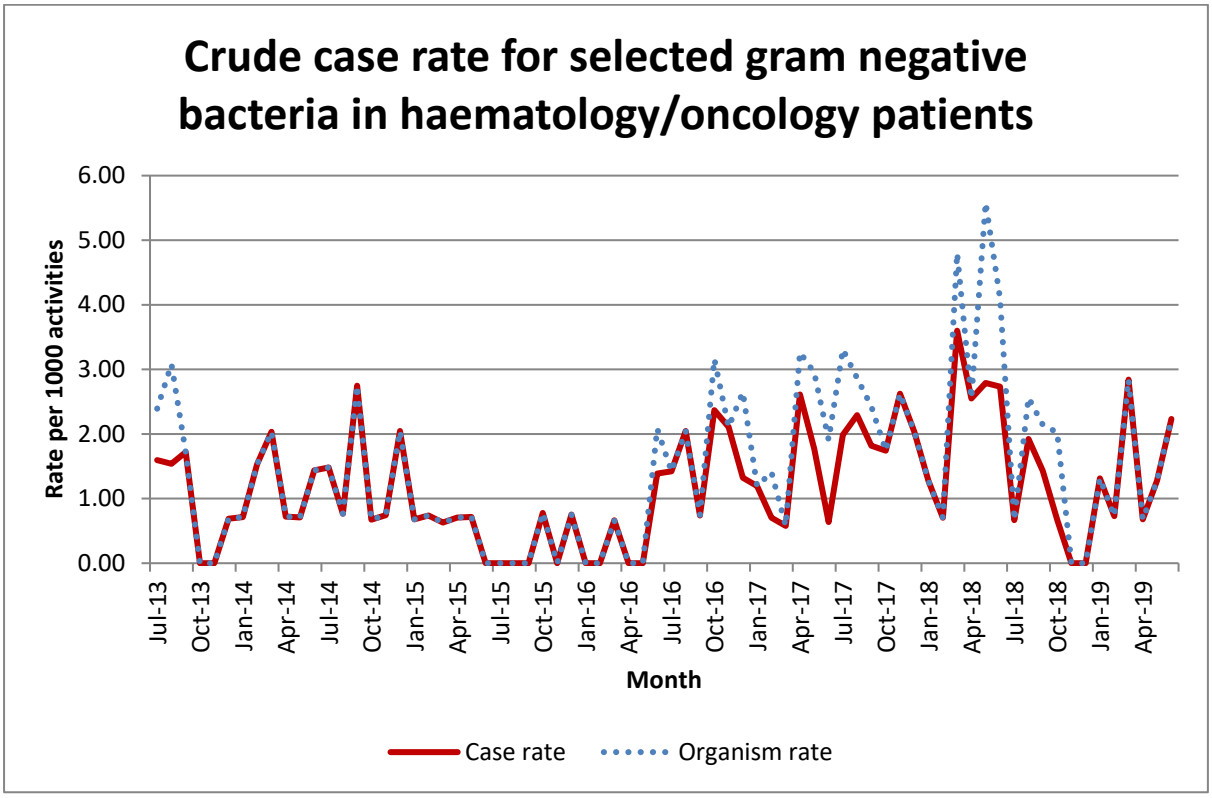


Table 1 Counts of most common organisms July-June.

		13/14	14/15	15/16	16/17	17/18	18/19
Klebsiella	*pneumoniae*	8	8	9	11	20	7
Enterobacter	*cloacae*	<5	<5	<5	6	14	12
Stenotrophomonas	*maltophilia*	<5	<5	<5	5	13	5
Pseudomonas	*aeruginosa*	<5	<5	<5	<5	8	<5
Serratia	*marcescens*	<5	<5	<5	6	<5	<5
Klebsiella	*oxytoca*	<5	<5	<5	<5	<5	<5
Acinetobacter	*spp*	<5	<5	<5	<5	5	<5
Other		8	7	<5	19	13	5

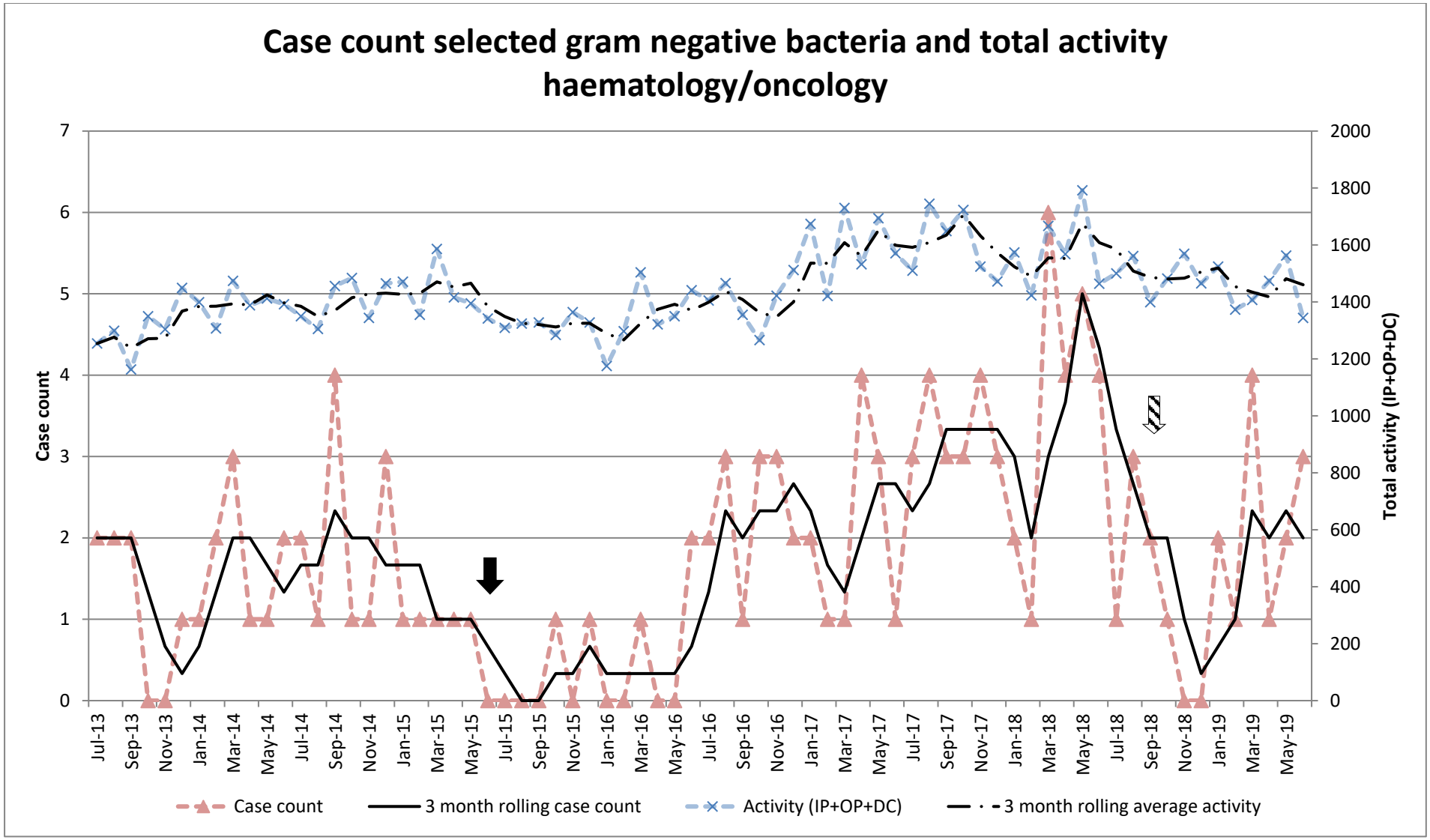
Overall, the number of cases in each category detailed in the table has fallen back to levels seen prior to the move to the new hospital. The exception to this is *E. cloacae* which remains elevated. The total number of positive results is much lower in 18/19, compared to the previous two years. This can also be seen in the chart, where recent months have a rate similar to that in the old Yorkhill hospital, and there has been a complete absence of polymicorbial episodes.

Haematology-oncology



Separating out the results from patients under the care of haematology and oncology services shows a similar pattern to that seen when examining the overall rates, though there are some differences in the pattern, particularly during 2017/18.

The chart over leaf separates out numerator and denominator data, and includes 3 month rolling average. When comparing across time in this chart it is important to remember that it is count data, and given the increase in activity (shown on secondary axis) an increase in incidence compared to earlier periods may be expected. The chart shows that since the decant to Ward 6A, the incidence has returned to levels similar to those seen prior to the current situation, though there is still some variability.

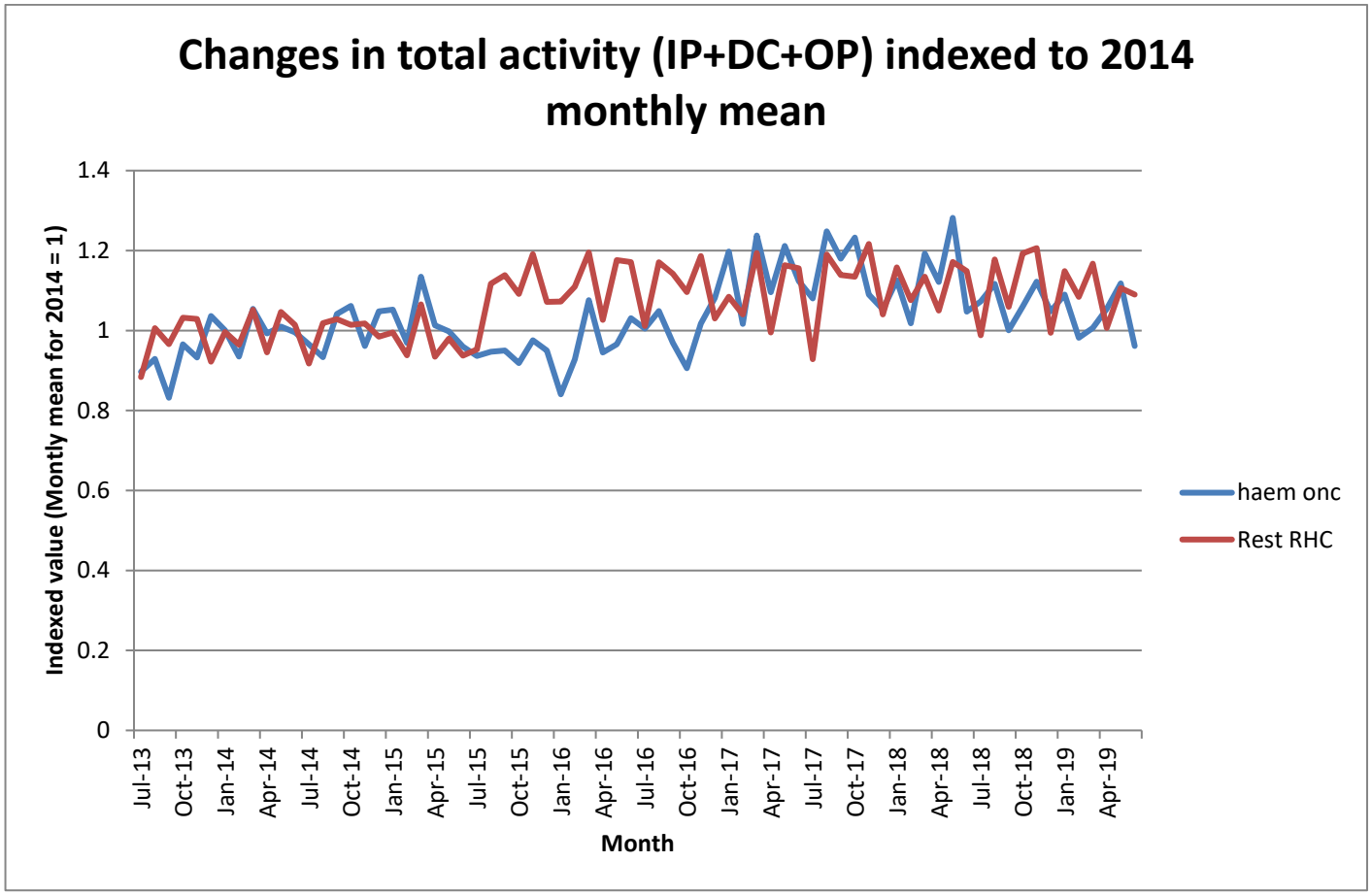

Case count selected gram negative bacteria and total activity haematology/oncology
Case count
Total activity (IP+OP+DC)
0
1
2
3
4
5
6
7
0
200
400
600
800
1000
1200
1400
1600
1800
2000
Jul-13
Sep-13
Nov-13
Jan-14
Mar-14
May-14
Jul-14
Sep-14
Nov-14
Jan-15
Mar-15
May-15
Jul-15
Sep-15
Nov-15
Jan-16
Mar-16
May-16
Jul-16
Sep-16
Nov-16
Jan-17
Mar-17
May-17
Jul-17
Sep-17
Nov-17
Jan-18
Mar-18
May-18
Jul-18
Sep-18
Nov-18
Jan-19
Mar-19
May-19
Case count
3 month rolling case count
Activity (IP+OP+DC)
3 month rolling average activity
Move to new hospital
Decant to Ward 6A

A43293438

Denominator

As discussed above, a monthly total activity combined denominator has been used for the majority of this report. Over the course of the time period studied, there has been significant service change with the move to the new hospital. By indexing the change it allows comparison of the change in activity between different cohorts, despite large differences in the underlying absolute numbers. reviewing the data, the 2014 calendar year appears the most stable time period, so the mean monthly activity for 201 was set =1, and then the data compared to see if it was above or below this value.

The Rest RHC activity increase by 15-20% following the move to the new hospital. The Haem/onc activity had a similar increase, but delayed until the end of 2016. Initially there was a slight decrease in Haem/onc activity for the first few months after opening of the new hospital, returning to previous levels in 2016, before rising a comparable amount to the rest of the hospital.



There are a number of other potentially relevent factors in considering the bed days. Although the have similar patterns when indexed, the number of bed days is three to five times higher than the number of day cases in any given month. The ratio of bed days: day cases follows a pattern of a gently decreasing slope, suggesting shift of acitvity from inpatient to day case, with a large increase

in November 2016, with the slope downwards restarting orm this new higher point. SImlarly ther eis a pattern in bed occupancy. haem/onc bed occupancy ran at around 70% at Yorkhill, and increased shortly after the move to the new hospital to between 80% and 90%. During Winter 2016, this increased to above 90%, dropping temporarily in autumn 2018, during the decant to Ward 6A. This change in activity preceeds the change in incidence seen from Q2 2017 onwards. The bed day data is complex. These patterns may be artefactual, or be as a result of service change. It is suggested that both these possibilities are examined before conclusions on the potential significance are drawn.

Summary

Since the previous draft report in October 2018, there has been noticeable improvement in the incidence of gram negative infections in the haematology/oncology population. There has been both a decrease in the incidence of cases, but also importantly an absence of samples positive for multiple gram negative organisms. During this period Wards 2A/2B were decanted and continuous chlorine dioxide dosing has been introduced. As well as these structural measures, there has been throughout the incident ongoing monitoring and education to ensure high standards of practice are maintained, and the introduction of point of use filters. It can be hypothesised that all of these various measures will have contributed to the improvements.

The following points which may assist the understanding the incident and the future expectations around gram negative organisms:

- *Enterobacter cloacae* incidence has remained higher than the historical baseline and has not seen the same reduction incidence as other organisms. Understanding this pattern will provide information that may help decisions around control measures . Ongoing monitoring of the trend in *Enterobacter* will therefore be important.
- More detailed analysis of changes in activity over the time period reviewed may help understand potential reasons for the incident, and hence future preventative measures. In particular, it may allow the use of formal analytical epidemiological techniques.

There are limitations to a study such as this, and these are detailed in the original report attached. Key amongst these is that this is a descriptive study, and no causality can be assumed. It is also prepared using routine data and is not a detailed study of individual cases.

Annex: Descriptive analysis of five year trends in bacteraemia rates for selected gram negative organisms

Introduction

As part of the investigation into the increase in gram negative bacteraemia in the Royal Hospital for Children, Glasgow, the trend in selected gram negative bacteraemia in RHC and the old RHSC (Yorkhill) over a 5 year period has been examined. Microbiological and environmental investigations have linked cases to water and drainage systems. Epidemiological information, in conjunction with other investigations, can assist in guiding further investigations and control measures, and is important for determining when the incident is closed, and in providing background information for any future surveillance.

Notes

- This report contains only descriptive epidemiology. Analytical epidemiology to quantify change in trends are on going and will be separately.
- These types of analysis cannot demonstrate causality – that is, they are for hypothesis generation, not hypothesis testing.
- During the time period examined there was significant service change with the move to the new RHC on the South Glasgow campus, as such it is not possible to directly compare count data. To allow comparison, rates per 1000 occupied bed days have been calculated. Changes in bed days are discussed later in this report.
- Gram negatives are a heterogeneous group, with variable ecology and pathology. However, given the small numbers for most of the bacteria, trend analysis requires aggregation. Further consideration would have to be given to how rates for these organisms can be monitored for future surveillance.
- Due to the changes in service, small counts, and challenges in disaggregating by specialty, data are presented at hospital level. Further consideration could be given to how best to carry out subgroup analysis, given these challenges.

Method

The ECOSS system was queried to obtain data on positive blood cultures for selected gram negative organisms reported from the GLA:SGH or GLA:GRI laboratories, age <16, date of report from July 2013 to June 2018. The list of gram negatives was provided by the NHS GGC lead Infection Control Doctor. This list is based on organisms identified in recent investigations. To increase sensitivity, data were pulled from ECOSS on basis of genus, rather than species.

Following extraction, the following exclusions were applied:

- Results from neonatal, maternity and pathology removed
- Results from areas not part of RHSC/RHC

During initial screening, laboratory GLA:RAH was also included, however as no relevant results noted, this parameter was removed from the query.

CHI numbers were replaced with new unique ID, and patient identifiers deleted.

Two separate counts were calculated, based on methodologies described by PHE and CDC:

- Organism count: Number of positive blood cultures per calendar month. Results within 14 days of a previous positive for the **same** organism in the same patient excluded.
- Case count: Number of positive blood cultures per calendar month results within 14 days of previous positive for **any** organism in the same patient excluded (ie only one positive per patient per 14 days)

In both cases the date of result was counted as day one.

Rates were then calculated as cases per 1000 bed days. Bed day data used were those produced by NHS GGC acute service information team.

Results

RHC gram-negatives

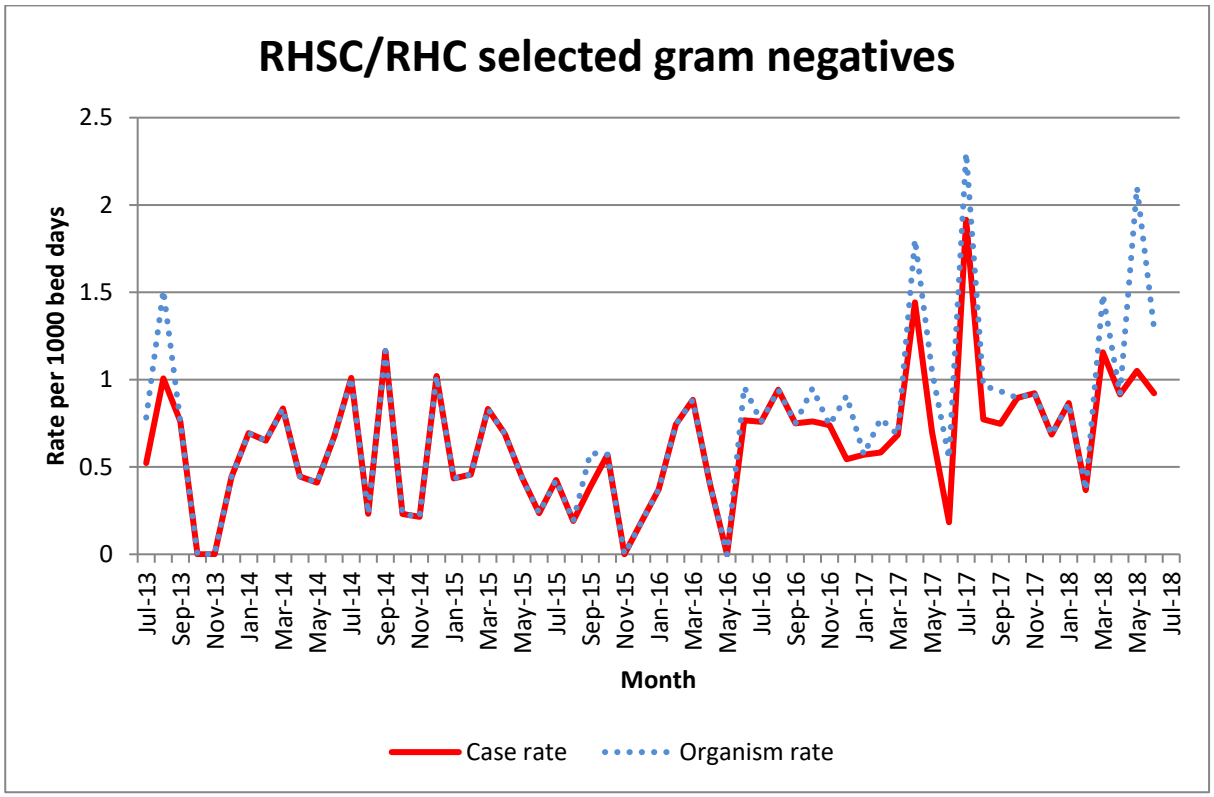


Figure 1 Organism and case rates for 61 month period. July 18 data was available after initial data extraction and has not been included in other analyses. Rate per 1000 bed days used to allow comparison between RHSC and RHC sites.

Other than a spike around August/September 2013, the rate of gram negative organisms at the Yorkhill RHSC had a fairly stable pattern, particularly between January 14 and May 15, fluctuating around the mean on a month to month basis (Range 0.21 to 1.16 cases per 1000 bed days).

Following move to the new RHC in June 2015 the case rate is lower than it was previously for 12 months, until quarter two 2016, when the case rate increases again. Despite this increase, the month-to month variation in rate is the smallest for any part of the time period examined. It is also inside the variation seen in the 14/15 stable period. The mean level at this point is higher than the old hospital. Formal testing is required to demonstrate if there is significant difference in the rates at this time.

From 2017 there are a series of spikes –

- April 17 – which is followed by a decrease through May and June 17, reaching the lowest monthly rate in 12 months.
- June 17 – the highest monthly rate for both case and organism count. Significant work on reducing CLABSI rate and general improvement in infection control practice have occurred following the detection of these increases in 2017.
- March 18 + May 18– RHC water incident. Case rate is similar to the peaks in rate during the 14/15 period, but without any troughs. However organism rate is much higher. These peaks are associated in time with the clusters of *Stenotrophomonas* and *Enterbacter.*

The organism rate is equal to the case rate in the majority of months. Prior to June 16 the two rates differ in only 3/36 months. This compares to 13/26 months from June 16 onwards. This indicates patients who have multiple identified organisms from a single blood culture. Potential reasons for this:

- Patients having multiple bacteraemia simultaneously.
- Some of the organisms are not causing systemic infection, but are line colonisations or local infection and detected as blood cultures are taken through contaminated line
- Change in lab practice in identifying multiple organisms.

Given the immunosupression of this patient cohort, multiple bacteraemias in a single patient is a much more plausible scenario than for other patient populations. However the other options cannot be excluded on basis of these data, and may contribute to the difference between organism rate and case rate.

Relying solely on the organism rate could be misleading. As an example – May 2018 the organism count is 12, however the case count is only 6. A further example is found with results for *Elizabethkingia, where* nearly 63% of these are from a single patient

Organisms

Based on the organism count, the following table details the frequency of the most common organisms. The four most common organisms follow a similar pattern, with stable counts for the first three years, with large increases in year 17/18. In some cases there is an indication that this increase is starting in 16/17. With *Serratia,* the peak is in 16/17, with a subsequent decrease in 17/18. The 5th most common organism, *Klebsiella oxytoca,* has been stable throughout the period. *Acinetobacter spp.* have higher

numbers in both 16/17 and 17/18, though there is variety in species, with *A. Baumannii* predominating in 16/17, and *A. Ursingii* in 17/18.

The "other" category is an aggregate of all other organisms, where the counts are too small to provide meaningful trend data. Due the heterogeneity in this group, interpretation should be cautious, though they do appear to peak in 16/17, and then decrease in 17/18.

Given the small numbers, looking at more detailed trends in individual species is problematic, as they all have counts average less than one per month. However these counts are not evenly distributed. As an example rates per 1000 bed days of *K. pneumonia*, the most common organism included in the data, in the chart below (figure 2). The rate is generally higher in most recent years, in particular there are few months with zero counts. A similar pattern can be seen for *E. cloacae* and *S. maltophilia* (as well as the clusters mentioned above).

Importantly, only identified organisms are accessible via ECOSS. Some results may have been reported as non-specific gram negative or oxidase negative gram negatives. If there has been a change in lab practice resulting in a higher proportion of organisms being identified, then this would impact on the infection rates. A request has been made for these data to allow consideration of this issue.

		13/14	14/15	15/16	16/17	17/18
Klebsiella	*pneumoniae*	8	8	9	11	20
Enterobacter	*cloacae*	<5	<5	<5	6	14
Stenotrophomonas	*maltophilia*	<5	<5	<5	5	13
Pseudomonas	*aeruginosa*	<5	<5	<5	<5	8
Serratia	*marcescens*	<5	<5	<5	6	<5
Klebsiella	*oxytoca*	<5	<5	<5	<5	<5
Acinetobacter	*spp*	<5	<5	<5	<5	5
Other		*	*	*	19	13

Figure 2 Table of counts of most common bacteria. Cells with counts less than 5 have been suppressed. To prevent cross-tab disclosure, additional cells have been suppressed for the "other" category.

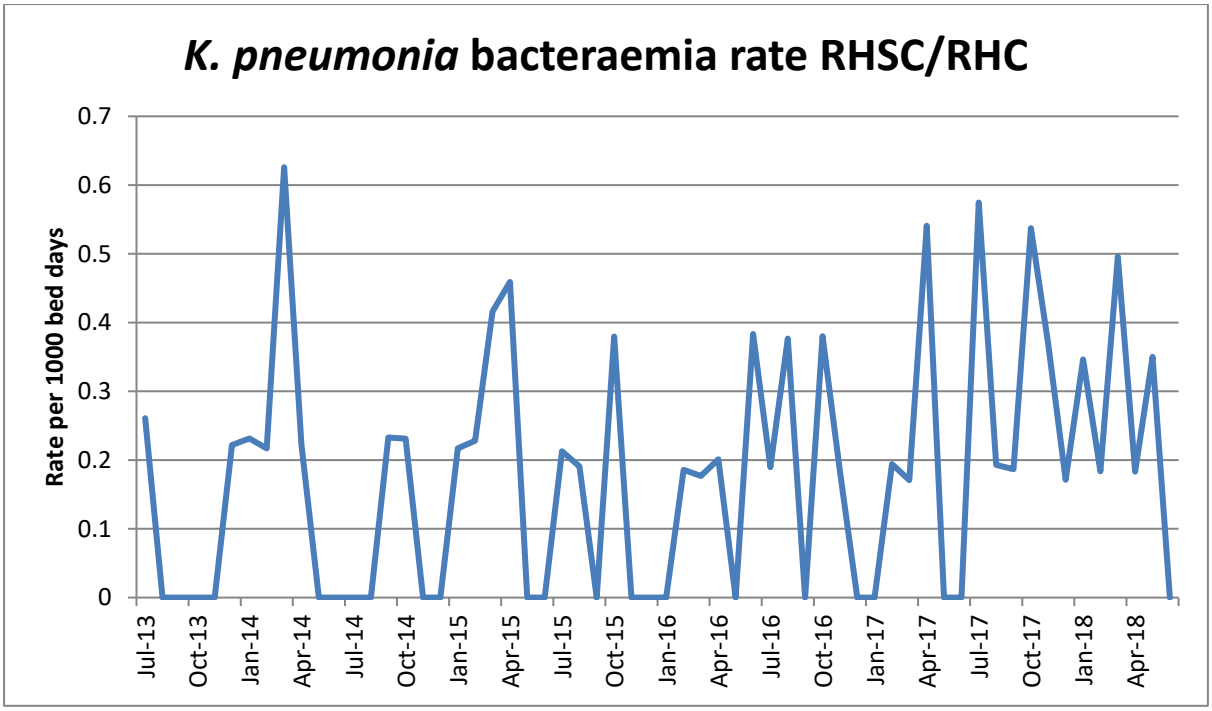


Figure 3 *Klebsiella pneumonia* rates over time, demonstrating change from mid-2016 onwards

Denominator

To allow comparison across time periods, bed days have been used as the denominator. There have been significant shifts in bed days for both RHC as a whole, as well as the haematology-oncology services. The shifts, though, occur at different times.

Figure 4 shows these changes over time, comparing the total bed days recorded for medical oncology and haematology compared to the rest of the hospital. To allow comparison the bed day numbers have been indexed, with 100=average monthly bed days in 2014 (2014 chosen due the relative stability in bed days).

With the move to the new hospital, there is a large increase in bed days for the hospital as a whole, which settles down to approximately 20% higher than the old hospital. Haematology/oncology bed days drift downwards at the time of the opening of the new hospital, demonstrating the controlled temporary restriction on activity during the move to the new hospital. The activity, as measured by bed days, does increase in the same proportion as the rest of RHC, but not until quarter 4 2016.

Given that infections from the selected organisms occur predominantly amongst the haematology-oncology population, the different pattern in change in bed days can cause artefact in the infection rates. This would explain the decrease in rate immediately after the opening of the new hospital, and a proportion of the increase in 2016, though it can only explain part of the increase.

It is also important to note two other factors: the bed day data is recorded by specialty, and not be ward, so does not represent specifically activity on Schiehallian/Ward 2A. Secondly, a large proportion of activity is on a daycase and outpatient basis, so not captured in the bed day data.

There has been an increase in daycase activity in recent years, and further consideration should be given to adjustment of the rate on the basis of the totality of haematology and oncology activity.

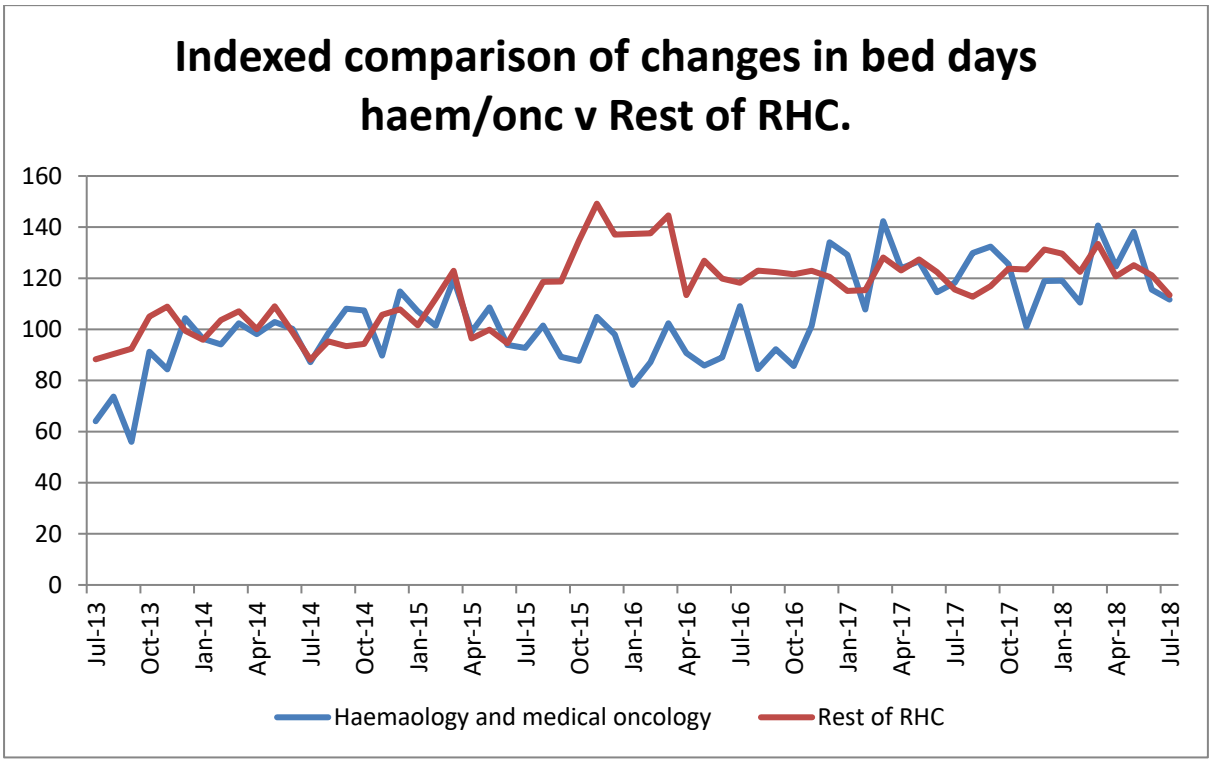


Figure 4 To allow comparison between the service and the rest of the hospital, changes are relative to index value. 100=mean monthly bed days Jan-Dec 14.

Comparators

Four comparators were chosen:

1. Ecoli bacteraemia at RHSC/RHC (one of most common gram negative bacteraemia in RHC)
2. Selected gram negatives at SGH/QEUH (to compare rates in adult hospital on same site)
3. Selected gram negatives at GRI (to compare rates on another site)
4. SAB rates at RHC (as general marker of bacteraemia and infection prevention practice)

Comparators 1-3 use same method as described for RHC selected gram negatives (with exception of limited organism for comparator 1, and using 17 or over as age criterion for comparators 2 and 3). Comparator 4 used routinely available data.

Charts for these comparators are appended at the end of this document.

Results

1. There is no clear trend in *E. Coli* bacteraemia rates, with significant month to month variability

2 and 3. There may be a slight trend upwards at both sites, but in general neither GRI nor QEUH demonstrate similar patterns to that seen at RHSC/RHC. For QEUH in particular, given the level of service reconfiguration involved in the opening of the hospital, it is likely that any change is secondary to change in service delivery on the South Glasgow site.

4. SAB rates in this chart are based on the local enhanced SAB surveillance counts, with rates calculated using the same bed day denominators as the main analysis. There is a large peak after the move to the new hospital. This temporary increase in SAB rates is what would be expected with such a significant service change, with staff working in unfamiliar environments. There are then two peaks in mid-2017, around the same period as seen in the gram negatives. There are other occasional peaks of similar magnitude across the time period. It does not appear to have the same pattern as the gram negatives overall.

Summary and next steps

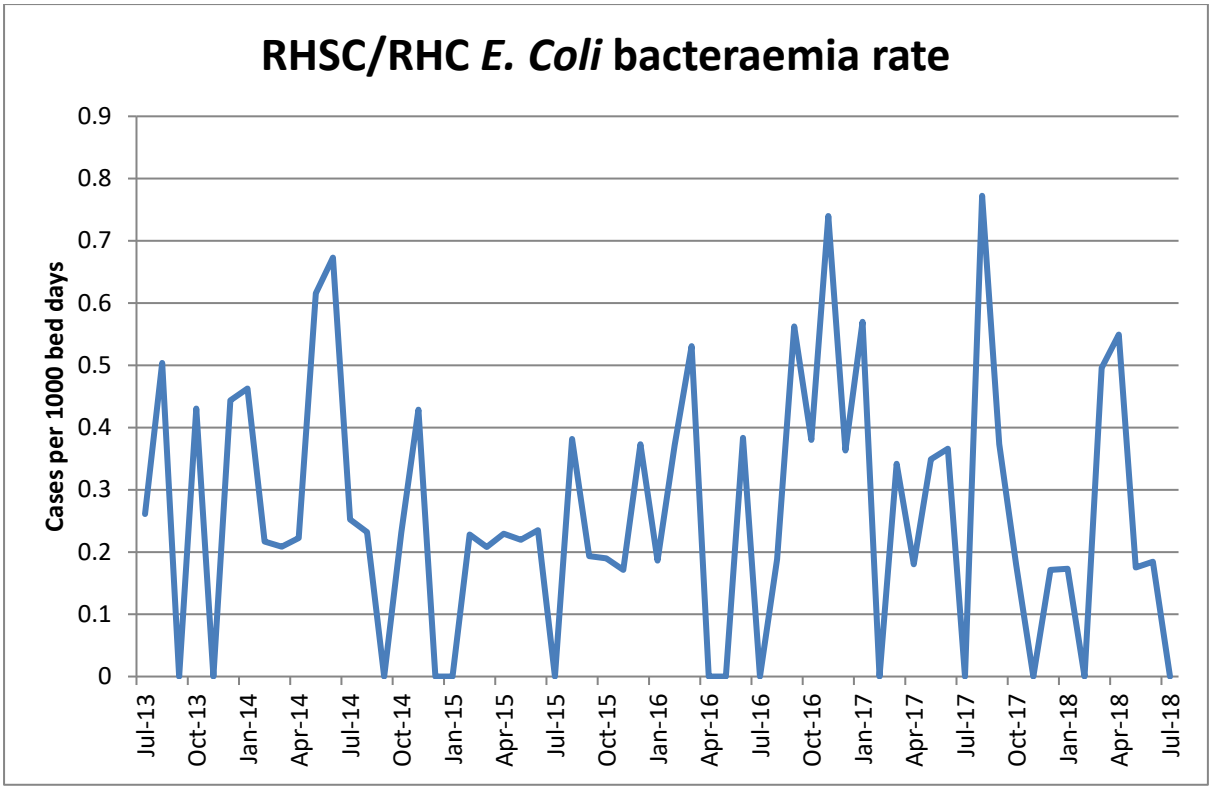
The data demonstrate a clear increase in the selected gram negatives in 2017 and 2018 compared to previous years, with a number of spikes in the rate of infection, which have been associated with certain clusters for which outbreak response and quality improvement activities have been under taken. There is also an increase in 2016, though further work is required to define the magnitude and asses if this is a “true” increase in infection rate, or is explained, at least in part, by changes that are not related to changes in the underlying risk. The other obvious change over the time period is the increase in the number of blood cultures positive for multiple organisms. Again, consideration should be given to potential causes of this change.

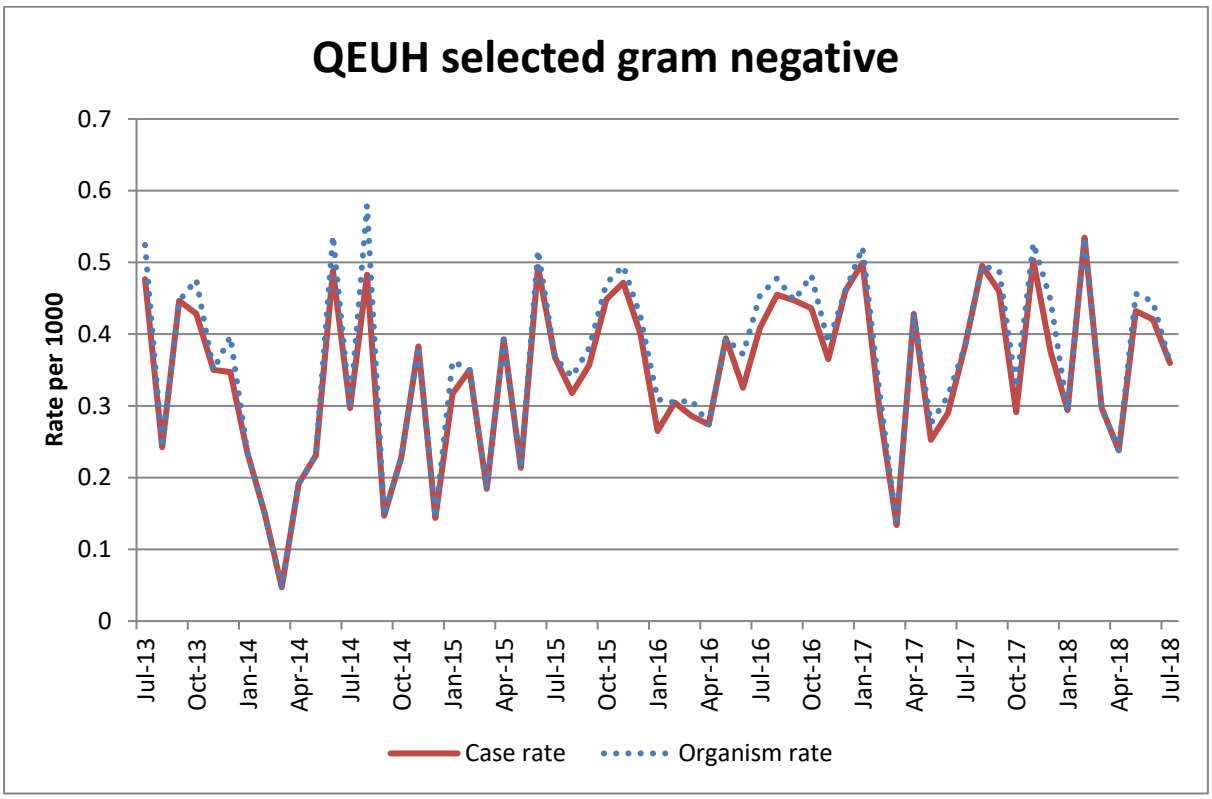
Further actions:

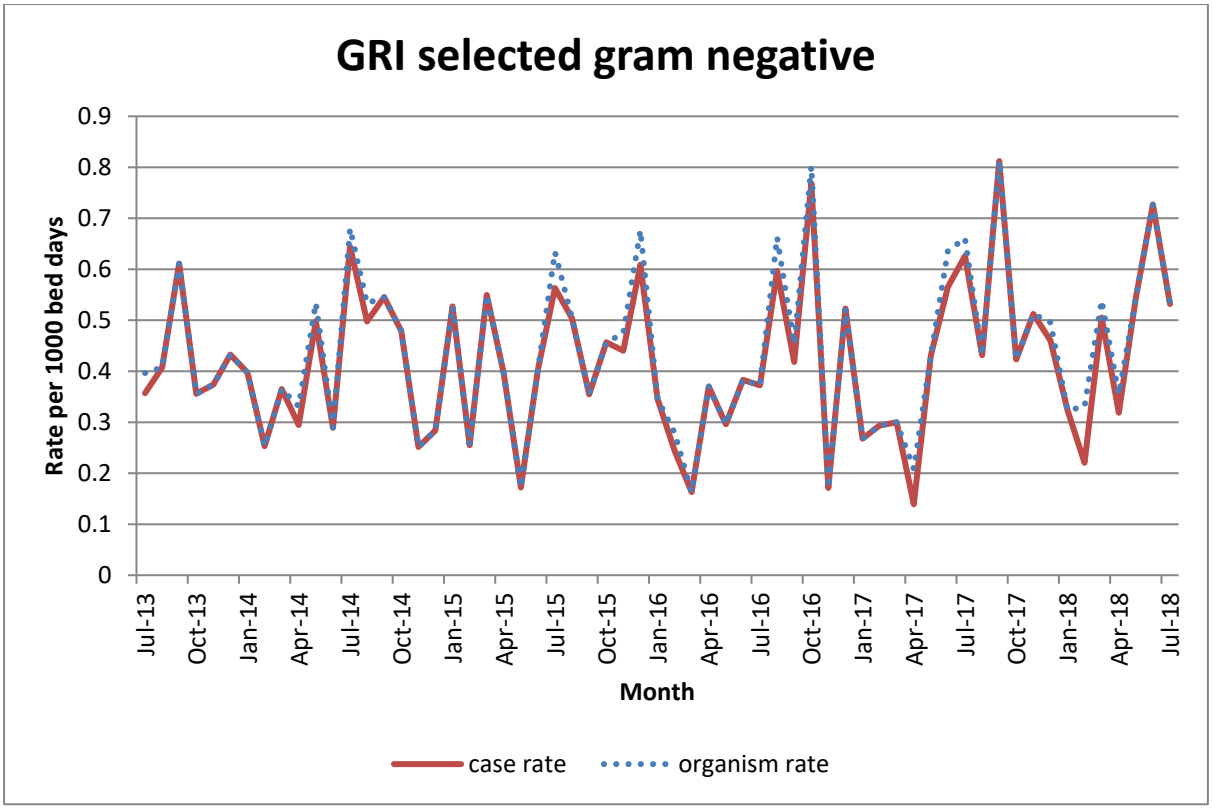
- Formal analysis to define trends in data, including testing of aberration detection
- Consider how best to analyse data to minimise denominator artefact
- Include oxidase negative/non-specific gram negatives in analysis

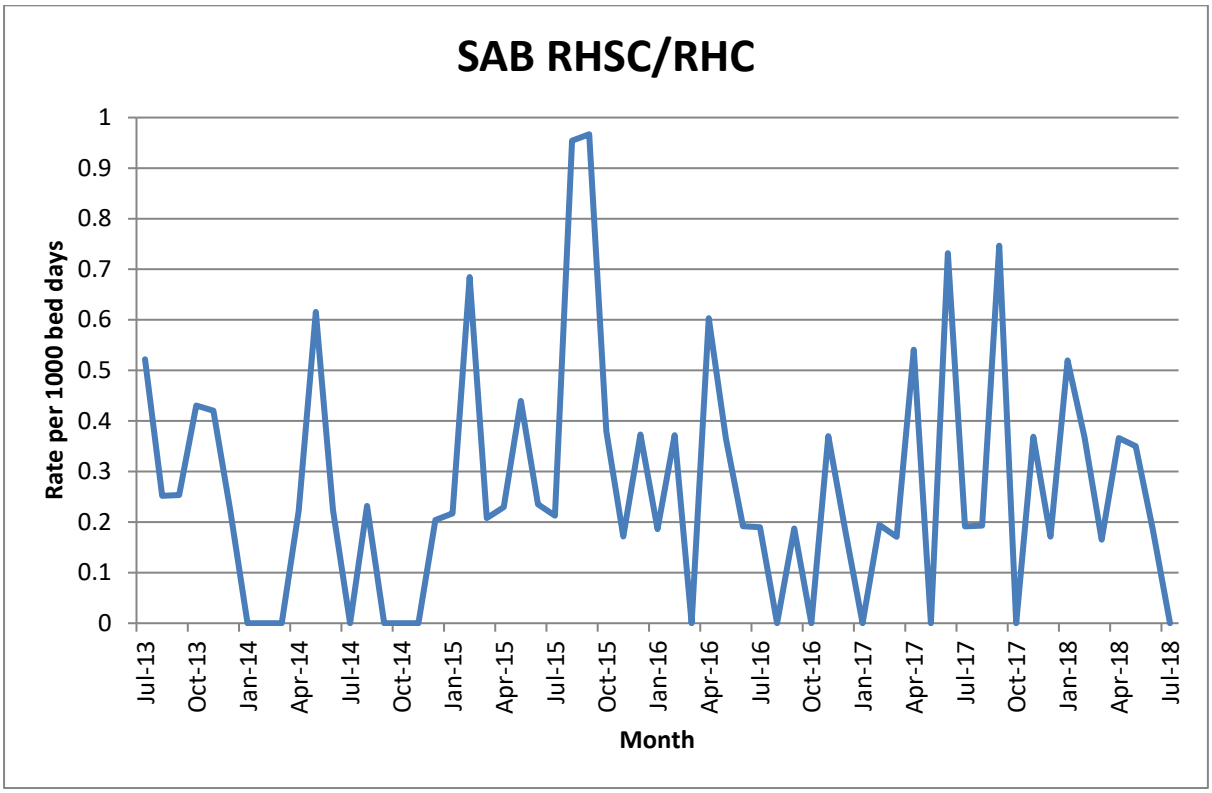
Once these additional analyses are completed, the IMT should consider:

- What is the true baseline rate of gram negative bacteraemia
- Potential causal factors for changes in level or trend, or for deviation from that baseline.


RHSC/RHC E. Coli bacteraemia rate
Cases per 1000 bed days
0.9
0.8
0.7
0.6
0.5
0.4
0.3
0.2
0.1
0
Jul-13
Oct-13
Jan-14
Apr-14
Jul-14
Oct-14
Jan-15
Apr-15
Jul-15
Oct-15
Jan-16
Apr-16
Jul-16
Oct-16
Jan-17
Apr-17
Jul-17
Oct-17
Jan-18
Apr-18
Jul-18


QEUH selected gram negative
Rate per 1000
0.7
0.6
0.5
0.4
0.3
0.2
0.1
0
Jul-13
Oct-13
Jan-14
Apr-14
Jul-14
Oct-14
Jan-15
Apr-15
Jul-15
Oct-15
Jan-16
Apr-16
Jul-16
Oct-16
Jan-17
Apr-17
Jul-17
Oct-17
Jan-18
Apr-18
Jul-18
Case rate
Organism rate


GRI selected gram negative
Rate per 1000 bed days
0.9
0.8
0.7
0.6
0.5
0.4
0.3
0.2
0.1
0
Jul-13
Oct-13
Jan-14
Apr-14
Jul-14
Oct-14
Jan-15
Apr-15
Jul-15
Oct-15
Jan-16
Apr-16
Jul-16
Oct-16
Jan-17
Apr-17
Jul-17
Oct-17
Jan-18
Apr-18
Jul-18
Month
case rate
organism rate


SAB RHSC/RHC
Rate per 1000 bed days
1
0.9
0.8
0.7
0.6
0.5
0.4
0.3
0.2
0.1
0
Jul-13
Oct-13
Jan-14
Apr-14
Jul-14
Oct-14
Jan-15
Apr-15
Jul-15
Oct-15
Jan-16
Apr-16
Jul-16
Oct-16
Jan-17
Apr-17
Jul-17
Oct-17
Jan-18
Apr-18
Jul-18
Month

Appendix: list of selected gram negative organisms

Achromobacter xylosoxidans

Acinetobacter lwofii

Acinetobacter ursingii

Brevundimonas versicularis

Burkholderia cepacia

Cedecea lapagei

Chryseobacterium indologenes

Commamonas testosterone

Cupriavidus gilardii

Cupriavidus pauculus

Delftia acidovorans

Elizabehtkingia meningospetica

Enterobacter cloacae

Klebsiella pnuemoniae

Morganella morganii

Pantoea agglomerans

Paracoccus sp

Pseudomonas chlororaphis

Pseudomonas fluorescens

Pseudomonas oryzihabitans

Pseudomonas putida

Pseudoxanthomonas Mexicana

Ralstonia picketii

Rhizobium radiobacter

Serratia fonticola

Shewanella puterfaciens

Sphingomonas species

Stenotrophomonas maltophilia

L8 Risk Assessment

(Pre-Occupancy)

NHS Greater Glasgow & Clyde

South Glasgow University Hospital

Site Survey Date: Site survey completed 29th April 2015
Issued as Draft Document for comment by NHS Estates
Next Review Date: Continual review recommended during occupation period.

VAT Registration No. 743 0970 35 Company Registration Number SC197200
14 Canyon Road, Wishaw ML2 0EG T: 01698 536790 E: office@dmawater.co.uk

LEGIONELLA RISK ASSESSMENT

Report carried out by	DMA Water Treatment Ltd
Address	14 Canyon Road Netherton Wishaw ML2 0EG
Telephone No.	[redacted]
Fax No.	[redacted]
e-mail	[redacted]
Website	www.dmawater.co.uk
DMA Contacts	Allan McRobbie Compliance Manager [redacted] Mike Kinghorn Director [redacted] David Watson Director [redacted]

Final Date of Assessment (On Site)	29th April 2015
Risk Assessor	Allan McRobbie [redacted]
Assisted By	David Watson [redacted]

Risk Assessment reviewed by	Mike Kinghorn
Position	Director/L8 Risk Assessor
Signature	[redacted]
Date	1st May 2015

Risk Assessor assisted on site by (Site Representative)	Various assistance provided to DMA by: Mercury Engineering – Ciaran Kellegher NHS – Ian Powrie, Jim Guthrie, Mel McMillan, Brian Lavery
Knowledge of systems being surveyed	Variable levels of knowledge as site survey being carried out immediately after handover and Estates staff still in familiarisation period.

Report Commissioned by:	Ian Powrie (NHS Estates)
Report Issued to:	Ian Powrie (NHS Estates)
Format of Report:	Electronic and Hard Copy
	The findings included within the report have been communicated throughout the assessment process by Allan McRobbie and David Watson of DMA Water Treatment Ltd to NHS Estates staff (Ian Powrie and Jim Guthrie) verbally in both formal and informal meetings and via email.

N.B. The findings and recommendations presented in this report have been based on information made available and inspection of areas made accessible by site staff during the survey. DMA are only able to assess areas/systems, which they have been given access to and using information supplied by site personnel. This survey was undertaken only on pipe work/areas that were accessible and visible, and it is possible that some sections remained hidden during the survey. Schematic drawings, where produced, and how services link up, have been assumed to run as indicated using basic engineering principles and our experience. However, no responsibility can be accepted for systems and/or areas, which DMA have not been provided access to, or as a result of incorrect, misleading information supplied or information not provided. No guarantees as to the completeness of the information within this report are provided.

LEGIONELLA RISK ASSESSMENT

Legionella Control Association
KEEPING WATER SYSTEMS SAFE

Legionella Control Association

A Recommended Code of Conduct for Service Providers

Certificate of Registration

This is to certify that the following company has submitted a registration under the Conditions of Compliance as laid out in the LCA's Code of Conduct for Service Providers

Name of Company: **DMA Water Treatment**

Registration Number: **2012/2218** Certificate valid until: **31st August 2015**

Registration under the following services categories:

- **(1) Legionella Risk Assessment Services**
  - 1.1 Hot and Cold Water Services
  - 1.2 Evaporative Cooling Systems
  - 1.3 Process and Other Systems
- **(2) Water Treatment Services**
  - 2.1 Chemicals
  - 2.2 Dosing and/or Control Systems
  - 2.3 On-site Analytical and Monitoring Services
- **(3) Hot and Cold Water Monitoring and Inspection Services**
- **(4) Cleaning and Disinfection Services**
- **(5) Independent Consultancy Services**
- **(6) Training Services**
- **(7) Legionella Analytical Services**
  - 7.1 Sampling
  - 7.2 Laboratory Analysis
  - 7.3 Interpretation of Analysis
- **(8) Plant and Equipment Services**
  - 8.1 Installation
  - 8.2 Refurbishment
  - 8.3 Servicing
  - 8.4 Design and Supply

This Certificate is only valid if the Company named is listed on the LCA website "Directory of Suppliers"

WMS THE WATER MANAGEMENT SOCIETY

Signed: [redacted] *Chairman, Executive Committee*

[redacted] *Certificate Secretary*

BACS British Association for Chemical Specialities

Legionella Control Association Limited. www.legionellacontrol.org.uk

Registered in England and Wales No. 8502723

Compliance with relevant health and safety regulations (including avoidance of, or reduction of risk to, exposure to Legionella) is the sole responsibility of the statutory duty holder, being the person in control of the premises or systems where any relevant risk is present. The Legionella Control Association (LCA) Code of Conduct is designed to help service providers establish appropriate management systems to control the risk from Legionella. The LCA assesses the systems of LCA members upon initial registration, reviews annually upon re-registration, and re-assesses by periodic company audits. The LCA cannot and does not carry out other regular supervision of its members' commitments to the Code of Conduct nor their compliance with other LCA guidelines. A valid LCA certificate of registration only confirms that a service provider has satisfied LCA requirements for registration and re-registration. It does not confirm the service provider's actual compliance with their commitments to the LCA Code of Conduct and/or other LCA guidelines. The LCA does not approve specific products or services as being effective in controlling Legionella or verify the competence of service providers' staff and sub-contractors. The LCA accepts no liability for any omission or any act carried out in reliance on the LCA Code of Conduct or other LCA guidelines, or any loss or damage resulting from non-compliance with such documents.

LEGIONELLA RISK ASSESSMENT

City & Guilds

The Frontline Skills Framework - Utilities (5831) - Legionella

is awarded to
Allan Ross McRobbie

who attended
Develop Training Ltd

This holder has a number of formal Unit Credits by which this Award was achieved

It is recommended that this qualification is renewed after a period of three years

Awarded 24 November 2014 241114/5831-54/023703P/IVN6131/M/11/09/81

5501246063/10

[redacted]

Sir John Armitt, CBE FREng FCGI
Chairman
The City and Guilds of London Institute

[redacted]

Chris Jones
Director-General
The City and Guilds of London Institute

C001

[redacted]

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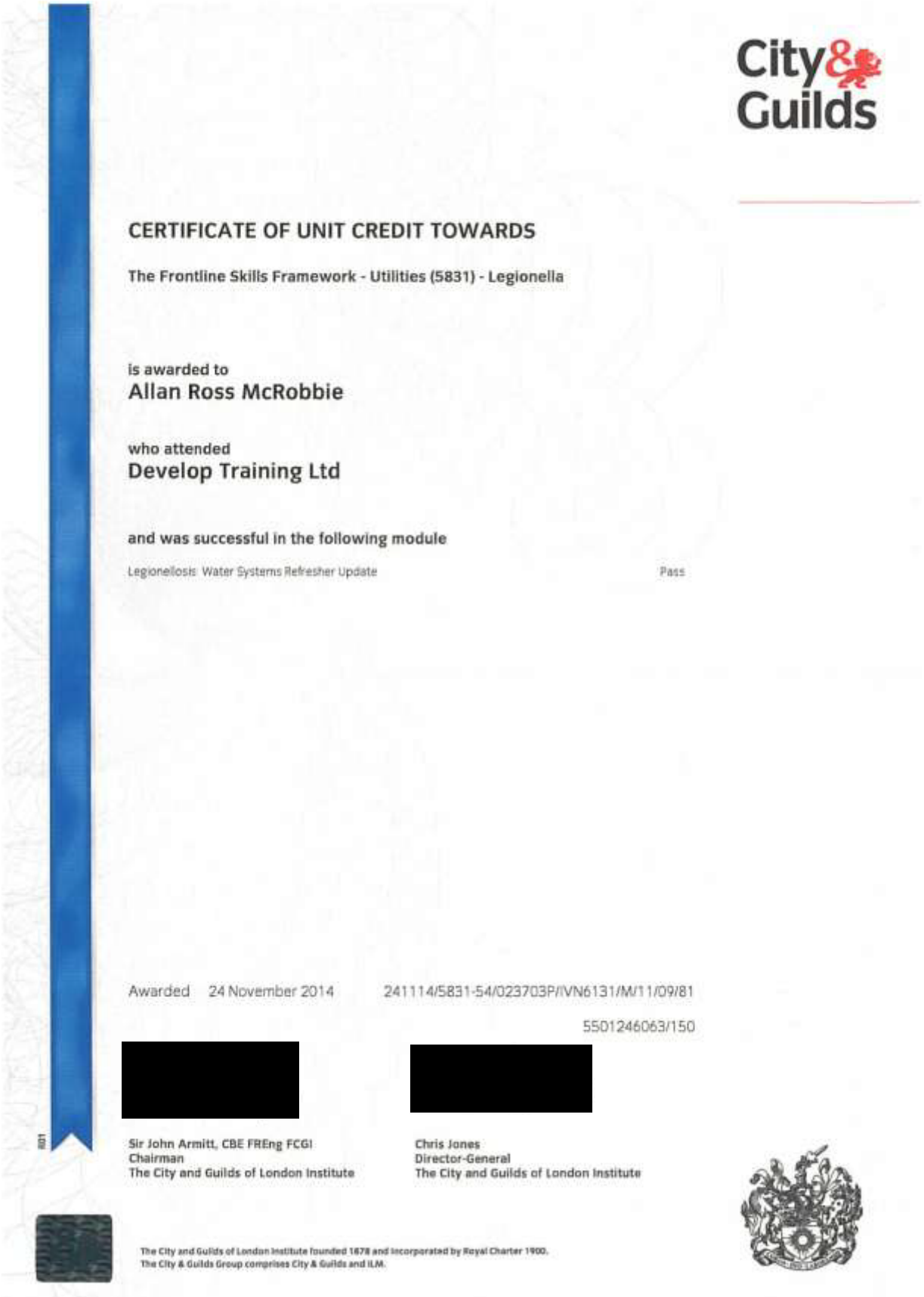
LEGIONELLA RISK ASSESSMENT



City & Guilds

CERTIFICATE OF UNIT CREDIT TOWARDS

The Frontline Skills Framework - Utilities (5831) - Legionella

is awarded to
Allan Ross McRobbie

who attended
Develop Training Ltd

and was successful in the following module

Legionellosis: Water Systems Refresher Update — Pass

Awarded 24 November 2014 241114/5831-54/023703P/IVN6131/M/11/09/81

5501246063/150

[redacted]

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LEGIONELLA RISK ASSESSMENT

DEVELOP
training that transforms

This is to certify that

Allan McRobbie

has successfully completed the course

BS8/SP – Legionella HSG 274 Part 1 Update and Interpretation

at

Falkirk

on

25 September 2014

[redacted]

00028523

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City & Guilds

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Develop Training Ltd

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Awarded 24 November 2014 241114/5831-54/023703P/RD4043/M/13/02/72

550124606J/110

[redacted]

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Chris Jones
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LEGIONELLA RISK ASSESSMENT

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CERTIFICATE OF UNIT CREDIT TOWARDS

The Frontline Skills Framework - Utilities (5831) - Legionella

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David Watson

who attended
Develop Training Ltd

and was successful in the following module

Legionellosis Water Systems Refresher Update — Pass

Awarded 24 November 2014 241114/5831/54/023703P/IRD4043/M/13/02/72

550124/063/250

[redacted]

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LEGIONELLA RISK ASSESSMENT

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BS8/SP – Legionella HSG 274 Part 1 Update and Interpretation

at

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on

25 September 2014

[redacted]

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DAVID WATSON

AB/01

MANUFACTURER'S CERTIFICATE OF CALIBRATION

Date Of Issue:Monday, 13 October 2014

Certificate Issued By:Joe Heath

Instrument Description:Therma Elite Thermometer

Instrument Serial Number:D14370227

Ambient Temperature:22°C±2°C Ambient Humidity: <80 %rh

UKAS Certified Reference Instruments: Prema 6001 / Hart 1502 + SPRT

Results:	Test Temperature °C	Instrument Reading °C
	0	0.0
	1000	1000

Uncertainty of Calibration ± 0.4°C
Instrument only results are conversion of electrical simulation calibration

This is to certify that the above Instrument has been calibrated against laboratory standards which are traceable via International Agreement, to all major National Standards, including the NPL and NIST.

Authorised by: [redacted]

www.etiltd.com

Easting Close, Worthing, West Sussex, BN14 8HQ
tel: 01903 202151, fax: 01903 202445 email: sales@etiltd.com

THE QUEEN'S AWARDS FOR ENTERPRISE: 2012

ALLAN M°ROBBIE

AC/01

MANUFACTURER'S CERTIFICATE OF CALIBRATION

Date Of Issue:Monday, 13 October 2014

Certificate Issued By:Joe Heath

Instrument Description:Therma Elite Thermometer

Instrument Serial Number:D14410227

Ambient Temperature:22°C±2°C Ambient Humidity: <80 %rh

UKAS Certified Reference Instruments: Prema 6001 / Hart 1502 + SPRT

Results:	Test Temperature °C	Instrument Reading °C
	0	0.0
	1000	1000

Uncertainty of Calibration ± 0.4°C
Instrument only results are conversion of electrical simulation calibration

This is to certify that the above Instrument has been calibrated against laboratory standards which are traceable via International Agreement, to all major National Standards, including the NPL and NIST.

Authorised by: [redacted]

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THE QUEEN'S AWARDS FOR ENTERPRISE: 2012

A43293438

LEGIONELLA RISK ASSESSMENT

Table of Contents

LEGIONELLA RISK ASSESSMENT

Section 1

Executive Summary

LEGIONELLA RISK ASSESSMENT

Executive Summary

Building Overview

The new South Glasgow University Hospital and Royal Hospital for Sick Children is a new 1109 bedded Adult Hospital and a 256 bedded Children's Hospital. This facility will have the biggest Critical Care complex and one of the biggest Emergency Departments in Scotland. The facility will offer acute specialist inpatient care, medical day care services and also outpatient clinics servicing the local population.

The 14-floor adult hospital and will contain 1,109 beds and state of the art Emergency, Acute Receiving, Critical Care, Theatres and Diagnostic Services.

The new children's hospital, with a separate identity and entrance, is adjoined to the adult hospital and with 256 beds over five storeys it will replace the existing Royal Hospital for Sick Children located in Yorkhill.

The children's hospital will provide a large number of specialist services to the West of Scotland and the wider population of Scotland in addition to the full range of secondary care services to people of Greater Glasgow and Clyde. Specialist services include: cardiology and cardiac surgery, renal and bone marrow transplantation. For a number of these specialised services, the children's hospital is recognised as the sole provider in Scotland.

The construction phase is due to end on 26th January 2015 with phased occupancy of patient areas beginning on 26th April 2015 and full working occupancy scheduled for 26th July 2015.

Water Services

There are 2 separate incoming mains water supplies serving the Adults and children's hospital building. These enter the building in the basement manifold room and basement tank room and run into the tank room to serve 4 off Raw Water storage tanks. These incoming mains both have double check valves and water meters fitted as they enter the building. The water meters are linked to the BMS system and allow the user to cross reference the quantity of water used against the quantity indicated on the external meter. This will highlight if there are any leaks on the external water main.

Each mains supply feeds a separate side of each split Raw Water storage tank ensuring continuity of supply if one of the mains services was to be in interrupted or contaminated.

From the Raw Water tanks the water is then filtered through the filtration plant before being stored in the potable bulk cold water storage tanks. All cold water storage tanks are 2 compartment tanks and are piped in such a way as to allow tank maintenance without disrupting the water supply to the building.

There are 5 water storage tanks in the building:

- 2 No. 100,000 Litre Raw water storage break tanks
- 2 No. 275,000 Litre Potable bulk cold water storage tanks
- 1 No. 2,800 Litre Trade water storage tank

There are 2 No. water booster sets in the water tank room. Each booster set is set to a different set point pressure depending on which plantroom it serves. In the event of failure each booster can also be switched to the other set point pressure.

- BS01 – Feeding Plantroom 31, 32 & 33 - 7.7 Bar
- BS02 – Feeding Plantroom 21, 22 & 41 – 5 Bar

LEGIONELLA RISK ASSESSMENT

From the 2 No. water booster sets there are 8 domestic water systems:

- Plantroom 21
  - Via a Pressure reducing valve (PRV) the BCWS feed 21CAL01/02/03
- Plantroom 22
  - Via a Pressure reducing valve (PRV) the BCWS feed 22CAL01/02/03
- Plantroom 31 – 122
  - BCWS feeds 31CAL01/02/03
- Plantroom 31 – 128
  - Via a Pressure reducing valve (PRV) the BCWS feeds 31CAL07/08/09
- Plantroom 31 – 129
  - BCWS feeds 31CAL04/05/06
- Plantroom 32
  - BCWS feeds 32CAL01/02/03
- Plantroom 33
  - BCWS feeds 33CAL01/02/03
- Plantroom 41
  - BCWS feeds 41CAL01/02/03

The water supply into each plantroom is metered by a CWS flow meter. This allows for monitoring of specific parts of the system for energy purposes.

From the plantroom supply the BCWS is distributed to each riser and the bank of calorifiers. The water in the calorifiers is heated via a plate heat exchanger (feed from the MTHW circuit) on each calorifier skid.

The BCWS and HWS F&R are then distributed together allowing for positive separation of systems/plantrooms on the floors. The hot water is circulated to the outlet and back to the calorifiers by a hot water return pump so that temperature is maintained throughout the system. This ensures hot water is available within 1 minute at every outlet.

N.B. *Domestic water system description above as provided by Brookfield Multiplex.*

LEGIONELLA RISK ASSESSMENT

Risk Assessment Summary

Site Name	South Glasgow University Hospital (Adult Hospital and Children's Hospital)	
No of Storeys	14 in Adult Hospital and 6 in Children's Hospital.	
Date of construction	Completed and handed over to NHS in January 2015 for phased occupation commencing April 26th 2015	
Date water services last upgraded	N/A	
Is building used by potentially "at Risk" groups?	Yes – persons with acute medical conditions	As the building is used by persons with acute underlying medical conditions which increases susceptibly to contracting legionellosis then the requirements for L8, HSG 274 and HTM/SHTM 04-01 compliance is of paramount importance.
Is there a history of legionella colonisation of the water system(s) on site?	A water sampling programme including potable samples (TVC at 22°C, 37°C, e-coli and coliforms) and Legionella samples was underway at the time or assessment with sentinel outlets due to be sampled by NHS Estates approximately six weeks prior to department/area occupation. DMA were advised sampling being carried out in accordance with the method statement used by the main contractor prior to handover in order to ensure continuity of methodology. DMA were advised this method statement had been reviewed and deemed as acceptable by NHS Microbiologists and was not submitted to DMA for review or comment. DMA were advised the NHS sampling programme has highlighted a number out of specification Legionella and Potable results and a responsive programme of daily flushing and local disinfections was underway in affected areas. Neither the actual microbiological results returned after sampling nor the method statement for disinfections was not submitted for comment or review by DMA.	
Legionella Management	At time of assessment there was no formal management structure, written scheme or communication protocols and there were significant communication issues between parties involved.	
	High Risk	
	Please refer to Section 9 for supporting data.	
Water Source	All incoming mains water enters the building in the basement plantrooms. Various flushing points have been installed on mains water creating short deadlegs and one Raw Water Tank and one Trades Water tank are valved off creating deadlegs.	
	Govan Road Hardgate Road (Large) Hardgate Road (Small)	Medium Risk Medium Risk Low Risk (As feeds basement sprinkler tanks only)
	Please refer to Section 4 for supporting data	

LEGIONELLA RISK ASSESSMENT

<table>
<tr><td rowspan="3">Domestic CWSTs</td><td colspan="2">The Domestic Cold Water Storage Tanks are located in the basement tank room.

Raw Water CWST 1A inlet isolated with the outlet remaining live and a similar set up on the trades system creating stagnation in both affected tanks which may contribute to any out of specification microbiological results.

There have been issues reported with filtration units failing leading to Bulk Water tanks draining down.

Various flushing points installed on surrounding pipework water creating short deadlegs and expansion vessels not of a flow through design.

N.B. It should be noted that there is no separate dedicated supply to the Renal (or other medical) systems, with all being fed from the Bulk Water system. This means that system disinfections will require to be very carefully scheduled or carried out locally as the disinfection procedure/chemical may interfere with the renal/medical systems and impact on patient welfare.</td></tr>
<tr><td>Raw Water Tanks (x4)
Bulk Water Tanks (x4)
Trades Tanks (x2)</td><td>High Risk
Medium Risk
High Risk</td></tr>
<tr><td colspan="2">Please refer to Section 5 for supporting data</td></tr>
<tr><td rowspan="3">Calorifiers</td><td colspan="2">The domestic hot water systems are fed from a series of Calorifiers located on the 2nd and 3rd floors in the adult hospital and on the 4th floor of the children’s hospital. These calorifiers feed different areas/zones within the Hospital running on a reverse return system.

There are various issues with the calorifiers including temperatures being low due to a heating failure on 21st April, individual calorifiers running at lower temperatures than the linked vessels and returns not achieving the design temperatures of 55°C.

It may be prudent to increase calorifier set points to help maintain 55°C through the system and at the return. This may also increase the cold water usage as more cold water will be required at TMVs to blend to required temperature.

Various flushing points installed on surrounding pipework water creating short deadlegs and expansion vessels not of a flow through design.</td></tr>
<tr><td>Plantroom 21-01/02/03
Plantroom 22-01/02/03
Plantroom 31-01/02/03
Plantroom 31-04/05/06
Plantroom 31-07/08/09
Plantroom 32-01/02/03
Plantroom 33-01/02/03
Plantroom 41-01/02/03</td><td>High Risk
High Risk
High Risk
Low Risk
High Risk
High Risk
Medium Risk
Low Risk</td></tr>
<tr><td colspan="2">Please refer to Section 6 for supporting data</td></tr>
</table>

LEGIONELLA RISK ASSESSMENT

Domestic Hot and Cold Water Outlets	The distribution temperatures on the domestic water systems recorded by DMA have largely replicated those provided to DMA (on Zutec) for the commissioning phase and those being recorded by estates staff. The cold water temperatures recorded by DMA vary considerably with the majority being more than 5°C higher than those recorded at the water tanks and with peak temperatures of 30°C being noted. Additional control measure such as flushing, disinfections and background dosing flushing should be implemented until such times as the area/department fully occupied, storage and distribution temperatures and microbiological results are consistently satisfactory. The vast majority of hot outlets are fed via TMV taps (Horne in clinical areas and Markwik in non-clinical areas). There are numerous long lengths to pipework to "non-domestic" systems connected onto the main Bulk Water system (see section 8 for details). No outlets on the Trades system have been designated as "sentinel outlets". Due to the type of system and the extended pipe runs to the outlets it may be prudent to designate all outlets from this system as sentinel and include in monthly monitoring and site flushing regime. There are connection points onto other "non-domestic" outlets (see Section 8 for details) which are connected to the Bulk Water system. It is advised that Estates (or Brookfield/Mercury) confirm these systems have suitable backflow protection installed or if necessary suitable backflow protection fitted. It is also advised that as the lines to these systems will often have a very low turnover a double check valve or similar should be fitted as close as practicable to the tee-off point to prevent potentially stagnant water from contaminating the domestic system.
	Some outlets on the water systems have been described as High Risk for this site.
	Please refer to Section 7 for supporting data.
Other Risk Systems	There are various other risk systems fitted throughout the hospital building including Hydrotherapy Pool, Arjo Baths, Dental equipment, Emergency showers, Irrigation systems, Sprinkler/Wet fire fighting systems, Renal dialysis (x 2), Endoscopy Wash, Water softeners, Medical Gases/Medical Equipment (e.g. Nebulisers, incubators, etc.), Dry/Wet (Adiabatic) Cooling (e.g. MRI chillers), Closed heating systems, Closed chilled water systems, Steam Humidification, Air Conditioning
	Some other risk systems within the building have been described as High Risk for this site.
	Please refer to Section 8 for supporting data.

LEGIONELLA RISK ASSESSMENT

Should background dosing be considered for this site?	Yes. However as renal dialysis, and other medical systems, are fed directly from the Raw/Bulk Water supply any background dosing system would have to be fully risk assessed and approved prior to installation.
Additional Comments	The identification/numbering system used as reference points within this document are the door numbers as provided by Brookfield on Zutec. The door numbers do not always run sequentially in each area which can make locating individual rooms/outlets very difficult, particularly in the larger department areas. It was also noted that there are some duplicate identifications in the A&E department with IDs being replicated in both the Adult and Children's Hospital. Where there were additional numbered doors/areas within a room DMA have referred only to the outlets within the room identified and have not included those in adjoining rooms.

LEGIONELLA RISK ASSESSMENT

Section 2

Domestic Water System Recommendations

LEGIONELLA RISK ASSESSMENT

Suggested Remedial Action Timescales

Remedial Action Category	Recommended Remedial Action Timescale	Action
1	**Immediately / as soon as reasonably practicable**	**Urgent Significant Investigation & Urgent Remedial Action Required.** Senior Management Action Required. Carryout Review of Control Procedures Recommendations within this category should be carried out immediately/as-soon as-is-reasonably practicable. where appropriate remedial actions to rectify the faults cannot be taken **immediately/as-soon as-is-reasonably practicable** alternative actions to reduce the risk should be carried out, and continue to be carried out, until such times as recommended actions can be completed.
2	**As soon as reasonably practicable**	**Significant Investigation & Remedial Action Required.** Senior Management Action Required. Carryout Review of Control Procedures Recommendations within this category should be carried out **as-soon as-is-reasonably practicable**. Where appropriate remedial actions to rectify the faults cannot be carried out quickly, alternative actions to reduce the risk should be carried out, and continue to be carried out, until such times as recommended actions can be completed.
3	**Within 3 months**	**Investigate/Reduce.** Remedial Actions Required. Management responsibility should be specified. Recommendations within this category should be carried out in a timely manner, though simple and/or inexpensive tasks which would reduce the risk should be carried out as-soon-as-reasonably-practicable (e.g. **Within 3 months**). Additional monitoring/inspection to ensure risk does not increase should be carried out until actions completed.
4	**At first available opportunity**	**Maintain Level** Managed by Routine Planned Preventative Maintenance Procedures Whilst recommendations within this category do not significantly Alter the risk it is still advised that these actions are carried out **at first available opportunity**, typically within a 12 month period of recommendations being made.

For Details of "Other Risk Systems" please refer to Section 8 and for Legionella Management Recommendations please refer to Section 9 of this assessment.

N.B. Prior to any alterations being carried out on fire systems (where recommended) the fire brigade and/or site fire safety consultants should be consulted and approval of changes received

LEGIONELLA RISK ASSESSMENT

Location/Plant Item	Recommendation	Remedial Action Category	Assigned to	Actions Taken	Completed
Water Source Basement Main Tank plantroom Hardgate Road (Small)	As this mains lines is likely to have a low turnover of water DMA would recommend the NHS confirms that this main is separated from domestic water mains by a double check valve or similar (possibly external to building) to prevent potentially stagnant water from contaminating the domestic mains.	2			
Water Source Basement Main Tank plantroom Hardgate Road (Large)	Mains to Raw Water Tank 1A valved off at time of survey (and had been for a considerable period of time) prior to DMA surveying. Mains line should be incorporated into the site flushing regime until such times as issues with valves etc corrected. Please refer to CWST section for further recommendations.	2			
Water Source Basement Main Tank plantroom Govan Road	RHS Trades Water Tank inlet valved off creating a deadleg. This should be incorporated into the weekly flushing regime until such times as CWST issue corrected. Please refer to CWST section for further recommendations.	2			
Water Source Basement Main Tank plantroom Hardgate Road (Large)	Deadlegs (drain points/injection points) should be removed or incorporated into low use outlets flushing regime (for recs on isolated mains into T1A please see CWST recommendations)	3			
Water Source Basement MTHW/Chilled plantroom Govan Road	Deadlegs (drain points/injection points) should be removed or incorporated into low use outlets flushing regime.	3			
Water Source Basement Main Tank plantroom Hardgate Road (Large)	All plant items, pipework and valves should be labelled for identification purposes.	4			
Water Source Basement Main Tank plantroom Hardgate Road (Small)	All plant items, pipework and valves should be labelled for identification purposes.	4			
Water Source Basement MTHW/Chilled plantroom Govan Road	All plant items, pipework and valves should be labelled for identification purposes.	4			

LEGIONELLA RISK ASSESSMENT

Location/Plant Item	Recommendation	Remedial Action Category	Assigned to	Actions Taken	Completed
Note:	It should be noted that there is no separate dedicated supply to the Renal (or other medical) systems, with all being fed from the Bulk Water system. This means that system disinfections will require to be very carefully scheduled or carried out locally as the disinfection procedure/chemical may interfere with the renal/medical systems and impact on patient welfare.				
CWST Basement Raw Water 1A	At the time of survey DMA noted that the Hardgate Road supply into Raw Water Tank 1A has been isolated creating a deadleg and NHS Estates confirmed this had been isolated for a number of weeks pending repair by Mercury Engineering. This has still not been completed at the time of this report. The outlet from this tank has remained live during this period which means this is acting as a balance tank with no through flow of water leading to stagnation and film formation on the water surface. DMA would recommend this tank is completely isolated from service until the mains inlet can be repaired, and the CWST cleaned and disinfected prior to re-use (including the mains line).	**2**			
All CWSTs	Ensure linked CWSTs are balanced to provide equal throughput of water through each tank.	**2**			
CWST Basement Raw Water	Storage temperatures indicate heat gain between incoming mains and stored water. Further monitoring recommended with capacities altered if required to match usage requirements.	**2**			
CWST Basement Tank plantroom Raw Water	Shut off mains to T-1A requires to be disinfected prior to reinstatement.	**2**			
CWST Basement Tank plantroom Raw Water	Greater than 2°C temp rise from mains to stored water in CWST 1A and 1B, investigate and correct.	**2**			
CWST Basement Tank plantroom Trades Water Water	RHS side of the Trades tank was valved off due to a reported inlet valve issue (though tank full with signs of stagnation). DMA would advise the tank is cleaned and disinfected prior to the tank being reinstated.	**2**			

LEGIONELLA RISK ASSESSMENT

Location/Plant Item	Recommendation	Remedial Action Category	Assigned to	Actions Taken	Completed
CWST Basement Tank plantroom Bulk Water	There are however some connection points onto other "non-domestic" outlets such as renal dialysis, endoscopy wash, pressurisation units, steam humidifier units and MRI Chiller cooling which are connected to the Bulk water system. It is advised that Estates (or Brookfield/Mercury) confirm these systems have suitable backflow protection installed or if necessary suitable backflow protection fitted. It is also advised that as the lines to these systems will often have a very low turnover a double check valve or similar should be fitted as close as practicable to the tee-off point to prevent potentially stagnant water from contaminating the domestic system.	2			
Bulk Water CWSTs (and Filtration Units)	Until site staff have access to the BEMS and the filter system monitoring it may be advantageous to leave the bypass on Bulk Water tanks open to link all 4 tank outlets, ensuring all tanks are balanced and to introduce an inspection/monitoring regime at suitable intervals.	2			
All Raw & Bulk CWSTs	A suitable screened vent should be fitted to the warning pipe.	3			
CWST Basement Tank plantroom Bulk Water	DMA noted small debris including washers in Bulk Water Tank 2B and would advise that this tank is cleaned to remove debris and then disinfected. The volume of debris within the water tanks appeared to be more than would be expected considering the Bulk Water tanks are fed via 0.5 micron filter sets.	3			
CWST Basement Tank plantroom Bulk Water	Ensure short connection between booster sets is thoroughly flushed before use should it ever be required.	3			
CWST Basement Tank plantroom Bulk Water	Ideally drain points should be fitted to pump manifolds to allow end of lines to be flushed.	3			
CWST Basement Tank plantroom Bulk Water	There are various drain points and bypass valves fitted to the pipework in the plantroom. These should be included in site flushing regime.	3			
All Raw & Bulk CWSTs	Additional access hatches on tanks for cleaning/inspection purposes should be considered.	3			
CWST Basement Tank plantroom Raw Water	There are drain down points on pipework. These should be included in site flushing regime.	3			
CWST Basement Tank plantroom Trades Water	A suitable screened vent should be fitted to the overflow.	3			
All expansion vessels	Wherever possible/practical expansion vessels should be 'flow through' vessels.	3			

LEGIONELLA RISK ASSESSMENT

Location/Plant Item	Recommendation	Remedial Action Category	Assigned to	Actions Taken	Completed
All expansion vessels	Expansion vessel should be suitably insulated.	3			
All expansion vessels	As expansion vessels as not 'flow through' vessels these should be included in the site flushing regime.	3			
CWST Basement Tank plantroom Trades Water	Ideally a drain should be fitted to pump manifold to allow end of lines to be flushed.	3			
All CWSTs	All plant items, pipework and valves should be labelled for identification purposes.	4			

LEGIONELLA RISK ASSESSMENT

Location/Plant Item	Recommendation	Remedial Action Category	Assigned to	Actions Taken	Completed
Calorifier Plantroom 21-01/02/03	When DMA were on site on the 21st of April there was a significant drop on the temperatures of the calorifiers which we understand was caused by a failure on the heating system. Temperatures recorded on these calorifiers on this day were 40-45°C. This represented a significant break in the control system and there were no records of any remedial or corrective actions and no records of additional control measures. DMA would advise corrective actions and additional control measures (e.g. system pasteurisation/disinfection) should be carried out in accordance with SHTM 04-01 in instances of this type. When DMA re-checked the affected calorifier temperatures on 27th April 2015 the temperatures had partially recovered though the central calorifier was still reading low.	2			
Calorifier Plantroom 21-01/02/0	Central calorifier (02) flow temperature lower than those wither side suggesting this is acting a lead calorifier. Ensure linked calorifiers are balanced to provide equal throughput of water through each calorifier.	2			
Calorifier Plantroom 22 01/02/03	Central Calorifier (02) temperature lower than the other calorifiers. Ensure linked calorifiers are balanced to provide equal throughput of water through each calorifier. DMA understand this is due to an issue with the MTHW system being shut off (or not operational in some other way). Corrective actions should be taken and calorifier pasteurised/disinfected and brought up to full temperature.	2			

LEGIONELLA RISK ASSESSMENT

Location/Plant Item	Recommendation	Remedial Action Category	Assigned to	Actions Taken	Completed
Calorifier Plantroom 31-01/02/03	When DMA were on site on the 21st of April there was a significant drop on the temperatures of the calorifiers which we understand was caused by a failure on the heating system. Temperatures recorded on these calorifiers on this day were 40-45°C. This represented a significant break in the control system and there were no records of any remedial or corrective actions and no records of additional control measures. DMA would advise corrective actions and additional control measures (e.g. system pasteurisation/disinfection) should be carried out in accordance with SHTM 04-01 in instances of this type. When DMA rechecked the calorifiers on 27th April they appeared to have recovered fully.	2			
Calorifier Plantroom 31-07/08/09	When DMA were on site on the 21st of April there was a significant drop on the temperatures of the calorifiers which we understand was caused by a failure on the heating system. Temperatures recorded on these calorifiers on this day were 40-45°C. When DMA re-checked the affected calorifier temperatures on 27th April 2015 the calorifiers were still significantly lower than expected (see return line gauge photos in Section 11). This represents a significant break in the control system and DMA would advise corrective actions and additional control measures (e.g. system pasteurisation/disinfection) should be carried out in accordance with SHTM 04-01.	2			
Calorifier Plantroom 32 01/02/03	CCalorifier 32-03 was offline when DMA had an initial site familiarisation walk-round with Mercury Engineering in early January 2015. This calorifier was still offline when DMA were on site on 21st April 2015. This was creating deadlegs on the cold supply, hot flow and hot return to the calorifier and Estates staff were unable to confirm the reason for this calorifier being offline. This calorifier had been reinstated when DMA revisited on 27/04/15 though Estates not aware of any flushing, pasteurisation or disinfection of calorifier being carried out prior to reinstatement. DMA would recommend the calorifier (and hot system) is disinfected/pasteurised and legionella samples taken from the calorifier and system prior to reinstatement to confirm these corrective actions have been effective.	2			

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Location/Plant Item	Recommendation	Remedial Action Category	Assigned to	Actions Taken	Completed
Calorifier Plantroom 33-01/02/03	There is a deadleg on the cold feed at these calorifiers – this should be removed or included in site flushing regime	2			
All calorifiers	The return temperatures recorded at the calorifiers were consistently below 55°C which DMA were advised was the control set point for these, though when calorifiers were at full temperature the returns were reaching 50°C. It may be prudent to increase calorifier set points to ensure calorifier returns remain above 55°C as this is the control set point. This may also help maintain a 60°C minimum flow temperature when demand is placed on the calorifiers as the building becomes occupied. Increasing the calorifier temperatures may also have the beneficial effect of increasing the cold water usage as more cold water will be required at TMVs to blend water to TMV set point and so may assist in reducing the high cold water temperatures being recorded within the system.	2			
All Calorifiers	Ensure linked calorifiers are balanced to provide equal throughput of water through each calorifier.	3			
All Calorifiers (Circulation Pumps)	Fit caps to ends of spare circulation pump.	3			
All expansion vessels	Wherever possible/practical expansion vessels should be 'flow through' vessels.	3			
All expansion vessels	Expansion vessel should be suitably insulated.	3			
All expansion vessels	As expansion vessels are not 'flow through' vessels these should be included in the site flushing regime.	3			
All Calorifiers	Where practical calorifier internal surfaces should be inspected annually.	4			
All Calorifiers	All plant items, pipework and valves should be labelled for identification purposes. The calorifiers do not have labels on them, instead being labelled at present by a marker pen, with a separate small identification plate on the side of each calorifier. The labelling does not match up in every instance between the hand written and id plate. It is advised that calorifiers have formal identification label attached to each one.	4			
Calorifier Plantroom 41 01/02/03	Vibration couplings should be regularly inspected and maintained in accordance with manufacturers instructions.	4			

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Location/Plant Item	Recommendation	Remedial Action Category	Assigned to	Actions Taken	Completed

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Location/Plant Item	Recommendation	Remedial Action Category	Assigned to	Actions Taken	Completed
Note:	It should be noted that the information and recommendations included within these pages relates to the outlets identified (mostly the sentinel outlets as uploaded onto Zutec), though many of the issues and conditions highlighted will be replicated throughout the hospital. Issues and information included should not be taken as a comprehensive or complete data set and should be treated as a representative sample of the system conditions found within the hospital.				
South Glasgow University Hospital (including Children's Hospital)	As the building is used by persons with acute underlying medical conditions which increases susceptibly to contracting legionellosis then the requirements for L8, HSG 274 and HTM/SHTM 04-01 compliance is of paramount importance.	**2**			
Domestic Water System	There are numerous connection points onto other "non-domestic" outlets such as renal dialysis, endoscopy wash, pressurisation units, steam humidifier units and MRI chiller cooling which are connected to the Bulk Water system. It is advised that Estates (or Brookfield/Mercury) confirm these systems have suitable backflow protection installed or if necessary suitable backflow protection fitted. It is also advised that as the lines to these systems will often have a very low turnover a double check valve or similar should be fitted as close as practicable to the tee-off point to prevent potentially stagnant water from contaminating the domestic system.	**2**			
Domestic Cold Water System	The distribution temperatures on the domestic water systems recorded by DMA have largely replicated those provided to DMA (on Zutec) for the commissioning phase and those being recorded by estates staff. The cold water temperatures recorded by DMA vary considerably with the majority being more than 5°C higher than those recorded at the water tanks and with peak temperatures of 30°C being noted. Additional control measure such as flushing, disinfections and background dosing flushing should be implemented until such times as the area/department fully occupied, storage and distribution temperatures and microbiological results are consistently satisfactory.	**2**			

LEGIONELLA RISK ASSESSMENT

Location/Plant Item	Recommendation	Remedial Action Category	Assigned to	Actions Taken	Completed
Domestic Water System Cold Water Dump Valve System	DMA have been advised by Estates there are ongoing commissioning problems on the cold water dump valve system and the system is not operating as intended. DMA have noted during site surveys there were areas with cold water temperatures in excess of 20°C and dump valves are fitted, but the valves not discharging. Corrective action should be taken and once fully operational the control set points and parameters for discharging should be referenced in site written scheme.	2			
Domestic Hot Water System(s)	The hot water distribution temperatures again largely replicate those from the commissioning phase and estates, with hot temperatures frequently recorded below 55°C at supply to TMVs. It should be noted though that direct hot taps did reach temperatures of 55°C and supply to TMVs was almost invariably above 50°C (see following pages for supportive data and exceptions). As 55°C at all outlets is the control parameter set by SHTM 04-01 corrective actions should be carried out to ensure this is achieved. This may include increasing the calorifier set points - see calorifier sections for further comments and recommendations. Increasing the calorifier temperatures may also have the beneficial effect of improving the cold water temperature profile as more cold water will be required at TMVs to blend water to TMV set point.	2			
Domestic Water System	Due to the temperature deviations from the control parameters noted during the commissioning and handover phase and out of specification NHS microbiological sampling results DMA would recommend fitting supplementary control systems (e.g. background dosing such as chlorine dioxide), in order to maintain microbiological control and/or biofilm monitors (such as BioSense sensors/controller) to assist in focusing remedial actions onto identified areas of microbial activity.	2			

LEGIONELLA RISK ASSESSMENT

Location/Plant Item	Recommendation	Remedial Action Category	Assigned to	Actions Taken	Completed
Domestic Water System	Domestic water pipework runs above ceilings throughout the building. Access for ongoing monitoring will be problematic as ceiling tiles cannot be easily removed within the hospital environment and alternative methods of monitoring should be considered should current BEMS monitoring points not be sufficient for the hot flow and return system (e.g. additional BEMS monitoring points installed).	2			
Domestic Water System	There are numerous connection points on the domestic water system within plantrooms and risers (which DMA have assumed were installed for flushing purposes and bypasses) which are creating deadlegs on the system. It is advised that these be removed wherever practicable or a register of the locations created and points incorporated into the site flushing regime.	2			
Arjo Baths (attached shower)	Consider shortening shower hoses as it was noted that these can in some areas reach into adjacent WCs and WHBs.	2			
All unused equipment connection points	Deadlegs were recorded though these appear to be connections for drinks machines or kitchen appliances which have not been fitted at the time of survey. These should be included into the site flushing regime until such times as they are installed and department area fully functioning.	2			
Outlet 00C Decontamination DCU-003 (Wet Room)	Area should be assessed after building works completed	2			
Outlet 00 Concourse ENT-054 (Shower)	Area/outlets should be flushed/disinfected prior to it being brought into use.	2			
Outlet 00 A&E Courtyard	Cold water temperature too high. Investigate and correct.	2			
Outlet 00 A&E EMC-018 (Toilet)	Cold water temperature too high. Investigate and correct.	2			
Outlet 00 A&E EMC-093 (Bed Bay 18)	Cold water temperature too high. Investigate and correct.	2			
Outlet 00 A&E EMC-111 (Female Change)	Cold water temperature too high. Investigate and correct.	2			
Outlet 00 A&E EMC-135 (Store)	Cold water temperature too high. Investigate and correct.	2			
Outlet 00 Acute Assess AAW-032 (Bathroom)	Cold water temperature too high. Investigate and correct.	2			

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Location/Plant Item	Recommendation	Remedial Action Category	Assigned to	Actions Taken	Completed
Outlet 00 Acute Assess AAW-038 (Toilet)	Cold water temperature too high. Investigate and correct.	2			
Outlet 00 Acute Assess AAW-045 (Treatment Room)	Cold water temperature too high. Investigate and correct.	2			
Outlet 00 Acute Assess AAW-060 (Toilet)	Cold water temperature too high. Investigate and correct.	2			
Outlet 00 Acute Assess AAW-096 (Bathroom)	Cold water temperature too high. Investigate and correct.	2			
Outlet 00 Acute Assess AAW-108 (Bathroom)	Cold water temperature too high. Investigate and correct.	2			
Outlet 00 Acute Assess AAW-163 (Toilet)	Cold water temperature too high. Investigate and correct.	2			
Outlet 00 Acute Assess AAW-193 (Toilet)	Cold water temperature too high. Investigate and correct.	2			
Outlet 00 Acute Assess AAW-226 (Lab)	Cold water temperature too high. Investigate and correct.	2			
Outlet 00 Acute Assess AAW-240 (Toilet)	Cold water temperature too high. Investigate and correct.	2			
Outlet 00 Acute Assess AAW-306 (Toilet)	Cold water temperature too high. Investigate and correct.	2			
Outlet 00 Concourse ENT-052 (Gents Toilet)	Cold water temperature too high. Investigate and correct.	2			
Outlet 00 Discharge DLO-006 (Toilet)	Cold water temperature too high. Investigate and correct.	2			
Outlet 00 Discharge DLO-008 (Consulting Room)	Cold water temperature too high. Investigate and correct.	2			
Outlet 00 OPD OPD0-049 (Treatment Room)	Cold water temperature too high. Investigate and correct.	2			
Outlet 00 Orthotics ORT-015-2 (Staff Change)	Cold water temperature too high. Investigate and correct.	2			
Outlet 00 Orthotics ORT-017 (Disabled)	Cold water temperature too high. Investigate and correct.	2			
Outlet 00 Radiology RAG-068 (Toilet)	Cold water temperature too high. Investigate and correct.	2			
Outlet 00 Radiology RAG-079 (Toilet)	Cold water temperature too high. Investigate and correct.	2			
Outlet 00C A&E EMC-006 (Toilet)	Cold water temperature too high. Investigate and correct.	2			
Outlet 00C A&E EMC-059 (Bed Bay 6)	Cold water temperature too high. Investigate and correct.	2			
Outlet 00C A&E EMC-060 (Bed Bay 5)	Cold water temperature too high. Investigate and correct.	2			

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Location/Plant Item	Recommendation	Remedial Action Category	Assigned to	Actions Taken	Completed
Outlet 00C A&E EMC-100 (Triage)	Cold water temperature too high. Investigate and correct.	2			
Outlet 00C Observation OBW-020 (Bathroom)	Cold water temperature too high. Investigate and correct.	2			
Outlet 00C Observation OBW-061 (Bedroom)	Cold water temperature too high. Investigate and correct.	2			
Outlet 00C OPD OPD-073 (Plaster Room)	Cold water temperature too high. Investigate and correct.	2			
Outlet 00C OPD OPD-075 (Toilet)	Cold water temperature too high. Investigate and correct.	2			
Outlet 00C OPD OPD-120 (Toilet)	Cold water temperature too high. Investigate and correct.	2			
Outlet 00C Radiology RCG-087 (Dirty Utility)	Cold water temperature too high. Investigate and correct.	2			
Outlet 01 Critical Care CCW-017 (Facilities)	Cold water temperature too high. Investigate and correct.	2			
Outlet 01 Medical Day Unit MDU-046 (Facilities)	Cold water temperature too high. Investigate and correct.	2			
Outlet 01 Medical Day Unit MDU-050 (Consulting Room)	Cold water temperature too high. Investigate and correct.	2			
Outlet 01 OPD POA-040 (Consulting Room)	Cold water temperature too high. Investigate and correct.	2			
Outlet 01 OPD OPD1-006 (Toilet)	Cold water temperature too high. Investigate and correct.	2			
Outlet 01 OPD OPD1-008 (Toilet)	Cold water temperature too high. Investigate and correct.	2			
Outlet 01 OPD OPD1-085 (Toilet)	Cold water temperature too high. Investigate and correct.	2			
Outlet 01 OPD OPD1-113 (Measurement Bay)	Cold water temperature too high. Investigate and correct.	2			
Outlet 01 Radiology RAF-087 (Male Change)	Cold water temperature too high. Investigate and correct.	2			
Outlet 01 Radiology RCF-001 (Facilities)	Cold water temperature too high. Investigate and correct.	2			
Outlet 01 Radiology RCF-003 (Facilities)	Cold water temperature too high. Investigate and correct.	2			
Outlet 01 Radiology RNM-007 (Toilet)	Cold water temperature too high. Investigate and correct.	2			
Outlet 01 Radiology RNM-027 (Office)	Cold water temperature too high. Investigate and correct.	2			
Outlet 01 Stroke STW-036 (Bathroom)	Cold water temperature too high. Investigate and correct.	2			

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Location/Plant Item	Recommendation	Remedial Action Category	Assigned to	Actions Taken	Completed
Outlet 01 Stroke STW-047 (Bathroom)	Cold water temperature too high. Investigate and correct.	2			
Outlet 01 Stroke STW-072 (Bathroom)	Cold water temperature too high. Investigate and correct.	2			
Outlet 01C Critical Care CCW-014 (Clinical Physics)	Cold water temperature too high. Investigate and correct.	2			
Outlet 01C Critical Care CCW-098 (Critical Care Bed)	Cold water temperature too high. Investigate and correct.	2			
Outlet 01C Medical Day Unit MDU-008 (Beverage Prep)	Cold water temperature too high. Investigate and correct.	2			
Outlet 01C Theatre THE-078 (Prep room)	Cold water temperature too high. Investigate and correct.	2			
Outlet 01C Theatre THE-102 (Facilities)	Cold water temperature too high. Investigate and correct.	2			
Outlet 01C Theatre THE-106 (Anesthetic room)	Cold water temperature too high. Investigate and correct.	2			
Outlet 01C Theatre THE-157 (Recovery room)	Cold water temperature too high. Investigate and correct.	2			
Outlet 02 Renal RENO-033 (Clean Utility)	Cold water temperature too high. Investigate and correct.	2			
Outlet 02 Theatres THE-280 (Disabled Toilet)	Cold water temperature too high. Investigate and correct.	2			
Outlet 02 Theatres THE-289 (Bed Bay A1)	Cold water temperature too high. Investigate and correct.	2			
Outlet 02 Theatres THE-327 (Recovery)	Cold water temperature too high. Investigate and correct.	2			
Outlet 02C Ward AFD-022 (Toilet)	Cold water temperature too high. Investigate and correct.	2			
Outlet 02C Ward SCH-022 (Bathroom)	Cold water temperature too high. Investigate and correct.	2			
Outlet 02C Ward SCH-023 (Bathroom)	Cold water temperature too high. Investigate and correct.	2			
Outlet 02C Ward SCH-040 (Toilet)	Cold water temperature too high. Investigate and correct.	2			
Outlet 02C Ward SCH-061 (Bedroom)	Cold water temperature too high. Investigate and correct.	2			
Outlet 02C Ward SCH-063 (Treatment Room)	Cold water temperature too high. Investigate and correct.	2			
Outlet 03C Ward GW1-002 (Renal Day Unit)	Cold water temperature too high. Investigate and correct.	2			
Outlet 03C Ward GW1-048 (Toilet)	Cold water temperature too high. Investigate and correct.	2			

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Location/Plant Item	Recommendation	Remedial Action Category	Assigned to	Actions Taken	Completed
Outlet 03C Ward GW2-025 (Bedroom)	Cold water temperature too high. Investigate and correct.	2			
Outlet 03C Ward GW2-035 (Bedroom)	Cold water temperature too high. Investigate and correct.	2			
Outlet 03C Ward GW2-036 (Play Room)	Cold water temperature too high. Investigate and correct.	2			
Outlet 03C Ward GW2-054 (Bathroom)	Cold water temperature too high. Investigate and correct.	2			
Outlet 03C Ward GW3-004 (Bathroom)	Cold water temperature too high. Investigate and correct.	2			
Outlet 03C Ward GW3-068 (Lab)	Cold water temperature too high. Investigate and correct.	2			
Outlet 03C Ward GWS-004 (Staff Kitchen)	Cold water temperature too high. Investigate and correct.	2			
Outlet 03C Ward GWS-033 (Toilet)	Cold water temperature too high. Investigate and correct.	2			
Outlet 04 WS4-017 (Male Change)	Cold water temperature too high. Investigate and correct.	2			
Outlet 04A HOW-024 (Bathroom)	Cold water temperature too high. Investigate and correct.	2			
Outlet 04A HOW-027 (Bathroom)	Cold water temperature too high. Investigate and correct.	2			
Outlet 04B HOW-030 (Bathroom)	Cold water temperature too high. Investigate and correct.	2			
Outlet 04C Child Forensic Psychology DCFP-049 (Kitchen)	Cold water temperature too high. Investigate and correct.	2			
Outlet 04C RENW-153 (Bathroom)	Cold water temperature too high. Investigate and correct.	2			
Outlet 04D RENW-091 (Bathroom)	Cold water temperature too high. Investigate and correct.	2			
Outlet 04D RENW-094 (Bathroom)	Cold water temperature too high. Investigate and correct.	2			
Outlet 05A GENWA-029 (Bathroom)	Cold water temperature too high. Investigate and correct.	2			
Outlet 05B GENWD-032 (Bathroom)	Cold water temperature too high. Investigate and correct.	2			
Outlet 05B GENWD-036 (Bathroom)	Cold water temperature too high. Investigate and correct.	2			
Outlet 05C GENWC-028 (Bedroom)	Cold water temperature too high. Investigate and correct.	2			
Outlet 05C GENWC-034 (Bathroom)	Cold water temperature too high. Investigate and correct.	2			

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Location/Plant Item	Recommendation	Remedial Action Category	Assigned to	Actions Taken	Completed
Outlet 05C GENWC-065 (Bedroom)	Cold water temperature too high. Investigate and correct.	2			
Outlet 05D GENWB-028 (Bedroom)	Cold water temperature too high. Investigate and correct.	2			
Outlet 05D GENWB-034 (Bathroom)	Cold water temperature too high. Investigate and correct.	2			
Outlet 05D GENWB-081 (Clean Utility)	Cold water temperature too high. Investigate and correct.	2			
Outlet 08 WS8-021 (Male Change)	Cold water temperature too high. Investigate and correct.	2			
Outlet 02 Dermatology DOPD-025 (Technician)	Confirm air gap on dump valve connection to waste is suitable and alter if required	2			
Outlet 00C Concourse ENT-028	Connection to vend machine capped off. Ensure this is included in flushing regime.	2			
Outlet 01C Critical Care CCW-014 (Clinical Physics)	Discoloured water from outlet(s). Investigate and correct.	2			
Outlet 01C Special Feeds SPF-007 (Facilities)	Discoloured water from outlet(s). Investigate and correct.	2			
Outlet 03C Ward GWS-004 (Staff Kitchen)	Dish washer connection not used currently. Include in flushing regime.	2			
Outlet 01 FM Facilities FMA1-001 (Facilities)	Drain leaking and should be repaired.	2			
Outlet 01 Radiology RAF-005 (Reception)	Ensure unused connection point included in flushing regime until put into use	2			
Outlet 00 Concourse ENT-003 (Bute vend)	Ensure unused vend connection included in flushing regime	2			
Outlet Basement KIT-031	Ensure unused vend connection included in flushing regime	2			
Outlet 02C Corridor ARU-001 (Kitchen)	Hot flow and return not working. This requires investigation and correcting.	2			
Outlet 00C Consultancy CPS-003 (Consulting Room)	Hot temperature slow to rise. It should be confirmed that hot outlet(s) are on a long leg and not that the flow and return has failed locally in this area.	2			
Outlet 01 Critical Care CCW-130 (Service)	Hot temperature slow to rise. It should be confirmed that hot outlet(s) are on a long leg and not that the flow and return has failed locally in this area.	2			
Outlet 01C Critical Care CCW-021 (Bathroom)	Hot temperature slow to rise. It should be confirmed that hot outlet(s) are on a long leg and not that the flow and return has failed locally in this area.	2			

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Location/Plant Item	Recommendation	Remedial Action Category	Assigned to	Actions Taken	Completed
Outlet 02C Ward SCH-087 (Store)	Hot temperature slow to rise. It should be confirmed that hot outlet(s) are on a long leg and not that the flow and return has failed locally in this area.	2			
Outlet 04C Child Forensic Psychology DCFP-049 (Kitchen)	Hot temperature slow to rise. It should be confirmed that hot outlet(s) are on a long leg and not that the flow and return has failed locally in this area.	2			
Outlet 00C Consultancy CPS-003 (Consulting Room)	Hot water temperature too low. Investigate and correct.	2			
Outlet 00C Observation OBW-061 (Bedroom)	Hot water temperature too low. Investigate and correct.	2			
Outlet 01 Critical Care CCW-130 (Service)	Hot water temperature too low. Investigate and correct.	2			
Outlet 01C Critical Care CCW-021 (Bathroom)	Hot water temperature too low. Investigate and correct.	2			
Outlet 01C Theatre 001-011	Hot water temperature too low. Investigate and correct.	2			
Outlet 03C Ward GWS-004 (Staff Kitchen)	Hot water temperature too low. Investigate and correct.	2			
Outlet 03C Ward GWS-033 (Toilet)	Hot water temperature too low. Investigate and correct.	2			
Outlet Hydrotherapy Plantroom A-1FMB-030	Include bib tap & Emergency Shower in flushing regime	2			
Outlet 00 OPD/Concourse OPD0-072 (Toilet)	IR tap not working creating deadlegs. Tap should be repaired and lines thoroughly flushed.	2			
Outlet 00 OPD/Concourse OPD0-073 (Shower)	IR tap not working creating deadlegs. Tap should be repaired and lines thoroughly flushed.	2			
General System	It may be prudent to consider installing a background dosing system on this site (e.g. Chlorine Dioxide) due to control issues identified during this assessment.	2			
Outlet 00 Radiology RAG-108 (Anaesthetic)	No access to TMV supply pipework. Access should be provided for further assessment.	2			
Outlet 01 Critical Care CCW-048 (Bed Bay 1)	No access to TMV supply pipework. Access should be provided for further assessment.	2			
Outlet 01 Stroke STW-082 (Bath)	No access to TMV supply pipework. Access should be provided for further assessment.	2			
Outlet 01 Stroke STW-082 (Bath)	'Out of Order' outlets in room creating deadleg – repair/replace.	2			
Outlet 00 Acute Assess AAW-088 (Bathroom)	Poor flow from outlet(s). Investigate and correct.	2			

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Location/Plant Item	Recommendation	Remedial Action Category	Assigned to	Actions Taken	Completed
Outlet 01 Radiology RNM-007 (Toilet)	Poor flow from outlet(s). Investigate and correct.	2			
Outlet 07A GENW5-029 (Bathroom)	Poor flow from outlet(s). Investigate and correct.	2			
Outlet 01 Medical Day Unit MDU-005 (Beverage)	Remove all deadleg pipework in this area.	2			
Outlet Hydrotherapy Plantroom A-1FMB-030	Remove all deadleg pipework in this area.	2			
Trades Water Outlets	The bib taps, irrigation points etc. and 12th floor heli-pad fire suppression system which are fed from the Trades system have very long runs through the building and plantrooms to the outlets. All points on the trades system should be included in the site flushing regime – though additional flushing (outlets run for extended periods) may be required to bring temperatures on distribution system down particularly during periods of low use (e.g. in winter when irrigation system is not required to operate frequently).	2			
Trades Water Outlets	No outlets on the Trades system have been designated as "sentinel outlets". Due to the type of system and the extended pipe runs to the outlets it may be prudent to designate all outlets from this system as sentinel and include in monthly monitoring and site flushing regime.	2			
Outlet 01 OPD OPD1-006 (Toilet)	Aeration at outlet(s). Investigate and correct.	3			
Outlet 01 OPD OPD1-008 (Toilet)	Aeration at outlet(s). Investigate and correct.	3			
Outlet 02C Corridor ARU-001 (Kitchen)	Aeration at outlet(s). Investigate and correct.	3			
Outlet 02C Ward AFD-022 (Toilet)	Aeration at outlet(s). Investigate and correct.	3			
Outlet 02C Ward SCH-022 (Bathroom)	Aeration at outlet(s). Investigate and correct.	3			
Outlet 02C Ward SCH-023 (Bathroom)	Aeration at outlet(s). Investigate and correct.	3			
Outlet 02C Ward SCH-092 (Hospital Night Team)	Aeration at outlet(s). Investigate and correct.	3			
Outlet 03C Ward GW1-002 (Renal Day Unit)	Aeration at outlet(s). Investigate and correct.	3			
Outlet 03C Ward GW1-048 (Toilet)	Aeration at outlet(s). Investigate and correct.	3			
Outlet 03C Ward GWS-004 (Staff Kitchen)	Aeration at outlet(s). Investigate and correct.	3			
Outlet 03C Ward GWS-011 (Facilities)	Aeration at outlet(s). Investigate and correct.	3			
Outlet 03C Ward GWS-014 (Renal Technician)	Aeration at outlet(s). Investigate and correct.	3			

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Location/Plant Item	Recommendation	Remedial Action Category	Assigned to	Actions Taken	Completed
Outlet 06 WS6-027 (Facilities)	Aeration at outlet(s). Investigate and correct.	3			
Domestic Water System Pressure Reducing Valves	Flexible hoses have been noted on the boosted bulk water system on pressure reducing valves. If possible these should be hard piped (stainless steel) or WRAS approved hoses with linings other than EPDM should be considered. Should these not be available for these types of units/connections then a regular inspection and replacement schedule should be implemented for these.	3			
Outlet 00 A&E EMC-086 (Facilities)	All EPDM flexible hoses should be removed and replaced with hard piped connection.	3			
Outlet 00 Acute Assess AAW-007 (Facilities)	All EPDM flexible hoses should be removed and replaced with hard piped connection.	3			
Outlet 00 Acute Assess AAW-125 (Facilities)	All EPDM flexible hoses should be removed and replaced with hard piped connection.	3			
Outlet 00 Acute Assess AAW-208 (Dirty Utility)	All EPDM flexible hoses should be removed and replaced with hard piped connection.	3			
Outlet 00 Acute Assess AAW-313 (Facilities)	All EPDM flexible hoses should be removed and replaced with hard piped connection.	3			
Outlet 00 Concourse ENT-003 (Bute vend)	All EPDM flexible hoses should be removed and replaced with hard piped connection.	3			
Outlet 00 Concourse ENT-062 (Facilities)	All EPDM flexible hoses should be removed and replaced with hard piped connection.	3			
Outlet 00 Concourse FMA0-001 (Facilities)	All EPDM flexible hoses should be removed and replaced with hard piped connection.	3			
Outlet 00 OPD OPD0-067 (Dirty Utility)	All EPDM flexible hoses should be removed and replaced with hard piped connection.	3			
Outlet 00 Pharmacy PHA-002 (Facilities)	All EPDM flexible hoses should be removed and replaced with hard piped connection.	3			
Outlet 00 Radiology RAG-004 (Dirty Utility)	All EPDM flexible hoses should be removed and replaced with hard piped connection.	3			
Outlet 00C Concourse ENT-036 (Facilities)	All EPDM flexible hoses should be removed and replaced with hard piped connection.	3			
Outlet 00C OPD OPD-026 (Facilities)	All EPDM flexible hoses should be removed and replaced with hard piped connection.	3			
Outlet 00C Radiology RCG-087 (Dirty Utility)	All EPDM flexible hoses should be removed and replaced with hard piped connection.	3			
Outlet 01 Critical Care CCU-004 (Patients Pantry)	All EPDM flexible hoses should be removed and replaced with hard piped connection.	3			

LEGIONELLA RISK ASSESSMENT

Location/Plant Item	Recommendation	Remedial Action Category	Assigned to	Actions Taken	Completed
Outlet 01 Critical Care CCW-017 (Facilities)	All EPDM flexible hoses should be removed and replaced with hard piped connection.	3			
Outlet 01 Critical Care CCW-126 (Dirty Utility)	All EPDM flexible hoses should be removed and replaced with hard piped connection.	3			
Outlet 01 Critical Care CCW-200 (Facilities)	All EPDM flexible hoses should be removed and replaced with hard piped connection.	3			
Outlet 01 FM Facilities FMA1-001 (Facilities)	All EPDM flexible hoses should be removed and replaced with hard piped connection.	3			
Outlet 01 Medical Day Unit MDU-005 (Beverage)	All EPDM flexible hoses should be removed and replaced with hard piped connection.	3			
Outlet 01 Medical Day Unit MDU-046 (Facilities)	All EPDM flexible hoses should be removed and replaced with hard piped connection.	3			
Outlet 01 Radiology RAF-127 (Dirty Utility)	All EPDM flexible hoses should be removed and replaced with hard piped connection.	3			
Outlet 01 Radiology RCF-001 (Facilities)	All EPDM flexible hoses should be removed and replaced with hard piped connection.	3			
Outlet 01 Radiology RCF-003 (Facilities)	All EPDM flexible hoses should be removed and replaced with hard piped connection.	3			
Outlet 01 Stroke STW-079 (Arjo Bathroom)	All EPDM flexible hoses should be removed and replaced with hard piped connection.	3			
Outlet 01C Critical Care CCW-092 (Dirty Utility)	All EPDM flexible hoses should be removed and replaced with hard piped connection.	3			
Outlet 01C Critical Care CCW-118 (Facilities)	All EPDM flexible hoses should be removed and replaced with hard piped connection.	3			
Outlet 01C Medical Day Unit MDU-008 (Beverage Prep)	All EPDM flexible hoses should be removed and replaced with hard piped connection.	3			
Outlet 01C Special Feeds SPF-007 (Facilities)	All EPDM flexible hoses should be removed and replaced with hard piped connection.	3			
Outlet 01C Theatre THE-102 (Facilities)	All EPDM flexible hoses should be removed and replaced with hard piped connection.	3			
Outlet 02 Decontamination DCT-015 (Wash Room DSR)	All EPDM flexible hoses should be removed and replaced with hard piped connection.	3			
Outlet 02 Endoscopy END-013 (Facilities)	All EPDM flexible hoses should be removed and replaced with hard piped connection.	3			
Outlet 02 Theatres THE-060 (Facilities)	All EPDM flexible hoses should be removed and replaced with hard piped connection.	3			
Outlet 02C Corridor ARU-001 (Kitchen)	All EPDM flexible hoses should be removed and replaced with hard piped connection.	3			
Outlet 02C Ward SCH-087 (Store)	All EPDM flexible hoses should be removed and replaced with hard piped connection.	3			
Outlet 03C Ward GWS-004 (Staff Kitchen)	All EPDM flexible hoses should be removed and replaced with hard piped connection.	3			

LEGIONELLA RISK ASSESSMENT

Location/Plant Item	Recommendation	Remedial Action Category	Assigned to	Actions Taken	Completed
Outlet 04 WS4-014 (Facilities Regen)	All EPDM flexible hoses should be removed and replaced with hard piped connection.	3			
Outlet 04C Child Forensic Psychology DCFP-049 (Kitchen)	All EPDM flexible hoses should be removed and replaced with hard piped connection.	3			
Outlet 06 WS6-027 (Facilities)	All EPDM flexible hoses should be removed and replaced with hard piped connection.	3			
Outlet 06A GENW1-001 (Arjo Bathroom)	All EPDM flexible hoses should be removed and replaced with hard piped connection.	3			
Outlet 08 WS8-027 (Facilities)	All EPDM flexible hoses should be removed and replaced with hard piped connection.	3			
Outlet Hydrotherapy Plantroom A-1FMB-030	Fit check valve to emergency shower (& bib tap if not fitted)	3			
Outlet 00 A&E EMC-059 (Bed Bay 5)	Hot outlets do not comply with latest SHTM regulations, though achieving temperatures of 50°C. Wherever possible/practical remedial action should be carried out to increase temperatures to 55°C.	3			
Outlet 00 A&E EMC-060 (Bed Bay 6)	Hot outlets do not comply with latest SHTM regulations, though achieving temperatures of 50°C. Wherever possible/practical remedial action should be carried out to increase temperatures to 55°C.	3			
Outlet 00 A&E EMC-063 (Bed Bay 8)	Hot outlets do not comply with latest SHTM regulations, though achieving temperatures of 50°C. Wherever possible/practical remedial action should be carried out to increase temperatures to 55°C.	3			
Outlet 00 A&E EMC-076 (Bed Bay 12)	Hot outlets do not comply with latest SHTM regulations, though achieving temperatures of 50°C. Wherever possible/practical remedial action should be carried out to increase temperatures to 55°C.	3			
Outlet 00 A&E EMC-093 (Bed Bay 18)	Hot outlets do not comply with latest SHTM regulations, though achieving temperatures of 50°C. Wherever possible/practical remedial action should be carried out to increase temperatures to 55°C.	3			
Outlet 00 A&E EMC-135 (Store)	Hot outlets do not comply with latest SHTM regulations, though achieving temperatures of 50°C. Wherever possible/practical remedial action should be carried out to increase temperatures to 55°C.	3			

LEGIONELLA RISK ASSESSMENT

Location/Plant Item	Recommendation	Remedial Action Category	Assigned to	Actions Taken	Completed
Outlet 00 Acute Assess AAW-017 (Bedroom)	Hot outlets do not comply with latest SHTM regulations, though achieving temperatures of 50°C. Wherever possible/practical remedial action should be carried out to increase temperatures to 55°C.	3			
Outlet 00 Acute Assess AAW-045 (Treatment Room)	Hot outlets do not comply with latest SHTM regulations, though achieving temperatures of 50°C. Wherever possible/practical remedial action should be carried out to increase temperatures to 55°C.	3			
Outlet 00 Acute Assess AAW-163 (Toilet)	Hot outlets do not comply with latest SHTM regulations, though achieving temperatures of 50°C. Wherever possible/practical remedial action should be carried out to increase temperatures to 55°C.	3			
Outlet 00 Acute Assess AAW-226 (Lab)	Hot outlets do not comply with latest SHTM regulations, though achieving temperatures of 50°C. Wherever possible/practical remedial action should be carried out to increase temperatures to 55°C.	3			
Outlet 00 Acute Assess AAW-375 (Bedroom)	Hot outlets do not comply with latest SHTM regulations, though achieving temperatures of 50°C. Wherever possible/practical remedial action should be carried out to increase temperatures to 55°C.	3			
Outlet 00 Concourse ENT-038 (Baby Change)	Hot outlets do not comply with latest SHTM regulations, though achieving temperatures of 50°C. Wherever possible/practical remedial action should be carried out to increase temperatures to 55°C.	3			
Outlet 00 Concourse ENT-052 (Gents Toilet)	Hot outlets do not comply with latest SHTM regulations, though achieving temperatures of 50°C. Wherever possible/practical remedial action should be carried out to increase temperatures to 55°C.	3			
Outlet 00 Discharge DLO-006 (Toilet)	Hot outlets do not comply with latest SHTM regulations, though achieving temperatures of 50°C. Wherever possible/practical remedial action should be carried out to increase temperatures to 55°C.	3			

LEGIONELLA RISK ASSESSMENT

Location/Plant Item	Recommendation	Remedial Action Category	Assigned to	Actions Taken	Completed
Outlet 00 Discharge DLO-008 (Consulting Room)	Hot outlets do not comply with latest SHTM regulations, though achieving temperatures of 50°C. Wherever possible/practical remedial action should be carried out to increase temperatures to 55°C.	3			
Outlet 00 Medical Illustration MIL-010 (Studio)	Hot outlets do not comply with latest SHTM regulations, though achieving temperatures of 50°C. Wherever possible/practical remedial action should be carried out to increase temperatures to 55°C.	3			
Outlet 00 OPD OPD0-013 (Consulting Room)	Hot outlets do not comply with latest SHTM regulations, though achieving temperatures of 50°C. Wherever possible/practical remedial action should be carried out to increase temperatures to 55°C.	3			
Outlet 00 OPD OPD0-049 (Treatment Room)	Hot outlets do not comply with latest SHTM regulations, though achieving temperatures of 50°C. Wherever possible/practical remedial action should be carried out to increase temperatures to 55°C.	3			
Outlet 00 OPD OPD0-067 (Dirty Utility)	Hot outlets do not comply with latest SHTM regulations, though achieving temperatures of 50°C. Wherever possible/practical remedial action should be carried out to increase temperatures to 55°C.	3			
Outlet 00 Orthotics ORT-015-2 (Staff Change)	Hot outlets do not comply with latest SHTM regulations, though achieving temperatures of 50°C. Wherever possible/practical remedial action should be carried out to increase temperatures to 55°C.	3			
Outlet 00 Orthotics ORT-017 (Disabled)	Hot outlets do not comply with latest SHTM regulations, though achieving temperatures of 50°C. Wherever possible/practical remedial action should be carried out to increase temperatures to 55°C.	3			
Outlet 00 Orthotics ORT-027 (Treatment Room)	Hot outlets do not comply with latest SHTM regulations, though achieving temperatures of 50°C. Wherever possible/practical remedial action should be carried out to increase temperatures to 55°C.	3			

LEGIONELLA RISK ASSESSMENT

Location/Plant Item	Recommendation	Remedial Action Category	Assigned to	Actions Taken	Completed
Outlet 00 Orthotics ORT-045 (Toilet)	Hot outlets do not comply with latest SHTM regulations, though achieving temperatures of 50°C. Wherever possible/practical remedial action should be carried out to increase temperatures to 55°C.	3			
Outlet 00 Pharmacy PHA-008 (Clinical Trial Prep)	Hot outlets do not comply with latest SHTM regulations, though achieving temperatures of 50°C. Wherever possible/practical remedial action should be carried out to increase temperatures to 55°C.	3			
Outlet 00 Radiology RAG-004 (Dirty Utility)	Hot outlets do not comply with latest SHTM regulations, though achieving temperatures of 50°C. Wherever possible/practical remedial action should be carried out to increase temperatures to 55°C.	3			
Outlet 00 Radiology RAG-029 (X-Ray 6)	Hot outlets do not comply with latest SHTM regulations, though achieving temperatures of 50°C. Wherever possible/practical remedial action should be carried out to increase temperatures to 55°C.	3			
Outlet 00 Radiology RAG-054 (Toilet)	Hot outlets do not comply with latest SHTM regulations, though achieving temperatures of 50°C. Wherever possible/practical remedial action should be carried out to increase temperatures to 55°C.	3			
Outlet 00 Rehab REH-006 (Toilet)	Hot outlets do not comply with latest SHTM regulations, though achieving temperatures of 50°C. Wherever possible/practical remedial action should be carried out to increase temperatures to 55°C.	3			
Outlet 00 Rehab REH-013 (OT Room)	Hot outlets do not comply with latest SHTM regulations, though achieving temperatures of 50°C. Wherever possible/practical remedial action should be carried out to increase temperatures to 55°C.	3			
Outlet 00C A&E EMC-006 (Toilet)	Hot outlets do not comply with latest SHTM regulations, though achieving temperatures of 50°C. Wherever possible/practical remedial action should be carried out to increase temperatures to 55°C.	3			

LEGIONELLA RISK ASSESSMENT

Location/Plant Item	Recommendation	Remedial Action Category	Assigned to	Actions Taken	Completed
Outlet 00C A&E EMC-059 (Bed Bay 6)	Hot outlets do not comply with latest SHTM regulations, though achieving temperatures of 50°C. Wherever possible/practical remedial action should be carried out to increase temperatures to 55°C.	3			
Outlet 00C A&E EMC-060 (Bed Bay 5)	Hot outlets do not comply with latest SHTM regulations, though achieving temperatures of 50°C. Wherever possible/practical remedial action should be carried out to increase temperatures to 55°C.	3			
Outlet 00C A&E EMC-100 (Triage)	Hot outlets do not comply with latest SHTM regulations, though achieving temperatures of 50°C. Wherever possible/practical remedial action should be carried out to increase temperatures to 55°C.	3			
Outlet 00C OPD OPD- (Consulting Room)	Hot outlets do not comply with latest SHTM regulations, though achieving temperatures of 50°C. Wherever possible/practical remedial action should be carried out to increase temperatures to 55°C.	3			
Outlet 00C Radiology RCG-068 (Baby sleep)	Hot outlets do not comply with latest SHTM regulations, though achieving temperatures of 50°C. Wherever possible/practical remedial action should be carried out to increase temperatures to 55°C.	3			
Outlet 00C Radiology RCG-087 (Dirty Utility)	Hot outlets do not comply with latest SHTM regulations, though achieving temperatures of 50°C. Wherever possible/practical remedial action should be carried out to increase temperatures to 55°C.	3			
Outlet 01 Critical Care CCU-036 (Bedroom)	Hot outlets do not comply with latest SHTM regulations, though achieving temperatures of 50°C. Wherever possible/practical remedial action should be carried out to increase temperatures to 55°C.	3			
Outlet 01 Critical Care CCW-087 (Bed Bay 37)	Hot outlets do not comply with latest SHTM regulations, though achieving temperatures of 50°C. Wherever possible/practical remedial action should be carried out to increase temperatures to 55°C.	3			

LEGIONELLA RISK ASSESSMENT

Location/Plant Item	Recommendation	Remedial Action Category	Assigned to	Actions Taken	Completed
Outlet 01 Critical Care CCW-089 (Bed Bay 38)	Hot outlets do not comply with latest SHTM regulations, though achieving temperatures of 50°C. Wherever possible/practical remedial action should be carried out to increase temperatures to 55°C.	3			
Outlet 01 Critical Care CCW-092 (Gowning Room)	Hot outlets do not comply with latest SHTM regulations, though achieving temperatures of 50°C. Wherever possible/practical remedial action should be carried out to increase temperatures to 55°C.	3			
Outlet 01 Critical Care CCW-109 (Bed Bay 26)	Hot outlets do not comply with latest SHTM regulations, though achieving temperatures of 50°C. Wherever possible/practical remedial action should be carried out to increase temperatures to 55°C.	3			
Outlet 01 Critical Care CCW-126 (Dirty Utility)	Hot outlets do not comply with latest SHTM regulations, though achieving temperatures of 50°C. Wherever possible/practical remedial action should be carried out to increase temperatures to 55°C.	3			
Outlet 01 Critical Care CCW-131 (Pharmacy Support)	Hot outlets do not comply with latest SHTM regulations, though achieving temperatures of 50°C. Wherever possible/practical remedial action should be carried out to increase temperatures to 55°C.	3			
Outlet 01 Critical Care CCW-141 (Bathroom)	Hot outlets do not comply with latest SHTM regulations, though achieving temperatures of 50°C. Wherever possible/practical remedial action should be carried out to increase temperatures to 55°C.	3			
Outlet 01 Critical Care CCW-214 (Male Change)	Hot outlets do not comply with latest SHTM regulations, though achieving temperatures of 50°C. Wherever possible/practical remedial action should be carried out to increase temperatures to 55°C.	3			
Outlet 01 Medical Day Unit MDU-012 (Treatment Room)	Hot outlets do not comply with latest SHTM regulations, though achieving temperatures of 50°C. Wherever possible/practical remedial action should be carried out to increase temperatures to 55°C.	3			

LEGIONELLA RISK ASSESSMENT

Location/Plant Item	Recommendation	Remedial Action Category	Assigned to	Actions Taken	Completed
Outlet 01 Medical Day Unit MDU-020 (Blood Test)	Hot outlets do not comply with latest SHTM regulations, though achieving temperatures of 50°C. Wherever possible/practical remedial action should be carried out to increase temperatures to 55°C.	3			
Outlet 01 Medical Day Unit MDU-050 (Consulting Room)	Hot outlets do not comply with latest SHTM regulations, though achieving temperatures of 50°C. Wherever possible/practical remedial action should be carried out to increase temperatures to 55°C.	3			
Outlet 01 Medical Day Unit MDU-051 (Consulting Room)	Hot outlets do not comply with latest SHTM regulations, though achieving temperatures of 50°C. Wherever possible/practical remedial action should be carried out to increase temperatures to 55°C.	3			
Outlet 01 OPD POA-006 (Consulting Room)	Hot outlets do not comply with latest SHTM regulations, though achieving temperatures of 50°C. Wherever possible/practical remedial action should be carried out to increase temperatures to 55°C.	3			
Outlet 01 OPD POA-015 (Consulting Room)	Hot outlets do not comply with latest SHTM regulations, though achieving temperatures of 50°C. Wherever possible/practical remedial action should be carried out to increase temperatures to 55°C.	3			
Outlet 01 OPD POA-040 (Consulting Room)	Hot outlets do not comply with latest SHTM regulations, though achieving temperatures of 50°C. Wherever possible/practical remedial action should be carried out to increase temperatures to 55°C.	3			
Outlet 01 OPD OPD1-006 (Toilet)	Hot outlets do not comply with latest SHTM regulations, though achieving temperatures of 50°C. Wherever possible/practical remedial action should be carried out to increase temperatures to 55°C.	3			
Outlet 01 OPD OPD1-008 (Toilet)	Hot outlets do not comply with latest SHTM regulations, though achieving temperatures of 50°C. Wherever possible/practical remedial action should be carried out to increase temperatures to 55°C.	3			

LEGIONELLA RISK ASSESSMENT

Location/Plant Item	Recommendation	Remedial Action Category	Assigned to	Actions Taken	Completed
Outlet 01 OPD OPD1-037 (Toilet)	Hot outlets do not comply with latest SHTM regulations, though achieving temperatures of 50°C. Wherever possible/practical remedial action should be carried out to increase temperatures to 55°C.	3			
Outlet 01 OPD OPD1-047 (Dietician)	Hot outlets do not comply with latest SHTM regulations, though achieving temperatures of 50°C. Wherever possible/practical remedial action should be carried out to increase temperatures to 55°C.	3			
Outlet 01 OPD OPD1-048 (Blood Lab)	Hot outlets do not comply with latest SHTM regulations, though achieving temperatures of 50°C. Wherever possible/practical remedial action should be carried out to increase temperatures to 55°C.	3			
Outlet 01 OPD OPD1-063 (Dirty Utility)	Hot outlets do not comply with latest SHTM regulations, though achieving temperatures of 50°C. Wherever possible/practical remedial action should be carried out to increase temperatures to 55°C.	3			
Outlet 01 OPD OPD1-085 (Toilet)	Hot outlets do not comply with latest SHTM regulations, though achieving temperatures of 50°C. Wherever possible/practical remedial action should be carried out to increase temperatures to 55°C.	3			
Outlet 01 OPD OPD1-113 (Measurement Bay)	Hot outlets do not comply with latest SHTM regulations, though achieving temperatures of 50°C. Wherever possible/practical remedial action should be carried out to increase temperatures to 55°C.	3			
Outlet 01 Radiology RAF-003 (Toilet)	Hot outlets do not comply with latest SHTM regulations, though achieving temperatures of 50°C. Wherever possible/practical remedial action should be carried out to increase temperatures to 55°C.	3			
Outlet 01 Radiology RAF-087 (Male Change)	Hot outlets do not comply with latest SHTM regulations, though achieving temperatures of 50°C. Wherever possible/practical remedial action should be carried out to increase temperatures to 55°C.	3			

LEGIONELLA RISK ASSESSMENT

Location/Plant Item	Recommendation	Remedial Action Category	Assigned to	Actions Taken	Completed
Outlet 01 Radiology RAF-095 (Toilet)	Hot outlets do not comply with latest SHTM regulations, though achieving temperatures of 50°C. Wherever possible/practical remedial action should be carried out to increase temperatures to 55°C.	3			
Outlet 01 Radiology RAF-115 (Toilet)	Hot outlets do not comply with latest SHTM regulations, though achieving temperatures of 50°C. Wherever possible/practical remedial action should be carried out to increase temperatures to 55°C.	3			
Outlet 01 Radiology RAF-127 (Dirty Utility)	Hot outlets do not comply with latest SHTM regulations, though achieving temperatures of 50°C. Wherever possible/practical remedial action should be carried out to increase temperatures to 55°C.	3			
Outlet 01 Radiology RNM-018 (Shower room)	Hot outlets do not comply with latest SHTM regulations, though achieving temperatures of 50°C. Wherever possible/practical remedial action should be carried out to increase temperatures to 55°C.	3			
Outlet 01 Radiology RNM-027 (Office)	Hot outlets do not comply with latest SHTM regulations, though achieving temperatures of 50°C. Wherever possible/practical remedial action should be carried out to increase temperatures to 55°C.	3			
Outlet 01 Restaurant RES-019 (Toilet)	Hot outlets do not comply with latest SHTM regulations, though achieving temperatures of 50°C. Wherever possible/practical remedial action should be carried out to increase temperatures to 55°C.	3			
Outlet 01 Restaurant RES-034 (Toilet)	Hot outlets do not comply with latest SHTM regulations, though achieving temperatures of 50°C. Wherever possible/practical remedial action should be carried out to increase temperatures to 55°C.	3			
Outlet 01 Stroke STW-014 (Bedroom)	Hot outlets do not comply with latest SHTM regulations, though achieving temperatures of 50°C. Wherever possible/practical remedial action should be carried out to increase temperatures to 55°C.	3			

LEGIONELLA RISK ASSESSMENT

Location/Plant Item	Recommendation	Remedial Action Category	Assigned to	Actions Taken	Completed
Outlet 01 Stroke STW-036 (Bathroom)	Hot outlets do not comply with latest SHTM regulations, though achieving temperatures of 50°C. Wherever possible/practical remedial action should be carried out to increase temperatures to 55°C.	3			
Outlet 01 Stroke STW-047 (Bathroom)	Hot outlets do not comply with latest SHTM regulations, though achieving temperatures of 50°C. Wherever possible/practical remedial action should be carried out to increase temperatures to 55°C.	3			
Outlet 01C Cardiology CAR-036 (Bedroom)	Hot outlets do not comply with latest SHTM regulations, though achieving temperatures of 50°C. Wherever possible/practical remedial action should be carried out to increase temperatures to 55°C.	3			
Outlet 01C Critical Care CCW-082 (Critical Care Bed)	Hot outlets do not comply with latest SHTM regulations, though achieving temperatures of 50°C. Wherever possible/practical remedial action should be carried out to increase temperatures to 55°C.	3			
Outlet 01C Critical Care CCW-098 (Critical Care Bed)	Hot outlets do not comply with latest SHTM regulations, though achieving temperatures of 50°C. Wherever possible/practical remedial action should be carried out to increase temperatures to 55°C.	3			
Outlet 01C Theatre 23HU-008 (Toilet)	Hot outlets do not comply with latest SHTM regulations, though achieving temperatures of 50°C. Wherever possible/practical remedial action should be carried out to increase temperatures to 55°C.	3			
Outlet 01C Theatre THE-009 (Toilet)	Hot outlets do not comply with latest SHTM regulations, though achieving temperatures of 50°C. Wherever possible/practical remedial action should be carried out to increase temperatures to 55°C.	3			
Outlet 01C Theatre THE-042 (Female Change)	Hot outlets do not comply with latest SHTM regulations, though achieving temperatures of 50°C. Wherever possible/practical remedial action should be carried out to increase temperatures to 55°C.	3			

LEGIONELLA RISK ASSESSMENT

Location/Plant Item	Recommendation	Remedial Action Category	Assigned to	Actions Taken	Completed
Outlet 01C Theatre THE-069 (Lab)	Hot outlets do not comply with latest SHTM regulations, though achieving temperatures of 50°C. Wherever possible/practical remedial action should be carried out to increase temperatures to 55°C.	3			
Outlet 01C Theatre THE-078 (Prep room)	Hot outlets do not comply with latest SHTM regulations, though achieving temperatures of 50°C. Wherever possible/practical remedial action should be carried out to increase temperatures to 55°C.	3			
Outlet 01C Theatre THE-090 (Theatre Scrub)	Hot outlets do not comply with latest SHTM regulations, though achieving temperatures of 50°C. Wherever possible/practical remedial action should be carried out to increase temperatures to 55°C.	3			
Outlet 01C Theatre THE-117 (Theatre Scrub)	Hot outlets do not comply with latest SHTM regulations, though achieving temperatures of 50°C. Wherever possible/practical remedial action should be carried out to increase temperatures to 55°C.	3			
Outlet 01C Theatre THE-157 (Recovery room)	Hot outlets do not comply with latest SHTM regulations, though achieving temperatures of 50°C. Wherever possible/practical remedial action should be carried out to increase temperatures to 55°C.	3			
Outlet 02 Dermatology DMW-004 (Photo Therapy)	Hot outlets do not comply with latest SHTM regulations, though achieving temperatures of 50°C. Wherever possible/practical remedial action should be carried out to increase temperatures to 55°C.	3			
Outlet 02 Dermatology DMW-025 (Bathroom)	Hot outlets do not comply with latest SHTM regulations, though achieving temperatures of 50°C. Wherever possible/practical remedial action should be carried out to increase temperatures to 55°C.	3			
Outlet 02 Dermatology DMW-031 (Bathroom)	Hot outlets do not comply with latest SHTM regulations, though achieving temperatures of 50°C. Wherever possible/practical remedial action should be carried out to increase temperatures to 55°C.	3			

LEGIONELLA RISK ASSESSMENT

Location/Plant Item	Recommendation	Remedial Action Category	Assigned to	Actions Taken	Completed
Outlet 02 Dermatology DOPD-004 (Toilet)	Hot outlets do not comply with latest SHTM regulations, though achieving temperatures of 50°C. Wherever possible/practical remedial action should be carried out to increase temperatures to 55°C.	3			
Outlet 02 Endoscopy END-029 (Examination Area)	Hot outlets do not comply with latest SHTM regulations, though achieving temperatures of 50°C. Wherever possible/practical remedial action should be carried out to increase temperatures to 55°C.	3			
Outlet 02 Renal RENO-003 (CAPD Training)	Hot outlets do not comply with latest SHTM regulations, though achieving temperatures of 50°C. Wherever possible/practical remedial action should be carried out to increase temperatures to 55°C.	3			
Outlet 02 Renal RENO-016 (Room 3)	Hot outlets do not comply with latest SHTM regulations, though achieving temperatures of 50°C. Wherever possible/practical remedial action should be carried out to increase temperatures to 55°C.	3			
Outlet 02 Renal RENO-046 (Female Toilet)	Hot outlets do not comply with latest SHTM regulations, though achieving temperatures of 50°C. Wherever possible/practical remedial action should be carried out to increase temperatures to 55°C.	3			
Outlet 02 Theatres THE-287 (Bed Bay A9)	Hot outlets do not comply with latest SHTM regulations, though achieving temperatures of 50°C. Wherever possible/practical remedial action should be carried out to increase temperatures to 55°C.	3			
Outlet 02 Theatres THE-289 (Bed Bay A1)	Hot outlets do not comply with latest SHTM regulations, though achieving temperatures of 50°C. Wherever possible/practical remedial action should be carried out to increase temperatures to 55°C.	3			
Outlet 02 Theatres THE-302 (Bed Bay A7)	Hot outlets do not comply with latest SHTM regulations, though achieving temperatures of 50°C. Wherever possible/practical remedial action should be carried out to increase temperatures to 55°C.	3			

LEGIONELLA RISK ASSESSMENT

Location/Plant Item	Recommendation	Remedial Action Category	Assigned to	Actions Taken	Completed
Outlet 02 Theatres THE-319 (Dirty Utility)	Hot outlets do not comply with latest SHTM regulations, though achieving temperatures of 50°C. Wherever possible/practical remedial action should be carried out to increase temperatures to 55°C.	3			
Outlet 02 Theatres THE-327 (Recovery)	Hot outlets do not comply with latest SHTM regulations, though achieving temperatures of 50°C. Wherever possible/practical remedial action should be carried out to increase temperatures to 55°C.	3			
Outlet 02 Transport Base TPB-001 (Clinical Workroom)	Hot outlets do not comply with latest SHTM regulations, though achieving temperatures of 50°C. Wherever possible/practical remedial action should be carried out to increase temperatures to 55°C.	3			
Outlet 02C Ward ARU-085 (Bedroom)	Hot outlets do not comply with latest SHTM regulations, though achieving temperatures of 50°C. Wherever possible/practical remedial action should be carried out to increase temperatures to 55°C.	3			
Outlet 02C Ward SCH-061 (Bedroom)	Hot outlets do not comply with latest SHTM regulations, though achieving temperatures of 50°C. Wherever possible/practical remedial action should be carried out to increase temperatures to 55°C.	3			
Outlet 03C Ward GW1-002 (Renal Day Unit)	Hot outlets do not comply with latest SHTM regulations, though achieving temperatures of 50°C. Wherever possible/practical remedial action should be carried out to increase temperatures to 55°C.	3			
Outlet 03C Ward GW2-035 (Bedroom)	Hot outlets do not comply with latest SHTM regulations, though achieving temperatures of 50°C. Wherever possible/practical remedial action should be carried out to increase temperatures to 55°C.	3			
Outlet 04 WS4-004 (Toilet)	Hot outlets do not comply with latest SHTM regulations, though achieving temperatures of 50°C. Wherever possible/practical remedial action should be carried out to increase temperatures to 55°C.	3			

LEGIONELLA RISK ASSESSMENT

Location/Plant Item	Recommendation	Remedial Action Category	Assigned to	Actions Taken	Completed
Outlet 04 WS4-009 (Toilet)	Hot outlets do not comply with latest SHTM regulations, though achieving temperatures of 50°C. Wherever possible/practical remedial action should be carried out to increase temperatures to 55°C.	3			
Outlet 04A HOW-024 (Bathroom)	Hot outlets do not comply with latest SHTM regulations, though achieving temperatures of 50°C. Wherever possible/practical remedial action should be carried out to increase temperatures to 55°C.	3			
Outlet 04A HOW-027 (Bathroom)	Hot outlets do not comply with latest SHTM regulations, though achieving temperatures of 50°C. Wherever possible/practical remedial action should be carried out to increase temperatures to 55°C.	3			
Outlet 04A RENW-005 (Bedroom)	Hot outlets do not comply with latest SHTM regulations, though achieving temperatures of 50°C. Wherever possible/practical remedial action should be carried out to increase temperatures to 55°C.	3			
Outlet 04A RENW-055 (Bedroom)	Hot outlets do not comply with latest SHTM regulations, though achieving temperatures of 50°C. Wherever possible/practical remedial action should be carried out to increase temperatures to 55°C.	3			
Outlet 04B HOW-030 (Bathroom)	Hot outlets do not comply with latest SHTM regulations, though achieving temperatures of 50°C. Wherever possible/practical remedial action should be carried out to increase temperatures to 55°C.	3			
Outlet 04B HOW-064 (Bedroom)	Hot outlets do not comply with latest SHTM regulations, though achieving temperatures of 50°C. Wherever possible/practical remedial action should be carried out to increase temperatures to 55°C.	3			
Outlet 04B HOW-193 (Bedroom)	Hot outlets do not comply with latest SHTM regulations, though achieving temperatures of 50°C. Wherever possible/practical remedial action should be carried out to increase temperatures to 55°C.	3			

LEGIONELLA RISK ASSESSMENT

Location/Plant Item	Recommendation	Remedial Action Category	Assigned to	Actions Taken	Completed
Outlet 04C RENW-127 (Consulting Room)	Hot outlets do not comply with latest SHTM regulations, though achieving temperatures of 50°C. Wherever possible/practical remedial action should be carried out to increase temperatures to 55°C.	3			
Outlet 04C RENW-188 (Bedroom)	Hot outlets do not comply with latest SHTM regulations, though achieving temperatures of 50°C. Wherever possible/practical remedial action should be carried out to increase temperatures to 55°C.	3			
Outlet 04D RENW-060 (Bedroom)	Hot outlets do not comply with latest SHTM regulations, though achieving temperatures of 50°C. Wherever possible/practical remedial action should be carried out to increase temperatures to 55°C.	3			
Outlet 04D RENW-091 (Bathroom)	Hot outlets do not comply with latest SHTM regulations, though achieving temperatures of 50°C. Wherever possible/practical remedial action should be carried out to increase temperatures to 55°C.	3			
Outlet 04D RENW-094 (Bathroom)	Hot outlets do not comply with latest SHTM regulations, though achieving temperatures of 50°C. Wherever possible/practical remedial action should be carried out to increase temperatures to 55°C.	3			
Outlet 04D RENW-124 (Consulting Room)	Hot outlets do not comply with latest SHTM regulations, though achieving temperatures of 50°C. Wherever possible/practical remedial action should be carried out to increase temperatures to 55°C.	3			
Outlet 05 WS5-005 (Toilet)	Hot outlets do not comply with latest SHTM regulations, though achieving temperatures of 50°C. Wherever possible/practical remedial action should be carried out to increase temperatures to 55°C.	3			
Outlet 05 WS5-011 (Toilet)	Hot outlets do not comply with latest SHTM regulations, though achieving temperatures of 50°C. Wherever possible/practical remedial action should be carried out to increase temperatures to 55°C.	3			

LEGIONELLA RISK ASSESSMENT

Location/Plant Item	Recommendation	Remedial Action Category	Assigned to	Actions Taken	Completed
Outlet 05A GENWA-001 (Bedroom)	Hot outlets do not comply with latest SHTM regulations, though achieving temperatures of 50°C. Wherever possible/practical remedial action should be carried out to increase temperatures to 55°C.	3			
Outlet 05A GENWA-029 (Bathroom)	Hot outlets do not comply with latest SHTM regulations, though achieving temperatures of 50°C. Wherever possible/practical remedial action should be carried out to increase temperatures to 55°C.	3			
Outlet 05A GENWA-065 (Bedroom)	Hot outlets do not comply with latest SHTM regulations, though achieving temperatures of 50°C. Wherever possible/practical remedial action should be carried out to increase temperatures to 55°C.	3			
Outlet 05B GENWD-032 (Bathroom)	Hot outlets do not comply with latest SHTM regulations, though achieving temperatures of 50°C. Wherever possible/practical remedial action should be carried out to increase temperatures to 55°C.	3			
Outlet 05B GENWD-065 (Bedroom)	Hot outlets do not comply with latest SHTM regulations, though achieving temperatures of 50°C. Wherever possible/practical remedial action should be carried out to increase temperatures to 55°C.	3			
Outlet 05C GENWC-028 (Bedroom)	Hot outlets do not comply with latest SHTM regulations, though achieving temperatures of 50°C. Wherever possible/practical remedial action should be carried out to increase temperatures to 55°C.	3			
Outlet 05C GENWC-065 (Bedroom)	Hot outlets do not comply with latest SHTM regulations, though achieving temperatures of 50°C. Wherever possible/practical remedial action should be carried out to increase temperatures to 55°C.	3			
Outlet 05D GENWB-001 (Bedroom)	Hot outlets do not comply with latest SHTM regulations, though achieving temperatures of 50°C. Wherever possible/practical remedial action should be carried out to increase temperatures to 55°C.	3			

LEGIONELLA RISK ASSESSMENT

Location/Plant Item	Recommendation	Remedial Action Category	Assigned to	Actions Taken	Completed
Outlet 05D GENWB-028 (Bedroom)	Hot outlets do not comply with latest SHTM regulations, though achieving temperatures of 50°C. Wherever possible/practical remedial action should be carried out to increase temperatures to 55°C.	3			
Outlet 05D GENWB-034 (Bathroom)	Hot outlets do not comply with latest SHTM regulations, though achieving temperatures of 50°C. Wherever possible/practical remedial action should be carried out to increase temperatures to 55°C.	3			
Outlet 05D GENWB-057 (Bedroom)	Hot outlets do not comply with latest SHTM regulations, though achieving temperatures of 50°C. Wherever possible/practical remedial action should be carried out to increase temperatures to 55°C.	3			
Outlet 05D GENWB-065 (Bedroom)	Hot outlets do not comply with latest SHTM regulations, though achieving temperatures of 50°C. Wherever possible/practical remedial action should be carried out to increase temperatures to 55°C.	3			
Outlet 06 WS6-005 (Toilet)	Hot outlets do not comply with latest SHTM regulations, though achieving temperatures of 50°C. Wherever possible/practical remedial action should be carried out to increase temperatures to 55°C.	3			
Outlet 06 WS6-011 (Toilet)	Hot outlets do not comply with latest SHTM regulations, though achieving temperatures of 50°C. Wherever possible/practical remedial action should be carried out to increase temperatures to 55°C.	3			
Outlet 06 WS6-019 (Toilet)	Hot outlets do not comply with latest SHTM regulations, though achieving temperatures of 50°C. Wherever possible/practical remedial action should be carried out to increase temperatures to 55°C.	3			
Outlet 06A GENW1-029 (Bathroom)	Hot outlets do not comply with latest SHTM regulations, though achieving temperatures of 50°C. Wherever possible/practical remedial action should be carried out to increase temperatures to 55°C.	3			

LEGIONELLA RISK ASSESSMENT

Location/Plant Item	Recommendation	Remedial Action Category	Assigned to	Actions Taken	Completed
Outlet 06A GENW1-065 (Bedroom)	Hot outlets do not comply with latest SHTM regulations, though achieving temperatures of 50°C. Wherever possible/practical remedial action should be carried out to increase temperatures to 55°C.	3			
Outlet 06B GENW4-032 (Bathroom)	Hot outlets do not comply with latest SHTM regulations, though achieving temperatures of 50°C. Wherever possible/practical remedial action should be carried out to increase temperatures to 55°C.	3			
Outlet 06B GENW4-036 (Bathroom)	Hot outlets do not comply with latest SHTM regulations, though achieving temperatures of 50°C. Wherever possible/practical remedial action should be carried out to increase temperatures to 55°C.	3			
Outlet 06B GENW4-065 (Bedroom)	Hot outlets do not comply with latest SHTM regulations, though achieving temperatures of 50°C. Wherever possible/practical remedial action should be carried out to increase temperatures to 55°C.	3			
Outlet 06C GENW3-028 (Bedroom)	Hot outlets do not comply with latest SHTM regulations, though achieving temperatures of 50°C. Wherever possible/practical remedial action should be carried out to increase temperatures to 55°C.	3			
Outlet 06C GENW3-034 (Bathroom)	Hot outlets do not comply with latest SHTM regulations, though achieving temperatures of 50°C. Wherever possible/practical remedial action should be carried out to increase temperatures to 55°C.	3			
Outlet 06C GENW3-065 (Bedroom)	Hot outlets do not comply with latest SHTM regulations, though achieving temperatures of 50°C. Wherever possible/practical remedial action should be carried out to increase temperatures to 55°C.	3			
Outlet 06D GENW2-001 (Bedroom)	Hot outlets do not comply with latest SHTM regulations, though achieving temperatures of 50°C. Wherever possible/practical remedial action should be carried out to increase temperatures to 55°C.	3			

LEGIONELLA RISK ASSESSMENT

Location/Plant Item	Recommendation	Remedial Action Category	Assigned to	Actions Taken	Completed
Outlet 06D GENW2-028 (Bedroom)	Hot outlets do not comply with latest SHTM regulations, though achieving temperatures of 50°C. Wherever possible/practical remedial action should be carried out to increase temperatures to 55°C.	3			
Outlet 06D GENW2-057 (Bedroom)	Hot outlets do not comply with latest SHTM regulations, though achieving temperatures of 50°C. Wherever possible/practical remedial action should be carried out to increase temperatures to 55°C.	3			
Outlet 06D GENW2-065 (Bedroom)	Hot outlets do not comply with latest SHTM regulations, though achieving temperatures of 50°C. Wherever possible/practical remedial action should be carried out to increase temperatures to 55°C.	3			
Outlet 07A GENW5-001 (Bedroom)	Hot outlets do not comply with latest SHTM regulations, though achieving temperatures of 50°C. Wherever possible/practical remedial action should be carried out to increase temperatures to 55°C.	3			
Outlet 07A GENW5-034 (Bathroom)	Hot outlets do not comply with latest SHTM regulations, though achieving temperatures of 50°C. Wherever possible/practical remedial action should be carried out to increase temperatures to 55°C.	3			
Outlet 07A GENW5-065 (Bedroom)	Hot outlets do not comply with latest SHTM regulations, though achieving temperatures of 50°C. Wherever possible/practical remedial action should be carried out to increase temperatures to 55°C.	3			
Outlet 07B GENW8-032 (Bathroom)	Hot outlets do not comply with latest SHTM regulations, though achieving temperatures of 50°C. Wherever possible/practical remedial action should be carried out to increase temperatures to 55°C.	3			
Outlet 07B GENW8-036 (Bathroom)	Hot outlets do not comply with latest SHTM regulations, though achieving temperatures of 50°C. Wherever possible/practical remedial action should be carried out to increase temperatures to 55°C.	3			

LEGIONELLA RISK ASSESSMENT

Location/Plant Item	Recommendation	Remedial Action Category	Assigned to	Actions Taken	Completed
Outlet 07B GENW8-065 (Bedroom)	Hot outlets do not comply with latest SHTM regulations, though achieving temperatures of 50°C. Wherever possible/practical remedial action should be carried out to increase temperatures to 55°C.	3			
Outlet 07C GENW7-028 (Bedroom)	Hot outlets do not comply with latest SHTM regulations, though achieving temperatures of 50°C. Wherever possible/practical remedial action should be carried out to increase temperatures to 55°C.	3			
Outlet 07C GENW7-034 (Bathroom)	Hot outlets do not comply with latest SHTM regulations, though achieving temperatures of 50°C. Wherever possible/practical remedial action should be carried out to increase temperatures to 55°C.	3			
Outlet 07C GENW7-065 (Bedroom)	Hot outlets do not comply with latest SHTM regulations, though achieving temperatures of 50°C. Wherever possible/practical remedial action should be carried out to increase temperatures to 55°C.	3			
Outlet 07D GENW6-001 (Bedroom)	Hot outlets do not comply with latest SHTM regulations, though achieving temperatures of 50°C. Wherever possible/practical remedial action should be carried out to increase temperatures to 55°C.	3			
Outlet 07D GENW6-028 (Bedroom)	Hot outlets do not comply with latest SHTM regulations, though achieving temperatures of 50°C. Wherever possible/practical remedial action should be carried out to increase temperatures to 55°C.	3			
Outlet 07D GENW6-057 (Bedroom)	Hot outlets do not comply with latest SHTM regulations, though achieving temperatures of 50°C. Wherever possible/practical remedial action should be carried out to increase temperatures to 55°C.	3			
Outlet 08 WS8-005 (Toilet)	Hot outlets do not comply with latest SHTM regulations, though achieving temperatures of 50°C. Wherever possible/practical remedial action should be carried out to increase temperatures to 55°C.	3			

LEGIONELLA RISK ASSESSMENT

Location/Plant Item	Recommendation	Remedial Action Category	Assigned to	Actions Taken	Completed
Outlet 08 WS8-011 (Toilet)	Hot outlets do not comply with latest SHTM regulations, though achieving temperatures of 50°C. Wherever possible/practical remedial action should be carried out to increase temperatures to 55°C.	3			
Outlet 08 WS8-021 (Male Change)	Hot outlets do not comply with latest SHTM regulations, though achieving temperatures of 50°C. Wherever possible/practical remedial action should be carried out to increase temperatures to 55°C.	3			
Outlet 08A GENW9-001 (Bedroom)	Hot outlets do not comply with latest SHTM regulations, though achieving temperatures of 50°C. Wherever possible/practical remedial action should be carried out to increase temperatures to 55°C.	3			
Outlet 08A GENW9-029 (Bathroom)	Hot outlets do not comply with latest SHTM regulations, though achieving temperatures of 50°C. Wherever possible/practical remedial action should be carried out to increase temperatures to 55°C.	3			
Outlet 08A GENW9-034 (Bathroom)	Hot outlets do not comply with latest SHTM regulations, though achieving temperatures of 50°C. Wherever possible/practical remedial action should be carried out to increase temperatures to 55°C.	3			
Outlet 08A GENW9-065 (Bedroom)	Hot outlets do not comply with latest SHTM regulations, though achieving temperatures of 50°C. Wherever possible/practical remedial action should be carried out to increase temperatures to 55°C.	3			
Outlet 08B GENW12-032 (Bathroom)	Hot outlets do not comply with latest SHTM regulations, though achieving temperatures of 50°C. Wherever possible/practical remedial action should be carried out to increase temperatures to 55°C.	3			
Outlet 08B GENW12-036 (Bathroom)	Hot outlets do not comply with latest SHTM regulations, though achieving temperatures of 50°C. Wherever possible/practical remedial action should be carried out to increase temperatures to 55°C.	3			

LEGIONELLA RISK ASSESSMENT

Location/Plant Item	Recommendation	Remedial Action Category	Assigned to	Actions Taken	Completed
Outlet 08B GENW12-065 (Bedroom)	Hot outlets do not comply with latest SHTM regulations, though achieving temperatures of 50°C. Wherever possible/practical remedial action should be carried out to increase temperatures to 55°C.	3			
Outlet 08C GENW11-028 (Bedroom)	Hot outlets do not comply with latest SHTM regulations, though achieving temperatures of 50°C. Wherever possible/practical remedial action should be carried out to increase temperatures to 55°C.	3			
Outlet 08C GENW11-034 (Bathroom)	Hot outlets do not comply with latest SHTM regulations, though achieving temperatures of 50°C. Wherever possible/practical remedial action should be carried out to increase temperatures to 55°C.	3			
Outlet 08C GENW11-065 (Bedroom)	Hot outlets do not comply with latest SHTM regulations, though achieving temperatures of 50°C. Wherever possible/practical remedial action should be carried out to increase temperatures to 55°C.	3			
Outlet 08D GENW10-001 (Bedroom)	Hot outlets do not comply with latest SHTM regulations, though achieving temperatures of 50°C. Wherever possible/practical remedial action should be carried out to increase temperatures to 55°C.	3			
Outlet 08D GENW10-028 (Bedroom)	Hot outlets do not comply with latest SHTM regulations, though achieving temperatures of 50°C. Wherever possible/practical remedial action should be carried out to increase temperatures to 55°C.	3			
Outlet 08D GENW10-034 (Bathroom)	Hot outlets do not comply with latest SHTM regulations, though achieving temperatures of 50°C. Wherever possible/practical remedial action should be carried out to increase temperatures to 55°C.	3			
Outlet 08D GENW10-057 (Bedroom)	Hot outlets do not comply with latest SHTM regulations, though achieving temperatures of 50°C. Wherever possible/practical remedial action should be carried out to increase temperatures to 55°C.	3			

LEGIONELLA RISK ASSESSMENT

Location/Plant Item	Recommendation	Remedial Action Category	Assigned to	Actions Taken	Completed
Outlet 08D GENW10-065 (Bedroom)	Hot outlets do not comply with latest SHTM regulations, though achieving temperatures of 50°C. Wherever possible/practical remedial action should be carried out to increase temperatures to 55°C.	3			
Outlet 09 WS9-005 (Toilet)	Hot outlets do not comply with latest SHTM regulations, though achieving temperatures of 50°C. Wherever possible/practical remedial action should be carried out to increase temperatures to 55°C.	3			
Outlet 09A GENW13-001 (Bedroom)	Hot outlets do not comply with latest SHTM regulations, though achieving temperatures of 50°C. Wherever possible/practical remedial action should be carried out to increase temperatures to 55°C.	3			
Outlet 09A GENW13-029 (Bathroom)	Hot outlets do not comply with latest SHTM regulations, though achieving temperatures of 50°C. Wherever possible/practical remedial action should be carried out to increase temperatures to 55°C.	3			
Outlet 09A GENW13-034 (Bathroom)	Hot outlets do not comply with latest SHTM regulations, though achieving temperatures of 50°C. Wherever possible/practical remedial action should be carried out to increase temperatures to 55°C.	3			
Outlet 09A GENW13-065 (Bedroom)	Hot outlets do not comply with latest SHTM regulations, though achieving temperatures of 50°C. Wherever possible/practical remedial action should be carried out to increase temperatures to 55°C.	3			
Outlet 09B GENW16-034 (Bathroom)	Hot outlets do not comply with latest SHTM regulations, though achieving temperatures of 50°C. Wherever possible/practical remedial action should be carried out to increase temperatures to 55°C.	3			
Outlet 09B GENW16-036 (Bathroom)	Hot outlets do not comply with latest SHTM regulations, though achieving temperatures of 50°C. Wherever possible/practical remedial action should be carried out to increase temperatures to 55°C.	3			

LEGIONELLA RISK ASSESSMENT

Location/Plant Item	Recommendation	Remedial Action Category	Assigned to	Actions Taken	Completed
Outlet 09B GENW16-065 (Bedroom)	Hot outlets do not comply with latest SHTM regulations, though achieving temperatures of 50°C. Wherever possible/practical remedial action should be carried out to increase temperatures to 55°C.	3			
Outlet 09C GENW15-028 (Bedroom)	Hot outlets do not comply with latest SHTM regulations, though achieving temperatures of 50°C. Wherever possible/practical remedial action should be carried out to increase temperatures to 55°C.	3			
Outlet 09C GENW15-034 (Bathroom)	Hot outlets do not comply with latest SHTM regulations, though achieving temperatures of 50°C. Wherever possible/practical remedial action should be carried out to increase temperatures to 55°C.	3			
Outlet 09C GENW15-065 (Bedroom)	Hot outlets do not comply with latest SHTM regulations, though achieving temperatures of 50°C. Wherever possible/practical remedial action should be carried out to increase temperatures to 55°C.	3			
Outlet 09D GENW14-001 (Bedroom)	Hot outlets do not comply with latest SHTM regulations, though achieving temperatures of 50°C. Wherever possible/practical remedial action should be carried out to increase temperatures to 55°C.	3			
Outlet 09D GENW14-028 (Bedroom)	Hot outlets do not comply with latest SHTM regulations, though achieving temperatures of 50°C. Wherever possible/practical remedial action should be carried out to increase temperatures to 55°C.	3			
Outlet 09D GENW14-034 (Bathroom)	Hot outlets do not comply with latest SHTM regulations, though achieving temperatures of 50°C. Wherever possible/practical remedial action should be carried out to increase temperatures to 55°C.	3			
Outlet 09D GENW14-057 (Bedroom)	Hot outlets do not comply with latest SHTM regulations, though achieving temperatures of 50°C. Wherever possible/practical remedial action should be carried out to increase temperatures to 55°C.	3			

LEGIONELLA RISK ASSESSMENT

Location/Plant Item	Recommendation	Remedial Action Category	Assigned to	Actions Taken	Completed
Outlet 09D GENW14-065 (Bedroom)	Hot outlets do not comply with latest SHTM regulations, though achieving temperatures of 50°C. Wherever possible/practical remedial action should be carried out to increase temperatures to 55°C.	3			
Outlet 10 WS10-005 (Toilet)	Hot outlets do not comply with latest SHTM regulations, though achieving temperatures of 50°C. Wherever possible/practical remedial action should be carried out to increase temperatures to 55°C.	3			
Outlet 10 WS10-011 (Toilet)	Hot outlets do not comply with latest SHTM regulations, though achieving temperatures of 50°C. Wherever possible/practical remedial action should be carried out to increase temperatures to 55°C.	3			
Outlet 10A GENW17-001 (Bedroom)	Hot outlets do not comply with latest SHTM regulations, though achieving temperatures of 50°C. Wherever possible/practical remedial action should be carried out to increase temperatures to 55°C.	3			
Outlet 10A GENW17-029 (Bathroom)	Hot outlets do not comply with latest SHTM regulations, though achieving temperatures of 50°C. Wherever possible/practical remedial action should be carried out to increase temperatures to 55°C.	3			
Outlet 10A GENW17-034 (Bathroom)	Hot outlets do not comply with latest SHTM regulations, though achieving temperatures of 50°C. Wherever possible/practical remedial action should be carried out to increase temperatures to 55°C.	3			
Outlet 10A GENW17-065 (Bedroom)	Hot outlets do not comply with latest SHTM regulations, though achieving temperatures of 50°C. Wherever possible/practical remedial action should be carried out to increase temperatures to 55°C.	3			
Outlet 10B GENW20-032 (Bathroom)	Hot outlets do not comply with latest SHTM regulations, though achieving temperatures of 50°C. Wherever possible/practical remedial action should be carried out to increase temperatures to 55°C.	3			

LEGIONELLA RISK ASSESSMENT

Location/Plant Item	Recommendation	Remedial Action Category	Assigned to	Actions Taken	Completed
Outlet 10B GENW20-036 (Bathroom)	Hot outlets do not comply with latest SHTM regulations, though achieving temperatures of 50°C. Wherever possible/practical remedial action should be carried out to increase temperatures to 55°C.	3			
Outlet 10B GENW20-065 (Bedroom)	Hot outlets do not comply with latest SHTM regulations, though achieving temperatures of 50°C. Wherever possible/practical remedial action should be carried out to increase temperatures to 55°C.	3			
Outlet 10C GENW19-028 (Bedroom)	Hot outlets do not comply with latest SHTM regulations, though achieving temperatures of 50°C. Wherever possible/practical remedial action should be carried out to increase temperatures to 55°C.	3			
Outlet 10C GENW19-034 (Bathroom)	Hot outlets do not comply with latest SHTM regulations, though achieving temperatures of 50°C. Wherever possible/practical remedial action should be carried out to increase temperatures to 55°C.	3			
Outlet 10C GENW19-065 (Bedroom)	Hot outlets do not comply with latest SHTM regulations, though achieving temperatures of 50°C. Wherever possible/practical remedial action should be carried out to increase temperatures to 55°C.	3			
Outlet 10D GENW18-001 (Bedroom)	Hot outlets do not comply with latest SHTM regulations, though achieving temperatures of 50°C. Wherever possible/practical remedial action should be carried out to increase temperatures to 55°C.	3			
Outlet 10D GENW18-028 (Bedroom)	Hot outlets do not comply with latest SHTM regulations, though achieving temperatures of 50°C. Wherever possible/practical remedial action should be carried out to increase temperatures to 55°C.	3			
Outlet 10D GENW18-057 (Bedroom)	Hot outlets do not comply with latest SHTM regulations, though achieving temperatures of 50°C. Wherever possible/practical remedial action should be carried out to increase temperatures to 55°C.	3			

LEGIONELLA RISK ASSESSMENT

Location/Plant Item	Recommendation	Remedial Action Category	Assigned to	Actions Taken	Completed
Outlet 11 WS11-005 (Toilet)	Hot outlets do not comply with latest SHTM regulations, though achieving temperatures of 50°C. Wherever possible/practical remedial action should be carried out to increase temperatures to 55°C.	3			
Outlet 11 WS11-011 (Toilet)	Hot outlets do not comply with latest SHTM regulations, though achieving temperatures of 50°C. Wherever possible/practical remedial action should be carried out to increase temperatures to 55°C.	3			
Outlet 11 WS11-019 (Toilet)	Hot outlets do not comply with latest SHTM regulations, though achieving temperatures of 50°C. Wherever possible/practical remedial action should be carried out to increase temperatures to 55°C.	3			
Outlet 11A GENW21-001 (Bedroom)	Hot outlets do not comply with latest SHTM regulations, though achieving temperatures of 50°C. Wherever possible/practical remedial action should be carried out to increase temperatures to 55°C.	3			
Outlet 11A GENW21-029 (Bathroom)	Hot outlets do not comply with latest SHTM regulations, though achieving temperatures of 50°C. Wherever possible/practical remedial action should be carried out to increase temperatures to 55°C.	3			
Outlet 11A GENW21-034 (Bathroom)	Hot outlets do not comply with latest SHTM regulations, though achieving temperatures of 50°C. Wherever possible/practical remedial action should be carried out to increase temperatures to 55°C.	3			
Outlet 11A GENW21-065 (Bedroom)	Hot outlets do not comply with latest SHTM regulations, though achieving temperatures of 50°C. Wherever possible/practical remedial action should be carried out to increase temperatures to 55°C.	3			
Outlet 11B GENW24-032 (Bathroom)	Hot outlets do not comply with latest SHTM regulations, though achieving temperatures of 50°C. Wherever possible/practical remedial action should be carried out to increase temperatures to 55°C.	3			

LEGIONELLA RISK ASSESSMENT

Location/Plant Item	Recommendation	Remedial Action Category	Assigned to	Actions Taken	Completed
Outlet 11B GENW24-036 (Bathroom)	Hot outlets do not comply with latest SHTM regulations, though achieving temperatures of 50°C. Wherever possible/practical remedial action should be carried out to increase temperatures to 55°C.	3			
Outlet 11C GENW23-028 (Bedroom)	Hot outlets do not comply with latest SHTM regulations, though achieving temperatures of 50°C. Wherever possible/practical remedial action should be carried out to increase temperatures to 55°C.	3			
Outlet 11C GENW23-034 (Bathroom)	Hot outlets do not comply with latest SHTM regulations, though achieving temperatures of 50°C. Wherever possible/practical remedial action should be carried out to increase temperatures to 55°C.	3			
Outlet 11C GENW23-065 (Bedroom)	Hot outlets do not comply with latest SHTM regulations, though achieving temperatures of 50°C. Wherever possible/practical remedial action should be carried out to increase temperatures to 55°C.	3			
Outlet 11D GENW22-001 (Bedroom)	Hot outlets do not comply with latest SHTM regulations, though achieving temperatures of 50°C. Wherever possible/practical remedial action should be carried out to increase temperatures to 55°C.	3			
Outlet 11D GENW22-028 (Bedroom)	Hot outlets do not comply with latest SHTM regulations, though achieving temperatures of 50°C. Wherever possible/practical remedial action should be carried out to increase temperatures to 55°C.	3			
Outlet 11D GENW22-034 (Bathroom)	Hot outlets do not comply with latest SHTM regulations, though achieving temperatures of 50°C. Wherever possible/practical remedial action should be carried out to increase temperatures to 55°C.	3			
Outlet 11D GENW22-057 (Bedroom)	Hot outlets do not comply with latest SHTM regulations, though achieving temperatures of 50°C. Wherever possible/practical remedial action should be carried out to increase temperatures to 55°C.	3			

LEGIONELLA RISK ASSESSMENT

Location/Plant Item	Recommendation	Remedial Action Category	Assigned to	Actions Taken	Completed
Outlet 11D GENW22-065 (Bedroom)	Hot outlets do not comply with latest SHTM regulations, though achieving temperatures of 50°C. Wherever possible/practical remedial action should be carried out to increase temperatures to 55°C.	3			
Outlet Basement KIT-031	Hot outlets do not comply with latest SHTM regulations, though achieving temperatures of 50°C. Wherever possible/practical remedial action should be carried out to increase temperatures to 55°C.	3			
Outlet 00C Concourse ENT-048 (Toilet)	Hot temperature slow to rise. It should be confirmed that hot outlet(s) are on a long leg and not that the flow and return has failed locally in this area.	3			
General System	Pipework runs above ceilings in throughout every floor of the building. Access to these for ongoing monitoring will be problematic as ceiling tiles cannot be easily removed within the hospital environment and alternative methods of monitoring should be considered should current BEMS monitoring points not be sufficient for the hot flow and return system. additional BEMS monitoring points installed). DMA identified a very small number of localities where the hot water system did not appear to be functioning correctly and these should be investigated with corrective actions taken.	3			
Outlet 03C Ward GWS-011 (Facilities)	Potential scald risk. Fit scald risk signs and/or consider fitting TMV(s) to hot outlets.	3			
Outlet 06A GENW1-001 (Arjo Bathroom)	TMV inaccessible during survey. Access should be provided for assessment/maintenance.	3			

LEGIONELLA RISK ASSESSMENT

Location/Plant Item	Recommendation	Remedial Action Category	Assigned to	Actions Taken	Completed
Domestic Water System	There are numerous connection points onto other "non-domestic" outlets such as renal dialysis, endoscopy wash, pressurisation units, steam humidifier units and MRI chiller cooling which are connected to the Bulk Water system. It is advised that Estates (or Brookfield/Mercury) confirm these systems have suitable backflow protection installed or if necessary suitable backflow protection fitted.	2			
	It is also advised that as the lines to these systems will often have a very low turnover a double check valve or similar should be fitted as close as practicable to the tee-off point to prevent potentially stagnant water from contaminating the domestic system.	2			
MRI Chillers Wet/Dry (Adiabatic) Cooling)	Depending on the actual design and operation of these units they may require to be registered with the local authority under the NCTEC Notification Requirements (See HSG 274 Part 1 Para 1.18 – 1.21 inclusive of Figure 1.4 and Info Box 1.1). These may also require ongoing treatment or monitoring programmes to be implemented depending on assessment. Maintain in accordance with manufacturers/installers instructions.	2			
	Consider use of POU disinfection system such as UV for spray water.	2			
	Connection point to MRI unit(s) should be included in site flushing regime and have suitable backflow protection fitted.	2			
Emergency Showers	HSG 274 Part 3 recommends minimum six monthly flushing of emergency/deluge shower, though Risk Control Notice 11/advises "flush through and purge to drain twice per week– source SHTM 04-01 Part G (Draft). NHS Estates should formulate an appropriate flushing regime and maintain in accordance with manufacturers/installers instructions.	2			

LEGIONELLA RISK ASSESSMENT

Location/Plant Item	Recommendation	Remedial Action Category	Assigned to	Actions Taken	Completed
Dental Chairs/System	HSG 274 Part 3 states "Drain down, clean, flush and disinfect all system components, pipework and bottles twice daily. Disinfectant contact time as recommended by manufacturer. Take microbiological measurements (Refer to Decontamination HTM 01-05)	2			
	SHTM 04-01 Part G (Draft) states "Drain down and clean at the end of each working day".	2			
	HTM 01-05 provides advice and recommendations for on-going maintenance and this should be followed in addition to manufacturers and installers instructions.	2			
Hydrotherapy Pool	Maintain in accordance with manufacturers/installers instructions and "PHLS Hygiene for Hydrotherapy Pools" and Pool Water Treatment Advisory Group (PWTAG) Code of Practice (Feb 2015).	2			
	CWST requires to be cleaned and disinfected as stagnation noted at time of survey.	2			
Air Conditioning/Ventilation	Maintain in accordance with manufacturers/installers instructions and SHTM 03-01 and SHTM 04-01 Part G (Draft).	2			
Steam Humidification	Maintain in accordance with manufacturers/installers instructions and SHTM 03-01 and SHTM 04-01 Part G (Draft). Offline at time of survey.	2			
Medical Gases/Medical Equipment (e.g. Nebulisers, incubators, etc.)	Conduct a risk assessment of each system, preferably using an assessment team comprising members knowledgeable in legionella management and control, as well as those familiar with the design and operation of the system and Infection Control/Clinical staff where appropriate. Control procedures within appropriate SHTM (or other relevant guidance) for system being assessed should be taken in to account during assessment(s). Any water softeners or other filtration equipment connected to these systems should be assessed at this time. Devise a control scheme based on the risk assessment.	2			
Sprinkler System	Minimise aerosol creation during maintenance procedures. Consider wearing suitable masks to prevent ingestion as recommended by the FIA guidance. Maintain in accordance with manufacturers/installers instructions.	2			

LEGIONELLA RISK ASSESSMENT

Location/Plant Item	Recommendation	Remedial Action Category	Assigned to	Actions Taken	Completed
12th Floor Heli-pad fire suppression system	Minimise aerosol creation during maintenance procedures. Consider wearing suitable masks to prevent ingestion as recommended by the FIA guidance. Maintain in accordance with manufacturers/installers instructions.	2			
	Include all points on the 12th floor Trades system (including inlet to fire tank) in site flushing regime.	2			
Irrigation System	Include in site flushing regime. Additional flushing may also be required (outlets run for extended periods) to bring temperatures on distribution system down particularly during periods of low use (e.g. in winter when irrigation system is not required to operate frequently).	2			
	Maintain in accordance with manufacturers/installers instructions.	3			
Arjo Bath	Consider shortening shower hoses as it was noted that these can in some areas reach into adjacent WCs and WHBs.	2			
	Maintain in accordance with manufacturers/installers instructions. Where flexible hoses (i.e. internal to bath unit) cannot be removed then replacing with alternative WRAS approved hoses with linings other than EPDM should be considered.	3			
Water Softeners	Maintain in accordance with manufacturers/installers instructions (including cleaning and disinfection of resin and brine tanks). Ensure aerosol creation is minimised during maintenance and testing procedures.	3			
Endoscopy Wash	Maintain in accordance with manufacturers/installers instructions and current NHS (SHTM) protocols. Ensure aerosol creation is minimised during maintenance and testing procedures.	3			

LEGIONELLA RISK ASSESSMENT

Location/Plant Item	Recommendation	Remedial Action Category	Assigned to	Actions Taken	Completed
Renal Dialysis (Adult)	Maintain in accordance with manufacturers/installers instructions, current NHS (SHTM) protocols and "Clinical Practice Guideline by the UK Renal Association of Renal Technologists". Ensure aerosol creation is minimised during maintenance and testing procedures.	3			
Renal Dialysis (Children's)	Maintain in accordance with manufacturers/installers instructions, current NHS (SHTM) protocols and "Clinical Practice Guideline by the UK Renal Association of Renal Technologists". Ensure aerosol creation is minimised during maintenance and testing procedures.	3			
Closed Chilled Systems	Minimise aerosol creation during maintenance procedures. Maintain in accordance with manufacturers/installers instructions.	3			
Closed Heating Systems	Minimise aerosol creation during maintenance procedures. Maintain in accordance with manufacturers/installers instructions.	3			
Decorative Bubble Lamps	Maintain in accordance with manufacturers/installers instructions and ensure aerosols minimised during maintenance.	3			
	If aerosols are likely to be released then this should be viewed as an "indoor water feature" and should be removed.	2			

Section 3

Site/Client Details

LEGIONELLA RISK ASSESSMENT

Site/Client Details

Client	**GG&C SGUH**
Client address	South Glasgow University Hospital 1345 Govan Road Glasgow
Client contact	Ian Powrie
Telephone No.	[redacted]
E-mail	[redacted]
Mobile No.	[redacted]

Site	**South Glasgow University Hospital (including Royal Hospital for Sick Children)**
Site Address	South Glasgow University Hospital 1345 Govan Road Glasgow
Client contact	Ian Powrie
Telephone No.	[redacted]
E-mail	[redacted]
Mobile No.	[redacted]

Signed on behalf of

Client	**Sign**
	Print
	Date

LEGIONELLA RISK ASSESSMENT

General Site Details

Site	South Glasgow University Hospital (including Children's Hospital)
Age of building	Completed and handed over to NHS in January 2015 for phased occupation commencing April 26th 2015
Years since upgrade/renovation of water services	N/A
Purpose/use of building	Office/administration, Hospital
Operational cycle of the water system being assessed?	Continuous
Potentially affected population	Staff, Contractors, Visitors, Patients, General public
Is the building used by "at risk" or "particularly vulnerable" persons	Yes - Acute medical conditions
Total number of people usually in building (including staff/sub-contractors visitors/pupils etc.)	Unknown - client to confirm
Applicable Legionella standard(s)	L8, SHTM 04-01

LEGIONELLA RISK ASSESSMENT

Identification of Systems and Scope of Assessment

Domestic Water System		Present on site,
Evaporative cooling tower or condenser systems (and associated water system)		None identified to DMA
Fountains and water features		None identified to DMA
Hydrotherapy Pool		Present on site
Whirlpool/Arjo Baths		Present on site
Dental equipment		Present on site
Vehicle wash systems (inc. Trolley Wash & Power Washing Plant)		None identified to DMA
Emergency showers		Present on site
Irrigation systems		Present on site
Sprinkler/Wet fire-fighting systems		Present on site
Water softeners		Present on site
Industrial process water systems		None identified to DMA
Machine coolants		None identified to DMA
Air washers, wet scrubbers, particle and trivial gas scrubbers		None identified to DMA
Spray humidifiers		Steam Humidifiers present
Ultrasonic humidifiers/foggers and water misting systems		None identified to DMA
Recycled Water Systems		None identified to DMA
Closed heating water systems (MTHW)		Present on site
Closed chilled water systems		Present on site
Other 'at-risk' systems	Renal Dialysis (x2)	Present on site
	Endoscopy Wash	Present on site
	Medical Gases/Medical Equipment (e.g. Nebulisers, incubators etc.)	Present on site
	Wet/Dry (Adiabatic) Cooling (e.g MRI chillers)	Present on site

N.B. Systems assessed in this document as per client specification.

LEGIONELLA RISK ASSESSMENT

Legionella Control Measures Currently Used on Site

What is the primary control method for legionella control for the domestic water systems currently used on site and are there any supplementary or replacement control systems on site?[#]	
	Control measure
Temperature controlled	Primary
Chlorine dioxide	Not used
Hydrogen peroxide/silver ion	Not used
Silver/copper ion	Not used
Ultraviolet	Not used
Other (detail)	-

[#] If any method other than, or in addition to, temperature is used as method of control then details of records/regime can be found in section 9.

Section 4

Water Source

Summary of Risk Potential

Town mains water is generally not expected to present a significant risk for the contamination of a system with legionella, though it may be assumed that legionella in low concentrations could be present in the mains water on occasion. Therefore it must be assumed that it is not practical to prevent legionella entering the water system at some point.

There are, in addition, other bacteria, contaminants and physical factors that can create a risk to mains water users in the building.

Where the water source to the site is from a natural source, e.g. River, lake, spring or private water supply then the potential for legionella contamination increases.

N.B. Unless specifically stated otherwise the incoming mains/water source has been assessed from point of entry to the building. External & underground water services which serve the building and are not visible have not been assessed.

Please refer to water source sheets for specific recommendations and risk ratings.

South Glasgow University Hospital Water Source

There are three mains supplies into the SGUH, two which are designated as domestic water supplying Raw Water CWSTs and a third fire mains supplying the sprinkler tanks in the basement.

The Govan Road domestic mains supplies Raw Water CWSTs 1B and 2B, with the Hardgate Road (Large) supplying Raw Water CWSTs 1A & 2A.

The Hardgate Road (small) mains supply feeds only the main fire sprinkler tanks in the basement fire tank plantroom.

CWST 1A and Trades Water (RHS) CWST were valved off (mains only) at the time of assessment.

There are various short deadlegs on the domestic water mains which may be used as drain down points, injection points or emergency bypass connection points. DMA would recommend these are included in the site flushing regime.

There was bypass pipework set up to run from the Hardgate Road mains to the domestic (Bulk) water supply system connecting in after the Booster Pumps (5.0 Bar set). This was noted during DMAs initial site walk round and reported to Estates. DMA again noted this during the site survey of the CWSTs on 02/04/15 and again reported this to Estates. DMA were advised in mid-April this had been removed by Mercury/Brookfield. This line could potentially have introduced debris to the distribution system which would otherwise have been removed by the filtration units and could be a contributory factor to any out of specification microbiological results.

N.B. It should be noted that there is no separate dedicated supply to the Renal (or other medical) systems, with all being fed from the Bulk Water system. This means that system disinfections will require to be very carefully scheduled or carried out locally as the disinfection procedure/chemical may interfere with the renal/medical systems and impact on patient welfare.

Id no.		Hardgate Road (Large)		
Labelled		Mains: Yes Pipework: Yes Valves: No		
Access		Good		
Type		Town mains		
Supply company		Scottish Water		
Services supplied		CWST(s)		
Location		Basement Main Tank plantroom		
Size		150		
Meter reading		2987	Time 10.15	Date 24/03/15
Material		MDPE, Other Stainless steel		
Double check valve fitted		Yes		
Drain/injection point		None visible		
Temperature (ºc)		7.0		
Pipework insulated		Yes		
Incoming Water	pH	7.3		
	Residual free chlorine	<0.1		
Isolation valve		Yes		
Deadlegs		See comments		
Non WRAS materials		None visible		
Level of Risk		Medium		

Recommendations and Comments	Assigned to	Completed
Mains to Raw Water Tank 1A valved off at time of survey (and had been for a considerable period of time) prior to DMA surveying. Mains line should be incorporated into the site flushing regime until such times as issues with valves etc. corrected. Please refer to CWST section for further recommendations. Deadlegs (drain points/injection points) should be removed or incorporated into low use outlets flushing regime. All plant items, pipework and valves should be labelled for identification purposes. **Comments:** There was bypass pipework set up to run from the Hardgate Road mains to the domestic (Bulk) water supply system connecting in after the Booster Pumps (5.0 Bar set). This was noted during DMAs initial site walk round and reported to Estates. DMA again noted this during the site survey of the CWSTs on 02/04/15 and again reported this to Estates. DMA were advised in mid-April this had been removed by Mercury/Brookfield. This line could potentially have introduced debris to the distribution system which would otherwise have been removed by the filtration units and could be a contributory factor to any out of specification microbiological results.		

Id no.		Govan Road		Recommendations and Comments	Assigned to	Completed
Labelled		Mains: Yes Pipework: Yes Valves: No		RHS Trades Water Tank inlet valved off creating a deadleg. This should be incorporated into the weekly flushing regime until such times as CWST issue corrected. Please refer to CWST section for further recommendations. Deadlegs (drain points/injection points) should be removed or incorporated into low use outlets flushing regime. All plant items, pipework and valves should be labelled for identification purposes. **Comments:** Water meter and check valve in main tank room.		
Access		Good				
Type		Town mains				
Supply company		Scottish Water				
Services supplied		CWST(s)				
Location		Basement MTHW/Chilled plantroom				
Size		150				
Meter reading		0830	Time: 11.18 / Date: 24/03/15			
Material		MDPE, Other Stainless steel				
Double check valve fitted		Yes				
Drain/injection point		Yes				
Temperature (ºc)		7.1				
Pipework insulated		Yes				
Incoming Water	pH	7.3				
	Residual free Chlorine	<0.1				
Isolation valve		Yes				
Deadlegs		See comments				
Non WRAS materials		None visible				
Level of Risk		Medium				

Id no.		Hardgate Road (Small)		Recommendations and Comments	Assigned to	Completed
Labelled		Mains: Yes Pipework: Yes Valves: No		As this mains lines is likely to have a low turnover of water DMA would recommend the NHS confirms that this main is separated from domestic water mains by a double check valve or similar (possibly external to building) to prevent potentially stagnant water from contaminating the domestic mains. All plant items, pipework and valves should be labelled for identification purposes. **Comments:** Mains valved off prior to fire tanks at time of survey creating a long deadleg on the fire main.		
Access		Good				
Type		Town mains				
Supply company		Scottish Water				
Services supplied		Fire tanks				
Location		Basement Main Tank plantroom				
Size		54				
Meter reading			Time	Date		
Material		MDPE, Other Stainless steel				
Double check valve fitted		Yes				
Drain/injection point		Yes				
Temperature (ºc)						
Pipework insulated		Yes				
Incoming Water	pH					
	Residual free Chlorine					
Isolation valve		Yes				
Deadlegs		None visible				
Non WRAS materials		None visible				
Level of Risk		Low as this is a dedicated Fire Mains feeding only the Fire tanks.				

Section 5

Cold Water Storage Tanks

Cold Water Storage Tanks (Cisterns)

Cold Water Storage Tanks (CWSTs), in themselves, present a low Legionella risk in general terms. However, where the tanked water supplies other plant that has a high risk factor (e.g. cooling towers, showers, etc.) The potential risk is much higher.

Poor control over water temperature and condition of the stored water, plus the condition of the tank itself, may lead to Legionella colonising and proliferating in the tank and therefore producing possible source of bacteria to infect other water services downstream.

Basic principles being looked at in this section are the physical condition and the design of the CWST and associated pipework, ensuring these comply with the relevant guidelines, and the condition of the water being stored within the water tank. The water stored within the tanks should be no more than 2°C higher than the incoming mains, and less than 20°C

All CWSTs inherently carry the risk associated with the make-up source to the CWST, and these risk factors must be taken into account in determining the actual risk posed by the system as a whole.

Please refer to appropriate sections on Legionella management, CWSTs and water source to determine the inherent risk factors of water being supplied to the CWSTs being assessed in this section.

Risk factors incorporated within this section refer only to the risk factors associated with the CWSTs.

Please refer to individual CWST sheets for specific recommendations and risk ratings.

South Glasgow University Hospital CWSTs

The Domestic Cold Water Storage Tanks are all situated in the basement tank room.

Raw Water Tanks 1A/1B and 2A/2B are supplied by two town mains (Govan Road and Hardgate Road) to ensure continuity of supply in case of a town mains failure. The Raw Water tanks supply the Bulk Water tanks 1A/1B and 2A/2B via two 0.5 micron filtration sets. All Raw Water tanks were linked at the time of survey, though can be set up to feed filters units separately if required.

The filtration units fill separate Bulk Water Tanks (filtration unit 1 supplying 1A & 1B and filtration unit 2 supplying 2A & 2B). There is no way to reconfigure set-up to allow the filtration units to fill the other tanks under fault conditions. Filtration sets should be maintained in accordance with manufacturer's instructions and Brookfield maintenance schedule.

Bulk Water Tanks 1A and 1B are linked, with 2A and 2B also linked. All four tanks can be linked together (via outlets) to supply domestic cold water including drinking water to the building with the exception of the trades system. The link between the tanks 1A/1B and 2A/2B was closed at the time survey with each set of tanks supplying separate zones and plantrooms (calorifiers) within the hospital, 1A/1B supplying plantrooms 21/22/41 and the corresponding outlets in these zones with 2A/2B supplying plantrooms 31/32/33 and the corresponding outlets in these zones.

At the time of survey DMA noted that the Hardgate Road supply into Raw Water Tank 1A has been isolated creating a deadleg and NHS Estates confirmed this had been isolated for a number of weeks pending repair by Mercury Engineering. This has still not been completed at the time of this report. The outlet from this tank has remained live during this period which means this is acting as a balance tank with no through flow of water leading to stagnation and film formation on the water surface. DMA would recommend this tank is completely isolated from service until the mains inlet can be repaired, and the CWST cleaned and disinfected prior to re-use (including the mains line).

DMA noted that an 'emergency bypass' had been left in place and open between the Hardgate Road town mains supply and the booster pump sets (5.0 Bar set), bypassing all CWSTs and filtration sets. This bypass was ultimately removed though information from Estates staff suggests it was in place for a number of weeks and may have led to sediment and other debris which would otherwise have been removed by the filtration set being introduced into the system and could be a contributory factor to any out of specification microbiological results.

Upon inspection DMA noted that water levels in Bulk Water Tanks 2A & 2B were extremely low. NHS Estates were informed and advised this was due to a fault on the filtration system which had led to the Raw Water supply to the tanks being shut down. As site estates staff do not currently have access to the BEMS system they were unaware of this fault.

DMA were later advised a similar fault had occurred on the other filtration set affecting Bulk Water Tanks 1A/1B. In order to ensure continuity of supply to all areas the bypass between 1A/1B and 2A/2B was opened on both occasions. DMA were advised Estates staff are unsure why the bypass is closed as all four Bulk Water Tanks were classified as linked. Until site staff have access to the BEMS and the filter system monitoring it may be advantageous to leave the bypass open, ensuring all tanks are balanced and to introduce an inspection/monitoring regime at suitable intervals.

DMA noted small debris including washers in Bulk Water Tank 2B and would advise that this tank is cleaned to remove debris and then disinfected. The volume of debris within the water tanks appeared to be more than would be expected considering the Bulk Water tanks are fed via 0.5 micron filter sets.

N.B. It should be noted that there is no separate dedicated supply to the Renal (or other medical) systems, with all being fed from the Bulk Water system. This means that system disinfections will require to be very carefully scheduled or carried out locally as the disinfection procedure/chemical may interfere with the renal/medical systems and impact on patient welfare.

The expansion vessels attached to the CWST booster sets are not of a flow through design and they are not insulated.

There are numerous connection points on the domestic water system within plantrooms and risers (which DMA have assumed were installed for flushing purposes and bypasses) which are creating deadlegs on the system. It is advised that these be removed wherever practicable or a register of the locations created and points incorporated into the site flushing regime.

The Trades Water System supplies "Non-domestic" outlets such as bib taps in plantrooms, irrigation connections points and the 12th floor heli-pad fire suppression system. One side of the Trades tank was valved off due to a reported inlet valve issue (though tank full with signs of stagnation). DMA would advise the tank is cleaned and disinfected prior to the tank being reinstated.

There are however some connection points onto other "non-domestic" outlets such as renal dialysis, endoscopy wash, pressurisation units, steam humidifier units and MRI chiller cooling which are connected to the Bulk Water system. It is advised that Estates (or Brookfield/Mercury) confirm these systems have suitable backflow protection installed or if necessary suitable backflow protection fitted. It is also advised that as the lines to these systems will often have a very low turnover a double check valve or similar should be fitted as close as practicable to the tee-off point to prevent potentially stagnant water from contaminating the domestic system.

Other tanks fitted though part of other non-domestic systems.

Temperatures recorded for the CWSTs were taken on 02/04/15

						Recommendations and Comments	Assigned to	Completed
Name/number of CWST		Raw Water (4 off)				At the time of survey DMA noted that the Hardgate Road supply into Raw Water Tank 1A has been isolated creating a deadleg and NHS Estates confirmed this had been isolated for a number of weeks pending repair by Mercury Engineering. This has still not been completed at the time of this report. The outlet from this tank has remained live during this period which mains this is acting as a balance tank with no through flow of water leading to stagnation and film formation on the water surface DMA would recommend this tank is completely isolated from service until the mains inlet can be repaired, and the CWST cleaned and disinfected prior to re-use (including the mains line). Ensure linked CWSTs are balanced to provide equal throughput of water through each tanks. Storage temperatures indicate heat gain between incoming mains and stored water. Further monitoring recommended with capacities altered if required to match usage requirements. A suitable screened vent should be fitted to the warning pipe. Additional access hatches on tanks for cleaning/inspection purposes should be considered. There is drain down points on pipework. These should be included in site flushing regime. All plant items, pipework and valves should be labelled for identification purposes.		
Location of CWST		Basement Tank plantroom						
Labelled		**CWST**	**Pipework**		**Valves**			
		No	Yes		No			
Type		Sectional						
Materials		GRP						
Lined		No						
Dimensions (m)		5x5x2 (1.6)						
Volume (litres)		50000 (40000)						
Linked/single		Linked						
M/U opposite draw off		Diagonal						
Make up source		Town mains						
Services supplied		CWST						
Temperature °C		**Make Up**	**Tank Water**		**Plantroom**			
		7.0/7.1	1A – 9.4 2A – 8.8	1B – 10.3 2B – 8.6	15.6			
Internal condition	Internal	Good						
	Waterline	No mark						
	Dirt & silt	1A & 2A Light sediment, 1B & 2B Medium Sediment						
Water condition		Clear						
Stagnation		Yes (1A)						
Deadlegs around CWST		Yes – See comments						
Close fitting lid/screened vent		Yes		Fitted				
Warning Pipe Screen		None visible						
Overflow Screen		Fitted						
Insulation		Yes - pre-fitted						
Access		Good						
Vents returning to CWST		No						
Is drain present?		Yes						
Booster pumps	Fitted	Yes 2						
	Vibration Couplings	No vibration coupling visible No flexible hoses visible						
	Expansion Vessel	No						
	Drain on Vessel?	-						
Overall risk rating		**High**						

						Recommendations and Comments	Assigned to	Completed
Name/number of CWST		Bulk Water (4 off)				Upon inspection DMA noted that water levels in Bulk Water Tanks 2A & 2B were extremely low. NHS Estates were informed and advised this was due to a fault on the filtration system which had led to the Raw Water supply to the tanks being shut down. As site estates staff do not currently have access to the BEMS system they were unaware of this fault. Ensure linked CWSTs are balanced to provide equal throughput of water through each tank. A suitable screened vent should be fitted to the warning pipe. Wherever possible/practical expansion vessels should be 'flow through' vessels or added to the flushing regime. Expansion vessel should be suitably insulated. Additional access hatches on tanks for cleaning/inspection purposes should be considered. Ensure short connection between booster sets is thoroughly flushed before use should it ever be required. Drain points should be fitted to pump manifolds to allow end of lines to be flushed. There are various drain points and bypass valves fitted to the pipework in the plantroom. These should be included in site flushing regime. All plant items, pipework and valves should be labelled for identification purposes		
Location of CWST		Basement Tank plantroom						
Labelled		**CWST**	**Pipework**	**Valves**				
		No	Yes	No				
Type		Sectional						
Materials		GRP						
Lined		No						
Dimensions (m)		13.5x5x2 (1.6)						
Volume (litres)		135000 (108000)						
Linked/single		Linked						
M/U opposite draw off		Diagonal						
Make up source		CWST						
Services supplied		See comments						
Temperature °C		**Make Up**	**Tank Water**		**Plantroom**			
		See comments	1A – 10.4 1B – 11.5 2A – low level 2B – low level		15.6			
Internal condition	Internal	Good						
	Waterline	No mark						
	Dirt & silt	Light sediment, though more than would be expected after filtration and washers on base of tank.						
Water condition		Clear						
Stagnation		No						
Deadlegs around CWST		Yes – see comments						
Close fitting lid/screened vent		Yes	Fitted					
Warning Pipe Screen		None visible						
Overflow Screen		Fitted						
Insulation		Yes - pre-fitted						
Access		Good						
Vents returning to CWST		No						
Is drain present?		Yes						
Booster pumps	Fitted	Yes 10						
	Vibration Couplings	No vibration coupling visible No flexible hoses visible						
	Expansion Vessel	Yes - upright						
	Drain on Vessel?	Able to be drained/flushed (large only)						
Overall risk rating		**Medium**						

					Recommendations and Comments	Assigned to	Completed
Name/number of CWST		Trades Water (2 off)			RHS side of the Trades tank was valved off due to a reported inlet valve issue (though tank full with signs of stagnation). DMA would advise the tank is cleaned and disinfected prior to the tank being reinstated. A suitable screened vent should be fitted to the overflow. Wherever possible/practical expansion vessels should be 'flow through' vessels. Expansion vessels should be included in site flushing regime. Expansion vessel should be suitably insulated. Ideally a drain should be fitted to pump manifold to allow end of lines to be flushed. All plant items, pipework and valves should be labelled for identification purposes.		
Location of CWST		Basement Tank plantroom					
Labelled		**CWST**	**Pipework**	**Valves**			
		No	Yes	No			
Type		Sectional					
Materials		GRP					
Lined		No					
Dimensions (m)		2x2x1 (0.7)					
Volume (litres)		4000 (2800)					
Linked/single		Linked					
M/U opposite draw off		Outlet on base					
Make up source		Town mains					
Services supplied		Designated "non-domestic" outlets (i.e. irrigation, 12th floor heli-pad fire suppression and plantroom bib taps)					
Temperature °C		**Make Up**	**Tank Water**	**Plantroom/Ambient**			
		7.0/offline	8.5/offline	15.6			
Internal condition	Internal	Good					
	Waterline	No mark					
	Dirt & silt	Light sediment					
Water condition		Clear					
Stagnation		Yes					
Deadlegs around CWST		Yes – on mains to linked tanks, Yes – on outlet to linked tanks					
Close fitting lid/screened vent		Yes	Fitted				
Warning Pipe Screen		Fitted					
Overflow Screen		None visible					
Insulation		Yes - pre-fitted					
Access		Good					
Vents returning to CWST		No					
Is drain present?		Yes					
Booster pumps	Fitted	Yes 3					
	Vibration Couplings	No vibration coupling visible No flexible hoses visible					
	Expansion Vessel	Yes - upright					
	Drain on Vessel?	Able to be drained/flushed					
Overall risk rating		**High Risk**					

Section 6

Calorifiers and Water Heaters

Calorifiers and Water Heaters

Calorifiers present a low Legionella risk, however when the calorifier water supplies other associated plant which may have a high risk potential (e.g. Showers etc.), the potential risk from such calorifiers is significantly higher.

Calorifiers have been a major source of proliferation of Legionella.

Poor control over the water temperature and condition of the calorifier are the most significant factors in determining the risk presented by hot water calorifiers to the down water services.

Basic principles being looked at in this section are the physical condition and the design of the calorifiers/water heaters and associated pipework, ensuring these comply with the relevant guidelines, and the condition of the water being stored within the heaters. The water should be stored at a minimum of 60°C, with the entire body of the calorifier achieving this temperature for a minimum period of 1 hour per day. The base temperature and return temperatures should maintain a minimum temperature of 50°C at all times.

Risk factors incorporated within this section refer only to the risk factors associated with the calorifiers (or water heaters).

All calorifiers inherently carry the risk associated with the make-up source e.g. CWST, and these risk factors must be taken into account in determining the actual risk posed by the system as a whole. Please refer to appropriate sections on Legionella management, CWSTs and water source to determine the inherent risk factors of water being supplied to the calorifiers being assessed in this section.

Please refer to calorifier sheets for specific recommendations and risk ratings.

Backflow protection: suitable backflow protection should be fitted to all water heaters on pressurised systems (e.g. Mains fed or boosted cold water fed). Before fitting any double check valves or other forms of backflow protection ensure that adequate pressure relief valves are fitted and working in the event of excessive pressure or temperature build up within water heaters.

South Glasgow University Hospital calorifiers & hot water systems

The calorifiers are situated in various plantrooms on the 2nd, 3rd and 4th floors of the building feeding designated zones within the hospital building. See supportive data following which identifies which calorifiers feed which areas.

Each set of calorifiers is a bank of 3 linked calorifiers fed from the boosted Bulk Water system, with heat source being via a plate heat exchanger on the outside of each calorifier fed from the MTHW system. A circulating pump on each calorifier/plate heat exchanger ensures the water is circulated throughout each vessel to maintain temperature.

The distribution temperatures were almost invariably above 50°C at all outlets (Supply to TMVs) with direct hot feeds above 55°C (see outlet section for supportive data and exceptions).

The return temperatures recorded at the calorifiers were consistently below 55°C which DMA were advised was the control set point for these, though when calorifiers were at full temperature the returns were reaching 50°C. It may be prudent to increase calorifier set points to ensure calorifier returns remain above 55°C as this is the control set point. This may also help maintain a 60C minimum flow temperature when demand is placed on the calorifiers as the building becomes occupied. Increasing the calorifier temperatures may also have the beneficial effect of increasing the cold water usage as more cold water will be required at TMVs to blend water to TMV set point and so may assist in reducing the high cold water temperatures being recorded within the system.

When DMA were on site on the 21st of April there was a significant drop on the temperatures of the calorifiers 31-01/02/03, 31-07/08/09 and 21-01/02/03 which we understand was caused by a failure on the heating system. Temperatures recorded on these calorifiers on this day (as recorded in the following sheets) was 40-45°C. This represented a significant break in the control system and there were no records of any remedial or corrective actions and no records of additional control measures. DMA would advise corrective actions and additional control measures (e.g. system pasteurisation/disinfection) should be carried out in accordance with SHTM 04-01 in instances of this type. When DMA re-checked the affected calorifier temperatures on 27th April 2015 the temperatures had improved though 31-07/08/09 were still significantly lower than expected.

When calorifiers are running at full temperature they appear to be achieving 60°C consistently, though this cannot be fully verified as estates staff did not have full access to the BEMS system at the time of survey. There have been some exceptions to this as highlighted in the supportive data following where one calorifier appears to be the lead calorifier and subsequently has lower temperatures than the connected calorifiers in the bank of 3. This may be a balancing issue and should be investigated and corrected (e.g. Calorifiers 22-01/02/03 with 02 being significantly lower temperature than 01 & 03).

Calorifier 32-03 was offline when DMA had an initial site familiarisation walk-round with Mercury Engineering in early January 2015. This calorifier was still offline when DMA were on site on 21st April 2015. This was creating deadlegs on the cold supply, hot flow and hot return to the calorifier and Estates staff were unable to confirm the reason for this calorifier being offline. This calorifier had been reinstated when DMA revisited on 27/04/15 though Estates not aware of any flushing, pasteurisation or disinfection of calorifier being carried out prior to reinstatement. DMA would recommend the calorifier (and hot system) is disinfected/pasteurised legionella samples taken from the calorifier and system prior to reinstatement to confirm these corrective actions have been effective.

The expansion vessels attached to the calorifiers are not of a flow through design as recommended in HSG 274 Part 2 (info Box 2.1) and SHTM 04-01 Part A (Para 8.22) and they are not insulated as recommended in SHTM 04-01 Part A (Para 8.22).

The calorifiers do not have labels on them, instead being labelled at present by a marker pen, with a separate small identification plate on the side of each calorifier. The labelling does not match up in every instance between the hand written and id plate. It is advised that calorifiers have formal identification label attached to each one.

ID No./Name		01/02/03						Recommendations and Comments	Assigned to	Completed
Location		Plantroom 21						When DMA were on site on the 21st of April there was a significant drop on the temperatures of the calorifiers which we understand was caused by a failure on the heating system. Temperatures recorded on these calorifiers on this day were 40-45°C. This represented a significant break in the control system and there were no records of any remedial or corrective actions and no records of additional control measures. DMA would advise corrective actions and additional control measures (e.g. system pasteurisation/disinfection) should be carried out in accordance with SHTM 04-01 in instances of this type. When DMA re-checked the affected calorifier temperatures on 27th April 2015 the temperatures had partially recovered though the central calorifier was still reading low. Central calorifier (02) flow temperature lower than those wither side suggesting this is acting a lead calorifier. Ensure linked calorifiers are balanced to provide equal throughput of water through each calorifier. Expansion vessel not flow through design – if practical these should be swapped to flow through vessels. As expansion vessels are not 'flow through' vessels these should be included in the site flushing regime. Expansion vessels should be suitably insulated. Where practical calorifier internal surfaces should be inspected annually. All plant items, pipework and valves should be labelled for identification purposes. **Notes:** Calorifier temperatures significantly dropped on 21/04/15 (those recorded on LHS). Temperatures recorded on RHS taken on 27/04/15 Distribution temperatures on the hot outlets fed from these calorifiers had been generally above 50°C in all locations (55°C at most direct hot outlets) during the survey works carried out by DMA up until this point		
Labelled		Cal	Yes	Pipes	Yes	Valves	No			
Type		Plate Heat Exchanger								
Materials		Stainless steel								
Access		Good								
Linked/single		Linked								
Heat source		MTHW								
Make up source		CWST bulk								
Services supplied (area)		Domestic hot water (Ground & 1st Floor - South)								
Cold feed location		Base								
Vent or pressure relief		Pressure relief								
Circulation pump	Fitted / No. / Check Valve	Yes		1		None visible				
Destrat pump	Fitted	None visible								
Pumps	Vibration couplings	None visible								
Expansion / buffer vessel	Fitted?	Yes - upright								
	Vessel able to be Flushed	Able to be drained/flushed								
Insulation		None visible								
Inspection Hatch (mm)		Yes 300								
Deadlegs around Calorifier		None visible								
Non WRAS materials		None visible								
Drain	Fitted/Water Quality	Yes								
Temperatures (°c)		Flow		**45/45/45**		60/**55**/60				
		Return		**41**		52				
		Base/Drain		**45/45/45**		58/55/58				
Risk Rating		**High**								

ID No./Name	01/02/03						Recommendations and Comments	Assigned to	Completed
Location	**Plantroom 22**						Central Calorifier (02) temperature lower than the other calorifiers. Ensure linked calorifiers are balanced to provide equal throughput of water through each calorifier. DMA understand this is due to an issue with the MTHW system being shut off (or not operational in some other way). Corrective actions should be taken and calorifier pasteurised/disinfected and brought up to full temperature. Expansion vessel not flow through design – if practical these should be swapped to flow through vessel. As expansion vessels are not 'flow through' vessels these should be included in the site flushing regime. Expansion vessels should be suitably insulated. Fit caps to ends of spare circulation pump. Where practical calorifier internal surfaces should be inspected annually. All plant items, pipework and valves should be labelled for identification purposes. **Notes:** Temperatures recorded on 21/04/15		
Labelled	Cal	Yes	Pipes	Yes	Valves	No			
Type	Plate Heat Exchanger								
Materials	Stainless steel								
Access	Good								
Linked/single	Linked								
Heat source	MTHW								
Make up source	CWST bulk								
Services supplied (area)	Domestic hot water Ground, 1st & 2nd Floors – North & Centre)								
Cold feed location	Base								
Vent or pressure relief	Pressure relief								
Circulation pump – Fitted / No. / Check Valve	Yes		1		None visible				
Destrat pump – Fitted	None visible								
Pumps – Vibration couplings	None visible								
Expansion / buffer vessel – Fitted?	Yes - upright								
Expansion / buffer vessel – Vessel able to be Flushed	Able to be drained/flushed								
Insulation	None visible								
Inspection Hatch (mm)	Yes 300								
Deadlegs around Calorifier	None visible								
Non WRAS materials	None visible								
Drain – Fitted/Water Quality	Yes								
Temperatures (°c)	Flow		60/**50**/60						
	Return		52						
	Base/Drain		50/50/50						
Risk Rating	**High**								

ID No./Name		01/02/03						Recommendations and Comments	Assigned to	Completed
Location		Plantroom 31						When DMA were on site on the 21st of April there was a significant drop on the temperatures of the calorifiers which we understand was caused by a failure on the heating system. Temperatures recorded on these calorifiers on this day were 40-45°C. This represented a significant break in the control system and there were no records of any remedial or corrective actions and no records of additional control measures. DMA would advise corrective actions and additional control measures (e.g. system pasteurisation/disinfection) should be carried out in accordance with SHTM 04-01 in instances of this type. When DMA rechecked the calorifiers on 27th April they appeared to have recovered fully.		
Labelled		Cal	Yes	Pipes	Yes	Valves	No			
Type		Plate Heat Exchanger								
Materials		Stainless steel								
Access		Good								
Linked/single		Linked								
Heat source		MTHW								
Make up source		CWST bulk								
Services supplied (area)		Domestic hot water (Ground, 1st & 2nd Floor East and 2nd Floor South)								
Cold feed location		Base						Ensure linked calorifiers are balanced to provide equal throughput of water through each calorifier.		
Vent or pressure relief		Pressure relief								
Circulation pump	Fitted / No. / Check Valve	Yes		1		None visible		Expansion vessel not flow through design – if practical these should be swapped to flow through vessels		
Destrat pump	Fitted	None visible						As expansion vessels are not 'flow through' vessels these should be included in the site flushing regime.		
Pumps	Vibration couplings	None visible								
Expansion / buffer vessel	Fitted?	Yes - upright						Expansion vessels should be suitably insulated.		
	Vessel able to be Flushed	Able to be drained/flushed						Fit caps to ends of spare circulation pump.		
Insulation		None visible								
Inspection Hatch (mm)		Yes 300						Where practical calorifier internal surfaces should be inspected annually.		
Deadlegs around Calorifier		None visible								
Non WRAS materials		None visible						All plant items, pipework and valves should be labelled for identification purposes.		
Drain	Fitted/Water Quality	Yes								
Temperatures (°c)		Flow		**45/45/45**		60/60/60		**Notes:** Calorifier temperatures significantly dropped on 21/04/15 Those recorded on LHS). Temperatures recorded on RHS taken on 27/04/15		
		Return		**42**		54				
		Base/Drain		**45/45/45**		59/58/59		Distribution temperatures on the hot outlets fed from these calorifiers had been generally above 50°C in all locations (55°C at most direct hot outlets) during the survey works carried out by DMA up until this point		
Risk Rating		**High**								

ID No./Name		04/05/06						Recommendations and Comments	Assigned to	Completed
Location		Plantroom 31								
Labelled		Cal	Yes	Pipes	Yes	Valves	No	Ensure linked calorifiers are balanced to provide equal throughput of water through each calorifier.		
Type		Plate Heat Exchanger								
Materials		Stainless steel						Expansion vessel not flow through design – if practical these should be swapped to flow through vessels		
Access		Good								
Linked/single		Linked								
Heat source		MTHW						As expansion vessels are not 'flow through' vessels these should be included in the site flushing regime.		
Make up source		CWST bulk								
Services supplied (area)		Domestic hot water (Floors 4-11 Zone E)						Expansion vessels should be suitably insulated.		
Cold feed location		Base								
Vent or pressure relief		Pressure relief						Fit caps to ends of spare circulation pump.		
Circulation pump	Fitted / No. / Check Valve	Yes				None visible		Where practical calorifier internal surfaces should be inspected annually.		
Destrat pump	Fitted	None visible						All plant items, pipework and valves should be labelled for identification purposes.		
Pumps	Vibration couplings	None visible								
Expansion / buffer vessel	Fitted?	Yes - upright						**Notes:** Temperatures recorded on 21/04/15		
	Vessel able to be Flushed	Able to be drained/flushed								
Insulation		None visible								
Inspection Hatch (mm)		Yes 300								
Deadlegs around Calorifier		None visible								
Non WRAS materials		None visible								
Drain	Fitted/Water Quality	Yes								
Temperatures (°c)		Flow	60/60/60							
		Return	55							
		Base/Drain	59/60/60							
Risk Rating		**Low**								

ID No./Name		07/08/09						Recommendations and Comments	Assigned to	Completed
Location		Plantroom 31								
Labelled		Cal	Yes	Pipes	Yes	Valves	No	When DMA were on site on the 21st of April there was a significant drop on the temperatures of the calorifiers which we understand was caused by a failure on the heating system. Temperatures recorded on these calorifiers on this day were 40-45°C. When DMA re-checked the affected calorifier temperatures on 27th April 2015 the calorifiers were still significantly lower than expected (see return line gauge photos in Section 11). This represents a significant break in the control system and DMA would advise corrective actions and additional control measures (e.g. system pasteurisation/disinfection) should be carried out in accordance with SHTM 04-01.		
Type		Plate Heat Exchanger								
Materials		Stainless steel								
Access		Good								
Linked/single		Linked								
Heat source		MTHW								
Make up source		CWST bulk								
Services supplied (area)		Domestic hot water (Floors 4-11 Zone H)								
Cold feed location		Base								
Vent or pressure relief		Pressure relief								
Circulation pump	Fitted / No. / Check Valve	Yes		1		Yes		Ensure linked calorifiers are balanced to provide equal throughput of water through each calorifier.		
Destrat pump	Fitted	None visible						Expansion vessel not flow through design – if practical these should be swapped to flow through vessels		
Pumps	Vibration couplings	None visible						As expansion vessels are not 'flow through' vessels these should be included in the site flushing regime.		
Expansion / buffer vessel	Fitted?	Yes - upright								
	Vessel able to be Flushed	Able to be drained/flushed						Expansion vessels should be suitably insulated.		
Insulation		None visible						Fit caps to ends of spare circulation pump.		
Inspection Hatch (mm)		Yes 300								
Deadlegs around Calorifier		None visible						Where practical calorifier internal surfaces should be inspected annually.		
Non WRAS materials		None visible								
Drain	Fitted/Water Quality	Yes						All plant items, pipework and valves should be labelled for identification purposes.		
Temperatures (°c)		Flow		**45/45/45**		**45/45/**60		**Notes:** Calorifier temperatures significantly dropped on 21/04/15 Those recorded on LHS).		
		Return		**42**		**46**				
		Base/Drain		**45/45/45**		**45/45/**58		Temperatures recorded on RHS taken on 27/04/15 Distribution temperatures on the hot outlets fed from these calorifiers had been generally above 50°C in all locations (55°C at most direct hot outlets) during the survey works carried out by DMA up until this point.		
Risk Rating		**High**								

ID No./Name		01/02/03						Recommendations and Comments	Assigned to	Completed
Location		Plantroom 32								
Labelled		Cal	Yes	Pipes	Yes	Valves	No	Calorifier 32-03 was offline when DMA had an initial site familiarisation walk-round with Mercury Engineering in early January 2015. This calorifier was still offline when DMA were on site on 21st April 2015. This was creating deadlegs on the cold supply, hot flow and hot return to the calorifier and Estates staff were unable to confirm the reason for this calorifier being offline. This calorifier had been reinstated when DMA revisited on 27/04/15 though Estates not aware of any flushing, pasteurisation or disinfection of calorifier being carried out prior to reinstatement. DMA would recommend the calorifier (and hot system) is disinfected/pasteurised and legionella samples taken from the calorifier and system prior to reinstatement to confirm these corrective actions have been effective.		
Type		Plate Heat Exchanger								
Materials		Stainless steel								
Access		Good								
Linked/single		Linked								
Heat source		MTHW								
Make up source		CWST bulk								
Services supplied (area)		Domestic hot water (Floors 4 - 11 Zone F)								
Cold feed location		Base								
Vent or pressure relief		Pressure relief								
Circulation pump	Fitted / No. / Check Valve	Yes		1		Yes		Ensure linked calorifiers are balanced to provide equal throughput of water through each calorifier.		
Destrat pump	Fitted	None visible						Expansion vessel not flow through design – if practical these should be swapped to flow through vessels		
Pumps	Vibration couplings	None visible						As expansion vessels are not 'flow through' vessels these should be included in the site flushing regime.		
Expansion / buffer vessel	Fitted?	Yes - upright						Expansion vessels should be suitably insulated.		
	Vessel able to be Flushed	Able to be drained/flushed						Fit caps to ends of spare circulation pump.		
Insulation		None visible						Where practical calorifier internal surfaces should be inspected annually.		
Inspection Hatch (mm)		Yes 300						All plant items, pipework and valves should be labelled for identification purposes.		
Deadlegs around Calorifier		None visible								
Non WRAS materials		None visible								
Drain	Fitted/Water Quality	Yes								
Temperatures (°c)		Flow		60/60/**offline**		60/60/60				
		Return		53		54				
		Base/Drain		60/60/**offline**		60/60/60				
Risk Rating		**High**								

ID No./Name		01/02/03						Recommendations and Comments	Assigned to	Completed
Location		Plantroom 33								
Labelled		Cal	Yes	Pipes	Yes	Valves	No	There is a deadleg on the cold feed at these calorifiers – this should be removed or included in site flushing regime. Ensure linked calorifiers are balanced to provide equal throughput of water through each calorifier. Expansion vessel not flow through design – if practical these should be swapped to flow through vessels As expansion vessels are not 'flow through' vessels these should be included in the site flushing regime. Expansion vessels should be suitably insulated. Fit caps to ends of spare circulation pump. Where practical calorifier internal surfaces should be inspected annually. All plant items, pipework and valves should be labelled for identification purposes. **Notes:** Temperatures recorded on 21/04/15 Gauge on base of calorifier 1 reading 70°C – this gauge should be checked to ensure working correctly and replaced if necessary.		
Type		Plate Heat Exchanger								
Materials		Stainless steel								
Access		Good								
Linked/single		Linked								
Heat source		MTHW								
Make up source		CWST bulk								
Services supplied (area)		Domestic hot water (Floors 4-11 Zone J)								
Cold feed location		Base								
Vent or pressure relief		Pressure relief								
Circulation pump	Fitted / No. / Check Valve	Yes		1		Yes				
Destrat pump	Fitted	None visible								
Pumps	Vibration couplings	None visible								
Expansion / buffer vessel	Fitted?	Yes - upright								
	Vessel able to be Flushed	Able to be drained/flushed								
Insulation		None visible								
Inspection Hatch (mm)		Yes 300								
Deadlegs around Calorifier		Yes								
Non WRAS materials		None visible								
Drain	Fitted/Water Quality	Yes								
Temperatures (°c)		Flow	65/60/60							
		Return	54.5							
		Base/Drain	55/55/55							
Risk Rating		**Medium**								

ID No./Name		01/02/03						Recommendations and Comments	Assigned to	Completed
Location		Plantroom 41						Ensure linked calorifiers are balanced to provide equal throughput of water through each calorifier. Expansion vessel not flow through design – if practical these should be swapped to flow through vessels As expansion vessels are not 'flow through' vessels these should be included in the site flushing regime. Expansion vessels should be suitably insulated. Fit caps to ends of spare circulation pump. Vibration couplings should be regularly inspected and maintained in accordance with manufacturer's instructions. Where practical calorifier internal surfaces should be inspected annually. All plant items, pipework and valves should be labelled for identification purposes.		
Labelled		Cal	Yes	Pipes	Yes	Valves	No			
Type		Plate Heat Exchanger								
Materials		Stainless steel								
Access		Good								
Linked/single		Linked								
Heat source		MTHW								
Make up source		CWST bulk								
Services supplied (area)		Domestic hot water Children's Hospital								
Cold feed location		Base								
Vent or pressure relief		Pressure relief								
Circulation pump	Fitted / No. / Check Valve	Yes		1		Yes				
Destrat pump	Fitted	None visible								
Pumps	Vibration couplings	Yes Appear in good condition								
Expansion / buffer vessel	Fitted?	Yes - upright								
	Vessel able to be Flushed	Able to be drained/flushed								
Insulation		Yes								
Inspection Hatch (mm)		Yes 300								
Deadlegs around Calorifier		None visible								
Non WRAS materials		None visible								
Drain	Fitted/Water Quality	Yes								
Temperatures (°c)		Flow	60/60/60							
		Return	55							
		Base/Drain	60/60/60							
Risk Rating		**Low**								

Section 7

Hot and Cold Water Outlets

Showers and other spray outlets

Since showers produce fine water droplets or spray they present a significantly higher risk for the development of Legionnaires ' disease than other types of hot and cold outlets.

Water temperature, system design/installation, showerhead design, frequency of use and cleanliness of the outlet are the most significant factors in determining the risk potential.

Hot and cold water outlets

Hot and cold-water outlets do not normally present a risk for the development of Legionnaires' disease unless the outlets create fine droplets or spray. Outlets that do create sprays/droplets significantly increase the risk.

Water temperature, system design/installation, frequency of use, tap design and cleanliness of the outlet are the most significant factors in determining the risk potential.

Basic principles being looked at in this section are the physical condition, and the design of the water services pipework and outlets, and the temperature profile of the water being distributed to the outlets. There should be no unused outlets or deadlegs (blank-ends) on any parts of the systems. Hot water should be delivered to all outlets at a minimum of 55°C within 1 minute of outlet being run and cold water below 20°C within 2 minutes of being run. Cold water should be no more than 2°C higher at the outlet then the water source for this outlet (e.g. CWST). This section also incorporates details of spray outlets/aerosol generators (showers etc.), low use outlets and unused outlets.

Please refer to outlet sheets for specific recommendations & risk ratings.

Risk factors incorporated within this section of the document are classified as "additional localised risk rating". This refers only to the condition of the localised pipework distribution and services and the risk rating applied is in addition to risk rating of the plant items feeding the services.

All outlets fed from CWSTs or calorifiers etc. Inherently carry the risk associated to these plant items, and these risk factors must be taken into account in determining the actual risk posed by the system as a whole.

Please refer to appropriate sections on legionella management, CWSTs, calorifiers and water source to determine the inherent risk factors of water being supplied to the outlets being assessed in this section.

Hot and Cold Water Outlet General Notes

1. DMA have not noted any spray outlets, other than showers and dish wash rinsers and have been advised no other spray outlets fitted. However should any have been fitted then wherever possible, DMA would recommend that spray taps are removed and replaced with taps which do not create an aerosol. Tap diffusers should also be removed where possible to minimise aerosol creation and the build-up of dirt/scale etc. on the diffusers wherever possible.

2. Very few drain cocks have been noted on piperuns, though there are some flushing points – see site specific notes following regarding these. Drain cocks fitted at the end of pipe runs should be removed if not required for operational reasons or periodically flushed and checks carried out to ensure that inserts/washers etc. are WRAS approved.

3. Adequate backflow protection as per Water Regulations Guide & Water Byelaws (Scotland) – section 6, should be incorporated into the water services within the building. See comments and recommendations regarding "non-domestic" outlets. Before fitting any double check valves or other forms of backflow protection ensure that adequate pressure relief valves/expansion vessels are fitted and working in the event of excessive pressure or temperature build up within system.

4. Water coolers and drinks machines should have regular servicing carried out (generally six monthly) as per manufacturers recommendations.

5. All low use outlets, and all associated pipework, should be removed leaving no deadlegs if outlets no longer required, or incorporated into low use flushing regime.

6. All deadlegs should be removed wherever possible. Where deadlegs are unable to be removed provision to allow flushing of the deadlegs as part of the site flushing regime should be made. (i.e. Valves fitted at end of deadlegs to allow flushing to be carried out).

7. Cold water should be delivered to outlets (and cold feed to thermostatic mixing valves) at less than 20°C within 2 minutes of outlet being run, and not more than 2°C above outlet water source temperature (i.e. CWST)

8. Hot water should be delivered to outlets (and hot feed to thermostatic mixing valves) at more than 55°C, within 1 minute of outlet being run.

South Glasgow University Hot and Cold Water Systems

The domestic cold water system within the hospital is fed from the Bulk Water tanks located in the basement tank room of the hospital. DMA have been informed there are no outlets fed directly from Town Mains within the building.

"Non-domestic" outlets such as bib taps in plantrooms, irrigation connections points and the 12th floor heli-pad fire suppression system are fed from the Trades Water tanks. Please refer to the section 5 for information and supporting data relating to the CWSTs.

There are however some connection points onto other "non-domestic" outlets such as renal dialysis, endoscopy wash, pressurisation units, steam humidifier units and MRI chiller cooling which are connected to the Bulk Water system. It is advised that Estates (or Brookfield/Mercury) confirm these systems have suitable backflow protection installed or if necessary suitable backflow protection fitted. It is also advised that as the lines to these systems will often have a very low turnover a double check valve or similar should be fitted as close as practicable to the tee-off point to prevent potentially stagnant water from contaminating the domestic system.

It should be noted that there is no separate dedicated supply to the Renal (or other medical) systems, with all being fed from the Bulk Water system. This means that system disinfections will require to be very carefully scheduled or carried out locally as the disinfection procedure/chemical may interfere with the renal/medical systems and impact on patient welfare.

The domestic hot water systems are fed from a series of Calorifiers located on the 2nd and 3rd floors in the adult hospital and on the 4th floor of the children's hospital. These calorifiers feed different areas/zones within the Hospital. Please refer to section 6 for information and supporting data relating to the calorifiers.

The distribution temperatures on the domestic water systems recorded by DMA have largely replicated those provided to DMA (on Zutec) for the commissioning phase and those being recorded by estates staff. The cold water temperatures recorded by DMA vary considerably with the majority being more than 5°C higher than those recorded at the water tanks and with peak temperatures of 30°C being noted. Additional control measure such as flushing, disinfections and background dosing flushing should be implemented until such times as the area/department fully occupied, storage and distribution temperatures and microbiological results are consistently satisfactory.

DMA have been advised by Estates there are ongoing commissioning problems on the cold water dump valve system and the system is not operating as intended. DMA have noted during site surveys there were areas with cold water temperatures in excess of 20°C and dump valves are fitted, but the valves not discharging. Corrective action should be taken and once fully operational the control set points and parameters for discharging should be referenced in site written scheme.

The hot water distribution temperatures again largely replicate those from the commissioning phase and estates, with hot temperatures frequently recorded below 55°C at supply to TMVs. It should be noted though that direct hot taps did reach temperatures of 55°C and supply to TMVs was almost invariably above 50°C (see following pages for supportive data and exceptions). As 55°C at all outlets is the control parameter set by SHTM 04-01 corrective actions should be carried out to ensure this is achieved. This may include increasing the calorifier set points - see calorifier sections for further comments and recommendations.

Increasing the calorifier temperatures may also have the beneficial effect of improving the cold water temperature profile as more cold water will be required at TMVs to blend water to TMV set point.

It should be noted that temperatures at outlets were recorded on various dates from 26th March through 21st April 2015. There were issues with calorifier temperatures on 21st April (refer to Section 6 for information) though this did not affect the temperatures at outlets taken by DMA as Plantroom 41 calorifiers did not appear to be affected and all outlet temperatures taken on this date by DMA were in the children's hospital.

Due to the temperature deviations from the control parameters noted during the commissioning and handover phase and out of specification NHS microbiological sampling results DMA would recommend fitting supplementary control systems (e.g. background dosing such as chlorine dioxide), in order to maintain microbiological control and/or biofilm monitors (such as BioSense sensors/controller) to assist in focusing remedial actions onto identified areas of microbial activity.

Domestic water pipework runs above ceilings throughout the building. Access for ongoing monitoring will be problematic as ceiling tiles cannot be easily removed within the hospital environment and alternative methods of monitoring should be considered should current BEMS monitoring points not be sufficient for the hot flow and return system (e.g. additional BEMS monitoring points installed).

DMA have been advised by Mercury Engineering that the domestic hot water systems do not operate on a conventional flow and return system, with principle, sub-ordinate and tertiary loops, instead utilising a reverse return circuit. This means that there are longer "deadlegs" to the outlets than SHTM 04-01 advises. However, it was noted that hot temperatures generally rose very quickly when DMA were recording temperatures throughout the building and the flow and return circuits appear to be circulating hot water to all areas, with only a few exceptions noted (please refer to following pages for supporting data and exceptions).

The pipework within the hospital is generally labelled and insulated throughout with only a few very short pieces of insulation missing being noted (see following pages for exceptions). It is advised that all missing sections of insulation are replaced.

The vast majority of TMVs installed are TMV taps, (Horne in clinical areas and Markwik in non-clinical areas) with the only exceptions noted being infrared outlets in non-patient area toilets with infrared taps which have a TMV mounted approximately 0.5m from the outlet. Thermostatic mixing valves (TMVs) should be serviced and have fail safe tests carried out routinely and strainers should be cleaned on a regular basis as per manufacturer's recommendations and in accordance with Written Scheme guidance.

DMA were unable to access the shower TMVs as Estates staff were unable to provide a key to open the shower casing as these have not been provided as yet. Showers appear to be a standard design throughout the hospital. A check as to the TMV and pipework layout for these should be carried out to ensure they are compliant.

There are numerous connection points on the domestic water system within plantrooms and risers (which DMA have assumed were installed for flushing purposes and bypasses) which are creating deadlegs on the system. It is advised that these be removed wherever practicable or a register of the locations created and points incorporated into the site flushing regime.

Flexible hoses have been noted in Kitchen/Pantry areas where there are flexible connections to dishwashers (not all fitted at present), in Facilities rooms (connections to double level sinks), in Dirty Utility rooms (connections to sluice machines) with the only patient areas DMA have noted as having flexible hoses being the connection to Arjo baths (both connections to the hot/cold system and internally within the actual bath). Wherever possible DMA would recommend all flexi hoses are removed and connections hard piped. Where flexible hoses cannot be removed then replacing with alternative WRAS approved hoses with linings other than EPDM should be considered. In healthcare premises additional guidance on the replacement and use of flexible hoses is provided in the "safety action notice SAN(SC)09/03".

Flexible hoses have also been noted on the boosted bulk water system on pressure reducing valves. If possible these should be hard piped (stainless steel) or WRAS approved hoses with linings other than EPDM should be considered. Should these not be available for these types of units/connections then a regular inspection and replacement schedule should be implemented for these.

DMA were advised by Mercury Engineering and Estates that all materials fitted during the construction are WRAs approved and therefore do not support bacterial growth. In particular Horne TMV taps were designed specifically with Legionella and Pseudomonas control in mind. The use of EPDM flexible hoses in some areas may contradict this statement and their use should be reviewed to ensure compliance.

There were deadlegs recorded in Plantroom 31 at calorifiers 31-07/08/09, in the hydrotherapy plantroom and in the Medical Day Unit (MDU-005). These should be removed or incorporated into the site flushing regime.

Other "deadlegs" were recorded though these appear to be connections for drinks machines or kitchen appliances which have not been fitted at the time of survey. These should be included into the site flushing regime until such times as they are installed and department area fully functioning.

It was noted that there were copper tails on connections to a small number of outlets e.g. Infrared taps in non-patient toilets and in the endoscopy wash room DCT-009.

There are alcohol gel wash points at most WHBs throughout the hospital which may discourage/reduce water usage at taps.

DMA were advised that connections to pressurisation units had double check valves fitted by Mercury Engineering during installation, though these are covered by insulation and DMA were unable to verify how close to the tee-off points these are. This should be checked and if necessary double check valves repositioned/fitted as necessary. It is also advised that fast fill connections are disconnected when not in use due to the different water categories between the wholesome domestic water and the chemically treated closed systems.

The steam humidifiers do not appear to have been commissioned as yet (and DMA were informed by Estates these may not actually be commissioned in the immediate future) creating deadlegs on the cold system within the relevant plantrooms. It is advised that these have suitable backflow protection installed on the lines where the tee-off from the main line or are included in the site flushing regime until such times as the units are commissioned and fully operational.

There is a connection to the MRI chillers on the 3rd floor room which branches from plantroom 31 via a RPZ valve. The domestic water supply to these chillers we would assume is for additional cooling at times of high demand which would classify the chillers as dry/wet cooling (or hybrid or Adiabatic depending on engineering terminology). Depending on the actual design and operation of these units they may require to be registered with the local authority under the NCTEC Notification Requirements (See HSG 274 Part 1 Para 1.18 – 1.21 inclusive of Figure 1.4 and Info Box 1.1). These may also require ongoing treatment or monitoring programmes to be implemented.

The turnover at present to the renal and endoscopy wash systems was unable be verified by DMA at the time of survey. It should be confirmed that these lines are included in the site flushing regime not only during the handover phase but also during times of low use once building is fully occupied (or confirmation that systems run on a daily basis recorded to remove requirement for flushing).

The bib taps, irrigation points etc. and 12th floor heli-pad fire suppression system which are fed from the Trades system have very long runs through the building and plantrooms to the outlets. All points on the trades system should be included in the site flushing regime – though additional flushing (outlets run for extended periods) may be required to bring temperatures on distribution system down particularly during periods of low use (e.g. in winter when irrigation system is not required to operate frequently).

No outlets on the Trades system have been designated as "sentinel outlets". Due to the type of system and the extended pipe runs to the outlets it may be prudent to designate all outlets from this system as sentinel and include in monthly monitoring and site flushing regime.

A microbiological sampling sweep was being undertaken whilst DMA were on site carrying out the site surveys. No results for these samples have been forwarded to DMA for comment or recommendations, though DMA were advised that system disinfections were being carried out on 24th April due to "out-of-specification" results being returned and that an increased flushing regime had been implemented in the areas where out of specifications results obtained.

Please refer to following pages within this section for supporting data and information relating to the hot and cold water systems. It should be noted that the information and recommendations included within these pages relates to the outlets identified (mostly the sentinel outlets as uploaded onto Zutec), though many of the issues and conditions highlighted will be replicated throughout the hospital. Issues and information included should not be taken as a comprehensive or complete data set and should be treated as a representative sample of the system conditions found within the hospital.

LEGIONELLA RISK ASSESSMENT

Location / Room No	Sentinel outlet?	Cold Supply & Temp (°C)	Hot Supply & Temp (°C)	TMV info					Deadlegs Present (Inc. Drain cocks)	Flow & Return Working	Outlet Usage	Outlets in location											Aerosol Created	Non WRAS Material	Flexi Hoses	Comment	Additional Localised Risk Rating
				No. Of TMVs	Access	<2m from outlet?	Mix Temps 37-45°C	No. TMV Fed Outlets				Mains	Cold	Hot	Mixer	Urinals	WCs	Shower	Drinks / vend	Water boiler	Drinking fountain	Arjo/whirlpool	Other					
Basement KIT-031	Hot, Cold	CWST 18.2	Calorifier 50.2	1	OK	Yes	Yes	1	Yes - on cold pipework	Not visible	Some outlets unused				1									Low	None visible	None visible	Unused equipment connection	Medium
Recommendations:			Ensure unused vend connection included in flushing regime																								
			Hot outlets do not comply with latest SHTM regulations, though achieving 50°C. Wherever practicable increase temperatures to 55°C.																								
Hydrotherapy Plantroom A-1FMB-030		CWST 14.3	No hot outlets	0		Yes		0	Yes - on cold pipework	Yes	Some outlets unused		1											High	None visible	None visible	Blind loop on hot - working ok Emergency Shower	Medium
Recommendations:			Remove all deadleg pipework in this area.																								
			Fit check valve to emergency shower (& bib tap if not fitted)																								
			Include bib tap & Emergency Shower in flushing regime																								
00 A&E Courtyard	No	CWST 24.4	No hot outlets	0		Yes		0	None visible	N/A	Flush Regime		1											Low	None visible	None visible		Medium
Recommendations:			Cold water temperature too high. Investigate and correct.																								
00 A&E EMC-018 (Toilet)	Hot, Cold	CWST 22.4	Calorifier 55.5	1	OK	Yes	Yes	1	None visible	Not visible	Flush Regime				1		1							Low	None visible	None visible	IR Tap	Medium
Recommendations:			Cold water temperature too high. Investigate and correct.																								

LEGIONELLA RISK ASSESSMENT

Location / Room No	Sentinel outlet?	Cold Supply & Temp (°C)	Hot Supply & Temp (°C)	TMV info					Deadlegs Present (Inc. Drain cocks)	Flow & Return Working	Outlet Usage	Outlets in location												Aerosol Created	Non WRAS Material	Flexi Hoses	Comment	Additional Localised Risk Rating
				No. Of TMVs	Access	<2m from outlet?	Mix Temps 37-45°C	No. TMV Fed Outlets				Mains	Cold	Hot	Mixer	Urinals	WCs	Shower	Drinks / vend	Water boiler	Drinking fountain	Arjo/whirlpool	Other					
00 A&E EMC-037 (Toilet)	Hot, Cold	CWST 14.1	Calorifier 55.2	1	OK	Yes	Yes	1	None visible	Not visible	Flush Regime				1		1							Low	None visible	None visible		Low
Recommendations:																												
00 A&E EMC-041 (Toilet)	Hot, Cold	CWST 14.2	Calorifier 55.3	1	OK	Yes	Yes	1	None visible	Not visible	Flush Regime				1		1							Low	None visible	None visible		Low
Recommendations:																												
00 A&E EMC-059 (Bed Bay 5)	Hot, Cold	CWST 11.4	Calorifier 51.4	1	OK	Yes	Yes	1	None visible	Not visible	Flush Regime		1	1										Low	None visible	None visible		Low
Recommendations:	Hot outlets do not comply with latest SHTM regulations, though achieving 50°C. Wherever practicable increase temperatures to 55°C.																											
00 A&E EMC-060 (Bed Bay 6)	Hot, Cold	CWST 11.6	Calorifier 51.1	1	OK	Yes	Yes	1	None visible	Not visible	Flush Regime		1	1										Low	None visible	None visible		Low
Recommendations:	Hot outlets do not comply with latest SHTM regulations, though achieving 50°C. Wherever practicable increase temperatures to 55°C.																											
00 A&E EMC-063 (Bed Bay 8)	Hot, Cold	CWST 11.8	Calorifier 52.0	1	OK	Yes	Yes	1	None visible	Not visible	Flush Regime		1	1										Low	None visible	None visible		Low
Recommendations:	Hot outlets do not comply with latest SHTM regulations, though achieving 50°C. Wherever practicable increase temperatures to 55°C.																											

LEGIONELLA RISK ASSESSMENT

Location / Room No	Sentinel outlet?	Cold Supply & Temp (°C)	Hot Supply & Temp (°C)	TMV info					Deadlegs Present (Inc. Drain cocks)	Flow & Return Working	Outlet Usage	Outlets in location											Aerosol Created	Non WRAS Material	Flexi Hoses	Comment	Additional Localised Risk Rating
				No. Of TMVs	Access	<2m from outlet?	Mix Temps 37-45°C	No. TMV Fed Outlets				Mains	Cold	Hot	Mixer	Urinals	WCs	Shower	Drinks / vend	Water boiler	Drinking fountain	Arjo/whirlpool	Other					
00 A&E EMC-076 (Bed Bay 12)	Hot, Cold	CWST 15.1	Calorifier 51.3	1	OK	Yes	Yes	1	None visible	Not visible	Flush Regime		1	1										Low	None visible	None visible		Low
Recommendations:			Hot outlets do not comply with latest SHTM regulations, though achieving 50°C. Wherever practicable increase temperatures to 55°C.																									
00 A&E EMC-086 (Facilities)	Hot, Cold	CWST 12.4	Calorifier 56.3	1	OK	Yes	Yes	1	None visible	Not visible	Flush Regime		3	3										Low	None visible	Yes		Low
Recommendations:			All EPDM flexible hoses should be removed and replaced with hard piped connection.																									
00 A&E EMC-093 (Bed Bay 18)	Hot, Cold	CWST 23.5	Calorifier 50.1	1	OK	Yes	Yes	1	None visible	Not visible	Flush Regime		1	1										Low	None visible	None visible		Medium
Recommendations:			Cold water temperature too high. Investigate and correct. Hot outlets do not comply with latest SHTM regulations, though achieving 50°C. Wherever practicable increase temperatures to 55°C.																									
00 A&E EMC-100 (Service)						Yes		0																	Yes		No access
Recommendations:			Locked – No Access. Area should be assessed once access obtained.																									
00 A&E EMC-111 (Female Change)	Hot, Cold	CWST 22.2	Calorifier 55.5	3	OK	Yes	Yes	3	None visible	Not visible	Flush Regime		3	3										Low	None visible	None visible		Medium
Recommendations:			Cold water temperature too high. Investigate and correct.																									

LEGIONELLA RISK ASSESSMENT

Location / Room No	Sentinel outlet?	Cold Supply & Temp (°C)	Hot Supply & Temp (°C)	TMV info					Deadlegs Present (Inc. Drain cocks)	Flow & Return Working	Outlet Usage	Outlets in location												Aerosol Created	Non WRAS Material	Flexi Hoses	Comment	Additional Localised Risk Rating
				No. Of TMVs	Access	<2m from outlet?	Mix Temps 37-45°C	No. TMV Fed Outlets				Mains	Cold	Hot	Mixer	Urinals	WCs	Shower	Drinks / vend	Water boiler	Drinking fountain	Arjo/whirlpool	Other					
00 A&E EMC-135 (Store)	Hot, Cold	CWST 23.1	Calorifier 54.5	1	OK	Yes	Yes	1	None visible	Not visible	Flush Regime		2	2										Low	None visible	None visible		Medium
Recommendations:			Cold water temperature too high. Investigate and correct.																									
			Hot outlets do not comply with latest SHTM regulations, though achieving 50°C. Wherever practicable increase temperatures to 55°C.																									
00 Acute Assess AAW-007 (Facilities)	Hot, Cold	CWST 16.6	Calorifier 57.2	1	OK	Yes	Yes	1	None visible	Not visible	Flush Regime		3	3										Low	None visible	Yes		Low
Recommendations:			All EPDM flexible hoses should be removed and replaced with hard piped connection.																									
00 Acute Assess AAW-017 (Bedroom)	Hot, Cold	CWST 17.9	Calorifier 53.1	1	OK	Yes	Yes	1	None visible	Not visible	Flush Regime		1	1										Low	None visible	None visible		Low
Recommendations:			Hot outlets do not comply with latest SHTM regulations, though achieving 50°C. Wherever practicable increase temperatures to 55°C.																									
00 Acute Assess AAW-032 (Bathroom)	Hot, Cold	CWST 25.3	Calorifier 55.3	2	OK	Yes	Yes	2	None visible	Not visible	Flush Regime				1		1	1						High	None visible	None visible		High
Recommendations:			Cold water temperature too high. Investigate and correct.																									
00 Acute Assess AAW-038 (Toilet)	Hot, Cold	CWST 23.0	Calorifier 55.7	1	OK	Yes	Yes	1	None visible	Not visible	Flush Regime				1		1							Low	None visible	None visible		Medium
Recommendations:			Cold water temperature too high. Investigate and correct.																									

LEGIONELLA RISK ASSESSMENT

Location / Room No	Sentinel outlet?	Cold Supply & Temp (°C)	Hot Supply & Temp (°C)	TMV info					Deadlegs Present (Inc. Drain cocks)	Flow & Return Working	Outlet Usage	Outlets in location												Aerosol Created	Non WRAS Material	Flexi Hoses	Comment	Additional Localised Risk Rating
				No. Of TMVs	Access	<2m from outlet?	Mix Temps 37-45°C	No. TMV Fed Outlets				Mains	Cold	Hot	Mixer	Urinals	WCs	Shower	Drinks / vend	Water boiler	Drinking fountain	Arjo/whirlpool	Other					
00 Acute Assess AAW-045 (Treatment Room)	Hot, Cold	CWST 22.1	Calorifier 54.2	1	OK	Yes	Yes	1	None visible	Not visible	Flush Regime		1	1										Low	None visible	None visible	Sampling being carried at same time	Medium
Recommendations:			Cold water temperature too high. Investigate and correct.																									
			Hot outlets do not comply with latest SHTM regulations, though achieving 50°C. Wherever practicable increase temperatures to 55°C.																									
00 Acute Assess AAW-060 (Toilet)	Hot, Cold	CWST 24.3	Calorifier 55.1	1	OK	Yes	Yes	1	None visible	Not visible	Flush Regime				1		1							Low	None visible	None visible		Medium
Recommendations:			Cold water temperature too high. Investigate and correct.																									
00 Acute Assess AAW-088 (Bathroom)	Hot, Cold	CWST	Calorifier	2	OK	Yes	Yes	2	None visible	Not visible	Flush Regime				1		1	1						High	None visible	None visible	Unable to take temps due to poor flow	High
Recommendations:			Poor flow from outlet(s). Investigate and correct.																									
00 Acute Assess AAW-096 (Bathroom)	Hot, Cold	CWST 28.1	Calorifier 55.1	2	OK	Yes	Yes	2	None visible	Not visible	Flush Regime				1		1	1						High	None visible	None visible		High
Recommendations:			Cold water temperature too high. Investigate and correct.																									
00 Acute Assess AAW-108 (Bathroom)	Hot, Cold	CWST 22.8	Calorifier 55.6	2	OK	Yes	Yes	2	None visible	Not visible	Flush Regime				1		1	1						High	None visible	None visible		High
Recommendations:			Cold water temperature too high. Investigate and correct.																									

LEGIONELLA RISK ASSESSMENT

Location / Room No	Sentinel outlet?	Cold Supply & Temp (°C)	Hot Supply & Temp (°C)	TMV info					Deadlegs Present (Inc. Drain cocks)	Flow & Return Working	Outlet Usage	Outlets in location											Aerosol Created	Non WRAS Material	Flexi Hoses	Comment	Additional Localised Risk Rating
				No. Of TMVs	Access	<2m from outlet?	Mix Temps 37-45°C	No. TMV Fed Outlets				Mains	Cold	Hot	Mixer	Urinals	WCs	Shower	Drinks / vend	Water boiler	Drinking fountain	Arjo/whirlpool	Other					
00 Acute Assess AAW-125 (Facilities)	Hot, Cold	CWST 18.3	Calorifier 59.3	1	OK	Yes	Yes	1	None visible	Not visible	Flush Regime		3	3										Low	None visible	Yes		Low
Recommendations:	All EPDM flexible hoses should be removed and replaced with hard piped connection.																										
00 Acute Assess AAW-156 (Kitchen)																									Yes		No access
Recommendations:	Locked – No Access. Area should be assessed once access obtained.																										
00 Acute Assess AAW-163 (Toilet)	Hot, Cold	CWST 23.7	Calorifier 51.8	1	OK	Tap	Yes	1	None visible	Not visible	Flush Regime				1		1							Low	None visible	None visible		Medium
Recommendations:	Cold water temperature too high. Investigate and correct.																										
	Hot outlets do not comply with latest SHTM regulations, though achieving 50°C. Wherever practicable increase temperatures to 55°C.																										
00 Acute Assess AAW-173 (Clinical Support)	Hot, Cold	CWST 17.4	Calorifier 55.2	2	OK	Yes	Yes	2	None visible	Not visible	Flush Regime		1	1										Low	None visible	None visible		Low
Recommendations:																											
00 Acute Assess AAW-193 (Toilet)	Hot, Cold	CWST 23.2	Calorifier 55.1	1	OK	Yes	Yes	1	None visible	Not visible	Flush Regime				1		1							Low	None visible	None visible		Medium
Recommendations:	Cold water temperature too high. Investigate and correct.																										

LEGIONELLA RISK ASSESSMENT

Location / Room No	Sentinel outlet?	Cold Supply & Temp (°C)	Hot Supply & Temp (°C)	TMV info					Deadlegs Present (Inc. Drain cocks)	Flow & Return Working	Outlet Usage	Outlets in location												Aerosol Created	Non WRAS Material	Flexi Hoses	Comment	Additional Localised Risk Rating
				No. Of TMVs	Access	<2m from outlet?	Mix Temps 37-45°C	No. TMV Fed Outlets				Mains	Cold	Hot	Mixer	Urinals	WCs	Shower	Drinks / vend	Water boiler	Drinking fountain	Arjo/whirlpool	Other					
00 Acute Assess AAW-208 (Dirty Utility)	Hot, Cold	CWST 14.5	Calorifier 55.3	2	OK	Yes	Yes	2	None visible	Not visible	Flush Regime		2	2			1							Low	None visible	Yes	1 x sluice	Low
Recommendations:			All EPDM flexible hoses should be removed and replaced with hard piped connection.																									
00 Acute Assess AAW-226 (Lab)	Hot, Cold	CWST 24.1	Calorifier 54.5	1	OK	Yes	Yes	1	None visible	Not visible	Flush Regime		1	1										Low	None visible	None visible		Medium
Recommendations:			Cold water temperature too high. Investigate and correct.																									
			Hot outlets do not comply with latest SHTM regulations, though achieving 50°C. Wherever practicable increase temperatures to 55°C.																									
00 Acute Assess AAW-240 (Toilet)	Hot, Cold	CWST 25.3	Calorifier 55.3	1	OK	Yes	Yes	1	None visible	Not visible	Flush Regime				1		1							Low	None visible	None visible		Medium
Recommendations:			Cold water temperature too high. Investigate and correct.																									
00 Acute Assess AAW-247 (Kitchen)								0																		Yes		No access
Recommendations:			Locked – No Access. Area should be assessed once access obtained.																									
00 Acute Assess AAW-265 (Bedroom)	Hot, Cold	CWST 14.4	Calorifier 55.3	1	OK	Yes	Yes	1	None visible	Not visible	Flush Regime		1	1										Low	None visible	None visible		Low
Recommendations:																												

LEGIONELLA RISK ASSESSMENT

Location / Room No	Sentinel outlet?	Cold Supply & Temp (°C)	Hot Supply & Temp (°C)	TMV info					Deadlegs Present (Inc. Drain cocks)	Flow & Return Working	Outlet Usage	Outlets in location												Aerosol Created	Non WRAS Material	Flexi Hoses	Comment	Additional Localised Risk Rating
				No. Of TMVs	Access	<2m from outlet?	Mix Temps 37-45°C	No. TMV Fed Outlets				Mains	Cold	Hot	Mixer	Urinals	WCs	Shower	Drinks / vend	Water boiler	Drinking fountain	Arjo/whirlpool	Other					
00 Acute Assess AAW-306 (Toilet)	Hot, Cold	CWST 22.3	Calorifier 55.6	1	OK	Yes	Yes	1	None visible	Not visible	Flush Regime				1		1							Low	None visible	None visible		Medium
Recommendations:			Cold water temperature too high. Investigate and correct.																									
00 Acute Assess AAW-313 (Facilities)	Hot, Cold	CWST 12.9	Calorifier 59.9	1	OK	Yes	Yes	1	None visible	Not visible	Flush Regime		3	3										Low	None visible	Yes		Low
Recommendations:			All EPDM flexible hoses should be removed and replaced with hard piped connection.																									
00 Acute Assess AAW-334 (Bathroom)	Hot, Cold	CWST 16.3	Calorifier 55.5	2	OK	Yes	Yes	2	None visible	Not visible	Flush Regime				1		1	1						High	None visible	None visible		Low
Recommendations:																												
00 Acute Assess AAW-375 (Bedroom)	Hot, Cold	CWST 17.3	Calorifier 51.5	1	OK	Yes	Yes	1	None visible	Not visible	Flush Regime		1	1										Low	None visible	None visible		Low
Recommendations:			Hot outlets do not comply with latest SHTM regulations, though achieving 50°C. Wherever practicable increase temperatures to 55°C.																									
00 Concourse ENT-003 (Bute vend)	No	CWST	No hot outlets	0					None visible	N/A	Some outlets unused								1					Low	None visible	Yes	Vending machines not connected	Medium
Recommendations:			All EPDM flexible hoses should be removed and replaced with hard piped connection. Ensure unused vend connection included in flushing regime																									

LEGIONELLA RISK ASSESSMENT

Location / Room No	Sentinel outlet?	Cold Supply & Temp (°C)	Hot Supply & Temp (°C)	TMV info					Deadlegs Present (Inc. Drain cocks)	Flow & Return Working	Outlet Usage	Outlets in location												Aerosol Created	Non WRAS Material	Flexi Hoses	Comment	Additional Localised Risk Rating
				No. Of TMVs	Access	<2m from outlet?	Mix Temps 37-45°C	No. TMV Fed Outlets				Mains	Cold	Hot	Mixer	Urinals	WCs	Shower	Drinks / vend	Water boiler	Drinking fountain	Arjo/whirlpool	Other					
00 Concourse ENT-038 (Baby Change)	Hot, Cold	CWST 16.1	Calorifier 51.9	1	OK	Yes	Yes	1	None visible	Not visible	Flush Regime		1	1										Low	None visible	None visible		Low
Recommendations:			Hot outlets do not comply with latest SHTM regulations, though achieving 50°C. Wherever practicable increase temperatures to 55°C.																									
00 Concourse ENT-048 (Gents Toilet)																										Yes	Sign on door "Toilet blocked - do not use"	No access
Recommendations:			Locked – No Access. Area should be assessed once access obtained.																									
00 Concourse ENT-052 (Gents Toilet)	Hot, Cold	CWST 24.3	Calorifier 50.0	3	OK	Yes	Yes	3	None visible	Not visible	Daily				3									Low	None visible	None visible	Copper tails to IR taps	Medium
Recommendations:			Cold water temperature too high. Investigate and correct.																									
			Hot outlets do not comply with latest SHTM regulations, though achieving 50°C. Wherever practicable increase temperatures to 55°C.																									
00 Concourse ENT-054 (Shower)								0							1		1	1						High	None visible	None visible	Outlets not run as area still being worked in	High
Recommendations:			Area/outlets should be flushed/disinfected prior to it being brought into use.																									
00 Concourse ENT-062 (Facilities)	Hot, Cold	CWST 10.7	Calorifier 56.0	1	OK		Yes	1	None visible	Not visible	Flush Regime		3	3										Low	None visible	Yes		Low
Recommendations:			All EPDM flexible hoses should be removed and replaced with hard piped connection.																									

LEGIONELLA RISK ASSESSMENT

Location / Room No	Sentinel outlet?	Cold Supply & Temp (°C)	Hot Supply & Temp (°C)	TMV info					Deadlegs Present (Inc. Drain cocks)	Flow & Return Working	Outlet Usage	Outlets in location												Aerosol Created	Non WRAS Material	Flexi Hoses	Comment	Additional Localised Risk Rating
				No. Of TMVs	Access	<2m from outlet?	Mix Temps 37-45°C	No. TMV Fed Outlets				Mains	Cold	Hot	Mixer	Urinals	WCs	Shower	Drinks / vend	Water boiler	Drinking fountain	Arjo/whirlpool	Other					
00 Concourse FMA0-001 (Facilities)	Hot, Cold	CWST 12.5	Calorifier 57.5	1	OK	Yes	Yes	1	None visible	Not visible	Daily		3	3										Low	None visible	Yes		Low
Recommendations:			All EPDM flexible hoses should be removed and replaced with hard piped connection.																									
00 Discharge DLO-006 (Toilet)	Hot, Cold	CWST 23.2	Calorifier 52.4	1	OK	Yes	Yes	1	None visible	Not visible	Flush Regime				1		1							Low	None visible	None visible	Copper tail to IR Tap	Medium
Recommendations:			Cold water temperature too high. Investigate and correct.																									
			Hot outlets do not comply with latest SHTM regulations, though achieving 50°C. Wherever practicable increase temperatures to 55°C.																									
00 Discharge DLO-008 (Consulting Room)	Hot, Cold	CWST 24.3	Calorifier 50.1	1	OK	Yes	Yes	1	None visible	Not visible	Flush Regime		1	1										Low	None visible	None visible		Medium
Recommendations:			Cold water temperature too high. Investigate and correct.																									
			Hot outlets do not comply with latest SHTM regulations, though achieving 50°C. Wherever practicable increase temperatures to 55°C.																									
00 Medical Illustration MIL-010 (Studio)	Hot, Cold	CWST 15.6	Calorifier 51.8	1	OK		Yes	1	None visible	Not visible	Daily			1	1									Low	None visible	None visible		Low
Recommendations:			Hot outlets do not comply with latest SHTM regulations, though achieving 50°C. Wherever practicable increase temperatures to 55°C.																									

LEGIONELLA RISK ASSESSMENT

Location / Room No	Sentinel outlet?	Cold Supply & Temp (°C)	Hot Supply & Temp (°C)	TMV info					Deadlegs Present (Inc. Drain cocks)	Flow & Return Working	Outlet Usage	Outlets in location												Aerosol Created	Non WRAS Material	Flexi Hoses	Comment	Additional Localised Risk Rating
				No. Of TMVs	Access	<2m from outlet?	Mix Temps 37-45°C	No. TMV Fed Outlets				Mains	Cold	Hot	Mixer	Urinals	WCs	Shower	Drinks / vend	Water boiler	Drinking fountain	Arjo/whirlpool	Other					
00 OPD OPD0-003 (Male Change)	Hot, Cold	CWST 16.4	Calorifier 55.0	1	OK	Yes	Yes	1	None visible	Not visible	Flush Regime				1									Low	None visible	None visible		Low
Recommendations:																												
00 OPD OPD0-013 (Consulting Room)	Hot, Cold	CWST 17.2	Calorifier 52.5	1	OK	Yes	Yes	1	None visible	Not visible	Flush Regime		1	1										Low	None visible	None visible		Low
Recommendations:			Hot outlets do not comply with latest SHTM regulations, though achieving 50°C. Wherever practicable increase temperatures to 55°C.																									
00 OPD OPD0-049 (Treatment Room)	Hot, Cold	CWST 25.3	Calorifier 52.2	1	OK		Yes	1	None visible	Not visible	Flush Regime		1	1										Low	None visible	None visible		Medium
Recommendations:			Cold water temperature too high. Investigate and correct.																									
			Hot outlets do not comply with latest SHTM regulations, though achieving 50°C. Wherever practicable increase temperatures to 55°C.																									
00 OPD OPD0-067 (Dirty Utility)	Hot, Cold	CWST 19.1	Calorifier 53.7	2	OK	Yes	Yes	2	None visible	Not visible	Flush Regime		2	2			1							Low	None visible	Yes	Cold dump valve in room 1 x sluice	Low
Recommendations:			All EPDM flexible hoses should be removed and replaced with hard piped connection.																									
			Hot outlets do not comply with latest SHTM regulations, though achieving 50°C. Wherever practicable increase temperatures to 55°C.																									

LEGIONELLA RISK ASSESSMENT

Location / Room No	Sentinel outlet?	Cold Supply & Temp (°C)	Hot Supply & Temp (°C)	TMV info					Deadlegs Present (Inc. Drain cocks)	Flow & Return Working	Outlet Usage	Outlets in location												Aerosol Created	Non WRAS Material	Flexi Hoses	Comment	Additional Localised Risk Rating
				No. Of TMVs	Access	<2m from outlet?	Mix Temps 37-45°C	No. TMV Fed Outlets				Mains	Cold	Hot	Mixer	Urinals	WCs	Shower	Drinks / vend	Water boiler	Drinking fountain	Arjo/whirlpool	Other					
00 OPD/Concourse OPD0-072 (Toilet)	Hot, Cold	CWST	Calorifier	1	OK	Yes		1	None visible	Not visible	Flush Regime				1		1							Low	None visible	None visible	IR tap not working.	Medium
Recommendations:			IR tap not working creating deadlegs. Tap should be repaired and lines thoroughly flushed.																									
00 OPD/Concourse OPD0-073 (Shower)	Hot, Cold	CWST	Calorifier	1	OK	Yes		1	None visible	Not visible	Flush Regime				1		1	1						Low	None visible	None visible	IR tap not working	High
Recommendations:			IR tap not working creating deadlegs. Tap should be repaired and lines thoroughly flushed.																									
00 OPD/Concourse OPD0-075 (Toilet)	Hot, Cold	CWST 15.2	Calorifier 55.1	1	OK	Yes	Yes	1	None visible	Not visible	Flush Regime				1		1							Low	None visible	None visible		Low
Recommendations:																												
00 Orthotics ORT-015-2 (Staff Change)	Hot, Cold	CWST 22.3	Calorifier 53.1	1	OK	Yes	Yes	1	None visible	Not visible	Flush Regime				1		1							Low	None visible	None visible		Medium
Recommendations:			Cold water temperature too high. Investigate and correct.																									
			Hot outlets do not comply with latest SHTM regulations, though achieving 50°C. Wherever practicable increase temperatures to 55°C.																									

LEGIONELLA RISK ASSESSMENT

Location / Room No	Sentinel outlet?	Cold Supply & Temp (°C)	Hot Supply & Temp (°C)	TMV info					Deadlegs Present (Inc. Drain cocks)	Flow & Return Working	Outlet Usage	Outlets in location											Aerosol Created	Non WRAS Material	Flexi Hoses	Comment	Additional Localised Risk Rating
				No. Of TMVs	Access	<2m from outlet?	Mix Temps 37-45°C	No. TMV Fed Outlets				Mains	Cold	Hot	Mixer	Urinals	WCs	Shower	Drinks / vend	Water boiler	Drinking fountain	Arjo/whirlpool	Other					
00 Orthotics ORT-017 (Disabled)	Hot, Cold	CWST 25.1	Calorifier 53.1	1	OK	Yes	Yes	1	None visible	Not visible	Flush Regime				1		1							Low	None visible	None visible		Medium
Recommendations:			Cold water temperature too high. Investigate and correct.																									
			Hot outlets do not comply with latest SHTM regulations, though achieving 50°C. Wherever practicable increase temperatures to 55°C.																									
00 Orthotics ORT-027 (Treatment Room)	Hot, Cold	CWST 14.0	Calorifier 52.6	1	OK	Yes	Yes	1	None visible	Not visible	Flush Regime		1	1										Low	None visible	None visible		Low
Recommendations:			Hot outlets do not comply with latest SHTM regulations, though achieving 50°C. Wherever practicable increase temperatures to 55°C.																									
00 Orthotics ORT-045 (Toilet)	Hot, Cold	CWST 12.5	Calorifier 54.3	1	OK	Yes	Yes	1	None visible	Not visible	Flush Regime				1		1							Low	None visible	None visible		Low
Recommendations:			Hot outlets do not comply with latest SHTM regulations, though achieving 50°C. Wherever practicable increase temperatures to 55°C.																									
00 Pharmacy PHA-002 (Facilities)	Hot, Cold	CWST 13.5	Calorifier 57.2	1	OK	Yes	Yes	1	None visible	Not visible	Flush Regime		3	3										Low	None visible	Yes		Low
Recommendations:			All EPDM flexible hoses should be removed and replaced with hard piped connection.																									
00 Pharmacy PHA-008 (Clinical Trial Prep)	Hot, Cold	CWST 15.5	Calorifier 51.5	1	OK	Yes	Yes	1	None visible	Not visible	Flush Regime		1	1										Low	None visible	None visible		Low
Recommendations:			Hot outlets do not comply with latest SHTM regulations, though achieving 50°C. Wherever practicable increase temperatures to 55°C.																									

LEGIONELLA RISK ASSESSMENT

Location / Room No	Sentinel outlet?	Cold Supply & Temp (°C)	Hot Supply & Temp (°C)	TMV info					Deadlegs Present (Inc. Drain cocks)	Flow & Return Working	Outlet Usage	Outlets in location												Aerosol Created	Non WRAS Material	Flexi Hoses	Comment	Additional Localised Risk Rating
				No. Of TMVs	Access	<2m from outlet?	Mix Temps 37-45°C	No. TMV Fed Outlets				Mains	Cold	Hot	Mixer	Urinals	WCs	Shower	Drinks / vend	Water boiler	Drinking fountain	Arjo/whirlpool	Other					
00 Radiology RAG-004 (Dirty Utility)	Hot, Cold	CWST 13.2	Calorifier 53.1	2	OK	Yes	Yes	2	None visible	Not visible	Flush Regime		2	2			1							Low	None visible	Yes	Small section of insulation missing 1 x sluice	Low
Recommendations:			All EPDM flexible hoses should be removed and replaced with hard piped connection.																									
			Hot outlets do not comply with latest SHTM regulations, though achieving 50°C. Wherever practicable increase temperatures to 55°C.																									
00 Radiology RAG-029 (X-Ray 6)	Hot, Cold	CWST 18.4	Calorifier 51.5	1	OK	Yes	Yes	1	None visible	Not visible	Flush Regime		1	1										Low	None visible	None visible		Low
Recommendations:			Hot outlets do not comply with latest SHTM regulations, though achieving 50°C. Wherever practicable increase temperatures to 55°C.																									
00 Radiology RAG-054 (Toilet)	Hot, Cold	CWST 19.2	Calorifier 54.4	1	OK	Yes	Yes	1	None visible	Not visible	Flush Regime				1		1							Low	None visible	None visible		Medium
Recommendations:			Hot outlets do not comply with latest SHTM regulations, though achieving 50°C. Wherever practicable increase temperatures to 55°C.																									
00 Radiology RAG-068 (Toilet)	Hot, Cold	CWST 23.1	Calorifier 55.2	1	OK	Yes	Yes	1	None visible	Not visible	Flush Regime				1		1							Low	None visible	None visible		Low
Recommendations:			Cold water temperature too high. Investigate and correct.																									
00 Radiology RAG-079 (Toilet)	Hot, Cold	CWST 24.8	Calorifier 55.3	1	OK	Yes	Yes	1	None visible	Not visible	Flush Regime				1		1							Low	None visible	None visible		Medium
Recommendations:			Cold water temperature too high. Investigate and correct.																									

LEGIONELLA RISK ASSESSMENT

Location / Room No	Sentinel outlet?	Cold Supply & Temp (°C)	Hot Supply & Temp (°C)	TMV info					Deadlegs Present (Inc. Drain cocks)	Flow & Return Working	Outlet Usage	Outlets in location											Aerosol Created	Non WRAS Material	Flexi Hoses	Comment	Additional Localised Risk Rating
				No. Of TMVs	Access	<2m from outlet?	Mix Temps 37-45°C	No. TMV Fed Outlets				Mains	Cold	Hot	Mixer	Urinals	WCs	Shower	Drinks / vend	Water boiler	Drinking fountain	Arjo/whirlpool	Other					
00 Radiology RAG-092 (Toilet)	Hot, Cold	CWST 15.1	Calorifier 55.2	1	OK	Yes	Yes	1	None visible	Not visible	Flush Regime				1		1							Low	None visible	None visible	IR Tap	Low
Recommendations:																												
00 Radiology RAG-108 (Anaesthetic)	Hot, Cold	CWST 17.8	Calorifier	1	Boxed in	Yes	Yes	1	None visible	Not visible	Flush Regime		1	1										Low	None visible	None visible		Low
Recommendations:				No access to TMV supply pipework. Access should be provided for further assessment.																								
00 Radiology RAG-130 (Toilet)	Hot, Cold	CWST 18.4	Calorifier 55.1	1	OK	Yes	Yes	1	None visible	Not visible	Flush Regime				1		1							Low	None visible	None visible	Small section of insulation missing	Low
Recommendations:																												
00 Rehab REH-006 (Toilet)	Hot, Cold	CWST 18.7	Calorifier 53.8	1	OK	Yes	Yes	1	None visible	Not visible	Daily				1		1							Low	None visible	None visible		Low
Recommendations:				Hot outlets do not comply with latest SHTM regulations, though achieving 50°C. Wherever practicable increase temperatures to 55°C.																								
00 Rehab REH-013 (OT Room)	Hot, Cold	CWST 17.1	Calorifier 54.2	1	OK	Yes	Yes	1	None visible	Not visible	Flush Regime				1									Low	None visible	None visible	Copper tail to IR tap	Low
Recommendations:				Hot outlets do not comply with latest SHTM regulations, though achieving 50°C. Wherever practicable increase temperatures to 55°C.																								

LEGIONELLA RISK ASSESSMENT

Location / Room No	Sentinel outlet?	Cold Supply & Temp (°C)	Hot Supply & Temp (°C)	TMV info					Deadlegs Present (Inc. Drain cocks)	Flow & Return Working	Outlet Usage	Outlets in location												Aerosol Created	Non WRAS Material	Flexi Hoses	Comment	Additional Localised Risk Rating
				No. Of TMVs	Access	<2m from outlet?	Mix Temps 37-45°C	No. TMV Fed Outlets				Mains	Cold	Hot	Mixer	Urinals	WCs	Shower	Drinks / vend	Water boiler	Drinking fountain	Arjo/whirlpool	Other					
00 Rehab REH-026 (Toilet)	Hot, Cold	CWST 17.1	Calorifier 55.3	1	OK	Yes	Yes	1	None visible	Not visible	Daily				1		1							Low	None visible	None visible		Low
Recommendations:																												
00 Rehab REH-033 (Workshop)	Hot, Cold	CWST 16.2	Calorifier 56.3	0				0	None visible	Not visible	Flush Regime		1	1										Low	None visible	None visible		Low
Recommendations:																												
00 Rehab REH-048 (Hydrotherapy Toilet)	Hot, Cold	CWST 16.3	Calorifier 55.1	1	OK	Yes	Yes	1	None visible	Not visible	Flush Regime				1		1							Low	None visible	None visible		Low
Recommendations:																												
00C A&E EMC-006 (Toilet)	Hot, Cold	CWST 25.3	Calorifier 50.0	1	OK	Yes	Yes	1	None visible	Not visible	Flush Regime				1		1							Low	None visible	None visible	IR Tap	Medium

Recommendations: Cold water temperature too high. Investigate and correct.

Hot outlets do not comply with latest SHTM regulations, though achieving 50°C. Wherever practicable increase temperatures to 55°C.

LEGIONELLA RISK ASSESSMENT

Location / Room No	Sentinel outlet?	Cold Supply & Temp (°C)	Hot Supply & Temp (°C)	TMV info					Deadlegs Present (Inc. Drain cocks)	Flow & Return Working	Outlet Usage	Outlets in location												Aerosol Created	Non WRAS Material	Flexi Hoses	Comment	Additional Localised Risk Rating
				No. Of TMVs	Access	<2m from outlet?	Mix Temps 37-45°C	No. TMV Fed Outlets				Mains	Cold	Hot	Mixer	Urinals	WCs	Shower	Drinks / vend	Water boiler	Drinking fountain	Arjo/whirlpool	Other					
00C A&E EMC-059 (Bed Bay 6)	Hot, Cold	CWST 26.8	Calorifier 50.8	1	OK	Yes	Yes	1	None visible	Not visible	Flush Regime		1	1										Low	None visible	None visible		Medium
Recommendations:			Cold water temperature too high. Investigate and correct.																									
			Hot outlets do not comply with latest SHTM regulations, though achieving 50°C. Wherever practicable increase temperatures to 55°C.																									
00C A&E EMC-060 (Bed Bay 5)	Hot, Cold	CWST 27.7	Calorifier 50.3	1	OK	Yes	Yes	1	None visible	Not visible	Flush Regime		1	1										Low	None visible	None visible		Medium
Recommendations:			Cold water temperature too high. Investigate and correct.																									
			Hot outlets do not comply with latest SHTM regulations, though achieving 50°C. Wherever practicable increase temperatures to 55°C.																									
00C A&E EMC-100 (Triage)	Hot, Cold	CWST 21.2	Calorifier 50.1	1	OK	Yes	Yes	1	None visible	Not visible	Flush Regime		1	1										Low	None visible	None visible		Medium
Recommendations:			Cold water temperature too high. Investigate and correct.																									
			Hot outlets do not comply with latest SHTM regulations, though achieving 50°C. Wherever practicable increase temperatures to 55°C.																									
00C Concourse ENT-014 (Children's Club)	Hot, Cold	CWST 18.2	Calorifier 57.1	1	OK	Yes	Yes	1	None visible	Not visible	Flush Regime		2	2										Low	None visible	None visible		Low
Recommendations:																												

LEGIONELLA RISK ASSESSMENT

Location / Room No	Sentinel outlet?	Cold Supply & Temp (°C)	Hot Supply & Temp (°C)	TMV info					Deadlegs Present (Inc. Drain cocks)	Flow & Return Working	Outlet Usage	Outlets in location											Aerosol Created	Non WRAS Material	Flexi Hoses	Comment	Additional Localised Risk Rating
				No. Of TMVs	Access	<2m from outlet?	Mix Temps 37-45°C	No. TMV Fed Outlets				Mains	Cold	Hot	Mixer	Urinals	WCs	Shower	Drinks / vend	Water boiler	Drinking fountain	Arjo/whirlpool	Other					
00C Concourse ENT-028	No	CWST	No hot outlets	0				0	Yes - on cold pipework	N/A	Never								1					Low	None visible	None visible		Medium
Recommendations:			Connection to vend machine capped off. Ensure this is included in flushing regime.																								
00C Concourse ENT-036 (Facilities)	Hot, Cold	CWST 11.5	Calorifier 56.0	1	OK	Yes	Yes	1	None visible	Not visible	Flush Regime		3	3										Low	None visible	Yes		Low
Recommendations:			All EPDM flexible hoses should be removed and replaced with hard piped connection.																								
00C Concourse ENT-048 (Toilet)	Hot, Cold	CWST 15.7	Calorifier 55.1	1	OK	Yes	Yes	1	None visible	Not visible	Flush Regime		1	1										Low	None visible	None visible		Low
Recommendations:			Hot temperature slow to rise. It should be confirmed that hot outlet(s) are on a long leg and not that the flow and return has failed locally in this area.																								
00C Consultancy CPS-003 (Consulting Room)	Hot, Cold	CWST 18.2	Calorifier 21.1	1	OK	Yes	Yes	1	None visible	Not visible	Flush Regime		1	1										Low	None visible	None visible		Medium
Recommendations:			Hot temperature slow to rise. It should be confirmed that hot outlet(s) are on a long leg and not that the flow and return has failed locally in this area. Hot water temperature too low. Investigate and correct.																								
00C Consultancy CPS-006 (Toilet)	Hot, Cold	CWST 17.7	Calorifier 55.9	2	OK	Yes	Yes	2	None visible	Not visible	Flush Regime				1		1	1						Low	None visible	None visible	Shower drain blocked	Low
Recommendations:																											

LEGIONELLA RISK ASSESSMENT

Location / Room No	Sentinel outlet?	Cold Supply & Temp (°C)	Hot Supply & Temp (°C)	TMV info					Deadlegs Present (Inc. Drain cocks)	Flow & Return Working	Outlet Usage	Outlets in location												Aerosol Created	Non WRAS Material	Flexi Hoses	Comment	Additional Localised Risk Rating
				No. Of TMVs	Access	<2m from outlet?	Mix Temps 37-45°C	No. TMV Fed Outlets				Mains	Cold	Hot	Mixer	Urinals	WCs	Shower	Drinks / vend	Water boiler	Drinking fountain	Arjo/whirlpool	Other					
00C Decontamination DCU-003 (Wet Room)																										Yes		No access
Recommendations:			Area should be assessed after building works completed																									
00C Observation OBW-020 (Bathroom)	Hot, Cold	CWST 24.8	Calorifier 55.2	2	OK	Yes	Yes	2	None visible	Not visible	Flush Regime				1		1	1						High	None visible	None visible		High
Recommendations:			Cold water temperature too high. Investigate and correct.																									
00C Observation OBW-061 (Bedroom)	Hot, Cold	CWST 24.4	Calorifier 24.4	1	OK	Yes	Yes	1	None visible	Not visible	Flush Regime		1	1										Low	None visible	None visible		Medium
Recommendations:			Cold water temperature too high. Investigate and correct. Hot water temperature too low. Investigate and correct.																									
00C OPD OPD-(Consulting Room)	Hot, Cold	CWST 13.1	Calorifier 54.2	1	OK	Yes	Yes	1	None visible	Not visible	Flush Regime		1	1										Low	None visible	None visible		Low
Recommendations:			Hot outlets do not comply with latest SHTM regulations, though achieving 50°C. Wherever practicable increase temperatures to 55°C.																									
00C OPD OPD-009 (Toilet)	Hot, Cold	CWST 11.2	Calorifier 55.6	1	OK	Yes	Yes	1	None visible	Not visible	Flush Regime				1		1							Low	None visible	None visible		Low
Recommendations:																												

LEGIONELLA RISK ASSESSMENT

Location / Room No	Sentinel outlet?	Cold Supply & Temp (°C)	Hot Supply & Temp (°C)	TMV info					Deadlegs Present (Inc. Drain cocks)	Flow & Return Working	Outlet Usage	Outlets in location												Aerosol Created	Non WRAS Material	Flexi Hoses	Comment	Additional Localised Risk Rating
				No. Of TMVs	Access	<2m from outlet?	Mix Temps 37-45°C	No. TMV Fed Outlets				Mains	Cold	Hot	Mixer	Urinals	WCs	Shower	Drinks / vend	Water boiler	Drinking fountain	Arjo/whirlpool	Other					
00C OPD OPD-026 (Facilities)	Hot, Cold	CWST 12.4	Calorifier 56.2	1	OK	Yes	Yes	1	None visible	Not visible	Flush Regime		3	3										Low	None visible	Yes		Low
Recommendations:	All EPDM flexible hoses should be removed and replaced with hard piped connection.																											
00C OPD OPD-060 (Toilet)	Hot, Cold	CWST 18.1	Calorifier 55.8	1	OK	Yes	Yes	1	None visible	Not visible	Flush Regime				1		1							Low	None visible	None visible		Low
Recommendations:																												
00C OPD OPD-073 (Plaster Room)	Hot, Cold	CWST 21.0	Calorifier 55.1	4	OK	Yes	Yes	4	None visible	Not visible	Flush Regime		4	4										Low	None visible	None visible		Medium
Recommendations:	Cold water temperature too high. Investigate and correct.																											
00C OPD OPD-075 (Toilet)	Hot, Cold	CWST 24.4	Calorifier 55.0	1	OK	Yes	Yes	1	None visible	Not visible	Flush Regime				1		1							Low	None visible	None visible		Medium
Recommendations:	Cold water temperature too high. Investigate and correct.																											
00C OPD OPD-08(Audiometry Room)		No cold outlets	No hot outlets					0																		Yes	No outlets	
Recommendations:																												

LEGIONELLA RISK ASSESSMENT

Location / Room No	Sentinel outlet?	Cold Supply & Temp (°C)	Hot Supply & Temp (°C)	TMV info					Deadlegs Present (Inc. Drain cocks)	Flow & Return Working	Outlet Usage	Outlets in location											Aerosol Created	Non WRAS Material	Flexi Hoses	Comment	Additional Localised Risk Rating
				No. Of TMVs	Access	<2m from outlet?	Mix Temps 37-45°C	No. TMV Fed Outlets				Mains	Cold	Hot	Mixer	Urinals	WCs	Shower	Drinks / vend	Water boiler	Drinking fountain	Arjo/whirlpool	Other					
00C OPD OPD-087-B (Toilet)	Hot, Cold	CWST 12.1	Calorifier 55.6	1	OK	Yes	Yes	1	None visible	Not visible	Flush Regime				1		1							Low	None visible	None visible	No room ID on door. Labelled as sentinel.	Low
Recommendations:																											
00C OPD OPD-103 (Toilet)	Hot, Cold	CWST 19.1	Calorifier 55.2	1	OK	Yes	Yes	1	None visible	Not visible	Flush Regime				1		1							Low	None visible	None visible		Low
Recommendations:																											
00C OPD OPD-120 (Toilet)	Hot, Cold	CWST 24.0	Calorifier 55.3	1	OK	Yes	Yes	1	None visible	Not visible	Flush Regime				1		1							Low	None visible	None visible		Medium
Recommendations:			Cold water temperature too high. Investigate and correct.																								
00C OPD OPD-125 (Changing)	Hot, Cold	CWST 19.4	Calorifier 57.2	1	OK	Yes	Yes	1	None visible	Not visible	Flush Regime		1	1										Low	None visible	None visible		Low
Recommendations:																											
00C Radiology RCG-022 (Male Change)	Hot, Cold	CWST 10.5	Calorifier 55.3	1	OK	Yes	Yes	1	None visible	Not visible	Flush Regime				1									Low	None visible	None visible		Low
Recommendations:																											

LEGIONELLA RISK ASSESSMENT

Location / Room No	Sentinel outlet?	Cold Supply & Temp (°C)	Hot Supply & Temp (°C)	TMV info					Deadlegs Present (Inc. Drain cocks)	Flow & Return Working	Outlet Usage	Outlets in location												Aerosol Created	Non WRAS Material	Flexi Hoses	Comment	Additional Localised Risk Rating
				No. Of TMVs	Access	<2m from outlet?	Mix Temps 37-45°C	No. TMV Fed Outlets				Mains	Cold	Hot	Mixer	Urinals	WCs	Shower	Drinks / vend	Water boiler	Drinking fountain	Arjo/whirlpool	Other					
00C Radiology RCG-068 (Baby sleep)	Hot, Cold	CWST 14.9	Calorifier 50.0	1	OK	Yes	Yes	1	None visible	Not visible	Flush Regime		1	1										Low	None visible	None visible		Low
Recommendations:			Hot outlets do not comply with latest SHTM regulations, though achieving 50°C. Wherever practicable increase temperatures to 55°C.																									
00C Radiology RCG-087 (Dirty Utility)	Hot, Cold	CWST 22.6	Calorifier 52.3	2	OK	Yes	Yes	2	None visible	Not visible	Flush Regime		2	2			1							Low	None visible	Yes	1 x sluice	Medium
Recommendations:			All EPDM flexible hoses should be removed and replaced with hard piped connection. Cold water temperature too high. Investigate and correct. Hot outlets do not comply with latest SHTM regulations, though achieving 50°C. Wherever practicable increase temperatures to 55°C.																									
01 Critical Care CCU-004 (Patients Pantry)	Hot, Cold	CWST 15.4	Calorifier 55.3	1	OK	Yes	Yes	1	None visible	Not visible	Flush Regime		1	1	1									Low	None visible	Yes	Copper tail to IR tap	Low
Recommendations:			All EPDM flexible hoses should be removed and replaced with hard piped connection.																									
01 Critical Care CCU-036 (Bedroom)	Hot, Cold	CWST 18.9	Calorifier 50.4	1	OK	Yes	Yes	1	None visible	Not visible	Flush Regime		1	1										Low	None visible	None visible		Low
Recommendations:			Hot outlets do not comply with latest SHTM regulations, though achieving 50°C. Wherever practicable increase temperatures to 55°C.																									

LEGIONELLA RISK ASSESSMENT

Location / Room No	Sentinel outlet?	Cold Supply & Temp (°C)	Hot Supply & Temp (°C)	TMV info					Deadlegs Present (Inc. Drain cocks)	Flow & Return Working	Outlet Usage	Outlets in location												Aerosol Created	Non WRAS Material	Flexi Hoses	Comment	Additional Localised Risk Rating
				No. Of TMVs	Access	<2m from outlet?	Mix Temps 37-45°C	No. TMV Fed Outlets				Mains	Cold	Hot	Mixer	Urinals	WCs	Shower	Drinks / vend	Water boiler	Drinking fountain	Arjo/whirlpool	Other					
01 Critical Care CCW-017 (Facilities)	Hot, Cold	CWST 22.5	Calorifier 58.0	1	OK	Yes	Yes	1	None visible	Not visible	Flush Regime		3	3										Low	None visible	Yes		Medium
Recommendations:			All EPDM flexible hoses should be removed and replaced with hard piped connection. Cold water temperature too high. Investigate and correct.																									
01 Critical Care CCW-029 (Toilet)	Hot, Cold	CWST 18.2	Calorifier 55.3	2	OK	Yes	Yes	2	None visible	Not visible	Flush Regime				1		1	1						High	None visible	None visible		Low
Recommendations:																												
01 Critical Care CCW-048 (Bed Bay 1)	Hot, Cold	CWST 11.9	Calorifier	1	No access - all	Yes	Yes	1	None visible	Not visible	Flush Regime		1	1										Low	None visible	None visible		Low
Recommendations:			No access to TMV supply pipework. Access should be provided for further assessment.																									
01 Critical Care CCW-087 (Bed Bay 37)	Hot, Cold	CWST 18.5	Calorifier 52.2	1	OK	Yes	Yes	1	None visible	Not visible	Flush Regime		1	1										Low	None visible	None visible		Low
Recommendations:			Hot outlets do not comply with latest SHTM regulations, though achieving 50°C. Wherever practicable increase temperatures to 55°C.																									
01 Critical Care CCW-089 (Bed Bay 38)	Hot, Cold	CWST 16.0	Calorifier 53.4	1	OK	Yes	Yes	1	None visible	Not visible	Flush Regime		1	1										Low	None visible	None visible		Low
Recommendations:			Hot outlets do not comply with latest SHTM regulations, though achieving 50°C. Wherever practicable increase temperatures to 55°C.																									

LEGIONELLA RISK ASSESSMENT

Location / Room No	Sentinel outlet?	Cold Supply & Temp (°C)	Hot Supply & Temp (°C)	TMV info					Deadlegs Present (Inc. Drain cocks)	Flow & Return Working	Outlet Usage	Outlets in location												Aerosol Created	Non WRAS Material	Flexi Hoses	Comment	Additional Localised Risk Rating
				No. Of TMVs	Access	<2m from outlet?	Mix Temps 37-45°C	No. TMV Fed Outlets				Mains	Cold	Hot	Mixer	Urinals	WCs	Shower	Drinks / vend	Water boiler	Drinking fountain	Arjo/whirlpool	Other					
01 Critical Care CCW-092 (Gowning Room)	Hot, Cold	CWST 16.4	Calorifier 51.3	1	OK	Yes	Yes	1	None visible	Not visible	Flush Regime		1	1										Low	None visible	None visible		Low
Recommendations:			Hot outlets do not comply with latest SHTM regulations, though achieving 50°C. Wherever practicable increase temperatures to 55°C.																									
01 Critical Care CCW-109 (Bed Bay 26)	Hot, Cold	CWST 13.7	Calorifier 53.0	1	OK	Yes	Yes	1	None visible	Not visible	Flush Regime		1	1										Low	None visible	None visible		Low
Recommendations:			Hot outlets do not comply with latest SHTM regulations, though achieving 50°C. Wherever practicable increase temperatures to 55°C.																									
01 Critical Care CCW-126 (Dirty Utility)	Hot, Cold	CWST 19.1	Calorifier 53.4	2	OK	Yes	Yes	2	None visible	Not visible	Flush Regime		2	2			1							Low	None visible	Yes	Small section of insulation missing 1 x Sluice	Low
Recommendations:			All EPDM flexible hoses should be removed and replaced with hard piped connection. Hot outlets do not comply with latest SHTM regulations, though achieving 50°C. Wherever practicable increase temperatures to 55°C.																									
01 Critical Care CCW-130 (Service)	Hot, Cold	CWST 19.3	Calorifier 42	1	OK	Yes	Yes	1	None visible	Not visible	Flush Regime		1	1										Low	None visible	None visible		Medium
Recommendations:			Hot temperature slow to rise. It should be confirmed that hot outlet(s) are on a long leg and not that the flow and return has failed locally in this area. Hot water temperature too low. Investigate and correct.																									

LEGIONELLA RISK ASSESSMENT

Location / Room No	Sentinel outlet?	Cold Supply & Temp (°C)	Hot Supply & Temp (°C)	TMV info					Deadlegs Present (Inc. Drain cocks)	Flow & Return Working	Outlet Usage	Outlets in location												Aerosol Created	Non WRAS Material	Flexi Hoses	Comment	Additional Localised Risk Rating
				No. Of TMVs	Access	<2m from outlet?	Mix Temps 37-45°C	No. TMV Fed Outlets				Mains	Cold	Hot	Mixer	Urinals	WCs	Shower	Drinks / vend	Water boiler	Drinking fountain	Arjo/whirlpool	Other					
01 Critical Care CCW-131 (Pharmacy Support)	Hot, Cold	CWST 16.3	Calorifier 53.8	1	OK	Yes	Yes	1	None visible	Not visible	Flush Regime		1	1										Low	None visible	None visible		Low
Recommendations:	Hot outlets do not comply with latest SHTM regulations, though achieving 50°C. Wherever practicable increase temperatures to 55°C.																											
01 Critical Care CCW-141 (Bathroom)	Hot, Cold	CWST 18.1	Calorifier 50.2	2	OK	Yes	Yes	2	None visible	Not visible	Flush Regime				1		1	1						High	None visible	None visible		Low
Recommendations:	Hot outlets do not comply with latest SHTM regulations, though achieving 50°C. Wherever practicable increase temperatures to 55°C.																											
01 Critical Care CCW-200 (Facilities)	Hot, Cold	CWST 8.0	Calorifier 56.1	1	OK	Yes	Yes	1	None visible	Not visible	Flush Regime		3	3										Low	None visible	Yes		Low
Recommendations:	All EPDM flexible hoses should be removed and replaced with hard piped connection.																											
01 Critical Care CCW-202 (Toilet)	Hot, Cold	CWST 13.4	Calorifier 55.3	2	OK	Yes	Yes	2	None visible	Not visible	Flush Regime				1		1	1						High	None visible	None visible		Low
Recommendations:																												
01 Critical Care CCW-214 (Male Change)	Hot, Cold	CWST 18.2	Calorifier 52.4	3	OK	Yes	Yes	3	None visible	Not visible	Flush Regime				3									Low	None visible	None visible		Low
Recommendations:	Hot outlets do not comply with latest SHTM regulations, though achieving 50°C. Wherever practicable increase temperatures to 55°C.																											

LEGIONELLA RISK ASSESSMENT

Location / Room No	Sentinel outlet?	Cold Supply & Temp (°C)	Hot Supply & Temp (°C)	TMV info					Deadlegs Present (Inc. Drain cocks)	Flow & Return Working	Outlet Usage	Outlets in location												Aerosol Created	Non WRAS Material	Flexi Hoses	Comment	Additional Localised Risk Rating
				No. Of TMVs	Access	<2m from outlet?	Mix Temps 37-45°C	No. TMV Fed Outlets				Mains	Cold	Hot	Mixer	Urinals	WCs	Shower	Drinks / vend	Water boiler	Drinking fountain	Arjo/whirlpool	Other					
01 FM Facilities FMA1-001 (Facilities)	Hot, Cold	CWST	Calorifier	1	OK	Yes	Yes	1	None visible	Not visible	Some outlets unused		3	3										Low	None visible	Yes	Taps not run due to leaking drain.	Medium
Recommendations:	All EPDM flexible hoses should be removed and replaced with hard piped connection. Drain leaking and should be repaired.																											
01 Medical Day Unit MDU-005 (Beverage)	No	CWST 15.7	Calorifier 58.3	1	OK	Yes	Yes	1	Yes - on cold pipework	Not visible	Flush Regime		2	2						1				Low	None visible	Yes		Medium
Recommendations:	Remove all deadleg pipework in this area. All EPDM flexible hoses should be removed and replaced with hard piped connection.																											
01 Medical Day Unit MDU-012 (Treatment Room)	Hot, Cold	CWST 18.8	Calorifier 50.5	1	OK	Yes	Yes	1	None visible	Not visible	Flush Regime		1	1										Low	None visible	None visible		Low
Recommendations:	Hot outlets do not comply with latest SHTM regulations, though achieving 50°C. Wherever practicable increase temperatures to 55°C.																											
01 Medical Day Unit MDU-020 (Blood Test)	Hot, Cold	CWST 18.3	Calorifier 50.7	1	OK	Yes	Yes	1	None visible	Not visible	Flush Regime		1	1										Low	None visible	None visible		Low
Recommendations:	Hot outlets do not comply with latest SHTM regulations, though achieving 50°C. Wherever practicable increase temperatures to 55°C.																											

LEGIONELLA RISK ASSESSMENT

Location / Room No	Sentinel outlet?	Cold Supply & Temp (°C)	Hot Supply & Temp (°C)	TMV info					Deadlegs Present (Inc. Drain cocks)	Flow & Return Working	Outlet Usage	Outlets in location												Aerosol Created	Non WRAS Material	Flexi Hoses	Comment	Additional Localised Risk Rating
				No. Of TMVs	Access	<2m from outlet?	Mix Temps 37-45°C	No. TMV Fed Outlets				Mains	Cold	Hot	Mixer	Urinals	WCs	Shower	Drinks / vend	Water boiler	Drinking fountain	Arjo/whirlpool	Other					
01 Medical Day Unit MDU-046 (Facilities)	Hot, Cold	CWST 24.4	Calorifier 55.4	1	OK	Yes	Yes	1	None visible	Not visible	Flush Regime		3	3										Low	None visible	Yes	Flexible hoses to 2 Tier sink	Medium
Recommendations:			All EPDM flexible hoses should be removed and replaced with hard piped connection.																									
			Cold water temperature too high. Investigate and correct.																									
01 Medical Day Unit MDU-048 (Dirty Utility)								0																		Yes		No access
Recommendations:			Locked – No Access. Area should be assessed once access obtained.																									
01 Medical Day Unit MDU-050 (Consulting Room)	Hot, Cold	CWST 20.2	Calorifier 51.9	1	OK	Yes	Yes	1	None visible	Not visible	Flush Regime		1	1										Low	None visible	None visible		Medium
Recommendations:			Cold water temperature too high. Investigate and correct.																									
			Hot outlets do not comply with latest SHTM regulations, though achieving 50°C. Wherever practicable increase temperatures to 55°C.																									
01 Medical Day Unit MDU-051 (Consulting Room)	Hot, Cold	CWST 16.1	Calorifier 52.1	1	OK	Yes	Yes	1	None visible	Not visible	Flush Regime		1	1										Low	None visible	None visible		Low
Recommendations:			Hot outlets do not comply with latest SHTM regulations, though achieving 50°C. Wherever practicable increase temperatures to 55°C.																									

LEGIONELLA RISK ASSESSMENT

Location / Room No	Sentinel outlet?	Cold Supply & Temp (°C)	Hot Supply & Temp (°C)	TMV info					Deadlegs Present (Inc. Drain cocks)	Flow & Return Working	Outlet Usage	Outlets in location												Aerosol Created	Non WRAS Material	Flexi Hoses	Comment	Additional Localised Risk Rating
				No. Of TMVs	Access	<2m from outlet?	Mix Temps 37-45°C	No. TMV Fed Outlets				Mains	Cold	Hot	Mixer	Urinals	WCs	Shower	Drinks / vend	Water boiler	Drinking fountain	Arjo/whirlpool	Other					
01 OPD POA-006 (Consulting Room)	Hot, Cold	CWST 18.4	Calorifier 54.2	1	OK	Yes	Yes	1	None visible	Not visible	Flush Regime		1	1										Low	None visible	None visible		Low
Recommendations:			Hot outlets do not comply with latest SHTM regulations, though achieving 50°C. Wherever practicable increase temperatures to 55°C.																									
01 OPD POA-015 (Consulting Room)	Hot, Cold	CWST 16.6	Calorifier 52.6	1	OK	Yes	Yes	1	None visible	Not visible	Flush Regime		1	1										Low	None visible	None visible		Low
Recommendations:			Hot outlets do not comply with latest SHTM regulations, though achieving 50°C. Wherever practicable increase temperatures to 55°C.																									
01 OPD POA-040 (Consulting Room)	Hot, Cold	CWST 21.4	Calorifier 53.5	1	OK	Yes	Yes	1	None visible	Not visible	Flush Regime		1	1										Low	None visible	None visible		Medium
Recommendations:			Cold water temperature too high. Investigate and correct. Hot outlets do not comply with latest SHTM regulations, though achieving 50°C. Wherever practicable increase temperatures to 55°C.																									
01 OPD OPD1-006 (Toilet)	Hot, Cold	CWST 23.4	Calorifier 54.2	1	OK	Yes	Yes	1	None visible	Not visible	Flush Regime				1		1							Low	None visible	None visible		Medium
Recommendations:			Aeration at outlet(s). Investigate and correct. Cold water temperature too high. Investigate and correct. Hot outlets do not comply with latest SHTM regulations, though achieving 50°C. Wherever practicable increase temperatures to 55°C.																									

LEGIONELLA RISK ASSESSMENT

Location / Room No	Sentinel outlet?	Cold Supply & Temp (°C)	Hot Supply & Temp (°C)	TMV info					Deadlegs Present (Inc. Drain cocks)	Flow & Return Working	Outlet Usage	Outlets in location												Aerosol Created	Non WRAS Material	Flexi Hoses	Comment	Additional Localised Risk Rating
				No. Of TMVs	Access	<2m from outlet?	Mix Temps 37-45°C	No. TMV Fed Outlets				Mains	Cold	Hot	Mixer	Urinals	WCs	Shower	Drinks / vend	Water boiler	Drinking fountain	Arjo/whirlpool	Other					
01 OPD OPD1-008 (Toilet)	Hot, Cold	CWST 22.4	Calorifier 52.1	1	OK	Yes	Yes	1	None visible	Not visible	Flush Regime				1		1							Low	None visible	None visible	Copper tail to tap	Medium
Recommendations:			Aeration at outlet(s). Investigate and correct.																									
			Cold water temperature too high. Investigate and correct.																									
			Hot outlets do not comply with latest SHTM regulations, though achieving 50°C. Wherever practicable increase temperatures to 55°C.																									
01 OPD OPD1-037 (Toilet)	Hot, Cold	CWST 12.4	Calorifier 54.3	1	OK	Yes	Yes	1	None visible	Not visible	Flush Regime				1		1							Low	None visible	None visible		Low
Recommendations:			Hot outlets do not comply with latest SHTM regulations, though achieving 50°C. Wherever practicable increase temperatures to 55°C.																									
01 OPD OPD1-047 (Dietician)	Hot, Cold	CWST 11.7	Calorifier 51.0	1	OK	Yes	Yes	1	None visible	Not visible	Flush Regime		1	1										Low	None visible	None visible		Low
Recommendations:			Hot outlets do not comply with latest SHTM regulations, though achieving 50°C. Wherever practicable increase temperatures to 55°C.																									
01 OPD OPD1-048 (Blood Lab)	Hot, Cold	CWST 16.0	Calorifier 54.1	1	OK	Yes	Yes	1	None visible	Not visible	Flush Regime		1	1										Low	None visible	None visible		Low
Recommendations:			Hot outlets do not comply with latest SHTM regulations, though achieving 50°C. Wherever practicable increase temperatures to 55°C.																									

LEGIONELLA RISK ASSESSMENT

Location / Room No	Sentinel outlet?	Cold Supply & Temp (°C)	Hot Supply & Temp (°C)	TMV info					Deadlegs Present (Inc. Drain cocks)	Flow & Return Working	Outlet Usage	Outlets in location												Aerosol Created	Non WRAS Material	Flexi Hoses	Comment	Additional Localised Risk Rating
				No. Of TMVs	Access	<2m from outlet?	Mix Temps 37-45°C	No. TMV Fed Outlets				Mains	Cold	Hot	Mixer	Urinals	WCs	Shower	Drinks / vend	Water boiler	Drinking fountain	Arjo/whirlpool	Other					
01 OPD OPD1-063 (Dirty Utility)	Hot, Cold	CWST 18.1	Calorifier 50.2	2	OK	Yes	Yes	2	None visible	Not visible	Flush Regime		2	2			1							Low	None visible	None visible	Small leak from WC flush pipe behind panel. 1 x sluice	Low
Recommendations:			Hot outlets do not comply with latest SHTM regulations, though achieving 50°C. Wherever practicable increase temperatures to 55°C.																									
01 OPD OPD1-070 (Podiatry Room)	Hot, Cold	CWST 14.8	Calorifier 56.7	1	OK	Yes	Yes	1	None visible	Not visible	Flush Regime		2	2										Low	None visible	None visible		Low
Recommendations:																												
01 OPD OPD1-085 (Toilet)	Hot, Cold	CWST 20.6	Calorifier 54.6	1	OK	Yes	Yes	1	None visible	Not visible	Flush Regime				1		1							Low	None visible	None visible		Medium
Recommendations:			Cold water temperature too high. Investigate and correct.																									
			Hot outlets do not comply with latest SHTM regulations, though achieving 50°C. Wherever practicable increase temperatures to 55°C.																									
01 OPD OPD1-113 (Measurement Bay)	Hot, Cold	CWST 25.1	Calorifier 51.3	1	OK	Yes	Yes	1	None visible	Not visible	Flush Regime		1	1										Low	None visible	None visible		Medium
Recommendations:			Cold water temperature too high. Investigate and correct.																									
			Hot outlets do not comply with latest SHTM regulations, though achieving 50°C. Wherever practicable increase temperatures to 55°C.																									

LEGIONELLA RISK ASSESSMENT

Location / Room No	Sentinel outlet?	Cold Supply & Temp (°C)	Hot Supply & Temp (°C)	TMV info					Deadlegs Present (Inc. Drain cocks)	Flow & Return Working	Outlet Usage	Outlets in location												Aerosol Created	Non WRAS Material	Flexi Hoses	Comment	Additional Localised Risk Rating
				No. Of TMVs	Access	<2m from outlet?	Mix Temps 37-45°C	No. TMV Fed Outlets				Mains	Cold	Hot	Mixer	Urinals	WCs	Shower	Drinks / vend	Water boiler	Drinking fountain	Arjo/whirlpool	Other					
01 OPD OPD1-145 (Facilities)								0																		Yes	Designated as sentinel but appears to be riser	No access
Recommendations:	Locked – No Access. Area should be assessed once access obtained.																											
01 OPD POA-016 (Reception)								0																		Yes	No outlets at this location.	No access
Recommendations:																												
01 OPD POA-019 (Clean Utility)	Hot, Cold	CWST 14.3	Calorifier 58.4	1	OK	Yes	Yes	1	None visible	Not visible	Flush Regime		2	2										Low	None visible	None visible		Low
Recommendations:																												
01 Radiology RAF-003 (Toilet)	Hot, Cold	CWST 14.1	Calorifier 52.3	1	OK	Yes	Yes	1	None visible	Not visible	Flush Regime				1		1							Low		None visible		Low
Recommendations:	Hot outlets do not comply with latest SHTM regulations, though achieving 50°C. Wherever practicable increase temperatures to 55°C.																											
01 Radiology RAF-005 (Reception)	No	CWST	No hot outlets	0				0	None visible	N/A	Some outlets unused								1					Low	None visible	None visible	1 x Connection	Medium
Recommendations:	Ensure unused connection point included in flushing regime until put into use																											

LEGIONELLA RISK ASSESSMENT

Location / Room No	Sentinel outlet?	Cold Supply & Temp (°C)	Hot Supply & Temp (°C)	TMV info					Deadlegs Present (Inc. Drain cocks)	Flow & Return Working	Outlet Usage	Outlets in location											Aerosol Created	Non WRAS Material	Flexi Hoses	Comment	Additional Localised Risk Rating
				No. Of TMVs	Access	<2m from outlet?	Mix Temps 37-45°C	No. TMV Fed Outlets				Mains	Cold	Hot	Mixer	Urinals	WCs	Shower	Drinks / vend	Water boiler	Drinking fountain	Arjo/whirlpool	Other					
01 Radiology RAF-087 (Male Change)	Hot, Cold	CWST 24.3	Calorifier 50.0	2	OK		Yes	2	None visible	Not visible	Flush Regime				2								Low	None visible	None visible		Low
Recommendations:			Cold water temperature too high. Investigate and correct.																								
			Hot outlets do not comply with latest SHTM regulations, though achieving 50°C. Wherever practicable increase temperatures to 55°C.																								
01 Radiology RAF-095 (Toilet)	Hot, Cold	CWST 19.3	Calorifier 50.5	1	OK	Yes	Yes	1	None visible	Not visible	Flush Regime				1		1						Low		None visible		Low
Recommendations:			Hot outlets do not comply with latest SHTM regulations, though achieving 50°C. Wherever practicable increase temperatures to 55°C.																								
01 Radiology RAF-115 (Toilet)	Hot, Cold	CWST 15.7	Calorifier 51.2	1	OK	Yes	Yes	1	None visible	Not visible	Flush Regime				1		1						Low		None visible		Low
Recommendations:			Hot outlets do not comply with latest SHTM regulations, though achieving 50°C. Wherever practicable increase temperatures to 55°C.																								
01 Radiology RAF-127 (Dirty Utility)	Hot, Cold	CWST 15.0	Calorifier 51.0	2	OK	Yes	Yes	2	None visible	Not visible	Flush Regime		2	2			1						Low	None visible	Yes	Flush not working on WC 1 x Sluice	Low
Recommendations:			All EPDM flexible hoses should be removed and replaced with hard piped connection.																								
			Hot outlets do not comply with latest SHTM regulations, though achieving 50°C. Wherever practicable increase temperatures to 55°C.																								

LEGIONELLA RISK ASSESSMENT

Location / Room No	Sentinel outlet?	Cold Supply & Temp (°C)	Hot Supply & Temp (°C)	TMV info					Deadlegs Present (Inc. Drain cocks)	Flow & Return Working	Outlet Usage	Outlets in location												Aerosol Created	Non WRAS Material	Flexi Hoses	Comment	Additional Localised Risk Rating
				No. Of TMVs	Access	<2m from outlet?	Mix Temps 37-45°C	No. TMV Fed Outlets				Mains	Cold	Hot	Mixer	Urinals	WCs	Shower	Drinks / vend	Water boiler	Drinking fountain	Arjo/whirlpool	Other					
01 Radiology RCF-001 (Facilities)	Hot, Cold	CWST 20.1	Calorifier 55.0	1	OK	Yes	Yes	1	None visible	Not visible	Flush Regime		3	3										Low	None visible	Yes		Medium
Recommendations:			All EPDM flexible hoses should be removed and replaced with hard piped connection. Cold water temperature too high. Investigate and correct.																									
01 Radiology RCF-003 (Facilities)	Hot, Cold	CWST 21.0	Calorifier 55.2	1	OK	Yes	Yes	1	None visible	Not visible	Flush Regime		3	3										Low	None visible	Yes		Low
Recommendations:			All EPDM flexible hoses should be removed and replaced with hard piped connection. Cold water temperature too high. Investigate and correct.																									
01 Radiology RNM-007 (Toilet)	Hot, Cold	CWST 23.1	Calorifier 55.1	1	OK	Yes	Yes	1	None visible	Not visible	Flush Regime				1		1							Low	None visible	None visible		Medium
Recommendations:			Poor flow from outlet(s). Investigate and correct. Cold water temperature too high. Investigate and correct.																									
01 Radiology RNM-018 (Shower room)	Hot, Cold	CWST 19.8	Calorifier 54.2	2	OK	Yes	Yes	2	None visible	Not visible	Flush Regime				1		1	1						High	None visible	None visible		Low
Recommendations:			Hot outlets do not comply with latest SHTM regulations, though achieving 50°C. Wherever practicable increase temperatures to 55°C.																									

LEGIONELLA RISK ASSESSMENT

Location / Room No	Sentinel outlet?	Cold Supply & Temp (°C)	Hot Supply & Temp (°C)	TMV info					Deadlegs Present (Inc. Drain cocks)	Flow & Return Working	Outlet Usage	Outlets in location											Aerosol Created	Non WRAS Material	Flexi Hoses	Comment	Additional Localised Risk Rating
				No. Of TMVs	Access	<2m from outlet?	Mix Temps 37-45°C	No. TMV Fed Outlets				Mains	Cold	Hot	Mixer	Urinals	WCs	Shower	Drinks / vend	Water boiler	Drinking fountain	Arjo/whirlpool	Other					
01 Radiology RNM-027 (Office)	Hot, Cold	CWST 21.3	Calorifier 51.2	1	OK	Yes	Yes	1	None visible	Not visible	Flush Regime		1	1										Low	None visible	None visible		Medium
Recommendations:			Cold water temperature too high. Investigate and correct.																									
			Hot outlets do not comply with latest SHTM regulations, though achieving 50°C. Wherever practicable increase temperatures to 55°C.																									
01 Radiology RNM-036 (Image Room - Adult)	Hot, Cold	CWST 14.1	Calorifier 55.2	1	OK	Yes	Yes	1	None visible	Not visible	Flush Regime		1	1										Low	None visible	None visible		Low
Recommendations:																												
01 Restaurant RES-019 (Toilet)	Hot, Cold	CWST 16.2	Calorifier 51.4	2	OK	Yes	Yes	2	None visible	Not visible	Flush Regime				2									Low	None visible	None visible	Copper tail to taps	Low
Recommendations:			Hot outlets do not comply with latest SHTM regulations, though achieving 50°C. Wherever practicable increase temperatures to 55°C.																									
01 Restaurant RES-034 (Toilet)	Hot, Cold	CWST 17.1	Calorifier 52.7	1	OK	Yes	Yes	1	None visible	Not visible	Flush Regime				1		1							Low	None visible	None visible		Low
Recommendations:			Hot outlets do not comply with latest SHTM regulations, though achieving 50°C. Wherever practicable increase temperatures to 55°C.																									
01 Stroke STW-014 (Bedroom)	Hot, Cold	CWST 15.2	Calorifier 51.9	1	OK	Yes	Yes	1	None visible	Not visible	Flush Regime		1	1										Low	None visible	None visible		Low
Recommendations:			Hot outlets do not comply with latest SHTM regulations, though achieving 50°C. Wherever practicable increase temperatures to 55°C.																									

LEGIONELLA RISK ASSESSMENT

Location / Room No	Sentinel outlet?	Cold Supply & Temp (°C)	Hot Supply & Temp (°C)	TMV info					Deadlegs Present (Inc. Drain cocks)	Flow & Return Working	Outlet Usage	Outlets in location											Aerosol Created	Non WRAS Material	Flexi Hoses	Comment	Additional Localised Risk Rating
				No. Of TMVs	Access	<2m from outlet?	Mix Temps 37-45°C	No. TMV Fed Outlets				Mains	Cold	Hot	Mixer	Urinals	WCs	Shower	Drinks / vend	Water boiler	Drinking fountain	Arjo/whirlpool	Other					
01 Stroke STW-036 (Bathroom)	Hot, Cold	CWST 23.3	Calorifier 53.8	2	OK	Yes	Yes	2	None visible	Not visible	Flush Regime				1		1	1						High	None visible	None visible		High
Recommendations:			Cold water temperature too high. Investigate and correct.																									
			Hot outlets do not comply with latest SHTM regulations, though achieving 50°C. Wherever practicable increase temperatures to 55°C.																									
01 Stroke STW-047 (Bathroom)	Hot, Cold	CWST 23.4	Calorifier 54.2	2	OK	Yes	Yes	2	None visible	Not visible	Flush Regime				1		1	1						High	None visible	None visible		High
Recommendations:			Cold water temperature too high. Investigate and correct.																									
			Hot outlets do not comply with latest SHTM regulations, though achieving 50°C. Wherever practicable increase temperatures to 55°C.																									
01 Stroke STW-072 (Bathroom)	Hot, Cold	CWST 25.1	Calorifier 55.1	2	OK	Yes	Yes	2	None visible	Not visible	Flush Regime				1		1	1						High	None visible	None visible		High
Recommendations:			Cold water temperature too high. Investigate and correct.																									
01 Stroke STW-079 (Arjo Bathroom)	No	CWST 15.0	Calorifier 55.1	1 (1)	OK	Yes	Yes	1	None visible	Yes	Flush Regime				1		1	1				1		High	None visible	Yes		Low
Recommendations:			All EPDM flexible hoses should be removed and replaced with hard piped connection.																									

LEGIONELLA RISK ASSESSMENT

Location / Room No	Sentinel outlet?	Cold Supply & Temp (°C)	Hot Supply & Temp (°C)	TMV info					Deadlegs Present (Inc. Drain cocks)	Flow & Return Working	Outlet Usage	Outlets in location												Aerosol Created	Non WRAS Material	Flexi Hoses	Comment	Additional Localised Risk Rating
				No. Of TMVs	Access	<2m from outlet?	Mix Temps 37-45°C	No. TMV Fed Outlets				Mains	Cold	Hot	Mixer	Urinals	WCs	Shower	Drinks / vend	Water boiler	Drinking fountain	Arjo/whirlpool	Other					
01 Stroke STW-082 (Bath)	Hot, Cold	CWST 19.2	Calorifier 55.0	2	No access – some	Yes	Yes	2	None visible	Not visible	Some outlets unused				2		1							Low	None visible	None visible	No access to bath TMV.	Medium
Recommendations:				No access to TMV supply pipework. Access should be provided for further assessment.																								
				'Out of Order' outlets in room creating deadleg – repair/replace.																								
01C Cardiology CAR-036 (Bedroom)	Hot, Cold	CWST 17.3	Calorifier 52.1	1	OK	Yes	Yes	1	None visible	Not visible	Flush Regime		1	1										Low	None visible	None visible		Low
Recommendations:				Hot outlets do not comply with latest SHTM regulations, though achieving 50°C. Wherever practicable increase temperatures to 55°C.																								
01C Critical Care CCW-014 (Clinical Physics)	Hot, Cold	CWST 22.1	Calorifier 55.5	1	OK	Yes	Yes	1	None visible	Not visible	Flush Regime		2	2										Low	None visible	None visible	Panel unable to be removed	Medium
Recommendations:				Discoloured water from outlet(s). Investigate and correct.																								
				Cold water temperature too high. Investigate and correct.																								
01C Critical Care CCW-021 (Bathroom)	Hot, Cold	CWST 19.6	Calorifier 39.7	2	OK	Yes	Yes	2	None visible	Not visible	Flush Regime				1		1	1						High	None visible	None visible		High
Recommendations:				Hot temperature slow to rise. It should be confirmed that hot outlet(s) are on a long leg and not that the flow and return has failed locally in this area.																								
				Hot water temperature too low. Investigate and correct.																								

LEGIONELLA RISK ASSESSMENT

Location / Room No	Sentinel outlet?	Cold Supply & Temp (°C)	Hot Supply & Temp (°C)	TMV info					Deadlegs Present (Inc. Drain cocks)	Flow & Return Working	Outlet Usage	Outlets in location												Aerosol Created	Non WRAS Material	Flexi Hoses	Comment	Additional Localised Risk Rating
				No. Of TMVs	Access	<2m from outlet?	Mix Temps 37-45°C	No. TMV Fed Outlets				Mains	Cold	Hot	Mixer	Urinals	WCs	Shower	Drinks / vend	Water boiler	Drinking fountain	Arjo/whirlpool	Other					
01C Critical Care CCW-027 (Shower)	Hot, Cold	CWST	Calorifier	1	OK	Yes	Yes	1	None visible	Not visible								1						High	None visible	None visible	Outlet not run as floor not sealed.	High
Recommendations:																												
01C Critical Care CCW-082 (Critical Care Bed)	Hot, Cold	CWST 13.5	Calorifier 52.3	4	OK	Yes	Yes	4	None visible	Not visible	Flush Regime		4	4										Low	None visible	None visible	1 x renal	Low
Recommendations:	Hot outlets do not comply with latest SHTM regulations, though achieving 50°C. Wherever practicable increase temperatures to 55°C.																											
01C Critical Care CCW-084 (Gowning Room)	Hot, Cold	CWST 12.3	Calorifier 55.6	1	OK	Yes	Yes	1	None visible	Not visible	Flush Regime		1	1										Low	None visible	None visible		Low
Recommendations:																												
01C Critical Care CCW-092 (Dirty Utility)	Hot, Cold	CWST 13.8	Calorifier 56.1	2	OK	Yes	Yes	2	None visible	Not visible	Flush Regime		2	2			1							Low	None visible	Yes	1 x Sluice	Low
Recommendations:	All EPDM flexible hoses should be removed and replaced with hard piped connection.																											
01C Critical Care CCW-098 (Critical Care Bed)	Hot, Cold	CWST 25.3	Calorifier 52.2	4	OK	Yes	Yes	4	None visible	Not visible	Flush Regime		4	4										Low	None visible	None visible	1 x renal	Medium
Recommendations:	Cold water temperature too high. Investigate and correct.																											
	Hot outlets do not comply with latest SHTM regulations, though achieving 50°C. Wherever practicable increase temperatures to 55°C.																											

LEGIONELLA RISK ASSESSMENT

Location / Room No	Sentinel outlet?	Cold Supply & Temp (°C)	Hot Supply & Temp (°C)	TMV info					Deadlegs Present (Inc. Drain cocks)	Flow & Return Working	Outlet Usage	Outlets in location												Aerosol Created	Non WRAS Material	Flexi Hoses	Comment	Additional Localised Risk Rating
				No. Of TMVs	Access	<2m from outlet?	Mix Temps 37-45°C	No. TMV Fed Outlets				Mains	Cold	Hot	Mixer	Urinals	WCs	Shower	Drinks / vend	Water boiler	Drinking fountain	Arjo/whirlpool	Other					
01C Critical Care CCW-118 (Facilities)	Hot, Cold	CWST 12.3	Calorifier 61.1	1	OK	Yes	Yes	1	None visible	Not visible	Flush Regime		3	3										Low	None visible	Yes	Flexible hose to double level sink	Low
Recommendations:			All EPDM flexible hoses should be removed and replaced with hard piped connection.																									
01C Medical Day Unit MDU-008 (Beverage Prep)	Hot, Cold	CWST 23.4	Calorifier 57.1	1	OK	Yes	Yes	1	None visible	Not visible	Flush Regime		2	2						1				Low	None visible	Yes	1 x sluice	Medium
Recommendations:			All EPDM flexible hoses should be removed and replaced with hard piped connection. Cold water temperature too high. Investigate and correct.																									
01C Special Feeds SPF-007 (Facilities)	Hot, Cold	CWST 12.5	Calorifier 58.4	1	OK	Yes	Yes	1	None visible	Not visible	Flush Regime		3	3										Low	None visible	Yes		Medium
Recommendations:			Discoloured water from outlet(s). Investigate and correct. All EPDM flexible hoses should be removed and replaced with hard piped connection.																									
01C Theatre 001-011	Hot, Cold	CWST 11.2	Calorifier 46.3	1	OK	Yes	Yes	1	None visible	Not visible	Flush Regime		1	1										Low	None visible	None visible		Medium
Recommendations:			Hot water temperature too low. Investigate and correct.																									

LEGIONELLA RISK ASSESSMENT

Location / Room No	Sentinel outlet?	Cold Supply & Temp (°C)	Hot Supply & Temp (°C)	TMV info					Deadlegs Present (Inc. Drain cocks)	Flow & Return Working	Outlet Usage	Outlets in location												Aerosol Created	Non WRAS Material	Flexi Hoses	Comment	Additional Localised Risk Rating
				No. Of TMVs	Access	<2m from outlet?	Mix Temps 37-45°C	No. TMV Fed Outlets				Mains	Cold	Hot	Mixer	Urinals	WCs	Shower	Drinks / vend	Water boiler	Drinking fountain	Arjo/whirlpool	Other					
01C Theatre 23HU-008 (Toilet)	Hot, Cold	CWST 17.6	Calorifier 53.8	1	OK	Yes	Yes	1	None visible	Not visible	Flush Regime				1		1							Low	None visible	None visible	Labelled as sentinel at outlet	Low
Recommendations:			Hot outlets do not comply with latest SHTM regulations, though achieving 50°C. Wherever practicable increase temperatures to 55°C.																									
01C Theatre 23HU-015 (Waiting Room)	Cold	CWST	No hot outlets	0				0	None visible	N/A	Flush Regime								1					Low	None visible	None visible	Designated as sentinel	Low
Recommendations:																												
01C Theatre 23HU-040 (Bathroom)	Hot, Cold	CWST 12.1	Calorifier 56.1	2	OK	Yes	Yes	2	None visible	Not visible	Flush Regime				1		1	1						High	None visible	None visible		Low
Recommendations:																												
01C Theatre 23HU-051 (Toilet)	Hot, Cold	CWST 12.8	Calorifier 55.4	1	OK	Yes	Yes	1	None visible	Not visible	Flush Regime				1		1							Low	None visible	None visible		Low
Recommendations:																												
01C Theatre THE-009 (Toilet)	Hot, Cold	CWST 11.2	Calorifier 50.9	1	OK	Yes	Yes	1	None visible	Not visible	Flush Regime				1		1							Low	None visible	None visible		Low
Recommendations:			Hot outlets do not comply with latest SHTM regulations, though achieving 50°C. Wherever practicable increase temperatures to 55°C.																									

LEGIONELLA RISK ASSESSMENT

Location / Room No	Sentinel outlet?	Cold Supply & Temp (°C)	Hot Supply & Temp (°C)	TMV info					Deadlegs Present (Inc. Drain cocks)	Flow & Return Working	Outlet Usage	Outlets in location											Aerosol Created	Non WRAS Material	Flexi Hoses	Comment	Additional Localised Risk Rating
				No. Of TMVs	Access	<2m from outlet?	Mix Temps 37-45°C	No. TMV Fed Outlets				Mains	Cold	Hot	Mixer	Urinals	WCs	Shower	Drinks / vend	Water boiler	Drinking fountain	Arjo/whirlpool	Other					
01C Theatre THE-025 (Toilet)	Hot, Cold	CWST 12.0	Calorifier 55.4	1	OK	Yes	Yes	1	None visible	Not visible	Flush Regime				1		1							Low	None visible	None visible	Copper tail to outlet	Low
Recommendations:																												
01C Theatre THE-042 (Female Change)	Hot, Cold	CWST 11.5	Calorifier 53.2	3	OK	Yes	Yes	3	None visible	Not visible	Flush Regime				3		2							Low	None visible	None visible	2 x WC doors not labelled	Low
Recommendations:			Hot outlets do not comply with latest SHTM regulations, though achieving 50°C. Wherever practicable increase temperatures to 55°C.																									
01C Theatre THE-069 (Lab)	Hot, Cold	CWST 12.5	Calorifier 51.8	1	OK	Yes	Yes	1	None visible	Not visible	Flush Regime		1	1										Low	None visible	None visible		Low
Recommendations:			Hot outlets do not comply with latest SHTM regulations, though achieving 50°C. Wherever practicable increase temperatures to 55°C.																									
01C Theatre THE-078 (Prep room)	Hot, Cold	CWST 21.3	Calorifier 53.4	1	OK	Yes	Yes	1	None visible	Not visible	Flush Regime		1	1										Low	None visible	None visible		Medium
Recommendations:			Cold water temperature too high. Investigate and correct. Hot outlets do not comply with latest SHTM regulations, though achieving 50°C. Wherever practicable increase temperatures to 55°C.																									
01C Theatre THE-090 (Theatre Scrub)	Hot, Cold	CWST 12.5	Calorifier 51.9	3	OK	Yes	Yes	3	None visible	Not visible	Flush Regime		3	3										Low	None visible	None visible		Low
Recommendations:			Hot outlets do not comply with latest SHTM regulations, though achieving 50°C. Wherever practicable increase temperatures to 55°C.																									

LEGIONELLA RISK ASSESSMENT

Location / Room No	Sentinel outlet?	Cold Supply & Temp (°C)	Hot Supply & Temp (°C)	TMV info					Deadlegs Present (Inc. Drain cocks)	Flow & Return Working	Outlet Usage	Outlets in location												Aerosol Created	Non WRAS Material	Flexi Hoses	Comment	Additional Localised Risk Rating
				No. Of TMVs	Access	<2m from outlet?	Mix Temps 37-45°C	No. TMV Fed Outlets				Mains	Cold	Hot	Mixer	Urinals	WCs	Shower	Drinks / vend	Water boiler	Drinking fountain	Arjo/whirlpool	Other					
01C Theatre THE-102 (Facilities)	Hot, Cold	CWST 22.6	Calorifier 56.4	1	OK	Yes	Yes	1	None visible	Not visible	Flush Regime		3	3										Low	None visible	Yes		Medium
Recommendations:			All EPDM flexible hoses should be removed and replaced with hard piped connection. Cold water temperature too high. Investigate and correct.																									
01C Theatre THE-106 (Anesthetic room)	Hot, Cold	CWST 22.3	Calorifier 55.1	1	OK	Yes	Yes	1	None visible	Not visible	Flush Regime		1	1										Low	None visible	None visible		Medium
Recommendations:			Cold water temperature too high. Investigate and correct.																									
01C Theatre THE-117 (Theatre Scrub)	Hot, Cold	CWST 13.3	Calorifier 51.6	3	OK	Yes	Yes	3	None visible	Not visible	Flush Regime		3	3										Low	None visible	None visible		Low
Recommendations:			Hot outlets do not comply with latest SHTM regulations, though achieving 50°C. Wherever practicable increase temperatures to 55°C.																									
01C Theatre THE-157 (Recovery room)	Hot, Cold	CWST 22.2	Calorifier 54.5	1	OK	Yes	Yes	1	None visible	Not visible	Flush Regime		1	1										Low	None visible	None visible		Medium
Recommendations:			Cold water temperature too high. Investigate and correct. Hot outlets do not comply with latest SHTM regulations, though achieving 50°C. Wherever practicable increase temperatures to 55°C.																									

LEGIONELLA RISK ASSESSMENT

Location / Room No	Sentinel outlet?	Cold Supply & Temp (°C)	Hot Supply & Temp (°C)	TMV info					Deadlegs Present (Inc. Drain cocks)	Flow & Return Working	Outlet Usage	Outlets in location												Aerosol Created	Non WRAS Material	Flexi Hoses	Comment	Additional Localised Risk Rating
				No. Of TMVs	Access	<2m from outlet?	Mix Temps 37-45°C	No. TMV Fed Outlets				Mains	Cold	Hot	Mixer	Urinals	WCs	Shower	Drinks / vend	Water boiler	Drinking fountain	Arjo/whirlpool	Other					
02 Decontamination DCT-009 (Endoscopy Wash)	No	CWST 14.8	Calorifier 56.8	26	OK	Yes	Yes	26	None visible	Yes	Flush Regime		2	2	24									Low	None visible	None visible	Suspect copper tails on Markwik taps	Low
Recommendations:																												
02 Decontamination DCT-015 (Wash Room DSR)	Hot, Cold	CWST 14.3	Calorifier 57.1	1	OK	Yes	Yes	1	None visible	Not visible	Flush Regime		3	3										Low	None visible	Yes		Low
Recommendations:	All EPDM flexible hoses should be removed and replaced with hard piped connection.																											
02 Dermatology DMW-004 (Photo Therapy)	Hot, Cold	CWST 14.8	Calorifier 50.0	1	OK	Yes	Yes	1	None visible	Not visible	Flush Regime		1	1										Low	None visible	None visible		Low
Recommendations:	Hot outlets do not comply with latest SHTM regulations, though achieving 50°C. Wherever practicable increase temperatures to 55°C.																											
02 Dermatology DMW-025 (Bathroom)	Hot, Cold	CWST 19.6	Calorifier 53.6	2	OK	Yes	Yes	2	None visible	Not visible	Flush Regime				1		1	1						High	None visible	None visible		Low
Recommendations:	Hot outlets do not comply with latest SHTM regulations, though achieving 50°C. Wherever practicable increase temperatures to 55°C.																											
02 Dermatology DMW-031 (Bathroom)	Hot, Cold	CWST 18.1	Calorifier 52.1	2	OK	Yes	Yes	2	None visible	Not visible	Flush Regime				1		1	1						High	None visible	None visible		Low
Recommendations:	Hot outlets do not comply with latest SHTM regulations, though achieving 50°C. Wherever practicable increase temperatures to 55°C.																											

LEGIONELLA RISK ASSESSMENT

Location / Room No	Sentinel outlet?	Cold Supply & Temp (°C)	Hot Supply & Temp (°C)	TMV info					Deadlegs Present (Inc. Drain cocks)	Flow & Return Working	Outlet Usage	Outlets in location												Aerosol Created	Non WRAS Material	Flexi Hoses	Comment	Additional Localised Risk Rating
				No. Of TMVs	Access	<2m from outlet?	Mix Temps 37-45°C	No. TMV Fed Outlets				Mains	Cold	Hot	Mixer	Urinals	WCs	Shower	Drinks / vend	Water boiler	Drinking fountain	Arjo/whirlpool	Other					
02 Dermatology DMW-060 (Facilities)								0																		Yes		No access
Recommendations:	Locked – No Access. Area should be assessed once access obtained.																											
02 Dermatology DOPD-004 (Toilet)	Hot, Cold	CWST 19.9	Calorifier 54.1	1	OK	Yes	Yes	1	None visible	Not visible	Flush Regime				1		1							Low	None visible	None visible	Infrared Tap	Low
Recommendations:	Hot outlets do not comply with latest SHTM regulations, though achieving 50°C. Wherever practicable increase temperatures to 55°C.																											
02 Dermatology DOPD-025 (Technician)	Hot, Cold	CWST 16.7	Calorifier 57.0	1	OK	Yes	Yes	1	None visible	Not visible	Flush Regime		2	2										Low	None visible	None visible		Low
Recommendations:	Confirm air gap on dump valve connection to waste is suitable and alter if required																											
02 Endoscopy END-013 (Facilities)	Hot, Cold	CWST 13.5	Calorifier 57.3	1	OK	Yes	Yes	1	None visible	Not visible	Flush Regime		3	3										Low	None visible	Yes		Low
Recommendations:	All EPDM flexible hoses should be removed and replaced with hard piped connection.																											
02 Endoscopy END-029 (Examination Area)	Hot, Cold	CWST 14.3	Calorifier 51.2	1	OK	Yes	Yes	1	None visible	Not visible	Flush Regime		1	1										Low	None visible	None visible		Low
Recommendations:	Hot outlets do not comply with latest SHTM regulations, though achieving 50°C. Wherever practicable increase temperatures to 55°C.																											

LEGIONELLA RISK ASSESSMENT

Location / Room No	Sentinel outlet?	Cold Supply & Temp (°C)	Hot Supply & Temp (°C)	TMV info					Deadlegs Present (Inc. Drain cocks)	Flow & Return Working	Outlet Usage	Outlets in location												Aerosol Created	Non WRAS Material	Flexi Hoses	Comment	Additional Localised Risk Rating
				No. Of TMVs	Access	<2m from outlet?	Mix Temps 37-45°C	No. TMV Fed Outlets				Mains	Cold	Hot	Mixer	Urinals	WCs	Shower	Drinks / vend	Water boiler	Drinking fountain	Arjo/whirlpool	Other					
02 FMA2-014 (Changing)	Hot, Cold	CWST 13.6	Calorifier 55.4	1	OK	Yes	Yes	1	None visible	Not visible	Flush Regime				1		1							Low	None visible	None visible	FMA2-013 noted as sentinel but no outlets.	Low
Recommendations:																												
02 Medical Physics MP-020 (Devices-Adult)	Hot, Cold	CWST 13.9	Calorifier 56.2	1	OK	Yes	Yes	1	None visible	Not visible	Daily		2	2										Low	None visible	None visible		Low
Recommendations:																												
02 Renal RENO-003 (CAPD Training)	Hot, Cold	CWST 14.3	Calorifier 52.4	1	OK	Yes	Yes	1	None visible	Not visible	Flush Regime		1	1										Low	None visible	None visible		Low
Recommendations:			Hot outlets do not comply with latest SHTM regulations, though achieving 50°C. Wherever practicable increase temperatures to 55°C.																									
02 Renal RENO-016 (Room 3)	Hot, Cold	CWST 19.8	Calorifier 53.0	1	OK	Yes	Yes	1	None visible	Not visible	Flush Regime		1	1										Low	None visible	None visible	Renal Connection	Low
Recommendations:			Hot outlets do not comply with latest SHTM regulations, though achieving 50°C. Wherever practicable increase temperatures to 55°C.																									
02 Renal RENO-033 (Clean Utility)	No	CWST 22.1	Calorifier 56.2	1	OK	Yes	Yes	1	None visible	Not visible	Flush Regime		2	2										Low	None visible	None visible		Medium
Recommendations:			Cold water temperature too high. Investigate and correct.																									

LEGIONELLA RISK ASSESSMENT

Location / Room No	Sentinel outlet?	Cold Supply & Temp (°C)	Hot Supply & Temp (°C)	TMV info					Deadlegs Present (Inc. Drain cocks)	Flow & Return Working	Outlet Usage	Outlets in location												Aerosol Created	Non WRAS Material	Flexi Hoses	Comment	Additional Localised Risk Rating
				No. Of TMVs	Access	<2m from outlet?	Mix Temps 37-45°C	No. TMV Fed Outlets				Mains	Cold	Hot	Mixer	Urinals	WCs	Shower	Drinks / vend	Water boiler	Drinking fountain	Arjo/whirlpool	Other					
02 Renal RENO-046 (Female Toilet)	Hot, Cold	CWST 19.1	Calorifier 54.2	1	OK	Yes	Yes	1	None visible	Not visible	Daily				1		1							Low	None visible	None visible		Low
Recommendations:	Hot outlets do not comply with latest SHTM regulations, though achieving 50°C. Wherever practicable increase temperatures to 55°C.																											
02 Renal RENO-064 (Equipment Servicing)	Hot, Cold	CWST 17.4	Calorifier 55.6	1	OK	Yes	Yes	1	None visible	Not visible	Flush Regime		2	2										Low	None visible	None visible	Renal (x7)	Low
Recommendations:																												
02 Theatres THE-026 (Female Toilet)	Hot, Cold	CWST 13.5	Calorifier 55.5	1	OK	Yes	Yes	1	None visible	Not visible	Daily				1		1							Low	None visible	None visible		Low
Recommendations:																												
02 Theatres THE-033 (Female Changing)	Hot, Cold	CWST 13.2	Calorifier 55.6	3	OK	Yes	Yes	3	None visible	Not visible	Flush Regime				6									Low	None visible	None visible		Low
Recommendations:																												
02 Theatres THE-044 (Male Changing)	Hot, Cold	CWST 13.1	Calorifier 55.2	3	OK	Yes	Yes	3	None visible	Not visible	Flush Regime				3									Low	None visible	None visible		Low
Recommendations:																												

LEGIONELLA RISK ASSESSMENT

Location / Room No	Sentinel outlet?	Cold Supply & Temp (°C)	Hot Supply & Temp (°C)	TMV info					Deadlegs Present (Inc. Drain cocks)	Flow & Return Working	Outlet Usage	Outlets in location												Aerosol Created	Non WRAS Material	Flexi Hoses	Comment	Additional Localised Risk Rating
				No. Of TMVs	Access	<2m from outlet?	Mix Temps 37-45°C	No. TMV Fed Outlets				Mains	Cold	Hot	Mixer	Urinals	WCs	Shower	Drinks / vend	Water boiler	Drinking fountain	Arjo/whirlpool	Other					
02 Theatres THE-060 (Facilities)	Hot, Cold	CWST 13.2	Calorifier 56.8	1	OK	Yes	Yes	1	None visible	Not visible	Flush Regime		3	3										Low	None visible	Yes		Low
Recommendations:	All EPDM flexible hoses should be removed and replaced with hard piped connection.																											
02 Theatres THE-079 (On Call)	Hot, Cold	CWST 13.5	Calorifier 55.4	2	OK	Yes	Yes	2	None visible	Not visible	Flush Regime				1		1	1						High	None visible	None visible		Low
Recommendations:																												
02 Theatres THE-091 (Dirty Utility)	Hot, Cold	CWST 13.5	Calorifier 55.7	1	OK	Yes	Yes	1	None visible	Not visible	Flush Regime		2	2										Low	None visible	None visible		Low
Recommendations:																												
02 Theatres THE-106 (Dirty Utility)	Hot, Cold	CWST 13.8	Calorifier 56.4	1	OK	Yes	Yes	1	None visible	Not visible	Flush Regime		2	2										Low	None visible	None visible		Low
Recommendations:																												
02 Theatres THE-106 (Scrub Room)	Hot, Cold	CWST 14.1	Calorifier 56.3	1	OK	Yes	Yes	1	None visible	Not visible	Flush Regime		3	3										Low	None visible	None visible		Low
Recommendations:																												

LEGIONELLA RISK ASSESSMENT

Location / Room No	Sentinel outlet?	Cold Supply & Temp (°C)	Hot Supply & Temp (°C)	TMV info					Deadlegs Present (Inc. Drain cocks)	Flow & Return Working	Outlet Usage	Outlets in location												Aerosol Created	Non WRAS Material	Flexi Hoses	Comment	Additional Localised Risk Rating
				No. Of TMVs	Access	<2m from outlet?	Mix Temps 37-45°C	No. TMV Fed Outlets				Mains	Cold	Hot	Mixer	Urinals	WCs	Shower	Drinks / vend	Water boiler	Drinking fountain	Arjo/whirlpool	Other					
02 Theatres THE-280 (Disabled Toilet)	Hot, Cold	CWST 23.5	Calorifier 55.2	1	OK	Yes	Yes	1	None visible	Not visible	Daily				1		1							Low	None visible	None visible	Small section of insulation missing	Medium
Recommendations:			Cold water temperature too high. Investigate and correct.																									
02 Theatres THE-287 (Bed Bay A9)	Hot, Cold	CWST 19.5	Calorifier 52.2	1	OK	Yes	Yes	1	None visible	Not visible	Flush Regime		1	1										Low	None visible	None visible		Low
Recommendations:			Hot outlets do not comply with latest SHTM regulations, though achieving 50°C. Wherever practicable increase temperatures to 55°C.																									
02 Theatres THE-289 (Bed Bay A1)	Hot, Cold	CWST 20.5	Calorifier 50.4	1	OK	Yes	Yes	1	None visible	Not visible	Flush Regime		1	1										Low	None visible	None visible		Medium
Recommendations:			Cold water temperature too high. Investigate and correct.																									
			Hot outlets do not comply with latest SHTM regulations, though achieving 50°C. Wherever practicable increase temperatures to 55°C.																									
02 Theatres THE-302 (Bed Bay A7)	Hot, Cold	CWST 14.1	Calorifier 51.5	1	OK	Yes	Yes	1	None visible	Not visible	Flush Regime		1	1										Low	None visible	None visible		Low
Recommendations:			Hot outlets do not comply with latest SHTM regulations, though achieving 50°C. Wherever practicable increase temperatures to 55°C.																									
02 Theatres THE-319 (Dirty Utility)	Hot, Cold	CWST 14.2	Calorifier 50.3	1	OK	Yes	Yes	1	None visible	Not visible	Flush Regime		2	2			1							Low	None visible	None visible	Sluice	Low
Recommendations:			Hot outlets do not comply with latest SHTM regulations, though achieving 50°C. Wherever practicable increase temperatures to 55°C.																									

LEGIONELLA RISK ASSESSMENT

Location / Room No	Sentinel outlet?	Cold Supply & Temp (°C)	Hot Supply & Temp (°C)	TMV info					Deadlegs Present (Inc. Drain cocks)	Flow & Return Working	Outlet Usage	Outlets in location												Aerosol Created	Non WRAS Material	Flexi Hoses	Comment	Additional Localised Risk Rating
				No. Of TMVs	Access	<2m from outlet?	Mix Temps 37-45°C	No. TMV Fed Outlets				Mains	Cold	Hot	Mixer	Urinals	WCs	Shower	Drinks / vend	Water boiler	Drinking fountain	Arjo/whirlpool	Other					
02 Theatres THE-327 (Recovery)	Hot, Cold	CWST 22.1	Calorifier 53.4	1	OK	Yes	Yes	1	None visible	Not visible	Flush Regime		1	1										Low	None visible	None visible		Medium
Recommendations:			Cold water temperature too high. Investigate and correct. Hot outlets do not comply with latest SHTM regulations, though achieving 50°C. Wherever practicable increase temperatures to 55°C.																									
02 Transport Base TPB-001 (Clinical Workroom)	Hot, Cold	CWST 14.2	Calorifier 52.1	2	OK	Yes	Yes	2	None visible	Not visible	Flush Regime		2	2										Low	None visible	None visible	Room being used to store cots	Low
Recommendations:			Hot outlets do not comply with latest SHTM regulations, though achieving 50°C. Wherever practicable increase temperatures to 55°C.																									
02C Aseptic Unit ASU-039 (Changing Room)	Hot, Cold	CWST 18.1	Calorifier 55.8	1	OK	Yes	Yes	1	None visible	Not visible	Flush Regime		1	1										Low	None visible	None visible		Low
Recommendations:																												
02C Aseptic Unit ASU-042 (Corridor)	Hot, Cold	CWST 18.0	Calorifier 55.8	1	OK	Yes	Yes	1	None visible	Not visible	Flush Regime		1	1										Low	None visible	None visible		Low
Recommendations:																												

LEGIONELLA RISK ASSESSMENT

Location / Room No	Sentinel outlet?	Cold Supply & Temp (°C)	Hot Supply & Temp (°C)	TMV info					Deadlegs Present (Inc. Drain cocks)	Flow & Return Working	Outlet Usage	Outlets in location											Aerosol Created	Non WRAS Material	Flexi Hoses	Comment	Additional Localised Risk Rating
				No. Of TMVs	Access	<2m from outlet?	Mix Temps 37-45°C	No. TMV Fed Outlets				Mains	Cold	Hot	Mixer	Urinals	WCs	Shower	Drinks / vend	Water boiler	Drinking fountain	Arjo/whirlpool	Other					
02C Corridor ARU-001 (Kitchen)	Hot, Cold	CWST 16.0	Calorifier 60.7	1	OK	Yes	Yes	1	None visible	No	Flush Regime		2	2	1			1						High	None visible	Yes	1	High
Recommendations:			Hot flow and return not working. This requires investigation and correcting.																									
			Aeration at outlet(s). Investigate and correct.																									
			All EPDM flexible hoses should be removed and replaced with hard piped connection.																									
02C Ward AFD-022 (Toilet)	Hot, Cold	CWST 25.2	Calorifier 55.2	1	OK	Yes	Yes	1	None visible	Not visible	Flush Regime				1		1							Low	None visible	None visible		Medium
Recommendations:			Aeration at outlet(s). Investigate and correct.																									
			Cold water temperature too high. Investigate and correct.																									
02C Ward ARU-003 (Office)								0																		Yes	No outlets in room, though identified as sentinel outlet.	
Recommendations:																												
02C Ward ARU-046 (Bedroom)	Hot, Cold	CWST 14.6	Calorifier 56.1	1	OK	Yes	Yes	1	None visible	Not visible	Flush Regime		1	1										Low	None visible	None visible	Next to designated sentinel (ARU-047)	Low
Recommendations:																												

LEGIONELLA RISK ASSESSMENT

Location / Room No	Sentinel outlet?	Cold Supply & Temp (°C)	Hot Supply & Temp (°C)	TMV info					Deadlegs Present (Inc. Drain cocks)	Flow & Return Working	Outlet Usage	Outlets in location												Aerosol Created	Non WRAS Material	Flexi Hoses	Comment	Additional Localised Risk Rating
				No. Of TMVs	Access	<2m from outlet?	Mix Temps 37-45°C	No. TMV Fed Outlets				Mains	Cold	Hot	Mixer	Urinals	WCs	Shower	Drinks / vend	Water boiler	Drinking fountain	Arjo/whirlpool	Other					
02C Ward ARU-047 (Reception)								0																		Yes	No outlets in room, though identified as sentinel outlet.	
Recommendations:																												
02C Ward ARU-085 (Bedroom)	Hot, Cold	CWST 14.2	Calorifier 53.5	1	OK	Yes	Yes	1	None visible	Not visible	Flush Regime		1	1										Low	None visible	None visible		Low
Recommendations:	Hot outlets do not comply with latest SHTM regulations, though achieving 50°C. Wherever practicable increase temperatures to 55°C.																											
02C Ward ARU-116 (Toilet)	No	CWST 19.4	Calorifier 57.1	1	OK	Yes	Yes	1	None visible	Not visible	Flush Regime				1		1							Low	None visible	None visible	Next to designated sentinel (ARU-003)	Low
Recommendations:																												
02C Ward DCU-005 (Toilet)	Hot, Cold	CWST 15.1	Calorifier 56.3	1	OK	Yes	Yes	1	None visible	Not visible	Flush Regime				1		1							Low	None visible	None visible		Low
Recommendations:																												
02C Ward DCU-011 (Waiting Area)	Hot, Cold	CWST 17.2	Calorifier 55.6	1	OK	Yes	Yes	1	None visible	Not visible	Flush Regime		1	1										Low	None visible	None visible		Low
Recommendations:																												

LEGIONELLA RISK ASSESSMENT

Location / Room No	Sentinel outlet?	Cold Supply & Temp (°C)	Hot Supply & Temp (°C)	TMV info					Deadlegs Present (Inc. Drain cocks)	Flow & Return Working	Outlet Usage	Outlets in location												Aerosol Created	Non WRAS Material	Flexi Hoses	Comment	Additional Localised Risk Rating
				No. Of TMVs	Access	<2m from outlet?	Mix Temps 37-45°C	No. TMV Fed Outlets				Mains	Cold	Hot	Mixer	Urinals	WCs	Shower	Drinks / vend	Water boiler	Drinking fountain	Arjo/whirlpool	Other					
02C Ward SCH-022 (Bathroom)	Hot, Cold	CWST 26.2	Calorifier 55.2	2	OK	Yes	Yes	2	None visible	Not visible	Flush Regime				1		1	1						High	None visible	None visible		High
Recommendations:			Aeration at outlet(s). Investigate and correct.																									
			Cold water temperature too high. Investigate and correct.																									
02C Ward SCH-023 (Bathroom)	Hot, Cold	CWST 26.1	Calorifier 58.5	2	OK	Yes	Yes	2	None visible	Not visible	Flush Regime				1		1	1						High	None visible	None visible		High
Recommendations:			Aeration at outlet(s). Investigate and correct.																									
			Cold water temperature too high. Investigate and correct.																									
02C Ward SCH-040 (Toilet)	Hot, Cold	CWST 25.9	Calorifier 61.0	1	OK	Yes	Yes	1	None visible	Not visible	Flush Regime				1		1							Low	None visible	None visible	Small leak from hot valve	Medium
Recommendations:			Cold water temperature too high. Investigate and correct.																									
02C Ward SCH-061 (Bedroom)	Hot, Cold	CWST 29.8	Calorifier 53.6	1	OK	Yes	Yes	1	None visible	Not visible	Flush Regime		1	1										Low	None visible	None visible		Medium
Recommendations:			Cold water temperature too high. Investigate and correct.																									
			Hot outlets do not comply with latest SHTM regulations, though achieving 50°C. Wherever practicable increase temperatures to 55°C.																									

LEGIONELLA RISK ASSESSMENT

Location / Room No	Sentinel outlet?	Cold Supply & Temp (°C)	Hot Supply & Temp (°C)	TMV info					Deadlegs Present (Inc. Drain cocks)	Flow & Return Working	Outlet Usage	Outlets in location												Aerosol Created	Non WRAS Material	Flexi Hoses	Comment	Additional Localised Risk Rating
				No. Of TMVs	Access	<2m from outlet?	Mix Temps 37-45°C	No. TMV Fed Outlets				Mains	Cold	Hot	Mixer	Urinals	WCs	Shower	Drinks / vend	Water boiler	Drinking fountain	Arjo/whirlpool	Other					
02C Ward SCH-063 (Treatment Room)	Hot, Cold	CWST 26.1	Calorifier 55.9	1	OK	Yes	Yes	1	None visible	Not visible	Flush Regime		1	1										Low	None visible	None visible		Medium
Recommendations:			Cold water temperature too high. Investigate and correct.																									
02C Ward SCH-087 (Store)	Hot, Cold	CWST 13.0	Calorifier 60.7	1	OK	Yes	Yes	1	None visible	Not visible	Flush Regime		3	3										Low	None visible	Yes		Medium
Recommendations:			Hot temperature slow to rise. It should be confirmed that hot outlet(s) are on a long leg and not that the flow and return has failed locally in this area.																									
			All EPDM flexible hoses should be removed and replaced with hard piped connection.																									
02C Ward SCH-092 (Hospital Night Team)	Hot, Cold	CWST 19.1	Calorifier 63.0	1	OK	Yes	Yes	1	None visible	Not visible	Flush Regime		2	2										Low	None visible	None visible	Small section of insulation missing	Low
Recommendations:			Aeration at outlet(s). Investigate and correct.																									
03C Ward GW1-002 (Renal Day Unit)	Hot, Cold	CWST 25.3	Calorifier 53.1	3	OK	Yes	Yes	3	None visible	Not visible	Flush Regime		3	3										Low	None visible	None visible	5 x renal	Medium
Recommendations:			Aeration at outlet(s). Investigate and correct.																									
			Cold water temperature too high. Investigate and correct.																									
			Hot outlets do not comply with latest SHTM regulations, though achieving 50°C. Wherever practicable increase temperatures to 55°C.																									

LEGIONELLA RISK ASSESSMENT

Location / Room No	Sentinel outlet?	Cold Supply & Temp (°C)	Hot Supply & Temp (°C)	TMV info					Deadlegs Present (Inc. Drain cocks)	Flow & Return Working	Outlet Usage	Outlets in location												Aerosol Created	Non WRAS Material	Flexi Hoses	Comment	Additional Localised Risk Rating
				No. Of TMVs	Access	<2m from outlet?	Mix Temps 37-45°C	No. TMV Fed Outlets				Mains	Cold	Hot	Mixer	Urinals	WCs	Shower	Drinks / vend	Water boiler	Drinking fountain	Arjo/whirlpool	Other					
03C Ward GW1-048 (Toilet)	Hot, Cold	CWST 24.1	Calorifier 59.1	1	OK	Yes	Yes	1	None visible	Not visible	Flush Regime				1		1							Low	None visible	None visible		Medium
Recommendations:			Aeration at outlet(s). Investigate and correct.																									
			Cold water temperature too high. Investigate and correct.																									
03C Ward GW2-025 (Bedroom)	Hot, Cold	CWST 22.2	Calorifier 55.1	1	OK	Yes	Yes	1	None visible	Not visible	Flush Regime		1	1										Low	None visible	None visible		Medium
Recommendations:			Cold water temperature too high. Investigate and correct.																									
03C Ward GW2-035 (Bedroom)	Hot, Cold	CWST 24.0	Calorifier 54.2	1	OK	Yes	Yes	1	None visible	Not visible	Flush Regime		1	1										Low	None visible	None visible		Medium
Recommendations:			Cold water temperature too high. Investigate and correct.																									
			Hot outlets do not comply with latest SHTM regulations, though achieving 50°C. Wherever practicable increase temperatures to 55°C.																									
03C Ward GW2-036 (Play Room)	Hot, Cold	CWST 24.0	Calorifier 59.3	1	OK	Yes	Yes	1	None visible	Not visible	Flush Regime		2	2										Low	None visible	None visible		Medium
Recommendations:			Cold water temperature too high. Investigate and correct.																									

LEGIONELLA RISK ASSESSMENT

Location / Room No	Sentinel outlet?	Cold Supply & Temp (°C)	Hot Supply & Temp (°C)	TMV info					Deadlegs Present (Inc. Drain cocks)	Flow & Return Working	Outlet Usage	Outlets in location												Aerosol Created	Non WRAS Material	Flexi Hoses	Comment	Additional Localised Risk Rating
				No. Of TMVs	Access	<2m from outlet?	Mix Temps 37-45°C	No. TMV Fed Outlets				Mains	Cold	Hot	Mixer	Urinals	WCs	Shower	Drinks / vend	Water boiler	Drinking fountain	Arjo/whirlpool	Other					
03C Ward GW2-054 (Bathroom)	Hot, Cold	CWST 24.4	Calorifier 55.1	2	OK	Yes	Yes	2	None visible	Not visible	Flush Regime				1		1	1						High	None visible	None visible		High
Recommendations:			Cold water temperature too high. Investigate and correct.																									
03C Ward GW3-001 (Store)								0																		Yes	No outlets in room, though identified as sentinel outlet.	
Recommendations:																												
03C Ward GW3-004 (Bathroom)	Hot, Cold	CWST 24.9	Calorifier 58.1	2	OK	Yes	Yes	2	None visible	Not visible	Flush Regime				1		1	1						High	None visible	None visible		High
Recommendations:			Cold water temperature too high. Investigate and correct.																									
03C Ward GW3-043 (Play Room)	Hot, Cold	CWST 16.5	Calorifier 64.1	1	OK	Yes	Yes	1	None visible	Not visible	Flush Regime		2	2										Low	None visible	None visible		Low
Recommendations:																												
03C Ward GW3-068 (Lab)	Hot, Cold	CWST 25.0	Calorifier 59.7	1	OK	Yes	Yes	1	None visible	Not visible	Flush Regime		2	2										Low	None visible	None visible	Next to designated sentinel (GW3-001)	High
Recommendations:			Cold water temperature too high. Investigate and correct.																									

LEGIONELLA RISK ASSESSMENT

Location / Room No	Sentinel outlet?	Cold Supply & Temp (°C)	Hot Supply & Temp (°C)	TMV info					Deadlegs Present (Inc. Drain cocks)	Flow & Return Working	Outlet Usage	Outlets in location											Aerosol Created	Non WRAS Material	Flexi Hoses	Comment	Additional Localised Risk Rating
				No. Of TMVs	Access	<2m from outlet?	Mix Temps 37-45°C	No. TMV Fed Outlets				Mains	Cold	Hot	Mixer	Urinals	WCs	Shower	Drinks / vend	Water boiler	Drinking fountain	Arjo/whirlpool	Other					
03C Ward GWS-004 (Staff Kitchen)	Hot, Cold	CWST 25.2	Calorifier 25.1	1	OK	Yes	No	1	None visible	Not visible	Some outlets unused	2	2							1				Low	None visible	Yes		Medium
Recommendations:			Aeration at outlet(s). Investigate and correct.																									
			All EPDM flexible hoses should be removed and replaced with hard piped connection.																									
			Cold water temperature too high. Investigate and correct.																									
			Hot water temperature too low. Investigate and correct.																									
			Dish washer connection not used currently. Include in flushing regime.																									
03C Ward GWS-011 (Facilities)	Hot, Cold	CWST 14.1	Calorifier 62.1	1	OK	Yes	Yes	1	None visible	Not visible	Flush Regime		1	1	1					1				Low	None visible	None visible		Low
Recommendations:			Aeration at outlet(s). Investigate and correct.																									
			Potential scald risk. Fit scald risk signs and/or consider fitting TMV(s) to hot outlets.																									
03C Ward GWS-014 (Renal Technician)	Hot, Cold	CWST 17.4	Calorifier 62.1	1	OK	Yes	Yes	1	None visible	Not visible	Flush Regime		2	2										Low	None visible	None visible	2 x Renal	Low
Recommendations:			Aeration at outlet(s). Investigate and correct.																									
03C Ward GWS-033 (Toilet)	Hot, Cold	CWST 23.8	Calorifier 25.5	1	OK	Yes	No	1	None visible	Not visible	Flush Regime				1		1							Low	None visible	None visible		Medium
Recommendations:			Cold water temperature too high. Investigate and correct.																									
			Hot water temperature too low. Investigate and correct.																									

LEGIONELLA RISK ASSESSMENT

Location / Room No	Sentinel outlet?	Cold Supply & Temp (°C)	Hot Supply & Temp (°C)	TMV info					Deadlegs Present (Inc. Drain cocks)	Flow & Return Working	Outlet Usage	Outlets in location												Aerosol Created	Non WRAS Material	Flexi Hoses	Comment	Additional Localised Risk Rating
				No. Of TMVs	Access	<2m from outlet?	Mix Temps 37-45°C	No. TMV Fed Outlets				Mains	Cold	Hot	Mixer	Urinals	WCs	Shower	Drinks / vend	Water boiler	Drinking fountain	Arjo/whirlpool	Other					
04 WS4-004 (Toilet)	Hot, Cold	CWST 14.9	Calorifier 54.0	1	OK	Yes	Yes	1	None visible	Not visible	Daily				1		1							Low	None visible	None visible		Low
Recommendations:			Hot outlets do not comply with latest SHTM regulations, though achieving 50°C. Wherever practicable increase temperatures to 55°C.																									
04 WS4-009 (Toilet)	Hot, Cold	CWST 14.5	Calorifier 53.2	1	OK	Yes	Yes	1	None visible	Not visible	Daily				1		1							Low	None visible	None visible	WC constantly running	Low
Recommendations:			Hot outlets do not comply with latest SHTM regulations, though achieving 50°C. Wherever practicable increase temperatures to 55°C.																									
04 WS4-014 (Facilities Regen)	Hot, Cold	CWST 18.1	Calorifier 57.3	1	OK	Yes	Yes	1	None visible	Yes	Flush Regime		2	2	1			1		1				High	None visible	Yes	Pipework un-insulated 1	Low
Recommendations:			All EPDM flexible hoses should be removed and replaced with hard piped connection.																									
04 WS4-017 (Male Change)	Hot, Cold	CWST 25.4	Calorifier 55.1	1	OK	Yes	Yes	1	None visible	Not visible	Flush Regime				1									Low	None visible	None visible		Medium
Recommendations:			Cold water temperature too high. Investigate and correct.																									
04A HOW-024 (Bathroom)	Hot, Cold	CWST 26.7	Calorifier 53.5	2	OK	Yes	Yes	2	None visible	Not visible	Flush Regime				1		1	1						High	None visible	None visible		High
Recommendations:			Cold water temperature too high. Investigate and correct. Hot outlets do not comply with latest SHTM regulations, though achieving 50°C. Wherever practicable increase temperatures to 55°C.																									

LEGIONELLA RISK ASSESSMENT

Location / Room No	Sentinel outlet?	Cold Supply & Temp (°C)	Hot Supply & Temp (°C)	TMV info					Deadlegs Present (Inc. Drain cocks)	Flow & Return Working	Outlet Usage	Outlets in location											Aerosol Created	Non WRAS Material	Flexi Hoses	Comment	Additional Localised Risk Rating
				No. Of TMVs	Access	<2m from outlet?	Mix Temps 37-45°C	No. TMV Fed Outlets				Mains	Cold	Hot	Mixer	Urinals	WCs	Shower	Drinks / vend	Water boiler	Drinking fountain	Arjo/whirlpool	Other					
04A HOW-027 (Bathroom)	Hot, Cold	CWST 25.8	Calorifier 53.5	2	OK	Yes	Yes	2	None visible	Not visible	Flush Regime				1		1	1						High	None visible	None visible		High
Recommendations:			Cold water temperature too high. Investigate and correct.																									
			Hot outlets do not comply with latest SHTM regulations, though achieving 50°C. Wherever practicable increase temperatures to 55°C.																									
04A RENW-005 (Bedroom)	Hot, Cold	CWST 14.8	Calorifier 52.3	1	OK	Yes	Yes	1	None visible	Not visible	Flush Regime		1	1										Low	None visible	None visible	Renal Connection	Low
Recommendations:			Hot outlets do not comply with latest SHTM regulations, though achieving 50°C. Wherever practicable increase temperatures to 55°C.																									
04A RENW-055 (Bedroom)	Hot, Cold	CWST 13.7	Calorifier 51.4	1	OK	Yes	Yes	1	None visible	Not visible	Flush Regime		1	1										Low	None visible	None visible	Renal Connection	Low
Recommendations:			Hot outlets do not comply with latest SHTM regulations, though achieving 50°C. Wherever practicable increase temperatures to 55°C.																									
04B HOW-030 (Bathroom)	Hot, Cold	CWST 23.9	Calorifier 53.4	2	OK	Yes	Yes	2	None visible	Not visible	Flush Regime				1		1	1						High	None visible	None visible		High
Recommendations:			Cold water temperature too high. Investigate and correct.																									
			Hot outlets do not comply with latest SHTM regulations, though achieving 50°C. Wherever practicable increase temperatures to 55°C.																									

LEGIONELLA RISK ASSESSMENT

Location / Room No	Sentinel outlet?	Cold Supply & Temp (°C)	Hot Supply & Temp (°C)	TMV info					Deadlegs Present (Inc. Drain cocks)	Flow & Return Working	Outlet Usage	Outlets in location												Aerosol Created	Non WRAS Material	Flexi Hoses	Comment	Additional Localised Risk Rating
				No. Of TMVs	Access	<2m from outlet?	Mix Temps 37-45°C	No. TMV Fed Outlets				Mains	Cold	Hot	Mixer	Urinals	WCs	Shower	Drinks / vend	Water boiler	Drinking fountain	Arjo/whirlpool	Other					
04B HOW-064 (Bedroom)	Hot, Cold	CWST 16.2	Calorifier 52.0	1	OK	Yes	Yes	1	None visible	Not visible	Flush Regime		1	1										Low	None visible	None visible		Low
Recommendations:	Hot outlets do not comply with latest SHTM regulations, though achieving 50°C. Wherever practicable increase temperatures to 55°C.																											
04B HOW-193 (Bedroom)	Hot, Cold	CWST 15.8	Calorifier 51.0	1	OK	Yes	Yes	1	None visible	Not visible	Flush Regime		1	1										Low	None visible	None visible	Renal Connection	Low
Recommendations:	Hot outlets do not comply with latest SHTM regulations, though achieving 50°C. Wherever practicable increase temperatures to 55°C.																											
04C RENW-127 (Consulting Room)	Hot, Cold	CWST 15.2	Calorifier 50.3	1	OK	Yes	Yes	1	None visible	Not visible	Flush Regime		1	1										Low	None visible	None visible		Low
Recommendations:	Hot outlets do not comply with latest SHTM regulations, though achieving 50°C. Wherever practicable increase temperatures to 55°C.																											
04C RENW-153 (Bathroom)	Hot, Cold	CWST 27.1	Calorifier 55.3	2	OK	Yes	Yes	2	None visible	Not visible	Flush Regime				1		1	1						High	None visible	None visible	Showerhead damaged	High
Recommendations:	Cold water temperature too high. Investigate and correct.																											
04C RENW-156 (Bathroom)	Hot, Cold	CWST 13.8	Calorifier 55.1	2	OK	Yes	Yes	2	None visible	Not visible	Flush Regime				1		1	1						High	None visible	None visible		Low
Recommendations:																												

LEGIONELLA RISK ASSESSMENT

Location / Room No	Sentinel outlet?	Cold Supply & Temp (°C)	Hot Supply & Temp (°C)	TMV info					Deadlegs Present (Inc. Drain cocks)	Flow & Return Working	Outlet Usage	Outlets in location												Aerosol Created	Non WRAS Material	Flexi Hoses	Comment	Additional Localised Risk Rating
				No. Of TMVs	Access	<2m from outlet?	Mix Temps 37-45°C	No. TMV Fed Outlets				Mains	Cold	Hot	Mixer	Urinals	WCs	Shower	Drinks / vend	Water boiler	Drinking fountain	Arjo/whirlpool	Other					
04C RENW-188 (Bedroom)	Hot, Cold	CWST 14.5	Calorifier 52.0	1	OK	Yes	Yes	1	None visible	Not visible	Flush Regime		1	1										Low	None visible	None visible	Small section of pipework un-insulated. Renal Connection	Low
Recommendations:			Hot outlets do not comply with latest SHTM regulations, though achieving 50°C. Wherever practicable increase temperatures to 55°C.																									
04D RENW-060 (Bedroom)	Hot, Cold	CWST 18.0	Calorifier 52.3	1	OK	Yes	Yes	1	None visible	Not visible	Flush Regime		1	1										Low	None visible	None visible	Renal Connection	Low
Recommendations:			Hot outlets do not comply with latest SHTM regulations, though achieving 50°C. Wherever practicable increase temperatures to 55°C.																									
04D RENW-091 (Bathroom)	Hot, Cold	CWST 24.0	Calorifier 51.5	2	OK	Yes	Yes	2	None visible	Not visible	Flush Regime				1		1	1						High	None visible	None visible	Section of pipework un-insulated	High
Recommendations:			Cold water temperature too high. Investigate and correct.																									
			Hot outlets do not comply with latest SHTM regulations, though achieving 50°C. Wherever practicable increase temperatures to 55°C.																									
04D RENW-094 (Bathroom)	Hot, Cold	CWST 24.0	Calorifier 53.1	2	OK	Yes	Yes	2	None visible	Not visible	Flush Regime				1		1	1						High	None visible	None visible		High
Recommendations:			Cold water temperature too high. Investigate and correct.																									
			Hot outlets do not comply with latest SHTM regulations, though achieving 50°C. Wherever practicable increase temperatures to 55°C.																									

LEGIONELLA RISK ASSESSMENT

Location / Room No	Sentinel outlet?	Cold Supply & Temp (°C)	Hot Supply & Temp (°C)	TMV info					Deadlegs Present (Inc. Drain cocks)	Flow & Return Working	Outlet Usage	Outlets in location												Aerosol Created	Non WRAS Material	Flexi Hoses	Comment	Additional Localised Risk Rating
				No. Of TMVs	Access	<2m from outlet?	Mix Temps 37-45°C	No. TMV Fed Outlets				Mains	Cold	Hot	Mixer	Urinals	WCs	Shower	Drinks / vend	Water boiler	Drinking fountain	Arjo/whirlpool	Other					
04D RENW-124 (Consulting Room)	Hot, Cold	CWST 14.5	Calorifier 52.1	1	OK	Yes	Yes	1	None visible	Not visible	Flush Regime		1	1										Low	None visible	None visible		Low
Recommendations:			Hot outlets do not comply with latest SHTM regulations, though achieving 50°C. Wherever practicable increase temperatures to 55°C.																									
04C Child Forensic Psychology DCFP-013 (Toilet)	Hot, Cold	CWST 15.1	Calorifier 55.2	1	OK	Yes	Yes	1	None visible	Not visible	Flush Regime				1		1							Low	None visible	None visible		Low
Recommendations:																												
04C Child Forensic Psychology DCFP-042 (Store)								0																		Yes	No outlets in room, though identified as sentinel outlet.	
Recommendations:																												
04C Child Forensic Psychology DCFP-049 (Kitchen)	No	CWST 26.3	Calorifier 57.0	1	OK	Yes	Yes	1	None visible	Not visible	Flush Regime		2	2	1			1		1				High	None visible	Yes	Next to designated sentinel (DCFP-042)	Medium
Recommendations:			Hot temperature slow to rise. It should be confirmed that hot outlet(s) are on a long leg and not that the flow and return has failed locally in this area.																									
			All EPDM flexible hoses should be removed and replaced with hard piped connection.																									
			Cold water temperature too high. Investigate and correct.																									

LEGIONELLA RISK ASSESSMENT

Location / Room No	Sentinel outlet?	Cold Supply & Temp (°C)	Hot Supply & Temp (°C)	TMV info					Deadlegs Present (Inc. Drain cocks)	Flow & Return Working	Outlet Usage	Outlets in location												Aerosol Created	Non WRAS Material	Flexi Hoses	Comment	Additional Localised Risk Rating
				No. Of TMVs	Access	<2m from outlet?	Mix Temps 37-45°C	No. TMV Fed Outlets				Mains	Cold	Hot	Mixer	Urinals	WCs	Shower	Drinks / vend	Water boiler	Drinking fountain	Arjo/whirlpool	Other					
05 WS5-005 (Toilet)	Hot, Cold	CWST 17.5	Calorifier 51.8	1	OK	Yes	Yes	1	None visible	Not visible	Daily				1		1							Low	None visible	None visible		Low
Recommendations:			Hot outlets do not comply with latest SHTM regulations, though achieving 50°C. Wherever practicable increase temperatures to 55°C.																									
05 WS5-011 (Toilet)	Hot, Cold	CWST 14.8	Calorifier 54.4	1	OK	Yes	Yes	1	None visible	Not visible	Daily				1		1							Low	None visible	None visible		Low
Recommendations:			Hot outlets do not comply with latest SHTM regulations, though achieving 50°C. Wherever practicable increase temperatures to 55°C.																									
05 WS5-021 (Male Change)	Hot, Cold	CWST 17.0	Calorifier 55.2	1	OK	Yes	Yes	1	None visible	Not visible	Flush Regime				1									Low	None visible	None visible		Low
Recommendations:																												
05 WS5-027 (Facilities)								0																		Yes		No access
Recommendations:			Locked – No Access. Area should be assessed once access obtained.																									
05A GENWA-001 (Bedroom)	Hot, Cold	CWST 13.5	Calorifier 52.1	1	OK	Yes	Yes	1	None visible	Not visible	Flush Regime		1	1										Low	None visible	None visible		Low
Recommendations:			Hot outlets do not comply with latest SHTM regulations, though achieving 50°C. Wherever practicable increase temperatures to 55°C.																									

LEGIONELLA RISK ASSESSMENT

Location / Room No	Sentinel outlet?	Cold Supply & Temp (°C)	Hot Supply & Temp (°C)	TMV info					Deadlegs Present (Inc. Drain cocks)	Flow & Return Working	Outlet Usage	Outlets in location												Aerosol Created	Non WRAS Material	Flexi Hoses	Comment	Additional Localised Risk Rating
				No. Of TMVs	Access	<2m from outlet?	Mix Temps 37-45°C	No. TMV Fed Outlets				Mains	Cold	Hot	Mixer	Urinals	WCs	Shower	Drinks / vend	Water boiler	Drinking fountain	Arjo/whirlpool	Other					
05A GENWA-029 (Bathroom)	Hot, Cold	CWST 26.0	Calorifier 53.9	2	OK	Yes	Yes	2	None visible	Not visible	Flush Regime				1		1	1						High	None visible	None visible		High
Recommendations:			Cold water temperature too high. Investigate and correct.																									
			Hot outlets do not comply with latest SHTM regulations, though achieving 50°C. Wherever practicable increase temperatures to 55°C.																									
05A GENWA-034 (Bathroom)	Hot, Cold	CWST 28.1	Calorifier 53.1	2	OK	Yes	Yes	2	None visible	Not visible	Flush Regime				1		1	1						High	None visible	None visible		High
Recommendations:																												
05A GENWA-065 (Bedroom)	Hot, Cold	CWST 13.5	Calorifier 51.9	1	OK	Yes	Yes	1	None visible	Not visible	Flush Regime		1	1										Low	None visible	None visible		Low
Recommendations:			Hot outlets do not comply with latest SHTM regulations, though achieving 50°C. Wherever practicable increase temperatures to 55°C.																									
05B GENWD-032 (Bathroom)	Hot, Cold	CWST 23.4	Calorifier 54.0	2	OK	Yes	Yes	2	None visible	Not visible	Flush Regime				1		1	1						High	None visible	None visible		High
Recommendations:			Cold water temperature too high. Investigate and correct.																									
			Hot outlets do not comply with latest SHTM regulations, though achieving 50°C. Wherever practicable increase temperatures to 55°C.																									

LEGIONELLA RISK ASSESSMENT

Location / Room No	Sentinel outlet?	Cold Supply & Temp (°C)	Hot Supply & Temp (°C)	TMV info					Deadlegs Present (Inc. Drain cocks)	Flow & Return Working	Outlet Usage	Outlets in location												Aerosol Created	Non WRAS Material	Flexi Hoses	Comment	Additional Localised Risk Rating
				No. Of TMVs	Access	<2m from outlet?	Mix Temps 37-45°C	No. TMV Fed Outlets				Mains	Cold	Hot	Mixer	Urinals	WCs	Shower	Drinks / vend	Water boiler	Drinking fountain	Arjo/whirlpool	Other					
05B GENWD-036 (Bathroom)	Hot, Cold	CWST 26.5	Calorifier 55.3	2	OK	Yes	Yes	2	None visible	Not visible	Flush Regime				1		1	1						High	None visible	None visible		High
Recommendations:			Cold water temperature too high. Investigate and correct.																									
05B GENWD-065 (Bedroom)	Hot, Cold	CWST 16.4	Calorifier 50.4	1	OK	Yes	Yes	1	None visible	Not visible	Flush Regime		1	1										Low	None visible	None visible	Tap dripping from diffuser.	Low
Recommendations:			Hot outlets do not comply with latest SHTM regulations, though achieving 50°C. Wherever practicable increase temperatures to 55°C.																									
05C GENWC-028 (Bedroom)	Hot, Cold	CWST 25.5	Calorifier 50.2	1	OK	Yes	Yes	1	None visible	Not visible	Flush Regime		1	1										Low	None visible	None visible		Medium
Recommendations:			Cold water temperature too high. Investigate and correct. Hot outlets do not comply with latest SHTM regulations, though achieving 50°C. Wherever practicable increase temperatures to 55°C.																									
05C GENWC-034 (Bathroom)	Hot, Cold	CWST 24.0	Calorifier 55.0	2	OK	Yes	Yes	2	None visible	Not visible	Flush Regime				1		1	1						High	None visible	None visible		High
Recommendations:			Cold water temperature too high. Investigate and correct.																									

LEGIONELLA RISK ASSESSMENT

Location / Room No	Sentinel outlet?	Cold Supply & Temp (°C)	Hot Supply & Temp (°C)	TMV info					Deadlegs Present (Inc. Drain cocks)	Flow & Return Working	Outlet Usage	Outlets in location												Aerosol Created	Non WRAS Material	Flexi Hoses	Comment	Additional Localised Risk Rating
				No. Of TMVs	Access	<2m from outlet?	Mix Temps 37-45°C	No. TMV Fed Outlets				Mains	Cold	Hot	Mixer	Urinals	WCs	Shower	Drinks / vend	Water boiler	Drinking fountain	Arjo/whirlpool	Other					
05C GENWC-065 (Bedroom)	Hot, Cold	CWST 22.9	Calorifier 53.5	1	OK	Yes	Yes	1	None visible	Not visible	Flush Regime		1	1										Low	None visible	None visible		Medium
Recommendations:			Cold water temperature too high. Investigate and correct.																									
			Hot outlets do not comply with latest SHTM regulations, though achieving 50°C. Wherever practicable increase temperatures to 55°C.																									
05D GENWB-001 (Bedroom)	Hot, Cold	CWST 14.2	Calorifier 50.3	1	OK	Yes	Yes	1	None visible	Not visible	Flush Regime		1	1										Low	None visible	None visible		Low
Recommendations:			Hot outlets do not comply with latest SHTM regulations, though achieving 50°C. Wherever practicable increase temperatures to 55°C.																									
05D GENWB-028 (Bedroom)	Hot, Cold	CWST 26.8	Calorifier 50.6	1	OK	Yes	Yes	1	None visible	Not visible	Flush Regime		1	1										Low	None visible	None visible		Low
Recommendations:			Cold water temperature too high. Investigate and correct.																									
			Hot outlets do not comply with latest SHTM regulations, though achieving 50°C. Wherever practicable increase temperatures to 55°C.																									
05D GENWB-034 (Bathroom)	Hot, Cold	CWST 23.9	Calorifier 54.1	2	OK	Yes	Yes	2	None visible	Not visible	Flush Regime				1		1	1						High	None visible	None visible		High
Recommendations:			Cold water temperature too high. Investigate and correct.																									
			Hot outlets do not comply with latest SHTM regulations, though achieving 50°C. Wherever practicable increase temperatures to 55°C.																									

LEGIONELLA RISK ASSESSMENT

Location / Room No	Sentinel outlet?	Cold Supply & Temp (°C)	Hot Supply & Temp (°C)	TMV info					Deadlegs Present (Inc. Drain cocks)	Flow & Return Working	Outlet Usage	Outlets in location												Aerosol Created	Non WRAS Material	Flexi Hoses	Comment	Additional Localised Risk Rating
				No. Of TMVs	Access	<2m from outlet?	Mix Temps 37-45°C	No. TMV Fed Outlets				Mains	Cold	Hot	Mixer	Urinals	WCs	Shower	Drinks / vend	Water boiler	Drinking fountain	Arjo/whirlpool	Other					
05D GENWB-057 (Bedroom)	Hot, Cold	CWST 18.1	Calorifier 51.2	1	OK	Yes	Yes	1	None visible	Not visible	Flush Regime		1	1										Low	None visible	None visible		Low
Recommendations:			Hot outlets do not comply with latest SHTM regulations, though achieving 50°C. Wherever practicable increase temperatures to 55°C.																									
05D GENWB-065 (Bedroom)	Hot, Cold	CWST 16.0	Calorifier 50.6	1	OK	Yes	Yes	1	None visible	Not visible	Flush Regime		1	1										Low	None visible	None visible		Low
Recommendations:			Hot outlets do not comply with latest SHTM regulations, though achieving 50°C. Wherever practicable increase temperatures to 55°C.																									
05D GENWB-066 (Facilities)								0																		Yes		No access
Recommendations:			Locked – No Access. Area should be assessed once access obtained.																									
05D GENWB-081 (Clean Utility)	No	CWST 24.2	Calorifier 56.5	1	OK	Yes	Yes	1	None visible	Not visible	Flush Regime		2	2										Low	None visible	None visible		Medium
Recommendations:			Cold water temperature too high. Investigate and correct.																									
06 WS6-005 (Toilet)	Hot, Cold	CWST 19.2	Calorifier 52.9	1	OK	Yes	Yes	1	None visible	Not visible	Daily				1		1							Low	None visible	None visible		Low
Recommendations:			Hot outlets do not comply with latest SHTM regulations, though achieving 50°C. Wherever practicable increase temperatures to 55°C.																									

LEGIONELLA RISK ASSESSMENT

Location / Room No	Sentinel outlet?	Cold Supply & Temp (°C)	Hot Supply & Temp (°C)	TMV info					Deadlegs Present (Inc. Drain cocks)	Flow & Return Working	Outlet Usage	Outlets in location												Aerosol Created	Non WRAS Material	Flexi Hoses	Comment	Additional Localised Risk Rating
				No. Of TMVs	Access	<2m from outlet?	Mix Temps 37-45°C	No. TMV Fed Outlets				Mains	Cold	Hot	Mixer	Urinals	WCs	Shower	Drinks / vend	Water boiler	Drinking fountain	Arjo/whirlpool	Other					
06 WS6-011 (Toilet)	Hot, Cold	CWST 17.7	Calorifier 53.1	1	OK	Yes	Yes	1	None visible	Not visible	Daily				1		1							Low	None visible	None visible		Low
Recommendations:			Hot outlets do not comply with latest SHTM regulations, though achieving 50°C. Wherever practicable increase temperatures to 55°C.																									
06 WS6-019 (Toilet)	Hot, Cold	CWST 24.1	Calorifier 52.8	1	OK	Yes	Yes	1	None visible	Not visible	Flush Regime				1		1							Low	None visible	None visible		Medium
Recommendations:			Cold water temperature too high. Investigate and correct.																									
			Hot outlets do not comply with latest SHTM regulations, though achieving 50°C. Wherever practicable increase temperatures to 55°C.																									
06 WS6-027 (Facilities)	Hot, Cold	CWST 12.7	Calorifier 57.4	1	OK	Yes	Yes	1	None visible	Not visible	Flush Regime		3	3										Low	None visible	Yes	Flexible hoses at double level sink.	Low
Recommendations:			Aeration at outlet(s). Investigate and correct.																									
			All EPDM flexible hoses should be removed and replaced with hard piped connection.																									
06A GENW1-001 (Arjo Bathroom)	No	CWST 15.1	Calorifier 55.2	1 (1)	No access – some	Yes	Yes	1	None visible	Yes	Flush Regime				1		1	1				1		High	None visible	Yes	TMV integral to Arjo bath.	Low
Recommendations:			TMV inaccessible during survey. Access should be provided for assessment/maintenance.																									
			All EPDM flexible hoses should be removed and replaced with hard piped connection.																									

LEGIONELLA RISK ASSESSMENT

Location / Room No	Sentinel outlet?	Cold Supply & Temp (°C)	Hot Supply & Temp (°C)	TMV info					Deadlegs Present (Inc. Drain cocks)	Flow & Return Working	Outlet Usage	Outlets in location											Aerosol Created	Non WRAS Material	Flexi Hoses	Comment	Additional Localised Risk Rating
				No. Of TMVs	Access	<2m from outlet?	Mix Temps 37-45°C	No. TMV Fed Outlets				Mains	Cold	Hot	Mixer	Urinals	WCs	Shower	Drinks / vend	Water boiler	Drinking fountain	Arjo/whirlpool	Other					
06A GENW1-029 (Bathroom)	Hot, Cold	CWST 24.9	Calorifier 53.5	2	OK	Yes	Yes	2	None visible	Not visible	Flush Regime				1		1	1						High	None visible	None visible		High
Recommendations:			Cold water temperature too high. Investigate and correct.																									
			Hot outlets do not comply with latest SHTM regulations, though achieving 50°C. Wherever practicable increase temperatures to 55°C.																									
06A GENW1-034 (Bathroom)	Hot, Cold	CWST 28.7	Calorifier 55.1	2	OK	Yes	Yes	2	None visible	Not visible	Flush Regime				1		1	1						High	None visible	None visible		High
Recommendations:			Cold water temperature too high. Investigate and correct.																									
06A GENW1-065 (Bedroom)	Hot, Cold	CWST 13.5	Calorifier 53.2	1	OK	Yes	Yes	1	None visible	Not visible	Flush Regime		1	1										Low	None visible	None visible		Low
Recommendations:			Hot outlets do not comply with latest SHTM regulations, though achieving 50°C. Wherever practicable increase temperatures to 55°C.																									
06B GENW4-032 (Bathroom)	Hot, Cold	CWST 23.8	Calorifier 52.4	2	OK	Yes	Yes	2	None visible	Not visible	Flush Regime				1		1	1						High	None visible	None visible		High
Recommendations:			Cold water temperature too high. Investigate and correct.																									
			Hot outlets do not comply with latest SHTM regulations, though achieving 50°C. Wherever practicable increase temperatures to 55°C.																									

LEGIONELLA RISK ASSESSMENT

Location / Room No	Sentinel outlet?	Cold Supply & Temp (°C)	Hot Supply & Temp (°C)	TMV info					Deadlegs Present (Inc. Drain cocks)	Flow & Return Working	Outlet Usage	Outlets in location											Aerosol Created	Non WRAS Material	Flexi Hoses	Comment	Additional Localised Risk Rating
				No. Of TMVs	Access	<2m from outlet?	Mix Temps 37-45°C	No. TMV Fed Outlets				Mains	Cold	Hot	Mixer	Urinals	WCs	Shower	Drinks / vend	Water boiler	Drinking fountain	Arjo/whirlpool	Other					
06B GENW4-036 (Bathroom)	Hot, Cold	CWST 24.6	Calorifier 53.4	2	OK	Yes	Yes	2	None visible	Not visible	Flush Regime				1		1	1						High	None visible	None visible		High
Recommendations:			Cold water temperature too high. Investigate and correct.																									
			Hot outlets do not comply with latest SHTM regulations, though achieving 50°C. Wherever practicable increase temperatures to 55°C.																									
06B GENW4-065 (Bedroom)	Hot, Cold	CWST 15.1	Calorifier 52.8	1	OK	Yes	Yes	1	None visible	Not visible	Flush Regime		1	1										Low	None visible	None visible		Low
Recommendations:			Hot outlets do not comply with latest SHTM regulations, though achieving 50°C. Wherever practicable increase temperatures to 55°C.																									
06C GENW3-028 (Bedroom)	Hot, Cold	CWST 24.6	Calorifier 51.0	1	OK	Yes	Yes	1	None visible	Not visible	Flush Regime		1	1										Low	None visible	None visible		Medium
Recommendations:			Cold water temperature too high. Investigate and correct.																									
			Hot outlets do not comply with latest SHTM regulations, though achieving 50°C. Wherever practicable increase temperatures to 55°C.																									
06C GENW3-034 (Bathroom)	Hot, Cold	CWST 25.6	Calorifier 52.0	2	OK	Yes	Yes	2	None visible	Not visible	Flush Regime				1		1	1						High	None visible	None visible		High
Recommendations:			Cold water temperature too high. Investigate and correct.																									
			Hot outlets do not comply with latest SHTM regulations, though achieving 50°C. Wherever practicable increase temperatures to 55°C.																									

LEGIONELLA RISK ASSESSMENT

Location / Room No	Sentinel outlet?	Cold Supply & Temp (°C)	Hot Supply & Temp (°C)	TMV info					Deadlegs Present (Inc. Drain cocks)	Flow & Return Working	Outlet Usage	Outlets in location												Aerosol Created	Non WRAS Material	Flexi Hoses	Comment	Additional Localised Risk Rating
				No. Of TMVs	Access	<2m from outlet?	Mix Temps 37-45°C	No. TMV Fed Outlets				Mains	Cold	Hot	Mixer	Urinals	WCs	Shower	Drinks / vend	Water boiler	Drinking fountain	Arjo/whirlpool	Other					
06C GENW3-065 (Bedroom)	Hot, Cold	CWST 14.5	Calorifier 50.4	1	OK	Yes	Yes	1	None visible	Not visible	Flush Regime		1	1										Low	None visible	None visible		Low
Recommendations:			Hot outlets do not comply with latest SHTM regulations, though achieving 50°C. Wherever practicable increase temperatures to 55°C.																									
06D GENW2-001 (Bedroom)	Hot, Cold	CWST 14.5	Calorifier 53.9	1	OK	Yes	Yes	1	None visible	Not visible	Flush Regime		1	1										Low	None visible	None visible		Low
Recommendations:			Hot outlets do not comply with latest SHTM regulations, though achieving 50°C. Wherever practicable increase temperatures to 55°C.																									
06D GENW2-028 (Bedroom)	Hot, Cold	CWST 25.4	Calorifier 51.2	1	OK	Yes	Yes	1	None visible	Not visible	Flush Regime		1	1										Low	None visible	None visible		Medium
Recommendations:			Cold water temperature too high. Investigate and correct. Hot outlets do not comply with latest SHTM regulations, though achieving 50°C. Wherever practicable increase temperatures to 55°C.																									
06D GENW2-034 (Bathroom)	Hot, Cold	CWST 27.1	Calorifier 55.0	2	OK	Yes	Yes	2	None visible	Not visible	Flush Regime				1		1	1						High	None visible	None visible		High
Recommendations:			Cold water temperature too high. Investigate and correct.																									
06D GENW2-057 (Bedroom)	Hot, Cold	CWST 18.4	Calorifier 53.2	1	OK	Yes	Yes	1	None visible	Not visible	Flush Regime		1	1										Low	None visible	None visible		Low
Recommendations:			Hot outlets do not comply with latest SHTM regulations, though achieving 50°C. Wherever practicable increase temperatures to 55°C.																									

LEGIONELLA RISK ASSESSMENT

Location / Room No	Sentinel outlet?	Cold Supply & Temp (°C)	Hot Supply & Temp (°C)	TMV info					Deadlegs Present (Inc. Drain cocks)	Flow & Return Working	Outlet Usage	Outlets in location												Aerosol Created	Non WRAS Material	Flexi Hoses	Comment	Additional Localised Risk Rating
				No. Of TMVs	Access	<2m from outlet?	Mix Temps 37-45°C	No. TMV Fed Outlets				Mains	Cold	Hot	Mixer	Urinals	WCs	Shower	Drinks / vend	Water boiler	Drinking fountain	Arjo/whirlpool	Other					
06D GENW2-065 (Bedroom)	Hot, Cold	CWST 18.1	Calorifier 53.0	1	OK	Yes	Yes	1	None visible	Not visible	Flush Regime		1	1										Low	None visible	None visible	TMV handles incorrectly labelled.	Low
Recommendations:			Hot outlets do not comply with latest SHTM regulations, though achieving 50°C. Wherever practicable increase temperatures to 55°C.																									
07 WS7-005 (Toilet)	Hot, Cold	CWST 17.4	Calorifier 55.1	1	OK	Yes	Yes	1	None visible	Not visible	Daily				1		1							Low	None visible	None visible		Low
Recommendations:																												
07 WS7-011 (Toilet)	Hot, Cold	CWST 16.8	Calorifier 55.2	1	OK	Yes	Yes	1	None visible	Not visible	Daily				1		1							Low	None visible	None visible		Low
Recommendations:																												
07A GENW5-001 (Bedroom)	Hot, Cold	CWST 13.1	Calorifier 53.1	1	OK	Yes	Yes	1	None visible	Not visible	Flush Regime		1	1										Low	None visible	None visible		Low
Recommendations:			Hot outlets do not comply with latest SHTM regulations, though achieving 50°C. Wherever practicable increase temperatures to 55°C.																									
07A GENW5-029 (Bathroom)	Hot, Cold	CWST	Calorifier	1	OK	Yes	No	1	None visible	Not visible	Daily				1		1	1						High	None visible	None visible	No flow from WHB tap	High
Recommendations:			Poor flow from outlet(s). Investigate and correct.																									

LEGIONELLA RISK ASSESSMENT

Location / Room No	Sentinel outlet?	Cold Supply & Temp (°C)	Hot Supply & Temp (°C)	TMV info					Deadlegs Present (Inc. Drain cocks)	Flow & Return Working	Outlet Usage	Outlets in location											Aerosol Created	Non WRAS Material	Flexi Hoses	Comment	Additional Localised Risk Rating
				No. Of TMVs	Access	<2m from outlet?	Mix Temps 37-45°C	No. TMV Fed Outlets				Mains	Cold	Hot	Mixer	Urinals	WCs	Shower	Drinks / vend	Water boiler	Drinking fountain	Arjo/whirlpool	Other					
07A GENW5-034 (Bathroom)	Hot, Cold	CWST 24.8	Calorifier 53.6	2	OK	Yes	Yes	2	None visible	Not visible	Flush Regime				1		1	1						High	None visible	None visible		High
Recommendations:			Cold water temperature too high. Investigate and correct.																									
			Hot outlets do not comply with latest SHTM regulations, though achieving 50°C. Wherever practicable increase temperatures to 55°C.																									
07A GENW5-065 (Bedroom)	Hot, Cold	CWST 13.5	Calorifier 54.1	1	OK	Yes	Yes	1	None visible	Not visible	Flush Regime		1	1										Low	None visible	None visible		Low
Recommendations:			Hot outlets do not comply with latest SHTM regulations, though achieving 50°C. Wherever practicable increase temperatures to 55°C.																									
07B GENW8-032 (Bathroom)	Hot, Cold	CWST 24.1	Calorifier 53.1	2	OK	Yes	Yes	2	None visible	Not visible	Flush Regime				1		1	1						High	None visible	None visible		High
Recommendations:			Cold water temperature too high. Investigate and correct.																									
			Hot outlets do not comply with latest SHTM regulations, though achieving 50°C. Wherever practicable increase temperatures to 55°C.																									
07B GENW8-036 (Bathroom)	Hot, Cold	CWST 21.1	Calorifier 53.0	2	OK	Yes	Yes	2	None visible	Not visible	Flush Regime				1		1	1						High	None visible	None visible		High
Recommendations:			Cold water temperature too high. Investigate and correct.																									
			Hot outlets do not comply with latest SHTM regulations, though achieving 50°C. Wherever practicable increase temperatures to 55°C.																									

LEGIONELLA RISK ASSESSMENT

Location / Room No	Sentinel outlet?	Cold Supply & Temp (°C)	Hot Supply & Temp (°C)	TMV info					Deadlegs Present (Inc. Drain cocks)	Flow & Return Working	Outlet Usage	Outlets in location												Aerosol Created	Non WRAS Material	Flexi Hoses	Comment	Additional Localised Risk Rating
				No. Of TMVs	Access	<2m from outlet?	Mix Temps 37-45°C	No. TMV Fed Outlets				Mains	Cold	Hot	Mixer	Urinals	WCs	Shower	Drinks / vend	Water boiler	Drinking fountain	Arjo/whirlpool	Other					
07B GENW8-065 (Bedroom)	Hot, Cold	CWST 24.0	Calorifier 52.6	1	OK	Yes	Yes	1	None visible	Not visible	Flush Regime		1	1										Low	None visible	None visible	Small piece of insulation missing	Low
Recommendations:			Hot outlets do not comply with latest SHTM regulations, though achieving 50°C. Wherever practicable increase temperatures to 55°C.																									
07C GENW7-028 (Bedroom)	Hot, Cold	CWST 19.4	Calorifier 52.9	1	OK	Yes	Yes	1	None visible	Not visible	Flush Regime		1	1										Low	None visible	None visible		Low
Recommendations:			Hot outlets do not comply with latest SHTM regulations, though achieving 50°C. Wherever practicable increase temperatures to 55°C.																									
07C GENW7-034 (Bathroom)	Hot, Cold	CWST 24.6	Calorifier 52.0	2	OK	Yes	Yes	2	None visible	Not visible	Flush Regime				1		1	1						High	None visible	None visible		High
Recommendations:			Cold water temperature too high. Investigate and correct. Hot outlets do not comply with latest SHTM regulations, though achieving 50°C. Wherever practicable increase temperatures to 55°C.																									
07C GENW7-065 (Bedroom)	Hot, Cold	CWST 14.7	Calorifier 52.9	1	OK	Yes	Yes	1	None visible	Not visible	Flush Regime		1	1										Low	None visible	None visible		Low
Recommendations:			Hot outlets do not comply with latest SHTM regulations, though achieving 50°C. Wherever practicable increase temperatures to 55°C.																									
07D GENW6-001 (Bedroom)	Hot, Cold	CWST 13.8	Calorifier 53.5	1	OK	Yes	Yes	1	None visible	Not visible	Flush Regime		1	1										Low	None visible	None visible		Low
Recommendations:			Hot outlets do not comply with latest SHTM regulations, though achieving 50°C. Wherever practicable increase temperatures to 55°C.																									

LEGIONELLA RISK ASSESSMENT

Location / Room No	Sentinel outlet?	Cold Supply & Temp (°C)	Hot Supply & Temp (°C)	TMV info					Deadlegs Present (Inc. Drain cocks)	Flow & Return Working	Outlet Usage	Outlets in location												Aerosol Created	Non WRAS Material	Flexi Hoses	Comment	Additional Localised Risk Rating
				No. Of TMVs	Access	<2m from outlet?	Mix Temps 37-45°C	No. TMV Fed Outlets				Mains	Cold	Hot	Mixer	Urinals	WCs	Shower	Drinks / vend	Water boiler	Drinking fountain	Arjo/whirlpool	Other					
07D GENW6-028 (Bedroom)	Hot, Cold	CWST 27.0	Calorifier 53.4	1	OK	Yes	Yes	1	None visible	Not visible	Flush Regime		1	1										Low	None visible	None visible		Medium
Recommendations:			Cold water temperature too high. Investigate and correct.																									
			Hot outlets do not comply with latest SHTM regulations, though achieving 50°C. Wherever practicable increase temperatures to 55°C.																									
07D GENW6-034 (Bathroom)	Hot, Cold	CWST 27.1	Calorifier 55.1	2	OK	Yes	Yes	2	None visible	Not visible	Flush Regime				1		1	1						High	None visible	None visible		High
Recommendations:			Cold water temperature too high. Investigate and correct.																									
07D GENW6-057 (Bedroom)	Hot, Cold	CWST 19.4	Calorifier 52.9	1	OK	Yes	Yes	1	None visible	Not visible	Flush Regime		1	1										Low	None visible	None visible		Low
Recommendations:			Hot outlets do not comply with latest SHTM regulations, though achieving 50°C. Wherever practicable increase temperatures to 55°C.																									
07D GENW6-065 (Bedroom)	Hot, Cold	CWST 18.0	Calorifier 55.0	1	OK	Yes	Yes	1	None visible	Not visible	Flush Regime		1	1										Low	None visible	None visible		Low
Recommendations:																												
08 WS8-005 (Toilet)	Hot, Cold	CWST 18.7	Calorifier 51.5	1	OK	Yes	Yes	1	None visible	Not visible	Daily				1		1							Low	None visible	None visible		Low
Recommendations:			Hot outlets do not comply with latest SHTM regulations, though achieving 50°C. Wherever practicable increase temperatures to 55°C.																									

LEGIONELLA RISK ASSESSMENT

Location / Room No	Sentinel outlet?	Cold Supply & Temp (°C)	Hot Supply & Temp (°C)	TMV info					Deadlegs Present (Inc. Drain cocks)	Flow & Return Working	Outlet Usage	Outlets in location												Aerosol Created	Non WRAS Material	Flexi Hoses	Comment	Additional Localised Risk Rating
				No. Of TMVs	Access	<2m from outlet?	Mix Temps 37-45°C	No. TMV Fed Outlets				Mains	Cold	Hot	Mixer	Urinals	WCs	Shower	Drinks / vend	Water boiler	Drinking fountain	Arjo/whirlpool	Other					
08 WS8-011 (Toilet)	Hot, Cold	CWST 14.2	Calorifier 53.9	1	OK	Yes	Yes	1	None visible	Not visible	Daily				1		1							Low	None visible	None visible		Low
Recommendations:			Hot outlets do not comply with latest SHTM regulations, though achieving 50°C. Wherever practicable increase temperatures to 55°C.																									
08 WS8-021 (Male Change)	Hot, Cold	CWST 24.4	Calorifier 52.9	1	OK	Yes	Yes	1	None visible	Not visible	Flush Regime				1									Low	None visible	None visible		Medium
Recommendations:			Cold water temperature too high. Investigate and correct.																									
			Hot outlets do not comply with latest SHTM regulations, though achieving 50°C. Wherever practicable increase temperatures to 55°C.																									
08 WS8-027 (Facilities)	Hot, Cold	CWST 24.6	Calorifier 56.1	1	OK	Yes	Yes	1	None visible	Not visible	Flush Regime		3	3										Low	None visible	Yes	Flexi hoses on double level sink	Medium
Recommendations:			All EPDM flexible hoses should be removed and replaced with hard piped connection.																									
			Cold water temperature too high. Investigate and correct.																									
08A GENW9-001 (Bedroom)	Hot, Cold	CWST 13.3	Calorifier 51.3	1	OK	Yes	Yes	1	None visible	Not visible	Flush Regime		1	1										Low	None visible	None visible		Low
Recommendations:			Hot outlets do not comply with latest SHTM regulations, though achieving 50°C. Wherever practicable increase temperatures to 55°C.																									

LEGIONELLA RISK ASSESSMENT

Location / Room No	Sentinel outlet?	Cold Supply & Temp (°C)	Hot Supply & Temp (°C)	TMV info					Deadlegs Present (Inc. Drain cocks)	Flow & Return Working	Outlet Usage	Outlets in location											Aerosol Created	Non WRAS Material	Flexi Hoses	Comment	Additional Localised Risk Rating
				No. Of TMVs	Access	<2m from outlet?	Mix Temps 37-45°C	No. TMV Fed Outlets				Mains	Cold	Hot	Mixer	Urinals	WCs	Shower	Drinks / vend	Water boiler	Drinking fountain	Arjo/whirlpool	Other					
08A GENW9-029 (Bathroom)	Hot, Cold	CWST 24.5	Calorifier 53.2	2	OK	Yes	Yes	2	None visible	Not visible	Flush Regime				1		1	1						High	None visible	None visible		High
Recommendations:			Cold water temperature too high. Investigate and correct.																									
			Hot outlets do not comply with latest SHTM regulations, though achieving 50°C. Wherever practicable increase temperatures to 55°C.																									
08A GENW9-034 (Bathroom)	Hot, Cold	CWST 26.9	Calorifier 54.0	2	OK	Yes	Yes	2	None visible	Not visible	Flush Regime				1		1	1						High	None visible	None visible		High
Recommendations:			Cold water temperature too high. Investigate and correct.																									
			Hot outlets do not comply with latest SHTM regulations, though achieving 50°C. Wherever practicable increase temperatures to 55°C.																									
08A GENW9-065 (Bedroom)	Hot, Cold	CWST 13.1	Calorifier 50.7	1	OK	Yes	Yes	1	None visible	Not visible	Flush Regime		1	1										Low	None visible	None visible		Low
Recommendations:			Hot outlets do not comply with latest SHTM regulations, though achieving 50°C. Wherever practicable increase temperatures to 55°C.																									
08B GENW12-032 (Bathroom)	Hot, Cold	CWST 23.2	Calorifier 54.8	2	OK	Yes	Yes	2	None visible	Not visible	Flush Regime				1		1	1						High	None visible	None visible		High
Recommendations:			Cold water temperature too high. Investigate and correct.																									
			Hot outlets do not comply with latest SHTM regulations, though achieving 50°C. Wherever practicable increase temperatures to 55°C.																									

LEGIONELLA RISK ASSESSMENT

Location / Room No	Sentinel outlet?	Cold Supply & Temp (°C)	Hot Supply & Temp (°C)	TMV info					Deadlegs Present (Inc. Drain cocks)	Flow & Return Working	Outlet Usage	Outlets in location											Aerosol Created	Non WRAS Material	Flexi Hoses	Comment	Additional Localised Risk Rating
				No. Of TMVs	Access	<2m from outlet?	Mix Temps 37-45°C	No. TMV Fed Outlets				Mains	Cold	Hot	Mixer	Urinals	WCs	Shower	Drinks / vend	Water boiler	Drinking fountain	Arjo/whirlpool	Other					
08B GENW12-036 (Bathroom)	Hot, Cold	CWST 23.2	Calorifier 53.0	2	OK	Yes	Yes	2	None visible	Not visible	Flush Regime				1		1	1						High	None visible	None visible		High
Recommendations:			Cold water temperature too high. Investigate and correct.																									
			Hot outlets do not comply with latest SHTM regulations, though achieving 50°C. Wherever practicable increase temperatures to 55°C.																									
08B GENW12-065 (Bedroom)	Hot, Cold	CWST 16.4	Calorifier 53.0	1	OK	Yes	Yes	1	None visible	Not visible	Flush Regime		1	1										Low	None visible	None visible		Low
Recommendations:			Hot outlets do not comply with latest SHTM regulations, though achieving 50°C. Wherever practicable increase temperatures to 55°C.																									
08C GENW11-028 (Bedroom)	Hot, Cold	CWST 14.5	Calorifier 53.1	1	OK	Yes	Yes	1	None visible	Not visible	Flush Regime		1	1										Low	None visible	None visible		Low
Recommendations:			Hot outlets do not comply with latest SHTM regulations, though achieving 50°C. Wherever practicable increase temperatures to 55°C.																									
08C GENW11-034 (Bathroom)	Hot, Cold	CWST 26.2	Calorifier 51.5	2	OK	Yes	Yes	2	None visible	Not visible	Flush Regime				1		1	1						High	None visible	None visible		High
Recommendations:			Cold water temperature too high. Investigate and correct.																									
			Hot outlets do not comply with latest SHTM regulations, though achieving 50°C. Wherever practicable increase temperatures to 55°C.																									

LEGIONELLA RISK ASSESSMENT

Location / Room No	Sentinel outlet?	Cold Supply & Temp (°C)	Hot Supply & Temp (°C)	TMV info					Deadlegs Present (Inc. Drain cocks)	Flow & Return Working	Outlet Usage	Outlets in location												Aerosol Created	Non WRAS Material	Flexi Hoses	Comment	Additional Localised Risk Rating
				No. Of TMVs	Access	<2m from outlet?	Mix Temps 37-45°C	No. TMV Fed Outlets				Mains	Cold	Hot	Mixer	Urinals	WCs	Shower	Drinks / vend	Water boiler	Drinking fountain	Arjo/whirlpool	Other					
08C GENW11-065 (Bedroom)	Hot, Cold	CWST 16.0	Calorifier 53.0	1	OK	Yes	Yes	1	None visible	Not visible	Flush Regime		1	1										Low	None visible	None visible		Low
Recommendations:			Hot outlets do not comply with latest SHTM regulations, though achieving 50°C. Wherever practicable increase temperatures to 55°C.																									
08D GENW10-001 (Bedroom)	Hot, Cold	CWST 14.9	Calorifier 53.1	1	OK	Yes	Yes	1	None visible	Not visible	Flush Regime		1	1										Low	None visible	None visible		Low
Recommendations:			Hot outlets do not comply with latest SHTM regulations, though achieving 50°C. Wherever practicable increase temperatures to 55°C.																									
08D GENW10-028 (Bedroom)	Hot, Cold	CWST 27.2	Calorifier 50.9	1	OK	Yes	Yes	1	None visible	Not visible	Flush Regime		1	1										Low	None visible	None visible		Medium
Recommendations:			Cold water temperature too high. Investigate and correct. Hot outlets do not comply with latest SHTM regulations, though achieving 50°C. Wherever practicable increase temperatures to 55°C.																									
08D GENW10-034 (Bathroom)	Hot, Cold	CWST 23.5	Calorifier 54.2	2	OK	Yes	Yes	2	None visible	Not visible	Flush Regime				1		1	1						High	None visible	None visible		High
Recommendations:			Cold water temperature too high. Investigate and correct. Hot outlets do not comply with latest SHTM regulations, though achieving 50°C. Wherever practicable increase temperatures to 55°C.																									

LEGIONELLA RISK ASSESSMENT

Location / Room No	Sentinel outlet?	Cold Supply & Temp (°C)	Hot Supply & Temp (°C)	TMV info					Deadlegs Present (Inc. Drain cocks)	Flow & Return Working	Outlet Usage	Outlets in location												Aerosol Created	Non WRAS Material	Flexi Hoses	Comment	Additional Localised Risk Rating
				No. Of TMVs	Access	<2m from outlet?	Mix Temps 37-45°C	No. TMV Fed Outlets				Mains	Cold	Hot	Mixer	Urinals	WCs	Shower	Drinks / vend	Water boiler	Drinking fountain	Arjo/whirlpool	Other					
08D GENW10-057 (Bedroom)	Hot, Cold	CWST 27.2	Calorifier 50.6	1	OK	Yes	Yes	1	None visible	Not visible	Flush Regime		1	1										Low	None visible	None visible		Medium
Recommendations:			Cold water temperature too high. Investigate and correct.																									
			Hot outlets do not comply with latest SHTM regulations, though achieving 50°C. Wherever practicable increase temperatures to 55°C.																									
08D GENW10-065 (Bedroom)	Hot, Cold	CWST 27.1	Calorifier 51.0	1	OK	Yes	Yes	1	None visible	Not visible	Flush Regime		1	1										Low	None visible	None visible		Medium
Recommendations:			Cold water temperature too high. Investigate and correct.																									
			Hot outlets do not comply with latest SHTM regulations, though achieving 50°C. Wherever practicable increase temperatures to 55°C.																									
09 WS9-005 (Toilet)	Hot, Cold	CWST 15.7	Calorifier 50.5	1	OK	Yes	Yes	1	None visible	Not visible	Daily				1		1							Low	None visible	None visible		Low
Recommendations:			Hot outlets do not comply with latest SHTM regulations, though achieving 50°C. Wherever practicable increase temperatures to 55°C.																									
09 WS9-011 (Toilet)	Hot, Cold	CWST 14.5	Calorifier 55.0	1	OK	Yes	Yes	1	None visible	Not visible	Daily				1		1							Low	None visible	None visible		Low
Recommendations:																												

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Location / Room No	Sentinel outlet?	Cold Supply & Temp (°C)	Hot Supply & Temp (°C)	TMV info					Deadlegs Present (Inc. Drain cocks)	Flow & Return Working	Outlet Usage	Outlets in location											Aerosol Created	Non WRAS Material	Flexi Hoses	Comment	Additional Localised Risk Rating
				No. Of TMVs	Access	<2m from outlet?	Mix Temps 37-45°C	No. TMV Fed Outlets				Mains	Cold	Hot	Mixer	Urinals	WCs	Shower	Drinks / vend	Water boiler	Drinking fountain	Arjo/whirlpool	Other					
09 WS9-021 (Male Change)	Hot, Cold	CWST 25.8	Calorifier 55.1	1	OK	Yes	Yes	1	None visible	Not visible	Flush Regime				1									Low	None visible	None visible		Medium
Recommendations:			Cold water temperature too high. Investigate and correct.																									
09 WS9-027								0																		Yes		No access
Recommendations:			Locked – No Access. Area should be assessed once access obtained.																									
09A GENW13-001 (Bedroom)	Hot, Cold	CWST 14.2	Calorifier 50.3	1	OK	Yes	Yes	1	None visible	Not visible	Flush Regime		1	1										Low	None visible	None visible		Low
Recommendations:			Hot outlets do not comply with latest SHTM regulations, though achieving 50°C. Wherever practicable increase temperatures to 55°C.																									
09A GENW13-029 (Bathroom)	Hot, Cold	CWST 26.7	Calorifier 53.7	2	OK	Yes	Yes	2	None visible	Not visible	Flush Regime				1		1	1						High	None visible	None visible		High
Recommendations:			Cold water temperature too high. Investigate and correct. Hot outlets do not comply with latest SHTM regulations, though achieving 50°C. Wherever practicable increase temperatures to 55°C.																									

LEGIONELLA RISK ASSESSMENT

Location / Room No	Sentinel outlet?	Cold Supply & Temp (°C)	Hot Supply & Temp (°C)	TMV info					Deadlegs Present (Inc. Drain cocks)	Flow & Return Working	Outlet Usage	Outlets in location											Aerosol Created	Non WRAS Material	Flexi Hoses	Comment	Additional Localised Risk Rating
				No. Of TMVs	Access	<2m from outlet?	Mix Temps 37-45°C	No. TMV Fed Outlets				Mains	Cold	Hot	Mixer	Urinals	WCs	Shower	Drinks / vend	Water boiler	Drinking fountain	Arjo/whirlpool	Other					
09A GENW13-034 (Bathroom)	Hot, Cold	CWST 25.4	Calorifier 53.5	2	OK	Yes	Yes	2	None visible	Not visible	Flush Regime				1		1	1						High	None visible	None visible		High
Recommendations:			Cold water temperature too high. Investigate and correct.																									
			Hot outlets do not comply with latest SHTM regulations, though achieving 50°C. Wherever practicable increase temperatures to 55°C.																									
09A GENW13-065 (Bedroom)	Hot, Cold	CWST 17.3	Calorifier 50.1	1	OK	Yes	Yes	1	None visible	Not visible	Flush Regime		1	1										Low	None visible	None visible		Low
Recommendations:			Hot outlets do not comply with latest SHTM regulations, though achieving 50°C. Wherever practicable increase temperatures to 55°C.																									
09B GENW16-034 (Bathroom)	Hot, Cold	CWST 25.2	Calorifier 54.3	2	OK	Yes	Yes	2	None visible	Not visible	Flush Regime				1		1	1						High	None visible	None visible		High
Recommendations:			Cold water temperature too high. Investigate and correct.																									
			Hot outlets do not comply with latest SHTM regulations, though achieving 50°C. Wherever practicable increase temperatures to 55°C.																									
09B GENW16-036 (Bathroom)	Hot, Cold	CWST 24.2	Calorifier 53.8	2	OK	Yes	Yes	2	None visible	Not visible	Flush Regime				1		1	1						High	None visible	None visible		High
Recommendations:			Cold water temperature too high. Investigate and correct.																									
			Hot outlets do not comply with latest SHTM regulations, though achieving 50°C. Wherever practicable increase temperatures to 55°C.																									

LEGIONELLA RISK ASSESSMENT

Location / Room No	Sentinel outlet?	Cold Supply & Temp (°C)	Hot Supply & Temp (°C)	TMV info					Deadlegs Present (Inc. Drain cocks)	Flow & Return Working	Outlet Usage	Outlets in location												Aerosol Created	Non WRAS Material	Flexi Hoses	Comment	Additional Localised Risk Rating
				No. Of TMVs	Access	<2m from outlet?	Mix Temps 37-45°C	No. TMV Fed Outlets				Mains	Cold	Hot	Mixer	Urinals	WCs	Shower	Drinks / vend	Water boiler	Drinking fountain	Arjo/whirlpool	Other					
09B GENW16-065 (Bedroom)	Hot, Cold	CWST 27.2	Calorifier 50.6	1	OK	Yes	Yes	1	None visible	Not visible	Flush Regime		1	1										Low	None visible	None visible		Medium
Recommendations:			Cold water temperature too high. Investigate and correct.																									
			Hot outlets do not comply with latest SHTM regulations, though achieving 50°C. Wherever practicable increase temperatures to 55°C.																									
09C GENW15-028 (Bedroom)	Hot, Cold	CWST 26.4	Calorifier 50.4	1	OK	Yes	Yes	1	None visible	Not visible	Flush Regime		1	1										Low	None visible	None visible		Medium
Recommendations:			Cold water temperature too high. Investigate and correct.																									
			Hot outlets do not comply with latest SHTM regulations, though achieving 50°C. Wherever practicable increase temperatures to 55°C.																									
09C GENW15-034 (Bathroom)	Hot, Cold	CWST 27.0	Calorifier 54.0	2	OK	Yes	Yes	2	None visible	Not visible	Flush Regime				1		1	1						High	None visible	None visible		High
Recommendations:			Cold water temperature too high. Investigate and correct.																									
			Hot outlets do not comply with latest SHTM regulations, though achieving 50°C. Wherever practicable increase temperatures to 55°C.																									
09C GENW15-065 (Bedroom)	Hot, Cold	CWST 15	Calorifier 52.1	1	OK	Yes	Yes	1	None visible	Not visible	Flush Regime		1	1										Low	None visible	None visible		Low
Recommendations:			Hot outlets do not comply with latest SHTM regulations, though achieving 50°C. Wherever practicable increase temperatures to 55°C.																									

LEGIONELLA RISK ASSESSMENT

Location / Room No	Sentinel outlet?	Cold Supply & Temp (°C)	Hot Supply & Temp (°C)	TMV info					Deadlegs Present (Inc. Drain cocks)	Flow & Return Working	Outlet Usage	Outlets in location												Aerosol Created	Non WRAS Material	Flexi Hoses	Comment	Additional Localised Risk Rating
				No. Of TMVs	Access	<2m from outlet?	Mix Temps 37-45°C	No. TMV Fed Outlets				Mains	Cold	Hot	Mixer	Urinals	WCs	Shower	Drinks / vend	Water boiler	Drinking fountain	Arjo/whirlpool	Other					
09D GENW14-001 (Bedroom)	Hot, Cold	CWST 14.3	Calorifier 52.1	1	OK	Yes	Yes	1	None visible	Not visible	Flush Regime		1	1										Low	None visible	None visible		Low
Recommendations:			Hot outlets do not comply with latest SHTM regulations, though achieving 50°C. Wherever practicable increase temperatures to 55°C.																									
09D GENW14-028 (Bedroom)	Hot, Cold	CWST 26.1	Calorifier 52.9	1	OK	Yes	Yes	1	None visible	Not visible	Flush Regime		1	1										Low	None visible	None visible		Medium
Recommendations:			Cold water temperature too high. Investigate and correct.																									
			Hot outlets do not comply with latest SHTM regulations, though achieving 50°C. Wherever practicable increase temperatures to 55°C.																									
09D GENW14-034 (Bathroom)	Hot, Cold	CWST 25.6	Calorifier 54.0	2	OK	Yes	Yes	2	None visible	Not visible	Flush Regime				1		1	1						High	None visible	None visible		High
Recommendations:			Cold water temperature too high. Investigate and correct.																									
			Hot outlets do not comply with latest SHTM regulations, though achieving 50°C. Wherever practicable increase temperatures to 55°C.																									
09D GENW14-057 (Bedroom)	Hot, Cold	CWST 22.2	Calorifier 52.8	1	OK	Yes	Yes	1	None visible	Not visible	Flush Regime		1	1										Low	None visible	None visible		Medium
Recommendations:			Cold water temperature too high. Investigate and correct.																									
			Hot outlets do not comply with latest SHTM regulations, though achieving 50°C. Wherever practicable increase temperatures to 55°C.																									

LEGIONELLA RISK ASSESSMENT

Location / Room No	Sentinel outlet?	Cold Supply & Temp (°C)	Hot Supply & Temp (°C)	TMV info					Deadlegs Present (Inc. Drain cocks)	Flow & Return Working	Outlet Usage	Outlets in location											Aerosol Created	Non WRAS Material	Flexi Hoses	Comment	Additional Localised Risk Rating
				No. Of TMVs	Access	<2m from outlet?	Mix Temps 37-45°C	No. TMV Fed Outlets				Mains	Cold	Hot	Mixer	Urinals	WCs	Shower	Drinks / vend	Water boiler	Drinking fountain	Arjo/whirlpool	Other					
09D GENW14-065 (Bedroom)	Hot, Cold	CWST 26.8	Calorifier 52.0	1	OK	Yes	Yes	1	None visible	Not visible	Flush Regime		1	1										Low	None visible	None visible		Medium
Recommendations:			Cold water temperature too high. Investigate and correct.																									
			Hot outlets do not comply with latest SHTM regulations, though achieving 50°C. Wherever practicable increase temperatures to 55°C.																									
10 WS10-005 (Toilet)	Hot, Cold	CWST 17.3	Calorifier 51.7	1	OK	Yes	Yes	1	None visible	Not visible	Daily				1		1							Low	None visible	None visible		Low
Recommendations:			Hot outlets do not comply with latest SHTM regulations, though achieving 50°C. Wherever practicable increase temperatures to 55°C.																									
10 WS10-011 (Toilet)	Hot, Cold	CWST 17.6	Calorifier 51.3	1	OK	Yes	Yes	1	None visible	Not visible	Daily				1		1							Low	None visible	None visible		Low
Recommendations:			Hot outlets do not comply with latest SHTM regulations, though achieving 50°C. Wherever practicable increase temperatures to 55°C.																									
10 WS10-018 (Kitchen)	Hot, Cold	CWST 25.1	Calorifier 58.2	1	OK	Yes	Yes	1	None visible	Yes	Flush Regime		2	2	1			1		1				High	None visible	Yes	Copper tail to WHB 1	High
Recommendations:			All EPDM flexible hoses should be removed and replaced with hard piped connection.																									
			Cold water temperature too high. Investigate and correct.																									

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Location / Room No	Sentinel outlet?	Cold Supply & Temp (°C)	Hot Supply & Temp (°C)	TMV info					Deadlegs Present (Inc. Drain cocks)	Flow & Return Working	Outlet Usage	Outlets in location												Aerosol Created	Non WRAS Material	Flexi Hoses	Comment	Additional Localised Risk Rating
				No. Of TMVs	Access	<2m from outlet?	Mix Temps 37-45°C	No. TMV Fed Outlets				Mains	Cold	Hot	Mixer	Urinals	WCs	Shower	Drinks / vend	Water boiler	Drinking fountain	Arjo/whirlpool	Other					
10 WS10-026 (Ladies Changing)	Hot, Cold	CWST 22.1	Calorifier 55.0	3	OK	Yes	Yes	3	None visible	Not visible	Never				2		2	1						High	None visible	None visible		High
Recommendations:			Cold water temperature too high. Investigate and correct.																									
10A GENW17-001 (Bedroom)	Hot, Cold	CWST 14.8	Calorifier 50.9	1	OK	Yes	Yes	1	None visible	Not visible	Flush Regime		1	1										Low	None visible	None visible		Low
Recommendations:			Hot outlets do not comply with latest SHTM regulations, though achieving 50°C. Wherever practicable increase temperatures to 55°C.																									
10A GENW17-029 (Bathroom)	Hot, Cold	CWST 24.2	Calorifier 51.4	2	OK	Yes	Yes	2	None visible	Not visible	Flush Regime				1		1	1						High	None visible	None visible		High
Recommendations:			Cold water temperature too high. Investigate and correct. Hot outlets do not comply with latest SHTM regulations, though achieving 50°C. Wherever practicable increase temperatures to 55°C.																									
10A GENW17-034 (Bathroom)	Hot, Cold	CWST 23.7	Calorifier 51.8	2	OK	Yes	Yes	2	None visible	Not visible	Flush Regime				1		1	1						High	None visible	None visible		High
Recommendations:			Cold water temperature too high. Investigate and correct. Hot outlets do not comply with latest SHTM regulations, though achieving 50°C. Wherever practicable increase temperatures to 55°C.																									

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Location / Room No	Sentinel outlet?	Cold Supply & Temp (°C)	Hot Supply & Temp (°C)	TMV info					Deadlegs Present (Inc. Drain cocks)	Flow & Return Working	Outlet Usage	Outlets in location												Aerosol Created	Non WRAS Material	Flexi Hoses	Comment	Additional Localised Risk Rating
				No. Of TMVs	Access	<2m from outlet?	Mix Temps 37-45°C	No. TMV Fed Outlets				Mains	Cold	Hot	Mixer	Urinals	WCs	Shower	Drinks / vend	Water boiler	Drinking fountain	Arjo/whirlpool	Other					
10A GENW17-065 (Bedroom)	Hot, Cold	CWST 19.5	Calorifier 50.0	1	OK	Yes	Yes	1	None visible	Not visible	Flush Regime		1	1										Low	None visible	None visible		Low
Recommendations:			Hot outlets do not comply with latest SHTM regulations, though achieving 50°C. Wherever practicable increase temperatures to 55°C.																									
10A GENW17-066 (Facilities)						Yes		0																		Yes		No access
Recommendations:			Locked – No Access. Area should be assessed once access obtained.																									
10B GENW20-032 (Bathroom)	Hot, Cold	CWST 23.5	Calorifier 52.5	2	OK	Yes	Yes	2	None visible	Not visible	Flush Regime				1		1	1						High	None visible	None visible		High
Recommendations:			Cold water temperature too high. Investigate and correct. Hot outlets do not comply with latest SHTM regulations, though achieving 50°C. Wherever practicable increase temperatures to 55°C.																									
10B GENW20-036 (Bathroom)	Hot, Cold	CWST 23.6	Calorifier 50.8	2	OK	Yes	Yes	2	None visible	Not visible	Flush Regime				1		1	1						High	None visible	None visible		High
Recommendations:			Cold water temperature too high. Investigate and correct. Hot outlets do not comply with latest SHTM regulations, though achieving 50°C. Wherever practicable increase temperatures to 55°C.																									

LEGIONELLA RISK ASSESSMENT

Location / Room No	Sentinel outlet?	Cold Supply & Temp (°C)	Hot Supply & Temp (°C)	TMV info					Deadlegs Present (Inc. Drain cocks)	Flow & Return Working	Outlet Usage	Outlets in location												Aerosol Created	Non WRAS Material	Flexi Hoses	Comment	Additional Localised Risk Rating
				No. Of TMVs	Access	<2m from outlet?	Mix Temps 37-45°C	No. TMV Fed Outlets				Mains	Cold	Hot	Mixer	Urinals	WCs	Shower	Drinks / vend	Water boiler	Drinking fountain	Arjo/whirlpool	Other					
10B GENW20-065 (Bedroom)	Hot, Cold	CWST 24.2	Calorifier 52.4	1	OK	Yes	Yes	1	None visible	Not visible	Flush Regime		1	1										Low	None visible	None visible		Medium
Recommendations:			Cold water temperature too high. Investigate and correct.																									
			Hot outlets do not comply with latest SHTM regulations, though achieving 50°C. Wherever practicable increase temperatures to 55°C.																									
10C GENW19-028 (Bedroom)	Hot, Cold	CWST 24.3	Calorifier 50.2	1	OK	Yes	Yes	1	None visible	Not visible	Flush Regime		1	1										Low	None visible	None visible		Medium
Recommendations:			Cold water temperature too high. Investigate and correct.																									
			Hot outlets do not comply with latest SHTM regulations, though achieving 50°C. Wherever practicable increase temperatures to 55°C.																									
10C GENW19-034 (Bathroom)	Hot, Cold	CWST 25.1	Calorifier 53.4	2	OK	Yes	Yes	2	None visible	Not visible	Flush Regime				1		1	1						High	None visible	None visible		High
Recommendations:			Cold water temperature too high. Investigate and correct.																									
			Hot outlets do not comply with latest SHTM regulations, though achieving 50°C. Wherever practicable increase temperatures to 55°C.																									
10C GENW19-065 (Bedroom)	Hot, Cold	CWST 18.0	Calorifier 50.0	1	OK	Yes	Yes	1	None visible	Not visible	Flush Regime		1	1										Low	None visible	None visible		Low
Recommendations:			Hot outlets do not comply with latest SHTM regulations, though achieving 50°C. Wherever practicable increase temperatures to 55°C.																									

LEGIONELLA RISK ASSESSMENT

Location / Room No	Sentinel outlet?	Cold Supply & Temp (°C)	Hot Supply & Temp (°C)	TMV info					Deadlegs Present (Inc. Drain cocks)	Flow & Return Working	Outlet Usage	Outlets in location												Aerosol Created	Non WRAS Material	Flexi Hoses	Comment	Additional Localised Risk Rating
				No. Of TMVs	Access	<2m from outlet?	Mix Temps 37-45°C	No. TMV Fed Outlets				Mains	Cold	Hot	Mixer	Urinals	WCs	Shower	Drinks / vend	Water boiler	Drinking fountain	Arjo/whirlpool	Other					
10D GENW18-001 (Bedroom)	Hot, Cold	CWST 17.5	Calorifier 51.1	1	OK	Yes	Yes	1	None visible	Not visible	Flush Regime		1	1										Low	None visible	None visible		Low
Recommendations:			Hot outlets do not comply with latest SHTM regulations, though achieving 50°C. Wherever practicable increase temperatures to 55°C.																									
10D GENW18-028 (Bedroom)	Hot, Cold	CWST 27.8	Calorifier 50.4	1	OK	Yes	Yes	1	None visible	Not visible	Flush Regime		1	1										Low	None visible	None visible		Medium
Recommendations:			Cold water temperature too high. Investigate and correct.																									
			Hot outlets do not comply with latest SHTM regulations, though achieving 50°C. Wherever practicable increase temperatures to 55°C.																									
10D GENW18-034 (Bathroom)	Hot, Cold	CWST 24.8	Calorifier 55.5	2	OK	Yes	Yes	2	None visible	Not visible	Flush Regime				1		1	1						High	None visible	None visible		High
Recommendations:			Cold water temperature too high. Investigate and correct.																									
10D GENW18-057 (Bedroom)	Hot, Cold	CWST 27.7	Calorifier 50.3	1	OK	Yes	Yes	1	None visible	Not visible	Flush Regime		1	1										Low	None visible	None visible		Medium
Recommendations:			Cold water temperature too high. Investigate and correct.																									
			Hot outlets do not comply with latest SHTM regulations, though achieving 50°C. Wherever practicable increase temperatures to 55°C.																									

LEGIONELLA RISK ASSESSMENT

Location / Room No	Sentinel outlet?	Cold Supply & Temp (°C)	Hot Supply & Temp (°C)	TMV info					Deadlegs Present (Inc. Drain cocks)	Flow & Return Working	Outlet Usage	Outlets in location												Aerosol Created	Non WRAS Material	Flexi Hoses	Comment	Additional Localised Risk Rating
				No. Of TMVs	Access	<2m from outlet?	Mix Temps 37-45°C	No. TMV Fed Outlets				Mains	Cold	Hot	Mixer	Urinals	WCs	Shower	Drinks / vend	Water boiler	Drinking fountain	Arjo/whirlpool	Other					
10D GENW18-065 (Bedroom)	Hot, Cold	CWST 25.6	Calorifier 55.5	1	OK	Yes	Yes	1	None visible	Not visible	Flush Regime		1	1										Low	None visible	None visible		Medium
Recommendations:			Cold water temperature too high. Investigate and correct.																									
11 WS11-005 (Toilet)	Hot, Cold	CWST 14.5	Calorifier 53.0	1	OK	Yes	Yes	1	None visible	Not visible	Daily				1		1							Low	None visible	None visible		Low
Recommendations:			Hot outlets do not comply with latest SHTM regulations, though achieving 50°C. Wherever practicable increase temperatures to 55°C. Pipework behind panel should be insulated.																									
11 WS11-011 (Toilet)	Hot, Cold	CWST 14.2	Calorifier 53.5	1	OK	Yes	Yes	1	None visible	Not visible	Daily				1		1							Low	None visible	None visible		Low
Recommendations:			Hot outlets do not comply with latest SHTM regulations, though achieving 50°C. Wherever practicable increase temperatures to 55°C.																									
11 WS11-018 (Kitchen)	Hot, Cold	CWST 18.1	Calorifier 55.6	1	OK	Yes	Yes	1	None visible	Yes	Flush Regime		2	2	1			1		1				High	None visible	Yes	1	Low
Recommendations:			All EPDM flexible hoses should be removed and replaced with hard piped connection.																									

LEGIONELLA RISK ASSESSMENT

Location / Room No	Sentinel outlet?	Cold Supply & Temp (°C)	Hot Supply & Temp (°C)	TMV info					Deadlegs Present (Inc. Drain cocks)	Flow & Return Working	Outlet Usage	Outlets in location												Aerosol Created	Non WRAS Material	Flexi Hoses	Comment	Additional Localised Risk Rating
				No. Of TMVs	Access	<2m from outlet?	Mix Temps 37-45°C	No. TMV Fed Outlets				Mains	Cold	Hot	Mixer	Urinals	WCs	Shower	Drinks / vend	Water boiler	Drinking fountain	Arjo/whirlpool	Other					
11 WS11-019 (Toilet)	Hot, Cold	CWST 25.6	Calorifier 54.2	1	OK	Yes	Yes	1	None visible	Not visible	Daily				1		1							Low	None visible	None visible		Medium
Recommendations:			Cold water temperature too high. Investigate and correct.																									
			Hot outlets do not comply with latest SHTM regulations, though achieving 50°C. Wherever practicable increase temperatures to 55°C.																									
11A GENW21-001 (Bedroom)	Hot, Cold	CWST 14.1	Calorifier 52.0	1	OK	Yes	Yes	1	None visible	Not visible	Flush Regime		1	1										Low	None visible	None visible		Low
Recommendations:			Hot outlets do not comply with latest SHTM regulations, though achieving 50°C. Wherever practicable increase temperatures to 55°C.																									
11A GENW21-029 (Bathroom)	Hot, Cold	CWST 26.1	Calorifier 51.5	2	OK	Yes	Yes	2	None visible	Not visible	Flush Regime				1		1	1						High	None visible	None visible		High
Recommendations:			Cold water temperature too high. Investigate and correct.																									
			Hot outlets do not comply with latest SHTM regulations, though achieving 50°C. Wherever practicable increase temperatures to 55°C.																									
11A GENW21-034 (Bathroom)	Hot, Cold	CWST 23.1	Calorifier 51.3	2	OK	Yes	Yes	2	None visible	Not visible	Flush Regime				1		1	1						High	None visible	None visible		High
Recommendations:			Cold water temperature too high. Investigate and correct.																									
			Hot outlets do not comply with latest SHTM regulations, though achieving 50°C. Wherever practicable increase temperatures to 55°C.																									

LEGIONELLA RISK ASSESSMENT

Location / Room No	Sentinel outlet?	Cold Supply & Temp (°C)	Hot Supply & Temp (°C)	TMV info					Deadlegs Present (Inc. Drain cocks)	Flow & Return Working	Outlet Usage	Outlets in location												Aerosol Created	Non WRAS Material	Flexi Hoses	Comment	Additional Localised Risk Rating
				No. Of TMVs	Access	<2m from outlet?	Mix Temps 37-45°C	No. TMV Fed Outlets				Mains	Cold	Hot	Mixer	Urinals	WCs	Shower	Drinks / vend	Water boiler	Drinking fountain	Arjo/whirlpool	Other					
11A GENW21-065 (Bedroom)	Hot, Cold	CWST 22.0	Calorifier 52.0	1	OK	Yes	Yes	1	None visible	Not visible	Flush Regime		1	1										Low	None visible	None visible		Medium
Recommendations:			Cold water temperature too high. Investigate and correct.																									
			Hot outlets do not comply with latest SHTM regulations, though achieving 50°C. Wherever practicable increase temperatures to 55°C.																									
11B GENW24-032 (Bathroom)	Hot, Cold	CWST 15.5	Calorifier 51.9	2	OK	Yes	Yes	2	None visible	Not visible	Flush Regime				1		1	1						High	None visible	None visible		Low
Recommendations:			Hot outlets do not comply with latest SHTM regulations, though achieving 50°C. Wherever practicable increase temperatures to 55°C.																									
11B GENW24-036 (Bathroom)	Hot, Cold	CWST 24.5	Calorifier 51.4	2	OK	Yes	Yes	2	None visible	Not visible	Flush Regime				1		1	1						High	None visible	None visible		High
Recommendations:			Cold water temperature too high. Investigate and correct.																									
			Hot outlets do not comply with latest SHTM regulations, though achieving 50°C. Wherever practicable increase temperatures to 55°C.																									
11B GENW24-065 (Bedroom)	Hot, Cold	CWST 22.1	Calorifier 55.1	1	OK	Yes	Yes	1	None visible	Not visible	Flush Regime		1	1										Low	None visible	None visible		Low
Recommendations:			Cold water temperature too high. Investigate and correct.																									

LEGIONELLA RISK ASSESSMENT

Location / Room No	Sentinel outlet?	Cold Supply & Temp (°C)	Hot Supply & Temp (°C)	TMV info					Deadlegs Present (Inc. Drain cocks)	Flow & Return Working	Outlet Usage	Outlets in location												Aerosol Created	Non WRAS Material	Flexi Hoses	Comment	Additional Localised Risk Rating
				No. Of TMVs	Access	<2m from outlet?	Mix Temps 37-45°C	No. TMV Fed Outlets				Mains	Cold	Hot	Mixer	Urinals	WCs	Shower	Drinks / vend	Water boiler	Drinking fountain	Arjo/whirlpool	Other					
11C GENW23-028 (Bedroom)	Hot, Cold	CWST 18.9	Calorifier 52.1	1	OK	Yes	Yes	1	None visible	Not visible	Flush Regime		1	1										Low	None visible	None visible		Low
Recommendations:			Hot outlets do not comply with latest SHTM regulations, though achieving 50°C. Wherever practicable increase temperatures to 55°C.																									
11C GENW23-034 (Bathroom)	Hot, Cold	CWST 22.3	Calorifier 50.6	2	OK		Yes	2	None visible	Not visible	Flush Regime				1		1	1						High	None visible	None visible		High
Recommendations:			Cold water temperature too high. Investigate and correct. Hot outlets do not comply with latest SHTM regulations, though achieving 50°C. Wherever practicable increase temperatures to 55°C.																									
11C GENW23-065 (Bedroom)	Hot, Cold	CWST 13.3	Calorifier 51.8	1	OK	Yes	Yes	1	None visible	Not visible	Flush Regime		1	1										Low	None visible	None visible		Low
Recommendations:			Hot outlets do not comply with latest SHTM regulations, though achieving 50°C. Wherever practicable increase temperatures to 55°C.																									
11C GENW23-081 (Clean Utility)	No	CWST 15.2	Calorifier 57.3	1	OK	Yes	Yes	1	None visible	Not visible	Flush Regime		2	2										Low	None visible	None visible		Low
Recommendations:																												
11D GENW22-001 (Bedroom)	Hot, Cold	CWST 13.0	Calorifier 52.5	1	OK	Yes	Yes	1	None visible	Not visible	Flush Regime		1	1										Low	None visible	None visible		Low
Recommendations:			Hot outlets do not comply with latest SHTM regulations, though achieving 50°C. Wherever practicable increase temperatures to 55°C.																									

LEGIONELLA RISK ASSESSMENT

Location / Room No	Sentinel outlet?	Cold Supply & Temp (°C)	Hot Supply & Temp (°C)	TMV info					Deadlegs Present (Inc. Drain cocks)	Flow & Return Working	Outlet Usage	Outlets in location												Aerosol Created	Non WRAS Material	Flexi Hoses	Comment	Additional Localised Risk Rating
				No. Of TMVs	Access	<2m from outlet?	Mix Temps 37-45°C	No. TMV Fed Outlets				Mains	Cold	Hot	Mixer	Urinals	WCs	Shower	Drinks / vend	Water boiler	Drinking fountain	Arjo/whirlpool	Other					
11D GENW22-028 (Bedroom)	Hot, Cold	CWST 26.2	Calorifier 53.5	1	OK	Yes	Yes	1	None visible	Not visible	Flush Regime		1	1										Low	None visible	None visible		Medium
Recommendations:			Cold water temperature too high. Investigate and correct.																									
			Hot outlets do not comply with latest SHTM regulations, though achieving 50°C. Wherever practicable increase temperatures to 55°C.																									
11D GENW22-034 (Bathroom)	Hot, Cold	CWST 22.0	Calorifier 52.6	2	OK	Yes	Yes	2	None visible	Not visible	Flush Regime				1		1	1						High	None visible	None visible		High
Recommendations:			Cold water temperature too high. Investigate and correct.																									
			Hot outlets do not comply with latest SHTM regulations, though achieving 50°C. Wherever practicable increase temperatures to 55°C.																									
11D GENW22-057 (Bedroom)	Hot, Cold	CWST 25.9	Calorifier 53.0	1	OK	Yes	Yes	1	None visible	Not visible	Flush Regime		1	1										Low	None visible	None visible		Medium
Recommendations:			Cold water temperature too high. Investigate and correct.																									
			Hot outlets do not comply with latest SHTM regulations, though achieving 50°C. Wherever practicable increase temperatures to 55°C.																									
11D GENW22-065 (Bedroom)	Hot, Cold	CWST 22.8	Calorifier 52.1	1	OK	Yes	Yes	1	None visible	Not visible	Flush Regime		1	1										Low	None visible	None visible		Medium
Recommendations:			Cold water temperature too high. Investigate and correct.																									
			Hot outlets do not comply with latest SHTM regulations, though achieving 50°C. Wherever practicable increase temperatures to 55°C.																									

LEGIONELLA RISK ASSESSMENT

Location / Room No	Sentinel outlet?	Cold Supply & Temp (°C)	Hot Supply & Temp (°C)	TMV info					Deadlegs Present (Inc. Drain cocks)	Flow & Return Working	Outlet Usage	Outlets in location											Aerosol Created	Non WRAS Material	Flexi Hoses	Comment	Additional Localised Risk Rating
				No. Of TMVs	Access	<2m from outlet?	Mix Temps 37-45°C	No. TMV Fed Outlets				Mains	Cold	Hot	Mixer	Urinals	WCs	Shower	Drinks / vend	Water boiler	Drinking fountain	Arjo/whirlpool	Other					
11D GENW22-081 (Clean Utility)	No	CWST 24.4	Calorifier 57.4	1	OK	Yes	Yes	1	None visible	Not visible	Flush Regime		2	2									Low	None visible	None visible		Medium
Recommendations:			Cold water temperature too high. Investigate and correct.																								
Plantroom 31 at Cals 01/02/03	No	Other	No hot outlets	0		Yes		0	None visible	N/A	Flush Regime		1										Low	None visible	None visible	Very long line to Bib Tap	Low
Recommendations:																											

Section 8

Other 'At Risk Systems'

Other Risk Systems

All other "at risk" systems should have a suitable L8 risk assessment carried out with an appropriate L8 monitoring regime implemented.

HSG 274 Legionnaire's disease: Technical guidance Part 3: The control of legionella bacteria in other risk systems provides guidance on identification and frequency of inspections for these systems.

Other systems identified to DMA as being present on site:

- Hydrotherapy Pool
- Whirlpool/Arjo Baths
- Dental equipment
- Emergency showers
- Irrigation systems
- Sprinkler/Wet firefighting systems
- Renal dialysis (x 2)
- Endoscopy Wash
- Water softeners
- Medical Gases/Medical Equipment (e.g. Nebulisers, incubators, etc.)
- Dry/Wet (Adiabatic) Cooling (e.g. MRI chillers)
- Closed heating systems
- Closed chilled water systems
- Steam Humidification
- Air Conditioning

DMA were advise no Ice making machines, machines with "open" cooling system (e.g. lathes)

System	Hydrotherapy Pool
Location(s)	Ground floor - Children's Hospital
Responsibility	Estates/Clinical staff
Description	Hydrotherapy pool
Water Source	Bulk Water supplies CWST in basement Hydrotherapy plantroom
Filtration Present	Pool filtration plant in hydrotherapy plantroom in basement
Running Temperature	Typically 35-40°C
Use	System not in use at time of assessment (Empty). Continually circulating system.
Aerosol Created	Potentially high
Comments	
Recommendations	Maintain in accordance with manufacturers/installers instructions and PHLS Hygiene for Hydrotherapy Pools and Pool Water Treatment Advisory Group (PWTAG) Code of Practice (Feb 2015). CWST requires to be cleaned and disinfected as stagnation noted at time of survey.
Risk (Legionella)	High

System	Arjo Baths
Location(s)	Various locations throughout the hospital (Wards)
Responsibility	Estates/Clinical staff
Description	Medical bath (Baths seen by DMA do not appear to have any obvious air or water jet facility)
Water Source	Bulk Water
Filtration Present	None
Running Temperature	Typically 35-45°C
Use	Not in use at time of assessment. On-going use may depend on patient welfare requirements and should be recorded.
Aerosol Created	High
Comments	Flexible hoses on connection to hot/cold water system in addition to internal flexible connections.
Recommendations	Maintain in accordance with manufacturers/installers instructions. Where flexible hoses (i.e. internal to bath unit) cannot be removed then replacing with alternative WRAS approved hoses with linings other than EPDM should be considered. Consider shortening shower hoses as it was noted that these can in some areas reach into adjacent WCs and WHBs.
Risk (Legionella)	Medium

System	Dental Equipment
Location(s)	Ground floor Children's Hospital
Responsibility	Estates/Clinical staff
Description	Water supply to 2 x dental chairs
Water Source	Bulk Water feeds CWST and booster pump. Also bottled water within chair. Confirmation as to what equipment is fed from CWST/booster and bottled water not provided to DMA.
Filtration Present	None
Running Temperature	TBC though 'Bulk water system'
Use	Not running (system empty) at time of assessment though anticipated daily use.
Aerosol Created	Potentially High (TBC)
Comments	
Recommendations	HSG 274 Part 3 states *"Drain down, clean, flush and disinfect all system components, pipework and bottles twice daily. Disinfectant contact time as recommended by manufacturer. Take microbiological measurements (Refer to Decontamination HTM 01-05)* SHTM 04-01 Part G (Draft) states *"Drain down and clean at the end of each working day".* HTM 01-05 provides advice and recommendations for on-going maintenance and this should be followed in addition to manufacturers and installers instructions.
Risk (Legionella)	High

System	Emergency Showers
Location(s)	Hydrotherapy Plantroom and A&E Decontamination Room
Responsibility	Estates
Description	Emergency drench system
Water Source	Bulk Water
Filtration Present	None
Running Temperature	TBC though 'Bulk water system'
Use	Very Infrequent (Emergency)
Aerosol Created	High
Comments	Decontamination room inaccessible at time of survey due to construction works.
Recommendations	HSG 274 Part 3 recommends minimum six monthly flushing of emergency/deluge shower, though Risk Control Notice 11/advises "flush through and purge to drain twice per week– source SHTM 04-01 Part G (Draft). NHS Estates should formulate an appropriate flushing regime and maintain in accordance with manufacturers/installers instructions.
Risk (Legionella)	High

System	Irrigation System
Location(s)	Various courtyards/roof gardens
Responsibility	Estates
Description	Soak away irrigation (Advised by Estates – DMA did not see system running)
Water Source	Trades Water
Filtration Present	None
Running Temperature	TBC though 'Trades water system'
Use	Not in use at time of assessment. Ongoing use likely to be intermittent depending of season/weather.
Aerosol Created	Low (Advised by Estates – DMA did not see system running)
Comments	Very long runs to outlets through the building.
Recommendations	Include in site flushing regime. Additional flushing may also be required (outlets run for extended periods) to bring temperatures on distribution system down particularly during periods of low use (e.g. in winter when irrigation system is not required to operate frequently). Maintain in accordance with manufacturers/installers instructions.
Risk (Legionella)	Medium

System	Sprinkler/wet fire-fighting system (Sprinkler System)
Location(s)	Main fire tanks in basement (Sprinkler system throughout the building)
Responsibility	Estates
Description	Fire suppression/sprinkler system
Water Source	Fed from dedicated fire main (Hardgate Road – Small).
Filtration Present	None
Running Temperature	Ambient
Use	Not in use at time of assessment. Emergency use only.
Aerosol Created	High when discharging. (Droplet size undetermined)
Comments	Further guidance on this can be found in *"FIA Guidance for the Fire Protection Industry - Guidance on Legionella in Fire Fighting Systems and Equipment"*
Recommendations	Minimise aerosol creation during maintenance procedures. Consider wearing suitable masks to prevent ingestion as recommended by the FIA guidance. Maintain in accordance with manufacturers/installers instructions.
Risk (Legionella)	High under discharge.

System	12th Floor Heli-pad fire suppression system
Location(s)	12th Floor heli-pad fire tank/suppression system
Responsibility	Estates
Description	Fire suppression/sprinkler system (including water canon). A foam suppressant can also be added to the discharged water.
Water Source	Trades Water (very long run through building to 12th Floor Plantroom)
Filtration Present	None
Running Temperature	Ambient
Use	Not in use at time of assessment. Emergency use only.
Aerosol Created	High when discharging. (Droplet size undetermined)
Comments	Further guidance on this can be found in *"FIA Guidance for the Fire Protection Industry - Guidance on Legionella in Fire Fighting Systems and Equipment"*
Recommendations	Minimise aerosol creation during maintenance procedures. Consider wearing suitable masks to prevent ingestion as recommended by the FIA guidance. Maintain in accordance with manufacturers/installers instructions. Include all points on the 12th floor Trades system (including inlet to fire tank) in site flushing regime.
Risk (Legionella)	High under discharge.

System	Renal Dialysis (Adult)
Location(s)	Plantroom 32 then runs to renal ward areas
Responsibility	Estates/Specialist
Description	A constantly circulating purified water system supplying renal dialysis outlets in the Adult hospital
Water Source	Bulk Water
Filtration Present	Various
Running Temperature	TBC though 'Bulk water system'
Use	System constantly circulating with short deadlegs to outlets where accessed by DMA. System not in use at time of assessment. Daily use anticipated.
Aerosol Created	Typically Low
Comments	As supplied by Bulk Water this makes domestic water system disinfections problematic.
Recommendations	Maintain in accordance with manufacturers/installers instructions, current NHS (SHTM) protocols and "Clinical Practice Guideline by the UK Renal Association of Renal Technologists". Ensure aerosol creation is minimised during maintenance and testing procedures.
Risk (Legionella)	Low

System	Renal Dialysis (Children)
Location(s)	Plantroom 22 then runs to renal ward areas
Responsibility	Estates/Specialist
Description	A constantly circulating purified water system supplying renal dialysis outlets in the Adult hospital
Water Source	Bulk Water
Filtration Present	Various
Running Temperature	TBC though 'Bulk water system'
Use	System constantly circulating with short deadlegs to outlets where accessed by DMA. System not in use at time of assessment. Daily use anticipated.
Aerosol Created	Typically Low
Comments	As supplied by Bulk Water this makes domestic water system disinfections problematic.
Recommendations	Maintain in accordance with manufacturers/installers instructions, current NHS (SHTM) protocols and "Clinical Practice Guideline by the UK Renal Association of Renal Technologists". Ensure aerosol creation is minimised during maintenance and testing procedures.
Risk (Legionella)	Low

System	Endoscopy Wash Filtration Unit
Location(s)	Plantroom 31
Responsibility	Estates/Specialist
Description	A constantly circulating purified water system supplying endoscopy wash machines in the Adult hospital
Water Source	Bulk Water
Filtration Present	Various
Running Temperature	TBC though 'Bulk water system'
Use	System not in use at time of assessment. Daily use expected.
Aerosol Created	Potentially High though contained within the endoscopy wash units.
Comments	System not fully operational at time of survey (undergoing testing).
Recommendations	Maintain in accordance with manufacturers/installers instructions and current NHS (SHTM) protocols. Ensure aerosol creation is minimised during maintenance and testing procedures.
Risk (Legionella)	Low

System	Water Softeners
Location(s)	Various
Responsibility	Estates/Specialist
Description	Softeners form part of various medical (e.g. Renal/Endoscopy) and other processes (e.g. steam ovens)
Water Source	Bulk Water
Filtration Present	N/A
Running Temperature	TBC though 'Bulk water system'
Use	Systems not in use at time of assessment. Daily use expected.
Aerosol Created	N/A (Contained systems)
Comments	
Recommendations	Maintain in accordance with manufacturers/installers instructions (including cleaning and disinfection of resin and brine tanks). Ensure aerosol creation is minimised during maintenance and testing procedures.
Risk (Legionella)	Low

System	**Medical Gases/Medical Equipment** (e.g. Nebulisers, incubators, etc.)
Location(s)	Throughout Hospital
Responsibility	Estates/Clinical Staff/Infection Control/Specialist
Recommendations	Conduct a risk assessment of each system, preferably using an assessment team comprising members knowledgeable in legionella management and control, as well as those familiar with the design and operation of the system and Infection Control/Clinical staff where appropriate. Control procedures within appropriate SHTM (or other relevant guidance) for system being assessed should be taken in to account during assessment(s). Any water softeners or other filtration equipment connected to these systems should be assessed at this time. Devise a control scheme based on the risk assessment.
Risk (Legionella)	Not assessed

System	**MRI Chillers Wet/Dry (Adiabatic) Cooling)**
Location(s)	3rd Floor Roof adjacent to Plantroom 31 at Calorifiers 31-04/05/06. DMA also advised there is a connection directly into the MRI unit(s) for additional cooling should the chillers fail (DMA have not seen these connections)
Responsibility	Estates/Specialist
Description	Wet/dry cooling system for MRI Chillers
Water Source	Bulk Water
Filtration Present	None noted (Fed via RPZ valve)
Running Temperature	TBC though 'Bulk water system'
Use	Additional cooling for periods of high demand/high external temperatures. System not in use at time of assessment. Only sporadic use anticipated.
Aerosol Created	TBC
Comments	DMA requested additional information on how the system operates though not received at time of report.
Recommendations	Depending on the actual design and operation of these units they may require to be registered with the local authority under the NCTEC Notification Requirements (See HSG 274 Part 1 Para 1.18 – 1.21 inclusive of Figure 1.4 and Info Box 1.1). These may also require ongoing treatment or monitoring programmes to be implemented depending on assessment. Maintain in accordance with manufacturers/installers instructions. Consider use of POU disinfection system such as UV for spray water. Connection point to MRI unit(s) should be included in site flushing regime and have suitable backflow protection fitted.
Risk (Legionella)	TBC - Not assessed.

System	Closed Heating Systems
Location(s)	Throughout hospital
Responsibility	Estates
Description	Closed heating systems
Water Source	Top up by Bulk Water system
Filtration Present	None
Running Temperature	70 – 105°C (approx.)
Use	Constantly circulating systems
Aerosol Created	N/A
Comments	
Recommendations	Minimise aerosol creation during maintenance procedures. Maintain in accordance with manufacturers/installers instructions.
Risk (Legionella)	Low

System	Closed Chilled Systems
Location(s)	Throughout hospital
Responsibility	Estates
Description	Closed chilled systems
Water Source	Top up by Bulk Water system
Filtration Present	None
Running Temperature	6 - 20°C (approx.)
Use	Constantly circulating systems
Aerosol Created	N/A
Comments	
Recommendations	Minimise aerosol creation during maintenance procedures. Maintain in accordance with manufacturers/installers instructions.
Risk (Legionella)	Low

System	Steam Humidification
Location(s)	Plantrooms (Air Handling Units)
Responsibility	Estates
Description	Steam humidifiers for air conditioning plant
Water Source	Bulk Water
Filtration Present	N/A
Running Temperature	>100°C
Use	Systems not in use at time of assessment. DMA advised these may not be commissioned.
Aerosol Created	N/A (Steam)
Comments	
Recommendations	Maintain in accordance with manufacturers/installers instructions and as required under SHTM 03-01 and SHTM 04-01 Part G (Draft).
Risk (Legionella)	Not assessed – offline.

System	Air Conditioning/Ventilation
Location(s)	Plantrooms (Air Handling Units)
Responsibility	Estates
Description	Air handling units
Water Source	N/A
Filtration Present	N/A
Running Temperature	N/A
Use	Variable depending building requirements
Aerosol Created	N/A (unless under fault conditions)
Comments	
Recommendations	Maintain in accordance with manufacturers/installers instructions and as required under SHTM 03-01 and SHTM 04-01 Part G (Draft).
Risk (Legionella)	Low

System	Decorative Bubble Lamps
Location(s)	Children's Hospital Atrium
Responsibility	Estates/Contractor (TBC)
Description	Decorative water and air bubble lamps
Water Source	N/A (Sealed System)
Filtration Present	N/A (Sealed System)
Running Temperature	Ambient
Use	Variable (Multiple times daily) - Bubbles released into water tubes at base when button pressed on unit
Aerosol Created	Unit appears to be completely sealed (though this requires to be confirmed) so aerosols would be contained.
Comments	
Recommendations	Maintain in accordance with manufacturers/installers instructions and ensure aerosols minimised during maintenance. If aerosols are likely to be released then this should be viewed as an "indoor water feature" and should be removed.
Risk (Legionella)	Low

LEGIONELLA RISK ASSESSMENT

Section 9

Legionella Control & Documentation

LEGIONELLA RISK ASSESSMENT

Legionella control and documentation

Inadequate management, lack of training and poor communication have all been identified as contributory factors in outbreaks of legionnaires' disease. This is particularly important where several people are responsible for different aspects of the treatment or precautions.

Communications should be 'fail-safe'. The record system is the method to ensure that precautions continue to be carried out and that information is available for checking what is done in practice.

Legionella Management Structure

Where "there is a reasonably foreseeable risk and it is reasonably practicable to prevent exposure or control the risk from exposure, the person on whom the statutory duty falls should appoint a person or persons to take managerial responsibility and to provide supervision for the implementation of precautions."

Legionella management structure	
Is there a legionella management structure in place?	General management structure in place though not specific to Legionella
Is management structure recorded in legionella management documentation?	No
Are lines of communication clearly defined and recorded within the log book/written scheme?	No
Is management structure adequate for legionella management control?	No

Persons identified within site documentation as having responsibility for legionella control:

Position	Name	Deputy
Statutory Duty Holder	To be confirmed by NHS GG&C	To be confirmed by NHS GG&C
Designated Responsible Person	To be confirmed by NHS GG&C	To be confirmed by NHS GG&C
Building Manager	To be confirmed by NHS GG&C	To be confirmed by NHS GG&C
Site Engineer	To be confirmed by NHS GG&C	To be confirmed by NHS GG&C
Legionella Consultant(s)	To be confirmed by NHS GG&C	To be confirmed by NHS GG&C
Contractors(s)	To be confirmed by NHS GG&C	To be confirmed by NHS GG&C
Others		

LEGIONELLA RISK ASSESSMENT

Who has operational control of the water systems on site? (e.g. Site/facilities company/maintenance company etc.)	To be defined as NHS Estates/NHS Projects/Building Contractor(s) all carrying out maintenance tasks independently

Comments: General management structure in place though not specific to legionella. Formal Legionella management roles and responsibilities have yet to be documented. Documentation should also include communication routes between NHS Estates, NHS Projects and Building Contractor(s).

DMA have been informed by Estates personnel there have been breakdowns in communication between Estates, Projects and Building Contractor(s) where defects highlighted by NHS Estates to other parties are being acted upon without Estates without Estates being informed to allow proper consideration of bacterial control to be made, or to review/sign off that actions have been carried out in a compliant manner minimising any potential bacterial control impacts.

Examples include:

- A direct and open connection installed by the Building Contractor(s) between the Hardgate Road mains supply and the PR 41/22/21 distribution pipe bypassing the filtration plant running for an unknown length of time which NHS Estates were previously unaware of.
- A calorifier which appeared to have been offline for over three months being reinstated by the Building Contractor(s) with no evidence of flushing/pasteurisation/disinfection.

In addition to problematic cold water temperature control (highlighted in section 7) and other mechanical concerns, a lack of defined communication between involved parties may be a contributing factor to the out of specification bacterial and legionella results recently recorded by NHS Estates.

Previous risk assessment & drawings	Produced by	Date
Previous L8 risk assessment	N/A New Building	-
Review of previous assessment	N/A New Building	-
System drawings	As fitted drawings	2015

Comments: No evidence of design or installation Risk Assessment provided to DMA.

LEGIONELLA RISK ASSESSMENT

Training	
Are training records held in logbook/record system?	No
Are competency records held in logbook/record system?	No
Have training requirements been established?	No

Comments: Training records not available at time of survey. DMA were advised not all Duty Managers have completed Appointed Person training.

Written scheme	
Is there a written scheme in place and recorded in site log book?	No
Are all tasks/duties assigned to named individuals or sub-contractors?	No
Are suitable method statements maintained in log book for all tasks/duties?	No
Is there an emergency procedure plan in place?	No
Are there procedures in place to deal with "out-of-specification" results?	Generic (from SHTM 04-01)
Does written scheme include instructions for safe operation of plant (and precautions if required)?	Generic (from Brookfield)
Are procedures for start-up and shut-down of plant included within written scheme?	No

Comments: An informal written scheme is in place at present based on SHTM 04-01 and written scheme guidance provided by DMA. However these have yet to be formulated into the Hospitals formal written scheme for on-going legionella control.

LEGIONELLA RISK ASSESSMENT

L8 monitoring		
Is a water systems monitoring regime already in place?		Partial
Are monitoring records held in suitable logbook/record system?		Records held separately
Do L8 monitoring records include:	Flushing of low use outlets?	Yes (High Risk Clinical Areas by Estates, Others by Domestic)
	Outlet temperature monitoring?	Yes (incomplete)
	Calorifier temperature monitoring	Yes (incomplete)
	Water heater temperature monitoring	N/A
	Shower/Spray Descaling	Not commenced
	Tank Inspections	Yes (Documented inspections by NHS Estates)
	Calorifier Base Flushing	Not commenced
	Calorifier Inspections	Not commenced
	C&D of Water Systems	Yes (Disinfections being carried out at present by contractors)
	TMV Servicing/Testing	Not commenced
	Maintenance/Service Records	No
	Pumps alternating	Yes (via BEMS – though BEMS records not available to NHS Estates or DMA)
	Biocidal Control	N/A
	Other (Specify)	N/A
Do all records indicate who carried out works? (e.g. Signed/Dated)		No
Are out of specification results recorded and appropriate remedial actions taken and logged?		No (e.g. no remedial actions after out of spec temperatures)
Do records go back 5 years?		Records only from handover date to NHS

Summary:

Twice weekly flushing is being carried out by NHS Estates staff in what have been deemed 'High Risk' clinical areas and by NHS Facilities (Domestics) staff in all other areas with all paper records being collated by NHS Estates. DMA noted that not all areas were flushed on each visit with some boxes left blank, some 'no accesses' recorded and no records of who completed flushing and when.

A temperature monitoring programme has recently commenced however only a small number of temperatures had been recorded at outlets by the time of assessment and daily monitoring of calorifiers (required under SHTM 04-01 as NHS Estates do not have access to the BEMS) was not recorded. TMV and showerhead ppm's had not been implemented by NHS Estates at time of assessment.

LEGIONELLA RISK ASSESSMENT

Microbiological sampling	
Is there a microbiological sampling regime in place?	Yes
Frequency of samples taken?	One-off sampling sweep being carried out prior to first patients being admitted to each department.
Are legionella samples taken as part of sampling regime?	Yes
Are potable samples taken as part of sampling regime?	Yes
Does sampling regime adequately reflect the complexity and scope of the water system?	Yes
Are suitable remedial actions and resamples taken after out of specification sample results recorded?	DMA informed localised disinfections being carried out upon receipt of out-of-specification results.
Is there a history of Legionella colonisation of the water systems on site?	Yes – positive results being reported as part of the pre-occupancy sampling sweep.

Comments:

A water sampling programme including potable samples (TVC at 22°C, 37°C, e-coli and coliforms) and Legionella samples was underway at the time or assessment with sentinel outlets due to be sampled by NHS Estates approximately six weeks prior to department/area occupation.

DMA were advised sampling being carried out in accordance with the method statement used by the main contractor prior to handover in order to ensure continuity of methodology. DMA were advised this method statement had been reviewed and deemed as acceptable by NHS Microbiologists and was not submitted to DMA for review or comment.

DMA were advised the NHS sampling programme has highlighted a number out of specification Legionella and Potable results and a responsive programme of daily flushing and local disinfections was underway in affected areas. The method statement for disinfections was not submitted for comment or review by DMA.

Logbook/Record Auditing	
Is an audit system in place for legionella management and control?	No

Legionella Management and Written Scheme Risk Rating	
Risk Rating	High

LEGIONELLA RISK ASSESSMENT

Recommendations

Inadequate management, lack of training and poor communication are all contributory factors in outbreaks of legionnaires' disease. It is therefore important that the people involved in assessing risk and applying precautions are competent, trained and aware of their responsibilities. There should be a full, site specific, management structure in place to manage and control the water system on site in order to comply with the requirements of L8/HSG 274 and SHTM 04-01 (and any other relevant guidance documents), and this should be recorded in the site legionella logbook. Lines of communication should be clear, unambiguous and audited regularly to ensure they are effective. This also applies to outside companies and consultants who may be responsible for certain parts of the control regime.

Those appointed to carry out to draw up and implement precautionary measures should have such ability, experience, instruction, information, training and resources to enable them to carry out their tasks competently and safely. They must be properly trained to a level that ensures tasks are carried out in a safe, technically competent manner; and receive regular refresher training. Training records should be held in the site logbook or clearly identified location.

A written scheme for controlling the risk from exposure to legionella bacteria should be properly implemented and managed. The written scheme should specify measures to take to ensure that it remains effective. The written scheme should include, where appropriate, and with reference to the risk assessment:

a) an up-to-date plan showing the layout of the plant or water system, including parts temporarily out of use (a schematic diagram is sufficient);

b) a description of the correct and safe operation of the system;

c) the precautions to take;

d) checks to carry out to ensure the written scheme is effective and the frequency of such checks;

e) the remedial action to take if the written scheme is shown to be not effective.

Where there is a reasonably foreseeable risk of exposure to legionella bacteria a regime for controlling the risk from exposure should be properly implemented and managed. For precautions to remain effective, the condition and performance of the system will need to be monitored. L8/HSG 274 and SHTM 04-01 require that records should be retained throughout the period they are current and for at least two years afterwards. Retain records of any monitoring inspection, test or check carried out, and the dates, for at least five years.

Site records or logbooks should include:

- System maintenance records
- Routine monitoring data
- Water treatment and service reports
- Cleaning and disinfection records
- Legionella and other microbial analysis results

Should biocide dosing be implemented a regime of flushing and monitoring is required to ensure the disinfectant reaches all parts of the system and is maintained at an adequate concentration level. All records should be signed, verified or authenticated by those people performing the various tasks assigned to them.

LEGIONELLA RISK ASSESSMENT

It is advised that legionella monitoring (sampling) be carried out where there is doubt about the efficacy of the control regime or where recommended temperatures, disinfectant concentrations or other precautions are not being consistently achieved or to prove the efficacy of the control regime in place i.e. in light of the out of specification temperatures and other issues highlighted within this report.

Where monitoring for legionella (sampling) is considered appropriate in hot and cold water systems, sampling should be carried out in accordance with BS 7592:2008 *Sampling for Legionella organisms in water and related materials*. The complexity of the system will need to be taken into account to determine the appropriate number of samples to take but wherever possible, systemic samples should be taken from separate hot and cold outlets rather than through mixer taps or outlets downstream of TMVs. This is to ensure the sample is representative of the water flowing around the system and not just of the area downstream of the mixing valve. Samples should be clearly labelled with their source location and if they were collected pre or post flushing.

In both hot and cold water systems, samples should be taken as required:

- as part of the risk assessment (DMA were not requested to carry this out)
- from areas where the target control parameters are not met (i.e. where disinfectant levels are low or where temperatures are below 55°C for hot water systems or exceed 20°C or cold water systems)
- from areas subject to low usage, stagnation, excess storage capacity, deadlegs, blind ends, excessive heat loss, crossflow from the water system or other anomaly.

In cold water systems, samples should also be taken as required:

- from the point of entry (or nearest outlet) if the water is supplied from a private water supply or where the temperature of the incoming mains supply is above 20°C from the cold water storage tank or tanks;
- from the furthest and nearest outlet on each branch of the system (far and near sentinel outlets);

In hot water systems, samples should also be taken as required:

- from the calorifier hot water outlet, if it safe to do so (some systems are under considerable pressure and the water is likely to be hot);
- from the base of the calorifier, if it safe to do so (some systems are under considerable pressure and the water is likely to be hot if there is no thermal stratification at the time of sampling);
- from the furthest and nearest outlet on each branch of a single pipe system (far and near sentinel outlets);
- from the furthest and nearest outlet on each loop of a circulating system (far and near sentinel outlets)

Section 10

Written Scheme Guidance

This section of the document sets out in writing guidance to assist the NHS Trust to create a written scheme to manage and control the risks from exposure to legionella bacteria within the South Glasgow University Hospital complex (Adult and Children's hospitals), from the commencement of the phased occupancy period which starts on 26th April.

The guidance includes domestic hot and cold water systems and other systems as identified by NHS Estates to DMA Water Treatment guided by SHTM 04-01 and L8/HSG 274.

Building Overview

The new South Glasgow University Hospital and Royal Hospital for Sick Children is a new 1109 bedded Adult Hospital and a 256 bedded Children's Hospital. This facility will have the biggest Critical Care complex and one of the biggest Emergency Departments in Scotland. The facility will offer acute specialist inpatient care, medical day care services and also outpatient clinics servicing the local population.

The 14-floor adult hospital and will contain 1,109 beds and state of the art Emergency, Acute Receiving, Critical Care, Theatres and Diagnostic Services.

The new children's hospital, with a separate identity and entrance, is adjoined to the adult hospital and with 256 beds over five storeys it will replace the existing Royal Hospital for Sick Children located in Yorkhill.

The children's hospital will provide a large number of specialist services to the West of Scotland and the wider population of Scotland in addition to the full range of secondary care services to people of Greater Glasgow and Clyde. Specialist services include: cardiology and cardiac surgery, renal and bone marrow transplantation. For a number of these specialised services, the children's hospital is recognised as the sole provider in Scotland.

The construction phase is due to end on 26th January 2015 with phased occupancy of patient areas beginning on 26th April 2015 and full working occupancy scheduled for 26th July 2015.

Risk Assessment

The assessment of risk is an on-going process and not merely a paper exercise. The Dutyholder should arrange to review the assessment regularly and specifically when there is reason to suspect it is no longer valid e.g. as phased occupancy proceeds, once occupancy is completed and all departments live etc.

Upon full occupation the Risk Assessment should be further reviewed to ensure it remains relevant to the fully functioning hospital rather than the simulated water usage conditions within unoccupied areas during the phased occupancy period.

Ongoing assessment reviews shall be required. An indication of when to review the assessment and what to consider should be recorded and this may result from, e.g.:

- a change to the water system or its use (e.g. during phased occupation period);
- a change to the use of the building/ward/clinical etc. areas;
- new information available about risks or control measures (e.g. updated legislation/SHTMs);
- the results of checks indicating that control measures are no longer effective;
- changes to key personnel;
- a case of legionnaires' disease/legionellosis associated with the system.

Greater Glasgow and Clyde Health Board Written Scheme and SHTM 04-01 Part G (Draft) provides further guidance on this matter.

Management structure:

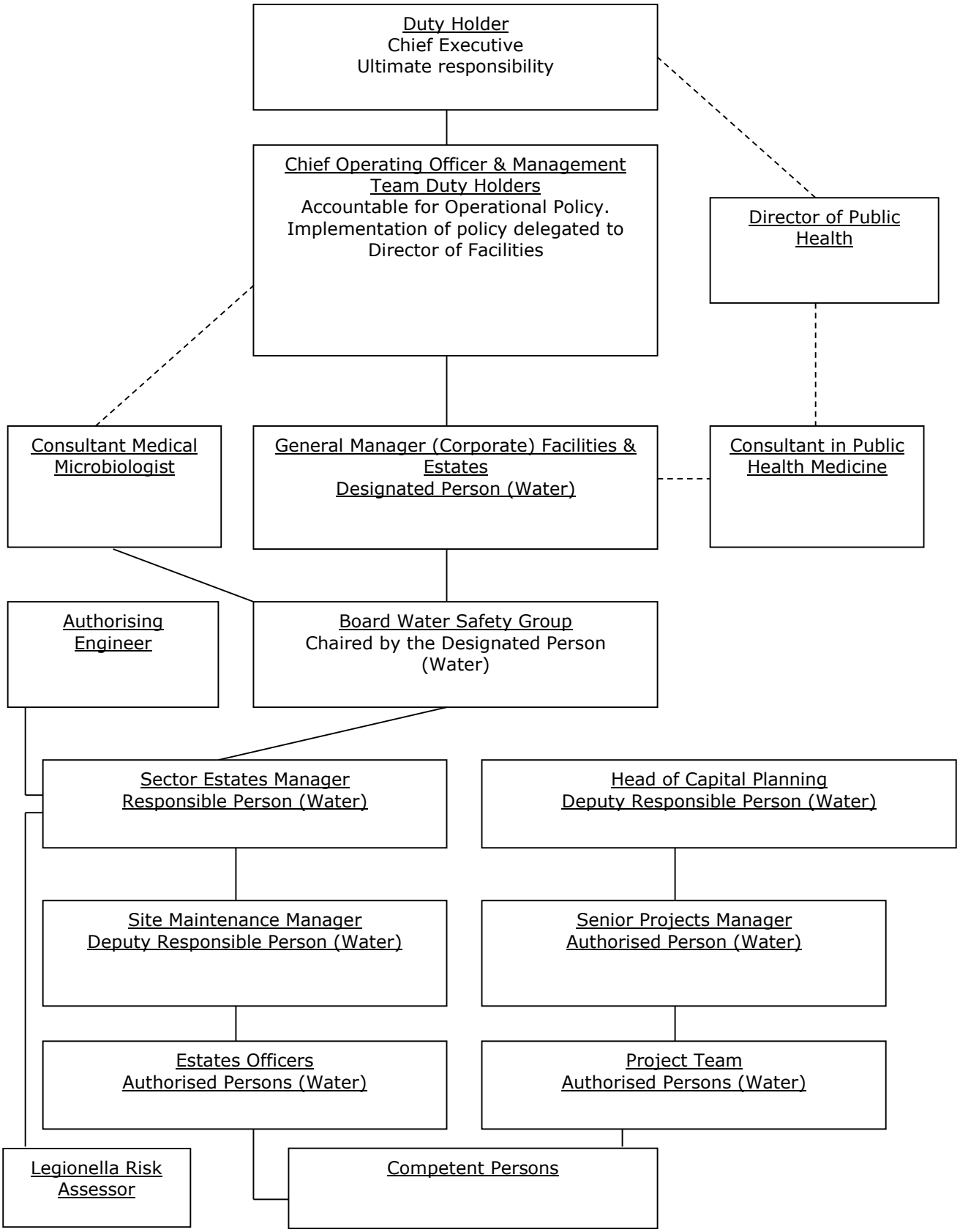
SHTM 04-01 Part B Section 2 gives guidance on Management Responsibilities and Section 6 provides guidance on hierarchy and designated staff functions along with definitions of individual positions and responsibilities. This is mirrored in Greater Glasgow and Clyde Health Board Written Scheme. These should be used when assigning specific job roles and populating the Legionella Management Hierarchy.

Management should implement a programme of staff training to ensure that those appointed to devise strategies and carry out control measures are appropriately informed, instructed and trained, and should be assessed as to their competency. It is also essential that they have an overall appreciation of the practices affecting water hygiene and safety and that they can interpret the available guidance and perform their tasks in a safe and technically competent manner. The rate of change in building service technology is not great, but knowledge of harmful bacteria continues to grow and management should review the competence of staff on a regular basis, and refresher training should be given; records of training attendance would need to be maintained. Although training is an essential element of ensuring competence, it should be viewed within the context of experience, knowledge and other personal qualities that are needed to work safely. Competence is dependent on specific needs of individual installations and the nature of risks involved.

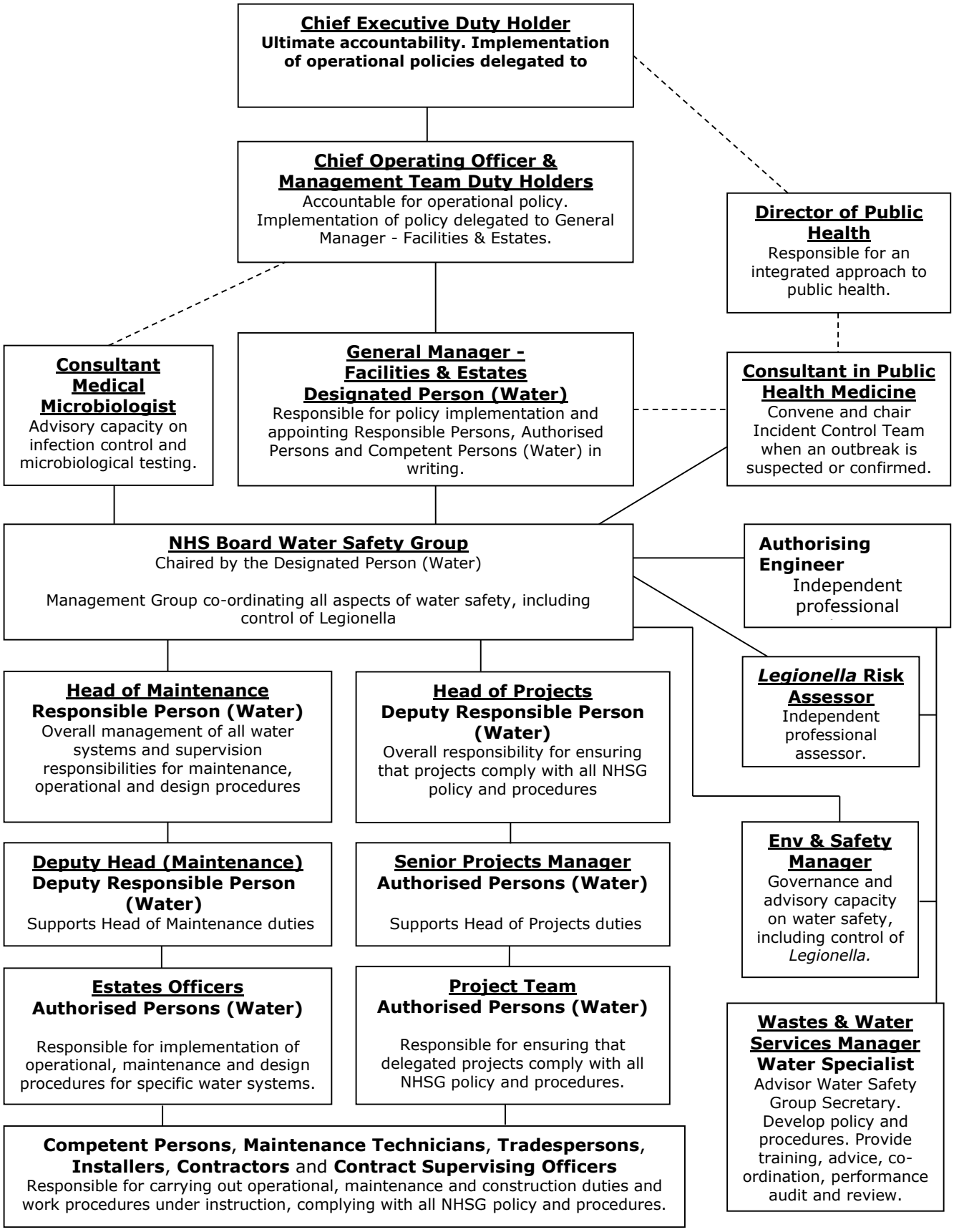
A training matrix for all persons involved in the management and/or carrying out control measures (e.g. flushing, maintenance/ppm tasks) should be created and maintained.

The management structure and roles/responsibilities should include management of contractors and communication between Estates and local duty holders in Ward/Departments for identification of underused outlets or other control issues.

Greater Glasgow and Clyde Written Scheme Hierarchy Diagram



SHTM 04-01 Part G (Draft) Written Scheme Hierarchy Diagram



Greater Glasgow and Clyde Written Scheme Hierarchy Appointment Table

Legionella Role	Name	Appointment	Generic Title	Phone
The Duty Holder			Chief Executive	
Duty Holders			Chief Operating Officer	
			Director of Facilities	
Designated Person (Water)		In writing by CEO for CE on xx	General Manager (Corporate)	
Authorising Engineer (Water)		In writing by DoF or GM (Corporate)		
Responsible Person (Water)		In writing by DoF or GM (Corporate)	Sector Estates Manager	
Deputy Responsible Person (Water)		In writing by DoF or GM (Corporate)	Site Maintenance Manager	
Deputy Responsible Person (Water)		In writing by DoF or GM (Corporate)	Head of Capital Projects	
Authorised Person (Water)		In writing by DoF or GM (Corporate)	Estates Officer, Supervisor, Water Technician	
Competent Person (water)		In writing by AP	Plumber	
Legionella Risk Assessor		In writing by Responsible Person (Water)	Sector Estates Manager	

Notes:
All persons appointed should be named in the above table. Where there are more than one member of staff nominated for a Legionella Role (e.g. Authorised and Competent Persons) each of these should be named along with the appropriate escalation pathway.

Date of training for all persons should also be recorded on this table as and when completed.

A similar table is provided within SHTM 04-01 Part G (Draft).

Others Involved

Legionella Role	Name	Appointment	Generic Title	Phone
Infection Prevention & Control			Consultant Medical Microbiologist	
Laboratory Services			Biomedical Scientist	
Governance and Advisor			Environment and Safety Support Team Manager	
Water Specialist Advisor			Wastes & Water Services Manager	
Public Health			Consultant in Public Health Medicine	
O H & S Auditor			Health & Safety Auditor	
HSE	Health and Safety Executive			

All training and competency assessments provided to and received by all NHS Board personnel involved in water systems should be recorded in the individual's personal training file and the national NHS eKSF system and site logbook.

The **Authorising Engineer** should conduct a regular annual assessment review of competency and training requirements and shall make Training Programme recommendations to the **Responsible Person (Water)** for approved courses run by approved training organisations and where appropriate by the manufacturers of equipment.

Additional roles and responsibilities during the phased occupancy period

Legionella Role	Name	Appointment	Title/Organisation	Phone	Reporting to
e.g. Estates Management	Ian Powrie		NHS Sector Estates Manager		
e.g. Role of Brookfield Multiplex					
e.g. System Designer					
e.g. System Installer	Cairan Kellegher		Mercury Engineering		
Flushing of outlets (Non-"High Risk" Areas)	TBC		NHS Facilities (Domestics)		Please see example table(s) regarding flushing responsibilities for individual areas in Appendix A
Flushing of outlets ("High Risk" Areas)	TBC		NHS Estates		
Written Scheme Guidance and Legionella Risk Assessment	Allan McRobbie David Watson	Appointed by Ian Powrie 6th January 2015	DMA Water Treatment Ltd	[redacted]	Ian Powrie NHS GG&C Sector Estates Manager

N.B. All persons appointed should be named in the above table.

Summary of L8 Management Tasks Required for L8 and SHTM 04-01 Compliance	Guidance Documents	Allocated to
Regular check to ensure that legislation and guidance has not changed	L8 HSG 274 Pt 2 SHTM 04-01	
Regular review of all policies relating to legionella control (e.g. Maintenance, Water Treatment, Water Management, Energy) to ensure still valid and correct	L8 HSG 274 Pt 2 SHTM 04-01	
Regular review of L8 Management Structure to ensure up-to-date and accurate	L8 HSG 274 Pt 2 SHTM 04-01	
Regular review of communication lines to ensure still accurate and correct	L8 HSG 274 Pt 2 SHTM 04-01	
Regular review of escalation & emergency procedures to ensure still valid and correct	L8 HSG 274 Pt 2 SHTM 04-01	
Regular review of duties allocated to site staff and ensure accurate and recorded	L8 HSG 274 Pt 2 SHTM 04-01	
Regular review of duties of sub-contractors and ensure accurate and recorded and contractors are suitably qualified/competent for tasks assigned to them (e.g. Water Hygiene contractors should be LCA Approved, Plumbing contractors should be SNIPEF and Water Safe Registered)	L8 HSG 274 Pt 2 SHTM 04-01	
Regular review of staff training requirements and update training matrix	L8 HSG 274 Pt 2 SHTM 04-01	
Regular review of method statements and risk assessments to ensure still valid and correct	L8 HSG 274 Pt 2 SHTM 04-01	
Regular review of site documentation to ensure all records up to date and present	L8 HSG 274 Pt 2 SHTM 04-01	
Regular update of "Patient Risk Rating" register for all areas of hospital.	SHTM 04-01 Part B	
Regular review of sentinel outlet locations register.	SHTM 04-01 Part B	
Regular review of primary, sub-ordinate and tertiary hot flow and return loops to reflect any system alterations.	HSG 274 Pt 2	
Regular review of plant and equipment maintenance schedules.	Manufacturer's Instructions	
Regular review of BEMS temperature sensor locations to reflect any system alterations	HSG 274 Pt 2	
Regular review of schematic/as-fitted drawings to ensure up-to-date and accurate	L8 HSG 274 Pt 2 SHTM 04-01	
Regular review of L8 risk assessment (particularly as the phased occupation process progresses) with a maximum period of two years between updates. (e.g. if change of use or changes in legislation or any other factor which could affect validity of current assessment)	L8 STHM 04-01 Part B	

N.B. By "Regular" DMA would advise a Quarterly or 6 monthly review of all tasks above or as and when there are changes in system operation, management or other control parameters which would warrant a review of any particular task. (e.g. if change of use or changes in legislation or any other factor which could affect validity any of the current documentation)

Description of Water Services

There are 2 separate incoming mains water supplies serving the Adults and children's hospital building. These enter the building in the basement manifold room and basement tank room and run into the tank room to serve 4 off Raw Water storage tanks. These incoming mains both have double check valves and water meters fitted as they enter the building. The water meters are linked to the BMS system and allow the user to cross reference the quantity of water used against the quantity indicated on the external meter. This will highlight if there are any leaks on the external water main.

Each mains supply feeds a separate side of each split Raw Water storage tank ensuring continuity of supply if one of the mains services was to be in interrupted or contaminated.

From the Raw Water tanks the water is then filtered through the filtration plant before being stored in the potable bulk cold water storage tanks. All cold water storage tanks are 2 compartment tanks and are piped in such a way as to allow tank maintenance without disrupting the water supply to the building.

There are 5 water storage tanks in the building:

- 2 No. 100,000 Litre Raw water storage break tanks
- 2 No. 275,000 Litre Potable bulk cold water storage tanks
- 1 No. 2,800 Litre Trade water storage tank

There are 2 No. water booster sets in the water tank room. Each booster set is set to a different set point pressure depending on which plantroom it serves. In the event of failure each booster can also be switched to the other set point pressure.

- BS01 – Feeding Plantroom 31, 32 & 33 - 7.7 Bar
- BS02 – Feeding Plantroom 21, 22 & 41 – 5 Bar

From the 2 No. water booster sets there are 8 domestic water systems:

- Plantroom 21
    - Via a Pressure reducing valve (PRV) the BCWS feed 21CAL01/02/03
- Plantroom 22
    - Via a Pressure reducing valve (PRV) the BCWS feed 22CAL01/02/03
- Plantroom 31 – 122
    - BCWS feeds 31CAL01/02/03
- Plantroom 31 – 128
    - Via a Pressure reducing valve (PRV) the BCWS feeds 31CAL07/08/09
- Plantroom 31 – 129
    - BCWS feeds 31CAL04/05/06
- Plantroom 32
    - BCWS feeds 32CAL01/02/03
- Plantroom 33
    - BCWS feeds 33CAL01/02/03
- Plantroom 41
    - BCWS feeds 41CAL01/02/03

The water supply into each plantroom is metered by a CWS flow meter. This allows for monitoring of specific parts of the system for energy purposes.

From the plantroom supply the BCWS is distributed to each riser and the bank of calorifiers. The water in the calorifiers is heated via a plate heat exchanger (feed from the MTHW circuit) on each calorifier skid.

The BCWS and HWS F&R are then distributed together allowing for positive separation of systems/plantrooms on the floors. The hot water is circulated to the outlet and back to the calorifiers by a hot water return pump so that temperature is maintained throughout the system. This ensures hot water is available within 1 minute at every outlet.

N.B. *Domestic water system description above as provided by Brookfield Multiplex.*

Drawings

The availability of accurate as-fitted drawings is essential for the safe operation of hot and cold water service systems. Schematic drawings of the system with numbered and labelled valves will reduce confusion and save time in trying to identify appropriate isolating valves and other system components.

The locations of as-fitted drawings and schematics should be recorded in the water system logbook(s) along with instruction on how to access them should these only be held electronically. Any alterations to the system should be recorded on all copies drawings (e.g. paper and electronic copies).

Separate schematic drawings should be prepared and displayed in in a frame in the relevant plantroom, complete with valve schedule such that all plant items, control valves etc. can be identified.

Correct and safe operation of the system

Mercury Engineering have provided documentation relating to General Start-up and Shut Down procedures for both the domestic hot and cold water systems, along with fault finding procedures and a PPM schedule for the system which should be followed. This documentation should be retained and included within the site logbook.

Water temperature, system design/installation, frequency of use, water turnover and cleanliness of the system are the most significant factors in determining the risk potential.

Incoming mains water should be delivered to site into the CWSTs at less than 20°C.

Primary water treatment is carried out by Scottish Water. NHS should confirm whether this is in the form of Chloramination or Chlorination and an appropriate monitoring regime formulated.

The water stored within the tanks should be no more than 2°C higher than the incoming mains, and less than 20°C

Cold water should be delivered to outlets (and cold feed to thermostatic mixing valves) at less than 20°C within 2 minutes of outlet being run, and not more than 2°C above outlet water source temperature.

Hot water should be stored at a minimum of 60°C, with the entire body of the calorifier achieving this temperature for a minimum period of 1 hour per day. Hot water return temperatures should maintain a minimum temperature of 55°C at all times.

Hot water should be delivered to outlets (and hot feed to thermostatic mixing valves) at more than 55°C, within 1 minute of outlet being run.

All plant should be maintained in accordance with the relevant manufacturers, and installer's instructions and the appropriate guidance documents (e.g. SHTM 04-01, L8/HSG 274).

Where deficiencies are found in the control parameters required the suitable escalation and remedial/corrective action procedures should be implemented.

All other uses of water should also be considered and appropriate action taken, as these may not be appropriate in an augmented care setting (e.g. use of ice machines, drinking water fountains, bottled water dispensers etc.). Where required, they should be considered as part of the risk assessment as there is an increased risk in compromised patients for legionella infection to occur following aspiration of ingested water contaminated with legionella.

No point of use filters for legionella control or background chemical dosing systems for legionella control are fitted at present. Details of any future policy decisions to fit, operate and maintain or remove point of use filters to/from specific points in the systems should be referenced in the written scheme and site logbook.

Initial tasks required to aid compilation of PPM schedules/registers within site written scheme	Guidance Documents	Allocated to
Identify, label and record all plant, valves and services	HSG 274 Pt 2 SHTM 04-01 (Part B)	
Identify, label and record sentinel outlets on hot and cold water services.[1]	SHTM 04-01 (Part B)	System Designer/NHS Estates
Identify, label and record all "drinking" and "non-drinking" water outlets	SHTM 04-01 (Part B)	System Designer/NHS Estates
Identify, label and record all primary, sub-ordinate and tertiary flow and return loops and their access points for temperature profile/mapping	HSG 274 Pt 2	System Designer/NHS Estates
Identify, label and record all BEMS temperature sensor locations for temperature profile/mapping	HSG 274 Pt 2	System Designer/NHS Estates
Identify, label and log all mixing devices (TMVs) with a unique identification as well as identification of its type. Hot and cold water pressures also need to be measured and recorded for each mixing device together with all the test parameters from the in-service tests	SHTM 04-01 (Part B)	System Designer/NHS Estates
Identify, label and log all "other uses of water" (e.g. use of ice machines, drinking water fountains, bottled water dispensers etc.)	HSG 274 Pt 2	

[1] Sentinel outlets are normally those that – on a hot water service – are the first and last outlets on a recirculating system with additional points on larger systems where monitoring of primary, sub-ordinate and tertiary loops is required. On cold water systems (or non-recirculating hot water systems), they are the closest and furthermost from the storage tank (or water heater). The choice of sentinel taps should also include other outlets that are considered to represent a particular risk, for example those installed in accommodation in which particularly susceptible patients are treated, or others identified in the risk assessment and temperature mapping exercise as having the least satisfactory temperature performance.

Summary of ppm tasks required within site written scheme to aid compliance with SHTM 04-01 and L8/HSG 274	Guidance Documents	Allocated to
Daily water draw-off should form part of the daily cleaning process.	HSG 274 Pt 2 SHTM 04-01 (Part B)	Domestics(?)
Daily check the flow and return temperatures on the domestic hot water calorifier systems using the temperature gauges fitted or a suitable surface temperature probe – required until such times as Estates staff have full access to BEMS system.	SHTM 04-01 (Part G Draft)	
Daily check of BEMS incidents and faults	SHTM 04-01 (Part G Draft)	
Incoming Water Mains - maintain in accordance with installation/design guidelines, ensuring alteration of incoming mains lines to run at least daily. (DMA advised 9 hourly swap over).	Brookfield Maintenance Schedule	BEMS(?)
Cyclical alteration of CWST booster pumps (ensuring every pump runs at least weekly)	HSG 274 Pt 2 SHTM 04-01 (Part B)	BEMS(?)
Daily check to ensure entire body of calorifier(top, middle, base) reaches 60°c for a period of 1 hour each day (generally at a time of low use e.g. Early morning/late evening)	HSG 274 Pt 2 SHTM 04-01 (Part A)	BEMS(?)
Daily flushing of all outlets[2] in "High Risk Areas"/ICUs. Hot and cold outlets should be flushed for a minimum of 3 minutes and until the water temperature stabilises in line with current temperature profile.[3]	SHTM 04-01 (Part G Draft) Risk Control Notice 11/04	
Twice-weekly flushing of all outlets in unoccupied areas and low use/sporadically used outlets. Hot and cold outlets should be flushed for a minimum of 3 minutes and until the water temperature stabilises in line with current temperature profile.[4]	HSG 274 Pt 2 SHTM 04-01 (Part B)	
Twice weekly flushing of emergency/deluge shower for a minimum of 3 minutes and the water temperature stabilises in line with current temperature profile.	SHTM 04-01 Part G (Draft) Risk Control Notice 11/04	
Twice weekly flushing of deadlegs/blind ends where these cannot be removed. All deadlegs should be flushed for a minimum of 3 minutes and until the water temperature stabilises in line with current temperature profile. [2]	HSG 274 Pt 2 SHTM 04-01 (Part B)	
Weekly water system check for chloramines (if required)	SHTM 04-01 (Part G)	
Weekly check to ensure that non-return valves shut off tightly. Remove covers and examine further if they do not.	Brookfield Maintenance Schedule	
Weekly check of water levels within water tanks	Brookfield Maintenance Schedule	
Check spray taps for satisfactory spray, where necessary remove spray orifice and clean, remove any accumulation of scale. *(DMA understands no spray taps fitted though this is to be confirmed)*	Brookfield Maintenance Schedule	
Monthly (minimum) manual test to confirm water system pumps operating correctly	HSG 274 Pt 2 SHTM 04-01 (Part B)	
Monthly calorifier storage temperatures checks at top (flow) and return pipework Flow temperature – min 60°C, return temperature – min 55°C[5]	HSG 274 Pt 2 SHTM 04-01 (Part B)	

Task frequencies described above are for guidance only. Frequencies may vary dependent on system conditions highlighted during routine monitoring or as risk assessment is updated.

[2] All outlets advised to be flushed daily in NHS GG&C Standard Operating Procedure (SOP) For Minimising The Risk Of Pseudomonas Aeruginosa Infection From Water

[3] Ensure aerosol creation is kept to a minimum when flushing of low use outlets and deadlegs.

[4] Ensure aerosol creation is kept to a minimum when flushing of low use outlets and deadlegs.

[5] 55°C being the control parameter DMA advised as being the design return temperature to the calorifiers on domestic hot water. (SHTM 0401 requires 50°C. HSG 274 Part 2 is contradictory, requiring 50°C in paragraph 2.156 and 55°C in Table 2.1.)

Summary of ppm tasks required within site written scheme to aid compliance with SHTM 04-01 and L8/HSG 274 (cont...)	Guidance Documents	Allocated to
Monthly temperature checks on hot outlets at sentinel, little-used & selected outlets. >55°c within 1 minute (also note potential scald risks and out of spec TMVs)[6] to create a temperature profile of building and monitor flow and return system with all primary flow and return loops being monitored monthly, sub-ordinates quarterly and tertiary loops annually.	HSG 274 Pt 2 SHTM 04-01 (Part B)	
Monthly temperature checks on cold outlets at sentinel, little-used & selected outlets. <20°c within 2 minutes to create a temperature profile of building and monitor heat gain within the cold water system.[4]	HSG 274 Pt 2 SHTM 04-01 (Part B)	
Monthly check to ensure CWST overflows are unobstructed	Brookfield Maintenance Schedule	
Monthly flushing of expansion vessels as not 'flow through' design	HSG 274 Pt 2	
Quarterly descaling, cleaning and disinfection of showerheads & hoses & spray outlets, or replace with replace with new disinfected Shower Head and Hose (or frequency as indicated by the rate of fouling or other risk factors, e.g. areas with high risk patients)	HSG 274 Pt 2 SHTM 04-01 (Part B)	
Quarterly each calorifier and any associated storage/buffer vessels should be flushed through its drain valve by opening the drain valve 3 times, each time for a 3 minute period.	SHTM 04-01 (Part G Draft)	
Quarterly servicing TMV's or mixer valves, including fail safe tests and cleaning/disinfection of strainers within "Designated High Risk Area"/ICUs (more frequently if manufacturer recommends – Documentation not available on Zutec at time of writing, or if 'drift' in excess of 1°C at mixed outlet temperature highlighted during temperature monitoring or other maintenance)	HSG 274 Pt 2 SHTM 04-01 (Part G Draft)	
Six monthly servicing TMV's or mixer valves, including fail safe tests and cleaning/disinfection of strainers. (more frequently if manufacturer recommends – Documentation not available on Zutec at time of writing, or if 'drift' in excess of 1°C at mixed outlet temperature highlighted during temperature monitoring or other maintenance)	HSG 274 Pt 2 SHTM 04-01 (Part B)	
Six monthly CWST condition inspection noting appearance of water, stagnation, odour, rust, scale, sediment, debris, paint/liner condition and bio film accumulation and tank lid fitting ok and insulation condition	Industry Good Practice	
Six monthly CWST temperature checks (summer and winter) on tank supply and stored water at opposite side from tank inlet if possible (inlet and stored water should be <20°C, with stored water no more than 2°C warmer than make-up water.)	HSG 274 Pt 2 SHTM 04-01 (Part B)	
Six monthly chemical and microbiological water samples from water tanks which feed drinking water outlets	BS 8558	
Annually arrange for samples to be taken from hot water calorifiers/water heaters in order to note condition of drain water.	SHTM 04-01 (Part B)	
Annual cleaning and disinfection CWST *and downservices* (more frequently if required dependant on CWST inspection & sample results). TVC and Legionella samples should be taken upon completion of disinfection works. **Please Note:** *Due to the system design and installation complete disinfection of all downservices fed from the Raw and Bulk water storage tanks may not be practical as "high risk" system such as renal dialysis is fed from these tanks. Alternative protocols/method statements for local disinfections should be prepared and maintained.*	SHTM 04-01 (Part B) SHTM 04-01 (Part G Draft)	
[A] Annual descaling, cleaning and disinfection of strainers (including angle valve strainers) (or frequency as indicated by the rate of fouling or other risk factors, e.g. areas with high risk patients)	HSG 274 Pt 2 SHTM 04-01 (Part B)	

Task frequencies described above are for guidance only. Frequencies may vary dependent on system conditions highlighted during routine monitoring or as risk assessment is updated.

Notes:
[A] – Brookfield Maintenance Schedule advises this task is carried out on a monthly basis.
[B] – Brookfield Maintenance Schedule advises this task is carried out on a six monthly basis.

[6] Representative outlets include conventional and mixed-temperature taps; 20% of the total number installed throughout the premises would be tested annually on a rotational basis: that is, all taps checked every five years.

Summary of ppm tasks required within site written scheme to aid compliance with SHTM 04-01 and L8/HSG 274 (cont…)	Guidance Documents	Allocated to
[B] Annual internal inspection and cleaning/descaling of the calorifier/water heater with disinfection/pasteurisation upon completion	HSG 274 Pt 2 SHTM 04-01 (Part B)	
Annual inspection of vibration coupling on pumps/plant, replacing as necessary (more frequently if recommended by manufacturer)	HSG 274 Pt 2	
Annual inspection of plant and pipework insulation, repairing where necessary.	SHTM 04-01 (Part B)	
Biennial stratification checks on plate heat exchangers/calorifiers. These checks should extend over a period of seven (7) days using a logging device to establish that the water temperature at the base of the vessel achieves 50ºC.	SHTM 04-01 (Part G Draft)	BEMS(?)
Arrange for microbiological samples to be taken from water system which represent the complexity of the water system(s) and particularly in areas of concern. All sampling should be carried out in accordance with BS 7592:2008 and all analysis by a UKAS accredited laboratory.[7]	HSG 274 Pt 2 SHTM 04-01 (Part C) GG&C Written Scheme	
[C] Pasteurisation/disinfection of calorifier/water heaters carried out as and when required dependent on temperature monitoring and sample results	HSG 274 Pt 2 SHTM 04-01 (Part B)	
Turnover test on cold water storage system. Checks should be carried out to ensure that volume of water stored is no more than would generally be used in a normal 12 hour period. **N.B.** This should be reviewed as part of the phased occupancy period with volume of sorted water adjusted as the building use alters during this process.	HSG 274 Pt 2 SHTM 04-01 (Part B)	
As required descaling of taps/outlets (including aerators and flow straighteners) (frequency dependent on inspection results and hardness of water on site)	Industry Good Practice	
All EPDM flexi hoses (where fitted to articulated taps/outlets e.g. assisted baths) should be WRAS approved and should be replaced every 2 years if alternative materials cannot be used.	Industry Good Practice	
All plant items should be maintained in accordance with manufacturer's instructions and maintenance schedules, with tasks/duties allocated and recorded.	Manufacturer's Instructions	
Filtration equipment (Elga) – maintain in accordance with manufacturers guidelines, ensuring alteration of filtration sets to run at least daily. (DMA advised 9 hourly swap over).	Elga Brookfield Maintenance Schedule	BEMS(?)

Task frequencies described above are for guidance only. Frequencies may vary dependent on system conditions highlighted during routine monitoring or as risk assessment is updated.

Notes:
[C] – Brookfield Maintenance Schedule advises this task is carried out on a monthly basis.

[7] Sampling regime should be formulated by site/client based on the known history of the water systems and the details included within this risk assessments, with assistance of specialist legionella consultant (e.g. DMA) if necessary. Although L8 does not specifically request legionella sampling, in cases where there are incorrect distribution or supply temperatures, water quality issues or other factors which may increase the likelihood of legionella proliferation and dissemination sampling should be carried out. For further guidance please refer to HSG 274 Part 2, SHTM 04-01 and BS 7592:2008

Other Risk Systems Identified to DMA

System/service	Task	Minimum Frequency
MRI Chillers Wet/Dry (Adiabatic) Cooling)	Depending on the actual design and operation of these units they may require to be registered with the local authority under the NCTEC Notification Requirements (See HSG 274 Part 1 Para 1.18 – 1.21 inclusive of Figure 1.4 and Info Box 1.1). These may also require ongoing treatment or monitoring programmes to be implemented depending on assessment. Maintain in accordance with manufacturers/installers instructions. Consider use of POU disinfection system such as UV for spray water.	TBC
	Connection point to MRI unit(s) should be included in site flushing regime and have suitable backflow protection fitted.	Twice weekly as part of site flushing regime
Emergency Showers	HSG 274 Part 3 recommends minimum six monthly flushing of emergency/deluge shower, though Risk Control Notice 11/advises "flush through and purge to drain twice per week– source SHTM 04-01 Part G (Draft). NHS Estates should formulate an appropriate flushing regime and maintain in accordance with manufacturers/installers instructions.	Twice weekly as part of site flushing regime
Dental Chairs/System	HSG 274 Part 3 states "Drain down, clean, flush and disinfect all system components, pipework and bottles twice daily. Disinfectant contact time as recommended by manufacturer. Take microbiological measurements (Refer to Decontamination HTM 01-05)	Twice daily
	SHTM 04-01 Part G (Draft) states "Drain down and clean at the end of each working day".	Daily
	HTM 01-05 provides advice and recommendations for on-going maintenance and this should be followed in addition to manufacturers and installers instructions.	As per manufacturers/installers instructions.
	Take microbiological measurements – refer to *Decontamination Health Technical Memorandum 01-05: Decontamination in primary care dental practices*[5]	As indicated by bespoke risk assessment *(to be carried out by others)*
Hydrotherapy Pool	Maintain in accordance with manufacturers/installers instructions and "PHLS Hygiene for Hydrotherapy Pools" and Pool Water Treatment Advisory Group (PWTAG) Code of Practice (Feb 2015).	Bespoke written scheme should be created for the hydrotherapy pool based on PHLS/PWTAG and manufacturers/installers instructions.

System/service	Task	Minimum Frequency
Air Conditioning & Ventilation	Maintain in accordance with manufacturers/installers instructions and SHTM 03-01 and SHTM 04-01 Part G (Draft).	Maintenance regime/Written Scheme should be created based on SHTMs and manufacturers/installers instructions.
	This may include:	
	Inspect, clean & log glass traps	Monthly
	Humidity Section Inspection, Cooling Section Inspection and Ventilation Plant Inspection and Disinfection	Six monthly
Steam Humidification	Maintain in accordance with manufacturers/installers instructions and SHTM 03-01 and SHTM 04-01 Part G (Draft). Offline at time of survey.	Maintenance regime/Written Scheme should be created based on SHTMs and manufacturers/installers instructions.
Medical Gases/Medical Equipment (e.g. Nebulisers, incubators, etc.)	Conduct a risk assessment of each system, preferably using an assessment team comprising members knowledgeable in legionella management and control, as well as those familiar with the design and operation of the system and Infection Control/Clinical staff where appropriate. Control procedures within appropriate SHTM (or other relevant guidance) for system being assessed should be taken in to account during assessment(s). Any water softeners or other filtration equipment connected to these systems should be assessed at this time. Devise a control scheme based on the risk assessment.	Monitoring, inspection, and testing frequencies to be determined as indicated by bespoke risk assessment *(to be carried out by others)*
Sprinkler System	Minimise aerosol creation during maintenance procedures. Consider wearing suitable masks to prevent ingestion as recommended by the FIA guidance. Maintain in accordance with manufacturers/installers instructions.	As per manufacturers/installers instructions.
12th Floor Heli-pad fire suppression system	Minimise aerosol creation during maintenance procedures. Consider wearing suitable masks to prevent ingestion as recommended by the FIA guidance. Maintain in accordance with manufacturers/installers instructions.	As per manufacturers/installers instructions.
	Include all points on the 12th floor Trades system (including inlet to fire tank) in site flushing regime.	Twice weekly as part of site flushing regime
Irrigation System	Include in site flushing regime. Additional flushing may also be required (outlets run for extended periods) to bring temperatures on distribution system down particularly during periods of low use (e.g. in winter when irrigation system is not required to operate frequently). Maintain in accordance with manufacturers/installers instructions.	Twice weekly as part of site flushing regime
Water Softeners	Maintain in accordance with manufacturers/installers instructions (including cleaning and disinfection of resin and brine tanks). Ensure aerosol creation is minimised during maintenance and testing procedures.	As per manufacturers/installers instructions.

Task frequencies described above are for guidance only. Frequencies may vary dependent on system conditions highlighted during routine monitoring or as risk assessment is updated.

System/service	Task	Minimum Frequency
Endoscopy Wash	Maintain in accordance with manufacturers/installers instructions and current NHS (SHTM) protocols. Ensure aerosol creation is minimised during maintenance and testing procedures.	Maintenance regime/Written Scheme should be created based on SHTMs and manufacturers/installers instructions.
Renal Dialysis (Adult)	Maintain in accordance with manufacturers/installers instructions, current NHS (SHTM) protocols and "Clinical Practice Guideline by the UK Renal Association of Renal Technologists". Ensure aerosol creation is minimised during maintenance and testing procedures.	Maintenance regime/Written Scheme should be created based on SHTMs and manufacturers/installers instructions.
Renal Dialysis (Children's)	Maintain in accordance with manufacturers/installers instructions, current NHS (SHTM) protocols and "Clinical Practice Guideline by the UK Renal Association of Renal Technologists". Ensure aerosol creation is minimised during maintenance and testing procedures.	Maintenance regime/Written Scheme should be created based on SHTMs and manufacturers/installers instructions.
Arjo Bath	Maintain in accordance with manufacturers/installers instructions. Where flexible hoses (i.e. internal to bath unit) cannot be removed then replacing with alternative WRAS approved hoses with linings other than EPDM should be considered.	As required
Closed Chilled Systems	Minimise aerosol creation during maintenance procedures. Maintain in accordance with manufacturers/installers instructions.	As required
Closed Heating Systems	Minimise aerosol creation during maintenance procedures. Maintain in accordance with manufacturers/installers instructions.	As required
Decorative Bubble Lamps	Maintain in accordance with manufacturers/installers instructions and ensure aerosols minimised during maintenance.	As required

Task frequencies described above are for guidance only. Frequencies may vary dependent on system conditions highlighted during routine monitoring or as risk assessment is updated.

Incident Plan

In the event of plant failure suppliers and installers guidance should be consulted. The location of all relevant literature should be recorded in the site logbook (e.g. Mercury fault finding guidance).

Mains and Stored Water

Currently there is no legal maximum water supply temperature from the Licensed Provider. In practice the water supply temperature to boundary point will be subject to seasonal variation. In winter this would normally be expected to be in the 5°C – 10°C range and in summer up to 20°C.

The following staged risk assessment escalation procedure should be employed where the water temperature in Cold Water Storage Tanks is 20°C or higher.

Stage 1 - Verification

- Where tepid cold water occurrence (i.e. ≥20°C) is reported from any numbers of cold water outlets, from maintenance/ppm, flushing procedures, from BEMS monitoring, or from the manual monitoring of storage tanks, the person identifying, or making a report must notify the relevant Authorised Person (Water) as soon as the problem is identified and confirm this in writing within 24 hours;

- The Authorised Person (Water) should liaise with the person identifying the problem and verify the problem by independently re-checking by means of taking the water temperature of the appropriate cold water storage tank, the temperature of each incoming mains supplies at the site boundary point (and building entry points of other buildings within the Southern General Hospital served by the same mains lines[8]) and the outflow distribution temperature;

- If the cold water storage temperature is confirmed as being 20°C or higher at any of the above noted points, then the Authorised Person (Water) should record this in writing as well as conducting continuous monitoring of the incoming cold water mains, the cold water storage and the outflow temperatures to establish the temperature profiles and in more detail over at least a one week period to determine the level of risk;

- If only one of the incoming mains lines is ≥20°C the consideration should be given to switching to the other mains supply until such times as "out-of-specification" mains line has returned to compliant parameters. Ensure if either mains line is non-operational it is included in a daily flushing regime and treated as per escalation procedures to follow.

- The Authorised Person (Water) should also review the Water Safety Log Book and take into account the recent water system history specifically to include:
    - the primary water treatment levels (for mains cold water supplied with Chlorine or Chloramination treatment);
    - any water sampling results;
    - system monitoring data including temperature monitoring and water quality chlorine or chloramination checks;
    - recent maintenance history; recent alterations, changes or additions to the water system;
    - any other changes made by Duty Holders or users of the water system;
    - On reviewing continuous monitoring temperature profiles action as Stage 2, 3 or 4 as appropriate of this escalation procedure should be undertaken. The Authorised Person (Water) will ensure that the Responsible Person (Water) is notified immediately in writing at each stage and also recorded in the Water Safety Log Book.

[8] Should other buildings within the Southern General not fall under the remit of the same Authorised Person (Water) then corresponding SGH Authorised Person (Water) should be notified of the issue to allow actions to be carried out. This escalation chain should be recorded in Greater Glasgow and Clyde Written Scheme Hierarchy Appointment Table.

Stage 2 - Initial Action – High Incoming Mains Cold Water Temperature

- Where the incoming mains cold water is 18°C or higher for more than a 48 hour period the Responsible Person (Water) should contact Business Stream (the Licensed Provider) who will work with Scottish Water to establish the reasons and determine a resolution. Continuous monitoring should continue and recorded in the risk assessment.

Stage 3 - water temperatures fluctuating above and below 20°C (but not higher than 25°C)

- Where water temperatures are fluctuating above and below 20°C in a regular cyclical manner over 72 hour periods in response to regular user water demand (but not higher than 25°C) and are more than 2°C higher than the incoming cold water mains supply temperature at the building entry point, then continuous monitoring should be continued by the Authorised Person (Water). The reason(s) for failure(s) should be identified and rectified as soon as possible. This should be recorded by updated risk assessment (specifically in relation to the patient risk rating – where there may be increased risk and appropriate actions may be required to mitigate exposure. An up to date register of all areas and their subsequent patient risk ratings should be maintained).

- considerations for failures include:
    - accuracy of temperature sensors (requiring recalibration);
    - temperature sensors being located in water (requiring reposition where tank storage levels been reduced and sensor no longer sensing stored water);
    - inappropriate standby tank configuration;
    - temperature sensor in standby system;
    - temperature sensor measuring stagnation (requires reposition);
    - inappropriate siting (not in a cool location);
    - heat gain to the tank and pipework (due to lack of appropriate insulation or located close to heat gain from other heat sources);
    - storage capacity not minimised to match daily use (12 hours storage is recommended);
    - ingress of hot water through cross connection or mixing valve failure (i.e. from DHW system or MTHW systems);

Stage 4 - water temperatures fluctuating above and below 25°C (and rarely below 20°C)

- In this situation continuous monitoring should be continued by the Authorised Person (Water), the reason(s) for failure(s) (as Stage 3) identified and rectified on an urgent basis. This should be recorded by updated risk assessment (specifically in relation to the patient risk rating – where there will be an increased risk and appropriate actions will be required to mitigate exposure. An up to date register of all areas and their subsequent patient risk ratings should be maintained);

- In this situation a permanent solution, such as ventilation for the plant room, or changing the water storage arrangements, or forming a circulating distribution system (with or without chilling depending on the circumstances) would require to be implemented;

- The Authorised Person (Water) should, unless instructed in writing to the contrary by Responsible Person (Water) implement the following:
    - arrange to drain the tank contents and clean if necessary *(and/or carry out local disinfections where appropriate)*;
    - inform the users of the failed system that they must not draw off any water from the affected system until further notice;
    - suitable disinfection of the tank and/or distribution system shall be carried out.
      Please Note: *Due to the system design and installation complete disinfection of all downservices fed from the Raw and Bulk water storage tanks may not be practical as "high risk" system such as renal dialysis is fed from these tanks. Alternative protocols/method statements for local disinfections should be prepared and maintained*;
    - thereafter the tank/local area being disinfected shall be brought back into service;
    - finally the users shall be informed that the system is back in operation.

The Authorised Person (Water) shall complete an Incident Report Record Form. An entry should also be made in the Water Safety Log Book and the Responsible Person (Water) should be notified in writing as soon as possible.

Hot Water Services

When hot water storage or distribution temperatures fall below those required (60°C storage, 55°C at outlets and returning to calorifier) these will almost inevitably be caused a mechanical fault. Appropriate maintenance procedures, including the Mercury Fault Finding guidance documents, should be created and referenced to assist in timely rectification.

This escalation procedure (taken from SHTM 04-01 Part G (Draft)) should be employed if the Calorifier/Plate Heat Exchangers outflow temperature falls below 45ºC.

The table below should be used to decide on the actions necessary in the event of a plant breakdown such as power failure or steam supply failure.

Breakdown leading to temperature <45ºC, lasting for:	**Risk Category**	**Action**
<12 hrs	High	Verify
	Significant	Verify
	Moderate	Verify
>12 hrs	High	Thermally pasteurise
	Significant	Verify
	Moderate	Verify
>24 hrs	High	Thermally pasteurise
	Significant	Thermally pasteurise
	Moderate	Verify
>72 hrs	High	Thermally pasteurise
	Significant	Thermally pasteurise
	Moderate	Thermally pasteurise

In the event of a reduction in domestic hot water temperature the **Authorised Person (Water)** should be notified in writing as soon as possible. The reason for failure must be identified and rectified as soon as possible.

The **Authorised Person (Water)** shall notify the **Duty Holder** and users on the failed system that they must not draw off any hot water from the affected services until further notice.

The relevant **Duty Holder** shall ensure that their staff are aware of the situation, and that they in turn shall prevent patients from using affected services.

Where thermal pasteurisation is to be carried out, the temperature of the calorifier or plate heat exchanger shall be raised to 70ºC, and the water shall be circulated throughout the affected distribution system for at least one 1 hour. Each tap or appliance should be run in sequence until full temperature is achieved (this should be measured). To be effective the temperature in the calorifier or plate heat exchanger should be high enough to ensure that all distribution outlets receive water at a temperature of greater than 60ºC. Ensure the return flow to the calorifier or plate heat exchanger is no less than **55ºC**.

The **Authorised Person (Water)** shall inform users that the system is back in operation.

Bacteriological samples should be taken in consultation with the Infection Prevention and Control team.

The **Authorised Person (Water)** shall complete an Incident Report Record and ensure the **Responsible Person (Water)** is notified in writing as soon as possible. Maintain hard copy records in the Water Safety Log Book.

Guidance for System Disinfections

SHTM 04-01 Part A Table 3: Water systems cleaning and disinfection

System/ Service	Circumstance Requiring Cleaning and Disinfection	Frequency
Domestic Cold Water and Domestic Hot Water Tanks	New installations and modifications or additions.	As required
	Re-commissioning empty/unused tanks.	As required
	Tank temperature exceeds 25°C. (Check with Risk Assessment).	As required
	Tank contains moderate sediment, i.e. a complete covering of the tank base.	As required
	Evidence of tank corrosion (check with Risk Assessment).	As required
	Any contamination of tank (by organic, by vermin or vermin faeces or similar).	As required
	Gross organic contamination e.g. large number of dead insects, feathers, animal or bird bodies etc.	As required
	Regular programme for high-risk healthcare category, with disinfection* where identified in the local Written Scheme (check with Risk Assessment).	Annually
	Regular programme for medium risk healthcare category, with disinfection* where identified in the local Written Scheme (check with Risk Assessment).	2 Yearly
	Regular programme for non-healthcare premises, with disinfection where identified in the local Written Scheme (check with Risk Assessment).	5 Yearly
Domestic Cold Water Distribution System	New installations and modifications or additions.	As required
	Temperature exceeds 25°C. (Check with Risk Assessment).	As required
	Any contamination of tank (by organic, by vermin or vermin faeces or similar).	As required
	Gross organic contamination e.g. large number of dead insects, feathers, animal or bird bodies etc.	As required
Domestic Hot Water Calorifier, Storage/Buffer Vessels	New installations and modifications or additions.	As required
	Temperature has fallen below 45°C.	As required
	Re-commissioning of empty/unused plant.	As required
	Any contamination of header tank (by organic, by vermin or vermin faeces or similar).	As required
	Regular programme.	Annually
Domestic Hot Water Distribution System	New installations and modifications or additions.	As required
	Temperature has fallen below 45°C.	As required
	Any contamination of header tank (by organic, by vermin or vermin faeces or similar).	As required
Air Handling Units	Any contamination (by organic, by vermin or vermin faeces or similar).	As required
	Gross organic contamination e.g. large number of dead insects, feathers, animal or bird bodies etc.	As required
	Chiller battery, drip trays and drainage pipework.	6 monthly

Notes:

- Due to the system design and installation complete disinfection of all downservices fed from the Raw and Bulk water storage tanks may not be practical as "high risk" system such as renal dialysis are fed from these tanks. Alternative protocols/method statements for local disinfections should be prepared and maintained.
- NHS/HFS Confined Spaces policies, procedures and guidance should be considered when preparing safety risk assessments and method statements for disinfection works where applicable.
- Please note that disinfectant chemical and the concentration/contact times may impact on plant and equipment warranties. This should be considered as part of any disinfection procedures.

Microbiological Sampling (Legionella)[9]

Sampling requirements and frequency are to be formulated by NHS and written scheme should be updated as appropriate.

Legionella testing may be required:

- In systems where the temperature control regimes are not consistently achieved, frequent testing e.g. weekly should be carried out to provide early warning of loss of control. Once the system is brought back under control as demonstrated by monitoring, the frequency of testing should be reviewed
- Weekly checks are recommended until the system is brought under control;
- When an outbreak is suspected or has been identified;
- In wards with at-risk patients – for example those who are immuno-compromised ("high risk patient" areas still to be confirmed to DMA).

As a minimum, samples should be taken as follows:

- From the cold water storage and the furthermost outlet from the tank, on every loop;
- From the calorifier flow, or the closest tap to the calorifier, and the furthermost tap on the hot water service circulating system (these should be identified on sentinel outlet register);
- Additional samples should be taken from the base of the calorifier via drain valves;
- From areas where the target control parameters are not met (i.e. where temperatures are below 55°c for hot water systems or ≥20°c for cold water systems);
- From areas subject to low usage, stagnation, excess storage capacity, dead legs, excessive heat loss, crossflow from the water system or other anomaly.
- High Risk Patient Areas
- Additional random samples may also be considered appropriate where systems are known to be susceptible to colonisation.

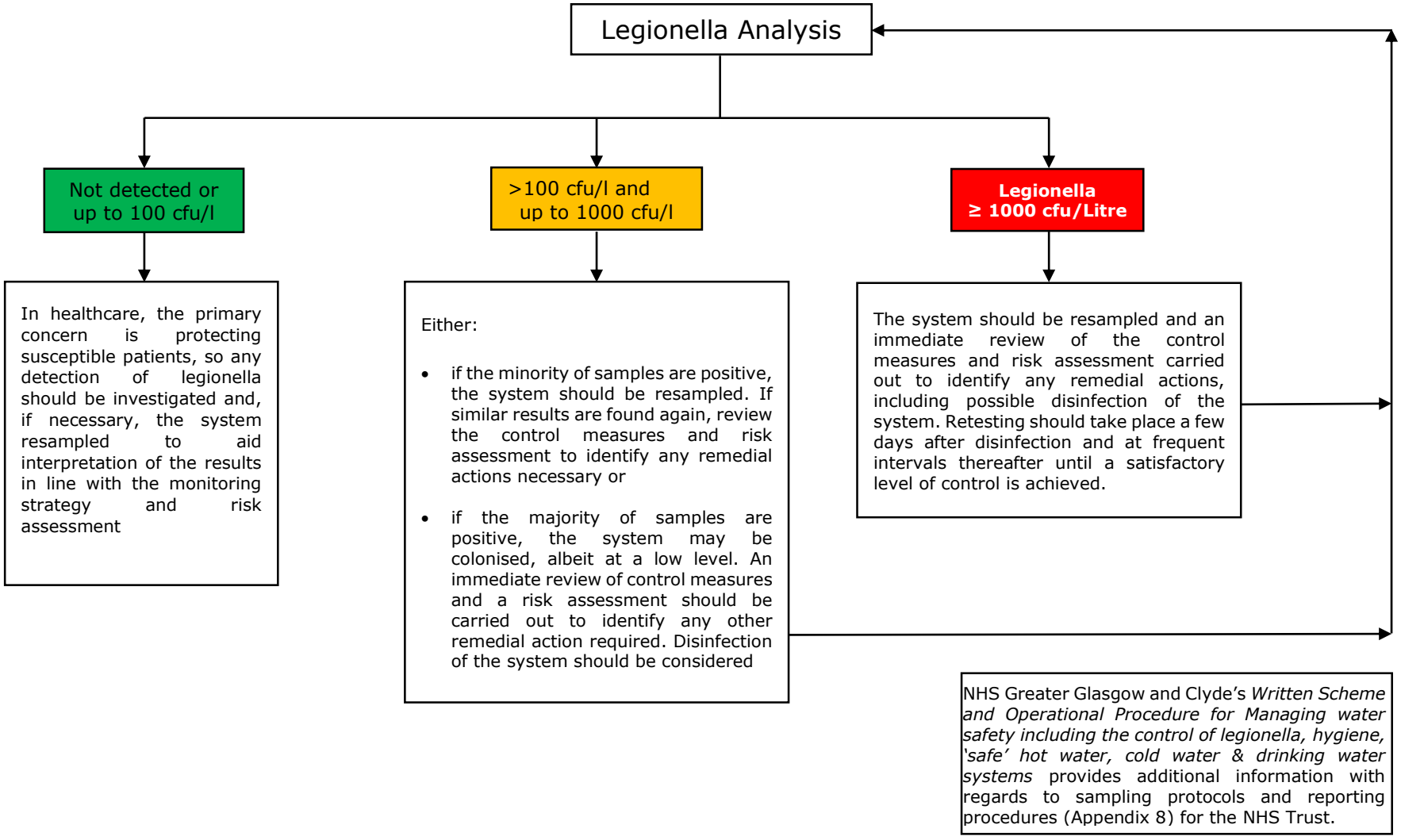
The temperature control regime is the preferred strategy for reducing the risk from *Legionella* and other waterborne organisms in water systems. This will require monitoring on a regular basis. The recommended test frequencies for various outlets are set out in Table 2 in Section 7.

HSG 274 Part 2 Table 2.3 Actions to be taken following legionella sampling in hot and cold water systems in healthcare premises with susceptible patients

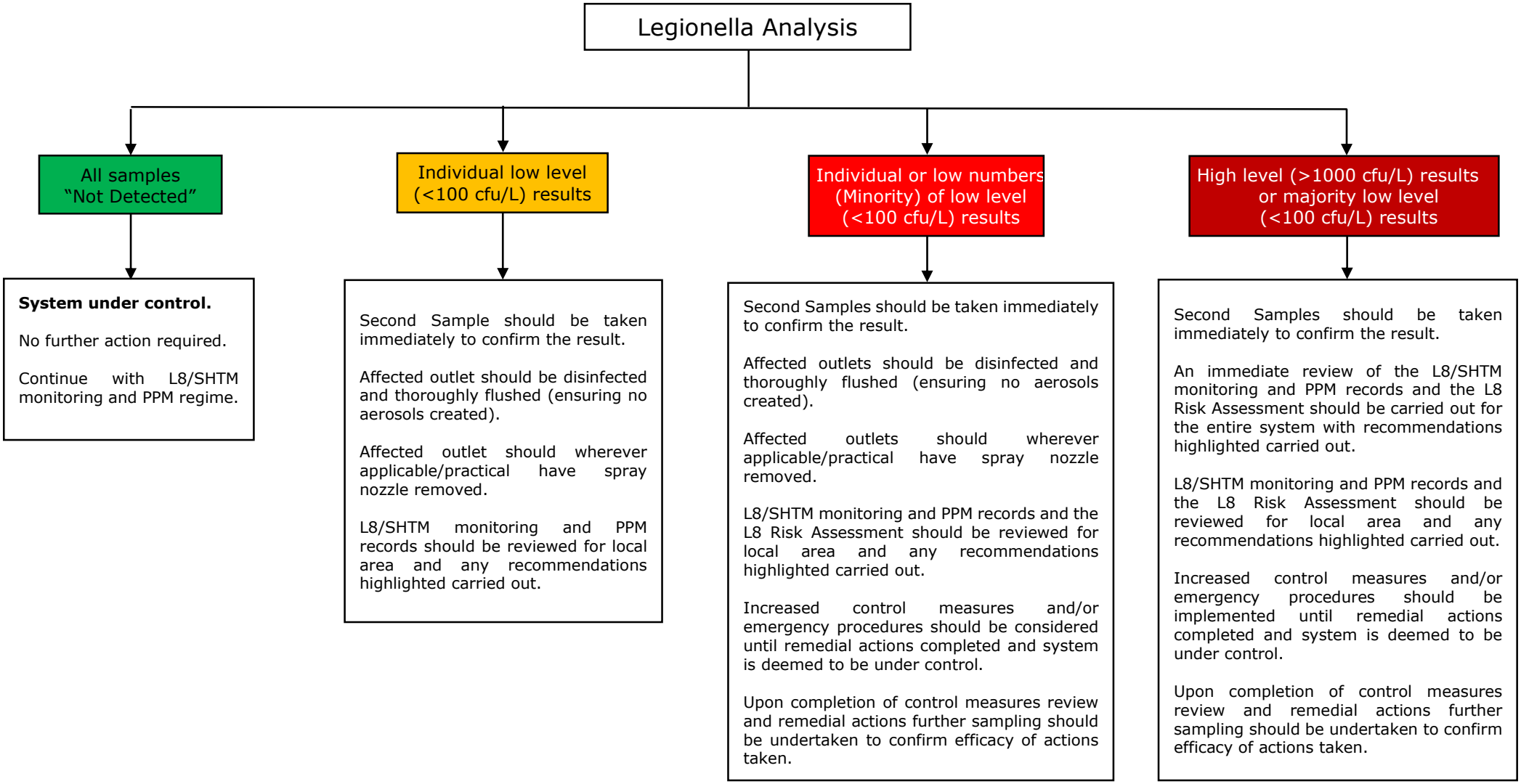
Legionella bacteria (cfu/l)	Recommended actions
Not detected or up to 100 cfu/l	In healthcare, the primary concern is protecting susceptible patients, so any detection of legionella should be investigated and, if necessary, the system resampled to aid interpretation of the results in line with the monitoring strategy and risk assessment
>100 cfu/l and up to 1000 cfu/l	Either: • if the minority of samples are positive, the system should be resampled. If similar results are found again, review the control measures and risk assessment to identify any remedial actions necessary or • if the majority of samples are positive, the system may be colonised, albeit at a low level. An immediate review of control measures and a risk assessment should be carried out to identify any other remedial action required. Disinfection of the system should be considered
>1000 cfu/l	The system should be resampled and an immediate review of the control measures and risk assessment carried out to identify any remedial actions, including possible disinfection of the system. Retesting should take place a few days after disinfection and at frequent intervals thereafter until a satisfactory level of control is achieved

[9] Sampling regime should be formulated by site/client based on the known history of the water systems and the details included within this and previous risk assessments, with assistance of specialist legionella consultant (e.g. DMA) if necessary. For further guidance please refer to HSG 274 Part 2, SHTM 04-01 Parts 2 & 3, Greater Glasgow and Clyde Written Scheme and Operational Procedure and BS 7592:2008

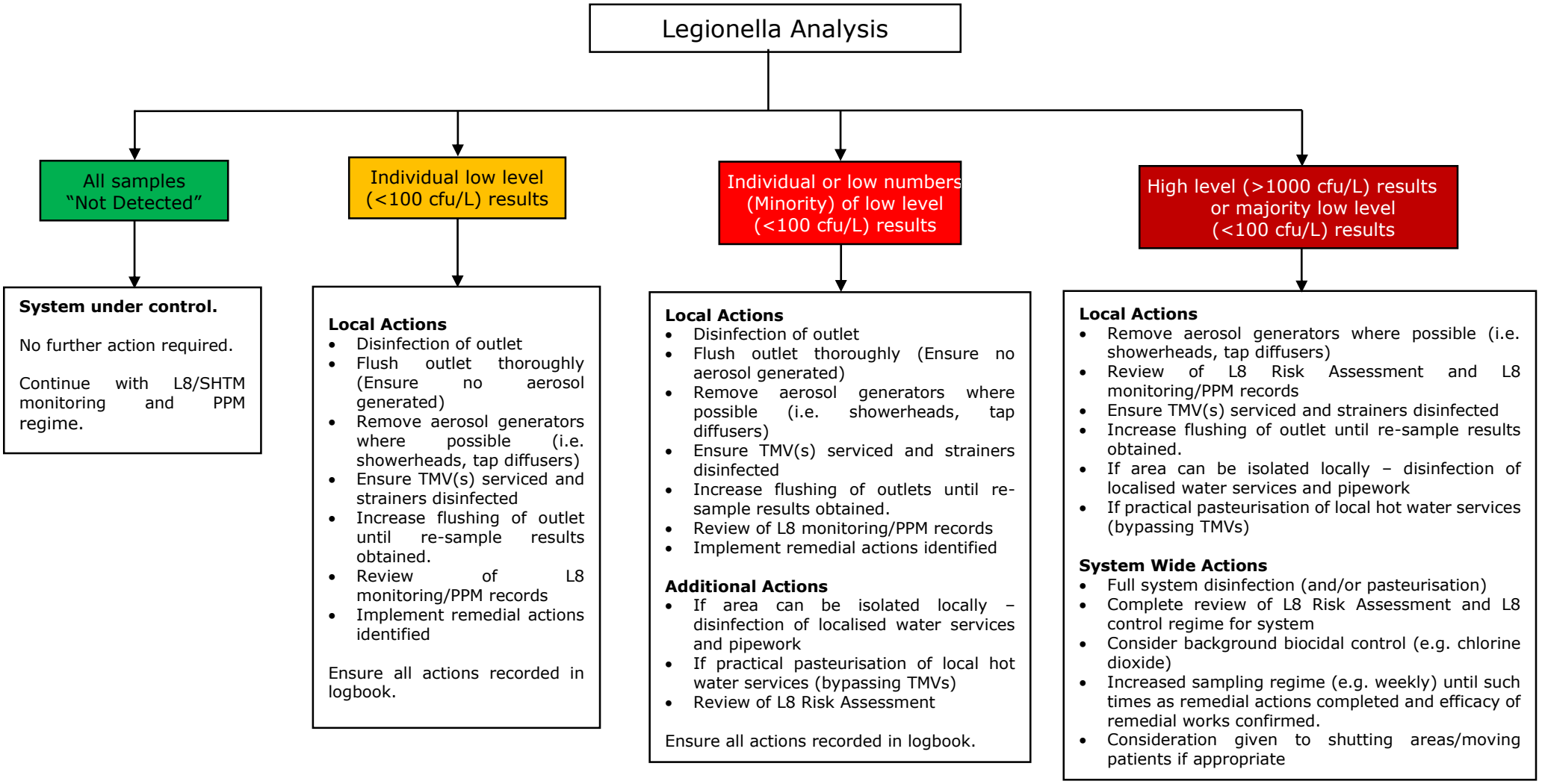
Legionella Sample Out-Of-Spec Results Escalation Procedure (L8/HSG 274 Part 2 and SHTM 04-01)



Legionella Sample Out-Of-Spec Results Escalation Procedure (Practical Guidance)



Legionella Sample Out-Of-Spec Results Remedial Actions Guidance



Microbiological (Potable/TVC) and Chemical Sampling

SHTM 04-01 Part C states:

Although TVCs are in themselves innocuous the testing procedures are intended to provide an early warning system whereby elevated TVCs should trigger some form of action to determine the identity of the organism and implement the appropriate treatment.

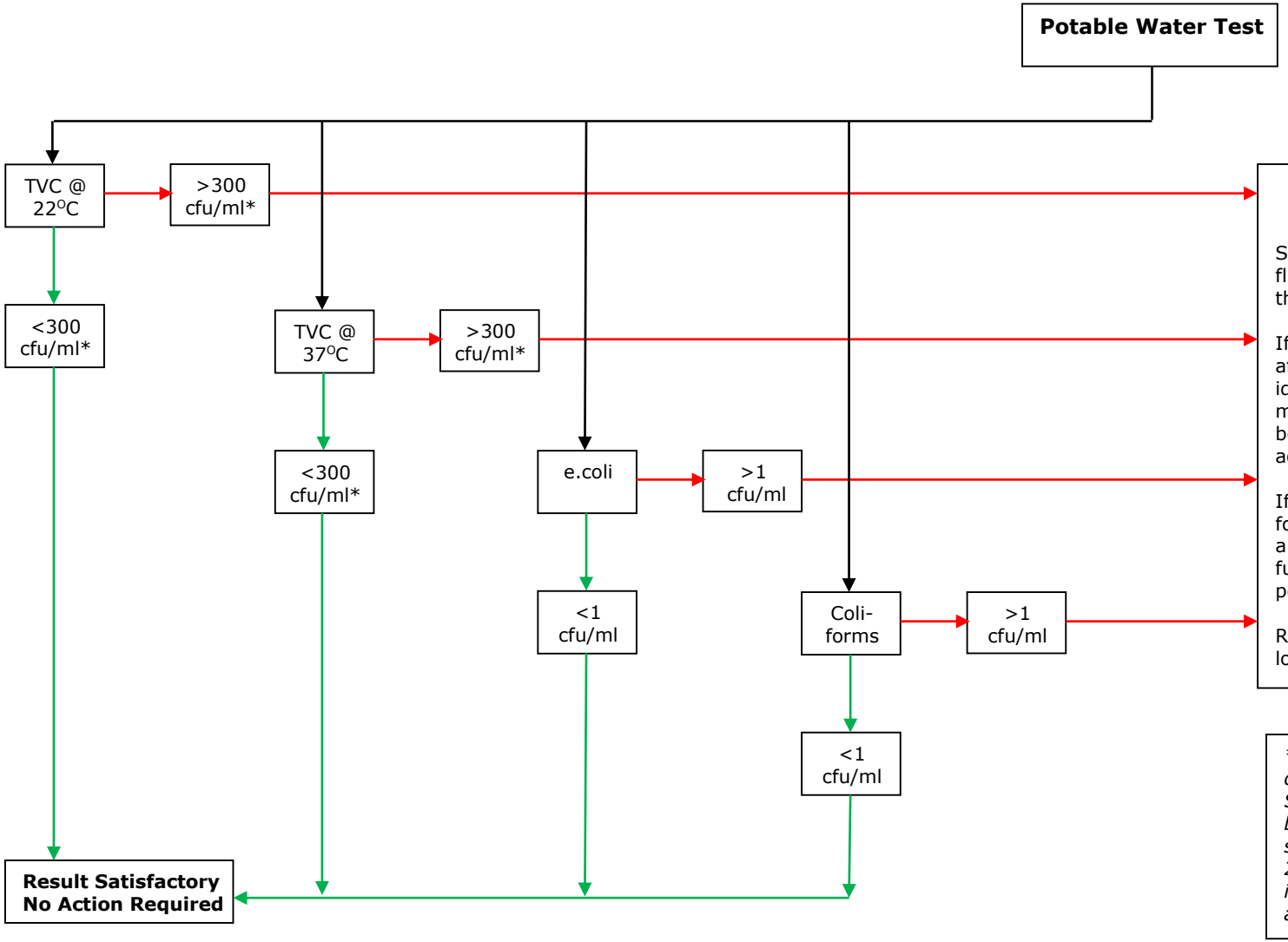
From BS 8558:2011

Regular analyses of water samples at intervals not exceeding six months should be carried out wherever drinking water is stored.

Periodic chemical and bacteriological analysis of water samples is a useful guide to the condition of an installation. For new installations in large buildings or complexes and where extensive repairs or alterations have been carried out to such installations, water samples should be collected and analysed.

Sampling requirements and frequency are to be formulated by NHS and written scheme should be updated as appropriate.

Potable Water Sample Out-Of-Spec Results Escalation Procedures



Result(s) Out of Specification

Sample point should be thoroughly flushed and cleaned/disinfected and then sample point re-sampled.

If 2nd Resample then area around the affected outlet should be inspected to identify potential problems, and control measures and risk assessment should be consulted to identify any remedial actions required.

If multiple out of specification results for a single system are identified then a full system disinfection in addition to further investigation to ascertain potential contamination issues.

Record actions and findings in site logbook.

** Please note that there are no definitive guidance limits for TVC. Scottish water advise that there should be "no abnormal change" and BS 8558 states "e.g. TVC results in excess of a 2 log difference above that found in incoming mains water, corrective action should be taken"*

The Course of Action for Suspected Nosocomial Legionnaires' Disease

from SHTM 04-01 Part G (Draft)

Suspected or confirmed incident or outbreak

NHS Board will follow the guidance presented in the following regulatory and mandatory guidance documents:

- HSE ACOP L8 "The control of *Legionella* bacteria in water systems", see Appendix 2;
- SHTM 04-01 "Water safety for healthcare premises", Part B, Appendix 1;
- HPN2, "Guideline on management of *Legionella* incidents, outbreaks and clusters in the community";
- The *NHS Board* "Outbreak Plan".

Legionellosis is an atypical and potentially life-threatening form of pneumonia (Legionnaires' Disease). The majority of cases are isolated although outbreaks can occur (including large community outbreaks and hospital outbreaks).

In the event of a nosocomial case(s) of Legionnaires' disease *NHS Board* will follow the Health Protection Network's (HPN) – *'Guideline on Management of Legionella, Incidents, Outbreaks and Clusters in the Community'* (2009), SHTM 04-01 and *NHS Board's* Outbreak Plan.

An outbreak is defined in HSE ACOP L8 by the Public Health Laboratory Service (PHLS) as two or more confirmed cases of *Legionellosis* occurring in the same locality within a six month period. However:

- HPN2 sets out and defines:

Incident	A (first) single case – presumptive or confirmed- where based on the evidence there are concerns about actual or suspected threats to the safety or quality of water systems that could require intervention to protect the public's interest.
Sporadic case	A single case not associated with any other case. No other case may be linked to probable source of exposure in last 2 years.
Outbreak	Two or more cases in the same locality for which there is strong epidemiological evidence of a common source of infection, with or without microbiological evidence, occurring within a 6 month period of the onset of illness from the first case confirmed.
Linked case	Two or more cases associated with a single source with dates of onset more than 6 months apart but less than 2 years apart.
Probable Nosocomial	Legionnaires' disease in a person who was in hospital for between one and nine of the ten days before the onset of symptoms and either became ill in a hospital associated with one or more previous cases of Legionnaires' disease or yielded an isolate that was indistinguishable (by monoclonal antibody subgrouping [mAB] or by molecular typing methods) from isolates obtained from the hospital water system at about the same time.
Possible Nosocomial	Legionnaires' disease in a person who was in hospital for between one and nine of the ten days before the onset of illness in a hospital not previously known to be associated with any case of Legionnaires' disease and where no microbiological link has been established between the infection and the hospital.

The *NHS Board* "Outbreak Plan" defines an outbreak and incident as:

- "An outbreak is defined either as two or more linked cases of the same illness or when the observed number of cases exceeds the number expected;
- An incident is defined as a case of communicable disease that has actual or potential serious implications for the public's health e.g. VHF or measles in a health care setting. An Incident Management Team (IMT) should be established using the approach described in this plan."

Actions

A nosocomial case(s) of Legionnaires' disease (definite/probable/possible) should be investigated immediately.

An Incident Management Team (IMT) or an Outbreak Control Team (OCT) will be convened for a single case or an outbreak of nosocomial Legionnaires' disease respectively;

The IMT/OCT will be convened by the Consultant in Public Health Medicine (CPHM) with responsibility for Health Protection (or the duty CPHM). The CPHM will lead and co-ordinate the investigation and control of the incident/outbreak in close collaboration with the Infection Prevention and Control Doctor. Further information on the roles and responsibilities of the different members of the IMT/OCT can be found in NHS Board's Outbreak Plan;

In the event of a case(s) of nosocomial Legionnaires' disease the following people/groups will be members of IMT/OCT and will be briefed by the CPHM:

- Consultant in Public Health Medicine (IMT/OCT Chair);
- Consultant Physician (involved with care of case);
- Consultant Medical Microbiologist/Infection Prevention and Control Doctor;
- Infection Prevention and Control Nurse;
- Health Protection Nurse Specialist;
- Facilities & Estates Department ;
- Environmental Health Officer;
- Health & Safety Executive;
- Health Protection Scotland;
- Reference Laboratory;
- Corporate Communications (*NHS Board*);
- Other members from partner agencies as decided by IMT/OCT Chair.

Guidance on the general response to a case(s) of nosocomial Legionnaires' disease can be found in the HPN Guidance, Section 3.1.1.2 and NHS Board's Outbreak Plan.

Completed Tables on Pages 3 – 6 should be used for contact details in the event of a confirmed or suspected incident:

Legionella Role	Name	Title	Phone
Designated Person (Water)			
Responsible Person (Water)			
Responsible Person, Defined			
Advisor Responsible Person, Defined			
Infection Control			
Laboratory Services			
Authorising Engineer			
Wastes & Water Services Manager – Water Specialist Advisor			
Public Health			
HSE			
Health Protection Scotland		Duty Epidemiologist advised by Public Health	
Reference Laboratory Microbiologist		Duty Microbiologist advised by Public Health	

When it is unclear whether there is a threat to public health the CPHM may choose to convene a Problem Assessment Group (PAG) in order to undertake an initial assessment of the problem and determine if an IMT is required. Further information on the role of the PAG can be found in the Scottish Government guidance on the *Management of Public Health Incidents: Guidance on the Roles and Responsibilities of NHS led Incident Management Team: October 2011*.

The general response to an incident or outbreak may include:

- investigation of all potential sources of *Legionella* infection. This shall include checking recent maintenance work and project work that may have been carried out on water or air handling systems;
- identifying the location of any medical equipment used for dental care, respiratory therapy and within Haemodialysis units;
- identifying off-site information such as excavation or earth moving works, alterations to water supply and drainage;
- shutting down any processes which are capable of generating and disseminating airborne water droplets and keeping them shut down until sampling procedures and any remedial cleaning or other work has been done. Final clearance to restart the system may be required;
- taking water samples from the system before any emergency disinfection being undertaken. This will help the investigation of the cause of the illness. The investigating officers from the local authority may take samples or require them to be taken;

- co-operating fully in an investigation of any plant that may be suspected of being involved in the cause of the outbreak. This may involve, for example:-
  - tracing of all pipework runs;
  - detailed scrutiny of all operational records;
  - statements from plant operatives and managers;
  - statements from water treatment contractors or consultants;
- any emergency cleaning and disinfection will be undertaken in accordance with *NHS Board* procedures;
- the **Designated Person (Water)** shall brief relevant Estates staff so that they are aware of the event and can respond to phone calls etc as instructed. The briefing shall include instructions that any comments to outside parties are agreed by Infection Prevention and Control;
- records shall be kept of all relevant information, including that provided by other departments.

Emergency cleaning and disinfection of water systems

If a water system, other than a cooling system, is implicated in an outbreak of Legionnaires ' disease, emergency treatment of that system should be carried out as soon as possible. This will involve disinfection as set out in Section 17 of SHTM 04-01 Part A and site method statements.

Documentation and Records

The documentation and records of all work undertaken to prevent the growth and spread of Legionella require to be maintained and performance reviewed by the Authorised Person. An index of all relevant documentation and records including location of supporting documentation identified in SHTM 04-01 Part G (Draft) such as 'Operational Procedures for the Written Scheme', Control of 'Water Records Forms' and 'Guidance for Alterations to Water Systems' should be formulated.

Examples of forms and procedures which may be used in formulation of the written scheme are provided below and in SHTM 04-01 Part G (Draft)

Appendix 1

Example Low Use (Sporadically Used) Outlet Flushing Responsibility Structure

Document Review Date	
Reviewed By	

Area/Ward	Location	Outlets Identified as Requiring Flushing	Locally Nominated Responsible Person (LNRP)	Person(s) Flushing Tasks Delegated To	Frequency of Flushing Required	Last update from LNRP (Date)
e.g. Haemo-oncology Ward	Fourth Floor Ward 4B		Ward Sister (?)		Daily	
e.g. Restaurant and Visitor Dining	First Floor		Domestics (?)		Twice Weekly	
e.g. Main Kitchen	Third Floor		Domestic (?)		Twice Weekly	
e.g. Roof Garden	Third Floor		Estates (?)		Twice Weekly	
e.g. Schiehallion Ward	Ward 2A Children's Hospital		Ward Sister (?)		Daily	

N.B. This register is in addition to the daily water draw-off from all outlets which should form part of the daily cleaning process.

Appendix 2

Example Register of 'Little' or 'Sporadically' Used Outlets and Showers

Area/Ward	**Location**	**Document Completion Date**	
		Completed By	

Room	Outlets Identified as Requiring Flushing	Dates Outlet(s) identified as requiring flushing	Reason	Frequency of Flushing Required	Dates Outlet(s) confirmed as no longer requiring flushing	Reason
e.g. 7	Toilet WHB, WC & Shower	01/01/15	Bedridden user	Twice Weekly		
e.g. DSR	All	01/01/15	Used as Store	Twice Weekly		
e.g. 12	All Outlets	01/01/15	Room Empty	Twice Weekly		

N.B. This register is in addition to the daily water draw-off from all outlets which should form part of the daily cleaning process.

Appendix 3

Example Method Statements

Method statements for mechanical tasks (e.g. checks to ensure pumps operating correctly, water tank level checks, TMV servicing) should be referenced or inserted into this section.

All record sheets should be signed by person carrying out the task with date and time of operation recorded.

Sentinel Outlets and Outlet Temperature Monitoring

Equipment required: Calibrated Thermometer with surface and immersion probe, Sentinel & Outlet Register
Method of identifying and recording outlet locations/asset number (e.g. barcode, QR, IR) and data capture method to be confirmed.

1. At each sentinel outlet location, inspect outlet and note any issues (e.g. out of order outlets, scale build-up, damaged diffusers).
2. Run cold tap for 2 minutes and monitor temperature throughout.
3. Record temperature after 2 minutes and any observations (e.g. heat gain/spike, temperature slow to fall, discoloured water etc.)
4. If temperature is 20°C or above (or anomalous with current temperature profile) record along with any noticeable reason for high temperature.
5. Run hot tap in first sentinel location for 1 minute and monitor temperature throughout.
6. Record temperature after 1 minute and any observations (e.g. heat loss, temperature slow to rise, discoloured water etc.) If temperature is 55°C or below (or anomalous with current temperature profile) record along with any noticeable reason for low temperature.
7. Repeat procedures 1 - 6 for each sentinel outlet location
8. Repeat procedures 1 - 6 for subsample of other outlets, aiming to cover 20% of outlets over the course of 12 months, with all outlets being monitored over a 5 year period (or a pre-defined period of time).
9. If unused outlets or unrecorded deadlegs or other issues are observed these should be recorded to allow remedial actions to be taken and appropriate registers to be updated.

Hot Flow and Return Loop Temperature Monitoring

Equipment required: Calibrated Thermometer with surface contact probe, Register of primary, sub-ordinate and tertiary hot flow and return loops
Method of identifying and recording flow and return locations (e.g. barcode, QR, IR) and data capture method to be confirmed.

1. Using contact probe record temperature at flow and return principle loops (monthly), sub-ordinate loops (Quarterly) and tertiary loops (annually) to create a temperature profile of building and monitor flow and return system. If temperature is 55°C or below record any noticeable reason for low temperature.

Where appropriate temperatures should be compared to those from BEMS to identify any discrepancies.

Calorifiers Temperature Monitoring

Equipment required: Calibrated Thermometer with surface contact probe, Calorifier Register
Method of identifying and recording calorifier locations/asset number (e.g. barcode, QR, IR) and data capture method to be confirmed.

1. At each calorifier inspect pipework & plant and note any relevant issues.
2. Record temperature of hot water flow as close to each calorifier as possible. If temperature is below 60°C record any obvious reason for low temperature and follow appropriate escalation procedures.
3. Record temperature of hot water return as close to each calorifier as possible. If temperature is below 55°C record any obvious reason for low temperature and follow appropriate escalation procedures.

Where appropriate temperatures should be compared to those from BEMS to identify any discrepancies.

Flushing Calorifier Drain/Base

Equipment required: Calibrated Thermometer with immersion probe, Calorifier Register, Suitable PPE
Method of identifying and recording calorifier locations/asset number (e.g. barcode, QR, IR) and data capture method to be confirmed.

1. At each calorifier inspect pipework & plant and note any issues, and ensure safe to proceed.
2. Attach hose to drain of calorifier and run to drain in plantroom or place suitable container under calorifier drain.
3. Suitable isolation should be carried out to ensure calorifier base is purged and not supply/distribution pipework only (e.g. isolate cold feed supply valve)
4. Test drain to ensure working correctly and will open/close safely. Record and escalate any faults as appropriate.
5. Calorifier drains should be opened and water flushed to drain until water runs clear and for a further 3 minutes. This procedure should be repeated 3 times for each calorifier.
6. Record temperature of water running from the calorifier base.
7. Close calorifier drain and dispose of collected water (if applicable)
8. Record water quality discharged from drain (e.g. clear, dirty for 10 seconds). Where water quality is poor and/or temperature indicates potential legionella control problems this should be escalated as appropriate.

Cold Water Storage Tank Inspection

Equipment required: Calibrated Thermometer with immersion probe, CWST Register, Suitable PPE, Camera, Torch
Method of identifying and recording calorifier locations/asset number (e.g. barcode, QR, IR) and data capture method to be confirmed.

1. At each CWST inspect pipework & plant and note any issues, and ensure safe to proceed.
2. Check security of tank lid and hatch(es).
3. Check integrity of rodent screens on overflow/warning pipes.
4. Check integrity of tank lid vents.
5. Open lid hatch(es) and inspect internal surfaces for signs of contamination/fouling and water clarity/quality within the tank. Record observations and escalate any faults as appropriate.
6. Take photographs of internal condition of tank, and any other relevant issues.
7. Record temperature of make-up water[10] noting which supply this relates to (e.g. Govan Road, Raw CWST 1A/B) and stored water as remote from inlet as possible - both should be below 20°C. Any variation of 2°C may indicate excess storage or low turnover and should be escalated as appropriate.

[10] This step should be repeated to ensure all supplies are recorded on each inspection cycle.

Cleaning, Descaling and Disinfection of Showerheads and Hoses (in-situ)

Equipment required: Outlet (or Shower) Register, Showerhead Plus Legionella specific descaler/degreaser, suitable lidded container, manual cleaning utensils (e.g. clean cloth, small soft brush)
Method of identifying and recording outlet/shower locations/asset number (e.g. barcode, QR, IR) and data capture method to be confirmed.

1. At each shower location, inspect outlet and record any issues (e.g. out of order outlets, scale build-up, damaged fittings, heads, hoses)
2. Remove shower head (and hose where applicable).
3. Dismantle removable parts (if possible) and physically clean.
4. Submerge the components in a solution of Showerhead Plus Legionella specific descaler/degreaser (maximum dilution 3-1) for a minimum time of 2 minutes ensuring colour is still yellow indicating active product present.
5. Remove components and flush disinfectant solution from external surfaces using fresh water.
6. Replace showerhead (and hose), purge vigorously with fresh water and return to normal service.
7. If adjustable showerhead is noted as present this should be recorded and escalated as appropriate for replacement.
8. Record actions and any issues and escalate as appropriate.
9. Where significant fouling is recorded frequency of cleaning, descaling and disinfection should be reviewed.

Flushing of Low Use/Sporadically Used Outlets

Equipment required: Calibrated Thermometer with surface and immersion probe, Register of 'Little' or 'Sporadically' Used Outlets and Showers (this will be "every outlet" in unoccupied areas/departments during the phased occupation period until full occupation).
Method of identifying and recording outlet/shower locations/asset number (e.g. barcode, QR, IR) and data capture method to be confirmed.

1. At each outlet location, inspect outlet and note any issues (e.g. out of order outlets, scale build-up, damaged diffusers).
2. Each outlet(s) shall be opened and flushed for a minimum of 3 minutes and the water temperature stabilises in line with current temperature profile.
3. WCs (where fitted) should be flushed on entry to the room and again prior to leaving room, whilst the other outlets are being flushed.
4. Where connection points are fitted awaiting equipment installation (or other deadlegs) these should be flushed as per point 2.
5. Flushing of multiple outlets at the same time (and indeed may be advantageous) in a room/area is perfectly acceptable so long as all outlets are flushed as per Point 2.
6. Record actions and any issues and escalate as appropriate.

Flushing Notes:

- Minimise aerosol creation wherever possible (E.g. do not fit showerheads until rooms are to be occupied)
- If flushing multiple outlets simultaneously care should be to ensure sinks etc. do not overflow.

Section 11

Photographic Appendix

LEGIONELLA RISK ASSESSMENT

Govan Road mains entry point

Govan Road mains – drain/injection points on supply to raw water CWSTs

Hardgate Road mains including temporary supply for commissioning

Typical CWST drain – tight to base

Emergency bypass points fitted around CWSTs (bulk CWST 2 pictured)

Bulk water pump bypass

LEGIONELLA RISK ASSESSMENT

Typical emergency bypass connection point (Bulk CWST 1 pictured)

Typical pump manifolds (Bulk pumps pictured)

Filter set bypass/switch over point

Drain off point at filter set

Trade boosters with manifold and expansion vessels (not flow through)

Hydrotherapy pool plant not yet completed or connected to water system at time of survey

LEGIONELLA RISK ASSESSMENT

Mains into T1A shut down for a number of weeks causing stagnation in T1A. T1A outlet still live to system.

Bypass fitted between Hardgate Road mains and booster set which has bypassed filtration systems.

Trades CWST RHS isolated creating deadlegs on mains and inlet. CWST was still full on stagnant water. Outlet was then reinstated releasing potentially stagnant water into system.

Hydrotherapy pool top up tank

Deadleg pipework in hydrotherapy pool plant room

Dump valves on cold water system – NHS Estates advised the system is working incorrectly as sensors positioned incorrectly

LEGIONELLA RISK ASSESSMENT

RPZ valve fitted on line to adiabatic chillers for MRI system. Check valve recommended at tee-off to all closed system tops or similar low flow areas to minimise potential for system contamination from low flow area.

Unused equipment connection points found throughout building. These were not included in flushing regime at time of report.

Unused equipment connection points found throughout building. These were not included in flushing regime at time of report.

Some very local lengths of insulation missing

Typical installation Non Clinical (Toilet) WHB

Typical installation Clinical WHB

LEGIONELLA RISK ASSESSMENT

Typical WC installation

EPDM flexible hoses fitted at double level sinks in facilities room (DSR's)

Small copper tails visible on Infra Red taps and Armitage Shanks taps in Endoscopy Wash Room

Sprinkler tank shut off at time of survey

EPDM flexible hose to dishwashers

Some areas used as stores or still under construction cannot not be accessed for flushing

LEGIONELLA RISK ASSESSMENT

Flexible hoses on pressure reducing valves (assume to be EPDM)

Typical calorifier set up. Expansion vessels are not flow through. (P31 04-05-06 pictured)

Spare pumps should be kept sterile where possible

Typical bib tap from trade water system

Steam humidifiers (P41 pictured)

Non return valve on tee off to pressurisation unit/fast fill (P21 pictured)

LEGIONELLA RISK ASSESSMENT

Generally drain points in risers appeared to be as close as possible to tee off point (New Childrens Hospital 4th floor pictured)

Drain point in P21

Drain points at bottom of risers/drops

Local outlet connections (CO OPD 140 pictured)

Local shower connection (C1 23HU-047 pictured)

Angle strainer valves on supplies to TMV Taps (C1 23HU-047 pictured)

LEGIONELLA RISK ASSESSMENT

Runaround Coil Pressurisation Unit Connection (Plantroom 22)

“Classroom” (SCh-077) still under construction – sink locations etc. marked on wall though no pipework fitted at time of survey.

“Classroom” (SCh-077) still under construction – sink locations etc. marked on wall though no pipework fitted at time of survey.

Tee-piece connections in risers.

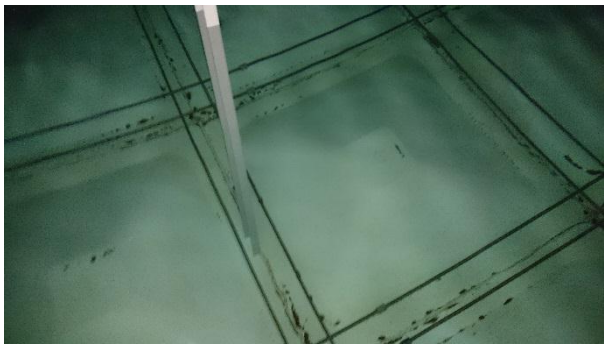
Low Hot return temperature (Gauge) Plantroom 33 (Cals 33-07/08/09 27/04/15)

Low Hot return temperature (Gauge) Plantroom 33 (Cals 33-07/08/09 27/04/15)

LEGIONELLA RISK ASSESSMENT

Trade LHS CWST

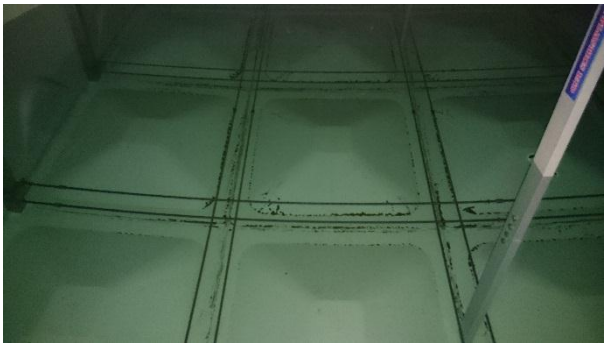
Trade RHS CWST



Raw 1A CWST

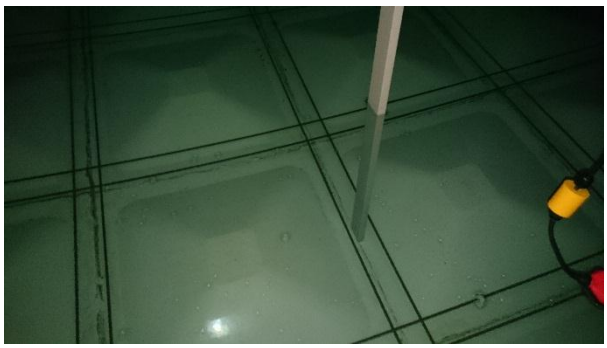
Raw 2A CWST

Raw 1B CWST



Raw 2B CWST

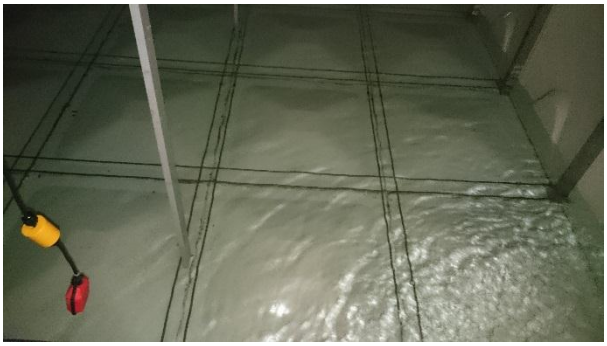
LEGIONELLA RISK ASSESSMENT



Bulk A1 CWST

Bulk A2 CWST

Bulk B1 CWST



Bulk B2 CWST

AHU Trap (Clear water within trap)

AHU Trap (Cloudy water within trap)

LEGIONELLA RISK ASSESSMENT

"Bubble Tube" in Children's Hospital atrium.

Children's Renal Unit CWST

Dental Booster System (off at time of survey)

Dental CWST (Empty at time of survey)

Dental Chair

Dental Chair Connections

LEGIONELLA RISK ASSESSMENT

Section 12

Guidance to L8 and Legionnaires Disease

LEGIONELLA RISK ASSESSMENT

Legionnaires' Disease

Legionnaires' disease is a potentially fatal form of pneumonia which can affect anybody, but which principally affects those who are susceptible because of age or illness.

This is caused by the bacterium Legionella pneumophila, though other legionella bacteria have also been implicated.

Background information

- Legionnaires disease was first identified following a large outbreak of pneumonia among people who attended an American legion convention in Philadelphia in 1976. A previously unrecognised bacterium was isolated from lung tissue samples which was subsequently named Legionella pneumophila.

- It is normally contracted by inhaling legionella bacteria, either in tiny droplets of water (aerosols), also by aspiration, or in droplet nuclei (the particles left after the water has evaporated) contaminated with legionella, deep into the lungs. There is evidence that the disease may also be contracted by inhaling legionella bacteria following ingestion of contaminated water by susceptible individuals. Person to person spread of the disease has not been documented. Initial symptoms of Legionnaires' disease include high fever, chills, headache and muscle pain. Patient may develop a dry cough and most suffer difficulty with breathing. About one third of patients infected also develop diarrhoea or vomiting and about half become confused or delirious. Legionnaires' disease can be treated affectively with appropriate antibiotics.

- The incubation period is between 2-10 days (usually 3-6 days). Not everyone exposed will develop symptoms of the disease and those that do not develop the 'full blown' disease may only present with a mild flu-like infection

- Infection with legionella bacteria can be fatal in approximately 12% of reported case. This rate can be higher in a more susceptible population; for example, immunosuppressed patients or those with underlying disease. Certain groups of people are known to be higher at risk of contracting Legionnaires' disease; for example, men appear more susceptible than women, as do those over 45 years of age, smokers, alcoholics, diabetics and those with cancer or chronic respiratory or kidney disease.

On average, there are approximately 200 - 250 reported cases in England and Wales per annum with approximately 12% fatalities, though it is now believed this may be under-reported by a factor of ten.

LEGIONELLA RISK ASSESSMENT

Legislation/Regulations[1]

- Legionnaires' disease – The control of legionella bacteria in water systems **(L8 – 4th Edition)**
- HSG 274 Parts 1 – 3 - Legionnaires' disease: Technical guidance
- Health and Safety at Work etc. Act 1974 (Sections 2, 3 4 and 6)
- Management of Health and Safety at Work Regulations 1999
- Control of Substances Hazardous to Health Regulations 2002
- BS 8580:2010 Water quality – Risk assessments for Legionella control – Code of practice
- The Notification of Cooling Towers and Evaporative Condensers Regulations 1992 (Regulations 6, 7, 8, 9 and 12)
- HTM/SHTM 04-01 - The control of Legionella, hygiene, 'safe' hot water, cold water and drinking water systems[2]
- Other relevant standards as applicable to site/system[3] (e.g. BS EN 806, BS 8558)

[1] Other advisory notes or technical memorandums issued may also be relevant for assessment and control purposes.
[2] HTM/SHTM 04-01 refers to healthcare premises only.
[3] Information provided in this section is for basic guidance only. The Dutyholder/Responsible Person should refer to the appropriate guidance documents as listed above for complete guidance.

LEGIONELLA RISK ASSESSMENT

Introduction to L8

Legionnaires' disease – the control of legionella bacteria in water systems (L8) came into effect on the 8th of January 2001 and is commonly referred to as **L8**.

By virtue of section 16(4) of the Health and Safety at Work etc Act 1974, and with the consent of the Secretary of State for Work and Pensions, the Health and Safety Executive has on 30 October 2013 approved the revised Code of Practice entitled *Legionnaires' disease: The control of legionella bacteria in water systems* (L8 - 4th Edition)

The revised Code of Practice gives practical guidance with respect to sections 2, 3, 4 and 6 of the Health and Safety at Work etc Act 1974, regulations 6, 7, 8, 9 and 12 of the Control of Substances Hazardous to Health Regulations 2002 (COSHH) and guidance on compliance with the relevant parts of the Management of Health and Safety at Work Regulations 1999.

By virtue of section 16(5) and with the consent of the Secretary of State for Work and Pensions under that paragraph, the Health and Safety Executive has withdrawn its approval of the Code of Practice entitled *Legionnaire's disease: The control of legionella bacteria in water systems* (L8), which came into effect on 8 January 2001 which shall cease to have effect on 25 November 2013.

The Code of Practice came into effect on 25 November 2013, with HSG 274 Parts 1 & 3 being issued at the same time, and HSG 274 Part 2 being issued in April 2014.

The 4th Edition of L8 was issued along with HSG 274 Legionnaires' disease: Technical guidance.

HSG 274 is separated into 3 parts:

Part1: The control of legionella bacteria in evaporative cooling systems

Part 2: The control of legionella bacteria in hot and cold water systems

Part 3: The control of legionella bacteria in other risk systems

The Code has been approved by the Health and Safety Executive, with the consent of the Secretary of State. It gives practical advice on how to comply with the law. If you follow the advice you will be doing enough to comply with the law in respect of those specific matters on which the Code gives advice. You may use alternative methods to those set out in the Code in order to comply with the law.

However, the Code has a special legal status. If you are prosecuted for breach of health and safety law, and it is proved that you did not follow the relevant provisions of the Code, you will need to show that you have complied with the law in some other way or a Court will find you at fault.

The guidance is issued by the Health and Safety Executive. Following the guidance is not compulsory, unless specifically stated, and you are free to take other action. But if you do follow the guidance you will normally be doing enough to comply with the law. Health and safety inspectors seek to secure compliance with the law and may refer to this guidance.

LEGIONELLA RISK ASSESSMENT

ACoP L8 (and HSG 274) applies whenever water is stored or used in a way that may create a reasonably foreseeable risk of legionellosis. In particular it applies to the following plant;

- Hot and cold water systems
- Evaporative cooling systems
- Ultrasonic humidifiers/foggers and water misting systems
- Spray humidifiers
- Air washers, wet scrubbers, particle and trivial gas scrubbers
- Water softeners
- Emergency showers/eye baths and face wash fountains
- Sprinkler and hose reel systems
- Spa pools
- Whirlpool baths
- Horticultural misting systems
- Dental equipment
- Industrial process water systems
- Misting devices used for humidifying vegetables, meat and other food products;
- Vehicle washers including automatic washers for cars, buses, lorries and railway rolling stock;
- Powered dental equipment;
- Fountains and decorative water features including those on display for sale;
- Non-disposable nebulisers used for respiratory therapy;
- Industrial effluent treatment plants;
- Irrigation systems;
- Fire, dust and odour suppression systems;
- Paint spray preparation equipment;
- Tunnel pasteurisers and similar equipment.

Whilst this is not an exhaustive list, it does identify those systems which are most likely to cause infection. Consideration should also be given to other systems, which can release spray or aerosol during operation, maintenance and testing e.g.

- Machine coolants
- Recycled water systems
- Closed water systems
- Any other systems which could potentially be colonised and create respirable aerosols (i.e. 'at-risk')

The scope of a legionellosis risk assessment is defined in ACoP L8, paragraphs 28-47 (inclusive).

In December 2010, BS 8580:2010 was issued which provides practical guidance on carrying out L8 risk assessments and should be complied with as far as is practical when carrying out risk assessments.

LEGIONELLA RISK ASSESSMENT

Management responsibilities, training and competence

Inadequate management, lack of training and poor communication are all contributory factors in outbreaks of legionnaires' disease. It is therefore important that the people involved in assessing risk and applying precautions are competent, trained and aware of their responsibilities.

Communications and management procedures are particularly important where several people are responsible for different aspects of the operational procedures. For example, responsibility for applying control measures may change when shift work is involved, or when the person who monitors the efficacy of a water treatment regime may not be the person who applies it. In such circumstances, responsibilities should be well defined in writing and understood by all concerned. Lines of communication should be clear, unambiguous and audited regularly to ensure they are effective. This also applies to outside companies and consultants who may be responsible for certain parts of the control regime.

Employing contractors or consultants does not absolve the dutyholder of responsibility for ensuring that control procedures are carried out to the standard required to prevent the proliferation of legionella bacteria. Dutyholders should make reasonable enquiries to satisfy themselves of the competence of contractors in the area of work before they enter into contracts for the treatment, monitoring, and cleaning of the water system, and other aspects of water treatment and control. An illustration of the levels of service to expect from Service Providers can be found in the Code of Conduct administered by the Legionella Control Association (LCA).

If the assessment shows that there is a reasonably foreseeable risk and it is reasonably practicable to prevent exposure or control the risk from exposure, the dutyholder under paragraph 28 of ACOP L8 should appoint a competent person or persons to help undertake the measures needed to comply with the requirements in COSHH. The appointed competent person or persons should have sufficient authority, competence and knowledge of the installation to ensure that all operational procedures are carried out in a timely and effective manner. Where the dutyholder does not employ anyone with the necessary competence, they may need to appoint people from outside the organisation. In such circumstances, the dutyholder should take all reasonable steps to ensure the competence of those carrying out work who are not under their direct control and that responsibilities and lines of communication are properly established and clearly laid down.

Those appointed under paragraph 48 of ACOP L8 to carry out the risk assessment and draw up and implement precautionary measures should have such ability, experience, instruction, information, training and resources to enable them to carry out their tasks competently and safely. In particular, they should know the:

a) potential sources of legionella bacteria and the risks they present;
b) measures to adopt, including the precautions to take to protect the people concerned, and their significance;
c) measures to take to ensure that the control measures remain effective, and their significance.

The dutyholder should also ensure that all employees involved in work that may expose an employee or other person to legionella are given suitable and sufficient information, instruction and training. This includes information, instruction and training on the significant findings of the risk assessment and the appropriate precautions and actions they need to take to safeguard themselves and others. This should be reviewed and updated whenever significant changes are made to the type of work carried out or methods used. Training is an essential element of an employee's capability to carry out work safely, but it is not the only factor: instructions, experience, knowledge and other personal qualities are also relevant to perform a task safely.

Additional information relating to management responsibilities, training and competence can be found in ACOP L8 paragraphs 48-57 (inclusive)

LEGIONELLA RISK ASSESSMENT

Dutyholder

Under general health and safety law, as an employer or person in control of a premises (eg a landlord), the dutyholder has health and safety duties and needs to take suitable precautions to prevent or control the risk of exposure to legionella. Details of the specific law that applies can be found in L8 Legionnaires' disease: The control of legionella bacteria in water systems.

Carrying out a risk assessment is the responsibility of the dutyholder and will help to establish any potential risks and implement measures to either eliminate or control risks. The dutyholder may be competent to carry out the assessment themselves but, if not, someone with the necessary skills to conduct a risk assessment should be contracted to do so. This can be done by someone from within the dutyholders organisation or from someone outside, eg an external consultant.

Note 1 The dutyholder is the employer where the risk is from their undertakings to their staff or others, the self-employed person where the risk is from their undertaking to themselves or others, or the person in control of the premises where the risk is from systems in the building (e.g. A landlord who remains responsible for the maintenance of the systems)

Note 2 In most cases there will be only one dutyholder, but in cases of shared accommodation there could be shared responsibility. The dutyholder cannot delegate this duty, but can delegate managerial responsibility to the responsible person

Further information is available in the HSE leaflet *Legionnaires' disease: A brief guide for dutyholders* and at www.hse.gov.uk/legionnaires/index.htm.

Responsible Person

The dutyholder should specifically appoint a competent person or persons to take day-to-day responsibility for controlling any identified risk from legionella bacteria, known as the 'responsible person'. It is important for the appointed responsible person to have *sufficient authority, competence and knowledge of the installation* to ensure that all operational procedures are carried out effectively and in a timely way. Those specifically appointed to implement the control measures and strategies should be suitably informed, instructed and trained and their suitability assessed. They must be properly trained to a level that ensures tasks are carried out in a safe, technically competent manner; and receive regular refresher training. Keep records of all initial and refresher training. If a dutyholder is self-employed or a member of a partnership, and is competent, they may appoint themselves. The appointed responsible person should have a clear understanding of their role and the overall health and safety management structure and policy in the organisation. See *Managing for health and safety at work* for further guidance.

Note 1 In a large undertaking there may be more than one responsible person, each responsible for a part of the undertaking, e.g. each block of a large teaching hospital

LEGIONELLA RISK ASSESSMENT

Record keeping

L8 require employers, where they have five or more employees, to record the significant findings of their risk assessment and the steps taken to prevent exposure to substances hazardous to health. Employers are also required to keep suitable records of examinations, tests and repairs of control measures.

Records should include details about:

a) the appointed responsible person(s) for conducting the risk assessment, managing, and implementing the written scheme;
b) any significant findings of the risk assessment;
c) the written scheme and its implementation;
d) details about the state of operation of the water system, ie in use/not in use;
e) the results of any monitoring inspection, test or check carried out, and the dates.

The following items should normally be recorded:

a) names and positions of people responsible, and their deputies, for carrying out the various tasks under the written scheme;
b) a risk assessment and a written scheme of actions and control measures;
c) schematic diagrams of the water systems;
d) details of precautionary measures that have been applied/implemented including enough detail to show that they were applied/implemented correctly, and the dates on which they were carried out;
e) remedial work required and carried out, and the date of completion;
f) a log detailing visits by contractors, consultants and other personnel;
g) cleaning and disinfection procedures and associated reports and certificates;
h) results of the chemical analysis of the water;
i) results of any biological monitoring;
j) information on other hazards, eg treatment chemicals;
k) cooling tower and evaporative condenser notification;
l) training records of personnel;
m) the name and position of the person or people who have responsibilities for implementing the written scheme, their respective responsibilities and their lines of communication;
n) records showing the current state of operation of the water system, eg when the system or plant is in use and, if not in use, whether it is drained down;
o) either the signature of the person carrying out the work, or other form of authentication where appropriate.

Records should be retained throughout the period they are current and for at least two years afterwards. Retain records of any monitoring inspection, test or check carried out, and the dates, for at least five years.

Information relating to Record Keeping is provided in in ACoP L8, paragraphs 70-74 (inclusive).

LEGIONELLA RISK ASSESSMENT

Risk Assessment

All systems require a risk assessment, however not all systems will require elaborate control measures. A simple risk assessment may show that the risks are low and being properly managed to comply with the law. In such cases, you may not need to take further action, but it is important to review your assessment regularly in case of any changes in your system, and specifically if there is reason to suspect it is no longer valid. There is more information specifically for those in control of premises, eg landlords, in *Part 2: Hot and cold water systems* at www.hse.gov.uk/pubns/books/hsg274.htm and at www.hse.gov.uk/legionnaires/what-you-must-do.htm.

A suitable and sufficient assessment must be carried out to identify and assess the risk of exposure to legionella bacteria from work activities and water systems on the premises and any precautionary measures needed. The dutyholder is responsible for ensuring the risk assessment is carried out. The dutyholder is either:
(a) the employer, where the risk from their undertaking is to their employees or others; or
(b) a self-employed person, where there is a risk from their undertaking to themselves or others; or
(c) the person who is in control of premises or systems in connection with work, where there is a risk from systems in the building, eg where a building is let to tenants, but the landlord keeps responsibility for its maintenance.

The risk assessment should identify and evaluate potential sources of risk and:

a) the particular means of preventing exposure to legionella bacteria; or
b) if prevention is not reasonably practicable, the particular means of controlling the risk from exposure to legionella bacteria.

The risk assessment should take into account the individual nature of each site and consider the system as a whole and not, eg the cooling tower in isolation. In complex systems, a site survey of all the water systems should be carried out, including an asset register of all associated plant, pumps, strainers and other relevant items. This should include an up-to-date schematic diagram showing the layout of the plant or system, including parts temporarily out of use.

The dutyholder under paragraph 28 should, with the help of the appointed responsible person, make reasonable enquiries to ensure that organisations such as water treatment companies or consultants, and staff from the occupier's organisation, are competent and suitably trained and have the necessary equipment to carry out their duties in the written scheme safely and adequately.

The risk assessment also enables the dutyholder to show they have considered all the relevant factors, and the steps needed to prevent or control the risk.

The assessment should be reviewed regularly and specifically when there is reason to believe that the original risk assessment may no longer be valid. You should also review management and communication procedures as appropriate.

Some of the factors to consider, as appropriate, when carrying out the risk assessment:

a) the source of system supply water, eg whether from a mains supply or not;
b) possible sources of contamination of the supply water in the premises before it reaches the cold water storage tank, calorifier, cooling tower or any other system using water that may present a risk of exposure to legionella bacteria;
c) the normal plant operating characteristics;
d) unusual, but reasonably foreseeable operating conditions, eg breakdowns;
e) any means of disinfection in use;
f) the review of any current control measures;
g) the local environment.

LEGIONELLA RISK ASSESSMENT

Factors to be considered in the risk assessment

There is a chain of events which can lead to infection by legionella, which should be considered in any risk assessment process:

A. The presence of legionella bacteria (Contamination)

Water systems can be contaminated by legionella by the water source feeding the system. Whilst town mains will have a relatively low potential for contaminating the system, it may be assumed that low levels of legionella may on occasion enter the system via the town mains. Natural water sources such as springs, rivers, lakes and bores holes will have a significantly higher potential for introducing legionellae into the water system. Other potential sources of contamination include dust/dirt in the air entering via uncovered cisterns or overflows, or from the construction process.

It must therefore be assumed that it is not practical to prevent legionella from contaminating the system at some point.

B. Conditions suitable for the growth of organisms (Amplification)

In order for legionella to multiply in water systems, sufficient nutrients and physico-chemical conditions require to be met. Temperature is particularly critical with legionella growth likely between 20°c & 45°c, with the most rapid growth occurring between 32°c and 42°c.

Areas of stagnation or low flow which can increase bio-film formation and or sedimentation can also increase the potential for amplification

Nutrients within the system (dirt, rust etc.) Are also contributory factors in the amplification of legionella within water systems, and the minimisation of legionella amplifying conditions within water systems is of critical importance

C. A Means of creating and spreading breathable droplets (Transmission)

The vast majority of cases of legionnaires disease are caused by the infected person inhaling contaminated water which has been aerosolised. Other cases have been caused by contaminated drinking water being aspirated into the lungs rather than just going into the stomach, and from breathing in contaminated dust from compost.

Any process which causes aerosols to be created will therefore increase the potential transmission of legionella to humans, though consideration of aspiration must be considered, especially in potentially immunocompromised or high risk groups. The higher the density of aerosols created the larger the number of people potentially affected.

D. The presence (and numbers) of people who may be exposed (Exposure)

The closer the person is to a contaminated source aerosol the higher the chance of the person inhaling the aerosol before it disseminates and the bacteria die. For example, in spa baths or using cutting tools, if the liquid is contaminated then the user is very close to the aerosol created and is much more likely to inhale the contaminated droplets. Those farther away form the aerosol are less likely to be affected. However, where large volumes of aerosols are created, which can be disseminated over large areas (e.g. Cooling towers) then the potential for people to come into contact with the contaminated aerosol increases.

This exposure risk must be considered for all aspects of the system operation. Where a system does not under normal circumstances create an aerosol, it may during maintenance tasks create aerosols can be created and can therefore create a potential for inhalation of contaminated droplets.

LEGIONELLA RISK ASSESSMENT

E. Susceptibility

Some individuals are more likely to become infected than others. This susceptibility increase with age, and whether or not a person smokes or is immune-compromised. Males are also much more likely to be infected than females.

The nature and proximity of individuals to a potentially contaminated system must be considered and where persons who would be considered as high risk are in the proximity of the system then more stringent control of the potential risk may be required.

Information relating to the identification and assessment of the risk can be found in ACoP L8, paragraphs 28-47 (inclusive).

LEGIONELLA RISK ASSESSMENT

Grading policy

The aim of a legionella risk assessment is to identify all plant and services and make an assessment of the actual risk posed by the systems. In assigning the actual risk, the condition of the plant, maintenance procedures, location, and compliance with current guidelines/codes of practice etc. should be considered.

The actual risk posed by the water systems and plant and services being assessed are based on the ratings from the tables below:

	Condition of system being assessed (deficiencies/non-compliances found)				
Potential for system to pose a hazard	**Negligible**	**Minor**	**Moderate**	**Major**	**Extreme**
Rare	**Low**	**Low**	**Low**	**Low**	**Medium**
Unlikely	**Low**	**Low**	**Medium**	**Medium**	**High**
Possible	**Low**	**Medium**	**Medium**	**High**	**High**
Likely	**Low**	**Medium**	**High**	**High**	**V high**
Almost certain	**Medium**	**High**	**High**	**V high**	**V high**

Risk guidance notes	**Either no recommendations or a small number of minor recommendations, which focus on minor quality improvement issues. Minor non-compliance with standards only**	**Recommendations made which can be addressed by low level management action, or minor remedial actions required. Non-compliance with standards**	**Challenging recommendations that can be addressed with appropriate action plan and/or major remedial actions required. Non-compliance with core standards**	**Critical reports of major/urgent remedial works being required. Major non-compliance with core standards**

Recommendations shall be made to accompany risk ratings where appropriate.

LEGIONELLA RISK ASSESSMENT

Recommendations

Recommendations to minimise the actual risk, which may involve changes/remedial actions to the plant and/or upgrading of maintenance regimes and documentation procedures etc. are included within relevant sections of this document. The conclusions and recommendations contained in this assessment are based upon information supplied by the sites responsible person and/or his/her deputies and the assessors findings at the time of survey. Should further information subsequently become available which may impact on this assessment, a review of the assessment may be required.

Remedial Action Category	Recommended Remedial Action Timescale	Action
1	**Immediately / as soon as reasonably practicable**	**Urgent Significant Investigation & Urgent Remedial Action Required.** Carryout review of control procedures. Recommendations within this category should be carried out immediately/as-soon as-is-reasonably practicable. where appropriate remedial actions to rectify the faults cannot be taken **immediately/as-soon as-is-reasonably practicable** alternative actions to reduce the risk should be carried out, and continue to be carried out, until such times as recommended actions can be completed. Senior Management action may be required.
2	**As soon as reasonably practicable**	**Significant Investigation & Remedial Action Required.** Carryout review of control procedures. Recommendations within this category should be carried out **as-soon as-is-reasonably practicable**. Where appropriate remedial actions to rectify the faults cannot be carried out quickly, alternative actions to reduce the risk should be carried out, and continue to be carried out, until such times as recommended actions can be completed. Senior Management action may be required.
3	**Within 3 months**	**Investigate/Reduce.** Remedial actions required. Recommendations within this category should be carried out in a timely manner, though simple and/or inexpensive tasks which would reduce the risk should be carried out as-soon-as-reasonably-practicable (e.g. **Within 3 months**). Additional monitoring/inspection to ensure risk does not increase should be carried out until actions completed. Management responsibility should be specified if required.
4	**At first available opportunity**	**Maintain Level** Whilst recommendations within this category do not significantly alter the risk it is still advised that these actions are carried out **at first available opportunity**, typically within a 12 month period of recommendations being made. Many of the recommendations within this category can be managed by routine Planned Preventative Maintenance (PPM).

LEGIONELLA RISK ASSESSMENT

Bacterial Analysis for Hot & Cold Water Systems

Microbiological analysis

DMA would advise that routine sampling can provide valuable information regarding the condition of water services and efficacy of the L8/HSG 274/(S)HTM 04-01 monitoring regime and/or highlight issues which require further corrective actions.

HSG 274 Part 2: The control of legionella bacteria in hot and cold water systems states:

> *Microbiological monitoring of domestic hot and cold water supplied from the mains is not usually required, unless the risk assessment or monitoring indicates there is a problem. The risk assessment should specifically consider systems supplied from sources other than the mains, such as private water supplies, and sampling and analysis may be appropriate.*
>
> *Legionella monitoring should be carried out where there is doubt about the efficacy of the control regime or it is known that recommended temperatures, disinfectant concentrations or other precautions are not being consistently achieved throughout the system. The risk assessment should also consider where it might also be appropriate to monitor in some high risk situations, such as certain healthcare premises. The circumstances when monitoring for legionella would be appropriate include:*
>
> - *water systems treated with biocides where water is stored or distribution temperatures are reduced. Initial testing should be carried out monthly to provide early warning of loss of control. The frequency of testing should be reviewed and continued until such a time as there is confidence in the effectiveness of the regime;*
> - *water systems where the control levels of the treatment regime, eg temperature or disinfectant concentrations, are not being consistently achieved. In addition to a thorough review of the system and treatment regimes, frequent testing, eg weekly, should be carried out to provide early warning of loss of control. Once the system is brought back under control as demonstrated by monitoring, the frequency of testing should be reviewed;*
> - *high-risk areas or where there is a population with increased susceptibility, e.g. in healthcare premises including care homes;*
> - *water systems suspected or identified in a case or outbreak of legionellosis where it is probable the Incident Control Team will require samples to be taken for analysis*
>
> *Where monitoring for legionella is considered appropriate in hot and cold water systems, sampling should be carried out in accordance with BS 7592:2008 Sampling for Legionella organisms in water and related materials. The complexity of the system will need to be taken into account to determine the appropriate number of samples to take. To ensure the sample is representative of the water flowing around the system and not just of the area downstream of the fitting, samples should be taken from separate hot and cold outlets rather than through mixer taps or outlets downstream of TMVs or showers. Samples should be clearly labelled with their source location and if collected pre- or post-flushing.*
>
> *In both hot and cold water systems, samples should be taken:*
>
> - *if considered necessary by the risk assessment;*
> - *from areas where the target control parameters are not met (i.e. where disinfectant levels are low or where temperatures are below 50°C (55°C in healthcare premises) for HWS or exceed 20°C for cold water systems);*
> - *from areas subject to low usage, stagnation, excess storage capacity, dead legs, excessive heat loss, crossflow from the water system or other anomaly.*
>
> *In cold water systems, samples should also be taken as required:*
>
> - *from the point of entry (or nearest outlet) if the water is supplied from a private water supply or where the temperature of the incoming mains supply is above 20 °C from the cold water storage tank or tanks;*
> - *from the furthest and nearest outlet on each branch of the system (far and near sentinel outlets).*

LEGIONELLA RISK ASSESSMENT

In hot water systems, samples should also be taken as required:

- *from the calorifier hot water outlet and from the base of the calorifier, if it safe to do so, as some systems are under considerable pressure;*
- *from the furthest and nearest outlet on each branch of a single pipe system (far and near sentinel outlets);*
- *from the furthest and nearest outlet on each loop of a circulating system (far and near sentinel outlets).*

Action levels following legionella sampling in hot and cold water systems

	Legionella bacteria (cfu/litre)	**Action required**
Healthcare premises only	*Not detected or up to 100 cfu/l*	*In healthcare, the primary concern is protecting susceptible patients, so any detection of legionella should be investigated and, if necessary, the system resampled to aid interpretation of the results in line with the monitoring strategy and risk assessment*
All Premises (Including Healthcare)	*>100 cfu/l and up to 1000*	*Either:* • *if the minority of samples are positive, the system should be resampled. If similar results are found again, a review of the control measures and risk assessment should be carried out to identify any remedial actions necessary or* • *if the majority of samples are positive, the system may be colonised, albeit at a low level. An immediate review of the control measures and risk assessment should be carried out to identify any other remedial action required. Disinfection of the system should be considered*
	>1000 cfu/l	*The system should be resampled and an immediate review of the control measures and risk assessment carried out to identify any remedial actions, including possible disinfection of the system. Retesting should take place a few days after disinfection and at frequent intervals afterwards until a satisfactory level of control is achieved.*

N.B. Limits in table above set out in HSG 274 Part 2: The control of legionella bacteria in hot and cold water systems. Due to growth periods of the legionella organism and time taken for legionella analysis to be completed DMA would advise that action should be undertaken on any legionella positive samples.

Please note:

1. Analysis of water samples for legionella should be carried out by a UKAS accredited laboratory.
2. Analysis of water samples for TVC (Potable) quality should be carried out by a UKAS accredited laboratory.
3. All samples should be taken in accordance with BS 7592:2008
4. No composite samples should be taken.
5. Cleaning and disinfection of evaporative cooling towers and condenser water systems should be carried out in accordance with L8/HSG 274 Part 1: The control of legionella bacteria in evaporative cooling systems guidelines.
6. Cleaning and disinfection of domestic water systems should be carried out in accordance with HSG 274 Part 2: The control of legionella bacteria in hot and cold water systems, (S)HTM 04-01 (for healthcare premises), BS 8558 and BS EN 806.
7. All records, reports, analysis certificates & correspondence should be kept in the site water treatment logbook.
8. All actions should be logged and recorded in the site water treatment logbook.
9. Records should be retained throughout the period they are current and for at least two years afterwards. Retain records of any monitoring inspection, test or check carried out, and the dates, for at least five years.
10. Where consistently out of specification temperatures or other issues are highlighted and recorded during

LEGIONELLA RISK ASSESSMENT

L8/HSG 274 checks then additional sampling should be considered until suitable remedial actions have been implemented.

Residential accommodation: Landlords

HSG 274 Part 2: The control of legionella bacteria in hot and cold water systems paragraphs 2.138 – 2.146 provides guidance on duties and responsibilities on landlords, managing (or letting) agents to ensure that the risk of exposure to tenants to legionella is properly assessed and controlled.

All water systems require a risk assessment but not all systems require elaborate control measures.

Shared premises

HSG 274 Part 2: The control of legionella bacteria in hot and cold water systems paragraphs 2.147– 2.151 provides guidance on shared premises.

Those who have, to any extent, control of premises for work-related activities or the water systems in the building, have a responsibility to those who are not their employees, but who use those premises. A suitable and sufficient assessment must be carried out to identify, assess and properly control the risk of exposure to legionella bacteria from work activities and the water systems on the premises.

In estate management, it is increasingly common for there to be several dutyholders in one building. In such cases, duties may arise where persons or organisations have clear responsibility through an explicit agreement, such as a contract or tenancy agreement.

Where employers share premises or workplaces, the Management of Health and Safety at Work Regulations 1999, regulation 11 (see www.hse.gov.uk/risk for more information) requires that they cooperate with each other to ensure their respective obligations are met.

Special considerations for healthcare and care homes

HSG 274 Part 2: The control of legionella bacteria in hot and cold water systems paragraphs 2.152 – 2.168 provides additional guidance on healthcare and care home premises.

Scottish Health Technical Memorandum 04-01 (Parts A to F)

and

Health Technical Memorandum 04-01: The control of Legionella, hygiene, "safe" hot water, cold water and drinking water systems (parts A & B)

also provide additional and specific guidance on the control of water systems within health and care home premises.

LEGIONELLA RISK ASSESSMENT

Action in the event of an outbreak of legionellosis

1. In England and Wales, legionnaires' disease is notifiable under the Health Protection (Notification) Regulations 2010 and in Scotland under the Public Health (Notification of Infectious Diseases) (Scotland) Regulations 1988. Under these Regulations, human diagnostic laboratories must notify Public Health England (PHE), Public Health Wales (PHW) or Health Protection Scotland (HPS) (see 'Further sources of advice') of microbiologically confirmed cases of legionnaires' disease.

2. An outbreak is defined as two or more cases where the onset of illness is closely linked in time (weeks rather than months) and where there is epidemiological evidence of a common source of infection, with or without microbiological evidence. An incident/outbreak control team should always be convened to investigate outbreaks. It is the responsibility of the Proper Officer to declare an outbreak. The Proper Officer, appointed by the local authority, is usually a Consultant in Communicable Diseases Control (CCDC) in England and Wales, or the Consultant in Public Health Medicine (CPHM) in Scotland. If there are suspected cases of the disease, medical practitioners must notify the Proper Officer in the relevant local authority.

3. Local authorities will have jointly established incident plans to investigate major outbreaks of infectious diseases, including legionellosis, and it is the Proper Officer who activates these and invokes an Outbreak Committee, whose primary purpose is to protect public health and prevent further infection.

4. HSE or local environmental health officers (EHOs) may be involved in the investigation of outbreaks, their aim being to pursue compliance with health and safety legislation. The local authority, Proper Officer or EHO acting on their behalf will make a visit, often with the relevant officer from the enforcing authorities (ie HSE or the local authority). Any infringements of relevant legislation may be subject to a formal investigation by the appropriate enforcing authority.

5. There are published guidelines (by PHE, PHW and HPS) for the investigation and management of incidents, clusters, and outbreaks of legionnaires' disease in the community. These are, for England and Wales, *Guidance on the Control and Prevention of Legionnaires' Disease in England* and for Scotland, *Guidelines on Management of Legionella Incidents, Outbreaks and Clusters in the Community*.

6. If a cooling water system has been implicated in an outbreak of legionnaires' disease, emergency disinfection and cleaning of that system must take place as soon as possible, in accordance with the site incident plan.

LEGIONELLA RISK ASSESSMENT

Terms & abbreviations used

aerosol	a suspension in a gaseous medium of solid particles, liquid particles, or solid and liquid particles having negligible falling velocity. In the context of this document, it is a suspension of particles which may contain legionella with a typical droplet size of <5µm that can be inhaled deep into the lungs.
algae	a small, usually aquatic, plant which requires light to grow, often found on exposed areas of **cooling towers**.
bacteria (singular bacterium)	a microscopic, unicellular (or more rarely multicellular) organism.
biofilm	a community of **bacteria** and other **microorganisms**, embedded in a protective layer with entrained debris, attached to a surface.
calorifier	an apparatus used for the transfer of heat to water in a vessel by indirect means, the source of heat being contained within a pipe or coil immersed in the water.
cold water service (CWS)	installation of plant, pipes and fitting in which cold water is stored, distributed and subsequently discharged.
CWST	cold water storage tank (or cistern)
cooling tower	an apparatus through which warm water is discharged against an air stream; in doing so part of the water is evaporated to saturate the air and this cools the water. The cooler water is usually pumped to a heat exchanger to be reheated and recycled through the tower.
deadleg/dead-end pipes blind-end	leading to a fitting through which water only passes infrequently when there is draw-off from the fitting, redundant or abandoned legs of pipework.
drift	circulating water lost from the tower as liquid droplets entrained in the exhaust air stream; usually expressed as a percentage of circulating water flow, but for more precise work it is parts of water per million by weight of air for a given liquid to gas ratio.
drift eliminator	more correctly referred to as drift reducers or minimisers – equipment containing a complex system of baffles designed to remove water droplets from **cooling tower** air passing through it.
dry/wet cooling systems	dry coolers with the capacity to employ evaporative cooling when required either due to high ambient air temperature or when cooling demand is high.
evaporative condenser	a heat exchanger in which refrigerant is condensed by a combination of air movement and water sprays over its surface.
evaporative cooling	*a process by which a small portion of a circulating body of water is caused to evaporate, taking the required latent heat of vaporisation from the remainder of the water and cooling it.*
fouling	organic growth or other deposits on heat transfer surfaces, causing loss in efficiency.
low use or infrequently used outlets	outlets which are used occasionally, though less than once per week
unused outlets	outlets which are never or very rarely used
destratification or anti-stratification pump	pump used to mix water from top of calorifier/storage vessel to bottom to ensure even temperature spread throughout vessel
dip slide	a means of testing the microbial content of liquids by dipping a strip of culture media into the liquid, incubating to allow microbial growth and then estimating the numbers.
disinfection	a process which destroys micro-organisms and reduces number to a non-hazardous level.
domestic services	hot and cold water intended for personal hygiene, culinary, drinking water or other domestic purposes.
hot water service (HWS)	installation of plant, pipes and fitting in which water is heated, stored, distributed and subsequently discharged.
legionnaires' disease	a form of pneumonia caused by bacteria of the genus legionella.
legionella	a single bacterium of the genus **legionellae**.
legionellae	the name of a genus of bacteria which includes over 50 species and belongs to the family *Legionellaceae*. They are ubiquitous in the environment and found in a wide spectrum of natural and artificial collections of water.

LEGIONELLA RISK ASSESSMENT

legionella pneumophila	one of the causative organisms of **legionnaires' disease**.
legionellosis	any illness caused by exposure to **legionella**. **Legionnaires' disease** a form of pneumonia caused by legionella bacteria
microorganism	an organism of microscopic size including **bacteria**, fungi and viruses.
nutrient	a food source for **microorganisms**.
pontiac fever	a disease caused by a species of legionella, an upper respiratory illness less severe than **legionnaires' disease**.
PPM	planned preventative maintenance
risk assessment	identifying and assessing the risk from exposure to legionella from work activities and water sources on premises and determining any necessary precautionary measures.
nutrient	a food source for micro-organisms
service provider	companies or individuals or their sub-contractors who are involved with providing advice, consultancy, operating, maintenance and management services or the supply of equipment or chemicals to the owner or occupier of premises.
sludge/dirt/silt	general terms for soft mud-like deposits found on heat transfer surfaces or other important sections of a cooling system. Also found at the base of calorifiers and cold water storage tanks.
shunt or circulation or return pump	a circulation pump fitted to hot water service/plant to overcome temperature stratification throughout the hot water services pipework.
slime	a mucous like exudate which covers a surface produced by some micro-organisms
stagnation	the condition where water ceases to flow and is therefore liable to microbiological growth.
strainers	a coarse filter usually positioned upstream of a sensitive component such as a pump control valve or heat exchanger to protect it from debris.
stratification	temperature gradient from top to bottom of calorifier/storage vessel
TMV thermostatic mixing valve	mixing valve in which the temperature at the outlet is pre-selected and controlled automatically by the valve
total viable counts (TVC)	the total number of culturable bacteria in a given sample (does not include legionella)

L8 Risk Assessment

NHS Greater Glasgow & Clyde

Queen Elizabeth University Hospital
And
Royal Hospital for Children

Site Survey Date: Site survey completed 8th September 2017 (Plant)
Outlets surveyed 10th, 12th, 13th, 16th, 20th & 24th October 2017
Management Review Meeting for Gap Analysis, 30th January 2018
Latest Recommended Review Date: September 2018

Report carried out by	DMA Canyon Ltd
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Website	www.dmawater.co.uk
DMA Contacts	Allan McRobbie Compliance Manager [redacted] Mike Kinghorn Director [redacted] David Watson Director [redacted]

Dates of Assessment (On Site)	Plant survey completed 8th September 2017 Outlets surveyed 10th, 12th, 13th, 16th, 20th & 24th October 2017 Management Review Meeting for Gap Analysis, 30th January 2018
Draft Submission for Review	4th April 2018
Final Submission	25th April 2018
Risk Assessors	Allan McRobbie/David Watson/Craig Guyer (Plant Items) Fraser Murray/Craig Guyer (Hot and Cold Water Outlets)

Risk Assessor assisted on site by (Site Representative)	No NHS representatives assisted with site survey
Knowledge of systems being surveyed	N/A

Report Commissioned by:	Tommy Romeo (NHS Estates)
Report Issued to:	Tommy Romeo (NHS Estates)
Format of Report:	Electronic
	The findings included within the report have been communicated throughout the assessment process by Craig Guyer, Allan McRobbie and David Watson of DMA Canyon Ltd to NHS Estates staff (Tommy Romeo) verbally.

N.B. The findings and recommendations presented in this report have been based on information made available and inspection of areas made accessible by site staff during the survey. DMA are only able to assess areas/systems, which they have been given access to and using information supplied by site personnel. This survey was undertaken only on pipe work/areas that were accessible and visible, and it is possible that some sections remained hidden during the survey. Schematic drawings, where produced, and how services link up, have been assumed to run as indicated using basic engineering principles and our experience. However, no responsibility can be accepted for systems and/or areas, which DMA have not been provided access to, or as a result of incorrect, misleading information supplied or information not provided. No guarantees as to the completeness of the information within this report are provided.

DMA Staff Training and Competency

All DMA staff attending site are fully trained and deemed competent by DMA management for the tasks they have been allocated to carryout.

DMA training records are held centrally by DMA Canyon Ltd.

Copies of the relevant personnel training certificates can be supplied upon request.

Training and competency records for site/client/other staff involved in Legionella control should also be held by client. Records for those carrying out the Risk Assessment will be submitted as an appendix to this document.

DMA will only offer Legionella control services for which we have LCA accreditation.

An up to date copy of our LCA certificate and accreditation details can be found at www.dmacanyon.co.uk

For information on the LCA code of conduct for service providers and other information on the LCA requirements please refer to http://www.legionellacontrol.org.uk/

Legionella Control Association
KEEPING WATER SYSTEMS SAFE

Legionella Control Association

A Recommended Code of Conduct for Service Providers

Certificate of Registration

This is to certify that the following company has submitted a registration under the Conditions of Compliance as laid out in the LCA's Code of Conduct for Service Providers

Name of Company: **DMA Canyon Ltd**

Registration Number: **2012/2218** Certificate valid until: **31st August 2018**

Registration under the following services categories:

(1) Legionella Risk Assessment Services
- 1.1 Hot and Cold Water Services
- 1.2 Evaporative Cooling Systems
- 1.3 Process and Other Systems

(2) Water Treatment Services
- 2.1 Chemicals
- 2.2 Dosing and/or Control Systems
- 2.3 On-site Analytical and Monitoring Services

(3) Hot and Cold Water Monitoring and Inspection Services
(4) Cleaning and Disinfection Services
(5) Independent Consultancy Services
(6) Training Services
(7) Legionella Analytical Services
- 7.1 Sampling
- 7.2 Laboratory Analysis
- 7.3 Interpretation of Analysis

(8) Plant and Equipment Services
- 8.1 Installation
- 8.2 Refurbishment
- 8.3 Servicing
- 8.4 Design and Supply

This Certificate is only valid if the Company named is listed on the LCA website www.legionellacontrol.org.uk/directory.php

THE WATER MANAGEMENT SOCIETY

Signed: [redacted] *Chairman, Executive Committee*

BACS

[redacted] *Certificate Secretary*

Legionella Control Association Limited. www.legionellacontrol.org.uk

Registered in England and Wales No. 8502723

The legal duty to comply with relevant health and safety legislation (including avoidance or control of risk to exposure to Legionella bacteria) rests solely with the statutory dutyholder, being either the employer or the person in control of the premises or systems where any relevant risk is present, and this cannot be delegated. Specific functions (e.g. carrying out risk assessment) can be delegated and the Legionella Control Association (LCA) Code of Conduct is designed to help service providers, who also have duties under health and safety legislation, to establish appropriate management systems for the prevention or control of risk from Legionella bacteria. The LCA assesses the management systems of LCA members upon initial registration, reviews annually upon re-registration, and re-assesses by annual company audits. The LCA cannot and does not carry out other regular supervision of its members' commitments to the Code of Conduct nor their compliance with other LCA guidelines. A valid LCA certificate of registration (which is only valid if the Company named is listed on the LCA website www.legionellacontrol.org.uk/directory.php) confirms only that a service provider has satisfied LCA requirements at registration, re-registration and its most recent company audit. It does not confirm the service provider's ongoing of continuing compliance with their commitments to the LCA Code of Conduct and/or other LCA guidelines. The LCA does not approve specific products or services as being effective in controlling Legionella or verify the competence of service providers' staff and sub-contractors, which is the duty of the service provider and the statutory dutyholder. The LCA accepts no liability for any omission or any act carried out in reliance on the LCA Code of Conduct or other LCA guidelines, or any loss or damage resulting from non-compliance with such documents.

Table of Contents

Section 1

Executive Summary

Executive Summary

Building Overview
(System information below adapted from information provided by Brookfield in 2015 with Legionella Control comments by DMA)

This assessment covers the QEUH (Adult) Hospital and the adjoining Royal Hospital for Children. The Adult Hospital is 14 storeys with approximately 1100 beds and the Children's Hospital is 5 storeys with approximately 250 beds.

This facility has the largest Critical Care complex, one of the largest Emergency Departments in Scotland, offers acute specialist inpatient care, medical day care services and outpatient clinics servicing the local population.

The Children's Hospital provides specialist services to the West of Scotland and the wider population of Scotland in addition to the full range of secondary care services to people of Greater Glasgow and Clyde. Specialist services include cardiology and cardiac surgery, renal and bone marrow transplantation. For a number of these specialised services, the Children's Hospital is recognised as the sole provider in Scotland.

The construction phase ended in January 2015 with phased occupancy of patient areas beginning in April 2015 and full working occupancy achieved in July 2015. There have been departmental changes and small scale works in the intervening period (e.g. ward use changes and the required service alterations) though no significant water system alterations have been notified to DMA.

Town Mains

There are 2 separate incoming mains water supplies serving the cold water storage tanks within the basement plantroom of the Adults and Children's hospital building, and a separate dedicated fire main line supplying the fire tanks in the adjacent plantroom.

The incoming mains enter the building in the MTHW/Chilled Plantroom (Govan Road Mains) and basement tank room (Hardgate Road Mains) and run into the tank room to serve four off "Raw" water storage tanks. These incoming mains both have double check valves and water meters fitted.

The water meters are linked to the BEMS system and allow the user to cross reference the quantity of water used against the quantity indicated on the external meter.

The Hardgate Road (small) mains supply feeds only the main fire sprinkler tanks in the basement fire tank plantroom.

Whilst DMA were completing the Legionella Management Gap Analysis (see section 9) we were advised the Hardgate Road mains supply was shut down due to operational issues creating a 'deadleg' on the supply.

In addition the RHS 'Trades' Water tank appears to have been isolated for approximately 3 years with no recorded flushing of the deadleg this has created.

There are various short deadlegs on the domestic water mains which may be used as drain down points, injection points or emergency bypass connection points. DMA would recommend these are included in the site flushing regime.

DMA have described both the Govan Road and Hardgate Road supplies as medium risk due to the drain points etc. on the pipework for which there is no record of flushing. We have described the Hardgate Road (small) as a High Risk due to the low turnover to the Fire Suppression system.

N.B. It should be noted that there is no separate dedicated supply to the Renal (or other medical) systems, with all being fed from the Bulk Water system. This means that system disinfections will require to be very carefully scheduled or carried out locally as the disinfection procedure/chemical may interfere with the renal/medical systems and impact on patient welfare. We would advise an emergency action plan is formulated to allow for system disinfection if/when required and this should include alternative supplies to Renal (or other medical) systems, or alternative arrangements made for the period disinfection is being carried out.

CWSTs and Filters

QEUH Adult and Children's Hospital CWSTs

There are 10 domestic water storage tanks in the building which are all situated in the basement tank room.

Raw Water Tanks 1A/1B and 2A/2B are supplied by two town mains (Govan Road and Hardgate Road) to ensure continuity of supply in case of a town mains failure. The Raw Water tanks supply the Bulk Water tanks 1A/1B and 2A/2B via two 0.2 micron filtration sets (level of filtration advised by Estates). All Raw Water tanks were linked at the time of survey, though can be set up to feed filters units separately if required.

The filtration units fill separate Bulk Water Tanks (filtration unit 1 supplying 1A & 1B and filtration unit 2 supplying 2A & 2B). There appears no way to reconfigure set-up to allow the filtration units to fill the other tanks under fault conditions. Filtration sets should be maintained in accordance with manufacturer's instructions and maintenance schedule.

Bulk Water Tanks 1A and 1B are linked, with 2A and 2B also linked. All four tanks can be linked together (via outlets) to supply domestic cold water including drinking water to the building with the exception of the trades system. The link between the tanks 1A/1B and 2A/2B was closed at the time survey with each set of tanks supplying separate zones and plantrooms (calorifiers) within the hospital, 1A/1B supplying plantrooms 21/22/41 and the corresponding outlets in these zones with 2A/2B supplying plantrooms 31/32/33 and the corresponding outlets in these zones.

DMA were advised Estates staff are unsure why the bypass is closed as all four Bulk Water Tanks were classified as linked.

DMA noted small debris including washers in Bulk Water Tank 2B in our initial assessment from 2015 and these are still present. We would advise that this tank is cleaned to remove debris and then disinfected. (We would also recommend site confirm CWST inspections are being completed and competency of staff completing the inspections)

Storage temperature in 2B combined with heavier water mark may indicate this CWST is not turning over as well as the others. This should be monitored and CWSTs balanced. In addition, it should be confirmed that the filter system is working adequately as this level of debris is unexpected being downstream of a 0.2 micron filter set.

However, DMA were advised during the initial occupation phase that the filter system was bypassed due to issues with the pumps and filter set and this may have introduced contamination, debris (and potentially bacteria) into the system. As the tanks have not been cleaned since this time any material or contamination then present could potentially have been flushed into the system and have colonised parts of the system.

Bulk Water CWST 1B was unable to be inspected as Estates were unable to provide keys for the tank lids.

N.B. It should be noted that there is no separate dedicated supply to the Renal (or other medical) systems, with all being fed from the Bulk Water system. This means that system disinfections will require to be very carefully scheduled or carried out locally as the disinfection procedure/chemical may interfere with the renal/medical systems and impact on patient welfare.

Emergency procedures should be considered and formulated to allow for system disinfection if required.

Alternatively, a separate independent supply should be considered for this system.

There are 2 No. water booster sets in the water tank room. Each booster set is set to a different set point pressure depending on which plantroom and area it serves. In the event of failure each booster can also be switched to the other set point pressure.

- BS01 – Feeding Plantroom 31, 32 & 33 - 7.7 Bar
- BS02 – Feeding Plantroom 21, 22 & 41 – 5 Bar

The expansion vessels attached to the CWST booster sets are not of a flow through design and they are not insulated.
From the 2 No. water booster sets there are 8 domestic water systems:

- Plantroom 21
    - Via a Pressure reducing valve (PRV) the BCWS feed 21CAL01/02/03
- Plantroom 22
    - Via a Pressure reducing valve (PRV) the BCWS feed 22CAL01/02/03
- Plantroom 31 – 122
    - BCWS feeds 31CAL01/02/03
- Plantroom 31 – 128
    - Via a Pressure reducing valve (PRV) the BCWS feeds 31CAL07/08/09
- Plantroom 31 – 129
    - BCWS feeds 31CAL04/05/06
- Plantroom 32
    - BCWS feeds 32CAL01/02/03
- Plantroom 33
    - BCWS feeds 33CAL01/02/03
- Plantroom 41
    - BCWS feeds 41CAL01/02/03

The water supply into each plantroom is metered by a CWS flow meter. This allows for monitoring of specific parts of the system for energy purposes.

There are numerous connection points on the domestic water system within plantrooms and risers (which DMA have assumed were installed for flushing purposes and bypasses) which are creating deadlegs on the system. It is advised that these be removed wherever practicable or a register of the locations created and points incorporated into the site flushing regime.

The Trades Water System supplies "Non-domestic" outlets such as bib taps in plantrooms, irrigation connections points and the 12th floor heli-pad fire suppression system. One side of the Trades tank was valved off due to a reported inlet valve issue in 2015 (though tank full with signs of stagnation). It would appear that this tank has been offline since the construction phase. DMA would advise the tank is cleaned and disinfected prior to the tank being reinstated – or if not required drained and left isolated, ensuring any deadlegs created on inlet and/or outlet are removed or incorporated into site flushing regime.

There are various connection points onto other "non-domestic" outlets such as renal dialysis, endoscopy wash, pressurisation units, steam humidifier units and MRI chiller cooling which are connected to the Bulk Water system. It is advised that Estates confirm these systems have suitable backflow protection installed or if necessary suitable backflow protection be fitted. It is also advised that as the lines to these systems will often have a very low turnover, a double check valve or similar should be fitted as close as practicable to the tee-off point to prevent potentially stagnant water from contaminating the domestic system.

N.B. for information on Fire Suppression Tanks please see section 8.

Calorifiers (PHE's with Storage Vessels)

The calorifiers are situated in various plantrooms on the 2nd, 3rd and 4th floors of the building feeding designated zones within the hospital building. See supportive data following which identifies which calorifiers feed which areas.

Each set of calorifiers is a bank of 3-linked calorifiers fed from the boosted Bulk Water system, with heat source being via a plate heat exchanger on the outside of each calorifier fed from the MTHW system. A circulating pump on each calorifier/plate heat exchanger ensures the water is circulated throughout each vessel to maintain temperature.

The distribution temperatures were almost invariably above 50°C at all outlets (Supply to TMVs) with direct hot feeds above 55°C (see outlet section for supportive data and exceptions).

The return temperatures recorded at the calorifiers were consistently below 55°C which DMA were advised was the control set point for these, though when calorifiers were at full temperature the returns were reaching 50°C. It may be prudent to increase calorifier set points to ensure calorifier returns remain above 55°C as this is the control set point. This may also help maintain a 60°C minimum flow temperature when demand is placed on the calorifiers at peak periods. Increasing the calorifier temperatures may also have the beneficial effect of increasing the cold water usage as more cold water will be required at TMVs to blend water to TMV set point and so may assist in reducing any high cold water temperatures being recorded within the system.

The majority of the calorifiers were running at full temperature (i.e. 60°C or above) though there were some exceptions to this as highlighted in the supportive data following where one calorifier appears to be the lead calorifier and subsequently has lower temperatures than the connected calorifiers in the bank of 3. This may be a balancing issue and should be investigated and corrected wherever necessary.

The expansion vessels attached to the calorifiers are not of a flow through design as recommended in HSG 274 Part 2 (info Box 2.1) and SHTM 04-01 Part A (Para 8.22) and they are not insulated as recommended in SHTM 04-01 Part A (Para 8.22). Estates advised during the Gap Analysis that no expansion vessel flushing is being carried out.

DMA noted very dirty water was purged from a number of calorifier drains which may indicate the flushing regime should be increased (Estates advised during the Gap Analysis that base flushing is being carried out though were unable to provide supporting evidence), or that the methodology for flushing should be reviewed to ensure the calorifier base is being purged and not just the supply pipework.

Hot and Cold Water Systems

The domestic cold water system within the hospital is fed from the Bulk Water tanks located in the basement tank room of the hospital. DMA have been informed there are no outlets fed directly from Town Mains within the building.

"Non-domestic" outlets such as bib taps in plantrooms, irrigation connections points and the 12th floor heli-pad fire suppression system are fed from the Trades Water tanks. Please refer to the section 5 for information and supporting data relating to the CWSTs.

There are however some connection points onto other "non-domestic" outlets such as renal dialysis (both plant and individual 'emergency' points), endoscopy wash, pressurisation units, steam humidifier units and MRI chiller cooling which are connected to the Bulk Water system. DMA were advised by Mercury Engineering in 2015 that connections to 'other risk systems' had double check valves fitted during installation, though these are covered by insulation and DMA were unable to verify how close to the tee-off points these are. This should be checked and if necessary double check valves repositioned/fitted as necessary. It is also advised that fast fill connections are disconnected when not in use due to the different water categories between the wholesome domestic water and the chemically treated closed systems.

N.B. NHS Estates have fitted 'Emergency Dialysis' points on cold water system since the initial installation. NHS should confirm location of all Emergency Dialysis Points and ensure System Drawings and Asset Lists (not produced as part of this assessment) are updated to reflect this.

There are also numerous connection points and drain points on the domestic water system within plantrooms and risers (which DMA have assumed were installed for flushing purposes and bypasses) which are creating deadlegs on the system. It is advised that these be removed wherever practicable or a register of the locations created and points incorporated into the site flushing regime (no evidence this is being completed at present).

The domestic hot water systems are fed from a series of Calorifiers located on the 2nd and 3rd floors in the adult hospital and on the 4th floor of the children's hospital. These calorifiers feed different areas/zones within the Hospital. Please refer to section 6 for information and supporting data relating to the calorifiers.

Access to record temperatures within the hospital were restricted as DMA were advised no panels could be removed during the survey. This means that in many areas only mixed hot temperatures could be recorded. Wherever practical (and where available) a direct hot fed tap (e.g. in Dirty Utility or similar) was recorded to provide guidance as to hot supply temperatures within each area.

Cold water temperatures recorded by DMA vary with some indicating heat gain on the cold water system. Investigations should be carried out as to the reasons for this with appropriate remedial actions taken e.g. additional insulation, installation of flushing valves, manual flushing of outlets, servicing of TMVs to reduce likelihood of back flow of hot into cold (or opposite). Sampling, disinfections and background dosing should be considered as part of the escalation process should any issues persist. Increasing the calorifier temperatures may also have the beneficial effect of improving the cold water temperature profile as more cold water will be required at TMVs to blend water to TMV set point.

DMA were advised flushing valves are installed at a number of points on the domestic cold water system in the lower floors of the Adult and Children's Hospitals however Estates were unable to confirm the location of all valves. The operating conditions for the valves (e.g. temperature controlled/timed) should be confirmed and included with the written scheme. It may be prudent to consider additional dump valves at the end of main or sub-ordinate pipe work runs to improve cold water flow throughout site. Venturi loop systems may also be installed as part of such as system.

The hot water temperatures recorded at outlets were generally satisfactory with only a small number of local excursions. We would advise this is investigated and the flow and return commissioned as appropriate. At the time of initial assessment in 2015 DMA were advised that there are minimal localised "tertiary" loops and that the drops to individual outlets were as short as was reasonably practical to install. It was noted that hot temperatures generally rose very quickly when DMA were recording temperatures throughout the building and the flow and return circuits appear to be circulating hot water in most areas (please refer to following pages for supporting data and exceptions).

Domestic water pipework runs above ceilings throughout the building. Access for ongoing monitoring will be problematic as ceiling tiles cannot be easily removed within the hospital environment and alternative methods of monitoring should be considered should current BEMS monitoring points not be sufficient for the hot flow and return system (e.g. additional BEMS monitoring points installed).

As noted during previous assessment pipework within the Hospital is generally labelled and insulated where visible (as noted previously IPS panels unable to be removed during this survey)

The vast majority of TMVs installed are TMV taps, (Horne Optitherm in clinical areas and Armitage Shanks in non-clinical areas) with the only exceptions noted being infrared outlets in non-patient area toilets with infrared taps which have a TMV mounted approximately 0.5m from the outlet. Thermostatic mixing valves (TMVs) should be regularly serviced as per the manufacturers instructions and in accordance with the Written Scheme for site which should include input from the relevant NHS departments (e.g. Estates, Clinical, Infection Control, Authorising Engineer, Compliance Team, Health & Safety, Water Safety Group etc. – please note DMA's attendance at Water Safety Group meetings has not been requested) for local infection control guidance for bacterial control taking into account the location, design, operation, servicing and requirements of infection control.

Horne Optitherm TMV taps are designed to be demounted for maintenance and servicing elsewhere but the facilities for this are yet to be completed and commissioned. Specific service method statements and maintenance requirements for these items in these areas should form part of the written scheme.

In addition, the strainers located on the supplies to the TMV taps in "Non-Clinical" areas (e.g. patient, visitor and staff toilets) are located behind panels and therefore infection control procedures are required (Scribe) in order to remove panels for service. We understand no servicing of any of these valves and the associated strainers in non-high risk areas has been carried out since the hospital opened and there has been a very limited program of servicing in 'high risk' areas.

We are unaware of any servicing works being carried out and had access to servicing records on TMV taps in other areas of the hospital at the time of assessment.

The recent (prior to assessment delivery) issue with regards to Cupriavidus bacteria being detected in the system water has highlighted that the servicing requirements of the TMV taps should be reviewed to ensure that in addition to manufacturers service instructions being carried out the servicing of TMV taps includes any additional control measures as deemed necessary by infection control e.g. full thermal bypass/disinfection of the taps where practicable and safe (this would require to be carried out remotely from patient areas) and flow regulator, O rings and other components cleaning, disinfection and/or replacement.

Showers appear to be a standard design throughout the hospital with no adjustable heads noted during the survey. However, as NHS Estates are unable to confirm the service history of the units and cleaning and disinfection of shower heads we would advise consideration is given to changing all heads and hoses with new WRAS approved heads and hoses.

DMA were advised by Mercury Engineering and Estates in 2015 that all materials fitted during the construction are WRAS approved and therefore do not support bacterial growth. In addition, EPDM flexible hoses have been installed in a small number of non-clinical areas with the only patient areas DMA have noted as having flexible hoses being the connection to Arjo baths (both connections to the hot/cold system and internally within the actual bath). Wherever possible DMA would recommend all flexi hoses are removed and connections hard piped. Where flexible hoses cannot be removed then replacing with alternative WRAS approved hoses with linings other than EPDM should be considered. In healthcare premises additional guidance on the replacement and use of flexible hoses is provided in the "safety action notice SAN(SC)09/03".

Flexible hoses have also been noted on the boosted bulk water system on pressure reducing valves. If possible, these should be hard piped (stainless steel) or WRAS approved hoses with linings other than EPDM should be considered. Should these not be available for these types of units/connections then a regular inspection and replacement schedule should be implemented for these.

It was also noted that there were copper tails on connections to a small number of outlets e.g. Infrared taps in non-patient toilets and in the endoscopy wash room DCT-009.

There are alcohol gel wash points at most WHBs throughout the hospital which may discourage/reduce water usage at taps (the position of these should also be considered with regards to Pseudomonas control where applicable)

The bib taps, irrigation points (which DMA have been informed are no longer connected to the water system) and 12th floor heli-pad fire suppression system are fed from the Trades system with very long pipework runs through the building and plantrooms to the outlets. DMA would advise all points on the trades system should be included in the site flushing regime. Please also refer to section 8 for information on other risk systems.

No outlets on the Trades system have been designated as "sentinel outlets". Due to the type of system and the extended pipe runs to the outlets it may be prudent to designate all outlets from this system as sentinel and include in monthly monitoring and site flushing regime.

It should be noted that the information and recommendations included within these pages relates to the outlets surveyed only though many of the conditions highlighted are likely to be replicated throughout the hospital. Issues and information included should not be taken as a complete data set and should be treated as a representative sample of the system conditions found within the hospital. (NHS records should also be consulted for additional information e.g. temperature excursions)

N.B. As part of the control measures implemented in response to Cupriavidus bacteria being detected initially within Ward 2A and then in other areas of the hospital anti-microbial filters have been installed in high risk patient areas as instructed by Infection Control and Estates. The use and management of these filters should be as per manufacturers instructions and in accordance with their guidance documents. Please refer to PALL and Fileder, instuctions for use, installation and filter exchange included within filters supplied.

Other Risk Systems

There are various 'Other Risk Systems' on site which may create a risk from Legionellosis.

- Hydrotherapy Pool (completed under separate assessment)
- Whirlpool/Arjo Baths
- Dental equipment
- Emergency showers
- Irrigation systems
- Sprinkler/Wet firefighting systems
- Renal dialysis (x2 systems) with additional 'Emergency Dialysis Points' which are directly supply from bulk domestic cold water system. NHS Estates should confirm location of all Emergency Dialysis Points.
- Endoscopy Wash
- Water softeners
- Medical Gases/Medical Equipment (e.g. Nebulisers, incubators, etc.)
- Emergency Cooling (MRI chiller)
- Closed heating systems
- Closed chilled water systems
- Steam Humidification
- Air Conditioning

Legionella Management

DMA completed a Gap Analysis as part of this assessment and recorded several gaps in the PPM program (verbally advised by NHS Estates). Records for tasks advised as completed by NHS Estates were not available for assessment at the time of issue and should be inspected by a competent person to confirm compliance with relevant requirements.

A Written Scheme guidance document was issued by DMA as part of the initial phased occupancy Risk Assessment however this has not been updated to provide the current Legionella Management structure and PPM program on site. DMA would advise a new Written Scheme is formulated as soon as possible and this distributed to all relevant personnel including Estates, Infection Control and others to ensure all parties are fully aware of their documented responsibilities with training provided where required, particularly to the Authorised Person for Water who is currently untrained. DMA understands that the compliance team are currently reviewing/updating the GGHB Template Written Scheme for roll out across the estate.

Risk Assessment Summary

Site Name	QEUH Adult and Children's Hospital	
No of Storeys	14 in Adult Hospital and 5 in Children's Hospital.	
Date of construction	Completed and handed over to NHS in January 2015 for phased occupation. Full occupancy achieved in July 2015.	
Date water services last upgraded	Original system with minor modifications	
Is building used by potentially "at Risk" groups?	Yes – persons with acute medical conditions	As the building is used by persons with acute underlying medical conditions which increases susceptibly to contracting legionellosis then the requirements for L8, HSG 274 and HTM/SHTM 04-01 compliance is of paramount importance.
Is there a history of legionella colonisation of the water system(s) on site?	DMA were advised the initial sampling programme carried out as part of the commissioning process highlighted a number of out of specification Legionella and Potable results and a responsive programme of flushing and local disinfections was carried out in affected areas. Since handover to NHS Estates a sampling programme has been implemented in 'High Risk' areas only though full results were not available for inspection at the time of assessment (DMA were instructed to carry out a single disinfection in Renal Ward which we understand was due to out of spec results in 2016 though full results not relayed to DMA). DMA have taken a small number of samples in late 2017 which have not returned any positive results. *Recently, in early 2018 several positive tests were returned for 'Cupriavadus', an organism thought to be similar in origin as Pseudomonas. These results may indicate bacterial contro issues and may also show conditions are also present for Legionella growth.* This sampling program, investigation and remedial works is being managed by the hospital Facilities team, ICT and Estates with DMA carrying out works when requested.	
Legionella Management (section 9)	High Risk	
Water Source (section 4)	Govan Road Hardgate Road (Large) Hardgate Road (Small)	Medium Risk Medium Risk High Risk (As feeds basement sprinkler tanks only)
Domestic CWSTs (section 5)	Raw Water Tanks (x4) Bulk Water Tanks (x4) Trades Tanks (x2)	Medium Risk Medium Risk High Risk
Calorifiers (section 6)	Plantroom 21-01/02/03 Plantroom 22-01/02/03 Plantroom 31-01/02/03 Plantroom 31-04/05/06 Plantroom 31-07/08/09 Plantroom 32-01/02/03 Plantroom 33-01/02/03 Plantroom 41-01/02/03	Medium Risk Medium Risk Medium Risk Low Risk Medium Risk Medium Risk Low Risk High Risk

Outlets (section 7)	This assessment included hot and cold outlets described as 'Sentinels' by the construction firm. Due to the lack of access to pipework to gather information on hot and cold water systems and the lack of 'straight' hot and cold sentinels, further 'straight' hot and cold water outlets have been taken in many areas to provide further feedback on the water system temperatures without any possible interference from thermostatic mixing mechanisms. DMA have also included a number of 'random' outlets, and direct hot and cold outlets within individual wards in the survey to enhance the temperature profile used in the assessment. Some outlets on the water systems have been described as High Risk for this site.
Other Risk Systems (section 8)	There are various other risk systems fitted throughout the hospital building including Hydrotherapy Pool, Arjo Baths, Dental equipment, Emergency showers, Irrigation systems, Sprinkler/Wet fire fighting systems, Renal dialysis (x 2), Endoscopy Wash, Water softeners, Medical Gases/Medical Equipment (e.g. Nebulisers, incubators, etc.), Back-up/Emergency Cooling (e.g. MRI chillers), Closed heating systems, Closed chilled water systems, Steam Humidification, Air Conditioning. This assessment provides a brief description of each system and an initial assessment however we would advise specialists in each field are consulted to confirm this initial assessment is reflective of the function of the system and would present these findings as draft only until this is confirmed. Some other risk systems within the building have been described as High Risk for this site.
Should background dosing be considered for this site?	DMA would advise this is considered by the Facilities Team, ICT and Estates based on the information supplied via this document and experience of the building services and any bacterial results reported. However, as renal dialysis, and other medical systems, are fed directly from the Raw/Bulk Water supply any background dosing system would have to be fully risk assessed and approved prior to installation with appropriate actions taken to protect renal dialysis and other medical system (e.g. re-pipe supplies from mains/new boosted water system, install suitable filters).
Additional Comments	The identification/numbering system used as reference points within this document are the door numbers as initially provided by Brookfield on Zutec. The door numbers do not always run sequentially in each area which can make locating individual rooms/outlets very difficult, particularly in the larger department areas. It was also noted that there are some duplicate identifications in the A&E department with IDs being replicated in both the Adult and Children's Hospital. Where there were additional numbered doors/areas within a room DMA have referred only to the outlets within the room identified and have not included those in adjoining rooms.

Section 2

Domestic Water System Recommendations

Suggested Remedial Action Timescales

Remedial Action Category	Recommended Remedial Action Timescale	Action
1	**Immediately / as soon as reasonably practicable**	**Urgent Significant Investigation & Urgent Remedial Action Required.** Senior Management Action Required. Carryout Review of Control Procedures Recommendations within this category should be carried out immediately/as-soon as-is-reasonably practicable. where appropriate remedial actions to rectify the faults cannot be taken **immediately/as-soon as-is-reasonably practicable** alternative actions to reduce the risk should be carried out, and continue to be carried out, until such times as recommended actions can be completed.
2	**As soon as reasonably practicable**	**Significant Investigation & Remedial Action Required.** Senior Management Action Required. Carryout Review of Control Procedures Recommendations within this category should be carried out **as-soon as-is-reasonably practicable**. Where appropriate remedial actions to rectify the faults cannot be carried out quickly, alternative actions to reduce the risk should be carried out, and continue to be carried out, until such times as recommended actions can be completed.
3	**Within 3 months**	**Investigate/Reduce.** Remedial Actions Required. Management responsibility should be specified. Recommendations within this category should be carried out in a timely manner, though simple and/or inexpensive tasks which would reduce the risk should be carried out as-soon-as-reasonably-practicable (e.g. **Within 3 months**). Additional monitoring/inspection to ensure risk does not increase should be carried out until actions completed.
4	**At first available opportunity**	**Maintain Level** Managed by Routine Planned Preventative Maintenance Procedures Whilst recommendations within this category do not significantly Alter the risk it is still advised that these actions are carried out **at first available opportunity**, typically within a 12 month period of recommendations being made.

For Details of "Other Risk Systems" please refer to Section 8 and for Legionella Management Recommendations please refer to Section 9 of this assessment.

N.B. Prior to any alterations being carried out on fire systems (where recommended) the fire brigade and/or site fire safety consultants should be consulted and approval of changes received

Location/Plant Item	Recommendation	Remedial Action Category	Assigned to	Actions Taken	Completed
Legionella Management	Significant gaps were identified in the Legionella Management on site. Please refer to the Gap Analysis for further information	2			
Other Risk Systems	Please refer to section 8 for recommendations on other risk systems identified on site. This assessment provides a brief description of each system and an initial assessment however we would advise specialists in each field are consulted to confirm this initial assessment is reflective of the function of the system and would present these findings as draft only until this is confirmed	2			

Location/Plant Item	Recommendation	Remedial Action Category	Assigned to	Actions Taken	Completed
Water Source Basement Main Tank plantroom Hardgate Road (Small)	As this mains lines is likely to have a low turnover of water DMA would recommend the NHS confirms that this main is separated from domestic water mains by a double check valve or similar (possibly external to building) to prevent potentially stagnant water from contaminating the domestic mains.	2			
Water Source Basement Main Tank plantroom Govan Road	RHS Trades Water Tank inlet valved off creating a deadleg. This should be incorporated into the weekly flushing regime until such times as CWST issue corrected. Please refer to CWST section for further recommendations.	2			
Water Source Basement Main Tank plantroom Hardgate Road (Large)	Deadlegs (drain points/injection points) should be removed or incorporated into low use outlets flushing regime (for recs on isolated mains into T1A please see CWST recommendations)	2			
Water Source Basement MTHW/Chilled plantroom Govan Road	Deadlegs (drain points/injection points) should be removed or incorporated into low use outlets flushing regime.	2			
Water Source Basement Main Tank plantroom Hardgate Road (Large)	There are return lines/vents from the check valve on the mains returning into the CWSTs. The operation of these should be confirmed and checks made to ensure they are not creating deadlegs/trapping stagnant water – incorporate into site flushing regime if lines not being flushed through at least twice weekly.	3			
Water Source Basement Main Tank plantroom Govan Road	There are return lines/vents from the check valve on the mains returning into the CWSTs. The operation of these should be confirmed and checks made to ensure they are not creating deadlegs/trapping stagnant water – incorporate into site flushing regime if lines not being flushed through at least twice weekly.	3			
All plant items	All plant items, pipework and valves should be labelled for identification purposes.	4			

Location/Plant Item	Recommendation	Remedial Action Category	Assigned to	Actions Taken	Completed
Note:	It should be noted that there is no separate dedicated supply to the Renal (or other medical) systems, with all being fed from the Bulk Water system. This means that system disinfections will require to be very carefully scheduled or carried out locally as the disinfection procedure/chemical may interfere with the renal/medical systems and impact on patient welfare.				
All CWSTs though particularly Bulk Water Tank 2B	Storage temperate in 2B combined with heavier water mark may indicate this CWST is not turning over as well as the others. This should be monitored and CWSTs balanced.	**2**			
Filter System	Ensure filter system is maintained in accordance with manufactures instructions.	**2**			
Bulk Water Tank 2B	The heavy water mark noted in 2B is unexpected following a 0.2micron filter though may have been introduced in initial occupation phase. We would advise this is investigated and it confirmed the filter system is operating	**2**			
CWST Basement Tank plantroom Bulk Water	DMA noted small debris including washers in Bulk Water Tank 2B and would advise that this tank is cleaned to remove debris and then disinfected.	**2**			
CWST Basement Tank plantroom Trades Water Water	RHS side of the Trades tank has been isolated on inlet for approx. 3 years. (though tank full of water with signs of stagnation). DMA would advise the tank is cleaned and disinfected prior to the tank being reinstated.	**2**			
CWST Basement Tank plantroom Bulk Water	CWSTs require to be cleaned and disinfected.	**2**			
All expansion vessels	Wherever possible/practical expansion vessels should be 'flow through' vessels and suitably insulated. Where this is not possible a expansion vessel should be included in site flushing regime (to correct procedure). Estates advised during the Gap Analysis that no expansion vessel flushing is being carried out and we would advise this is started immediately in addition to any servicing of the vessel which may also have been missed previously	**2**			
Raw Water CWSTs	Some evidence of biofilm forming on baffles at mains inlets, possibly due to splashing etc. Baffles should be inspected periodically (e.g. monthly) and cleaned as and when required.	**2**			

Location/Plant Item	Recommendation	Remedial Action Category	Assigned to	Actions Taken	Completed
All Raw & Bulk CWSTs	A suitable screened screen should be fitted to the warning pip and it should be confirmed that the overflow is suitably screened	3			
CWST Basement Tank plantroom Bulk Water	Ensure short connection between booster sets is thoroughly flushed before use should it ever be required.	3			
CWST Basement Tank plantroom Bulk Water	Ideally drain points should be fitted to pump manifolds to allow end of lines to be flushed.	3			
CWST Basement Tank plantroom Bulk Water	There are various drain points and bypass valves fitted to the pipework in the plantroom. These should be included in site flushing regime.	3			
All Raw & Bulk CWSTs	Additional access hatches on tanks for cleaning/inspection purposes should be considered.	3			
CWST Basement Tank plantroom Raw Water	There are drain down points on pipework. These should be included in site flushing regime.	3			
CWST Basement Tank plantroom Trades Water	A suitable screened vent should be fitted to the overflow.	3			
CWST Basement Tank plantroom Trades Water	Ideally a drain should be fitted to pump manifold to allow end of lines to be flushed (if practicable).	3			
All CWSTs	All plant items, pipework and valves should be labelled for identification purposes.	4			

Location/Plant Item	Recommendation	Remedial Action Category	Assigned to	Actions Taken	Completed
All Calorifiers	DMA noted very dirty water was purged from a number of calorifier drains which may indicate the flushing regime should be increased (Estates advised during the Gap Analysis that base flushing is being carried out though were unable to provide supporting evidence), or that the methodology for flushing should be reviewed to ensure the calorifier base is being purged and not just the supply pipework. Additionally, Estates were unable to advise on the completion of annual calorifier inspections, clean/descale and disinfections. We would therefore advise all calorifiers are inspected, cleaned/descaled and disinfected.	2			
All expansion vessels	Wherever possible/practical expansion vessels should be 'flow through' vessels and suitably insulated. Where this is not possible a expansion vessel should be included in site flushing regime (to correct procedure). Estates advised during the Gap Analysis that no expansion vessel flushing is being carried out and we would advise this is started immediately in addition to any servicing of the vessel which may also have been missed previously	2			
Calorifier Plantroom P22 -01/02/03	Calorifier P22 01 temperature very slightly lower than the other calorifiers. Ensure linked calorifiers are balanced to provide equal throughput of water through each calorifier and calorifier brought up to full temperature.	2			
Calorifier Plantroom P22 -01/02/03	Deadleg pipework in this area should be removed (see also outlet recommendations regarding drain points/flushing points etc. in plantrooms)	2			
Calorifier Plantroom 33-01/02/03	There is a deadleg on the cold feed at these calorifiers – this should be removed or included in site flushing regime	2			
Calorifier Plantroom 41 01/02/03	P41 Calorifiers 01, 02 & 03 temperatures all low. Ensure calorifiers set to store and deliver water at a minimum of 60°C at all times.	2			

Location/Plant Item	Recommendation	Remedial Action Category	Assigned to	Actions Taken	Completed
All calorifiers	The return temperatures recorded at the calorifiers were consistently below 55°C (P31 04/05/06 being the exception) which DMA were advised was the control set point for these, though all calorifier returns were reaching 50°C. It may be prudent to increase calorifier set points to ensure calorifier returns remain above 55°C as this is the control set point. This may also help maintain a 60°C minimum flow temperature when demand is placed on the calorifiers at peak periods. Increasing the calorifier temperatures may also have the beneficial effect of increasing the cold water usage as more cold water will be required at TMVs to blend water to TMV set point and so may assist in reducing any high cold water temperatures being recorded within the system.	**3**			
All Calorifiers	Ensure linked calorifiers are balanced to provide equal throughput of water through each calorifier.	**3**			
All Calorifiers (Circulation Pumps)	Fit caps to ends of spare circulation pump.	**3**			
Calorifier Plantroom 22 01/02/03	Water flushed from drains on Calorifiers P22 01 & 02 ran very dirty for approx. 20 seconds before beginning to clear up. This should be investigated to determine cause – increased flushing frequency may be necessary if no cause and/or corrective action determined.	**3**			
Calorifier Plantroom 31-01/02/03	Calorifier P31 03 temperature very slightly lower than the other calorifiers. Ensure linked calorifiers are balanced to provide equal throughput of water through each calorifier and calorifier brought up to full temperature.	**3**			

Location/Plant Item	Recommendation	Remedial Action Category	Assigned to	Actions Taken	Completed
Calorifier Plantroom 31-07/08/09	Water flushed from drains on Calorifiers P31 - 07, 08 & 09 ran very dirty for approx. 20 seconds before beginning to clear up. This should be investigated to determine cause – increased flushing frequency may be necessary if no cause and/or corrective action determined.if no cause and/or corrective action determined.	3			
Calorifier Plantroom 32 01/02/03	Water flushed from drains on Calorifiers P32 - 01, 02 & 03 ran very dirty for approx. 15 seconds before beginning to clear up. This should be investigated to determine cause – increased flushing frequency may be necessary if no cause and/or corrective action determined.	3			
Calorifier Plantroom 33-01/02/03	Calorifier pump insulation stripped off due to previous leak – confirm fitting is stainless steel and not mild steel (Unable to confirm at time of survey). Replace if not stainless steel.	3			
Calorifiers Plantroom P41 - 01/02/03	Water flushed from drains on Calorifiers P41 - 01, 02 & 03 ran very dirty for approx. 15 seconds before beginning to clear up. This should be investigated to determine cause – increased flushing frequency may be necessary if no cause and/or corrective action determined.	3			
All Calorifiers	All plant items, pipework and valves should be labelled for identification purposes. The calorifiers do not have labels on them, instead being labelled at present by a marker pen, with a separate small identification plate on the side of each calorifier. The labelling does not match up in every instance between the hand written and id plate. It is advised that calorifiers have formal identification label attached to each one.	4			
Calorifier Plantroom 33-01/02/03	P33 Calorifier 01 gauge at base appears to be reading incorrectly – This should be replaced.	4			

Location/Plant Item	Recommendation	Remedial Action Category	Assigned to	Actions Taken	Completed
Note:	It should be noted that the information and recommendations included within these pages relates to the outlets surveyed only though many of the conditions highlighted are likely to be replicated throughout the hospital. Issues and information included should not be taken as a complete data set and should be treated as a representative sample of the system conditions found within the hospital. (NHS records should also be consulted for additional information e.g. temperature excursions)				
QEUH (Adults) and Royal Hospital for Children	As the building users include persons with acute underlying medical conditions which increases susceptibly to contracting legionellosis then the requirements for L8, HSG 274 and HTM/SHTM 04-01 compliance is of paramount importance.	**2**			
Connections to non domestic outlets.	There are connection points onto other "non-domestic" outlets such as renal dialysis (both plant and individual 'emergency' points), endoscopy wash, pressurisation units, steam humidifier units and MRI chiller cooling which are connected to the Bulk Water system. DMA were advised by Mercury Engineering in 2015 that connections to 'other risk systems' had double check valves fitted during installation, though these are covered by insulation and DMA were unable to verify how close to the tee-off points these are. This should be checked and if necessary double check valves repositioned/fitted as necessary. It is also advised that fast fill connections are disconnected when not in use due to the different water categories between the wholesome domestic water and the chemically treated closed systems.	**2**			

Location/Plant Item	Recommendation	Remedial Action Category	Assigned to	Actions Taken	Completed
Emergency Dialysis Points	NHS Estates have fitted 'Emergency Dialysis' points on cold water system since the initial installation. NHS should confirm location of all Emergency Dialysis Points and ensure System Drawings and Asset Lists (not produced as part of this assessment) are updated to reflect this.	**2**			
Drain Points/Connection	There are also numerous connection points and drain points on the domestic water system within plantrooms and risers (which DMA have assumed were installed for flushing purposes and bypasses) which are creating deadlegs on the system. It is advised that these be removed wherever practicable or a register of the locations created and points incorporated into the site flushing regime (no evidence this is being completed at present).	**2**			
Renal Plant and Disinfections	It should be noted that there is no separate dedicated supply to the Renal Plant (or other medical) systems, with all being fed from the Bulk Water system. This means that system disinfections will require to be very carefully scheduled or carried out locally as the disinfection procedure/chemical may interfere with the renal/medical systems and impact on patient welfare. Emergency procedures should be formulated to allow for system disinfection	**2**			

Location/Plant Item	Recommendation	Remedial Action Category	Assigned to	Actions Taken	Completed
Cold Water Temperatures	Cold water temperatures recorded by DMA vary with some indicating heat gain on the cold water system. Investigations should be carried out as to the reasons for this with appropriate remedial actions taken e.g. additional insulation, installation of flushing valves, manual flushing of outlets, servicing of TMVS to reduce likelihood of back flow of hot into cold (or opposite). Sampling, disinfections and background dosing should be considered as part of the escalation process should issues persist. Increasing the calorifier temperatures may also have the beneficial effect of improving the cold water temperature profile as more cold water will be required at TMVs to blend water to TMV set point. DMA were advised flushing valves are installed at a number of points on the domestic cold water system in the lower floors of the Adult and Childrens hospitals however Estates were unable to confirm the location of all valves. The operating conditions for the valves (e.g. temperature controlled/timed) should be confirmed and included with the written scheme. It may be prudent to consider additional dump valves at the end of main or sub-ordinate pipe work runs to improve cold water flow throughout site. Venturi loop systems may also be installed as part of such as system.	**2**			

Location/Plant Item	Recommendation	Remedial Action Category	Assigned to	Actions Taken	Completed
Access for Monitoring	Domestic water pipework runs above ceilings throughout the building. Access for ongoing monitoring will be problematic as ceiling tiles cannot be easily removed within the hospital environment and alternative methods of monitoring should be considered should current BEMS monitoring points not be sufficient for the hot flow and return system (e.g. additional BEMS monitoring points installed).	2			

Location/Plant Item	Recommendation	Remedial Action Category	Assigned to	Actions Taken	Completed
Thermostatic Mixing Valves/Taps/Showers	TMV servicing in high risk areas (advised to DMA by Estates) including flushing of hot and cold supplies to tap via flushing adapters has recently been carried out by DMA as we were advised the Estates regime may have lapsed. Servicing of some outlets (e.g. Armitage Contour Taps) is restricted as DMA have been advised we are unable to remove IPS panels. This gives further cause for concern as Estates were unable to confirm if the strainers on the supplies have ever been removed for cleaning/disinfection or taps fully serviced. The vast majority of TMVs installed are TMV taps, (Horne Optitherm in clinical areas and Armitage Shanks in non-clinical areas) with the only exceptions noted being infrared outlets in non-patient area toilets with infrared taps which have a TMV mounted approximately 0.5m from the outlet. Thermostatic mixing valves (TMVs) should be regularly serviced as per the manufacturers instructions and in accordance with the Written Scheme for site which should include input from the relevant NHS departments (e.g. Estates, Clinical, Infection Control, Authorising Engineer, Compliance Team, Health & Safety, Water Safety Group etc. – please note DMA's attendance at Water Safety Group meetings has not been requested) for local infection control guidance for bacterial control taking into account the location, design, operation, servicing and requirements of infection control. Horne Optitherm TMV taps are designed to be demounted for maintenance and servicing elsewhere but the facilities for this are yet to be completed and commissioned. Specific service method statements and maintenance requirements for these items in these areas should form part of the written scheme.	**2**			

Location/Plant Item	Recommendation	Remedial Action Category	Assigned to	Actions Taken	Completed
Thermostatic Mixing Valves/Taps/Showers	In addition, the strainers located on the supplies to the TMV taps in "Non-Clinical" areas (e.g. patient, visitor and staff toilets) are located behind panels and therefore infection control procedures are required (Scribe) in order to remove panels for service. We understand no servicing of any of these valves and the associated strainers in non-high risk areas has been carried out since the hospital opened and there has been a very limited program of servicing in 'high risk' areas. We are unaware of any servicing works being carried out and had access to servicing records on TMV taps in other areas of the hospital at the time of assessment. The recent (prior to assessment delivery) issue with regards to Cupriavidus bacteria being detected in the system water has highlighted that the servicing requirements of the TMV taps should be reviewed to ensure that in addition to manufacturers service instructions being carried out the servicing of TMV taps includes any additional control measures as deemed necessary by infection control e.g. full thermal bypass/disinfection of the taps where practicable and safe (this would require to be carried out remotely from patient areas) and flow regulator, O rings and other components cleaning, disinfection and/or replacement. There are no records that manufacturers recommendations have been implemented to date regarding commissioning and component changes. Estates advised there is currently no mechanism in place for 'no access' reports to be re-actioned to ensure all valves are completed in the necessary time frame.				

Location/Plant Item	Recommendation	Remedial Action Category	Assigned to	Actions Taken	Completed
Shower heads and hoses	Showers appear to be a standard design throughout the hospital with no adjustable heads noted during the survey. However, as NHS Estates are unable to confirm the service history of the units and cleaning and disinfection of shower heads we would advise consideration is given to changing all heads and hoses with new WRAS approved heads and hoses.	2			
Flexible Hoses	DMA were advised by Mercury Engineering and Estates in 2015 that all materials fitted during the construction are WRAS approved and therefore do not support bacterial growth. In addition, EPDM flexible hoses have been installed in a small number of non-clinical areas with the only patient areas DMA have noted as having flexible hoses being the connection to Arjo baths (both connections to the hot/cold system and internally within the actual bath). Wherever possible DMA would recommend all flexi hoses are removed and connections hard piped. Where flexible hoses cannot be removed then replacing with alternative WRAS approved hoses with linings other than EPDM should be considered. In healthcare premises additional guidance on the replacement and use of flexible hoses is provided in the "safety action notice SAN(SC)09/03". Flexible hoses have also been noted on the boosted bulk water system on pressure reducing valves. If possible, these should be hard piped (stainless steel) or WRAS approved hoses with linings other than EPDM should be considered. Should these not be available for these types of units/connections then a regular inspection and replacement schedule should be implemented for these.	2			

Location/Plant Item	Recommendation	Remedial Action Category	Assigned to	Actions Taken	Completed
Trades Water System	The bib taps, irrigation points (which DMA have been informed are no longer connected to the water system) and 12th floor heli-pad fire suppression system are fed from the Trades system with very long pipework runs through the building and plantrooms to the outlets. DMA would advise all points on the trades system should be included in the site flushing regime. Please also refer to section 8 for information on other risk systems. No outlets on the Trades system have been designated as "sentinel outlets". Due to the type of system and the extended pipe runs to the outlets it may be prudent to designate all outlets from this system as sentinel and include in monthly monitoring and site flushing regime.	2			
Outlet 00 OPD/Concourse OPD0-073 (Shower)	Shower not working creating deadlegs. Outlet should be repaired and lines thoroughly flushed.	2			
Outlet 00C Decontamination DCU-003 (Wet Room)	Cold water temperature too high. Investigate and correct.	2			
Outlet 00C Radiology RCG-068 (Baby sleep)	Cold water temperature too high. Investigate and correct.	2			
Outlet 01 Radiology RAF-005 (Reception)	Ensure unused connection point included in flushing regime until put into use	2			
Outlet 01 Stroke STW-082 (Bath)	Out of order outlets (bath) in room creating deadlegs - these should be repaired and lines thoroughly flushed.	2			
Outlet 01C Critical Care CCW-021 (Bathroom)	Hot temperature slow to rise. It should be confirmed that hot outlet(s) are on a long leg and not that the flow and return has failed locally in this area.	2			
Outlet 01C Critical Care CCW-021 (Bathroom)	Hot water temperature too low. Investigate and correct.	2			
Outlet 01C Theatre 001-011	Cold water temperature too high. Investigate and correct.	2			
Outlet 01C Theatre THE-009 (Toilet)	High cold temperature. Investigate and correct.	2			
Outlet 01C Theatre THE-078 (Prep room)	High cold temperature. Investigate and correct.	2			

Location/Plant Item	Recommendation	Remedial Action Category	Assigned to	Actions Taken	Completed
Outlet 01C Theatre THE-102 (Facilities)	Evidence of heat gain in cold water - investigate and correct.	2			
Outlet 01C Theatre THE-106 (Anesthetic room)	Cold water temperature too high. Investigate and correct.	2			
Outlet 01C Theatre THE-157 (Recovery room)	Cold water temperature too high. Investigate and correct.	2			
Outlet 04A - RENW-028	Cold water temperature too high. Investigate and correct.	2			
Outlet 04A HOW-024 (Bathroom)	Cold water temperature too high. Investigate and correct.	2			
Outlet 04A HOW-027 (Bathroom)	Cold water temperature too high. Investigate and correct.	2			
Outlet 04B HOW-030 (Bathroom)	Cold water temperature too high. Investigate and correct.	2			
Outlet 04B HOW-065	Cold water temperature too high. Investigate and correct.	2			
Outlet 04C RENW-153 (Bathroom)	Cold water temperature too high. Investigate and correct.	2			
Outlet 04D RENW-094 (Bathroom)	Cold water temperature too high. Investigate and correct.	2			
Outlet 05A GENWA-029 (Bathroom)	Cold water temperature too high. Investigate and correct.	2			
Outlet 06A GENW1-029 (Bathroom)	Cold water temperature too high. Investigate and correct.	2			
Outlet 06D GENW2-034 (Bathroom)	Cold water temperature too high. Investigate and correct.	2			
Outlet 06D GENW2-065 (Bedroom)	Cold water temperature too high. Investigate and correct.	2			
Outlet 08D GENW10-057 (Bedroom)	Cold water temperature too high. Investigate and correct.	2			
Outlet 09A GENW13-029 (Bathroom)	Cold water temperature too high. Investigate and correct.	2			
Outlet 09B GENW16-036 (Bathroom)	Cold water temperature too high. Investigate and correct.	2			
Outlet 09D GENW14-028 (Bedroom)	Cold water temperature too high. Investigate and correct.	2			
Outlet 09D GENW14-065 (Bedroom)	Cold water temperature too high. Investigate and correct.	2			
Outlet 10A GENW17-029 (Bathroom)	Cold water temperature too high. Investigate and correct.	2			
Outlet 4B HOW-039 CDC	Cold water temperature too high. Investigate and correct.	2			

Location/Plant Item	Recommendation	Remedial Action Category	Assigned to	Actions Taken	Completed
Outlet Basement KIT-031	Unused vend connectionshould be removed or included in flushing regime	2			
Outlet Hydrotherapy Plantroom A-1FMB-030	Include bib tap & Emergency Shower in flushing regime	2			
Outlet Hydrotherapy Plantroom A-1FMB-030	Remove all deadleg pipework in this area.	2			
General System	Pipework runs above ceilings in throughout every floor of the building. Access to these for ongoing monitoring will be problematic as ceiling tiles cannot be easily removed within the hospital environment and alternative methods of monitoring should be considered should current BEMS monitoring points not be sufficient for the hot flow and return system. additional BEMS monitoring points installed). DMA identified a very small number of localities where the hot water system did not appear to be functioning correctly and these should be investigated with corrective actions taken.	3			
Oultet 06A GENW1-034 (Bathroom)	Evidence of heat gain in cold water - investigate and correct.	3			
Outlet 00 A&E EMC-100 (Service)	Evidence of heat gain on cold - investigate and correct	3			
Outlet 00 A&E EMC-100 (Service)	Include Unused outlets into site flushing regime.	3			
Outlet 00 Acute Assess AAW-173 (Clinical Support)	Include Unused outlets into site flushing regime.	3			
Outlet 00 Concourse ENT-038 (Baby Change)	Include Unused outlets into site flushing regime.	3			
Outlet 00 Discharge DLO-008 (Consulting Room)	Low mixed water temperature - Investigate and crrect (TMV may require servicing)	3			
Outlet 00 Medical Illustration MIL-010 (Studio)	Evidence of heat gain in cold water - investigate and correct.	3			
Outlet 00 OPD OPD0-003 (Male Change)	Include Unused outlets into site flushing regime.	3			

Location/Plant Item	Recommendation	Remedial Action Category	Assigned to	Actions Taken	Completed
Outlet 00 OPD OPD0-049 (Treatment Room)	Evidence of heat gain in cold water - investigate and correct.	3			
Outlet 00 Orthotics ORT-017 (Disabled)	Include Unused outlets into site flushing regime.	3			
Outlet 00 Pharmacy PHA-002 (Facilities)	Low mixed water temperature - Investigate and crrect (TMV may require servicing)	3			
Outlet 00 Radiology RAG-108 (Anaesthetic)	Evidence of heat gain in cold water - investigate and correct.	3			
Outlet 00 Rehab REH-013 (OT Room)	Evidence of heat gain in cold water - investigate and correct.	3			
Outlet 00 Rehab REH-013 (OT Room)	Include Unused outlets into site flushing regime.	3			
Outlet 00C A&E EMC-059 (Bed Bay 6)	Evidence of heat gain in cold water - investigate and correct.	3			
Outlet 00C A&E EMC-060 (Bed Bay 5)	Evidence of heat gain in cold water - investigate and correct.	3			
Outlet 00C Consultancy CPS-003 (Consulting Room)	Evidence of heat gain in cold water - investigate and correct.	3			
Outlet 00C Consultancy CPS-003 (Consulting Room)	Include Unused outlets into site flushing regime.	3			
Outlet 00C Consultancy CPS-006 (Toilet)	Include Unused outlets into site flushing regime.	3			
Outlet 00C Decontamination DCU-003 (Wet Room)	Include Unused outlets into site flushing regime.	3			
Outlet 00C Observation OBW-061 (Bedroom)	Evidence of heat gain in cold water - investigate and correct.	3			
Outlet 00C Observation OBW-061 (Bedroom)	Include Unused outlets into site flushing regime.	3			

Location/Plant Item	Recommendation	Remedial Action Category	Assigned to	Actions Taken	Completed
Outlet 00C OPD OPD-125 (Changing)	Include Unused outlets into site flushing regime.	3			
Oultet 01 Radiology RCF-001 (Facilities)	Ensure any outlets which have been removed have not left deadlegs behind panels.	3			
Outlet 00C Radiology RCG-068 (Baby sleep)	Include Unused outlets into site flushing regime.	3			
Outlet 00C Radiology RCG-087 (Dirty Utility)	Evidence of heat gain in cold water - investigate and correct.	3			
Outlet 00C Radiology RCG-087 (Dirty Utility)	Include Unused outlets into site flushing regime.	3			
Outlet 01 Critical Care CCU-036 (Bedroom)	Evidence of heat gain in cold water - investigate and correct.	3			
Outlet 01 Critical Care CCW-029 (Toilet)	Include Unused outlets into site flushing regime.	3			
Outlet 01 Critical Care CCW-087 (Bed Bay 37)	Evidence of heat gain in cold water - investigate and correct.	3			
Outlet 01 Critical Care CCW-089 (Bed Bay 38)	Evidence of heat gain in cold water - investigate and correct.	3			
Outlet 01 Critical Care CCW-092 (Gowning Room)	Evidence of heat gain in cold water - investigate and correct.	3			
Outlet 01 Critical Care CCW-126 (Dirty Utility)	Include Unused outlets into site flushing regime.	3			
Outlet 01 Critical Care CCW-131 (Pharmacy Support)	Evidence of heat gain in cold water - investigate and correct.	3			
Outlet 01 Medical Day Unit MDU-012 (Treatment Room)	Low mixed water temperature - Investigate and crrect (TMV may require servicing)	3			
Outlet 01 Medical Day Unit MDU-046 (Facilities)	Evidence of heat gain in cold water - investigate and correct.	3			

Location/Plant Item	Recommendation	Remedial Action Category	Assigned to	Actions Taken	Completed
Outlet 01 OPD POA-015 (Consulting Room)	Evidence of heat gain in cold water - investigate and correct.	3			
Outlet 01 OPD OPD1-063 (Dirty Utility)	Evidence of heat gain in cold water - investigate and correct.	3			
Outlet 01 Stroke STW-047 (Bathroom)	Evidence of heat gain in cold water - investigate and correct.	3			
Outlet 01 Stroke STW-079 (Arjo Bathroom)	Include Unused outlets into site flushing regime.	3			
Outlet 01C Critical Care CCW-014 (Clinical Physics)	Evidence of heat gain in cold water - investigate and correct.	3			
Outlet 01C Critical Care CCW-098 (Critical Care Bed)	Evidence of heat gain in cold water - investigate and correct.	3			
Outlet 01C Theatre 001-011	Include Unused outlets into site flushing regime.	3			
Outlet 01C Theatre 23HU-008 (Toilet)	Evidence of heat gain in cold water - investigate and correct.	3			
Outlet 01C Theatre 23HU-051 (Toilet)	Evidence of heat gain in cold water - investigate and correct.	3			
Outlet 01C Theatre THE-009 (Toilet)	Include Unused outlets into site flushing regime.	3			
Outlet 01C Theatre THE-069 (Lab)	Evidence of heat gain in cold water - investigate and correct.	3			
Outlet 01C Theatre THE-069 (Lab)	Include Unused outlets into site flushing regime.	3			
Outlet 01C Theatre THE-117 (Theatre Scrub)	Evidence of heat gain in cold water - investigate and correct.	3			
Outlet 02 Dermatology DMW-025 (Bathroom)	Evidence of heat gain in cold water - investigate and correct.	3			

Location/Plant Item	Recommendation	Remedial Action Category	Assigned to	Actions Taken	Completed
Outlet 02 Dermatology DMW-031 (Bathroom)	Evidence of heat gain in cold water - investigate and correct.	3			
Outlet 02 Dermatology DOPD-025 (Technician)	Evidence of heat gain in cold water - investigate and correct.	3			
Outlet 02 FMA2-014 (Changing)	Include Unused outlets into site flushing regime.	3			
Outlet 02 Renal RENO-016 (Room 3)	Evidence of heat gain in cold water - investigate and correct.	3			
Outlet 02 Renal RENO-033 (Clean Utility)	Evidence of heat gain in cold water - investigate and correct.	3			
Outlet 02 Renal RENO-064 (Equipment Servicing)	Evidence of heat gain in cold water - investigate and correct.	3			
Outlet 02 Theatres THE-033 (Female Changing)	Evidence of heat gain in cold water - investigate and correct.	3			
Outlet 02 Theatres THE-091 (Dirty Utility)	Evidence of heat gain in cold water - investigate and correct.	3			
Outlet 02 Theatres THE-105 (Dirty Utility)	Evidence of heat gain in cold water - investigate and correct.	3			
Outlet 02 Theatres THE-287 (Bed Bay A9)	Evidence of heat gain in cold water - investigate and correct.	3			
Outlet 02 Theatres THE-289 (Bed Bay A1)	Evidence of heat gain in cold water - investigate and correct.	3			
Outlet 02 Theatres THE-289 (Bed Bay A1)	Include Unused outlets into site flushing regime.	3			
Outlet 02 Theatres THE-302 (Bed Bay A7)	Evidence of heat gain in cold water - investigate and correct.	3			
Outlet 02 Theatres THE-319 (Dirty Utility)	Evidence of heat gain in cold water - investigate and correct.	3			

Location/Plant Item	Recommendation	Remedial Action Category	Assigned to	Actions Taken	Completed
Outlet 02 Theatres THE-327 (Recovery)	Evidence of heat gain in cold water - investigate and correct.	3			
Outlet 02 Theatres THE-327 (Recovery)	Include Unused outlets into site flushing regime.	3			
Outlet 02 Transport Base TPB-001 (Clinical Workroom)	Evidence of heat gain in cold water - investigate and correct.	3			
Outlet 02C Aseptic Unit ASU-039 (Changing Room)	Ensure no deadlegs remain after outlets removed.	3			
Outlet 02C Ward SCH-063 (Treatment Room)	Include Unused outlets into site flushing regime.	3			
Outlet 02C Ward SCH-092 (Hospital Night Team)	Evidence of heat gain in cold water - investigate and correct.	3			
Outlet 03C Ward GW2-035 (Bedroom)	Evidence of heat gain in cold water - investigate and correct.	3			
Outlet 03C Ward GW3-068 (Lab)	Include Unused outlets into site flushing regime.	3			
Outlet 04 WS4-017 (Male Change)	Evidence of heat gain in cold water - investigate and correct.	3			
Outlet 04B HOW-064 (Bedroom)	Include Unused outlets into site flushing regime.	3			
Outlet 04B HOW-193 (Bedroom)	Include Unused outlets into site flushing regime.	3			
Outlet 04C RENW-127 (Consulting Room)	Include Unused outlets into site flushing regime.	3			
Outlet 04C RENW-156 (Bathroom)	Include Unused outlets into site flushing regime.	3			
Outlet 04D RENW-060 (Bedroom)	Include Unused outlets into site flushing regime.	3			

Location/Plant Item	Recommendation	Remedial Action Category	Assigned to	Actions Taken	Completed
Outlet 10D GENW18-001 (Bedroom)	Include Unused outlets into site flushing regime.	3			

Section 3

Site/Client Details

Site/Client Details

Client	**GG&C QEUH**
Client address	Queen Elizabeth University Hospital 1345 Govan Road Glasgow
Client contact	Ian Powrie
Telephone No.	[redacted]
E-mail	[redacted]
Mobile No.	[redacted]

Site	**Queen Elizabeth University Hospital (Adults) and Royal Hospital for Children**
Site Address	Queen Elizabeth University Hospital 1345 Govan Road Glasgow
Client contact	Tommy Romeo
Telephone No.	[redacted]
E-mail	[redacted]
Mobile No.	TBC

Method of Submission	Electronic

General Site Details

Site	Queen Elizabeth University Hospital (Adults) and Royal Hospital for Children
Age of building	Opened in 2015 (Building and Commissioning 2011-2015)
Years since upgrade/renovation of water services	Original System with small local modifications only
Purpose/use of building	Office/administration, Hospital
Operational cycle of the water system being assessed?	Continuous
Potentially affected population	Staff, Contractors, Visitors, Patients, General public
Is the building used by "at risk" or "particularly vulnerable" persons	Yes - Acute medical conditions
Total number of people usually in building (including staff/sub-contractors visitors/pupils etc.)	Unknown - client to confirm
Applicable Legionella standard(s)	L8, SHTM 04-01

Identification of Systems and Scope of Assessment

Domestic Water System		Present on site
Evaporative cooling tower or condenser systems (and associated water system)		None identified to DMA
Fountains and water features		None identified to DMA
Hydrotherapy Pool		Present on site NOT included in assessment
Whirlpool/Arjo Baths		Present on site
Dental equipment		Present on site
Vehicle wash systems (inc. Trolley Wash & Power Washing Plant)		None identified to DMA
Emergency showers		Present on site
Irrigation systems		Present on site
Sprinkler/Wet fire-fighting systems		Present on site
Water softeners		Present on site
Industrial process water systems		None identified to DMA
Machine coolants		None identified to DMA
Air washers, wet scrubbers, particle and trivial gas scrubbers		None identified to DMA
Spray humidifiers		Steam Humidifiers present
Ultrasonic humidifiers/foggers and water misting systems		None identified to DMA
Recycled Water Systems		None identified to DMA
Closed heating water systems (MTHW)		Present on site
Closed chilled water systems		Present on site
Other 'at-risk' systems	Renal Dialysis (x2)	Present on site
	Endoscopy Wash	Present on site
	Medical Gases/Medical Equipment (e.g. Nebulisers, incubators etc.)	Present on site
	Cooling Loop (e.g MRI chillers)	Present on site

N.B. Systems assessed in this document as per client specification.

Legionella Control Measures Currently Used on Site

What is the primary control method for legionella control for the domestic water systems currently used on site and are there any supplementary or replacement control systems on site?[#]	
	Control measure
Temperature controlled	Primary
Chlorine dioxide	Not used
Hydrogen peroxide/silver ion	Not used
Silver/copper ion	Not used
Ultraviolet	Not used
Other (0.2µm filters between Raw and Bulk Tanks)	Secondary

[#] If any method other than, or in addition to, temperature is used as method of control then details of records/regime can be found in section 9.

Section 4

Water Source

Summary of Risk Potential

Town mains water is generally not expected to present a significant risk for the contamination of a system with legionella, though it may be assumed that legionella in low concentrations could be present in the mains water on occasion. Therefore it must be assumed that it is not practical to prevent legionella entering the water system at some point.

There are, in addition, other bacteria, contaminants and physical factors that can create a risk to mains water users in the building.

Where the water source to the site is from a natural source, e.g. River, lake, spring or private water supply then the potential for legionella contamination increases.

N.B. Unless specifically stated otherwise the incoming mains/water source has been assessed from point of entry to the building. External & underground water services which serve the building and are not visible have not been assessed.

Please refer to water source sheets for specific recommendations and risk ratings.

Id no.		Hardgate Road (Large)			Recommendations and Comments	Assigned to	Completed
Labelled		Mains: Yes Pipework: Yes Valves: No			Deadlegs (drain points/injection points) should be removed or incorporated into low use outlets flushing regime. All plant items, pipework and valves should be labelled for identification purposes. There are return lines/vents from the check valve on the mains returning into the CWSTs. The operation of these should be confirmed and checks made to ensure they are not creating deadlegs/trapping stagnant water – incorporate into site flushing regime if lines not being flushed through at least twice weekly. **Comments:** No access to point where incoming mains enters into the building as passage locked off. Access only available up to point where it enters into the tank room.		
Access		Good					
Type		Town mains					
Supply company		Scottish Water					
Services supplied		CWSTs – (Raw Water)					
Location		Basement Main Tank plantroom					
Size		150mm					
Meter reading		015758	Time	Date			
			09.30	08/09/17			
Material		MDPE, Stainless steel					
Double check valve fitted		Yes					
Drain/injection point		None visible					
Temperature (ºc)		15.5					
Pipework insulated		Yes					
Incoming Water	pH	7.2					
	Residual free chlorine	<0.1					
Isolation valve		Yes					
Deadlegs		See comments					
Non WRAS materials		None visible					
Level of Risk		Medium					

Id no.		Govan Road			Recommendations and Comments	Assigned to	Completed
Labelled		Mains: Yes Pipework: Yes Valves: No			RHS Trades Water Tank inlet valved off creating a deadleg. This should be incorporated into the weekly flushing regime until such times as CWST issue corrected. Please refer to CWST section for further recommendations. Deadlegs (drain points/injection points) should be removed or incorporated into low use outlets flushing regime. There are return lines/vents from the check valve on the mains returning into the CWSTs. The operation of these should be confirmed and checks made to ensure they are not creating deadlegs/trapping stagnant water – incorporate into site flushing regime if lines not being flushed through at least twice weekly. All plant items, pipework and valves should be labelled for identification purposes. **Comments:** Water meter and check valve in main tank room after connection to trades water tank.		
Access		Good					
Type		Town mains					
Supply company		Scottish Water					
Services supplied		CWSTs (Raw Water and Trades)					
Location		Basement MTHW/Chilled Plantroom					
Size		150mm					
Meter reading		25921	Time	Date			
			09.50	08/09/17			
Material		MDPE, Stainless steel					
Double check valve fitted		Yes					
Drain/injection point		Yes					
Temperature (ºc)		15.8					
Pipework insulated		Yes					
Incoming Water	pH	7.2					
	Residual free Chlorine	<0.1					
Isolation valve		Yes					
Deadlegs		See comments					
Non WRAS materials		None visible					
Level of Risk		Medium					

Id no.		Hardgate Road (Small)			Recommendations and Comments	Assigned to	Completed
Labelled		Mains: Yes Pipework: Yes Valves: No			As this mains lines is likely to have a low turnover of water DMA would recommend the NHS confirms that this main is separated from domestic water mains by a double check valve or similar (possibly external to building) to prevent potentially stagnant water from contaminating the domestic mains. All plant items, pipework and valves should be labelled for identification purposes.		
Access		Good					
Type		Town mains					
Supply company		Scottish Water					
Services supplied		Fire tanks					
Location		Basement Main Tank plantroom					
Size		54mm					
Meter reading		N/A	Time	Date			
Material		MDPE, Stainless steel					
Double check valve fitted		Yes					
Drain/injection point		Yes					
Temperature (ºc)		-					
Pipework insulated		Yes					
Incoming Water	pH	-					
	Residual free Chlorine	-					
Isolation valve		Yes					
Deadlegs		None visible					
Non WRAS materials		None visible					
Level of Risk		High					

Section 5

Cold Water Storage Tanks

Cold Water Storage Tanks (Cisterns)

Cold Water Storage Tanks (CWSTs), in themselves, present a low Legionella risk in general terms. However, where the tanked water supplies other plant that has a high risk factor (e.g. cooling towers, showers, etc.) The potential risk is much higher.

Poor control over water temperature and condition of the stored water, plus the condition of the tank itself, may lead to Legionella colonising and proliferating in the tank and therefore producing possible source of bacteria to infect other water services downstream.

Basic principles being looked at in this section are the physical condition and the design of the CWST and associated pipework, ensuring these comply with the relevant guidelines, and the condition of the water being stored within the water tank. The water stored within the tanks should be no more than 2°C higher than the incoming mains, and less than 20°C

All CWSTs inherently carry the risk associated with the make-up source to the CWST, and these risk factors must be taken into account in determining the actual risk posed by the system as a whole.

Please refer to appropriate sections on Legionella management, CWSTs and water source to determine the inherent risk factors of water being supplied to the CWSTs being assessed in this section.

Risk factors incorporated within this section refer only to the risk factors associated with the CWSTs.

Please refer to individual CWST sheets for specific recommendations and risk ratings.

CWSTs and Filters

QEUH Adult and Children's Hospital CWSTs

There are 10 domestic water storage tanks in the building which are all situated in the basement tank room.

Raw Water Tanks 1A/1B and 2A/2B are supplied by two town mains (Govan Road and Hardgate Road) to ensure continuity of supply in case of a town mains failure. The Raw Water tanks supply the Bulk Water tanks 1A/1B and 2A/2B via two 0.2 micron filtration sets (level of filtration advised by Estates). All Raw Water tanks were linked at the time of survey, though can be set up to feed filters units separately if required.

The filtration units fill separate Bulk Water Tanks (filtration unit 1 supplying 1A & 1B and filtration unit 2 supplying 2A & 2B). There appears no way to reconfigure set-up to allow the filtration units to fill the other tanks under fault conditions. Filtration sets should be maintained in accordance with manufacturer's instructions and maintenance schedule.

Bulk Water Tanks 1A and 1B are linked, with 2A and 2B also linked. All four tanks can be linked together (via outlets) to supply domestic cold water including drinking water to the building with the exception of the trades system. The link between the tanks 1A/1B and 2A/2B was closed at the time survey with each set of tanks supplying separate zones and plantrooms (calorifiers) within the hospital, 1A/1B supplying plantrooms 21/22/41 and the corresponding outlets in these zones with 2A/2B supplying plantrooms 31/32/33 and the corresponding outlets in these zones.

DMA were advised Estates staff are unsure why the bypass is closed as all four Bulk Water Tanks were classified as linked.

DMA noted small debris including washers in Bulk Water Tank 2B in our initial assessment from 2015 and these are still present. We would advise that this tank is cleaned to remove debris and then disinfected. (We would also recommend site confirm CWST inspections are being completed and competency of staff completing the inspections)

Storage temperate in 2B combined with heavier water mark may indicate this CWST is not turning over as well as the others. This should be monitored and CWSTs balanced. In addition, it should be confirmed that the filter system is working adequately as this level of debris is unexpected being downstream of a 0.2 micron filter set. However, DMA were advised during the initial occupation phase that the filter system was bypassed due to issues with the pumps and filter set and this may have introduced debris (and potentially bacteria) into the system and as the tanks have not been cleaned since this time anything flushed into the system may have colonised parts of the system.

Bulk Water CWST 1B was unable to be inspected as Estates were unable to provide keys for the tank lids.

N.B. It should be noted that there is no separate dedicated supply to the Renal (or other medical) systems, with all being fed from the Bulk Water system. This means that system disinfections will require to be very carefully scheduled or carried out locally as the disinfection procedure/chemical may interfere with the renal/medical systems and impact on patient welfare.

There are 2 No. water booster sets in the water tank room. Each booster set is set to a different set point pressure depending on which plantroom and area it serves. In the event of failure each booster can also be switched to the other set point pressure.

- BS01 – Feeding Plantroom 31, 32 & 33 - 7.7 Bar
- BS02 – Feeding Plantroom 21, 22 & 41 – 5 Bar

The expansion vessels attached to the CWST booster sets are not of a flow through design and they are not insulated.

From the 2 No. water booster sets there are 8 domestic water systems:

- Plantroom 21
  - Via a Pressure reducing valve (PRV) the BCWS feed 21CAL01/02/03
- Plantroom 22
  - Via a Pressure reducing valve (PRV) the BCWS feed 22CAL01/02/03
- Plantroom 31 – 122
  - BCWS feeds 31CAL01/02/03
- Plantroom 31 – 128
  - Via a Pressure reducing valve (PRV) the BCWS feeds 31CAL07/08/09
- Plantroom 31 – 129
  - BCWS feeds 31CAL04/05/06
- Plantroom 32
  - BCWS feeds 32CAL01/02/03
- Plantroom 33
  - BCWS feeds 33CAL01/02/03
- Plantroom 41
  - BCWS feeds 41CAL01/02/03

The water supply into each plantroom is metered by a CWS flow meter. This allows for monitoring of specific parts of the system for energy purposes.

There are numerous connection points on the domestic water system within plantrooms and risers (which DMA have assumed were installed for flushing purposes and bypasses) which are creating deadlegs on the system. It is advised that these be removed wherever practicable or a register of the locations created and points incorporated into the site flushing regime.

The Trades Water System supplies "Non-domestic" outlets such as bib taps in plantrooms, irrigation connections points and the 12th floor heli-pad fire suppression system. One side of the Trades tank was valved off due to a reported inlet valve issue in 2015 (though tank full with signs of stagnation). It would appear that this tank has been offline since the construction phase. DMA would advise the tank is cleaned and disinfected prior to the tank being reinstated – or if not required drained and left isolated, ensuring any deadlegs created on inlet and/or outlet are removed or incorporated into site flushing regime.

There are various connection points onto other "non-domestic" outlets such as renal dialysis, endoscopy wash, pressurisation units, steam humidifier units and MRI chiller cooling which are connected to the Bulk Water system. It is advised that Estates confirm these systems have suitable backflow protection installed or if necessary suitable backflow protection be fitted. It is also advised that as the lines to these systems will often have a very low turnover, a double check valve or similar should be fitted as close as practicable to the tee-off point to prevent potentially stagnant water from contaminating the domestic system.

N.B. for information on Fire Suppression Tanks please see section 8.

Name/number of CWST		Raw Water (4 off)			**Recommendations and Comments**	**Assigned to**	**Completed**
Location of CWST		Basement Tank plantroom					
Labelled		**CWST**	**Pipework**	**Valves**	Some evidence of biofilm forming on baffles at mains inlets, possibly due to splashing etc. Baffles should be inspected periodically (e.g. monthly) and cleaned as and when required. A suitable screened screen should be fitted to the warning pip and it should be confirmed that the overflow is suitably screened Additional access hatches on tanks for cleaning/inspection purposes should be considered. There are drain down points on pipework. These should be included in site flushing regime. All plant items, pipework and valves should be labelled for identification purposes. N.B. no evidence of clean and disinfection since the hospital opened in 2015.		
		No	Yes	No			
Type		Sectional					
Materials		GRP					
Lined		No					
Dimensions (m)		5x5x2 (1.6)					
Volume (litres)		50000 (40000)					
Linked/single		Linked					
M/U opposite draw off		Diagonal					
Make up source		Town mains					
Services supplied		CWST (via filtration unit)					
Temperature °C		**Make Up**	**Tank Water**	**Plantroom**			
		15.5/15.8	1A – 15.5 1B – 15.8 2A – 15.8 2B – 15.8	18			
Internal condition	Internal	Good					
	Waterline	Light					
	Dirt & silt	Generally light sediment with small patches of heavier sediment on base.					
Water condition		Clear					
Stagnation		No					
Deadlegs around CWST		Yes – See comments					
Close fitting lid/screened vent		Yes	Fitted				
Warning Pipe Screen		None visible					
Overflow Screen		Fitted (in flange)					
Insulation		Yes - pre-fitted					
Access		Good					
Vents returning to CWST		No					
Is drain present?		Yes					
Booster pumps	Fitted	Yes - 2					
	Vibration Couplings	No vibration coupling visible No flexible hoses visible					
	Expansion Vessel	No					
	Drain on Vessel?	-					
Overall risk rating		**Medium**					

						Recommendations and Comments	Assigned to	Completed
Name/number of CWST		Bulk Water (4 off)				CWSTs require to be cleaned and disinfected. Storage temperate in 2B combined with heavier water mark may indicate this CWST is not turning over as well as the others. This should be monitored and CWSTs balanced. The heavy water mark noted in 2B is unexpected following a 0.2micron filter though may have been introduced in initial filing/occupation phase when the filter system was bypassed. We would advise this is investigated and confirmed the filter system is operating correctly. Ensure filter system is maintained in accordance with manufactures instructions. A suitable screened screen should be fitted to the warning pip and it should be confirmed that the overflow is suitably screened Wherever possible/practical expansion vessels should be 'flow through' vessels and suitably insulated. Where this is not possible a drain (and isolation valve where compliant with Water regs) should be fitted (if not present already) and included in site flushing regime Additional access hatches on tanks for cleaning/inspection purposes should be considered. Ensure short connection between booster sets is thoroughly flushed before use should it ever be required. Drain points should be fitted to pump manifolds to allow end of lines to be flushed (if practicable). There are various drain points and bypass valves fitted to the pipework in the plantroom. These should be included in site flushing regime. **Comments:** No access to CWST 1b – no keys available from Estates – This should be inspected and assessed as soon as possible. **N.B.** no evidence of clean and disinfection since the hospital opened in 2015.		
Location of CWST		Basement Tank plantroom						
Labelled		**CWST**	**Pipework**	**Valves**				
		No	Yes	No				
Type		Sectional						
Materials		GRP						
Lined		No						
Dimensions (m)		13.5x5x2 (1.6)						
Volume (litres)		135000 (108000)						
Linked/single		Linked						
M/U opposite draw off		Diagonal						
Make up source		Raw Water CWSTs via filters						
Services supplied		See comments						
Temperature °C		**Make Up**	**Tank Water**		**Plantroom**			
		See comments	1A – 16.1 1B –No access 2A – 16.2 2B – 16.7		18			
Internal condition	Internal	Good						
	Waterline	Light Mark in 1A & 2A, 2B has heavy watermark						
	Dirt & silt	Light sediment 1A, 2A & 2B. Washers visible on base of CWST 2B						
Water condition		Clear						
Stagnation		No						
Deadlegs around CWST		Yes – see comments						
Close fitting lid/screened vent		Yes		Fitted				
Warning Pipe Screen		None visible						
Overflow Screen		Fitted (in flange)						
Insulation		Yes - pre-fitted						
Access		Good						
Vents returning to CWST		No						
Is drain present?		Yes						
Booster pumps	Fitted	Yes – 10 (5 High Pressure / 5 Lower Pressure)						
	Vibration Couplings	No vibration coupling visible No flexible hoses visible						
	Expansion Vessel	Yes - upright						
	Drain on Vessel?	Able to be drained/flushed (large only)						
Overall risk rating		**Medium**						

Name/number of CWST		Trades Water (2 off)			**Recommendations and Comments**	**Assigned to**	**Completed**
Location of CWST		Basement Tank plantroom					
Labelled		**CWST**	**Pipework**	**Valves**	RHS side of the Trades tank has been isolated on inlet for approx. 3 years. (though tank full of water with signs of stagnation). DMA would advise the tank is cleaned and disinfected prior to the tank being reinstated. A suitable screened vent should be fitted to the overflow. Wherever possible/practical expansion vessels should be 'flow through' vessels and suitably insulated. Where this is not possible a drain (and isolation valve where compliant with Water regs) should be fitted (if not present already) and included in site flushing regime Ideally a drain should be fitted to pump manifold to allow end of lines to be flushed (if practicable). All plant items, pipework and valves should be labelled for identification purposes. **Comment** Trades Water Tank Meter Reading 472681 - 08/09/17 10.30		
		No	Yes	No			
Type		Sectional					
Materials		GRP					
Lined		No					
Dimensions (m)		2 off - 2x1x1 (0.7)					
Volume (litres)		2 off at 2000 (1400)litres					
Linked/single		Linked					
M/U opposite draw off		Outlet on base					
Make up source		Town mains					
Services supplied		Designated "non-domestic" outlets (i.e. irrigation, 12th floor heli-pad fire suppression and plantroom bib taps)					
Temperature °C		**Make Up**	**Tank Water**	**Plantroom/Ambient**			
		15.8/offline	16.9/20.8	18			
Internal condition	Internal	Good					
	Waterline	T2 - No mark / T1 - Stagnant					
	Dirt & silt	T2 - Light sediment / T1 - Stagnant					
Water condition		T2 - Clear / T1 - Stagnant					
Stagnation		Yes					
Deadlegs around CWST		Yes – on mains to linked tanks, Yes – on outlet to linked tanks					
Close fitting lid/screened vent		Yes	Fitted				
Warning Pipe Screen		Fitted					
Overflow Screen		None visible					
Insulation		Yes - pre-fitted					
Access		Good					
Vents returning to CWST		No					
Is drain present?		Yes					
Booster pumps	Fitted	Yes - 3					
	Vibration Couplings	No vibration coupling visible No flexible hoses visible					
	Expansion Vessel	Yes - upright					
	Drain on Vessel?	Able to be drained/flushed					
Overall risk rating		**High Risk**					

Section 6

Calorifiers and Water Heaters

Calorifiers and Water Heaters

Calorifiers present a low Legionella risk, however when the calorifier water supplies other associated plant which may have a high risk potential (e.g. Showers etc.), the potential risk from such calorifiers is significantly higher.

Calorifiers have been a major source of proliferation of Legionella.

Poor control over the water temperature and condition of the calorifier are the most significant factors in determining the risk presented by hot water calorifiers to the down water services.

Basic principles being looked at in this section are the physical condition and the design of the calorifiers/water heaters and associated pipework, ensuring these comply with the relevant guidelines, and the condition of the water being stored within the heaters. The water should be stored at a minimum of 60°C, with the entire body of the calorifier achieving this temperature for a minimum period of 1 hour per day. The base temperature and return temperatures should maintain a minimum temperature of 50°C at all times.

Risk factors incorporated within this section refer only to the risk factors associated with the calorifiers (or water heaters).

All calorifiers inherently carry the risk associated with the make-up source e.g. CWST, and these risk factors must be taken into account in determining the actual risk posed by the system as a whole. Please refer to appropriate sections on Legionella management, CWSTs and water source to determine the inherent risk factors of water being supplied to the calorifiers being assessed in this section.

Please refer to calorifier sheets for specific recommendations and risk ratings.

Backflow protection: suitable backflow protection should be fitted to all water heaters on pressurised systems (e.g. Mains fed or boosted cold water fed). Before fitting any double check valves or other forms of backflow protection ensure that adequate pressure relief valves are fitted and working in the event of excessive pressure or temperature build up within water heaters.

Calorifiers (PHE's with Storage Vessels)

The calorifiers are situated in various plantrooms on the 2nd, 3rd and 4th floors of the building feeding designated zones within the hospital building. See supportive data following which identifies which calorifiers feed which areas.

Each set of calorifiers is a bank of 3-linked calorifiers fed from the boosted Bulk Water system, with heat source being via a plate heat exchanger on the outside of each calorifier fed from the MTHW system. A circulating pump on each calorifier/plate heat exchanger ensures the water is circulated throughout each vessel to maintain temperature.

The distribution temperatures were almost invariably above 50°C at all outlets (Supply to TMVs) with direct hot feeds above 55°C (see outlet section for supportive data and exceptions).

The return temperatures recorded at the calorifiers were consistently below 55°C which DMA were advised was the control set point for these, though when calorifiers were at full temperature the returns were reaching 50°C. It may be prudent to increase calorifier set points to ensure calorifier returns remain above 55°C as this is the control set point. This may also help maintain a 60°C minimum flow temperature when demand is placed on the calorifiers at peak periods. Increasing the calorifier temperatures may also have the beneficial effect of increasing the cold water usage as more cold water will be required at TMVs to blend water to TMV set point and so may assist in reducing any high cold water temperatures being recorded within the system.

The majority of the calorifiers were running at full temperature (i.e. 60°C or above) though there were some exceptions to this as highlighted in the supportive data following where one calorifier appears to be the lead calorifier and subsequently has lower temperatures than the connected calorifiers in the bank of 3. This may be a balancing issue and should be investigated and corrected wherever necessary.

The expansion vessels attached to the calorifiers are not of a flow through design as recommended in HSG 274 Part 2 (info Box 2.1) and SHTM 04-01 Part A (Para 8.22) and they are not insulated as recommended in SHTM 04-01 Part A (Para 8.22). Estates advised during the Gap Analysis that no expansion vessel flushing is being carried out.

DMA noted very dirty water was purged from a number of calorifier drains which may indicate the flushing regime should be increased (Estates advised during the Gap Analysis that base flushing is being carried out though were unable to provide supporting evidence), or that the methodology for flushing should be reviewed to ensure the calorifier base is being purged and not just the supply pipework.

ID No./Name		P21 - 01/02/03						Recommendations and Comments	Assigned to	Completed
Location		Plantroom 21						Wherever possible/practical expansion vessels should be 'flow through' vessels and suitably insulated. Where this is not possible a expansion vessel should be included in site flushing regime. Return temperature lower that the 55°C Brookfield specified return temperature though reaches the SHTM 04-01 guidance temperature of 50°C.		
Labelled		Cal	Yes	Pipes	Yes	Valves	No			
Type		Plate Heat Exchanger								
Materials		Stainless steel								
Access		Good								
Linked/single		Linked								
Heat source		MTHW								
Make up source		CWST (Bulk)								
Services supplied (area)		Domestic hot water (Ground & 1st Floor - South)								
Cold feed location		Base								
Vent or pressure relief		Pressure relief								
Circulation pump	Fitted / No. / Check Valve	Yes		1		None visible				
Destrat pump	Fitted	None visible								
Pumps	Vibration couplings	None visible								
Expansion / buffer vessel	Fitted?	Yes - upright								
	Vessel able to be Flushed	Able to be drained/flushed								
Insulation		None visible								
Inspection Hatch (mm)		Yes 300								
Deadlegs around Calorifier		None visible								
Non WRAS materials		None visible								
Drain	Fitted/Water Quality	Yes (Clear)								
Temperatures (°c)		Flow	60/60/61							
		Return	52							
		Base/Drain	58/58/59							
Risk Rating		Medium								

ID No./Name		P22 - 01/02/03						Recommendations and Comments	Assigned to	Completed
Location		Plantroom 22						Calorifier P22 01 temperature very slightly lower than the other calorifiers. Ensure linked calorifiers are balanced to provide equal throughput of water through each calorifier and calorifier brought up to full temperature. Wherever possible/practical expansion vessels should be 'flow through' vessels and suitably insulated. Where this is not possible a expansion vessel should be included in site flushing regime. Fit caps to ends of spare circulation pump. Water flushed from drains on Calorifiers P22 01 & 02 ran very dirty for approx. 20 seconds before beginning to clear up. This should be investigated to determine cause – increased flushing frequency may be necessary if no cause and/or corrective action determined. Return temperature lower that the 55°C Brookfield specified return temperature though reaches the SHTM 04-01 guidance temperature of 50°C. Deadleg pipework in this area should be removed (see also outlet recommendations regarding drain points/flushing points etc. in plantrooms)		
Labelled		Cal	Yes	Pipes	Yes	Valves	No			
Type		Plate Heat Exchanger								
Materials		Stainless steel								
Access		Good								
Linked/single		Linked								
Heat source		MTHW								
Make up source		CWST (Bulk)								
Services supplied (area)		Domestic hot water Ground, 1st & 2nd Floors – North & Centre)								
Cold feed location		Base								
Vent or pressure relief		Pressure relief								
Circulation pump	Fitted / No. / Check Valve	Yes		1		None visible				
Destrat pump	Fitted	None visible								
Pumps	Vibration couplings	None visible								
Expansion / buffer vessel	Fitted?	Yes - upright								
	Vessel able to be Flushed	Able to be drained/flushed								
Insulation		None visible								
Inspection Hatch (mm)		Yes 300								
Deadlegs around Calorifier		None visible								
Non WRAS materials		None visible								
Drain	Fitted/Water Quality	Yes (Dirty)								
Temperatures (°c)		Flow		59/60/60						
		Return		52						
		Base/Drain		58/58/58						
Risk Rating		Medium								

ID No./Name		P31 - 01/02/03						Recommendations and Comments	Assigned to	Completed
Location		Plantroom 31						Calorifier P31 03 temperature very slightly lower than the other calorifiers. Ensure linked calorifiers are balanced to provide equal throughput of water through each calorifier and calorifier brought up to full temperature. Wherever possible/practical expansion vessels should be 'flow through' vessels and suitably insulated. Where this is not possible a expansion vessel should be included in site flushing regime. Fit caps to ends of spare circulation pump. All plant items, pipework and valves should be labelled for identification purposes. DMA did not flush calorifier drains as not piped to floor drains. Return temperature lower that the 55°C Brookfield specified return temperature though reaches the SHTM 04-01 guidance temperature of 50°C. N.B. See also outlet recommendations regarding drain points/flushing points etc. in plantrooms.		
Labelled		Cal	Yes	Pipes	Yes	Valves	No			
Type		Plate Heat Exchanger								
Materials		Stainless steel								
Access		Good								
Linked/single		Linked								
Heat source		MTHW								
Make up source		CWST (Bulk)								
Services supplied (area)		Domestic hot water (Ground, 1st & 2nd Floor East and 2nd Floor South)								
Cold feed location		Base								
Vent or pressure relief		Pressure relief								
Circulation pump	Fitted / No. / Check Valve	Yes		1		None visible				
Destrat pump	Fitted	None visible								
Pumps	Vibration couplings	None visible								
Expansion / buffer vessel	Fitted?	Yes - upright								
	Vessel able to be Flushed	Able to be drained/flushed								
Insulation		None visible								
Inspection Hatch (mm)		Yes 300								
Deadlegs around Calorifier		None visible								
Non WRAS materials		None visible								
Drain	Fitted/Water Quality	Yes								
Temperatures (°c)		Flow	63/60/59							
		Return	52							
		Base/Drain	60/60/56							
Risk Rating		Medium								

ID No./Name		P31 - 04/05/06						Recommendations and Comments	Assigned to	Completed
Location		Plantroom 31						Wherever possible/practical expansion vessels should be 'flow through' vessels and suitably insulated. Where this is not possible a expansion vessel should be included in site flushing regime. Fit caps to ends of spare circulation pump. All plant items, pipework and valves should be labelled for identification purposes. N.B. See also outlet recommendations regarding drain points/flushing points etc. in plantrooms.		
Labelled		Cal	Yes	Pipes	Yes	Valves	No			
Type		Plate Heat Exchanger								
Materials		Stainless steel								
Access		Good								
Linked/single		Linked								
Heat source		MTHW								
Make up source		CWST (Bulk)								
Services supplied (area)		Domestic hot water (Floors 4-11 Zone E)								
Cold feed location		Base								
Vent or pressure relief		Pressure relief								
Circulation pump	Fitted / No. / Check Valve	Yes				None visible				
Destrat pump	Fitted	None visible								
Pumps	Vibration couplings	None visible								
Expansion / buffer vessel	Fitted?	Yes - upright								
	Vessel able to be Flushed	Able to be drained/flushed								
Insulation		None visible								
Inspection Hatch (mm)		Yes 300								
Deadlegs around Calorifier		None visible								
Non WRAS materials		None visible								
Drain	Fitted/Water Quality	Yes								
Temperatures (°c)		Flow	62/60/60							
		Return	56							
		Base/Drain	60/62/62							
Risk Rating		Low								

ID No./Name		P31 - 07/08/09						Recommendations and Comments	Assigned to	Completed
Location		Plantroom 31						Wherever possible/practical expansion vessels should be 'flow through' vessels and suitably insulated. Where this is not possible a expansion vessel should be included in site flushing regime. Fit caps to ends of spare circulation pump. All plant items, pipework and valves should be labelled for identification purposes. Water flushed from drains on Calorifiers P31 - 07, 08 & 09 ran very dirty for approx. 20 seconds before beginning to clear up. This should be investigated to determine cause – increased flushing frequency may be necessary if no cause and/or corrective action determined. Return temperature lower that the 55°C Brookfield specified return temperature though reaches the SHTM 04-01 guidance temperature of 50°C. N.B. See also outlet recommendations regarding drain points/flushing points etc. in plantrooms.		
Labelled		Cal	Yes	Pipes	Yes	Valves	No			
Type		Plate Heat Exchanger								
Materials		Stainless steel								
Access		Good								
Linked/single		Linked								
Heat source		MTHW								
Make up source		CWST (Bulk)								
Services supplied (area)		Domestic hot water (Floors 4-11 Zone H)								
Cold feed location		Base								
Vent or pressure relief		Pressure relief								
Circulation pump	Fitted / No. / Check Valve	Yes		1		Yes				
Destrat pump	Fitted	None visible								
Pumps	Vibration couplings	None visible								
Expansion / buffer vessel	Fitted?	Yes - upright								
	Vessel able to be Flushed	Able to be drained/flushed								
Insulation		None visible								
Inspection Hatch (mm)		Yes 300								
Deadlegs around Calorifier		None visible								
Non WRAS materials		None visible								
Drain	Fitted/Water Quality	Yes – very dirty								
Temperatures (°c)		Flow	60/58/62							
		Return	52							
		Base/Drain	60/58/62							
Risk Rating		Medium								

ID No./Name		P32 - 01/02/03						Recommendations and Comments	Assigned to	Completed
Location		Plantroom 32								
Labelled		Cal	Yes	Pipes	Yes	Valves	No	Wherever possible/practical expansion vessels should be 'flow through' vessels and suitably insulated. Where this is not possible a expansion vessel should be included in site flushing regime. Fit caps to ends of spare circulation pump. All plant items, pipework and valves should be labelled for identification purposes. Water flushed from drains on Calorifiers P32 - 01, 02 & 03 ran very dirty for approx. 15 seconds before beginning to clear up. This should be investigated to determine cause – increased flushing frequency may be necessary if no cause and/or corrective action determined. P32 Calorifier 01 gauge appears to be reading low. – This should be replaced. Return temperature lower that the 55°C Brookfield specified return temperature though reaches the SHTM 04-01 guidance temperature of 50°C. N.B. See also outlet recommendations regarding drain points/flushing points etc. in plantrooms.		
Type		Plate Heat Exchanger								
Materials		Stainless steel								
Access		Good								
Linked/single		Linked								
Heat source		MTHW								
Make up source		CWST (Bulk)								
Services supplied (area)		Domestic hot water (Floors 4 - 11 Zone F)								
Cold feed location		Base								
Vent or pressure relief		Pressure relief								
Circulation pump	Fitted / No. / Check Valve	Yes		1		Yes				
Destrat pump	Fitted	None visible								
Pumps	Vibration couplings	None visible								
Expansion / buffer vessel	Fitted?	Yes - upright								
	Vessel able to be Flushed	Able to be drained/flushed								
Insulation		None visible								
Inspection Hatch (mm)		Yes 300								
Deadlegs around Calorifier		None visible								
Non WRAS materials		None visible								
Drain	Fitted/Water Quality	Yes – very dirty								
Temperatures (°c)		Flow	62/62/62							
		Return	51							
		Base/Drain	66/60/64							
Risk Rating		Medium								

ID No./Name		P33 - 01/02/03						Recommendations and Comments	Assigned to	Completed
Location		Plantroom 33						There is a deadleg on the cold feed at these calorifiers – this should be removed or included in site flushing regime. Wherever possible/practical expansion vessels should be 'flow through' vessels and suitably insulated. Where this is not possible a expansion vessel should be included in site flushing regime. Fit caps to ends of spare circulation pump. All plant items, pipework and valves should be labelled for identification purposes. P33 Calorifier 01 gauge at base appears to be reading incorrectly – This should be replaced. Calorifier pump insulation stripped off due to previous leak – confirm fitting is stainless steel and not mild steel (Unable to confirm at time of survey). Replace if not stainless steel. DMA did not flush calorifier drains as not piped to floor drains. Return temperature lower that the 55°C Brookfield specified return temperature though reaches the SHTM 04-01 guidance temperature of 50°C. N.B. See also outlet recommendations regarding drain points/flushing points etc. in plantrooms.		
Labelled		Cal	Yes	Pipes	Yes	Valves	No			
Type		Plate Heat Exchanger								
Materials		Stainless steel								
Access		Good								
Linked/single		Linked								
Heat source		MTHW								
Make up source		CWST (Bulk)								
Services supplied (area)		Domestic hot water (Floors 4-11 Zone J)								
Cold feed location		Base								
Vent or pressure relief		Pressure relief								
Circulation pump	Fitted / No. / Check Valve	Yes		1		Yes				
Destrat pump	Fitted	None visible								
Pumps	Vibration couplings	None visible								
Expansion / buffer vessel	Fitted?	Yes - upright								
	Vessel able to be Flushed	Able to be drained/flushed								
Insulation		None visible								
Inspection Hatch (mm)		Yes 300								
Deadlegs around Calorifier		Yes								
Non WRAS materials		None visible								
Drain	Fitted/Water Quality	Yes – not run								
Temperatures (°c)		Flow	64/62/62							
		Return	51							
		Base/Drain	72/62/62							
Risk Rating		Low								

ID No./Name		P41 - 01/02/03						Recommendations and Comments	Assigned to	Completed
Location		Plantroom 41						P41 Calorifiers 01, 02 & 03 temperatures all low. Ensure calorifiers set to store and deliver water at a minimum of 60°C at all times. Wherever possible/practical expansion vessels should be 'flow through' vessels and suitably insulated. Where this is not possible a expansion vessel should be included in site flushing regime. Expansion vessels should be suitably insulated. Fit caps to ends of spare circulation pump. All plant items, pipework and valves should be labelled for identification purposes. Water flushed from drains on Calorifiers P41 - 01, 02 & 03 ran very dirty for approx. 15 seconds before beginning to clear up. This should be investigated to determine cause – increased flushing frequency may be necessary if no cause and/or corrective action determined. Return temperature lower that the 55°C Brookfield specified return temperature though reaches the SHTM 04-01 guidance temperature of 50°C. N.B. See also outlet recommendations regarding drain points/flushing points etc. in plantrooms.		
Labelled		Cal	Yes	Pipes	Yes	Valves	No			
Type		Plate Heat Exchanger								
Materials		Stainless steel								
Access		Good								
Linked/single		Linked								
Heat source		MTHW								
Make up source		CWST (Bulk)								
Services supplied (area)		Domestic hot water Children's Hospital								
Cold feed location		Base								
Vent or pressure relief		Pressure relief								
Circulation pump	Fitted / No. / Check Valve	Yes		1		Yes				
Destrat pump	Fitted	None visible								
Pumps	Vibration couplings	Yes, Appear in good condition								
Expansion / buffer vessel	Fitted?	Yes - upright								
	Vessel able to be Flushed	Able to be drained/flushed								
Insulation		Yes								
Inspection Hatch (mm)		Yes 300								
Deadlegs around Calorifier		None visible								
Non WRAS materials		None visible								
Drain	Fitted/Water Quality	Yes – very dirty								
Temperatures (°c)		Flow	58/58/56							
		Return	50							
		Base/Drain	58/58/56							
Risk Rating		High								

Section 7

Hot and Cold Water Outlets

Showers and other spray outlets

Since showers produce fine water droplets or spray they present a significantly higher risk for the development of Legionnaires ' disease than other types of hot and cold outlets.

Water temperature, system design/installation, showerhead design, frequency of use and cleanliness of the outlet are the most significant factors in determining the risk potential.

Hot and cold water outlets

Hot and cold-water outlets do not normally present a risk for the development of Legionnaires' disease unless the outlets create fine droplets or spray. Outlets that do create sprays/droplets significantly increase the risk.

Water temperature, system design/installation, frequency of use, tap design and cleanliness of the outlet are the most significant factors in determining the risk potential.

Basic principles being looked at in this section are the physical condition, and the design of the water services pipework and outlets, and the temperature profile of the water being distributed to the outlets. There should be no unused outlets or deadlegs (blank-ends) on any parts of the systems. Hot water should be delivered to all outlets at a minimum of 55°C within 1 minute of outlet being run and cold water below 20°C within 2 minutes of being run. Cold water should be no more than 2°C higher at the outlet then the water source for this outlet (e.g. CWST). This section also incorporates details of spray outlets/aerosol generators (showers etc.), low use outlets and unused outlets.

Please refer to outlet sheets for specific recommendations & risk ratings.

Risk factors incorporated within this section of the document are classified as "additional localised risk rating". This refers only to the condition of the localised pipework distribution and services and the risk rating applied is in addition to risk rating of the plant items feeding the services.

All outlets fed from CWSTs or calorifiers etc. Inherently carry the risk associated to these plant items, and these risk factors must be taken into account in determining the actual risk posed by the system as a whole.

Please refer to appropriate sections on legionella management, CWSTs, calorifiers and water source to determine the inherent risk factors of water being supplied to the outlets being assessed in this section.

Hot and Cold Water Outlet General Notes

1. DMA have not noted any spray outlets, other than showers and dish wash rinsers and have been advised no other spray outlets fitted. However should any have been fitted then wherever possible, DMA would recommend that spray taps are removed and replaced with taps which do not create an aerosol. Tap diffusers should also be removed where possible to minimise aerosol creation and the build-up of dirt/scale etc. on the diffusers wherever possible.

2. Very few drain cocks have been noted on piperuns, though there are some flushing points – see site specific notes following regarding these. Drain cocks fitted at the end of pipe runs should be removed if not required for operational reasons or periodically flushed and checks carried out to ensure that inserts/washers etc. are WRAS approved.

3. Adequate backflow protection as per Water Regulations Guide & Water Byelaws (Scotland) – section 6, should be incorporated into the water services within the building. See comments and recommendations regarding "non-domestic" outlets. Before fitting any double check valves or other forms of backflow protection ensure that adequate pressure relief valves/expansion vessels are fitted and working in the event of excessive pressure or temperature build up within system.

4. Water coolers and drinks machines should have regular servicing carried out (generally six monthly) as per manufacturers recommendations.

5. All low use outlets, and all associated pipework, should be removed leaving no deadlegs if outlets no longer required, or incorporated into low use flushing regime.

6. All deadlegs should be removed wherever possible. Where deadlegs are unable to be removed provision to allow flushing of the deadlegs as part of the site flushing regime should be made. (i.e. Valves fitted at end of deadlegs to allow flushing to be carried out).

7. Cold water should be delivered to outlets (and cold feed to thermostatic mixing valves) at less than 20°C within 2 minutes of outlet being run, and not more than 2°C above outlet water source temperature (i.e. CWST)

8. Hot water should be delivered to outlets (and hot feed to thermostatic mixing valves) at more than 55°C, within 1 minute of outlet being run

Location / Room No	Sentinel outlet?	Cold Supply & Temp (°C)	Hot Supply & Temp (°C)	TMV info					Deadlegs Present (Inc. Drain cocks)	Flow & Return Working	Outlet Usage	Outlets in location												Aerosol Created	Non WRAS Material	Flexi Hoses	Comment	Additional Localised Risk Rating
				No. Of TMVs	Access	<2m from outlet?	Mix Temps 37-45°C	No. TMV Fed Outlets				Mains	Cold	Hot	Mixer	Urinals	WCs	Shower	Drinks / vend	Water boiler	Drinking fountain	Arjo/whirlpool	Other					
Basement KIT-031	Hot, Cold	CWST 15.1	Calorifier 58.9	1	OK	Yes	Yes	1	None visible	Not visible					1									Low	None visible	None visible	Unused equipment connection	Medium
Recommendations:			Unused vend connection should be removed or included in flushing regime																									
Hydrotherapy Plantroom A-1FMB-030		CWST 14.3	No hot outlets	0		Yes		0	Yes - on cold pipework	Yes	Some outlets unused		1											High	None visible	None visible	Blind loop on hot - working ok Emergency Shower	High
Recommendations:			Remove all deadleg pipework in this area. Fit check valve to emergency shower (& bib tap if not fitted) Include bib tap & Emergency Shower in flushing regime																									
00 A&E Courtyard	No	No access (Trades CWST)	No hot outlets	0		Yes		0	None visible	N/A	Rarely - Inc. in Flush Regime		1											Low	None visible	None visible	No Access	No Access
Recommendations:			Include Unused outlets into site flushing regime.																									
00 A&E EMC-018 (Toilet)	Hot, Cold	CWST	Calorifier	1	OK	Yes	Yes	1	None visible	Not visible	Daily				1		1							Low	None visible	None visible	IR Tap	Low
Recommendations:																												

Location / Room No	Sentinel outlet?	Cold Supply & Temp (°C)	Hot Supply & Temp (°C)	TMV info					Deadlegs Present (Inc. Drain cocks)	Flow & Return Working	Outlet Usage	Outlets in location												Aerosol Created	Non WRAS Material	Flexi Hoses	Comment	Additional Localised Risk Rating
				No. Of TMVs	Access	<2m from outlet?	Mix Temps 37-45°C	No. TMV Fed Outlets				Mains	Cold	Hot	Mixer	Urinals	WCs	Shower	Drinks / vend	Water boiler	Drinking fountain	Arjo/whirlpool	Other					
00 A&E EMC-037 (Toilet)	Hot, Cold	CWST	Calorifier	1	OK	Yes	Yes	1	None visible	Not visible	Daily				1		1							Low	None visible	None visible		Low
Recommendations:																												
00 A&E EMC-041 (Toilet)	Hot, Cold	CWST 15.8	Calorifier 62	1	OK	Yes	Yes	1	None visible	Not visible	Daily				1		1							Low	None visible	None visible		Low
Recommendations:																												
00 A&E EMC-059 (Bed Bay 5)	Hot, Cold	CWST 14.2	Calorifier 57.9	1	OK	Yes	Yes	1	None visible	Not visible	Daily		1	1										Low	None visible	None visible		Low
Recommendations:																												
00 A&E EMC-060 (Bed Bay 6)	Hot, Cold	CWST 14.3	Calorifier 58.1	1	OK	Yes	Yes	1	None visible	Not visible	Daily		1	1										Low	None visible	None visible		Low
Recommendations:																												
00 A&E EMC-063 (Bed Bay 8)	Hot, Cold	CWST 14.0	Calorifier 58.1	1	OK	Yes	Yes	1	None visible	Not visible	Daily		1	1										Low	None visible	None visible		Low
Recommendations:																												

Location / Room No	Sentinel outlet?	Cold Supply & Temp (°C)	Hot Supply & Temp (°C)	TMV info					Deadlegs Present (Inc. Drain cocks)	Flow & Return Working	Outlet Usage	Outlets in location												Aerosol Created	Non WRAS Material	Flexi Hoses	Comment	Additional Localised Risk Rating
				No. Of TMVs	Access	<2m from outlet?	Mix Temps 37-45°C	No. TMV Fed Outlets				Mains	Cold	Hot	Mixer	Urinals	WCs	Shower	Drinks / vend	Water boiler	Drinking fountain	Arjo/whirlpool	Other					
00 A&E EMC-076 (Bed Bay 12)	Hot, Cold	CWST 16.2	Calorifier 55.5	1	OK	Yes	Yes	1	None visible	Not visible	Daily		1	1										Low	None visible	None visible		Low
Recommendations:																												
00 A&E EMC-086 (Facilities)	Hot, Cold	CWST 17.3	Calorifier 57.7	1	OK	Yes	Yes	1	None visible	Not visible	Daily		2	2	1									Low	None visible	None visible		Low
Recommendations:																												
00 A&E EMC-093 (Bed Bay 18)	Hot, Cold	CWST 16.1	Calorifier 57.9	1	OK	Yes	Yes	1	None visible	Not visible	Daily		1	1										Low	None visible	None visible		Low
Recommendations:																												
00 A&E EMC-100 (Service)	Hot, Cold	CWST 15.6	Calorifier 59.7	1	OK	Yes		1	None visible	Not visible	Rarely - Inc. in Flush Regime		1	1	1									Low	None visible	None visible	Heat gain on cold, 70 secs to drop <20°C	Medium
Recommendations:			Include Unused outlets into site flushing regime.																									
			Evidence of heat gain on cold - investigate and correct																									
00 A&E EMC-111 (Female Change)	Hot, Cold	CWST 15.2	Calorifier 59.1	3	OK	Yes	Yes	3	None visible	Not visible	Daily		3	3			4	2						High	None visible	None visible		Low
Recommendations:																												

Location / Room No	Sentinel outlet?	Cold Supply & Temp (°C)	Hot Supply & Temp (°C)	TMV info					Deadlegs Present (Inc. Drain cocks)	Flow & Return Working	Outlet Usage	Outlets in location												Aerosol Created	Non WRAS Material	Flexi Hoses	Comment	Additional Localised Risk Rating
				No. Of TMVs	Access	<2m from outlet?	Mix Temps 37-45°C	No. TMV Fed Outlets				Mains	Cold	Hot	Mixer	Urinals	WCs	Shower	Drinks / vend	Water boiler	Drinking fountain	Arjo/whirlpool	Other					
00 A&E EMC-135 (Store)	Hot, Cold	CWST 15.9	Calorifier 60.6	1	OK	Yes	Yes	1	None visible	Not visible	Daily		1	1	1									Low	None visible	None visible		Low
Recommendations:																												
00 Acute Assess AAW-007 (Facilities)	Hot, Cold	CWST 15.7	Calorifier 63.3	1	OK	Yes	Yes	1	None visible	Not visible	Daily		2	2	1									Low	None visible	None visible		Low
Recommendations:																												
00 Acute Assess AAW-017 (Bedroom)	Hot, Cold	CWST 15.2	Calorifier	1	OK	Yes	Yes	1	None visible	Not visible	Daily		1	1										Low	None visible	None visible		Low
Recommendations:																												
00 Acute Assess AAW-032 (Bathroom)	Hot, Cold	CWST 16.5	Calorifier 61.2	2	OK	Yes	Yes	2	None visible	Not visible	Daily				1		1	1						High	None visible	None visible		Low
Recommendations:																												
00 Acute Assess AAW-038 (Toilet)	Hot, Cold	CWST 16.8	Calorifier 61.7	1	OK	Yes	Yes	1	None visible	Not visible	Daily				1		1							Low	None visible	None visible		Low
Recommendations:																												

Location / Room No	Sentinel outlet?	Cold Supply & Temp (°C)	Hot Supply & Temp (°C)	TMV info					Deadlegs Present (Inc. Drain cocks)	Flow & Return Working	Outlet Usage	Outlets in location												Aerosol Created	Non WRAS Material	Flexi Hoses	Comment	Additional Localised Risk Rating
				No. Of TMVs	Access	<2m from outlet?	Mix Temps 37-45°C	No. TMV Fed Outlets				Mains	Cold	Hot	Mixer	Urinals	WCs	Shower	Drinks / vend	Water boiler	Drinking fountain	Arjo/whirlpool	Other					
00 Acute Assess AAW-045 (Treatment Room)	Hot, Cold	CWST 14.9	Calorifier	1	OK	Yes	Yes	1	None visible	Not visible	Daily		1	1	1									Low	None visible	None visible		Low
Recommendations:																												
00 Acute Assess AAW-060 (Toilet)	Hot, Cold	CWST 17.8	Calorifier 61.7	1	OK	Yes	Yes	1	None visible	Not visible	Daily				1		1							Low	None visible	None visible		Low
Recommendations:																												
00 Acute Assess AAW-088 (Bathroom)	Hot, Cold	CWST 17.4	Calorifier 60.7	2	OK	Yes	Yes	2	None visible	Not visible	Daily				1		1	1						High	None visible	None visible		Low
Recommendations:																												
00 Acute Assess AAW-096 (Bathroom)	Hot, Cold	CWST 16.9	Calorifier 60.2	2	OK	Yes	Yes	2	None visible	Not visible	Daily				1		1	1						High	None visible	None visible		Low
Recommendations:																												
00 Acute Assess AAW-108 (Bathroom)	Hot, Cold	CWST 15.7	Calorifier 56	2	OK	Yes	Yes	2	None visible	Not visible	Daily				1		1	1						High	None visible	None visible		Low
Recommendations:																												

Location / Room No	Sentinel outlet?	Cold Supply & Temp (°C)	Hot Supply & Temp (°C)	TMV info					Deadlegs Present (Inc. Drain cocks)	Flow & Return Working	Outlet Usage	Outlets in location												Aerosol Created	Non WRAS Material	Flexi Hoses	Comment	Additional Localised Risk Rating
				No. Of TMVs	Access	<2m from outlet?	Mix Temps 37-45°C	No. TMV Fed Outlets				Mains	Cold	Hot	Mixer	Urinals	WCs	Shower	Drinks / vend	Water boiler	Drinking fountain	Arjo/whirlpool	Other					
00 Acute Assess AAW-125 (Facilities)	Hot, Cold	CWST 16.0	Calorifier 64.3	1	OK	Yes	Yes	1	None visible	Not visible	Daily		2	2	1									Low	None visible	None visible		Low
Recommendations:																												
00 Acute Assess AAW-156 (Kitchen)	Hot, Cold	CWST 15.7	Calorifier 64.0	1	OK		Yes	1	None visible	Not visible	Daily		1	1	1					1			1	Low	None visible	None visible	1 x Dish Wash	Low
Recommendations:																												
00 Acute Assess AAW-163 (Toilet)	Hot, Cold	CWST 15.5	Calorifier 61.3	1	OK	Tap	Yes	1	None visible	Not visible	Daily				1		1							Low	None visible	None visible		Low
Recommendations:																												
00 Acute Assess AAW-173 (Clinical Support)	Hot, Cold	CWST 15.4	Calorifier	2	OK	Yes	Yes	2	None visible	Not visible	Rarely - Inc. in Flush Regime		1	1			0							Low	None visible	None visible		Low
Recommendations:	Include Unused outlets into site flushing regime.																											
00 Acute Assess AAW-193 (Toilet)	Hot, Cold	CWST 15.2	Calorifier	1	OK	Yes	Yes	1	None visible	Not visible	Daily				1		1							Low	None visible	None visible		Low
Recommendations:																												

Location / Room No	Sentinel outlet?	Cold Supply & Temp (°C)	Hot Supply & Temp (°C)	TMV info					Deadlegs Present (Inc. Drain cocks)	Flow & Return Working	Outlet Usage	Outlets in location												Aerosol Created	Non WRAS Material	Flexi Hoses	Comment	Additional Localised Risk Rating
				No. Of TMVs	Access	<2m from outlet?	Mix Temps 37-45°C	No. TMV Fed Outlets				Mains	Cold	Hot	Mixer	Urinals	WCs	Shower	Drinks / vend	Water boiler	Drinking fountain	Arjo/whirlpool	Other					
00 Acute Assess AAW-208 (Dirty Utility)	Hot, Cold	CWST 14.9	Calorifier 56.6	2	OK	Yes	Yes	2	None visible	Not visible	Daily		2	2			1							Low	None visible	None visible		Low
Recommendations:																												
00 Acute Assess AAW-226 (Lab)	Hot, Cold	CWST 15.1	Calorifier	1	OK	Yes	Yes	1	None visible	Not visible	Daily		1	1										Low	None visible	None visible		Low
Recommendations:																												
00 Acute Assess AAW-240 (Toilet)	Hot, Cold	CWST 16.8	Calorifier 61.1	1	OK	Yes	Yes	1	None visible	Not visible	Daily				1		1							Low	None visible	None visible		Low
Recommendations:																												
00 Acute Assess AAW-247 (Kitchen)	Hot, Cold	CWST 16.3	Calorifier 64.7	1	OK		Yes	1	None visible	Not visible	Daily		1	1	1					1			1		None visible	None visible	1 x Dish Wash	Low
Recommendations:																												
00 Acute Assess AAW-265 (Bedroom)	Hot, Cold	CWST 15.3	Calorifier	1	OK	Yes	Yes	1	None visible	Not visible	Daily		1	1										Low	None visible	None visible		Low
Recommendations:																												

Location / Room No	Sentinel outlet?	Cold Supply & Temp (°C)	Hot Supply & Temp (°C)	TMV info					Deadlegs Present (Inc. Drain cocks)	Flow & Return Working	Outlet Usage	Outlets in location												Aerosol Created	Non WRAS Material	Flexi Hoses	Comment	Additional Localised Risk Rating
				No. Of TMVs	Access	<2m from outlet?	Mix Temps 37-45°C	No. TMV Fed Outlets				Mains	Cold	Hot	Mixer	Urinals	WCs	Shower	Drinks / vend	Water boiler	Drinking fountain	Arjo/whirlpool	Other					
00 Acute Assess AAW-306 (Toilet)	Hot, Cold	CWST 16.7	Calorifier 61.9	1	OK	Yes	Yes	1	None visible	Not visible	Daily				1		1							Low	None visible	None visible		Low
Recommendations:																												
00 Acute Assess AAW-313 (Facilities)	Hot, Cold	CWST 15.9	Calorifier 63.8	1	OK	Yes	Yes	1	None visible	Not visible	Daily		2	2	1									Low	None visible	None visible		Low
Recommendations:																												
00 Acute Assess AAW-334 (Bathroom)	Hot, Cold	CWST 18.1	Calorifier 57	1	OK	Yes	Yes	2	None visible	Not visible	Daily				1		1	1						High	None visible	None visible		Low
Recommendations:																												
00 Acute Assess AAW-375 (Bedroom)	Hot, Cold	CWST 14.9	Calorifier	1	OK	Yes	Yes	1	None visible	Not visible	Daily		1	1										Low	None visible	None visible		Low
Recommendations:																												
00 Concourse ENT-003 (Bute vend)	No	CWST	No hot outlets	0					None visible	N/A	Some outlets unused								1					Low	None visible	Yes	Vending connected	Medium

Recommendations: All EPDM flexible hoses should be removed and replaced with hard piped connection (if practicable)

Location / Room No	Sentinel outlet?	Cold Supply & Temp (°C)	Hot Supply & Temp (°C)	TMV info					Deadlegs Present (Inc. Drain cocks)	Flow & Return Working	Outlet Usage	Outlets in location												Aerosol Created	Non WRAS Material	Flexi Hoses	Comment	Additional Localised Risk Rating
				No. Of TMVs	Access	<2m from outlet?	Mix Temps 37-45°C	No. TMV Fed Outlets				Mains	Cold	Hot	Mixer	Urinals	WCs	Shower	Drinks / vend	Water boiler	Drinking fountain	Arjo/whirlpool	Other					
00 Concourse ENT-038 (Baby Change)	Hot, Cold	CWST 14.9	Calorifier	1	OK	Yes	Yes	1	None visible	Not visible	Rarely - Inc. in Flush Regime		1	1										Low	None visible	None visible		Low
Recommendations: Include Unused outlets into site flushing regime.																												
00 Concourse ENT-048 (Gents Toilet)	Hot, Cold	CWST 14.7	Calorifier	1	OK		Yes	1	None visible	Not visible	Daily				1		1							Low	None visible	None visible		Low
Recommendations:																												
00 Concourse ENT-052 (Gents Toilet)	Hot, Cold	CWST	Calorifier	3	OK	Yes	Yes	3	None visible	Not visible	Daily				3		3							Low	None visible	None visible	Copper tails to IR taps	Low
Recommendations:																												
00 Concourse ENT-054 (Shower)	Hot, Cold			2	OK		Yes	2	None visible	Not visible	Daily				1		1	1						High	None visible	None visible		Low
Recommendations:																												
00 Concourse ENT-062 (Facilities)	Hot, Cold	CWST 15.4	Calorifier 64.5	1	OK		Yes	1	None visible	Not visible	Daily		2	2	1									Low	None visible	None visible		Low
Recommendations:																												

Location / Room No	Sentinel outlet?	Cold Supply & Temp (°C)	Hot Supply & Temp (°C)	TMV info					Deadlegs Present (Inc. Drain cocks)	Flow & Return Working	Outlet Usage	Outlets in location												Aerosol Created	Non WRAS Material	Flexi Hoses	Comment	Additional Localised Risk Rating
				No. Of TMVs	Access	<2m from outlet?	Mix Temps 37-45°C	No. TMV Fed Outlets				Mains	Cold	Hot	Mixer	Urinals	WCs	Shower	Drinks / vend	Water boiler	Drinking fountain	Arjo/whirlpool	Other					
00 Concourse FMA0-001 (Facilities)	Hot, Cold	CWST 15.3	Calorifier 63.8	1	OK	Yes	Yes	1	None visible	Not visible	Daily		2	2	1									Low	None visible	None visible		Low
Recommendations:																												
00 Discharge DLO-006 (Toilet)	Hot, Cold	CWST	Calorifier	1	OK	Yes	Yes	1	None visible	Not visible	Daily				1		1							Low	None visible	None visible	Copper tail to IR Tap	Low
Recommendations:																												
00 Discharge DLO-008 (Consulting Room)	Hot, Cold	CWST	Calorifier	1	OK	Yes	No	1	None visible	Not visible	Daily				1									Low	None visible	None visible		Medium
Recommendations:			Low mixed water temperature - Investigate and correct (TMV may require servicing)																									
00 Medical Illustration MIL-010 (Studio)	Hot, Cold	CWST 15.8	Calorifier	1	OK		Yes	1	None visible	Not visible	Daily			1	1									Low	None visible	None visible	Heat gain on cold, 70 secs to drop <20°C	Medium
Recommendations:			Evidence of heat gain in cold water - investigate and correct.																									
00 OPD OPD0-003 (Male Change)	Hot, Cold	CWST 15.8	Calorifier	1	OK	Yes	Yes	1	None visible	Not visible	Rarely - Inc. in Flush Regime				1									Low	None visible	None visible		Low
Recommendations:																												

Location / Room No	Sentinel outlet?	Cold Supply & Temp (°C)	Hot Supply & Temp (°C)	TMV info					Deadlegs Present (Inc. Drain cocks)	Flow & Return Working	Outlet Usage	Outlets in location												Aerosol Created	Non WRAS Material	Flexi Hoses	Comment	Additional Localised Risk Rating
				No. Of TMVs	Access	<2m from outlet?	Mix Temps 37-45°C	No. TMV Fed Outlets				Mains	Cold	Hot	Mixer	Urinals	WCs	Shower	Drinks / vend	Water boiler	Drinking fountain	Arjo/whirlpool	Other					
00 OPD OPD0-013 (Consulting Room)	Hot, Cold	CWST 16.2	Calorifier	1	OK	Yes	Yes	1	None visible	Not visible	Daily		1	1										Low	None visible	None visible		Low
Recommendations:																												
00 OPD OPD0-049 (Treatment Room)	Hot, Cold	CWST 16.5	Calorifier	1	OK		No	1	None visible	Not visible	Daily		1	1	1									Low	None visible	None visible		Medium
Recommendations:			Low mixed water temperature - Investigate and crrect (TMV may require servicing)																									
00 OPD OPD0-067 (Dirty Utility)	Hot, Cold	CWST 15.1	Calorifier 57.8	2	OK	Yes	Yes	2	None visible	Not visible	Daily		2	2			1							Low	None visible	None visible	Cold dump valve in room 1 x sluice	Low
Recommendations:																												
00 OPD/Concourse OPD0-072 (Toilet)	Hot, Cold	CWST	Calorifier	1	OK	Yes	Yes	1	None visible	Not visible	Daily				1		1							Low	None visible	None visible		Low
Recommendations:																												
00 OPD/Concourse OPD0-073 (Shower)	Hot, Cold	CWST	Calorifier	1	OK	Yes	Yes	1	None visible	Not visible	Daily				1		1	0						Low	None visible	None visible	Shower not running	High
Recommendations:			Shower not working creating deadlegs. Outlet should be repaired and lines thoroughly flushed.																									

Location / Room No	Sentinel outlet?	Cold Supply & Temp (°C)	Hot Supply & Temp (°C)	TMV info					Deadlegs Present (Inc. Drain cocks)	Flow & Return Working	Outlet Usage	Outlets in location												Aerosol Created	Non WRAS Material	Flexi Hoses	Comment	Additional Localised Risk Rating
				No. Of TMVs	Access	<2m from outlet?	Mix Temps 37-45°C	No. TMV Fed Outlets				Mains	Cold	Hot	Mixer	Urinals	WCs	Shower	Drinks / vend	Water boiler	Drinking fountain	Arjo/whirlpool	Other					
00 OPD/Concourse OPD0-075 (Toilet)	Hot, Cold	CWST	Calorifier	1	OK	Yes	Yes	1	None visible	Not visible	Daily				1		1							Low	None visible	None visible		Low
Recommendations:																												
00 Orthotics ORT-015-2 (Staff Change)	Hot, Cold	CWST 18	Calorifier 56.2	1	OK	Yes	Yes	1	None visible	Not visible	Daily				1		1							Low	None visible	None visible		Low
Recommendations:																												
00 Orthotics ORT-017 (Disabled)	Hot, Cold	CWST 16.3	Calorifier 57.8	1	OK	Yes	Yes	1	None visible	Not visible	Rarely - Inc. in Flush Regime				1		1							Low	None visible	None visible		Medium
Recommendations:	Include unused outlets into site flushing regime.																											
00 Orthotics ORT-027 (Treatment Room)	Hot, Cold	CWST	Calorifier	1	OK	Yes	Yes	1	None visible	Not visible	Daily		1	1										Low	None visible	None visible		Low
Recommendations:																												
00 Orthotics ORT-045 (Toilet)	Hot, Cold	CWST 16.8	Calorifier 60.2	1	OK	Yes	Yes	1	None visible	Not visible	Daily				1		1							Low	None visible	None visible		Low
Recommendations:																												

Location / Room No	Sentinel outlet?	Cold Supply & Temp (°C)	Hot Supply & Temp (°C)	TMV info					Deadlegs Present (Inc. Drain cocks)	Flow & Return Working	Outlet Usage	Outlets in location												Aerosol Created	Non WRAS Material	Flexi Hoses	Comment	Additional Localised Risk Rating
				No. Of TMVs	Access	<2m from outlet?	Mix Temps 37-45°C	No. TMV Fed Outlets				Mains	Cold	Hot	Mixer	Urinals	WCs	Shower	Drinks / vend	Water boiler	Drinking fountain	Arjo/whirlpool	Other					
00 Pharmacy PHA-002 (Facilities)	Hot, Cold	CWST 16.1	Calorifier 64.3	1	OK	Yes	Yes	1	None visible	Not visible	Daily		3	3										Low	None visible	None visible		Medium
Recommendations: Low mixed water temperature - Investigate and correct (TMV may require servicing)																												
00 Pharmacy PHA-008 (Clinical Trial Prep)	Hot, Cold	CWST 15.8	Calorifier 39 mixed	1	OK	Yes	Yes	1	None visible	Not visible	Daily		1	1										Low	None visible	None visible		Low
Recommendations:																												
00 Radiology RAG-004 (Dirty Utility)	Hot, Cold	CWST 15.8	Calorifier	2	OK	Yes	Yes	2	None visible	Not visible	Daily		2	2			1							Low	None visible	None visible		Low
Recommendations:																												
00 Radiology RAG-029 (X-Ray 6)	Hot, Cold	CWST 16.3	Calorifier	1	OK	Yes	Yes	1	None visible	Not visible	Daily		1	1										Low	None visible	None visible		Low
Recommendations:																												
00 Radiology RAG-054 (Toilet)	Hot, Cold	CWST 17.1	Calorifier 60.3	1	OK	Yes	Yes	1	None visible	Not visible	Daily				1		1							Low	None visible	None visible		Low
Recommendations:																												

Location / Room No	Sentinel outlet?	Cold Supply & Temp (°C)	Hot Supply & Temp (°C)	TMV info					Deadlegs Present (Inc. Drain cocks)	Flow & Return Working	Outlet Usage	Outlets in location												Aerosol Created	Non WRAS Material	Flexi Hoses	Comment	Additional Localised Risk Rating
				No. Of TMVs	Access	<2m from outlet?	Mix Temps 37-45°C	No. TMV Fed Outlets				Mains	Cold	Hot	Mixer	Urinals	WCs	Shower	Drinks / vend	Water boiler	Drinking fountain	Arjo/whirlpool	Other					
00 Radiology RAG-068 (Toilet)	Hot, Cold	CWST 16.0	Calorifier 58.6	1	OK	Yes	Yes	1	None visible	Not visible	Daily				1		1							Low	None visible	None visible		Low
Recommendations:																												
00 Radiology RAG-079 (Toilet)	Hot, Cold	CWST 15.8	Calorifier 62.2	1	OK	Yes	Yes	1	None visible	Not visible	Daily				1		1							Low	None visible	None visible		Low
Recommendations:																												
00 Radiology RAG-092 (Toilet)	Hot, Cold	CWST	Calorifier	1	OK	Yes	Yes	1	None visible	Not visible	Daily				1		1							Low	None visible	None visible	IR Tap	Low
Recommendations:																												
00 Radiology RAG-108 (Anaesthetic)	Hot, Cold	CWST 16.7	Calorifier	1	OK	Yes	Yes	1	None visible	Not visible	Daily		1	1		1								Low	None visible	None visible	Heat gain in cold, 25 secs to drop <20°C	Medium
Recommendations:			Evidence of heat gain in cold water - investigate and correct.																									
00 Radiology RAG-130 (Toilet)	Hot, Cold	CWST 16.5	Calorifier 61.7	1	OK	Yes	Yes	1	None visible	Not visible	Daily				1		1							Low	None visible	None visible		Low
Recommendations:																												

Location / Room No	Sentinel outlet?	Cold Supply & Temp (°C)	Hot Supply & Temp (°C)	TMV info					Deadlegs Present (Inc. Drain cocks)	Flow & Return Working	Outlet Usage	Outlets in location												Aerosol Created	Non WRAS Material	Flexi Hoses	Comment	Additional Localised Risk Rating
				No. Of TMVs	Access	<2m from outlet?	Mix Temps 37-45°C	No. TMV Fed Outlets				Mains	Cold	Hot	Mixer	Urinals	WCs	Shower	Drinks / vend	Water boiler	Drinking fountain	Arjo/whirlpool	Other					
00 Rehab REH-006 (Toilet)	Hot, Cold	CWST 17.2	Calorifier 58.7	1	OK	Yes	Yes	1	None visible	Not visible	Daily				1		1							Low	None visible	None visible		Low
Recommendations:																												
00 Rehab REH-013 (OT Room)	Hot, Cold	CWST 18.1	Calorifier 59.4	1	OK	Yes	Yes	1	None visible	Not visible	Rarely - Inc. in Flush Regime				1									Low	None visible	None visible	Copper tail to IR tap. Heat gain in cold, 50 secs to drop <20°C	Medium
Recommendations:			Evidence of heat gain in cold water - investigate and correct. Include unused outlets into site flushing regime.																									
00 Rehab REH-026 (Toilet)	Hot, Cold	CWST 16.2	Calorifier 59.8	1	OK	Yes	Yes	1	None visible	Not visible	Daily				1		1							Low	None visible	None visible		Low
Recommendations:																												
00 Rehab REH-033 (Workshop)	Hot, Cold	CWST	Calorifier	1	OK	No	Yes	1	None visible	Not visible	Daily		1	1										Low	None visible	None visible		Low
Recommendations:																												
00 Rehab REH-048 (Hydrotherapy Toilet)	Hot, Cold	CWST 16.3	Calorifier 58.6	1	OK	Yes	Yes	1	None visible	Not visible	Rarely - Inc. in Flush Regime				1		1							Low	None visible	None visible		Low
Recommendations:																												

Location / Room No	Sentinel outlet?	Cold Supply & Temp (°C)	Hot Supply & Temp (°C)	TMV info					Deadlegs Present (Inc. Drain cocks)	Flow & Return Working	Outlet Usage	Outlets in location												Aerosol Created	Non WRAS Material	Flexi Hoses	Comment	Additional Localised Risk Rating
				No. Of TMVs	Access	<2m from outlet?	Mix Temps 37-45°C	No. TMV Fed Outlets				Mains	Cold	Hot	Mixer	Urinals	WCs	Shower	Drinks / vend	Water boiler	Drinking fountain	Arjo/whirlpool	Other					
00C A&E EMC-006 (Toilet)	Hot, Cold	CWST	Calorifier	1	OK	Yes	Yes	1	None visible	Not visible	Rarely - Inc. in Flush Regime				1		1							Low	None visible	None visible	IR Tap	Low
Recommendations:																												
00C A&E EMC-059 (Bed Bay 6)	Hot, Cold	CWST 16.6	Calorifier	1	OK	Yes	Yes	1	None visible	Not visible	Daily		1	1										Low	None visible	None visible	Heat gain in cold, 70 secs to drop <20°C	Medium
Recommendations:			Evidence of heat gain in cold water - investigate and correct.																									
00C A&E EMC-060 (Bed Bay 5)	Hot, Cold	CWST 16.3	Calorifier	1	OK	Yes	Yes	1	None visible	Not visible	Daily		1	1										Low	None visible	None visible	Heat gain in cold, 80 secs to drop <20°C	Medium
Recommendations:			Evidence of heat gain in cold water - investigate and correct.																									
00C A&E EMC-100 (Triage)	Hot, Cold	CWST 15.8	Calorifier Mix 38.9	1	OK	Yes	Yes	1	None visible	Not visible	Daily		1	1										Low	None visible	None visible		Low
Recommendations:																												
00C Concourse ENT-014 (Children's Club)	Hot, Cold	CWST 15.2	Calorifier 60.9	1	OK	Yes	Yes	1	None visible	Not visible	Daily		1	1	1									Low	None visible	None visible		Low
Recommendations:																												

Location / Room No	Sentinel outlet?	Cold Supply & Temp (°C)	Hot Supply & Temp (°C)	TMV info					Deadlegs Present (Inc. Drain cocks)	Flow & Return Working	Outlet Usage	Outlets in location											Aerosol Created	Non WRAS Material	Flexi Hoses	Comment	Additional Localised Risk Rating
				No. Of TMVs	Access	<2m from outlet?	Mix Temps 37-45°C	No. TMV Fed Outlets				Mains	Cold	Hot	Mixer	Urinals	WCs	Shower	Drinks / vend	Water boiler	Drinking fountain	Arjo/whirlpool	Other					
00C Concourse ENT-028	No	CWST	No hot outlets	0				0	Yes - on cold pipework	N/A	Daily								1					Low	None visible	None visible		Low
Recommendations:																												
00C Concourse ENT-036 (Facilities)	Hot, Cold	CWST 15.0	Calorifier 62.4	1	OK	Yes	Yes	1	None visible	Not visible	Daily		3	3	1									Low	None visible	None visible		Low
Recommendations:																												
00C Concourse ENT-048 (Toilet)	Hot, Cold	CWST 14.3		1	OK	Yes	Yes	1	None visible	Not visible	Daily		1	1										Low	None visible	None visible		Low
Recommendations:																												
00C Consultancy CPS-003 (Consulting Room)	Hot, Cold	CWST 14.8	Calorifier	1	OK	Yes	Yes	1	None visible	Not visible	Rarely - Inc. in Flush Regime		1	1										Low	None visible	None visible	Heat gain in cold, 50 secs to drop <20°C	Medium
Recommendations:			Evidence of heat gain in cold water - investigate and correct. Include unused outlets into site flushing regime.																									
00C Consultancy CPS-006 (Toilet)	Hot, Cold	CWST 16.6	Calorifier 60.0	2	OK	Yes	Yes	2	None visible	Not visible	Rarely - Inc. in Flush Regime				1		1	1						Low	None visible	None visible		Low
Recommendations:			Include Unused outlets into site flushing regime.																									

Location / Room No	Sentinel outlet?	Cold Supply & Temp (°C)	Hot Supply & Temp (°C)	TMV info					Deadlegs Present (Inc. Drain cocks)	Flow & Return Working	Outlet Usage	Outlets in location												Aerosol Created	Non WRAS Material	Flexi Hoses	Comment	Additional Localised Risk Rating
				No. Of TMVs	Access	<2m from outlet?	Mix Temps 37-45°C	No. TMV Fed Outlets				Mains	Cold	Hot	Mixer	Urinals	WCs	Shower	Drinks / vend	Water boiler	Drinking fountain	Arjo/whirlpool	Other					
00C Decontamination DCU-003 (Wet Room)		CWST 21.1	Calorifier 58.1	2	OK		Yes	2	None visible	Not visible	Rarely - Inc. in Flush Regime				1			1						High	None visible	None visible	High cold water temp	High
Recommendations:			High cold water temperature. Investigate and correct and ensure flushing regime in place. Include unused outlets into site flushing regime.																									
00C Observation OBW-020 (Bathroom)	Hot, Cold	CWST 16.0	Calorifier 60.3	2	OK	Yes	Yes	2	None visible	Not visible	Daily				2		1	1						High	None visible	None visible		Low
Recommendations:																												
00C Observation OBW-061 (Bedroom)	Hot, Cold	CWST 16.0	Calorifier	1	OK	Yes	Yes	1	None visible	Not visible	Rarely - Inc. in Flush Regime		1	1										Low	None visible	None visible	Heat gain in cold, 75 secs to drop <20°C	Medium
Recommendations:			Evidence of heat gain in cold water - investigate and correct. Include unused outlets into site flushing regime.																									
00C OPD OPD-009 (Toilet)	Hot, Cold	CWST 17.6	Calorifier 58.8	1	OK	Yes	Yes	1	None visible	Not visible	Daily				1		1							Low	None visible	None visible		Low
Recommendations:																												

Location / Room No	Sentinel outlet?	Cold Supply & Temp (°C)	Hot Supply & Temp (°C)	TMV info					Deadlegs Present (Inc. Drain cocks)	Flow & Return Working	Outlet Usage	Outlets in location												Aerosol Created	Non WRAS Material	Flexi Hoses	Comment	Additional Localised Risk Rating
				No. Of TMVs	Access	<2m from outlet?	Mix Temps 37-45°C	No. TMV Fed Outlets				Mains	Cold	Hot	Mixer	Urinals	WCs	Shower	Drinks / vend	Water boiler	Drinking fountain	Arjo/whirlpool	Other					
00C OPD OPD-026 (Facilities)	Hot, Cold	CWST 14.9	Calorifier 63.8	1	OK	Yes	Yes	1	None visible	Not visible	Daily		2	2	1									Low	None visible	None visible		Low
Recommendations:																												
00C OPD OPD-060 (Toilet)	Hot, Cold	CWST 15.8	Calorifier 56.7	1	OK	Yes	Yes	1	None visible	Not visible	Daily				1		1							Low	None visible	None visible		Low
Recommendations:																												
00C OPD OPD-073 (Plaster Room)	Hot, Cold	CWST 14.9	Calorifier	4	OK	Yes	Yes	4	None visible	Not visible	Daily		4	4										Low	None visible	None visible	Heat gain in cold, 40 secs to drop <20°C	Low
Recommendations:			Evidence of heat gain in cold water - investigate and correct.																									
00C OPD OPD-075 (Toilet)	Hot, Cold	CWST 18.6	Calorifier 61.8	1	OK	Yes	Yes	1	None visible	Not visible	Daily				1		1							Low	None visible	None visible		Low
Recommendations:																												
00C OPD OPD-080(Audiometry Room)		No cold outlets	No hot outlets					0																		Yes	No outlets	Low
Recommendations:			All EPDM flexible hoses should be removed and replaced with hard piped connection (if practicable)																									

Location / Room No	Sentinel outlet?	Cold Supply & Temp (°C)	Hot Supply & Temp (°C)	TMV info					Deadlegs Present (Inc. Drain cocks)	Flow & Return Working	Outlet Usage	Outlets in location												Aerosol Created	Non WRAS Material	Flexi Hoses	Comment	Additional Localised Risk Rating
				No. Of TMVs	Access	<2m from outlet?	Mix Temps 37-45°C	No. TMV Fed Outlets				Mains	Cold	Hot	Mixer	Urinals	WCs	Shower	Drinks / vend	Water boiler	Drinking fountain	Arjo/whirlpool	Other					
00C OPD OPD-087-B (Toilet)	Hot, Cold	CWST 16.1	Calorifier 63.8	1	OK	Yes	Yes	1	None visible	Not visible	Daily				1		1							Low	None visible	None visible	No room ID on door. Labelled as sentinel.	Low
Recommendations:																											
00C OPD OPD-103 (Toilet)	Hot, Cold	CWST 16.3	Calorifier 61.2	1	OK	Yes	Yes	1	None visible	Not visible	Daily				1		1							Low	None visible	None visible		Low
Recommendations:																											
00C OPD OPD-120 (Toilet)	Hot, Cold	CWST 19.2	Calorifier 57.3	1	OK	Yes	Yes	1	None visible	Not visible	Daily				1		1							Low	None visible	None visible		Low
Recommendations:																											
00C OPD OPD-125 (Changing)	Hot, Cold	CWST 19.4	Calorifier 57.2	1	OK	Yes	Yes	1	None visible	Not visible	Rarely - Inc. in Flush Regime		1	1										Low	None visible	None visible		Medium
Recommendations:			Include unused outlets into site flushing regime.																									
00C Radiology RCG-022 (Male Change)	Hot, Cold	CWST 16.8	Calorifier 60.9	1	OK	Yes	Yes	1	None visible	Not visible	Daily				1									Low	None visible	None visible		Low
Recommendations:																											

Location / Room No	Sentinel outlet?	Cold Supply & Temp (°C)	Hot Supply & Temp (°C)	TMV info					Deadlegs Present (Inc. Drain cocks)	Flow & Return Working	Outlet Usage	Outlets in location												Aerosol Created	Non WRAS Material	Flexi Hoses	Comment	Additional Localised Risk Rating
				No. Of TMVs	Access	<2m from outlet?	Mix Temps 37-45°C	No. TMV Fed Outlets				Mains	Cold	Hot	Mixer	Urinals	WCs	Shower	Drinks / vend	Water boiler	Drinking fountain	Arjo/whirlpool	Other					
00C Radiology RCG-068 (Baby sleep)	Hot, Cold	CWST 24.5	Calorifier	1	OK	Yes	Yes	1	None visible	Not visible	Rarely - Inc. in Flush Regime		1	1	1									Low	None visible	None visible	High cold water temp	Medium
Recommendations:			Cold water temperature too high. Investigate and correct. Include unused outlets into site flushing regime.																									
00C Radiology RCG-087 (Dirty Utility)	Hot, Cold	CWST 14.9	Calorifier	2	OK	Yes	Yes	2	None visible	Not visible	Rarely - Inc. in Flush Regime		2	2	2		1							Low	None visible	None visible	1 x sluice Heat gain in cold, 30 secs to drop <20°C	Medium
Recommendations:			Evidence of heat gain in cold water - investigate and correct.																									
01 Critical Care CCU-004 (Patients Pantry)	Hot, Cold	CWST 15.4	Calorifier 63.4	1	OK	Yes	Yes	1	None visible	Not visible	Daily		1	1	1					1			1	Low	None visible	None visible	Copper tail to IR tap (1 x dishwash)	Low
Recommendations:																												
01 Critical Care CCU-036 (Bedroom) Room 65	Hot, Cold	CWST 16.9	Calorifier	1	OK	Yes	Yes	1	None visible	Not visible	Daily		1	1										Low	None visible	None visible	Heat gain in cold, 100 secs to drop <20°C	Medium
Recommendations:			Evidence of heat gain in cold water - investigate and correct.																									
01 Critical Care CCW-017 (Facilities)	Hot, Cold	CWST 16.4	Calorifier 62.4	1	OK	Yes	Yes	1	None visible	Not visible	Daily		3	3										Low	None visible	None visible		Low
Recommendations:																												

Location / Room No	Sentinel outlet?	Cold Supply & Temp (°C)	Hot Supply & Temp (°C)	TMV info					Deadlegs Present (Inc. Drain cocks)	Flow & Return Working	Outlet Usage	Outlets in location												Aerosol Created	Non WRAS Material	Flexi Hoses	Comment	Additional Localised Risk Rating
				No. Of TMVs	Access	<2m from outlet?	Mix Temps 37-45°C	No. TMV Fed Outlets				Mains	Cold	Hot	Mixer	Urinals	WCs	Shower	Drinks / vend	Water boiler	Drinking fountain	Arjo/whirlpool	Other					
01 Critical Care CCW-029 (Toilet)	Hot, Cold	CWST 17.2	Calorifier 60.7	2	OK	Yes	Yes	2	None visible	Not visible	Rarely - Inc. in Flush Regime				1		1	1						High	None visible	None visible		Medium
Recommendations:			Include unused outlets into site flushing regime.																									
01 Critical Care CCW-048 (Bed Bay 1)	Hot, Cold	CWST 16.0	Calorifier	1	OK	Yes	Yes	1	None visible	Not visible	Daily		1	1										Low	None visible	None visible		Low
Recommendations:																												
01 Critical Care CCW-087 (Bed Bay 37)	Hot, Cold	CWST 16.2	Calorifier	1	OK	Yes	Yes	1	None visible	Not visible	Daily		1	1										Low	None visible	None visible	Heat gain in cold, 80 secs to drop <20°C	Low
Recommendations:			Evidence of heat gain in cold water - investigate and correct.																									
01 Critical Care CCW-089 (Bed Bay 38)	Hot, Cold	CWST 15.5	Calorifier	1	OK	Yes	Yes	1	None visible	Not visible	Daily		1	1										Low	None visible	None visible	Heat gain in cold, 60 secs to drop <20°C	Low
Recommendations:			Evidence of heat gain in cold water - investigate and correct.																									
01 Critical Care CCW-092 (Gowning Room)	Hot, Cold	CWST 15.9	Calorifier	1	OK	Yes	Yes	1	None visible	Not visible	Daily		1	1										Low	None visible	None visible	Heat gain in cold, 45 secs to drop <20°C	Low
Recommendations:			Evidence of heat gain in cold water - investigate and correct.																									

Location / Room No	Sentinel outlet?	Cold Supply & Temp (°C)	Hot Supply & Temp (°C)	TMV info					Deadlegs Present (Inc. Drain cocks)	Flow & Return Working	Outlet Usage	Outlets in location												Aerosol Created	Non WRAS Material	Flexi Hoses	Comment	Additional Localised Risk Rating
				No. Of TMVs	Access	<2m from outlet?	Mix Temps 37-45°C	No. TMV Fed Outlets				Mains	Cold	Hot	Mixer	Urinals	WCs	Shower	Drinks / vend	Water boiler	Drinking fountain	Arjo/whirlpool	Other					
01 Critical Care CCW-109 (Bed Bay 26)	Hot, Cold	CWST 15.2	Calorifier	1	OK	Yes	Yes	1	None visible	Not visible	Daily		1	1										Low	None visible	None visible		Low
Recommendations:																												
01 Critical Care CCW-126 (Dirty Utility)	Hot, Cold	CWST 14.8	Calorifier	2	OK	Yes	Yes	2	None visible	Not visible	Rarely - Inc. in Flush Regime		2	2			1							Low	None visible	None visible		Medium
Recommendations:			Include unused outlets into site flushing regime.																									
01 Critical Care CCW-130 (Service)	Hot, Cold	CWST 14.7	Calorifier	1	OK	Yes	Yes	1	None visible	Not visible	Daily		1	1										Low	None visible	None visible		Low
Recommendations:																												
01 Critical Care CCW-131 (Pharmacy Support)	Hot, Cold	CWST 15.8	Calorifier	1	OK	Yes	Yes	1	None visible	Not visible	Daily		1	1										Low	None visible	None visible	Heat gain in cold, 45 secs to drop <20°C	Medium
Recommendations:			Evidence of heat gain in cold water - investigate and correct.																									
01 Critical Care CCW-141 (Bathroom)	Hot, Cold	CWST 18.1	Calorifier 56.0	2	OK	Yes	Yes	2	None visible	Not visible	Daily				1		1	1						High	None visible	None visible		Low
Recommendations:																												

Location / Room No	Sentinel outlet?	Cold Supply & Temp (°C)	Hot Supply & Temp (°C)	TMV info					Deadlegs Present (Inc. Drain cocks)	Flow & Return Working	Outlet Usage	Outlets in location												Aerosol Created	Non WRAS Material	Flexi Hoses	Comment	Additional Localised Risk Rating
				No. Of TMVs	Access	<2m from outlet?	Mix Temps 37-45°C	No. TMV Fed Outlets				Mains	Cold	Hot	Mixer	Urinals	WCs	Shower	Drinks / vend	Water boiler	Drinking fountain	Arjo/whirlpool	Other					
01 Critical Care CCW-200 (Facilities)	Hot, Cold	CWST 15.7	Calorifier 63.4	1	OK	Yes	Yes	1	None visible	Not visible	Daily		3	3										Low	None visible	None visible		Low
Recommendations:																												
01 Critical Care CCW-202 (Toilet)	Hot, Cold	CWST 17.2	Calorifier 61.3	2	OK	Yes	Yes	2	None visible	Not visible	Daily				1		1	1						High	None visible	None visible		Low
Recommendations:																												
01 Critical Care CCW-214 (Male Change)	Hot, Cold	CWST 16.8	Calorifier 56.7	3	OK	Yes	Yes	3	None visible	Not visible	Daily				3		3		3					Low	None visible	None visible		Low
Recommendations:																												
01 FM Facilities FMA1-001 (Facilities)	Hot, Cold	CWST	Calorifier	1	OK	Yes	Yes	1	None visible	Not visible			3	3										Low	None visible	Yes		No access
Recommendations:																												
01 Medical Day Unit MDU-005 (Beverage)	No	CWST 15.0	Calorifier 63.1	1	OK	Yes	Yes	1	None visible	Not visible	Daily		2	2						1			1	Low	None visible	None visible	1 x dishwash	Low
Recommendations:																												

Location / Room No	Sentinel outlet?	Cold Supply & Temp (°C)	Hot Supply & Temp (°C)	TMV info					Deadlegs Present (Inc. Drain cocks)	Flow & Return Working	Outlet Usage	Outlets in location												Aerosol Created	Non WRAS Material	Flexi Hoses	Comment	Additional Localised Risk Rating
				No. Of TMVs	Access	<2m from outlet?	Mix Temps 37-45°C	No. TMV Fed Outlets				Mains	Cold	Hot	Mixer	Urinals	WCs	Shower	Drinks / vend	Water boiler	Drinking fountain	Arjo/whirlpool	Other					
01 Medical Day Unit MDU-012 (Treatment Room)	Hot, Cold	CWST 15.8	Calorifier	1	OK	Yes	No	1	None visible	Not visible	Daily		1	1										Low	None visible	None visible		Medium
Recommendations:	Low mixed water temperature - Investigate and crrect (TMV may require servicing)																											
01 Medical Day Unit MDU-020 (Blood Test)	Hot, Cold	CWST 16.2	Calorifier	1	OK	Yes	Yes	1	None visible	Not visible	Daily		1	1										Low	None visible	None visible		Low
Recommendations:																												
01 Medical Day Unit MDU-046 (Facilities)	Hot, Cold	CWST 15.3	Calorifier 58.7	1	OK	Yes	Yes	1	None visible	Not visible	Daily		3	3										Low	None visible	None visible	Heat gain in cold, 20 secs to drop <20°C	Medium
Recommendations:	Evidence of heat gain in cold water - investigate and correct.																											
01 Medical Day Unit MDU-048 (Dirty Utility)	Hot, Cold	CWST 15.2	Calorifier	2	OK		Yes	2	None visible	Not visible	Daily				2		1						1	Low	None visible	None visible	Dishwash & macerator in room	Low
Recommendations:																												
01 Medical Day Unit MDU-050 (Consulting Room)	Hot, Cold	CWST 16.0	Calorifier	1	OK	Yes	Yes	1	None visible	Not visible	Daily		1	1										Low	None visible	None visible		Low
Recommendations:																												

Location / Room No	Sentinel outlet?	Cold Supply & Temp (°C)	Hot Supply & Temp (°C)	TMV info					Deadlegs Present (Inc. Drain cocks)	Flow & Return Working	Outlet Usage	Outlets in location												Aerosol Created	Non WRAS Material	Flexi Hoses	Comment	Additional Localised Risk Rating
				No. Of TMVs	Access	<2m from outlet?	Mix Temps 37-45°C	No. TMV Fed Outlets				Mains	Cold	Hot	Mixer	Urinals	WCs	Shower	Drinks / vend	Water boiler	Drinking fountain	Arjo/whirlpool	Other					
01 Medical Day Unit MDU-051 (Consulting Room)	Hot, Cold	CWST 15.8	Calorifier	1	OK	Yes	Yes	1	None visible	Not visible	Daily		1	1										Low	None visible	None visible	Mix 39.3	Low
Recommendations:																												
01 OPD POA-006 (Consulting Room)	Hot, Cold	CWST 17.5	Calorifier 58.1	1	OK	Yes	Yes	1	None visible	Not visible	Daily		1	1										Low	None visible	None visible		Low
Recommendations:																												
01 OPD POA-015 (Consulting Room)	Hot, Cold	CWST 16.8	Calorifier Mix 40.5	1	OK	Yes	Yes	1	None visible	Not visible	Daily		1	1										Low	None visible	None visible	Heat gain in cold, 40 secs to drop <20°C	Medium
Recommendations:			Evidence of heat gain in cold water - investigate and correct.																									
01 OPD POA-004 (Consulting Room)	Hot, Cold	CWST 15.4	Calorifier	1	OK	Yes	Yes	1	None visible	Not visible	Daily		1	1										Low	None visible	None visible		Low
Recommendations:																												
01 OPD OPD1-006 (Toilet)	Hot, Cold	CWST 17.5	Calorifier 58.1	1	OK	Yes	Yes	1	None visible	Not visible	Daily				1		1							Low	None visible	None visible		Low
Recommendations:																												

Location / Room No	Sentinel outlet?	Cold Supply & Temp (°C)	Hot Supply & Temp (°C)	TMV info					Deadlegs Present (Inc. Drain cocks)	Flow & Return Working	Outlet Usage	Outlets in location												Aerosol Created	Non WRAS Material	Flexi Hoses	Comment	Additional Localised Risk Rating
				No. Of TMVs	Access	<2m from outlet?	Mix Temps 37-45°C	No. TMV Fed Outlets				Mains	Cold	Hot	Mixer	Urinals	WCs	Shower	Drinks / vend	Water boiler	Drinking fountain	Arjo/whirlpool	Other					
01 OPD OPD1-008 (Toilet)	Hot, Cold	CWST	Calorifier	1	OK	Yes	Yes	1	None visible	Not visible	Daily				1		1							Low	None visible	None visible	Infra red tap	Low
Recommendations:																												
01 OPD OPD1-037 (Toilet)	Hot, Cold	CWST 15.9	Calorifier 61.8	1	OK	Yes	Yes	1	None visible	Not visible	Daily				1		1							Low	None visible	None visible		Low
Recommendations:																												
01 OPD OPD1-047 (Dietician)	Hot, Cold	CWST 14.9	Calorifier	1	OK	Yes	Yes	1	None visible	Not visible	Daily		1	1										Low	None visible	None visible		Low
Recommendations:																												
01 OPD OPD1-048 (Blood Lab)	Hot, Cold	CWST 15.3	Calorifier	1	OK	Yes	Yes	1	None visible	Not visible	Daily		1	1										Low	None visible	None visible		Low
Recommendations:																												
01 OPD OPD1-063 (Dirty Utility)	Hot, Cold	CWST 19.2	Calorifier	2	OK	Yes	Yes	2	None visible	Not visible	Daily		2	2			1							Low	None visible	None visible	Heat gain in cold, 100 secs to drop <20°C	Low

Recommendations: Evidence of heat gain in cold water - investigate and correct.

Location / Room No	Sentinel outlet?	Cold Supply & Temp (°C)	Hot Supply & Temp (°C)	TMV info					Deadlegs Present (Inc. Drain cocks)	Flow & Return Working	Outlet Usage	Outlets in location												Aerosol Created	Non WRAS Material	Flexi Hoses	Comment	Additional Localised Risk Rating
				No. Of TMVs	Access	<2m from outlet?	Mix Temps 37-45°C	No. TMV Fed Outlets				Mains	Cold	Hot	Mixer	Urinals	WCs	Shower	Drinks / vend	Water boiler	Drinking fountain	Arjo/whirlpool	Other					
01 OPD OPD1-070 (Podiatry Room)	Hot, Cold	CWST 15.2	Calorifier 61.9	1	OK	Yes	Yes	1	None visible	Not visible	Daily		2	2										Low	None visible	None visible		Low
Recommendations:																												
01 OPD OPD1-085 (Toilet)	Hot, Cold	CWST 16.2	Calorifier 60.5	1	OK	Yes	Yes	1	None visible	Not visible	Daily				1		1							Low	None visible	None visible		Low
Recommendations:																												
01 OPD OPD1-113 (Measurement Bay)	Hot, Cold	CWST 17.0	Calorifier	1	OK	Yes	Yes	1	None visible	Not visible	Daily		1	1										Low	None visible	None visible		Low
Recommendations:																												
01 OPD POA-019 (Clean Utility)	Hot, Cold	CWST 15.0	Calorifier 63.2	1	OK	Yes	Yes	1	None visible	Not visible	Daily		2	2										Low	None visible	None visible		Low
Recommendations:																												
01 Radiology RAF-003 (Toilet)	Hot, Cold	CWST 15.9	Calorifier 61.1	1	OK	Yes	Yes	1	None visible	Not visible	Daily				1		1							Low		None visible		Low
Recommendations:																												

Location / Room No	Sentinel outlet?	Cold Supply & Temp (°C)	Hot Supply & Temp (°C)	TMV info					Deadlegs Present (Inc. Drain cocks)	Flow & Return Working	Outlet Usage	Outlets in location												Aerosol Created	Non WRAS Material	Flexi Hoses	Comment	Additional Localised Risk Rating
				No. Of TMVs	Access	<2m from outlet?	Mix Temps 37-45°C	No. TMV Fed Outlets				Mains	Cold	Hot	Mixer	Urinals	WCs	Shower	Drinks / vend	Water boiler	fountain Drinking	Arjo/whirlpool	Other					
01 Radiology RAF-005 (Reception)	No	CWST	No hot outlets	0				0	None visible	N/A	Some outlets unused								1					Low	None visible	None visible	1 x Connection	Medium
Recommendations:	Ensure unused connection point included in flushing regime until put into use																										
01 Radiology RAF-087 (Male Change)	Hot, Cold	CWST 17.1	Calorifier 59.2	2	OK		Yes	2	None visible	Not visible	Daily				2									Low	None visible	None visible		Low
Recommendations:																											
01 Radiology RAF-095 (Toilet)	Hot, Cold	CWST 16.4	Calorifier 57.0	1	OK	Yes	Yes	1	None visible	Not visible	Daily				1		1							Low		None visible		Low
Recommendations:																											
01 Radiology RAF-115 (Toilet)	Hot, Cold	CWST 16.1	Calorifier 59.7	1	OK	Yes	Yes	1	None visible	Not visible	Daily				1		1							Low		None visible		Low
Recommendations:																											
01 Radiology RAF-127 (Dirty Utility)	Hot, Cold	CWST 15.9	Calorifier	2	OK	Yes	Yes	2	None visible	Not visible	Daily		2	2			1							Low	None visible	None visible		Low
Recommendations:																											

Location / Room No	Sentinel outlet?	Cold Supply & Temp (°C)	Hot Supply & Temp (°C)	TMV info					Deadlegs Present (Inc. Drain cocks)	Flow & Return Working	Outlet Usage	Outlets in location												Aerosol Created	Non WRAS Material	Flexi Hoses	Comment	Additional Localised Risk Rating
				No. Of TMVs	Access	<2m from outlet?	Mix Temps 37-45°C	No. TMV Fed Outlets				Mains	Cold	Hot	Mixer	Urinals	WCs	Shower	Drinks / vend	Water boiler	Drinking fountain	Arjo/whirlpool	Other					
01 Radiology RCF-001 (Facilities)	Hot, Cold	CWST	Calorifier	1	OK	Yes	Yes	1	None visible	Not visible														Low	None visible	Yes	Outlets removed?	No outlets
Recommendations:	Ensure any outlets which have been removed have not left deadlegs behind panels.																											
01 Radiology RCF-003 (Facilities)	Hot, Cold	CWST	Calorifier	1	OK	Yes	Yes	1	None visible	Not visible			3	3										Low	None visible	Yes		No Access
Recommendations:																												
01 Radiology RNM-007 (Toilet)	Hot, Cold	CWST 17.3	Calorifier 61.9	1	OK	Yes	Yes	1	None visible	Not visible	Daily				1		1							Low	None visible	None visible		Low
Recommendations:																												
01 Radiology RNM-018 (Shower room)	Hot, Cold	CWST 17.3	Calorifier 58.8	2	OK	Yes	Yes	2	None visible	Not visible	Daily				1		1	1						High	None visible	None visible		Low
Recommendations:																												
01 Radiology RNM-027 (Office)	Hot, Cold	CWST 16.3	Calorifier	1	OK	Yes	Yes	1	None visible	Not visible	Daily		1	1										Low	None visible	None visible		Low
Recommendations:																												

Location / Room No	Sentinel outlet?	Cold Supply & Temp (°C)	Hot Supply & Temp (°C)	TMV info					Deadlegs Present (Inc. Drain cocks)	Flow & Return Working	Outlet Usage	Outlets in location												Aerosol Created	Non WRAS Material	Flexi Hoses	Comment	Additional Localised Risk Rating
				No. Of TMVs	Access	<2m from outlet?	Mix Temps 37-45°C	No. TMV Fed Outlets				Mains	Cold	Hot	Mixer	Urinals	WCs	Shower	Drinks / vend	Water boiler	Drinking fountain	Arjo/whirlpool	Other					
01 Radiology RNM-036 (Image Room - Adult)	Hot, Cold	CWST 17.1	Calorifier	1	OK	Yes	Yes	1	None visible	Not visible	Daily		1	1										Low	None visible	None visible		Low
Recommendations:																												
01 Restaurant RES-019 (Toilet)	Hot, Cold	CWST	Calorifier	2	OK	Yes	Yes	2	None visible	Not visible	Daily				2									Low	None visible	None visible	2 x infrared	Low
Recommendations:																												
01 Restaurant RES-034 (Toilet)	Hot, Cold	CWST 15.9	Calorifier 57.8	1	OK	Yes	Yes	1	None visible	Not visible	Daily				1		1							Low	None visible	None visible		Low
Recommendations:																												
01 Stroke STW-014 (Bedroom)	Hot, Cold	CWST 15.1	Calorifier	1	OK	Yes	Yes	1	None visible	Not visible	Daily		1	1										Low	None visible	None visible		Low
Recommendations:																												
01 Stroke STW-036 (Bathroom)	Hot, Cold	CWST 18.2	Calorifier 57.8	2	OK	Yes	Yes	2	None visible	Not visible	Daily				1		1	1						High	None visible	None visible		Low
Recommendations:																												

Location / Room No	Sentinel outlet?	Cold Supply & Temp (°C)	Hot Supply & Temp (°C)	TMV info					Deadlegs Present (Inc. Drain cocks)	Flow & Return Working	Outlet Usage	Outlets in location												Aerosol Created	Non WRAS Material	Flexi Hoses	Comment	Additional Localised Risk Rating
				No. Of TMVs	Access	<2m from outlet?	Mix Temps 37-45°C	No. TMV Fed Outlets				Mains	Cold	Hot	Mixer	Urinals	WCs	Shower	Drinks / vend	Water boiler	Drinking fountain	Arjo/whirlpool	Other					
01 Stroke STW-047 (Bathroom)	Hot, Cold	CWST 18.6	Calorifier 57.1	2	OK	Yes	Yes	2	None visible	Not visible	Daily				1		1	1						High	None visible	None visible	Heat gain in cold, 70 secs to drop <20°C	Medium
Recommendations:			Evidence of heat gain in cold water - investigate and correct.																									
01 Stroke STW-072 (Bathroom)	Hot, Cold	CWST 17.1	Calorifier 59.5	2	OK	Yes	Yes	2	None visible	Not visible	Daily				1		1	1						High	None visible	None visible		Low
Recommendations:																												
01 Stroke STW-079 (Arjo Bathroom)	No	CWST 17.2	Calorifier 61.8	1 (1)	OK	Yes	Yes	1	None visible	Yes	Rarely - Inc. in Flush Regime				1		1	1				1		High	None visible	Yes		Medium
Recommendations:			All EPDM flexible hoses should be removed and replaced with hard piped connection (If practicable). Include unused outlets into site flushing regime.																									
01 Stroke STW-082 (Bath)	Hot, Cold	CWST 16.6	Calorifier 59.7	2	No access – some	Yes	Yes	2	None visible	Not visible	Rarely - Inc. in Flush Regime				2		1							Low	None visible	None visible	Bath not working	Medium
Recommendations:			Out of order outlets (bath) in room creating deadlegs - these should be repaired and lines thoroughly flushed.																									

Location / Room No	Sentinel outlet?	Cold Supply & Temp (°C)	Hot Supply & Temp (°C)	TMV info					Deadlegs Present (Inc. Drain cocks)	Flow & Return Working	Outlet Usage	Outlets in location												Aerosol Created	Non WRAS Material	Flexi Hoses	Comment	Additional Localised Risk Rating
				No. Of TMVs	Access	<2m from outlet?	Mix Temps 37-45°C	No. TMV Fed Outlets				Mains	Cold	Hot	Mixer	Urinals	WCs	Shower	Drinks / vend	Water boiler	Drinking fountain	Arjo/whirlpool	Other					
01C Cardiology CAR-036 (Bedroom)	Hot, Cold	CWST 17.2	Calorifier	1	OK	Yes	Yes	1	None visible	Not visible	Daily		1	1										Low	None visible	None visible		Low
Recommendations:																												
01C Critical Care CCW-014 (Clinical Physics)	Hot, Cold	CWST 16.4	Calorifier 64.1	1	OK	Yes	Yes	1	None visible	Not visible	Daily		2	2	1									Low	None visible	None visible	Heat gain in cold, 60 secs to drop <20°C	Medium
Recommendations:			Evidence of heat gain in cold water - investigate and correct.																									
01C Critical Care CCW-021 (Bathroom)	Hot, Cold	CWST 19.0	Calorifier 47.1	2	OK	Yes	Yes	2	None visible	Not visible	Daily		1	1			1	1						High	None visible	None visible		High
Recommendations:			Hot temperature slow to rise. It should be confirmed that hot outlet(s) are on a long leg and not that the flow and return has failed locally in this area. Hot water temperature too low. Investigate and correct.																									
01C Critical Care CCW-027 (Shower)	Hot, Cold	CWST	Calorifier	1	OK	Yes	Yes	1	None visible	Not visible	Daily							1						High	None visible	None visible		Low
Recommendations:																												
01C Critical Care CCW-082 (Critical Care Bed)	Hot, Cold	CWST 16.1	Calorifier	4	OK	Yes	Yes	4	None visible	Not visible	Daily		4	4										Low	None visible	None visible	1 x renal	Low
Recommendations:																												

Location / Room No	Sentinel outlet?	Cold Supply & Temp (°C)	Hot Supply & Temp (°C)	TMV info					Deadlegs Present (Inc. Drain cocks)	Flow & Return Working	Outlet Usage	Outlets in location												Aerosol Created	Non WRAS Material	Flexi Hoses	Comment	Additional Localised Risk Rating
				No. Of TMVs	Access	<2m from outlet?	Mix Temps 37-45°C	No. TMV Fed Outlets				Mains	Cold	Hot	Mixer	Urinals	WCs	Shower	Drinks / vend	Water boiler	Drinking fountain	Arjo/whirlpool	Other					
01C Critical Care CCW-084 (Gowning Room)	Hot, Cold	CWST 16.4	Calorifier	1	OK	Yes	Yes	1	None visible	Not visible	Daily		1	1										Low	None visible	None visible		Low
Recommendations:																												
01C Critical Care CCW-092 (Dirty Utility)	Hot, Cold	CWST 16.3	Calorifier	2	OK	Yes	Yes	2	None visible	Not visible	Daily		2	2			1							Low	None visible	None visible	1 x Sluice	Low
Recommendations:																												
01C Critical Care CCW-098 (Critical Care Bed)	Hot, Cold	CWST 17.3	Calorifier	4	OK	Yes	Yes	4	None visible	Not visible	Daily		4	4										Low	None visible	None visible	1 x renal Heat gain in cold, 70 secs to drop <20°C	Medium
Recommendations:			Evidence of heat gain in cold water - investigate and correct.																									
01C Critical Care CCW-118 (Facilities)	Hot, Cold	CWST 14.9	Calorifier 63.7	1	OK	Yes	Yes	1	None visible	Not visible	Daily		3	3										Low	None visible	None visible		Low
Recommendations:																												
01C Medical Day Unit MDU-008 (Beverage Prep)	Hot, Cold	CWST 14.5	Calorifier 63.2	1	OK	Yes	Yes	1	None visible	Not visible	Daily		2	2						1			1	Low	None visible	None visible	Dishwasher	Low
Recommendations:																												

Location / Room No	Sentinel outlet?	Cold Supply & Temp (°C)	Hot Supply & Temp (°C)	TMV info					Deadlegs Present (Inc. Drain cocks)	Flow & Return Working	Outlet Usage	Outlets in location												Aerosol Created	Non WRAS Material	Flexi Hoses	Comment	Additional Localised Risk Rating
				No. Of TMVs	Access	<2m from outlet?	Mix Temps 37-45°C	No. TMV Fed Outlets				Mains	Cold	Hot	Mixer	Urinals	WCs	Shower	Drinks / vend	Water boiler	Drinking fountain	Arjo/whirlpool	Other					
01C Special Feeds SPF-007 (Facilities)	Hot, Cold	CWST 15.5	Calorifier 62.6	1	OK	Yes	Yes	1	None visible	Not visible	Weekly		3	3										Low	None visible	None visible		Low
Recommendations:																												
01C Theatre 001-011	Hot, Cold	CWST 24.1	Calorifier mix 40.0	1	OK	Yes	Yes	1	None visible	Not visible	Rarely - Inc. in Flush Regime		1	1										Low	None visible	None visible	High cold temp	Medium
Recommendations:			High cold temperature. Investigate and correct.																									
			Include unused outlets into site flushing regime.																									
01C Theatre 23HU-008 (Toilet)	Hot, Cold	CWST 19.0	Calorifier 58.1	1	OK	Yes	Yes	1	None visible	Not visible	Daily				1		1							Low	None visible	None visible	Labelled as sentinel at outlet. Heat gain in cold, 90 secs to drop <20°C	Medium
Recommendations:			Evidence of heat gain in cold water - investigate and correct.																									
01C Theatre 23HU-015 (Waiting Room)	Cold	CWST	No hot outlets	0				0	None visible	N/A	Daily								1					Low	None visible	None visible	Designated as sentinel	Low
Recommendations:																												
01C Theatre 23HU-040 (Bathroom)	Hot, Cold	CWST 18.3	Calorifier 58.7	2	OK	Yes	Yes	2	None visible	Not visible	Daily				1		1	1						High	None visible	None visible		Low

Location / Room No	Sentinel outlet?	Cold Supply & Temp (°C)	Hot Supply & Temp (°C)	TMV info					Deadlegs Present (Inc. Drain cocks)	Flow & Return Working	Outlet Usage	Outlets in location											Aerosol Created	Non WRAS Material	Flexi Hoses	Comment	Additional Localised Risk Rating
				No. Of TMVs	Access	<2m from outlet?	Mix Temps 37-45°C	No. TMV Fed Outlets				Mains	Cold	Hot	Mixer	Urinals	WCs	Shower	Drinks / vend	Water boiler	Drinking fountain	Arjo/whirlpool	Other					
Recommendations:																											
01C Theatre 23HU-051 (Toilet)	Hot, Cold	CWST 18.8	Calorifier 61.0	1	OK	Yes	Yes	1	None visible	Not visible	Daily				1		1							Low	None visible	None visible	Heat gain in cold, 70 secs to drop <20°C	Medium
Recommendations:			Evidence of heat gain in cold water - investigate and correct.																								
01C Theatre THE-009 (Toilet)	Hot, Cold	CWST 24.1	Calorifier 25.1	1	OK	Yes	Yes	1	None visible	Not visible	Rarely - Inc. in Flush Regime				1		1							Low	None visible	None visible	High cold temps	Medium
Recommendations:			High cold temperature. Investigate and correct. Include Unused outlets into site flushing regime.																								
01C Theatre THE-025 (Toilet)	Hot, Cold	CWST	Calorifier	1	OK	Yes	Yes	1	None visible	Not visible	Daily				1		1							Low	None visible	None visible	Infra red tap	Low
Recommendations:																											
01C Theatre THE-042 (Female Change)	Hot, Cold	CWST 16.3	Calorifier 61.8	3	OK	Yes	Yes	3	None visible	Not visible	Daily				3		4							Low	None visible	None visible		Low
Recommendations:																											
01C Theatre THE-069 (Lab)	Hot, Cold	CWST 17.3	Calorifier	1	OK	Yes	Yes	1	None visible	Not visible	Rarely - Inc. in Flush Regime		1	1										Low	None visible	None visible	Heat gain in cold, 90 secs to drop <20°C	Medium
Recommendations:			Evidence of heat gain in cold water - investigate and correct.																								

Location / Room No	Sentinel outlet?	Cold Supply & Temp (°C)	Hot Supply & Temp (°C)	TMV info					Deadlegs Present (Inc. Drain cocks)	Flow & Return Working	Outlet Usage	Outlets in location											Aerosol Created	Non WRAS Material	Flexi Hoses	Comment	Additional Localised Risk Rating
				No. Of TMVs	Access	<2m from outlet?	Mix Temps 37-45°C	No. TMV Fed Outlets				Mains	Cold	Hot	Mixer	Urinals	WCs	Shower	Drinks / vend	Water boiler	Drinking fountain	Arjo/whirlpool	Other					
			Include unused outlets into site flushing regime.																								
01C Theatre THE-078 (Prep room)	Hot, Cold	CWST 22.3	Calorifier	1	OK	Yes	Yes	1	None visible	Not visible	Daily		1	1										Low	None visible	None visible		Medium
Recommendations:			Cold water temperature too high. Investigate and correct.																								
01C Theatre THE-090 (Theatre Scrub)	Hot, Cold	CWST 19.2	Calorifier	3	OK	Yes	Yes	3	None visible	Not visible	Daily		3	3										Low	None visible	None visible		Low
Recommendations:																											
01C Theatre THE-102 (Facilities)	Hot, Cold	CWST 17.2	Calorifier 61.9	1	OK	Yes	Yes	1	None visible	Not visible	Daily		3	3										Low	None visible	None visible	Heat gain in cold, 70 secs to drop <20°C	Medium
Recommendations:			Evidence of heat gain in cold water - investigate and correct.																								

Location / Room No	Sentinel outlet?	Cold Supply & Temp (°C)	Hot Supply & Temp (°C)	TMV info					Deadlegs Present (Inc. Drain cocks)	Flow & Return Working	Outlet Usage	Outlets in location												Aerosol Created	Non WRAS Material	Flexi Hoses	Comment	Additional Localised Risk Rating
				No. Of TMVs	Access	<2m from outlet?	Mix Temps 37-45°C	No. TMV Fed Outlets				Mains	Cold	Hot	Mixer	Urinals	WCs	Shower	Drinks / vend	Water boiler	Drinking fountain	Arjo/whirlpool	Other					
01C Theatre THE-106 (Anesthetic room)	Hot, Cold	CWST 22.1	Calorifier	1	OK	Yes	Yes	1	None visible	Not visible	Daily		1	1										Low	None visible	None visible	Heat gain in cold, above 2 mins to drop <20°C	Medium
Recommendations:			Cold water temperature too high. Investigate and correct.																								
01C Theatre THE-117 (Theatre Scrub)	Hot, Cold	CWST 19.2	Calorifier	3	OK	Yes	Yes	3	None visible	Not visible	Daily		3	3										Low	None visible	None visible	Heat gain in cold, 70 secs to drop <20°C	Medium
Recommendations:			Evidence of heat gain in cold water - investigate and correct.																								
01C Theatre THE-157 (Recovery room)	Hot, Cold	CWST 23.1	Calorifier	1	OK	Yes	Yes	1	None visible	Not visible	Daily		1	1										Low	None visible	None visible		Medium
Recommendations:			Cold water temperature too high. Investigate and correct.																								
02 Decontamination DCT-009 (Endoscopy Wash)	No	CWST 18.5	Calorifier	26	OK	Yes	Yes	26	None visible	Yes	Daily		2	2										Low	None visible	None visible	Suspect copper tails on Markwik taps	Low
Recommendations:																											
02 Decontamination DCT-015 (Wash Room DSR)	Hot, Cold	CWST 17.2	Calorifier 64.5	1	OK	Yes	Yes	1	None visible	Not visible	Daily		3	3										Low	None visible	None visible		Low
Recommendations:																											

Location / Room No	Sentinel outlet?	Cold Supply & Temp (°C)	Hot Supply & Temp (°C)	TMV info					Deadlegs Present (Inc. Drain cocks)	Flow & Return Working	Outlet Usage	Outlets in location												Aerosol Created	Non WRAS Material	Flexi Hoses	Comment	Additional Localised Risk Rating
				No. Of TMVs	Access	<2m from outlet?	Mix Temps 37-45°C	No. TMV Fed Outlets				Mains	Cold	Hot	Mixer	Urinals	WCs	Shower	Drinks / vend	Water boiler	Drinking fountain	Arjo/whirlpool	Other					
02 Dermatology DMW-004 (Photo Therapy)	Hot, Cold	CWST 17.3	Calorifier	1	OK	Yes	Yes	1	None visible	Not visible	Daily		1	1										Low	None visible	None visible		Low
Recommendations:																												
02 Dermatology DMW-025 (Bathroom)	Hot, Cold	CWST 19.8	Calorifier 59.3	2	OK	Yes	Yes	2	None visible	Not visible	Daily				1		1	1						High	None visible	None visible	Heat gain in cold, 90 secs to drop <20°C	Medium
Recommendations:			Evidence of heat gain in cold water - investigate and correct.																									
02 Dermatology DMW-031 (Bathroom)	Hot, Cold	CWST 18.7	Calorifier 57.7	2	OK	Yes	Yes	2	None visible	Not visible	Daily				1		1	1						High	None visible	None visible	Heat gain in cold, 60 secs to drop <20°C	Medium
Recommendations:			Evidence of heat gain in cold water - investigate and correct.																									
02 Dermatology DMW-060 (Facilities)	Yes	CWST 14.2	Calorifier 65.1	0	OK			0	None visible	Not visible	Daily		2	2										Low	None visible	None visible		Low
Recommendations:																												
02 Dermatology DOPD-004 (Toilet)	Hot, Cold	CWST	Calorifier	1	OK	Yes	Yes	1	None visible	Not visible	Daily				1		1							Low	None visible	None visible	Infrared Tap	Low
Recommendations:																												

Location / Room No	Sentinel outlet?	Cold Supply & Temp (°C)	Hot Supply & Temp (°C)	TMV info					Deadlegs Present (Inc. Drain cocks)	Flow & Return Working	Outlet Usage	Outlets in location												Aerosol Created	Non WRAS Material	Flexi Hoses	Comment	Additional Localised Risk Rating
				No. Of TMVs	Access	<2m from outlet?	Mix Temps 37-45°C	No. TMV Fed Outlets				Mains	Cold	Hot	Mixer	Urinals	WCs	Shower	Drinks / vend	Water boiler	Drinking fountain	Arjo/whirlpool	Other					
02 Dermatology DOPD-025 (Technician)	Hot, Cold	CWST 18.6	Calorifier 63.0	1	OK	Yes	No	1	None visible	Not visible	Daily		2	2										Low	None visible	None visible	Heat gain in cold, 30 secs to drop <20°C. Mixed temps out of spec	Low
Recommendations:			Evidence of heat gain in cold water - investigate and correct.																									
02 Endoscopy END-013 (Facilities)	Hot, Cold	CWST 18.7	Calorifier 63.5	1	OK	Yes	Yes	1	None visible	Not visible	Daily		3	3										Low	None visible	None visible		Low
Recommendations:																												
02 Endoscopy END-029 (Examination Area)	Hot, Cold	CWST 17.5	Calorifier	1	OK	Yes	Yes	1	None visible	Not visible	Daily		1	1										Low	None visible	None visible		Low
Recommendations:																												
02 FMA2-014 (Changing)	Hot, Cold	CWST 13.6	Calorifier 55.4	1	OK	Yes	Yes	1	None visible	Not visible	Rarely - Inc. in Flush Regime				1		1							Low	None visible	None visible	FMA2-013 noted as sentinel but no outlets.	Medium
Recommendations:			Include Unused outlets into site flushing regime.																									
02 Medical Physics MP-020 (Devices-Adult)	Hot, Cold	CWST 16.4	Calorifier 63.6	1	OK	Yes	Yes	1	None visible	Not visible	Daily		2	2	1									Low	None visible	None visible		Low
Recommendations:																												

Location / Room No	Sentinel outlet?	Cold Supply & Temp (°C)	Hot Supply & Temp (°C)	TMV info					Deadlegs Present (Inc. Drain cocks)	Flow & Return Working	Outlet Usage	Outlets in location												Aerosol Created	Non WRAS Material	Flexi Hoses	Comment	Additional Localised Risk Rating
				No. Of TMVs	Access	<2m from outlet?	Mix Temps 37-45°C	No. TMV Fed Outlets				Mains	Cold	Hot	Mixer	Urinals	WCs	Shower	Drinks / vend	Water boiler	Drinking fountain	Arjo/whirlpool	Other					
02 Renal RENO-003 (CAPD Training)	Hot, Cold	CWST 17.1	Calorifier	1	OK	Yes	Yes	1	None visible	Not visible	Daily		1	1	1									Low	None visible	None visible		Low
Recommendations:																												
02 Renal RENO-016 (Room 3)	Hot, Cold	CWST 17.5	Calorifier	1	OK	Yes	Yes	1	None visible	Not visible	Daily		1	1	1									Low	None visible	None visible	Renal Connection. Heat gain in cold, 90 secs to drop <20°C.	Medium
Recommendations:			Evidence of heat gain in cold water - investigate and correct.																									
02 Renal RENO-033 (Clean Utility)	No	CWST 19.3	Calorifier 56.9	1	OK	Yes	Yes	1	None visible	Not visible	Daily		2	2										Low	None visible	None visible	Heat gain in cold, 100 secs to drop <20°C.	Medium
Recommendations:			Evidence of heat gain in cold water - investigate and correct.																									
02 Renal RENO-046 (Female Toilet)	Hot, Cold	CWST 16.1	Calorifier 62.0	1	OK	Yes	Yes	1	None visible	Not visible	Daily				1		1							Low	None visible	None visible		Low
Recommendations:																												
02 Renal RENO-064 (Equipment Servicing)	Hot, Cold	CWST 19.7	Calorifier 63.5	1	OK	Yes	Yes	1	None visible	Not visible	Daily		2	2										Low	None visible	None visible	Renal (x7). Heat gain in cold, 110 secs to drop <20°C	Medium
Recommendations:			Evidence of heat gain in cold water - investigate and correct.																									

Location / Room No	Sentinel outlet?	Cold Supply & Temp (°C)	Hot Supply & Temp (°C)	TMV info					Deadlegs Present (Inc. Drain cocks)	Flow & Return Working	Outlet Usage	Outlets in location												Aerosol Created	Non WRAS Material	Flexi Hoses	Comment	Additional Localised Risk Rating
				No. Of TMVs	Access	<2m from outlet?	Mix Temps 37-45°C	No. TMV Fed Outlets				Mains	Cold	Hot	Mixer	Urinals	WCs	Shower	Drinks / vend	Water boiler	Drinking fountain	Arjo/whirlpool	Other					
02 Theatres THE-026 (Female Toilet)	Hot, Cold	CWST 16.2	Calorifier 59.7	1	OK	Yes	Yes	1	None visible	Not visible	Daily				1		1							Low	None visible	None visible		Low
Recommendations:																												
02 Theatres THE-033 (Female Changing)	Hot, Cold	CWST 16.8	Calorifier 60.3	3	OK	Yes	Yes	3	None visible	Not visible	Daily				6		6	6						High	None visible	None visible	Heat gain in cold, 50 seces to drop <20°C	Medium
Recommendations:			Evidence of heat gain in cold water - investigate and correct.																									
02 Theatres THE-044 (Male Changing)	Hot, Cold	CWST 18.7	Calorifier 56.0	3	OK	Yes	Yes	3	None visible	Not visible	Daily				3		3	3						Low	None visible	None visible		Low
Recommendations:																												
02 Theatres THE-060 (Facilities)	Hot, Cold	CWST 16.2	Calorifier 58.7	1	OK	Yes	Yes	1	None visible	Not visible	Daily		3	3										Low	None visible	None visible		Low
Recommendations:																												
02 Theatres THE-079 (On Call)	Hot, Cold	CWST 16.4	Calorifier 60.2	2	OK	Yes	Yes	2	None visible	Not visible	Daily				1		1	1						High	None visible	None visible		Low
Recommendations:																												

Location / Room No	Sentinel outlet?	Cold Supply & Temp (°C)	Hot Supply & Temp (°C)	TMV info					Deadlegs Present (Inc. Drain cocks)	Flow & Return Working	Outlet Usage	Outlets in location												Aerosol Created	Non WRAS Material	Flexi Hoses	Comment	Additional Localised Risk Rating
				No. Of TMVs	Access	<2m from outlet?	Mix Temps 37-45°C	No. TMV Fed Outlets				Mains	Cold	Hot	Mixer	Urinals	WCs	Shower	Drinks / vend	Water boiler	Drinking fountain	Arjo/whirlpool	Other					
02 Theatres THE-091 (Dirty Utility)	Hot, Cold	CWST 16.5	Calorifier 59.6	1	OK	Yes	Yes	1	None visible	Not visible	Daily		2	2										Low	None visible	None visible	Heat gain in cold, 60 secs to drop <20°C	Medium
Recommendations:			Evidence of heat gain in cold water - investigate and correct.																									
02 Theatres THE-105 (Dirty Utility)	Hot, Cold	CWST 14.9	Calorifier 61.5	1	OK	Yes	Yes	1	None visible	Not visible	Daily		2	2										Low	None visible	None visible	Heat gain in cold, 70 secs to drop <20°C	Medium
Recommendations:			Evidence of heat gain in cold water - investigate and correct.																									
02 Theatres THE-106 (Scrub Room)	Hot, Cold	CWST	Calorifier	1	OK	Yes	Yes	1	None visible	Not visible	Daily		3	3										Low	None visible	None visible		Low
Recommendations:																												
02 Theatres THE-280 (Disabled Toilet)	Hot, Cold	CWST 15.7	Calorifier 58.1	1	OK	Yes	Yes	1	None visible	Not visible	Daily				1		1							Low	None visible	None visible		Low
Recommendations:																												
02 Theatres THE-287 (Bed Bay A9)	Hot, Cold	CWST 19.2	Calorifier	1	OK	Yes	Yes	1	None visible	Not visible	Daily		1	1										Low	None visible	None visible	Heat gain in cold, 100 secs to drop <20°C	Medium
Recommendations:			Evidence of heat gain in cold water - investigate and correct.																									

Location / Room No	Sentinel outlet?	Cold Supply & Temp (°C)	Hot Supply & Temp (°C)	TMV info					Deadlegs Present (Inc. Drain cocks)	Flow & Return Working	Outlet Usage	Outlets in location												Aerosol Created	Non WRAS Material	Flexi Hoses	Comment	Additional Localised Risk Rating
				No. Of TMVs	Access	<2m from outlet?	Mix Temps 37-45°C	No. TMV Fed Outlets				Mains	Cold	Hot	Mixer	Urinals	WCs	Shower	Drinks / vend	Water boiler	Drinking fountain	Arjo/whirlpool	Other					
02 Theatres THE-289 (Bed Bay A1)	Hot, Cold	CWST 19.7	Calorifier	1	OK	Yes	Yes	1	None visible	Not visible	Rarely - Inc. in Flush Regime		1	1										Low	None visible	None visible	Heat gain in cold, 100 secs to drop <20°C	Medium
Recommendations:			Evidence of heat gain in cold water - investigate and correct. Include Unused outlets into site flushing regime.																								
02 Theatres THE-302 (Bed Bay A7)	Hot, Cold	CWST 19.1	Calorifier	1	OK	Yes	Yes	1	None visible	Not visible	Daily		1	1										Low	None visible	None visible	Heat gain in cold, 100 secs to drop <20°C	Medium
Recommendations:			Evidence of heat gain in cold water - investigate and correct.																								
02 Theatres THE-319 (Dirty Utility)	Hot, Cold	CWST 18.8	Calorifier 56.3	1	OK	Yes	Yes	1	None visible	Not visible	Daily		2	2			1							Low	None visible	None visible	Sluice. Heat gain in cold, 70 secs to drop <20°C	Medium
Recommendations:			Evidence of heat gain in cold water - investigate and correct.																								
02 Theatres THE-327 (Recovery)	Hot, Cold	CWST 19.6	Calorifier	1	OK	Yes	Yes	1	None visible	Not visible	Rarely - Inc. in Flush Regime		1	1										Low	None visible	None visible	Heat gain in cold, 40 secs to drop <20°C	Medium
Recommendations:			Evidence of heat gain in cold water - investigate and correct. Include Unused outlets into site flushing regime.																								

Location / Room No	Sentinel outlet?	Cold Supply & Temp (°C)	Hot Supply & Temp (°C)	TMV info					Deadlegs Present (Inc. Drain cocks)	Flow & Return Working	Outlet Usage	Outlets in location												Aerosol Created	Non WRAS Material	Flexi Hoses	Comment	Additional Localised Risk Rating
				No. Of TMVs	Access	<2m from outlet?	Mix Temps 37-45°C	No. TMV Fed Outlets				Mains	Cold	Hot	Mixer	Urinals	WCs	Shower	Drinks / vend	Water boiler	Drinking fountain	Arjo/whirlpool	Other					
02 Transport Base TPB-001 (Clinical Workroom)	Hot, Cold	CWST 17.5	Calorifier	2	OK	Yes	Yes	2	None visible	Not visible	Daily		2	2										Low	None visible	None visible	Heat gain in cold, 40 secs to drop <20°C	Medium
Recommendations:			Evidence of heat gain in cold water - investigate and correct.																									
02C Aseptic Unit ASU-039 (Changing Room)		CWST	Calorifier	1	OK	Yes	Yes	1																				Removed
Recommendations:			Ensure no deadlegs remain after outlets removed.																									
02C Aseptic Unit ASU-042 (Corridor)	Hot, Cold	CWST 18.5	Calorifier	1	OK	Yes	Yes	1	None visible	Not visible	Daily		1	1										Low	None visible	None visible		Low
Recommendations:																												
02C Corridor ARU-001 (Kitchen)	Hot, Cold	CWST 15.8	Calorifier 62.6	1	OK	Yes	Yes	1	None visible	Not visible	Daily		2	2	1			1 S T					1	High	None visible	Yes	Dishwash	Low
Recommendations:																												
02C Ward AFD-022 (Toilet)	Hot, Cold	CWST 15.1	Calorifier 58.0	1	OK	Yes	Yes	1	None visible	Not visible	Daily				1		1							Low	None visible	None visible		Low
Recommendations:																												

Location / Room No	Sentinel outlet?	Cold Supply & Temp (°C)	Hot Supply & Temp (°C)	TMV info					Deadlegs Present (Inc. Drain cocks)	Flow & Return Working	Outlet Usage	Outlets in location												Aerosol Created	Non WRAS Material	Flexi Hoses	Comment	Additional Localised Risk Rating
				No. Of TMVs	Access	<2m from outlet?	Mix Temps 37-45°C	No. TMV Fed Outlets				Mains	Cold	Hot	Mixer	Urinals	WCs	Shower	Drinks / vend	Water boiler	Drinking fountain	Arjo/whirlpool	Other					
02C Ward ARU-046 (Bedroom)	Hot, Cold	CWST 16.2	Calorifier	1	OK	Yes	Yes	1	None visible	Not visible	Daily		1	1										Low	None visible	None visible	Next to designated sentinel (ARU-047)	Low
Recommendations:																												
02C Ward ARU-085 (Bedroom)	Hot, Cold	CWST 16.8	Calorifier	1	OK	Yes	Yes	1	None visible	Not visible	Daily		1	1	1									Low	None visible	None visible		Low
Recommendations:																												
02C Ward ARU-116 (Toilet)	No	CWST 19.4	Calorifier 57.1	1	OK	Yes	Yes	1	None visible	Not visible	Daily				1		1							Low	None visible	None visible	Infrared tap. Next to designated sentinel (ARU-003)	Low
Recommendations:																												
02C Ward DCU-005 (Toilet)	Hot, Cold	CWST 17.0	Calorifier 57.7	1	OK	Yes	Yes	1	None visible	Not visible	Daily				1		1							Low	None visible	None visible		Low
Recommendations:																												
02C Ward DCU-011 (Waiting Area)	Hot, Cold	CWST	Calorifier	1	OK	Yes	Yes	1	None visible	Not visible	Daily		1	1										Low	None visible	None visible		Low
Recommendations:																												

Location / Room No	Sentinel outlet?	Cold Supply & Temp (°C)	Hot Supply & Temp (°C)	TMV info					Deadlegs Present (Inc. Drain cocks)	Flow & Return Working	Outlet Usage	Outlets in location												Aerosol Created	Non WRAS Material	Flexi Hoses	Comment	Additional Localised Risk Rating
				No. Of TMVs	Access	<2m from outlet?	Mix Temps 37-45°C	No. TMV Fed Outlets				Mains	Cold	Hot	Mixer	Urinals	WCs	Shower	Drinks / vend	Water boiler	Drinking fountain	Arjo/whirlpool	Other					
02C Ward SCH-022 (Bathroom)	Hot, Cold	CWST	Calorifier	2	OK	Yes	Yes	2	None visible	Not visible					1		1	1						High	None visible	None visible		No Access
Recommendations:																												
02C Ward SCH-023 (Bathroom)	Hot, Cold	CWST 10.8	Calorifier 60.7	2	OK	Yes	Yes	2	None visible	Not visible	Daily				1		1	1						High	None visible	None visible		Low
Recommendations:																												
02C Ward SCH-040 (Toilet)	Hot, Cold	CWST 14.7	Calorifier 59.7	1	OK	Yes	Yes	1	None visible	Not visible	Daily				1		1							Low	None visible	None visible		Low
Recommendations:																												
02C Ward SCH-061 (Bedroom)	Hot, Cold	CWST 15.5	Calorifier	1	OK	Yes	Yes	1	None visible	Not visible	Daily		1	1										Low	None visible	None visible		Low
Recommendations:																												
02C Ward SCH-063 (Treatment Room)	Hot, Cold	CWST 17.4	Calorifier	1	OK	Yes	Yes	1	None visible	Not visible	Rarely - Inc. in Flush Regime		1	1										Low	None visible	None visible		Medium
Recommendations:	Include unused outlets into site flushing regime.																											

Location / Room No	Sentinel outlet?	Cold Supply & Temp (°C)	Hot Supply & Temp (°C)	TMV info					Deadlegs Present (Inc. Drain cocks)	Flow & Return Working	Outlet Usage	Outlets in location												Aerosol Created	Non WRAS Material	Flexi Hoses	Comment	Additional Localised Risk Rating
				No. Of TMVs	Access	<2m from outlet?	Mix Temps 37-45°C	No. TMV Fed Outlets				Mains	Cold	Hot	Mixer	Urinals	WCs	Shower	Drinks / vend	Water boiler	Drinking fountain	Arjo/whirlpool	Other					
02C Ward SCH-087 (Store)	Hot, Cold	CWST 14.3	Calorifier 64.2	1	OK	Yes	Yes	1	None visible	Not visible	Daily		2	2	1									Low	None visible	None visible		Low

Recommendations:

02C Ward SCH-092 (Hospital Night Team)	Hot, Cold	CWST 14.5	Calorifier 63.2	1	OK	Yes	Yes	1	None visible	Not visible	Daily		1	1	1									Low	None visible	None visible	Heat gain in cold, 80 secs to drop <20°C	Medium

Recommendations: Evidence of heat gain in cold water - investigate and correct.

03C Ward GW1-002 (Renal Day Unit)	Hot, Cold	CWST 19.0	Calorifier	3	OK	Yes	Yes	3	None visible	Not visible	Daily		3	3										Low	None visible	None visible	5 x renal	Low

Recommendations:

03C Ward GW1-048 (Toilet)	Hot, Cold	CWST 16.1	Calorifier 57.6	1	OK	Yes	Yes	1	None visible	Not visible	Daily				1		1							Low	None visible	None visible		Low

Recommendations:

Location / Room No	Sentinel outlet?	Cold Supply & Temp (°C)	Hot Supply & Temp (°C)	TMV info					Deadlegs Present (Inc. Drain cocks)	Flow & Return Working	Outlet Usage	Outlets in location												Aerosol Created	Non WRAS Material	Flexi Hoses	Comment	Additional Localised Risk Rating
				No. Of TMVs	Access	<2m from outlet?	Mix Temps 37-45°C	No. TMV Fed Outlets				Mains	Cold	Hot	Mixer	Urinals	WCs	Shower	Drinks / vend	Water boiler	Drinking fountain	Arjo/whirlpool	Other					
03C Ward GW2-025 (Bedroom)	Hot, Cold	CWST 16.3	Calorifier	1	OK	Yes	Yes	1	None visible	Not visible	Daily		1	1										Low	None visible	None visible		Low
Recommendations:																												
03C Ward GW2-035 (Bedroom)	Hot, Cold	CWST 16.3	Calorifier	1	OK	Yes	Yes	1	None visible	Not visible	Daily		1	1	1									Low	None visible	None visible	Heat gain in cold, 75 secs to drop <20°C	Medium
Recommendations:			Evidence of heat gain in cold water - investigate and correct.																									
03C Ward GW2-036 (Play Room)	Hot, Cold	CWST 15.9	Calorifier 63.0	1	OK	Yes	Yes	1	None visible	Not visible	Daily		2	2										Low	None visible	None visible		Low
Recommendations:																												
03C Ward GW2-054 (Bathroom)	Hot, Cold	CWST 16.8	Calorifier 60.4	2	OK	Yes	Yes	2	None visible	Not visible	Daily				1		1	1						High	None visible	None visible		Low
Recommendations:																												
03C Ward GW3-005 (Bathroom)	Hot, Cold	CWST 18.1	Calorifier 55.7	2	OK	Yes	Yes	2	None visible	Not visible	Daily				1		1	1						High	None visible	None visible		Low
Recommendations:																												

Location / Room No	Sentinel outlet?	Cold Supply & Temp (°C)	Hot Supply & Temp (°C)	TMV info					Deadlegs Present (Inc. Drain cocks)	Flow & Return Working	Outlet Usage	Outlets in location												Aerosol Created	Non WRAS Material	Flexi Hoses	Comment	Additional Localised Risk Rating
				No. Of TMVs	Access	<2m from outlet?	Mix Temps 37-45°C	No. TMV Fed Outlets				Mains	Cold	Hot	Mixer	Urinals	WCs	Shower	Drinks / vend	Water boiler	Drinking fountain	Arjo/whirlpool	Other					
03C Ward GW3-043 (Play Room)	Hot, Cold	CWST 13.9	Calorifier 64.1	1	OK	Yes	Yes	1	None visible	Not visible	Daily		2	2										Low	None visible	None visible		Low
Recommendations:																												
03C Ward GW3-068 (Lab)	Hot, Cold	CWST 16.7	Calorifier 60.7	1	OK	Yes	Yes	1	None visible	Not visible	Rarely - Inc. in Flush Regime		2	2										Low	None visible	None visible	Sentinel (GW3-001)	Medium
Recommendations:			Include unused outlets into site flushing regime.																									
03C Ward GWS-004 (Staff Kitchen)	Hot, Cold	CWST 15.2	Calorifier 56.7	1	OK	Yes	No	1	None visible	Not visible	Daily		1	1	1					1			1	Low	None visible	None visible	Dishwash	Low
Recommendations:																												
03C Ward GWS-011 (Kitchen)	Hot, Cold	CWST 14.6	Calorifier 63.5	1	OK	Yes	Yes	1	None visible	Not visible	Rarely - Inc. in Flush Regime		1	1	1					1				Low	None visible	None visible		Medium
Recommendations:			Include unused outlets into site flushing regime.																									
03C Ward GWS-014 (Renal Technician)	Hot, Cold	CWST 15.2	Calorifier 64.3	1	OK	Yes	Yes	1	None visible	Not visible	Daily		2	2	1									Low	None visible	None visible	2 x Renal	Low
Recommendations:																												

Location / Room No	Sentinel outlet?	Cold Supply & Temp (°C)	Hot Supply & Temp (°C)	TMV info					Deadlegs Present (Inc. Drain cocks)	Flow & Return Working	Outlet Usage	Outlets in location											Aerosol Created	Non WRAS Material	Flexi Hoses	Comment	Additional Localised Risk Rating
				No. Of TMVs	Access	<2m from outlet?	Mix Temps 37-45°C	No. TMV Fed Outlets				Mains	Cold	Hot	Mixer	Urinals	WCs	Shower	Drinks / vend	Water boiler	Drinking fountain	Arjo/whirlpool	Other					
03C Ward GWS-033 (Toilet)	Hot, Cold	CWST 18.2	Calorifier 57.1	1	OK	Yes	No	1	None visible	Not visible	Daily				1		1							Low	None visible	None visible		Low
Recommendations:																												
04 WS4-004 (Toilet)	Hot, Cold	CWST 16.5	Calorifier 61.0	1	OK	Yes	Yes	1	None visible	Not visible	Daily				1		1							Low	None visible	None visible		Low
Recommendations:																												
04 WS4-009 (Toilet)	Hot, Cold	CWST 17.0	Calorifier 56.9	1	OK	Yes	Yes	1	None visible	Not visible	Daily				1		1							Low	None visible	None visible		Low
Recommendations:																												
04 WS4-014 (Facilities Regen)	Hot, Cold	CWST 17.0	Calorifier 59.0	1	OK	Yes	Yes	1	None visible	Yes	Daily		2	2	1			1		1				High	None visible	Yes	Pipework un-insulated 1	Medium
Recommendations:	All EPDM flexible hoses should be removed and replaced with hard piped connection (if practicable)																											
04 WS4-017 (Male Change)	Hot, Cold	CWST 19.0	Calorifier 58.0	1	OK	Yes	Yes	1	None visible	Not visible	Daily				1									Low	None visible	None visible	Cold slow to drop from 24.1°	Medium
Recommendations:	Cold water showing evidence of heat gain. Investigate and correct.																											

Location / Room No	Sentinel outlet?	Cold Supply & Temp (°C)	Hot Supply & Temp (°C)	TMV info					Deadlegs Present (Inc. Drain cocks)	Flow & Return Working	Outlet Usage	Outlets in location												Aerosol Created	Non WRAS Material	Flexi Hoses	Comment	Additional Localised Risk Rating
				No. Of TMVs	Access	<2m from outlet?	Mix Temps 37-45°C	No. TMV Fed Outlets				Mains	Cold	Hot	Mixer	Urinals	WCs	Shower	Drinks / vend	Water boiler	Drinking fountain	Arjo/whirlpool	Other					
04A HOW-024 (Bathroom)	Hot, Cold	CWST 23.0	Calorifier 50.8	2	OK	Yes	Yes	2	None visible	Not visible	Daily				1		1	1						High	None visible	None visible		Medium
Recommendations:			Cold water temperature too high. Investigate and correct.																									
04A HOW-027 (Bathroom)	Hot, Cold	CWST 23.4	Calorifier 50.8	2	OK	Yes	Yes	2	None visible	Not visible	Daily				1		1	1						High	None visible	None visible	Cold rose to 26.1° before dropping slowly	High
Recommendations:			Cold water temperature too high. Investigate and correct.																									
04A RENW-005 (Bedroom)	Hot, Cold	CWST 17.6	Calorifier	1	OK	Yes	Yes	1	None visible	Not visible	Daily		1	1										Low	None visible	None visible	Renal Connection	Low
Recommendations:																												
04A RENW-055 (Bedroom)	Hot, Cold	CWST 18.0	Calorifier	1	OK	Yes	Yes	1	None visible	Not visible	Daily		1	1										Low	None visible	None visible	Renal Connection	Low
Recommendations:																												
04B HOW-030 (Bathroom)	Hot, Cold	CWST 22.7	Calorifier 58.3	2	OK	Yes	Yes	2	None visible	Not visible	Daily				1		1	1						High	None visible	None visible		High
Recommendations:			Cold water temperature too high. Investigate and correct.																									

Location / Room No	Sentinel outlet?	Cold Supply & Temp (°C)	Hot Supply & Temp (°C)	TMV info					Deadlegs Present (Inc. Drain cocks)	Flow & Return Working	Outlet Usage	Outlets in location												Aerosol Created	Non WRAS Material	Flexi Hoses	Comment	Additional Localised Risk Rating
				No. Of TMVs	Access	<2m from outlet?	Mix Temps 37-45°C	No. TMV Fed Outlets				Mains	Cold	Hot	Mixer	Urinals	WCs	Shower	Drinks / vend	Water boiler	Drinking fountain	Arjo/whirlpool	Other					
04B HOW-064 (Bedroom)	Hot, Cold	CWST 19.3	Calorifier	1	OK	Yes	Yes	1	None visible	Not visible	Rarely - Inc. in Flush Regime		1	1										Low	None visible	None visible		Medium
Recommendations:			Include unused outlets into site flushing regime.																									
04B HOW-193 (Bedroom)	Hot, Cold	CWST 16.7	Calorifier	1	OK	Yes	Yes	1	None visible	Not visible	Rarely - Inc. in Flush Regime		1	1										Low	None visible	None visible	Renal Connection	Medium
Recommendations:			Include Unused outlets into site flushing regime.																									
04C RENW-127 (Consulting Room)	Hot, Cold	CWST 16.5	Calorifier	1	OK	Yes	Yes	1	None visible	Not visible	Rarely - Inc. in Flush Regime		1	1										Low	None visible	None visible		Medium
Recommendations:			Include unused outlets into site flushing regime.																									
04C RENW-153 (Bathroom)	Hot, Cold	CWST 22.4	Calorifier 56.0	2	OK	Yes	Yes	2	None visible	Not visible	Rarely - Inc. in Flush Regime				1		1	1						High	None visible	None visible	Showerhead damaged	Medium
Recommendations:			Cold water temperature too high. Investigate and correct.																									
04C RENW-156 (Bathroom)	Hot, Cold	CWST 17.0	Calorifier 57.2	2	OK	Yes	Yes	2	None visible	Not visible	Rarely - Inc. in Flush Regime				1		1	1						High	None visible	None visible		Medium
Recommendations:			Include Unused outlets into site flushing regime.																									

Location / Room No	Sentinel outlet?	Cold Supply & Temp (°C)	Hot Supply & Temp (°C)	TMV info					Deadlegs Present (Inc. Drain cocks)	Flow & Return Working	Outlet Usage	Outlets in location												Aerosol Created	Non WRAS Material	Flexi Hoses	Comment	Additional Localised Risk Rating
				No. Of TMVs	Access	<2m from outlet?	Mix Temps 37-45°C	No. TMV Fed Outlets				Mains	Cold	Hot	Mixer	Urinals	WCs	Shower	Drinks / vend	Water boiler	Drinking fountain	Arjo/whirlpool	Other					
04C RENW-188 (Bedroom)	Hot, Cold	CWST 17.8	Calorifier	1	OK	Yes	Yes	1	None visible	Not visible	Daily		1	1										Low	None visible	None visible	Renal Connection	Low
Recommendations:																												
04D RENW-060 (Bedroom)	Hot, Cold	CWST 16.6	Calorifier	1	OK	Yes	Yes	1	None visible	Not visible	Rarely - Inc. in Flush Regime		1	1										Low	None visible	None visible	Renal Connection	Medium
Recommendations:			Include unused outlets into site flushing regime.																									
04D RENW-091 (Bathroom)	Hot, Cold	CWST 18.3	Calorifier 56.0	2	OK	Yes	Yes	2	None visible	Not visible	Daily				1		1	1						High	None visible	None visible	Section of pipework un-insulated	Low
Recommendations:																												
04D RENW-094 (Bathroom)	Hot, Cold	CWST 21.2	Calorifier 56.2	2	OK	Yes	Yes	2	None visible	Not visible	Daily				1		1	1						High	None visible	None visible	Cold slow to drop from 25.6°C	Medium
Recommendations:			Cold water temperature too high. Investigate and correct.																									

Location / Room No	Sentinel outlet?	Cold Supply & Temp (°C)	Hot Supply & Temp (°C)	TMV info					Deadlegs Present (Inc. Drain cocks)	Flow & Return Working	Outlet Usage	Outlets in location												Aerosol Created	Non WRAS Material	Flexi Hoses	Comment	Additional Localised Risk Rating
				No. Of TMVs	Access	<2m from outlet?	Mix Temps 37-45°C	No. TMV Fed Outlets				Mains	Cold	Hot	Mixer	Urinals	WCs	Shower	Drinks / vend	Water boiler	Drinking fountain	Arjo/whirlpool	Other					
04D RENW-124 (Consulting Room)	Hot, Cold	CWST 16.0	Calorifier	1	OK	Yes	Yes	1	None visible	Not visible	Daily		1	1										Low	None visible	None visible		Low
Recommendations:																												
04C Child Forensic Psychology DCFP-013 (Toilet)	Hot, Cold	CWST 16.2	Calorifier	1	OK	Yes	Yes	1	None visible	Not visible	Daily				1		1							Low	None visible	None visible		Low
Recommendations:																												
04C Child Forensic Psychology DCFP-049 (Kitchen)	No	CWST 17.0	Calorifier 59.1	1	OK	Yes	Yes	1	None visible	Not visible	Rarely - Inc. in Flush Regime		2	2	1			1		1				High	None visible	Yes	Next to designated sentinel (DCFP-042)	Medium
Recommendations:	All EPDM flexible hoses should be removed and replaced with hard piped connection (if practicable) Include unused outlets into site flushing regime.																											
05 WS5-005 (Toilet)	Hot, Cold	CWST 17.0	Calorifier 57.6	1	OK	Yes	Yes	1	None visible	Not visible	Daily				1		1							Low	None visible	None visible		Low
Recommendations:																												
05 WS5-011 (Toilet)	Hot, Cold	CWST 16.0	Calorifier 57.5	1	OK	Yes	Yes	1	None visible	Not visible	Daily				1		1							Low	None visible	None visible		Low
Recommendations:																												

Location / Room No	Sentinel outlet?	Cold Supply & Temp (°C)	Hot Supply & Temp (°C)	TMV info					Deadlegs Present (Inc. Drain cocks)	Flow & Return Working	Outlet Usage	Outlets in location												Aerosol Created	Non WRAS Material	Flexi Hoses	Comment	Additional Localised Risk Rating
				No. Of TMVs	Access	<2m from outlet?	Mix Temps 37-45°C	No. TMV Fed Outlets				Mains	Cold	Hot	Mixer	Urinals	WCs	Shower	Drinks / vend	Water boiler	Drinking fountain	Arjo/whirlpool	Other					
05 WS5-021 (Male Change)	Hot, Cold	CWST 16.4	Calorifier 59.1	1	OK	Yes	Yes	1	None visible	Not visible	Daily				1									Low	None visible	None visible		Low
Recommendations:																												
05 WS5-027 (Facilities)		CWST 16.4	Calorifier 62.9	1	OK	Yes	Yes	1	None visible	Not visible	Daily		2	2	1									Low	None visable	Yes		Medium
Recommendations:			All EPDM felxible hoses should be removed and replaced with hard piped connection.																									
05A GENWA-001 (Bedroom)	Hot, Cold	CWST 17.4	Calorifier	1	OK	Yes	Yes	1	None visible	Not visible	Daily		1	1										Low	None visible	None visible		Low
Recommendations:																												
06 WS6-006 (Staff Meeting)	Hot, Cold	CWST	N/A	1	OK	Yes	Yes	1	None visible	Not visible	Daily										1			Low	None visible	None visible		Low
Recommendations:																												
05A GENWA-029 (Bathroom)	Hot, Cold	CWST 24.2	Calorifier 58.0	2	OK	Yes	Yes	2	None visible	Not visible	Daily				1		1	1						High	None visible	None visible	Cold slow to drop from 26.3°C	Medium
Recommendations:			Cold water showing evidence of heat gain. Investigate and correct.																									

Location / Room No	Sentinel outlet?	Cold Supply & Temp (°C)	Hot Supply & Temp (°C)	TMV info					Deadlegs Present (Inc. Drain cocks)	Flow & Return Working	Outlet Usage	Outlets in location												Aerosol Created	Non WRAS Material	Flexi Hoses	Comment	Additional Localised Risk Rating
				No. Of TMVs	Access	<2m from outlet?	Mix Temps 37-45°C	No. TMV Fed Outlets				Mains	Cold	Hot	Mixer	Urinals	WCs	Shower	Drinks / vend	Water boiler	Drinking fountain	Arjo/whirlpool	Other					
05A GENWA-034 (Bathroom)	Hot, Cold	CWST 18.0	Calorifier 56.5	2	OK	Yes	Yes	2	None visible	Not visible	Daily				1		1	1						High	None visible	None visible		Low
Recommendations:																												
05A GENWA-065 (Bedroom)	Hot, Cold	CWST 17.6	Calorifier	1	OK	Yes	Yes	1	None visible	Not visible	Daily		1	1										Low	None visible	None visible		Low
Recommendations:																												
05B GENWD-032 (Bathroom)	Hot, Cold	CWST 17.2	Calorifier 57.4	2	OK	Yes	Yes	2	None visible	Not visible	Daily				1		1	1						High	None visible	None visible		Low
Recommendations:																												
05B GENWD-036 (Bathroom)	Hot, Cold	CWST 17.8	Calorifier 58.0	2	OK	Yes	Yes	2	None visible	Not visible	Daily				1		1	1						High	None visible	None visible		Low
Recommendations:																												
05B GENWD-065 (Bedroom)	Hot, Cold	CWST 16.9	Calorifier 57.4	1	OK	Yes	Yes	1	None visible	Not visible	Daily		1	1										Low	None visible	None visible	Tap dripping from diffuser.	Low
Recommendations:																												

Location / Room No	Sentinel outlet?	Cold Supply & Temp (°C)	Hot Supply & Temp (°C)	TMV info					Deadlegs Present (Inc. Drain cocks)	Flow & Return Working	Outlet Usage	Outlets in location												Aerosol Created	Non WRAS Material	Flexi Hoses	Comment	Additional Localised Risk Rating
				No. Of TMVs	Access	<2m from outlet?	Mix Temps 37-45°C	No. TMV Fed Outlets				Mains	Cold	Hot	Mixer	Urinals	WCs	Shower	Drinks / vend	Water boiler	Drinking fountain	Arjo/whirlpool	Other					
05C GENWC-028 (Bedroom)	Hot, Cold	CWST 17.2	Calorifier	1	OK	Yes	Yes	1	None visible	Not visible	Daily		1	1										Low	None visible	None visible		Low
Recommendations:																												
05C GENWC-034 (Bathroom)	Hot, Cold	CWST 16.7	Calorifier 57.0	2	OK	Yes	Yes	2	None visible	Not visible	Daily				1		1	1						High	None visible	None visible		Low
Recommendations:																												
05C GENWC-065 (Bedroom)	Hot, Cold	CWST 17.0	Calorifier	1	OK	Yes	Yes	1	None visible	Not visible	Daily		1	1										Low	None visible	None visible		Low
Recommendations:																												
05D GENWB-001 (Bedroom)	Hot, Cold	CWST 16.7	Calorifier	1	OK	Yes	Yes	1	None visible	Not visible	Daily		1	1										Low	None visible	None visible		Low
Recommendations:																												
05D GENWB-028 (Bedroom)	Hot, Cold	CWST 17.5	Calorifier	1	OK	Yes	Yes	1	None visible	Not visible	Daily		1	1										Low	None visible	None visible		Low
Recommendations:																												

Location / Room No	Sentinel outlet?	Cold Supply & Temp (°C)	Hot Supply & Temp (°C)	TMV info					Deadlegs Present (Inc. Drain cocks)	Flow & Return Working	Outlet Usage	Outlets in location												Aerosol Created	Non WRAS Material	Flexi Hoses	Comment	Additional Localised Risk Rating
				No. Of TMVs	Access	<2m from outlet?	Mix Temps 37-45°C	No. TMV Fed Outlets				Mains	Cold	Hot	Mixer	Urinals	WCs	Shower	Drinks / vend	Water boiler	Drinking fountain	Arjo/whirlpool	Other					
05D GENWB-034 (Bathroom)	Hot, Cold	CWST 16.8	Calorifier 56.0	2	OK	Yes	Yes	2	None visible	Not visible	Daily				1		1	1						High	None visible	None visible		Low
Recommendations:																												
05D GENWB-057 (Bedroom)	Hot, Cold	CWST 16.4	Calorifier	1	OK	Yes	Yes	1	None visible	Not visible	Daily		1	1										Low	None visible	None visible		Low
Recommendations:																												
05D GENWB-065 (Bedroom)	Hot, Cold	CWST 16.7	Calorifier	1	OK	Yes	Yes	1	None visible	Not visible	Daily		1	1										Low	None visible	None visible		Low
Recommendations:																												
05D GENWB-081 (Clean Utility)	No	CWST 16.5	Calorifier 64.1	1	OK	Yes	Yes	1	None visible	Not visible	Daily		2	2										Low	None visible	None visible		Low
Recommendations:																												
06 WS6-005 (Toilet)	Hot, Cold	CWST 16.5	Calorifier 56.8	1	OK	Yes	Yes	1	None visible	Not visible	Daily				1		1							Low	None visible	None visible		Low
Recommendations:																												

Location / Room No	Sentinel outlet?	Cold Supply & Temp (°C)	Hot Supply & Temp (°C)	TMV info					Deadlegs Present (Inc. Drain cocks)	Flow & Return Working	Outlet Usage	Outlets in location												Aerosol Created	Non WRAS Material	Flexi Hoses	Comment	Additional Localised Risk Rating
				No. Of TMVs	Access	<2m from outlet?	Mix Temps 37-45°C	No. TMV Fed Outlets				Mains	Cold	Hot	Mixer	Urinals	WCs	Shower	Drinks / vend	Water boiler	Drinking fountain	Arjo/whirlpool	Other					
06 WS6-011 (Toilet)	Hot, Cold	CWST 16.3	Calorifier 56.9	1	OK	Yes	Yes	1	None visible	Not visible	Daily				1		1							Low	None visible	None visible		Low
Recommendations:																												
06 WS6-019 (Toilet)	Hot, Cold	CWST 17.6	Calorifier 57.5	1	OK	Yes	Yes	1	None visible	Not visible	Daily				1		1							Low	None visible	None visible		Low
Recommendations:																												
06 WS6-027 (Facilities)	Hot, Cold	CWST 15.9	Calorifier 61.0	1	OK	Yes	Yes	1	None visible	Not visible	Daily		3	3										Low	None visible	Yes	Flexible hoses at double level sink.	Medium
Recommendations:	All EPDM flexible hoses should be removed and replaced with hard piped connection (if practicable)																											
06A GENW1-001 (Arjo Bathroom)	No	CWST 16.2	Calorifier 59.0	1 (1)	No access – some	Yes	Yes	1	None visible	Yes	Daily				1		1	1				1		High	None visible	Yes	TMV integral to Arjo bath.	Medium
Recommendations:	All EPDM flexible hoses should be removed and replaced with hard piped connection (if practicable)																											
06A GENW1-029 (Bathroom)	Hot, Cold	CWST 23.2	Calorifier 56.7	2	OK	Yes	Yes	2	None visible	Not visible	Daily				1		1	1						High	None visible	None visible	Cold rose to 25.8°C before dropping slowly	Medium
Recommendations:	Cold water temperature too high. Investigate and correct.																											

Location / Room No	Sentinel outlet?	Cold Supply & Temp (°C)	Hot Supply & Temp (°C)	TMV info					Deadlegs Present (Inc. Drain cocks)	Flow & Return Working	Outlet Usage	Outlets in location												Aerosol Created	Non WRAS Material	Flexi Hoses	Comment	Additional Localised Risk Rating
				No. Of TMVs	Access	<2m from outlet?	Mix Temps 37-45°C	No. TMV Fed Outlets				Mains	Cold	Hot	Mixer	Urinals	WCs	Shower	Drinks / vend	Water boiler	Drinking fountain	Arjo/whirlpool	Other					
06A GENW1-034 (Bathroom)	Hot, Cold	CWST 19.1	Calorifier 58.0	2	OK	Yes	Yes	2	None visible	Not visible	Daily				1		1	1						High	None visible	None visible	Cold slow to drop and outlets recently used.	Medium
Recommendations:	Cold water showing evidence of heat gain. Investigate and correct.																										
06A GENW1-065 (Bedroom)	Hot, Cold	CWST 18.0	Calorifier	1	OK	Yes	Yes	1	None visible	Not visible	Daily		1	1										Low	None visible	None visible		Low
Recommendations:																											
06B GENW4-032 (Bathroom)	Hot, Cold	CWST 17.5	Calorifier 56.9	2	OK	Yes	Yes	2	None visible	Not visible	Daily				1		1	1						High	None visible	None visible		Low
Recommendations:																											
06B GENW4-036 (Bathroom)	Hot, Cold	CWST 18.0	Calorifier 56.7	2	OK	Yes	Yes	2	None visible	Not visible	Daily				1		1	1						High	None visible	None visible		Low
Recommendations:																											
06B GENW4-065 (Bedroom)	Hot, Cold	CWST 16.9	Calorifier	1	OK	Yes	Yes	1	None visible	Not visible	Daily		1	1										Low	None visible	None visible		Low
Recommendations:																											

Location / Room No	Sentinel outlet?	Cold Supply & Temp (°C)	Hot Supply & Temp (°C)	TMV info					Deadlegs Present (Inc. Drain cocks)	Flow & Return Working	Outlet Usage	Outlets in location												Aerosol Created	Non WRAS Material	Flexi Hoses	Comment	Additional Localised Risk Rating
				No. Of TMVs	Access	<2m from outlet?	Mix Temps 37-45°C	No. TMV Fed Outlets				Mains	Cold	Hot	Mixer	Urinals	WCs	Shower	Drinks / vend	Water boiler	Drinking fountain	Arjo/whirlpool	Other					
06C GENW3-028 (Bedroom)	Hot, Cold	CWST 17.3	Calorifier	1	OK	Yes	Yes	1	None visible	Not visible	Daily		1	1										Low	None visible	None visible		Low
Recommendations:																												
06C GENW3-034 (Bathroom)	Hot, Cold	CWST 17.8	Calorifier 56.8	2	OK	Yes	Yes	2	None visible	Not visible	Daily				1		1	1						High	None visible	None visible		Low
Recommendations:																												
06C GENW3-065 (Bedroom)	Hot, Cold	CWST 16.8	Calorifier	1	OK	Yes	Yes	1	None visible	Not visible	Daily		1	1										Low	None visible	None visible		Low
Recommendations:																												
06D GENW2-001 (Bedroom)	Hot, Cold	CWST 17.1	Calorifier	1	OK	Yes	Yes	1	None visible	Not visible	Daily		1	1										Low	None visible	None visible		Low
Recommendations:																												
06D GENW2-028 (Bedroom)	Hot, Cold	CWST 18.6	Calorifier	1	OK	Yes	Yes	1	None visible	Not visible	Daily		1	1										Low	None visible	None visible		Low
Recommendations:																												

Location / Room No	Sentinel outlet?	Cold Supply & Temp (°C)	Hot Supply & Temp (°C)	TMV info					Deadlegs Present (Inc. Drain cocks)	Flow & Return Working	Outlet Usage	Outlets in location												Aerosol Created	Non WRAS Material	Flexi Hoses	Comment	Additional Localised Risk Rating
				No. Of TMVs	Access	<2m from outlet?	Mix Temps 37-45°C	No. TMV Fed Outlets				Mains	Cold	Hot	Mixer	Urinals	WCs	Shower	Drinks / vend	Water boiler	Drinking fountain	Arjo/whirlpool	Other					
06D GENW2-034 (Bathroom)	Hot, Cold	CWST 22.9	Calorifier 57.9	2	OK	Yes	Yes	2	None visible	Not visible	Daily				1		1	1						High	None visible	None visible	Cold rose to 25.5°C before dropping slowly	Medium
Recommendations:			Cold water temperature too high. Investigate and correct.																								
06D GENW2-057 (Bedroom)	Hot, Cold	CWST 17.2	Calorifier	1	OK	Yes	Yes	1	None visible	Not visible	Daily		1	1										Low	None visible	None visible		Low
Recommendations:																											
06D GENW2-065 (Bedroom)	Hot, Cold	CWST 23.0	Calorifier	1	OK	Yes	Yes	1	None visible	Not visible	Daily		1	1										Low	None visible	None visible	Cold rose to 26.4°C	Medium
Recommendations:			Cold water temperature too high. Investigate and correct.																								
07 WS7-005 (Toilet)	Hot, Cold	CWST 17.8	Calorifier 58.5	1	OK	Yes	Yes	1	None visible	Not visible	Daily				1		1							Low	None visible	None visible		Low
Recommendations:																											
07 WS7-011 (Toilet)	Hot, Cold	CWST 17.2	Calorifier 56.0	1	OK	Yes	Yes	1	None visible	Not visible	Daily				1		1							Low	None visible	None visible		Low
Recommendations:																											

Location / Room No	Sentinel outlet?	Cold Supply & Temp (°C)	Hot Supply & Temp (°C)	TMV info					Deadlegs Present (Inc. Drain cocks)	Flow & Return Working	Outlet Usage	Outlets in location												Aerosol Created	Non WRAS Material	Flexi Hoses	Comment	Additional Localised Risk Rating
				No. Of TMVs	Access	<2m from outlet?	Mix Temps 37-45°C	No. TMV Fed Outlets				Mains	Cold	Hot	Mixer	Urinals	WCs	Shower	Drinks / vend	Water boiler	Drinking fountain	Arjo/whirlpool	Other					
07A GENW5-001 (Bedroom)	Hot, Cold	CWST 17.9	Calorifier	1	OK	Yes	Yes	1	None visible	Not visible	Daily		1	1										Low	None visible	None visible		Low
Recommendations:																												
07A GENW5-029 (Bathroom)	Hot, Cold	CWST 17.5	Calorifier 58.4	1	OK	Yes	No	1	None visible	Not visible	Daily				1		1	1						High	None visible	None visible		Low
Recommendations:																												
07A GENW5-034 (Bathroom)	Hot, Cold	CWST 18.1	Calorifier 57.3	2	OK	Yes	Yes	2	None visible	Not visible	Daily				1		1	1						High	None visible	None visible		Low
Recommendations:																												
07A GENW5-065 (Bedroom)	Hot, Cold	CWST 17.4	Calorifier	1	OK	Yes	Yes	1	None visible	Not visible	Daily		1	1										Low	None visible	None visible		Low
Recommendations:																												
07B GENW8-032 (Bathroom)	Hot, Cold	CWST 18.0	Calorifier 57.5	2	OK	Yes	Yes	2	None visible	Not visible	Daily				1		1	1						High	None visible	None visible		Low
Recommendations:																												

Location / Room No	Sentinel outlet?	Cold Supply & Temp (°C)	Hot Supply & Temp (°C)	TMV info					Deadlegs Present (Inc. Drain cocks)	Flow & Return Working	Outlet Usage	Outlets in location												Aerosol Created	Non WRAS Material	Flexi Hoses	Comment	Additional Localised Risk Rating
				No. Of TMVs	Access	<2m from outlet?	Mix Temps 37-45°C	No. TMV Fed Outlets				Mains	Cold	Hot	Mixer	Urinals	WCs	Shower	Drinks / vend	Water boiler	Drinking fountain	Arjo/whirlpool	Other					
07B GENW8-036 (Bathroom)	Hot, Cold	CWST 18.3	Calorifier 56.8	2	OK	Yes	Yes	2	None visible	Not visible	Daily				1		1	1						High	None visible	None visible		Low

Recommendations:

07B GENW8-065 (Bedroom)	Hot, Cold	CWST 17.4	Calorifier	1	OK	Yes	Yes	1	None visible	Not visible	Daily		1	1										Low	None visible	None visible	Small piece of insulation missing	Low

Recommendations:

07C GENW7-028 (Bedroom)	Hot, Cold	CWST 16.9	Calorifier	1	OK	Yes	Yes	1	None visible	Not visible	Daily		1	1										Low	None visible	None visible		Low

Recommendations:

07C GENW7-034 (Bathroom)	Hot, Cold	CWST 17.4	Calorifier 56.7	2	OK	Yes	Yes	2	None visible	Not visible	Daily				1		1	1						High	None visible	None visible		Low

Recommendations:

07C GENW7-065 (Bedroom)	Hot, Cold	CWST 18.0	Calorifier	1	OK	Yes	Yes	1	None visible	Not visible	Daily		1	1										Low	None visible	None visible		Low

Recommendations:

Location / Room No	Sentinel outlet?	Cold Supply & Temp (°C)	Hot Supply & Temp (°C)	TMV info					Deadlegs Present (Inc. Drain cocks)	Flow & Return Working	Outlet Usage	Outlets in location												Aerosol Created	Non WRAS Material	Flexi Hoses	Comment	Additional Localised Risk Rating
				No. Of TMVs	Access	<2m from outlet?	Mix Temps 37-45°C	No. TMV Fed Outlets				Mains	Cold	Hot	Mixer	Urinals	WCs	Shower	Drinks / vend	Water boiler	Drinking fountain	Arjo/whirlpool	Other					
07D GENW6-001 (Bedroom)	Hot, Cold	CWST 16.8	Calorifier	1	OK	Yes	Yes	1	None visible	Not visible	Daily		1	1										Low	None visible	None visible		Low
Recommendations:																												
07D GENW6-028 (Bedroom)	Hot, Cold	CWST 17.4	Calorifier	1	OK	Yes	Yes	1	None visible	Not visible	Daily		1	1										Low	None visible	None visible		Low
Recommendations:																												
07D GENW6-034 (Bathroom)	Hot, Cold	CWST 17.9	Calorifier 56.0	2	OK	Yes	Yes	2	None visible	Not visible	Daily				1		1	1						High	None visible	None visible		Low
Recommendations:																												
07D GENW6-057 (Bedroom)	Hot, Cold	CWST 17.3	Calorifier	1	OK	Yes	Yes	1	None visible	Not visible	Daily		1	1										Low	None visible	None visible		Low
Recommendations:																												
07D GENW6-065 (Bedroom)	Hot, Cold	CWST 16.9	Calorifier	1	OK	Yes	Yes	1	None visible	Not visible	Daily		1	1										Low	None visible	None visible		Low
Recommendations:																												

Location / Room No	Sentinel outlet?	Cold Supply & Temp (°C)	Hot Supply & Temp (°C)	TMV info					Deadlegs Present (Inc. Drain cocks)	Flow & Return Working	Outlet Usage	Outlets in location												Aerosol Created	Non WRAS Material	Flexi Hoses	Comment	Additional Localised Risk Rating
				No. Of TMVs	Access	<2m from outlet?	Mix Temps 37-45°C	No. TMV Fed Outlets				Mains	Cold	Hot	Mixer	Urinals	WCs	Shower	Drinks / vend	Water boiler	Drinking fountain	Arjo/whirlpool	Other					
08 WS8-005 (Toilet)	Hot, Cold	CWST 17.6	Calorifier 58.0	1	OK	Yes	Yes	1	None visible	Not visible	Daily				1		1							Low	None visible	None visible		Low
Recommendations:																												
08 WS8-011 (Toilet)	Hot, Cold	CWST 15.9	Calorifier 56.9	1	OK	Yes	Yes	1	None visible	Not visible	Daily				1		1							Low	None visible	None visible		Low
Recommendations:																												
08 WS8-021 (Male Change)	Hot, Cold	CWST 17.0	Calorifier 58.0	1	OK	Yes	Yes	1	None visible	Not visible	Daily				1									Low	None visible	None visible		Low
Recommendations:																												
08 WS8-027 (Facilities)	Hot, Cold	CWST 16.9	Calorifier 57.7	1	OK	Yes	Yes	1	None visible	Not visible	Daily		3	3										Low	None visible	Yes	Flexi hoses on double level sink	Medium
Recommendations:	All EPDM flexible hoses should be removed and replaced with hard piped connection (if practicable)																											
08A GENW9-001 (Bedroom)	Hot, Cold	CWST 17.0	Calorifier	1	OK	Yes	Yes	1	None visible	Not visible	Daily		1	1										Low	None visible	None visible		Low
Recommendations:																												

Location / Room No	Sentinel outlet?	Cold Supply & Temp (°C)	Hot Supply & Temp (°C)	TMV info					Deadlegs Present (Inc. Drain cocks)	Flow & Return Working	Outlet Usage	Outlets in location												Aerosol Created	Non WRAS Material	Flexi Hoses	Comment	Additional Localised Risk Rating
				No. Of TMVs	Access	<2m from outlet?	Mix Temps 37-45°C	No. TMV Fed Outlets				Mains	Cold	Hot	Mixer	Urinals	WCs	Shower	Drinks / vend	Water boiler	Drinking fountain	Arjo/whirlpool	Other					
08A GENW9-029 (Bathroom)	Hot, Cold	CWST 17.8	Calorifier 57.4	2	OK	Yes	Yes	2	None visible	Not visible	Daily				1		1	1						High	None visible	None visible		Low
Recommendations:																												
08A GENW9-034 (Bathroom)	Hot, Cold	CWST 16.7	Calorifier 56.8	2	OK	Yes	Yes	2	None visible	Not visible	Daily				1		1	1						High	None visible	None visible		Low
Recommendations:																												
08A GENW9-065 (Bedroom)	Hot, Cold	CWST 15.9	Calorifier	1	OK	Yes	Yes	1	None visible	Not visible	Daily		1	1										Low	None visible	None visible		Low
Recommendations:																												
08B GENW12-032 (Bathroom)	Hot, Cold	CWST 17.3	Calorifier 58.0	2	OK	Yes	Yes	2	None visible	Not visible	Daily				1		1	1						High	None visible	None visible		Low
Recommendations:																												
08B GENW12-036 (Bathroom)	Hot, Cold	CWST 16.5	Calorifier 57.5	2	OK	Yes	Yes	2	None visible	Not visible	Daily				1		1	1						High	None visible	None visible		Low
Recommendations:																												

Location / Room No	Sentinel outlet?	Cold Supply & Temp (°C)	Hot Supply & Temp (°C)	TMV info					Deadlegs Present (Inc. Drain cocks)	Flow & Return Working	Outlet Usage	Outlets in location												Aerosol Created	Non WRAS Material	Flexi Hoses	Comment	Additional Localised Risk Rating
				No. Of TMVs	Access	<2m from outlet?	Mix Temps 37-45°C	No. TMV Fed Outlets				Mains	Cold	Hot	Mixer	Urinals	WCs	Shower	Drinks / vend	Water boiler	Drinking fountain	Arjo/whirlpool	Other					
08B GENW12-065 (Bedroom)	Hot, Cold	CWST 17.0	Calorifier	1	OK	Yes	Yes	1	None visible	Not visible	Daily		1	1										Low	None visible	None visible		Low
Recommendations:																												
08C GENW11-028 (Bedroom)	Hot, Cold	CWST 16.7	Calorifier	1	OK	Yes	Yes	1	None visible	Not visible	Daily		1	1										Low	None visible	None visible		Low
Recommendations:																												
08C GENW11-034 (Bathroom)	Hot, Cold	CWST 17.5	Calorifier 59.0	2	OK	Yes	Yes	2	None visible	Not visible	Daily				1		1	1						High	None visible	None visible		Low
Recommendations:																												
08C GENW11-065 (Bedroom)	Hot, Cold	CWST 16.9	Calorifier	1	OK	Yes	Yes	1	None visible	Not visible	Daily		1	1										Low	None visible	None visible		Low
Recommendations:																												
08D GENW10-001 (Bedroom)	Hot, Cold	CWST 17.3	Calorifier	1	OK	Yes	Yes	1	None visible	Not visible	Daily		1	1										Low	None visible	None visible		Low
Recommendations:																												

Location / Room No	Sentinel outlet?	Cold Supply & Temp (°C)	Hot Supply & Temp (°C)	TMV info					Deadlegs Present (Inc. Drain cocks)	Flow & Return Working	Outlet Usage	Outlets in location												Aerosol Created	Non WRAS Material	Flexi Hoses	Comment	Additional Localised Risk Rating
				No. Of TMVs	Access	<2m from outlet?	Mix Temps 37-45°C	No. TMV Fed Outlets				Mains	Cold	Hot	Mixer	Urinals	WCs	Shower	Drinks / vend	Water boiler	Drinking fountain	Arjo/whirlpool	Other					
08D GENW10-028 (Bedroom)	Hot, Cold	CWST 16.4	Calorifier	1	OK	Yes	Yes	1	None visible	Not visible	Daily		1	1										Low	None visible	None visible		Low
Recommendations:																												
08D GENW10-034 (Bathroom)	Hot, Cold	CWST 16.9	Calorifier 57.2	2	OK	Yes	Yes	2	None visible	Not visible	Daily				1		1	1						High	None visible	None visible		Low
Recommendations:																												
08D GENW10-057 (Bedroom)	Hot, Cold	CWST 22.6	Calorifier	1	OK	Yes	Yes	1	None visible	Not visible	Daily		1	1										Low	None visible	None visible	Cold rose to 25.8°C before dropping slowly	Medium
Recommendations:			Cold water temperature too high. Investigate and correct.																									
08D GENW10-065 (Bedroom)	Hot, Cold	CWST 17.6	Calorifier	1	OK	Yes	Yes	1	None visible	Not visible	Daily		1	1										Low	None visible	None visible		Low
Recommendations:																												
09 WS9-005 (Toilet)	Hot, Cold	CWST 16.1	Calorifier 59.0	1	OK	Yes	Yes	1	None visible	Not visible	Daily				1		1							Low	None visible	None visible		Low
Recommendations:																												

Location / Room No	Sentinel outlet?	Cold Supply & Temp (°C)	Hot Supply & Temp (°C)	TMV info					Deadlegs Present (Inc. Drain cocks)	Flow & Return Working	Outlet Usage	Outlets in location												Aerosol Created	Non WRAS Material	Flexi Hoses	Comment	Additional Localised Risk Rating
				No. Of TMVs	Access	<2m from outlet?	Mix Temps 37-45°C	No. TMV Fed Outlets				Mains	Cold	Hot	Mixer	Urinals	WCs	Shower	Drinks / vend	Water boiler	Drinking fountain	Arjo/whirlpool	Other					
09 WS9-011 (Toilet)	Hot, Cold	CWST 15.8	Calorifier 57.6	1	OK	Yes	Yes	1	None visible	Not visible	Daily				1		1							Low	None visible	None visible		Low
Recommendations:																												
09 WS9-021 (Male Change)	Hot, Cold	CWST 17.5	Calorifier 59.3	1	OK	Yes	Yes	1	None visible	Not visible	Daily				1									Low	None visible	None visible		Low
Recommendations:																												
09 WS9-027		CWST 14.8	Calorifier 63.4	1	OK	Yes	Yes	1	None visible	Not visible	Daily		3	3										Low	None visable	Yes		Low
Recommendations:																												
09A GENW13-001 (Bedroom)	Hot, Cold	CWST 16.8	Calorifier	1	OK	Yes	Yes	1	None visible	Not visible	Daily		1	1										Low	None visible	None visible		Low
Recommendations:																												
09A GENW13-029 (Bathroom)	Hot, Cold	CWST 22.5	Calorifier 57.8	2	OK	Yes	Yes	2	None visible	Not visible	Daily				1		1	1						High	None visible	None visible	rose to 26.1°C before dropping slowly	Medium
Recommendations:	Cold water temperature too high. Investigate and correct.																											

Location / Room No	Sentinel outlet?	Cold Supply & Temp (°C)	Hot Supply & Temp (°C)	TMV info					Deadlegs Present (Inc. Drain cocks)	Flow & Return Working	Outlet Usage	Outlets in location											Aerosol Created	Non WRAS Material	Flexi Hoses	Comment	Additional Localised Risk Rating
				No. Of TMVs	Access	<2m from outlet?	Mix Temps 37-45°C	No. TMV Fed Outlets				Mains	Cold	Hot	Mixer	Urinals	WCs	Shower	Drinks / vend	Water boiler	Drinking fountain	Arjo/whirlpool	Other					
09 WS9-18	Hot Cold	CWST 14.7	Calorifier 63.0	1	OK	Yes	Yes	1	None visible	Yes	Daily		2	2	1				1	1				High	None visible	None visible	Copper tails on outlets	Low
Recommendations:																												
09A GENW13-034 (Bathroom)	Hot, Cold	CWST 18.1	Calorifier 57.8	2	OK	Yes	Yes	2	None visible	Not visible	Daily				1		1	1						High	None visible	None visible		Low
Recommendations:																												
09A GENW13-065 (Bedroom)	Hot, Cold	CWST 18.1	Calorifier	1	OK	Yes	Yes	1	None visible	Not visible	Daily		1	1										Low	None visible	None visible		Low
Recommendations:																												
09B GENW16-034 (Bathroom)	Hot, Cold	CWST 17.6	Calorifier 58.3	2	OK	Yes	Yes	2	None visible	Not visible	Daily				1		1	1						High	None visible	None visible		Low
Recommendations:																												
09B GENW16-036 (Bathroom)	Hot, Cold	CWST 21.9	Calorifier 57.6	2	OK	Yes	Yes	2	None visible	Not visible	Daily				1		1	1						High	None visible	None visible	rose to 25.4°C before dropping slowly	Medium

Recommendations: Cold water temperature too high. Investigate and correct.

Location / Room No	Sentinel outlet?	Cold Supply & Temp (°C)	Hot Supply & Temp (°C)	TMV info					Deadlegs Present (Inc. Drain cocks)	Flow & Return Working	Outlet Usage	Outlets in location												Aerosol Created	Non WRAS Material	Flexi Hoses	Comment	Additional Localised Risk Rating
				No. Of TMVs	Access	<2m from outlet?	Mix Temps 37-45°C	No. TMV Fed Outlets				Mains	Cold	Hot	Mixer	Urinals	WCs	Shower	Drinks / vend	Water boiler	Drinking fountain	Arjo/whirlpool	Other					
09B GENW16-065 (Bedroom)	Hot, Cold	CWST 16.8	Calorifier	1	OK	Yes	Yes	1	None visible	Not visible	Daily		1	1										Low	None visible	None visible		Low
Recommendations:																												
09C GENW15-028 (Bedroom)	Hot, Cold	CWST 17.0	Calorifier	1	OK	Yes	Yes	1	None visible	Not visible	Daily		1	1										Low	None visible	None visible		Low
Recommendations:																												
09C GENW15-034 (Bathroom)	Hot, Cold	CWST 16.2	Calorifier 58.2	2	OK	Yes	Yes	2	None visible	Not visible	Daily				1		1	1						High	None visible	None visible		Low
Recommendations:																												
09C GENW15-065 (Bedroom)	Hot, Cold	CWST 16.3	Calorifier	1	OK	Yes	Yes	1	None visible	Not visible	Daily		1	1										Low	None visible	None visible		Low
Recommendations:																												
09D GENW14-001 (Bedroom)	Hot, Cold	CWST 15.9	Calorifier	1	OK	Yes	Yes	1	None visible	Not visible	Daily		1	1										Low	None visible	None visible		Low
Recommendations:																												

Location / Room No	Sentinel outlet?	Cold Supply & Temp (°C)	Hot Supply & Temp (°C)	TMV info					Deadlegs Present (Inc. Drain cocks)	Flow & Return Working	Outlet Usage	Outlets in location												Aerosol Created	Non WRAS Material	Flexi Hoses	Comment	Additional Localised Risk Rating
				No. Of TMVs	Access	<2m from outlet?	Mix Temps 37-45°C	No. TMV Fed Outlets				Mains	Cold	Hot	Mixer	Urinals	WCs	Shower	Drinks / vend	Water boiler	Drinking fountain	Arjo/whirlpool	Other					
09D GENW14-028 (Bedroom)	Hot, Cold	CWST 22.1	Calorifier	1	OK	Yes	Yes	1	None visible	Not visible	Daily		1	1										Low	None visible	None visible	rose to 27.0°C before dropping slowly	Medium
Recommendations:			Cold water temperature too high. Investigate and correct.																								
09D GENW14-034 (Bathroom)	Hot, Cold	CWST 17.3	Calorifier 56.5	2	OK	Yes	Yes	2	None visible	Not visible	Daily				1		1	1						High	None visible	None visible		Low
Recommendations:																											
09D GENW14-057 (Bedroom)	Hot, Cold	CWST 18.0	Calorifier	1	OK	Yes	Yes	1	None visible	Not visible	Daily		1	1										Low	None visible	None visible		Low
Recommendations:																											
09D GENW14-065 (Bedroom)	Hot, Cold	CWST 22.0	Calorifier	1	OK	Yes	Yes	1	None visible	Not visible	Daily		1	1										Low	None visible	None visible	rose to 25.3°C before dropping slowly	Medium
Recommendations:			Cold water temperature too high. Investigate and correct.																								
10 WS10-005 (Toilet)	Hot, Cold	CWST 16.2	Calorifier 58.7	1	OK	Yes	Yes	1	None visible	Not visible	Daily				1		1							Low	None visible	None visible		Low
Recommendations:																											

Location / Room No	Sentinel outlet?	Cold Supply & Temp (°C)	Hot Supply & Temp (°C)	TMV info					Deadlegs Present (Inc. Drain cocks)	Flow & Return Working	Outlet Usage	Outlets in location												Aerosol Created	Non WRAS Material	Flexi Hoses	Comment	Additional Localised Risk Rating
				No. Of TMVs	Access	<2m from outlet?	Mix Temps 37-45°C	No. TMV Fed Outlets				Mains	Cold	Hot	Mixer	Urinals	WCs	Shower	Drinks / vend	Water boiler	Drinking fountain	Arjo/whirlpool	Other					
10 WS10-011 (Toilet)	Hot, Cold	CWST 16.4	Calorifier 56.4	1	OK	Yes	Yes	1	None visible	Not visible	Daily				1		1							Low	None visible	None visible		Low
Recommendations:																												
10 WS10-018 (Kitchen)	Hot, Cold	CWST 16.0	Calorifier 62.0	1	OK	Yes	Yes	1	None visible	Yes	Daily		2	2	1			1		1			1	High	None visible	Yes	Copper tail to WHB 1	Low
Recommendations:			All EPDM flexible hoses should be removed and replaced with hard piped connection (if practicable)																									
10 WS10-026 (Ladies Changing)	Hot, Cold	CWST 17.5	Calorifier 56.3	3	OK	Yes	Yes	3	None visible	Not visible	Daily				2		2	1						High	None visible	None visible		Low
Recommendations:																												
10A GENW17-001 (Bedroom)	Hot, Cold	CWST 16.9	Calorifier	1	OK	Yes	Yes	1	None visible	Not visible	Daily		1	1										Low	None visible	None visible		Low
Recommendations:																												
10A GENW17-029 (Bathroom)	Hot, Cold	CWST 22.7	Calorifier 57.0	2	OK	Yes	Yes	2	None visible	Not visible	Daily				1		1	1						High	None visible	None visible	rose to 20.1°C before dropping slowly	High
Recommendations:			Cold water temperature too high. Investigate and correct.																									

Location / Room No	Sentinel outlet?	Cold Supply & Temp (°C)	Hot Supply & Temp (°C)	TMV info					Deadlegs Present (Inc. Drain cocks)	Flow & Return Working	Outlet Usage	Outlets in location												Aerosol Created	Non WRAS Material	Flexi Hoses	Comment	Additional Localised Risk Rating
				No. Of TMVs	Access	<2m from outlet?	Mix Temps 37-45°C	No. TMV Fed Outlets				Mains	Cold	Hot	Mixer	Urinals	WCs	Shower	Drinks / vend	Water boiler	Drinking fountain	Arjo/whirlpool	Other					
10A GENW17-034 (Bathroom)	Hot, Cold	CWST 18.0	Calorifier 57.5	2	OK	Yes	Yes	2	None visible	Not visible	Daily				1		1	1						High	None visible	None visible		Low
Recommendations:																												
10A GENW17-065 (Bedroom)	Hot, Cold	CWST 17.3	Calorifier	1	OK	Yes	Yes	1	None visible	Not visible	Daily		1	1										Low	None visible	None visible		Low
Recommendations:																												
10A GENW17-066 (Facilities)		CWST 15.3	Calorifier 63.2	1	OK	Yes	Yes	1	None visible	Not visible	Daily		3	3										Low	None visable	Yes	Hot water signage fitted	Low
Recommendations:																												
10B GENW20-032 (Bathroom)	Hot, Cold	CWST 16.7	Calorifier 57.3	2	OK	Yes	Yes	2	None visible	Not visible	Daily				1		1	1						High	None visible	None visible		Low
Recommendations:																												
10B GENW20-036 (Bathroom)	Hot, Cold	CWST 16.5	Calorifier 56.2	2	OK	Yes	Yes	2	None visible	Not visible	Daily				1		1	1						High	None visible	None visible		Low
Recommendations:																												

Location / Room No	Sentinel outlet?	Cold Supply & Temp (°C)	Hot Supply & Temp (°C)	TMV info					Deadlegs Present (Inc. Drain cocks)	Flow & Return Working	Outlet Usage	Outlets in location												Aerosol Created	Non WRAS Material	Flexi Hoses	Comment	Additional Localised Risk Rating
				No. Of TMVs	Access	<2m from outlet?	Mix Temps 37-45°C	No. TMV Fed Outlets				Mains	Cold	Hot	Mixer	Urinals	WCs	Shower	Drinks / vend	Water boiler	Drinking fountain	Arjo/whirlpool	Other					
10B GENW20-065 (Bedroom)	Hot, Cold	CWST 17.0	Calorifier	1	OK	Yes	Yes	1	None visible	Not visible	Daily		1	1										Low	None visible	None visible		Low
Recommendations:																												
10C GENW19-028 (Bedroom)	Hot, Cold	CWST 16.2	Calorifier	1	OK	Yes	Yes	1	None visible	Not visible	Daily		1	1										Low	None visible	None visible		Low
Recommendations:																												
10C GENW19-034 (Bathroom)	Hot, Cold	CWST 17.4	Calorifier 55.8	2	OK	Yes	Yes	2	None visible	Not visible	Daily				1		1	1						High	None visible	None visible		Low
Recommendations:																												
10C GENW19-065 (Bedroom)	Hot, Cold	CWST 16.4	Calorifier	1	OK	Yes	Yes	1	None visible	Not visible	Daily		1	1										Low	None visible	None visible		Low
Recommendations:																												
10D GENW18-001 (Bedroom)	Hot, Cold	CWST 16.3	Calorifier	1	OK	Yes	Yes	1	None visible	Not visible	Rarely - Inc. in Flush Regime		1	1										Low	None visible	None visible		Medium
Recommendations:	Include unused outlets into site flushing regime.																											

Location / Room No	Sentinel outlet?	Cold Supply & Temp (°C)	Hot Supply & Temp (°C)	TMV info					Deadlegs Present (Inc. Drain cocks)	Flow & Return Working	Outlet Usage	Outlets in location												Aerosol Created	Non WRAS Material	Flexi Hoses	Comment	Additional Localised Risk Rating
				No. Of TMVs	Access	<2m from outlet?	Mix Temps 37-45°C	No. TMV Fed Outlets				Mains	Cold	Hot	Mixer	Urinals	WCs	Shower	Drinks / vend	Water boiler	Drinking fountain	Arjo/whirlpool	Other					
10D GENW18-028 (Bedroom)	Hot, Cold	CWST 16.8	Calorifier	1	OK	Yes	Yes	1	None visible	Not visible	Rarely - Inc. in Flush Regime		1	1										Low	None visible	None visible		Medium
Recommendations:			Include unused outlets into site flushing regime.																									
10D GENW18-034 (Bathroom)	Hot, Cold	CWST 16.4	Calorifier 56.3	2	OK	Yes	Yes	2	None visible	Not visible	Rarely - Inc. in Flush Regime				1		1	1						High	None visible	None visible		Medium
Recommendations:			Include unused outlets into site flushing regime.																									
10D GENW18-057 (Bedroom)	Hot, Cold	CWST 17.0	Calorifier	1	OK	Yes	Yes	1	None visible	Not visible	Rarely - Inc. in Flush Regime		1	1										Low	None visible	None visible		Medium
Recommendations:			Include Unused outlets into site flushing regime.																									
10D GENW18-065 (Bedroom)	Hot, Cold	CWST 18.2	Calorifier	1	OK	Yes	Yes	1	None visible	Not visible	Daily		1	1										Low	None visible	None visible		Low
Recommendations:																												
11 WS11-005 (Toilet)	Hot, Cold	CWST 17.8	Calorifier 57.3	1	OK	Yes	Yes	1	None visible	Not visible	Daily				1		1							Low	None visible	None visible		Low
Recommendations:																												

Location / Room No	Sentinel outlet?	Cold Supply & Temp (°C)	Hot Supply & Temp (°C)	TMV info					Deadlegs Present (Inc. Drain cocks)	Flow & Return Working	Outlet Usage	Outlets in location												Aerosol Created	Non WRAS Material	Flexi Hoses	Comment	Additional Localised Risk Rating
				No. Of TMVs	Access	<2m from outlet?	Mix Temps 37-45°C	No. TMV Fed Outlets				Mains	Cold	Hot	Mixer	Urinals	WCs	Shower	Drinks / vend	Water boiler	Drinking fountain	Arjo/whirlpool	Other					
11 WS11-011 (Toilet)	Hot, Cold	CWST 16.5	Calorifier 57.0	1	OK	Yes	Yes	1	None visible	Not visible	Daily				1		1							Low	None visible	None visible		Low
Recommendations:																												
11 WS11-018 (Kitchen)	Hot, Cold	CWST 16.2	Calorifier 59.8	1	OK	Yes	Yes	1	None visible	Yes	Daily		2	2	1			1		1			1	High	None visible	Yes		Low
Recommendations:			All EPDM flexible hoses should be removed and replaced with hard piped connection (if practicable)																									
11 WS11-019 (Toilet)	Hot, Cold	CWST 18.0	Calorifier 57.3	1	OK	Yes	Yes	1	None visible	Not visible	Daily				1		1							Low	None visible	None visible		Low
Recommendations:																												
11A GENW21-001 (Bedroom)	Hot, Cold	CWST 16.9	Calorifier	1	OK	Yes	Yes	1	None visible	Not visible	Daily		1	1										Low	None visible	None visible		Low
Recommendations:																												
11A GENW21-029 (Bathroom)	Hot, Cold	CWST 18.2	Calorifier 56.8	2	OK	Yes	Yes	2	None visible	Not visible	Daily				1		1	1						High	None visible	None visible		Low
Recommendations:																												

Location / Room No	Sentinel outlet?	Cold Supply & Temp (°C)	Hot Supply & Temp (°C)	TMV info					Deadlegs Present (Inc. Drain cocks)	Flow & Return Working	Outlet Usage	Outlets in location												Aerosol Created	Non WRAS Material	Flexi Hoses	Comment	Additional Localised Risk Rating
				No. Of TMVs	Access	<2m from outlet?	Mix Temps 37-45°C	No. TMV Fed Outlets				Mains	Cold	Hot	Mixer	Urinals	WCs	Shower	Drinks / vend	Water boiler	Drinking fountain	Arjo/whirlpool	Other					
11A GENW21-034 (Bathroom)	Hot, Cold	CWST 17.8	Calorifier 56.5	2	OK	Yes	Yes	2	None visible	Not visible	Daily				1		1	1						High	None visible	None visible		Low
Recommendations:																												
11A GENW21-065 (Bedroom)	Hot, Cold	CWST 17.9	Calorifier	1	OK	Yes	Yes	1	None visible	Not visible	Daily		1	1										Low	None visible	None visible		Low
Recommendations:																												
11B GENW24-032 (Bathroom)	Hot, Cold	CWST 16.7	Calorifier 55.6	2	OK	Yes	Yes	2	None visible	Not visible	Daily				1		1	1						High	None visible	None visible		Low
Recommendations:																												
11B GENW24-036 (Bathroom)	Hot, Cold	CWST 17.4	Calorifier 57.1	2	OK	Yes	Yes	2	None visible	Not visible	Daily				1		1	1						High	None visible	None visible		Low
Recommendations:																												
11B GENW24-065 (Bedroom)	Hot, Cold	CWST 18.0	Calorifier	1	OK	Yes	Yes	1	None visible	Not visible	Daily		1	1										Low	None visible	None visible		Low
Recommendations:																												

Location / Room No	Sentinel outlet?	Cold Supply & Temp (°C)	Hot Supply & Temp (°C)	TMV info					Deadlegs Present (Inc. Drain cocks)	Flow & Return Working	Outlet Usage	Outlets in location												Aerosol Created	Non WRAS Material	Flexi Hoses	Comment	Additional Localised Risk Rating
				No. Of TMVs	Access	<2m from outlet?	Mix Temps 37-45°C	No. TMV Fed Outlets				Mains	Cold	Hot	Mixer	Urinals	WCs	Shower	Drinks / vend	Water boiler	Drinking fountain	Arjo/whirlpool	Other					
11C GENW23-028 (Bedroom)	Hot, Cold	CWST 17.5	Calorifier	1	OK	Yes	Yes	1	None visible	Not visible	Daily		1	1										Low	None visible	None visible		Low
Recommendations:																												
11C GENW23-034 (Bathroom)	Hot, Cold	CWST 18.0	Calorifier 55.9	2	OK		Yes	2	None visible	Not visible	Daily				1		1	1						High	None visible	None visible		Low
Recommendations:																												
11C GENW23-065 (Bedroom)	Hot, Cold	CWST 17.2	Calorifier	1	OK	Yes	Yes	1	None visible	Not visible	Daily		1	1										Low	None visible	None visible		Low
Recommendations:																												
11C GENW23-081 (Clean Utility)	No	CWST 15.9	Calorifier 62.3	1	OK	Yes	Yes	1	None visible	Not visible	Daily		2	2										Low	None visible	None visible	Hot water signage fitted	Low
Recommendations:																												
11D GENW22-001 (Bedroom)	Hot, Cold	CWST 16.7	Calorifier	1	OK	Yes	Yes	1	None visible	Not visible	Daily		1	1										Low	None visible	None visible		Low
Recommendations:																												

Location / Room No	Sentinel outlet?	Cold Supply & Temp (°C)	Hot Supply & Temp (°C)	TMV info					Deadlegs Present (Inc. Drain cocks)	Flow & Return Working	Outlet Usage	Outlets in location												Aerosol Created	Non WRAS Material	Flexi Hoses	Comment	Additional Localised Risk Rating
				No. Of TMVs	Access	<2m from outlet?	Mix Temps 37-45°C	No. TMV Fed Outlets				Mains	Cold	Hot	Mixer	Urinals	WCs	Shower	Drinks / vend	Water boiler	Drinking fountain	Arjo/whirlpool	Other					
11D GENW22-028 (Bedroom)	Hot, Cold	CWST 17.0	Calorifier	1	OK	Yes	Yes	1	None visible	Not visible	Daily		1	1										Low	None visible	None visible		Low
Recommendations:																												
11D GENW22-034 (Bathroom)	Hot, Cold	CWST 16.8	Calorifier 55.8	2	OK	Yes	Yes	2	None visible	Not visible	Daily				1		1	1						High	None visible	None visible		Low
Recommendations:																												
11D GENW22-057 (Bedroom)	Hot, Cold	CWST 17.4	Calorifier	1	OK	Yes	Yes	1	None visible	Not visible	Daily		1	1										Low	None visible	None visible		Low
Recommendations:																												
11D GENW22-065 (Bedroom)	Hot, Cold	CWST 17.2	Calorifier	1	OK	Yes	Yes	1	None visible	Not visible	Daily		1	1										Low	None visible	None visible		Low
Recommendations:																												
11D GENW22-081 (Clean Utility)	No	CWST 17.0	Calorifier 59.8	1	OK	Yes	Yes	1	None visible	Not visible	Daily		2	2										Low	None visible	None visible		Low
Recommendations:																												

Location / Room No	Sentinel outlet?	Cold Supply & Temp (°C)	Hot Supply & Temp (°C)	TMV info					Deadlegs Present (Inc. Drain cocks)	Flow & Return Working	Outlet Usage	Outlets in location												Aerosol Created	Non WRAS Material	Flexi Hoses	Comment	Additional Localised Risk Rating
				No. Of TMVs	Access	<2m from outlet?	Mix Temps 37-45°C	No. TMV Fed Outlets				Mains	Cold	Hot	Mixer	Urinals	WCs	Shower	Drinks / vend	Water boiler	Drinking fountain	Arjo/whirlpool	Other					
Plantroom 31 at Cals 01/02/03	No	Trades CWST	No hot outlets	0		Yes		0	None visible	N/A	Rarely - Inc. in Flush Regime		1											Low	None visible	None visible	Very long line to Bib Tap	Medium
Recommendations:			Include unused outlets into site flushing regime.																									
4 WS4-002 (Toilet)		CWST	Calorifier	1	OK	Yes	Yes	1	None visable	Not visable	Daily				1		1							Low	None visable	None visable		Low
Recommendations:																												
04A - RENW-028		CWST 23.7	Calorifier 57.0	2	Ok	Yes	Yes	2	None visable	Not visable	Daily				1		1	1						High	None visable	None visable	Cold rose to 25+°C before dropping	Medium
Recommendations:			Cold water temperature too high. Investigate and correct.																									
04B HOW-065		CWST 24.3	Calorifier 59.2	2	OK	Yes	Yes	2	None visable	Not visible	Daily				1		1	1						High	None visible	None visible	Cold rose to 26.8°C before dropping	Medium
Recommendations:			Cold water temperature too high. Investigate and correct.																									
05A GENWA-021		CWST 16.7	Calorifier 58.0	2	OK	Yes	Yes	2	None visable	Not visible	Daily				1		1	1						High	None visible	None visible		Low
Recommendations:																												

Location / Room No	Sentinel outlet?	Cold Supply & Temp (°C)	Hot Supply & Temp (°C)	TMV info					Deadlegs Present (Inc. Drain cocks)	Flow & Return Working	Outlet Usage	Outlets in location												Aerosol Created	Non WRAS Material	Flexi Hoses	Comment	Additional Localised Risk Rating
				No. Of TMVs	Access	<2m from outlet?	Mix Temps 37-45°C	No. TMV Fed Outlets				Mains	Cold	Hot	Mixer	Urinals	WCs	Shower	Drinks / vend	Water boiler	Drinking fountain	Arjo/whirlpool	Other					
05A GENW-041		CWST 17.2	Calorifier 57.3	2	OK	Yes	Yes	2	None visible	Not visible	Daily				1		1	1						High	None visible	None visible		Low
Recommendations:																												
05D GENWB-046		CWST 16.8	Calorifier 56.9	2	OK	Yes	Yes	2	None visible	Not visible	Daily				1		1	1						High	None visible	None visible		Low
Recommendations:																												
5 GENWA-077 Staff Pantry		CWST 17.0	Calorifier 63.4	1	OK	Yes	Yes	1	None visible	Not visible	Daily		2	2					1	1			1	Low	None visible	None visible	1 x Dishwasher hot water signage in situ.	Low
Recommendations:																												
6A GENW1-025		CWST 16.7	Calorifier 59.8	2	OK	Yes	Yes	2	None visable	Not visible	Daily				1		1	1						High	None visable	None visable		Low
Recommendations:																												
6D GENW2-051		CWST 17.2	Calorifier 57.4	2	OK	Yes	Yes	2	None visable	Not visable	Daily				1		1	1						High	None visable	None visable		Low
Recommendations:																												

Location / Room No	Sentinel outlet?	Cold Supply & Temp (°C)	Hot Supply & Temp (°C)	TMV info					Deadlegs Present (Inc. Drain cocks)	Flow & Return Working	Outlet Usage	Outlets in location												Aerosol Created	Non WRAS Material	Flexi Hoses	Comment	Additional Localised Risk Rating
				No. Of TMVs	Access	<2m from outlet?	Mix Temps 37-45°C	No. TMV Fed Outlets				Mains	Cold	Hot	Mixer	Urinals	WCs	Shower	Drinks / vend	Water boiler	Drinking fountain	Arjo/whirlpool	Other					
GENW18-081		CWST 17.0	Calorifier 62.0	1	OK	Yes	Yes	1	None visible	Not visible	Daily		2	2										Low	None visible	None visible		Low
Recommendations:																												
GENW19- 081		CWST 16.3	Calorifier 62.7	1	OK	Yes	Yes	1	None visible	Not visible	Daily		2	2										Low	None visible	None visible	Hot water signage fitted	Low
Recommendations:																												
GENW20-066		CWST 16.1	Calorifier 63.0	1	OK	Yes	Yes	1	None visible	Not visible	Daily		3	3										Low	None visible	Yes	Hot water signage fitted	Low
Recommendations:																												
GENW13-031		CWST 15.4	Calorifier 61.8	1	OK	Yes	Yes	1	None visible	Not visible	Daily		2	2										Low	None visible	None visible	Hot water signage fitted	Low
Recommendations:																												
GENW14-066		CWST 14.8	Calorifier 62.7	1	OK	Yes	Yes	1	None visible	Not visible	Daily		3	3										Low	None visible	Yes	Hot water signage fitted	Medium

Recommendations: All EPDM flexible hoses should be removed and replaced with hard piped connection (if practicable)

Location / Room No	Sentinel outlet?	Cold Supply & Temp (°C)	Hot Supply & Temp (°C)	TMV info					Deadlegs Present (Inc. Drain cocks)	Flow & Return Working	Outlet Usage	Outlets in location												Aerosol Created	Non WRAS Material	Flexi Hoses	Comment	Additional Localised Risk Rating
				No. Of TMVs	Access	<2m from outlet?	Mix Temps 37-45°C	No. TMV Fed Outlets				Mains	Cold	Hot	Mixer	Urinals	WCs	Shower	Drinks / vend	Water boiler	Drinking fountain	Arjo/whirlpool	Other					
4B HOW-039 CDC		CWST 24.2	Calorifier 63.5	1	OK	Yes	Yes	1	None visible	Not visible	Daily		2	2										Low	None visible	None visible	Cold rose to 27.0°C before dropping slowly	Medium
Recommendations:			Cold water temperature too high. Investigate and correct.																									
5A GENWD-081		CWST 17.5	Calorifier 62.0	1	OK	Yes	Yes	1	None visible	Not visible	Daily		2	2										Low	None visible	None visible		Low
Recommendations:																												
5A GENWA-066		CWST 15.5	Calorifier 62.6	1	OK	Yes	Yes	1	None visible	Not visible	Daily		3	3										Low	None visible	Yes	Hot water signage in situ	Medium
Recommendations:			All EPDM flexible hoses should be removed and replaced with hard piped connection (if practicable)																									
5D GENWB-066		CWST 15.7	Calorifier 63.0	1	OK	Yes	Yes	1	None visible	Not visible	Daily		3	3										Low	None visible	Yes	Hot water signage in situ	Medium
Recommendations:			All EPDM flexible hoses should be removed and replaced with hard piped connection (if practicable)																									
6A GENW1-081		CWST 16.3	Calorifier 63.8	1	OK	Yes	Yes	1	None visible	Not visible	Daily		2	2										Low	None visible	None visible		Low
Recommendations:																												

Location / Room No	Sentinel outlet?	Cold Supply & Temp (°C)	Hot Supply & Temp (°C)	TMV info					Deadlegs Present (Inc. Drain cocks)	Flow & Return Working	Outlet Usage	Outlets in location												Aerosol Created	Non WRAS Material	Flexi Hoses	Comment	Additional Localised Risk Rating
				No. Of TMVs	Access	<2m from outlet?	Mix Temps 37-45°C	No. TMV Fed Outlets				Mains	Cold	Hot	Mixer	Urinals	WCs	Shower	Drinks / vend	Water boiler	Drinking fountain	Arjo/whirlpool	Other					
GENW1-066		CWST 16.0	Calorifier 63.7	1	OK	Yes	Yes	1	None visible	Not visible	Daily		3	3										Low	None visible	Yes	Hot water signage fitted	Medium
Recommendations:	All EPDM flexible hoses should be removed and replaced with hard piped connection (if practicable)																											
GENW-081		CWST 16.4	Calorifer 62.8	1	OK	Yes	Yes	1	None visible	Not visible	Daily		2	2										Low	None visible	None visible		Low
Recommendations:																												
GENW2-045		CWST 17.3	Calorifier 58.2	2	OK	Yes	Yes	2	None visible	Not visible	Daily				1		1	1						High	None visible	None visible		Low
Recommendations:																												
GENW2-066		CWST 16.7	Calorifier 63.0	1	OK	Yes	Yes	1	None visible	Not visible	Daily		3	3										Low	None visible	Yes	Hot water signage fitted	Medium
Recommendations:	All EPDM flexible hoses should be removed and replaced with hard piped connection (if practicable)																											
GENW21-081		CWST 17.0	Calorifier 62.8	1	OK	Yes	Yes	1	None visible	Not visible	Daily		2	2										Low	None visible	None visible		Low
Recommendations:																												

Location / Room No	Sentinel outlet?	Cold Supply & Temp (°C)	Hot Supply & Temp (°C)	TMV info					Deadlegs Present (Inc. Drain cocks)	Flow & Return Working	Outlet Usage	Outlets in location												Aerosol Created	Non WRAS Material	Flexi Hoses	Comment	Additional Localised Risk Rating
				No. Of TMVs	Access	<2m from outlet?	Mix Temps 37-45°C	No. TMV Fed Outlets				Mains	Cold	Hot	Mixer	Urinals	WCs	Shower	Drinks / vend	Water boiler	Drinking fountain	Arjo/whirlpool	Other					
GENW22-066		CWST 15.4	Calorifier 63.0	1	OK	Yes	Yes	1	None visible	Not visible	Daily		3	3										Low	None visible	Yes	Hot water signage fitted	Medium
Recommendations:	All EPDM flexible hoses should be removed and replaced with hard piped connection (if practicable)																											
GENW17-081		CWST 16.3	Calorifier 62.3	1	OK	Yes	Yes	1	None visible	Not visable	Daily		2	2										Low	None visable	None visable		Low
Recommendations:																												
GENW18-066		CWST 15.7	Calorifier 63.1	1	OK	Yes	Yes	1	None visible	Not visable	Daily		3	3										Low	None visable	Yes	Hot water signage fitted	Low
Recommendations:																												
Basement Kit 030	N	CWST 15.7	Calorifier 64.4	1	OK		Yes	1	None visible	Not visible	Rarely - Inc. in Flush Regime		2	2	1									Low	None visible	None visible		Medium
Recommendations:	Include unused outlets into site flushing regime.																											
Basement Kit 014	N	CWST 16	Calorifier 64.6	2	OK		Yes	2	None visible	Not visible	Daily		1	1	2									Low	None visible	None visible		Low
Recommendations:																												

Location / Room No	Sentinel outlet?	Cold Supply & Temp (°C)	Hot Supply & Temp (°C)	TMV info					Deadlegs Present (Inc. Drain cocks)	Flow & Return Working	Outlet Usage	Outlets in location												Aerosol Created	Non WRAS Material	Flexi Hoses	Comment	Additional Localised Risk Rating
				No. Of TMVs	Access	<2m from outlet?	Mix Temps 37-45°C	No. TMV Fed Outlets				Mains	Cold	Hot	Mixer	Urinals	WCs	Shower	Drinks / vend	Water boiler	Drinking fountain	Arjo/whirlpool	Other					
Basement Kit 006	N	CWST 17.7	Calorifier 63.1	1	OK		Yes	1	None visible	Not visible	Flush Regime		2	2	1									Low	None visible	None visible	Heat gain on cold, 20 secs to drop <20°C	Medium
Recommendations:			Evidence of heat gain in cold water - investigate and correct.																									
Basement FMB 010	N	CWST 16.5	Calorifier 63.9	0	OK			0	None visible	Not visible	Rarely - Inc. in Flush Regime		2	2										Low	None visible	None visible	Heat gain on cold, 30 secs to drop <20°C	Medium
Recommendations:			Evidence of heat gain in cold water - investigate and correct. Include unused outlets into site flushing regime.																									
A+E CMC 113	N	CWST 15.7	Calorifier 63.4	1	OK			1	None visible	Not visible	Daily		2	2										Low	None visible	None visible		Low
Recommendations:																												
IAU AAW - 197	N	CWST 16.5	Calorifier 62.3	1	OK		Yes	1	None visible	Not visible	Daily		1	1	1									Low	None visible	None visible	Heat gain on cold, 60 secs to drop <20°C	Medium
Recommendations:			Evidence of heat gain in cold water - investigate and correct.																									
ARU 2 AAW 264	N	CWST 16	Calorifier 61.4	1	OK		Yes	1	None visible	Not visible	Daily				1		1	1						High	None visible	Shower hose		Low
Recommendations:																												

Location / Room No	Sentinel outlet?	Cold Supply & Temp (°C)	Hot Supply & Temp (°C)	TMV info					Deadlegs Present (Inc. Drain cocks)	Flow & Return Working	Outlet Usage	Outlets in location												Aerosol Created	Non WRAS Material	Flexi Hoses	Comment	Additional Localised Risk Rating
				No. Of TMVs	Access	<2m from outlet?	Mix Temps 37-45°C	No. TMV Fed Outlets				Mains	Cold	Hot	Mixer	Urinals	WCs	Shower	Drinks / vend	Water boiler	Drinking fountain	Arjo/whirlpool	Other					
ARU 2 AAW 365	N	CWST 16	Calorifier 64.4	1	OK		Yes	1	None visible	Not visible	Daily		1	1	1					1				Low	None visible	None visible		Low
Recommendations:																												
ARU 1 AAW 319	N	CWST 16.3	Calorifier 62.9	1	OK		Yes	1	None visible	Not visible	Daily		1	1	1									Low	None visible	None visible	Heat gain on cold, 40 secs to drop <20°C	Medium
Recommendations:			Evidence of heat gain in cold water - investigate and correct.																									
ARU 1 AAW 295	N	CWST 16.9	Calorifier 61.9	2	OK		Yes	2	None visible	Not visible	Daily				1		1	1						High	None visible	None visible		Low
Recommendations:																												
ARU 5 AAW 051	N	CWST 15.6	Calorifier6 3.9	1	OK		Yes	1	None visible	Not visible	Daily		2	2	1									Low	None visible	None visible		Low
Recommendations:																												
ARU 3 AAW 018	N	CWST 16.3	Calorifier 62.9	2	OK		Yes	2	None visible	Not visible	Daily				2		1	1						High	None visible	None visible		Low
Recommendations:																												

Location / Room No	Sentinel outlet?	Cold Supply & Temp (°C)	Hot Supply & Temp (°C)	TMV info					Deadlegs Present (Inc. Drain cocks)	Flow & Return Working	Outlet Usage	Outlets in location												Aerosol Created	Non WRAS Material	Flexi Hoses	Comment	Additional Localised Risk Rating
				No. Of TMVs	Access	<2m from outlet?	Mix Temps 37-45°C	No. TMV Fed Outlets				Mains	Cold	Hot	Mixer	Urinals	WCs	Shower	Drinks / vend	Water boiler	Drinking fountain	Arjo/whirlpool	Other					
ARU 4 AAW 376	N	CWST 16.8	Calorifier 60.3	2	OK		Yes	2	None visible	Not visible	Daily				2		1	1						High	None visible	None visible		Low
Recommendations:																												
ODD 004 Male WC	N	CWST 16.7	Calorifier 61.4	1	OK		Yes	1	None visible	Not visible	Daily				1		1							Low	None visible	None visible		Low
Recommendations:																												
Facilities OPD 044	N	CWST 15.9	Calorifier 59.4	1	OK		Yes	1	None visible	Not visible	Daily		2	2	1									Low	None visible	None visible		Low
Recommendations:																												
Facilities ORT 038	N	CWST 15.5	Calorifier 63.6	1	OK		Yes	1	None visible	Not visible	Daily		2	2	1									Low	None visible	None visible		Low
Recommendations:																												
Female Changing Room ORT 015-1	N			1	OK		Yes	1	None visible	Not visible	Daily							1						High	None visible	None visible		Low
Recommendations:																												

Location / Room No	Sentinel outlet?	Cold Supply & Temp (°C)	Hot Supply & Temp (°C)	TMV info					Deadlegs Present (Inc. Drain cocks)	Flow & Return Working	Outlet Usage	Outlets in location												Aerosol Created	Non WRAS Material	Flexi Hoses	Comment	Additional Localised Risk Rating
				No. Of TMVs	Access	<2m from outlet?	Mix Temps 37-45°C	No. TMV Fed Outlets				Mains	Cold	Hot	Mixer	Urinals	WCs	Shower	Drinks / vend	Water boiler	Drinking fountain	Arjo/whirlpool	Other					
Facilities RAG 122	N	CWST 15	Calorifier 64.4	1	OK		Yes	1	None visible	Not visible	Daily		2	2	1									Low	None visible	None visible		Low
Recommendations:																												
Facilities RAG 069	N	CWST 17.2	Calorifier 63.4	1	OK		Yes	1	None visible	Not visible	Daily		2	2	1									Low	None visible	None visible		Low
Recommendations:																												
EMC 067	N	CWST 15.5	Calorifier 63.2	1	OK		Yes	1	None visible	Not visible	Daily		1	1	1				1					Low	None visible	None visible		Low
Recommendations:																												
CDU Kitchen OBW 042	N	CWST 15.6	Calorifier 64.9	1	OK		Yes	1	None visible	Not visible	Daily		1	1	1					1			1	Low	None visible	None visible	Dishwasher	Low
Recommendations:																												
Facilities REM 052	N	CWST 15.8	Calorifier 63.1	1	OK		Yes	1	None visible	Not visible	Daily		2	2	1									Low	None visible	None visible	Heat gain on cold, 50 secs to drop <20°C	Medium
Recommendations:			Evidence of heat gain in cold water - investigate and correct.																									

Location / Room No	Sentinel outlet?	Cold Supply & Temp (°C)	Hot Supply & Temp (°C)	TMV info					Deadlegs Present (Inc. Drain cocks)	Flow & Return Working	Outlet Usage	Outlets in location												Aerosol Created	Non WRAS Material	Flexi Hoses	Comment	Additional Localised Risk Rating
				No. Of TMVs	Access	<2m from outlet?	Mix Temps 37-45°C	No. TMV Fed Outlets				Mains	Cold	Hot	Mixer	Urinals	WCs	Shower	Drinks / vend	Water boiler	Drinking fountain	Arjo/whirlpool	Other					
Disabled WC OPD 170	N	CWST 15.6	Calorifier6 1.1	1	OK		Yes	1	None visible	Not visible	Daily				1		1							Low	None visible	None visible		Low
Recommendations:																												
Audiometry OPD 080	N	CWST 17.9	Calorifier 63.6	1	OK		Yes	1	None visible	Not visible	Daily		1	1	1									Low	None visible	None visible		Low
Recommendations:																												
Kitchen CCW 149	N	CWST 17.3	Calorifier 57.6	1	OK		Yes	1	None visible	Not visible	Daily		1	1	1					1			1	Low	None visible	None visible	Dishwash	Low
Recommendations:																												
Kitchen CCW	N	CWST 17.5	Calorifier 61.8	1	OK		No	1	None visible	Not visible	Daily		1	1	1					1			1	Low	None visible	None visible	Dishwash No hot water to infra-red WHB	Low
Recommendations:																												
Radiology reception RAF 002	N	CWST			OK				1	Not Visible	Rarely - Inc. in Flush Regime		1											Low	None visible	None visible	Pipework - no outlet	Medium
Recommendations:		Include unused outlets into site flushing regime (or remove if no longer required)																										

Location / Room No	Sentinel outlet?	Cold Supply & Temp (°C)	Hot Supply & Temp (°C)	TMV info					Deadlegs Present (Inc. Drain cocks)	Flow & Return Working	Outlet Usage	Outlets in location											Aerosol Created	Non WRAS Material	Flexi Hoses	Comment	Additional Localised Risk Rating
				No. Of TMVs	Access	<2m from outlet?	Mix Temps 37-45°C	No. TMV Fed Outlets				Mains	Cold	Hot	Mixer	Urinals	WCs	Shower	Drinks / vend	Water boiler	Drinking fountain	Arjo/whirlpool	Other					
Kitchen STW 042	N	CWST 15.7	Calorifier 62.5	1	OK		Yes	1	None visible	Not visible	Daily		2	2	1					1			1	Low	None visible	On dish sink	Dishwash	Low
Recommendations:																												
Facilities RENO 079	N	CWST 17.9	Calorifier 63.3	1	OK		1	Yes	None visible	Not visible	Daily		2	2	1									Low	None visible	None visible		Low
Recommendations:																												
CWS 004 Kitchen	Y	CWST 15.2	Calorifier 56.7	0	OK			0	None visible	Not visible	Daily		1	1						1			1	Low	None visible	None visible	Dishwash	Low
Recommendations:																												
Facilities TNS 014	N	CWST 16.4	Calorifier 63.6	1	OK		Yes	1	None visible	Not visible	Daily		3	3										Low	None visible	None visible		Low
Recommendations:																												
Recommendations:																												

Section 8

Other 'At Risk Systems'

Other Risk Systems

All other "at risk" systems should have a suitable L8 risk assessment carried out with an appropriate L8 monitoring regime implemented.

HSG 274 Legionnaire's disease: Technical guidance Part 3: The control of legionella bacteria in other risk systems provides guidance on identification and frequency of inspections for these systems.

Please also refer to outlets (section 7 for information and section 2 for recommendation) relating to supplies from domestic water system to process systems described below.

Other systems identified to DMA as being present on site:

- Hydrotherapy Pool (completed under separate assessment)
- Whirlpool/Arjo Baths
- Dental equipment
- Emergency showers
- Irrigation systems
- Sprinkler/Wet firefighting systems
- Renal dialysis (x2 systems) with additional 'Emergency Dialysis Points' which are directly supply from bulk domestic cold water system. NHS Estates should confirm location of all Emergency Dialysis Points.
- Endoscopy Wash
- Water softeners
- Medical Gases/Medical Equipment (e.g. Nebulisers, incubators, etc.)
- Emergency Cooling (MRI chiller)
- Closed heating systems
- Closed chilled water systems
- Steam Humidification
- Air Conditioning

This assessment provides a brief description of each system and an initial assessment however we would advise specialists in each field are consulted to confirm this initial assessment is reflective of the function of the system and would present these findings as draft only until this is confirmed.

N.B. DMA were advise no Ice making machines or machines with "open" cooling system (e.g. lathes) are used on site

System	**Hydrotherapy Pool**
Location(s)	Ground floor - Children's Hospital
Responsibility	Estates/Clinical staff
Description	Hydrotherapy pool
Water Source	Bulk Water supplies CWST in basement Hydrotherapy plantroom
Filtration Present	Pool filtration plant in hydrotherapy plantroom in basement
Running Temperature	Typically 35-40°C
Use	System not in use at time of assessment (Empty). Continually circulating system.
Aerosol Created	Potentially high
Comments	This is being assessed under separate cover by Brio Group
Recommendations	
Risk (Legionella)	See separate Hydrotherapy Pool Risk Assessment

System	**Arjo Baths**
Location(s)	Various locations throughout the hospital (Wards)
Responsibility	Estates/Clinical staff
Description	Medical bath (Baths seen by DMA do not appear to have any obvious air or water jet facility)
Water Source	Bulk Water
Filtration Present	None
Running Temperature	Typically 35-45°C
Use	DMA were unable to confirm at the time of assessment as local clinical staff were unsure. We would advise this is confirmed immediately.
Aerosol Created	High
Comments	Flexible hoses on connection to hot/cold water system in addition to internal flexible connections. Estates unable to confirm maintenance instructions.
Recommendations	Maintain in accordance with manufacturers/installers instructions. Where flexible hoses (i.e. internal to bath unit) cannot be removed then replacing with alternative WRAS approved hoses with linings other than EPDM should be considered. Consider shortening shower hoses as it was noted that these can in some areas reach into adjacent WCs and WHBs.
Risk (Legionella)	High (if used infrequently)

System	**Dental Equipment**
Location(s)	Ground floor Children's Hospital
Responsibility	Estates/Clinical staff
Description	Water supply to 2 x dental chairs
Water Source	Bulk Water feeds CWST and booster pump. Also bottled water within chair. Confirmation as to what equipment is fed from CWST/booster and bottled water not provided to DMA.
Filtration Present	None
Running Temperature	TBC though 'Bulk water system'
Use	TBC
Aerosol Created	Potentially High (TBC)
Comments	
Recommendations	HSG 274 Part 3 states *"Drain down, clean, flush and disinfect all system components, pipework and bottles twice daily. Disinfectant contact time as recommended by manufacturer. Take microbiological measurements (Refer to Decontamination HTM 01-05)* SHTM 04-01 Part G states *"Drain down and clean at the end of each working day".* It should be confirmed what equipment is fed from CWST/booster and bottled water. HTM 01-05 provides advice and recommendations for on-going maintenance and this should be followed in addition to manufacturers and installers instructions.
Risk (Legionella)	High

System	**Emergency Showers**
Location(s)	Hydrotherapy Plantroom and A&E Decontamination Room
Responsibility	Estates
Description	Emergency drench system
Water Source	Bulk Water
Filtration Present	None
Running Temperature	TBC though 'Bulk water system'
Use	Estates advised these are included in a flushing regime though no records available at time of assessment.
Aerosol Created	High
Comments	Estates advised flushing regime is intermittent.
Recommendations	HSG 274 Part 3 recommends minimum six-monthly flushing of emergency/deluge shower, though Risk Control Notice 11/advises "flush through and purge to drain twice per week– source SHTM 04-01 Part G. NHS Estates should formulate an appropriate flushing regime and maintain in accordance with manufacturers/installers instructions.
Risk (Legionella)	High

System	**Irrigation System**
Location(s)	Various courtyards/roof gardens
Responsibility	Estates
Description	Soak away irrigation (Advised by Estates – DMA did not see system running)
Water Source	Trades Water
Filtration Present	None
Running Temperature	TBC though 'Trades water system'
Use	DMA advised in January 2018 by NHS Estates that these systems had been disconnected and were no longer in use.
Aerosol Created	See 'Use'
Comments	Very long runs to outlets through the building.
Recommendations	Ensure former connection points are included in site flushing regime or removed leaving no deadlegs with stored capacity reduced as required.
Risk (Legionella)	N/A as disconnected

System	**Sprinkler/wet fire-fighting system (Sprinkler System)**
Location(s)	Main fire tanks in basement (Sprinkler system throughout the building)
Responsibility	Estates
Description	Fire suppression/sprinkler system
Water Source	Fed from dedicated fire main (Hardgate Road – Small) via Dedicated Sprinkler System Storage Tanks in the Basement
Filtration Present	None
Running Temperature	Ambient
Use	NHS Estates were unable to confirm if any manual testing is carried out. Out with any manual testing, the system is used for Emergency use only.
Aerosol Created	High when discharging. (Droplet size undetermined)
Comments	The CWSTs were very dirty internally when inspected and heavily stagnant. Further guidance on this can be found in *"FIA Guidance for the Fire Protection Industry - Guidance on Legionella in Fire Fighting Systems and Equipment"*
Recommendations	Consider clean and disinfection of the CWST and then regular inspection as per domestic water tanks with cleaning/disinfection as required by inspection. Minimise aerosol creation during maintenance procedures. Consider wearing suitable masks to prevent ingestion as recommended by the FIA guidance. Maintain in accordance with manufacturers/installers instructions.
Risk (Legionella)	High under discharge.

System	**12th Floor Heli-pad fire suppression system**
Location(s)	12th Floor heli-pad fire tank/suppression system
Responsibility	Estates
Description	Fire suppression/sprinkler system (including water cannon). NHS Estates advised a foam suppressant is added to the discharged water when in use for emergency only, during weekly testing only water is used with no foam. DMA were not provided access to the roof to witness testing of the system
Water Source	Trades Water via 12m^3 Cold Water Storage Tank in 12th floor Plantroom. Trades system runs approx. 100m from last tee-off in 12th floor before supplying the tank (and last tee-off is itself approx. 50m to a tap which is unlikely to be used)
Filtration Present	None
Running Temperature	Ambient (CWST temperature measured at 19.2°C during assessment)
Use	Not in use at time of assessment. DMA have not been provided access to inspect the system and not witnessed testing though were advised a weekly test using water (no foam) is carried out through all areas of the system. Thereafter this for Emergency use only.
Aerosol Created	High when discharging. (Droplet size undetermined). As the system is located on the rooftop any aerosol could be dispersed over a larger area (similar to a cooling tower)
Comments	It is not anticipated that weekly testing will turn over the full contents of the storage tank though this requires confirmation from NHS Estates. DMA were advised that following use, the system drains down naturally which we understand will mean some lower points of the system remain fully wetted and other areas dry. This may create conditions for biofilm formation within the pipework, increasing the likelihood of legionella proliferation. Pipework is constructed from Mild Steel and Galvanised Steel which also may be conducive to Legionella growth. There are 3 x recirculation lines back to the tank which may also return potential contamination from pipework back to the tank. The CWST was very dirty internally when inspected. Further guidance on this can be found in *"FIA Guidance for the Fire Protection Industry - Guidance on Legionella in Fire Fighting Systems and Equipment"*

Recommendations	We would advise the CWST is cleaned and disinfected (though it should be remembered that the fire system would be out of use during such works). Minimise aerosol creation during maintenance procedures. Consider wearing suitable masks to prevent ingestion as recommended by the FIA guidance. Maintain in accordance with manufacturers/installers instructions. Ensure all points on the trades system (including inlet to fire tank) in site flushing regime. Consider implementing a sampling regime to include the storage tank and points on the system and the supply. This would be particularly important during summer months where ambient temperatures are likely to be higher. We would also advise temperature monitoring and visual inspection should be carried out on the Storage Tank on a weekly basis prior to testing and should the storage temperature exceed 20ºC then additional precautions should be considered (E.g. flush the tank to reduce stored water temperature, manually dose tank with suitable disinfectant chemical if no automated system installed) Given the potential control issues described above, but the need for such a system to be in place, it would be prudent to consider a permanent chemical dosing system for this water system (though it should be confirmed that any chemicals used on this system would not interfere with the foam used for emergencies)
Risk (Legionella)	High under discharge.

System	**Renal Dialysis (Adult)**
Location(s)	Plantroom 32 then runs to renal ward areas
Responsibility	Estates/Specialist
Description	A constantly circulating purified water system supplying renal dialysis outlets in the Adult hospital
Water Source	Bulk Water
Filtration Present	Various
Running Temperature	TBC though 'Bulk water system'
Use	Daily
Aerosol Created	Typically Low
Comments	As supplied by Bulk Water this makes domestic water system disinfections problematic.
Recommendations	Maintain in accordance with manufacturers/installers instructions, current NHS (SHTM) protocols and "Clinical Practice Guideline by the UK Renal Association of Renal Technologists". Ensure aerosol creation is minimised during maintenance and testing procedures.
Risk (Legionella)	Low

System	**Renal Dialysis (Adult – Emergency Points)**
Location(s)	To be confirmed by NHS Estates
Responsibility	Estates/Specialist
Description	Emergency connection points have been installed in rooms which were not in the proximity of the dedicated renal dialysis systems.
Water Source	Bulk Water (Domestic Cold Water)
Filtration Present	On renal dialysis machines
Running Temperature	See section 7 for description of cold water conditions.
Use	Points are for emergency use only and are likely to be creating deadlegs on the system.
Aerosol Created	Typically, Low
Comments	As supplied by Bulk Water this makes domestic water system disinfections problematic.
Recommendations	Maintain in accordance with manufacturers/installers instructions, current NHS (SHTM) protocols and "Clinical Practice Guideline by the UK Renal Association of Renal Technologists". Ensure aerosol creation is minimised during maintenance and testing procedures. Include in twice weekly flushing regime. Ensure suitable backflow prevention in placed
Risk (Legionella)	Low

System	**Renal Dialysis (Children)**
Location(s)	Plantroom 22 then runs to renal ward areas
Responsibility	Estates/Specialist
Description	A constantly circulating purified water system supplying renal dialysis outlets in the Adult hospital
Water Source	Bulk Water
Filtration Present	Various
Running Temperature	TBC though 'Bulk water system'
Use	Daily
Aerosol Created	Typically Low
Comments	As supplied by Bulk Water this makes domestic water system disinfections problematic.
Recommendations	Maintain in accordance with manufacturers/installers instructions, current NHS (SHTM) protocols and "Clinical Practice Guideline by the UK Renal Association of Renal Technologists". Ensure aerosol creation is minimised during maintenance and testing procedures.
Risk (Legionella)	Low

System	**Endoscopy Wash Filtration Unit**
Location(s)	Plantroom 31
Responsibility	Estates/Specialist
Description	A constantly circulating purified water system supplying endoscopy wash machines in the Adult hospital
Water Source	Bulk Water
Filtration Present	Various
Running Temperature	TBC though 'Bulk water system'
Use	Daily (TBC)
Aerosol Created	Potentially high though contained within the endoscopy wash units.
Comments	
Recommendations	Maintain in accordance with manufacturers/installers instructions and current NHS (SHTM) protocols. Ensure aerosol creation is minimised during maintenance and testing procedures.
Risk (Legionella)	Low

System	**Water Softeners**
Location(s)	Various
Responsibility	Estates/Specialist
Description	Softeners form part of various medical (e.g. Renal/Endoscopy) and other processes (e.g. steam ovens)
Water Source	Bulk Water
Filtration Present	N/A
Running Temperature	TBC though 'Bulk water system'
Use	See relevant process/equipment
Aerosol Created	N/A (Contained systems)
Comments	Estates unable to confirm servicing history or local responsibilities (Estates/Medical Physics/Clinical)
Recommendations	Maintain in accordance with manufacturers/installers instructions (including cleaning and disinfection of resin and brine tanks). Confirm responsibilities. Ensure aerosol creation is minimised during maintenance and testing procedures.
Risk (Legionella)	Medium

System	**Medical Gases/Medical Equipment** (e.g. Nebulisers, incubators, etc.)
Location(s)	Throughout Hospital
Responsibility	Estates/Clinical Staff/Infection Control/Specialist
Recommendations	Conduct a risk assessment of each system, preferably using an assessment team comprising members knowledgeable in legionella management and control, as well as those familiar with the design and operation of the system and Infection Control/Clinical staff where appropriate. Control procedures within appropriate SHTM (or other relevant guidance) for system being assessed should be taken in to account during assessment(s). Any water softeners or other filtration equipment connected to these systems should be assessed at this time. Devise a control scheme based on the risk assessment.
Risk (Legionella)	Not assessed

System	**Emergency Cooling (MRI chiller)**
Location(s)	3rd Floor Roof adjacent to Plantroom 31 at Calorifiers 31-04/05/06.
Responsibility	Estates/Specialist
Description	DMA were advised by NHS Estates that the water supply to these units (via an RPZ valve) is for emergency use in the event the chillers fail. The water would be used in a once through loop flowing through the unit and direct to drain.
Water Source	Bulk Water
Filtration Present	None noted (Fed via RPZ valve)
Running Temperature	TBC though 'Bulk water system'
Use	Emergency use only
Aerosol Created	TBC – DMA have not witnessed this system in use.
Comments	DMA requested additional information on how the system operates though not received at time of report. DMA had previously requested that site confirm there is no adiabatic function on the chillers with water where water would be sprayed over the chiller in the event that natural air cooling was insufficient however, NHS Estates advised during Gap Analysis review meeting in January 2018 there was no adiabatic function.
Recommendations	Connection point to MRI unit(s) should be included in site flushing regime or have suitable backflow protection fitted at the connection point (or RPZ moved to tee-off). Ensure aerosol creation minimised when running to drain in emergency use – consider disinfection of system prior to instatement of emergency loop.
Risk (Legionella)	Low (based on information from site)

System	**Closed Heating Systems**
Location(s)	Throughout hospital
Responsibility	Estates
Description	Closed heating systems
Water Source	Top up by Bulk Water system
Filtration Present	None
Running Temperature	70 – 105°C (approx.)
Use	Constantly circulating systems
Aerosol Created	N/A
Comments	
Recommendations	Minimise aerosol creation during maintenance procedures. Maintain in accordance with manufacturers/installers instructions.
Risk (Legionella)	Low

System	**Closed Chilled Systems**
Location(s)	Throughout hospital
Responsibility	Estates
Description	Closed chilled systems
Water Source	Top up by Bulk Water system
Filtration Present	None
Running Temperature	6 - 20°C (approx.)
Use	Constantly circulating systems
Aerosol Created	N/A
Comments	
Recommendations	Minimise aerosol creation during maintenance procedures. Maintain in accordance with manufacturers/installers instructions.
Risk (Legionella)	Low

System	**Steam Humidification**
Location(s)	Plantrooms (Air Handling Units)
Responsibility	Estates
Description	Steam humidifiers for air conditioning plant
Water Source	Bulk Water
Filtration Present	N/A
Running Temperature	>100°C
Use	DMA were advised by Estates these are not in use and are likely to be disconnected.
Aerosol Created	N/A (Steam)
Comments	Supplies will be creating deadlegs and should be included in flushing regime until systems disconnected.
Recommendations	Maintain in accordance with manufacturers/installers instructions and as required under SHTM 03-01 and SHTM 04-01 Part G.
Risk (Legionella)	Not assessed – offline.

System	**Air Conditioning/Ventilation**
Location(s)	Plantrooms (Air Handling Units)
Responsibility	Estates
Description	Air handling units
Water Source	N/A
Filtration Present	N/A
Running Temperature	N/A
Use	Variable depending on building requirements
Aerosol Created	N/A (unless under fault conditions)
Comments	Air systems not inspected during survey and as such do not form part of this assessment
Recommendations	Maintain in accordance with manufacturers/installers instructions and as required under SHTM 03-01 and SHTM 04-01 Part G.
Risk (Legionella)	Not assessed

System	**Decorative Bubble Lamps**
Location(s)	Children's Hospital Atrium
Responsibility	Estates/Contractor (TBC)
Description	Decorative water and air bubble lamps
Water Source	N/A (Sealed System)
Filtration Present	N/A (Sealed System)
Running Temperature	Ambient
Use	Variable (Multiple times daily) - Bubbles released into water tubes at base when button pressed on unit
Aerosol Created	Unit appears to be completely sealed (though this requires to be confirmed) so aerosols would be contained.
Comments	Estates unable to confirm maintenance
Recommendations	Maintain in accordance with manufacturers/installers instructions and ensure aerosols minimised during maintenance. If aerosols are likely to be released then this should be viewed as an "indoor water feature" and should be removed.
Risk (Legionella)	Low assuming maintained and lids kept closed. Otherwise the risk is elevated.

Gap Analysis of L8/HSG 274 and SHTM 04-01 requirements

Queen Elizabeth University Hospital and Royal Hospital for Children

Tuesday 30th January 2018

DMA Representatives: Allan McRobbie and Craig Guyer

NHS Estates Representatives: David Brattey, Paul McAllister and Tommy Romeo with additional information from Ian Powrie

All information gathered in this process was as verbally advised by NHS Estates on the above date.

Where Estates have advised tasks are being completed records had not been made available for inspection by the time of issue. We would advise these made available to establish the level of compliance achieved where tasks are being completed.

The information gathered highlights significant gaps in the Legionella (and potentially other bacterial) control on site both in terms of management processes and the implementation of the recommended planned preventative maintenance tasks.

The Estates Manager placed in the role of 'AP Water' has not undergone any training in Legionella control (or other bacteria) and has limited knowledge of the water systems on site and the requirements of L8, HSG 274 and SHTM 04-01.

It is unclear which responsibilities lie with which departments (E.g. Clinical, Estates) and to which persons within these departments. It is also unclear which responsibilities lie with site Estates and which lie with the NHS GG&C Compliance Team (or HFS).

A Written Scheme guidance was issued by DMA in 2015 though has not been updated as anticipated to be fully utilised as the Written Scheme for site, and become the overarching control document for Legionella control. NHS Greater Glasgow Estates have since issued a general 'Written Scheme' to be implemented on each of their sites however, DMA are awaiting feedback from NHS Estates (Compliance Team) on a number of queries raised before any changes are made to make this site specific. A draft document for discussion has been supplied to Phyllis Urquhart and DMA are awaiting feedback on this.

We would advise corrective actions are taken as a matter of immediate urgency to ensure an accurate and compliant Written Scheme is compiled and the appropriate PPM schedule implemented.

We would describe the Legionella Management on site as being High Risk until remedial actions highlighted within the legionella risk assessment and within this Gap Analysis are implemented.

Summary of L8 Management Tasks Required for L8 and SHTM 04-01 Compliance	In place or being carried at present (as verbally advised by NHS Estates)?
Regular check to ensure that legislation and guidance has not changed	This is the responsibility of the NHS GG&C Compliance Team however, this is not documented.
Regular review of all policies relating to legionella control (e.g. Maintenance, Water Treatment, Water Management, Energy) to ensure still valid and correct	This is the responsibility of Health Facilities Scotland (HFS) and NHS GG&C Compliance Team however, this is not documented.
Regular review of L8 Management Structure to ensure up-to-date and accurate	This is responsibility of the Water Safety Group with local estates responsible for legionella management at a local level only however this is not documented.
Regular review of communication lines to ensure still accurate and correct	This is responsibility of the Water Safety Group with local estates responsible for legionella management at a local level only however, this is not documented.
Regular review of escalation & emergency procedures to ensure still valid and correct	This is responsibility of the Water Safety Group however, this is not documented.
Regular review of duties allocated to site staff and ensure accurate and recorded	Tasks are allocated via the 'FM First' system and a spreadsheet however the review period for this is not recorded.
Regular review of duties of sub-contractors and ensure accurate and recorded and contractors are suitably qualified/competent for tasks assigned to them (e.g. Water Hygiene contractors should be LCA Approved, Plumbing contractors should be SNIPEF and Water Safe Registered)	There is no documented review period, details of contractual responsibilities for sub contractors or evidence of contractor/operator competence for many tasks.
Regular review of staff training requirements and update training matrix	Staff training is the responsibility of Joe McElvey, Training Manager. Estates then allocate jobs based on core competencies however, Tommy Romeo has been allocating water PPMs for approx. 18 months without Authorised Person training.
Regular review of method statements and risk assessments to ensure still valid and correct	This is the responsibility of Estates though there is no evidence of completion.
Regular review of site documentation to ensure all records up to date and present	This is the responsibility of Estates though there is no evidence of completion.
Regular update of "Patient Risk Rating" register for all areas of hospital.	This is the responsibility of Infection Control and the Water Safety Group however, there is no evidence of a recorded review process, e.g. Infection Control updating estates on a monthly basis of current 'higher' risk areas and the Written Scheme for site being updated.
Regular review of sentinel outlet locations register.	There have been no significant alterations to the water system since initial installation which would warrant changes to the original list as defined by the building contractor however, we would advise a regular review is signed off particularly as the wards are altered to reflect varying occupants (E.g. as recently in Ward 4B).
Regular review of principle, sub-ordinate and tertiary hot flow and return loops to reflect any system alterations.	As per comment above regarding sentinel outlets a regular review is recommended with actions taken as appropriate.
Regular review of plant and equipment maintenance schedules.	It would be the responsibility of the Compliance Team to ensure local Estates are provided with up to date manufacturer's instructions and maintenance schedules for equipment to enable PPMs and RAMS to be updated accordingly.
Regular review of BEMS temperature sensor locations to reflect any system alterations	As per sentinel and flow & return comments above these should be reviewed as required by system alterations. In addition, where temperature monitoring or microbiological sampling indicates potential problems the installation of BEMS sensors may form part of the response.
Regular review of schematic/as-fitted drawings to ensure up-to-date and accurate	As per comment above regarding sentinel outlets a regular review is recommended with actions taken as appropriate.
Regular review of L8 risk assessment (e.g. if change of use or changes in legislation or any other factor which could affect validity of current assessment)	This Gap Analysis forms part of a Risk Assessment review. Given the nature of the building we would advise an annual review is carried out.

N.B. By "Regular" DMA would advise a Quarterly or 6 monthly review of all tasks above or as and when there are changes in system operation, management or other control parameters which would warrant a review of any particular task. (e.g. if change of use or changes in legislation or any other factor which could affect validity any of the current documentation)

Initial tasks required to aid compilation of PPM schedules/registers within site written scheme	In place or being carried at present?
Identify, label and record all plant, valves and services	All labelling carried out at construction phase and Estates advised they "assume" still up to date.
Identify, label and record sentinel outlets on hot and cold water services.[1]	All sentinel outlets are recorded on a sentinel outlet register (provided by Mercury Engineering at time of construction).
Identify, label and record all "drinking" and "non-drinking" water outlets	All cold water is deemed as "wholesome" throughout the hospital, though it should be noted that some wards have signs up advising patients not to drink the system water.
Identify, label and record all primary, sub-ordinate and tertiary flow and return loops and their access points for temperature profile/mapping	NHS Estates advised they will review with BEMS operators and confirm.
Identify, label and record all BEMS temperature sensor locations for temperature profile/mapping	NHS Estates advised they will review with BEMS operators and confirm.
Identify, label and log all mixing devices (TMVs) with a unique identification as well as identification of its type. Hot and cold water pressures also need to be measured and recorded for each mixing device together with all the test parameters from the in-service tests	Estates are in the process of applying coding labels to assets which will form the basis of PPM schedules etc. however, this is not complete. DMA not requested to provide hot and cold water pressure tests for the devices and no records available to confirm if this is carried out.
Identify, label and log all "other uses of water" (e.g. use of ice machines, drinking water fountains, bottled water dispensers etc.)	DMA advised no bottled water dispensers within the building. No ice machines fitted, though DMA were advised that wards/clinical staff may initiate or arrange installation of equipment without notifying estates management. DMA would advise estates emphasise to clinical staff the importance of keeping estates staff abreast of any changes to the water system (including with regards to unused outlets) and issue regular advice notices. Clog washers installed in the theatre changing rooms (DMA Advised these are sealed units "identical" to a dishwasher). Endoscope washers, Renal System (Maintained by Veolia) MRI Chillers – DMA advised by Estates (Ian Powrie, Deputy General Manager) these are not adiabatic chillers and the water supply is an emergency back-up should cooling fail at which point wholesome water would be drawn into the system and run 'once through' to drain.

[1] Sentinel outlets are normally those that – on a hot water service – are the first and last outlets on a recirculating system with additional points on larger systems where monitoring of primary, sub-ordinate and tertiary loops is required. On cold water systems (or non-recirculating hot water systems), they are the closest and furthermost from the storage tank (or water heater). The choice of sentinel taps should also include other outlets that are considered to represent a particular risk, for example those installed in accommodation in which particularly susceptible patients are treated, or others identified in the risk assessment and temperature mapping exercise as having the least satisfactory temperature performance.

Summary of ppm tasks required within site written scheme to aid compliance with SHTM 04-01 and L8/HSG 274	**In place or being carried at present?**
Daily water draw-off should form part of the daily cleaning process.	Estates advised this is the responsibility of domestic staff however, procedures are not available for review.
Daily check the flow and return temperatures on the domestic hot water calorifier systems using the temperature gauges fitted or a suitable surface temperature probe	BEMS systems are fully operational so this is not required as present. However, this should form part of an escalation process should BEMS monitoring fail.
Daily check of BEMS incidents and faults	This is the responsibility of the Service Engineer however contractual obligation and confirmation of competency not available for review.
Incoming Water Mains - maintain in accordance with installation/design guidelines, ensuring alteration of incoming mains lines to run at least daily. (DMA advised 9 hourly swap over).	This should be carried out automatically by BEMS however DMA were advised there is an issue with the Hardgate Road supply at present which may be creating a significant dead leg on the system. We would advise this supply is thoroughly flushed to drain prior to re-use or, if off for an extended period the pipework disinfected if practical. In addition, one of trades CWSTs has been offline possibly since 2015 creating a dead leg on the supply.
Cyclical alteration of CWST booster pumps (ensuring every pump runs at least weekly)	Automatic via BEMS
Daily check to ensure entire body of calorifier (top, middle, base) reaches 60°c for a period of 1 hour each day (generally at a time of low use e.g. Early morning/late evening)	BEMS monitors top, base and return temperatures to all calorifiers. The control parameters for the base temperature within BEMS setup should be confirmed.
Daily flushing of all outlets in "High Risk Areas"/ICUs. Hot and cold outlets should be flushed for a minimum of 3 minutes and until the water temperature stabilises in line with current temperature profile.	Estates advised this is the responsibility of ward staff with reminders issued by estates (process, procedure and responsibility for Estates should also be confirmed, e.g. do Estates check and log these reports)
Twice-weekly flushing of all outlets in unoccupied areas and low use/sporadically used outlets. Hot and cold outlets should be flushed for a minimum of 3 minutes and until the water temperature stabilises in line with current temperature profile.	The responsibilities for this are unconfirmed at present. Wards and other areas not in use should be included in the flushing register e.g. Ward 4B of which approx. half the ward is unused and we understand there is no intention from clinical staff to bring the unused rooms into use (due to the nature of patients within the ward area). Where services are likely to remain unused disconnection without creating dead legs should be considered as the preferred long term option.
Twice weekly flushing of emergency/deluge shower for a minimum of 3 minutes and the water temperature stabilises in line with current temperature profile.	Estates advised this is being completed though records not available for review at time of assessment.
Twice weekly flushing of deadlegs/blind ends where these cannot be removed. All deadlegs should be flushed for a minimum of 3 minutes and until the water temperature stabilises in line with current temperature profile. [2]	Estates advised this is being completed though records not available for review at time of assessment. Due to the number of flushing points and drain valves/drain cocks on the system it is vital that an up to date register is maintained to confirm all relevant points are flushed. Similarly any supplies to 'other-risk systems' should also be included in flushing regime where required.
Weekly water system check for chloramines (if required)	DMA recently contacted Scottish Water who advised Chloramines are not used in the local town mains supply however, this should be confirmed.
Weekly check to ensure that non-return valves shut off tightly. Remove covers and examine further if they do not.	This is not being carried out. (Construction Contractor Brookfield recommended this frequency in their initial PPM requirements in 2015)
Weekly check of water levels within water tanks	Estates advised this is being completed though records not available for review at time of assessment.
Check spray taps for satisfactory spray, where necessary remove spray orifice and clean, remove any accumulation of scale. *(DMA understands no spray taps fitted though this is to be confirmed)*	DMA advised no spray taps fitted (and no spray taps noted by DMA). Spray washers in kitchens are cleaned/disinfected by catering staff – the record keeping requirements for these should be confirmed by Estates.
Monthly (minimum) *manual* test to confirm water system pumps operating correctly	Estates advised this is being completed though records not available for review at time of assessment.
Monthly calorifier storage temperatures checks at top (flow) and return pipework Flow temperature – min 60°C, return temperature – min 55°C	This is monitored by BEMS. No manual checks are completed to confirm BMS readings.

Summary of ppm tasks required within site written scheme to aid compliance with SHTM 04-01 and L8/HSG 274 (cont…)	**In place or being carried at present?**
Monthly temperature checks on hot outlets at sentinel, little-used & selected outlets. >55°c within 1 minute (also note potential scald risks and out of spec TMVs)[2] to create a temperature profile of building and monitor flow and return system with all primary flow and return loops being monitored monthly, sub-ordinates quarterly and tertiary loops annually.	Estates advised this is being completed though records not available for review at time of assessment, though no other monitoring carried out. No other outlets being monitored. High risk areas do not have a specific monitoring regime.
Monthly temperature checks on cold outlets at sentinel, little-used & selected outlets. <20°c within 2 minutes to create a temperature profile of building and monitor heat gain within the cold water system.	Sentinel outlets completed by Estates (though records not available for review at time of assessment) though no other monitoring carried out. No other outlets being monitored. High risk areas do not have a specific monitoring regime. Estates unsure if trades system being monitored.
Monthly check to ensure CWST overflows are unobstructed	Estates were uncertain if this was being completed and will confirm.
Monthly flushing of expansion vessels as not 'flow through' design	Not currently being carried out. There is potentially convert systems to flow through with retro-fit valves however significant re-piping may also be required. add
Quarterly descaling, cleaning and disinfection of showerheads & hoses, or replace with new disinfected Shower Head and Hose (or frequency as indicated by the rate of fouling or other risk factors, e.g. areas with high risk patients)	High risk areas (advised to DMA by Estates) are being *descaled/disinfected* quarterly by DMA. Estates advised other areas are being completed (though records not available for review at time of assessment). There is currently no mechanism in place for 'no access' reports to be re-actioned to ensure all showers are completed in the necessary time frame. Due to the length of time shower heads have been in place, the lack of records and the patient groups involved we would advise showers heads and hoses are changed.
Quarterly each calorifier and any associated storage/buffer vessels should be flushed through its drain valve by opening the drain valve 3 times, each time for a 3 minute period.	Estates advised this is being completed however we would advise the procedure for this task is reviewed as DMA purged dirty water from the bases of various calorifiers (see section 6),

[2] Representative outlets include conventional and mixed-temperature taps; 20% of the total number installed throughout the premises would be tested annually on a rotational basis: that is, all taps checked every five years.

Summary of ppm tasks required within site written scheme to aid compliance with SHTM 04-01 and L8/HSG 274 (cont.)	In place or being carried at present?
Quarterly servicing TMV's or mixer valves, including fail safe tests and cleaning/disinfection of strainers within "Designated High Risk Area"/ICUs (more frequently if manufacturer recommends – or if 'drift' in excess of 1°C at mixed outlet temperature highlighted during temperature monitoring or other maintenance)	TMV servicing in high risk areas (advised to DMA by Estates) including flushing of hot and cold supplies to tap via flushing adapters has recently been carried out by DMA as we were advised the Estates regime may have lapsed. Servicing of some outlets (e.g. Armitage Contour Taps) is restricted as DMA have been advised we are unable to remove IPS panels. This gives further cause for concern as Estates were unable to confirm if the strainers on the supplies have ever been removed for cleaning/disinfection or taps fully serviced. The vast majority of TMVs installed are TMV taps, (Horne Optitherm in clinical areas and Armitage Shanks in non-clinical areas) with the only exceptions noted being infrared outlets in non-patient area toilets with infrared taps which have a TMV mounted approximately 0.5m from the outlet. Thermostatic mixing valves (TMVs) should be regularly serviced as per the manufacturers instructions and in accordance with the Written Scheme for site which should include input from the relevant NHS departments (e.g. Estates, Clinical, Infection Control, Authorising Engineer, Compliance Team, Health & Safety, Water Safety Group etc. – please note DMA's attendance at Water Safety Group meetings has not been requested) for local infection control guidance for bacterial control taking into account the location, design, operation, servicing and requirements of infection control. Horne Optitherm TMV taps are designed to be demounted for maintenance and servicing elsewhere but the facilities for this are yet to be completed and commissioned. Specific service method statements and maintenance requirements for these items in these areas should form part of the written scheme. In addition, the strainers located on the supplies to the TMV taps in "Non-Clinical" areas (e.g. patient, visitor and staff toilets) are located behind panels and therefore infection control procedures are required (Scribe) in order to remove panels for service. We understand no servicing of any of these valves and the associated strainers in non-high risk areas has been carried out since the hospital opened and there has been a very limited program of servicing in 'high risk' areas. We are unaware of any servicing works being carried out and had access to servicing records on TMV taps in other areas of the hospital at the time of assessment. The recent (prior to assessment delivery) issue with regards to Cupriavidus bacteria being detected in the system water has highlighted that the servicing requirements of the TMV taps should be reviewed to ensure that in addition to manufacturers service instructions being carried out the servicing of TMV taps includes any additional control measures as deemed necessary by infection control e.g. full thermal bypass/disinfection of the taps where practicable and safe (this would require to be carried out remotely from patient areas) and flow regulator, O rings and other components cleaning, disinfection and/or replacement. There are no records that manufacturers recommendations have been implemented to date regarding commissioning and component changes. Estates advised there is currently no mechanism in place for 'no access' reports to be re-actioned to ensure all valves are completed in the necessary time frame.
Six monthly servicing TMV's or mixer valves, including fail safe tests and cleaning/disinfection of strainers. (more frequently if manufacturer recommends – or if 'drift' in excess of 1°C at mixed outlet temperature highlighted during temperature monitoring or other maintenance)	Not currently being carried out.

Summary of ppm tasks required within site written scheme to aid compliance with SHTM 04-01 and L8/HSG 274 (cont…)	**In place or being carried at present?**
Six monthly CWST condition inspection noting appearance of water, stagnation, odour, rust, scale, sediment, debris, paint/liner condition and bio film accumulation and tank lid fitting ok and insulation condition	Estates advised this is being completed though records not available for review at time of assessment, however DMA had previously recommended disinfections and had also noted one of the trades tanks has been offline, possible for a number of years though no remedial actions have been taken. Additionally, DMA recommended clean and disinfection of the bulk water tanks in 2015 though no actions have been taken since.
Six monthly CWST temperature checks (summer and winter) on tank supply and stored water at opposite side from tank inlet if possible (inlet and stored water should be <20°C, with stored water no more than 2°C warmer than make-up water.)	Estates advised this is being completed though records not available for review at time of assessment.
Six monthly chemical and microbiological water samples from water tanks which feed drinking water outlets	This is not being carried out at present.
Annually arrange for samples to be taken from hot water calorifiers/water heaters in order to note condition of drain water.	Estates advised this is being completed however we would advise the procedure for this task is reviewed as DMA purged dirty water from the bases of various calorifiers (see section 6),
Annual cleaning and disinfection CWST *and downservices* (more frequently if required dependant on CWST inspection & sample results). TVC and Legionella samples should be taken upon completion of disinfection works. **Please Note:** *Due to the system design and installation complete disinfection of all downservices fed from the Raw and Bulk water storage tanks may not be practical as "high risk" system such as renal dialysis is fed from these tanks. Alternative protocols/method statements for local disinfections should be prepared and maintained.*	No clean and disinfections have been carried out since the building has been handed over to the NHS in 2015 despite previous Risk Assessment recommendations.
[A] Annual descaling, cleaning and disinfection of strainers (including angle valve strainers) (or frequency as indicated by the rate of fouling or other risk factors, e.g. areas with high risk patients)	Not being carried out at present. Please also see TMV comments.
[B] Annual internal inspection and cleaning/descaling of the calorifier/water heater with disinfection/pasteurisation upon completion	Not being carried out at present. This may also include expansion vessel and component servicing (see Plant maintenance below)
Annual inspection of vibration coupling on pumps/plant, replacing as necessary (more frequently if recommended by manufacturer)	Not being carried out at present.
Annual inspection of plant and pipework insulation, repairing where necessary.	Ongoing task – very little works have been carried out on the water system.
Biennial stratification checks on plate heat exchangers/calorifiers. These checks should extend over a period of seven (7) days using a logging device to establish that the water temperature at the base of the vessel achieves 50ºC.	Covered by BEMS
Arrange for microbiological samples to be taken from water system which represent the complexity of the water system(s) and particularly in areas of concern. All sampling should be carried out in accordance with BS 7592:2008 and all analysis by a UKAS accredited laboratory.	There is a sampling regime in place at present for designated 'High Risk' areas though we would advise this list is re-evaluated to ensure it is fit for purpose as the purpose of wards and designation of 'High Risk' changes. Pseudomonas and other bacterial samples are taken on a as requested from infection control. Given the user groups of site and the gaps identified with the PPM programmes we would advise a program of Legionella sampling (and other bacteria as advised by Infection Control e.g. Pseudomonas) sampling is carried out throughout site and the 'High Risk' sampling program reformulated as required. In addition, DMA noted during a 2015 Risk Assessment that the filter systems had been bypassed introducing unfiltered water into the system for an unknown length of time – no details of additional microbiological sampling being completed at this time (or should this have re-occurred) have been made available. In "High Risk" areas DMA are advised every water outlet is being sampled over a period of two years (with temperatures being recorded). Samples are both first flush and 2 minute flush samples. For pseudomonas (and other) sampling we would advise input from infection control and microbiologists to determine the sampling regime which should be put in place and any appropriate remedial actions required in light of out of specification results.

Summary of ppm tasks required within site written scheme to aid compliance with SHTM 04-01 and L8/HSG 274 (cont…)	**In place or being carried at present?**
[c] Pasteurisation/disinfection of calorifier/water heaters carried out as and when required dependent on temperature monitoring and sample results	Not being carried out at present.
Turnover test on cold water storage system. Checks should be carried out to ensure that volume of water stored is no more than would generally be used in a normal 12 hour period.	No records of a turnover test (or water meters readings/flow meter readings which could provided similar information)
As required descaling of taps/outlets (including aerators and flow straighteners) (frequency dependent on inspection results and hardness of water on site)	No inspections records and/or instances of taps being scaled have been recorded by or reported to estates however it should be confirmed that this is included in site inspections.
All EPDM flexi hoses (where fitted to articulated taps/outlets e.g. assisted baths) should be WRAS approved and should be regularly inspected	Flexible hoses fitted in some non-clinical areas though no record of inspection.
All plant items should be maintained in accordance with manufacturer's instructions and maintenance schedules, with tasks/duties allocated and recorded.	Further review of manufacturers/installers instructions required.
Filtration equipment (Elga) – maintain in accordance with manufacturers guidelines, ensuring alteration of filtration sets to run at least daily. (DMA advised 9 hourly swap over).	Filtration units swapped automatically by BEMS system. Veolia maintaining filtration unit though details of maintenance specification not available to confirm this fully satisfies the manufacturer's instructions.

System/ service	Task	Minimum Frequency	In place or being carried at present?
MRI Chillers Wet/Dry (Adiabatic) Cooling)	Depending on the actual design and operation of these units they may require to be registered with the local authority under the NCTEC Notification Requirements (See HSG 274 Part 1 Para 1.18 – 1.21 inclusive of Figure 1.4 and Info Box 1.1). These may also require ongoing treatment or monitoring programmes to be implemented depending on assessment. Maintain in accordance with manufacturers/installers instructions. Consider use of POU disinfection system such as UV for spray water.	TBC	DMA were advised by Estates (Ian Powrie) these are not adiabatic chillers and the water supply is a back-up should cooling fail at which point wholesome water would be drawn into the system and run 'once through' to drain. No details of any maintenance procedures in place.
	Connection point to MRI unit(s) should be included in site flushing regime or have suitable backflow protection fitted at the connection point (or RPZ moved to tee-off). Ensure aerosol creation minimised when running to drain in emergency use – consider disinfection of system prior to instatement of emergency loop.	Twice weekly as part of site flushing regime	Not included at present. These should be formally included in site flushing regime. In addition, the RPZ valve on the supply should be serviced annually.
Emergency Showers	HSG 274 Part 3 recommends minimum six monthly flushing of emergency/deluge shower, though Risk Control Notice 11/advises "flush through and purge to drain twice per week– source SHTM 04-01 Part G (Draft). NHS Estates should formulate an appropriate flushing regime and maintain in accordance with manufacturers/installers instructions.	Twice weekly as part of site flushing regime	Intermittent flushing at present. These should be formally included in site flushing regime.
Dental Chairs/System	HSG 274 Part 3 states "Drain down, clean, flush and disinfect all system components, pipework and bottles twice daily. Disinfectant contact time as recommended by manufacturer. Take microbiological measurements (Refer to Decontamination HTM 01-05)	Twice daily	No information on this at present. Estates have not carried out any work on these systems and advise these should be managed by "clinical" staff. It should also be confirmed whether the CWST 'break tank' is to be inspected and maintained by Estates or clinical staff and this information include in the Written Scheme.
	SHTM 04-01 Part G (Draft) states "Drain down and clean at the end of each working day".	Daily	
	HTM 01-05 provides advice and recommendations for on-going maintenance and this should be followed in addition to manufacturers and installers instructions.	As per manufacturers/ installers instructions.	
	Take microbiological measurements – refer to *Decontamination Health Technical Memorandum 01-05: Decontamination in primary care dental practices*[5]	As indicated by bespoke risk assessment *(to be carried out by others)*	
Hydrotherapy Pool	Maintain in accordance with manufacturers/installers instructions and "PHLS Hygiene for Hydrotherapy Pools" and Pool Water Treatment Advisory Group (PWTAG) Code of Practice (Feb 2015).	Bespoke written scheme should be created for the hydrotherapy pool based on PHLS/PWTAG and manufacturers/ installers instructions.	Daily checks carried out by estates staff and clinical staff however there is no operational manual/written scheme in place formalising responsibilities, PPMs etc and management responsibilities appear disjointed with little feedback between different stakeholders. A Legionella Risk Assessment has been commissioned by Estates for the pool by the Brio Group and will provide further information.

System/ service	Task	Minimum Frequency	In place or being carried at present?
Air Conditioning & Ventilation	Maintain in accordance with manufacturers/installers instructions and SHTM 03-01 and SHTM 04-01 Part G (Draft).	Maintenance regime/Written Scheme should be created based on SHTMs and manufacturers/installers instructions.	No information provided by Estates though DMA previously advised a Written Scheme in accordance with SHTM 03-01 was being introduced.
	This may include:		
	Inspect, clean & log glass traps	Monthly	No information available from Estates.
	Humidity Section Inspection, Cooling Section Inspection and Ventilation Plant Inspection and Disinfection	Six monthly	No information available from Estates.
Steam Humidification	Maintain in accordance with manufacturers/installers instructions and SHTM 03-01 and SHTM 04-01 Part G (Draft). Offline at time of survey.	Maintenance regime/Written Scheme should be created based on SHTMs and manufacturers/ installers instructions.	No information available from Estates.
Medical Gases/Medical Equipment (e.g. Nebulisers, incubators, etc.)	Conduct a risk assessment of each system, preferably using an assessment team comprising members knowledgeable in legionella management and control, as well as those familiar with the design and operation of the system and Infection Control/Clinical staff where appropriate. Control procedures within appropriate SHTM (or other relevant guidance) for system being assessed should be taken in to account during assessment(s). Any water softeners or other filtration equipment connected to these systems should be assessed at this time. Devise a control scheme based on the risk assessment.	Monitoring, inspection, and testing frequencies to be determined as indicated by bespoke risk assessment *(to be carried out by others)*	No information available from Estates.
Sprinkler System	Consider clean and disinfection of the CWST and then regular inspection as per domestic water tanks with cleaning/disinfection as required by inspection. Minimise aerosol creation during maintenance procedures. Consider wearing suitable masks to prevent ingestion as recommended by the FIA guidance. Maintain in accordance with manufacturers/installers instructions	As per manufacturers/ installers instructions.	Estates unable to confirm testing procedures – information to be provided for assessment.

System/ service	Task	Minimum Frequency	In place or being carried at present?
12th Floor Heli-pad fire suppression system	We would advise the CWST is cleaned and disinfected (though it should be remembered that the fire system would be out of use during such works). Minimise aerosol creation during maintenance procedures. Consider wearing suitable masks to prevent ingestion as recommended by the FIA guidance. Maintain in accordance with manufacturers/installers instructions. Ensure all points on the trades system (including inlet to fire tank) in site flushing regime. Consider implementing a sampling regime to include the storage tank and points on the system and the supply. This would be particularly important during summer months where ambient temperatures are likely to be higher. We would also advise temperature monitoring and visual inspection should be carried out on the Storage Tank on a weekly basis prior to testing and should the storage temperature exceed 20ºC then additional precautions should be considered (E.g. flush the tank to reduce stored water temperature, manually dose tank with suitable disinfectant chemical if no automated system installed) Given the potential control issues described above, but the need for such a system to be in place, it would be prudent to consider a permanent chemical dosing system for this water system (though it should be confirmed that any chemicals used on this system would not interfere with the foam used for emergencies)	As per manufacturers/ installers instructions.	DMA advised this system is tested by the porters on a weekly basis – please refer to DMA Risk Assessment for recommendations.
Irrigation System	Include in site flushing regime. Additional flushing may also be required (outlets run for extended periods) to bring temperatures on distribution system down particularly during periods of low use (e.g. in winter when irrigation system is not required to operate frequently). Maintain in accordance with manufacturers/installers instructions.	Twice weekly as part of site flushing regime	DMA advised by Estates (Ian Powrie) these systems have been disconnected. Old connection points should be removed leaving no deadlegs or included in site flushing regime. CWST capacity should also be altered as required by turnover test.
Water Softeners	Maintain in accordance with manufacturers/installers instructions (including cleaning and disinfection of resin and brine tanks). Ensure aerosol creation is minimised during maintenance and testing procedures.	As per manufacturers/ installers instructions.	As per other installed equipment maintenance schedules allocation of responsibilities unclear at this time. This requires to be formalised and PPM schedule created.
Endoscopy Wash	Maintain in accordance with manufacturers/installers instructions and current NHS (SHTM) protocols. Ensure aerosol creation is minimised during maintenance and testing procedures.	Maintenance regime/Written Scheme should be created based on SHTMs and manufacturers/ installers instructions.	DMA advised this is a clinical responsibility with no input from estates.
Renal Dialysis (Adult)	Maintain in accordance with manufacturers/installers instructions, current NHS (SHTM) protocols and "Clinical Practice Guideline by the UK Renal Association of Renal Technologists". Ensure aerosol creation is minimised during maintenance and testing procedures.	Maintenance regime/Written Scheme should be created based on SHTMs and manufacturers/ installers instructions.	DMA advised this is a clinical responsibility with no input from estates.
System/ service	**Task**	**Minimum Frequency**	**In place or being carried at present?**

Renal Dialysis (Adult) – Emergency Points	Ensure included in site flushing regime	Twice Weekly	Estates unable to confirm this is being completed.
Renal Dialysis (Children's)	Maintain in accordance with manufacturers/installers instructions, current NHS (SHTM) protocols and "Clinical Practice Guideline by the UK Renal Association of Renal Technologists". Ensure aerosol creation is minimised during maintenance and testing procedures.	Maintenance regime/Written Scheme should be created based on SHTMs and manufacturers/ installers instructions.	DMA advised this is a clinical responsibility with no input from estates.
Arjo Bath	Maintain in accordance with manufacturers/installers instructions. Where flexible hoses (i.e. internal to bath unit) cannot be removed then replacing with alternative WRAS approved hoses with linings other than EPDM should be considered.	As required	These are maintained by a sub-contractor, though as per other installed equipment the details of maintenance contracts have not been formalised.
Closed Chilled Systems	Minimise aerosol creation during maintenance procedures. Maintain in accordance with manufacturers/installers instructions.	As required	No details over biocide dosing or maintenance procedures
Closed Heating Systems	Minimise aerosol creation during maintenance procedures. Maintain in accordance with manufacturers/installers instructions.	As required	No details over biocide dosing or maintenance procedures
Decorative Bubble Lamps	Maintain in accordance with manufacturers/installers instructions and ensure aerosols minimised during maintenance.	As required	No information available from Estates.

Section 10

Written Scheme Guidance

A Written Scheme guidance was issued by DMA in 2015 though has not been updated as anticipated to be fully utilised as the Written Scheme for site, and become the overarching control document for Legionella control. NHS Greater Glasgow Estates have since issued a general 'Written Scheme' to be implemented on each of their sites however, DMA are awaiting feedback from NHS Estates (Compliance Team) on a number of queries raised before any changes are made to make this site specific. A draft document for discussion has been supplied to Phyllis Urquhart and DMA are awaiting feedback on this.

We would advise corrective actions are taken as a matter of immediate urgency to ensure an accurate and compliant Written Scheme is compiled and the appropriate PPM schedule implemented.

Section 11

Photographic Appendix

No photographs included in draft copy – CWST inspection photographs provided previously to Tommy Romeo

Section 12

Guidance to L8 and Legionnaires Disease

Legionnaires' Disease

Legionnaires' disease is a potentially fatal form of pneumonia which can affect anybody, but which principally affects those who are susceptible because of age or illness.

This is caused by the bacterium Legionella pneumophila, though other legionella bacteria have also been implicated.

Background information

- Legionnaires disease was first identified following a large outbreak of pneumonia among people who attended an American legion convention in Philadelphia in 1976. A previously unrecognised bacterium was isolated from lung tissue samples which was subsequently named Legionella pneumophila.

- It is normally contracted by inhaling legionella bacteria, either in tiny droplets of water (aerosols), also by aspiration, or in droplet nuclei (the particles left after the water has evaporated) contaminated with legionella, deep into the lungs. There is evidence that the disease may also be contracted by inhaling legionella bacteria following ingestion of contaminated water by susceptible individuals. Person to person spread of the disease has not been documented. Initial symptoms of Legionnaires' disease include high fever, chills, headache and muscle pain. Patient may develop a dry cough and most suffer difficulty with breathing. About one third of patients infected also develop diarrhoea or vomiting and about half become confused or delirious. Legionnaires' disease can be treated affectively with appropriate antibiotics.

- The incubation period is between 2-10 days (usually 3-6 days). Not everyone exposed will develop symptoms of the disease and those that do not develop the 'full blown' disease may only present with a mild flu-like infection

- Infection with legionella bacteria can be fatal in approximately 12% of reported case. This rate can be higher in a more susceptible population; for example, immunosuppressed patients or those with underlying disease. Certain groups of people are known to be higher at risk of contracting Legionnaires' disease; for example, men appear more susceptible than women, as do those over 45 years of age, smokers, alcoholics, diabetics and those with cancer or chronic respiratory or kidney disease.

On average, there are approximately 200 - 250 reported cases in England and Wales per annum with approximately 12% fatalities, though it is now believed this may be under-reported by a factor of ten.

Legislation/Regulations[1]

- Legionnaires' disease – The control of legionella bacteria in water systems **(L8 – 4th Edition)**
- HSG 274 Parts 1 – 3 - Legionnaires' disease: Technical guidance
- Health and Safety at Work etc. Act 1974 (Sections 2, 3 4 and 6)
- Management of Health and Safety at Work Regulations 1999
- Control of Substances Hazardous to Health Regulations 2002
- BS 8580:2010 Water quality – Risk assessments for Legionella control – Code of practice
- The Notification of Cooling Towers and Evaporative Condensers Regulations 1992 (Regulations 6, 7, 8, 9 and 12)
- HTM/SHTM 04-01 - The control of Legionella, hygiene, 'safe' hot water, cold water and drinking water systems[2]
- Other relevant standards as applicable to site/system[3] (e.g. BS EN 806, BS 8558)

[1] Other advisory notes or technical memorandums issued may also be relevant for assessment and control purposes.
[2] HTM/SHTM 04-01 refers to healthcare premises only.
[3] Information provided in this section is for basic guidance only. The Dutyholder/Responsible Person should refer to the appropriate guidance documents as listed above for complete guidance.

Introduction to L8

Legionnaires' disease – the control of legionella bacteria in water systems (L8) came into effect on the 8th of January 2001 and is commonly referred to as **L8**.

By virtue of section 16(4) of the Health and Safety at Work etc Act 1974, and with the consent of the Secretary of State for Work and Pensions, the Health and Safety Executive has on 30 October 2013 approved the revised Code of Practice entitled *Legionnaires' disease: The control of legionella bacteria in water systems* (L8 - 4th Edition)

The revised Code of Practice gives practical guidance with respect to sections 2, 3, 4 and 6 of the Health and Safety at Work etc Act 1974, regulations 6, 7, 8, 9 and 12 of the Control of Substances Hazardous to Health Regulations 2002 (COSHH) and guidance on compliance with the relevant parts of the Management of Health and Safety at Work Regulations 1999.

By virtue of section 16(5) and with the consent of the Secretary of State for Work and Pensions under that paragraph, the Health and Safety Executive has withdrawn its approval of the Code of Practice entitled *Legionnaire's disease: The control of legionella bacteria in water systems* (L8), which came into effect on 8 January 2001 which shall cease to have effect on 25 November 2013.

The Code of Practice came into effect on 25 November 2013, with HSG 274 Parts 1 & 3 being issued at the same time, and HSG 274 Part 2 being issued in April 2014.

The 4th Edition of L8 was issued along with HSG 274 Legionnaires' disease: Technical guidance.

HSG 274 is separated into 3 parts:

Part1: The control of legionella bacteria in evaporative cooling systems

Part 2: The control of legionella bacteria in hot and cold water systems

Part 3: The control of legionella bacteria in other risk systems

The Code has been approved by the Health and Safety Executive, with the consent of the Secretary of State. It gives practical advice on how to comply with the law. If you follow the advice you will be doing enough to comply with the law in respect of those specific matters on which the Code gives advice. You may use alternative methods to those set out in the Code in order to comply with the law.

However, the Code has a special legal status. If you are prosecuted for breach of health and safety law, and it is proved that you did not follow the relevant provisions of the Code, you will need to show that you have complied with the law in some other way or a Court will find you at fault.

The guidance is issued by the Health and Safety Executive. Following the guidance is not compulsory, unless specifically stated, and you are free to take other action. But if you do follow the guidance you will normally be doing enough to comply with the law. Health and safety inspectors seek to secure compliance with the law and may refer to this guidance.

ACoP L8 (and HSG 274) applies whenever water is stored or used in a way that may create a reasonably foreseeable risk of legionellosis. In particular it applies to the following plant;

- Hot and cold water systems
- Evaporative cooling systems
- Ultrasonic humidifiers/foggers and water misting systems
- Spray humidifiers
- Air washers, wet scrubbers, particle and trivial gas scrubbers
- Water softeners
- Emergency showers/eye baths and face wash fountains
- Sprinkler and hose reel systems
- Spa pools
- Whirlpool baths
- Horticultural misting systems
- Dental equipment
- Industrial process water systems
- Misting devices used for humidifying vegetables, meat and other food products;
- Vehicle washers including automatic washers for cars, buses, lorries and railway rolling stock;
- Powered dental equipment;
- Fountains and decorative water features including those on display for sale;
- Non-disposable nebulisers used for respiratory therapy;
- Industrial effluent treatment plants;
- Irrigation systems;
- Fire, dust and odour suppression systems;
- Paint spray preparation equipment;
- Tunnel pasteurisers and similar equipment.

Whilst this is not an exhaustive list, it does identify those systems which are most likely to cause infection. Consideration should also be given to other systems, which can release spray or aerosol during operation, maintenance and testing e.g.

- Machine coolants
- Recycled water systems
- Closed water systems
- Any other systems which could potentially be colonised and create respirable aerosols (i.e. 'at-risk')

The scope of a legionellosis risk assessment is defined in ACoP L8, paragraphs 28-47 (inclusive).

In December 2010, BS 8580:2010 was issued which provides practical guidance on carrying out L8 risk assessments and should be complied with as far as is practical when carrying out risk assessments.

Management responsibilities, training and competence

Inadequate management, lack of training and poor communication are all contributory factors in outbreaks of legionnaires' disease. It is therefore important that the people involved in assessing risk and applying precautions are competent, trained and aware of their responsibilities.

Communications and management procedures are particularly important where several people are responsible for different aspects of the operational procedures. For example, responsibility for applying control measures may change when shift work is involved, or when the person who monitors the efficacy of a water treatment regime may not be the person who applies it. In such circumstances, responsibilities should be well defined in writing and understood by all concerned. Lines of communication should be clear, unambiguous and audited regularly to ensure they are effective. This also applies to outside companies and consultants who may be responsible for certain parts of the control regime.

Employing contractors or consultants does not absolve the dutyholder of responsibility for ensuring that control procedures are carried out to the standard required to prevent the proliferation of legionella bacteria. Dutyholders should make reasonable enquiries to satisfy themselves of the competence of contractors in the area of work before they enter into contracts for the treatment, monitoring, and cleaning of the water system, and other aspects of water treatment and control. An illustration of the levels of service to expect from Service Providers can be found in the Code of Conduct administered by the Legionella Control Association (LCA).

If the assessment shows that there is a reasonably foreseeable risk and it is reasonably practicable to prevent exposure or control the risk from exposure, the dutyholder under paragraph 28 of ACOP L8 should appoint a competent person or persons to help undertake the measures needed to comply with the requirements in COSHH. The appointed competent person or persons should have sufficient authority, competence and knowledge of the installation to ensure that all operational procedures are carried out in a timely and effective manner. Where the dutyholder does not employ anyone with the necessary competence, they may need to appoint people from outside the organisation. In such circumstances, the dutyholder should take all reasonable steps to ensure the competence of those carrying out work who are not under their direct control and that responsibilities and lines of communication are properly established and clearly laid down.

Those appointed under paragraph 48 of ACOP L8 to carry out the risk assessment and draw up and implement precautionary measures should have such ability, experience, instruction, information, training and resources to enable them to carry out their tasks competently and safely. In particular, they should know the:

a) potential sources of legionella bacteria and the risks they present;
b) measures to adopt, including the precautions to take to protect the people concerned, and their significance;
c) measures to take to ensure that the control measures remain effective, and their significance.

The dutyholder should also ensure that all employees involved in work that may expose an employee or other person to legionella are given suitable and sufficient information, instruction and training. This includes information, instruction and training on the significant findings of the risk assessment and the appropriate precautions and actions they need to take to safeguard themselves and others. This should be reviewed and updated whenever significant changes are made to the type of work carried out or methods used. Training is an essential element of an employee's capability to carry out work safely, but it is not the only factor: instructions, experience, knowledge and other personal qualities are also relevant to perform a task safely.

Additional information relating to management responsibilities, training and competence can be found in ACOP L8 paragraphs 48-57 (inclusive)

Dutyholder

Under general health and safety law, as an employer or person in control of a premises (eg a landlord), the dutyholder has health and safety duties and needs to take suitable precautions to prevent or control the risk of exposure to legionella. Details of the specific law that applies can be found in L8 Legionnaires' disease: The control of legionella bacteria in water systems.

Carrying out a risk assessment is the responsibility of the dutyholder and will help to establish any potential risks and implement measures to either eliminate or control risks. The dutyholder may be competent to carry out the assessment themselves but, if not, someone with the necessary skills to conduct a risk assessment should be contracted to do so. This can be done by someone from within the dutyholders organisation or from someone outside, eg an external consultant.

Note 1 The dutyholder is the employer where the risk is from their undertakings to their staff or others, the self-employed person where the risk is from their undertaking to themselves or others, or the person in control of the premises where the risk is from systems in the building (e.g. A landlord who remains responsible for the maintenance of the systems)

Note 2 In most cases there will be only one dutyholder, but in cases of shared accommodation there could be shared responsibility. The dutyholder cannot delegate this duty, but can delegate managerial responsibility to the responsible person

Further information is available in the HSE leaflet *Legionnaires' disease: A brief guide for dutyholders* and at www.hse.gov.uk/legionnaires/index.htm.

Responsible Person

The dutyholder should specifically appoint a competent person or persons to take day-to-day responsibility for controlling any identified risk from legionella bacteria, known as the 'responsible person'. It is important for the appointed responsible person to have *sufficient authority, competence and knowledge of the installation* to ensure that all operational procedures are carried out effectively and in a timely way. Those specifically appointed to implement the control measures and strategies should be suitably informed, instructed and trained and their suitability assessed. They must be properly trained to a level that ensures tasks are carried out in a safe, technically competent manner; and receive regular refresher training. Keep records of all initial and refresher training. If a dutyholder is self-employed or a member of a partnership, and is competent, they may appoint themselves. The appointed responsible person should have a clear understanding of their role and the overall health and safety management structure and policy in the organisation. See *Managing for health and safety at work* for further guidance.

Note 1 In a large undertaking there may be more than one responsible person, each responsible for a part of the undertaking, e.g. each block of a large teaching hospital

Record keeping

L8 require employers, where they have five or more employees, to record the significant findings of their risk assessment and the steps taken to prevent exposure to substances hazardous to health. Employers are also required to keep suitable records of examinations, tests and repairs of control measures.

Records should include details about:

a) the appointed responsible person(s) for conducting the risk assessment, managing, and implementing the written scheme;
b) any significant findings of the risk assessment;
c) the written scheme and its implementation;
d) details about the state of operation of the water system, ie in use/not in use;
e) the results of any monitoring inspection, test or check carried out, and the dates.

The following items should normally be recorded:

a) names and positions of people responsible, and their deputies, for carrying out the various tasks under the written scheme;
b) a risk assessment and a written scheme of actions and control measures;
c) schematic diagrams of the water systems;
d) details of precautionary measures that have been applied/implemented including enough detail to show that they were applied/implemented correctly, and the dates on which they were carried out;
e) remedial work required and carried out, and the date of completion;
f) a log detailing visits by contractors, consultants and other personnel;
g) cleaning and disinfection procedures and associated reports and certificates;
h) results of the chemical analysis of the water;
i) results of any biological monitoring;
j) information on other hazards, eg treatment chemicals;
k) cooling tower and evaporative condenser notification;
l) training records of personnel;
m) the name and position of the person or people who have responsibilities for implementing the written scheme, their respective responsibilities and their lines of communication;
n) records showing the current state of operation of the water system, eg when the system or plant is in use and, if not in use, whether it is drained down;
o) either the signature of the person carrying out the work, or other form of authentication where appropriate.

Records should be retained throughout the period they are current and for at least two years afterwards. Retain records of any monitoring inspection, test or check carried out, and the dates, for at least five years.

Information relating to Record Keeping is provided in in ACoP L8, paragraphs 70-74 (inclusive).

Risk Assessment

All systems require a risk assessment, however not all systems will require elaborate control measures. A simple risk assessment may show that the risks are low and being properly managed to comply with the law. In such cases, you may not need to take further action, but it is important to review your assessment regularly in case of any changes in your system, and specifically if there is reason to suspect it is no longer valid. There is more information specifically for those in control of premises, eg landlords, in *Part 2: Hot and cold water systems* at www.hse.gov.uk/pubns/books/hsg274.htm and at www.hse.gov.uk/legionnaires/what-you-must-do.htm.

A suitable and sufficient assessment must be carried out to identify and assess the risk of exposure to legionella bacteria from work activities and water systems on the premises and any precautionary measures needed. The dutyholder is responsible for ensuring the risk assessment is carried out. The dutyholder is either:
(a) the employer, where the risk from their undertaking is to their employees or others; or
(b) a self-employed person, where there is a risk from their undertaking to themselves or others; or
(c) the person who is in control of premises or systems in connection with work, where there is a risk from systems in the building, eg where a building is let to tenants, but the landlord keeps responsibility for its maintenance.

The risk assessment should identify and evaluate potential sources of risk and:

a) the particular means of preventing exposure to legionella bacteria; or
b) if prevention is not reasonably practicable, the particular means of controlling the risk from exposure to legionella bacteria.

The risk assessment should take into account the individual nature of each site and consider the system as a whole and not, eg the cooling tower in isolation. In complex systems, a site survey of all the water systems should be carried out, including an asset register of all associated plant, pumps, strainers and other relevant items. This should include an up-to-date schematic diagram showing the layout of the plant or system, including parts temporarily out of use.

The dutyholder under paragraph 28 should, with the help of the appointed responsible person, make reasonable enquiries to ensure that organisations such as water treatment companies or consultants, and staff from the occupier's organisation, are competent and suitably trained and have the necessary equipment to carry out their duties in the written scheme safely and adequately.

The risk assessment also enables the dutyholder to show they have considered all the relevant factors, and the steps needed to prevent or control the risk.

The assessment should be reviewed regularly and specifically when there is reason to believe that the original risk assessment may no longer be valid. You should also review management and communication procedures as appropriate.

Some of the factors to consider, as appropriate, when carrying out the risk assessment:

a) the source of system supply water, eg whether from a mains supply or not;
b) possible sources of contamination of the supply water in the premises before it reaches the cold water storage tank, calorifier, cooling tower or any other system using water that may present a risk of exposure to legionella bacteria;
c) the normal plant operating characteristics;
d) unusual, but reasonably foreseeable operating conditions, eg breakdowns;
e) any means of disinfection in use;
f) the review of any current control measures;
g) the local environment.

Factors to be considered in the risk assessment

There is a chain of events which can lead to infection by legionella, which should be considered in any risk assessment process:

A. The presence of legionella bacteria (Contamination)

Water systems can be contaminated by legionella by the water source feeding the system. Whilst town mains will have a relatively low potential for contaminating the system, it may be assumed that low levels of legionella may on occasion enter the system via the town mains. Natural water sources such as springs, rivers, lakes and bores holes will have a significantly higher potential for introducing legionellae into the water system. Other potential sources of contamination include dust/dirt in the air entering via uncovered cisterns or overflows, or from the construction process.

It must therefore be assumed that it is not practical to prevent legionella from contaminating the system at some point.

B. Conditions suitable for the growth of organisms (Amplification)

In order for legionella to multiply in water systems, sufficient nutrients and physico-chemical conditions require to be met. Temperature is particularly critical with legionella growth likely between 20°c & 45°c, with the most rapid growth occurring between 32°c and 42°c.

Areas of stagnation or low flow which can increase bio-film formation and or sedimentation can also increase the potential for amplification

Nutrients within the system (dirt, rust etc.) Are also contributory factors in the amplification of legionella within water systems, and the minimisation of legionella amplifying conditions within water systems is of critical importance

C. A Means of creating and spreading breathable droplets (Transmission)

The vast majority of cases of legionnaires disease are caused by the infected person inhaling contaminated water which has been aerosolised. Other cases have been caused by contaminated drinking water being aspirated into the lungs rather than just going into the stomach, and from breathing in contaminated dust from compost.

Any process which causes aerosols to be created will therefore increase the potential transmission of legionella to humans, though consideration of aspiration must be considered, especially in potentially immunocompromised or high risk groups. The higher the density of aerosols created the larger the number of people potentially affected.

D. The presence (and numbers) of people who may be exposed (Exposure)

The closer the person is to a contaminated source aerosol the higher the chance of the person inhaling the aerosol before it disseminates and the bacteria die. For example, in spa baths or using cutting tools, if the liquid is contaminated then the user is very close to the aerosol created and is much more likely to inhale the contaminated droplets. Those farther away form the aerosol are less likely to be affected. However, where large volumes of aerosols are created, which can be disseminated over large areas (e.g. Cooling towers) then the potential for people to come into contact with the contaminated aerosol increases.

This exposure risk must be considered for all aspects of the system operation. Where a system does not under normal circumstances create an aerosol, it may during maintenance tasks create aerosols can be created and can therefore create a potential for inhalation of contaminated droplets.

E. Susceptibility

Some individuals are more likely to become infected than others. This susceptibility increase with age, and whether or not a person smokes or is immune-compromised. Males are also much more likely to be infected than females.

The nature and proximity of individuals to a potentially contaminated system must be considered and where persons who would be considered as high risk are in the proximity of the system then more stringent control of the potential risk may be required.

Information relating to the identification and assessment of the risk can be found in ACoP L8, paragraphs 28-47 (inclusive).

Grading policy

The aim of a legionella risk assessment is to identify all plant and services and make an assessment of the actual risk posed by the systems. In assigning the actual risk, the condition of the plant, maintenance procedures, location, and compliance with current guidelines/codes of practice etc. should be considered.

The actual risk posed by the water systems and plant and services being assessed are based on the ratings from the tables below:

	Condition of system being assessed (deficiencies/non-compliances found)				
Potential for system to pose a hazard	**Negligible**	**Minor**	**Moderate**	**Major**	**Extreme**
Rare	**Low**	**Low**	**Low**	**Low**	**Medium**
Unlikely	**Low**	**Low**	**Medium**	**Medium**	**High**
Possible	**Low**	**Medium**	**Medium**	**High**	**High**
Likely	**Low**	**Medium**	**High**	**High**	**V high**
Almost certain	**Medium**	**High**	**High**	**V high**	**V high**

Risk guidance notes	**Either no recommendations or a small number of minor recommendations, which focus on minor quality improvement issues. Minor non-compliance with standards only**	**Recommendations made which can be addressed by low level management action, or minor remedial actions required. Non-compliance with standards**	**Challenging recommendations that can be addressed with appropriate action plan and/or major remedial actions required. Non-compliance with core standards**	**Critical reports of major/urgent remedial works being required. Major non-compliance with core standards**

Recommendations shall be made to accompany risk ratings where appropriate.

Recommendations

Recommendations to minimise the actual risk, which may involve changes/remedial actions to the plant and/or upgrading of maintenance regimes and documentation procedures etc. are included within relevant sections of this document. The conclusions and recommendations contained in this assessment are based upon information supplied by the sites responsible person and/or his/her deputies and the assessors findings at the time of survey. Should further information subsequently become available which may impact on this assessment, a review of the assessment may be required.

Remedial Action Category	Recommended Remedial Action Timescale	Action
1	**Immediately / as soon as reasonably practicable**	**Urgent Significant Investigation & Urgent Remedial Action Required.** Carryout review of control procedures. Recommendations within this category should be carried out immediately/as-soon as-is-reasonably practicable. where appropriate remedial actions to rectify the faults cannot be taken **immediately/as-soon as-is-reasonably practicable** alternative actions to reduce the risk should be carried out, and continue to be carried out, until such times as recommended actions can be completed. Senior Management action may be required.
2	**As soon as reasonably practicable**	**Significant Investigation & Remedial Action Required.** Carryout review of control procedures. Recommendations within this category should be carried out **as-soon as-is-reasonably practicable**. Where appropriate remedial actions to rectify the faults cannot be carried out quickly, alternative actions to reduce the risk should be carried out, and continue to be carried out, until such times as recommended actions can be completed. Senior Management action may be required.
3	**Within 3 months**	**Investigate/Reduce.** Remedial actions required. Recommendations within this category should be carried out in a timely manner, though simple and/or inexpensive tasks which would reduce the risk should be carried out as-soon-as-reasonably-practicable (e.g. **Within 3 months**). Additional monitoring/inspection to ensure risk does not increase should be carried out until actions completed. Management responsibility should be specified if required.
4	**At first available opportunity**	**Maintain Level** Whilst recommendations within this category do not significantly alter the risk it is still advised that these actions are carried out **at first available opportunity**, typically within a 12 month period of recommendations being made. Many of the recommendations within this category can be managed by routine Planned Preventative Maintenance (PPM).

Bacterial Analysis for Hot & Cold Water Systems

Microbiological analysis

DMA would advise that routine sampling can provide valuable information regarding the condition of water services and efficacy of the L8/HSG 274/(S)HTM 04-01 monitoring regime and/or highlight issues which require further corrective actions.

HSG 274 Part 2: The control of legionella bacteria in hot and cold water systems states:

> *Microbiological monitoring of domestic hot and cold water supplied from the mains is not usually required, unless the risk assessment or monitoring indicates there is a problem. The risk assessment should specifically consider systems supplied from sources other than the mains, such as private water supplies, and sampling and analysis may be appropriate.*
>
> *Legionella monitoring should be carried out where there is doubt about the efficacy of the control regime or it is known that recommended temperatures, disinfectant concentrations or other precautions are not being consistently achieved throughout the system. The risk assessment should also consider where it might also be appropriate to monitor in some high risk situations, such as certain healthcare premises. The circumstances when monitoring for legionella would be appropriate include:*
>
> - *water systems treated with biocides where water is stored or distribution temperatures are reduced. Initial testing should be carried out monthly to provide early warning of loss of control. The frequency of testing should be reviewed and continued until such a time as there is confidence in the effectiveness of the regime;*
> - *water systems where the control levels of the treatment regime, eg temperature or disinfectant concentrations, are not being consistently achieved. In addition to a thorough review of the system and treatment regimes, frequent testing, eg weekly, should be carried out to provide early warning of loss of control. Once the system is brought back under control as demonstrated by monitoring, the frequency of testing should be reviewed;*
> - *high-risk areas or where there is a population with increased susceptibility, e.g. in healthcare premises including care homes;*
> - *water systems suspected or identified in a case or outbreak of legionellosis where it is probable the Incident Control Team will require samples to be taken for analysis*
>
> *Where monitoring for legionella is considered appropriate in hot and cold water systems, sampling should be carried out in accordance with BS 7592:2008 Sampling for Legionella organisms in water and related materials. The complexity of the system will need to be taken into account to determine the appropriate number of samples to take. To ensure the sample is representative of the water flowing around the system and not just of the area downstream of the fitting, samples should be taken from separate hot and cold outlets rather than through mixer taps or outlets downstream of TMVs or showers. Samples should be clearly labelled with their source location and if collected pre- or post-flushing.*
>
> *In both hot and cold water systems, samples should be taken:*
>
> - *if considered necessary by the risk assessment;*
> - *from areas where the target control parameters are not met (i.e. where disinfectant levels are low or where temperatures are below 50°C (55°C in healthcare premises) for HWS or exceed 20°C for cold water systems);*
> - *from areas subject to low usage, stagnation, excess storage capacity, dead legs, excessive heat loss, crossflow from the water system or other anomaly.*
>
> *In cold water systems, samples should also be taken as required:*
>
> - *from the point of entry (or nearest outlet) if the water is supplied from a private water supply or where the temperature of the incoming mains supply is above 20 °C from the cold water storage tank or tanks;*
> - *from the furthest and nearest outlet on each branch of the system (far and near sentinel outlets).*

In hot water systems, samples should also be taken as required:

- *from the calorifier hot water outlet and from the base of the calorifier, if it safe to do so, as some systems are under considerable pressure;*
- *from the furthest and nearest outlet on each branch of a single pipe system (far and near sentinel outlets);*
- *from the furthest and nearest outlet on each loop of a circulating system (far and near sentinel outlets).*

Action levels following legionella sampling in hot and cold water systems

	Legionella bacteria (cfu/litre)	**Action required**
Healthcare premises only	*Not detected or up to 100 cfu/l*	*In healthcare, the primary concern is protecting susceptible patients, so any detection of legionella should be investigated and, if necessary, the system resampled to aid interpretation of the results in line with the monitoring strategy and risk assessment*
All Premises (Including Healthcare)	*>100 cfu/l and up to 1000*	*Either:* • *if the minority of samples are positive, the system should be resampled. If similar results are found again, a review of the control measures and risk assessment should be carried out to identify any remedial actions necessary or* • *if the majority of samples are positive, the system may be colonised, albeit at a low level. An immediate review of the control measures and risk assessment should be carried out to identify any other remedial action required. Disinfection of the system should be considered*
	>1000 cfu/l	*The system should be resampled and an immediate review of the control measures and risk assessment carried out to identify any remedial actions, including possible disinfection of the system. Retesting should take place a few days after disinfection and at frequent intervals afterwards until a satisfactory level of control is achieved.*

N.B. Limits in table above set out in HSG 274 Part 2: The control of legionella bacteria in hot and cold water systems. Due to growth periods of the legionella organism and time taken for legionella analysis to be completed DMA would advise that action should be undertaken on any legionella positive samples.

Please note:

1. Analysis of water samples for legionella should be carried out by a UKAS accredited laboratory.
2. Analysis of water samples for TVC (Potable) quality should be carried out by a UKAS accredited laboratory.
3. All samples should be taken in accordance with BS 7592:2008
4. No composite samples should be taken.
5. Cleaning and disinfection of evaporative cooling towers and condenser water systems should be carried out in accordance with L8/HSG 274 Part 1: The control of legionella bacteria in evaporative cooling systems guidelines.
6. Cleaning and disinfection of domestic water systems should be carried out in accordance with HSG 274 Part 2: The control of legionella bacteria in hot and cold water systems, (S)HTM 04-01 (for healthcare premises), BS 8558 and BS EN 806.
7. All records, reports, analysis certificates & correspondence should be kept in the site water treatment logbook.
8. All actions should be logged and recorded in the site water treatment logbook.
9. Records should be retained throughout the period they are current and for at least two years afterwards. Retain records of any monitoring inspection, test or check carried out, and the dates, for at least five years.
10. Where consistently out of specification temperatures or other issues are highlighted and recorded during L8/HSG 274 checks then additional sampling should be considered until suitable remedial actions have been

implemented.

Residential accommodation: Landlords

HSG 274 Part 2: The control of legionella bacteria in hot and cold water systems paragraphs 2.138 – 2.146 provides guidance on duties and responsibilities on landlords, managing (or letting) agents to ensure that the risk of exposure to tenants to legionella is properly assessed and controlled.

All water systems require a risk assessment but not all systems require elaborate control measures.

Shared premises

HSG 274 Part 2: The control of legionella bacteria in hot and cold water systems paragraphs 2.147– 2.151 provides guidance on shared premises.

Those who have, to any extent, control of premises for work-related activities or the water systems in the building, have a responsibility to those who are not their employees, but who use those premises. A suitable and sufficient assessment must be carried out to identify, assess and properly control the risk of exposure to legionella bacteria from work activities and the water systems on the premises.

In estate management, it is increasingly common for there to be several dutyholders in one building. In such cases, duties may arise where persons or organisations have clear responsibility through an explicit agreement, such as a contract or tenancy agreement.

Where employers share premises or workplaces, the Management of Health and Safety at Work Regulations 1999, regulation 11 (see www.hse.gov.uk/risk for more information) requires that they cooperate with each other to ensure their respective obligations are met.

Special considerations for healthcare and care homes

HSG 274 Part 2: The control of legionella bacteria in hot and cold water systems paragraphs 2.152 – 2.168 provides additional guidance on healthcare and care home premises.

Scottish Health Technical Memorandum 04-01 (Parts A to F)

and

Health Technical Memorandum 04-01: The control of Legionella, hygiene, "safe" hot water, cold water and drinking water systems (parts A & B)

also provide additional and specific guidance on the control of water systems within health and care home premises.

Action in the event of an outbreak of legionellosis

1. In England and Wales, legionnaires' disease is notifiable under the Health Protection (Notification) Regulations 2010 and in Scotland under the Public Health (Notification of Infectious Diseases) (Scotland) Regulations 1988. Under these Regulations, human diagnostic laboratories must notify Public Health England (PHE), Public Health Wales (PHW) or Health Protection Scotland (HPS) (see 'Further sources of advice') of microbiologically confirmed cases of legionnaires' disease.

2. An outbreak is defined as two or more cases where the onset of illness is closely linked in time (weeks rather than months) and where there is epidemiological evidence of a common source of infection, with or without microbiological evidence. An incident/outbreak control team should always be convened to investigate outbreaks. It is the responsibility of the Proper Officer to declare an outbreak. The Proper Officer, appointed by the local authority, is usually a Consultant in Communicable Diseases Control (CCDC) in England and Wales, or the Consultant in Public Health Medicine (CPHM) in Scotland. If there are suspected cases of the disease, medical practitioners must notify the Proper Officer in the relevant local authority.

3. Local authorities will have jointly established incident plans to investigate major outbreaks of infectious diseases, including legionellosis, and it is the Proper Officer who activates these and invokes an Outbreak Committee, whose primary purpose is to protect public health and prevent further infection.

4. HSE or local environmental health officers (EHOs) may be involved in the investigation of outbreaks, their aim being to pursue compliance with health and safety legislation. The local authority, Proper Officer or EHO acting on their behalf will make a visit, often with the relevant officer from the enforcing authorities (ie HSE or the local authority). Any infringements of relevant legislation may be subject to a formal investigation by the appropriate enforcing authority.

5. There are published guidelines (by PHE, PHW and HPS) for the investigation and management of incidents, clusters, and outbreaks of legionnaires' disease in the community. These are, for England and Wales, *Guidance on the Control and Prevention of Legionnaires' Disease in England* and for Scotland, *Guidelines on Management of Legionella Incidents, Outbreaks and Clusters in the Community*.

6. If a cooling water system has been implicated in an outbreak of legionnaires' disease, emergency disinfection and cleaning of that system must take place as soon as possible, in accordance with the site incident plan.

Terms & abbreviations used

aerosol	a suspension in a gaseous medium of solid particles, liquid particles, or solid and liquid particles having negligible falling velocity. In the context of this document, it is a suspension of particles which may contain legionella with a typical droplet size of <5µm that can be inhaled deep into the lungs.
algae	a small, usually aquatic, plant which requires light to grow, often found on exposed areas of **cooling towers**.
bacteria (singular bacterium)	a microscopic, unicellular (or more rarely multicellular) organism.
biofilm	a community of **bacteria** and other **microorganisms**, embedded in a protective layer with entrained debris, attached to a surface.
calorifier	an apparatus used for the transfer of heat to water in a vessel by indirect means, the source of heat being contained within a pipe or coil immersed in the water.
cold water service (CWS)	installation of plant, pipes and fitting in which cold water is stored, distributed and subsequently discharged.
CWST	cold water storage tank (or cistern)
cooling tower	an apparatus through which warm water is discharged against an air stream; in doing so part of the water is evaporated to saturate the air and this cools the water. The cooler water is usually pumped to a heat exchanger to be reheated and recycled through the tower.
deadleg/dead-end pipes blind-end	leading to a fitting through which water only passes infrequently when there is draw-off from the fitting, redundant or abandoned legs of pipework.
drift	circulating water lost from the tower as liquid droplets entrained in the exhaust air stream; usually expressed as a percentage of circulating water flow, but for more precise work it is parts of water per million by weight of air for a given liquid to gas ratio.
drift eliminator	more correctly referred to as drift reducers or minimisers – equipment containing a complex system of baffles designed to remove water droplets from **cooling tower** air passing through it.
dry/wet cooling systems	dry coolers with the capacity to employ evaporative cooling when required either due to high ambient air temperature or when cooling demand is high.
evaporative condenser	a heat exchanger in which refrigerant is condensed by a combination of air movement and water sprays over its surface.
evaporative cooling	*a process by which a small portion of a circulating body of water is caused to evaporate, taking the required latent heat of vaporisation from the remainder of the water and cooling it.*
fouling	organic growth or other deposits on heat transfer surfaces, causing loss in efficiency.
low use or infrequently used outlets	outlets which are used occasionally, though less than once per week
unused outlets	outlets which are never or very rarely used
destratification or anti-stratification pump	pump used to mix water from top of calorifier/storage vessel to bottom to ensure even temperature spread throughout vessel
dip slide	a means of testing the microbial content of liquids by dipping a strip of culture media into the liquid, incubating to allow microbial growth and then estimating the numbers.
disinfection	a process which destroys micro-organisms and reduces number to a non-hazardous level.
domestic services	hot and cold water intended for personal hygiene, culinary, drinking water or other domestic purposes.
hot water service (HWS)	installation of plant, pipes and fitting in which water is heated, stored, distributed and subsequently discharged.
legionnaires' disease	a form of pneumonia caused by bacteria of the genus legionella.
legionella	a single bacterium of the genus **legionellae**.
legionellae	the name of a genus of bacteria which includes over 50 species and belongs to the family *Legionellaceae*. They are ubiquitous in the environment and found in a wide spectrum of natural and artificial collections of water.
legionella pneumophila	one of the causative organisms of **legionnaires' disease**.

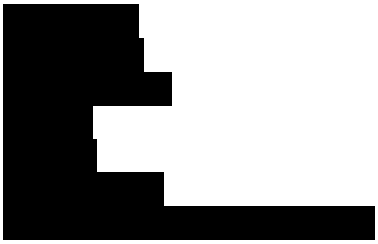
legionellosis	any illness caused by exposure to **legionella**. **Legionnaires' disease** a form of pneumonia caused by legionella bacteria
microorganism	an organism of microscopic size including **bacteria**, fungi and viruses.
nutrient	a food source for **microorganisms**.
pontiac fever	a disease caused by a species of legionella, an upper respiratory illness less severe than **legionnaires' disease**.
PPM	planned preventative maintenance
risk assessment	identifying and assessing the risk from exposure to legionella from work activities and water sources on premises and determining any necessary precautionary measures.
nutrient	a food source for micro-organisms
service provider	companies or individuals or their sub-contractors who are involved with providing advice, consultancy, operating, maintenance and management services or the supply of equipment or chemicals to the owner or occupier of premises.
sludge/dirt/silt	general terms for soft mud-like deposits found on heat transfer surfaces or other important sections of a cooling system. Also found at the base of calorifiers and cold water storage tanks.
shunt or circulation or return pump	a circulation pump fitted to hot water service/plant to overcome temperature stratification throughout the hot water services pipework.
slime	a mucous like exudate which covers a surface produced by some micro-organisms
stagnation	the condition where water ceases to flow and is therefore liable to microbiological growth.
strainers	a coarse filter usually positioned upstream of a sensitive component such as a pump control valve or heat exchanger to protect it from debris.
stratification	temperature gradient from top to bottom of calorifier/storage vessel
TMV thermostatic mixing valve	mixing valve in which the temperature at the outlet is pre-selected and controlled automatically by the valve
total viable counts (TVC)	the total number of culturable bacteria in a given sample (does not include legionella)

Client Details

The Queen Elizabeth University Hospital

Report By

D. Holloway BSc (Hons) MRSPH
Water Microbiology Manager
Intertek



Date Work Commenced

22/06/2018

Date Of Report

11/07/2018 – continuing work will be reported separately at a later date

Signed By:

D. Holloway BSc (Hons) MRSPH

Purpose of Work Undertaken

Investigation into contamination of flow Straighteners.

Analysis method

An initial visual inspection of each flow straightener was performed looking for presence of soiling and potential contamination of the flow straightener. A rating was given to each flow straightener to reflect the level of soiling

Soiling assessment.
No= no visible soiling all holes appear clear with no ingress.
Light= some visible soiling no detachment during washing, >70% of holes appear clear with no ingress.
Moderate= Visible soiling, some detachment during washing, no more than 50% of holes showing indication of ingress.
Heavy= heavy visible soiling, large fragments detached during washing, all holes show significant ingress or blockage.

Microbiological Analysis

A modified Bio-Burden test was used to analyse the flow straighteners.

a. 200ml of sterilised deionised water (SDW) was added to the bag containing the flow straightener and the bag was agitated for 30 seconds. The 200ml of liquid was then classed as the sample.

b. 1ml of the sample is used to create a serial dilution. Neat and 1 dilution was tested for total viable count (TVC)

c. 100ml of sample was filtered and the filter transferred to a TVC plate

d. 100ml of sample was filtered and transferred to a Pseudomonas aeruginosa specific plate

e. All plates were incubated at 35oC for 48 hours to stimulate bacterial growth.

f. After the incubation period all visible colonies were counted and recorded (any unusual growth types on the P. aeruginosa plates was recorded as non-typical (NT#)

Bioburden assessment

For the assessment of bioburden, a specialist product (Biofinder™) was used

Biofinder™ is a transparent yellow liquid which when sprayed onto a surface reacts with the protein structure to produce a catalase reaction.

Assessment of the levels of biofilm was made based on the strength and speed of the reaction

Biofilm assessed on a score 0-5.
0= No reaction. No biofilm presence
5= strong instant reaction large biofilm presence/ mature biofilm

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sample number	location	asset number	date stamp on sample	200ml SDW added	tvc 1ml	tvc1ml -1	tvc100ml	Pseud 100ml	Estimate total count per Item (cfu/straighter	soiling visual		biofilm
1	Ward 9A Room 2	GENW13-004	07/06/2018	yes	>1000	>1000	>1000	>1000	>2000000	HEAVY		5
2	HDU3 Bay 29	CCW-106	21/06/2018	yes	>1000	>1000	>1000	>1000 NT#	>2000000	NO		1
3	Ward 9B Room 95 WHB	GEN16-040		yes	>1000	>1000	>1000	>1000 NT#	>2000000	HEAVY		5
4	Ward 9C Clean Utility WHB	GEN15-081		yes	>1000	>1000	>1000	>1000 NT#	>2000000	NO		2
5	Ward 8A Room 1	GENW9-001	11/06/2018	yes	>1000	>1000	>1000	>1000	>2000000	HEAVY		5
6	Ward 8B Bed 107 WHB	GENW13-13		yes	>1000	>1000	>1000	>1000 NT#	>2000000	HEAVY		5
7	Ward 5C Bed 66 WHB	GENW2-022	14/06/2018	yes	>1000	>1000	>1000	>1000 NT#	>2000000	HEAVY		5
8	Ward 8D Bed 29	GENW10-065	11/06/2018	yes	>1000	>1000	>1000	>1000 NT#	>2000000	LIGHT		5
9	Ward 6B Bed101 WHB	GENW4-023	12/06/2018	yes	>1000	>1000	>1000	>1000 NT#	>2000000	NO		5
10	Ward6D Bed53	GENW2-006	13/06/2018	yes	>1000	>1000	>1000	>1000 NT#	>2000000	HEAVY		5
	due to excessive counts dilution of TVC changed			200ml SDW added	TVC 1ml	TVC 1ml-1	TVC 1ml-2	Pseud 100ml				
11	HDU2 Bed11	CCW-051	19/06/2018	yes	>1000	>1000	350	>1000	7000000	NO		1
12	HDU1 Bay7	CCW-033	19/06/2018	yes	>1000	>1000	250	>1000	5000000	NO		3
13	Ward6C Bed73 WYB	GENW3- 040	12/06/2018	yes	>1000	200	600	>1000	12000000	Moderate		5
14	HDU4 Bay35	CCW-085	21/06/2018	yes	>1000	>1000	20	400	400000	NO		2
15	Ward6A Bed2	GENW1-006	12/06/2018	yes	>1000	>1000	>1000	>1000	20000000	HEAVY		5
16	Ward 5B Bed85	GENWD-065	13/06/2018	yes	>1000	>1000	>1000	>1000	20000000	HEAVY		5
17	Ward5A Bed16	GENWA-035	13/06/2018	yes	>1000	>1000	900	>1000	18000000	HEAVY		5

Several colonies were identified from the original flow straightener analysis were selected and were sent to a specialist laboratory for further identification.

These consisted of colonies from 7 of the TVC analysis of the flow straighteners to represent the colony morphologies most dominant on the plates

An isolate from the P. aeruginosa analysis was also sent for further identification because in the opinion of the analyst the growth was not typical of p. aeruginosa. This could be due to the growth being a closely related species or that the P. aeruginosa bacteria present are conditioned to growth in a biofilm environment which may cause them to exhibit different characteristics when grown under laboratory conditions.

Photographs of Flow straighteners during testing supplied in supplemental report ITSS-0718-0001W(A)

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Report Number ITSS-0718-0001W

Flow Straighteners In Use for 1 Week

sample number	location	asset number	200ml SDW added	tvc 1ml	tvc1ml -1	tvc100ml	Pseud 100ml	Estimate total count per Item (cfu/straighteners	soiling visual		biofilm
1	HDU4 BAY35	CCW-085	yes	280		2500	0	5000	NO		0
2	HDU4 BAY39	CCW-090	yes	>300		>3000	0	>30000	NO		0
3	HDU5 DIRTY UTILITY	CCW-148	yes	219		2500	0	5000	NO		0
4	HDU1 LAB	CCW-066	yes	234		2500	0	5000	NO		0
5	HDU1 BAY01	CCW-036	yes	0		0	0	0	NO		0
6	HDU2 CLEAN UTILITY	CCW-075	yes	219		2000	0	4000	NO		0
7	UNUSED	UNUSED	yes	0		120	8	240	NO		0
8	HDU3 BAY25	CCW-110	yes	0		221	0	450	NO		0
9	HDU8 BAY53	CCW-171	yes	0		58	0	110	NO		0
10	HDU3 BAY30	CCW-105	yes	173		2000	0	4000	NO		0

Morphology of organisms detected is that of common environmental organisms see frequently in water samples in the lab

Drain Traps

Ward 3c	GW1-044	visual							swab	Estimated count per swab (CFU/SWAB)	
		rubber seal showed evidence of significant decomposition. Heavy biofilm presence	large piece of clear plastic (50mmX40mm)	large clumps of tangled hair present	bulb trap clear	gap between down pipe and bulb trap heavily soiled to 10mm depth			X6 dilution	$210X10^6$	swab taken as dab from steal conector area(1cmX1cm)

Ward 3A	GWS-004	Visual							Swab	Estimated count per swab (CFU/SWAB)	
		light staining inside the bulb trap	single piece of physical debris present in the trap (5p piece)	seal between metal fixing appeared sound and intact	no soiling between down pipe and bulb trap				X5 dilution	$115X10^5$	swab taken from bulb trap circle around the internal side of the trap

Isolate Identification

Sample ID	Sample discription	Additional information	Isolate ID	Isolate type	Identification
6	Ward 8A Room 1	piece of bifilm removed from sample 6	Solid B	solid fragment from washing	Sphingomonas paucimobils
1	Ward 9A Room 2	piece of bifilm removed from sample 1	Solid 1	solid fragment from washing	Micobacterium laevaniformans
16	Ward 5B Bed85	Isolate Taken from PCN plate non typical morphology for P. aeruginosa	PCN16	suspect P. aeruginosa	Stenotrophomonas multophilia
2	HDU3 Bay 29	taken at highest dilution with good colony seperation	TVC 2 (1)	Dominant morphology from TVC plate	Acidovorax temperans
2	HDU3 Bay 29	Taken from crowded plate at lower dilution	TVC2 (2)	Dominant morphology from TVC plate	Acidovorax temperans
15	Ward6A Bed2		TVC15	Dominant morphology from TVC plate	Chryseobacterium spp
4	Ward 9C Clean Utility WHB	taken at highest dilution with good colony seperation	TVC D-4	Dominant morphology from TVC plate	Stenotrophomonas multophilia
12	HDU1 Bay7	taken at highest dilution with good colony seperation	TVC15	Dominant morphology from TVC plate	Caulobacter

Drain

Ward 3c	GW1-044	visual					swab		
		rubber seal showed evidence of significant decomposition. Heavy biofilm presence	large piece of clear plastic (50mmX40mm)	large clumps of tangled hair present	bulb trap clear		X6 dilution	210 cfu/swab	swab taken as dab from steal conector area(1cmX1cm)

Ward 3A	GWS-004	Visual					Swab		
		light staining inside the bulb trap	single piece of physical debris present in the trap (5p piece)	seal between metal fixing appeared sound and intact	no soiling between down pipe and bulb trap		X5 dilution	115cfu/swab	swab taken from bulb trap circle around the internal side of the trap

Identified Organisms

Sphingomonas paucimobils

S. paucimobilis is a frequently encountered organism in the environment. It contaminates water supplies and hospital equipment. In addition to the occasional propensity to cause human disease, it is implicated in microbial influenced corrosion of water pipes. Because of their ability to accumulate copper in their cell walls, *Sphingomonas* spp. can bind to copper in the copper containing water pipes, facilitating an anodic reaction and corrosion of copper . Heating the water to 64°C decreases these reactions and microbial growth, as does low concentrations of antibiotics like cefoxitin, in the circulating water.
Sphingomonas spp. show antagonism to some plant pathogens, such as the fungus Verticillium dahliae, which affects several commercial plant species. Several *Sphingomonas* species have been recovered from sub-surface tunnels, where they may account for up to 11% of the culturable bacteria. Many species (though not *S. paucimobilis*) can degrade toluene, naphthalene, benzoate and other refractory environmental contaminants, suggesting a potential role in ecological clearance of such materials, including use for oil spills. More research is needed to determine how much of a threat *S. paucimobilis* can be clinical
(http://www.antimicrobe.org/b232.asp)

Micobacterium laevaniformans

M. lacticum has been isolated from milk or dairy sources after laboratory pasteurization or from dairy products that have been heat treated. This species may form a considerable part of the thermoduric bacterial flora of raw and pasteurized milk, powdered milk, cheese and dairy equipment.
M. laevaniformans is reported to occur in raw sewage and in activated sludge. *M. imperiale* was isolated originally from the alimentary canal of the Imperial moth *Eacles imperialis* . Bacteria resembling microbacteria have been reported to occur in fresh beef, poultry giblets and raw and pasteurized egg fluid.

Stenotrophomonas multophilia

Stenotrophomonas maltophilia is a Gram-negative bacterium found in a variety of environments including soil, water, and plants. It also occurs in the hospital environment and may cause bloodstream infections, respiratory infections, urinary infections and surgical-site infections.
Clinically-significant infections usually only occur in those with significantly impaired immune defences, such as severely immuno-compromised patients. Infections in previously healthy patients are unusual.
Risk factors pre-disposing a hospitalised patient towards infection include prior exposure to antimicrobials (especially broad-spectrum antibiotics), mechanical ventilation, and prolonged hospitalisation. It may also affect the lungs of patients with cystic fibrosis.
S. maltophilia does not readily spread between patients and is not a common cause of healthcare-associated infection. Hospital outbreaks for many pathogens, like Acinetobacter baumannii, are usually caused by a single strain. Apparent outbreaks attributed to S. maltophilia are frequently caused by multiple strains, implying acquisition from environmental sources as opposed to inter-patient spread.
(https://www.gov.uk/guidance/stenotrophomonas-maltophilia)

Chryseobacterium spp

The newly classified and renamed *Elizabethkingia, Chryseobacterium* and *Myroides* genera were originally included among the different species that belong to the genus *Flavobacterium*. The genus *Flavobacterium* was created in 1923 for a group of non-spore forming, aerobic gram- negative rods, with the ability to produce yellow pigmented colonies . Based on this broad characterization many species were added to the Flavobacterium genus including *F. meningosepticum*, *F. indologenes* and *F. odoratum*, well known today as human pathogens. Further studies showed that many of these species were not truly related, and the genus underwent a series of reclassifications. More recently, new data on genotypic, chemotaxonomic and phenotypic analysis allowed regrouping of these species into four separate genus, *Chryseobacterium* spp., *Flavobacterium* spp., and *Myroides* spp. All belong to the family Flavobacteriaceae .
Ubiquitous in nature, *Chryseobacterium* species are found primarily in soil and water. Environmental studies have revealed that these organisms can survive in chlorine-treated municipal water supplies, often colonizing sink basins and taps and creating potential reservoirs for infections inside hospital environments. Colonization of patients via contaminated medical devices involving fluids (respirators, intubation tubes, mist tents, humidifiers, incubators for newborns, ice chests, syringes, etc.) has been documented (8, 12). Contaminated surgically implanted devices such as intravascular catheters and prosthetic valves have also been reported (18). In other clinical settings, chryseobacteria have been described as etiological agents of meningitis, bacteremia, pneumonia, endocarditis, infections of skin and soft tissue, ocular infections, and other infections (6). Primarily opportunistic pathogens, they infect mainly newborns and immunocompromised hosts from all age groups.

(http://www.antimicrobe.org/b94.asp)

Caulobacter

Caulobacter crescentus has a dimorphic life cycle composed of a motile stage and a sessile stage. In the sessile stage, *C. crescentus* is often found tightly attached to a surface through its adhesive holdfast. In this study, we examined the contribution of growth and external structures to the attachment of *C. crescentus* to abiotic surfaces. We show that the holdfast is essential but not sufficient for optimal attachment. Rather, adhesion in *C. crescentus* is a complex developmental process. We found that the attachment of *C. crescentus* to surfaces is cell cycle regulated and that growth or energy or both are essential for this process. The initial stage of attachment occurs in swarmer cells and is facilitated by flagellar motility and pili. Our results suggest that strong attachment is mediated by the synthesis of a holdfast as the swarmer cell differentiates into a stalked cell.

(https://www.ncbi.nlm.nih.gov/pmc/articles/PMC344395/)

Disscussion

The flow straighteners provided for the first round of sampling all showed significant levels of biofilm contamination. The levels were consistent throughout the sampling indicting that this is not an localised

issue but effecting all flow straighteners. Work is continuing analysing flow straighteners which have been connected to the system for different lengths of time to attempt to establish how quickly the biofilm is attaching to the flow straighteners in an attempt to offer some insight into reasonable service time for the flow straighteners.

Biofilm formation and significance

When looking at biofilm formation in complex water systems there are a number of common factors which should be considered.

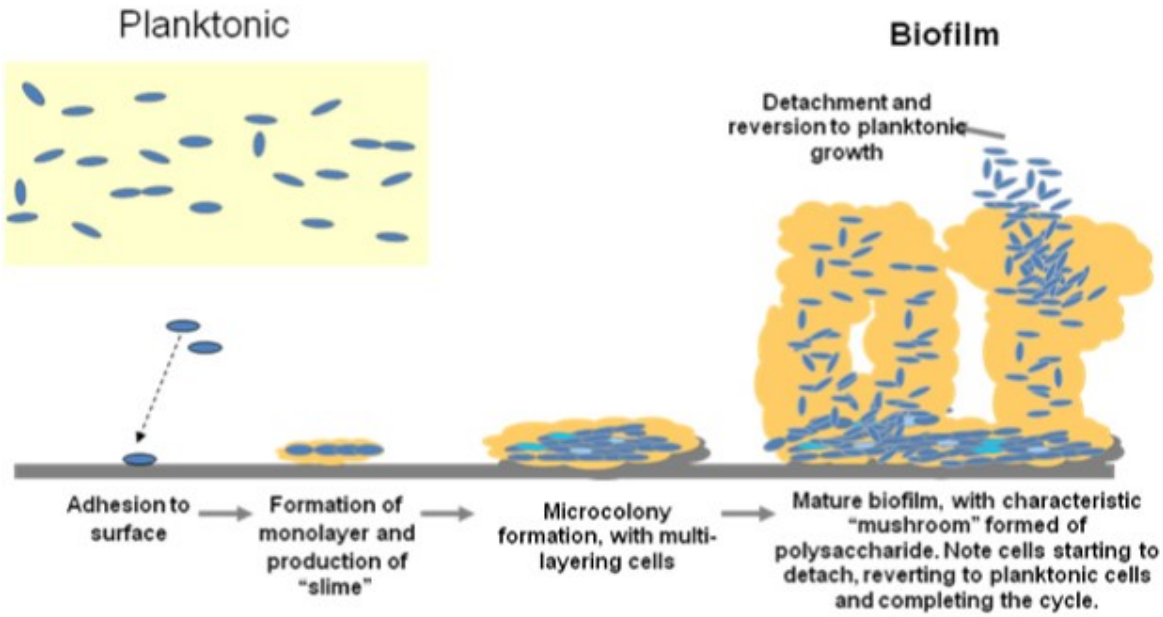
Any part of the system where the flow rate is slowed increases the chance of a biofilm forming as organisms are more likely to be able to attach to the surface.

Increased surface area gives more opportunity for organisms to attach and a biofilm to form.

Materials used in the construction of the water system have the potential to provide nutrients potentially increasing the natural fauna in the water.

Temperature ambient temperature water offers better conditions for organisms to develop in higher concentrations- there are exceptions to this and an example of this is Chryseobacterium spp which was detected in this project is resilient to low temperatures and higher acidity levels

the maturity of a biofilm also impacts on the levels of organisms released into the water



Source- http://medcraveonline.com/JMEN/JMEN-01-00014.php

A biofilm also supplies a degree of protection to the organisms living in it. The extracellular polymers secreted by the organisms and used as the building structure for the biofilm form a protective layer which provides more resistance to physical and chemical treatment than the organisms would have in their

planktonic state. It is not unusual in biofilms to find a low number of dominant species although the total number of species could in reality be significantly higher.

A large number of microbial cells are generally counted on surfaces in contact with drinking water (in the order of 10^6 to 10^8 cells per cm2) (Donlan and Pipes 1988; Pedersen 1990; Lévi et al. 1992; Mathieu et al. 1992). This biomass represents only 0.1 to 20 micrograms of organic carbon per cm2 (Niquette et al. 2000; Fass et al. 2003).

Of the total cell count of a water system biofilm it has been estimated that only 0.1-1% (WHO) is made up of clinically significant organisms with the rest being not clinically significant but the significance of this number varies dependant on the location of the water system, the maturity of the biofilm and the susceptibility of the people coming into contact with the water.

The organisms identified in this project do have some clinical significance although the level is variable and, in some cases, relatively unknown. The organisms that were identified all have proven ability to produce and sustain themselves in a biofilm and Caulobacter being specifically adapted to adhere to surfaces.

A comparison was made in the morphology of the organisms grown from the flow straighteners to that of organisms recovered from flow straighteners that had been in place for 1 week. There was significant difference in the morphology of the colonies on the plates with the morphology of the colonies that were chosen from the original samples for identification were not present in the 1-week old flow straightener samples. This indicates that although these organisms are present in low concentrations, as would be expected for these type of environmental organisms, once a biofilm has become established these specialised organisms are becoming dominant.

The level of contamination identified on the flow straighteners does indicate that they are a factor in the forming of the biofilm (as visible evidence of biofilm contamination was observed during testing) although the exact reason for this can not be concluded form this study. It can only be speculated that the design or construction materials may play a part although the more significant part in the biofilm formation is likely to be the whole water system condition.

Debris from the raw water tank.

Tests were done on debris recovered from the base of the raw water tank. Part of the sample was sent to an Intertek sister lab for composition analysis. A biofilm test was done on part of the remaining sample which showed a strong reaction indicating a large biofilm presence on the debris

Test run for 20 seconds

Drains.

2 drain traps were received into the lab for analysis

1/ Ward 3C GW1-044

(fig1-6)

This drain showed significant evidence of solid contamination. The bulb drain was clear of any debris but the space between the down pipe and bulb trap showed 10mm of debris build up. The debris was removed and examined to attempt to determine the contents to possibly give an indication of the potential source.

A large piece of plastic film (fig6) measuring 50mmx40mm was imbedded in the debris.

Clumps of hair was identified mixed into the debris (fig7) shown protruding from the pipe and the side of the debris.
The remaining debris consisted of decaying organic matter. Microbiological assessment of this debris was not deemed possible due to the expected high levels it would not be possible to obtain a dilution high enough to produce a workable result and when dealing with waste water systems with high levels of contamination the associated risk to the lab from potential virus contamination would be to great.

The metal fitting at the base of the trap showed significant levels of corrosion to the surface. A rubber seal attached to the fitting was split and showed high levels of decay throughout the seal. It is the opinion of the analyst that this seal would not be water tight in this condition.
Biofilm test was performed o the seal to determine the level of contamination (fig8). The biofilm indicator showed a very strong instant reaction indicating the presence of a large mature biofilm.
Due to the level of contamination a traditional swabbing method of the drain was not seen as practical. On assessment it was decided that due to the seal being in a failed condition that a swab would be taken from the metal fitting where the seal attaches. The tip of a swab was dabbed onto an area of $10mm^2$ to perform the test. The result for the swab test gave a result of 210cfu at 6 dilutions. This would give and estimated total organism count of $210x10^6/cm^2$ of the metal fitting.

Fig7

fig8

2/ Ward 3A GWS-004

Fig9-13

The drain showed little or no evidence of contamination. All seals were intact and sound although the seal fitted to the metal fitting appeared to be fixed using an adhesive. All the channels in the drain were clear

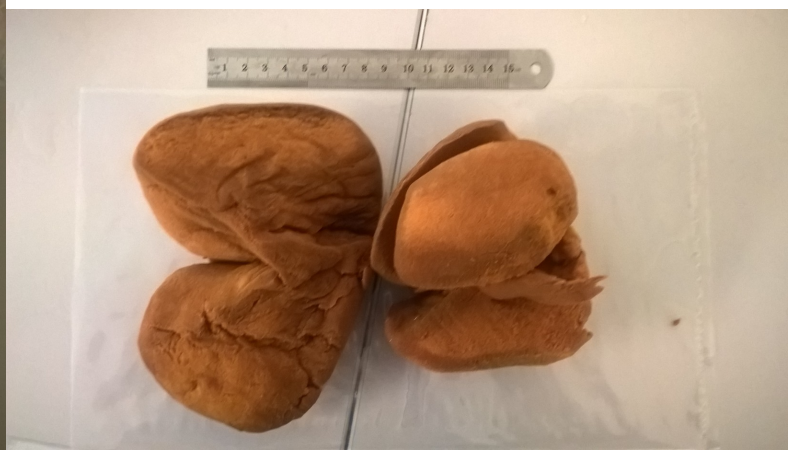
and no debris was found in the trap. A single foreign body was found in the drain and this was identified as a 5p piece.

A swab was taken from a sweep of the inside of the bowl trap the result for the swab test gave a result of 115cfu at 5 dilutions giving an estimated total count of $115x10^5$

At this point it is worth noting the difference in organism levels between the two drain swab samples. The 2nd drain swab was taken by wiping the inside area of the bowl trap where as the first swab was taken by a single dab of the tip of the swab on the surface of the metal plate.

Sponges

2 sponges were supplied to the laboratory (fig14&15). These sponges had been discovered in the cold-water storage tank. It is estimated that the sponges had been in the tank for a period exceeding 2 years although the time period can not be verified at the time of this report.



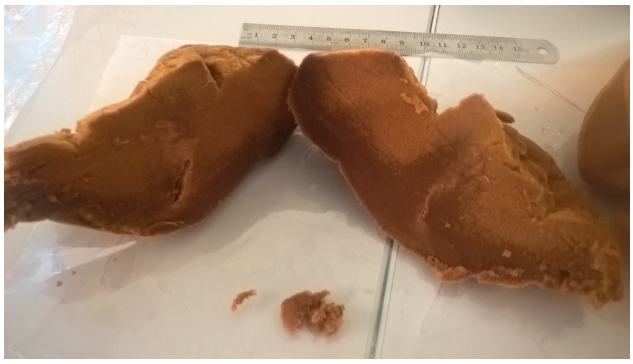
Due to the porous nature of sponge 2 portions of the sponge were chosen to be tested for the presence of biofilm. From this both the presence of biofilm and the depth of penetration could be determined

1/ a slice of sponge taken from the surface (fig15)

2/ a core sample taken from the centre of the sponge (fig 16)

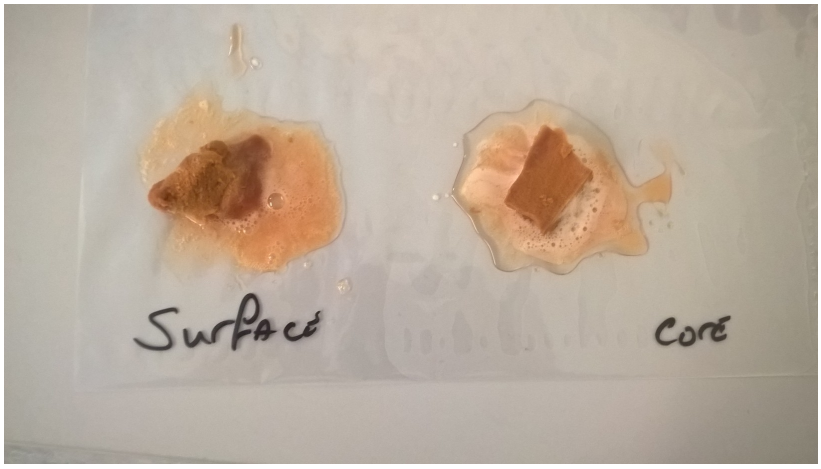
Fig15

fig 16



When tested both samples showed a reaction indicating the presence of biofilm (fig 17). There was some delay in the reaction. It is unclear why the delay in reaction occurred, due to the porous nature of the sponge the possibility that the Biofinder [tm] was absorbed into the sponge and this delayed the visible reaction.

Fig 17



Client Details

Glasgow Royal Infirmary

Report By

D. Holloway BSc (Hons) MRSPH
Water Microbiology Manager
Intertek
[redacted]

Date Work Commenced

27/09/2019

Date Of Report

04/10/2019

Signed By:

[redacted]

D. Holloway BSc (Hons) MRSPH

Background

Queen Elisabeth Hospital Glasgow sent 31 flow straighteners to the laboratory. The laboratory was asked to perform the same testing as done for the flow straighteners tested in report ITSS-0718-001W (contamination investigation of flow straighteners) and assess the bacterial load against those original samples.

Analysis method

An initial visual inspection of each flow straightener was performed looking for presence of soiling and potential contamination of the flow straightener. A rating was given to each flow straightener to reflect the level of soiling

Soiling assessment:
No= nNo visible soiling all holes appear clear with no ingress.
Light= Some visible soiling, no detachment during washing, >70% of holes appear clear with no ingress.
Moderate= Visible soiling, some detachment during washing, no more than 50% of holes showing indication of ingress.
Heavy= Heavy visible soiling, large fragments detached during washing, all holes show significant ingress or blockage.

Microbiological Analysis

A modified Bio-Burden test was used to analyse the flow straighteners.

a. 200ml of sterilised deionised water (SDW) was added to the bag containing the flow straightener and the bag was agitated for 30 seconds. The 200ml of liquid was then classed as the sample.

b. 1ml of the sample is used to create a serial dilution. Neat and 1:10 dilution was tested for total viable count (TVC)

c. 100ml of sample was filtered and the filter transferred to a TVC plate

d. The remainder of sample was filtered and transferred to a Pseudomonas aeruginosa specific plate

e. All plates were incubated at 35oC for 48 hours to stimulate bacterial growth.

f. After the incubation period all visible colonies were counted and recorded (any unusual growth types on the *P. aeruginosa* plates was recorded as non-typical (NT#)

Biofilm assessment

For the assessment of bioburden, a specialist product (Biofinder™) was used

Biofinder™ is a transparent yellow liquid which is sprayed onto a surface. When coming into contact with the biofilm protein structure produces a catalase reaction.

Assessment of the levels of biofilm was made based on the strength and speed of the reaction

Biofilm assessed on a score 0-5. 0= No reaction. No biofilm presence 5= Strong instant reaction large biofilm presence/ mature biofilm

Fully dismantled flow straightener.

intertek
Total Quality. Assured.

sample number	location	asset number	inset date	removal date	200ml SDW added	tvc 1ml	tvc1ml -1	tvc100ml	Pseud 100ml	Estimate total count per Item (cfu/straightener	soiling visual		biofilm
1	ARU4 Bed 61	AAW-270	19/07/2019	19/07/2019	yes	0		48	0	96	No		1
2	3A Bed 23	GW3-028	19/08/2019	26/09/2019	yes	450		<1000	0	90000	No		0
3	6B Bed 96	GENW-035	05/08/2019	26/09/2019	yes	10		210	0	420	No		0
4	10B Clean Utility	GENW20-081	29/07/2019	26/09/2019	yes	47		750	0	1500	No		0
5	Kids A&E Resus SS sink	EMC-018	29/08/2019	26/09/2019	yes	8		600	0	1200	No		0
6	3B Bed Bay 11-14 sink RHS	GW2-037	13/08/2019	26/09/2019	yes	6		400	0	800	No		0
7	11B Bedd 50	GENW-014	21/08/2019	26/09/2019	yes	38		500	0	1000	No		0
8	1E Bed Bay 1-4 Sink LHS	CAR-050	13/06/2019	26/09/2019	yes	310		<1000	0	62000	No		0

9	Kids X-ray Dirty Utility	RGG-087	24/07/2019	26/09/2019	yes	0		55	0	110	No		0
10	IAU Bed Bay 4	AAW-183	22/07/2010	26/09/2019	yes	0		106	0	212	No		0
11	ARU3 Bed 118	AAW-142	22/07/2019	26/09/2019	yes	12		200	0	400	No		0
12	1C MDU Kids Interview Room	MDU-026	13/06/2019	26/09/2019	yes	5		75	0	150	No		1
13	8D Bed 49	GENW10-017	30/08/2019	26/09/2019	yes	0		23	0	46	No		0
14	8A Bed 7	GENW9-014	01/08/2019	26/09/2019	yes	0		11	0	22	No		0
15	Clinic 5 Con Room 29	OPD-114	28/08/2019	26/09/2019	yes	2		105	0	210	No		0
16	5B Dirty Utility WHB	GENWD-079	14/08/2019	26/09/2019	yes	0		12	0	24	No		0
17	5D Bed 41	GENW1-035	15/08/2019	26/09/2019	yes	0		31	0	62	No		0
18	8B Bed 99	GENW12-031	05/08/2019	26/09/2019	yes	210		35	0	70	No		0

19	9B Bed 85	GENW16-065	31/07/2019	26/09/2019	yes	0		50	0	100	No		0
20	Clinic 1 Treatment Room A	OPD-031	27/08/2019	26/09/2019	yes	17		244	0	488	No		0
21	9A Bed 26	GEN13-060	31/07/2019	26/09/2019	yes	44		500	0	1000	No		0
22	9C Clean Utilty	GENW15-081	01/08/2019	26/09/2019	yes	0		61	0	122	No		0
23	11A Bed 14	GENW21-031	25/07/2019	26/09/2019	yes	0		11	0	22	No		0
24	6C Bed 68	GENW3-028	06/08/2019	26/09/2019	yes	0		5	0	10	No		0
25	ARU1 Clean Utility	AAW-319	18/07/2019	26/09/2019	yes	0		67	0	134	No		0
26	11B Bed 99	GENW23-031	26/07/2019	26/09/2019	yes	0		36	0	72	No		0
27	5A Bed 18	GENWA-040	14/07/2019	26/09/2019	yes	0		102	0	204	No		0
28	10C Bed 76	GENW19-044	30/07/2019	26/09/2019	yes	23		300	0	600	No		0

29	5C Beed 73	GENWC-038	15/08/2019	26/09/2019	yes	0		11	0	22	No		0
30	6D Bed 39	GENW2-038	12/08/2019	26/09/2019	yes	450		<1000	0	90000	No		0
31	10D Bed 55	GENW18-004	30/07/2019	26/09/2019	yes	0		7	0	14	No		0

Average count CFU/flow straightener 325cfu/straightener (3 of the results have been omitted when calculating the average. These three results were considered statistically significantly different and classed as outliers).

With the 3 omitted results included the average CFU/ flow straightener is 8100.

The results of the testing were compared to the results obtained from previous testing of flow straighteners.

To get a meaningful comparison that would allow a comparison assessment to be made the results were compared to the previous results for

- Unused flow straighteners
- Flow straighteners on the system for 1 week
- Flow straighteners on the system for 1 month.

Original testing results

UNUSED				1 WEEK				1 MONTH			
Estimate total count per Item (cfu/straighteners	soiling visual		biofilm	Estimate total count per Item (cfu/straighteners	soiling visual		biofilm	Estimate total count per Item (cfu/straighteners	soiling visual		biofilm
500	0		0	5000	NO		0	7000000	Non		1
400	0		0	>30000	NO		0	4400000	Non		3
720	0		0	5000	NO		0	>20000000	Non		1
1400	0		0	5000	NO		0	>20000000	Non		0
80	0		0	0	NO		0	>20000000	Non		0
14	0		0	4000	NO		0	9400000	Non		4
24	0		0	450	NO		0	4200000	Non		5
108	0		0	110	NO		0	>20000000	Non		0
20	0		0	4000	NO		0	>20000000	Non		0
average count per straightener											
363				2651				6800000			

Conclusion

No Biofilm was detected during this analysis

No visual soiling was detected during this analysis

Comparing the results from this testing against previous samples tested has shown a significant improvement against all three of the perimeters tested.

the results for this testing had an average cfu/flow straightener result of 325. This is in line with the results obtained from the original testing of unused flow straighteners.
This shows a significant improvement in the bacterial load and attachment in the period of use.

With this information it can be assumed that the additional work performed on the water system have made significant improvements on the condition of the flow straighteners attached to the water system. Pervious testing suggested that the flow straighteners were becoming heavily contaminated within 1 month of use. The result of this analysis suggest that this is no longer the case and the impact is greatly reduced with the flow straighteners being in a condition closer to that of unused with only a minimal bacterial load over 2 to 3 months of use.

INNOVATED
DESIGN SOLUTIONS

Queen Elizabeth University Hospital

Adult & Children's Hospital

Feasibility Study Regarding
Increasing Ventilation Air Change Rates
within Ward 2B

Client	NHS Greater Glasgow & Clyde, Queen Elizabeth University Hospital, 1345 Govan Road, Glasgow, G51 4TF
Project Ref.	141819
Date	15th October 2018
Revision	-

CONTENTS

SECTION 1 – EXECUTIVE SUMMARY

1.01 Executive Summary

The desired increase in mechanical supply and extract air change rates (i.e. to 6ac/hr) within Day Care Unit (DCU) and Bone Marrow Transplant (BMT) Wards is deemed to be unachievable, without undertaking significant modifications to the existing system installations.

As noted within the report we estimate necessary system modification works would cost in the region of £100-125K, and take approximately 4-6 weeks on site.

Whilst not requested, within the report we have also explored an alternate option with regards to increasing air change rates within only the BMT Ward. In terms of this option, we estimate system modification works to cost in the region of £60-80K, with associated site works likely to take in the region of 3-5 weeks.

During our analysis works we discovered numerous potential issues pertaining to the existing installations, which have been outlined within the report accordingly.

Of particular note, a significant discrepancy was identified with regards to the selection of air handling units. According to the manufacturer, all air handling unit fans/motors (i.e. both supply and extract) were sized and selected based on 100% air volume, with clean filters. Therefore, in some instances we anticipate intended room air change rates are not being achieved (i.e. due to reduction in filter free area during operation/use). This would be of further concern with regards to any specific areas/zones within the building that require a specific positive/negative air differential pressure strategy.

Other significant potential issues identified include the installation of thermal wheel type heat recovery devices serving areas where the risk of cross-contamination may require further consideration, the unidentified pressure classification of ductwork distribution installations, the installation of single fan units serving numerous areas/floor levels, and the selection of single module induction units.

SECTION 2 – GENERAL

2.01 Purpose of Analysis

Purpose of this analysis is to determine the viability of increasing mechanical supply and extract air change rates within the Day Care Unit Ward (DCU) & Bone Marrow Transplant Ward (BMT) areas to 6ac/hr, and ascertaining what impact increased air volumes would have with regards to existing installations (i.e. air handling unit, ductwork, terminal devices, etc.).

2.02 General System Description

Multiple ceiling mounted induction units within each Ward area are utilised to distribute primary supply air into the occupied space, whist also tempering air supplies utilising integral heating and cooling facilities. Air is extracted from each Ward via a single ceiling mounted diffuser.

In addition, WC's located adjacent to each Ward space are equipped with extract valve inlets, with make-up air being transferred via the associated Ward (i.e. natural ducted air transfer between Ward and WC).

Tempered fresh air supply to each Ward space, and extract air from the Ward space, is derived via air handling unit (AHU) reference 41-AHU24, located within Plant Room 41. Air extracted from the WC's, located adjacent to each Ward space, is ducted via a completely separate 'dirty' extract system.

AHU24 also provides primary supply and extract air provision to other induction units, supply air diffusers, and extract diffusers/grilles located elsewhere within the 2nd Floor Ward, and within the Mother Day Unit (MDU) facilities located directly below on the 1st Floor level. Similarly, the 'dirty' extract system also serves other areas within the building.

It is also prudent to note that primary supply air is ducted to induction units and supply air diffusers separately from the Plant Room area, with a common LTHW heating re-heat coil fitted to ductwork serving diffusers.

SECTION 3 – Air Change Rates

3.01 Existing Air Change Rates

Note – Room volumes based on 2.72m ceiling height.

Day Stay Ward

Day Stay Ward room volume = 191.5m³

Associated WC room volume = 14.4m³

Combined primary air supplied via 3Nr modules (H&V balancing data) = 124l/s (446m³/hr)

Extract air from Ward diffuser (H&V balancing data) = 87l/s (313m³/hr)

Extract air from Ward WC valve (H&V balancing data) = 42l/s (151m³/hr)

Therefore, current air change rates are calculated to be approximately:-

Ward Supply = 2.33 ac/hr

Ward Extract = 1.64 ac/hr
Ward WC = 10.5 ac/hr

= 2.43 ac/hr (effective Ward area extract air change rate)

As identified above, the Day Stay Ward area currently operates on a slightly negative pressure, as the extract air duty exceeds that of the supply air.

BMT Day Ward

BMT Day Ward room volume = 107.2m³

Associated WC room volume = 14.4m³

Combined primary air supplied via 2Nr modules (H&V balancing data) = 83l/s (299m³/hr)

Extract air from Ward diffuser (H&V balancing data) = 43l/s (155m³/hr)

Extract air from Ward WC valve = 41l/s (148m³/hr)
(H&V balancing data)

Therefore, current air change rates are calculated to be approximately:-

Ward Supply = 2.79 ac/hr

Ward Extract = 1.44 ac/hr
Ward WC = 10.25 ac/hr

= 2.82 ac/hr (effective Ward area extract air change rate)

As identified above, the BMT Ward area currently operates on a slightly negative pressure, as the extract air duty exceeds that of the supply air.

3.02 Proposed Air Volumes

Proposal to provide 6 ac/hr within each Ward would necessitate the following increase to air volumes:-

Day Stay Ward

Proposed Ward Supply = increase from 124l/s to 319l/s (additional 195l/s)

Proposed Ward Extract = increase from 87l/s to 277l/s (additional 190l/s)

* WC 'dirty' extract air volume would be retained as installed (42l/s, 10.5 ac/hr), as existing air change rate is deemed to be appropriate.

BMT Day Ward

Proposed Ward Supply = increase from 83l/s to 179l/s (additional 96l/s)

Proposed Ward Extract = increase from 43l/s to 138l/s (additional 95l/s)

* WC 'dirty' extract air volume would be retained as installed (41l/s, 10.25 ac/hr), as existing air change rate is deemed to be appropriate.

SECTION 4 – Impact on Existing Installations

4.01 Air Handling Unit (AHU)

AHU manufacturers technical documentation contained within Zutec identified the following:-

- Designed on the basis of providing 2.46m³/s supply air flow rate at an external pressure of 600Pa (i.e. system/ductwork resistance).
- Designed on the basis of providing 1.89m³/s extract air flow rate at an external pressure of 490Pa (i.e. system/ductwork resistance).
- Technical data is provided for the AHU operating at 125% duty (i.e. supply and extract fans, heating/cooling coils, thermal wheel, etc.).
- The AHU was manufactured in accordance with Class B leakage standard.

H&V commissioning data from Zutec identified the actual supply and extract fan duties as shown below;

Supply : 2.56m³/s @ 430Pa external resistance

Extract : 2.02m³/s @ 488Pa external resistance

In terms of additional air volume requirements, the supply air volume would require to be increased by 291l/s (0.291m³/s), with the extract air duty increasing by 285l/s (0.285m³/s).

These additional air flow rates would increase the actual operational AHU duties as shown below;

Supply : 2.56m³/s + 0.291m³/s = 2.851m³/s

Extract : 2.02m³/s + 0.285m³/s = 2.305m³/s

Deducting the revised actual flow rate requirements from the ***anticipated*** AHU capabilities (i.e. @ 125% duty), identified the following;

Supply : (125%) 3.08m³/s – 2.851m³/s = 0.229m³/s (i.e. 229l/s presumed spare capacity)

Extract : (125%) 2.36m³/s – 2.305m³/s = 0.055m³/s (i.e. 55l/s presumed spare capacity)

Following our analysis of record documentation (i.e. Zutec), we made direct contact with the AHU manufacturer to clarify the total extent of spare capacity that would be available after increasing air duties (i.e. assuming there to be slightly more than 125% capacity within fan selections).

During these discussions we ascertained that AHU supply and extract fan units were sized and selected based on 100% air duty, with clean filters. Therefore, the initially assumed 25% additional capacity within each fan duty was not afforded at design/installation stage, albeit the AHU carcass, heat recovery device, and heating/cooling coils, were sized and selected to accommodate a 25% increase.

Maximum AHU 24 duties, and current spare capacities, are shown below;

Supply : 2.77m³/s @ 501Pa external resistance (spare capacity of 0.2m³/s & 71Pa)

Extract : 2.065m³/s @ 512Pa external resistance (spare capacity of 0.05m³/s & 24Pa)

Note
AHU capabilities are based on clean filters, and therefore, we anticipate there will be a reduction in existing air volumes (i.e. ac/hr) as filter free areas diminish. This could also potentially adversely influence any positive/negative air differential pressure strategies, if applicable to this particular system.

We would also emphasise the probability of these issues/inadequacies being applicable to other AHU's/systems.

4.02 Supply & Extract Ductwork

Supply Air Ductwork

Reviewing existing supply air distribution ductwork relative to the desired increased air volume requirements identified the following;

- Main 1000x600mm rectangular ductwork from AHU would increase in velocity from 4.3m/s to 4.8m/s.

  CIBSE guidance recommends a maximum duct velocity of 7.5m/s for rectangular ductwork installed within a riser, relative to a normal type environment (i.e. we have considered this to be ductwork installed within a plant room area).

- 450x400mm rectangular riser ductwork (i.e. ductwork serving all induction modules) routed from plant room area would increase in velocity from 4.8m/s to 6.4m/s.

  CIBSE guidance recommends a maximum duct velocity of 5m/s for rectangular ductwork installed within a riser, relative to a critical type environment. In addition, the increase in associated ductwork pressure drop, and potential noise generation via the volume control damper, would also be of concern.

- 350x300mm rectangular ductwork branch from the riser, serving 2nd Floor induction modules, would increase in velocity from 4m/s to 6.8m/s.

CIBSE guidance recommends a maximum duct velocity of 3m/s for rectangular ductwork installed above a suspended ceiling, relative to a critical type environment. In addition, the increase in associated ductwork pressure drop, and potential noise generation via the volume control damper, would be of concern.

- 200mm diameter ductwork branch serving induction modules within the BMT Day Ward would increase from 2.6m/s to 5.6m/s.

  CIBSE guidance recommends a maximum duct velocity of 5m/s for circular ductwork installed above a suspended ceiling, relative to a critical type environment.

  Whilst additional noise generation created within the ductwork may be deemed acceptable, the associated increase in pressure drop, and potential noise generation via the volume control damper, would be of concern.

- 250mm diameter ductwork branch serving all 3Nr induction modules within the DCU Ward would increase from 2.5m/s to 6.6m/s.

  CIBSE guidance recommends a maximum duct velocity of 5m/s for circular ductwork installed above a suspended ceiling, relative to a critical type environment. In addition, the increase in associated ductwork pressure drop, and potential noise generation via the volume control damper, would be of concern.

- 200mm diameter ductwork branch serving 2Nr induction modules within the DCU Ward would increase from 2.6m/s to 5.6m/s.

  CIBSE guidance recommends a maximum duct velocity of 5m/s for circular ductwork installed above a suspended ceiling, relative to a critical type environment.

  Whilst additional noise generation created within the ductwork may be deemed acceptable, the associated increase in pressure drop would be of concern.

- 160mm diameter supply ductwork serving each induction module unit would increase from 2m/s to 4.4m/s.

  CIBSE guidance recommends a maximum duct velocity of 1.5m/s for supply air openings (i.e. terminals) within a critical type environment.

<u>Extract Air Ductwork</u>

Reviewing existing extract air distribution ductwork relative to the desired increased air volume requirements identified the following;

- Main 850x500mm rectangular ductwork to AHU would increase in velocity from 4.7m/s to 5.4m/s.

CIBSE guidance recommends a maximum duct velocity of 7.5m/s for rectangular ductwork installed within a riser, relative to a normal type environment (i.e. we have considered this to be ductwork installed within a plant room area).

- Vertical rectangular riser ductwork is the same size as main ductwork within the plant room.

- 500x350mm rectangular ductwork branch to the riser would increase in velocity from 4.7m/s to 6.4m/s.

  CIBSE guidance recommends a maximum duct velocity of 3m/s for rectangular ductwork installed above a suspended ceiling, relative to a critical type environment. In addition, the increase in associated ductwork pressure drop, and potential noise generation via the volume control damper, would be of concern.

- 350x300mm rectangular ductwork routed from DCU/BMT Wards would increase in velocity from 4.5m/s to 7.3m/s.

  CIBSE guidance recommends a maximum duct velocity of 3m/s for rectangular ductwork installed above a suspended ceiling, relative to a critical type environment. In addition, the increase in associated ductwork pressure drop, and potential noise generation via the volume control damper, would be of concern.

- 315mm diameter circular ductwork, serving DCU Ward inlet and other inlets elsewhere within the zone, would increase from 4.12m/s to 6.6m/s.

  CIBSE guidance recommends a maximum duct velocity of 5m/s for circular ductwork installed above a suspended ceiling, relative to a critical type environment. In addition, the increase in associated ductwork pressure drop, and potential noise generation via the volume control damper, would be of concern.

- 250mm diameter circular ductwork serving DCU Ward inlet would increase from 1.8m/s to 5.7m/s.

  CIBSE guidance recommends a maximum duct velocity of 2m/s for extract air openings (i.e. terminals) within a critical type environment.

- 160mm diameter circular ductwork serving BMT Ward inlet would increase from 2.1m/s to 6.5m/s.

  CIBSE guidance recommends a maximum duct velocity of 2m/s for extract air openings (i.e. terminals) within a critical type environment.

4.03 Supply & Extract Air Terminals

Supply Air Terminals

Primary supply air is delivered into each Ward via ceiling mounted Swegon Parasol heating/cooling comfort modules, each supplying approximately 40l/s. It should be noted that these comfort modules are not chilled beams, as incorrectly identified within record documentation.

Manufacturers technical literature (i.e. from Zutec) identifies that 'HF' double modules are capable of supplying up to 55l/s. At a primary air supply volume of 40l/s, module sound level is stated as being 28dB(A), with a nozzle pressure of 63Pa. At the upper limit of 55l/s, module sound level is stated as being 36dB(A), with a nozzle pressure of 119Pa. Therefore, the relatively low increase in air volume (i.e. 15l/s) creates significant increase to both sound level and nozzle pressure.

In addition, 1Nr induction module installed within the DCU Ward is defined as being an 'HF' single unit, with a commissioned primary supply air flow rate of 41l/s. Manufacturers technical literature indicates that single modules are only available in type 'MF', with an associated maximum primary air flow rate of 34l/s.

Extract Air Terminals

1Nr ceiling mounted extract air diffuser is installed within each Ward. The manufacturers literature (i.e. Mr VENT) contained on Zutec was insufficiently detailed to assess the impact of increasing air flow rates and associated resistances. As such, Waterloo Air Management 4-way blow air diffuser catalogue data was utilised for guidance.

Our findings identify that existing extract diffusers are likely capable of handling more than 500l/s.

4.04 LTHW Heating & Chilled Water Installations

The AHU manufacturer confirmed heating and cooling coils are capable of providing the associated additional duties required for a 25% increase to air flow rate.

LTHW heating constant temperature circuit load serving the AHU frost and re-heat coils would be increased by approximately 4kW, and 7kW, respectively. Associated pump set flow rate requirement serving this heating circuit would also increase accordingly (i.e. 11kW).

Chilled water circuit load serving the AHU cooling coil would be increased by approximately 4kW. Associated pump set flow rate requirement serving this chilled water circuit would also increase accordingly.

From our indicative calculations, we note the following;

- Frost coil heating circuit appears to have adequate spare capacity for additional load/flow rate.

- Re-heat coil heating circuit pressure drop per meter length is above typical sizing parameters (i.e. Pa/m), although deemed unlikely to be problematic in terms associated pump pressure availability. The circuit balancing valve may require replacement (i.e. revised flow rate potentially excessive in terms of obtaining accurate commissioning reading).

- Constant temperature heating circuit pump set, which serves numerous AHU's, currently operates at a flow rate of 37.3kg/s. Therefore, the proposed additional flow rate is unlikely to be problematic.

- Cooling coil chilled water circuit pressure drop per meter length is above typical sizing parameters (i.e. Pa/m), although deemed unlikely to be problematic in terms associated pump pressure availability. The circuit balancing valve may require replacement (i.e. revised flow rate potentially excessive in terms of obtaining accurate commissioning reading).

- Chilled water circuit pump set, which serves numerous AHU's, currently operates at a flow rate of 71.3kg/s. Therefore, the proposed additional flow rate is unlikely to be problematic.

4.05 Summary of Findings

- Existing Ward area air change rates are significantly lower than would be expected, and not in accordance with recommendations defined within in either SHTM 03-01, or HTM 03-01.

  Whilst we were unable to locate documentation on Zutec defining system design criteria, HTM 03-01 was available in 2007. If there was an agreed deviation from recommendations defined within guidance documents, we would expect this to be clarified within the Health and Safety File documentation, and/or associated system descriptions.

- Ventilation installations within both Ward areas appear to have been commissioned to operate under a slightly negative pressure, and therefore, there is a risk that air is being entrained into the Wards via the adjacent Corridor.

- AHU supply and extract fans were apparently sized and selected based on 100% air duty with clean filters, and commissioned to operate at/near full duty. In view of this, the AHU does not have sufficient spare capacity to facilitate the desired increase in air volumes necessary to achieve 6 ac/hr.

  Operating the AHU at/near full duty on a continued basis may adversely influence life expectancy of associated components.

  As AHU capabilities are based on clean filters, we anticipate there will be a reduction in current/existing air volumes (i.e. ac/hr) as filter free areas diminish. This could also potentially adversely influence any positive/negative air differential pressure strategies, if applicable to this particular system.

  We would also emphasise the probability of these issues/inadequacies being applicable to other AHU's/systems.

- AHU heating and cooling coils have sufficient spare capacity to facilitate the necessary increased air volumes. Associated LTHW heating and chilled water system pumps and distribution are deemed to be adequate, however, existing balancing valves may require replacement.

- The majority of existing supply and extract ductwork distribution serving the Ward areas is deemed to be inadequate to facilitate the desired increase in air volumes to support 6 ac/hr (i.e. due to potential noise and increased pressure drop).

- Existing supply air induction modules are capable of delivering up to 55l/s of primary air (i.e. ignoring the increase to sound level and nozzle pressure). As both Ward areas would require considerably higher primary air flow rates to achieve 6 ac/hr, existing installed modules are not deemed suitable.

- The single module installed within the DCU Ward does not appear to be adequately selected based on the commissioned volume of primary air, and heating/chilled water flow rates.

  Whilst we would need to confirm with the manufacturer, we anticipate the associated sound level from this particular module will be > 40dB(A), with nozzle pressure > 175Pa.

- Existing extract terminals appear to be suitably sized to accommodate the additional air volumes, however, associated plenum boxes at the rear of each terminal would require replacement.

- Additional primary air supplied into each space would need to be conditioned by the associated terminals, and therefore, minor localised modification to the existing heating and chilled water distribution services would be required.

SECTION 5 – System Alterations Required

5.01 Outline of Works

The following list outlines the probable works required to the existing installations to facilitate an increase in air volume flow rates, necessary to achieve 6 ac/hr.

- Removal and reinstatement of existing ceilings and all associated fixtures/fittings (i.e. light fittings, fire alarms, etc.).

  It may also be necessary to relocate, or temporarily remove, elements of existing services located within the ceiling voids to facilitate the works (i.e. to access ductwork, remove ductwork, install new ductwork, etc).

  A detailed intrusive site inspection would be required in order to accurately establish the associated requirements/costs relative to the eventual preferred works, which we recommend be undertaken prior to proceeding with detailed design.

- AHU supply and extract fan assemblies would require replacement. Assuming the associated inverter drives are matched, these would also require replacement.

- Replacement of existing heating and chilled water balancing valves, serving the AHU coils. Works will also necessitate recommissioning of associated pumps.

- Installation of new supply and extract ductwork distribution within the 2nd Floor Level ceiling voids, and the main vertical riser between 2nd and 4th Floor Levels (i.e. to plant room).

- Installation of additional supply air terminals within each Ward, with associated supplementary primary air conditioned accordingly.

  Another option would be to replace existing with new larger capacity terminals, thereby removing the current induction strategy from these specific spaces.

  Works would necessitate localised modification to existing heating and chilled water services within ceiling voids.

- Replacement of existing extract terminal plenum boxes.

- Balancing, commissioning, and cleaning works (assuming only proportional balancing required).

5.02 Approximate Timescales & Associated Costs

Design : 2 weeks
Site : 4-6 weeks
Cost : £100-125K

Notes

1. Approximate cost excludes installation of additional back-up / standby AHU.

2. Approximate cost assumes only minor works required in relation to the accessibility of existing ductwork installations (i.e. to enable removal of existing and install new).

3. Accurate AHU upgrade costs are still to be confirmed by the manufacturer.

4. It should emphasised that whilst some particular works are ongoing (i.e. AHU upgrade, balancing, etc.), the mechanical ventilation to all areas served will be out of use (i.e. MDU).

5.03 Alternate Option – Increasing Only BMT Air Volumes

As an alternate option, consideration could be given to increasing air volume flow rates to 6 ac/hr within only the BMT Ward areas. This would reduce the impact on existing installations, particularly with regards to ductwork distribution.

An outline of works deemed required, together with associated indicative timescales and costs, are provided below.

- Removal and reinstatement of existing ceilings and all associated fixtures/fittings (i.e. light fittings, fire alarms, etc.).

  It may still be necessary to relocate, or temporarily remove, elements of existing services located within ceiling voids to facilitate the works. A detailed intrusive inspection would be required to ascertain extent of same prior to commencing detailed design.

- Given the limitations with regards to existing supply and extract fans (i.e. flows & pressures), we would still recommend consideration be given to the replacement of both fan assemblies and associated inverters.

  As a minimum, the extract fan assembly and associated inverter would require replacement to facilitate the necessary additional flow rate to serve only the BMT Ward (i.e. currently 50l/s spare capacity, based on clean filters). If retained, the existing spare air volume capacity within the supply fan (i.e. 205l/s) would be further reduced.

- Allowance should still be made for the replacement of existing heating and chilled water balancing valves, serving AHU coils. Detailed design would accurately ascertain if existing could be retained (i.e. require to re-size valves). Associated pump set recommissioning should also still be included for.

- Installation of new supply and extract ductwork distribution within the 2nd Floor Level ceiling voids. Extent of replacement works could be limited if higher than desired/recommend duct air velocities were deemed to be acceptable (i.e. above particular areas, such as corridors and examination rooms).

- Installation of additional supply air terminals within the BMT Ward, with associated supplementary primary air conditioned accordingly.

  Replacement of existing with new larger capacity terminals should also still be considered, which would remove the current induction strategy from this space.

  Works would necessitate localised modification to existing heating and chilled water services within the BMT Ward ceiling void.

- Replacement of existing BMT Ward extract terminal plenum box.

- Balancing, commissioning, and cleaning works (assuming only proportional balancing required).

Approximate Timescales & Associated Costs

Design : 1-2 weeks
Site : 3-5 weeks
Cost : £60-80K

Notes

1. Approximate cost excludes installation of additional back-up / standby AHU.

2. Approximate cost assumes only minor works required in relation to the accessibility of existing ductwork installations (i.e. to enable removal of existing and install new).

3. Accurate AHU upgrade costs are still to be confirmed by the manufacturer.

5. It should emphasised that whilst some particular works are ongoing (i.e. AHU upgrade, balancing, etc.), the mechanical ventilation to all areas served will be out of use (i.e. MDU).

SECTION 6 – Additional Notes

6.01 Additional Points Identified During Analysis

The following additional points were noted whilst undertaking our feasibility analysis.

1. Whilst technical literature provided on Zutec would suggest there is 125% capacity available in AHU's, the manufacturer has advised that fans/motors were selected based on 100% duty with clean air filters (i.e. all AHU's).

   In view of this, in some instances we anticipate there will be a reduction to existing/commissioned air volumes as the free area of filters reduces during operation/use. Furthermore, this may adversely influence positive/negative air differential pressure strategies, depending on facilities served.

   Please note, this issue may also be applicable to other individual extract fan units (i.e. dirty extract systems).

2. We were unable to acquire any information pertaining to the intended ductwork system classification. We anticipate some systems are operating within medium pressure classification (i.e. Class B), and should therefore be verified.

   This should be verified prior to any potential increase in air volumes.

3. AHU 24 is equipped with a thermal wheel, and therefore, identifies a potential risk associated with cross-contamination. We recommend this be further investigated, and level of associated risk considered against the use of facilities.

   Furthermore, we anticipate the majority of AHU's installed within the building are also equipped with thermal wheels (i.e. Critical Care, General Theatres, Theatre Recovery, Endoscopy, Ultra CT Suite, Nuclear Medicine, etc.). Again, we recommend this be further investigated/considered accordingly.

4. AHU 24 is equipped with single supply and extract fan units, thereby not affording resilience in the event of failure to same. Failure would result in complete loss of all mechanical supply and extract ventilation to areas served from the AHU, effectively rendering the use of associated facilities unsuitable.

   Again, we anticipate this potential issue is applicable to other systems installed within the building.

5. H&V commissioning data relative to AHU 24 extract system states the fan chamber was "*full of water*".

6. We anticipate there could be numerous single module induction units installed throughout the building that are being supplied with excessive primary air volume (i.e. as per DCU Ward module).

7. Manufacturers literature relating to the supply air induction units identifies 'HF' double type modules are equipped with 125mm diameter ductwork connections. Record drawings indicate 160mm diameter run-outs to these terminals, and therefore, we assume ductwork is being reduced at connections.

   CIBSE recommend the maximum velocity for supply air openings (i.e. terminals) within critical type environments as being 1.5m/s. We anticipate the supply air velocity at connections to the induction units to be in the region of 3.3m/s.

8. As-Fitted record documentation, and associated technical literature, pertaining to terminal devices is deemed to be inadequate.

   For instance, record drawings do not identify the type (i.e. diffuser/grille/valve), size, number of throws, or associated air volume flow rates. Furthermore, extract terminals are identified on drawings as 'EG' (i.e. typically identifying extract/eggcrate grille), however, when reviewed on site these were found to be 4-way type diffusers.

INNOVATED
DESIGN SOLUTIONS

Queen Elizabeth University Hospital

Adult & Children's Hospital

Feasibility Study Regarding
Increasing Ventilation Air Change Rates
within Ward 2A

Client	NHS Greater Glasgow & Clyde, Queen Elizabeth University Hospital, 1345 Govan Road, Glasgow, G51 4TF
Project Ref.	141819
Date	24nd October 2018
Revision	01 (30.10.18)

CONTENTS

SECTION 1 – EXECUTIVE SUMMARY

1.01 Executive Summary

Following analysis of the current ventilation strategy within upper areas of Ward 2A (Mid-Ward & TCT areas), we anticipate the original accommodation design philosophy was not intended for use by patients with immune response impairment/deficiency. On the contrary, the existing ventilation strategy would appear only likely to promote the risks associated with uncontrolled ingress of infectious aerosols into patient areas.

Existing Bedroom supply air change rates were found to be in the region of 3ac/hr, which is significantly lower than would normally be expected, and not in accordance with recommendations defined within either SHTM 03-01, or HTM 03-01. Furthermore, we were unable to locate any details within the Zutec as-fitted record documentation pertaining to an agreed deviation from recommended guidance.

The desired increase in air change rates, to achieve 6ac/hr whilst utilising existing installations, is deemed impractical. Notwithstanding this, in view of numerous deficiencies/inadequacies discovered with regards to existing system installations we consider that significant system modification/replacement will be necessary in any event. Works recommended within the report generally involve the complete separation of upper Ward 2A facilities from the existing centralised plant/system, with new dedicated air handling plant and distribution installed accordingly.

The viability of creating dedicated Isolation Suites throughout the upper Ward 2A areas was considered, however, deemed to be impractical primarily due to the probable significant resultant reduction in accommodation. With a view to improving patient protection, we have recommended consideration be given to the installation of completely new ventilation systems, providing a positive pressure within each Bedroom with air cascade into adjacent Corridors. We believe this would be deemed to essentially afford Enhanced Single Room (with En-Suite facilities) accommodation, and be more appropriate for the intended purpose/patient group.

We have also explored the viability of creating a limited number of dedicated Isolation Suites. This option typically involves conversion of the existing Teenage Cancer Trust (TCT) Corridor into individual lobbies, and directly positively pressurising each TCT Bedroom space. We consider this to present the most practical and cost effective solution should additional Isolation Suites be deemed necessary.

In addition to the foregoing, during our analysis works we discovered numerous significant deficiencies/inadequacies appertaining to the existing system installations, which are outlined within the report accordingly.

Of particular note, it was identified that extract ductwork distribution derived from the Ward 2A air handling unit is utilised to serve numerous ‘dirty’ type spaces (i.e. Toilets, Shower Rooms, Dirty Utility Rooms, Disposal Rooms, Cleaners Stores, etc.), on various floor levels. This is deemed to be a very abnormal strategy, differs from design methodology adopted within other areas, and should be investigated further.

Moreover, whilst thermal wheel devices are regarded as an acceptable technique for energy recovery within SHTM 03-01, we would be hesitant with regards to the appropriateness of application in this instance, especially when air cleanliness would appear to be of vital importance in terms of patient safety.

Other significant discrepancies identified include, limitations in terms of air handling unit fan selections, the installation of single supply and extract fans within a unit serving numerous floor levels and acute facilities, substantial irregularities in terms of extract system air volumes, and undefined ductwork distribution pressure classification.

SECTION 2 – GENERAL

2.01 Purpose of Analysis

The purpose of this analysis is to determine the viability of increasing mechanical supply and extract air volumes to achieve 6 air changes per hour within the upper Single Bedroom spaces located within Ward 2A, including those situated within the Teenage Cancer Trust zone (also known as Mid-Ward & TCT areas). The analysis shall also involve ascertaining the impact increased air volumes would have with regards to existing installations (i.e. air handling unit, ductwork, terminal devices, etc.).

In addition to the above, it was requested that consideration be given in terms of the probable extent of system modifications necessary in order to ensure mechanical ventilation provisions were suitable for the environment/facilities served.

The ventilation installations within the lower portion of Ward 2A (i.e. BMT area) does not form part of this analysis.

2.02 General System Description

There are 17Nr Single Bedrooms, each with En-Suite facilities, located within the upper portion of Ward 2A. Primary supply air is delivered directly into each Bedroom via a ceiling mounted double type induction unit, which locally tempers air supply utilising integral heating/cooling facilities. Air is extracted from each En-Suite via a ceiling mounted circular valve type terminal.

Mechanical supply and extract facilities serving the upper Ward 2A Bedrooms/En-Suites is derived via air handling unit (AHU) reference 41-AHU20A, which is located within Plant Room 41 on the 4th Floor Level. This AHU also provides mechanical supply and extract ventilation to numerous other areas/facilities within the building, located on Level 3 (Ward 3A), Level 1 (23Hr Ward 1A), and Ground Floor Level (OPD - ENT / GP out of hours).

Primary supply air is ducted to induction units and supply air diffusers separately from the 4th Floor Level Plant Room area, with a common LTHW heating re-heat coil fitted to ductwork serving diffusers.

SECTION 3 – Air Change Rates

3.01 Existing Air Change Rates

H&V commissioning data for each supply and extract terminal was utilised to calculate current room air change rates, as shown within the table below.

Note : As indicated, room volumes were calculated based on 2.72m ceiling height throughout.

Room Reference	Area (m^2)	Height (m)	Volume (m^3)	Air Changes Per Hour	m^3/hr	Supply (l/s)	Extract (l/s)
SCH - 041 (Bedroom)	17.3	2.72	47.1	3.1	144	40	
SCH - 042 (En-Suite)	5.2	2.72	14.1	11.7	166		46
SCH - 044 (Bedroom)	17.2	2.72	46.8	3.1	144	40	
SCH - 043 (En-Suite)	4.9	2.72	13.3	12.4	166		46
SCH - 046 (Bedroom)	17.1	2.72	46.5	3.1	144	40	
SCH - 048 (En-Suite)	4.9	2.72	13.3	12.4	166		46
TCT - 010 (Bedroom)	18.6	2.72	50.6	2.8	144	40	
TCT - 009 (En-Suite)	5.8	2.72	15.8	10.5	166		46
TCT - 007 (Bedroom)	17.8	2.72	48.4	3.0	144	40	
TCT - 008 (En-Suite)	5.2	2.72	14.1	11.7	166		46
TCT - 006 (Bedroom)	17.5	2.72	47.6	3.0	144	40	
TCT - 005 (En-Suite)	5.5	2.72	15.0	11.1	166		46
TCT - 003 (Bedroom)	18.5	2.72	50.3	2.9	144	40	
TCT - 004 (En-Suite)	5.2	2.72	14.1	11.7	166		46
SCH - 049 (Bedroom)	16.9	2.72	46.0	3.1	144	40	
SCH - 047 (En-Suite)	5.2	2.72	14.1	11.7	166		46
SCH - 050 (Bedroom)	16.9	2.72	46.0	3.1	144	40	
SCH - 051 (En-Suite)	4.6	2.72	12.5	13.5	169		47
SCH - 053 (Bedroom)	16.9	2.72	46.0	3.1	144	40	
SCH - 052 (En-Suite)	5.3	2.72	14.4	11.7	169		47
SCH - 054 (Bedroom)	17	2.72	46.2	3.1	144	40	
SCH - 056 (En-Suite)	5.3	2.72	14.4	11.7	169		47

SCH - 057 (Bedroom)	16.9	2.72	46.0	3.1	144	40	
SCH - 055 (En-Suite)	4.6	2.72	12.5	13.5	169		47
SCH - 058 (Bedroom)	16.9	2.72	46.0	3.1	144	40	
SCH - 059 (En-Suite)	4.6	2.72	12.5	13.2	166		46
SCH - 061 (Bedroom)	17	2.72	46.2	3.1	144	40	
SCH - 060 (En-Suite)	5.3	2.72	14.4	11.7	169		47
SCH - 027 (Bedroom)	17.5	2.72	47.6	3.0	144	40	
SCH - 022 (En-Suite)	5.8	2.72	15.8	10.5	166		46
SCH - 028 (Bedroom)	17.5	2.72	47.6	3.0	144	40	
SCH - 031 (En-Suite)	5.7	2.72	15.5	10.9	169		47
SCH - 033 (Bedroom)	17.8	2.72	48.4	3.0	144	40	
SCH - 032 (En-Suite)	4.8	2.72	13.1	13.0	169		47
						680	**789**

As illustrated above, existing Bedroom air change rates were found to vary between 2.8 - 3.1ac/hr, with associated En-Suite air change rates varying between 10.5 - 13.5ac/hr.

It should also be noted that the extract rate is above that of the supply air, thereby identifying Bedrooms were apparently designed and commissioned to operate under a slightly negative pressure relative to adjacent Corridors.

3.02 Proposed Air Volumes

The table shown below identifies the air volumes required within each space to facilitate the desired 6 ac/hr within Bedrooms, together with the resultant increase to En-Suite air change rates.

Room Reference	Area (m^2)	Height (m)	Volume (m^3)	Air Changes Per Hour	m^3/hr	Supply (l/s)	Extract (l/s)
SCH - 041 (Bedroom)	17.3	2.72	47.1	6.0	282	78	
SCH - 042 (En-Suite)	5.2	2.72	14.1	20.0	282		78
SCH - 044 (Bedroom)	17.2	2.72	46.8	6.0	281	78	
SCH - 043 (En-Suite)	4.9	2.72	13.3	21.1	281		78
SCH - 046 (Bedroom)	17.1	2.72	46.5	6.0	279	78	
SCH - 048 (En-Suite)	4.9	2.72	13.3	20.9	279		78
TCT - 010 (Bedroom)	18.6	2.72	50.6	6.0	304	84	
TCT - 009 (En-Suite)	5.8	2.72	15.8	19.2	304		84

TCT - 007 (Bedroom)	17.8	2.72	48.4	6.0	290	81	
TCT - 008 (En-Suite)	5.2	2.72	14.1	20.5	290		81
TCT - 006 (Bedroom)	17.5	2.72	47.6	6.0	286	79	
TCT - 005 (En-Suite)	5.5	2.72	15.0	19.1	286		79
TCT - 003 (Bedroom)	18.5	2.72	50.3	6.0	302	84	
TCT - 004 (En-Suite)	5.2	2.72	14.1	21.3	302		84
SCH - 049 (Bedroom)	16.9	2.72	46.0	6.0	276	77	
SCH - 047 (En-Suite)	5.2	2.72	14.1	19.5	276		77
SCH - 050 (Bedroom)	16.9	2.72	46.0	6.0	276	77	
SCH - 051 (En-Suite)	4.6	2.72	12.5	22.0	276		77
SCH - 053 (Bedroom)	16.9	2.72	46.0	6.0	276	77	
SCH - 052 (En-Suite)	5.3	2.72	14.4	19.1	276		77
SCH - 054 (Bedroom)	17	2.72	46.2	6.0	277	77	
SCH - 056 (En-Suite)	5.3	2.72	14.4	19.2	277		77
SCH - 057 (Bedroom)	16.9	2.72	46.0	6.0	276	77	
SCH - 055 (En-Suite)	4.6	2.72	12.5	22.0	276		77
SCH - 058 (Bedroom)	16.9	2.72	46.0	6.0	276	77	
SCH - 059 (En-Suite)	4.6	2.72	12.5	22.0	276		77
SCH - 061 (Bedroom)	17	2.72	46.2	6.0	277	77	
SCH - 060 (En-Suite)	5.3	2.72	14.4	19.2	277		77
SCH - 027 (Bedroom)	17.5	2.72	47.6	6.0	286	79	
SCH - 022 (En-Suite)	5.8	2.72	15.8	18.1	286		79
SCH - 028 (Bedroom)	17.5	2.72	47.6	6.0	286	79	
SCH - 031 (En-Suite)	5.7	2.72	15.5	18.4	286		79
SCH - 033 (Bedroom)	17.8	2.72	48.4	6.0	290	81	
SCH - 032 (En-Suite)	4.8	2.72	13.1	22.3	290		81
						1339	**1339**

Note

Air volumes above are related to increasing air change rates only, and are not intended to rectify any potential problems associated with the current ventilation strategies, in terms of positive/negative differential pressures.

SECTION 4 – Impact on Existing Installations

4.01 Air Handling Unit (AHU)

AHU manufacturers technical documentation contained within Zutec identified the following:-

- Designed on the basis of providing 4.05m³/s supply air flow rate at an external pressure of 690Pa (i.e. system/ductwork resistance).
- Designed on the basis of providing 2.65m³/s extract air flow rate at an external pressure of 530Pa (i.e. system/ductwork resistance).
- Technical data is provided for the AHU operating at 125% duty (i.e. supply and extract fans, heating/cooling coils, thermal wheel, etc.).
- The AHU was manufactured in accordance with Class B leakage standard.

Following further discussion with the AHU manufacturer, existing maximum supply and extract fan capabilities were advised to be as follows;

Supply : 4.809m³/s @ 1075Pa

Extract : 3.189m³/s @ 562Pa

Note
This identifies that AHU supply and extract fans were not sized or selected to afford a 25% spare capacity (i.e. as suggested by record documentation).

H&V commissioning data from Zutec identified the following;

Supply (Design) : 4.047m³/s. Design external resistance section states "*no detail*".

Supply (Actual) : 4.151m³/s @ 802Pa external resistance

Extract (Design) : 2.563m³/s @ 530Pa external resistance

Extract (Actual) : 2.913m³/s @ 468Pa external resistance

In terms of additional air volume requirements, the supply air system would require to be increased by 659l/s (0.659m³/s), with the extract air system increased by 550l/s (0.55m³/s).

These additional air flow rates would increase the actual operational AHU duties as shown below;

Supply : 4.151m³/s + 0.659m³/s = **4.81m³/s**

Extract : 2.913m³/s + 0.55m³/s = **3.463m³/s**

4.02 Supply & Extract Ductwork

Supply Air Ductwork

Reviewing existing supply air distribution ductwork relative to the desired increased air volume requirements identified the following;

- Level 2 record drawing indicates main riser ductwork to be 7550x600mm, however, duct size detailed on H&V commissioning data, and other record drawings (i.e. main plant room layout), identifies this section of as 600x500mm. For the purpose of analysis we have assumed 600x500mm.

  Main 600x500mm rectangular ductwork within plant room would increase in velocity from 4.6m/s to 6.7m/s.

  CIBSE guidance recommends a maximum duct velocity of 7.5m/s for rectangular ductwork installed within a riser, relative to a normal type environment (i.e. we have considered this to be ductwork installed within a plant room area).

  Whilst additional noise generation created within the ductwork may be deemed acceptable, the associated increase in pressure drop would be of concern.

- 600x500mm rectangular riser ductwork from plant room to Level 3 would increase in velocity from 4.6m/s to 6.7m/s.

  CIBSE guidance recommends a maximum duct velocity of 5m/s for rectangular ductwork installed within a riser, relative to a critical type environment. In addition, the increase in associated ductwork pressure drop would also be of concern.

- 600x500mm section of rectangular riser ductwork between Level 3 and Level 2 would increase in velocity from 3.3m/s to 5.3m/s.

  CIBSE guidance recommends a maximum duct velocity of 5m/s for rectangular ductwork installed within a riser, relative to a critical type environment.

  Whilst additional noise generation created within the ductwork may be deemed acceptable, the associated increase in pressure drop would be of concern.

- 500x350mm rectangular ductwork from riser to ceiling void of Level 2, routed above TCT-007 Bedroom, would increase in velocity from 3.9m/s to 7.8m/s.

CIBSE guidance recommends a maximum duct velocity of 3m/s for rectangular ductwork installed above a suspended ceiling, relative to a critical type environment. In addition, the increase in associated ductwork pressure drop, and potential noise generation via the volume control damper, would be of concern.

- 450x300mm rectangular ductwork routed above TCT-006 Bedroom would increase in velocity from 4.4m/s to 8.9m/s.

  CIBSE guidance recommends a maximum duct velocity of 3m/s for rectangular ductwork installed above a suspended ceiling, relative to a critical type environment. In addition, the increase in associated ductwork pressure drop would be of concern.

- 250mm diameter ductwork branch routed above TCT-003 Bedroom would increase in velocity from 3.3m/s to 6.6m/s.

  CIBSE guidance recommends a maximum duct velocity of 5m/s for circular ductwork installed above a suspended ceiling, relative to a critical type environment. In addition, the increase in associated ductwork pressure drop, and potential noise generation via the volume control damper, would be of concern.

- 200mm diameter ductwork routed above TCT-002 Contingency & SCH-033 Bedroom would increase in velocity from 3.8m/s to 7.6m/s.

  CIBSE guidance recommends a maximum duct velocity of 5m/s for circular ductwork installed above a suspended ceiling, relative to a critical type environment. In addition, the increase in associated ductwork pressure drop would be of concern.

- 200mm diameter ductwork routed above SCH-033 Bedroom and SCH-028 Bedroom would increase in velocity from 2.6m/s to 5.2m/s.

  Whilst additional noise generation created within the ductwork may be deemed acceptable, the associated increase in pressure drop would be of concern.

- 350x300mm rectangular ductwork branch routed above TCT-001 Corridor & SCH-045 Corridor would increase in velocity from 3.8m/s to 7.6m/s.

  CIBSE guidance recommends a maximum duct velocity of 3m/s for rectangular ductwork installed above a suspended ceiling, relative to a critical type environment. In addition, the increase in associated ductwork pressure drop would be of concern.

- 315mm diameter ductwork routed above SCH-046 Bedroom & SCH-049 Bedroom would increase in velocity from 3.6m/s to 7.2m/s.

  CIBSE guidance recommends a maximum duct velocity of 5m/s for circular ductwork installed above a suspended ceiling, relative to a critical type environment. In addition, the increase in associated ductwork pressure drop would be of concern.

- 315mm diameter ductwork routed above SCH-50 Bedroom & SCH-53 Bedroom would increase in velocity from 2.6m/s to 5.2m/s.

  Whilst additional noise generation created within the ductwork may be deemed acceptable, the associated increase in pressure drop would be of concern.

- 250mm diameter ductwork routed above SCH-053 Bedroom & SCH-054 Bedroom would increase in velocity from 3.3m/s to 6.6m/s.

  CIBSE guidance recommends a maximum duct velocity of 5m/s for circular ductwork installed above a suspended ceiling, relative to a critical type environment. In addition, the increase in associated ductwork pressure drop would be of concern.

- 200mm diameter ductwork routed above SCH-054 Bedroom & SCH-057 Bedroom would increase in velocity from 3.8m/s to 7.6m/s.

  CIBSE guidance recommends a maximum duct velocity of 5m/s for circular ductwork installed above a suspended ceiling, relative to a critical type environment. In addition, the increase in associated ductwork pressure drop would be of concern.

- 160mm diameter ductwork serving each ceiling mounted induction module would typically increase from around 2m/s to approximately 4m/s.

  CIBSE guidance recommends a maximum duct velocity of 1.5m/s for supply air openings (i.e. terminals) within a critical type environment.

Extract Air Ductwork

Reviewing existing extract air distribution ductwork relative to the desired increased air volume requirements identified the following;

- Due to the extent of uncertainty with regards to design air volume, commissioned air volume, and our calculated total air volume, we were unable to accurately ascertain existing or proposed velocities within main plant room, or vertical riser, ductwork distribution.

  Note
  Please refer to 'Additional Notes' section of this report for further detail pertaining to same.

- 500x350mm rectangular ductwork from Level 2 ceiling void to riser, routed above TCT-010 Bedroom, would increase in velocity from 4.9m/s to 8m/s.

  CIBSE guidance recommends a maximum duct velocity of 3m/s for rectangular ductwork installed above a suspended ceiling, relative to a critical type environment. In addition, the increase in associated ductwork pressure drop would be of concern.

- 450x300mm rectangular ductwork branch routed above TCT-010 Bedroom & TCT-001 Corridor would increase in velocity from 3.7m/s to 6.1m/s.

  CIBSE guidance recommends a maximum duct velocity of 3m/s for rectangular ductwork installed above a suspended ceiling, relative to a critical type environment. In addition, the increase in associated ductwork pressure drop, and potential noise generation via the volume control damper, would be of concern.

- 350x300mm rectangular ductwork routed above TCT-001 Corridor, SCH-039 Corridor, & SCH-041 Bedroom would increase in velocity from 4.4m/s to 7.5m/s.

  CIBSE guidance recommends a maximum duct velocity of 3m/s for rectangular ductwork installed above a suspended ceiling, relative to a critical type environment. In addition, the increase in associated ductwork pressure drop would be of concern.

- 355mm diameter ductwork routed above SCH-043 Bedroom & SCH-046 Bedroom would increase in velocity from 3.8m/s to 6.4m/s.

  CIBSE guidance recommends a maximum duct velocity of 5m/s for circular ductwork installed above a suspended ceiling, relative to a critical type environment. In addition, the increase in associated ductwork pressure drop would be of concern.

- 315mm diameter ductwork routed above SCH-049 Bedroom & SCH-050 Bedroom would increase in velocity from 3.6m/s to 6.1m/s.

  CIBSE guidance recommends a maximum duct velocity of 5m/s for circular ductwork installed above a suspended ceiling, relative to a critical type environment. In addition, the increase in associated ductwork pressure drop would be of concern.

- 250mm diameter ductwork routed above SCH-053 Bedroom & SCH-054 Bedroom would increase in velocity from 3.8m/s to 6.4m/s.

  CIBSE guidance recommends a maximum duct velocity of 5m/s for circular ductwork installed above a suspended ceiling, relative to a critical type environment. In addition, the increase in associated ductwork pressure drop would be of concern.

- 200mm diameter ductwork routed above SCH-057 Bedroom & SCH-058 Bedroom would increase in velocity from 3m/s to 5m/s.

  Whilst additional noise generation created within the ductwork may be deemed acceptable, the associated increase in pressure drop would be of concern.

- 355mm diameter ductwork branch routed above TCT-010 Bedroom would increase in velocity from 3.6m/s to 5.9m/s.

  CIBSE guidance recommends a maximum duct velocity of 5m/s for circular ductwork installed above a suspended ceiling, relative to a critical type environment. In addition, the increase in

associated ductwork pressure drop, and potential noise generation via the volume control damper, would be of concern.

- 315mm diameter ductwork routed above TCT-007 Bedroom & TCT-006 Bedroom would increase in velocity from 3.3m/s to 5.4m/s.

  Whilst additional noise generation created within the ductwork may be deemed acceptable, the associated increase in pressure drop would be of concern.

- 250mm diameter ductwork routed above TCT-003 Bedroom & TCT-002 Contingency would increase in velocity from 3.4m/s to 5.4m/s.

  Whilst additional noise generation created within the ductwork may be deemed acceptable, the associated increase in pressure drop would be of concern.

- 200mm diameter ductwork branches (i.e. each serving 2Nr En-Suite terminals), would increase in velocity from 3m/s to 5m/s.

  Velocity would be at the maximum recommended by CIBSE, and additional noise generation created within the ductwork may be deemed unacceptable from within En-Suite space. Associated resulting increase in pressure drop would also be of concern.

- 160mm diameter ductwork serving each extract valve terminal would typically increase from around 2.3m/s to approximately 3.9m/s.

  CIBSE guidance recommends a maximum duct velocity of 2m/s for extract air openings (i.e. terminals) within a critical type environment.

4.03 Supply & Extract Air Terminals

Supply Air Terminals

Primary supply air is delivered into each Bedroom space via a ceiling mounted double type Swegon Parasol heating/cooling comfort module, apparently supplying exactly 40l/s in the majority of instances. It should be noted that comfort modules are not chilled beams, as incorrectly identified within record documentation, albeit functionality is very similar.

Manufacturers technical literature (i.e. from Zutec) identifies that 'HF' double modules are capable of supplying up to 55l/s. At a primary air supply volume of 40l/s, module sound level is stated as being 28dB(A), with a nozzle pressure of 63Pa. At the upper limit of 55l/s, module sound level is stated as being 36dB(A), with a nozzle pressure of 119Pa.

Therefore, the above demonstrates a relatively low increase in air volume (i.e. 15l/s) would cause a significant increase to both sound level and nozzle pressure (i.e. resistance).

Extract Air Terminals

Air is extracted from each En-Suite via a ceiling mounted circular valve type terminal. Whilst record documentation does not identify the valve type installed within each space, we anticipate that the MRV-DVE type 200 has been installed.

Manufacturers literature (i.e. Mr Vent) is very limited in terms of varying air flow rates, however, it does identify that a DVE200 is capable of extracting 110l/s with a sound level of 30dB(A), and resistance of 60Pa.

4.04 LTHW Heating & Chilled Water Installations

The AHU manufacturer has confirmed heating and cooling coils are capable of providing the associated additional duties required for a 25% increase to air flow rate.

LTHW heating constant temperature circuit load serving the AHU frost and re-heat coils would be increased by approximately 9kW, and 15kW, respectively. Associated pump set flow rate requirement serving this heating circuit would also increase accordingly (i.e. 0.38kg/s).

Chilled water circuit load serving the AHU cooling coil would be increased by approximately 10kW. Associated pump set flow rate requirement serving this chilled water circuit would also increase accordingly (i.e. 0.4kg/s).

From our indicative calculations relative to existing installations, we note the following;

- 54mm diameter frost coil heating circuit appears to have adequate spare capacity for additional load/flow rate.
- 54mm diameter re-heat coil heating circuit appears to have adequate spare capacity for additional load/flow rate.
- Both frost coil and re-heat coil circuit balancing valves may require replacement, due to potential excessive flow rate to obtain accurate commissioning reading.
- 65mm diameter cooling coil chilled water circuit appears to have adequate spare capacity for additional load/flow rate.
- Cooling coil chilled water circuit balancing valve may require replacement, due to potential excessive flow rate to obtain accurate commissioning reading.
- Both LTHW heating and chilled water circuit pump sets are deemed to have adequate capacity to facilitate additional load/flow requirements.

With regards to LTHW heating and chilled water distribution within Ward 2A, indicative calculations indicate that installations (i.e. pipework and valves) are capable of accommodating additional load/flow requirements.

4.05 Summary of Findings

- Existing Bedroom supply air change rates were typically found to be in the region of 3ac/hr, which is significantly lower than would normally be expected (i.e. 6ac/hr). It should also be noted that current air change rates are not in accordance with recommendations defined within either SHTM 03-01, or HTM 03-01.

  Whilst we were unable to locate documentation on Zutec defining system design criteria, HTM 03-01 was available in 2007. If there was an agreed deviation from recommendations defined within guidance documents, available at the time of design, we would expect this to be clarified within the Health and Safety File documentation and/or associated system descriptions.

- Bedroom/En-Suite areas were designed/commissioned to operate under a slightly negative pressure. As Corridors areas were designed/commissioned to operate under a positive pressure strategy we anticipate air is likely being entrained into Bedrooms from the adjacent circulation spaces. This issue is applicable to all upper circulation areas within Ward 2A (i.e. Mid-Ward & TCT areas).

- AHU supply and extract fans were apparently sized and selected based on 100% design air volume, with clean filters.

  Following analysis, we have determined that AHU supply and extract fan capabilities are insufficient to facilitate the desired increase in air volumes necessary to achieve 6ac/hr (i.e. based on clean air filters).

  Whilst supply and extract fans both have a limited extent of spare capacity (i.e. estimated to be 15.5% and 9.5% air volume, respectively), operating near full duty on a continued basis may adversely influence life expectancy.

  In addition, and as AHU capabilities are based on clean filters, we anticipate there is a risk associated with a reduction in current/existing air volumes (i.e. ac/hr) as filter free areas diminish. This may also potentially adversely influence positive/negative air differential pressure strategies.

  <u>We would also emphasise the probability of these issues/inadequacies being applicable to other air handling equipment installed within the A&C Hospital.</u>

- In view of various anomalies identified with regards to both main supply and extract ductwork distribution installations (refer to Additional Notes), we were unable to accurately establish existing/proposed ductwork air velocities for either the vertical risers or within the 4th floor plant room.

Notwithstanding the foregoing, we anticipate that supply air ductwork would require complete replacement from the air handling unit location to Level 2.

- The majority of existing supply and extract ductwork distribution within the Level 2 ceiling void is deemed inadequate to facilitate the desired increase in air volumes to support 6 ac/hr (i.e. due to potential noise and increased pressure drop).

  Furthermore, it was identified that air velocities within various sections of existing ductwork distribution is higher than would normally be deemed acceptable relative to a 'critical' type environment. This issue was predominately found to be related to rectangular ductwork installations.

- Existing supply air induction modules are capable of delivering up to 55l/s of primary air (i.e. ignoring the increase to sound level and nozzle pressure). As the air volume required to achieve 6 ac/hr is considerably higher, existing induction modules are not deemed suitable.

- Existing circular extract valve terminals, located within each En-Suite, appear to be capable of accommodating the desired increased air volumes. However, detailed technical literature would be required to determine this accurately, and establish the resultant increase in sound level and resistance.

- AHU heating and cooling coils are deemed to have sufficient spare capacity to facilitate the desired increase to air volume.

  LTHW heating and chilled water circuits serving the AHU coils are also deemed to be adequate, however, associated balancing valves may require replacement.

  Both LTHW heating and chilled water circuit pump facilities are deemed to have adequate capacity to accommodate the desired increase in load/flow.

- Any supplementary primary air being supplied into Bedroom areas would require local reconditioning, as to ensure thermally comfortable for the occupant.

  Existing LTHW heating and chilled water distribution installations are deemed to be capable of accommodating the additional loads/flow rates required, and therefore, only localised modifications within the ceiling void of each room are anticipated to be necessary.

SECTION 5 – System Alterations Required

5.01 Outline of Works

The following list outlines the probable works required to the existing installations to facilitate an increase in air volume flow rates, necessary to achieve 6 ac/hr.

Note
Works identified below are related to increasing air change rates only, and are not intended to rectify any potential problems associated with the current ventilation installations (i.e. positive/negative differential pressures, use of thermal wheel, single supply and extract fan units, etc.).

- Removal and reinstatement of existing ceilings and all associated fixtures/fittings (i.e. light fittings, fire alarms, etc.).

  It may also be necessary to relocate, or temporarily remove, elements of existing services located within the ceiling voids to facilitate the works (i.e. to access ductwork, remove ductwork, install new ductwork, etc).

  A detailed intrusive site inspection would be required in order to accurately establish the associated requirements/costs relative to the eventual preferred works, which we recommend be undertaken prior to proceeding with detailed design.

- New AHU supply and extract fan motors would be required, together with associated pulleys/belts. Assuming the associated inverter drives are matched, these would also require replacement.

- Replacement of existing heating and chilled water balancing valves, located on circuits serving the AHU coils. Works would also necessitate recommissioning of associated pumps.

- Complete replacement of supply and extract ductwork distribution within the 2nd Floor Level ceiling voids. Allowance should also be made for the replacement of main supply air ductwork distribution between the AHU and Level 2.

- Installation of additional supply air terminals within each Bedroom, with associated supplementary primary air conditioned accordingly.

  Another option would be to replace existing with new larger capacity terminals, thereby removing the current induction strategy from these specific spaces.

  Works would necessitate localised modification to existing heating and chilled water services within ceiling voids.

- Installation of new transfer grilles between each Bedroom and associated En-Suite.

- Balancing, commissioning, and cleaning works (assuming only proportional balancing required).

5.02 Approximate Timescales & Associated Costs

Design : 4 weeks
Site : 8-12 weeks
Cost : £200-300K

Notes

1. Approximate cost excludes installation of additional back-up / standby AHU.

2. Approximate cost assumes only minor works required in relation to the accessibility of existing ductwork installations (i.e. to enable removal of existing and install new).

3. Accurate AHU upgrade costs are still to be confirmed by the manufacturer.

4. It should emphasised that whilst some particular works are ongoing (i.e. AHU upgrade, balancing, etc.), the mechanical ventilation to all areas served will be out of use (i.e. Level 3/Ward 3A, Level 1/23Hr Ward 1A, and Ground Floor Level/OPD - ENT / GP out of hours.

SECTION 6 – Options for Facility Upgrade

6.01 General

Following our review of the current ventilation strategy within upper areas of Ward 2A (i.e. Mid-Ward & TCT), we anticipate the original accommodation design philosophy was not intended for use by patients with immune response impairment/deficiency. On the contrary, the existing ventilation strategy would appear only likely to promote the risks associated with uncontrolled ingress of infectious aerosols into patient areas.

In view of this, and given the other various deficiencies discovered with regards to existing system installations, we consider that significant system modifications will be necessary in any event. As such, we recommend consideration be given to completely separating the upper Ward 2A facilities from the existing centralised plant/system, with new dedicated air handling plant and distribution installed accordingly.

In terms of guidance provided within SHPN 04 : Supplement 1 (Isolation Facilities in Acute Settings), this document is not intended to offer direction with respect to Wards where severely immune-compromised patients are nursed. However, due to the absence of any other clear requirements relative to this particular subject, direction from this document has been adopted where regarded practical/applicable, together with guidance from SHTM 03-01 in terms of positive pressure cascade design philosophies (i.e. to facilitate establish a protective control regime).

6.02 Individual Isolation Suites Throughout

We do not anticipate providing individual comprehensive Isolation Suite accommodation throughout the upper Ward 2A areas to be a viable/practical proposition, given the associated necessity of forming new ventilated lobbies for each suit, and the probability of significant reduction in accommodation facilities. In view of this, the feasibility of creating new Isolation Suites throughout the upper Ward 2A areas has been disregarded.

6.03 Enhanced Single Rooms (Positive Pressure)

In the absence of providing numerous positive pressure ventilated lobbies, and with a view to improving patient protection from infection, we recommend consideration be given to creating a positive pressure directly within each Bedroom space (i.e. all Mid-Ward & TCT). This strategy would typically involve the delivery of supply air directly into each Bedroom with air cascading into the adjacent Corridor(s), where a lower/negative pressure would be maintained, whilst also extracting a proportion of air via the associated En-Suite. This strategy would also necessitate air transfer facilities between the TCT and Ward 2A Corridors.

It should be emphasised that this option would not afford comprehensive Isolation Suite facilities, nor be deemed completely appropriate to provide adequate protection for use by immune-

compromised patients. However, we believe it would essentially provide Enhanced Single Room (with En-Suite facilities) accommodation more appropriate for the intended purpose.

As previously noted, we do not consider the use of existing air handling equipment or associated distribution to be suitable. In view of this, works would involve the installation of completely new dedicated air handling plant and associated distribution, with the removal of existing accordingly.

In addition to new plant and distribution, we recommend consideration also be given to the following;

- Provision of backup air handling plant, particularly given that the system would be utilised to serve acute facilities, and where failure would give rise to the risk of infection. Standby plant would also be beneficial from a practical perspective (i.e. validation, cleaning, maintenance, etc.).

  Alternatively, and whilst not affording complete resilience, run and standby fan units could be considered.

- Ensuring new air handling plant is capable of providing necessary air duties under dirty filter conditions, with variable speed fan units to facilitate same. Selection of heat recovery device should also be considered, particularly with regards to areas/facilities served.

  Although the use of thermal wheel heat recovery devices are acceptable within SHTM 03-01, the risks associated with air leakage and/or contaminate migration are likely not absolute, and should therefore be duly considered accordingly.

- Any potential problems associated with cleaning/maintaining equipment within individual rooms.

  For instance, the facilities will in all probability be served via a centralised system in view of space limitations within ceiling voids (i.e. ductwork distribution). Consideration should therefore be given to any requirement for individual room isolation, as this would influence the selection of plant, ductwork distribution, dampers, etc.

  For estimated cost purposes it has been assumed individual room system isolation would not be necessary.

- Requirement to ensure each envelope is appropriately sealed, as necessary to afford sufficient pressure differential between the Bedroom and adjacent Corridor.

  This may necessitate replacing existing suspended ceilings with solid ceilings, ensuring any internal/external windows are adequately sealed, modification/replacement of services installations (i.e. ceiling mounted light fittings), and potentially replacement doors/door seals.

- Replacement of existing Bedroom supply air induction modules, in lieu of installing supplementary terminals (i.e. as would be required to facilitate the necessary increase in supply air volume to achieve appropriate air change rate).

Consideration should also be given to the suitability of utilising induction modules within this particular environment (i.e. given concerns raised previously with regards to difficulty cleaning/maintaining and the absence of dew point control).

- The potential use of HEPA filters, which could be installed centrally within the AHU or locally to each supply air terminal.

  Please note, retaining existing induction modules may not be viable should localised HEPA filters be deemed required.

- The installation of new transfer grilles between Bedroom and En-Suite spaces, as to facilitate air movement between same.

- The installation of pressure differential sensors, to ensure Corridor/Bedroom pressure differentials are maintained. Consideration should also be given to providing alarms to notify nursing staff, should Bedroom doors be inadvertently left open to the Corridor. Furthermore, consideration could also be given to interfacing any alarms with the BMS, to facilitate future monitoring/logging.

Indicative Cost & Timescale

Without undertaking further detailed investigation/feasibility works it is very difficult to predict probable cost and/or associated timescales with regards to undertaking the eventual preferred works. However, we would not anticipate upwards of £1M, and 9 months, as being unrealistic at this stage.

6.04 Conversion of TCT Zone

Should further dedicated Isolation Suites be deemed required, we anticipate the conversion of the TCT zone to present the most practical and cost effective solution.

Please note, the philosophy outlined below is based on the NHS GG&C adopted method of creating a positive pressure directly within the Bedroom space, in lieu of the approach defined with SPHN 04 : Supplement 1 (i.e. affording positive pressurised lobbies).

The fundamental principle with regards to this strategy would involve dividing the TCT Corridor into four separate compartments, forming individual lobbies. Each TCT Bedroom would be positively pressurised by the introduction of supply air directly into the space, with a proportion of the air extracted via associated En-Suite (i.e. via transfer grille between Bedroom/En-Suite). The residual volume of Bedroom supply air would then be conveyed into the newly formed lobbies, via differential pressure stabilisers.

Additional differential pressure stabilisers would also be installed between each lobby and the adjacent section of Ward 2A Corridor, with Ward 2A Corridor maintained at a negative pressure.

New dedicated plant, equipment, distribution, and ancillaries would be required for each Isolation Suite, as per SPHN 04 guidance.

It should be noted that the existing TCT zone is situated adjacent to the main services riser, thereby facilitating relatively direct access to the 4th floor level plant room for ductwork distribution.

Associated works would also involve all other necessary installations applicable to the conversion of existing spaces into Isolation Suites, as defined within current guidance documents. In particular, the requirement to ensure air tightness within each envelope would be of critical importance, and likely necessitate significant fabric upgrade throughout the entire existing TCT zone and adjacent Ward 2A Corridor.

The access/egress strategy in relation to the upper section of the Ward 2A Corridor, the Isolation Suite Lobbies, and the adjacent Bedrooms, would require due consideration as to ensure pressure differentials were appropriately maintained at all times. This may necessitate creating additional pressurised lobbies within the upper section of the Ward 2A Corridor (i.e. at each end).

The use of the TCT Contingency space should also be considered, given that the above works would likely result in access to this area being limited to via the main Ward 2A Corridor only.

Indicative Cost & Timescale

Again, without undertaking further detailed investigation/feasibility works it is very difficult to predict probable cost and/or associated timescales.

Notwithstanding this, providing the limited number of additional positive pressure Isolation Suites within the existing TCT zone, in conjunction with conversion works associated with forming positive pressure type Enhanced Single Bedrooms (i.e. as per 6.03 above), would likely require in the region of £1.5M, and probably require in the order of 12 months to complete.

SECTION 7 – Additional Notes

7.01 Additional Points Identified During Analysis

The following additional points were noted whilst undertaking our feasibility analysis.

1. It was identified that the extract system derived from AHU 20A is utilised to serve various 'dirty' type areas (i.e. such as Toilets, Shower Rooms, Dirty Utility Rooms, Disposal Rooms, Cleaners Stores, etc.), whereas extracted air from 'cleaner' type areas is discharged via a dedicated exhaust only system.

   This design philosophy is very abnormal, differs from design methodology adopted within other areas, and should be investigated accordingly.

   It should also be emphasised that undertaking remedial works within Ward 2A (i.e. installation of dedicated plant/distribution, etc.) will not resolve this issue in terms of facilities served on Level 3 (Ward 3A), Level 1 (23Hr Ward 1A), and Ground Floor Level (OPD - ENT / GP out of hours).

2. AHU 20A is equipped with a thermal wheel, and therefore, we consider this to identify a potential risk associated with cross-contamination. We recommend this be further investigated and level of associated risk considered against the use of facilities.

   Furthermore, we anticipate the majority of AHU's installed within the building are also equipped with thermal wheels (i.e. Critical Care, General Theatres, Theatre Recovery, Endoscopy, Ultra CT Suite, Nuclear Medicine, etc.). Again, we recommend this be further investigated/considered against the use of facilities.

3. AHU 20A is equipped with single supply and extract fan units, thereby not affording resilience in the event of failure to same. Failure would result in complete loss of all mechanical supply and extract ventilation to areas served from the AHU, effectively rendering facilities unsuitable for use (i.e. 3rd, 2nd, 1st, and Ground Floor facilities).

   Furthermore, as AHU 20A provides extract from multiple Toilet facilities, we would expect this unit to be equipped with standby facilities (i.e. if ignoring potential risks associated with cross-contamination).

   This issue is possibly applicable to other systems installed within the building.

4. Significant irregularities were identified with regards to the AHU 20A extract air volume, generally as outlined below;

   - Manufacturers technical literature pertaining to AHU20A states the extract fan unit was selected based on a design air volume of 2.65m³/s.

- H&V commissioning records identify the extract system was designed for an air volume of 2.563m³/s, with the commissioned air volume being 2.913m³/s.

- The cumulative total of all extract terminal air volumes, as defined within the H&V commissioning documentation, equates to approximately 2.76m³/s.

- A particular Ground Floor level ventilation record drawing indicates extract ductwork being connected to different systems (i.e. EF02 & AHU20A).

We recommend further investigation be undertaken to accurately establish current system installation/operation due to evident anomalies.

5. Whilst technical literature provided on Zutec would suggest there is 125% capacity available in AHU's, the manufacturer has advised that fans/motors were selected based on 100% duty with clean air filters (i.e. all AHU's).

   In view of this, in some instances we anticipate there will be a reduction to existing/commissioned air volumes as the free area of filters reduces during operation/use. Furthermore, this may adversely influence positive/negative air differential pressure strategies, depending on facilities served.

   Please note, this issue may also be applicable to other individual extract fan units (i.e. dirty extract systems).

6. Supply air humidity should be maintained below 70% during winter periods, as to minimise risks associated with condensation forming. During inspection we noted the primary supply air relative humidity from AHU 20A was recorded via the BMS as 77.5%.

7. We were unable to acquire any information pertaining to the intended ductwork system classification. We anticipate some systems are operating within medium pressure classification (i.e. Class B), and should therefore be verified.

   This should be verified prior to any potential increase in air volumes.

8. Manufacturers literature relating to the supply air induction units identifies 'HF' double type modules are equipped with 125mm diameter ductwork connections. Record drawings indicate 160mm diameter run-outs to these terminals, and therefore, we assume ductwork is being reduced at connections.

   CIBSE recommend the maximum velocity for supply air openings (i.e. terminals) within critical type environments as being 1.5m/s. We anticipate the supply air velocity at connections to the induction units to be in the region of 3.3m/s.

9. As-Fitted record documentation, and associated technical literature, pertaining to terminal devices is deemed to be inadequate.

For instance, record drawings do not identify the type (i.e. diffuser/grille/valve), size, number of throws, or associated air volume flow rates. Furthermore, extract terminals are identified on drawings as 'EG' (i.e. typically identifying extract/eggcrate grille), however, when reviewed on site these were found to be 4-way type diffusers.

INTERIM REPORT

The Queen Elizabeth University Hospital/NHS Greater Glasgow and Clyde Oversight Board

Progress

Findings

December 2020
A43293438

Scottish Government
Riaghaltas na h-Alba
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Contents

Summary: Interim Report Recommendations

This Interim Report sets out the initial findings and recommendations developed to date through the NHS Greater Glasgow and Clyde (GGC) Oversight Board's programme of work in response to the infection issues affecting the Queen Elizabeth University Hospital (QEUH) and the Royal Hospital for Children between 2015 and 2019. It summarises the work on investigation, dialogue and improvement from the Oversight Board's establishment in December 2019 to October 2020, and looks ahead to its remaining work and the Final Report, expected in early 2021. It captures progress and early conclusions.

The Oversight Board was put in place by the Director-General of Health and Social Care in the Scottish Government and Chief Executive of NHS Scotland in November 2019. This was done to address critical issues relating to the operation of infection prevention and control, governance, and communication and engagement with respect to the Queen Elizabeth University Hospital and the handling of infection incidents affecting children, young people and their families within the paediatric haemato-oncology service. The Oversight Board was a direct consequence of the escalation of the Health Board to Stage 4 of NHS Scotland's national performance framework.

The Oversight Board consists of a group of experts and key representatives drawn from other Health Boards, the Scottish Government and the affected families themselves. Chaired by Scotland's Chief Nursing Officer, Professor Fiona McQueen, the work of the Board was carried out principally through three Subgroups: Infection Prevention and Control and Governance; Technical Issues; and Communication and Engagement. Overall, the Oversight Board has been focused on assurance of current systems and reviewing the historical issues that gave rise to escalation.

In addition, an independent Case Note Review has been established to examine the individual incidents of infection among the children and young people. This report is being overseen by an Expert Panel that will be reporting in early 2021. Its findings and recommendations will inform the Oversight Board's Final Report.

This is an Interim Report; it does not provide the final summation of the Oversight Board's work, as some key activity – such as the Case Note Review – is continuing. Consequently, this report sets out the Oversight Board's views on several (but not all) of the issues that led to escalation, and the work that remains to be done to provide assurance to Ministers and to the affected families, children and young people. It has also drawn out the wider lessons for national improvement.

Overall, the Oversight Board endorses the changes that have been introduced by NHS GGC in these areas, and welcomes its commitment to improvement. The Interim Report recommendations aim to support that continuing work, and their implementation should be integrated as far as possible into this programme of work. The recommendations are summarised below under the relevant key sets of escalation issues.

Infection Prevention and Control: Processes, Systems and Approach to Improvement

The Interim Report covers the following selected areas of Infection Prevention and Control (IPC):

- the degree to which specific IPC processes in the QEUH have been aligned with national standards and good practice; and
- the extent to which the IPC Team has demonstrated a sustained commitment to improvement in infection management across the Health Board.

It notes the improvement work already undertaken by the Health Board and sets out areas where further action is required to restore assurance.

The Final Report will set out findings and recommendations for the remaining IPC issues, particularly: IPC governance; the responsiveness of the Health Board's IPC to the infection incidents; how staff have worked together in support of IPC; and the way in which leadership has been organised for IPC.

Local Recommendations

- With the support of ARHAI Scotland and Healthcare Improvement Scotland, NHS GGC should undertake a wide-ranging programme to benchmark key IPC processes. Particular attention should be given to the approach to IPC audits, surveillance and the use of Healthcare Infection Incident Assessment Tools (HIIATs).
- With the support of ARHAI Scotland, NHS GGC should review its local translation of national guidance (especially the National Infection Prevention and Control Manual) and its set of Standard Operating Procedures to avoid any confusion about the clarity and primacy of national standards.
- With the support of Health Facilities Scotland, NHS GGC should undertake a review of current Healthcare Associated Infection Systems for Controlling Risk in the Build Environment (HAI-SCRIBE) practice to ensure conformity with relevant national guidance.
- A NHS GGC-wide improvement collaborative for IPC should be taken forward that prioritises addressing environmental infection risks and ensuring that IPC is less siloed across the Health Board.

National Recommendations

- ARHAI Scotland should review the National Infection Prevention and Control Manual in light of the QEUH infection incidents.
- Health Facilities Scotland should lead a programme of work to provide greater consistency and good practice across all Health Boards with respect to the use of HAI-SCRIBE.
- ARHAI Scotland should review the existing national surveillance programme with a view to ensuring there is a sustained programme of quality improvement training for IPC Teams in each Health Board, not least with respect to surveillance and environmental infection issues.

- ARHAI Scotland should lead on work to develop clearer guidance and practice on how HIIAT assessments should be undertaken for the whole of NHS Scotland.

Communication and Engagement

Recommendations are set out below with respect to the overarching question considered by the Oversight Board: **is communication and engagement by NHS GGC adequate to address the needs of the children, young people and families with a continuing relationship with the Health Board in the context of the infection incidents?** The Oversight Board acknowledged the improvements that have been made to date, but notes that more needs to be done to address the issues that gave rise to escalation.

Further work is being undertaken on other key aspects of engagement with patients and families, particularly processes of review by the Health Board and how they were applied in the instances of these infections. Consequently, issues relating to the organisational duty of candour and review processes such as Significant Adverse Event Reviews will be addressed in the Final Report.

Local Recommendations

- NHS GGC should pursue more active and open transparency by reviewing how it has engaged with the children, young people and families affected by the incidents, in line with the person-centred principles of its communication strategies. That review should include close involvement of the patients and families themselves.
- NHS GGC should ensure that the recommendations and learning set out in this report should inform an updating of the Healthcare Associated Infection Communications Strategy and an accompanying work programme for the Health Board.
- NHS GGC should make sure that there is a systematic, collaborative and consultative approach in place for taking forward communication and engagement with patients and families. Co-production should be pursued in learning from the experience of these infection incidents.
- NHS GGC should embed the value of early, visible and decisive senior leadership in its communication and engagement efforts and, in so doing, more clearly demonstrate a leadership narrative that reflects this strategic intent.
- NHS GGC should review and take action to ensure that staff can be open about what is happening and discuss patient safety events promptly, fully and compassionately.

National Recommendations

- The experience of NHS GGC should inform how all of NHS Scotland can improve communication with patients and families 'outside' hospitals in relation to infection incidents.
- The experience of NHS GGC in systematically eliciting and acting on people's personal preferences, needs and wishes as part of the management of communication in these infection incidents should be shared more widely across NHS Scotland.
- NHS GGC should learn from other Health Boards' good practice in addressing the demand for speedier communication in a quickly-developing and social media context. The issue should be considered further across NHS Scotland as a point of national learning.
- The Scottish Government, with Healthcare Improvement Scotland and ARHAI Scotland, should review the external support for communication to Health Boards facing similar intensive media events.

Introduction

1. In November 2019, NHS Greater Glasgow and Clyde (NHS GGC) was escalated to Stage 4 of NHS Scotland's National Performance Framework as a result of a continuing series of infection incidents at the Queen Elizabeth University Hospital (QEUH) and the Royal Hospital for Children (RHC). The Cabinet Secretary for Health and Sport's letter[1] to the Scottish Parliament's Health and Sport Committee stated:

> "In light of the on-going issues around the systems, processes and governance in relation to infection prevention, management and control at the QEUH and the RHC and the associated communication and public engagement issues, I have concluded that further action is necessary to support the Board to ensure appropriate governance is in place to increase public confidence in these matters and therefore that for this specific issue the Board will be escalated to Stage 4 of our performance framework."

An Oversight Board was established by the Director-General of Health and Social Care in the Scottish Government and Chief Executive of NHS Scotland to address critical issues arising from the operation of infection prevention and control (IPC), governance, and communication and engagement at the QEUH and the RHC.

2. The following Interim Report sets out the findings and recommendations that have been developed to date by this Oversight Board. The report summarises the work on investigation, dialogue and improvement from the Oversight Board's establishment in December 2019 through to October 2020. A Final Report – capturing the results of its remaining programme of work – is due in early 2021.

3. The Oversight Board consists of a group of experts and key representatives drawn from other Health Boards, the Scottish Government and the affected families themselves (full membership is set out in **Annex A**). Chaired by Scotland's Chief Nursing Officer, Professor Fiona McQueen, the work of the Board has been principally carried out through three Subgroups, each focusing on a specific set of issues.

- **Infection Prevention and Control and Governance**: this Subgroup has examined whether or not appropriate IPC processes, systems and governance were (and are currently) in place across NHS GGC and what recommendations are needed to strengthen these. It was chaired initially by Irene Barkby MBE (Executive Director of Nursing, Midwifery and Allied Health Professionals in NHS Lanarkshire), and latterly by Scotland's Deputy Chief Nursing Officer, Diane Murray.
- **Technical Issues**: this Subgroup has focused on relevant specific elements of the technical workings of the hospitals in question, with a particular focus on infrastructure issues. It has been chaired by Alan Morrison, Deputy Director for Health Infrastructure in the Scottish Government.

[1] Update on NHS Greater Glasgow and Clyde - gov.scot (www.gov.scot).

- **Communication and Engagement**: this Subgroup has considered the operation of effective communication with the children, young people and families affected by the infection incidents, as well as whether a wider, robust, consistent and reliable person-centred approach to engagement has been evident. In addition, it is examining the organisational duty of candour and other key review processes, such as the Significant Adverse Event Review policy. It has been chaired by Professor Craig White, Divisional Clinical Lead in the Healthcare Quality and Improvement Directorate of the Scottish Government.

The Terms of Reference for the Oversight Board and its supporting Subgroups are presented in **Annex A**.

4. The Oversight Board and the Subgroups have been aided by a number of special reports commissioned to examine specific issues relating to NHS GGC. Of particular importance for this Interim Report is the **Peer Review of IPC**: led by Lesley Shepherd (national professional advisor to the Scottish Government) and Frances Lafferty (Senior Infection Control Nurse in NHS Ayrshire and Arran), this examined key IPC systems and processes in NHS GGC and how national policy on IPC has been implemented. Its terms of reference are set out in **Annex B**.

5. Lastly, the work of the Oversight Board was supported by several key individuals appointed to work alongside and within NHS GGC on improvement:

- Professor Marion Bain (Deputy Chief Medical Officer, Scottish Government), who was appointed as the Executive Lead for Healthcare Associated Infection within NHS GGC in December 2019 to set the strategic direction for IPC improvement;
- Professor Angela Wallace (Nurse Director, NHS Forth Valley), who was appointed in February 2020 to work with and succeed Professor Bain as the Health Board's Interim Operational Director for IPC; and
- Professor Craig White, who was appointed by the Cabinet Secretary for Health and Sport in October 2019 to work with the families to address communication issues within NHS GGC (and subsequently, to chair the Communication and Engagement Subgroup).

Their insights informed the Oversight Board's conclusions and their work to date will be set out here and in the Final Report.

6. In parallel, the Cabinet Secretary for Health and Sport commissioned a **Case Note Review** in her statement to Parliament on 28 January 2020. The Case Note Review is examining the individual case documents of the children and young people in the haemato-oncology service from 2015 to 2019 who had a gram-negative environmental pathogen bacteraemia and/or selected other organisms. It is overseen by Professor Marion Bain and a panel of independent external experts led by Professor Mike Stevens (Emeritus Professor of Paediatric Oncology at the University of Bristol). The work of the Case Note Review is continuing and so does not form part of this Interim Report, though there is an update on progress. It is expected to report in early 2021, and its conclusions will be included in the Oversight Board's Final Report.

7. In addition, the Oversight Board has acted alongside to, though separate from the **Independent Review**. On 5 March 2019, Dr Andrew Fraser and Dr Brian Montgomery were appointed by the Cabinet Secretary for Health and Sport to lead an Independent Review with the aim of: "establish[ing] whether the design, build, commissioning and maintenance of the QEUH and the RHC has had an adverse impact on the risk of Healthcare Associated Infection and whether there is wider learning for NHS Scotland." The Independent Review's report was published on 15 June 2020.[2] At various points in this Interim Report, the Oversight Board references issues that have been addressed by the Independent Review, but the latter's report is independent of the work of the Oversight Board. NHS GGC and the Scottish Government have both acknowledged the Independent Review's report and are planning action in response to the recommendations.

8. As with other aspects of public sector activity, the Covid-19 pandemic has proven disruptive to the Oversight Board. From mid-March 2020 onwards, it was not possible to hold regular meetings, as many of its members had vital roles in the NHS Scotland response to the pandemic. This delayed the final stages of the Oversight Board's programme, but it did not substantively alter what was done to reach the findings and recommendations set out here.

9. Following this introduction, the Interim Report consists of several sections:

- **Background and approach**: the context for the establishment of the Oversight Board and the infection issues within the QEUH and the RHC and the way the Oversight Board has been taking forward its work;
- **Infection prevention and control**: a review of the issues that gave rise to escalation to Stage 4, particularly the processes/systems and approach to improvement of IPC in NHS GGC, as well as a description of the remaining work for the Final Report;
- **Governance and risk management**: the full findings on IPC governance will be made in the Final Report, but an update on the work is provided here;
- **Technical review**: the full findings on the technical review will be set out in the Final Report, but a progress update is provided here;
- **Communication and engagement**: a review of the way in which the Health Board communicated and engaged with patients and families and an update on the work to be done for the Final Report;
- **Case Note Review**: an update on progress of this independent examination of the individual children and young people and infection incidents; and
- **Interim Report findings and recommendations**: the findings and initial Oversight Board recommendations of this Interim Report.

10. In addition, there are several annexes:

A. the terms of reference for the Oversight Board and its Subgroups;

B. the terms of reference for the IPC Peer Review;

[2] Queen Elizabeth University Hospital Review: Review Report (nrscotland.gov.uk).

C. the stages of escalation in the NHS Scotland Board Performance Escalation Framework; and

D. the Key Success Indicators identified by the Oversight Board

Background and Approach

Context for Escalation

11. On 22 November 2019, the decision was taken by Malcolm Wright, Director-General for Health and Social Care in the Scottish Government and Chief Executive of NHS Scotland, to escalate NHS GGC to Stage 4 of the NHS Scotland Board Performance Escalation Framework. In a statement about the establishment of the Oversight Board, the Cabinet Secretary for Health and Sport, Jeane Freeman, said:

> "Families deserve to have confidence that the places they take their children to be cared for are as safe as they possibly can be. That means their engagement with their Health Board must be open, honest, and rooted in evidence. This is even more important in the tragic circumstances where a child's life is lost. It is, in my view, simply cruel for the grief of a parent to be compounded by a lack of clear answers… I want now to set out the action and steps we are taking to give parents, families and patients the answers they legitimately seek and to, step by step ensure that we are working on evidenced data, putting in place all the required infection prevention and control measures and by doing so secure the confidence of clinical teams, patients and families."

12. Escalation came against a background of a series of infection issues affecting children and young people in the paediatric haemato-oncology service at the QEUH and the RHC over a number of years. A handful of cases of children and young people with infections occurred in 2016 and 2017, but concerns mounted between January and September 2018 when the number and diversity of type of infections increased. According to Health Protection Scotland (HPS), there were at least 23 cases, involving 11 different organisms. Water testing in Ward 2A in 2018 identified contamination of water outlets and drains, and as a result, control measures were put in place, including sanitisation of the water supply to Ward 2A and installation of point-of-use filters in wash hand basins and showers. Despite these measures, concerns remained and in September 2018, more drastic steps were taken when Wards 2A and 2B in the RHC were closed and the children and young people were moved to the main QEUH building. Concerns about the water supply led to installation of an enhanced water-testing regime and a chlorine dioxide dosing system, first operating across the RHC in late 2018, then the QEUH in 2019.

13. An additional series of infections in 2019 in Ward 6A in the QEUH heightened concerns, and eventually led to the temporary closure of that ward to new patient admissions. Media reports claimed several deaths of patients were linked to infection in the hospital, raising further concerns among patients and families about safety. There was increasing dissatisfaction among some families at the level and quality of communication by NHS GGC throughout this period, leading to the appointment of Professor Craig White by the Cabinet Secretary for Health and Sport in October 2019 as a lead contact and facilitator for the families. In addition, internal NHS GGC reports came to light that suggested that some of the problems with the QEUH site had been identified as early as 2015, but did not appear to have been acted upon at the time (although they were at a later stage).

14. This occurred against a background of concerns that had been consistently raised by several clinicians at the QEUH about the potential environmental risks of the building and the link to emerging infections. Some of these concerns dated back to the period of the completion and handover of the new building. Some of the clinicians did not feel that their concerns – particularly about water and ventilation and the risk of their contribution to infection of such a vulnerable patient population – were being effectively addressed, and in some cases, formal whistleblowing procedures were triggered. These issues were raised in correspondence with the Cabinet Secretary for Health and Sport and featured in evidence submitted to the Scottish Parliament's Health and Sport Committee. The Oversight Board has reviewed this evidence.

15. Finally, there were a number of relevant reports by external bodies over the period that underlined these various concerns. This included the report undertaken by HPS, which was invited to examine the infection incidents by the Health Board. Its report – *Queen Elizabeth University Hospital/Royal Hospital for Children: Water Contamination Incident*[3] – was published in February 2019. As well as setting out a number of recommendations for NHS GGC and for national action, the report recognised that the environmental risks of the hospital could not be discounted.

16. Escalation of NHS GGC to Stage 4 was set within the procedure for assessing NHS Board performance. The NHS Scotland Board Performance Escalation Framework lays out the triggers and actions when Health Boards are unable or hindered in taking forward their essential responsibilities. The Framework outlines a guide to inform action, and what steps are needed following the decision to escalate, depend on the 'stage' on the framework. Stage 5 is the most serious stage; Stage 4 is defined as "significant risks to delivery, quality, financial performance or safety, (and) senior level external transformational support (is) required." It is applied where the Scottish Government believes that a Health Board's capacity or capability requires enhancement to address local issues, and additional direct management or transformation support may be required. **Annex C** describes the five stages of escalation.

17. The decision to move a Health Board to Stage 4 is made on the advice of the Health and Social Care Management Board of the Scottish Government. In the case of escalation to Stage 4, consideration of the Health Board's position within the Escalation Framework would normally be prompted by the identification of significant weaknesses in particular areas considered to pose an acute risk to the following issues: financial sustainability; reputation; governance; and quality of care or patient safety (or in some cases, by a Health Board failing to deliver on the recovery actions agreed at Stage 3).

18. Action typically takes the form of a transformation team led by a Scottish Government Director, Board Chief Executive or other responsible person appointed by the Director-General of Health and Social Care in the Scottish Government and Chief Executive of NHS Scotland to support the delivery of sustainable transformation. The Health Board Chief Executive continues to act as

[3] https://www.gov.scot/publications/qe-university-hospital-royal-hospital-children-water-incident/.

Accountable Officer and be responsible for matters of resource allocation to deliver any transformation plan. The Board Chief Executive and the executive team are expected to work in conjunction with the appointed transformation Director to construct required plans and take full responsibility for delivery.

19. In the case of the escalation of NHS GGC to Stage 4, the transformation Director is Professor Fiona McQueen, the Chief Nursing Officer for Scotland. She has been supported in the programme of transformation by the Oversight Board, and individuals appointed to work within and with NHS GGC, notably Professors Bain, Wallace and White.

20. In February 2020, NHS GGC was escalated again to Stage 4 for a range of issues *beyond* IPC, governance and communication and engagement; these included performance management on waiting times, the Board's out-of-hours service and financial matters. Work on these escalation issues is overseen by a separate Performance Oversight Group, chaired by John Connaghan (interim Chief Executive of NHS Scotland), thought it has had to suspend work as a result of the pandemic. Its programme of work has not informed this Interim Report, although the Oversight Board has been careful not to duplicate areas being covered more thoroughly by this companion group.

The NHS Greater Glasgow and Clyde/Queen Elizabeth University Hospital Oversight Board

21. The purpose of the NHS GGC/QEUH Oversight Board has been to ensure NHS GGC takes the necessary actions to restore and enhance public confidence in safe, accessible, high-quality, person-centred care at the QEUH and RHC with respect to the matters on which the Health Board was escalated. It will advise the Director-General of Health and Social Care in the Scottish Government and Chief Executive of NHS Scotland when steps have been taken – as set out in the Cabinet Secretary's statement in November 2019 – to restore "confidence that the places families take their children to be cared for are as safe as they possibly can be." In particular, the Oversight Board aimed to:

i. ensure appropriate governance is in place in relation to infection prevention, management and control;

ii. strengthen practice to mitigate avoidable harms, particularly with respect to infection prevention, management and control;

iii. improve how families with children and young people being cared for or monitored by the haemato-oncology service have received relevant information and been engaged with;

iv. confirm that relevant environments at the QEUH and RHC are, and continue to be, safe;

v. oversee and consider recommendations for action further to the review of relevant cases, including cases of infection;

vi. provide oversight on connected issues that emerged;

vii. consider the lessons learned that could be applied across NHS Scotland; and

viii. provide advice to the Director-General of Health and Social Care in the Scottish Government and Chief Executive of NHS Scotland and Scottish Ministers about the escalation status of NHS GGC.

22. This Interim Report sets out the Oversight Board's view on the Health Board's progress in addressing several (but not all) of the issues that led to escalation, and the work that remains to be done. This is a 'first phase' report; it does not give a final summation of the Oversight Board's activity and conclusions, which will come in the Final Report, and address the overarching questions posed about the Health Board's 'fitness for purpose' on these specific matters. In particular, the Oversight Board has not been able to conclude its work on point **v** in the list above, as the Case Note Review is vital to this, and the Review will not conclude its work until early next year. As a result, the Oversight Board will not examine individual cases or incidents, as these are being covered by the Case Note Review.

23. There are other areas the Oversight Board is not reviewing, particularly where they are being addressed by other processes. In particular, a full accounting of the issues around the building of the hospital is the responsibility of the **Hospitals Public Inquiry**. The Inquiry is chaired by the Right Honourable Lord Brodie QC PC. Its Terms of Reference have now been published[4] and the Inquiry has formally started. The Oversight Board is not pre-empting this work, but has necessarily covered similar territory in some instances as part of its own remit. It has done so with the intention of collecting sufficient evidence to take a view on assurance on NHS GGC's *current* systems, and thereby set out the actions that should be taken to achieve any necessary improvements.

24. Care has also been applied when considering issues raised as part of whistleblowing procedures, which have been activated by some clinicians within NHS GGC in relation to these infection incidents. Much of the substance of the issues raised has been necessary for the Oversight Board to review, and we are particularly thankful for the generous support and courage of those clinicians in raising them to the Cabinet Secretary and to the Scottish Parliament. It has been important that the Oversight Board's work does not cut across these whistleblowing processes, and for that reason, the Oversight Board does not offer a view on any specific internal matters directly relating to these procedures.

Key Working Relationships

25. The Oversight Board established three Subgroups with necessary experts and other participants, with the Scottish Government providing the Secretariat. It commissioned a number of key reports to support its programme of work. Overall, the Oversight Board met on nine occasions between December 2019 and March 2020, when meetings were temporarily suspended because of the Covid-19 pandemic. Further meetings took place in September and October to review all of the relevant materials and agree the Interim Report. Each of the Subgroups had a similar calendar of meetings.

[4] https://www.gov.scot/publications/inquiry-into-the-construction-of-the-qeuh-glasgow-and-the-rhcyp-dcn-edinburgh-terms-of-reference/.

26. Relationships with key groups and communities have been vital for the work of the Oversight Board. This has been essential with respect to the families affected by the infections. Representatives of the families have been part of the Oversight Board itself (and the Communication and Engagement Subgroup in particular). In addition, extensive use has been made of the 'closed' Facebook page (described in more detail in the Communication and Engagement chapter below) to update patients and families on the Oversight Board's progress. Professor Craig White provided a central communication role as historical and new concerns were raised during the course of this work.

27. The Oversight Board also established a positive and constructive relationship with NHS GGC – a critical element to ensure that there was joint investigation of relevant issues and common agreement on how to improve. NHS GGC has worked with the Oversight Board to develop and deliver improvement plans, working through the appointments of Professors Bain and Wallace. NHS GGC staff helped to source and provide a significant amount of information to support Oversight Board and Subgroup discussions, for which the Oversight Board has been particularly grateful. In this context, special mention should be made of the dedicated and highly responsive Programme Management Office set up in NHS GGC to coordinate participation of the Health Board and requests for information. The Programme Management Office offers a good model of how to coordinate and expedite the provision of information, analysis and engagement for such external review processes. Its work – and the support from relevant staff across the Health Board – has been significant, and should be particularly acknowledged in light of the huge health challenges during the pandemic.

28. NHS GGC staff took part in several meetings of the Oversight Board and its Subgroups as invited participants, although the Health Board representatives were not formally part of these groups. Provision was also made for private discussions by the Oversight Board and the Subgroups where appropriate. The findings and recommendations of this Interim Report are the Oversight Board's alone, though in several cases, they reflect and reinforce actions already being taken by the Health Board. Discussions have been held with the Health Board and extensive feedback provided on the development of the Interim Report.

Governing Principles

29. The work of review and direction in these circumstances can be highly challenging, and given the nature of the subject, sensitive and emotionally charged for the children, young people, families and staff involved. The Oversight Board has adopted a values-based approach, based on NHS Scotland values. These governed the behaviours of the Oversight Board, both individually and collectively to:

- treat all our people with kindness, dignity and compassion;
- respect the rule of law; and
- act in an open and transparent way.

30. Above all, the Oversight Board has been focused on opportunities and requirements for improving existing systems and behaviours. While that needs an understanding of what has happened in the past and how processes operated at different points in the period since the opening of the QEUH, it has all been in the service of assessing the quality and impact of processes in place now. 'History' has been important in reflecting the NHS GGC's own capacity to learn lessons, make any necessary improvements and track the implementation and adequacy of those changes going forward. The Oversight Board has aimed to ensure that learning is captured and implemented locally as well as nationally. It has also highlighted improvements already put in place by the Health Board.

31. The work of the Oversight Board has largely related to a specific patient community within the QEUH, but its focus has widened where larger implications are important to acknowledge. For example, the problems with building the hospital and its links with IPC have potential consequences for other vulnerable patient groups across the site, so assurance has been sought that appropriate actions have been taken on the learning arising from what happened with the paediatric haemato-oncology service.

Priority Issues to Be Examined

32. The Oversight Board has concentrated primarily on structures and procedures and not specific individuals and isolated incidents. These have been central to its role of considering the extent to which assurance can be provided about the Health Board's capability and capacity to deliver on the key areas highlighted in escalation. For the Final Report, the Oversight Board will review the narrative of key milestones to understand the circumstances that gave rise to escalation and provide the essential context for an emerging, progressively more complex set of circumstances. For the key areas it was examining – IPC, governance, and communication and engagement – the Oversight Board set out what 'good looks like' through a set of key success indicators (the full set of indicators is described in **Annex D**). The aim has been to concentrate on a set of principles for each area that governed how the Oversight Board and its Subgroups pursued investigation and recommendation. These principles have been applied through a focus on a set of overarching questions:

- **To what extent can the source of the infections be linked to the environment and what is the current environmental risk?**
- **Are IPC functions 'fit for purpose' in NHS GGC, not least in light of any environmental risks?**
- **Is the governance and risk management structure adequate to pick up and address infection risks?**
- **Is communication and engagement by NHS GGC sufficient in addressing the needs of the children, young people and families with a continuing relationship with the Health Board in the context of the infection incidents?**

33. These questions are threaded through the issues considered in the Interim Report. This report does not make final conclusions on these questions, but a full assessment will be included in the Final Report. The questions also link the key areas that the Oversight Board has been tasked to review in the context of these infection incidents:

- **IPC**: the processes, structures, relationships and behaviours in place to ensure that there is effective identification of infections, management of outbreaks and incidents, and appropriate preventative and improvement work around these issues;
- **governance**: the framework and systems in place for the issues and risks associated with infections to be raised and actioned, and the assurance secured within the organisation's senior management that this is happening; and
- **communication and engagement**: how the issues and implications of incidents and outbreaks are communicated with the children, young people, families and the wider public in line with the person-centred principles of NHS Scotland.

34. The issues are inter-locking. Robust IPC procedures should highlight major issues and risks through the structure of governance and risk management. Strong governance will give clear direction and resourcing to IPC across the organisation and ensure a culture of transparency and responsiveness to patient, family and public concerns. Good communication and engagement should ensure that the decisions with governance and the actions taken forward through the IPC Team are clearly presented to those affected by them.

35. Each set of issues required dedicated assessments. For **IPC**, the Oversight Board considered NHS GGC practice in light of the infection incidents, focusing on the QEUH (and where appropriate, across the Board), with reference to two key principles, as set out in its key success indicators:

- There is appropriate governance for infection prevention and control in place to provide assurance on the safe, effective and person-centred delivery of care and increase public confidence.
- 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.

36. Similarly, for **communication and engagement**, the key success indicators that the Oversight Board have used are that:

- Families and children and young people within the haemato-oncology service receive relevant information and are engaged with in a manner that reflects the values of the NHS Scotland in full.
- Families and children and young people within the haemato-oncology service are treated with respect to their rights to information and participation in a culture reflecting the values of the NHS Scotland in full.

The Oversight Board's findings and recommendations should be seen through the 'lens' of these key success indicators.

37. As noted above, the findings and recommendations will be reported across two reports: this Interim Report; and a final Report. Different issues relating to escalation will be covered by the Interim and Final Reports: the table below sets out what issues will be covered by which report. Each set of themes arose from continuing exploration of the escalation issues, an iterative process that led to the emergence of matters requiring investigation at different points in the work programme (as the Terms of Reference note: "(to) provide oversight on connected issues that emerge"). Throughout, the Oversight Board has been careful to ensure that it avoids duplication with other review processes, as outlined above.

Escalation Issue	What Is Covered in This Interim Report	What Will Be Covered in the Final Report
Infection prevention and control	• Assurance on a selection of IPC processes/systems in NHS GGC following Peer Review • Review of approach to improvement in IPC in NHS GGC • Findings and recommendations on the above set of issues	• Review of how the infection incidents were addressed by NHS GGC and wider mitigation/responses • Review of how different staff have worked together in support of IPC in the QEUH • Review of the organisation of IPC leadership • Findings and recommendations on the above set of issues and the overarching question of the 'fitness for purpose' of IPC within the Health Board
Governance	• Update on work of IPC governance	• Review of how infection incidents were escalated and addressed by the NHS GGC governance structure • Assurance on how IPC issues are currently escalated and addressed within NHS GGC • Review of NHS GGC risk management in light of the infection incidents • Findings and recommendations on IPC governance issues, and the overarching question of the 'fitness for purpose' of IPC governance within the Health Board

Escalation Issue	What Is Covered in This Interim Report	What Will Be Covered in the Final Report
Related technical issues	• Update on refurbishment of Wards 2A/2B in the RHC	• Assurance on NHS GGC's water testing and safety policy in the RHC/QEUH • Assurance on plans to address any remedial works relating to infection arising from infrastructure issues on the QEUH site
Communication and engagement	• Review of how communication and engagement was undertaken by NHS GGC with the children, young people and families affected by the infection incidents – including findings and recommendations	• Review of how the Health Board engaged with families through formal review processes, notably the organisational duty of candour and the Significant Adverse Events Review policy for these infection incidents – including findings and recommendations
Case Note Review	• Update of the work of the Case Note Review	• Summary of findings and recommendations of the Case Note Review
Review of escalation to Stage 4		• Advice on whether/how de-escalation should take place

38. The Oversight Board is conducting its work through the review of key documentation and direct inquiry with NHS GGC involving the experts who took part in the Oversight Board and its Subgroups. For the Interim Report, evidence included:

- the papers and material presented by NHS GGC to the meetings, including minutes of the Board, relevant committees (such as the Board Infection Control Committee and the Clinical and Care Governance Committee) and Incident Management Teams (IMTs), relevant action plans, special presentations and 'situation, background, assessment, recommendation' papers (SBARs);
- material provided previously to the Cabinet Secretary for Health and Sport and the Health and Sport Committee of the Scottish Parliament by several clinicians;
- specially-commissioned, topic-specific SBARs from external experts and statements on specific issues, such as water testing and the progress of refurbishment of Wards 2A and 2B in the RHC; and
- key external documents, such as the Health Facilities Scotland (HFS) report, 'Water Management Issues Technical Review: NHS Greater Glasgow and Clyde – Queen Elizabeth University Hospital and Royal Hospital for Children' (finalised March 2019), and the HPS report, 'Summary of Incident and Findings of the NHS Greater Glasgow and Clyde: Queen Elizabeth University Hospital/Royal Hospital for Children Water Contamination Incident and Recommendations for NHSScotland' (published February 2019).

39. There was no programme of comprehensive interviewing or evidence gathering from individuals and organisations, apart from what was undertaken for commissioned work such as the Peer Review described above. However, specific clarifying discussions were held with some QEUH clinicians that had previously raised concerns about the Health Board, representatives of the affected children, young people and families, and NHS GGC representatives throughout the Oversight Board's programme of work.

Infection Prevention and Control

40. Long before the recent incidents at the QEUH, IPC procedures in hospitals had been under a spotlight. Following an outbreak of Clostridium difficile infection at the Vale of Leven Hospital within NHS GGC, which led to the deaths of 34 patients, the Scottish Government established an Inquiry under Lord MacLean to investigate not just C. difficile infection, but all deaths at the hospital associated with this infection in the period between 1 December 2007 and 1 June 2008. Its final report was published in November 2014[5], and found, amongst other things, that:

- governance and management failures within NHS GGC had created an environment in which patient care was compromised and the approach to IPC was inadequate;
- there were significant deficiencies in IPC practices and systems which had had a profound impact on the care provided to patients in the hospital; and
- strong management was lacking, which contributed to a culture unsuited to a caring and compassionate hospital environment.

41. NHS GGC accepted the recommendations, which included the following of particular relevance to the Oversight Board's work (not all directed exclusively at the Health Board, but across NHS Scotland more widely):

- In any major structural reorganisation in the NHS in Scotland a due diligence process including risk assessment, should be undertaken by the Board or Boards responsible for all patient services before the reorganisation takes place. Subsequent to that reorganisation regular review s of the process should be conducted to assess its impact upon patient services, up to the point at which the new structure is fully operational. The review process should include an independent audit.
- In any major structural reorganisation in the NHS in Scotland the Board or Boards responsible should ensure that an effective and stable management structure is in place for the success of the project and the maintenance of patient safety throughout the process.
- Health Boards should ensure that IPC policies are reviewed promptly in response to any new policies or guidance issued by or on behalf of the Scottish Government, and in any event at specific review dates no more than two years apart;
- Health Boards should ensure that all those working in a healthcare setting have mandatory IPC training;
- Health Boards should ensure that the Infection Control Manager (ICM) has direct responsibility for the IPC service and its staff;
- Health Boards should ensure that the ICM reports direct to the Chief Executive or, at least, to an executive board member;

5 https://webarchive.nrscotland.gov.uk/20170401011220/http://www.valeoflevenhospitalinquiry.org/report.aspx.

- Health Boards should ensure that any Infection Control Team functions as a team, with clear lines of communication and regular meetings;
- Health Boards should ensure that surveillance systems are fit for purpose, are simple to use and monitor, and provide information on potential outbreaks in real time; and
- Health Boards should ensure that IPC groups meet at regular intervals and that there is appropriate reporting upwards through the management structure.

42. The Vale of Leven Inquiry provides important context here. Not only did the Health Board set out plans to implement all the relevant recommendations, but the recommendations as a whole helped to shape the development of national standards and the current framework for IPC across NHS Scotland. This culminated with the issuing of the key guidance letter, DL (2019) 23 in December 2019[6] by the Chief Nursing Officer of NHS Scotland. This set out the mandatory Healthcare Associated Infection (HCAI) and Anti-microbial Resistance (AMR) policy requirements for all NHS Scotland healthcare settings. As the letter noted:

> "Despite the progress made over recent years, reducing HCAI and containing AMR remains a constant challenge. Therefore, it is important at both a national and NHS Board level and beyond, that there is ongoing and increased monitoring for accurate, and, as far as is possible, real time assessments of current and emerging threats."

43. This background of increasing sensitivity to the need for ever-more robust IPC procedures and the drive for improvement form an important backdrop for the Oversight Board's work. In its terms of reference, the Oversight Board recognised that there would be key points of learning and need for improvement for both NHS GGC individually as well as for NHS Scotland as a whole. In this context, it is important to understand the distinctive circumstances of what took place in the QEUH.

- **The unique circumstances of a modern, large hospital**. There was little precedent for the challenges arising from a large, newly-built hospital complex such as the QEUH – not least in understanding the scale and nature of the infection issues and the diversity of organisms that appeared. This manifested itself in the limited experience that NHS GGC – and NHS Scotland more widely – could draw upon to fathom the particular issues relating to infection in the context of a modern hospital such as the QEUH. Indeed, there are few comparators whose experience on which the Health Board has been able to draw. This context is by no means justification for any of the actions taken – or not taken – as standards should rightfully be expected to be met in all healthcare settings. However, it is essential for understanding how NHS GGC had to adapt to an often novel, and in many respects, 'non-textbook' situation. Recognition of this is important, not least from the perspective of the national learning the Health Board's experience can provide going forward.

[6] https://www.sehd.scot.nhs.uk/dl/DL(2019)23.pdf.

- **The scale of the Health Board**. The issue of NHS GGC's unique scale as the largest Health Board in Scotland (and one of the largest in Europe) is relevant, as the sheer size and expanse of the Health Board were defining features for some of its approach to these issues. For example, IPC responsibilities are divided between a number of different geographical teams, each covering a mixture of hospitals and other healthcare settings. The Oversight Board's comments are largely focused on the operation of processes at the QEUH. At no point was the issue of scale ever offered as a mitigating or explanatory factor for how the Health Board should have fulfilled its responsibilities in the circumstances under review. However, it was cited as a factor at points in how the Health Board did and could have responded to the circumstances and what might be improved going forward.
- **Focus on selected aspects of IPC**. Throughout the Oversight Board's work, there were many good examples presented of a range of IPC functions in NHS GGC. As a result, it is important to separate out issues that applied specifically to the particular infection incidences under review – both in terms of the specific site (the QEUH) and the specific patient group (those in the paediatric haemato-oncology service) – and those which applied more widely to how IPC was pursued across NHS GGC as a whole. For example, the Oversight Board did not set out to examine the experience, responsibilities and processes in place for dealing with the bulk of gram-*positive* infections, and the steps that the IPC Team and other staff had taken to eradicate their transmission (such as approaches to hand cleanliness). This is especially important in understanding the Oversight Board's focus on IPC in the context of environmentally-related infections (which includes both gram-negative and positive organisms). Consequently, the Oversight Board did not examine the full range of IPC functions in NHS GGC, only those directly relevant to these particular incidents.

44. At the same time, there is a **historical context** that should be understood. While not delving into these issues, as already noted, the Oversight Board recognised that there were significant shortcomings in: the construction and handover of the QEUH; and how NHS GGC responded to emerging and related problems. These include the concerns that were raised by a number of clinicians at an early stage as well as how 'warning signals' about potential problems were – or were not – acted upon over the years. The Oversight Board discussed these issues, but they have only been highlighted where they: remained a continuing and current factor that would compromise any assurance on the issues relating escalation; or were corrected and led to improvements that are important to acknowledge. It is recognised that relationships and trust were impacted as part of these historical issues, resulting in the early decisions to appoint Professors Marion Bain and Angela Wallace in key positions within the Health Board to take forward urgent work.

45. Ultimately, the Oversight Board has sought assurance that current IPC processes within NHS GGC are 'fit for purpose': in terms of national standards and good practice and in light of how they addressed the infection incidents of the last few years. In this respect, the Oversight Board has measured Health Board IPC against the key success factor: "the current approaches that are in place to mitigate avoidable harms, with respect to IPC, are sufficient to deliver safe, effective and

person-centred care" (see **Annex D**). Consequently, the Oversight Board commissioned a range of work. As part of this programme, the Oversight Board has:

- commissioned a detailed description of the timeline of infection incidents between 2015 and 2019 and formal meetings to address the incidents (this will be presented in full in the Final Report);
- commissioned a system-wide Peer Review of current IPC systems and processes and associated governance scheme of delegation and escalation mechanisms against relevant national standards and guidance;
- commissioned bespoke SBARs on particular issues, such as the use of HIIATs by the Health Board;
- received reports from key individuals placed within NHS GGC, particularly Professors Bain and Wallace; and
- assessed if there were any gaps when mapped against national standards and guidance and, if so, identify areas for improvement and shared learning with respect to operational delivery of IPC, including staffing/resourcing, minimum skills and joint working between relevant units.

46. As noted already, some work could not be done in full due to curtailment caused by the Covid-19 pandemic. Nevertheless, the Oversight Board amassed sufficient evidence to set out a series of findings in the following key areas:

- **Processes and systems**: the degree to which specific IPC processes and systems have been aligned with national standards and good practice and their effective and reliable implementation; and
- **Approach to improvement**: the extent to which the IPC Team has demonstrated a sustained commitment to improvement, and acted as an agent for improvement in infection management across NHS GGC.

Other IPC issues – and overall view of the efficacy of IPC within the Health Board – will be set out in the Final Report.

Processes and Systems

47. A critical element of the work of assurance by the Oversight Board is IPC processes and procedures within the Health Board. National compliance is important, not least given the efforts in recent years to codify good practice in IPC in the wake of the Vale of Leven Inquiry. There is a recognisable balance between compliance in national standards with flexibility in applying local innovation/ improvement, but as with much healthcare, fidelity in crucial areas is important.

48. To examine in greater detail the way that IPC operated within NHS GGC, a Peer Review was commissioned by the Oversight Board to explore some processes and procedures in more forensic detail. This exercise was designed to gain an understanding of how IPC systems and processes were embedded. The objectives of the Review were to:

- investigate the ways in which IPC at NHS GGC is operationalised across the system; and
- determine the ways in which national policy has been implemented within NHS GGC, identifying areas where this was carried out and where it could be improved.

The focus has been on the current operation of these processes.

49. Several areas of focus were originally identified for the Review, but owing to the restrictions caused by the Covid-19 pandemic, only the following could be taken forward:

- implementation of the National IPC Manual (NIPCM);
- implementation of Healthcare Associated Infection Systems for Controlling Risk in the Built Environment (HAI-SCRIBEs);
- audit;
- surveillance; and
- the use of the Healthcare Infection Incident Assessment Tools (HIIATs).

Action on two other areas – outbreak and incident investigation, and water safety – could not be taken forward through this Peer Review as planned, but are still recommended to be examined at some stage.

50. A team comprising members of the Infection Prevention and Control and Governance (IPCG) Subgroup was established to undertake the Peer Review. The Peer Review was undertaken on 16 March 2020 by Lesley Shepherd (national professional advisor to the Scottish Government) and Frances Lafferty (Senior Infection Control Nurse in NHS Ayrshire and Arran). Additionally, the Oversight Board requested Anti-microbial Resistance and Healthcare Associated Infection (ARHAI) Scotland to undertake an assessment of NHS GGC reporting of Healthcare Infection Incidents, specifically relating to the QEUH site. The focus of the SBAR was on how HIIATs were used.

Application of the National IPC Manual

51. As set out above, over the last few years there has been significant work nationally to set a common approach to improvement and standards in IPC. Central to this has been the NIPCM. Published in 2012[7], the National Manual sets out the standards, good practice and resources for improvement for IPC across NHS Scotland. Alignment between Health Board practice and the NIPCM reflects a Health Board's commitment to a recognised, consensus set of practices associated with 'what good looks like' for IPC. The NIPCM aims to:

- facilitate the effective application of IPC precautions by appropriate staff;
- reduce variation and optimise IPC practices throughout Scotland;
- improve the application of knowledge and skills in IPC;

[7] http://www.nipcm.scot.nhs.uk/.

- reduce the risk of HAI; and
- help alignment of practice, education, monitoring, quality improvement and scrutiny.

52. The National Manual is central to the Health Board's approach to IPC – indeed, NHS GGC placed the NIPCM as a link on the IPC Portal on its intranet site. In addition, the IPC Team has developed a series of new 'Standard Operating Procedures' (SOPs) to supplement national guidance for the Health Board – NHS GGC described these as a way of 'operationalising' the NIPCM, making it easier for frontline staff to understand the Manual.

53. However, as the aim of the NIPCM has been to "make it easy for care staff to apply effective infection prevention and control precautions", it was not clear to the Peer Review team why NHS GGC has developed so many SOPs. These typically require regular updating based on the current scientific evidence reviews within the NIPCM. The SOPs do not provide contradictory information – they reflected national advice – but given that this work has already been undertaken as part of the NIPCM, the production of the SOPs seems to be unnecessary, if not redundant.

54. Moreover, the NHS GGC IPC Portal does not differentiate between local SOPs and the NIPCM. This is likely to cause confusion as to what constitutes national policy and what, local guidance. Moving forward, NHS GGC must ensure that staff are directed initially to the NIPCM and that SOPs should only be provided where there is a clear, compelling justification for their added value.

55. Nevertheless, there are some SOPs that *should* be developed going forward. In particular, disease-specific SOPs or aide-memoires would be a useful tool for facilitating easy access to key IPC information supported by the NIPCM. This could be important for novel and emerging pathogens which were linked to significant outbreaks of infection. The NIPCM includes information around transmission-based precautions required for specific pathogens/conditions within its Appendix 11, but there is a national need for extra guidance. It would be appropriate for some additional disease-specific, evidence-based SOPs/aide memoires to be produced nationally for inclusion within the NIPCM as part of national work.

Use of Healthcare Associated Infection Systems for Controlling Risk in the Built Environment

56. HAI-SCRIBE implementation was chosen as part the Peer Review to illuminate the wider issues of IPC governance being considered by the Oversight Board. HFS published the Scottish Health Facilities Note (SHFN) 30[8] in January 2007 to support Health Boards to manage IPC in the built environment. The guidance comprised:

- Part A – the National Manual, which provides information for teams to support decision making so that identified risks can either be eliminated or successfully managed; and

[8] Scottish Health Facilities Note 30 (infectioncontrol.co.nz).

- Part B – the HAI-SCRIBE Implementation Strategy and Assessment Process, which supports built environment project groups to identify, manage and record built environment infection control risks.

The main aim of the guidance is to ensure that IPC issues are identified, analysed and planned for at all stages of a project in the healthcare built environment. HAI-SCRIBE ensures that IPC measures are designed as part of plans and can be maintained throughout the lifetime of the healthcare facility.

57. The Peer Review team found that while this process is largely adopted within NHS GGC, there are inconsistencies. When both the Facilities and Estates staff and Lead Infection Control Nurses (LICNs) were asked if there was a consistent and systematic approach to HAI-SCRIBE risk assessment across NHS GGC, their answers differed: Facilities and Estates representatives stated that there was, while the LICNs said there was not. Moreover, a review of a selection of completed HAI-SCRIBE documents highlighted:

- inconsistencies in approach regarding levels of work, patient risk categorisation and subsequent control measures required to mitigate risk to patients;
- evidence of involvement of the IPC Team in compiling the document, when it was often the responsibility of the relevant Estates Manager;
- inconsistencies within the documentation in terms of the type of work and control measures as well as those personnel involved in the document completion – for example, the names of those involved were found on the front of the HAI-SCRIBE document, however, at the foot, there were no signatures and on occasion, a different LICN noted; and
- an impression that several had been 'cut and pasted' from previous HAI-SCRIBE documents.

58. Good practice is clear that this should be a joint responsibility between Facilities and Estates and IPC Team staff, ensuring that the approach to reporting does not become siloed and relevant expertise and judgement is systematically and appropriately deployed.

Approach to Audit

59. In 2018, HPS issued the National Monitoring Framework for Safe and Clean Care Audits[9], which provides an agreed, recommended minimum approach to auditing for all Health Boards. This gives a set of principles for the quality assurance of all Safe and Clean Care auditing while supporting a Quality Improvement (QI) approach for compliance and improvement. The Framework clearly defines where the responsibility for undertaking audits, developing action plans and taking forward actions to address any issues lies. It stresses that IPC within Health Boards is not the sole responsibility of IPC Teams, but also falls to local teams, and is underpinned by organisational governance structures which ensure strategic oversight.

[9] http://www.nipcm.hps.scot.nhs.uk/resources/audit-tools/.

60. The audit process within NHS GGC has been recently updated in line with the National Monitoring Framework for Safe and Clean Care Audits. A bespoke, quality dashboard has been developed to provide an overview of other quality metrics which can impact staff's ability to undertake good IPC practice, such as staffing levels and patient acuity. The dashboard can show a breakdown of information by each individual clinical area. Senior Charge Nurses have access to the dashboard for monitoring quality within their area and are owners of their local improvement plans, a good example of the Health Board finding ways to strengthen responsibility for improvement at local levels.

61. Audits employing IPC Audit Tools (IPCAT) are undertaken using a collaborative approach to enable the appropriate individuals to take ownership of relevant actions and respond accordingly. Facilities and Estates teams are involved in audit processes in some areas, but there is no standard specifying who should be involved in the audit process at local level. A Combined Care Assurance Audit tool is currently being developed, which is expected to further strengthen collaborative working. NHS GGC reported that the IPCAT audit report and action plan are shared with ward staff, and discussed during ward huddles

62. IPCAT audits reflect a point in time and give a snapshot of IPC policy. The audit alone does not improve compliance – this must be achieved through a change in behaviours, adaptations to practice or processes and, where required, repairs/alterations to the built environment. Investigatory management beyond the immediate correction/action is essential if sustained change is to be achieved. Action plans arising from IPC need to use a quality improvement approach with local teams reviewing current systems and processes and agreeing, testing and implementing change ideas with improvement progress regularly assessed via local data collection.

63. It is not evident from either the IPCAT strategy or discussion with the IPC Team how local improvement is measured other than by undertaking a re-audit at set intervals based on the RAG status. The use of audits to drive improvement does not appear to be fully embedded in the relevant action plans, suggesting that there is a disconnect between the process of audit and follow up and the wider goals of improvement those processes should be supporting.

<u>Approach to Surveillance</u>

64. Surveillance is crucial in order to gather intelligence to identify HAIs and outbreak clusters, and facilitate rapid action to address them. National guidance sets out a requirement that organisations have a surveillance system to ensure a rapid response to HAI.

65. NHS GGC uses the IPC clinical surveillance platform, ICNet, to record surveillance data. ICNet is designed to enable a comprehensive approach to clinical surveillance, outbreak management and anti-microbial stewardship, and is customisable to the specific requirement of the user. Having used the system for a number of years, it appears that the system is effective in NHS GGC. The IPC Team in NHS GGC includes data analysts, who support data collation and outputs of

surveillance enabling the Infection Control Nurses (ICNs) to focus on their clinical remit.

66. During the Peer Review, issues were raised about how regularly the triggers and organisms in ICNet system are updated regularly. For example, Appendix 13 of the NIPCM[10] is a nationally-agreed minimum list of alert organism/conditions with the purpose of alerting Health Board IPC Teams and Health Protection (HP) Teams of occurrences which may require further investigation. Unless otherwise stated, a single case would require an IPC or HP Team review to advise that the correct IPC measures were in place to reduce transmission risk. Typically, two or more linked cases should trigger further investigations into a possible outbreak. The list provided in Appendix 13 of the NIPCM is not exhaustive and specialist units – such as bone marrow transplant or cystic fibrosis – will also be guided by local policy regarding other alert organisms pertinent to these areas.

67. The Peer Review team understood that despite previous infection outbreaks within NHS GGC, the only additional environmental alert gram-negative organisms added to their ICNet system (other than those within Appendix 13) were C.pauculus and Cryptococcus. This meant that the IPC Team had been purely reliant on laboratory surveillance alerting them to the presence of other environmental gram-negative isolates within patient specimens. Given the history of outbreaks, the diversity of environmental organisms seen and the rare nature of some of the organisms, a more pro-active approach to surveillance would have given a more systemic early-warning system given the recurrence of infections.

68. HPS/NSS conducted an 'External peer review of NHSGG&C processes (infection surveillance) related to Appendix 13 of the National Infection and Control Manual' in January 2018 (at the IPC Team's request), which found that:

> "the processes around response to MRSA, SAB and C difficile were highly developed and extremely thorough. However, the processes for response to some of the other infectious threats highlighted in Appendix 13 are less well developed and further consideration needs to be given as to how to ensure consistent and equitable response to all of these infectious threats by the local team."

The Oversight Board Peer Review suggests that this further consideration is still required.

Use of Healthcare Infection Incident Assessment Tools

69. The NIPCM sets out the requirements for NHS Boards to assess all healthcare infection incidents using the HIIAT. An early and effective response to an actual or potential healthcare infection incident or outbreak is crucial. The local Health Board's IPC and HP Team should be aware of, and refer to, the national minimum list of alert organisms/conditions set out in Appendix 13 of the NIPCM. Within hospital settings the IPC Team normally take the lead in investigating and managing any incidents with support from the HP Team. Every healthcare infection incident in any healthcare setting should be assessed using the HIIAT.

[10] http://www.nipcm.hps.scot.nhs.uk/media/1365/2017-06-19-appendix-13.pdf.

70. In reviewing the HIIATs reported to ARHAI Scotland (formerly part of HPS), particular attention was given by the review team to 'green'-rated incidents. Incidents reported as 'green' have been provided to HPS/ARHAI Scotland 'for information only' with no escalation required to the Scottish Government. These are all reviewed by a Senior Infection Control Nurse within ARHAI Scotland and further information has been sought from the reporting Health Board where the assessment and scoring of the incident appears inconsistent with the HIIAT tool guidance.

71. A number of the 'green' incidents reported by NHS GGC over the period had been challenged by HPS/ARHAI Scotland. There were questions raised about whether the 'green' ratings were appropriate and how the recurrence of environmental infections within the QEUH site had been factored into the rating. HIIAT assessments rely on individual review and judgements that are necessarily subjective. Indeed, the ARHAI Scotland review of QEUH HIIATs for the Oversight Board noted some variation between different assessments across all Health Boards. But with respect to NHS GGC, several HIIAT assessments did not seem to take sufficient account of previous incidents within the same hospital site. Assessment should not focus exclusively on individual occasions of infection, but take into consideration wider backdrop issues. Indeed, there had been cases when HPS/ARHAI Scotland requested the Health Board to reassess an incident, taking into account previous incidents, although NHS GGC often chose not to change its initial assessment.

72. ARHAI Scotland concluded that there is a need for national as well as local learning here. *Context* should be a key element in the application of this alert system, a recognition that incidents may assume a different significance when considered in light of any potential pattern of infection incidents faced by the Health Board and the possibility of links to the environment. Opportunities for intervention by the Health Board as a consequence of taking a wider view of infections may have been lost. As a result, there is need for a deeper investigation of how NHS GGC continues to rate its infection incidents in the QEUH going forward.

Approach to Improvement

73. A systematic approach to healthcare improvement and better IPC have been ever more closely linked in recent years. Indeed, the Scottish Patient Safety Programme, which has embedded a more comprehensive improvement ethos across NHS Scotland, was in large part a response to the implications of the Vale of Leven Inquiry. Health Boards should not only be fulfilling current operational duties with respect to IPC, but ensuring that actions are taken to support improvements in their approach.

74. Improvement is explicitly highlighted within the overarching IPC guidance in NHS GGC, but it is not a responsibility lodged in a single part of the organisation. As set out in the Health Board's own Governance and Quality Assurance Framework for IPC Services, the IPC Team is responsible for, amongst other things:

- ensuring advice on IPC is available;
- in liaison with other relevant staff preparing, reviewing and updating evidence-based policies and guidelines in line with relevant UK Department of Health notifications and/or guidelines, when available and applicable;
- ensuring the provision of appropriate education to all grades of staff working within the scope of the policy; and
- providing specialist advice to key committees, groups, departments or individual staff members in relation to IPC practice.

Consequently, the role of the IPC Team is not standalone, but part of the wider conduct of Health Board responsibilities, recognising that IPC can only be successfully carried out when it is embedded across NHS GGC and driven by a commitment to continuous improvement. The IPC Team has the central role in this process of mainstreaming – in effect, ensuring that IPC is not just the responsibility of the IPC Team.

75. Based on international work undertaken between the Institute of Healthcare Improvement in Boston and Healthcare Improvement Scotland, the Model for Improvement (MFI) is the most widely used improvement methodology used within healthcare in Scotland. The MFI asks three questions:

- what are we trying to accomplish (aim);
- how will we know that change has made an improvement (data collection); and
- what change can we make that will result in improvement (change ideas).

These can be laid out in terms of the improvement journey which outlines the stages on an improvement initiative or project. Successful change occurs when there is commitment, a sense of urgency or momentum (for example, higher infection rates), stakeholder engagement, openness and a clear vision that is communicated well. Involvement of those people in the system is vital to success as they understand the system better than anyone else as development of change ideas will come from their experience of the local practice. These changes require: small-scale, iterative testing ('plan, do, study act', or PDSA); refining and adapting these using the knowledge from each successive test and all the time gathering data to indicate whether change is resulting in improvement. Once the local team is confident that the process change is improving outcome (and this is clearly monitored and verified), then and only then, should wholesale local implementation commence.

76. As an agent of Board-wide improvement change, there are excellent examples of this kind of change in NHS GGC. One good example is the quality improvement project to reduce the central line-associated bloodstream infection (CLABSI) rate in the paediatric haemato-oncology population.

Quality improvement to reduce the CLABSI rate in paediatric haemato-oncology

From 2017, the Health Board undertook an exercise to improve infection rates and infection prevention behavior in the paediatric haemato-oncology unit. Surveillance data showed fluctuations in CLABSI rates in the Schiehallion Unit. Before de-canting to QEUH wards in September 2018, Ward 2A in the RHC was a haemato-oncology unit and housed the National Bone Marrow Transplant Unit as well as the Teenage Cancer Trust. Ward 2B was the daycare component of Ward 2A. Staff began researching evidence on the topic and found benchmarking guidance from the Cincinnati Children's Hospital in the US. This led to a Quality Improvement Project using the Model for Improvement and a focused test of change to reduce the incidence of CLABSI in the haemato oncology population. Elements of the project included introducing unified line insertion protocols as well as staff and family education around line care and maintenance.

The methodology was applied with a specific, measurable target: to reduce the number of CLABSIs in Schiehallion Unit patients to 1 per 1,000 total line-days. This was supported by a clearly-defined driver diagram with primary and secondary drivers defined by tailored measurements, and a set of successful outcomes.

Key outcomes

- An issue identified and acted on using QI methodology locally led with support and reporting through Health Board structures
- CLABSI rate reduced and stabilised: from a rate of 6.33 in June 2017 to just over 1 by the start of 2020
- Almost 80 percent reduction from peak phase and just under 60 percent reduction from baseline
- Benchmarking 'like-for-like data' challenging, however, best in country when compared to similar paediatric units
- Going forward – focused on improvement of services continuous improvement, shared learning

77. Across NHS GGC as a whole, there are other instances of IPC focusing on improvement. For example, with respect to gram-*positive* infections, there is notable performance against national expectations. The Clinical Outcomes Review commissioned by the Chief Executive as part of a trio of stocktaking reports on the QEUH, and which reported to the Board at its meeting in October 2019, concluded: "both internal and external review of available data indicates the QEUH and the RHC are not outliers in terms of rates of Healthcare Associated Infection (HAI) or practice."[11] Timeous and effective action across NHS GGC was also evident in responding to individual infection issues, as the Oversight Board saw in the case of the 2019 Stenotrophomonas maltophilia outbreak at the Royal Alexandria Hospital in Paisley.

[11] www.nhsggc.org.uk/media/257579/item-14-int-review16decfinal.pdf.

2019 infection outbreak at the Royal Alexandria Hospital

A number of instances of Stenotrophomonas maltophilia were identified at the Royal Alexandra Hospital in Paisley in early 2019. Infections in previously healthy patients are typically unusual. Nosocomial infections (ie. originating in a hospital) has been increasingly recognised, and usually only occur in those with significantly-impaired immune defences, such as severely immuno-compromised patients. This can cause bloodstream, respiratory, urinary and surgical-site infections. Risk factors pre-disposing a hospitalised patient towards infection include prior exposure to anti-microbials (especially broad-spectrum antibiotics), mechanical ventilation and prolonged hospitalisation. It may also affect the lungs of patients with cystic fibrosis.

S. maltophilia is resistant to many antibiotic classes. This means that treatment options are relatively limited. However, most strains remain susceptible to co-trimoxazole which is regarded as the drug of choice for treating infections. In January 2019, the IPC Team was informed of three instances related to Stenotrophomonas, which led to an IMT being convened by the end of the month. The Board was updated via the Healthcare Associated Infection Reporting Template (HAIRT) in February, and further updates were provided to the Care and Clinical Governance Committee, the Board Infection Control Committee and the Acute Infection Control Committee in March.

When the outbreak took place, a robust structure was in place which meant the incidents were managed timely and effectively at all stages. The key outcomes were:

- timely management of the incident and establishment of multidisciplinary team improves outcomes and communication;
- strict adherence to IPC procedures to reduce the risk of transmission of infection;
- communication with patients and families was pursued as a central part of incident management and managed by the clinical team with support from the IMT;
- a recognition that roles and responsibilities in environmental sampling needed to be clarified; and
- information flow from Reference labs needed to be streamlined.

78. What was notable in the above incident was the highlighting of the 'lessons learned' and the determination that relevant improvements were made in the local IPC Team. The Oversight Board saw abundant evidence of the hardworking and diligent nature of the staff in this area, with commitments to improving outcomes and ensuring patient safety and better care.

79. It is clear that the Health Board could learn from the experience of its infection incidents and adjust accordingly its approach, structures and actions, especially from 2018 onward. This was notable in several key developments (as discussed in more detail in the Final Report): the establishment and active work of a Technical Water Group to provide a targeted response to the set of 2018 infections; the updating of

NHS GGC's Water Safety Policy in 2018; and the development of a single IPC Assurance and Accountability Framework from a set of separate documents.

80. Nevertheless, these instances did not appear to be part of a more systematic approach to learning led by the IPC Team. Apart from a handful of commendable but seemingly isolated examples, there did not appear to be a sustained approach to IPC improvement across the Health Board. It was a recurring theme of the issues examined by the Peer Review and the approach taken to HIIATs discussed above.

81. For example, as part of the work of the Peer Review, the investigating team asked NHS GGC for examples of how local surveillance data was used to inform quality improvement work. The IPC Team has been involved in much of the quality improvement work that was cited, including development of Peripheral Venous Cannula (PVC) care plans which supported frontline staff in undertaking the correct, evidenced-based care of PVCs. This work was led by the IPC Team without apparent implementation of the model for improvement – consequently, ownership of the required improvement was not taken up by the clinical teams or services. There was no evidence of a structured use of quality improvement methodology and a focus on outcomes. Importantly, it was not evident that the relevant local teams were leading this work. Put simply, improvement work was too often siloed within the IPC Team without sufficient mainstreaming across other teams.

82. Similarly, the role of the IPC Team in producing guidance and policy raised concerns. In addition to the individual standard infection control and transmission-based precautions, there were a number of other SOPs that seemed to have been produced principally by the IPC Team. One example was a SOP Team for the insertion and maintenance of urethral urinary catheters – as catheter insertion and maintenance is typically the role of local bowel and bladder teams, the role of the IPC Team in leading the drafting of this SOP was confusing. Whilst the IPC Team should support and advise this work, it is inappropriate for them to lead. Indeed, it was not clear whether the local bowel and bladder reference group was involved in this work.

83. This does not reflect an IPC service which is integrated and collaborative. It appears to be one that provides a standalone service rather than advises and works towards the mainstreaming of IPC improvement. The ethos of improvement should be to work together across existing professional and organisational boundaries when the opportunity to find better ways of delivering shared outcomes can be achieved, and to focus on outcomes. That approach was inherent in the CLABSI work described above and should be more systematically pursued across the IPC Team.

84. In this context, the new IPC improvement collaborative being established through work led by Professor Angela Wallace is welcomed. This collaborative should encompass explicit learning from the QEUH infection incidents, not least with respect to handling gram-negative bacteria infections and working against the background of a potentially-compromised building. The recent refocusing of Executive responsibilities within NHS GGC around a 'Gold Command' structure – led by the Health Board's Chief Executive – and the creation of a new strand of transformation activity on 'Better Safe, Clean Clinical Environment' under the leadership of the Interim Deputy Director for IPC, the Chief Operating Officer and the

Director of Facilities and Estates is an opportunity to drive such improvement. If this strand of work is rooted in a comprehensive review of processes and performance issues for IPC, informed by the findings and recommendations made through the Oversight Board and other review processes, this could prove a powerful vehicle for delivering a change in approach to improvement.

Remaining Work

85. As already stated, this Interim Report does not cover all aspects of the Oversight Board's review of IPC. Several critical aspects are still being examined and will feature in the Final Report, including:

- Responsiveness: how responsive were IPC functions in identifying and taking appropriate action with regards to the children and young people in these infection incidents – not just in terms of addressing the incidents themselves and learning quickly from the experience, but also the efforts to understand the source of infections and take appropriate preventative measures;
- Joint working in IPC: effective IPC within a Health Board depends not just on the strength of the IPC Team, but how that Team link with other key functions across the organisation – this will review how well cooperative working to support IPC was evident in the QEUH, particularly between key staff with a responsibility for undertaking IPC such as Facilities and Estates and microbiologists; and
- Leadership: the strength of the current structure of responsibilities for the IPC Team in NHS GGC, and whether those divisions of responsibilities are best suited in these circumstances.

86. While recommendations on the aspects of IPC discussed here are made at the end of this Interim Report, the full conclusions of the Oversight Board on IPC will be made in the Final Report. This will include assurance on IPC within NHS GGC in the context of the infection incidents in the QEUH.

Governance and Risk Management

88. The second set of escalation issues which the Oversight Board is examining is IPC governance. Its importance has been captured in the Blueprint for Good Governance for NHS Scotland[12], which sets out key principles Health Boards should embody, including the ability to:

- identify current and future corporate, clinical, legislative, financial and reputational risks; and
- oversee an effective risk management system that assesses level of risk, identifies mitigation and provides assurance that risk is being effectively treated, tolerated or eliminated.

This is supplemented by the descriptions of good governance and the approach all Health Boards should take towards quality planning and management in key documents by HIS[13].

89. With respect to IPC, that covers a range of important areas, such as the way in which infection incidents and corresponding actions have been escalated, scrutinised, endorsed and monitored by the governance structure within a Health Board. It also includes how IPC and associated risks are identified, reviewed and overseen by relevant Committees (as well as the Board itself). Consequently, the Oversight Board is reviewing in detail:

- how infection incidents from 2015 onwards were identified and escalated through the governance structures of NHS GGC;
- how risk management was used and adopted accordingly,
- how well the relevant Committees and groups provided direction, monitoring, scrutiny and assurance about the handling of individual incidents, the way in which staff responded, how people were kept informed about what was happening, any weaknesses identified in the building/environment as a result, and the actions taken to address those weaknesses and prevent further problems in future; and
- the overall leadership shown in acting effectively in response and with foresight in dealing with the complicated challenges highlighted by the building.

Progress Update

90. Assessment of these issues has also been led by the IPCG Subgroup for the Oversight Board. This includes the following specially-commissioned work:

- a ‘timeline’ of infections and the Health Board’s responses between 2015 and 2019;

[12] https://www.sehd.scot.nhs.uk/dl/DL(2019)02.pdf.
[13] http://www.healthcareimprovementscotland.org/his/idoc.ashx?docid=e4e2a8ce-342e-4e5c-b998-1f81859b282f&version=-1.

- detailed analysis of the minutes and papers of the IMTs, various groups and Committees about how the issues were reported, escalated, actioned and reviewed within the governance structure; and
- a specific peer review of IPC governance, taking account of the recent changes introduced within the Health Board following the appointments of Professors Bain and Wallace.

91. All of this work is still to be finalised so the Oversight Board will set out its findings and recommendations on IPC Governance in the Final Report.

Technical Review

92. Part of the Oversight Board's role has been to provide assurance not just on practice, but – as far as possible – the relevant physical environment of the QEUH and the Health Board's approach to inspecting and maintaining that environment. The Technical Issues Subgroup was established to provide advice on key aspects of this, including:

- assurance that the relevant environments at the QEUH and the RHC are, and continue to be, safe;
- progress on the refurbishment and reopening of Wards 2A and 2B in the RHC, following its closure in September 2018, so that children and young people can return to the Unit specially designed for their needs;
- how appropriate action plans have been developed and taken forward to address any technical issues highlighted by competent authorities such as the Health and Safety Executive, HPS and HFS; and
- lessons learned that could be shared more widely across NHS Scotland.

Progress Update

93. The work of the Subgroup is continuing and will be set out in full in the Final Report. Given its technical focus, there have been difficulties arising from the Covid-19 pandemic in progressing this work as quickly as desired. Nevertheless, working closely with NHS GGC, the Subgroup is currently undertaking reviews of:

- NHS GGC's water safety policy, with specific attention given to its water testing regime and how testing results are being used as part of IPC and the key water and ventilation infrastructure in light of the infections across the hospital site; and
- NHS GGC plans to review the impact of the chemical dosing system introduced from late 2018 to address water system contamination, especially any potential implications for the existing water infrastructure.

Refurbishment of Wards 2A and 2B in the RHC

94. The Subgroup has also reviewed progress on refurbishing Wards 2A and 2B in the RHC. Originally, when the children and young people were first de-canted from the wards, it was hoped that the work would be relatively limited. However, as further investigation was conducted on the state of the wards, it was clear that significant additional work would be required to redress shortcomings in the original building work, particularly with respect to ventilation issues.

95. The completion date for Wards 2A and 2B has now shifted to May 2021. The principal reason for the delay has been Covid-19, which has had an impact in an number of areas, including the procurement of relevant plant and equipment, essential staff being furloughed, social distancing being enforced (which has affected timescales) and the site needing to be shut down on one occasion following a

positive Covid-19 test result. In addition to these issues, as it has been upgrading the ward, NHS GGC has identified additional problems with mould, fire stopping and insulation in external walls which have all needed to be rectified and that has added time to the programme of work.

Communication and Engagement

96. The Oversight Board was established against a background of increasing dissatisfaction and distress among families of the children and young people in the paediatric haemato-oncology service, reacting to how NHS GGC had been communicating the continuing issues around infection in the hospital. In November 2019, the Cabinet Secretary for Health and Sport met with several families, which led to a set of 71 issues and questions about the hospital and the infections being posed to NHS GGC. The issues on which families felt frustrated in getting information from the Health Board included (but were not limited to):

- assurances on the current safety of the water system and the wider clinical environment for the children and young people;
- progress with key remedial work on different wards, including 2A and 2B in the RHC from which the Schiehallion Unit had been de-canted in 2018;
- issues relating to the current location of the children and young people in the haemato-oncology services in Ward 6A in the QEUH;
- the adequacy of IPC measures in place;
- conflicting messages in the communications given to patients and families as the infection incidents had progressed; and
- a perceived lack of compliance with the organisational duty of candour.

Responses to those questions were provided to families and subsequently posted by NHS GGC on its website, and the issues raised helped to set the remit of this Oversight Board.

97. Discontent with NHS GGC's communication was also evident in the survey conducted by Professor Craig White of this group of families in December 2019. Twenty responses were received, with the majority of respondents saying they were not satisfied with the level of communication about the ongoing issues by the Health Board, with clear dissatisfaction expressed about NHS GGC's performance in this regard. The issues experienced by families were many and varied: some were individual and personal matters relating to their own children, while others reflected a more common set of concerns about how the Health Board was engaging with them.

98. Supporting patients and families in the midst of a prolonged crisis would have been challenging to any Health Board. It was made particularly complex for NHS GGC by the difficulties in providing the children, young people and families with certainty and clarity about what has happening, as will be seen below. Nevertheless, the experience of some patients and families pointed to problems of the Health Board in its approach to communication, and the view by some that the Health Board was failing to exhibit the essential person-centred principles to communication that are the cornerstone of NHS Scotland.

99. The strength of feeling among several families highlighted the importance of engaging with families throughout the Oversight Board's work. A dedicated Communication and Engagement Subgroup was established, chaired by Professor White and with membership including communication experts from other Health

Boards as well as representatives of the families themselves. It provided a forum for direct exchange of views and discussions between the Health Board and family representatives.

100. The Oversight Board set two key success indicators for NHS GGC in its approach to reviewing communication and engagement. Patients and families within the paediatric haemato-oncology service should receive relevant information and are engaged with – and are treated with respect to their rights to information and participation – in a culture that reflects the values of NHS Scotland in full. That should be seen in the following.

- Families and children and young people within the haemato-oncology service receive relevant information and are engaged with in a manner that reflects the values of the NHS Scotland in full.
- Families and children and young people within the haemato-oncology service are treated with respect to their rights to information and participation in a culture reflecting the values of the NHS Scotland in full.

101. In its work, the Subgroup concluded that evidence of this kind of success should be seen through the following:

- priority is placed on communication and information provided to patients and families with a focus on respect and transparency (with an initial focus on ensuring that all outstanding patient and family questions raised are answered);
- the Health Board ensures there is an appropriate Communication and Engagement Plan with a person-centred approach, including a clear Executive Lead for implementing and monitoring; and
- a review is conducted of key materials, policies and procedures in NHS GGC with respect to the organisational duty of candour and Significant Adverse Event Reviews, and identification of any national learning/lessons learnt.

102. Not all of the work carried out for the Oversight Board through the Subgroup is set out in the Interim Report. NHS GGC's approach to its organisational duty of candour and how it addressed Significant Adverse Event Reviews are key elements of how a Health Board should engage with patients and families when death or harm occurs within a hospital setting. They are processes that are governed by legal, regulatory and guidance frameworks, and the Oversight Board's findings here will be set out in the Final Report.

103. The Interim Report focuses on the extent to which communication and engagement by NHS GGC has reflected consistent delivery of the overarching principles outlined above, rooted in the NHS Scotland approach to person-centred care. These issues are considered under the following headings:

- the strategic approach to communication in NHS GGC;
- application of this approach in IPC, and the issues experienced by patients and families through this period; and
- scope for improvement.

Strategic Approach to Communication

104. The principles of good communication in healthcare settings have been clearly expressed nationally. The Director-General of Health and Social Care in the Scottish Government's and Chief Executive of NHS Scotland's letter of 22 February 2019[14] stressed the importance of appropriate communication:

> "Our learning so far from the degree of public interest in these issues makes very clear that communication is always better done directly with those most closely affected first. We should, as far as possible, be alerting staff, patients and families before making any public statements and the service and Scottish Government should work closely together in our communications with the public."

105. NHS GGC's own stated objectives for person-centred care are set out in it 2019-23 Healthcare Quality Strategy[15]. This represents a level of aspiration – and a means of measuring how well NHS GGC currently operates – that the Oversight Board endorses. Responding to what patients and families wanted, the Strategy aims for a high-quality service that:

- takes time with patients and listens to them;
- takes care of people, looks after them and makes sure they get the right treatment;
- communicates well with patients by explaining all they need to know and involving them in decision making;
- is knowledgeable, safe and trustworthy;
- is efficient;
- is caring, compassionate and shows empathy;
- has friendly, kind, competent and professional staff; and
- communicates with the people who matter to them regarding their progress and condition.

106. The Health Board has recognised the kind of communication and engagement that should be expected for these patients and families in its description of 'Person-Centred Care' with the following series of commitments in that document.

- We will enable people to share their personal preferences, needs and wishes about their care and treatment and include these in their care plan, care delivery and in our interactions with them.
- We will involve the people who matter to them in their care in a way that they wish and that meets the requirements of the Carer's Act (2018).

[14] https://www.sicsag.scot.nhs.uk/hai/_docs/HCAI-DL-2019-23-Dec-2019.pdf.

[15] https://www.nhsggc.org.uk/media/253754/190219-the-pursuit-of-healthcare-excellence-paper_low-res.pdf.

- We will develop further the person centred approaches to visiting throughout NHS GGC.
- We will make sure people experience care, which is coordinated and that they receive information in a clear, accurate and understandable format, which helps support them to make informed decisions about their care and treatment.
- We will give people the opportunity to be involved and/or be present in decisions about their care and treatment and include the people who they want to be involved in accordance with their expressed wishes and preferences.
- We will provide training and education, to enable staff to treat people with kindness and compassion, whilst respecting their individuality, dignity and privacy.
- We will inform people about how to provide their feedback, comments and concerns about their care and treatment. We will review our approach to collecting and managing feedback to make sure it is fit for purpose.
- We will make sure there is a collaborative and consultative approach in place to enable staff to actively listen, learn, reflect and act on all care experience feedback received and to ensure continual improvement in the quality of care delivered and the professional development of all staff.
- We will continue to identify and build opportunities for volunteers to help improve the health and wellbeing of patients, families and carers.
- We will engage with people, communities and the population we serve to deliver high quality services to meet their needs.

107. The centrality of these communication principles is reflected in other NHS GGC strategies. In particular, the Health Board developed a dedicated communication strategy for infection issues: Healthcare Associated Infection Communications Strategy[16], published in 2015 (and due for review in 2019). The Strategy stressed "the importance of a culture of openness, transparency and candour". It acknowledged the need to learn from incidents such as the Mid Staffordshire NHS Foundation Trust Public Inquiry as well as the impact of the Vale of Leven Hospital outbreak of C. difficile and the recommendations from Lord Maclean's Inquiry.

108. The Strategy set out the principles of communicating infection diagnosis and risks, and included key actions to be taken forward in individual cases such as (but not limited to) the following:

- every patient should be informed of the risk of infection and the actions being taken to prevent healthcare associated infection;
- if a patient is diagnosed with an infection, the diagnosis should be discussed with the patient by one of the members of the clinical team if possible; and

[16] https://www.nhsggc.org.uk/media/243043/hai-communication-strategy-july-2015.pdf.

- the Health Board should ensure that if a patient dies with an infection which is either the primary cause of death or a contributing factor, families are provided with a clear explanation of the role played by the infection.

109. The Strategy presented a clear baseline of principles against which the actions with respect to the QEUH infection incidents can be considered. As noted, the Strategy is several years old and is due to be updated; in light of recent experiences with the QEUH, and the recommendations set out here (and in the Independent Review), there is a strong impetus for a new, revised version of the Strategy to be produced and issued.

Communication in the Context of Infection Prevention and Control

110. While a statement of principles and standards is vital, what matters most is how strategic aspiration is translated into action. Good practice was clearly evident. When reviewing how the Health Board responded to the unfolding circumstances of infections, the Oversight Board noted evidence of improvement already at work within the Health Board. It is important to highlight this, not least as practice that could support national learning.

111. Throughout the incidents, there was generally a recognition (not least by the children, young people and families themselves) of good communication at the point of care. At ward level, communication was often effective and sensitive, displaying the Health Board's person-centred values in how it responded to individual patients' and families' circumstances. Direct communication by the clinical and medical staff have been highly regarded by the children, young people and families throughout, not least when it related to the individual care of patients.

112. Communication to patients and families individually at the point of care was undertaken with compassion, care and support by the relevant staff, especially in the Schiehallion Unit. Ward staff were often the key means by which major, and often unsettling news was conveyed, such as the decision to de-cant Wards 2A and 2B in September 2018 (as discussed more fully below). As noted by one respondent in the December 2019 survey of families:

> "Clinical staff provide timely and relevant information on… treatment. Someone is always available when we have questions. When I was stressed about a delay to surgery, nursing staff picked up on that and arranged for consultant to contact me."

Despite the pressures to provide regular communication on the infections and the impact that they had on day-to-day operations, the focus on providing a high-quality service was never lost in the engagement with the children, young people and families. The Oversight Board commends that commitment by staff in the hospital to keeping patients and families directly informed.

113. There was also evidence that the Health Board was capable of learning to address the challenges of maintaining complex and often prolonged communication with patients and families in difficult circumstances. A good example of this was the development of the 'closed' Facebook page for patients and families, as described in

more detail in the box below. This Facebook page has been a critical means of alerting patients and families to key developments and issues as well as enabling them to raise important issues with the Health Board – indeed, the value of the mechanism has extended beyond the immediate infection issues for the patients and families, and developed into a means of supporting the group of families, children and young people for other issues. For example, it has become an important means of identifying and acting on issues affecting this group of patients during the Covid-19 pandemic. Although the key to its value is ultimately the responsiveness of the Health Board to the issues raised on the page, it was an innovative and useful tool that highlights the capacity of the Health Board to improve.

'Closed' Facebook page for patients and families

The decision to develop a customised Facebook page for the Schiehallion Unit patients and families emerged from the experience of using the existing social media services. In the first few months of 2019, public and media attention on the problems of the QEUH was particularly acute, increasing the need for families to find a way to express and discuss their concerns, seek and receive information, and engage with the Health Board on the continuing implications of the infections for their children.

In January, it was agreed that a 'closed' Facebook page would be established for the benefit of patients and families – a decision that was endorsed by the Board itself, commendably demonstrating the importance of improving patients' and families' communication within NHS GGC. A form of 'gate-keeping' of the page's membership would be provided by NHS GGC itself to protect the privacy of the discussions, but the forum was allowed open and full access to members.

The Facebook Group was launched in September 2019 for patients and families associated with their paediatric haemato-oncology service. Initially, the number of members was approximately 50, but over time, membership increased significantly; currently around 180 members are listed. It has the potential to become a central mechanism for parents to engage collectively with NHS GGC clinical leaders within the ward and the Board's staff who support corporate communication and engagement activity. Executive-level responsibility for engaging with patients and families has now been placed with the Health Board's Nursing Director – the first time a Board member was explicitly and visibly put forward in such a way.

Since escalation, families have expressed positive feedback about how the Facebook page keeps them informed of statements from Scottish Government Ministers as well as the work of other key reviews (and indeed, the work of the Oversight Board). There are some encouraging recent examples of this being used effectively to support dialogue with patients and families who have expressed concerns about (for example) the quality of the food in Ward 6A, including engagement on an event involving parents who wish to work with staff on improvement planning. While discussions on the pages are sometimes critical of NHS GGC, it represents a willingness by NHS GGC to support constructive debate and challenge for those most affected by the continuing problems and decisions taken by the Health Board, though it must continue to be used pro-actively and there remains work to ensure that this is done consistently.

114. NHS GGC has also undertaken work to ensure that individual children, young people and families have relevant communication/information specific to their needs and relevant of their histories. Not all patients and families have wanted the same level of engagement and information with the Health Board, and it was important to recognise their different circumstances and preferences. Given the sensitivities arising from the experience of many of these children and young people, it was also important that Health Board communications did not appear unnecessarily generic, but recognised a history of communication with particular families, and indeed, reflected the often difficult circumstances of their children that lay behind individual communications.

115. This led to the development of a specially-commissioned database to facilitate improved engagement with concerned patients and families and how they preferred to be contacted; the box below describes this in more detail. This as an important development that would be of value across NHS Scotland more widely. It has enabled communications to be formulated in a way that respects communication and engagement preferences, and clearly embeds a person-centred approach.

Database of contacts and communication preferences for patients and families

A database of contacts with the Scottish Government and NHS GGC was commissioned following the escalation of NHS GGC to Stage 4 in the NHS Scotland Performance Framework in November 2019. Based on the existing communication with over 400 families, the database compiles key information on preferences. It uses NHS National Office 365 SharePoint to capture the history of communication with particular patients and families. It has strict permissions settings in place and is sharable with colleagues in NHS GGC and Scottish Government links. The database supports improved oversight, makes it manageable to incorporate enhancements and changing requirements, and to add users. Its protocols can potentially be adapted to support future oversight requirements if/when Scottish Government/NHS Scotland coordination and comprehensive overview is required.

There is scope for improving the value of the database further. This tool could be supplemented by enhancing the existing family 'induction' packs with clear information on where patients and families could go for information about continuing issues such as the infection incidents. It also has applicability that goes beyond the paediatric haemato-oncology service, but could be deployed usefully whenever there is prolonged communication between the Health Board and a particular patient/family group.

116. Nevertheless, where communication and engagement went beyond the ward level – particularly with respect to 'corporate' communications on behalf of NHS GGC as a whole – there were a number of deficiencies. Such corporate communication has an essential role, as ward staff were not always the most appropriate channels for information, particularly when it involved a wider communication effort, targeted not just at the children, young people and families but staff and the wider public and media. In this context, the approach to communication and engagement by the Health Board did not consistently match the person-centred principles of its strategies.

117. This can be highlighted when considering how communication operated at specific points over the period. Key milestones in the timeline of infections spotlight how the Health Board acted:

- the decision to de-cant Wards 2A and 2B in the RHC in 2018;
- the introduction of a comprehensive water dosing system in 2018;
- the series of new infections in QEUH wards in 2019; and
- recent issues in the wake of the announcement of legal action.

All provided critical points when communication with patients and families was particularly sensitive, and are worth examining in detail.

Decision to De-cant Wards 2A and 2B in 2018

118. The decision to de-cant the children and young people from Wards 2A and 2B in the RHC to Wards 6A and 4B in the QEUH in September 2018 was one of the most visible and public milestones in the development of the infection incidents. Closing the wards would inevitably be regarded as an admission of the seriousness of the series of infection issues and open up the Health Board to potential accusations that it was not in full control of the situation. Consequently, good handling was vital.

119. The decision came on the back of a resurgence of infections within the RHC wards, leading to the restoration of the IMT after it had been stood down twice since March of that year. It was made relatively quickly, reflecting an urgency around the need to investigate the source of infections in the wards more thoroughly and mounting concerns by staff on the wards and families around the safety of the environment. It was also made at a point when concern, investigation and speculation had resulted in substantial disruption in the care of this group of children and young people. There was a significant physical/logistical challenge in ensuring that the new wards were altered to provide appropriate care for these vulnerable children and young people and manage the movement of patients on 26 September, but there was an equally important challenge in communicating the key information and the rationale to patients and families, addressing their questions while providing reassurance around the continuity and security of care.

120. The news was put out in a number ways on 18 September and the days that followed. For those on the wards, much of his was done through face-to-face briefing by the Chief Nurse and General Manager, supported by a written briefing for families. A hand-out, dated 18 September, set out the details of the de-cant. It highlighted the need for further invasive exploratory work on the source of infections, involving the drains as the primary reason for moving the children and young people, and emphasised the priority of their safety and care. The statement – which formed the basis of a media release the same day – did not offer details of where most children and young people in the Schiehallion Unit were moving to in the adult hospital (arguably a singular omission, given that the location had already been discussed in planning with senior management). On its own, the lack of detail on the nature and duration of the move would not have given sufficient reassurance to the children, young people and families. Nevertheless, the communication work – particularly through the direct support of those in situ on the wards – seems to have

been effective in managing a sudden and sensitive change of circumstances for the patients and families. The challenge for the Health Board was not made easier by false information carried in news outlets that the de-cant had already taken place, resulting in distress in some families on which swift and targeted action was taken by senior managers within NHS GGC.

121. The de-cant was originally envisaged as a short-term move, and presented as such to patients and families. As the investigation of Wards 2A and 2B revealed a succession of environmental deficiencies, going back to the original construction of the wards, it became clear in the succeeding months that it was unlikely that the children and young people would be restored to the original wards soon, and the stay in Wards 6A and 4B would be prolonged. However, the communication of this to patients and families appeared to be faltering. No formal updates on the work on Wards 2A and 2B seemed to have been made to the patients and families through October and November 2018, and it was evident that staff were reluctant to discuss the changing work timetable until a fuller picture of the problems in the wards was known (in particular, staff were waiting on key external reports on ventilation before providing an update). The absence of corporate updates in this period would have not been reassuring to those already experiencing considerable distress and uncertainty. The decision seemed to have been taken that it was better to 'have something to say', but this lack of communication was not reflective of the Board's strategic commitment to person-centredness. It compromised the confidence and trust that families with ongoing concerns and unanswered questions had in the Health Board.

122. When an update was forthcoming in December, it downplayed the emerging environmental issues emerging from the investigations of the wards. Briefing to patients and families on 6 December 2018 cast the further delays as an 'opportunity' to upgrade the ventilation. This suggested a lack of transparency about the emerging scale of issues encountered on Wards 2A and 2B. While communications should be mindful of causing unnecessary alarm, the approach seems to have contributed to a deepening suspicion among some families that the Health Board was 'covering up' issues relating to the hospital building. While there is no evidence of deliberate concealment of any such information, throughout 2019, the formal updates to patients and families about progress with Wards 2A and 2B seemed intermittent and not transparent about either the real difficulties experienced with the programme of work or the delay to a return of the children and young people to the RHC. It was known in January 2019 that any prospective return to Wards 2A and 2B was unlikely to occur before the end of that year, but this does not appear to have been fully and openly communicated to patients and families likely to be affected by these decisions.

123. This apparent omission might be indicative of the highly reactive environment that the Health Board faced, not least in the early part of 2019, as there were a number of immediate communication issues on which action needed to be taken. But it reinforced an impression that NHS GGC was not forthcoming about key information regarding the situation with the building, leading to an avoidable increase in distress and subsequent deterioration in the relationship between some families and the Health Board.

Introduction of the Water Dosing System in 2018 and 2019

124. The installation of a site-wide, water dosing system was a decisive step taken by the Health Board to address what seemed to be mounting environmental risks in 2018. The decision was not taken lightly, but followed extensive options appraisal by the specially-created Technical Water Group and careful planning to manage its introduction with minimum disruption to staff, children, young people and families. The option was raised quickly by the newly-established Group in the early stages of the 'water incident' in the first half of 2018; by the end of the year, the implementation of dosing was completed for the QEUH and extended to the RHC through 2019. It represented the most emphatic action by the Health Board to address the risks of widespread water contamination, a significant achievement in terms of the speed and scale of response.

125. From a communication perspective, the use of comprehensive chlorine dioxide dosing has several important dimensions. It demonstrated the responsiveness of the Health Board and its willingness to 'do what was necessary' to mitigate risks to patient safety and provide assurance to patients, families and the wider public about hospital safety. At the same time, it needed to be explained carefully to ameliorate any concerns (not least among patients and families) that might have arisen about having to treat the water with 'chemicals' and the impact that could have on patient health. Moreover, there was a risk it could be framed by some as a Health Board admission that there was widespread water contamination in the hospital and the impossibility of removing the source of the contamination without such dosing action. There were communication implications that went beyond the paediatric haemato-oncology patient group, as the water dosing would affect a wider number of patients. As a result, careful handling of information and messages with patients and families was critical.

126. Dosing for the adult hospital was agreed in early November 2018, and a communication was to be issued as soon as the timeline for the work was finalised. It was not clear how this was widely communicated, either in the lead up to the point at which the adult hospital dosing system was put in place (28 November) or in the period afterwards through information presented to patients and families. In mid-January 2019, apparently following complaints made by some families directly to the Scottish Government about the more general quality of information being provided by the Health Board, briefing was provided about the dosing. However, the written information was opaque:

> "It is also important to note that the additional measures to ensure water quality have been put in place for the whole site (QEUH/RHC) and these have been successful. Our rigorous water quality testing is demonstrating good results alongside the ongoing use of water filtration devices."

A fuller description of the chemical dosing system and its implications did not appear to be forthcoming in the following months, though references were made in subsequent briefings to patients and families. It further highlights what seems to be a different approach between what was communicated on the ward – where there would have been opportunities for direct questions from those patients and families present – and what was communicated through corporate channels.

New Infection Incidents in Wards 6A and 4B in 2019

127. The de-canting of the children and young people into Wards 6A and 4B should have been seen as an end to a period of severe anxiety about environmental risks. Consequently, the appearance of new infection incidents in the QEUH wards in 2019 caused renewed, if not higher levels of distress and raised further questions about the capacity of the Health Board to manage IPC. The new series of infections from June presented the Health Board with new communication challenges. At this point, the issues had features that were not present before. It carried a strong risk of suggesting that whatever action had been taken before had 'not worked' and that NHS GGC was not 'in control of the situation'. This was compounded by the difficulties that the IMT in the second half of 2019 faced in identifying the source of the new infections. As with the 2018 'water incident', strong IPC measures were required such as the closure of Ward 6A to new patients for a period, which led to disruption for the children and young people. The potential for undermining trust in NHS GGC was acute.

128. During that period, the Health Board endeavoured to keep patients and families updated on what was going on at different points. Verbal and written briefings continued to be provided after each IMT meeting, and a new dedicated Facebook group/page was established. While there was significant (and arguably inevitable) repetition of information across the different updates, the fact that they were being made was evidence of the Health Board recognising the importance of maintaining the flow of information to patients and families.

129. However, there seemed little open recognition of potentially deeper issues with regards to the environment. By this stage, the notion of widespread water contamination was becoming increasingly accepted – while the pathways and sources of infection eluded detection, the idea that the water system may have been contaminated at some stage in the construction/commissioning of the hospital was present in the HPS report on Wards 2A/2B and the accompany HFS report. The briefings to patients and families did not acknowledge these issues, but instead emphasised that "we have undertaken extensive testing of the ward environment and at this stage no link has been detected between the infections and the ward environment or our infection control practices" (as set out in an October 2019 briefing, but presented in similar phrasing in other briefings at that time). Patients and families were, of course, increasingly aware of the wider issues relating to the building, which meant that through this period there may have been a widening divergence between what several families understood from other sources and what they were being told by the Health Board.

130. Statements by the Health Board, of course, must be factually accurate. There is a risk in conveying perceived risks about the environment without fully understanding what is happening. Nevertheless, as more infections occurred in 2019, uncertainty around the environment would not go away, and communication efforts should have adapted to recognise and respond to that uncertainty. The lack of reference to these wider risks seems to have exacerbated a perception that the Health Board was increasingly focused on 'managing' rather than providing information. It reflected what appeared to be a greater priority on reputation management than regular, pro-active and supportive communication more explicitly

informed by the perspective of patients and families. This approach to communication – one that provided messages that were supportive of the organisation but did not consistently respond to individual patient concerns – seemed to have diminishing returns with an (understandably) increasingly vocal and expanding group of families that were unhappy about the lack of transparency in what was going on. By not openly acknowledging more readily what was *not* known about the infections, the Health Board created the impression that it was simply hiding something that was alleged to be known about the building. This potential trap is perhaps most tellingly demonstrated in the following more recent milestone.

Recent Issues Following the Announcement of Legal Action by NHS GGC

131. Since the Oversight Board was established, NHS GGC has announced that it was launching a legal case against the QEUH builders, Multiplex. As a result, the Health Board has become notably more sensitive to communication that could have a bearing on the conduct of the legal case, and as a result, has become increasingly reluctant to comment or discuss aspects of the infection incidents and the related issues, citing the risks of compromising the forthcoming legal case. This featured recently in its responses to the Independent Review's report on the commissioning, design, construction and handover of the hospital complex and a BBC Scotland Disclosure documentary on the QEUH (which aired in June 2020), when the Health Board was notably limited in its response to the issues raised. This has exacerbated a sense among several families that the Health Board had continued not to pursue a policy of transparency and sensitivity to the affected children, young people and families.

132. The Oversight Board appreciates the legal sensitivities facing the Health Board, particularly where it is likely to be made on the back of internal legal advice, but considers that continuing reluctance to be more open on many of these issues is exacerbating rather than resolving the fundamental concerns on communication and engagement that gave rise to escalation to Stage 4. This is particularly relevant given that the timescales for the legal action are not clear at this point, but could last for a prolonged period. A better balance about engaging on the challenges and history of addressing the problems of the QEUH is needed if there is to be restoration and trust in the Board's commitment to, and delivery of pro-active, transparent, compassionate and supportive communication and engagement where patients and families express concerns or ask questions. This should be irrespective of the number of families involved or any perceptions regarding their 'representativeness' with respect to the wider group of affected families.

Observations

133. All of the incidents described above show strong direct communications, but problems with corporate communication to the wider group of patients, families and ultimately, the public. There seems to be several recurring themes.

134. First, there was a lack of timely information on what was known about the infection issues and what actions were being taken as a result. Points raised by some families included:

- a widespread feeling that the Health Board was slow to respond to specific queries put to them about their children's care (for example, concerns in respect of the time taken to respond to the issues later reflected in the summary of 71 questions and issues that were put to the Cabinet Secretary for Health and Sport by family representatives in late 2019), and that communication with patients and families could sometimes 'lag' official press releases on media stories;
- suggestions that patients and families were hearing about key information through the media and press releases by the Health Board, rather than directly, adding to an impression of too often being 'kept in the dark'; and
- in a few cases, allegations that the Health Board was not answering questions "properly or truthfully", as one of the respondents to the family survey noted.

135. Such comments have been persistent across the period. For example, suggestions that there was a lack of transparency by the Health Board were made by some families at the start of the 'water incident' in March 2018. They have continued through to more recent discussions and the reaction of families on the Facebook page to the BBC Disclosure Scotland documentary in June this year. Across the period, communication did not always demonstrate to these families a clear, person-centred tone in addressing such sensitive issues. The work by Professor Craig White as 'family liaison' to support the way NHS GGC was drafting its public messages from late 2019 also highlights the need of the Health Board to develop more person-centred language in how it reacts to critical media stories.

136. Several families, particularly those with prolonged and continuing engagement with the Health Board because of the care and circumstances of their children, felt that the Board was often reluctant to provide direct answers to their questions and information about the hospital. This reluctance was fed by a sense of sluggish responses to questions posed, a strong impression of information being partial or misleading and a belief that the Health Board would not admit any mistakes that might have been made regarding the environment of the building or the care of their children. These views were not shared by the Health Board, and it was occasionally suggested that the responses reflected a minority of families that were explicitly expressing their views. Nevertheless, it was clear that the views of several families became more entrenched over the period, and that any communication and engagement efforts by NHS GGC to address distrust and lack of confidence in the Health Board did not fundamentally shift this sense of distrust. The obligations of the Health Board to respond openly, compassionately and supportively to any patient or family who raises concerns has not been consistently evident in the thinking, decision-making or actions of senior staff.

Scope for Improvement

137. While the Health Board has strived to learn from the unique situation it faced, there remains a continuing need for improvement in how communication, engagement and information provision takes place. Part of this requires a fuller understanding of the challenges facing the Health Board with respect to

communication, not least in terms of national learning to be gained from how to respond to infection outbreaks.

138. One key challenge was how to communicate a complex set of issues where uncertainty would not go away. This uncertainty had different dimensions to it. The exact source of infections was not clear throughout the period –- this proved a complex problem for the Health Board through 2018, where the picture of what was taking place developed incrementally. Knowing what and how to communicate with children, young people and families in this situation was not relatively straightforward. This was complicated with the difficulties of engaging with patients and families who were no longer in regular contact with the service. In particular, the timing of when to update patients and families was often hard to determine, not least in an environment of significant media scrutiny. Providing timely, full information to families was not always easy. Social media was a particularly complicating factor, as it could convey stories more quickly than the Health Board was accustomed to responding act as an amplifier – if not in some cases, a distorter – of some of the concerns being expressed. At the same time, the Health Board was seen as slow to take advantage of social media as a means of communicating with patients and families, and indeed, the wider public, about key developments, or addressing any misconceptions being disseminated.

139. Nevertheless, while these challenges made communication decisions more difficult to take forward, there are several areas where NHS GGC must take action to ensure the delivery of necessary improvements:

- the communication responsibilities of IMTs;
- coordination between different teams/services in communication;
- communication with staff;
- visibility and approach of senior management in communication; and
- the role of external bodies in supporting communication.

Incident Management Team Responsibilities

140. In line with national practice, the responsibility for communication decisions is typically lodged with IMTs – what to communicate, when and through what media – with communication advisors providing support and IMT Chairs with a key role in taking decisions. Throughout 2018 and 2019 in particular, IMTs were clearly active in response to communicating the infection incidents.

141. IMTs are often necessarily focused on specific outbreaks. While understanding a wider context of infection can be critical for determining the source and mitigation, the idea of a *communication* context to outbreaks seems less well appreciated. For the children, young people and families affected, a series of infections may appear part of a single continuum of events, potentially marked by escalating anxiety and disruption. This perception of a continuing 'crisis' did not seem to inform the approach to communication across the period, where actions were regarded typically in terms of addressing short-term issues. The IMT process, while useful for these more incident-based situations, was potentially less effective for a prolonged scenario when a number of incidents could be linked together by

patients and families (and as became the case in 2019, in the eyes of the media, politicians and the public).

142. A better process should be identified to allow for infection incidents to be more explicitly considered within that broader context. This should take full account of previous communications, consistency in messages where appropriate and the recognition that the audiences of these communications have changing expectations of what they want to know from the Health Board as the 'crisis' develops (particularly if initial questions about the source of infections cannot be quickly addressed). The learning for NHS GGC here would have a clear national dimension as well. Such a process may involve shifting some communication responsibilities away from the individual IMTs when it becomes clear that the incidents are being seen in a larger context. This would need to have clearly defined triggers, roles and responsibilities. This was particularly evident in relation to the responsibilities for developing and issuing press releases, as it was not clear to the Oversight Board where full responsibility was being exercised and the extent to which this was led by IMTs in practice.

Coordination of Communications

143. Infection issues can draw in the work of several services within the Health Board, including clinical staff, the IPC Team, Facilities and Estates, and senior managers. Clear coordination and a common approach to information, messages and the culture of communication is essential.

144. NHS GGC was not consistently integrated in its communication in this context. Key messages, especially when delivered directly on wards, would have often benefited from a more systematically joined-up approach, particularly between the IPC Team and facilities/environment personnel. Some families had reported that while ward-level communication was delivered compassionately and usually at the right time, that communication would have been more effectively delivered if they were made with the visible involvement of other staff who have a clear link to what was being communicated.

145. This was particularly highlighted for issues relating to changes in the estate and the physical environment as a result of the incidents – whether local changes such as the use of water filters on taps in rooms or wider changes, such as the de-canting of the whole of Wards 2A and 2B. Assurance would have been more strongly communicated to patients and families had these messages been more regularly undertaken jointly by clinical and Facilities and Estates staff.

146. Overall, the Health Board's corporate messaging needed to be more joined up in terms of recognising the range of activity that was taking place at any one time. The issuing of single-narrative corporate briefing points to NHS GGC's recognition of the importance of a common message. But as these briefings sometimes needed to be supplemented with questions directly posed by the families, it resulted in ward staff sometimes appearing not fully informed enough to address the concerns presented to them. This was particularly true in 2019 with the new series of infections in the QEUH wards, when many of the families' questions related to more technical, environmental subjects that were best addressed by Facilities and Estates

staff. As a result, the consistency of the information and messages across different levels of the organisation was not evident across the period, adding to the frustration experienced by some families and putting more pressure on ward staff.

Communications with Staff

147. This chapter has focused on communication and engagement with patients, families and the public, but there was an equally important need to provide regular information and reassurance to staff as well. This was important because of the duty of care of the Health Board to its staff, recognising their concerns about working in a potentially 'unsafe' environment as well as their natural compassion for their patients. It was also critical given the vital role that staff – especially those on the wards – played in providing information to patients and families. Communication with staff was another aspect of wider engagement with the public.

148. Staff concerns were evident throughout this period. While the concerns about the risks of the building tended to be expressed by individuals before 2018, from the 'water incident' onwards it became a continuing source of anxiety for groups of staff. For example, in September 2018 (before the de-canting), staff in Wards 2A and 2B were reported to have been visibly upset and anxious at a staff information event, and some approached their union for advice about the safety of their patients remaining within the ward. Specific decisions could raise concerns, such as the blanket use of anti-fungal prophylaxis as part of the IPC measures – in December 2018, some medics expressed concerns about the prescription of prophylaxis, as several children had experienced severe reactions. Moreover, when the Cryptococcus neoformans infection was drawing intense media scrutiny in early 2019, staff were reporting their own respiratory problems that they felt might be linked to ventilation /infection issues.

149. The Health Board responded actively to these concerns: there were regular briefing updates to staff (often weekly during the most intense periods), face-to-face meetings with senior hospital managers and active engagement by the IMTs through the Lead Infection Control Doctor. The commitment to keep staff up-to-date and supported through this period was evident, and there is no suggestion that the Health Board was not forthcoming to its staff about what was happening.

150. Nevertheless, while the regularity of such communications may have allayed anxieties, they could not remove them, for the same reason that some families remained dissatisfied with Health Board communication efforts. The prolonged uncertainty around what was causing the infections and the risks associated with the building could not disappear, forming an ever-present background to healthcare operations on the site. Moreover, as set out already, the apparent reluctance of the Health Board to be more forthcoming about the risks and issues around water contamination was making this issue of how to be open about what was known, and what was not known, as critical for staff as it was for the children, young people and families.

Role of Senior Management in Communication

151. While frontline staff were seen as important communicators, especially by the patients and families, it was not always appropriate for them to communicate on issues related to more corporate responsibilities, and where high-level decisions (such as de-canting or temporarily closing wards) were being taken. The perception of some families was that frontline staff were 'unfairly' put in the position of communicating 'difficult' messages.

152. Moreover, there was a strong feeling among some families that senior management in NHS GGC were not sufficiently and consistently visible in speaking/communicating with them at an early stage. While acknowledging that communication roles were rightly placed at different management levels within such a large Health Board, the nature of the incidents, particularly when such disruptive steps such as de-canting had to be taken, required a clear and unequivocal demonstration of senior leadership in communication. Its perceived absence was regarded as a key factor in undermining family confidence in NHS GGC to address these issues.

153. Senior management in NHS GGC did remain close to the development of the issues at different stages, but the importance placed on what was happening to the children, young people and families was not always communicated widely and effectively by those with Executive responsibilities. There was a gap between the perception of some families that senior Board management in NHS GGC were not closely involved with the emerging infection issues and the evidence that they were being regularly monitored by the Executive team within NHS GGC. This appeared to be an issue of visibility in many cases, and in retrospect, there were missed opportunities to highlight the priority with which this was being considered at senior levels within NHS GGC. As the issues became more prominent in the media, several families commented that more direct engagement with more senior staff within NHS GGC at an earlier stage would have helped to bolster confidence, and defuse much of the tension that has continued to play out publicly.

154. Senior leaders within NHS GGC did become directly involved, with letters to families from the Chief Executive being issued later in this period (including a letter of apology in early 2019) and opportunities extended for families to meet with them. In this context, the Oversight Board welcomes the identification of the Nursing Director as the key Executive for communication with families by the Health Board. It further suggests that more visible senior leadership in communication with the public and with the children, young people and families at an earlier stage should be systematically considered to inform future practice.

Support from External National Bodies

155. The Health Board admitted that the complexity of the communication challenges meant that it could have benefitted from greater external support and advice in how to handle patient, family and public expectations. That support was not perceived to be present for much of the period, and indeed, it is not clear that this kind of support is regularly provided and coordinated across NHS Scotland. As a result, there is national learning to be gained in the external support and positioning

around Board communication. The role and coordination of messaging by external bodies, particularly HPS and the Scottish Government, could also improve to ensure that these issues are not regarded as exclusively local.

156. In this respect, the difficulties faced by NHS GGC should not be regarded as exclusive to it, but potentially something that can be shared by other Health Boards facing similar situations and acting within the existing expectations and approaches to communication. Just as there are national bodies on hand to provide centralised specialist expertise to the Health Board in terms of the IPC challenges, similar national consideration should be given to having analogous expertise and advice on communication and engagement as well.

Remaining Work

157. As well as a general responsibility to inform patients, families and the wider public through the infection incidents, the Health Board is subject to a series of specific duties to investigate, inform and enter into dialogue when harm occurs in hospital settings. These duties are governed by a range of legislative, regulatory and guidance frameworks, but they all require compliance of Health Boards in the fulfilment of defined actions. They include:

- the organisational duty of candour: this is a legal duty which sets out how organisations (such as Health Boards) should tell those affected that an unintended or unexpected incident appears to have caused harm or death, and which requires the organisations to apologise and meaningfully involve those affected in a review of what happened – the Communication and Engagement Subgroup has undertaken work on this area, but that work will need to be linked into the wider assessment of reviews set out below;
- reviews of Significant Adverse Incidents: a national framework now exists to provide an overarching approach for best practice in how care providers effectively manage adverse events; and
- morbidity and mortality reviews: the reviews of patient deaths or care complications are designed to support organisations improve patient care and provide professional learning.

158. It is important that the Oversight Board can provide assurance that these obligations and commitments to good practice were met during these incidents. The Oversight Board is continuing to review these matters and will report its findings in the Final Report.

Case Note Review

Background to the Case Note Review

159. As part of the work of the Oversight Board, the Cabinet Secretary for Health and Sport set out plans for a Case Note Review in a Parliamentary statement on 28 January 2020. The Case Review team would review the case notes of paediatric haemato-oncology patients in the QEUH and RHC from 2015 to 2019 who had a gram-negative environmental pathogen bacteraemia (and selected other organisms) identified in laboratory tests.

160. The Case Note Review is currently reviewing the clinical records of all children and young people diagnosed with qualifying infections and who were cared for at the QEUH and RHC between 1 May 2015 and 31 December 2019. It is focusing on several key aspects: the number of patients (in particular, immuno-compromised children and young people) who may have been put at risk because of the environment in which they were cared; and how that infection may have influenced their health outcomes. Such work will be vital in determining the number and nature of the children and young people affected, providing assurance and identifying improvement actions, not just for NHS GGC, but more widely across NHS Scotland. It is also an important element in improving the communication and engagement with the affected children and young people and their families.

161. The Review will consider the balance of probability on the following set of specific questions:

- How many children in the specified patient population have been affected, details of when, which organism etc?
- Is it possible to associate these infections with the environment of the QEUH and RHC?
- Was there an impact on care and outcomes in relation to infection?
- What recommendations should be considered by NHS GGC – and, where appropriate, by NHS Scotland, more generally – to address the issues arising from these incidents to strengthen IPC in future?

162. There are two specific sets of outputs:

- reporting to the Oversight Board; and
- specific feedback to patients and families (including responses to questions raised by individual families).

Reporting to the Oversight Board

163. The independent Expert Panel will be responsible for providing a Final Report to the Oversight Board, which will include:

- a description of the approach and methodology to the Review;
- a description of the children and young people included in the Review;

- a description of the cases according to specified data types;
- analysis to answer the questions set out above; and
- observations on any prior NHS GGC internal reviews of individual episodes of care
- recommendations for NHS GGC and NHS Scotland, based on this analysis.

Individual case details will not be set out in the Report and the cases will be anonymised. This Report will be published.

Reporting to Patients and Families

164. The Expert Panel will provide individual private reports to patients and families that have requested details of the results of the reviews on the experiences of the individual children and young people.

Progress Update

165. As with the work of the Oversight Board, the Case Note Review's timescales have been affected by the impact of the pandemic – however, its work has progressed, albeit at a slower pace. The Expert Panel has agreed a classification of relevant infecting organisms, and the case notes of all children and young people defined as follows:

- those with a gram-negative environmental bacteraemia (bloodstream infection) – most patients fall into this group;
- other environment-related infections – there are a few other types of infection which may be associated with the environment (such as M. chelonae), but this includes only a small number of cases, some with bloodstream infection and some with similar infections found at other sites; and
- a smaller number of individual children and young people identified for inclusion for special reasons, where concerns have been raised that are related to the issues affecting the QEUH/RHC.

Currently, 85 children and young people have been identified, and whose clinical records will be reviewed (some have had more than one 'qualifying' infection episode).

166. The Expert Panel has estimated that it will complete its review of the instances of infection and be presenting its report in early 2021.

Interim Report Findings and Recommendations

167. The core of the Oversight Board's work has been the issue of assurance. Escalation has arisen from a history of complex issues since at least the opening of the QEUH, but the primary matter that gave rise to escalation to Stage 4 was a question of the 'fitness for purpose' of NHS GGC relating to: how IPC is conducted; the way that governance operates with respect to infections; and the communication and engagement approach to these events. Understanding the history of what has happened to the children, young people and the families in the paediatric haemato-oncology service and the clinicians that have supported them has been essential for the Oversight Board. Knowing this history is critical in ensuring that the right lessons have been learned and in further considering the current fitness of the structures and functions of NHS GGC within the Oversight Board's terms of reference.

168. Ultimately, the main question before the Oversight Board has been whether NHS GGC should be 'de-escalated' from Stage 4. As this is an Interim Report, the Final Report will provide a final assessment of all the issues that gave rise to escalation, the contributory factors, the learning and improvement evident to date from the Health Board – and ultimately, assurance on the issues on which NHS GGC were escalated. Notwithstanding that this remains work in progress, this Interim Report has already identified a number of areas where improvement needs to take place for that assurance to be robust. This forms the basis for the findings and recommendations set out in this chapter. The Final Report will set out the conclusions from the rest of the Oversight Board's work, taking account of the Case Note Review, and provide the full list of recommendations.

Findings

169. Findings are given for each of the different issues that led to the Health Board being escalated to Stage 4. Of the three areas for escalation, one – governance – is not examined in detail in the Interim Report. In addition, the work of the Technical Issues Subgroup has not been finalised for this report either, as noted above. Consequently, the findings (and recommendations) here focus on major elements of the two following areas: IPC; and communication and engagement.

Infection Prevention and Control: Processes, Systems and Approach to Improvement

170. Expectations around the scope and pursuit of IPC have changed over the last few years, reflecting, amongst other things, the impact of the Vale of Leven Inquiry. The Inquiry had a major impact on NHS GGC, of course, but it has changed the national context for ensuring that there are consistent, good-practice and evidenced approaches to effective, safe IPC. This has not been a single point of national transformation, but a continuing drive for improvement, one that will continue with the creation of a national centre of expertise for healthcare built environments. The constant evolution of a Scotland-wide agenda in IPC highlights both the challenges that the Health Board faced in addressing the infection incidents in the QEUH site – which presented complexities and unexpected issues that were far from recognised

experience in Scotland – as well as the opportunities for using NHS GGC's learning to support NHS Scotland as a whole.

171. What has become clear is the importance of all Health Boards to balance a commitment to these national standards and the codified processes that they set out, rooted in evidence-based good practice, with the flexibility and professional judgement to go beyond set processes where required. Practice has been captured in national guidance and standards with clearly-established reporting and monitoring regimes. Finding that balance has been essential to be able to respond to the new situations and developments in infection control, as indeed, the current pandemic is exemplifying to an alarming degree.

172. NHS GGC showed itself capable on repeated occasions of achieving that balance. Outside of these infection incidents, the recognition of the need to drive improvement was present in its work on CLABSI (and more widely, Methicillin-resistant Staphylococcus aureus (MRSA)). In the series of gram-negative infection outbreaks, the Health Board could respond innovatively and positively, with examples including specific responses to incidents (such as the establishment of the Technical Water Group in response to the 2018 'water incident', which will be discussed in more detail in the Final Report). That work is continuing through the recent reforms put in place in NHS GGC through a new 'Gold Command' structure and the formation of a dedicated programme of work to support improvement in IPC with joint executive leadership from the IPC Team, hospital operations, and Facilities and Estates.

173. However, these instances were not sufficiently consistent to provide assurance. An improvement-based learning approach – vital in addressing circumstances as novel and challenging as the environmentally-based infections in the QEUH – did not appear to be mainstreamed across the organisation. A structured use of quality improvement and good learning in one area did not seem to be systematically mainstreamed across the organisation. The IPC Team was seen as remaining too siloed and not fulfilling its role as the service that embeds improvement and mainstreams good IPC across the Health Board. Recognising recent progress, the Oversight Board welcomes the NHS GGC's creation of a new IPC work programme, and believes that one of its early priorities must be how improvement principles can be deepened in its work.

174. Through the work of the Peer Review, the Oversight Board highlighted a number of specific processes where improvement was required.

- Health Board compliance with the NIPCM was translated through a profusion of additional local guidance and interpretations of national standards, which ran the risk of promoting a 'GGC way of doing things' rather than nationally-endorsed standards.
- HAI-SCRIBEs were not pursued with full diligence and fidelity to process. Too often there seemed to be 'shortcuts' being taken in how HAI-SCRIBEs were put together that suggested a lack of understanding behind the good practice captured in the NIPCM.

- Audit and surveillance showed an inconsistent approach to improvement overall, with insufficient follow-through actions on audits and the absence of a pro-active approach to additional environmental alert organisms in surveillance.
- The scoring of HIIATs raised some concerns that the Health Board was not giving full (and in the Oversight Board's view, necessary) consideration to the wider context of infection at the QEUH site when rating infections. Elements of this issue have a national dimension, and the Oversight Board recognises the opportunity to improve practice across all Health Boards. But in the context of the environmental risks in the QEUH, the approach to HIIATs may indicate an underestimation of the wider infection risks facing the site.

175. The Interim Report has focused on how the IPC Team tackles different aspects of IPC. The Final Report will focus on how the Health Board handled the specific incidents, and what that reveals of the way IPC is conducted by the Health Board.

Communication and Engagement

176. It is hard to imagine a group of children, young people and families for whom the principles of person-centred communication would be more relevant in a healthcare setting. Within the paediatric haemato-oncology service, families were experiencing the sustained impact of the problems in the clinical environment on their children, including significant disruption and uncertainty. Given the nature of the patients, there were high-risk consequences of the issues remaining unresolved – communication and engagement through regular, sensitively-presented and clear information was vital.

177. The Health Board seems to understand this. It espouses person-centred principles in its overarching communication strategies. Indeed, throughout its work, the Oversight Board was presented with a lot of good evidence of a compassionate approach to communication within NHS GGC, especially by staff at the point of care. Families singled out the medical and nursing staff for their support, not least in how they kept themselves and their children as well informed as they could, a clear reflection of the person-centred approach to discussing individual care with patients and families. At this level, transparency and sensitivity seems to be regularly balanced in a way that patients and families regard positively – albeit sometimes limited and constrained by the problems with corporate and senior management communication referred to in this report.

178. However such an approach is inconsistently applied across the organisation. When it comes to communication that goes beyond ward level, too many patients and families feel that it has not been actioned, timely or fulsome, and that they are too often the last to know. This sense accumulated over several years, and it currently strains relationships between some families and the Board (and in a few cases, contributed to those relationships breaking down). Several families have felt that the Board has been too slow, if not reluctant, to provide them with answers to their questions, and have developed a deepening view of a Health Board that cannot admit to mistakes – or even, simply acknowledge uncertainty – about the environment of the building or the care of their children. Wherever the causes lie with

this, the results demonstrate a clear failure of the goals of communication for this group of children and young people and their families as a whole. Indeed, the appointment of Professor Craig White, in part a response to the gaps that had appeared between families and the Health Board, has been an acknowledgement of this.

179. From the Health Board's perspective, it is important to understand the challenges facing NHS GGC with communication.

- There was long-term uncertainty in how to explain the infection incidents, especially over the source of infections and the picture of environmental risk that started to appear.
- At some points over the period (notably in the aftermath of the Cryptococcus neoformans infections in early 2019), media coverage was experienced as a 'siege', heightening wariness of how public communication was managed. This created some logistical challenges in ensuring children, young people and their families were given correct information before any misleading or false news spread through the media.
- Those challenges were particularly acute in providing consistent and timely communication with patients and families no longer in regular contact with ward-based staff.

180. The Health Board mainstreamed a commitment to tailored and sensitive responses to individual patients and families through a database to reliably note individual family communication and information preferences. The creation of the closed Facebook page recognised that communication was not simply between individual patients and families with the Health Board, but amongst each other, as part of a community sharing the common experience of a child or young person in contact with the service and concerned by the impact of infection issues on their child's care experience and outcome.

181. The gradual unfolding of the scale of problems at the QEUH, with the emergence of hypotheses relating to the environment and building that could not be quickly verified or discounted, presented particular challenges in communication. The responsibility for decisions in respect of communication about incidents and outbreaks is typically lodged with IMTs, with communication advisors providing support for discussions to inform decisions by IMT chairs. While IMTs were active through this period in response to the infections, the IMT process itself – useful in more incident-based situations – was potentially less effective for a continuing 'crisis'. A new, or at the very least, enhanced process may need to be identified to address this with national support.

182. The recent legal action against the builders of the QEUH complex seems to be complicating the ability of the Health Board to be as open and responsive as patients and families need. There is a risk of the Health Board becoming increasingly reluctant to comment or discuss aspects of what has happened in relation to the infection incidents, citing the risks of compromising the forthcoming legal case. This has exacerbated a sense among several families that NHS GGC has not been pursuing a policy that gives primacy to transparency and sensitivity to the affected children, young people and families. While the Oversight Board appreciates the legal

issues facing NHS GGC and the force of legal advice, it considers that alternative approaches were and are possible and that the current continuing silence on many of these issues will not address fundamental concerns on communication and engagement that gave rise to escalation to Stage 4.

183. Lastly, there is a national dimension to this as well. Just as with other aspects of healthcare, there is a clear value in pooling experience and practice in NHS Scotland to address complicated communication challenges and developing national expertise. External bodies such as HPS and others did not have the expertise to providing NHS GGC with advice and support in this area. While the responsibilities may fall locally to NHS GGC, the implications are Scotland-wide, and deserve the same approach to improvement and learning found in other areas of healthcare.

Recommendations

184. The recommendations of the Oversight Board are rooted in the findings described above. As noted earlier, there are important lessons for NHS Scotland as a whole as well as specifically for NHS GGC – indeed, the unusual experiences of the Health Board could provide important lessons for Scotland. The Oversight Board has been well aware of the novelty of the challenges faced by the Health Board, the absence of national guidance in some areas and the importance of making an assessment that is not distorted by hindsight. They have been driven by the importance of ensuring that there is learning and change to address any similar set of challenges in future, whether within NHS GGC or across NHS Scotland more widely.

185. The recommendations are based on what needs to be done by NHS GGC and others to provide assurance and address escalation. In terms of the Key Success Indicators of the Oversight Board, they identify the changes that are required to satisfy the Oversight Board that these success indicators will be met and assurance restored, at least for the areas reviewed in the Interim Report. The recommendations are grouped according to each set of escalation issues: IPC; and communication and engagement. National recommendations are set out in the **green** boxes below.

<u>Infection Prevention and Control: Processes, Systems and Approach to Improvement</u>

186. The Interim Report recommendations cover the following key areas:

- the degree to which specific IPC processes in the QEUH have been aligned with national standards and good practice; and
- the extent to which the IPC Team has demonstrated a sustained commitment to improvement in infection management across NHS GGC.

Recommendation 1: With the support of ARHAI Scotland and Healthcare Improvement Scotland, NHS GGC should undertake a wide-ranging programme to benchmark key IPC processes. Particular attention should be given to the approach to IPC audits, surveillance and the use of Healthcare Infection Incident Assessment Tools (HIIATs).

187. With support from ARHAI Scotland and Healthcare Improvement Scotland, NHS GGC should undertake a comprehensive programme of work to address the shortcomings identified here. This should build on the existing Peer Review process, led from within its IPC Team but drawing on external expertise. It should also fit into the existing programme of work being taken forward as part of the Silver Command workstream in the Health Board. The scope and terms of reference should be agreed with the Scottish Government by March 2021.

188. This exercise should be undertaken as soon as feasible (acknowledging the pressure of other circumstances, not least the pandemic), and completed by the end of August 2021. The recommendations of that work should be jointly presented to the NHS GGC Board and the Scottish Government, and the former should authorise an action plan to implement any relevant recommendations.

189. This should include a review of audit programmes to ensure consistency in RAG rating and a stronger link to a continuing culture of improvement. This would help to confirm that there is an organisational approach to safe care auditing, in particular ensuring that it is not the sole responsibility of the IPC team. This should be done in the context of existing Quality Framework for improvement and planning as set out by HIS and involve the latter in a support role.

190. As seen above, the rating of HIIATs for the relevant infections in the QEUH raised concerns about consistency for the Oversight Board. A more in-depth and wide-ranging review needs to be undertaken by NHS GGC, looking at the local criteria and judgements applied to ratings for infection incidents related to the QEUH. Attention should focus on how known environmental risks in the hospital, especially with respect to potential water contamination, are explicitly factored into assessment.

Recommendation 2: With the support of ARHAI Scotland, NHS GGC should review its local translation of national guidance (especially the National Infection Prevention and Control Manual) and its set of Standard Operating Procedures to avoid any confusion about the clarity and primacy of national standards.

191. NHS GGC has not applied the NIPCM as fully and transparently as it could. Moreover, there was a view that not all guidance in the NIPCM was appropriate for NHS GGC. Consequently, NHS GGC should conduct a review of its guidance portal so that clinical staff are referred to the NIPCM and all relevant national guidance (as set out in DL 2019 (23)) more clearly as a single 'point of truth'. This should build on progress already made to feed into national structures, minimising the development of new local guidance. This exercise should set clear, consistent principles for the

development of local translations of national guidance, as well as the responsibility for developing, implementing and overseeing the relevant set of standards/guidance. This should be completed by end April 2021 and the results presented to the Scottish Government.

Recommendation 3: ARHAI Scotland should review the National Infection Prevention and Control Manual in light of the QEUH infection incidents.

192. Surveillance issues need to be addressed at national level as well. ARHAI Scotland should review the NIPCM to consolidate and prioritise content in relation to alert organism surveillance. In particular, Appendix 11 and the A-Z guidance list of organisms of the national manual should be enhanced as required so there is national consistency to any aide-memoires developed for clinical staff to use locally. The guidance could benefit from additional disease-specific evidence-based SOPs or aide-memoires for some novel pathogens to be produced nationally. This review should be taken forward in collaboration with the Scottish Government and completed by end August 2021.

Recommendation 4: With the support of Health Facilities Scotland, NHS GGC should undertake an internal review of current Healthcare Associated Infection Systems for Controlling Risk in the Build Environment (HAI-SCRIBE) practice to ensure conformity with relevant national guidance.

193. NHS GGC should undertake an internal review of current HAI-SCRIBE practice against SHFN 30 to check that HAI-SCRIBEs are being developed consistently across the whole of NHS GGC and in line with national guidance. This review should include: the level of engagement and input from the IPC Team to take account of level of risk, as well as the scale of the project; the level and nature of the required input from the IPC Team for projects which are deemed smaller; and the overall use of HAI-SCRIBE and the consistency of use across NHS GGC, including consistency training for those undertaking HAI-SCRIBE. The review should be undertaken in cooperation with HFS and the results presented to the Scottish Government by end August 2021.

Recommendation 5: Health Facilities Scotland should lead a programme of work to provide greater consistency and good practice across all Health Boards with respect to the use of HAI-SCRIBEs.

194. HFS should work with Health Boards across Scotland to develop a governance system for ensuring HAI-SCRIBEs are completed consistently across and within all Health Boards. This should entail the establishment of a national forum to enable better sharing of design issues and lessons learned, with plans and a timetable for the forum to be agreed with the Scottish Government by March 2021.

This should be supported by a review of the current HAI-SCRIBE guidance across all Health Boards, which should be led by HFS in cooperation with the Scottish Government and completed by end August 2021.

Recommendation 6: ARHAI Scotland should review the existing national surveillance programme with a view to ensuring there is a sustained programme of quality improvement training for IPC Teams in each Health Board, not least with respect to surveillance and environmental infection issues.

195. IPC teams across Scotland are involved in vast amount of data collection in terms of audit and surveillance. It is vital that this data is used to support both local and national quality improvement in terms of patient outcomes. The Oversight Board recommends that this should include:

- a national surveillance system for Scotland which would seamlessly follow each patient across each interface of health and care – this would ensure that IPC and HP teams have the ability to act timeously where there individuals who may pose a public health risk, such as those who are isolating multi-drug resistant organisms; and
- provision of training for IPC teams regarding quality improvement, utilising the data and intelligence from both audit and surveillance to ensure better outcomes for patients.

ARHAI Scotland, working with the Scottish Government, should set out plans for the required programme of work before the end of August 2021, potentially using the national forum referenced in Recommendation 5 above to develop and monitor the work going forward.

Recommendation 7: ARHAI Scotland should lead on work to develop clearer guidance and practice on how HIIAT assessments should be undertaken for the whole of NHS Scotland.

196. The review of HIIATs found that national improvement is needed. All Health Boards should be encouraged to report all infection-related incidents in an open and transparent manner. To support this nationally, by the end of August 2021:

- ARHAI Scotland should further develop the HIIAT assessment and reporting tools to allow service, ARHAI Scotland and the Scottish Government to visualise easily all incidents within a healthcare facility over time;
- ARHAI Scotland should coordinate a working group through the NIPCM steering group to consider the HIIAT assessment more generally, including a standardised scoring system to provide a more robust risk assessment of infection-related incidents within care systems;
- a programme of work to improve national guidance and good practice should be drawn up to ensure NHS Boards and other organisations IMT consider

previous incidents and any possible links when assessing all new infection-related incidents;

- a programme of work to develop education tools nationally to assist staff responsible for assessing and reporting infection-related incidents across NHS Scotland; and
- the Scottish Government should consider the communication and escalation process for all incidents, including a 'green' HIIAT.

Recommendation 8: A NHS GGC-wide improvement collaborative for IPC should be taken forward that prioritises addressing environmental infection risks an ensuring that IPC is less siloed across the Health Board.

197. The Oversight Board welcomes the development of a new improvement collaborative for IPC, and suggests that it takes forward early priorities that address the findings and recommendations set out here. As part of this, to ensure that IPC is more effectively mainstreamed across the different parts of the organisation, a cross-NHS GGC exercise should be undertaken to develop a plan for ensure IPC operates in a less siloed fashion across different service/functions in the Board. That exercise should consider the role of the IPC Team and the aspects of IPC that should be the responsibility of other parts of the organisation and other teams. It should undertake any necessary benchmarking with other Health Boards. The results of the work should be considered by the Board Infection Control Committee and the Clinical Care and Governance Committee. Monitoring arrangements for implementing the plan should be clearly set out as part of this.

198. The scope of the work should be agreed with the Scottish Government and the Health Board by end March 2021 and the work completed by end August 2021.

Communication and Engagement

199. Recommendations are set out below with respect to the overarching question: **is communication and engagement by NHS GGC adequate to address the needs of the children, young people and families with a continuing relationship with the Health Board in the context of the infection incidents?** Issues relating to how the Health Board formally reviewed these incidents and engaged with patients and families, particularly decisions not to activate the statutory organisational duty of candour procedure and the implementation of review processes such as Significant Adverse Event Reviews, will be considered in the Final Report.

Recommendation 9: NHS GGC should pursue more active and open transparency by reviewing how it has engaged with the children, young people and families affected by the incidents, in line with the person-centred principles of its communication strategies. That review should include close involvement of the patients and families themselves.

200. The particular problems of communicating information on HAI in the paediatric haemato-oncology service – when key information remains uncertain, or at best, nuanced – was acknowledged by the Oversight Board. It was challenging for NHS GGC to balance assurance in its approach to addressing the infection incidents when there was continuing, longer-term uncertainty on the sources of infection. Nevertheless, the focus should remain on transparency and this did not appear to be consistently applied by NHS GGC.

201. In that context, it is vital that there is clear and widespread consistency of messages and information shared in these situations. Similarly, it is critical that the Health Board undertakes a more transparent approach in its communication against any similar background of uncertainty, even if it leads to NHS GGC admitting its inability to answer key questions immediately. Expressing uncertainty should not be seen as detracting from providing reassurance. The Health Board should be more open about what is known and what can be said.

202. This should form the governing principles of a NHS GGC review of how it undertook communication with the affected children, young people and families of the infection incidents and what learning should be taken and mainstreamed. That review should closely involve the families themselves and be presented to the Scottish Government by end June 2021, not least as a source of national learning for other Health Boards. It should focus on the transparency and timeliness of how information was presented and communication experienced by patients and families.

Recommendation 10: NHS GGC should ensure that the recommendations and learning set out in this report should inform an updating of the Healthcare Associated Infection Communications Strategy and an accompanying work programme for the Health Board.

203. NHS GGC should review and renew its existing HAI Communication. A revised strategy – taking account of the learning set out in this report and the actions identified in the recommendations – could become the basis of an exemplar to other Boards, or a plan modelled on national strategic and IPC requirements. This should be completed by end August 2021.

204. Communication and engagement activities were being brigaded together under a 'Silver Command' strand in the new 'Gold Command' structure. As the 'Better Together' work strand develops, there should be a priority in developing a revised version of the strategy with an accompanying action plan and commitment to undertake the reviews set out in these Interim Report recommendations.

Recommendation 11: NHS GGC should make sure that there is a systematic, collaborative and consultative approach in place for taking forward communication and engagement with patients and families. Co-production should be pursued in learning from the experience of these infection incidents.

205. The experience of the communication regarding infections in the paediatric haemato-oncology service has highlighted the need for deploying a range of approaches. This should be routinely pursued through collaborative work with families with direct experience of how best to navigate the complexities of making contact when an organisational or public interest matter may require that. A partnership approach should be explicitly recognised by NHS GGC and actively pursued as part of the 'Silver Command' work programme and reflected in the HAI Communication Strategy referenced in the previous recommendation.

Recommendation 12: NHS GGC should embed the value of early, visible and decisive senior leadership in its communication and engagement efforts and, in so doing, more clearly demonstrate a leadership narrative that reflects this strategic intent.

206. Leadership in addressing the challenge of communication on these infections was clearly demonstrated in much of the response to the emerging issues by senior staff within the hospital. But more senior leadership within the Health Board was not always presented visibly or experienced positively by the children, young people, their families and the public as the situation unfolded in the public eye. The lack of consistency in the approach was a significant issue for some families.

207. NHS GGC should review its approach to ensuring the right tone and sensitivity in handling is pursued in future, especially for its corporate communication, and determine if guidance or training is required to embed the Health Board's learning in this context. There should be more systematic assurance by the Health Board that this is happening across the organisation. This should also ensure that the views and experiences of patients and families remain central to how excellence in healthcare is pursued. Regular reviews of patient experiences and the use of Care Opinion is good, but opportunities for a more targeted review of communication in key incidents by relevant patients and families should be considered. This should build on the recent work led by the Executive Nurse Director as presented to the Board's Clinical and Care Governance Committee. This could take the form of some form of regular monitoring/review on the quality and effectiveness of communication in IPC as part of the revised HAI strategy. The results of that review should be regularly presented to the Care and Clinical Governance Committee, and, where appropriate, the Board.

208. The Health Board should present a proposal for putting these measures in place to the Scottish Government by the end of March 2021 so that it can feed into the development of a revised HAI Strategy.

Recommendation 13: The experience of NHS GGC should inform how all of NHS Scotland can improve communication with patients and families 'outside' of hospitals in relation to infection incidents.

209. There was a challenge for NHS GGC in communicating when it was not person-to-person. That challenge should be explicitly recognised and addressed pro-actively by the Health Board in preparation for any similar future challenges by ensuring its communication infrastructure has a strategic emphasis that recognises and plans and delivers on these principles. This includes due recognition of the role of strategic intent, leadership, skills and culture.

210. That should include learning from and establishing as routine practice the establishment of specific communication channels for patients and families. The example of the 'closed' Facebook page has already been cited, and while it remains a 'work in progress', it has been a key element in restoring good communication with many of the families including a significant uptake in participation. There is an excellent opportunity for national learning, and it is recommended that NHS GGC pursues this through the NHS Scotland strategic communication group in the first half of 2021.

Recommendation 14: The experience of NHS GGC in systematically eliciting and acting on people's personal preferences, needs and wishes as part of the management of communication in these infection incidents should be shared more widely across NHS Scotland.

211. To ensure that people remain at the centre of communication and engagement efforts and that they are listened to, special attention should be placed on ways of capturing communication preferences. This is particularly critical in particular operational services such as paediatric haemato-oncology service. NHS GGC demonstrated useful learning in this context, particularly through the development, updating and use of its database of communication preferences for affected patients and families. There is an excellent opportunity for national learning, and it is recommended that NHS GGC pursues this through the NHS Scotland strategic communication group. It should share learning of the use of the shared database (both software and approach) as well as the mechanism they developed to have single list of all those across service elements receiving care.

Recommendation 15: NHS GGC should learn from other Health Boards' good practice in addressing the demand for speedier communication in a quickly-developing and social media context. The issue should be considered further across NHS Scotland as a point of national learning.

212. The impact of social media on amplifying speculation was presented by NHS GGC as a key challenge, often overwhelming messages, narrative, and the ability to reassure families and present clear information. The Health Board should consider how it can provide more adept and quicker confirmation of lines and messages in this context, guarding against any harmful lag in communication, and how best to make positive and effective use of social media in this context. There is good practice that can be learnt from other Boards around the use of social media in this context, particularly around the value of different types of social media in different contexts. This is an excellent opportunity for national learning, and should be pursued through the NHS Scotland strategic communication group in the first half of 2021.

Recommendation 16: NHS GGC should review and take action to ensure that staff can be open about what is happening and discuss patient safety events promptly, fully and compassionately.

213. Good communications with the staff is important to ensure that staff are well informed and can contribute to supporting the children, young people and their families. This only works if there is a good flow of information from the Board to the point of care, without internal organisational boundaries becoming barriers. Key factors to support this include active, transparent and consistent communication across different, relevant parts of the Health Board. This is also likely to involve empowering and supporting 'clinical voices' to lead, shape and deliver public-facing communication reflecting transparent, respectful and compassionate communication, including the improved use of clinical expertise and voices in corporate responses to media enquiries and briefings.

214. NHS GGC is invited to review its the experience of the communications on HAI in the paediatric haemato-oncology service, and where lessons learned can improve staff communication in future. Plans for taking this forward should be presented to the Scottish Government by end March 2021.

Recommendation 17: The Scottish Government, with Healthcare Improvement Scotland and ARHAI Scotland, should review the external support for communication to Health Boards facing similar intensive media events.

215. While communication and engagement in these circumstances can and should be the responsibility of individual Boards, there are points where there is a clear role of other key bodies in supporting messaging and the flow of information. That role was not clearly and consistently acted upon in these circumstances. Scottish Government, HIS and ARHAI Scotland should review how other bodies should support and engage with individual Boards in similar situations in future, through the NHS Scotland strategic communication group. The Scottish Government should ensure any plans for improvement are developed by end August 2021.

Annex A: Terms of Reference for the Oversight Board and its Subgroups

Oversight Board

Authority

The Oversight Board for the Queen Elizabeth University Hospital (QEUH) and the Royal Hospital for Children (RHC), NHS GGC (hereinafter, "the Oversight Board") is convened at the direction of the Scottish Government Director General for Health and Social Care and Chief Executive of NHS Scotland, further to his letter of 22 November 2019 to the Chairman and Chief Executive of NHS GGC. These terms of reference have been set by the Director General, further to consultation with the members of the Oversight Board.

Purpose and Role

The purpose of the Oversight Board is to support NHS GGC in determining what steps are necessary to ensure the delivery of and increase public confidence in safe, accessible, high-quality, person-centred care at the QEUH and RHC, and to advise the Director General that such steps have been taken. In particular, the Oversight Board will seek to:

- ensure appropriate governance is in place in relation to infection prevention, management and control;
- strengthen practice to mitigate avoidable harms, particularly with respect to infection prevention, management and control;
- improve how families with children and young people being cared for or monitored by the haemato-oncology service have received relevant information and been engaged with;
- confirm that relevant environments at the QEUH and RHC are and continue to be safe;
- oversee and consider recommendations for action further to the review of relevant cases, including cases of infection;
- provide oversight on connected issues that emerge;
- consider the lessons learned that could be shared across NHS Scotland; and
- provide advice to the Director-General of Health and Social Care in the Scottish Government and Chief Executive of NHS Scotland about potential de-escalation of the NHS GGC from Stage 4.

Background

In light of the on-going issues around the systems, processes and governance in relation to infection prevention, management and control at the QEUH and RHC and the associated communication and public engagement issues, the Director General for Health and Social Care and Chief Executive of NHS Scotland has concluded that

further action is necessary to support the Board to ensure appropriate governance is in place to increase public confidence in these matters and therefore that for this specific issue the Board will be escalated to Stage 4 of the Performance Framework. This stage is defined as 'significant risks to delivery, quality, financial performance or safety; senior level external transformational support required'.

Approach

The Oversight Board will agree a programme of work to pursue the objectives described above. In this, it will establish subgroups with necessary experts and other participants. The remit of the subgroups will be set by the chair of the Oversight Board, in consultation with Board members. The Board will receive reports and consider recommendations from the subgroups.

In line with the NHS Scotland escalation process, NHS GGC will work with the Oversight Board to construct required plans and to take responsibility for delivery. The NHS GGC Chief Executive as Accountable Officer continues to be responsible for matters of resource allocation connected to delivering actions agreed by the Oversight Board.

The Oversight Board will take a values-based approach in line with the Scottish Government's overarching National Performance Framework (NPF) and the values of NHS Scotland.

The NPF values inform the behaviours people in Scotland should see in everyday life, forming part of our commitment to improving individual and collective wellbeing, and will inform the behaviours of the Oversight Board individually and collectively:

- to treat all our people with kindness, dignity and compassion;
- to respect the rule of law; and
- to act in an open and transparent way.

The values of NHS Scotland are:

- care and compassion;
- dignity and respect;
- openness, honesty and responsibility; and
- quality and teamwork.

The Oversight Board Members will endeavour to adopt the NPF and NHS Scotland values in their delivery of their work and in their interaction with all stakeholders.

The OB's work will also be informed by engagement work undertaken with other stakeholder groups, in particular family members/patient representatives and also NHS GGC staff.

The Oversight Board is focused on improvement. Oversight Board members, and subgroup members, will ensure a lessons-learned approach underpins their work in order that learning is captured and shared locally and nationally.

Meetings

The Oversight Board will meet weekly for the first four weeks and thereafter meet fortnightly. Video-conferencing and tele-conferencing will be provided.

Full administrative support will be provided by officials from CNOD. The circulation list for meeting details/agendas/papers/action notes will comprise Oversight Board members, their PAs and relevant CNOD staff. The Chairman and Chief Executive of NHS Greater Glasgow and Clyde will also receive copies of the papers.

Objectives, Deliverables and Milestones

The objectives for the Oversight Board are to:

- improve the provision of responses, information and support to patients and families;
- if identified, support any improvements in the delivery of effective governance and assurance within the Directorates identified;
- provide specific support for infection prevention and control, if required;
- provide specific support for communication and engagement; and
- oversee progress on the refurbishment of Wards 2A/B and any related facilities and estates issues as they pertain to haemato-oncology services.

Matters that are not related to the issues that gave rise to escalation are assumed not to be in scope, unless Oversight Board work establishes a significant link to the issues set out above.

In order to meet these objectives, the Oversight Board will retrospectively assess issues around the systems, processes and governance in relation to infection prevention, management and control at the QEUH and RHC and the associated communication and public engagement; having identified these issues, produce a gap analysis and work with NHS GGC to seek assurance that they have already been resolved or that action is being taken to resolve them; compare systems, processes and governance with national standards, and make recommendations for improvement and how to share lessons learned across NHS Scotland. The issues will be assessed with regards to the information available at the particular point in time and relevant standards that were extant at that point in time. Consideration will also be given to any subsequent information or knowledge gained from further investigations and the lessons learned reported.

Governance

The Oversight Board will be chaired by the Chief Nursing Officer, Professor Fiona McQueen, and will report to the Director General for Health and Social Care.

Membership

Member	Job Title
Professor Fiona McQueen (Chair)	Chief Nursing Officer, Scottish Government
Keith Morris (Deputy Chair)	Medical Advisor, Chief Nursing Officer's Directorate (CNOD), Scottish Government
Professor Hazel Borland	Executive Director of Nursing, Midwifery and Allied Health Professionals and Healthcare Associated Infection Executive Lead, NHS Ayrshire and Arran
Professor Craig White	Divisional Clinical Lead, Healthcare Quality and Improvement Directorate, Scottish Government
Dr Andrew Murray	Medical Director, NHS Forth Valley and Co-chair of Managed Service Network for Children and Young People with Cancer
Professor John Cuddihy	Families representative
Lesley Shepherd	Professional Advisor, CNOD, Scottish Government
Alan Morrison	Health Finance Directorate, Scottish Government
Sandra Aitkenhead	CNOD, Scottish Government (secondee)
Greig Chalmers	Interim Deputy Director, CNOD, Scottish Government
Carole Campariol-Scott/ Jim Dryden/ Calum Henderson/ Phil Raines (Secretariat)	CNOD, Scottish Government

The Co-chair of Area Partnership Forum and the Chair of the Area Clinical Forum will be in attendance at the meetings. In addition to these members, other attendees may be present at meetings based on agenda items, as observers: senior executives and Board Members from NHS GGC including, Medical Director, Nurse Director, Director of Facilities and estates, Director of Communications, Board Chair and Chief Executive; and representatives from HPS, HFS, HIS, HEI and HSE.

Stakeholders

The Oversight Board recognises that a broad range of stakeholder groups have an interest in their work, and will seek to ensure their views are represented and considered. These stakeholders include:

- patients, service users and their families;
- the general public;
- the Scottish Parliament;
- the Scottish Government, particularly the Health and Social Care Management Board;
- the Board of NHS GGC and the senior leadership team of NHS GGC; and
- the staff of NHS GGC and Trade Unions.

Special focus will be given to patients of the haemato-oncology service and their families, as highlighted by their direct involvement in the Communication and Engagement Subgroup.

Infection Prevention and Control, and Governance Subgroup

Purpose and Role

The Infection Prevention and Control Governance (IPCG) Subgroup for the NHS GGC Scottish Government Oversight Board is a time-limited group which has been convened to work with NHS GGC to:

- determine whether appropriate Infection Prevention and Control Governance is in place across the organisation to increase public confidence; and
- make recommendations, if required and where appropriate, to strengthen current approaches to mitigate avoidable infection harms

The IPCG Subgroup directly reports to the Oversight Board, which is chaired by the Chief Nursing Officer, Professor Fiona McQueen. It has specific responsibilities for supporting the Oversight Board to ensure, where necessary and appropriate, improvements are made in the delivery of effective governance and provide assurance relating to infection prevention and control within and across NHS GGC.

Background

In light of the on-going issues around the systems, processes and governance in relation to infection prevention, management and control at the QEUH and RHC and the associated communication and public engagement issues, the Director General for Health and Social Care and Chief Executive of NHS Scotland has concluded that further action is necessary to support the Board to ensure appropriate governance is in place to increase public confidence in these matters and, therefore, that for this specific issue the Board was escalated to Stage 4 of the performance framework. This stage is defined as 'significant risks to delivery, quality, financial performance or safety; senior level external transformational support required.'

The IPCG Subgroup will focus on issues relating to infection prevention and control and associated governance that gave rise to escalation to Stage 4.

Approach

The IPCG Subgroup will take a values based approach in line with NPF and the values of NHS Scotland.

The NPF values inform the behaviours people in Scotland should see in everyday life, forming part of our commitment to improving individual and collective wellbeing, and will inform the behaviours of the Oversight Board individually and collectively:

- to treat all our people with kindness, dignity and compassion;
- to respect the rule of law; and

- to act in an open and transparent way.

The values of NHS Scotland are:

- care and compassion;
- dignity and respect;
- openness, honesty and responsibility; and
- quality and teamwork.

These values will be embedded in the work of the IPCG Subgroup and will be informed by engagement work undertaken with key stakeholder groups.

The Subgroup is focused on improvement and as such the Subgroup members will ensure an evidence based, risk based, lessons-learned approach underpins their work in order that assurance can be articulated and learning is captured and shared both locally and nationally.

Meetings

The Subgroup will meet frequently for the first four weeks, with frequency thereafter to be determined as required. Video-conferencing or tele-conferencing will be provided.

Full administrative support will be provided by officials from CNOD. The circulation list for meeting details/agendas/papers/action notes will comprise Subgroup members, their PAs and relevant CNOD staff.

Objectives

The objectives for the Subgroup are to:

- carry out a system wide review of current systems and processes relating to the infection prevention and control and associated governance scheme of delegation and escalation mechanisms against relevant national standards and guidance;
- determine if there are any gaps when mapped against national standards and guidance and, if so, identify areas for improvement and shared learning with respect to IPC risk management, audit, performance, compliance and assurance;
- provide support to the IPC Team within NHS GGC in the identification of measures for assurance as part of the review process and for future improvement/implementation; and
- make recommendations where appropriate to the Oversight Board on areas of learning for other Health Boards

In Scope

In order to meet these objectives, the Subgroup will retrospectively assess systems, processes and governance arrangements in relation to IPC management and control across the whole of NHS GGC. It will do so by reviewing:

- alignment of IPC and wider Board structures within the span of influence of NHS GGC; and
- a range of reports considered by the Board Corporate Governance Committees and the network of Operational Governance Groups and Committees including those reports presented to the associate Integrated Joint Boards.

Deliverables will be agreed in the early meetings of the Subgroup and with the Oversight Board.

Out of Scope

The Subgroup will not review:

- roles and responsibilities of individual staff members within NHS GGC; and
- aspects covered by either the Communication and Engagement or Technical Subgroups of the Oversight Board.

Governance

The Subgroup will be chaired by Diane Murray, and will report to the Chair of the Oversight Board.

Member	Job Title
Diane Murray (Chair)	Deputy Chief Nursing Officer, Scottish Government
Hazel Borland	Executive Director of Nursing, Midwifery and Allied Health Professionals and Healthcare Associated Infection Executive Lead, NHS Ayrshire and Arran
Professor Angela Wallace	Nurse Director, NHS Forth Valley
Professor Craig White	Divisional Clinical Lead, Healthcare Quality and Improvement Directorate, Scottish Government
Frances Lafferty	Infection Control Nurse, NHS Ayrshire and Arran
Martin Connor	Infection Control Doctor, NHS Dumfries and Galloway
Helen Buchanan	Executive Director of Nursing, Midwifery and Allied Health Professionals and Healthcare Associated Infection Executive Lead, NHS Fife
Christina Coulombe	Infection Control Manager, NHS Lanarkshire
Lisa Ritchie	Nurse Consultant, Health Protection Scotland, NHS National Services Scotland
Professor Marion Bain	Director for Infection Prevention and Control, NHS GGC (secondee)
Phil Raines	Chief Nursing Officer's Directorate (CNOD), Scottish Government

Sandra Aitkenhead	CNOD, Scottish Government (secondee)
Lesley Shepherd	Professional Nurse Advisor, CNOD, Scottish Government
Carole Campariol-Scott/ Jim Dryden/ Calum Henderson (Secretariat)	CNOD, Scottish Government

Associated Participant	Job Title
Sandra Devine	Infection Control Manager, NHS GGC
Pamela Joannidis	Infection Control Nurse, NHS GGC
Dr. A Leonard	Infection Control Doctor, NHS GGC
Dr. J Armstrong	Medical Director, NHS GGC
Elaine Vanhegan	NHS GGC Board Governance Lead

NHS GGC may have other officers in attendance dependant on the issue being discussed and agreed through the chair.

Technical Issues Subgroup

Authority

The Oversight Board for the QEUH and RHC, NHS GGC has been established at the direction of the Scottish Government Director General for Health and Social Care and Chief Executive of NHS Scotland, further to his letter of 22 November 2019 to the Chairman and Chief Executive of NHS GGC.

A technical subgroup of the Oversight Board has been established to provide technical review, advice and assurance on the relevant technical matters relating to the built environment of the hospitals.

Purpose and Objectives

The purpose of the Technical Subgroup is to support the work of the Oversight Board, with a particular focus on the technical workings of the hospitals and any related technical reviews or reports. In particular the Technical Subgroup will:

- confirm that relevant environments at the QEUH and the RHC are and continue to be safe;
- oversee progress on the refurbishment and reopening of Wards 2A/B at the RHC and any related facilities and estates issues as they pertain to haemato-oncology services, such as Ward 6A at the QEUH;
- ensure that there are appropriate action plans in place to address any technical issues highlighted by competent authorities such as the Health and Safety Executive, Health Protection Scotland or Health Facilities Scotland and that these action plans are being delivered and provide oversight on connected issues that emerge;

- consider the lessons learned that could be shared across NHS Scotland; and
- provide advice to Oversight Board about potential de-escalation of the NHS GGC Board from Stage 4, in relation to these issues.

Background

In light of the on-going issues around the systems, processes and governance in relation to infection prevention, management and control at the QEUH and RHC and the associated communication and public engagement issues, the Director General for Health and Social Care and Chief Executive of NHS Scotland has concluded that further action is necessary to support the Board to ensure appropriate governance is in place to increase public confidence in these matters and therefore that for this specific issue the Board will be escalated to Stage 4 of the Performance Framework. This stage is defined as 'significant risks to delivery, quality, financial performance or safety; senior level external transformational support required'.

Approach

The Oversight Board is required to establish subgroups with necessary experts and other participants; this subgroup will address the requirement to ensure that relevant environments at the QEUH and RHC are and continue to be safe. To ensure delivery of that overarching objective, the Technical Subgroup will agree a programme of work to ensure that it complies with the purpose and objectives of the group.

The Oversight Board, and its subgroups, is focused on improvement. Members of this subgroup, will ensure a lessons-learned approach underpins their work in order that learning is captured and shared locally and nationally.

Governance/Accountability

The Subgroup will be chaired by the Alan Morrison, Health Finance and Infrastructure, Scottish Government and will report direct to the Oversight Board.

Membership

Member	Job Title
Alan Morrison (Chair)	Health Finance Directorate, Scottish Government
Tom Steele	Director of Estates, NHS GGC
Gerry Cox	Deputy Director of Estates, NHS GGC
Ian Storrar	Principal Engineer, Health Facilities Scotland
Lisa Ritchie	Nurse Consultant, Health Protection Scotland, NHS National Services Scotland
Sandra Aitkenhead	Chief Nursing Officers Directorate (CNOD), Scottish Government (secondee)
Phil Raines	CNOD, Scottish Government
Calum Henderson (Secretariat)	CNOD, Scottish Government

Additional involvement will be requested as necessary.

Communication and Engagement Subgroup

Purpose and Role

The Communication and Engagement Subgroup is a time-limited group to offer advice and assurance working with the Scottish Government and NHS GGC on:

- effective communication and engagement with patients and families; and
- robust, consistent and reliable person-centred engagement and communication.

Background

In light of the on-going issues around the systems, processes and governance in relation to infection prevention, management and control at the QEUH and RHC and the associated communication and public engagement issues, the Director General for Health and Social Care and Chief Executive of NHS Scotland has concluded that further action is necessary to support the Board to ensure appropriate governance is in place to increase public confidence in these matters and therefore that for this specific issue the Board will be escalated to Stage 4 of the performance framework. This stage is defined as 'significant risks to delivery, quality, financial performance or safety; senior level external transformational support required.'

Approach

The Communication and Engagement Subgroup will take a values based approach in line with the NPF and the values of NHS Scotland. The NPF values inform the behaviours people in Scotland should see in everyday life, forming part of our commitment to improving individual and collective wellbeing, and will inform the work of the Subgroup individually and collectively:

- to treat all our people with kindness, dignity and compassion;
- to respect the rule of law; and
- to act in an open and transparent way.

The values of NHS Scotland are:

- care and compassion;
- dignity and respect;
- openness, honesty and responsibility; and
- quality and teamwork.

These values will be embedded in the work of the Communication and Engagement Subgroup, and this work will also be informed by engagement work undertaken with other stakeholder groups, in particular family members/patient representatives,

respecting the importance of specific values informed actions linked to personal context and experiences.

The Communication and Engagement Subgroup is focused on improvement. Subgroup members, will ensure a 'lessons learned' approach, as well as respecting the experience of families must underpin and inform the identification of improvements for dissemination both locally and nationally.

Meetings

The Communication and Engagement Subgroup will meet fortnightly initially and then at a frequency to be determined thereafter. Tele-conferencing will be provided. A range of communication and engagement mechanisms will be agreed to enable patients and families to feed into the work of the Communication and engagement Subgroup.

Full administrative support will be provided by officials from Scottish Government. The circulation list for meeting details/agendas/papers/action notes will comprise Oversight Board members, their PAs and relevant CNOD staff.

Outcomes

The Outcomes for the Communication and Engagement Subgroup are to:

- positively impact on patients and their families in relation to how complex infection control issues and all related matters are identified, managed and communicated;
- demonstrate a pro-active approach to engagement, communication and the provision of information; and
- identify what has worked well and where the provision of information, communication and engagement could have been and could be enhanced and improved.to ensure that the outputs from the group are disseminated to key stakeholders and any wider learning points or recommendations are shared nationally.

In order to achieve these outcomes, the Subgroup will retrospectively assess factors influencing the approach to communication and public engagement associated with the infection prevention and control issues and related matters at the QEUH and RHC.

Having identified these issues, the Subgroup will work with NHS GGC to seek assurance that they have already been resolved or that action is being taken to resolve them; compare systems, processes and governance with national standards, and make recommendations for improvement and good practice as well as lessons learned across NHS Scotland.

Deliverables

The Deliverables for the Communication and Engagement Subgroup are:

- a prioritised description of communication and information to be provided to families, with a focus on respect and transparency (with an initial focus on ensuring that all outstanding patient and family questions raised are answered);
- development of a strategic Communication and Engagement Plan with a person-centred approach as key. This should link to and be informed by consideration of existing person-centred care and engagement work within the Board, to ensure continued strong links between families and NHS GGC. Specific enhancements and improvement proposals should also be clearly identified and should consider how the proposals from parent representatives on an approach that identifies and supports the delivery of personalised actions through the 'PACT' proposal can inform further work;
- a description of findings following a review of materials, policies and procedures in respect of existing practices with regards to communication, engagement and decision-making arising from corporate and operational communication and engagement, linked to infection prevention and control and related issues. This will include consideration of organisational duty of candour, significant clinical incident reviews, supported access to medical records (including engagement, involvement and provision of information to families in relation to these processes); and
- a description of findings and recommendations to: (a) NHS GGC; (b) Health Protection Scotland; (c) NHS Scotland; and (d) Scottish Government on learning to support any required changes and improvements for communication and public engagement relating to the matters considered by the Subgroup.

Governance

The Communication and Engagement Subgroup will be chaired by Professor Craig White, and will report to the Oversight Board. The Oversight Board is chaired by the Chief Nursing Officer, Scottish Government and reports to the Cabinet Secretary for Health and Sport. Members and those present at Subgroup meetings should ensure that they circulate information about the work of the Subgroup to colleagues and networks with an interest, contribution and perspective that can inform the work to be undertaken. It has been agreed that this must include clinical/care staff in relevant operational services, as well as senior management/corporate staff in NHS GGC.

Membership

Member	Job Title
Professor Craig White (Chair)	Divisional Clinical Lead, Healthcare Quality and Improvement Directorate, Scottish Government
Lynsey Cleland	Director of Community Engagement, Healthcare Improvement Scotland
Andrew Moore	Head of Excellence in Care, Healthcare Improvement Scotland
Professor Angela Wallace	Nursing Director, NHS Forth Valley
Jane Duncan	Director of Communications, NHS Tayside
Professor John Cuddihy	Families representative
Alfie Rawson	Families representative (until March 2020)
Suzanne Hart	Communications, Scottish Government
Phil Raines	Chief Nursing Officer's Directorate (CNOD), Scottish Government
Calum Henderson (Secretariat)	CNOD, Scottish Government

In addition to these members, other attendees may be present at meetings based on agenda items, for example: Chair of Infection Prevention and Control and Governance subgroup; relevant Directors and senior staff from NHS GGC and communication staff from Scottish Government.

Stakeholders

The Subgroup recognise that a broad range of stakeholder groups have an interest in their work, and will seek to ensure their views are represented and considered. These stakeholders include:

- patients and their families;
- the general public;
- the Scottish Parliament;
- Scottish Government, particularly the Health and Social Care Management Board;
- the staff of NHS GGC, Trade Unions and professional bodies; and
- the senior leadership team of NHS GGC and the Board.

Annex B: Peer Review Terms of Reference

Purpose and Governance

The Infection Prevention and Control Governance (IPCG) Subgroup of the NHS GGC Scottish Government Oversight Board has examined an array of documentation from NHS GGC which outlines the form and function of governance regarding IPC. The purpose of the Peer Review is to understand how these systems are operationalised at all levels of the organisation.

The Peer Review group will report to the IPCG Subgroup which itself reports directly into the Oversight Board, Chaired by the Chief Nursing Officer, Professor Fiona McQueen.

Approach

The Peer Review will take a values-based approach in line with the National Performance Framework (NPF) and the values of NHS Scotland (NHS Scotland).

The focus of the Peer Review is to gain an understanding of how IPC systems and processes are embedded and also establish how the governance framework which supports these systems and processes is operationalised.

It is important to state that ensuring that IPC systems and processes are embedded and governed is not the sole responsibility of the IPC Team. It requires support and collaboration at all levels of the organisation; across specialties, teams and directorates both at Board and also at national level. Therefore, the Peer Review plans to liaise with many other disciplines where patient safety associated with IPC is key. This liaison will include directors and managers, facilities and estates, senior charge nurses as well as local IPC teams.

Objectives

The Peer Review objectives are to:

- review how the IPC governance framework provided and described by NHS GGC at the IPCG Subgroup is operationalised across the system; and
- determine how national policy has been implemented within NHS GGC; identifying areas where this has carried out in line with national requirements as well as areas where this could be improved.

Having reviewed the documentation provided by NHS GGC, the Peer Review has identified five areas of focus:

- implementation of HAI-SCRIBE;
- implementation of the National IPC Manual;

- audit and surveillance;
- outbreak and incident investigation (including escalation/de-escalation); and
- water safety.

In Scope

In order to meet these objectives, and with the support of NHS GGC Programme Management Office, the Peer Review team will retrospectively review the relevant (and perhaps supplementary) documentation with the objective of developing a question set. The Peer Review will also review how IPC intelligence and lessons learned are communicated and shared across disciplines, including within the IPC Team.

The Peer Review Team will then meet informally with various stakeholders as described above to gain a deeper understanding of how these systems and processes operate and how key information and lessons learned are communicated locally. This will allow the Team to develop a set of recommendations based on their expert knowledge and skills in the IPC Team and Facilities and Estates.

Out of Scope

As stated in the Terms of Reference for the IPCG Subgroup, the Peer Review Team will not undertake a review of the roles and responsibilities of individual staff members within NHS GGC. However, the Peer Review will review how IPC key information and lessons learned are shared across disciplines, including within the IPC Team.

Governance

The Peer Review Team will report to the IPCG Subgroup, which is chaired by Diane Murray.

Reporting

A report and recommendations will be developed by the Peer Review Team and submitted through the IPCG Subgroup to the Oversight Board.

Peer Review Team Members

Member	Job Title	Review Area
Frances Lafferty	Senior IPC Nurse, NHS Ayrshire and Arran	Implementation of HAI-SCRIBE
Lesley Shepherd	Professional Nurse Advisor, HCAI/AMR, Scottish Government	Audit Surveillance National IPC Manual

Annex C: Stages of Escalation in NHS Scotland Board Performance Escalation Framework

Stage	Description	Response
Stage 1	Steady state 'on-plan' and normal reporting	Surveillance through published statistics and scheduled engagement of ARs/MYRs
Stage 2	Some variation from plan; possible delivery risk if no action	Local Recovery Plan – advice and support tailored if necessary. Increased surveillance and monitoring Scottish Government. SG Directors aware.
Stage 3	Significant variation from plan; risks materialising; tailored support required	Formal Recovery Plan agreed with Scottish Government. Milestones and responsibilities clear. External expert support. Relevant SG Directors engaged with CEO and top team. The Chief Executive of NHS Scotland is aware.
Stage 4	Significant risks to delivery, quality, financial performance or safety; senior level external support required	Transformation team reporting to the Chief Executive of NHS Scotland.
Stage 5	Organisational structure/configuration unable to deliver effective care.	Ministerial powers of Intervention.

Annex D: Key Success Indicators of the Oversight Board

Outcome	Action	Example of evidence
Infection Prevention and Control and Governance		
There is appropriate governance for infection prevention and control (IPC) in place to provide assurance on the safe, effective and person-centred delivery of care and increase public confidence.	Carry out a system wide review of current IPC systems and processes and associated governance scheme of delegation and escalation mechanisms against relevant national standards and guidance.	• Confirmation of current/sustainable effective governance with respect to: HAIRT Reports; Care and Clinical Governance Committee and Audit and Risk Committee Reports; AOP and Corporate Objectives and Performance Reports; IPC Inspection and Escalation Reports; IPC Audit Reports and Action Plans; relevant Antimicrobial Management/ Infection Control/ Decontamination/ Water Safety/ Education and Training/ Surveillance/ Outbreak Preparedness and Management/ Audits/ Policy and Procedures/ Inspection and Action Plans/ IPC Escalation Reports/ SBARs/ Research and Development and Voluntary Action Plan Updates; and IPC Risks. • Active action plans to address recommendations/action on relevant HPS/ HEI/ Internal reports since 2015 with clear timelines, monitoring, action responsibility and appropriate oversight.
	Determine if there are any gaps when mapped against national standards and guidance and, if so, identify areas for improvement and shared learning with respect to IPC risk management, audit, performance, compliance and assurance.	• Report setting out gaps in national standards/guidance and provision of NHS GGC action plan to address issues and monitoring arrangements for action plan. • Report setting out wider learning with regards to IPC risk management, audit, performance, compliance and assurance for consideration by DG Health and Social Care, SG Ministers, and NHS Chairs and NHS Chief Executives fora (as part of wider Oversight Board reporting).

Outcome	Action	Example of evidence
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.	Conduct a detailed review of relevant individual instances of infection and identify actions on individual cases and systemic improvements.	• Clear methodology for identifying and undertaking review of all relevant cases, validated by external experts. • Identification of general issues relating to the IPC governance issues and provision of NHS GGC action plan to address issues and monitoring arrangements for action plan. • Identification of individual issues relating to specific cases and NHS GGC action plan to communicate and engage with relevant families/patients and monitoring arrangements for action plan.
	Ensure that the physical environment to the relevant wards in QEUH and RHC support the delivery of safe, effective and person-centred care with respect IPC, particularly in the delivery of any refurbishments/physical improvements.	• Action plan setting out identification of key issues in Ward 6A in QEUH and implementation of how they have been dealt with. • Assessment setting out completion of refurbishment works in Wards 2A/2B in RHC and how identified issues were addressed. • Confirmation of action plan and assessment above by HPS.
	Determine if there are any gaps when mapped against national standards and guidance and, if so, identify areas for improvement and shared learning with respect to operational delivery of IPC, including staffing/ resourcing, minimum skills and joint working between relevant units.	• Evidence of full implementation of mandatory national HCAI and AMR policy requirements as set out in DL (2019) 23. • NHS GGC action plan to identify staffing/ resourcing gaps in IPC operations with respect to putting in place policy requirements in DL (2019) 23, address the identified gaps with clear actions/ timetables and monitoring arrangements for delivery.

Outcome	Action	Example of evidence
Communication and Engagement		
Families and children and young people within the haemato-oncology service receive relevant information and are engaged with in a manner that reflects the values of NHS Scotland (NHSS) in full.	Prioritise communication and information provided to families and patients with a focus on respect and transparency (with an initial focus on ensuring that all outstanding patient and family questions raised are answered).	• Compilation of outstanding questions by families and publication of responses on NHS GGC website. • Published process for responding to questions in future as part of NHS GGC Communication strategy. • All additions/revisions/updates to questions previously answered have been made as soon as additional information has been received and/or reviewed.
Families and children and young people within the haemato-oncology service are treated with respect to their rights to information and participation in a culture reflecting the values of the NHSS in full.	Develop and implement a strategic NHS GGC Communication strategy with a person-centred approach, including a clear Executive Lead for implementing and monitoring.	• Publication of relevant NHS GGC Communication strategy with evidence of co-production with families. • Identification of Executive Lead to implement strategy with monitoring arrangements and measures of implementation and measures of effectiveness in place.
	Review key materials, policies and procedures in respect of existing practices with regards to communication, engagement and decision-making regarding consideration of the organisational duty of candour similar reviews (including engagement, involvement and provision of information to families in relation to these processes), and identification of any national learning/ lessons learnt.	• Report setting out gaps in compliance, opportunities for improvement, recommendations for action and provision of NHS GGC action plan to address issues and monitoring arrangements for action plan. • Identification of individual issues relating to specific cases and NHS GGC action plan to communicate and engage with relevant families/patients. • Reporting setting out wider learning with regards to organisational duty of candour and other review processes and management of IPC activities for consideration by DG Health and Social Care, SG Ministers, and NHS Chairs and NHS Chief Executives fora (as part of wider Oversight Board reporting). • Clear description of how communication, engagement, information provision and support dimensions of Oversight Board case reviews will integrate family involvement and engagement in accordance with best practice case reviews and individual family preferences.

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The Queen Elizabeth University Hospital/ NHS Greater Glasgow and Clyde Oversight Board

Final Report

March 2021
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Contents

Summary: Full List of Recommendations

This Final Report sets out the findings and recommendations of the NHS Greater Glasgow and Clyde (GGC) Oversight Board's programme of work in response to the infection issues affecting the Queen Elizabeth University Hospital (QEUH) and the Royal Hospital for Children between 2015 and 2019. It summarises the work on investigation, dialogue and improvement driven by the Oversight Board since its establishment in December 2019 through to March 2021.

The Oversight Board was established by the Director-General of Health and Social Care in the Scottish Government and Chief Executive of NHS Scotland in November 2019. This decision was taken in response to critical issues relating to the operation of infection prevention and control, governance, and communication and engagement with respect to the Queen Elizabeth University Hospital and the handling of infection incidents affecting children, young people and their families within the paediatric haemato-oncology service. The appointment of an Oversight Board was a direct consequence of the escalation of the Health Board to Stage 4 of NHS Scotland's national performance framework.

The Oversight Board consists of a group of experts and representatives drawn from other Health Boards, the Scottish Government and the affected families themselves. Chaired by Scotland's Chief Nursing Officer, Professor Fiona McQueen, the work of the Board was carried out principally through three Subgroups: Infection Prevention and Control and Governance; Technical Issues; and Communication and Engagement. Overall, the Oversight Board has focused on assurance of current systems and reviewing the historical issues that gave rise to escalation , essentially through a focus on a set of overarching questions:

- To what extent can the source of the infections be linked to the environment and what is the current environmental risk?
- Are infection prevention and control (IPC) functions 'fit for purpose' in NHS GGC, not least in light of any environmental risks?
- Is the governance and risk management structure in NHS GGC adequate to pick up and address infection risks?
- Has communication and engagement by NHS GGC been sufficient in addressing the needs of the children, young people and families with a continuing relationship with the Health Board in the context of the infection incidents?

In addition, an independent Case Note Review was commissioned to examine the individual incidents of infection among the children and young people. This review is being overseen by an Expert Panel that is reporting separately but at the same time as the Oversight Board. Its findings have informed this Final Report.

Infection Prevention and Control

The Interim Report[1] covered the following selected areas of Infection Prevention and Control (IPC):

- the degree to which specific IPC processes in the QEUH have been aligned with national standards and good practice; and
- the extent to which the IPC Team has demonstrated a sustained commitment to improvement in infection management across the Health Board.

These recommendations are set out in **blue** in the boxes below.

The Final Report makes further findings and recommendations for the remaining IPC issues, particularly: IPC governance; the responsiveness of the Health Board's IPC to the infection incidents; the effectiveness of joint working in support of IPC in the QEUH; and the strength and organisation of leadership in IPC.

Local Recommendations

Interim Report

- With the support of ARHAI Scotland and Healthcare Improvement Scotland, NHS GGC should undertake a wide-ranging benchmarking of key IPC processes through a more comprehensive Peer Review exercise. Particular attention should be given to the approach to IPC audits, surveillance and the use of Healthcare Infection Incident Assessment Tools (HIIATs).
- With the support of ARHAI Scotland, NHS GGC should review its local translation of national guidance (especially the National Infection Prevention and Control Manual) and its set of Standard Operating Procedures to avoid any confusion about the clarity and primacy of national standards.
- With the support of Health Facilities Scotland, NHS GGC should undertake a review of current Healthcare Associated Infection Systems for Controlling Risk in the Build Environment (HAI-SCRIBE) practice to ensure conformity with relevant national guidance.
- A NHS GGC-wide improvement collaborative for IPC should be taken forward that prioritises addressing environmental infection risks and ensuring that IPC is less siloed across the Health Board.

[1] https://www.gov.scot/publications/queen-elizabeth-university-hospital-nhs-greater-glasgow-clyde-oversight-board-interim-report/.

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- Strengthened arrangements for IPC, commensurate with the complexity and size of the Health Board, should be put in place in line with relevant national guidelines.
- The structure of IPC should reflect the continuing need to address the complex and continuing issues within the QEUH. IPC resourcing and skills should be reviewed, and active consideration given to whether there should be appointment of specific IPC roles with QEUH responsibility.
- NHS GGC should ensure that there is a full, effective and standardised approach to the relevant microbiological, water testing and other information regarding the QEUH outbreaks. Relevant data should be integrated in a way that allows effective collecting, recording and analysis of information relating to the incidents, which will be reported through the IPC governance system.
- Building on work already in place, there should be further visible and systematic planning for strengthening coordination between IPC and Facilities and Estates, particularly with respect to forward planning in addressing continuing infection risks with the QEUH and specifically in relation to water testing.

National Recommendations

Interim Report

- ARHAI Scotland should review the National Infection Prevention and Control Manual in light of the QEUH infection incidents.
- Health Facilities Scotland should lead a programme of work to provide greater consistency and good practice across all Health Boards with respect to the use of HAI-SCRIBE.
- ARHAI Scotland should review the existing national surveillance programme with a view to ensuring there is a sustained programme of quality improvement training for IPC Teams in each Health Board, not least with respect to surveillance and environmental infection issues.
- ARHAI Scotland should lead on work to develop clearer guidance and practice on how HIIAT assessments should be undertaken for the whole of NHS Scotland.

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- ARHAI Scotland should lead in developing and implementing a research programme to address any current gaps in the understanding of environmental infections and how hospitals can address them.
- There are a number of existing national recommendations that were made in the 2018 Health Protection Scotland report that have yet to be fully implemented. ARHAI Scotland should provide an update and timebound action plan for implementing these.
- IMTs in NHS GGC should be more rigorous in developing and making accessible key documentation to support records and analyses of a series of outbreaks over a prolonged period. This should be implemented by NHS GGC, with support from ARHAI Scotland who can identify best practice and make changes to national guidance if this is required.
- Where there are a number of successive infection incidents in the same or a related location, NHS GGC should work with ARHAI Scotland to pilot a process that goes beyond the current IMT focus on individual incidents on behalf of NHS Scotland.

Governance and Risk Management

To address one of its key questions – is the governance structure in NHS GGC adequate to pick up and address infection risks? – the Oversight Board considered how infection management and risk was addressed by NHS GGC. This included reviewing: the framework for governance around IPC; how that system was implemented over the period; and how the risks around these infection incidents were identified, assessed and managed.

Local Recommendations

Final Report

- The Health Board should finalise and implement its IPC Assurance and Accountability Framework.
- A review should be undertaken of how the environmental risk of significant water contamination within the QEUH is being assessed and managed in the Health Board's approach to risk management, and changes made to relevant risk registers and risk management planning as a result.
- The Health Board should set out a clearer, more targeted focus on the corporate risk process.
- The Health Board should review how concerns raised about environmental risks are communicated to senior Committees and the Board, and the procedures to ensure that such concerns are addressed. Moreover, it should also ensure the responses are communicated appropriately to those raising concerns.

National Recommendations

Final Report

- The experience of NHS GGC in addressing the unique challenges of the QEUH should be systematically used to shape NHS Assure as early as possible. This should be part of a comprehensive process of developing a template for a 'ward-through-Board' governance system that ensures risks of this nature are appropriately escalated and de-escalated.

Communication and Engagement

Recommendations are set out below with respect to the overarching question considered by the Oversight Board: has communication and engagement by NHS GGC been sufficient to address the needs of the children, young people and families with a continuing relationship with the Health Board in the context of the infection incidents? The recommendations from the Interim Report are presented in blue.

Local Recommendations

Interim Report

- NHS GGC should pursue more active and open transparency by reviewing how it has engaged with the children, young people and families affected by the incidents, in line with the person-centred principles of its communication strategies. That review should include close involvement of the patients and families themselves.
- NHS GGC should ensure that the recommendations and learning set out in this report should inform an updating of the Healthcare Associated Infection Communications Strategy and an accompanying work programme for the Health Board.
- NHS GGC should make sure that there is a systematic, collaborative and consultative approach in place for taking forward communication and engagement with patients and families. Co-production should be pursued in learning from the experience of these infection incidents.
- NHS GGC should embed the value of early, visible and decisive senior leadership in its communication and engagement efforts and, in so doing, more clearly demonstrate a leadership narrative that reflects this strategic intent.
- NHS GGC should review and take action to ensure that staff can be open about what is happening and discuss patient safety events promptly, fully and compassionately.

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- Given that organisational duty of candour was considered, but not formally activated, NHS GGC should review its approach to ensure that it is not simply focused on patient safety incidents and circumstances where causality is clear. There should be greater consideration of the duty where events could result in death or harm. There should also be improved guidance on how the Health Board will balance with other duties perceived as barriers to meeting the organisational duty of candour obligations.

National Recommendations

Interim Report

- The experience of NHS GGC should inform how all of NHS Scotland can improve communication with patients and families 'outside' hospitals in relation to infection incidents.
- The experience of NHS GGC in systematically eliciting and acting on people's personal preferences, needs and wishes as part of the management of communication in these infection incidents should be shared more widely across NHS Scotland.
- NHS GGC should learn from other Health Boards' good practice in addressing the demand for speedier communication in a quickly-developing and social media context. The issue should be considered further across NHS Scotland as a point of national learning.
- The Scottish Government, with Healthcare Improvement Scotland and ARHAI Scotland, should review the external support for communication to Health Boards facing similar intensive media events.

Final Report

- The findings of the Oversight Board in respect of the application of the organisational duty of candour in NHS GGC should be considered by the Scottish Government and Healthcare Improvement Scotland in order that further implementation support and guidance can be developed around the issues noted.

General Issues

Local Recommendations

Final Report

- The Health Board should expedite the refurbishment of Wards 2A and 2B in the RHC as safely and quickly as possible, and keep affected children, young people and families fully informed of the developments.
- A programme of testing and review should be put in place to assess any potential impacts of the chemical dosing water solution on infrastructure.

- The various action plans and reviews attached to these recommendations should be compiled into a single response to the Oversight Board, and implementation overseen by NHS GGC and the Scottish Government.

1. Introduction

1. The Oversight Board was established by the Director-General of Health and Social Care in the Scottish Government and Chief Executive of NHS Scotland in November 2019. Its aim has been 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 handling of infection incidents affecting children, young people and their families within the paediatric haemato-oncology service of NHS Greater Glasgow and Clyde (GGC). The Oversight Board was a direct consequence of the escalation of the Health Board to Stage 4 of NHS Scotland's National Performance Framework (as described more fully in the Interim Report).

2. The Oversight Board consists of a group of experts and representatives drawn from other Health Boards, the Scottish Government and the affected families themselves. Chaired by Scotland's Chief Nursing Officer, Professor Fiona McQueen, the work of the Board has been carried out through three Subgroups, each focusing on distinctive groups of issues.

- **Infection Prevention and Control and Governance**: this Subgroup has examined whether or not appropriate IPC and IPC governance was (and is currently) in place across NHS GGC in relation to these incidents and to recommend how to strengthen current approaches to mitigate avoidable infection harms. It was chaired initially by Irene Barkby MBE (Executive Director of Nursing, Midwifery and Allied Health Professionals in NHS Lanarkshire), and latterly by Scotland's Deputy Chief Nursing Officer, Diane Murray.
- **Technical Issues**: this Subgroup has 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. It has been chaired by Alan Morrison (Deputy Director for Health Infrastructure in the Scottish Government).
- **Communication and Engagement**: this Subgroup has considered 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. It has examined the organisational duty of candour and other key review processes, such as the Significant Adverse Events Review (SAER) policy. It has been chaired by Professor Craig White (Divisional Clinical Lead, Healthcare Quality and Improvement Directorate of the Scottish Government).

The Terms of Reference for the Oversight Board and its supporting Subgroups are set out in **Annex A**.

3. The following Final Report sets out the findings, conclusions and recommendations arising from Oversight Board's programme of work from its establishment in December 2019 through to March 2021. The Oversight Board was

supported by a number of special reports which were commissioned to examine specific issues relating to the Health Board, including:

- a timeline of infections and governance – this report set out a timeline of the incidents where a Gram-negative and other unusual bacteria (such as Mycobacterium Chelonae) were identified and which occurred in Wards 2A and 2B of the RHC and latterly in Wards 4B and 6A in the QEUH (the timeline is presented in **Annex F**);
- a review of NHS GGC's IPC governance, particularly with respect to escalation as part of outbreak management, by the IPC and Governance Subgroup;
- a review of NHS GGC water safety policy within the QEUH, undertaken through the Technical Issues Subgroup; and
- reviews of the Health Board's policy on Significant Adverse Events Reviews and Mortality/Morbidity Reviews, overseen by the Scottish Government's Directorate for Healthcare Quality and Improvement.

4. The work programme was also supported by a number of key individuals who worked alongside and within NHS GGC to support specific aspects of improvement:

- Professor Marion Bain (Deputy Chief Medical Officer, Scottish Government), who was appointed as the Executive Lead for Healthcare Associated Infection (HAI) within NHS GGC in December 2019 to set the strategic direction for IPC improvement (jointly reporting to the Chair of the Oversight Board as well as the Chief Executive for NHS GGC);
- Professor Angela Wallace (Nurse Director, NHS Forth Valley), who was appointed in February 2020 to work with and succeed Professor Bain as the Health Board's Interim Operational Director for IPC (also jointly reporting to the Chair of the Oversight Board as well as the Chief Executive for NHS GGC); and
- Professor Craig White, who was appointed by the Cabinet Secretary for Health and Sport in October 2019 to work with the families of the children and young people in the paediatric haemato-oncology service to address communication issues within NHS GGC.

5. Alongside the Oversight Board, the Cabinet Secretary for Health and Sport commissioned a **Case Note Review** in her statement to Parliament on 28 January 2020. Overseen by Professor Marion Bain and a panel of independent external experts led by Professor Mike Stevens (Emeritus Professor of Paediatric Oncology at the University of Bristol), the Case Note Review team has examined the individual case notes of those children and young people in the paediatric haemato-oncology service in the RHC and the QEUH from 2015 to 2019 who had a Gram-negative environmental pathogen bacteraemia (and selected other organisms, as identified in laboratory tests). Its terms of reference are presented in **Annex B** and it has contributed to the Oversight Board's final report. Its own final report is being published separately and alongside this Final Report.

6. The Oversight Board has already set out some of its findings and recommendations in its Interim Report, which was published in December 2020.[2] The Interim Report specifically set out findings and recommendations:

- for infection prevention and control, a review of key processes/systems and the approach to improvement of IPC in NHS GGC; and
- for communication and engagement, a review of the way in which the Health Board communicated and engaged with affected patients.

The Final Report does not repeat these findings. **Annex C** sets out what has been covered by the Interim Report, and what is covered in the Final Report, and the Interim Report recommendations are set out again in the Summary.

7. The Final Report presents findings and recommendations in the remaining areas that have been examined. Following this introduction, the report consists of several sections:

- **Background to the Oversight Board**: the context for the establishment of the Oversight Board and the infection issues within the QEUH and the way the Oversight Board took forward its work;
- **Infection prevention and control**: a review of the responsiveness, joint working between IPC and other key staff, and senior leadership of IPC within the QEUH, and how the Health Board has learned from the experience of the infection incidents;
- **Governance and risk management**: a review of the governance and management of risk with respect to these infection issues;
- **Technical review**: a review of the Health Board's current water safety policy in the QEUH and its approach to infrastructure maintenance given the infection issues faced by the hospital;
- **Communication and engagement**: a review of the Health Board's approach to the organisational duty of candour, its Significant Adverse Events Review policy and approach to Mortality/Morbidity Reviews;
- **Case Note Review**: a summary of the Case Note Review's independent Expert Panel's key findings as they relate to the Oversight Board's programme of work; and
- **Conclusions and the way forward**: the findings and recommendations of this Final Report, including an overarching assessment of NHS GGC's current escalation to Stage 4.

8. In addition, there are several annexes:

A. the terms of reference for the Oversight Board and its Subgroups;

B. the terms of reference for the Case Note Review;

C. a description of what is covered in the Interim and the Final Reports;

[2] Queen Elizabeth University Hospital/NHS Greater Glasgow and Clyde Oversight Board: interim report - gov.scot (www.gov.scot).

D. the Key Success Indicators identified by the Oversight Board;
E. the current structure of IPC governance and assurance in NHS GGC; and
F. a timeline of infection incidents in the QEUH between 2015 and 2019.

2. Background to the Oversight Board

2.1 Context for Escalation

9. On 22 November 2019, the decision was taken by Malcolm Wright, Director-General of Health and Social Care in the Scottish Government and Chief Executive to NHS Scotland, to escalate NHS GGC to Stage 4 of the NHS Scotland Board Performance Escalation Framework. An Oversight Board was established to focus on three broad areas:

- infection, prevention and control;
- governance; and
- communication and engagement.

10. Escalation of NHS GGC to Stage 4 was set within the procedure for NHS Board performance. The Escalation Framework lays out the triggers and actions when Health Boards are unable or hindered in taking forward their essential responsibilities. The Framework describes a scale of acuteness for taking action, and what steps are needed following a decision to escalation, depending on the 'stage' on the framework. Stage 5 is the most serious stage; Stage 4 is defined as "significant risks to delivery, quality, financial performance or safety, (and) senior level external transformational support (is) required." It is applied where the Scottish Government believes that a NHS Board requires enhancement to address local issues and additional direct management or transformation support may be required.

11. Escalation came against a background of a series of infection issues affecting children and young people in the paediatric haemato-oncology service at the QEUH and the RHC over a number of years, combined with rising concerns about the source(s) of those infections and how they were being handled.

- While cases were reported in 2016 and 2017, concerns significantly mounted between January and September 2018 when the number and diversity of type of infections substantially increased. According to Health Protection Scotland (HPS), there were at least 23 cases, involving 11 different organisms.
- From Spring 2018, there was a succession of outbreaks, including one in September in the RHC which led to the de-canting of patients into the QEUH and extensive (and continuing) refurbishment of Wards 2A and 2B. In 2019, there was a further major outbreak in Ward 6A in the QEUH, into where the children and young people had been moved after de-canting.
- The organisms associated with these outbreaks were unusual and often linked to environmental bacteria. In 2018, water testing results suggested that there was systemic water contamination in the QEUH, prompting the introduction of a site-wide chemical dosing solution later that year.

- Concerns had been raised about the fitness of the new hospitals by several clinicians and microbiologists with respect to environmental infections at various points over the period, dating back to the completion and handover of the building. Some QEUH/RHC clinicians and microbiologists did not feel that their concerns – particularly about water and ventilation safety – were being effectively addressed, and in some cases, formal whistleblowing procedures were triggered.
- Concerns were also raised by families of the patients involved about how the Health Board was communicating and engaging with them in light of their increasing anxieties about the safety of the hospitals. (These issues have been discussed in the Oversight Board's Interim Report.)
- It was not until summer 2018 that senior management were made aware of the existence of external reports highlighting the risks of water contamination as early as 2015, but which had not been acted upon at the time. These reports were discussed publicly for the first time in November 2019.

12. In February 2020, NHS GGC was escalated again to Stage 4 for a range of issues beyond the circumstances of the QEUH incidents, including wider performance management on waiting times, the Board's out-of-hours service and financial matters. Work on this has been overseen by a separate Performance Oversight Group, chaired by John Connaghan, then-Interim Chief Executive of NHS Scotland. Care has been taken throughout not to duplicate areas being covered more thoroughly by this group.

13. The purpose of the NHS GGC/QEUH Oversight Board has been to ensure NHS GGC takes the necessary actions to deliver and increase public confidence in safe, accessible, high-quality, person-centred care at the QEUH and RHC, and to advise the Chief Executive of NHS Scotland that such steps have been taken – or as set out in the Cabinet Secretary's statement, to "[restore] confidence that the places families take their children to be cared for are as safe as they possibly can be." In particular, the Oversight Board has sought to:

i. ensure appropriate governance is in place in relation to infection prevention, management and control;

ii. strengthen practice to mitigate avoidable harms, particularly with respect to infection prevention, management and control;

iii. build on and improve how families with children being cared for or monitored by the haemato-oncology service have received relevant information and been engaged with;

iv. confirm that relevant environments at the QEUH and RHC are and continue to be safe;

v. oversee and consider recommendations for action further to the review of relevant cases, including cases of infection;

vi. provide oversight on connected issues that emerge;

vii. consider the lessons learned that could be shared across NHS Scotland; and

viii. provide advice to the Chief Executive of NHS Scotland about potential de-escalation of the NHS GGC Board from Stage 4.

14. Throughout this work of robust scrutiny and challenge, the Oversight Board has been focused on improvement. While that requires an understanding of what has happened in the past and how processes operated at different points in the period since the opening of the QEUH and the RHC, this has been in the service of understanding what happened with these incidents to support patients and families and assessing the quality and efficacy of processes in place now. History has been important in reflecting the Health Board's own capacity for learning lessons, making any necessary improvements and tracking the implementation and adequacy over those changes going forward. The Oversight Board has consequently aimed to ensure that learning is captured, shared locally and nationally, and most importantly, acted upon. It has also sought to highlight the improvements that have already been put in place by the Health Board in advance of and throughout this process.

Context of Other Reviews

15. The Oversight Board has acted separately from the **Independent Review**. On 5 March 2019, Dr Andrew Fraser and Dr Brian Montgomery were appointed by the Cabinet Secretary for Health and Sport to lead an Independent Review with the aim of: "establish[ing] whether the design, build, commissioning and maintenance of the QEUH and the RHC has had an adverse impact on the risk of Healthcare Associated Infection and whether there is wider learning for NHS Scotland." The Independent Review's report was published on 15 June 2020. NHS GGC has welcomed the Independent Review, and the Scottish Government has committed to implement the relevant recommendations.[3]

16. A fuller accounting of these issues will be the responsibility of the **Hospitals Public Inquiry**. The Oversight Board has been careful not to duplicate its prospective work, but has necessarily covered similar territory in some instances in order to get to address the key issues of Stage 4. The Inquiry is chaired by the Right Honourable Lord Brodie QC PC and its terms of reference have been published.[4]

2.2 Priority Issues

17. The Oversight Board has focused on assurance of current systems. Consequently, for the key areas that it has examined – IPC, governance and communication and engagement – the Oversight Board set out what 'good should look like' through a set of key success indicators (described in **Annex D**). These principles have been applied in how the Board has considered its terms of reference, essentially through a set of overarching questions:

[3] Queen Elizabeth University Hospital Independent Review - report recommendations: Scottish Government response - gov.scot (www.gov.scot).
[4] Inquiry into the construction of the QEUH, Glasgow and the RHCYP/DCN, Edinburgh: terms of reference - gov.scot (www.gov.scot).

i. **To what extent can the source of the infections be linked to the environment and what is the current environmental risk?**

ii. **Are IPC functions 'fit for purpose' in NHS GGC, not least in light of any environmental risks?**

iii. **Is the governance and risk management structure in NHS GGC adequate to pick up and address infection risks?**

iv. **Has communication and engagement by NHS GGC been sufficient in addressing the needs of the children, young people and families with a continuing relationship with the Health Board in the context of the infection incidents?**

Major aspects of questions **iii** and **iv** were addressed in the Interim Report (as summarised in **Annex C**). The concluding chapter of the Final Report returns to these questions as a whole.

18. These issues have arisen in relation to a particular patient group within the QEUH, but the Oversight Board has widened its focus where wider implications have been important to acknowledge, whether for the whole Health Board or NHS Scotland.

19. The Oversight Board conducted its work through a review of key documents and direct inquiry with NHS GGC involving experts who took part in the Oversight Board and its Subgroups. Documentation included:

- the papers and material presented by NHS GGC to the Oversight Board's meetings, including minutes of the Health Board, relevant committees (such as the Board Infection Control Committee and the Clinical and Care Governance Committee) and Incident Management Teams (IMTs), action plans and special presentations;
- specially-commissioned topic-specific 'situation, background, assessment, recommendation' papers (SBARs) from NHS GGC as well as external experts and statements on specific issues, such as the use of anti-fungal prophylaxis, water testing policies and the approach to Significant Adverse Events Reviews;
- material provided previously to the Cabinet Secretary and the Health and Sport Committee of the Scottish Parliament by several NHS GGC clinicians and microbiologists; and
- key external documents, such as the Health Facilities Scotland (HFS) report, 'Water Management Issues Technical Review: NHS Greater Glasgow and Clyde – Queen Elizabeth University Hospital and Royal Hospital for Children' (finalised March 2019), and the HPS reports, 'Summary of Incident and Findings of the NHS Greater Glasgow and Clyde: Queen Elizabeth University Hospital/Royal Hospital for Children Water Contamination Incident and Recommendations for NHSScotland' (published February 2019) and 'Review of NHSGG&C Paediatric Haemato-oncology Data' (published November 2019).

20. There was no programme of comprehensive interviewing or evidence gathering from individuals and organisations, apart from what was undertaken as part of the commissioned work described above. However, specific clarifying discussions were held with representatives of the affected children, young people and families, some NHS GGC clinicians and microbiologists that had raised concerns about the Health Board and NHS GGC representatives throughout the Oversight Board's programme of work. The Oversight Board is grateful for the full support provided by all to this work.

3. Infection Prevention and Control

21. As noted in the Interim Report, the last few decades have witnessed an increased sensitivity to the risks associated with hospital-associated infections. The Vale of Leven Inquiry underlined the importance of rigorous processes, monitoring and escalation procedures in addressing the new challenges to IPC, and its recommendations[5] have underpinned the current systems across NHS Scotland, and the requirements set out in the National Infection Prevention and Control Manual[6].

22. New national guidance and expectations (especially through the National IPC Manual) form one part of the context to reviewing the approach to IPC in NHS GGC. The other is recognising the unprecedented challenges of the problems associated with the building of the QEUH: these have been rehearsed in the Independent Review's final report and are not repeated here. However, the shortcomings of the hospital environment formed a challenging set of difficulties for the Health Board as it experienced an unusual number and diversity of environment-related infections. While the National Manual now contains aide-mémoires[7] addressing water- and ventilation-associated infections, national advice and support on these unusual infections was not consistently available through this period.

23. The background of an increasing need for ever-more robust IPC procedures and the drive for improvement form an important backdrop for the Oversight Board's assessment of IPC within NHS GGC. In its terms of reference, the Oversight Board recognised that there would be key points of learning and a need for improvement for NHS Scotland as a whole. Consequently, while it can be difficult at points to separate out historical and current matters, the Oversight Board has concentrated on issues and incidents and considered this in relation to the current and future capability of IPC in the Health Board. The following chapter balances a review of how the Health Board reacted to the emerging infection challenges with an understanding of what it has learnt from those experiences and whether the current systems provide assurance that any future outbreaks would be managed in a satisfactory way.

24. The concept of assurance is at the heart of the Oversight Board's work. Specifically, the overarching question before the Oversight Board has been whether current IPC processes within NHS GGC have been 'fit for purpose', in terms of national standards and good practice. In this respect, the Oversight Board has measured the Health Board against the key success factor: "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" (as set out in **Annex D**). It has also emphasised assessment of whether NHS GGC has been able to recognise any shortcomings through the succession of incidents, taken

5 https://webarchive.nrscotland.gov.uk/20170401011220/http://www.valeoflevenhospitalinquiry.org/report.aspx.
6 National Infection Prevention and Control Manual: Home (scot.nhs.uk).
7 1_water-incidents-info-sheet-v1.0.pdf (windows.net) and 1_2019-10-16-ventilation-crib-card-v1.0.pdf (windows.net).

appropriate steps to address them (and indeed, acknowledge them to relevant parties, such as patients and families) and sought to prevent them being repeated. These are essential features of an organisation which has the ability to learn from its experience and find better ways to deliver care and support patients and families.

25. To answer the overarching questions for this work – particularly, **are IPC functions fit for purpose in NHS GGC, not least in light of any environmental risks?** – the Oversight Board set in motion a range of work. In particular, the Oversight Board has:

- commissioned a detailed description of the timeline of infection incidents between 2015 and 2019 and formal meetings to address the incidents, to present a narrative of how the outbreaks seemed to emerge and acted upon (as set out in **Annex F**);
- commissioned a system-wide peer review of current IPC systems and processes and associated governance scheme of delegation and escalation mechanisms against relevant national standards and guidance through the IPC and Governance Subgroup;
- commissioned bespoke SBARs on particular issues, such as the use of prophylaxis drugs and the current water safety policy;
- received reports from key individuals placed within the Health Board, as noted above, particularly Professors Bain, Wallace and White; and
- determined if there were any gaps when mapped against national standards and guidance and, if so, identify areas for improvement and shared learning with respect to IPC audit, performance, compliance and assurance, as well as operational delivery of IPC, including staffing/resourcing, minimum skills and joint working between relevant units.

26. Several IPC issues have already been reviewed in the Interim Report, specifically certain systems and processes (such as compliance with the National Manual and the use of Healthcare Infection Incident Assessment Tools) as well as the approach to improvement in IPC. The Final Report addresses the remaining key issues for IPC:

- **Responsiveness**: over the period, how did IPC functions identify relevant contamination issues and respond to the outbreaks, particularly with respect to identifying infections early enough, taking appropriate action and learning from each incident through understanding the potential sources;
- **Joint working in IPC**: as was described in the Interim Report, the systems and processes that enable effective IPC within a Health Board depend not just on the effectiveness of the IPC Team, but how that Team links with other key functions across the organisation – this section reviews how well cooperative working to support IPC was evident in the QEUH, particularly between key staff with a responsibility for undertaking IPC such as Facilities and Estates and microbiologists;
- **Leadership**: the effectiveness of the current structure of responsibilities for the IPC Team in NHS GGC, and whether those divisions of responsibilities are best suited in these circumstances; and

- **Learning from the Experience**: the programme of work that NHS GGC has put in place to start addressing the issues arising from escalation, led by the Board Chief Executive.

3.1 Responsiveness

27. The responsiveness of a Health Board to infection incidents is critical to assurance on IPC. A responsive approach to IPC would be characterised by: clear descriptions of processes and systems within the governance system; the ability to identify and respond quickly, appropriately and effectively to incidents; ensuring the right processes remain in place (and adapted as appropriate in an improvement culture over time); having the right individuals and services working together; knowing when to stand down support; and having a robust approach to any 'lessons learned' in reference to best practice and national standards.

28. How the Health Board should respond to infection outbreaks was provisionally set out in the Governance and Quality Assurance and Accountability Framework for Infection Prevention and Control Services developed by NHS GGC (as described in more detail in the Governance section, which will focus on how escalation and risk management has taken place). The document was developed by NHS GGC in response to a Healthcare Improvement Scotland (HIS) inspection in January 2019.[8] A requirement of this inspection (which was to be implemented immediately) was to improve governance in both estates and facilities and infection prevention and control teams to assure themselves of safe patient care in line with the Scottish Government's guidance Blueprint for Good Governance (2019). Plans for implementing this in NHS GGC have been progressing through the lifetime of this Oversight Board.

29. The document describes a process for the management of infection incidents/outbreaks, including the establishment of an IMT, reporting mechanisms to the Board Infection Control Committee and relevant Sector, Directorate and other Board Committees, including inclusion in the weekly Healthcare Infection Incident Assessment Tool (HIIAT) reports to HPS (formerly, but Antimicrobial Resistance and Healthcare Associated Infection (ARHAI) Scotland latterly). The Framework also aims to describe the formal delegation of authority and responsibilities within the Health Board.

30. To assess NHS GGC's responsiveness, several elements have been considered by the Oversight Board:

- its response to the 'phases' of incidents over the period, particularly in the context of whether appropriate action was taken at the earliest possible juncture;

[8] http://www.healthcareimprovementscotland.org/news_and_events/news/news_qeuh_mar_19.aspx.

- how precautionary (or prophylactic) antibiotic and anti-fungal treatment was prescribed to the patient group, apparently as part of the mitigation of potential infection risks, in response to the concerns that were raised by some families about the implications of their use and as part of an understanding of how the Health Board responded to the prolonged uncertainty regarding the infection incidents; and
- the learning derived from the incidents and the Health Board's responses.

Responding to the Incidents

31. Infection incidents in hospitals have regrettably been a regular occurrence across Scotland over the last few decades; indeed, internationally it is recognised as a key risk within the clinical setting. In seeking assurance that a Health Board is addressing incidents effectively and timeously, the issue is consequently about prevention as well as control. It is also important to consider whether a Health Board is acting in line with established good practice and national standards. In the case of the incidents at the QEUH, there are significant additional elements to consider.

- First, the number of Gram-negative and other environmental bacteria and the link to environmental risk presented challenges to the Health Board because of the diversity and rare occurrence of the organisms identified, and indeed, the absence of comprehensive national guidance on these matters at the key points in the timeline.
- Second, the succession of incidents over the period raised questions related to the environment of the building, as described in some detail in the Independent Review.

Consequently, it is important to recount the sequence of incidents (through the timeline of incidents found in **Annex F**).

32. Reviewing the period from 2016 to 2019, 2018 emerges as a critical point; before then, incidents of environmental-related infections seemed to be treated by the Health Board as isolated. In its report published in February 2019, HPS summarised the incidents in this 'earlier' period, but focused on incidents within specific locations in the QEUH: ie. "any child linked to wards 2A/B RHC with a blood stream infection caused by a gram negative bacillus that had been identified from organisms identified within the water system." A focus on infections in the specific RHC wards for paediatric haemato-oncology patients does not give a full picture of the number and diversity of Gram-negative environmental infections seen before 2018 in the QEUH (as the timeline in **Annex F** shows).

- In 2016, in both Ward 2A and the Paediatric Intensive Care Unit (PICU), there were four infection incidents, involving ten patients.
- In 2017, there were 14 incidents, involving at least 25 patients and what appears to be 26 organisms. Three patients who died had infections during the course of their treatment.

33. At this point, IMTs focused on actions that typically addressed the cleanliness of the immediate environment and possible transmission via individuals. For example, there was a succession of extensive environmental cleaning exercises (or

'deep cleans') of the affected locations, and in 2017, a review of the cleanliness of the environment in terms of compliance with national standards by the Lead Nurse for IPC, the Senior Charge Nurse and the Domestic Manager. Staff also acted quickly to determine what might be done to improve practice through work to reduce Central Line Associated Bloodstream Infections (CLABSI) rates. IMTs were diligent and focused in their responsiveness – for example, in response to an incident of infection cases in Ward 2A in the RHC that were given a 'Red' HIIAT, in June 2017, the following actions were taken:

- cleaning of rooms occupied by patients;
- typing of bacteria;
- review of the environment by the Lead Nurse for IPC, the Senior Charge Nurse and Domestic Manager, covering cleanliness of ward and equipment and compliance of staff with IPC processes;
- education work with families about infection control;
- review of line care;
- regular reporting, including the updating of the Healthcare Infection, Incident and Outbreak Reporting Template (HIIORT) (13 times between 26 July and 15 August);
- increasing water sampling in Ward 2A; and
- advice explicitly from HPS of any further action that could be taken.

34. The isolated nature of these incidents did not necessarily point to any wider links with the wider environment. For the Gram-negative and unusual environmental bacteria incidents in the Schiehallion Unit in 2017, a connection to a common source was not made as each bacteria had a unique strain. Water testing results were consistently proving negative: 151 water samples were tested between 7 March 2017 and 17 November 2017, and all were negative for Elizabethkingia, coliforms, Pseudomonas sp., Legionella and Stenotrophomonas maltophilia within the water system. Although water testing results cannot be definitive that there are not environmental issues, there was no clear evidence of a 'pattern'.

35. Nevertheless, concerns about the environment had been raised by some clinicians and microbiologists since before the handover of the hospital, some of whom were raising the possibility of water contamination. The Independent Review has already discussed the succession of problems associated with the building at handover and commissioning that were starting to appear through this period. A list of failures to meet buildings standards and environmental defects was recorded in a SBAR in October 2017 by a number of QEUH clinicians and microbiologists, which prompted action by senior management to address the problems.

36. There is evidence of a recognition of the unusualness of the number and diversity of infections. For example, in early March 2017, a Problem Assessment Group (PAG) was convened to discuss the seemingly high number of positive blood cultures in Ward 2A. This group agreed several actions including a retrospective look back at blood culture rates on the unit by the IPC Team, revealing a gradual upward trend over the six months prior. Links between problems with the building and some

infections were already being actively explored in IMTs. For example, in investigating suspected cases of Aspergillus in Ward 2A in 2016 (and again, in 2017 with another Aspergillus case), condensation resulting from the leaking of chilled beams as a source of infection was being considered as a potential source in the IMT (although the hypothesis was discounted after investigation).

37. For the Oversight Board, this raises the question of whether the potential risks associated with the building – especially water contamination – which were identified and acted upon in 2018 should have triggered action earlier by the Health Board. As already noted, action was being taken to explore environmental hypotheses through IMTs, although it is not clear if consideration of environmental risks was taking place in the relevant governance committees. For example, meetings of the Board Infection Control Committee (in November 2017), the Acute Infection Control Committee (also in November) and the Clinical and Care Governance Committee (December) highlighted several incidents of infection, but did not seem to discuss the number of infections as a whole or the reports of building issues.

38. Moreover, information about the individual incidents and the concerns about the building were not brought together in a way that might raise these questions. As will be explored further, this partly arose from the structure of reporting/escalation within the Health Board, and in particular, relationships (at the time) between IPC and Facilities and Estates staff. Of particular relevance here is a water risk assessment prepared by an external water specialist consultant (DMA Canyon Ltd) in April 2015, which drew attention to significant risks associated with Legionella arising from a large number of building defects, problems with the water system as well as high total viable counts (TVCs). The report was not shared with relevant IPC staff and microbiologists, nor indeed was it acted upon at the time (the issue is examined in more detail in the Governance section of this report). Consequently, while there was increasing evidence of environmental infection risks associated with the QEUH, the Health Board's mechanisms for identifying and transmitting relevant information to the right staff did not support staff considering in full any potential link between the infections and the emerging problems with the building.

39. The key period for infection issues was 2018, when a succession of incidents ultimately prompted more challenging questions to (and indeed, by) the Health Board in how to respond. This was the point where the evidence pointing to a more significant set of environmental risks proliferated. Throughout 2018, there was an increase in the number of infection incidents involving unusual organisms. As the February 2019 HPS report noted: "between the period of 29th January and 26th September 2018, 23 cases of blood stream infections (11 different organisms) with organisms potentially linked to water contamination were identified."

40. The cases occurred at different points across the year. After a series of infection cases in March 2018, IMTs were held until no new cases were reported and control measures were in place, at which point the IMT was closed (27 March). Following seven new cases of Gram-negative bacteraemia in Wards 2A and 2B in April and May, a further IMT was held, which was closed on 21 June, again when no further cases were reported. The IMT was reconvened in September when three new Gram-negative cases were identified in Ward 2A, and IMT meetings continued

to be held through to the end of November, a period that included the decisions to de-cant the affected wards and to put in place a chlorine dioxide dosing system.

41. Despite the 'stop-start' nature of these outbreaks, the actions in themselves in this period were timely, robust and focused, although there were issues regarding their monitoring and follow up (as discussed in the Case Note Review chapter). The full Incident Management Report in April noted the actions that were taken in the first infection outbreak. In terms of investigation, these included:

- "patient timelines;
- retrospective analysis of bacteraemias;
- ongoing analysis with HPS support looking at current cases, retrospective cases and national picture;
- review of epidemiology from Public Health Consultant; and
- sampling of water, taps, showers, drains."

A range of control measures were deployed as well, including:

- "dosing of system with Sanosil and Chlorine;
- patient showers taken out of use for immunocompromised patients across RHC/QEUH site;
- extra hand hygiene precautions put in place, additional alcohol gel step;
- bottled water for drinking;
- bottled water to brush teeth;
- sterile water for [bone-marrow transplant] BMT patients;
- portable sinks to provide warm water for washing children on 2A and for parents use during periods of dosing;
- point-of-use filters fitted to hand wash basins and showers in all high-risk wards. A small number of filters were fitted in all other inpatient areas so that immunocompromised patients could be cared for in any ward if necessary. Some other day wards/departments had filters fitted depending on patient group. Quality assurance checks carried out at time of fitting by estates staff; and
- ciproxin prophylaxis for high-risk patient groups."

In addition, longer-term control measures were also identified and taken forward:

- "dosing with chlorine dioxide or copper-silver ionisation;
- removal of mixer taps in high-risk areas and replacement with more simple taps; and
- regular maintenance of tap-flow straighteners in other areas; [and]
- use of filters long term in high-risk areas."

The April Incident Management Report noted that these measures appeared to have been successful with the cessation of new bacteria (at least at that stage).

42. The actions did not always result in the anticipated outcomes. There were several actions whose results did not fit analytical expectations, often in ways that were unprecedented, for example:

- the failure of 'shock doses' of silver hydrogen peroxide to bring about rapid reduction in bacteria, suggesting the issue was not simply a problem with outlets as originally hypothesised;
- the application of filters leading to new problems with the drains, as the filters reduced distance between the tap and drain, causing increased splashing and new opportunities for bacteria to develop; and
- extensive mould in the showers and bathrooms, a reflection that the gyprock was not as water resistant as had been stated in the original building plans.

43. Throughout this period, a variety of hypotheses were explored with regards to the source of infections.

- Discovery of Gram-negative organisms in tap outlets – alongside negative water testing results for the main water supply – originally favoured a hypothesis that the individual water outlets were the source of infection (potentially as a result of the design of the flow straighteners and their encouragement of the development of bio-film). On the back of this hypothesis, the IMT sanctioned appropriate action in the widespread replacement of taps and installation of point-of-use filters.
- By May 2018, as drain swabs revealed a range of Gram-negative organisms, the hypothesis that the interaction of the sinks and the new point-of-use filters (and the resulting 'splash' effect spreading bacteria around the sink areas) was the source was being actively explored – and as a result, metal waste pipes in Wards 2A and 2B were replaced with plastic ones, sink drains were removed and drains were decontaminated with hydrogen peroxide.

44. Increasingly, there was a recognition of potential contamination of the water system for the site. By the IMT meeting on 16 March 2018, water testing had expanded from Ward 2A where the original infections had been detected to include a number of other locations across the RHC and the QEUH. By 27 March, it was reported at the IMT that "RHC, therefore, has evidence of [a] widespread problem", and that "overall Gram-negative pathogens and fungal counts… have been found throughout the QEUH and RHC sites." In the April Incident Management Report, it was concluded that:

> "Water testing revealed contamination of water supply within RHC and QEUH… Hypothesis is that contamination took place during installation and has built up in the system creating thick biofilm."

The Incident Management Report further noted that the likelihood of a similar event occurring again was "high, in a new build hospital." This was reflected in the reports to relevant oversight groups, for example, the Board Infection Control Committee which heard on 28 March that "the issue is now widespread and they have positive results for RHC Hospital and in Ward 4B, QEUH," as well as that "it is unusual to have this level of bacteria in a hospital water supply."

45. The implications of this conclusion led to the introduction of longer-term and more comprehensive control measures. On 27 March 2018, when the IMT was stood down, a new **Technical Water Group** was announced, "consisting of IPC [Team], Facilities, HPS and HFS [which] will look into the remit of filter replacement, introduction of new taps, introduction of chlorine dioxide dosing to the water system and drain cleaning." The Technical Water Group brought together microbiologists, facilities and other key staff and gave direct advice to the IMT.

46. By June, the Group had concluded that a more comprehensive solution was required to address the environmental risks, and prepared its recommendations on the use of system-wide chemical dosing for the Board. Indeed, these longer-term measures became the focus for control and prevention going forward in the latter half of 2018, when it became clear that the key action to be taken by the Health Board to address the long-term safety of the water supply was chemical dosing.

47. The Technical Water Group was active and thorough in its planning for implementation of the system and in ensuring that water testing could provide verification of the expected results of water dosing. The planning led to the rapid installation of the system throughout the site by early 2019. Although it was expected to take a longer period for the full benefit of chemical dosing to be reflected in the incidence of infections, water testing results in the early months of 2019 seemed to suggest it was having some impact. Throughout the period, the Group was characterised by a clear focus, a sense of urgency and thought through the options and their execution, an example of how the Health Board was capable of an emphatic and effective approach to addressing the issues in the infection incidents. The Technical Water Group was an exemplary approach to recognising and acting upon the longer-term needs of infection control, and the model and experience merits national learning. The decision to introduce chemical dosing shows that the Health Board could take major decisions to support the health and safety of patients.

48. The Health Board was also active in 2018 in drawing in external advice. In March 2018, HPS and HFS were formally called in to review the range of incidents as a whole, triggered by the Scottish Government invoking the National Support Framework. Independently, NHS GGC sought out other Health Boards in Scotland as well as Public Health in England to see if there were any similar experiences of such incidents. Other hospitals, such as Great Ormond Street, were also visited to understand their practices in relation to water and ventilation systems. While such advice did not always provide NHS GGC with a decisive set of answers or solutions to its unique challenges, it demonstrated that the Health Board recognised the limits of its ability to understand and act on these incidents and the need to turn to appropriate expert advice from outside.

49. The role of external support is important to draw out. Although the Health Board had clear responsibilities for action here, it did so within a wider national framework of reporting and advice. Infections incidents were systematically reported to HPS (and latterly, ARHAI Scotland) throughout the period. As has been seen, HPS and HFS were invited to examine the issues from their perspectives. In March 2018, HPS had informed the Scottish Government of its findings of systemic water contamination, and later that month, the Chief Nursing Officer invoked the National

Support Framework (escalation process). From this point on, there was regular – and at times, intensive engagement – nationally on these issues. While the Health Board clearly led on these issues, for this period up until escalation to Stage 4 in November 2019, there was broad agreement on the nature and timing of the actions that the Health Board was putting forward and alternative courses of action were not being recommended from outside.

50. Nevertheless, the recurrence of infection suggested that all of these actions may not have been sufficient. Frustration was particularly expressed by clinicians. Early in 2018, exasperation was evident among some clinicians that concerns about the building and environment had been raised before, but not addressed (as noted in an October 2017 SBAR, described in detail later). On 6 March 2018, some felt that, while concerns had been reported "to the highest level in GGC and HPS over two years ago", they "felt dissatisfied that there had been any response from senior management or outwith GGC which offered reassurance to clinicians." At 8 June IMT, it was reported that "[clinicians were] saying they are not confident [the IPC Team] are in control of the environment as there have been numerous issues surrounding Ward 2A since its opening" (though they were met after the meeting and were reassured by the steps being taken by the IMT). This persisted into 2019 – for example, at an IMT in August, it was noted that:

> "[Clinicians] feel that it has been over a year since this has been highlighted and the problem still exists even after moving into Ward 6A, QEUH. Clinicians think the control measures are not working and it is still unclear what the underlying problem results in these Gram-negative bacteria."

As the infection incidents continued, it created an increasingly difficult environment for IPC action to be taken emphatically and in a way that would command widespread confidence.

51. Ultimately, in September 2018, the proliferation of cases and the need to work on the affected wards led to the decision to de-cant the patients of Wards 2A and 2B in the RHC to Wards 4A and 6B in the QEUH. The background and handling of this de-cant has been discussed in the Oversight Board's Interim Report, but the action is notable in the context of IPC for several reasons.

- First, it demonstrated the importance of patient safety that the Health Board continued to prioritise through these incidents – taking the decision to de-cant would have been a difficult one, and its implementation required significant planning and communication with the children, young people and families.
- Second, such a major step could be seen as an admission that other IPC measures were not working sufficiently to address the issues, and that the last recourse for the Health Board was to remove the patients from the immediate environment. This was envisaged as a short-term move but has since become a prolonged removal because of the succession of building problems uncovered in Wards 2A and 2B. This has had the risk of strengthening the perception that the Health Board is unable to address the infection problems.

52. In 2019, a number of cases arose that re-ignited environmental concerns about the QEUH. What was particularly striking about these cases was their appearance in new locations of the building (though with the same immuno-

compromised patient group), including Ward 6A in the QEUH and the PICU. These included:

- One paediatric case of Cryptococcus neoformans in January (as well as one adult case). Potential links to the environment were debated by the microbiologists, although the Independent Review and an internal Health Board report concluded that this hypothesis was highly unlikely. (As the Independent Review covered this issue, the Oversight Board did not review this in detail.)
- A series of infections in Ward 6A that started in June 2019, including incidents of Enterobacter cloacae, Mycobacteria chelonae, Chryseomonas, Stenotrophomonas spp. and Elizabethkinga miricola, with a particular spike between August and November.

53. By 2019, when the new incidents were appearing in Ward 6A , a range of alternative hypotheses were being explored as to the source of infection. Water testing results suggested that the chemical dosing was working, but environmental explanations were still being sought (and as has been seen, water testing results could be limited as a predictor of infection – the negative results in 2017 were followed by the extensive evidence of contamination in the 2018 outbreaks). For example, it was hypothesised that the leaking of chilled beams was giving rise to the growth of the bacteria, though ultimately this was concluded not to be a source. In August, the IMT was reporting:

> "The hypothesis of Gram-negative environment bacteraemia is still unexplained. It is the nature of the Gram-negative environment organisms being found and not the number which is convincing. The group are happy with the water coming out of the taps. The only other source is the chilled beam."

However, by the end of the year, following further analysis, that hypothesis was no longer being actively explored. Throughout the 2019 set of incidents, IMT action seemed to concentrate on local explanations – such as the chilled beams and the 'smart hubs' located in the wards – and there was limited discussion of the implications of a potentially wider-ranging contamination of the water system.

54. The infections in Ward 6A led to the establishment of an IMT in June 2019, which largely continued through until November. The number and diversity of cases prompted significant discussions within the IMT on the source of the infections (which is considered in the following section), but it is important to note the range of actions taken in response, including:

- restricting admissions into Ward 6A from 2 August onwards, with new patients being diverted to other Health Boards;
- consideration of alternative accommodation;
- a dedicated action plan by Facilities and Estates to address the issue of chilled beams in Ward 6A;
- a Standard Operating Procedure (SOP) developed for obtaining regular water, environmental and chilled beams samples; and
- prescription of precautionary prophylaxis.

There was also a review of the triggers for IMTs and actions to be taken, which was agreed in November and included:

- Root Cause Analyses to be done on all cases going forward (a significant change in practice that it is surprising had not been more explicitly and widely considered earlier, given the succession of incidents);
- a procedure for PAGs to be set up where two Gram-negative bacteria cases are reported within 30 days, or the upper warning limits of Statistical Process Charts are met; and
- if an immediate source is not identified, external advice to be sought early on a more systematic basis.

However, when the IMT was formally closed that year, and the November 2019 HPS report echoed its February 2019 report on the lack of evidence of a single source of infections, efforts to further understand the sources of infection in the context of potentially widespread water contamination continued to be challenging.

55. Several points are striking about what took place in 2019. The context was a set of infection incidents showing a similar scale and diversity of environmental-related bacteria to what had occurred to the same patient group before the de-cant in the RHC. Sources of the infections were proving very difficult to identify, frustrating to both the clinicians working with the patient group (as already highlighted) and the microbiologists seeking to understand what was happening. The continuing uncertainty – and increasing media focus on what was happening – created a highly pressured climate for staff grappling with an elusive, complex problem. Despite this, the IMT was responsive to the immediate infection issues, not simply in terms of actions to address the environment of Ward 6A, but identification of alternative accommodation as well.

56. However, despite the consistent commitment of staff to determining the sources and providing the best care to the patients, what was notable about the IMTs during this period – and the staff working together on IPC and the consequences of the outbreaks – was an increasing lack of cohesion and disintegrating working relationships between some staff, which seemed to spill out over into the conduct of the IMT meetings. The lack of unity has been discussed at length in the Independent Review's report and will not be rehearsed here, but it presented an important backdrop to the actions being taken.

57. What remained – and could not be discounted – was the persistent possibility of a link to the building. While actions in response to individual incidents appeared robust and appropriate, there continued to be a lack of an explanation for the source of these infections. This is not unusual for infection incidents, and the Health Board cannot be faulted for the efforts put in place to try to understand what was happening. However, by 2019, it was becoming clear that the question of whether the infections should be more systematically considered as a whole rather than individually should have been pressing. This was the view taken by the Scottish Government in 2019 when it asked the Health Board to examine a number of incidents in the PICU together rather than separately; and indeed, the Health Board is currently pioneering new methodologies to consider how such a 'long view' can be developed for the benefit of NHS Scotland. In that context, what is equally important

to the responsiveness of individual IMTs was how the Health Board as a whole was using risk management and escalation to address these environmental risks against this background of significant uncertainty; this is reviewed in the chapter on Governance.

Use of Precautionary Prophylaxis

58. The use of precautionary prophylaxis treatment has been a complementary approach to the IPC measures introduced to address the specific environment of infection locations and embedding good hygiene measures among staff. Their use has provided an additional protection to the children and young people against potential infections. However, there have been questions raised by some of the families about the approach to such prescription, not least around its prolonged and what appeared to be at times blanket use for the group of affected children and young people as a whole (as noted by the Cabinet Secretary in Parliament in December 2019[9]). Additional medication for such a vulnerable patient group needs to be considered carefully on a case-by-case basis, and communicated in a way that is clear and open about the rationale for its provision and which complements existing messages about the safety of the environment. Reviewing the approach has been an important aspect of the Oversight Board's work.

59. Prophylaxis treatment has been provided throughout the period of heightened awareness of infection risks. In October 2017, control measures included clinical teams risk assessing Ward 2A patients on a case-by-case basis on the prescription of anti-fungal prophylaxis. In response to infection incidents in March 2018, children and young people received Ciprofloxacin prophylaxis, while high-risk patients were provided with anti-fungal prophylaxis in January 2019 in the wake of the Cryptococcus cases. Its significant use was increasingly subject to clinician review towards the end of 2019. For example, in October, it was decided that patients in daycare should not be receiving it, a reflection of issues that were becoming more apparent in the widespread approach to their use.

60. The Oversight Board asked one of its members – Dr Andrew Murray, Medical Director of NHS Forth Valley and the co-chair of the Managed Clinical Network for Children's Cancer Services Scotland – to meet with a multi-disciplinary team of senior RHC clinicians for a clinician-led review of the use of these medicines in December 2019. The frontline team confirmed to Dr Murray that the use of antibiotic prophylaxis was being tailored to the needs of each individual patient and that families would be fully informed on their use and why. The haemato-oncologists confirmed that they had been reassured by Infectious Diseases and Infection Control specialists in the Health Board that ciprofloxacin was no longer required as a precaution for every patient with a central venous catheter.

61. Implementing this change in practice immediately was challenging given the heterogeneity of the patients in terms of the stage of their illness and other clinical features, but the approach was clearly set out. Similarly, anti-fungal prescribing was based on clear criteria and required to be continued when clinicians determined that

[9] Official Report - Parliamentary Business : Scottish Parliament.

patients met those criteria. The guidelines for anti-fungal prescribing are being reviewed to ensure alignment with latest evidence.

62. Following the meeting, Dr Murray recommended that the haemato-oncology clinicians should meet regularly with Infectious Diseases and IPC colleagues to ensure that the prescribing of antibiotics and anti-fungals remained case-by-case, clinically appropriate and in keeping with agreed guidance, and to review any adverse events through their prescribing, either in their regular weekly departmental meetings or separate governance group. It was also agreed that families and patients should be informed:

- any prescribing of antibiotics such as ciprofloxacin would be because the consultant had risk-assessed that patient on an individual basis;
- there would be no policy to prescribe all patients precautionary antibiotics because of environmental safety concerns;
- anti-fungals would be prescribed for patients according to a new protocol to be introduced, irrespective of location or current concerns; and
- all prescribing would be reviewed as appropriate by an oversight group with all consultants, meeting regularly – the Oversight Board suggests that the Clinical and Care Governance Committee undertakes a short review to ensure that these actions have been taken and to designate an appropriate means by which it can continue to assure themselves that these processes are being fulfilled.

Summary

63. In summarising the responsiveness of IPC within the Health Board, the Oversight Board concludes that once outbreaks were identified, the actions were swift and effective. Throughout the period, there was significant evidence that IMTs were characterised by commitment and pace in responding to individual incidents, notable for the determination of staff to put in place remedial actions to support patients and identify the sources of the infections.

64. That responsiveness also extends to more significant actions, particularly in 2018. The establishment of the Technical Water Group showed the Health Board capable of taking innovative and bold steps, carrying through to the difficult and resource-intensive decisions to introduce a site-wide chemical dosing system and to de-cant patients from Wards 2A and 2B, ultimately allowing extensive work to be carried out to address the environmental issues discovered there.

65. As the infection issues continued, the involvement of national bodies – and the Scottish Government – became more prominent. The Health Board showed itself open to external advice and reported the incidents and the actions being taken to others. While the responsibility for action remained with the Health Board, those actions were not being challenged by others.

66. However, the Oversight Board concludes that the Health Board's responsiveness was limited by problems in how different sources of information were being brought together to examine an ever more complex problem. The failure to

share the DMA Canyon reports compromised the ability of IMTs and the IPC Team to act because key information was not available. The concerns raised by some staff before the October 2017 SBAR did not lead to full consideration of the emerging problems with the building in the appropriate committees. Staffing tensions and problems in working relationships seemed to make it difficult for relevant information to come together and consensus decisions on action to be taken consistently.

67. This seemed to limit more active exploration of the implications of environmental risk and the ability to see potential links between the infection incidents. This issue will be returned to in the last section of this chapter, and the chapter on Governance.

3.2 Joint Working in Infection Prevention and Control

68. IPC is not a standalone function, and the IPC Team does not operate in isolation. As set out in NHS Health Department Letter (HDL) 2005(8)[10], the Chief Executive has overall responsibility for ensuring that IPC is integrated with clinical governance and patient safety. Clear good practice about the importance of joint working is embedded in national standards, and seen in IPC when operated at its best in NHS GGC. For example, the Technical Water Group showed the importance of bringing together Facilities and Estates staff, technical experts, microbiologists and those leading IPC. That cooperative approach is essential for early detection of any problems and robust prevention measures, and was an important theme in both the recommendations of the Vale of Leven Inquiry and the key guidance letter, DL (2019) 23[11], issued by the Chief Nursing Officer on mandatory Healthcare Associated Infection and Anti-microbial Resistance policy requirements for all NHS Scotland healthcare settings.

69. In carrying out its functions, the IPC Team, in particular, needs to establish close links with other functions within the Health Board. For example, one of the IPC Team responsibilities is to "participate in the planning and upgrading of hospital facilities", as set out in the Health Board's Governance and Quality Assurance Framework for IPC Services (as reviewed in more detail in the Governance chapter), and that requires a close set of relationships with Facilities and Estates. As the infection incidents arose, particularly from 2018 on, and the issue of a potential environmental source of the infections was increasingly in the spotlight, the strength and effectiveness of those links came under closer inspection.

70. Aspects of those relationships have been assessed elsewhere. They have already been discussed in connection with the design, construction and handover of the hospital in the Independent Review. The Independent Review concluded that: "[the] quality of infection control advice relating to vital systems and standards, specifically with respect to both the water and air ventilation systems, was not sufficient to underline the importance of quality design and high standards of building practice." Its report highlighted issues around the relationship between IPC and Facilities and Estates during the handover of the building, reflecting, in part, a lack of

[10] https://www.sehd.scot.nhs.uk/mels/HDL2005_08.pdf.
[11] https://www.sehd.scot.nhs.uk/dl/DL(2019)23.pdf.

operational readiness in taking responsibility for the building and the significant number of defects that needed to be addressed initially.

71. The Oversight Board concluded that the links between Facilities and Estates and IPC staff were inconsistent over the years. This has been most clearly highlighted by the failure of Facilities and Estates staff to take timeous action on the 2015 and 2017 DMA Canyon reports on water testing, which identified serious infection risks, and communicating those risks to relevant IPC and microbiologist colleagues. In the period up to 2018 in particular, requests for water testing results by IMTs and their Chairs did not receive a consistently adequate response – indeed, there seemed to be a lack of systematic rigour in such requests, how they were recorded and how they were responded to. As the Independent Review also noted: "There was extensive and inconclusive correspondence between ICDs, with Estates and Facilities management, and general management of the hospital. Management and technical information was not forthcoming that was needed to inform ICDs' decision-making."

72. In large part, this seemed to be a consequence of the pressures placed on Facilities and Estates in the hospital's early years and the inadequacy of its existing structures to deal with those pressures fully. The pressures included an unexpected requirement to oversee extensive remedial work on the building at handover and continuing coordination of a significant number of sub-contractors, contributing to an overall sense of 'fire-fighting' within the Health Board. In addition, there were other notable weaknesses that contributed to the failure to address the report. There was no formal Authorised Person responsible for the water system within the Facilities and Estates team before 2018. While it was recognised that certain people had particular expertise or knowledge of an area, such as water, they were not formally assigned responsibility for looking after an area. This seemed to have been compounded by a high turnover of staff within Facilities and Estates at this time with what has been described as lack of systematic handovers. Again, to cite the Independent Review: "A lack of clarity over the roles and responsibilities within the Estates and Facilities team, combined with overwhelming workloads, due to defects, snagging and incomplete works, meant there was a missed opportunity to address the significant problems with the water system over a period of around two years, during which the risk remained 'high'."

73. Latterly, there have been significant improvements within Facilities and Estates that have resulted in improved coordination, in response to the failures identified through the DMA Canyon report incident. With the appointment of the new Director of Facilities and Estates in 2018 (and indeed, a new Chief Executive taking up post earlier), there has been significant reflection and improvement in Facilities and Estates. There has been evidence of structural and procedural changes that improved lines of accountability within the function and with other parts of the organisation, the effectiveness of these functions and its coordination with IPC. NHS GGC acknowledged these historical issues in discussions with the Oversight Board. The structure of the Facilities and Estates team has significantly changed and there is assignment of specific roles and responsibilities to ensure that issues (and reports) would not be overlooked in future. There has been a greater level of formal compliance introduced within the organisation, supported by the formal training and appointment of Approved Persons, not only for water, but for other systems as well.

Electronic compliance dashboards have been created for senior and estates managers to allow instant visibility of the compliance level on a site/sector and at Board level for all AE Audits, Water Risk Assessments, sustainability issues as well as the action plans supporting these reports. SOPs have also been introduced to ensure consistency among the work performed by the various sector estates teams.

74. This was reflected in improved coordination in support of IPC. A good example of the integrated approach was the Technical Water Group, as already detailed. This was particularly evident in consideration of the hypotheses of water contamination, assessment of different options for mitigation and taking forward the chlorine dioxide dosing solution. Overall, the terms of reference and minutes of the Technical Water Group and relevant oversight groups (such as the Board Infection Control Committee) showed integration working actively.

75. Staffing issues among microbiologists and IPC staff also created challenges in responding to the infection incidents. Periodically, these issues surfaced, complicating the environment for taking clear and coherent action. For example, questions were raised about roles and responsibilities by some individual clinical staff in 2017. In a SBAR of October by several microbiologists, it was noted that "roles within the infection control team are unclear and appear to have changed… [and] there appears to be a lack of resources to investigate potential outbreaks/ increase in infection rates". The Health Board took action to respond to these issues with a targeted action plan. A number of clinicians and microbiologists raised whistleblowing procedures within the Health Board. Also, as already noted, it is clear that there were notable tensions between staff. The Independent Review has commented on this more extensively, and noted:

> "The whistleblowing episode beginning in 2017, lack of resilience of management arrangements and instability of the lead IP&C Team's relationships set the scene for contested leadership into a particularly turbulent period, when the microbiologist community could not find the capability that would have enabled them, when it was important, to be able to agree to disagree respectfully. The IP&C team continued not to function as a leadership team."

76. The Oversight Board did not review these specific issues in depth, but staffing problems were a consistent thread through much of the period, compromising, at the very least, a cohesive and focused IPC response to a highly complex set of challenges. Recognising the importance of these issues, Professors Bain and Wallace undertook Organisational Development work in 2020 as a matter of priority to address their potentially harmful effects. This entailed in-depth discussions with staff within and working with the IPC Team in an environment that encouraged frank review and reflection. The work consisted of a five-stage programme:

i. 'entry and contracting': facilitating a series of interventions to ensure that staff are working in a positive and improvement work environment with appropriate support and governance;

ii. 'data collection and diagnosis': interviews with staff and stakeholders;

iii. 'feedback and action proposal': assessment and sharing of key findings and development of action plan;

iv. ‘implementation’: taking forward actions with appropriate points of review; and

v. ‘impact evaluation and recommendations’: fixing of end points and drawing out and implementing recommendations.

The results of this work have been important in identifying issues for immediate action and setting the long-term challenges and goals of the strategic work for change under the ‘Silver Command’ work discussed in the last section of this chapter.

3.3 Leadership

77. Leadership in healthcare is critical, perhaps no more so than when a health organisation is forced to address crises, not least prolonged ones. The impact on staff morale, patient, family and public confidence, and the ability to respond and learn from challenging situations cannot be underestimated. NHS Scotland – through programmes such as the Scottish Government-sponsored Project Lift[12] – has recognised the importance of this. Ultimately that will depend on the quality and performance of individuals, but equally, it is important that the right structure of leadership responsibilities is set out for individuals to fulfil the expectations of their roles. That structure needs to be clear and appropriate for the challenges of the role. The Oversight Board has considered how responsibilities for IPC have been organised within NHS GGC with a view to considering assurance for the approach. The focus is wholly on how relevant posts and management structures have been defined.

78. One aspect of their responsibilities – how senior leaders communicated and engaged with patients and families affected by the outbreaks – was treated at length in the Oversight Board’s Interim Report. Issues more closely related to staff management – not least in the context of the whistleblowing issues noted in earlier sections – are not reviewed here, as they will be more properly covered by other processes such as the Scottish Hospitals Inquiry. This section concentrates on how the key roles with IPC responsibilities have been defined within the Health Board.

Senior Executive Role

79. The draft Governance and Quality Assurance Framework for the Health Board clearly sets out key senior roles within the Health Board. The document itself remains draft (to take account of further changes to be made as part of current reform work, as described below) – this and the wider issue of governance are discussed in more detail in the Governance chapter. Within the draft Framework, the most senior responsibility for IPC lies with the Board Medical Director, to whom the Chief Executive delegated the role of Executive Lead for IPC. In overseeing and providing assurance on behalf of the Chief Executive, the Medical Director:

- “is aware of their legal responsibilities to identify, assess and control risks of infection in the workplace;

[12] https://projectlift.scot/.

- has appointed an Infection Control Manager as required by HDL (2001)10 and HDL (2005)8 with sufficient resources to undertake this role;
- is aware of factors within services deliverer/NHS Boards which promote low levels of HAIs [Healthcare Associated Infections] and ensures that appropriate action is taken;
- has designated the prevention and control of infection as a core part of their organisation's clinical governance and patient safety programmes;
- ensures that there is progress towards appropriate provision of isolation facilities within their healthcare facilities; and
- ensures that IPC Teams work with nursing, medical staff and bed managers to optimise bed use, assess the infection impact of bed management policies, and implement changes to local policy to minimise the risks of infection."

The designation of the Medical Director as the Executive Lead is unusual within NHS Scotland – typically that role tends to sit with the Nurse Director in individual Health Boards – but there is no national specification. As IPC is a cross-cutting issue within Boards, arguably there is no 'natural' place for such responsibility to sit. What matters – and what the Oversight Board has focused on – is whether the nature of the responsibility is adequately set out and whether the supporting structure of leadership within the Health Board is appropriate for that responsibility.

80. The Oversight Board recognised the need for a dedicated senior role to lead change in IPC and address the IPC issues that have been highlighted by the infection incidents. That prompted the designation of a new Healthcare Associated Infections (HAI) Executive lead role, and eventually, the role of the Interim Director of IPC. This interim role has reported directly to the NHS GGC Chief Executive and has been positioned with the Senior Executive Group (not least as part of the COVID-19 pandemic emergency footing structures). The Interim Director of IPC attends Board meetings to present the HAI Reporting Template (HAIRT). From the outset, the Interim Director has had the brief from both the Nurse Director and the Board Chief Executive to direct all aspects of IPC, with the freedom and authority to identify system learning and improvement to ensure safe care for patients and to support staff across NHS GGC.

81. This is clearly an interim role, which Professor Wallace is fulfilling as part of a time-limited period to embed the work of transforming IPC. The Oversight Board understands that the Health Board, following publication of the Final Report, will put in place strengthened and permanent arrangements for the leadership and oversight of IPC within the Board.

Senior IPC and Management Roles

82. There are two other key roles that the Oversight Board reviewed: the Infection Control Manager; and the Lead Infection Control Doctor.

83. The draft Governance and Quality Assurance Framework described the responsibilities of the Infection Control Manager as follows:

- "coordinate IPC throughout the Board area;
- deliver the Board approved Infection Control Programme in conjunction with the Board Infection Control Committee and Senior IPC [Team];
- provide clear mechanisms for access to specialist infection control advice and support, including primary care (eg. general medical practitioners);
- assess the impact of all existing and new policies and plans on HAI, and make recommendations for change;
- challenge non-compliance with local and national protocols and guidance relating to prevention and control of infection, decontamination, antimicrobial prescribing and cleaning;
- report directly to the Director of Diagnostics;
- be an integral member of the organisations clinical governance structures; and
- produce the bi-monthly Healthcare Associated Infection Reporting Template (HAIRT) report for the NHS Board."

84. The Oversight Board endorses the description of the role, but would recommend that the role does not report to the Director of Diagnostics. Rather the relevant HDLs should be implemented to ensure clear and effective lines of reporting and accountability.

85. The Framework does not set out a description of the Lead Infection Control Doctor role – the Oversight Board recommends this role, and indeed, the role of Infection Control Doctors (ICDs) more generally, are clearly set out to present a complete picture of the key roles. The ICD role is much more complex than a label of 'ICD' – for a Health Board of NHS GGC's size, there should be numerous infection specialist roles covering ventilation, water, decontamination and surveillance and acute infection control (analogous with the Authorised Persons roles within Facilities and Estates).

86. At the same time, all microbiologists should have 'IPC' in their job plan given the potential urgent need for microbiologists to chair PAGs/IMTs at short notice. Similarly, work should be taken forward to ensure specialisation in the ICD role so that there is appropriate expertise in key microbiological issues – such as water and air ventilation – particularly for a Health Board of the size and complexity of NHS GGC. There is an imperative for national work to define these roles and expertise that should be taken forward by ARHAI Scotland.

87. The structure of IPC leadership was fluid throughout the period. For a prolonged period, several key leadership roles within IPC were being filled on an interim, rather than a permanent basis. While this may clearly address interim staffing issues, it may be indicative of difficulties in long-term recruitment to these posts and underlines a lack of stability about the roles. Similarly, the role of Lead ICD changed at several points over the period, and not always in a clearly planned manner: the illness of the incumbent led to temporary measures being put in place in the second half of 2017 was an examples of a point that would have presented challenges to clarity and continuity in IPC leadership when they were most needed.

The issues were highlighted by the Independent Review, which noted that: "the resilience of IP&C leadership eroded, and it was not capable of addressing adequately the series of further adverse events that then arose".

88. The Oversight Board recommends that interim arrangements for these senior roles should be resolved and permanent incumbents decided as soon as practicable. However, since escalation, significant work is already being put in place to support changing staffing roles and structures as part of the Silver Command workstream (as discussed in more detail below). This includes giving two of the ICD roles additional sessions to enable creation of a Deputy Lead ICD and an ICD with dedicated responsibility for the built environment. The Oversight Board endorses these actions.

3.4 Learning from the Experience

89. With such a prolonged series of incidents, expectations are that the Health Board would learn from the experience, developing new ways of addressing the issues that were arising and ensuring the 'lessons learned' reflection was systematically undertaken. Certainly, evidence of learning is apparent across the period. There is a notable commitment to codifying learning in SOPs that captured new issues and required changes to processes arising from the infection incidents, such as the list of new infection organisms to be part of regular surveillance and the range of SOPs in 2018 introduced to address specific issues in Facilities and Estates (for example, ventilation to ensure consistency in compliance). The development of a single governance and assurance framework for IPC and the review of water safety policy are treated in later sections, but should be highlighted as NHS GGC's response to address the requirement of the HIS report.

90. A good example is the work of the Facilities and Estates compliance team, which created an electronic compliance dashboard for senior managers and estates managers to allow instant visibility of the compliance level on a site/sector and Board level for all AE Audits, Water Risk Assessments, sustainability issues along with all action plans supporting these reports. Evidence to support completed actions would also be held. The work was completed in early 2020 and means that all compliance-related documents and action plans are now in a single place, allowing tracking and follow up on action plans. Other evidence of responding to the challenges of these infections can be found in the introduction of the Infection Control and Built Environment Group and the Clinical Review Group in 2019 (the latter brings together infection issues with clinical issues and estates and formally reports to the management team).

91. However, the evidence of explicit and systematic reflection has not been apparent across the period. While there were occasional 'hot debriefs' (retrospective reviews of incidents with an emphasis on the lessons learned) – notably in May 2018 after the first 'wave' of infection incidents association with the 'water incident' – they were not regular. There was little structured review of past incidents and handling within the Health Board. IMTs did not 'call back' to previous incidents and actions taken, even though by the second half of 2018, the risk of systemic water contamination was being regarded as sufficiently high enough to lead to the site-

wide chemical dosing solution. It is somewhat surprising that this was not more visibly considered by IMTs in the second half of 2019.

92. Similarly, there was no comprehensive review of the infection risks to the whole site from systemic water contamination. While there was some consideration of risks to other vulnerable patient groups – for example, by the Technical Water Group to guide the installation of point-of-use filters – there was no comprehensive review of the implications of this risk for the whole hospital. This is considered in more detail in the Governance section, but it meant that there may have been missed opportunities for full learning from these incidents. This seemed notably different from the approach taken to review the issues around the construction of the building, where the Chief Executive commissioned a comprehensive review of the building's defects, the hospital's capacity and flow, and the clinical outcomes for patients, which was presented to the Board at its meeting in December 2019.

93. Nevertheless, more recently there has been recognition of the need for a full-scale approach to reviewing IPC processes and structures. The recent work – put in place by Professor Angela Wallace – has been an encouraging step. Recently, the Health Board has launched a 'Gold Command' programme of work to address the different issues that gave rise to escalation to Stage 4 in the NHS Scotland Performance Framework. The 'Better Every Day' programme is chaired by the Chief Executive, and consists of four key strands of work:

- 'Better Performance', which addresses acute services performance, amongst other issues;
- 'Better Care and Experience', which covers the Quality Strategy's aims;
- 'Better Together', which aims to improve communication and engagement (and address issues discussed in the Oversight Board's Interim Report); and
- 'Better Safe, Clean and Clinical Environment' (under the banner of 'Infection Control is everybody's business'), in which improvements to IPC will be taken forward.

94. The latter 'Silver Command' workstream is jointly chaired by Professor Angela Wallace, the Director of Facilities and Estates and the Chief Operating Officer. It has several key elements with the following aims:

- Better Built Environment: "[to ensure] our Estate will support and enable safe, effective clinical care, irrespective of the care setting";
- IPC [Team]: "to provide expert IPC consultancy in order to deliver Quality – safe, effective, person-centred care to every person every time, and through a business partnering model that provides data, educates and supports the service to exceed the required standards";
- Microbiology: "to provide excellence in prevention, diagnosis and management of infection for every patient, every time"; and
- 'Everybody's business': "to ensure a Better, Safe, Clean Clinical Environment – a built environment to support and enable clinical excellence".

A work programme – rooted in the Organisational Development work discussed above – is being developed, and its key features are summarised below:

- IPC Team transformation and renewal work, including: internal ‘best in class’ benchmarking with stretch goals; redesign and reaffirming of IPC systems and processes; repositioning of the IPC Team as part of systems, roles and responsibility review work; and a transformation delivery plan informed by the above work incorporating external review recommendations;
- whole-system IPC improvement programme, including: a Board-wide IPC improvement collaborative; building capacity and capability in improvement skills; and the Organisational Development programme in support; and
- redefining system IPC roles and responsibilities, including: clarity on roles, responsibilities across the system in relation to IPC Team performance and delivery.

95. Detailed workplans and success measures are being put in place for this work by early 2021, and to date, key changes can already be seen.

- The new Whole Systems Infection Control Improvement collaborative is starting to focus on how to build improvement capacity within IPC, and will contain a workstream for the RHC.
- The North and South IPC Teams are developing a single-team approach to support shared learning and improvement.
- A weekly multi-disciplinary overview meeting on IPC is held to provide a form for early warning on issues and discussion of key reviews.

96. The Oversight Board commends this work, and suggests that the recommendations in its Interim and Final Reports are used to shape it going forward. This also applies to the Case Note Review, whose Overview Report also contains a number of key recommendations on the operation of IPC (some of which are noted in a later chapter). The Oversight Board also strongly suggests that success measures are set out and visibly used to track improvements as a way to strengthen assurance, not least with patients, family and the wider public.

97. There has also been discussion of how the experience of the Health Board can be used nationally to support NHS Scotland (and more specifically, NHS Assure), though the pandemic has delayed some of this work going forward. The Oversight Board welcomes this suggestion and urges it is taken forward when circumstances allow.

98. While the Oversight Board was primarily focused on the escalation of a single Health Board to Stage 4, the issues that led to escalation were not exclusively local. From a national perspective, the experience of NHS GGC provided two clear national ‘lessons’ for the Oversight Board. The first was the importance of ensuring the Health Board’s experience of understanding and responding to potential environmental infections should be also used for national benefit. As the Scottish Hospitals Inquiry is committed to investigate in greater detail, the design and construction issues that have been linked to the potential for environmental infection may not have been unique to NHS GGC, and indeed, may continue to be a source of risk in health infrastructure policy in future.

99. Second, the experience highlighted a national gap in the understanding of how such unusual environmental-related infections can develop in hospital settings. NHS GGC's own research work will be of value here. The Oversight Board also determined there is a need for systematic national review of the limits of understanding and a research programme to address the gaps in IPC knowledge and practice.

100. At the same time, it is clear that NHS GGC did not receive sufficient external support to address these unusual challenges. Support was readily provided when requested but the provision of effective expert advice (and indeed, sustained challenge to what the Health Board was doing, or not doing) was not consistently forthcoming. The Health Board has noted that there was little national guidance for some of the issues relating to the infections, and there was tacit endorsement of the actions it did take. This reflects the lack of a strong set of dedicated institutions to provide that kind of specialist expertise – and where necessary, oversight and challenge – in how NHS GGC handled these issues. Put simply, there does not appear to have been a national organisation or process which could have pro-actively supported and assured NHS GGC in its IPC handling when these issues were becoming acute. The need for a strong national presence in this space will be returned to in the Final Report's last chapter.

101. The Oversight Board also noted that national recommendations in this area have been made in the past. The February 2019 HPS report noted key actions that should be taken forward nationally, including the following:

- HPS (supported by HFS) to undertake an urgent national water review of all healthcare premises built since 2013 to provide assurance that a similar incident has not and is not likely to occur elsewhere;
- HPS (supported by HFS) to establish a national expert group to review NHS Scotland current approach to water safety including as a minimum: review NHS Scotland current approach to water testing in healthcare settings, review NHS Scotland current surveillance and reporting of potentially linked water-related HAI cases, and based on findings develop risk based guidance on water testing protocols, results interpretation roles and responsibilities and remedial steps to be considered; and
- give consideration to the development of a best practice built environment manual which will be evidence based and cover, as a minimum, current and emerging evidence and the technical requirements from a clinical, patient safety and HAI perspective that will be adopted by all NHS Boards. This will include as a minimum: a review existing national and international guidance relating to water safety; development of robust requirements and guidance for all aspects of water safety; development of robust handover requirements in relation to water systems; review of the role of the IPC Team into the built environment, and produce clear guidance on roles and responsibilities; establishment of a risk-based approach to water testing and any remedial action required, including the roles and responsibilities that NHS Boards will adopt; review of the requirement for 100 percent en-suite single-side rooms and the number of clinical wash-hand basins per patient/bed; and review of the use of flow regulators across NHS Scotland and identify and associated risks and recommend any remedial actions required.

The Oversight Board understands that these recommendations are still being taken forward. They remain critical actions to be implemented, and are re-affirmed as national priorities in this Final Report.

4. Governance and Risk Management

102. In recent years, NHS Scotland has clearly articulated the principles and practice of good governance in Health Boards. In February 2019, DL (2019)2 was published, setting out requirements for Health Boards to adopt the Blueprint for Good Governance. The Blueprint drew on current best practice to ensure all Health Boards assessed and developed their corporate governance systems. As the Blueprint described: "Good governance is essential in addressing the challenges the public sector faces and providing high quality, safe, sustainable health and social care services depends on NHS Boards developing robust, accountable and transparent corporate governance systems."[13]

103. Amongst other responsibilities, good governance should:

- identify current and future corporate, clinical, legislative, financial and reputational risks; and
- oversee an effective risk management system that assesses level of risk, identifies mitigation and provides assurance that risk is being effectively treated, tolerated or eliminated.

This is reflected in the responsibilities of individual Board Members, which include:

- providing effective scrutiny, challenge, support and advice to the Executive Leadership Team on the delivery of the organisation's aims, objectives, standards and targets; and
- contributing to the identification and management of strategic and operational risks.

104. The principles outlined above are clearly essential with respect to IPC issues. In order for the Oversight Board to address one of its key questions – **is the governance structure adequate to pick up and address infection risks?** – it was necessary to consider how infection management and risk was addressed by the Health Board. Against this baseline of the Blueprint, the following sections in this chapter review:

- the **framework for governance around IPC** – in effect, how the system was set out 'on paper';
- how that system worked in action, by examining **key incidents in this period of escalation**; and
- **how the risks around these infection incidents were captured and managed**.

[13] https://learn.nes.nhs.scot/28418/board-development/blueprint-for-good-governance.

4.1 Principles of Governance and Risk Management for Infection Prevention and Control

105. It is vital for a Health Board to have a clear description of its governance and risk management. Such a description should not be expected to be static, but adapting to improve practice within a clear governance and assurance structure. Before examining whether NHS GGC practice in governance and risk management met national expectations in the context of these infection incidents, it is important to consider how the Health Board articulated its approach to management and escalation of incidents in general.

106. In implementing the Blueprint for Good Governance, NHS GGC explicitly set out its principles in the Governance and Quality Assurance Framework for Infection Prevention and Control Services (described in more detail in the box below). Moreover, the approach to IPC sits within a wider, robust approach to governance and risk management. Within NHS GGC, assurance on the structure of governance and risk has been actively sought by the Board: it has been reviewed by external organisations (such as Price Waterhouse Cooper and Scott Moncrieff).

Governance and Quality Assurance Framework for Infection Prevention and Control Services

NHS GGC's Governance and Quality Assurance Framework for IPC Services brought together a number of earlier documents to provide a complete statement of responsibilities and checks on IPC within the Health Board. It described how the Board sets and delivers its strategic aims, the risk management process and how it gives stakeholders and the public assurance that the service is delivering for patients, staff and the organisation. It also described how the Board uses information from the point of care to the NHS Board to improve outcomes for patients and how it reports incidents and outbreaks that may affect the health of patients, staff or visitors.

The framework clearly set out the role of the Chief Executive of the Health Board, which is to ensure that there is successful prevention and control of infection throughout the NHS Board area. The accountabilities of this role are outlined in the Healthcare Improvement Scotland Standards for HAI and have been further emphasised within the NHS HIS report on the second review of these standards. The framework included details on the structure and responsibilities of key elements of the governance structure and how escalation should take place, including: IPC Senior Management team; the sector-based IPC teams the NHS GGC Board Infection Control Committee; and the Acute Infection Prevention and Control Committee.

107. The Oversight Board welcomes the creation of this Framework document. The Framework has not yet been published, and has been maintained in draft form – 'version 5', dated November 2019, was shared with the Oversight Board and was clearly a work in progress. The document should be finalised as soon as possible and published to support transparency in the governance of IPC.

108. The IPC and Governance Subgroup reviewed the document. It found that IPC issues and escalation would be treated in the Health Board with clear lines of responsibility through the ICM through the HAI Executive Lead to the Chief Executive. In terms of Committees, the structure is also clear and logical, and there is evidence that it has been used appropriately throughout this period. In particular:

- Infection incidents (including actions taken) have been reported to the Acute Board Infection Control Committee (which has responsibility for supporting local infection control teams in their responsibilities and reporting upwards on IPC issues that have wider implications), and then onto the Board Infection Control Committee (chaired by the Medical Director, and which provides leadership and support to the IPC services 'from ward to Board').
- The Board Infection Control Committee has reported directly to the Chief Executive, and the Board Clinical Governance Forum, and regular HAI reports have been provided to the Board.

109. In addition, incidents have been reported through the Clinical and Care Governance Committee, which reports directly to the Board. Handling of infection incidents are relevant to the Committee, not least in the context of its remit to "ensure the clinical and care governance arrangements are effective, including interactions with other organisational arrangements, in improving and monitoring the quality of clinical care" and "provide assurance to the Board that NHS GGC meetings its statutory and mandatory obligations relating the NHS Duty of Quality". In effect, it allows an additional line for key incidents, risks and their handling to be addressed within the Health Board.

110. The IPC and Governance Subgroup did make a number of recommendations about this document which should be included as part of a final revision of the Framework.

- There is no mention of how IPC should be 'everyone's responsibility', a clear theme of the recent Silver Command work. It would be useful to see the service leads, senior managers and other key roles mentioned in terms of responsibilities for IPC.
- While escalation from the IPC Team is clearly described, there would be value in describing how escalation should take place within the Team as well.
- The role of Infection Control Nurses should be set out in the context of the full description of responsibilities.
- The IPC Senior Management Team would benefit from a clear description of the involvement of the Lead ICD and the new role of Director of IPC.
- Routine reporting of IPC activity and incidents/outbreaks should be explicitly set out, rather than just the escalation of issues.

- The document should be clear about other key links, particularly between the IPC Team and the Board Infection Control Committee with other key groups/functions, including the Water Safety Group, Decontamination Committee, Facilities and Cleaning, Built Environment and Ventilation.
- Linking with the discussion of how national IPC standards and practice are reflected in the Health Board, the Framework would benefit from a clear designation of responsibilities for monitoring and overseeing compliance with what is set out in the National IPC Manual, not least with respect to the IPC Team.
- The issues relating to how infection risks are captured as part of the Health Board's approach to risk management are detailed further below.
- As noted earlier, the Oversight Board believes governance would be strengthened if HAI Executive responsibilities for IPC were concentrated in a new permanent post (potentially the proposed Director of IPC). That individual should be clearly given the responsibility for overseeing the implementation of the Framework and any updating of its contents.

111. As part of the Gold Command work put in place by the Chief Executive, there has been recent review and revisions to the governance framework. These are set out in **Annex E**, and show how the Gold and Silver Command programmes of work fit into the IPC governance and assurance framework. The Oversight Board supports the changes and the new structure.

112. This structure has allowed for infection issues to be highlighted in a number of different places and for action to be taken and monitored, before being brought ultimately (and as appropriate) to the full Board to act in its role of providing assurance that the right steps have been taken. The Oversight Board found significant evidence that infection incidents were regularly brought before the relevant Committees, particularly from the 2018 'water incident' onwards. As the Executive lead on IPC for the Board, the Medical Director actively led on the reporting of infections to these Committees, and indeed the full Board itself. HAIRTs (and outbreak reports) were systematically provided to the Board Infection Control Committee and the Board. The issues were clearly being made visible to senior governance as soon as their seriousness appeared to be recognised through IMTs.

113. This can be clearly seen in the meetings that took place in 2018. For example:

- the Board Infection Control Committee was informed at meetings on 28 March (including a paper discussing the water testing results and the draft terms of reference of the new Technical Water Group), 23 May and 25 July (when it was notified of the closure of the incident and the plans for widespread chemical dosing);
- the Clinical and Care Governance Committee was updated on the 'water incident' at its 12 June meeting through a paper that set out the incidents in wards 2A and 2B, the steps taken to address and the risk of wider water contamination, and the closure of the incident at its 4 September meeting; and

- the full Board was appraised of the incident and developments on 17 April, 19 June and 21 August – as noted in the 19 June minutes:

  "Dr Armstrong advised that following the bacteria in the water system incident at Queen Elizabeth University Hospital (QEUH) and the Royal Hospital for Children (RHC), a number of immediate actions had been undertaken to address the issue including domestic cleaning, cleaning of equipment, hand hygiene, the installation of end of tap filters and the installation of new drain spigots. The longer term plan was to chemically dose the water supply and then replace taps in high risk units."

In addition, the full Board received a regular update on infection matters via the Medical Director's HAIRT reports.

4.2 Key Incidents in Escalation

114. The Blueprint emphasises an active role in good governance for senior leaders to show prioritisation, challenge and assurance of what the organisation as a whole is doing. In the context of infections, this raises a series of fundamental questions: when did different parts of the relevant part of the governance structure know about the infections (and were these the right points for escalation); was their understanding of the implications of the infections (and any pattern) appropriate and timely; and did they provide the right challenge and enforce the right accountability about the actions being taken in response.

115. An important way to understand these issues is to review the organisation's response when evidence of potentially significant risks associated with the infections were appropriately raised in line with guidance and good practice. It is important to acknowledge that the infection issues presented a complex, not easily comprehensible set of challenges, though that complexity was itself a risk that was not captured in risk registers. Over the period under review, there were a myriad of meetings and issues that can be traced in terms of incident response and review. To illuminate the effectiveness of governance, the Oversight Board has examined a handful of key points in that period in greater detail. Significant shortcomings of governance at these points would raise critical issues about governance as a whole in the context of the escalation of the Health Board to Stage 4. In effect, the test is whether these specific issues, once identified by staff (or raised by families), were reviewed and, given their significance, escalated, scrutinised and acted upon appropriately at the right level of governance.

116. The Oversight Board considered several relevant instances in the period under review:

- the 2015 DMA Canyon water testing report (one of the clearest early indications of potential water contamination);
- the October 2017 SBAR by a number of clinicians and microbiologists at the QEUH (the point at which a number of concerns about environmental risk were formally raised);

- the development of the 'water hypothesis' through IMTs and the Technical Water Group in 2018 (the point at which an understanding of environmental risk prompted a range of major actions by the Health Board, including installation of a comprehensive water dosing system); and
- the decision to de-cant Wards 2A and 2B in 2018 (a major milestone in how the issues were addressed, with huge implications for the affected children, young people and families).

2015 DMA Canyon Report

117. In April 2015, a water specialist consultant (DMA Canyon Ltd) undertook a water risk assessment of the QEUH for the handover of the water system, with a particular focus on the risks associated with Legionella. The report highlighted a number of significant concerns with the system at that point, including temperature control of the water system, installation of flexi-hoses (and the risks associated with bacterial growth) and the lack of effective management, notably with respect to the communication and control of contractor activity at the point of handover. The risks clearly had significant implications for IPC within the new hospital complex, and given the serious issues outlined, it would have been expected to have not only been actioned 'locally' but that higher levels of governance would have been alerted in line with the principles of the committee structure and infection risk management set out above. Indeed, it is exactly the kind of scenario that the governance/risk management structure for IPC was designed to address to ensure that relevant action and assurance is taking place within the Health Board.

118. The report was an internal Health Board report, commissioned of an external company, and was not disclosed publicly until November 2019. What was a particular concern was the absence of action on this report until 2018 – indeed, the lack of record of how the report was received and considered. Action was not taken within the Health Board on the report between 2015 and 2018, and that the report was not considered by the relevant committees. It did not seem to have been brought to the attention of relevant staff within IPC, particularly through the relevant IMTs through 2018. Indeed, when the external company undertook a follow-up report in 2017, the same issues and recommendations – and similar high risks – were identified.

119. The Oversight Board understands that the reports only 'surfaced' as part of the review of historical documentation to be provided to HPS and HFS for their reviews of water system and infection issues in March 2018. At that point, the Health Board took rapid action with an action plan drawn up and monitored to address the specific issues set out in the reports, as well as an internal investigation into how the report had not been picked up before. Mitigating actions to address both 2015 and 2017 reports were subsumed within action plans addressing issues arising from the HPS reports (and as of September 2019, had all been completed).

120. While it is clear that these reports were taken 'seriously' at that stage – admittedly in the context of more recent assessments and surveys of water issues, such as the HPS and HFS reports – it was not clear to the Oversight Board the extent to which the implications for governance were shared with IMTs or discussed by the relevant committees, although an internal review was conducted by the Health

Board in 2018 on what had happened to the 2015 report (and later in 2018, a new SOP was introduced on how to handle DMA reports). Moreover, issues of transparency remained even on the 'discovery' of the reports during 2018, as the Oversight Board understands that the reports were not shared with relevant IPC staff and microbiologists or IMTs at that stage– somewhat surprising given that the reports were provided to the external review bodies, HFS and HPS. As the contents of the report seemed directly relevant to considering the source of infections during 2018, this apparent omission raises questions about the rationale for withholding this material and what consideration was given to the implications for IPC staff and microbiologists to fulfil their responsibilities for patient safety and care.

121. The Independent Review has addressed the issues with respect to the handover of the building following completion of work, and so this aspect of this issue is not reviewed by the Oversight Board. Nevertheless, the receipt of the 2015 DMA Canyon report should have alerted senior management within the Health Board at that time to the fact that there were potentially serious issues with the water system with respect to infection risks. The report seemed to be lodged within the Facilities and Estates service at a local level and not properly considered, nor was it escalated through the appropriate governance. The failure was a local one and relevant managers – not least in IPC – did not seem to have been made aware of the report.

122. Such reports would not normally be considered by the higher levels of governance; there were intended to be considered and acted upon by those with local operational responsibilities. However, that failure to consider and act should have been a matter of concern at different levels of governance when the reports came to light. While the steps to redress that operational failure within Facilities and Estates were monitored appropriately in the Health Board – notably by the Facilities Planning and Performance Committee – a more systematic questioning of how such relevant environmental information was being conveyed within the organisation (and indeed, escalated) seems warranted, but absent. In essence, this can be characterised by the question: was the right information being provided to the right point in the governance of IPC to allow assurance to take place?

123. The failure in governance is a significant oversight. Wider awareness and consideration of the 2015 report – in conjunction with the issues raised by a number of staff, as described below – would most likely have raised the level of urgency around potential environmental risks at an earlier stage and more forcefully. It would have presented a different context to the isolated infection incidents that occurred before 2018 and may have resulted in preventative course of action being pursued earlier.

124. While the failure to escalate the reports may have largely arisen from limited, and by now, historical, weaknesses in Facilities and Estates, the later discovery of the reports should have prompted more formal and visible reflection by relevant committees, and indeed, by the full Board itself. As noted, the Chief Executive commissioned a series of reports as part of a review of a number of concerns at the QEUH, which were presented to the full Board in December 2019 – an exercise that the Oversight Board commends. However, a 'lessons learned' exercise that ensured all the key failures in governance related to the 2015 DMA Canyon report had been

identified and addressed has not taken place, not least the impact of not being pro-active in sharing the reports with relevant services internally. There is a need for such learning to be transparent and comprehensive to provide suitable assurance about appropriate information sharing and escalation.

2017 SBAR on Potential Environmental Risks

125. From before the formal handover of the new building, concerns had been raised by some clinicians about emerging environmental risks arising from its design and construction. The history of concerns – particularly among microbiologists at the QEUH – is not detailed here, but provides an important backdrop to the second spotlight incident considered in the context of governance: the October 2017 SBAR. While the raising of concerns was not new, the manner in which it was raised and considered within IPC governance was.

126. This SBAR was produced by several clinicians and microbiologists in the QEUH at the request of the Medical Director. It drew attention to a range of risks to patients arising from infection control issues in the hospital. The issues were drawn from discussions with colleagues as well as weekly meetings among the consultants. They included:

- delays and scope of water testing;
- lack of consistent reporting of sewage leakage issues (in the Institute of Neurosciences and Spinal Unit);
- lack of remedial action to address inadequate decontamination facilities in paediatric and adult respiratory clinics;
- the insufficient standard of the Positive Ventilated Lobbied rooms, as they did not provide appropriate airborne protection to patients and the absence of HEPA filters in key locations, as well as other ventilation issues;
- concerns around some cleaning arrangements;
- roles within the IPC team being unclear, including ICDs not being informed of HAI-SCRIBE meetings and incidents in a timely manner; and
- lack of resources to investigate infection outbreaks, and a particular gap in experience and knowledge arising from the then-Lead ICD's absence at the time.

The SBAR was accompanied by several clinicians and microbiologists raising their concerns through Step 1 of the whistleblowing process.

127. In this instance, action was quickly taken. A meeting was held that same month with the Medical Director to discuss these concerns, and an action plan was produced. The action plan was ratified by the Clinical and Care Governance Committee at its 5 December 2017 meeting, demitted to the Board Infection Control Committee for ongoing oversight and noted by the full Board in February 2018. The Oversight Board has been informed that work has been substantially completed on the action plan, but the most recent version of the action plan seems to be dated to January 2019 (with several actions shown as still in progress); a further update (and

closure) of the action plan should be put forward and reviewed by the Clinical and Care Governance Committee.

128. It is unclear how (and indeed, whether) all of the original authors of the SBAR were fully engaged in the development of the action plan, as differing accounts were presented to the Oversight Board about the quality of this engagement. Nevertheless, the incident does show the Health Board taking action in response to the raising of concerns – even if the effectiveness of the response remains disputed –and appropriate governance being applied in that context.

Development of the 'Water Hypothesis'

129. The cluster of infection incidents in 2018 prompted a prolonged search for the sources of infection, drawing in concerns that had been raised by some clinicians and microbiologists previously and resulting in continuing debate and review of the overall environmental risks of the QEUH by the IPC service and microbiologists through 2019 to the present. This was not the first time a supposition of water contamination was considered within the Health Board, but the cluster brought a more sustained and widespread focus on water contamination as a potential source, and a move towards supplementing existing infection strategies focused on endogenous bacteria towards actions that targeted the environment, particularly the water system.

130. The earlier section on IPC discussed how an understanding of water contamination emerged and evolved through IMTs by 2018. This section focuses on how the implications of the 'water hypothesis' were considered within NHS GGC governance, not least as those implications had major consequences not just for the paediatric haemato-oncology patient group, but potentially the hospital as a whole. That the source of infections related to water was evident in the succession of hypotheses examined by IMTs and followed through with the actions, including the presence of biofilm in taps and other elements of water infrastructure and the testing undertaken by Intertek in 2018 on taps, sinks and drains in Wards 2A and 2B. However, the extent to which this contamination was lodged within the wider water system – and could have arisen from issues relating to building and handover of the hospital – remains a hypothesis over which different views continue to be held. As the Health Board set out for the Oversight Board: "after investigation, various hypotheses may be considered, with certain findings informing what might be considered the most probable source of contamination, but it is simply not possible to prove beyond doubt what the exact source might have been." Indeed, in its response to a series of questions on the environmental risks of the hospital, posed by families of paediatric haemato-oncology patients in July 2020 on the 'closed Facebook page' (which is described in more detail in the Interim Report), the Health Board cited the HPS reports not finding a single source for the infection and that any more systemic contamination of the water system had not been proven, as well as the Independent Review's overall conclusion that there was no conclusive evidence that failures of the environment could be directly attributable to deaths arising from the infection incidents. However, as the Independent Review also noted: "the design, construction, stewardship and early maintenance of the water system is of sufficient concern to make strong enough links, merit decisions and actions that have resulted

in taking substantial precautionary measures to repair and replace parts of the water and drainage systems, maintain the water system with extra chlorination."

131. One important milestone was the HPS report in November 2019. The retrospective analysis of infection data by HPS has been seen by the Health Board as an important document in supporting the view that what was happening was not 'unusual' when compared to other hospitals. Of course, the report would not have directly influenced actions being taken or analysis by the Health Board before that date. However, it has been cited as supporting the Health Board view about assumptions about what might be taking place in the QEUH and RHC.

132. In October 2019, HPS was asked to provide independent support to review the data being used to inform their risk assessment and decision making in relation to Wards 6A and 4B at the QEUH and RHC. This request resulted in the HPS report, 'Review of NHSGG&C paediatric haemato-oncology data'[14]. The report concluded that there was no evidence of a single point of exposure causing the bloodstream infections. For the period June 2015 to September 2019 as a whole, it compared the rate of positive blood cultures with those in two other hospitals – the Royal Aberdeen Children's Hospital (NHS Grampian) and Royal Hospital for Sick Children (NHS Lothian) – and found that there was no difference in the rates of the Gram-negative group. Moreover, internal work was done to examine infection rates and was presented to the December 2019 meetings of the Clinical and Care Governance Committee and the Board, concluding that: "in the last year following the move to QEUH (October 2018 – September 2019), there was no difference in the rate for Gram-negative group, environmental including the enteric group or environmental group [and] no single source of 'exposure' to specific micro-organisms which may cause infections had been identified across the six year period." At that Clinical and Care Governance Committee meeting, it was concluded that infection rates were within range or better than other Health Boards, and that the steps being taken had been sufficient.

133. However, the Oversight Board does not believe the HPS analysis demonstrates that there was nothing 'unusual' occurring with infection incidents in the RHC and QEUH. The report principally focused on a review of data quality and datasets. While it clearly set out some findings on comparisons with other hospitals, it equally caveated its work by noting the different sample sizes of the patient groups in each hospital (for example, the Aberdeen and Edinburgh hospitals did not have bone marrow transplant units in this analysis). There were numerous 'breaches' of the upper control limits, showing spikes in infection rates throughout the period. Ultimately, the report did not comment on the issue of water contamination, or offer a view about what kind of action should or should not have been taken in response to the infection incidents being identified.

134. Moreover, the Case Note Review – undertaken in parallel with this Oversight Board's work (and published at the same time) – concluded that there was a likelihood of links between infection and the environment in several cases. It found that 28 percent of the infection episodes it examined were 'probably' or 'strongly

[14] www.hps.scot.nhs.uk/web-resources-container/review-of-nhsggc-paediatric-haemato-oncology-data/.

probably' linked to the environment, and a further 50 percent were 'possibly' or 'strongly possibly' so. This was on the basis of the existing documentation and case note files within the Health Board. Indeed, the Case Note Review concluded:

> "We are surprised that the evidence for an excess of Gram-negative environmental bacteraemia in the Paediatric Haematology Oncology patients was challenged by some within the organisation. By 2018, we suggest that simple observation should have identified a disturbing pattern characterised by the occurrence of bacteraemias caused by some very unusual microorganisms and apparent clusters of some of those more commonly encountered. The widespread contamination of the water system seems to have been accepted and NHS GGCs response, notably its decision to close and relocate an entire clinical unit in September 2018, must be interpreted as evidence of the organisation's acceptance that the environment presented a risk of serious infection to a vulnerable group of patients. Although the investigations undertaken to that date had failed to identify a single cohesive hypothesis for the origin of many of the infections, the approach taken to surveillance thereafter did not appear to match the severity of what had already occurred."

135. What this should demonstrate is the significant uncertainty that the Health Board faced in examining for a pattern of infection. The lack of a consensus view suggests that what may be more important in this context is the balance of risk and how that informs decisions, not certainty regarding source. Indeed, within the Health Board itself, grounds for urgency were being raised about the need to respond to the risks of water contamination. Clinical staff in the March IMTs were questioning whether the IMT was able to cope with the apparently escalating environmental risks. The 'water hypothesis' was being raised internally throughout 2018:

- On 23 March, the possibility of contamination of water points at the time of commissioning was explicitly noted by Facilities staff at the IMT meeting.
- On 28 March, the Board Infection Control Committee (minutes and special paper) noted the hypothesis that the problem could have originated in water outlet commissioning actions.
- On 27 April, the Acute Infection Control Committee noted the hypothesis that biofilm could have been present in the water system since the building's commissioning and dispersed by outlet flushing.
- By May 2018, in a paper to the Clinical and Care Governance Committee, IPC staff were highlighting that "it became evident from further water testing that the problem with water contamination was more extensive and involved both RHC and QEHU".
- On 21 August, the full Board was updated on the actions being taken and noted that a possible link to contaminated water system was made early in the incident.

Lastly, as well as the HPS February 2019 report, the accompanying HFS technical report – 'Water Management issues Technical Review: NHS Greater Glasgow and Clyde – Queen Elizabeth University Hospital and Royal Hospital for Children' – which was available in final draft by August 2018, noted the probability of a system-wide contamination of the water from 2015 onwards.

136. As has already been noted, significant action was being taken on what appears to be the presumption of widespread water contamination, notably the installation of point-of-use filters and the water dosing system. What is not apparent is any systematic investigation of the implications of the 'water hypothesis' for the hospital as a whole. While the introduction of point-of-use filters was applied to other vulnerable groups as well as the paediatric haemato-oncology group and water testing was conducted throughout the complex, the focus remained on addressing the immediate issues in the affected wards rather than a more comprehensive review of what this might mean to different parts of the hospital and different patient groups. The risk of water contamination has several different dimensions:

- clinical risk to the range of different patient groups (not just those in the paediatric haemato-oncology service);
- infrastructure implications, not just in terms of the short-term actions such as the use of filters, but wider ones about a programme of remedial work to identify and resolve problems through the hospital's water infrastructure;
- a thorough approach to water sampling and testing based on the water contamination risk;
- the financial and public assurance consequences arising from this; and
- the implications for staff working in such an environment and addressing patient and family concerns.

While many of these actions were taken forward, there did not appear to be a strategic overview that considered all these risks and responses to water contamination as a whole, not least their inter-dependencies. Such an approach would have necessarily spanned the whole governance framework of the Health Board.

137. This kind of approach was not being requested of the Health Board by those working with it nationally, but it seems equally clear that it was not actioned internally. Throughout the period, the governance system was active in addressing and containing the individual incidents, taking impressive actions of redress, but there did not appear to be consideration of the wider risks that the incidents suggested and which the succession of outbreaks demanded. It was not just a question of the 'long view' of the succession of incidents, but the 'wider view' of what that might mean across the Health Board's operations. Again, there is learning here not just for NHS GGC, but for all Health Boards.

<u>Decision to De-cant Wards 2A and 2B</u>

138. The decision to de-cant Wards 2A and 2B in 2018 remains one of the most significant actions taken by the Health Board in response to the series of infection incidents. Moving children and young people into the QEUH building itself allowed substantial works to be undertaken on the RHC wards. To date, refurbishment work has not been completed and paediatric haemato-oncology patients continue to be treated in Wards 6A and 4C within the QEUH.

139. The decision was taken relatively quickly. At the Board meeting on 21 August 2018 and the Clinical and Care Governance Committee meeting on 4 September, the minutes do not show that there might be a need to de-cant, reflecting the understanding that the issues were under control following the closure of the earlier incident and the actions set in motion as a result. The de-cant took place on 26 September. How communication of the event took place with children, young people and families has already been reviewed in the Interim Report. The relevant wards were inspected and made ready for patients with a programme of repairs and full deep cleans. Weekly IMT meetings continued to monitor the de-cant, and no issues were initially raised about the move. An update on the de-cant was provided to the Board Infection Control Committee, where some concerns at the clinical risks of the move were expressed. The full Board was updated at its meeting on 26 October, where the decision to close the RHC wards was formalised.

140. The rapid decision and follow-up action here shows that NHS GGC was capable of responding quickly when urgent action was required. However, the move was not without its own series of risks, given that the children and young people were being transferred to wards that had not been specifically designed for their needs. While a risk assessment of different options was undertaken, concerns were brought forward by clinicians and microbiologists when a new series of infection incidents occurred in Ward 6A and a new IMT was established in June 2019. This led to a SBAR in August, produced by seven microbiologists, outlining a number of concerns including: issues about air changes and pressure; use of HEPA filtration; infection risks from chilled beam technology; existence of pathogenic fungi; exposure of the children and young people to unfiltered water; risk from toilet plume; the absence of 'solid' ceilings; and the lack of play area. This SBAR argued that what was originally considered a short-term de-cant had become longer term, owing to the greater scale of issues uncovered in the original wards as part of the refurbishment; as a result, it was necessary for a new, longer-term risk assessment and appraisal to be carried out of the 'temporary' wards, particularly 6A. Indeed, the SBAR concluded that this was a matter of significant public safety, as it concluded: "6A should be considered to have significant unacceptable levels of infection risk for the immune compromised patients due to the built environment."

141. What gives particular significance to the August 2019 SBAR was not just the number of microbiologists who set out their concerns, but the implications for NHS GGC senior managers of an argument that Ward 6A (in particular) was not a 'safe' place for this patient group. In many respects, the alternative choices facing the Health Board were more limited and stark than those in the original decision to de-cant from the RHC, so this provides a significant test of how the issues were assessed and addressed within the governance structure. While the evidence is strong throughout 2019 that there was considerable discussion and reporting of the measures being taken to mitigate the infection issues in Wards 6A and 4B, including discussions at the Clinical and Care Governance Committee and the Board itself (via the regular HAI reports), it is important to understand how these more fundamental concerns about the long-term appropriateness of the QEUH wards were being considered.

142. The issues and responses to the August 2019 SBAR was discussed at the first IMT meeting in September, but it was not clear what further action/consideration

was to be taken forward. The Oversight Board was aware that several of the authors of the SBAR sought a formal response to their SBAR, but there is no indication that a formal action plan was created (or that the issues were incorporated into an existing action plan). Indeed, IMT minutes in September following the internal discussion on the SBAR's points held an action point for the IMT's views and responses to be communicated back to the authors of the SBAR; this was raised again at a subsequent meeting, where it was confirmed that such a response had been provided. Nevertheless, several of the SBAR's authors have reported that no such confirmation was made.

143. The Oversight Board is not aware that the issue was formally raised or discussed with any of the relevant committees/groups in the subsequent period. The December 2019 meeting of the Clinical and Care Governance Committee noted that whistleblowing concerns had been raised by some clinicians and microbiologists and noted that the relevant processes were being followed. It also set out actions that addressed some of the issues raised in this SBAR, such as cleaning focused on the chilled beams. The lack of clarity and formal recording of considering and acting on the SBAR is surprising in light of the continuing issues with infection at the QEUH.

144. Alongside these concerns about the appropriateness of Ward 6A for this vulnerable group of patients, there was internal speculation on why Gram-negative bacterium were continuing to appear despite the chemical dosing regime. Such actions can take significant periods of time to prove effective (and indeed levels of bacteria had reduced, as seen by the water testing results), but questions were raised about whether resistance to chlorine dioxide might be present. At its meeting on 16 July 2019, the Acute Infection Control Committee was informed that while the QEUH chlorination system had been fully fitted and Gram-negative counts had fallen, the mycobacteria issue had recently re-emerged despite the dosing. Such concerns posed risks to the strategy being pursued by the Health Board to addressing potential environment risks. On 29 July, similar concerns were noted at the Board Infection Control Committee, but no specific action seems to have been taken.

145. While such discussions may have taken place among senior managers, these risks do not seem to have been discussed at formal meetings. Instead, the emphasis seems to have principally been on assurance that immediate measures to address concerns – such as the provision of taps or cleaning regimes – were in place. The high level of uncertainty over continuing safety to the children and young people, environmental risk did not make decision and action easy. However, the complexity of these issues did not seem reflected fully to more senior levels of governance, and there was insufficient recognition of the concerns around environmental risks – not least with respect to the de-canted wards in the QEUH – continually raised by some clinicians.

146. Issues about escalation were also apparent in the handling of Mycobacterium Chelonae cases within the hospital – Gram-positive bacterium, but related to the environment and just as potentially threatening to this vulnerable patient group. The National IPC Manual does not refer specifically to MC in its list in Appendix 13, and it is an unusual organism. It was reported in May 2018 in Ward 2A in the RHC, although it did not feature in the HAIRTs provided later to the full Board. A second

incident occurred in June 2019 in Ward 6A in the QEUH; that incident was reported to the full Board's October meeting in the HAIRT, but there was no reference to the earlier 2018 incident in that report. While the issues were discussed in other Committees (and reported to HPS, including the earlier 2018 case), it may have been useful if this had been reported to the full Board for consistency and to give an adequate profile to the occurrence of an unusual organism (again in the context of the risks of water contamination). The Board did report this to HPS at the time and following active consideration by the ICD, the organism was excluded as not meeting the case definition. Further national guidance on reporting would be helpful to support Health Boards in future.

147. In the Oversight Board's view, both instances warranted being brought to the full Board's attention in a consistent manner that noted the issue of apparent recurrence. IPC governance in a Health Board as large and complex as NHS GGC depends on issues being addressed at the appropriate place and relevant reporting being undertaken to higher levels of governance. In the view of the Oversight Board, this was not consistently done in the period under review.

148. IPC governance also depends on higher levels of governance seeking assurance of the system as a whole. The Oversight Boarded noted that targeted internal audits of IPC governance did not appear to take place during the period under review. Such action should also be considered as part of wider work on reviewing governance within the Health Board described below (and indeed, as part of wider work on audit and governance for NHS Scotland as a whole).

Summary

149. In reviewing how IPC governance handled the infection incidents, the Oversight Board found governance as a whole was fulfilling many of its primary responsibilities. No obvious 'weak links' in a chain of good IPC governance were identified. Infection incidents were, for the most part, reported at different committees, up to and including the full Board, and actions were reported and largely monitored and followed up. Indeed, there are several examples of good governance in action. For example, following reporting of the Cryptococcus incident in January 2019, the Board requested regular updates on air sampling at subsequent meetings. Improvements in Wards 2A and 2B. The improvements in Facilities and Estates operations were given proper and commendable attention by the Facilities Planning and Performance Committee through 2019. In this, the different Committees were fulfilling a clear role on assurance, particularly of the infection issues being raised and the actions taken.

150. However, the Oversight Board is not satisfied that the full Board was appraised of all the relevant issues. In part this may reflect what was presented to these Committees, and the absence of important information (such as the loss of the DMA Canyon reports). There was also no systematic review of the implications of water contamination presented to – or indeed, requested by – the full Board. Arguably these are issues that can only have been brought together at the level of the full Board, where the work of different Committees looking at different dimensions to the QEUH issues came together. The lack of some information and of a cross-cutting review of the implications of water contamination may have hindered

the Board's ability to fulfil the key elements of its role in assurance: seeing the 'big picture' in full; and providing challenge. It also highlights another key aspect of how IPC governance should have addressed the infection incidents: risk management.

4.3 Risk Management

151. Risk is not the responsibility of any one part of the organisation; while more senior parts of the governance system have clear roles on overall oversight, it should be mainstreamed through all levels and services. As stated to the Oversight Board: "[NHS GGC] believe that the provision of high standards of health, safety and welfare within a risk management framework is fundamental to the provision of high standards of health care". The Board itself retains ultimate corporate responsibility for the risk management strategy and ensuring that corporate risks are properly captured and addressed, as well as assuring itself that all parts of the organisation are managing risk appropriately.

152. Relevant risk registers – not least the Corporate Risk Register – do reflect infection risks, and are necessary to ensure there is a systematic approach to considering and taking action on the right issues. However, the environmental infection risks increasingly apparent from 2018 onwards were not reflected in the Health Board's risk record. While infection incidents were reported individually to oversight committees within NHS GGC (as noted above), the significance of potentially widespread water contamination was not quickly raised within the governance structure.

153. As risk should be mainstreamed throughout the organisation, an appreciation of risk management should not be limited to what was and was not discussed at formal meetings. In its discussions with the Oversight Board, the Health Board noted that issues of risk were consistently being discussed and addressed by senior managers outside of formal meetings, and indeed, for some groups, such as the Technical Water Group, it clearly shaped the urgency and work programme to address risks. However, the abiding impression from the formal reflection on these matters within NHS GGC – not least by the Board itself – was of the senior levels of governance simply noting actions and not demonstrating a more active approach to seeking assurance around the risks. This is a view echoed by the Independent Review, which concluded: "There is little evidence in the [Board Infection Control Committee] or Board papers of a strategic approach to IP&C but rather of a responsive approach to exceptions that otherwise demonstrates good compliance with activities and standard."

154. Recording of risk is a key part of risk management. As the Blueprint for Good Governance sets out: "Assessing risk requires that the Board should… identify current and future corporate, clinical, legislative, financial and reputational risks [and] oversee an effective risk management system that assesses level of risk, identifies mitigation and provides assurance that risk is being effectively treated, tolerated or eliminated." The Oversight Board found that capture of the infection risks relating to the QEUH was scant.

155. A dedicated IPC risk register exists, which has been regularly reviewed and submitted to the Board Infection Control Committee for approval – its highest rated risks are then submitted to the Corporate Risk Register. The risk register for 2019 noted key risks that are clearly of relevance to the incidents in the QEUH, for example: "failure to provide appropriate infection control advice and support in the assessment and reduction of risks associated with new builds and renovation projects" (rated in the 2019 document as 'moderate'); and "failure to adequately engage with public and service users" (rated in 2019 as 'low'). However, the description of the risk and mitigation focuses on improved processes – such as the links with key groups and the production of relevant SOPs – rather than any operational set of risks arising from the continuing infection issues in the QEUH.

156. Moreover, the risks of water contamination were not reflected in the Corporate Risk Register. The latter did include a recurring risk of "failure to comply with recognised policies and procedures in relation to infection and control", but this does not relate specifically to the environmental and other associated risks. Indeed, the only reference in the Corporate Risk Register was in June 2019: "there is a reputational risk in respect of the recent issues and concerns expressed to the QEUH, including facilities and environmental issues, capacity flow across the south sector, and intense media scrutiny regarding patient care." This focus on 'reputational risk' does not include a wider sense of the patient safety and financial consequences of systemic water contamination.

157. Apart from a reference to the issue of cladding in the QEUH in the Corporate Risk Register, facilities/environmental risks did not feature significantly. This might reflect the way that risks are phrased and an assumption that more 'operational' risks are captured elsewhere (though where infection does feature, it does reflect operational granularity, as in the focus on maintaining good hygiene strategies to reduce MRSA/MSSA (Methicillin-resistant Staphylococcus aureus/ Methicillin-sensitive Staphylococcus aureus) rates). Given that these issues have proven so damaging to the affected children and young people and families, as well as staff and indeed, the Health Board itself (not least with the escalation to Stage 4), risk management in NHS GGC – at least with respect to IPC and in the context of corporate risks – had not prepared the Health Board properly. This is not to suggest that more visible and systematic capturing of these risks in relevant risk registers would have necessarily led to different courses of action – the lack of reference in the Corporate Risk Register, for example, did not affect the commendable approach to implementing the water dosing system in 2018. But risk management must aim at providing systematic assurance that such responsiveness is neither assumed nor simply dependent on local competence or expertise. Indeed, this does raise difficult questions about whether risk management in NHS GGC as a whole is performing its required role in enabling the Health Board to fulfil its duties, at least with respect to infection issues.

158. Overall, it presents a picture of a Health Board that did not fully – or at least overtly – appreciate the risks and issues arising from the QEUH incidents and act appropriately to address the issues as a result. Such a picture may not, of course, do justice to the commitment and actions of individual staff and services in addressing the huge challenges of the infection incidents. However, at the very least, it should represent a key challenge that the full Board itself should review, not least in the

context of the review of governance and assurance in IPC captured in the Gold and Silver Command programme of work.

159. The Oversight Board recognises that the full Board has initiated work to address wider governance, and that this work has the potential to improve some of the issues identified here. As part of work to embed the Blueprint of Good Governance in the Health Board, it is taking forward a three-stage project to improve its governance and assurance. It has adopted the national principle of ‘‘Active Governance’, which requires NHS Boards to have not only a clear and accurate picture of what is happening within the organisation at a given point in time, but also regard to the wider strategic and policy context in which the Board operates. This is described as:

- ensuring the right things are being considered by the correct individuals/committees;
- ensuring there is a review of the right information and support given to ensure understanding and context; and
- facilitating an appropriate response by committees/Board and thus assessment of scrutiny and assurance can be elicited and governance active ensured.

160. The application of these principles to IPC is not clear at this stage, but early indications show that such links are being made. One of the early steps in this work is defining corporate objectives and allocating them clearly within the governance structure: there is a clear designation of the corporate objective “to provide safe and appropriate working practices that minimise the risk of infection, injury or harm to our patients and our people” to the Clinical and Care Governance Committee as lead. Moreover, in his letter of 3 December 2020 to the Cabinet Secretary for Health and Sport, the Health Board Chair noted that the Health Board’s 2020/21 winter priorities included “the issues around the design, build and maintenance of the QEUH campus, including the legal case and the liaison with the Oversight Boards and the Public Inquiry”. He also noted that a comprehensive review of the existing risk management system has now been commissioned, which will include both corporate and operational risk management. A Senior Risk Officer has been appointed as part of this activity.

161. The Oversight Board welcomes the approach and recommends that the principles are applied to ensuring that IPC strategic and operational risks are captured within this system, and relevant information escalated more effectively, as soon as possible.

162. In addition, the Oversight Board draws attention to whether the Gold and Silver Command programme of work has been considered under the Health Board’s obligations under Part 1, Section 2 of the Children and Young People (Scotland) Act 2014. This places obligations on organisations such as Health Boards to report every three years on the steps they have taken to secure better or further effect of the requirements of the United Nations Convention on the Rights of the Child (UNCRC). Typically this would entail the use of children’s rights and wellbeing impact assessments on key policy and service changes that affect children and young

people.[15] Given the range of UNCRC rights likely to have been engaged by this work, the use of an impact assessment and highlighting of the results in the next three-yearly report would be strongly advised, not least as an active part of risk management going forward.

[15] Children's rights and wellbeing impact assessments: guidance - gov.scot (www.gov.scot).

5. Technical Review

163. Given the prominence of the physical environment in responding to and understanding the infection incidents, the Health Board's systems of assurance, particularly around water safety, are critical. The Technical Issues Subgroup focused on these technical issues of assurance. In the Interim Report, an update was given on progress on the refurbishment and reopening of Wards 2A and 2B in the RHC, following its closure in September 2018. The Final Report focuses on the following remaining issues:

- **NHS GGC's water safety policy**, with specific attention given to its water testing regime and how testing results are being used as part of IPC and the key water and ventilation infrastructure in light of the infections across the hospital site; and
- **NHS GGC's plans to monitor infrastructure improvements** required in response to the issues around the building of the hospital as well as the impact of the chemical dosing system introduced from late 2018 to address water system contamination.

5.1 Review of Water Safety Policy

164. Water safety policy in NHS GGC is governed by a Board-wide policy document, with specific issues covered in a written scheme for the QEUH site. In particular, the written scheme document outlines the specific roles, responsibilities, training requirements and regular maintenance procedures to be followed in order to ensure compliance with statutory and mandatory guidance. Given the heightened importance of water testing against a backdrop of water contamination issues, the policy has a particular significance in providing assurance of the Health Board's ability to handle outbreaks.

165. At the request of the Oversight Board, HFS reviewed the Health Board's water policy and the NHS GGC QEUH campus water systems written scheme. This involved reviewing Health Board documents against national guidance and expectations including:

- SHTM 04-01;
- HSE ACOP L8;
- HGS 274 Part 2;
- BS 7592:2008 Sampling for Legionella bacteria in water systems. Code of practice;
- BS 8580-1:2019 Water quality. Risk assessments for Legionella control. Code of practice; and
- BS 8680:2020 – Water Quality – Water Safety Plans – Code of Practice.

166. HFS concluded that the documents set out a sufficient and appropriate description of the water policy. A number of areas for further improvement were

suggested for the two key documents – the water safety policy and the QEUH written scheme – to add resilience.

- For the QEUH written scheme:
    - point-of-use filter installation and management was not identified, and should be enhanced given the heightened maintenance needs around this in the QEUH;
    - there should be clear patient cohort susceptibility and risk assessments relating to various organisms, particularly environmental ones, to demonstrate that there is a clear recognition of addressing the vulnerability of certain patient groups, given the water contamination risks: those risk assessments should be explicitly referenced (and summarised where useful) and a process for triggering and considering such risk assessments in future should be included in the scheme;
    - a chlorine dioxide management and strategy was not identified – the whole-site dosing system brings additional infrastructure and maintenance issues for the Health Boards which need to be explicitly acknowledged;
    - dental, hydrotherapy and scalding risks should be detailed as appropriate; and
    - it would be prudent to update the formatting of the documents to reflect recent changes, such as BS 7592, BS 8580 and BS 8680 (2020).
- For the water policy: the Health Board should consider a shorter policy document with all detail placed in the QEUH written scheme.
- It is also recommended that there is explicit reference in the documents to who interprets the testing results. From the Facilities and Estates perspective, the renewed focus on the use of Authorised Persons is welcomed, and this would be strengthened with clear links to microbiologists – especially ICDs – in the formal and systematic consideration of results for the site.

167. Sampling procedures are explicitly set out in accompanying documents. Gram-negative bacteria are checked at different frequencies throughout the QEUH, but in targeted locations. For example, regular samples have been carried out in Ward 6A in the QEUH since December 2019, including Pseudomonas and a variety of Gram-negative bacteria; a quarter of outlets are sampled weekly on a rotational basis so the whole ward is covered each month. This would also appear to be proportionate.

168. The governance around flagging any ‘out of specification’ results should be strengthened. There should be a clearly expressed route for raising these results within the IPC governance structures and relevant committees having explicit oversight of high-TVC results with accompanying advice from appropriate Facilities and Estates, IPC and microbiologists presented for consideration.

169. However, the Oversight Board also notes the criticisms of water sampling and testing practice identified in the Case Note Review, particularly in how environmental results were used to support IPC. As recommended in its Overview Report:

> "A systematic, fit for purpose, routine, microbiological water sampling and testing system is required to provide assurance going forwards. How the results from such sampling/testing are recorded, accessible and used to highlight concerns should be reviewed, including to ensure that investigations of possible links between clinical isolates and water/environment sources can be informed in a timely way."

5.2 Plans for Infrastructure Review

170. An enhanced approach to infrastructure maintenance, particularly with respect to water systems, is an inevitable expectation of the Health Board against a context of continuing problems with the building. The site-wide chemical dosing system introduces new maintenance challenges, while the Independent Review set out a number of recommendations which had implications for remedial work on the building. Assurance that actions are being taken to address the identified problems and risks and monitor them going forward is an important consideration for the Oversight Board.

171. With respect to the Independent Review, a detailed action plan is currently being developed in accordance with the methodology set out in the NHS Scotland 'Improvement Focused Governance' guidance document[16]. Each action has a nominated lead executive. The NHS GGC Gold Command Steering Group, 'Better Every Day', will review, monitor and report progress against the action plan to the executive management team and onward to the Finance Planning and Performance Committee.

172. One other issue that the Oversight Board specifically considered was the programme for addressing water taps across the hospital. At the height of the 'water incident' in 2018, it was recognised that taps and flow straighteners were harbouring biofilm and work commenced on swapping the Horne taps with an alternative. However this was halted following the chemical dosing system's installation. Further to the introduction of chlorine dioxide it was demonstrably evident that biofilm was no longer within the flow straightener. This issue will remain under constant review by the Water Technical Group. It has been agreed, however, that during any future upgrading works that the Marwick taps will be installed.

[16] Improvement focused governance: guidance for non-executive directors - gov.scot (www.gov.scot).

6. Communication and Engagement

173. Communication and engagement issues related to the escalation of the Health Board were extensively discussed in the Interim Report, and findings and recommendations were put forward (and set out again in the Summary above). The Final Report is considering another dimension of communications and engagement in the context of the infections: the Health Board's responsibilities (and duties) to review incidents where death or harm has occurred or could result from incidents.. Engagement is not simply about communications during an incident, but how the Health Board had reviewed what happened, its own actions and how patients and families are involved in such reviews of contributory factors. As the Scottish Government's guidance on the organisational duty of candour[17] notes:

> "Openness and honesty should be central to the actions of those providing care to others. It should be at the heart of every relationship between those providing, receiving and/or experiencing treatment and care. Trust and effective communication can be difficult to maintain and easy to lose when things have gone wrong."

174. The Oversight Board has a particular focus on the **organisational duty of candour** with respect to the infection incidents. Parents of some affected children and young people expressed concerns about the Health Board's duties and commitment to a person-centred approach to decision-making on reviews and the associated involvement, engagement and support provided to the children, young people and families through very difficult circumstances. It is important to understand how the Health Board deployed other review processes during these infection incidents, notably **Significant Adverse Events Review** and **Mortality and Morbidity Reviews**. They all form a critical part of NHS Scotland's strategic commitments to quality and improvement, both reflecting statutory and strategic obligations set out in underpinning legislation for NHS Scotland.

6.1 Organisational Duty of Candour

175. The organisational duty of candour procedure is a legal duty to support the implementation of consistent responses across health and social care providers where there has been an unexpected event or incident that has resulted in death or harm, or could result in death or harm, that is not related to the course of the condition for which the person is receiving care. Provisions in the Health (Tobacco, Nicotine etc. and Care) (Scotland) Act 2016 and the Duty of Candour Procedure (Scotland) Regulations 2018 set out the procedure that organisations providing health services, care services and social work services in Scotland are required by law to follow when such an incident has occurred. The provisions were enacted on 1 April 2018, and applied to information considered about earlier incidents that became available after enactment. Guidance setting out how those provisions should be implemented was published in 2018.

[17] Organisational duty of candour: guidance - gov.scot (www.gov.scot).

176. The organisational duty of candour legislation places a legal requirement on health and care providers, including Health Boards, to: review certain types of adverse events; meet personally with those affected to provide an account of the incident; provide an apology on behalf of the organisation; and provide an explanation of the actions that the organisation will take as part of the procedure. Under the duty of candour legislation, organisations must provide their employees with details of any services or support which may be able to provide assistance or support, taking into account the circumstances relating to the incident. Furthermore, organisations must provide patients and/ or their families with details of needs-based services or support, and through meetings and discussions, organisations should determine the impact of the incident on their health and wellbeing.

177. Organisations are required to apologise and to meaningfully involve patients and families in a review of what happened. When the review is complete, the organisation should agree any actions required to improve the quality of care, informed by the principles of learning and continuous improvement. They should tell the person who appears to have been harmed (or those acting on their behalf) what those actions are and when they will happen.

178. Given the vulnerability of the patient group who experienced these infections, the organisational duty of candour would be a highly relevant consideration here. It was actively considered by NHS GGC with respect to patients of the paediatric haemato-oncology service during the period under review. However, it was not formerly activated for any of the specific instances of infection, a concern raised by some of the families.

179. The decision not to activate was in line with NHS GGC policy in support of the organisational duty of candour, which the Oversight Board reviewed. However, the Health Board's policy does not fully reflect the legislation and guidance – primarily in respect of the reliance placed upon harm being viewed to be avoidable and/or related to acts of omission/commission by the organisation. It was focused on the concept of a 'patient safety incident' – which is not a concept set out in the legislation – and did not fully consider the legislative requirement to consider an unintended or unexpected incident that could result in harm (including actual or potential psychological harm). By this definition, a number of the incidents under review were clearly within the scope of the organisational duty of candour.

180. Work on developing how the organisational duty of candour should be implemented in relation to HAI had been initiated by ICDs in NHS GGC. This had identified the need for further action to consider complex interactions relating to the professional duty of candour obligations of clinicians, the organisational duty of candour and balancing related organisational duties relating to confidentiality. NHS GGC should identify the further actions required to address the issues identified by the Oversight Board relating to HAIs and organisational decision-making where concerns are expressed in respect of balancing organisational duties on candour and confidentiality.

181. While implementation of the organisational duty in these circumstances has particular challenges, it is clear that the legislation does not require a view on causation to be determined in deciding whether to activate the duty. This includes

provision for unexpected or unintended events that have resulted or could result in outcomes included in legislation (including increases in treatment) to activate the relevant procedures. National work is progressing on this issue, and some of the issues faced by the Health Board are likely shared by other Health Boards. This work should inform the continuing improvement of the Health Board's policy, but steps should be taken sooner to address the issues set out here.

6.2 Significant Adverse Events Review Policy

182. In the complex systems and practices that underpin much of health and social care, adverse events can be expected to occur, despite the continuing efforts of staff and organisations to provide safe care. When such events do take place, it is essential that those affected most by those events – particularly patients and families – are given the opportunity to understand how they came about. It is equally essential that such events become opportunities for reflection to ensure that there is learning and improvement as a result.

183. For that reason, there is a national approach to reviewing significant adverse events across NHS Scotland. Guidance is provided through the National Framework by HIS[18], ensuring consistency in how they are conducted, recorded, how they are communicated, and how learning can be gathered and disseminated. As the Framework notes: "the national approach seeks to ensure that no matter where an adverse event occurs in Scotland: the affected person receives the same high quality response, organisations are open, honest and supportive towards the affected person, apologising for any harm that occurred."

184. Within NHS GGC, judgements are made on a case-by-case basis. For the patients affected by infection in the paediatric haemato-oncology services, incidents were reviewed by the local clinical teams as well as retrospectively by senior medical colleagues in a few instances.

185. NHS GGC recently updated its policy on how to handle these events in August 2020 (when it was approved by the Board). HIS was commissioned by the Oversight Board to review this policy in line with national guidance as part of its focus on communication and engagement issues.[19]

186. The HIS review found that the revised policy was generally in line with national guidance. The definition and categorisation of adverse events was appropriate, and the system for conducting a review and reporting to the right parts of the governance structure were clear. Overall, the policy was robust, though there were areas of improvement that were highlighted, and which the Oversight Board recommends the Health Board addresses in reviewing its policy.

[18] Learning from adverse events through reporting and review - A national framework for Scotland: December 2019 (healthcareimprovementscotland.org).
[19] Adverse events management within NHS Scotland - gov.scot (www.gov.scot).

- The NHS GGC policy states that there is no requirement for the investigation team to be independent of the service in question. HIS recommends that this wording be reviewed in line with the National Framework which states that "the review team should be sufficiently removed from the event, have no conflict of interest (real or perceived) to be able to provide an objective view". It may be difficult to find the expertise to review cases appropriately in some smaller specialties – including the paediatric haemato-oncology service – but it remains important for Health Boards to strive actively for independence and objectivity as much as is possible.
- The involvement of patients and families in the process should be set out more clearly and explicitly. In particular, it would be helpful to include information in the policy about how patient/family feedback can be used to develop and improve the process. Moreover, families need to be clearly involved in the reviews.
- Further work in relation to assurance of the policy through clinical governance and committees/groups is worth testing to ensure that the right learning and communication to families is being undertaken.
- The language of adverse events is slightly out of alignment, in that NHS GGC refer to 'serious events', rather than the national practice of 'significant events', as instructed by the Cabinet Secretary for Health and Sport. This presents some scope for confusion given the mobility of patients and staffs across NHS Scotland.

6.3 Mortality and Morbidity Reviews

187. Mortality and Morbidity Reviews are key opportunities for learning from experience. In the Mortality and Morbidity Practice Guide[20] produced by HIS, it states that such a review can be:

> "a unique opportunity for caregivers to improve the quality of care offered through case studies. They provide clinicians and members of the healthcare team with a routine forum for the open examination of adverse events, complications, and errors that may have led to illness or death in patients."

They provide a systematic means to reviewing patient deaths or care complications with a view to improving patient care and professional learning. As has been stressed throughout the Oversight Board's reports, the complexity of the challenges arising from the infection incidents has given significant opportunities for such learning to be gathered.

188. Seventeen of the 19 cases examined in the Case Note Review were subject to the Morbidity and Mortality review process within NHS GGC. The other two cases were not reviewed locally as the patients had died in other Board settings – but in 2018, the review team changed its process so that all such cases would be discussed going forward.

[20] Mortality and Morbidity Reviews Practice Guide – Working Version: July 2018 (healthcareimprovementscotland.org).

189. NHS GGC has a number of key documents to support mortality and morbidity reviews. These include the following guidance and practice materials:

- Guidelines for Morbidity and Mortality Review Meetings;
- GG&C M&M Review Process;
- Morbidity and Mortality Meeting Analysis Prompts; and
- Morbidity and Mortality Principles for Practice/Code of Conduct.

190. NHS Education in Scotland (NES) was commissioned by the Oversight Board to review the Board's key documents against national practice guidance (though not the individual cases here). Overall, the NES review concluded: "the guidance content and learning approach advocated are good and are to be commended." Indeed, the Health Board demonstrated that "the importance of these meetings and processes in contributing to effective governance and improvement in care." Where comments were made, they were with a view to improving the approach in NHS GGC.

- In line with modern safety science approaches, it is advised that the concept of 'systems thinking' should be more explicitly incorporated within the guidance. The visible aim should be to better support recommendations for improvement of patient care and working practices at the systemic level rather than simply the individual level – in other words, individual actions and performance should not distract from opportunities for learning across the wider organisation.
- Given the time available, the selection of cases for review at meetings should arguably be informed by the greatest potential for learning and improvement – indeed, 'near-miss' events can often be overlooked but be equally and sometimes more important.
- Consideration should be given to weekly one-hour meetings to support up-to-date review of cases (including what works well and how it can be shared) and prevent backlog.
- Whilst the guidelines are noted for Morbidity and Mortality Review Meetings, there can be further emphasis in describing how these meetings are integrated into NHS GGC's wider governance process. Greater visibility of the learning arising from these meetings – particularly for the wider organisation – should be considered for relevant clinical oversight committees within the Health Board, with a particular view to considering standardising their format.

191. The Oversight Board also notes the Case Note Review comments on these Reviews with regard to infection incidents.

> "The Paediatric Haematology Oncology service should ensure that Morbidity and Mortality reports are not restricted to a review of patients who die. Future Gram-negative environmental infections should be used as a trigger for an M&M (Morbidity and Mortality) review."

7. Case Note Review

192. A Case Note Review was established in January 2020 to examine individual cases of infections. Undertaken by a Panel of independent external experts, the Case Note Review team has examined the case notes of those children and young people in the paediatric haemato-oncology service in the RHC and the QEUH from 2015 to 2019 who had a bacteraemia caused by a Gram-negative environmental microorganism (and selected other bacteria, as identified in laboratory tests). The terms of reference are set out in **Annex B**. While its Overview Report is published separately to this Final Report, the following digest summarises its findings on several of the wider, systemic issues relating to IPC in NHS GGC, and has been prepared for inclusion in this report.

193. As part of its work, the Panel confirmed that 84 patients, with 118 infection episodes, fell within the scope of its review. This included the following:

- One patient had two episodes of infection, the first of which was a Stenotrophomonas spp. bacteraemia, but this was excluded as it occurred prior to the transfer of the hospital to its new site in 2015. This patient remained in the Review because of a second eligible episode.
- One patient had a single episode of bacteraemia within the period of the review, but this was not caused by a Gram-negative environmental (GNE) microorganism; on that basis, both the patient and the episode were excluded from the analysis.
- There was one further patient, who experienced four infection episodes, whose parents did not wish their child to be included in the Review.

194. The Case Note Review final report will review these issues and the individual cases in more detail. This chapter draws out key Expert Panel findings as they relate to the Oversight Board's scope of work, focusing particularly on the availability and use of data within the Health Board, and how potentially hospital (environment) related infections were identified, mapped and responded to.

7.1 Data Issues

195. In examining the microbiological, environmental and clinical data relating to the individual cases, the Expert Panel reached conclusions on a number of issues relating to how NHS GGC has collected, organised and use key data in the infection incidents.

196. Environmental data did not appear to be organised as well as it should have been. The data initially provided to the Expert Panel by the Health Board about water and surface samples were incomplete and without adequate place location identifiers. Samples and their locations were inconsistently labelled and the format in which they were presented rendered cross tabulation with individual patient records almost impossible. This raised questions about how the Health Board was able to make use of such data in its continuing investigation of the bacteraemias.

197. Typing of bacterial organisms is key to understanding whether or not isolates from different patients or from the environment may be closely related/ indistinguishable (ie. evidence for potential common/environmental sources). Reference was found in clinical notes for individual cases in IMT records and in the ICNet and Telepath systems to samples being sent from the isolates identified in patients in the review to a reference laboratory (normally outside NHS GGC). However, this was not done consistently and on many occasions no results were recorded or only a simple statement provided that the bacterial strain in question was described in the lab report as 'unique'. This latter statement is meaningless unless it is clear to how many and which other strains the index strain has been compared.

198. Following discussion with NHS GGC, it became apparent that a database recording all typing data for the cases included in the Review, and contemporaneous environmental samples, did not exist. Indeed, an electronic laboratory record system for typing data appears to have been created only towards the end of the period covered by the Review; prior to this, reports had been received from the reference lab as individual pdf files and filed as such. In order to provide this information to the Panel, NHS GGC had to request resubmission of original data from the external laboratory (Public Health England (PHE) Colindale). In the process of discussing the availability and format of these data with NHS GGC, the Panel reached the conclusion that, notwithstanding concern about, and investigation of GNE bacteraemias in paediatric haemato-oncology patients within NHS GGC over a period of five years, and even by 2020, systems had not been created for the collection, collation, storage or analysis of data in a manner readily available to optimise internal investigations and decision making, either in real time or retrospectively.

Use of Data Systems

199. Telepath is the laboratory information management system used in NHS GGC. The Panel found that it generally provided good evidence of frequent engagement between the microbiology and clinical teams in sharing information, including about the identification of infecting organisms and their susceptibility profiles to guide optimal antibiotic therapy choices.

200. The ICNet system relies on data being transferred from Telepath when an organism is identified for which a pre-set alert exists. The National Infection Prevention and Control Manual (NIPCM) provides a nationally-agreed minimum list of alert organisms/conditions. The purpose of this list is to alert NHS Boards of the occurrence of these organisms/conditions, which may require further investigation. The guidance states: "the list is not exhaustive and specialist units, for example those managing patients with Cystic Fibrosis, will also be guided by local policy regarding other alert organisms not included within these lists". However, the Panel found little evidence, even as late as 2019, that the NHS GGC alert list had been modified in light of the evolving experience with GNE bacteraemias. This resulted in frequent absence of alerts being triggered within ICNet, and the subsequent absence of IPC input in episodes of GNE bacteraemia in the cases reviewed.

Patient Location Records

201. The locations of patients during hospital attendance and inpatient stays were obtained from Trackcare. Whilst a specific bed was identified for almost all inpatient stays, the system did not provide locations to the level of a specific bed space when patients were receiving day care in Ward 2B or, subsequently, in Ward 6A. This limited the capacity of the Panel to assess specific locations of care as risk factors for infection.

202. One unexpected issue was the continuing coding of haemato-oncology day care patients as attending Ward 2B after the date both Wards 2A and 2B were closed in September 2018. This occurred inconsistently within individual records and, although the Panel was made aware that Ward 2B was used for the RHC pre-assessment service from 29 April 2019 to 15 November 2019, it was assured that no haemato-oncology patients attended that area during this period. It seemed self-evident for the benefit of tracking purposes that patients should never be coded to an area other than that which they physically attended.

203. It was often difficult to identify from the clinical records in which operating theatre surgical procedures took place. It was also likely that procedures (for example, bone marrow sampling and lumbar puncture procedures) were undertaken in anaesthetic rooms, also without a record of the location.

Clinical Records

204. The NHS GGC Clinical Portal stored scanned copies of written inpatient medical notes which should be dated to the day of discharge. For the episodes included in the Review, complete written notes were found for 65 percent of cases, incomplete notes for 18 percent and no written notes for 16 percent. Of the episodes identified with written notes, 61 percent were filed under the date of discharge, but written notes for other episodes were found to have been filed up to 14 months after the date of discharge.

205. The Clinical Portal also contained digital inpatient medical records for some patients. These records include Generic Continuation notes. These were not linked to specific admissions and contained diverse inpatient and outpatient records from different professions and specialties. If the Generic Continuation was labelled Paediatrics, then it usually contained digital inpatient medical notes. These were detailed and fully electronic, which enabled word searching. However, these notes might cover several admissions and the median length of records for patients in the review was 12 months (maximum 35 months). These structural issues made the searching for data from records in the clinical portal very difficult at times.

7.2 Addressing Bacteraemia Clusters

206. The Panel also examined how bacteraemia clusters (possible outbreaks) were investigated. In the initial stages of investigation, thresholds for calling a PAG or subsequently proceeding to an IMT did not appear to evolve during the period of the review, despite the continuing existence of concern about GNE bacteraemias over

several years. There seemed to have been little recognition that the use of standard definitions of an outbreak may be less useful in a situation where unusual infections emerge in relatively small numbers within a small subset of the overall hospital population (as was the case in paediatric haemato-oncology). Some IMT minutes and other internal reports seen by the Panel that have analysed data about infection trends may also have provided inappropriate reassurance from the use of SPC methodology without accurate ascertainment of an appropriate baseline.

207. There were examples of PAG meetings being called separately for clusters/outbreaks of different microorganisms despite the fact that they were all GNE bacteria occurring within a closely-related timeframe. There were also examples where, contrary to the Panel's expectation, an IMT appeared to be either never called or terminated prematurely. In other situations, IMTs were called to investigate bacteraemias caused by specific organisms, but did not always recognise and document the concurrent emergence of other GNE infections. Opportunities for seeing the wider picture were likely lost by this approach.

208. Distinctions between hospital-acquired and healthcare-associated infections sometimes appeared to have been considered important in discussion of the significance of a reported bacteraemia. Yet it was clear that the utility of these definitions was less informative in a clinical setting where patients are attending for day care or outpatient appointments at the very high frequency seen in this patient group.

209. Root Cause Analysis (RCA) methodology was only agreed as the basis for future IMT investigation in late 2019 and applied prospectively in two patients in the Review. The template subsequently created to support RCA goes beyond the HPS Outbreak/Incident Data Collection Tool provided as an appendix to the NHS GGC outbreak SOP.

210. A requirement (or even recommendation) for the use of RCA did not feature in the NHS GGC 2020 Outbreak SOP and it is hard to see why, given the experience of repeated GNE bacteraemias over five years, this would not have been introduced earlier or more generally. The Panel noted, however, that recommendations for use of a structured approach to the investigation of infection using RCA methodology did not feature nationally in the NIPCM.

211. IMT minutes were not always easy to understand in retrospect – patients may not have been identified in a way that would allow them to be tracked across a series of meetings; staff were not identified by their role; the structure of the documents varied and the style was sometimes informal; actions were not presented or summarised in a consistent way; and recording of progress in following up on previously agreed actions was inconsistent (including whether these were implemented and/or sustained).

212. IMT action logs were rarely apparent either within the minutes or separately, which must have limited the ability to track completion or evolution of actions from one meeting to the next either within an IMT sequence or between consecutive IMT sequences. This suggested a fragmentation of approach and risked lack of learning for the future.

213. The Panel did not see 'hot debrief' or full reports at the close of a series of IMT meetings relating to cases included in the review despite this being mandated in the NHS GGC outbreak SOP. Examples of such documents had been provided to the Panel from IMTs in other clinical areas within NHS GGC, raising questions about consistency in practice across the organisation.

214. The SOP also indicated that these reports should be signed off by members of the IMT and sent to the Acute Infection Control Committee from where upward reporting was expected to the Board itself. There was little or no documented evidence that IMT members were asked to approve such reports, even if they existed.

215. Whilst it was evident from NHS GGC Board papers that reports about the problems encountered within Wards 2A/B and subsequently 6A were provided at Executive level, the significance and scale of what was happening might not have been adequately expressed. By way of example, the HAIRT report made to the NHS GGC Board on 17 October 2017 stated only the following:

> "Two cases of Stenotrophomonas maltophilia bacteraemia were identified over an 8-day period in July. A Problem Assessment Group (PAG) was held on the 26.07.17. HPS were notified and a Healthcare Incident Infection and Outbreak Reporting Template (HIIORT) was completed. No further cases were identified and the two cases were later confirmed to be different types".

It was not why it was important for the Board to hear that there had been two infections, that they had been appropriately reported and that they were considered to be of different types but not to be told that one of the children had died. The Expert Panel was told by NHS GGC that the infections and the death were reported at the Board Infection Control Committee but that, as the full Board was a public meeting, there was a need to ensure awareness of infections but no requirement to discuss individual patient details (for patient confidentiality and Data Protection reasons). However, the Expert Panel noted that the occurrence of another bacteraemia, caused by the same organism, earlier in the same year, following which the child also died, was not reported to the Board. This showed an inconsistency in the process and purpose of reporting and could represent an organisational culture which promoted a focus on process (ie. that a report was received) rather than being clear what the cause or consequences were.

216. There were occasions when the minutes record that clinicians presented at an IMT directly questioned if the environmental risks had been reported to senior management within NHS GGC; this was mainly in 2018 and 2019, but there was also an unsubstantiated suggestion that this could also have been in 2017 (the Panel did not see written evidence for this). It was interesting to hear, at a meeting with RHC clinicians in February 2020, the IMT process described as "lacking integration and fails to recognise patterns". This simple statement reflected the overall impression of the Panel.

217. The Expert Panel was less able to form a view of the overall effect on the clinical service although it was obvious that disruption was substantial, particularly in relation to the decisions to close Ward 2A and 2B in September 2018, to move patients out of Ward 6A for a short period at the beginning of 2019, and to limit admissions to Ward 6A in the summer and early autumn of that year. Throughout the Review, the Expert Panel saw few documents prepared by the clinical team, NHS GGC management or the Managed Service Network that set out an analysis of how these decisions affected the overall delivery of paediatric haemato-oncology care. Measures that would have been of interest were, for example: timeliness in delivering planned chemotherapy; deferral of planned treatment (eg. surgery, radiotherapy, stem cell transplantation); use of shared care; and transfers to other units.

218. Two documents were provided. One was an audit of admissions with bacteraemia from 1 July 2017 to 31 August 2018, which looked at characteristics of patients affected by age, gender, diagnosis and the profile of the microorganisms causing infection and their antibiotic sensitivities. The main focus of the audit seemed to be on defining the optimal choice of empirical antibiotics: it did not attempt to look at the observed frequency of bacteraemia against that which might have been expected. The second document was an analysis of episodes of care transferred to other wards/hospitals/Health Boards for delivery of chemotherapy. It related to data collected from 29 July 2019 to 4 November 2019, during the period when there were restrictions on admission to Ward 6A. Short-term adjustment to patient flow is expected under such circumstances and it was good that these transfers were able to take place to limit delay to treatment. It seems, however, that there may also have been some more permanent change to shared care activity as a result of the impact of these infections. The wider development of shared care with local hospitals may have been helpful to individual families in offering more care closer to home, but appropriate structures and processes are needed to ensure that a shared care network is both supported and safe. Evidence was not provided that the issues that arose at NHS GGC were supported by any action from the Managed Service Network.

8. Conclusions

219. The core of the Oversight Board's work has been the issue of assurance. Escalation arose from a history of complex issues that the Health Board had been experiencing since at least the opening of the QEUH, but the primary matter that gave rise to Stage 4 was a question of the 'fitness of purpose' of NHS GGC with respect to how IPC has been conducted in the QEUH, the way that governance has operated in relation to these infection incidents and the communication and engagement approach that has been placed under scrutiny by these events. Understanding the history of what has happened to the group of paediatric haemato-oncology patients and their families has been essential for the Oversight Board, but providing the full narrative and conclusions to be drawn on that history has properly been the prerogative of the Independent Review (and will be that of the Scottish Hospitals Inquiry). History is critical in ensuring that the right lessons are learnt. However, this Final Report has not sought to provide a complete account of what has happened, and by extension, an analysis of the individual and collective failures that have occurred.

220. In setting out this series of recommendations, the Oversight Board acknowledges that several are based on steps NHS GGC has already taken in recognition of these shortcomings. Throughout the period of the Oversight Board's work, significant improvements have been proceeding in parallel – indeed, some pre-date the decision to escalate, such as the substantial improvements that have been introduced in the operations and governance of Facilities and Estates, but clearly accelerated through the current Gold and Silver Command programmes. The Oversight Board has seen a clear commitment by the Health Board to start making the necessary improvements, a willingness that has underpinned the Health Board's engagement with this process.

221. In that spirit of cooperation, and on the basis that this is part of a wider trajectory of improvement for the Health Board, the Oversight Board believes the following changes are necessary to embed new improvements and accelerate improvement. This final chapter starts with the **findings** of the Oversight Board on the set of questions set out at the start of this report, then under each of the headings for the issues that led to escalation, a set of **recommendations** is described. Lastly, the next steps and **way forward** are set out.

8.1 Findings

222. In reviewing the material through the work of the Subgroups and the other commissioned work, the Oversight Board's investigation of the issues for escalation have crystallised around four key questions. As already noted, they link together, each contributing to a web of issues that have not always been easy to separate or understand the inter-linkages. The first question represents the fundamental challenge faced by the Health Board; the next three focus on how NHS GGC responded to this fundamental challenge, in line with the issues that gave rise to escalation.

i. To what extent can the source of the infections be linked to the environment and what is the current environmental risk?

ii. Are IPC functions 'fit for purpose' in NHS GGC, not least in light of any environmental risks?

iii. Is the governance and risk management structure in NHS GGC adequate to pick up and address infection risks?

iv. Has communication and engagement by NHS GGC been sufficient in addressing the needs of the children, young people and families with a continuing relationship with the Health Board in the context of the infection incidents?

(i) To what extent can the source of the infections be linked to the environment and what is the current environmental risk?

223. This has become a key question over the last few years. It is clear to the Oversight Board that the infections have taken place against a background of systemic water contamination. As the HPS report in 2019 stated:

> "Between the period of 29th January and 26th September 2018, 23 cases of blood stream infections (11 different organisms) with organisms potentially linked to water contamination were identified. As a result further testing of the water supply was undertaken across both hospital sites early in the investigation. This testing identified widespread contamination of the water system."

However, what is less clear is the extent to which these environmental issues can be linked with specific infections. As the Independent Review concluded:

> "In the course of the Review, through examination of documentation, listening to witnesses, discussion with experts and input from the Review's expert advisers, and site visits, we have not established a sound evidential basis for asserting that avoidable deaths have resulted from failures in the design, build, commissioning or maintenance of the QEUH and RHC."

224. Pathways between water contamination and specific infection incidents have proven very difficult to establish by the Health Board itself, as the succession of hypotheses looking for sources of infection in the individual incidents has shown. However, in the absence of definitive sources, the strong possibility of a link has been – in the Oversight Board's view – undeniable. The Case Note Review concluded that a link was 'most likely' in 31 percent of the cases (ie. 'strongly probable', 'probable' and 'strongly possible' cases), noting that "by 2018, we suggest that simple observation should have identified a disturbing pattern characterised by the occurrence of bacteraemias caused by some very unusual microorganisms and apparent clusters of some of those more commonly encountered." In parallel, by 2018, there was significant evidence coming from clinicians and micro-biologists drawing attention to a succession of environmental defects within the hospital which could be typically linked with infection risks.

225. The question arises did the Board take the right actions at the right time in face of the balance of probability of water contamination. In reviewing this question,

the Oversight Board acknowledges the exceptional challenges of the situation presented to the Health Board and the difficulties in establishing a clear picture of what was happening. The cases themselves did not necessarily suggest a pattern at first. Before 2018, water testing results did not provide evidence of water contamination (although the evidence of the DMA Canyon reports suggests that this evidence may be mixed). However, this is less a matter of numbers and whether infection rates were significantly different from other locations, but a reflection of the timing and sharp increase in infections, the diversity of organisms encountered, and the fact that a modern hospital should not be expected to see a sequence of infections like this.

226. A key moment of reflection was before the 'water incident' in 2018. Hindsight can only be partially helpful in this instance, but it is impossible not to speculate what action might have been taken, for example, had the DMA Canyon water report of 2015 (or indeed, 2017) been escalated to relevant staff and senior managers at an earlier stage. It is hard not conclude that this was a missed opportunity.

227. Through 2018 and beyond, it is clear that the Health Board accepted there was environmental risk by the actions it took in response, including the de-canting of Wards 2A and 2B, the introduction of chemical dosing, and in 2019, the temporary closure of Ward 6A. However, environmental risk has not featured more systematically and consistently in the consideration and actions across the Health Board. Much of the Health Board's response has been reactive – understandable in terms of immediate action to address individual incidents, but with a limited longer-term perspective and framework for action over the period as a whole. There is a strong record of IMTs focusing appropriately and effectively on specific incidents, often with a comprehensive set of measures to address the relevant issues, including cleaning regimes and programmes to replace parts of the water infrastructure. However, there has not been a comprehensive review of the potential risks across the hospital and all patient groups and how to address them across the period – one that considers the clinical, environmental, financial and public assurance risks of water contamination holistically and for the site as a whole. Applying the risk of water contamination in a consistently predictive and pro-active way was not evident. As the Case Note Review noted in its chapter in this report, there seems to have been a greater concern with process rather than risk and impact.

228. Strong remedial action has been taken by the Health Board. Given the water testing results, the chemical dosing system appears to have proven effective, Nevertheless, it is clear from the work of the Independent Review that there are significant problems associated with the building that will take time to unpick and fully rectify. The Oversight Board notes that there continue to be unusual environmental bacteria incidents at different points in the site. Whilst unusual environmental bacteria occur in all healthcare settings, the risk must continue to be monitored, evaluated, mitigated and reported. In light of this, ongoing vigilance is required with regards to effective control measures, good IPC, surveillance and risk escalation to maintain patient safety. The actions that the NHS Board has already taken, along with implementation of these recommendations, will ensure appropriate management of a safe and effective environment for patients.

229. The national dimension is highlighted by this question as well. While the Health Board had clear responsibilities and duties here, they turned for support and advice at different points to national bodies and the Scottish Government. The complexity of the issues faced by the Health Board was equally faced by these national bodies. Although the circumstances leading to the decision to escalate the Health Board reflected the specific problems and actions of NHS GGC, the incidents should be reviewed as a point of national rather than simply local Health Board concern. If there are shortcomings found by the Oversight Board now in how the Health Board was applying a strategic understanding to the implications of water contamination, they were not shortcomings highlighted nationally to the Health Board at the time. The Health Board has an acute need to learn from this, but the benefits of the learning will be for NHS Scotland as a whole.

230. The environmental risks associated with hospitals and infection control are increasingly better understood – not least through the efforts of NHS GGC in the course of these incidents – but there is more that could be done nationally, and arguably, should have been done before now, in terms of understanding the nature of those risks and developing and putting in place recognised good practice in how to address those risks. The Scottish Hospitals Inquiry will shed further light on these issues, but the Oversight Board believes that there is need for national action in advance of this. The recommendations below reflect on areas of national improvement and common, if not standard approaches, not least with respect to water testing and the collating and sharing of results.

(ii) Are IPC functions fit for purpose in NHS GGC, not least in light of any environmental risks?

231. The Oversight Board has already commented on aspects of IPC within NHS GGC in the Interim Report. That report noted that throughout the series of outbreaks, the Health Board was quick to react to individual incidents with clear IPC actions, and indeed showed capacity to learn and improve. For example, this was demonstrated by the establishment of the Technical Water Group in 2018 to provide a multi-disciplinary focus on the risks of water contamination and the options for addressing these across the site. IMTs were regularly held and responded systematically to trying to understand the source of infections and taking steps to mitigate the risks. Moreover, the willingness to take steps that were highly challenging, but justified by the risks to care and safety, was notable, not least in the decision to close Wards 2A and 2B in September 2018.

232. However, as the Interim Report detailed, these instances were not sufficiently consistent to provide full assurance. When examining a number of the key processes of IPC – such as the use of HAIRTs and the approaches to audit and surveillance – the Oversight Board concluded that there were necessary improvements to be made, and these were set out in the Interim Report recommendations. The Interim Report found that the IPC Team was still working in silos and not fulfilling its role as the service that embeds improvement and mainstreams good IPC across the Health Board. Moreover, work across different IMTs was hampered by the lack of systems for tracking actions and reviewing data.

233. Reviewing the history of how IPC in the QEUH responded to the incidents in detail, the Oversight Board would add a number of other findings.

- IPC's approach to the challenges was dominated by an incident-based, reactive approach. Imagination and determination were evident in how specific issues and incidents were addressed – especially in 2018 – but the ability to see and act on a wider perspective framed by the environmental risks and the infection incidents was not apparent. By 2019, the presumption of a water contamination risk should have been more explicitly considered. There also was no thorough and systematic consideration of the wider risks across the site of water contamination in terms of patient safety and environmental impact, or at least, it was not explicit. Apart from the introduction of the water dosing system – which the Oversight Board commends in terms of how this was put in place – a strategic approach to addressing these IPC risks was not evident.
- This reactive approach has been further hampered by the lack of systematic processes to examining infections and recording and following through key actions. The absence of data systems that bring together microbiological and environmental testing across the period suggests that the Health Board has not been in a position to examine these outbreaks as effectively as it should. As the November 2019 HPS report noted: "the microbiological and clinical data should be set in the environmental context including the environmental microbiology results such as water and ventilation sampling." The absence of continuing recording and monitoring of actions across different IMT meetings suggests that the Health Board has been taking short-term and reactive approaches to addressing the incidents (with the exception, as noted, of more exemplary decisions such as the introduction of chemical dosing). Moreover, as the review of HIIORTs in the Interim Report underlines, there are questions over whether the Health Board has been reviewing the risks associated with particular infection risks in a satisfactory way.
- As noted by the Case Note Review, there was little change in the thresholds for calling a PAG or proceeding to an IMT across the period. Given the recurrence of incidents, there should have been more active consideration of whether the standard definitions of an outbreak (as set out in the Health Board's own SOP) might need to alter to address a situation where unusual infections emerge in relatively small numbers.
- The Oversight Board received assurance on both the water safety/testing policy of the Health Board and its arrangements for addressing the building issues that have been exposed in recent years. Nevertheless, it notes the recommendations by the Case Note Review for improvements in how water testing and sampling are taken forward and the results used to support IPC.

- IPC requires active and strong relationships between a variety of staff and Health Board functions. These relationships were weak throughout much of this period. This was particularly mirrored in the poor links that have existed between IPC and key services, especially Facilities and Estates. The failure to act on the 2015 DMA report has already been discussed, and there were related issues with the provision of water testing results to IPC on a timeous and jointly cooperative basis. Moreover, some relationships between and among microbiologists and IPC were fraught within the QEUH and allowed to compromise effective working of services. It is clear that building better cooperation has been a priority within the Health Board through the recent Organisational Development work (and earlier, the changes introduced into Facilities and Estates), and the Oversight Board welcomes this focus on resolving these issues.
- The scale and intensity of the IPC issues facing NHS GGC strongly suggest the importance of adapting the leadership structure of IPC. The need for more dedicated roles to support IPC and a long-term solution to the Executive responsibilities for IPC has become increasingly clear through the continuation of these incidents. The Oversight Board welcomes the Health Board's recognition of this and the strengthening of leadership and management within IPC through the Silver Command work.

234. The Oversight Board recognises the significant work undertaken by the Health Board to address these issues. Once the Recommendations set out here (and in the Case Note Review) are being implemented, the Oversight Board will have the necessary assurance that the IPC issues that led to escalation will have been sufficiently addressed.

235. These findings also echo some of the findings in Lord Maclean's 2014 report from the Value of Leven Inquiry[21]. Since it was published, NHS GGC has set out its implementation of that report's recommendations in full. The findings suggest a continuing need for the Health Board to be vigilant so that there is no recurrence of some of the problems identified by Lord Maclean. This seems to be particularly evident around the importance of strong, functioning IPC Teams, effective surveillance systems and robust channels for escalating and acting on key IPC issues. As already noted above, while the focus of any shortcomings are on NHS GGC, the implications of these issues must be recognised as national in scope, and demand national attention and action (as the recommendations will emphasise below).

(iii) Is the governance structure and risk management in NHS GGC adequate to pick up and address infection risks?

236. Leadership within a Health Board does not simply rely on the quality of key individuals, but how the organisation's governance systems are designed and operated in providing assurance and ensuring fidelity to organisational aims and decisions and NHS Scotland values. How that governance worked with respect to

[21] https://webarchive.nrscotland.gov.uk/20170401011220/http://www.valeoflevenhospitalinquiry.org/report.aspx.

these incidents was a critical question for the Oversight Board. The reasons that gave rise to escalation were not sudden developments, and elements of them were arguably 'predictable' in light of the continuing problems with the QEUH given the prolonged problems and the increasing anxiety of the children, young people and families. It is legitimate to ask how senior levels of governance were made aware of the nature and scale of the problems over different points of the period and their responses.

237. As already noted, this leads to some overlap with the work of the Independent Review, and indeed, there is an artificial distinction to be applied to looking at the troubling history of the commissioning, design and handover of the building from an IPC perspective and how the incidents that arose thereafter were addressed. The events do not separate themselves neatly into distinctive bundles of issues, not least in terms of how the staff in the Health Board and the children, young people and families experienced them. But the Oversight Board has maintained a primary focus on responses to the infection incidents and understanding what took place, rather than how any shortcomings or issues with the building itself.

238. The Blueprint for Good Governance NHS Scotland has articulated the principles and practice of good governance in Health Boards. As the Blueprint sets out: "good governance is essential in addressing the challenges the public sector faces and providing high quality, safe, sustainable health and social care services depends on NHS Boards developing robust, accountable and transparent corporate governance systems." Amongst other responsibilities, good governance should identify current and future corporate, clinical, legislative, financial and reputational risks.

239. Against this test, there were significant failings in governance at key points. The receipt of the 2015 DMA Canyon report should have alerted NHS GGC at its most senior level to the fact that there were potential issues with the water system – but this report was 'lost' by Facilities and Estates at the time. Indeed, the DMA Canyon report of 2017 contained most of the same recommendations, suggesting that little or no action was taken with the 2015 report. Early and widely-broadcast warning of these issues would almost certainly have resulted in an accelerated focus and attention on what was going on (though it may not have avoided the same problems with identifying a source of infection in the incidents). This breakdown of responsibilities was a critical failure within the Health Board in the early stages of these incidents.

240. With respect to its role in assurance of the current systems, some of the issues that caused that breakdown have been addressed, particularly within Facilities and Estates. This has become part of the systematic review of IPC governance and procedures captured in the Gold Command work, and which are summarised in the governance and assurance description in **Annex E**. However, the Oversight Board is not yet assured that the wider weaknesses in governance this exposed have been fully addressed. The steps towards developing a clear description of IPC assurance and accountability have been welcomed, not least through the wider work on governance being led by the Chair. This should be accelerated with respect to IPC governance.

241. In many respects, the problems with governance can be presented as a series of breakdowns in parts of the Health Board (such as Facilities and Estates): in other words, the right channels for reporting and escalation were in place, but specific areas were not using them to draw sufficient attention to higher levels of governance. Nevertheless, while there was good evidence of assurance on the actions being taken, challenge was not apparent from minutes of meetings, and questions can be raised about whether the succession of incidents was sufficiently interrogated. Relevant committees and the Board were updated on developments, but the absence of more explicit direction and inquiry is not apparent from the record.

242. The review of escalation also underlines the difficulties of key IPC issues being raised by key IPC staff within IPC governance. The Oversight Board notes that some Health Boards facilitate the ability of Lead ICDs – for example – to raise particular concerns more easily and directly with relevant oversight committees. That approach might not be easily applied for a Health Board of the size and diversity of NHS GGC, but it is important that escalation processes are reviewed in light of the experience of the incidents.

243. These issues were further reflected in the absence of the infection incidents in risk management. The lack of full consideration of environmental risks is notable through this period. The approach to infection risk management needs to reviewed by NHS GGC, given the significant clinical, financial and ultimately, reputational damage that the infection incidents have caused. Governance cannot be expected to operate properly without the backbone of strong risk identification, analysis, recording and monitoring.

244. The incidents suggest the need to bring together the work of different parts of the governance structure for a more comprehensive overview, notably that covered by the Facilities Planning and Performance and the Clinical and Care Governance Committees. In a Health Board as large as NHS GGC, there is always a challenge of improving how cross-cutting issues can be addressed by the governance system as a whole. The work being put in place by the Health Board is a commendable step towards making the necessary changes. With good progress in implementing the relevant Recommendations below, the Oversight Board will have the necessary assurance that the issues giving rise to escalation will be addressed.

(iv) Has communication and engagement by NHS GGC been sufficient in addressing the needs of patients and families in the context of the infection incidents?

245. The Interim Report has already set out the Oversight Board findings with respect to communication and engagement issues. The Interim Report found the following.

- Within the paediatric haemato-oncology service, families were experiencing the prolonged impact of the potential problems in the clinical environment on their children, with significant disruption and uncertainty. Clear and regular communication and engagement was particularly vital.

- In that context, there was substantial evidence of a compassionate approach to communication by frontline staff. Transparency and sensitivity were regularly balanced in a way that families regarded positively.
- However, such an approach was found to be inconsistently applied across the Health Board. Too many patients and families felt that communication was not timely or fulsome, particularly from more 'corporate' services (as opposed to frontline staff); they felt they were too often the last to know and an impression deepened over the years of not being presented with a full and accurate picture of what was happening in relation to the incidents which has left a legacy of distrust among some families.

246. Another critical aspect of engagement is how the Health Board carried out its legal responsibilities to investigate and share information where deaths or serious failings have occurred. In this final report, the Oversight Board examined this with respect to the organisational duty of candour and the policies on SAERs and mortality/morbidity reviews.

- The organisational duty of candour was not activated for the infection incidents under review. The Health Board did not fully consider the legislative requirement to consider these cases in terms of how they could have resulted in harm, including actual or potential psychological harm. By this definition, a number of these incidents were within the scope of the organisational duty of candour. Concerns about competing organisational duties of confidentiality could have been addressed through more proactive engagement and involvement with the affected families and clinicians.
- However, with respect to the policy for SAERs and mortality/morbidity reviews, while noting areas for improvement, there are robust policies in place for these review processes within NHS GGC.

247. Through the Gold Command work, the Oversight Board understands that many of these issues are being addressed within the Health Board. Again, progress in taking forward the Recommendations here and in the Interim Report, the Oversight Board believes that the issues that gave rise to escalation will be addressed.

8.2 Recommendations

248. The recommendations of the Oversight Board are rooted in these findings. As already noted, the Interim Report has already set out recommendations on a number of issues – these have been included again in the Summary section at the start of this Final Report.

249. The recommendations note that there are important lessons for NHS Scotland as a whole as well as specifically for NHS GGC – indeed, the unusual experiences of the Health Board could provide important lessons for Scotland as a whole. The recommendations are based on what is required by the Health Board to provide assurance to justify de-escalation from Stage 4. In terms of the Key Success Indicators of the Oversight Board, set out in **Annex D**, they identify the changes that

would be required to ensure that these success indicators can be met and assurance restored.

250. The recommendations are grouped according to each set of escalation issues – IPC, governance, and communication and engagement – as well as a more general group of recommendations at the end. National recommendations are set out in the **green** boxes below.

Infection Prevention and Control

251. Some recommendations for IPC have already been set out in the Interim Report. These are not repeated here.

252. The Final Report recommendations address the remaining IPC issues: the responsiveness of the Health Board's IPC to the infection incidents; the effectiveness of joint working in support of IPC in the QEUH; the strength and organisation of leadership in IPC; and the national dimension to improvement in these areas.

Recommendation 1: ARHAI Scotland should lead in developing and implementing a research programme to address any current gaps in the understanding of environmental infections and how hospitals can address them.

253. The lack of research and guidance that was available for the infection issues associated with the QEUH hindered NHS GGC's response. Much of its approach was necessarily reactive but given the lack of policy and guidance this should not have been wholly unexpected. Now that this experience has been gained, both the Scottish Government and the Health Board should consider how best this knowledge can be retained and utilised going forward – nationally, with respect to NHS Assure, the new national Centre of Expertise, and locally, in relation to how NHS GGC can respond better to any future such incidents – to ensure that investigation of any further incidents can be resolved much more quickly and effectively.

254. It is particularly clear that there are continuing gaps in the research and guidance available when it comes to managing an infection or outbreak suspected to be associated with the water supply. Further research needs to be undertaken to gain a detailed understanding of how unusual environmental bacteria can develop within a water system and how they can be transmitted from water systems to patients. Similarly, further work is needed on understanding how biofilm can grow, the time it takes, how it impacts on the growth of such bacteria and how such organisms mutate. It is important that future research takes account of the conditions in a sealed water system so that it is applicable to both new and existing hospitals.

255. The research should also take into account the occurrence of unusual environmental bacterial and fungal infections and outbreaks so that a baseline can be established on what should trigger consideration of 'unusual' levels of such infections, especially with respect to patients with suppressed immune systems.

256. Consequently, in collaboration with NHS GGC and other relevant bodies, ARHAI Scotland should set out a research programme identifying where the research and practice gaps are where further understanding is required and how such research can enhance the practical guidance available for Health Boards nationally. This should be set out by September 2021.

Recommendation 2: There are a number of existing national recommendations that were made in the 2018 Health Protection Scotland report that have yet to be fully implemented. ARHAI Scotland should provide an update and time-bound action plan for implementing these.

257. The national implications of what has happened at the QEUH have been raised at different points in the past, and indeed, clear recommendations have already been made historically (such as the Independent Review). These recommendations remain critical priorities for national action. The Oversight Board recognises that there has already been learning arising from the experience of the QEUH, but there is an urgency to ensuring that these lessons are mainstreamed across NHS Scotland as a whole.

258. The experience strengthens the existing recommendations for a national review of water infrastructure across the NHS Scotland estate, the establishment of a single, clearly-authorised national water review group and relevant changes to national guidance. An update and action plan (with clearly set and bound timescales) for implementing these recommendations, taking into account what has been set out in the Interim and Final Reports of the Oversight Board, should be provided to the Scottish Government by ARHAI Scotland by June 2021.

Recommendation 3: Strengthened arrangements for IPC, commensurate with the complexity and size of the Health Board, should be put in place in line with relevant national guidelines.

259. As part of strengthening the IPC arrangements within the Health Board, the Oversight Board recommends that consideration is given to securing a more dedicated Executive role for IPC. Such a role has emerged from the work of Professors Bain and Wallace, and the Oversight Board recognises the improvements that have taken place in IPC in NHS GGC as a result of their efforts. This role should have several overarching goals: it should provide a clear operational remit for IPC and dedicated senior-level oversight of emerging infection issues; it should be responsible for strategic forward planning, not least with respect to pursuing a continuing improvement agenda for NHS GGC, but also in ensuring the implementation of recommendations made by successive reports are embedded across the organisation; and the post-holder should be part of the Board and provide regular updates and lead Board-level consideration of infection issues and risks as appropriate.

260. It is recommended that the Health Board takes forward a long-term, permanent recruitment for this role as soon as practicable. It also recommends that

particular attention is given the level of expertise and IPC knowledge required of candidates for this role.

261. An early priority for this role should be ensuring that the resourcing, expertise and structure of IPC – particularly with respect to the QEUH – is sufficient (within the context of the existing Silver Command work), and that the recommendations set out here are taken forward as quickly as possible.

Recommendation 4: **The structure of IPC should reflect the continuing need to address the complex and continuing issues within the QEUH. IPC resourcing and skills should be reviewed, and active consideration given to whether there should be appointment of specific IPC roles with QEUH responsibility.**

262. The expertise and resourcing of the IPC Team at the QEUH should be reviewed as part of the Silver Command work currently underway. Interim roles should be filled permanently as soon and as appropriately as possible. Potential new roles to support capacity should include consideration of additional capacity to support any further work that might be required, such as driving the key improvement programmes and work being set out as part of Silver Command action plans (and not least with respect to the recommendations presented here).

263. The skills and knowledge required to deal with the complex issues facing the Health Board such as water and ventilation expertise should also be developed within the current workforce where absent. Workforce planning for IPC – particularly in the QEUH – should ensure that there is sufficient expertise and specialisation in key areas (such as water and ventilation) and ensure it is accessible among ICDs across the whole of NHS GGC. The Oversight Board notes that the Independent Review recommended that those with IPC as part of their job role should undergo regular performance appraisal; this should be considered as part of this work, both by NHS GGC and ARHAI Scotland as part of wider work referenced in other recommendations made here.

Recommendation 5: **NHS GGC should ensure that there is a full, effective and standardised approach to the relevant microbiological, water testing and other information regarding the QEUH outbreaks. Relevant data should be integrated in a way that allows effective collecting, recording and analysis of information relating to the incidents, which will be reported through the IPC governance system.**

264. There was no readily available, clearly organised and accessible database in NHS GGC for recording microbiological typing results to ascertain links between patient and environmental isolates. Such a database would have been valuable in supporting more systematic and longitudinal analysis of the infection outbreaks to support IMTs and any oversight role by the relevant committees. Data has been specifically used and stored with respect to individual incidents and not brought together in a way that would support wider assessments.

265. It is recommended that the Health Board develops a means of bringing the relevant data together for the QEUH and for the period since 2015, to be used going forward. This work should complement the recommendations of the November 2019 HPS report which the Oversight Board understands the Health Board are already implementing. This should be done in conjunction with ARHAI Scotland and HFS with a view to producing a potential exemplar for how to collect and consider such data for future outbreaks experienced by other Health Boards. These bodies should give consideration on how this exemplar can drive change in practice in other Health Boards. Within NHS GGC, the work should be completed by September 2021.

Recommendation 6: IMTs in NHS GGC should be more rigorous in developing and making accessible key documentation to support records and analyses of a series of outbreaks over a prolonged period. This should be implemented by NHS GGC, with support from ARHAI Scotland who can identify best practice and make changes to national guidance if this is required.

266. A lack of systematic development and storage of key documentation for IMTs characterised the period of incidents. This may well have hindered the capacity of the Health Board to recognise and act upon the risk of a pattern of systemic contamination. In particular, there is a need for:

- regular and standardised action logs for IMTs with clear designation of action owners, timescales and active recording of updates;
- a more standardised approach to IMT minute taking with a more rigorous approach to noting and recording key decisions and their reasons (potentially including a Decision Log);
- more regular development, recording and escalation of hot debriefs following IMTs; and
- more regular consideration of whether a full IMT report or SBAR is required for the Acute Infection Control Committee with a view to specific review and application of any lessons learned and recommendations to prevent or better respond to further incidents.

267. It is important that this more comprehensive approach to lesson learning is reflected nationally. ARHAI Scotland should work with other Health Boards and relevant national bodies to consider guidance and systems to support a central repository for IMT and SBAR reports and/or hot debriefs for these (and potentially other) public health incidents through the existing Scottish Health Protection Information Resource (SHPIR) web site. Learning points could be extracted and collated nationally from submitted reports/debriefs to inform future guidance and service improvement, potentially as a regular publication.

268. These actions should be implemented by September 2021.

Recommendation 7: **Where there are a number of successive infection incidents in the same or a related location, NHS GGC should work with ARHAI Scotland to pilot a process that goes beyond the current IMT focus on individual incidents on behalf of NHS Scotland.**

269. The IMT process lends itself to rapid and effective response to individual incidents, but potentially not to a series of potentially linked incidents. While other parts of IPC governance should provide that wider strategic view, the QEUH experience provides a strong argument for considering other longer-term approaches to addressing such incidents. NHS GGC has already shown the value of this kind of approach with the establishment of the Technical Water Group.

270. A new mechanism may be needed to support better analysis of the results of epidemiological, microbiological and environmental investigations in the round. While there is still a need for IMTs to exert specific controls on individual incidents, a new mechanism could be triggered in particular situations to allow better linking to what was known previously of the infection involved and wider local circumstances. Such a mechanism should review associations which may be considered causal and assess whether there is evidence of bias in the investigation and/or the strength of a specific association. As the Independent Review recommended, IMTs should allow for candid and confidential material to be discussed with a view to continuous improvement.

271. NHS GGC has developed significant experience to be in a position to support the development of such a mechanism. It should work with the Scottish Government and ARHAI Scotland to advise on a process that could be applied across NHS Scotland as a whole. A plan for such work should be developed and presented to the Scottish Government for September 2021.

Recommendation 8: **Building on work already in place, there should be further visible and systematic planning for strengthening coordination between IPC and Facilities and Estates, particularly with respect to forward planning in addressing continuing infection risks with the QEUH and specifically in relation to water testing.**

272. A key reason for the apparent 'loss' of the DMA Canyon report was the structure and conduct of Facilities and Estates at that time, not least the apparent lack of clarity over the roles and responsibilities within the team. The issues here have been rehearsed in the Independent Review report, and the Oversight Board acknowledges that the structure of the Facilities and Estates team has since changed. There is assignment of specific roles and responsibilities, and with the appointment of the new Director of Facilities and Estates, a greater level of formal compliance systems was introduced within the organisation and formal training and appointment of Approved Persons, not only for water, but for other systems as well.

273. Nevertheless, there are still areas where scope for improvement can be highlighted. For example, the Interim Report noted that the evidence that HAI-SCRIBEs for low-risk/maintenance projects were systematically being reviewed by

both Facilities and Estates and IPC colleagues was not apparent. Building on the notable improvement in how Facilities and Estates supports IPC across the organisation, NHS GGC should develop a more systematic approach to reviewing and deepening the coordination between IPC and Facilities and Estates functions, particularly with respect to the QEUH. The Health Board should ensure this approach is consistently reflected in the membership and joint working of key groups and oversight committees that focus on IPC and Facilities and Estates functions. Moreover, it should feature explicitly in the work programmes being developed to support the Silver Command strand of work.

Governance and Risk Management

274. Recommendations are set out here with respect to how IPC governance and risk management within NHS GGC should be improved.

Recommendation 9: The experience of NHS GGC in addressing the unique challenges of the QEUH should be systematically used to shape NHS Assure as early as possible. This should be part of a comprehensive process of developing a template for a 'ward-through-Board' governance system that ensures risks of this nature are appropriately escalated and de-escalated.

275. The knowledge and experience gained by NHS GGC staff, especially those who were involved in the IMTs that investigated the infection incidents, should not be lost. Their knowledge and experience should be retained, capitalised on and utilised in future, not just for local improvement but for national benefit. Particular consideration should be given to establishing a specialist group within the Health Board, with relevant, experienced staff invited to join. If further incidents did occur, the group could provide advice, support and expertise in investigation and action. This could quicken the process of any future investigations as the group would have the benefit of 'hindsight' from previous experience, potentially having a better idea of what to look for and what to consider in these circumstances. This should also take account of the Independent Review's recommendation that governance ensures that hypotheses are sound, contestable and the debate that strengthens or removes hypotheses is respectful and transparent.

276. In addition, as soon as appropriate, the Scottish Government should facilitate an effective transfer of relevant learning from NHS GGC to the new national Centre for Expertise and ensure that the maximum use is made of that learning. This could take the form of working with the specialist group above or formal engagement with the Health Board on 'lessons learnt' on particular infection issues to inform the early priorities of the new Centre's work programme. In preparation, NHS GGC should be invited to capture good practice and learning from its handling of the infection incidents to inform both local and national practice, taking account of these findings and recommendations and the work of the Independent Review.

Recommendation 10: The Health Board should finalise and implement its IPC Assurance and Accountability Framework.

277. The Oversight Board welcomed the Health Board's creation of the IPC Assurance and Accountability Framework and found it a very useful compilation of key documents fashioned into a single appropriate collection of guidance. That document has not been finalised, in part in anticipation of the outcome of the Oversight Board process. NHS GGC should revise the document to take account of changes arising from its Silver Command work and the recommendations set out here and in the Interim Report, and put it into operation by September 2021. That should include a clear governance structure for IPC and the escalation of issues.

Recommendation 11: A review should be undertaken of how the environmental risk of significant water contamination within the QEUH is being assessed and managed in the Health Board's approach to risk management, and changes made to relevant risk registers and risk management planning as a result.

278. As risks are conveyed up the governance structure, they are bound to be compressed in ways that may result in risks becoming less specific. Given the size of NHS GGC, it should not be surprising that capturing such risks with sufficient specificity can be particularly difficult. However, the lack of a clearly-articulated risk associated with the QEUH environmental situation has been notable. Indeed, it would be prudent to expect that the risks may continue in light of the significant issues uncovered in the building. These should be articulated clearly within the Corporate Risk Register as a potential risk to patient safety.

279. NHS GGC should set out how the risk of water contamination in the QEUH, as described in key external reports, will be captured on the governance and risk management systems to allow for early identification, monitoring and management of increased risk. Consideration should be given to conducting further review to gain a greater practical understanding of the risk process. This should include how in practice risks are identified at the ground level and fed up the risk process through the various committees to the Corporate Risk Register, specifically with reference to infection issues. This review of the treatment of such environmental risks should be completed by September 2021.

280. Related to this work, NHS GGC should ensure that the Gold and Silver Command work is subject to children's rights and wellbeing impact assessment processes and their results noted in the next three-yearly report required by relevant legislation.

Recommendation 12: The Health Board should set out a clearer, more targeted focus on the corporate risk process.

281. In terms of risk, there was a lack of transparency as to how environmental risks were escalated within the structure of IPC governance. There is a disconnect between the concerns expressed by many at the 'ground level' with those articulated in the Corporate Risk Register.

282. One way to strengthen the approach to risk would be a clearer designation of responsibility within the governance structure. The Oversight Board understands that a Senior Risk Officer has been appointed – it is hoped that this will achieve a more dedicated focus on the risk process. The aim of such an appointment would be to ensure that each risk area receives the appropriate individual focus that is required within the organisation with direct reporting to the Board itself. The transparency of the risk process needs to be clearer and the role of a chief risk officer would be to ensure that this transparency is achieved. Across the pillars of governance (clinical, financial and staff), it would provide assurance that where required, risks would be escalated quickly to the Board to ensure issues are addressed appropriately and without delay. This should be considered as an early priority in the wider Governance work being led by the Board Chair.

283. The Health Board should set out its plans for this role by June 2021.

Recommendation 13: The Health Board should review how concerns raised about environmental risks are communicated to senior Committees and the Board, and the procedures to ensure that such concerns are addressed. Moreover, it should also ensure the responses are communicated appropriately to those raising concerns.

284. While the Oversight Board did not review how individual concerns and addressed internally within the Health Board – as these have been addressed through separate whistleblowing processes – there are more general points that should be made about how significant concerns of environmental and IPC risks can be raised within the governance structure.

285. One approach is to consider whether there should be more formal and regular updating of the Board Infection Control Committee and the Clinical and Care Governance Committee by the Lead ICD. This happened periodically through the set of infection outbreaks, but a regular reporting to these committees would facilitate how these committees can fulfil their oversight roles and ensure relevant escalation of issues.

Communication and Engagement

286. Some recommendations for communications and engagement have already been set out in the Interim Report. These are not repeated here.

287. The Final Report recommendations address the remaining issues, particularly how the organisational duty of candour policy has been applied by the Health Board.

Recommendation 14: Given that organisational duty of candour was considered, but not formally activated, NHS GGC should review its approach to ensure that it is not simply focused on patient safety incidents and circumstances where causality is clear. There should be greater consideration of the duty where events could result in death or harm. There should also be improved guidance on how the Health Board will balance with other duties perceived as barriers to meeting the organisational duty of candour obligations.

288. NHS GGC undertook benchmarking of its organisational duty of candour response to the infection incidents, which was done on what appeared to be an informal basis. The Health Board is asked to undertake a review of its supporting policy and procedures to support implementation of the organisational duty of candour, outline the interface with the professional duty of candour and support decision-making when there are concerns about competing organisational duties of confidentiality with respect to incidents involving more than one relevant person. It should provide feedback to the Scottish Government on how this is addressed and any areas where revisions to national non-statutory guidance would be helpful. This should include how revised implementation support materials regarding the duty and multiple instances of HAI might be developed through HIS. This should be completed by September 2021.

Recommendation 15: The findings of the Oversight Board in respect of the application of the organisational duty of candour in NHS GGC should be considered by the Scottish Government and Healthcare Improvement Scotland in order that further implementation support and guidance can be developed around the issues noted.

289. NHS GGC suggested that they might not be alone in their ambiguous approach to applying the organisational duty of candour in situations where causality is not easily understood, and other Boards might be experiencing similar challenges in interpreting the legal duty. The Oversight Board could not explore this in detail within the scope of its work, but have asked teams in the Scottish Government and HIS to consider ways in which national guidance and implementation support plans take account of this feedback from NHS GGC. It notes that similar recommendations about the opportunity for national learning were made by the Independent Review in this area, and endorses those recommendations.

General Issues

290. The final set of recommendations relate to technical matters arising from the infection incidents and other more general matters.

Recommendation 16: The Health Board should expedite the refurbishment of Wards 2A and 2B in the RHC as safely and quickly as possible, and keep affected children, young people and families fully informed of the developments.

291. The Interim Report noted that work on refurbishing Wards 2A and 2B had been delayed owing to the impact of the pandemic and the extent of work needing to be undertaken. It is essential that children and young people are returned to the clinical environment specifically designed to support their care as soon as can be safely done. Any further delays should be clearly and readily explained to patients and families.

Recommendation 17: A programme of testing and review should be put in place to assess any potential impacts of the chemical dosing water solution on infrastructure.

292. NHS GGC should ensure that there is monitoring of the potential impact of the chemical dosing system on the existing building and infrastructure of the QEUH site. The Oversight Board is assured of the diligence of the Technical Water Group and the Health Board more generally to ensuring that the system would not put any undue pressure on the integrity and quality of the water infrastructure. Nevertheless, the solution is a radical one that should continue to be monitored, not just with respect to its outcomes (through water testing), but any potential unintended consequences on the infrastructure.

Recommendation 18: The various action plans and reviews attached to these recommendations should be compiled into a single response to the Oversight Board, and implementation overseen by NHS GGC and the Scottish Government.

293. The recommendations set out here (and in the Interim Report) call for a number of actions. These should be compiled into a single plan, integrated into and fully complementing the work of Silver Command. It should be jointly reviewed by NHS GGC and the Scottish Government at appropriate intervals.

8.3 The Way Forward

294. The recommendations signal that the Oversight Board does not think the Health Board can be de-escalated from Stage 4 at this point. NHS GGC is embracing the need and opportunity for improvement and taken a number of decisive steps in IPC and governance. Its energy and commitment is laudable in this context. Nevertheless, the Oversight Board has identified a number of areas where improvement needs to take place before de-escalation can be recommended. Progress in addressing the recommendations will be essential for the Oversight Board to take a final view on advice for de-escalation (and for the national recommendations, to ensure that NHS Scotland learns and acts on the relevant lessons).

295. Ultimately, it is not a question of a checklist of recommendations, but an understanding of ‘what good looks like’. The Health Board should embrace this spirit of improvement, and its work to restore confidence and assurance should be measured against achievement of a set of measures of what good IPC should look like. The Oversight Board has set out its view of this in the Key Success Indicators presented in the annex, and invites the Health Board to consider – and build – on these to create a culture of continual improvement, sensitivity to risk, openness and respect in its communications and engagement, and challenge and rigour in facing the unusual public health challenges it faced in these incidents.

296. The Oversight Board has concluded this phase of its work. The Scottish Government will put in place continuing arrangements to ensure oversight of this work going forward. It is proposed that the Chief Nursing Officer and the Chair of NHS GGC jointly agree on an appropriate point when a review can be conducted and a further view on escalation can be taken.

Annex A: Terms of Reference for the Oversight Board and its Subgroups

Oversight Board

Authority

The Oversight Board for the Queen Elizabeth University Hospital (QEUH) and the Royal Hospital for Children (RHC), NHS GGC (hereinafter, "the Oversight Board") is convened at the direction of the Scottish Government Director General for Health and Social Care and Chief Executive of NHS Scotland (NHS Scotland), further to his letter of 22 November 2019 to the Chairman and Chief Executive of NHS GGC. These terms of reference have been set by the Director General, further to consultation with the members of the Oversight Board.

Purpose and Role

The purpose of the Oversight Board is to support NHS GGC in determining what steps are necessary to ensure the delivery of and increase public confidence in safe, accessible, high-quality, person-centred care at the QEUH and RHC, and to advise the Director General that such steps have been taken. In particular, the Oversight Board will seek to:

- ensure appropriate governance is in place in relation to infection prevention, management and control;
- strengthen practice to mitigate avoidable harms, particularly with respect to infection prevention, management and control;
- improve how families with children being cared for or monitored by the haemato-oncology service have received relevant information and been engaged with;
- confirm that relevant environments at the QEUH and RHC are and continue to be safe;
- oversee and consider recommendations for action further to the review of relevant cases, including cases of infection;
- provide oversight on connected issues that emerge;
- consider the lessons learned that could be shared across NHS Scotland; and
- provide advice to the Director General about potential de-escalation of the NHS GGC Board from Stage 4.

Background

In light of the on-going issues around the systems, processes and governance in relation to infection prevention, management and control at the QEUH and RHC and the associated communication and public engagement issues, the Director General for Health and Social Care and Chief Executive of NHS Scotland has concluded that further action is necessary to support the Board to ensure appropriate governance is

in place to increase public confidence in these matters and therefore that for this specific issue the Board will be escalated to Stage 4 of the Performance Framework. This stage is defined as 'significant risks to delivery, quality, financial performance or safety; senior level external transformational support required'.

Approach

The Oversight Board will agree a programme of work to pursue the objectives described above. In this, it will establish subgroups with necessary experts and other participants. The remit of the subgroups will be set by the chair of the Oversight Board, in consultation with Board members. The Board will receive reports and consider recommendations from the subgroups.

In line with the NHS Scotland escalation process, NHS GGC will work with the Oversight Board to construct required plans and to take responsibility for delivery. The NHS GGC Chief Executive as Accountable Officer continues to be responsible for matters of resource allocation connected to delivering actions agreed by the Oversight Board.

The Oversight Board will take a values-based approach in line with the Scottish Government's overarching National Performance Framework (NPF) and the values of NHS Scotland.

The NPF values inform the behaviours people in Scotland should see in everyday life, forming part of our commitment to improving individual and collective wellbeing, and will inform the behaviours of the Oversight Board individually and collectively:

- to treat all our people with kindness, dignity and compassion;
- to respect the rule of law; and
- to act in an open and transparent way.

The values of NHS Scotland are:

- care and compassion;
- dignity and respect;
- openness, honesty and responsibility; and
- quality and teamwork.

The Oversight Board Members will endeavour to adopt the NPF and NHS Scotland values in their delivery of their work and in their interaction with all stakeholders.

The OB's work will also be informed by engagement work undertaken with other stakeholder groups, in particular family members/patient representatives and also NHS GGC staff.

The Oversight Board is focused on improvement. Oversight Board members, and subgroup members, will ensure a lessons-learned approach underpins their work in order that learning is captured and shared locally and nationally.

Meetings

The Oversight Board will meet weekly for the first four weeks and thereafter meet fortnightly. Video-conferencing and tele-conferencing will be provided.

Full administrative support will be provided by officials from CNOD. The circulation list for meeting details/agendas/papers/action notes will comprise Oversight Board members, their Personal Assistants and relevant CNOD staff. The Chairman and Chief Executive of NHS Greater Glasgow and Clyde will also receive copies of the papers.

Objectives, Deliverables and Milestones

The objectives for the Oversight Board are to:

- improve the provision of responses, information and support to patients and their families;
- if identified, support any improvements in the delivery of effective governance and assurance within the Directorates identified;
- provide specific support for infection prevention and control, if required;
- provide specific support for communication and engagement; and
- oversee progress on the refurbishment of Wards 2A/B and any related estates and facilities issues as they pertain to haemato-oncology services.

Matters that are not related to the issues that gave rise to escalation are assumed not to be in scope, unless Oversight Board work establishes a significant link to the issues set out above.

In order to meet these objectives, the Oversight Board will retrospectively assess issues around the systems, processes and governance in relation to infection prevention, management and control at the QEUH and RHC and the associated communication and public engagement; having identified these issues, produce a gap analysis and work with NHS GGC to seek assurance that they have already been resolved or that action is being taken to resolve them; compare systems, processes and governance with national standards, and make recommendations for improvement and how to share lessons learned across NHS Scotland. The issues will be assessed with regards to the information available at the particular point in time and relevant standards that were extant at that point in time. Consideration will also be given to any subsequent information or knowledge gained from further investigations and the lessons learned reported.

Governance

The Oversight Board will be chaired by the Chief Nursing Officer, Professor Fiona McQueen, and will report to the Director General for Health and Social Care.

Membership

Member	Job Title
Professor Fiona McQueen (Chair)	Chief Nursing Officer, Scottish Government
Keith Morris (Deputy Chair)	Medical Advisor, Chief Nursing Officer's Directorate (CNOD), Scottish Government
Professor Hazel Borland	Executive Director of Nursing, Midwifery and Allied Health Professionals and Healthcare Associated Infection Executive Lead, NHS Ayrshire and Arran
Professor Craig White	Divisional Clinical Lead, Healthcare Quality and Improvement Directorate, Scottish Government
Dr Andrew Murray	Medical Director, NHS Forth Valley and Co-chair of Managed Service Network for Children and Young People with Cancer (MSN CYPC)
Professor John Cuddihy	Families representative
Lesley Shepherd	Professional Advisor, CNOD, Scottish Government
Alan Morrison	Health Finance Directorate, Scottish Government
Sandra Aitkenhead	CNOD, Scottish Government (secondee)
Greig Chalmers	Interim Deputy Director, CNOD, Scottish Government
Jim Dryden Carole Campariol-Scott Calum Henderson Phil Raines (Secretariat)	CNOD, Scottish Government

The Co-chair of Area Partnership Forum and the Chair of the Area Clinical Forum will be in attendance at the meetings. In addition to these members, other attendees may be present at meetings based on agenda items, as observers: senior executives and Board Members from NHS GGC including, Medical Director, Nurse Director, Director of Estates and Facilities, Director of Communications, Board Chair and Chief Executive; and representatives from HPS, HFS, HIS, HEI and HSE.

Stakeholders

The Oversight Board recognises that a broad range of stakeholder groups have an interest in their work, and will seek to ensure their views are represented and considered. These stakeholders include:

- patients, service users and their families;
- the general public;
- the Scottish Parliament;
- the Scottish Government, particularly the Health and Social Care Management Board;
- the Board of NHS GGC and the senior leadership team of NHS GGC; and
- the staff of NHS GGC and Trade Unions.

Special focus will be given to patients of the haemato-oncology service and their families, as highlighted by their direct involvement in the Communication and Engagement Subgroup.

Infection Prevention and Control, and Governance Subgroup

Purpose and Role

The Infection Prevention and Control Governance (IPCG) Subgroup for the NHS GGC Scottish Government Oversight Board is a time-limited group which has been convened to work with NHS GGC to:

- determine whether appropriate Infection Prevention and Control Governance is in place across the organisation to increase public confidence; and
- make recommendations, if required and where appropriate, to strengthen current approaches to mitigate avoidable infection harms

The IPCG Subgroup directly reports to the Oversight Board, which is chaired by the Chief Nursing Officer, Professor Fiona McQueen. It has specific responsibilities for supporting the Oversight Board to ensure, where necessary and appropriate, improvements are made in the delivery of effective governance and provide assurance relating to infection prevention and control within and across NHS GGC.

Background

In light of the on-going issues around the systems, processes and governance in relation to infection prevention, management and control at the QEUH and RHC and the associated communication and public engagement issues, the Director General for Health and Social Care and Chief Executive of NHS Scotland has concluded that further action is necessary to support the Board to ensure appropriate governance is in place to increase public confidence in these matters and, therefore, that for this specific issue the Board was escalated to Stage 4 of the performance framework. This stage is defined as ‘significant risks to delivery, quality, financial performance or safety; senior level external transformational support required.’

The IPCG Subgroup will focus on issues relating to infection prevention and control and associated governance that gave rise to escalation to Stage 4.

Approach

The IPCG Subgroup will take a values based approach in line with NPF and the values of NHS Scotland.

The NPF values inform the behaviours people in Scotland should see in everyday life, forming part of our commitment to improving individual and collective wellbeing, and will inform the behaviours of the Oversight Board individually and collectively:

- to treat all our people with kindness, dignity and compassion;
- to respect the rule of law; and

- to act in an open and transparent way.

The values of NHS Scotland are:

- care and compassion;
- dignity and respect;
- openness, honesty and responsibility; and
- quality and teamwork.

These values will be embedded in the work of the IPCG Subgroup and will be informed by engagement work undertaken with key stakeholder groups.

The Subgroup is focused on improvement and as such the Subgroup members will ensure an evidence based, risk based, lessons-learned approach underpins their work in order that assurance can be articulated and learning is captured and shared both locally and nationally.

Meetings

The Subgroup will meet frequently for the first four weeks, with frequency thereafter to be determined as required. Video-conferencing or tele-conferencing will be provided.

Full administrative support will be provided by officials from CNOD. The circulation list for meeting details/agendas/papers/action notes will comprise Subgroup members, their PAs and relevant CNOD staff.

Objectives

The objectives for the Subgroup are to:

- carry out a system wide review of current systems and processes relating to the infection prevention and control and associated governance scheme of delegation and escalation mechanisms against relevant national standards and guidance;
- determine if there are any gaps when mapped against national standards and guidance and, if so, identify areas for improvement and shared learning with respect to IPC risk management, audit, performance, compliance and assurance;
- provide support to the IPC Team within NHS GGC in the identification of measures for assurance as part of the review process and for future improvement/implementation; and
- make recommendations where appropriate to the Oversight Board on areas of learning for other Health Boards

In Scope

In order to meet these objectives, the Subgroup will retrospectively assess systems, processes and governance arrangements in relation to IPC management and control across the whole of NHS GGC. It will do so by reviewing:

- alignment of IPC and wider Board structures within the span of influence of NHS GGC; and
- a range of reports considered by the Board Corporate Governance Committees and the network of Operational Governance Groups and Committees including those reports presented to the associate Integrated Joint Boards.

Deliverables will be agreed in the early meetings of the Subgroup and with the Oversight Board.

Out of Scope

The Subgroup will not review:

- roles and responsibilities of individual staff members within NHS GGC; and
- aspects covered by either the Communication and Engagement or Technical Subgroups of the Oversight Board.

Governance

The Subgroup will be chaired by Diane Murray, and will report to the Chair of the Oversight Board.

Member	Job Title
Diane Murray (Chair)	Deputy Chief Nursing Officer, Scottish Government
Hazel Borland	Executive Director of Nursing, Midwifery and Allied Health Professionals and Healthcare Associated Infection Executive Lead, NHS Ayrshire and Arran
Professor Angela Wallace	Nurse Director, NHS Forth Valley
Professor Craig White	Divisional Clinical Lead, Healthcare Quality and Improvement Directorate, Scottish Government
Frances Lafferty	Infection Control Nurse, NHS Ayrshire and Arran
Martin Connor	Infection Control Doctor, NHS Dumfries and Galloway
Helen Buchanan	Executive Director of Nursing, Midwifery and Allied Health Professionals and Healthcare Associated Infection Executive Lead, NHS Fife
Christina Coulombe	Infection Control Manager, NHS Lanarkshire
Lisa Ritchie	Nurse Consultant, Health Protection Scotland, NHS National Services Scotland
Professor Marion Bain	Director for Infection Prevention and Control, NHS GGC (secondee)
Phil Raines	Chief Nursing Officer's Directorate (CNOD), Scottish Government

Sandra Aitkenhead	CNOD, Scottish Government (secondee)
Lesley Shepherd	Professional Nurse Advisor, CNOD, Scottish Government
Jim Dryden Carole Campariol-Scott Calum Henderson (Secretariat)	CNOD, Scottish Government

Associated Participant	Job Title
Sandra Devine	Infection Control Manager, NHS GGC
Pamela Joannidis	Infection Control Nurse, NHS GGC
Dr. A Leonard	Infection Control Doctor, NHS GGC
Dr. J Armstrong	Medical Director, NHS GGC
Elaine Vanhegan	NHS GGC Board Governance Lead

NHS GGC may have other officers in attendance dependant on the issue being discussed and agreed through the chair.

Technical Issues Subgroup

Authority

The Oversight Board for the QEUH and RHC, NHS GGC has been established at the direction of the Scottish Government Director General for Health and Social Care and Chief Executive of NHS Scotland, further to his letter of 22 November 2019 to the Chairman and Chief Executive of NHS GGC.

A technical subgroup of the Oversight Board has been established to provide technical review, advice and assurance on the relevant technical matters relating to the built environment of the hospitals.

Purpose and Objectives

The purpose of the Technical Subgroup is to support the work of the Oversight Board, with a particular focus on the technical workings of the hospitals and any related technical reviews or reports. In particular the Technical Subgroup will:

- confirm that relevant environments at the QEUH and the RHC are and continue to be safe;
- oversee progress on the refurbishment and reopening of Wards 2A/B at the RHC and any related estates and facilities issues as they pertain to haemato-oncology services, such as Ward 6A at the QEUH;
- ensure that there are appropriate action plans in place to address any technical issues highlighted by competent authorities such as the Health and Safety Executive, Health Protection Scotland or Health Facilities Scotland and that these action plans are being delivered and provide oversight on connected issues that emerge;
- consider the lessons learned that could be shared across NHS Scotland; and

- provide advice to Oversight Board about potential de-escalation of the NHS GGC Board from Stage 4, in relation to these issues.

Background

In light of the on-going issues around the systems, processes and governance in relation to infection prevention, management and control at the QEUH and RHC and the associated communication and public engagement issues, the Director General for Health and Social Care and Chief Executive of NHS Scotland has concluded that further action is necessary to support the Board to ensure appropriate governance is in place to increase public confidence in these matters and therefore that for this specific issue the Board will be escalated to Stage 4 of the Performance Framework. This stage is defined as 'significant risks to delivery, quality, financial performance or safety; senior level external transformational support required'.

Approach

The Oversight Board is required to establish subgroups with necessary experts and other participants; this subgroup will address the requirement to ensure that relevant environments at the QEUH and RHC are and continue to be safe. To ensure delivery of that overarching objective, the Technical Subgroup will agree a programme of work to ensure that it complies with the purpose and objectives of the group described above.

The Oversight Board, and its subgroups, is focused on improvement. Members of this subgroup, will ensure a lessons-learned approach underpins their work in order that learning is captured and shared locally and nationally.

Meetings

The Technical Subgroup will meet every three weeks, but if necessary more regular meetings will be arranged.

Full administrative support will be provided by officials from CNOD in the Scottish Government.

Governance/Accountability

The Subgroup will be chaired by the Alan Morrison, Health Finance and Infrastructure, Scottish Government and will report direct to the Oversight Board.

Membership

Member	Job Title
Alan Morrison (Chair)	Health Finance Directorate, Scottish Government
Tom Steele	Director of Estates, NHS Greater Glasgow and Clyde
Gerry Cox	Deputy Director of Estates, NHS Greater Glasgow and Clyde
Ian Storrar	Principal Engineer, Health Facilities Scotland
Lisa Ritchie	Nurse Consultant, Health Protection Scotland, NHS National Services Scotland
Sandra Aitkenhead	Chief Nursing Officers Directorate (CNOD), Scottish Government (secondee)
Phil Raines	CNOD, Scottish Government
Calum Henderson (Secretariat)	CNOD, Scottish Government

Additional involvement will be requested as necessary.

Communication and Engagement Subgroup

Purpose and Role

The Communication and Engagement Subgroup the QEUH and the RHC, NHS GGC, is a time limited group to offer advice and assurance working with Scottish Government and NHS GGC on:

- effective communication and engagement with patients and families; and
- robust, consistent and reliable person-centred engagement and communication.

Background

In light of the on-going issues around the systems, processes and governance in relation to infection prevention, management and control at the QEUH and RHC and the associated communication and public engagement issues, the Director General for Health and Social Care and Chief Executive of NHS Scotland has concluded that further action is necessary to support the Board to ensure appropriate governance is in place to increase public confidence in these matters and therefore that for this specific issue the Board will be escalated to Stage 4 of the performance framework. This stage is defined as ‘significant risks to delivery, quality, financial performance or safety; senior level external transformational support required.’

Approach

The Communication and Engagement Subgroup will take a values based approach in line with the NPF and the values of NHS Scotland. The NPF values inform the behaviours people in Scotland should see in everyday life, forming part of our

commitment to improving individual and collective wellbeing, and will inform the work of the Subgroup individually and collectively:

- to treat all our people with kindness, dignity and compassion;
- to respect the rule of law; and
- to act in an open and transparent way.

The values of NHS Scotland are:

- care and compassion;
- dignity and respect;
- openness, honesty and responsibility; and
- quality and teamwork.

These values will be embedded in the work of the Communication and Engagement Subgroup, and this work will also be informed by engagement work undertaken with other stakeholder groups, in particular family members/patient representatives, respecting the importance of specific values informed actions linked to personal context and experiences.

The Communication and Engagement Subgroup is focused on improvement. Subgroup members, will ensure a 'lessons learned' approach, as well as respecting the experience of families must underpin and inform the identification of improvements for dissemination both locally and nationally.

Meetings

The Communication and Engagement Subgroup will meet fortnightly initially and then at a frequency to be determined thereafter. Tele-conferencing will be provided. A range of communication and engagement mechanisms will be agreed to enable patients and families to feed into the work of the Communication and Engagement Subgroup.

Full administrative support will be provided by officials from Scottish Government. The circulation list for meeting details/agendas/papers/action notes will comprise Oversight Board members, their PAs and relevant CNOD staff.

Outcomes

The Outcomes for the Communication and Engagement Subgroup are to:

- positively impact on patients and their families in relation to how complex infection control issues and all related matters are identified, managed and communicated;
- demonstrate a proactive approach to engagement, communication and the provision of information; and

- identify what has worked well and where the provision of information, communication and engagement could have been and could be enhanced and improved.to ensure that the outputs from the group are disseminated to key stakeholders and any wider learning points or recommendations are shared nationally.

In order to achieve these outcomes, the Communication and Engagement Subgroup will retrospectively assess factors influencing the approach to communication and public engagement associated with the infection prevention and control issues and related matters at the QEUH and RHC.

Having identified these issues, the Subgroup will work with NHS GGC to seek assurance that they have already been resolved or that action is being taken to resolve them; compare systems, processes and governance with national standards, and make recommendations for improvement and good practice as well as lessons learned across NHS Scotland.

Deliverables

The Deliverables for the Communication and Engagement Subgroup are:

- a prioritised description of communication and information to be provided to families, with a focus on respect and transparency (with an initial focus on ensuring that all outstanding patient and family questions raised are answered);
- development of a strategic Communication and Engagement Plan with a person-centred approach as key. This should link to and be informed by consideration of existing person-centred care and engagement work within the Board, to ensure continued strong links between families and NHS GGC. Specific enhancements and improvement proposals should also be clearly identified and should consider how the proposals from parent representatives on an approach that identifies and supports the delivery of personalised actions through the 'PACT' proposal can inform further work;
- a description of findings following a review of materials, policies and procedures in respect of existing practices with regards to communication, engagement and decision-making arising from corporate and operational communication and engagement, linked to infection prevention and control and related issues. This will include consideration of organisational duty of candour, significant clinical incident reviews, supported access to medical records (including engagement, involvement and provision of information to families in relation to these processes); and
- a description of findings and recommendations to: (a) NHS GGC; (b) Health Protection Scotland; (c) NHS Scotland; and (d) Scottish Government on learning to support any required changes and improvements for communication and public engagement relating to the matters considered by the Subgroup.

Governance

The Communication and Engagement Subgroup will be chaired by Professor Craig White, and will report to the Oversight Board. The Oversight Board is chaired by the Chief Nursing Officer, Scottish Government and reports to the Cabinet Secretary for Health and Sport. Members and those present at Subgroup meetings should ensure that they circulate information about the work of the Subgroup to colleagues and networks with an interest, contribution and perspective that can inform the work to be undertaken. This must include clinical and care staff within relevant operational services, as well as senior management and corporate staff within NHS GGC.

Membership

Member	Job Title
Professor Craig White (Chair)	Divisional Clinical Lead, Healthcare Quality and Improvement Directorate, Scottish Government
Lynsey Cleland	Director of Community Engagement, Healthcare Improvement Scotland
Andrew Moore	Head of Excellence in Care, Healthcare Improvement Scotland
Professor Angela Wallace	Nursing Director, NHS Forth Valley
Jane Duncan	Director of Communications, NHS Tayside
Professor John Cuddihy	Families representative
Suzanne Hart	Communication, Scottish Government
Phil Raines	Chief Nursing Officer's Directorate (CNOD), Scottish Government
Jim Dryden Calum Henderson (Secretariat)	CNOD, Scottish Government

In addition to these members, other attendees may be present at meetings based on agenda items, for example: Chair of Infection Prevention and Control and Governance subgroup; relevant Directors and senior staff from NHS GGC and communication staff from Scottish Government.

Stakeholders

The Communication and Engagement Subgroup recognise that a broad range of stakeholder groups have an interest in their work, and will seek to ensure their views are represented and considered. These stakeholders include:

- patients and their families;
- the general public;
- the Scottish Parliament;
- Scottish Government, particularly the Health and Social Care Management Board;
- the staff of NHS GGC, Trade Unions and professional bodies; and
- the senior leadership team of NHS GGC and the Board.

Annex B: Terms of Reference for the Case Note Review

Introduction

1. As a result of continuing problems arising from infection incidents on the Queen Elizabeth University Hospital (QEUH) campus, on 22 November 2019, the Scottish Government's Health and Social Care Management Board escalated NHS Greater Glasgow and Clyde to 'Stage 4' of its escalation ladder. That stage represents a level where there are "significant risks to delivery, quality, financial performance or safety, and senior level external transformational support [is] required." As a result, a new Oversight Board under the chair of the Chief Nursing Officer, Professor Fiona McQueen, has been set up to address two specific sets of issues that led to escalation: infection prevention and control and associated governance with respect to the QEUH; and communication and engagement with affected families.

2. As part of the work of the Oversight Board, the Cabinet Secretary for Health and Sport set out plans for a Case Note Review in Parliamentary statement on 28 January 2020. The Case Review team would review the case notes of paediatric haemato-oncology patients in the Royal Hospital for Children (RHC) and the QEUH from 2015 to 2019 who have had a Gram-negative environmental pathogen bacteraemia (and selected other organisms) identified in laboratory tests. The following note sets out the terms of reference for this work, specifically:

- its purpose and authority;
- the outputs/deliverables;
- key elements of its methodology, particularly the identification of cases for review, the use of the Paediatric Trigger Tool and the epidemiological review;
- communication and engagement of the Review and its outputs;
- key responsibilities;
- timelines for different phases of work; and
- risk management.

Purpose

3. The Case Note Review will review the medical records of all children diagnosed with qualifying infections (see definition below) and who were cared for at RHC between 1.5.15 and 31.12.19 to establish several key issues: the number of children – in particular, immunocompromised children – who were likely to have been put at risk because of the environment in which they were cared; and how that infection may have influenced their health outcomes. Such work will be vital in determining the number and nature of the children affected, providing assurance and identifying improvement actions, not just for NHS GGC, but more widely across NHSScotland, including Health Protection Scotland (HPS), and the Scottish

Government.. It is also an important element in improving the communication and engagement with families and affected patients.

4. The Review will consider the following set of specific questions:

- How many children in the specified patient population have been affected, details of when, which organism etc?
- Is it possible to associate these infections with the environment of the RHC and the QEUH?
- Was there an impact on care and outcomes in relation to infection?
- What recommendations should be considered by NHS GGC – and, where appropriate, by NHS Scotland, more generally – to address the issues arising from these incidents to strengthen infection prevention and control in future?

5. Through Professor Marion Bain (see below), the Review will report directly to Professor Fiona McQueen as Chair of the Oversight Board.

Outputs/Deliverables

6. There are two specific sets of outputs, described in more detail below:

- reporting to the Oversight Board; and
- specific feedback to patients and families.

Reporting to the Oversight Board

7. The Expert Panel (see below) will be responsible for providing a Final Report to Professor Bain and the Oversight Board, which should include:

- a description of the approach and methodology to the Review;
- a description of the patients included in the Review;
- a description of the cases according to specified data types;
- analysis to answer the questions set out in the Purpose section above; and
- recommendations for NHS GGC and NHS Scotland, based on this analysis.

Individual case details will not be set out in the Report and the cases will be anonymised. The Final Report will be provided to the Cabinet Secretary for Health and Sport thereafter. The Final Report will be published by the Scottish Government.

8. Reporting on progress to the Oversight Board will be undertaken by Professor Marion Bain, which may include the provision of an interim report, subject to agreement between her and the Chair.

Reporting to Patients and Families

9. The Expert Panel will provide individual reporting to patients and families that request a description of the results of their individual patient case review. Patients and families will be invited to take up the offer of engagement with the Panel through Professor Craig White, Chair of the Oversight Board's Communication and Engagement Subgroup. The format of reporting will accommodate, as far as practicable, the wishes of the family, and will be decided in conjunction with the Expert Panel. All reporting will be carried out within three months of the submission of the Final Report to the Oversight Board.

10. Arrangements for engaging with patients and families, the format of individual reporting and the timetabling of any meetings will be determined by the Expert Panel with Professor Bain and Professor White.

Methodology

11. In its overall approach to developing a methodology for the Case Note Review, these terms of reference set out key elements for how the Review should be conducted. Its overarching principles will be:

- respect and sensitivity to individual patients and their families in the handling of data and the conduct and reporting of results;
- rigorous handling, recording and storage of data, respecting patient confidentiality and family sensitivity; and
- use of internationally-respected and clearly-explained methodological tools and data sources, which will be documented for the Final Report.

12. A range of information will need to be gathered for the Expert Panel analysis and reporting. This includes several key elements, described in more detail below:

- the epidemiological and clinical outcomes review;
- the use of the Paediatric Trigger tool; and
- the gathering of other key data.

Identification of Cases

13. HPS has undertaken an analysis of a variety of options to define the sample. The Expert Panel has agreed the following cohort definition, but will continue to review the sample as the Review progresses.

14. The cohort currently consists of 85 patients (and a larger number of infection episodes):

- patients with blood cultures of a Gram-negative environmental pathogen (including enteric pathogens associated with the environment) (there are 81 patients that meet this inclusion criteria);

- patients with a M. chelonae (Acid Fast Environmental) infection (there are 3 patients that meet this criteria – only 2 with bacteraemia, and 1 with a skin infection); and
- patients included for other reasons: this includes one child with a Gram-negative infection (not blood stream detected) and Aspergillus

Epidemiological and Clinical Outcomes Review

15. An epidemiological and clinical outcomes review of the cases is required to collect patient, outcome and risk data systematically using agreed definitions and for the findings to support the incident investigation. The objectives of this epidemiological investigation are to:

- determine a timeline for each of the cases;
- characterise the cases in terms of time, place and person:
    - time: describe the episodes of BSI over time and create a timeline for outbreak, including plotting of control measures against number of cases,
    - place: describe the location of patients (hospital, ward, bed/bay) and describe their movements in the hospital, and
    - person: characterise the patients with infection in terms of intrinsic and extrinsic risk factors; outcomes; antimicrobial prophylaxis and treatment; and individual infection prevention and control measures in place; and
- describe the cases in the context of environmental risks and incidents (where possible).

The epidemiological components of the review will be carried out by HPS staff and data items to inform clinical outcomes will be extracted in collaboration with the Clinical Team responsible for the Paediatric Trigger Tool work (see below). A full description of the agreed data set is provided in the separate Epidemiological and Clinical Outcomes Protocol.

Paediatric Trigger Tool

16. The review of the case notes is set against the background of Healthcare Improvement Scotland's document, 'Learning from adverse events through reporting and review – A national framework for Scotland: July 2018'. The aims of the national approach to learning from adverse events are to:

- learn locally and nationally to make service improvements that enhance the safety of the care system for everyone;
- support adverse event management in a timely and effective manner;
- support a consistent national approach to the identification, reporting and review of adverse events, and allow best practice to be actively promoted across Scotland;
- present an approach that allows reflective review of events which can be adapted to different settings; and

- provide national resources to develop the skills, culture and systems required to effectively learn from adverse events to improve health and care services across Scotland.

The national approach seeks to ensure that no matter where an adverse event occurs in Scotland:

- the affected person receives the same high quality response;
- organisations are open, honest and supportive towards the affected person, apologising for any harm that occurred;
- any staff involved are supported in a consistent manner;
- events are reviewed in a consistent way; and
- learning is shared and implemented across the organisation and more widely to improve the quality of services.

17. The intention of using an adapted Paediatric Trigger Tool (PTT) in the study of NHS GGC is not to determine preventable or non-preventable harm but to create opportunities to learn from the triggers and adverse events identified. It forms only part of the overarching case review process and it is anticipated the information from the PTT will underpin the epidemiological and clinical outcome review and the contextual organisational data and reports. The PTT methodology will examine harm in the processes of healthcare in the group of patients selected for case note review and its objectives are to contribute to the overall aim of the case note review by:

- identify all triggers and adverse events in the cohort of patients identified by the epidemiological review using an adapted PTT; and
- describe the rate and severity of harm occurring in hospitalised children in the cohort group.

18. Dr Pat O'Connor is adapting the PTT for use for this patient population, in coordination with Dr Peter Lachman, one of the Tool's creators.

Other Data Collection

19. The Epidemiological and Clinical Outcomes Review and the PTT may not provide all the data that the Expert Panel requires to conduct its work. The Expert Panel will review its data requirements on a continuing basis and request these through the Clinical and Support Team leads as well as Professor Bain as required.

Communication and Engagement

20. Communication and engagement is distinct from reporting, as described above. There are key 'audiences' whose communication needs should be supported through the work of the Case Note Review. Key among these are:

- patients and families, both those who will be part of the Case Note Review and those who may want to know more, or feel they should be part of the Review; and

- the staff of the relevant parts of the RHC and the QEUH.

More detailed work on communication and engagement will be reflected in the Programme Plan for the work.

Patients and Families

21. Initial communication with patients and families – setting out which cases would be reviewed – has now taken place. That set out the purpose and details of the Case Note Review, and invite any questions and issues to be raised through the signatories of the letters, Professor Bain and Professor McQueen.

22. Progress reporting on the Case Note Review as a whole will be conducted through the NHS GGC web pages and 'closed' Facebook page to the affected families.

23. Specific engagement with families wishing to discuss their particular cases will be handled on a case-by-case basis through Professor Bain and Professor White.

Staff

24. The medical, nursing and other relevant staff of the relevant parts of the RHC and the QEUH (including the NHS GGC Board and relevant committees) will want to be kept appraised of the progress of the Review. Professor Bain will organise:

- an initial overview session of the methodology/approach of the Review to reviewing the cases;
- regular progress reports from representatives of the Expert Panel, ideally delivered in face-to-face meetings; and
- a final 'debrief' of the key results and recommendations of the Final Report.

Key Responsibilities

25. As Executive Lead for infection prevention and control within NHS GGC, as appointed by Professor McQueen, Professor Bain will have oversight of the project as a whole. She will be responsible for its progress and reporting to Professor McQueen, including advice – provided by the Expert Panel and other members of the team below – for any necessary change in key elements of these Terms of Reference.

Expert Panel

26. The Expert Panel will be responsible for:

- agreeing, within the scope of these Terms of Reference, the definitions used to select patients for the review; the scope and direction of the data collection; and the methodological tools required;

- overseeing and interpreting the analysis of data obtained and developing the Final Report (and, in discussion with Professor Bain, the provision of any agreed interim reporting);
- progress reporting to relevant audiences, including the RHC/QEUH staff; and
- providing reporting to individual patients and families.

27. The Expert Panel consists of:

- Professor Mike Stevens (Emeritus Professor of Paediatric Oncology at the University of Bristol), who will be head of the Expert Panel and report to Professor Bain;
- Gaynor Evans (Clinical Lead for the Gram-negative Bloodstream Infection Programme at NHS Improvement England); and
- Professor Mark Wilcox (Professor of Medical Microbiology at the University of Leeds).

Clinical Team

28. The Clinical Team will be responsible for:

- undertaking the data collection, storage and submission of case note review material to the Expert Panel;
- resolving data/sampling issues with Professor Bain, the Support Team and the Expert Panel; and
- supporting the analysis and reporting of the Case Note Review through the Expert Panel.

All handling of patient data will be covered by relevant data-sharing agreements and protocols.

Epidemiology and Clinical Outcomes Review Team	
Dr Fiona Murdoch, Epidemiology and Clinical Outcomes Review Lead	March 2020-end of Review
Jane McNeish, Epidemiology and Clinical Outcomes Review	May 2020-end of Review
Shona Cairns, Epidemiology and Clinical Outcomes Review	January-March 2020
Paediatric Trigger Tool Review Team	
Dr Pat O'Connor, Paediatric Trigger Tool Review Lead	February 2020-end of Review
Professor Peter Davey, Paediatric Trigger Tool Review	April 2020-end of Review
Advisers to Expert Panel	
Hayley Kane, Infection Control Manager, IPC (ICNet and Telepath) Review	September 2020-end of Review
Dr Julie Aitken, Clinical Adviser to Expert Panel	September 2020-end of Review
Linda Dempster, IPC Adviser to Expert Panel	October 2020-end of Review

Support Team

29. The Support Team will be responsible for:

- resolving practicalities and resourcing issues with Professor Bain, Professor Stevens and Dr O'Connor;
- undertaking key communication and engagement functions with Professor Bain;
- developing and maintaining the Review workplan;
- providing secretariat and related functions to the Expert Panel; and
- ensuring submission of Final Report to the Cabinet Secretary and publication.

30. The Support Team consists of:

- Diane Murray (Deputy Chief Nursing Office for Scotland), who will lead the Support Team;
- Lesley Shepherd (Professional Nurse Advisor to the Scottish Government), who will provide expert methodological advice and work with HPS;
- Professor Craig White (Chair of the Communication and Engagement Subgroup of the Oversight Board), who will work with Professor Bain in handling the communication and engagement with patients and families and provide the 'families' voice' in the development of key elements of the Review;
- Marie Brown (seconded Programme Manager from NHS National Services Scotland), who will develop and maintain the workplan and advise Diane Murray and Professor Bain of key delivery issues (role to be confirmed);
- Emma Mackay (seconded from NHS National Services Scotland); and
- Jim Dryden, Carole Campariol-Scott and Phil Raines: (QEUH Support Unit, Scottish Government), who will provide policy and practicalities support, and ensure timely progress updating to the Oversight Board and the Cabinet Secretary.

31. Additional key support will be provided by:

- Shona Cairns (Health Protection Scotland), who will head up the team responsible for final identification of patients to be included in the Case Note Review and leading the epidemiological component of the Epidemiology and Clinical Outcomes Review, working with Lesley Shepherd and reporting to the Expert Panel; and
- Professor Peter Lachman, who will supply consultancy advice on adapting the PTT for the particular patient population as one of the creators of the Tool, working with Dr Pat O'Connor.

Timelines

32. The timelines for the Review will be reviewed on an ongoing basis by Professor Bain in conjunction with the heads of the Expert Panel, the Clinical and Support Teams, and Professor McQueen. They will be encapsulated in the workplan to be developed and maintained by the Support Team. The Review is currently anticipated to provide a final report to the Oversight Board in 2020, but timelines will necessarily continue to be reviewed in light of the impact of Covid-19.

Annex C: Description of Interim and Final Report Coverage

Escalation Issue	What Is Covered in the Interim Report	What Is Covered in the Final Report
Infection prevention and control	• Assurance on a selection of IPC processes/systems in NHS GGC following Peer Review • Review of approach to improvement in IPC in NHS GGC • Findings and recommendations on the above set of issues	• Review of how the infection incidents were addressed by NHS GGC and wider mitigation/responses • Review of how different staff have worked together in support of IPC in the QEUH • Review of the organisation of IPC leadership • Findings and recommendations on the above set of issues and the overarching question of the 'fitness for purpose' of IPC within the Health Board
Governance	• Update on work of IPC governance	• Review of how infection incidents were escalated and addressed by the NHS GGC governance structure • Assurance on how IPC issues are currently escalated and addressed within NHS GGC • Review of NHS GGC risk management in light of the infection incidents • Findings and recommendations on IPC governance issues, and the overarching question of the 'fitness for purpose' of IPC governance within the Health Board
Related technical issues	• Update on refurbishment of Wards 2A/2B in the RHC	• Assurance on NHS GGC's water testing and safety policy in the RHC/QEUH • Assurance on plans to address any remedial works relating to infection arising from infrastructure issues on the QEUH site
Communication and engagement	• Review of how communication and engagement was undertaken by NHS GGC with the children, young people and families affected by the infection incidents – including findings and recommendations	• Review of how the organisational duty of candour, the Significant Adverse Events Policy and related review processes operated for these infection incidents – including findings and recommendations

Escalation Issue	What Is Covered in the Interim Report	What Is Covered in the Final Report
Case Note Review	• Update of the work of the Case Note Review	• Summary of findings and recommendations of the Case Note Review
Review of escalation to Stage 4		• Advice on whether/how de-escalation should take place

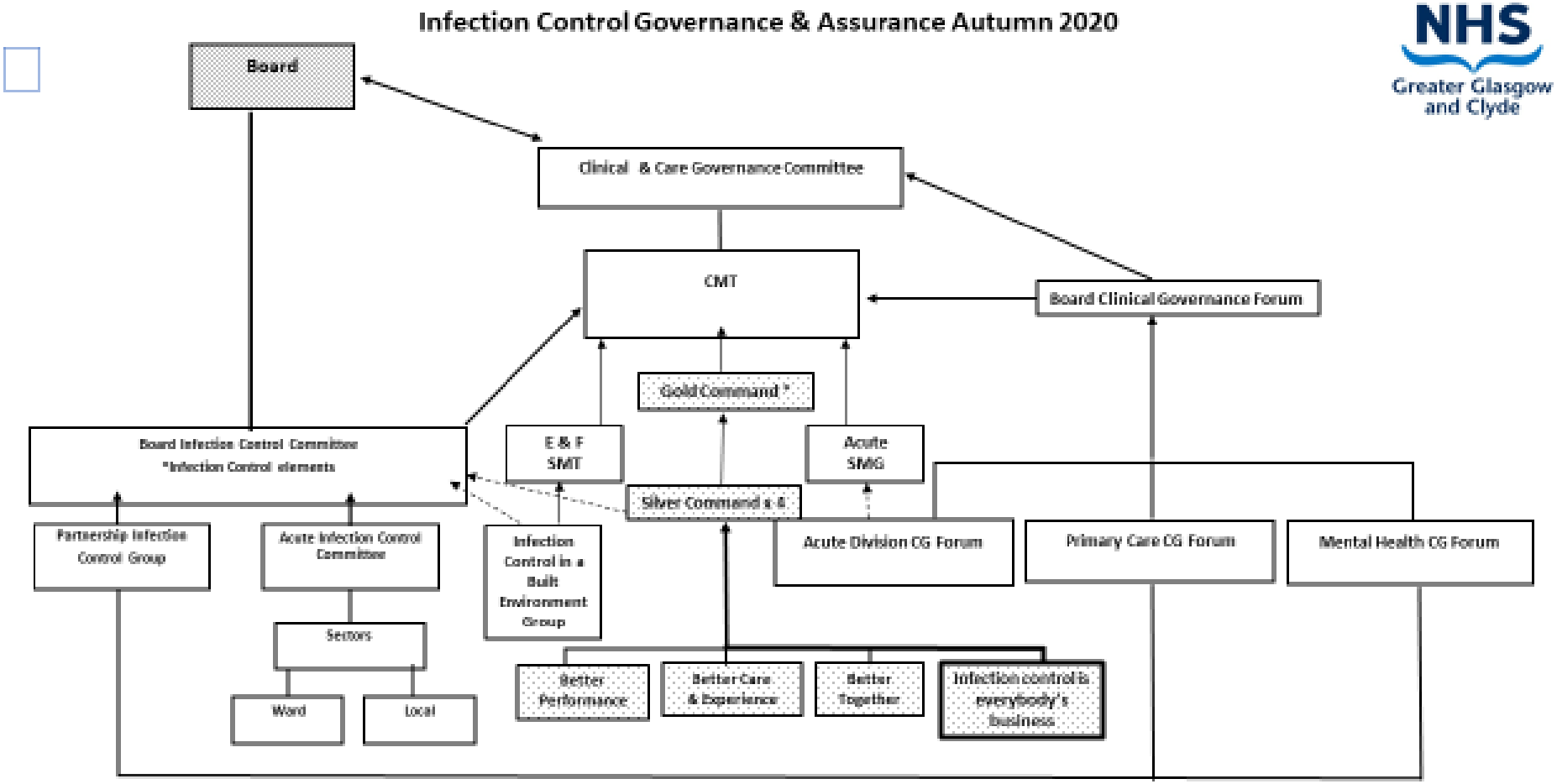
Annex D: Key Success Indicators of the Oversight Board

Outcome	Action	Example of Evidence
Infection Prevention and Control and Governance		
There is appropriate governance for infection prevention and control (IPC) in place to provide assurance on the safe, effective and person-centred delivery of care and increase public confidence.	Carry out a system wide review of current IPC systems and processes and associated governance scheme of delegation and escalation mechanisms against relevant national standards and guidance.	• Confirmation of current/sustainable effective governance with respect to: HAIRT Reports; Clinical and Care Governance Committee and Audit and Risk Committee Reports; AOP and Corporate Objectives and Performance Reports; IPC Inspection and Escalation Reports; IPC Audit Reports and Action Plans; relevant Antimicrobial Management/ Infection Control/ Decontamination/ Water Safety/ Education and Training/ Surveillance/ Outbreak Preparedness and Management/ Audits/ Policy and Procedures/ Inspection and Action Plans/ IPC Escalation Reports/ SBARs/ Research and Development and Voluntary Action Plan Updates; and IPC Risks. • Active action plans to address recommendations/action on relevant HPS/ HEI/ Internal reports since 2015 with clear timelines, monitoring, action responsibility and appropriate oversight.
	Determine if there are any gaps when mapped against national standards and guidance and, if so, identify areas for improvement and shared learning with respect to IPC risk management, audit, performance, compliance and assurance.	• Report setting out gaps in national standards/guidance and provision of NHS GGC action plan to address issues and monitoring arrangements for action plan. • Report setting out wider learning with regards to IPC risk management, audit, performance, compliance and assurance for consideration by DG Health and Social Care, SG Ministers, and NHS Chairs and NHS Chief Executives fora (as part of wider Oversight Board reporting).

Outcome	Action	Example of Evidence
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.	Conduct a detailed review of relevant individual instances of infection and identify actions on individual cases and systemic improvements.	• Clear methodology for identifying and undertaking review of all relevant cases, validated by external experts. • Identification of general issues relating to the IPC governance issues and provision of NHS GGC action plan to address issues and monitoring arrangements for action plan. • Identification of individual issues relating to specific cases and NHS GGC action plan to communicate and engage with relevant families/patients and monitoring arrangements for action plan.
	Ensure that the physical environment to the relevant wards in QEUH and RHC support the delivery of safe, effective and person-centred care with respect IPC, particularly in the delivery of any refurbishments/physical improvements.	• Action plan setting out identification of key issues in Ward 6A in QEUH and implementation of how they have been dealt with. • Assessment setting out completion of refurbishment works in Wards 2A/2B in RHC and how identified issues were addressed. • Confirmation of action plan and assessment above by HPS.
	Determine if there are any gaps when mapped against national standards and guidance and, if so, identify areas for improvement and shared learning with respect to operational delivery of IPC, including staffing/ resourcing, minimum skills and joint working between relevant units.	• Evidence of full implementation of mandatory national HCAI and AMR policy requirements as set out in DL (2019) 23. • NHS GGC action plan to identify staffing/ resourcing gaps in IPC operations with respect to putting in place policy requirements in DL (2019) 23, address the identified gaps with clear actions/ timetables and monitoring arrangements for delivery.

Outcome	Action	Example of evidence
Communication and Engagement		
Families and children and young people within the haemato-oncology service receive relevant information and are engaged with in a manner that reflects the values of NHS Scotland (NHSS) in full.	Prioritise communication and information provided to families and patients with a focus on respect and transparency (with an initial focus on ensuring that all outstanding patient and family questions raised are answered).	• Compilation of outstanding questions by families and publication of responses on NHS GGC website. • Published process for responding to questions in future as part of NHS GGC Communication strategy. • All additions/revisions/updates to questions previously answered have been made as soon as additional information has been received and/or reviewed.
Families and children and young people within the haemato-oncology service are treated with respect to their rights to information and participation in a culture reflecting the values of the NHSS in full.	Develop and implement a strategic NHS GGC Communication strategy with a person-centred approach, including a clear Executive Lead for implementing and monitoring.	• Publication of relevant NHS GGC Communication strategy with evidence of co-production with families. • Identification of Executive Lead to implement strategy with monitoring arrangements and measures of implementation and measures of effectiveness in place.
	Review key materials, policies and procedures in respect of existing practices with regards to communication, engagement and decision-making regarding consideration of the organisational duty of candour similar reviews (including engagement, involvement and provision of information to families in relation to these processes), and identification of any national learning/ lessons learnt.	• Report setting out gaps in compliance, opportunities for improvement, recommendations for action and provision of NHS GGC action plan to address issues and monitoring arrangements for action plan. • Identification of individual issues relating to specific cases and NHS GGC action plan to communicate and engage with relevant families/patients. • Reporting setting out wider learning with regards to organisational duty of candour and other review processes and management of IPC activities for consideration by DG Health and Social Care, SG Ministers, and NHS Chairs and NHS Chief Executives fora (as part of wider Oversight Board reporting). • Clear description of how communication, engagement, information provision and support dimensions of Oversight Board case reviews will integrate family involvement and engagement in accordance with best practice case reviews and individual family preferences.

Annex E:


Infection Control Governance & Assurance Autumn 2020
NHS
Greater Glasgow and Clyde
Board
Clinical & Care Governance Committee
CMT
Board Clinical Governance Forum
Gold Command *
Board Infection Control Committee
*Infection Control elements
E & F SMT
Acute SMG
Silver Command x 4
Partnership Infection Control Group
Acute Infection Control Committee
Infection Control in a Built Environment Group
Acute Division CG Forum
Primary Care CG Forum
Mental Health CG Forum
Sectors
Ward
Local
Better Performance
Better Care & Experience
Better Together
Infection control is everybody's business
Delivering better health
www.nhsggc.org.uk
1

Annex F: Timeline of Infection Incidents in the Queen Elizabeth University Hospital 2015-19

This can be found as a supporting file, published alongside this report.

This publication is available at **www.gov.scot**

Any enquiries regarding this publication should be sent to us at
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A43293438 **w w w . g o v . s c o t**

Timeline of incidents in the Queen Elizabeth University Hospital and Royal Hospital for Children for the period 2015 to 2019

A43293438

Section 1
Introduction

Introduction and Summary of the Timeline

Introduction

In 2018 Ward 2A and 2B of the Royal Hospital for Children (RHC) experienced a number of "incidents" where a Gram Negative Bacteria (GNB) (or other environmental bacteria) or fungal organism were identified as being present. Wards 2A and 2B of the RHC treat paediatric haemato-oncology and Bone Marrow Transplant (BMT) patients.

An "incident" is defined as an occurrence where a patient or patients are identified as having one of these bacterial and/or fungal infections. Such patients were identified through a number of sources. Although the source was not always identified in the information used to construct the timeline, it did include blood and line cultures and bronchoalveolar lavage (BAL) procedures (where a bronchoscope is used to squirt water into the lungs and then collect it for examination).

A number of hypotheses were explored to determine the cause of the presence of the bacteria and fungi; however, the main hypothesis investigated was in relation to contamination of the water system. This hypothesis came to the fore during 2018 when, following one incident, water sampling identified contamination of water outlets and drains. However, there were diverse views on the source of the contamination and in September 2018 both wards were closed as a definitive source of the bacteria could not be determined. The closure was also to allow a full investigation of the issues identified in relation to water outlets, drains and ventilation to be carried out and to conduct remedial action in the wards to address these issues. Patients in Ward 2A were transferred to Ward 6A of the Queen Elizabeth University Hospital (QEUH) with BMT patients transferred to Ward 4B of the QEUH.

The slides in this report set out a timeline of the incidents where a GNB or a fungal organism were identified and which occurred in Wards 2A and 2B of the RHC and latterly the QEUH (in Wards 4B and 6A only). The timeline has been created to assist in the understanding of the sequence of incidents that occurred, the control measures put in place and the various hypotheses investigated to identify the source of the incidents.

The timeline covers the period from when the hospitals were first opened in 2015 through to 2019. It also considers incidents which occurred in other wards of the RHC (as patients could be temporarily accommodated in other parts of the RHC due to the severity of their illness) but also to demonstrate exactly where all of the incidents reported actually occurred. The objective of the timeline is purely to set out the sequence of events as evidenced by the documentation provided by NHS Greater Glasgow and Clyde (GGC) and does not express an opinion on the actions taken or activities performed.

The timeline does not cover any such incidents reported in the QEUH hospital other than following the transfer of patients to Wards 6A and 4B.

Investigation of Incidents

A set procedure is followed when an incident occurs. A Problem Assessment Group (PAG) is set up when certain infection/colonisation triggers (which NHS GGC advised are agreed locally) are breached. The trigger is normally based on a certain level of an organism in a specified time period. The level and period are dependent on which organism is being considered. Microbiologists (MBs) and Infection Control Doctors (ICDs) advise that PAGs may also be set up where triggers have not been activated but, in the MB/ICD professional judgement, one is warranted.

The trigger will be reviewed by the PAG and, if infections or colonisations are found to be linked or are a Hospital Acquired Infection (HAI) or a Healthcare Associated Infection (HCAI), then an Incident Management Team (IMT) may be convened to investigate the incident more fully. Where the PAG finds that the trigger was activated by two community acquired infections then no further action will be taken with regards to the source but control measures would be put in place to contain any spread of the infection. It should be noted that the process for reporting and investigating any infection/colonisation is the same for both the RHC and the QEUH.

Interaction with Facilities and Estates Team

The timeline looks at both the activities of the Infection Prevention and Control Team (IPCT) and also the Facilities and Estates (F&E) team, who are normally both involved with the IMT, to show the interaction between these two teams. In respect of the F&E team, the timeline incorporates activities performed by the team in responding to issues with the RHC/QEUH following them being handed over by the main contractor who built the hospitals. The timeline also considers the development of the F&E team over that period in respect of its levels of compliance and also the handling of two reports prepared by a company called DMA Canyon Ltd (DMA) which highlighted concerns with the water system at the time the hospitals were handed over.

Involvement of Other Parties

The timeline also includes details of other parties who were involved with the IMT, especially from 2018 onwards. Other parties include Health Protection Scotland (HPS) and Health Facilities Scotland (HFS) who provided NHS GGC with guidance and support in managing the incidents from 2018 onwards. Advice, guidance and other expertise was also sought from, for example, Public Health England, other Health Boards and experts in water and ventilation systems.

Summary of Timeline

Haemato-oncology and BMT patients were originally accommodated in Ward 2A and day patients were seen in Ward 2B of the RHC. Patients could also be accommodated in or transferred to and from the Paediatric Intensive Care Unit (PICU) depending on the severity of their condition. The timeline shows that an increasing number of incidents were recorded in Ward 2A from 2017 onwards – NHS GGC advise that this was a direct result of the update to the National Infection Prevention Control Manual (NIPCM) which occurred in June 2017 and included environmental organisms (such as GNB and fungi) as alerts. NHS GGC further advise that this resulted in processes being put in place to capture these organisms even though there was no guidance as to what to do with them or how to implement surveillance.

In 2018 the level of incidents resulted in Wards 2A and 2B being closed and BMT patients being moved to Ward 4B of the QEUH with the remainder of patients moved to Ward 6A of the QEUH. This relocation occurred at the end of September 2018 but was intended only to be for a short time.

Prior to the closure of Wards 2A and 2B a number of hypotheses were investigated to determine the source of the infections and colonisations. The investigations included research and work to reduce line infections, review of hand hygiene, ward cleanliness and operating practices, and issues with the water and ventilation systems. NHS GGC advise that a definitive source of the infections/colonisations was never conclusively determined as the source of such incidents can be difficult to establish.

One of the hypotheses explored was the potential contamination of the water system (due to a build up of

Introduction and Summary of Timeline

biofilm in taps and drains which certain MBs/ICDs note were confirmed from the results of water sampling) as some forms of GNB can originate in water. MBs/ICDs have advised that GNB can be either endogenous bacteria, meaning they originate from patient's own flora (body), or they can be exogenous bacteria, meaning they are acquired from the environment. Such infections can therefore originate from organisms in the patient's own body or from an external source.

Patients such as haemato-oncology patients are at greater risk of both types of GNB as their immune system is compromised making them more susceptible to infections. NHS GGC have advised that endogenous infections, i.e. from the patient's own flora, are a very common source of infections in patients whose immune system is compromised. MBs/ICDs advise that strategies exist to minimise the risk of endogenous bacteria, such as through line care, screening for the bacteria and skin hygiene. They also advise that while the strategies to target endogenous and exogenous bacteria differ, there is overlap with hand hygiene and environmental cleanliness strategies being employed for both as they are critical to stop the spread of the bacteria.

Certain MBs/ICDs have advised that initially there were concerns about endogenous infection rates but these were drastically reduced by work performed by NHS GGC to improve the quality of line care (referred to as the CLABSI work in the timeline) and improvements in cleaning and hand hygiene. Certain MBs/ICDs advise that, following these improvements, it was predominantly exogenous infections rates which became of concern and led to the development of the hypothesis that the water system or at least the water outlets and drains were contaminated and were the source of the infections.

The timeline shows that the hypothesis around the water system started to be formerly investigated by NHS GGC in 2018 when the first incidents started to occur in March of that year. A Technical Water Group (TWG) was set up in April 2018 to investigate this hypothesis further and to consider and come up with both short and long term solutions to the problem. The timeline, however, also notes that certain MBs/ICDs have raised their concerns over the water system before the hospital opened and formerly registered their concerns in an SBAR in October 2017. Certain MBs/ICDs advise that concerns were reported to tier consultant colleagues in relation to the number of infections, including unusual ones at RHC, not all of which related to a possible water source.

Investigation of the other hypotheses noted above were also being progressed at this time or had already started to be investigated prior to 2018 (such as the work to reduce line infections).

The decant of patients from Ward 2A and 2B was in order to allow a thorough investigation of the wards to understand what the cause of the infections/colonisations was and where the contamination of water outlets and drains had originated from - was this from the water itself or simply contained to the water outlets and drains? It was also to allow replacement taps, showers and drains to be fitted.

As work begun, further issues in relation to the ventilation of the wards became apparent and following receipt of a report on the ventilation system the decision was made that the extent of the work required was much more extensive and the decant would not be for the short term. It should be noted that the report on the ventilation system was not reviewed when preparing this timeline.

As the work progressed other problems were discovered, such as mould in shower rooms due to faulty floor sealings. At the time of writing the work on the wards is still progressing having been delayed by Covid-19.

Following the move to Ward 6A incidents continued to occur during 2019 and led to a more detailed analysis of patient pathways and their access to other sources of water and locations outside of the ward. New admissions to the ward were restricted until no further cases were reported for a period of time. Ward 4B continues to accommodate BMT patients to the present day.

It should be noted that the timeline also includes infections in other areas of the RHC, such as PICU, Wards 1E, 3A and Theatre 6. The level of incidents in these wards was much less, with the exception of PICU which also saw more incidents in 2019. All these wards remained open and preventative measures were taken to control the spread of the organisms.

Water Groups

The TWG continues to meet since it was first convened in April 2018 but now meets on a quarterly basis. There is a section in the timeline (pages 28 to 39) dedicated to the TWG that summarises the minutes of the group from when it was first instigated in April 2018 to December 2019. This section details the actions of the group to investigate the hypothesis around potential water contamination and the matters taken into consideration when deciding on both short and long term solutions to rectify the problem, if the water system was proven to be contaminated.

Initially the TWG conducted a large number of water tests across both the RHC and the QEUH to ascertain whether the issues with the water supply were confined to just Ward 2A or beyond. The results of these tests revealed that the problem was widespread, and a solution to address it would have to cover both the RHC and the QEUH. This was a key milestone moment in that it confirmed that the contamination was system wide and that biofilm existed. Following discussion with third parties and water experts, the long term solution agreed was the installation of a chlorine dioxide (CD) plant and continual dosing of the water supply in both the RHC and the QEUH. The CD plant was installed and the RHC has received dosing of the water supply since November 2019 and the QEUH since January 2020. Weekly water tests of 142 water outlets are conducted with the results producing a large number of negative results, indicating that the CD is having a positive effect.

The water testing undertaken by the TWG was in addition to that normally conducted by the F&E team (with water samples being collected by outside contractors and analysis of samples performed by either the NHS GGC's own laboratory or an external laboratory). Water testing conducted by the F&E team tests for Legionella, E.Coli and Pseudomonas, as well a total number of viable microorganisms present. Testing for other organisms, such as GNB, would normally be done at the request of the IPCT or individual IMTs as part of their investigations. However, as noted above, the weekly water tests currently being conducted now also cover GNB as part of the 142 water outlet tests.

In addition to the TWG, NHS GGC has a number of water groups which were in existence prior to the opening of the RHC and the QEUH. There is a water safety group for each of the NHS GGC sectors and these will deal with local related water matters within the hospitals in that sector. The RHC and the QEUH come under the remit of the South Clyde Water Safety Group (SCWSG).

The local sector water groups report up to the Board Water Safety Group (BWSG). The BWSG's responsibilities include the development of a water safety policy and plan, identifying and monitoring appropriate control measures for water safety in high risk clinical areas, coordinating and monitoring the

Introduction and Summary of Timeline

work of the sector water safety groups, and effective planning and management of any clinical incidents where the water supply is implicated. The BWSG used to report directly to the Board Infection Control Committee (BICC) but in late 2019 a new group, the Infection Control Built Environment Group (ICBEG), was set up to review and agree policies and the BWSG now reports to this group. The ICBEG now reports to the BICC who in turn report to the NHS GGC Board.

Both the BSWG and SCWSG were kept informed of the work of the TWG, as were the BICC and other NHS GGC sub-committees. A summary of the relevant minutes for each group/sub-committee is also included in the TWG timeline.

Structure of Timeline

There are a number of sections contained in this timeline as follows

- **Timeline for the period from 2015 to 2019 (section 3 to 7)** – these sections set out the investigations made by the IMTs and the control measures put in place to prevent the spread and transmission of the infections/colonisations. The type of GNB or fungus is noted together with the ward/location where the infection/colonisation occurred and also the number of patients that were affected.

- **Timeline of Technical Water Group (section 8) –** this section looks at the work of the TWG and the decisions taken in relation to the instalment of the chemical dosing (CD) plant from April 2018 (when the TWG was first convened) up to December 2019. The TWG continues to meet but now on a quarterly basis. The timeline also details the issues identified with Wards 2A and 2B as work progressed and details the reasons for the delay in being able to return patients to these wards.

- **Summary Table of Incidents (section 9)** – this section brings together in one table all the incidents that occurred during the period from 2015 to 2019. The table shows where the incidents occurred, which month they occurred in, the organisms involved and the number of patients that were identified with that organism at the time. The table highlights the increase in incidents in years 2018 and 2019.

Information Source

The information contained in this timeline has been taken from a number of sources as detailed below:

- Minutes of meetings of IMTs and/or PAGs set up to investigate each incident;
- Minutes of meetings and associated papers of the NHS GGC Board, Acute Infection Control Committee (AICC), BICC, Board Clinical Governance Forum (BCGF), Clinical and Care Governance Committee (CCGC), the Acute Clinical and Governance Committee (ACGC) and associated Committee and Board papers;
- Interviews with members of the NHS GGC IPCT to understand how incidents associated with GNB and fungi were reported up through NHS GGC's governance structure to the Board, HPS and Scottish Government;
- Interviews with members of the F&E team to understand the procedures around water risk assessments, audit and compliance of water systems and water testing;
- Papers provided by F&E team in relation to water risk assessments, audit and compliance documents;
- IPC Summary documents attached to papers of the AICC;
- Minutes of meetings of the TWG, BWSG and SCWSG;
- Copy of the HPS Report entitled "Technical Review Water Management Issues NHS GGC QEUH and RHC";
- Copy of HPS reported entitled "Summary and Incident Finding of NHS GGC QEUH/RHC";
- Copy of HPS report entitled "Review of NHS GG&C haemato-oncology data";
- Copy of DMA report "Legionella L8 Risk Assessment 2015 (pre-occupancy)"; and
- Copy of DMA report "Legionella L8 Risk Assessment 2017".

This timeline also reflects comments made by NHS GGC and a number of MBs/ICDs on the content of the timeline.

Limitations

The timeline has been completed for the period from 2015 to 2019 and has not taken into account, unless specifically stated otherwise, the events that have occurred after that period. The minutes of the NHS GGC Board and its various committees have not been reviewed for 2020.

The timeline does not include any information in relation to infections and colonisations that occurred during the period from 2015 to 2019 in the adult hospital or within the adult patient population. The exception to this is when the paediatric haemato-oncology patient group moved to Wards 6A and 4B in the adult hospital. The absence of any such similar incidents relating to the adult population from the timeline should not be taken to mean that such incidents did not occur.

The timeline was created from a paper based review of documentation supplied by NHS GGC and does not include detailed or extensive interviews with members of staff. Meetings held with staff were, as noted in the Information Source section, to clarify points within the documentation provided or to understand reporting procedures. The timeline is not the result of a forensic investigation into the events that occurred and are contained in the timeline.

The information for this timeline is based on that provided up to and including 27 March 2020.

Section 2
Key and Glossary

Glossary

- A - *Aspergillus*
- AB – *Acinetobacter baumanii*
- AC - *Achromobacter*
- AE – Authorised Engineer
- AICC – Acute Infection Control Committee
- ACGC - Acute Clinical and Governance Committee
- ACGF – Acute Clinical Governance Forum
- BCGF – Board Clinical Governance Forum
- BICC - Board Infection Control Committee
- BMT – Bone Marrow Transplant
- Board – NHS Greater Glasgow and Clyde Board
- BWSG – Board Water Safety Group
- CA – *Cryptococcus albidus*
- CCGC - Clinical and Care Governance Committee
- CD – Chlorine Dioxide
- CH - *Chryseomonas*
- CEO – Chief Executive Officer
- CN – Cryptococcus Neoformans
- CRO – Chief Risk Officer
- CRR – Corporate Risk Register
- CU – *Cupriavidus*
- DA – *Delftia acidovorans*
- DSR – Domestic Services Room
- EA – *Enterobacter aeromonas*
- EC – *Enterobacter cloaecae*
- EM – *Elizabethkingia miricola*
- E.coli - *Escherichia coli*
- F&E – Facilities and Estates
- FG – Fungal Growth
- GNB – Gram Negative Bacteria
- GPB – Gram Positive Bacteria
- HAIRT – Healthcare Associated Infection Reporting Template
- HaN – Hospital at Night
- HEPA - High-efficiency particulate air filter
- HH – Hand Hygiene
- HIIAT – Healthcare Infection Incident Assessment Tool
- HIIORT – Healthcare Incident Infection and Outbreak and Incident Reporting Template (predecessor of HIIAT)
- HFS – Health Facilities Scotland
- HIS – Health Improvement Scotland
- HPS – Health Protection Scotland
- IMT – Incident Management Team
- ICD – Infection Control Doctor
- ICM – Infection Control Manager
- ICN – Infection Control Nurse
- ID – Infectious Diseases
- IPCT – Infection Prevention and Control Team
- LICD – Lead Infection Control Doctor
- MB – Microbiologists
- MC – *Mycobacteria chelonae*
- MD – Medical Director
- NHS GGC – NHS Greater Glasgow and Clyde
- OPD – Out Patient Department
- Pan - *Pantoea*
- PAG – Problem Assessment Group
- PanS – *Pantoae septica*
- POUF – Point of Use Filters
- PICU – Paediatric Intensive Care Unit
- Ps - *Pseudomonas*
- PsA – *Pseudomonas aeruginosa*
- PsP – *Pseudomonas putida*
- QEUH – Queen Elizabeth University Hospital, Glasgow
- RCA - Root Cause Analysis
- RHC – Royal Hospital for Children, Glasgow
- SCN – Senior Charge Nurse
- SCSWG – South and Clyde Sector Water Group
- SG – Scottish Government
- SICP – Standard Infection Control Precautions
- SM - *Serratia marcescens*
- SPC – Statistical Process Charts
- STM – *Stenotrophomonas maltophilia*
- TBP – Transmission Based Precautions
- TCV – Temperature Control Value
- TVC – total viable count (total number of viable individual microorganisms present)
- ToR - Terms of Reference
- TWG – Technical Water Group
- VGNB – Variety of Gram Negative Bacteria
- VHF – Viral Haemorrhagic Fever

Key

Gram Negative Bacteria

- AB - *Acinetobacter baumanii*
- AC - *Achromobacter*
- CH - *Chryseomonas*
- CU - *Cupriavidus*
- DA - *Delftia acidovorans*
- EA - *Enterobacter aeromonas*
- EC - *Enterobacter cloaecae*
- EM - *Elizabethkingia miricola*
- Pan - *Pantoea*
- PanS - *Pantoae septica*
- Ps - *Pseudomonas*
- PsA - *Pseudomonas aeruginosa*
- PsP - *Pseudomonas putida*
- SM - *Serratia marcescens*
- STM - *Stenotrophomonas matophilia*
- GNB - *Gram Negative Bacterial not yet identified*
- NUO - *Numerous unidentified organisms*

Fungal Infections

- A - *Aspergillus*
- CN - *Cryptococcus neoformans*
- FG - Fungal Growth

Gram Positive Bacteria

- MA - *Mycobacteria abscessus*
- MC - *Mycobacteria chelonae*

Locations

- 1E - Ward 1E, RHC
- 2A - Ward 2A, RHC
- 2B - Ward 2B, RHC
- 3A - Ward 3A, RHC
- 4B - Ward 4B, QEUH
- 6A - Ward 6A, QEUH
- PICU - Paediatric Intensive Care Unit (PICU), RHC
- ??? - Unidentified ward
- T6 - Theatre 6, RHC

Other Symbols

- → - activity continues into future
- ← - activity continues from the past
- ↔ - activity continues from the past and continues into the future

Section 3
Timeline for 2015

Timeline for 2015 (January to June)

- Hospital campus handed over.
- Contractor tests water in Dec 2014, Jan 2015 results show high TVC and E.coli.
- Outlets with high TVC counts are disinfected, but still fail test. No further evidence that further action taken.
- Initial water results and water testing methodology reviewed by the lead ICD. No evidence that final water testing results were presented to or reviewed by the lead ICD.

26 Jan

- DMA Legionella L8 Risk Assessment 2015 (pre-occupancy) is received.
- Recommendations refer to adjustments to water temperature, removal of dead legs and debris in water tanks. No evidence has been seen which demonstrates that the DMA report was actioned prior to 2018 or that there was widespread knowledge that it had been received, i.e. there is no evidence to show that it was shared with the senior management or F&E team or with IPCT.
- Noted that sampling programme (for TVC, E.coli, coliforms and Legionella) was being conducted and daily flushing and local disinfections were underway where positive results were found. Method of sampling was acceptable to microbiologists. The DMA reports notes that DMA were not given the sample results and disinfection process to review.

Early May

Facilities and Estates (F&E)

1 Jan 2015

End Jan to June?

- Flushing regime is instigated to ensure turnover of water prior to occupation.
- This is performed by estates staff and also agency staff.

2 Feb

- 200 contractors appear on campus to finish work on hospital systems and address issues being found. These contractors had been working with the main contractor to deal with snagging issues.

Apr

- NHS GGC conducts testing of water outlets from April to December. Testing is for Legionella only which was in line with National Requirements. There was no requirement to test for any other organisms.
- April results show positive results for Legionella species in certain areas.
- Sampling is performed by 2 estates managers with no training in taking samples which are taken from 500-600 sentinel points throughout the campus.
- Where positive samples were found, the area/outlet was disinfected until 3 consecutive samples were negative.

18 May

BICC Meeting

- Noted that there is a concern with treating immunocompromised patients at the new hospital due to the ongoing building work there. Minutes note that dust control people have been asked for method statement and list of demolition work planned together with the timescale.

23 June

NHS GGC Board Meeting

- Paper presented to Board details the move to the new campus. Noted some initial operational difficulties but these were quickly and effectively resolved by staff.
- Other operational issues which have emerged include ongoing issues with the pneumatic tube system. No mention of any water issues either in this paper or the Board minutes.

30 June 2015

18 May

- Completion of the move by all units and hospitals to the new campus.

14 June

23 June

Infection Prevention and Control (IPC)

1 Jan 2015

26 Jan

BICC Meeting

- While discussing the new hospital, Infectious Disease (ID) physicians commented that if there was a VHF (viral hemorrhagic fever) patient the ante room should be adequately sized to deal with this eventuality and requires to be assessed. ID physicians wish to see the beds and ante room used for these types of patients.
- MD stresses that keys for new hospital are being handed over the next day and would need to discuss urgently with F&E team to see if ID physicians can look at the area that day.
- ID physicians note that ID Unit has only two beds for VHF patients and the rest of the unit is for managing all other patients.
- Noted by Public Health consultant that a sub group is commencing to look at VHF type of patient.

27 Apr

- Southern General Out Patient move to new campus.
- Commencement of adult patient move from Western Infirmary, Victoria Infirmary and Mansion House Unit, Gartnavel General Hospital.

1 May

- Southern General In Patient Department moves to new campus.

10 June

- The Royal Hospital for Sick Children at Yorkhill moves Into the new RHC on the campus.

30 June 2015

Timeline for 2015 (July to December)

Work continues at the hospital to address issues being identified.

July to Dec (F&E)

1 July 2015

27 July

BICC Meeting

- Noted at BICC meeting that the patients in the Bone Marrow Transplant (BMT) Unit have been transferred to the Beatson as the unit was not built to the correct specification and the main contractor has agreed to fund the rebuild for this area. Timeframe is 12 weeks.
- Concerns again raised around treatment of immunocompromised patients due to demolition of surgical block in September. Alternative route will be identified for these patients so that they enter the hospital at the further point away from the demolition work.

5 Oct

BICC Meeting

- BICC noted that rooms in the adult Tower are now completed except for two rooms (assumed to be reference to the BMT Unit previously vacated).
- Meeting arranged to discuss dust particles from demolition of surgical block. Alternative routes are being found for immunocompromised patients.
- Noted that after a significant flood in neuro theatre, they were closed for approximately 6 weeks but are now in use after air monitoring was deemed satisfactory.

31 Dec 2015

Psuedomonas aeruginosa (PsA)

- Isolated in 2 patients from respiratory specimens taken on 17/12/15. Two different strains identified.

Investigation performed

- Water safety checklist done. SBAR on these cases issued to SCN.

Control measures put in place

- Cases reviewed and an action plan agreed in respect of these cases. .

1 July 2015

27 July

6 July

AICC Meeting

- The draft minutes record that there is discussion of theatre maintenance and validation. One MB advises there are issues with ventilation in QEUH in a couple of areas and one room in particular.
- The minutes note 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.
- The MB and Lead ICD are to meet with the Director of Regional Services to discuss these issues.
- The AICC minutes of 7 September note a correction to the draft minutes by the MB in relation to the above discussion. The correction was to include wording to reflect the issues that were raised around the design of the room. The minute does not give any further details as to what specific concerns were raised.
- The MB/ICDs have advised that at the meeting of 6th July 2015 a number of concerns were raised about the new build and claim the wording was not recorded correctly. A correction was requested at the meeting of 7 Sep. The MB/ICDs do not consider that this change reflects the issues raised.
- The minutes also record that there was some discussion about the implication of the 1100 single rooms in the QEUH on the Infection Control Implementation Plan. The minutes note the IPCT and Lead ICM were cognisant of the concerns raised and agreement to review the implementation plan was captured. The exact implications for the plan are not noted in the minutes.

5 Oct

IMT 24 Dec – HIIAT GREEN

31 Dec 2015

PsA PICU IPC

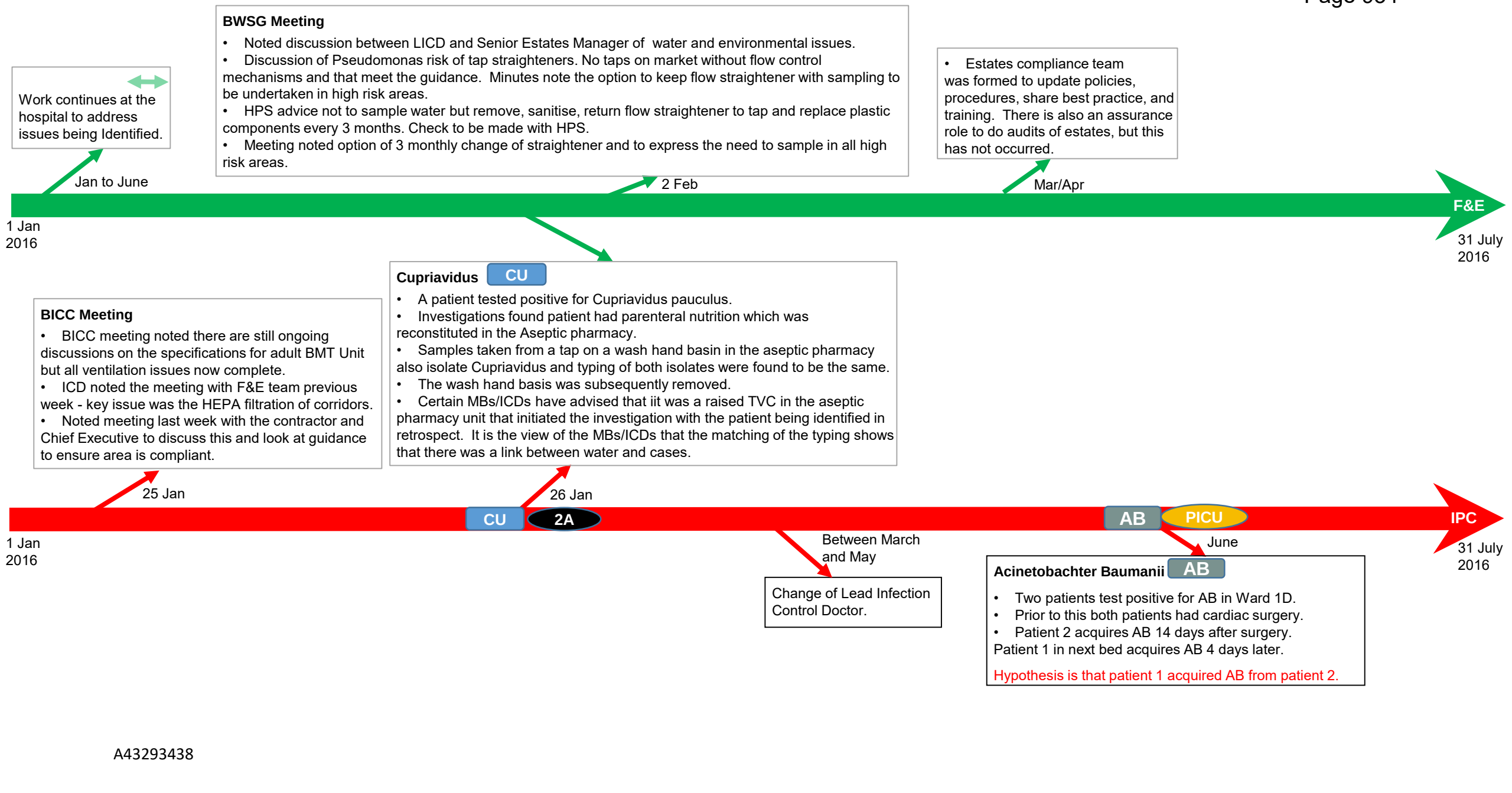
30 Nov

BICC Meeting

- Minutes note that Co-ordinating ICD ("CICD") advises adult BMT services are due to transfer to the new QEUH. MD asks if testing had been done in the new unit and if the timeframe for the transfer on 19 Dec is still on track.
- CICD advises there is no national standard for testing BMT rooms. MD asks for some members, including IPCT and CICD, to discuss this further after the meeting.

Section 4
Timeline for 2016

Timeline for 2016 (January to July)



Timeline for 2016 (August to December)

Work continues at the hospital to address issues being identified.

Original structure included estates officers on day, back and night shifts. Due to the activities that were ongoing at the hospital and requirement to "fire fight" issues, it was decided to change those officers on back and night shifts to day shifts to assist with the volume of work being undertaken. Year on year cost savings also required this to be done as resource was being cut. Once work completed (circa end of 2017/beginning of 2018) these individuals were moved to the compliance team.

1 Aug 2016

July to Dec

Between Aug and Dec (exact date not known)

31 Dec 2016

F&E

PAG on 4 Aug followed by IMT on 5 Aug

Aspergillus A

- 2 cases in Ward 2A – 1 definite and 1 probable case.
- Subsequently confirmed as not Aspergillus - Medical Director notified.

Contributing factors considered

- Tears identified in ventilation ductwork now repaired.
- Condensation from chilled beams creating damp conditions and dust had been cleaned and disinfected. Noted that condensation issue had been raised with main contractor as this should not occur.
- Construction/demolition work on site.

Investigations performed

- Air samples of chill beams were taken and were negative. Samples from air handing unit showed fungus.
- Ceiling area of previous water leak inspected and no fungus found.

Control measures put in place included

1) Increased cleaning and cleaning of chilled beams.
2) Proplyaxis given to high risk patients with Ambisome.
3) Portable HEPA filter units to be placed in unit – noted all rooms filtered but not HEPA filtered due to design of air handling units and chilled beams.

Incident closed by ICD on 16 August and HIIORT updated.

Serratia Marcescens (SM) SM

- 6 patients reported with SM in PICU.
- HIIAT Green at IMT on 04/10/2016.
- Typing confirmed all cases were different types.
- BICC meeting of 3 Oct noted that 1 patient in PICU was identified with SM and had transferred from Neonatal Intensive Care Unit.
- IMT held on 27 Sep recommended carrying out standard infection control precautions.
- LICD asked for review of when the patient came into the room and when water and environment were sampled. Environment screened negative for SM and Pseudomonas and ICPT advised water sampling results are awaited.
- MD asked if this related to hand hygiene and it was noted that this could be a possibility.
- LICD noted there are practice issues with washing equipment in sinks which could potentially be contaminating the environment.

Reported to:

- **3 Oct** – **BIICC**
- **20 Dec** – **Board**
- **9 Jan** 2017 - **AICC**
- **6 Feb** 2017 - **BCGF**
- **December HAIRT**

AICC Meeting

- The minutes note that the Adult and Paediatric BMT rooms fall below standards implemented in other units. Risks to adult patients and corrective action were considered. Work is ongoing in Paediatric BMT Unit to achieve required specification.
- IPCT involved in design/functionality of 4 new neurological theatres to meet building standards.
- Guidance awaited from HPS/HFS on suitability of QEUH for infectious disease patients.

5 Sep

Sep/Oct

A 2A SM PICU IPC

1 Aug 2016

5 Aug

16 Aug

31 Dec 2016

HIIAT – reported as **AMBER**

- First case on 25 July
- Second case on 4 August

HIIAT – updated to **Green**

Reported to:

- **18 Oct – Board**
- **28 Nov – BICC**
- **December HAIRT**
- **14 Nov - AICC**
- **October HAIRT**

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Section 5
Timeline for 2017

Timeline for 2017 (January to May)

- Report of the audit conducted by the Authorised Engineer (AE) on 4 May is received. This audit is normally conducted annually but this is the first time since the campus was occupied. It is assumed an audit did not take place in 2015 as the Campus was in the process of being occupied. The reasons why an audit did not take place in 2016, however, is not known.
- The audit focuses on the compliance processes and documentation that is in place around the management of water quality and not of the physical system itself. So, for example, it will consider if a risk assessment process is in place and what it covers, if it is documented, whether actions identified from the risk assessment are recorded and whether there is evidence to show these have been addressed. Other areas considered, for example, will be servicing records, whether staff have requisite training and experience and if documentation of roles and responsibilities and sampling protocols is in place (including those for escalation of positive results, but this is noted only for legionella and the report does not include a review of the results).
- A review of the audit report for 2017 shows that apart from one entry, all actions have been completed. The one entry shown to be in progress is completed by the 2018 audit. The report gives a score of 99% compliance, but it is not clear whether this is before or after the actions noted were taken.

Work continues at the hospital to address issues Identified.

Reported to:
6 Mar – AICC meeting - Included in paper "IPC Summary Dec – Jan 2017"

Reported to:
8 May – AICC meeting – Included in paper "IPC Summary Feb – Mar 2017"

Jan - April

4 May

1 Jan 2017

31 May 2017

F&E

Serratia marcescens (SM) SM

- Cases of SM in PICU and Ward 1D.
- Review of domestic Cleaning, especially pendants.
- Estates review of trough sink relocation from trolley bay.
- Typing of isolates.
- Chlorine clean of bed spaces.
- Timeline created.
- Patients reported as not giving cause for concern at the time of reporting.

Elizabethkingia Miricola (EM) EM

- Three cases are isolated from patient line cultures between Sep 2016 and February 2017. All unique strains.
- Review of vent cleaning and maintenance by estates.
- Sampling of vents, chill beams and water outlets were negative.
- IPCN carried out visual inspection of environment.
- Incident closed 27/3/17.

Increased bacteraemia rates (NUO) NUO

- Increased bacteraemia rate July 2016-February 2017 amongst paediatric haematology patients.
- Gradual upward trend since July 2016. Multiple organisms.
- Review of vascular access devices to be carried out.
- Aim to reconvene SLWG for vascular devices.
- Surveillance to continue at present.

HIIAT reported as **Green**

Aspergillus A

- Three cases in Ward 2A reported to HPS.

Investigations performed

- IPCT review level of dust from ongoing works at site.
- IPCT review full ward and ceiling void after mouldy ceiling tiles noted caused by a leak into the ceiling void.
- Cleaning of ward was inadequate.
- Inspection of cooling beams which leaked periodically.
- Air and water sampling done – both were negative.
- Hand hygiene performed – score 85%.

Control measures put in place

- Removal of mouldy tiles and ceiling void repairs.
- Full terminal clean of ward.
- Anti-fungal given to all patients.
- Ongoing surveillance by clinical teams to alert IPCT as lab testing unreliable.
- ICD and Estates produce water damage policy.

- Working group to reduce CLABSI rate first meets.
- CLABSI cases reviewed from Mar 2006 to Mar 2010.
- Measures developed were: 1) Standardisation of clinical practice regarding line access, insertion and maintenance. 2) Education and awareness for both staff and families on line care and hand hygiene.
- Rate reduces from median of 6.33 in June 2017 to 1.34 in Dec 2019.

Serratia marcescens (SM) SM

- SM incident in PICU.

BICC meeting - concern about disruption in Ward 2A due to a Rotovirus/ Astrovirus outbreak. Concerns were:
- Level of cleaning/use of professional cleaners.
- Shortage nursing resource to implement IPC measures.
- Low level of HH actions taken are HH education, seeking extra nursing/domestic staff.
- BICC ask IPCT to check resource issue is being addressed.

1 Jan 2017

6 Feb

PAG 3 Mar

3 Mar

IMTs between 7 March to 28 April

10 Mar?

May

15 May

31 May 2017

SM PICU EM 2A NUO 2A A 2A SM PICU IPC

30 Jan

6 Feb

3 Mar

3 Mar

6 Mar

10 Mar ?

8 May

HIIAT reported as **Green**

HIIAT reported as **Green**

BICC meeting
- LICD submits a paper entitled "Role of Infection Control Team in New Builds".
- Notes approved by Director of F&E and states that IPCT should be involved in all stages of project from initial planning through to completion and handover. Paper submitted due to issues with new build and was an abbreviation of SHFN 30 – which covers the role of IPCT in new builds. MD questions if specialist expertise in ventilation beyond ICT is needed.

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Reported to:
8 May – AICC meeting - Included in paper "IPC Summary Feb - Mar 2017"

Noted at **AICC meeting** that QEUH isolation rooms are not suitable for air borne infectious disease. Physicians will review the facilities based on HFS report. In interim, patients will be transferred to GRI or Monklands.

HIIAT initially reported as **RED** then downgraded to **AMBER** and then **Green** once ceiling repairs completed. Incident closed on 28 April.

HIIAT initially reported as **AMBER** and subsequently upgraded to **RED**. No details of when down-graded and incident closed.

- **AICC Meeting** – noted 2 isolation rooms in Ward 2A are being changed from positive to negative pressure. Patients will remain in situ while work is done.
- Certain MBs/ICDs advise above minutes are incorrect and that change was from from negative to positive.

Reported to:
8 May and **3 July** – **AICC**. Meeting on 8 May updated through "IPC Summary Feb – Mar 2017" document. **27 June** - **Board**
31 July – **BICC** **7 Aug** – **BCGF** **June 2017 HAIRT**

Timeline for 2017 (June to August)

Work continues at the hospital to address issues Identified

- The AE report for 2018 of the audit conducted on 23 July 2018 is received and actioned.
- The report gives a score of 99% compliance, but it is not clear whether this is before or after the actions noted were taken .
- A review of the report shows all actions are completed.

1 June 2017 — July - Aug — 23 July — 31 Aug 2017 — F&E

- NHS GGC advised that in June 2017 there was an update to the National Infection Prevention and Control Manual (NIPCM) to include 4 environmental organisms.
- As per the IPCM appendix 13 these organisms are PsA, AB, STM and SM.
- It is important to note that there was a change in LICD between June 2017 and Jan 2018.

AICC Meeting

- Records that some extra alert organisms have been added onto the minimum alert organisms listed in appendix 13 of the NIPCM. This includes GNB and GPB.
- Minutes note that no changes are required as IPCT already include these extra organisms in its systems.
- NHS GGC have advised that the ICD developed triggers for these organisms based on available scientific literature. NHS GGC also advised that no guidance was provided in the NIPCM on how to manage these organisms or implement surveillance.

Stenotrophomonas Maltophilia (STM) STM

- 2 cases of STM line associated bacteria in 8 days. Typing of bacteria from both patients revealed isolates were unique.
- One patient discharged home well. The other became septic when line removed and was too ill to have line reinserted. Admitted to PICU but died on 31 August. The patient had been reviewed by IPCT almost daily. STM recorded on part 1c of the death certificate.
- On 4 Sep ICD requested water sampling in Ward 2A. NHS GGC advised that during the course of 2017 118 samples were taken and all were negative for STM.
- On 4 Sep HPS were informed by email of the death of the patient and asked if any further action was required. HPS advised no further action was required.

Control measures put in place

- Many control measures were already ongoing from previous incidents on Ward 2A.
- Terminal clean of the 2 rooms occupied by the affected patients.
- Review of the environment led by Lead Nurse for IPC, SCN and Domestic Manager. This review assessed cleanliness of the ward and if staff were complying with infection control precautions, e.g. hand hygiene, use of gloves/aprons.
- Additional staff and parent education was introduced in July. Teaching provided for medical staff by IPCD on 2 Aug.
- Review of line care was already in progress (CLABSI work).
- Some MBs/ICDs have advised that they believe that STM had been isolated before or around the time the hospital opened. However, no confirmation of this has been found in the information sources reviewed. MBs/ICDs also note that SPC chart showed a marked increase in STM cases - not just the 2 noted here, but there had been 5 cases after a long period of none. MBs/ICDs also advise that the ICD asked for water samples to be taken – the Health Board advised that a test and process were set up and samples reported to the ICD.

Pseudomonas (Ps) Ps

- One patient with Pseudomonas positive blood culture and one patient with a colonisation.
- Epidemiological link between the two.
- Neither patients giving cause for concern as a result of the Ps.

Control measures put in place

- Full terminal clean of unit.
- IPCAT of unit by IPCT – 78% which is an amber marking. Action list is generated to address failings.
- Water checklist completed and practice issues identified and reported to SCN.
- Monitoring continues.

1 June 2017 — End of June — 3 July — PAG 26 July — 26 July — 31 July — PAG 2 Aug — 2 Aug — Aug — 31 Aug 2017 — IPC

STM — 2A — MA — ??? — Ps — PICU

- HIIAT status **RED** due to severity of illness.
- PAG held on 26 Jul but no IMTs – reason recorded in HIIORT.
- Downgraded to **Green** on 15 Augt after discussion with HPS
- HIIORT was updated 13 times between 26 Jul and 15 Aug.

BICC Meeting

- Report on meeting of 16 Jun on genome sequencing of Mycobacterium Abscessus. Samples sent to Reference Lab who said some are linked.
- IPC unclear on how it transmitted and national guidance awaited.
- Lothian and Aberdeen also have cases. HPS content this is not an ongoing incident.
- Noted in the minutes that work is ongoing in Ward 2A with hand hygiene and SICPs training for medics with ward being reviewed on an ongoing basis.
- Member of BICC comments that the cubicles in Ward 2A had fungal counts in them and there were also high counts in the teenage cancer area. IPCT advise that the areas have been cleaned and re-sampled with acceptable results.

- HIIAT status is **Green**
- PAG held on 2/8/17.

SBAR issued by NHS GGC advising IPCTs of a list of alert organisms in appendix 13 of the NIPCM which may require further investigation. This list includes GNB and GPB.

Reported to:

- **17 Oct** – **Board** **4 Sep** and **6 Nov** – **AICC** – Meeting of 4 Sep Incident noted through "IPC Summary Jun – Jul 2017" document in papers.
- **2 Oct and 4 Dec** – **BCFG** through October HAIRT **9 Oct and 27 Nov** – **BICC** (see next slide) **October HAIRT**

Timeline for 2017 (September to October)

Work continues at the hospital to address issues Identified

- Work on September 2017 DMA report begins.

1 Sep 2017 — Sep - Oct — Sep — 31 Oct 2017 — F&E

Sep to 2020

Still ongoing in 2021

- During September three consultant microbiologists ("MBs") in the South Glasgow sector raised Step 1 of NHS GGC's whistle blowing procedures, following which they were asked by the MD to submit an SBAR. The MBs/ICDs have advised that there was some confusion if Step1 had been raised. The MBs/ICDs advised that they challenged NHS GGC's view that Step 1 had not been raised and this challenge was successfully upheld. The MBs/ICDs advise NHS GGC acknowledged there had been a misunderstanding. The matters of concern raised in the SBAR were about the facilities in the QEUH and the RHC and the structure of the IPCT Service in NHS GGC. Themes raised by the MBs were as follows:
  - Ventilation issues;
  - Protective Isolation;
  - Cleaning;
  - Water quality (with regard to taps having TCVs (temperature control values); policy for cleaning and maintenance of these taps is not reported) and concerns about delays on water testing and reporting of results, and that ICDs need to request water testing as this is key to investigating/managing outbreaks;
  - Plumbing in neurosurgical block;
  - Decontamination of respiratory equipment; and
  - Structure of IPCT.
- A meeting was held on 4 Oct with the MBs to discuss concerns. A 27 point action plan was developed to address the concerns in the SBAR. This action plan was ratified by the CCGC on 5 Dec and noted by the Board on 20 Feb 2018. Work to address the action plan is extensive and continues from this point onwards and is still ongoing in 2021. Certain MBs maintain that the action plan was never agreed with them at any point and that it contained inaccuracies and misrepresentations.
- The MBs/ICDs advise they raised concerns over the water system prior to the hospital opening. They also advise that concerns were reported to their consultant colleagues in relation to the number of infections, including unusual ones at RCH, not all of which were related to a possible water source.

Serratia marcescens (SM) SM

- One SM case attributable to Ward 1D during a period of increased burden of SM cases (3 other patients on the unit colonised with SM).

Control measures put in place

- Terminal clean of affected bay carried out.
- Hand hygiene audit carried out and training provided for staff to carry out local audits.
- No further action unless new cases identified.

BICC meeting

MD noted the receipt of a number of emails concerning the ventilation and negative pressure rooms in QEUH and RHC. The minutes note the MD had a meeting last week to progress matters on these issues. It is not clear from the minutes if this is referring to the meeting with MBs/ICDs on 4 Oct.

- Discussion on STM cases in July when 1 patient died. IPCT are monitoring the ward closely and worked with ward and facilities staff on environmental cleanliness and clinical practice.
- Questions raised on line infections - IPCT are reviewing line care. RHC Chief Nurse is supporting a quality improvement group on line care. Update on this to be given at next meeting (this relates to the work on CLABSI which reduced line infections).

Acinetobacter baumannii (AB) AB

- New case of AB on Ward 3A. Same strain as one of the two previously colonised cases on ward at the same time.
- Review of cases/patient placement shows none in the same room but 2 patients with same strain played together.
- A fourth case, colonised since 2016, returned to the unit after the new HAI. The strain matches the 2 cases above.

Control measures put in place

- IPCT have reiterated good SICP's and continue to monitor Ward 3A for any onward transmission.

Aspergillus (A) A

- One patient with A from a Bronchoscope procedure on 23 Oct 2017.
- HPS informed on 27 Oct and agreed HIIAT is green.

Control measures put in place

- On anti-fungal since 20 Oct.
- Clinical Team are risk assessing all Ward 2A patients on a case by case basis before prescribing anti-fungal prophylaxis.
- Twice weekly IPCN visits to ward to monitor environment, cleaning and practice.
- Ongoing cleaning of ward with chlorine based detergent.

Sep to 2020 — CU — 2A — SM — PAG 6 Oct — PICU — 9 Oct — AB — 3A — 11 Oct??? — A — 2A — PAG 27 Oct — 31 Oct 2017 — IPC

1 Sep 2017 — 4 Sep — Sep — 6 Oct — 11 Oct??? — 27 Oct

AICC Meeting

- Noted SBAR circulated at 3 Jul meeting is withdrawn as there is some outstanding work to be performed on environmental issues.

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CCGC Meeting

- A paper presented at the CCGC meeting in June 2018 notes that a patient presented with Cupriavidus bacteraemia.
- The paper notes the patient received a product from the aseptic pharmacy. The date the incident occurred is not noted in the paper.

- PAG held on 06/10/17.
- HIIAT marked as N/A.

Reported to:
- **8 Jan 2018** – AICC Meeting through "IPC Summary Oct – Nov 2017" document

- Date of PAG or IMT is not noted.
- HIIAT marked as N/A.

Reported to:
- **6 Nov and 8 Jan 2018** – AICC Meeting on 8 Jan noted incident in "IPC Summary Oct – Nov 2017" document in papers

- HIIAT status **GREEN.**
- PAG held by phone 27/10/17.
- HPS informed 27/10/17.
- IMT not required unless a new case is identified.

Reported to:
- **6 Nov and 8 Jan 2018** – AICC meeting on 8 Jan noted incident in "IPC Summary Oct – Nov 2017" document in papers

Timeline for 2017 (November to December)

Work continues at the hospital to address issues identified

Nov - Dec

1 Nov 2017

31 Dec 2017

F&E

AICC Meeting

- Committee advised that in relation to Ward 2A work is ongoing as they have had a high number of outbreaks with lines associated with blood cultures (reference to CLABSI work). There have been a few issues in the ward and enhanced visits and education have been carried out.
- Compliance with the Care Plan resulted in a score of 50%.
- A single case of Aspergillus was identified in a patient (see previous slide for case in October). The patient is clinically well and there is ongoing cleaning of the ward with chlorine based detergent. Committee advised that the patient did not have anti fungal prophylaxis.
- Committee advised that Ward 2A has 8 beds that are PPL rooms and 4 of these have been converted to positive pressure rooms but there would be a significant expenditure required to change all these to positive pressure rooms.
- Committee asked whose Risk Register this would sit under and were informed that it would be Women & Children's directorate. They have been invited to the next BICC meeting to provide an update on Ward 2A.

Acinetobacter baumannii (AB) AB

- Two new cases of HAI colonisation although only 1 is an HAI from PICU (2nd is an HAI from 1E).
- There is also a third case noted, previously diagnosed in Oct 2017, currently in PICU (this seems to relate to incident in Ward 3A, see previous slide, but it is unclear from the document if that is the case).

Investigations performed

- Time and place link to one bed bay for all 3 cases above.
- Look back at 3 cases from September and October found 2 further cases associated with this bed bay.
- 2 patients remain in Ward 1D. Neither giving cause for concern.

Control measures put in place

- TBP's around bed spaces.
- Hand hygiene, audit and environmental sampling completed.
- Ongoing IPCT investigations and monitoring - date of PAG/IMT is not noted.

CCGC Meeting

- CCGC were informed of the concerns raised by MBs/ICDs in Sep and were provided with papers detailing these concerns.
- CCGC were advised that the concerns raised were in relation to the facilities in QEUH and RHC and structure of the IPCT service.
- Noted that the Chief of Medicine for Diagnostics and members of the IPCT Senior Management team met with the MBs to discuss all concerns raised.
- The consultant MBs tabled a list of concerns and it was confirmed all of the issues were reviewed and, where required, acted upon to address all concerns.
- CCGC were also advised that the infection rates on the QEUH site are some of the lowest in the health board and in line with Scottish infection rate standards.
- It was recognised that the QEUH was planned and designed in 2007/08 but a number of changes in the structure and patient case mix meant original planning assumptions needed to be updated.
- The CCGC noted that the paper was clear and gave assurances.
- Certain MBs/ICDs note that the above was presented at the meeting without any feedback from those raising concerns and that NHS GGC had not obtained any clarification from them as to whether these actions address the concerns they raised; the Health Board contests this view.

6 Nov

13 Nov

5 Dec

AB PICU 1E

IPC

1 Nov 2017

27 Nov

31 Dec 2017

Reporting to 8 Jan 2018 – AICC Meeting through document "IPC Summary Oct – Nov 2017" included in committee papers

BICC Meeting

- Minutes include an update on work being done on CLABSI which has been ongoing since the group first met in May 2017. It is noted in the minutes that the group has focused on 4 main area – service, infection control, domestics and estates.
- The minutes note the group collects data weekly on CLABSI rates within the RHC site including haemato-oncology patients cared for at home and those attending day care. Initial rates had doubled in Jun 2017. On 14 Aug the group introduced the use of a Curos port protector tip which eliminates the need for staff to disinfect the hub attached to the line as this is done by the device itself. This resulted in a reduction in the CLABSI rate. Member noted there had been a lot of changes at once regarding staff, new equipment being introduced and ensuring staff are adhering to decontamination/line care, but this had contributed to the improvements in the CLABSI rate.
- Minutes note that from December every CLABSI will be subject to a rigorous review utilising Event Cause Analysis methodology within 72 hours of a reported case.

Section 6
Timeline for 2018

Timeline for 2018 (January to April)

- DMA report for 2017 has been completed and finalised.
- A work plan is being formulated by Facilities and Estates to action recommendations.

- HFS and HPS requested in March 2018 to assist with the investigation of the water incident detailed below.
- Papers sent to HFS include a copy of the DMA report for 2015.
- NHS GGC conduct an internal investigation as to why the 2015 DMA report had not been actioned.
- The DMA 2015 report recommendations are similar to those in the 2017 DMA report and were included in the work plan created by F&E for the 2017 DMA report.

BICC Meeting

- The minutes record that when providing an update on the "water incident" the ICD advised NHS GGC water testing is fully compliant with national guidance and MBs receive both routine results and those requested during outbreaks of water borne bacteria. Certain MBs/ICDs, however, note that water results go to the ICDs and not MBs.
- The minutes also note that yearly risk assessments are done for areas not included in the guidance but which may benefit from additional water testing.
- A routine investigation into an unusual type bacteria found in a clinical case led to additional testing and positive results being found in Ward 2A in RHC and 4B in QEUH.
- MD asks if there is a clear way forward for handling this incident and to involve Public Health and IPCT. ICD and Interim Director advise they want to get a water expert on board along with HPS/HFS to look at short and long term solutions.

First meeting of the Technical Water Group (TWG). (See details on pages 28 to 39)

1 Jan 2018 — 31 Jan — Mar onwards — 28 Mar — 28 Apr — 30 Apr 2018 — **F&E**

IMTs held 2 Mar to 27 March – HIIAT RED until 27 Mar then changes to AMBER — 17 April

Pseudomonas aeruginosa

PsA

- Two cases in PICU. Two cases linked in time and place with another 2 cases on the unit (long-term). Cases at the opposite ends of the ward.
- All isolates sent for tying – confirmed to be different strains so no evidence of cross-transmission.
- Water and environmental tests are both negative.
- IPC audit completed and scored 91%.
- Review of cleaning practice of sinks and drains performed..

Various Gram Negative Bacteraemia

Patient on Ward 2A has Cupriavidus at the end of January 2018.

Investigation performed

- Comparison with a Cupriavidus case in 2016 attributed to the aseptic pharmacy. Water tests from that location are negative. Comparisons made to historical cases and other hospitals to identify links. MB's epidemiological report concludes organism introduced to a particular water outlet via an unknown route followed by cross transmission via patient interaction, contaminated cleaning/clinical equipment or healthcare worker.
- MB's report confirms various gram negative organisms (different strains) and fungal growth in tap outlets (flow straighteners particularly) and shower heads in RHC/QEUH (including Wards 2A, 2B and 4B). It is noted that taps were evaluated by HPS/HFS prior to fitting in RHC/QEUH.
- Main water supply tests negative but test positive in sinks in Prep and Treatment room.
- Consultation with HPS, HFS, SG, Public Health England and water experts.
- Minutes of 6 Mar note that concerns raised by the clinical team over environmental risks (not detailed in the minutes) in Ward 2A were communicated higher and to HPS over 2 years ago.
- Members are dissatisfied that responses from senior management and outside of NHS GGC do not provide reassurance. Members are encouraged to share their concerns with senior management.

Hypothesis is outlets are source. Flow straighteners linked to other outbreaks as prone to biofilm growth.

Control measure put in place

- Water dosing performed but it only reduces organism counts, so taps are replaced, sanitised and POUFs fitted.
- Removal of sinks in Prep and Treatment room.
- Filter changed every 25 days and taps tested weekly.
- Disposable shower heads fitted and changed quarterly.
- Mobile wash hand basins and bottled/sterile water used for washing and drinking while above actions taken.
- CU and STM added to IPCT alert organism software system.
- Patients receive Ciprofloxacin prophylaxis and additional line protection measures are introduced.
- Increased hand hygiene and cleaning regime.
- Technical Water Group created to find long term solutions.

Board Meeting

- Board updated on recent identification of infections which may be linked to water and overview given of the circumstances, ongoing work to identify the cause and measures put in place to prevent further contamination.
- Advised risk rating was reduced to amber and investigations confirmed no cross-transmission had occurred.
- Board asked if source of the infections had been identified. Advised Scottish Water are regularly testing the water supply to both the hospital site and the neighbouring residential properties but state that infection is not present in water supply.
- Board told extensive work is ongoing to identify infection's origin in the water system.

Jan — Feb — 1 Mar — 15 Mar — 19 Mar — 13 Apr — 17 Apr

PsA — **PICU** — **CU** — **PsA** — **STM** — **2A** — **STM** — **FG** — **IPC**

1 Jan 2018 — Jan — 30 Apr 2018

HIIAT status:
19 Jan – AMBER
24 Jan - GREEN

MBs/ICDs advise that two MBs raised Step 2 of GGC's whistle blowing policy due to concerns around the ongoing issues raised in Step 1 in Sep 2017. Evidence of this action has not been noted in the various committee and Board minutes reviewed.

- From 26 Jan to 1 Mar – 4 cases in Ward 2A: Cupriavidus (CU) (1 case), Pseudomonas (Ps) (1 case) and Stenotrophomonas (STM) (2 cases).

4 new cases of Stenotrophomonas:
- 1 patient in Ward 2A and 1 in PICU
- 1 discharged from Ward 2A but came into Ward 2B for line care
- 1 in Ward 3C (renal) – unsure if HAI as day care

- Two cases in Ward 2A of patients with pyrexia.
- Some patient cases in Ward 3C with possible fungal growth. IPCT to investigate.

- Full incident management report – details incident and actions taken. Final case count is 1 Cupriavidus, 5 Stenotrophomonas and 1 Pseudomonas auerginosa (later excluded following different identity of water isolate).

Reported to: 31 Jan – BICC (PsA incident only) **28 Mar - BICC** – noted discussions on the potential long term solutions and that the Executive team and Board updated on progress. **17 April – Board** **27 Apr** – AICC – update provided to Committee on incident and upgrading of Ward 2A BMT rooms. Questions on impact of chlorine dioxide on renal system. Assured this a different water supply and water expert involved Further 3 RHC rooms and 4 QEUH rooms to be converted from positive to negative pressure. **4 June** – BCGF noted April HAIRT. **12 Mar** – ACGC – reports issues with Mixer taps in ward 2A but IMT set up and equipment sanitised. **9 April –** ACGC – incident reported and situation resolved with appropriate filters fitted over all taps. **April** HAIRT

Timeline for 2018 (May to June)

During the period from May to June, members of the F&E team received formal training as an Authorised Person for water as well as other services such as Mechanical and Electrical. Certificates were obtained and signed off by the Authorised Engineer to state that the person has passed the training and is now responsible the safe operation and maintenance of the water or another relevant system.

1 May 2018 — May to June — 30 June 2018

F&E

PAG/IMTs held 11 May to 6 June. HIIAT **GREEN**

Acinetobacter baumannii (AB)
- Three colonisations of AB in April, then 2 in May. IMT count a further case (bringing total to 6 cases) colonised in Feb 2018 - patient remains in the unit.

Investigations performed
- Two patients in adjacent bed spaces.
- Domestic audit identifies cleaning concerns.
- IPCT raise concerns over TBP adherence.
- All isolates sent for typing.

Control measures put in place
- A list of actions relating to above is put in place including a review of TBPs in the unit.
- IPCT monitor for new cases.
- NHS GGC advised that the hypothesis was that these infections were due to direct contact between patients.

IMTs held 29 May to 21 June – HIIAT Amber changed to Red on 4 June until 18 June when Amber and Green on 21 June (Water Incident)

- IMT set up following PAG on 18 May which looked at the incidence of 4 EC cases from 28 April to 14 May and 3 STM cases since 4 May.

Investigation and Testing
- Drain swabs reveal a variety of GNB (different strains) including those listed below plus Sphingomnas, Klebsiella oxytoca and Elizabethakinga. Black grime was seen in the RHC and QEUH drains.
- Dissection of a sink waste pipe shows exposed metal parts with bio-film. All waste pipes are replaced in Wards 2A/4B with new plastic ones, as were sink drains, following complaints of water not draining away.
- Review of cleaning regime and additional resource allocated following issues identified. Noted that rooms are cluttered and there is a large number of visitors/medical staff in the ward. In response, numbers are restricted and parent education is provided to prevent clutter
- Analysis was being done by HPS through comparison with Yorkhill taking into account changes in the environment, patient population, and historic lookback and comparison with rest of Scotland. HPS and water experts were being consulted.
- Ongoing meetings with clinical staff to discuss their concerns that the IMT is not in control of the environment as there have been issues (not detailed in the minutes) since the ward opened. Hypothesis – drains are the source due to links in time, place and person. Belief that water is clean but bio-film can build up due to hand washing and inappropriate liquids poured down the drains e.g. coffee/tea. Research shows aerolisation of bio-film can occur when tap turned on and this spreads around the sink area.

Control measures put in place
- Drains are cleaned and then decontaminated with Hydrogen Peroxide Vapour in Wards 2A, 2B, 7A, 7D, PICU and elsewhere on site.
- Replacement of waste pipes and sink drains.
- Enhanced hand hygiene introduced – alcohol gel to be used after washing.
- Chemotherapy and BMTs are delayed/stopped, admissions restricted and patients given Ciprofloxacin while drains are decontaminated.
- IPCT to conduct peer reviews focusing on SICPs, TBPs and the environment.
- Site visited twice by water experts to advise on long term solutions including use of chlorine dioxide to dose and decontaminate the water system.
- TWG confirms chlorine dioxide dosing began in November, followed by tap replacement in January 2019.

12 June

CCGC Meeting
- CCGC updated and provided with a paper on the "water incident" in Wards 2A/2B which details all incidents in 2018, investigations performed and control measures put in place.
- CCGC told further water tests revealed evidence of a systemic problem in RHC and QEUH.
- Noted that working closely with HPS/HFS on this incident.
- Noted that a special water group was set up and UK water experts consulted to develop a long term solution, which includes chemical dosing of the water supply.
- Members noted the above and were assured by long term preventative methods and use of water experts.

Pan **2A** **AB** **PICU** **EC** **STM** **Ps** **2A** **EC** **STM** **Ps** **A** **CU** **2A** **IPC**

1 May 2018

6 May — Case of Pantoea in Ward 2A on 6 May.

Reported to: **19 June – AICC** through "IPC Summary Apr – May" included in papers.

4 June

BCGF meeting + April HAIRT
- Update provided on this incident and actions taken.
- Noted that outlets remain positive even after chemical dosing so POUFs were fitted to outlets.
- Further testing found evidence of a Systemic problem and work is ongoing to solve these problems.
- Further updates to be provided. Forum noted update.

4 June

HIIAT reported a total of 9 cases in Ward 2A/2B with;
- Stenotrophomonas
- Pseudomonas Aeruginosa
- Enterobacter cloaecae

Patient who out on pass and was well returned peri arrest.

During this period there were 17 GNB cases with some patients displaying multiple organisms. Total of 23 organisms were identified.
- **Enterobacter** (6) **Stenotrophomonas** (9) **Pseudomonas** (4)
- **Acinetobackter** (2) **Cupriviavidus** (1)
- **Pantoea** (1) – occurred in Ward 2A on 6/5/18 and reported to HPS.

Reported to: 23 May and 25 Jul – **BICC** – 28 May noted chlorine dioxide system to go out to tender. **26 Jun, 21 Aug** – **Board** **6 Aug**– **BCGF** **11 Jun** – **ACGC** – Noted infection controls working, Technical Water Group set up to address wider implications. Still significant clinical concern. **19 Jun AICC** – Update provided on incident and TWG actions. **13 Aug** – **ACGC** – noted control measures appear to be effective. **June and August HAIRT**

12 June — 26 June — 30 June 2018

Board Meeting + June HAIRT
- Update provided to Board on actions taken to address the bacteria in the water system.
- Board disappointed to note that QEUH had consistently been worst performer in NHS GGC for cleanliness over past 12 months. Comparison made with Glasgow Royal Infirmary as superior performer despite more challenges.
- Another member noted QEUH complied with national requirement of >90% compliance and methodology used at sites was different.
- Board asked for further update at October meeting.

Timeline for 2018 (July to August)

- The work plan to address the recommendations of the 2 DMA Reports from 2015 and 2017 is completed. Actions are allocated to members of the F&E team and work starts from July onwards. All actions are completed by the end of 2018.
- A record is kept setting out the recommendations from the 2 DMA reports and the details of the work performed to address each recommendation plus any supporting evidence. The date the work is performed (a job ticket) and the supporting evidence is contained on the F&E's own computer systems.
- It was noted that this record was updated during Jul, Sep, Nov and Dec to reflect work completed at these points and the status of work not started or not yet completed.

5 July onwards

- HFS/HPS produce a draft report on their findings from the investigation into the suspected contamination of the water system. The report entitled "Technical Review Water Management Issues NHS GGC QEUH and RHS" is passed to NHS GGC in a final draft status for comments. The conclusion of the Report is that the system was potentially either contaminated during the construction phase and lack of proper maintenance has led to the build up of bio-film and consequently GNB, or that bio-film built up in the tap flow straighteners and regressed back into the water system. HFS recommend that NHS GGC implement the recommendations set out in the DMA reports.
- NHS GGC responded with comments and discussions took place between the Board and HFS/HPS. There is a general, broad concern about the size and technical content of this report given it is intended as briefing information.
- The recommendations in the report for NHS GGC are to address the recommendations made in the 2 DMA reports of 2015 and 2017 which (as highlighted earlier in this timeline) are already being actioned.

Aug

F&E

1 July 2018

23 July

- The AE report for 2018 of the audit conducted on 23 Jul 2018 is received and actioned.
- The report gives a score of 99% compliance but it is not clear whether this is before or after the actions noted were taken.
- A review of the report shows all actions were completed.

21 Aug

31 Aug 2018

Board Meeting + August HAIRT

- Update on water incident is provided to the Board.
- Noted that they continue to work closely with HPS/HFS.
- A report from HPS is expected and will be presented to Board in due course.
- Board noted concern regarding the water issues given this was a new hospital and query if there were issues with the building specifications.
- Chief Executive advised that work to identify problems with the initial specifications is underway so that learning can be obtained and shared.

21 Aug

IPC

1 July 2018

31 Aug 2018

A43293438

Timeline for 2018 (September)

- A review of NHS GGC's Water Safety Policy by an external consultant is commenced and a first draft is produced in Sep with the final version being created in Jan 2019.
- The policy sets out the roles and responsibilities, governance structure, risk reduction strategy, operational arrangements, water testing and reporting and monitoring requirements in respect of the management of water safety.

1 Sep 2018 — Sep — 30 Sep 2018 — F&E

IMTs held 5 from Sep to 28 Sep – HIIAT initially Green, RED from 13 Sep then changed to AMBER on 28 Sep

Investigations performed

- Drains swabbed in Ward 2A on 29 Aug as thick black and yellow grime visible after cleaning only 4-6 weeks ago - findings are that 2 of 3 cases match the patients. Tests show Coliforms, Delftia acidovarons, Chryseomonas indologenes, Cupriavadis, Pseiudomonas aeruginosa and Klebsiella oxytoca. It is also noted that in one case the patient had a positive blood culture prior to being in one of the rooms from which a positive swab was taken and the hypothesis was that this patient may have contaminated the drain.
- Further investigation of drains and trough sinks show that only some have a problem. This issue is only in RHC and not QEUH. HPS advised drains should not be cleaned so regular cleaning had stopped. Further guidance awaited from HPS.
- IPCT had been visiting the ward daily with more formalised reporting twice weekly. High Standard of environmental and equipment cleanliness was achieved and visits now decreased to twice weekly. IPCT have no concerns and environment and domestic audits score well. IPCT note less people and clutter on ward.
- IPCT conduct physical inspection of drains and sinks and note some appear to have sealant in the drain and black gunge is noted. Reported to F&E team who confirm sealant is a gasket in the drain that has become porous due to the use of hydrochloride cleaning products. Speaking to manufacturer as known issue.
- Greater level of domestic hours for cleaning but general build up of dust especially vents and chill beans. Noted that air changes are 3 in RHC and 6 in Adult Hospital which may explain levels of dust. Air sampling on chill beams is negative.
- Noted staff are being pulled from the ward to work elsewhere in the hospital which makes maintaining standards difficult. Additional funding is being requested.
- Discussion with water experts results in a survey of the drains being agreed as well as scopes down the drains to see if there is any blockage.
- On 17 Sep IMT notes an Executive Management meeting rejected a decant until the results of the drain survey are known. Clinicians concerned about decision and a paper is sent to the Director of Women and Children asking for decant to go ahead.

Hypothesis - Concerns expressed that IMT is no nearer the source of these infections. Feeling is that there are more gram negative cases than usual. Noted that TWG is doing a lot of work to investigate the source. Dust levels consistently high and ventilation changes lower than recommended which may explain dust. HPS reviewing ventilation for Wards 2A/2B. Feeling is that the wards should close

- NHS GGC advise that by this point, SG, HPS and HFS were all involved and regular teleconferences were held with them regarding the incidents in Ward 2A.

Control measures put in place

- Reinstatement of weekly cleaning of sinks and shower drains, with mechanical brush cleaning monthly to agitate any build up.
- Charting of patient pathways to and from theatre with review of drains and sinks in those areas.
- Drain survey and ventilation survey are commissioned. The drain survey did not find any issues.
- Admissions to Ward 2A continue but are restricted and judged on a case by case basis.
- On 18 Sep TWG take decision to decant BMT patients in Ward 2A to Ward 4B in adult hospital.
- On 26 Sep Ward 2A was decanted with BMT patients moving to Ward 4B and all other patients to Ward 6A, both in the Adult Hospital.
- Both wards were inspected by F&E and IPCT and made ready for patients, including repairs being made, full deep cleans (including drain and vent cleaning) and POUF inserted on taps and showers. Prior to decant, IPCT did a final inspection to confirm they are satisfied with the wards.
- Following decant, IPCT make daily visits to Wards 4B and 6A to offer advice and support.

1 Sep 2018 — GNB 2A — GNB 2A — SM 2A — STM 2A — GNB 2A — 30 Sep 2018 — IPC

4 Sep

CCGC Meeting

- Update on the above "water incident" is given along with progress on actions.
- CCGC advised that a report from HPS is awaited and there is close supervision of the ward with no further cases to date.

5 Sep

Since 5/8/18 there have been 3 cases in Ward 2A of bacteraemia caused by gram negative organisms isolated from drains.

10 Sep

1 new gram negative bacteraemia in Ward 2A.

Total of 21 Cases this year.

13 Sep

1 new case of Serratia in Ward 2A.

Total of 22 cases this year.

17 Sep

1 new case of Stenotrophomonas in Ward 2A.

Total of 23 cases this year.

20 Sep

1 new patient with gram negative in Ward 2A - not yet identified.

This is the last case making the total now 24 cases for this year.

Reported to:

10 Sep – ACGC – update regarding 3 bacteraemia cases since 5 Sep and link found to drains. Noted enhanced inspection and cleaning process remain in place.

26 Sep – BICC - update on latest outbreak and relocation of patients. Member noted concerns of the clinical risks of a move. MD advised risk assessment was performed and several options given to the Executive Group which included the Chief Executive and Board Directors to discuss. Risk Assessment of all issues/options to be shared with AICC and ACGC. MD to set up a meeting with SG Policy Unit, HPA and NHS GGC to discuss the incident fully.

1 Oct – BCGF **16 Oct** – Board **26 Oct** – AICC – update given on latest incident and decant.

October and December HAIRT

Timeline for 2018 (October to December)

- New Director of F&E takes up post.

- As a result of the "water incident" the Compliance team starts to review and develop standard operating practices for sector estates offices to follow to ensure consistency and appropriate quality of work is performed. The Water Policy is also being reviewed at this time. This work continues into 2019.

- Following the appointment of the new Director of F&E and the lessons learned from the water incident, new standard operating procedures (SOPs) were created for water and other services (e.g. ventilation, electrical, etc) to provide consistency and enhance compliance. This includes protocols for dealing with DMA reports and AE audits to ensure findings are discussed and actioned, and also for flushing and sampling regimes. Registers are created to record the location of little used outlets, dead legs and flexible hoses to ensure they are monitored and maintained.
- Compliance managers are appointed for each service, including water, and are responsible for ensuring completion of Standard Compliance and Risk Tool process and compliance with SOPs. Internal audits are conducted to identify any issues and ensure these are addressed and best practices shared.
- The above work is progressed over the next 18 months to 2 years.

1 Oct 2018 — 1 Oct — From Oct onwards — Oct onwards — **F&E** — 31 Oct 2018

16 Oct

Board Meeting

- Update provided on current water incident. Noted there had been no cases since June but there had been further cases in September which were thought to be associated with drainage issues in Ward 2A.
- Following a risk assessment a recommendation was made to the Board Directors to close the ward. This was approved with patients relocated to QEUH on 26 Sep.
- A detailed investigation of the water system in 2A and 2B was underway by external experts.
- Director of F&E advised that plans to dose the water system with chlorine dioxide continued and a mobile dosing plant would be installed by the end of week. Future plans to remove wash hand basins and taps and replace draining system were being taken forward.
- Board questioned about frequency of these incidents in similar facilities. MD advised these did not appear to be common.

IMTs continue in October and HIIAT is AMBER

- IMTs continue to assess environment. Contents of blocked drains discussed, which contain a variety of foreign objects e.g. small toys, syringes, metal and plastic material and lumps of adhesive. ICD to address this issue.
- Consideration of whether waterless ITU can be put in place in BMT setting, but this not fully possible.
- Technical Water Group (TWG) outline scope of work and Completion expected on 14 Dec. Dosing of water with CD to be implemented, taps and wash hand basins changed and elements of plumping to be replaced.
- Consideration also given to changing roles of the prep and treatment rooms.
- Call with Scottish Government on 18 Oct to update on current position with proposed work on Ward 2A and on patients in Wards 6A and 4B.

1 Oct 2018 — Oct — 16 Oct — **IPC** — 31 Oct 2018

Reported to:
16 Oct – Board - updated on current plans and work being performed. **28 Nov – BICC** - update provided of ongoing work in Wards 2A and 2B with expectation that work will be completed in December. Noted that the ventilation system is being looked at and implications for this and discussions are ongoing with clinicians. Advised that chlorine dioxide will also be done in the adult hospital in January. SG being kept informed. **3 Dec** – **BCGF** - noted as part of the December HAIRT which covers incidents from Feb to Nov 2018. **28 Jan 2019** – **BICC** – update given on chlorine dioxide system and "discussion" over removal of sinks in Ward 2A. **October and December HAIRT** – continues to be reported in HAIRTs and the various committees during 2019. **February 2019 HAIRT** - covers incidents from Feb 2018 to Jan 2019 noting HIIAT returned to Red on 13 Sep, then Amber on 28 Sep. **April 2019 HAIRT** - covers period from February 2018 to February 2019 noting CD system now installed in both QEUH and RHC.

Timeline for 2018 (November to December)

- Register of assets is received from main contractor in late 2018 after 3 years of asking for the maintenance schedules for the systems in the hospital to be provided.
This allowed the F&E team to construct more appropriate maintenance schedules for all systems in the hospital and was completed in 2 to 3 months.

- Children's hospital is dosed with CD. This continues to the present day.

- The actions to address the recommendations set out in the 2015 and 2017 DMA report are completed by 16 December.

- QEUH is dosed with CD. This continues to the present day.

1 Nov 2018 — Late Nov — 22 Nov — Dec — Dec — F&E

IMTs on 2 Nov and 14 Nov – HIIAT GREEN

Pseudomonas Aeruginosa (PsA) PsA

Following a PAG held on 25 October an IMT was set up on 2 Nov to investigate 5 cases of PsA isolated from patients who had all had appendectomies in same theatre in October 2018.

Investigations performed

- A number of investigations have taken place including sampling of equipment which was all negative.
- Typing results have shown 2 matches, 2 unique strains and 1 results as outstanding.
- Sample of drains found PsA growth in the anaesthetic trough and this was sent for typing.
- Excessive amount of debris, including nail picks, found in u-bend traps of drains also.

Control measures put in place

- All drains throughout theatre have been cleaned.
- No further meetings were planned unless new cases identified. .

Reported to:
7 Jan 2019 –
AICC – briefing given and included in document "IPC Summary Oct to Nov 2018" which included in papers

BICC Meeting
Noted that the SOP Entitled "Environmental Organisms in High Risk Areas" is being issued.

New SOP is issued by NHS GGC entitled "Environmental Organisms in High Risk Areas". This refers to Appendix 13 of the NIPCM and appears to be the replacement to the SOP that was circulated and then withdrawn in Aug/Sep 2017.

IMTs ongoing during November and HIIAT is AMBER

Ward 2A

- Updates provided on the progress of work in Wards 2A/2B. Ventilation was discussed and it should be positive in all rooms other than BMT rooms. Design had stipulated rooms to be neutral/slightly negative pressure. Not clear what impact this will have on return of patients if rooms cannot be transferred to positive pressure.
- Following review of ventilation system and other issues noted, an option appraisal is requested from a specialist ventilation engineer on what is required to rectify and bring the system up to standard.
- Significant discussions between ICD and Clinicians over removal of trough sinks and them being replaced with 2 stage hand hygiene process. Trough sinks seen as potential source of bacteria. ICD decides to remove against the wishes of Clinicians.
- Further debris found from scrubbing brushes in theatre drains. Communication strategy had been a previous action of IMT to prevent items in drains. ICD to email lead surgeon and lead nurse to ensure all staff are made aware of findings. Alternative brushes to be sourced.
- Call with Scottish Government on 18 Oct to update on current position, proposed work on Ward 2A and on patients in Wards 6A and 4B.
- ICD noted that now wards are decanted there is marked reduction in bacteraemia. Final HIIAT completed and incident closed on 30 Nov.

11 Dec — 20 Dec — 31 Dec 2018

CCGC Meeting

- CCGC advised that installation of chlorine dioxide plant is complete with a further 12 localised dosing sites being installed.
- Ongoing reviews of the efficacy of the dosing will be undertaken.
- HPS/HFS and external advisors continue to investigate cause.
- Update on the work being performed in Wards 2A/2B was given. This included replacement of taps, drainage, outlets and air handling unit. CCGC were advised this work may take some months.
- Questions raised by CCGC regarding original design of facility. CCGC were advised that work was underway to consider all the identified issues across the site in relation to the original specification requirements of the building.

- Following concerns on the length of the HFS/HPS report issued in Aug, HPS create a summary report entitled "Summary of Incident and Findings of NHS GGC QEUH/ RHC".
- The report's recommendations refer to those already contained in the Aug HFS report, i.e. to implement the DMA 2015 and 2017 recommendations.

1 Nov 2018 — PsA — T 6 — Nov — 28 Nov — Nov — 11 Dec — 20 Dec — 31 Dec 2018 — IPC

Reported to:
16 Oct – Board - updated on current plans and work being performed. **28 Nov – BICC** - update provided on ongoing work in Wards 2A and 2B with expectation that work will be completed in December. Noted that the ventilation system is being looked at and implications for this and discussions are ongoing with clinicians. Advised that chlorine dioxide will also be done in the adult hospital in January. SG being kept informed. **3 Dec – BCGF** - noted as part of the December HAIRT which covers incidents from Feb to Nov 2018. **28 Jan 2019 – BICC** – update given on chlorine dioxide system and "discussion" over removal of sinks in Ward 2A.
October and December HAIRT – continues to be reported in HAIRTs and the various committees during 2019.
February 2019 HAIRT - covers incidents from Feb 2018 to Jan 2019 noting HIIAT returned to Red on 13 Sep, then Amber on 28 Sep.
April 2019 HAIRT - covers period from February 2018 to February 2019 noting CD system now installed in both QEUH and RHC.

12 Nov

ACGF Meeting

- Noted cases of bacteraemia continue and Wards 2A and 2B have been decanted to 4B (for BMT patients) and 6A (for all other patients) in the adult hospital.
- Noted investigation work continues and decant still in place
- Noted discussion about removal of Sinks from Ward 2A is a "hot topic".

10 Dec

ACGF Meeting

- Noted the investigation into the water issues in Ward 2A has uncovered a ventilation issue which may require significant infrastructure work and prolong the current decant arrangements.

20 Dec

- On 20 Dec an IMT is set up following 2 cases of Cryptococcus identified on 17 Dec.
- A PAG was held on 18 Dec and control measures were put in place.
- See first slide of 2019 for further details.

Section 7
Timeline for 2019

Timeline for 2019 (January to February)

The 2018 DMA Risk Assessment Report is finalised and a work plan created to address the recommendations.

Each year the AP for water completes a Standard Compliance and Risk Tool. This is a national tool for monitoring water quality developed by HFS. A series of 60 questions are answered with supporting documents provided. Once completed the tool calculates the level of compliance against national water standards. This results are reviewed by HFS and also by the AE during the course of their audit. The score for Jan 2019 was 98.21%. In Jan 2020 the score rose to 98.96% following introduction of the CD plant and servicing of all thematic mixer taps and values on site.

The HPS report "Summary of Incidents and Findings of NHS GGC QEUH/RHC" is published on the HPS website.

1 Jan 2019 — Jan — Jan — Feb — Feb — 28 Feb 2019 — F&E

19 Feb

Cryptococcus Neoformans (CN)

- Two isolated cases (1 adult and 1 paediatric case) of a fungal infection, CN, which is a fungi found in soil and pigeon droppings. NHS GGC have advised each patient had a different type of CN.
- On 16 Jan 2019 air sampling found Cryptococcus albidus (CA) in Ward 6A, which is a different species. No CN was found.
- The potential source was thought to be the plant room on the roof of the adult hospital as pigeon droppings were found there, but air samples did not support this. Pest control removed droppings and the area was cleaned. NHS GGC had advised it was highly unlikely for the plant room to have been the source.
- During investigation a separate issue was identified with the sealant in some of the shower rooms. In order to perform remedial work, some patients were moved to Ward 4B with others moved to the Clinical Decision Unit in the RHC.
- Repairs now complete and air sampling results confirmed air quality in the ward is optimal. Patients have returned to Ward 6A. HEPA filters have been placed in all rooms, corridors and treatment areas in Ward 6A as a precaution.
- No further cases have been identified and of 1,800 samples taken, only 10 detected CA but none have identified CN. Air sampling is ongoing. NHS GGC have advised that no CN has been found in over 8 months of air sampling.
- High risk patients are on antifungal prophylaxis.
- Ongoing work to create more protection isolation rooms which are sealed, under positive pressure and with HEPA filtered air.
- Short life Expert Advisory Group is convened which will report to the IMT. This includes representatives from NHS GGC, HPS, HFS and UK experts on ventilation. The group will review the hypotheses to establish whether a definitive source of Cryptococcus can be established.
- Certain MBs/ICD's advise that CN is a rare organism and all MBs were struck by the fact that 2 patients within 3 weeks contracted this organism – it was considered unusual. They advised that this organism is difficult to isolate from the environment, even if it is present, and that air samples were taken after the pigeons had been removed and the plant room cleaned. The MBs/ICDs note that there was considerable disagreement between NHS GGC and the LICD about the source of this organism. In relation to the showers in Ward 6A, the MBs/ICDs noted that there was a large volume of black mould in all the bathrooms which posed risk of fungal infections to patients and which was caused by water hitting a defective join and water damage to the surrounding areas (these were supposed to be waterproof but were not).

AICC Meeting – Cases of PsA

- The minutes record that South Glasgow Paediatrics advise of 5 cases of Pseudomonas aeruginosa (PsA).
- Patients had all been in Theatre 6 during October 2018.
- Some typing returned – 2 matches.
- Drain samples from the anaesthetic trough found PsA.
- Inspection of drains found excessive amounts of debris including nail picks in the u-bend.
- All drains now cleaned.
- Although not recorded in the minutes, NHS GGC advised that it was accepted at this meeting that these cases represented a normal background level of PsA and there was no evidence of a match between the anaesthetic trough and the patients.

Board Meeting

- The CEO updates the Board on the recent issues at the QEUH and RHC and advises that 3 work streams are to be commissioned, as follows:
  - review of the Estates, Facilities and environmental issues at the QEUH and RHC;
  - review of capacity and flow to assess the current position against original model and planning assumptions for the hospitals; and
  - review of clinical outcomes over the period to provide assurance.
- The CEO advises a Programme Board will be established, chaired by the CEO and comprising the leads of the 3 work streams and other key members of senior staff.
- The Board is also advised that the Cabinet Secretary has announced an independent external review of the QEUH and RHC.
- Following questions around timescales, the Board is advised these will be made explicit through the relevant governance committee for each work stream and a final report will be presented to the Board in due course.
- It was noted that members were pleased with the organisation's good work over the last few months to address the issues and expressed gratitude for the continued work and actions to provide safe, reliable and professional healthcare.

Jan – HIIAT **RED** on 20 Dec and **GREEN** from 15 Feb

7 Jan — 19 Feb

CN — 6A — PsA — 6A — Ps — SM — PICU — AB — IPC

1 Jan 2019 — 28 Feb 2019

Reported to:
7 Jan – AICC – update on PA and NICU. **14 Jan, 8 Feb** – **ACGC** – update provided on CN. **28 Jan, 25 Mar, 3 June – BICC** - update given on CN and information to be shared with SCI team. **4 Feb, 8 Apr, 27 May – BCGF –** update on CN on 4 Feb. Minutes of 8 April refer to April HAIRT which covers CN. Minutes of 27 May refer to June HAIRT which covers CN **19 Feb, 16 Apr, 25 Jun and 20 Aug – GGC Board -** told and noted CN incident on 19 Feb. Questions on 16 Apr on the publication of Cryptococcus data from sampling. MD advised this is being reviewed and will be presented in the near future. **5 Mar** – **CCGC** - provided with update on the CN incident. Questions asked and the national recommendations and guidance in respect of the use of HEPA filters and nature of the fungus. **February, April and June HAIRT –** includes CN incident.

Jan/Feb

GNB - From 5 Jan to 3 Feb there are 2 Ps, 2 AB and 1 SM cases. A PAG is held on 7 Feb:
- Environmental issues identified
- Repeat of SPE audit section due to low score
- Ongoing monitoring surveillance by IPC Team.

Reported on: 12 Mar and 13 May – **AICC**

Timeline for 2019 (March to May)

AICC Meeting
Noted CD system in both QEUH and RHC to be completed by end of March.

12 Mar

The HFS/HPS report entitled "Technical Review Water Management Issues NHS GGC QEUH and RHS" is finalised but not published.

Mar

The work plan to address the recommendations in the DMA 2018 report is completed and tasks are allocated to the the F&E team to begin to complete the work required.

April

1 Mar 2019

F&E

31 May 2019

Meetings: CCGC on 5 Mar, BICC on 25 Mar, BCGC on 8 Apr, ACGC on 15 Apr

- Paper presented providing update on concerns raised by MBs in 2017. Update as at Dec 2017 and Jan 2019 provided. Confirmed paper will be presented to all appropriate governance groups.
- **CCGC –** Question on issues associated with the move of the Adult and Paediatric BMT units into facility in 2015. MD advised adult BMT Unit had high particle counts so unit was moved back to the Beatson and an extensive refurbishment took place.
- CCGC asked about a number of vacancies in the F&E Team and level of training and experience requirements. F&E Director noted they are working with universities to develop expertise in required areas, create modern apprenticeships and management opportunities.
- CCGC asked the LICD if they and their colleagues were content with progress of actions to address their concerns. The LICD confirmed they were content with the good progress made in all areas. The minutes of the subsequent CCGC meeting on 11 June note a correction to this last sentence and that the LICD advised that one colleague had since retired and other colleagues had not raised any further issues with the LICD.
- CCGC were assured of actions being taken, progress made, that patient safety was the top priority and noted lack of water incidents in the last 6 months.
- **BCGC -** noted the plan could be clearer on where concerns were not factually accurate, were already addressed and where there are new concerns with proposed actions.
- **ACGC** noted issues had been addressed, it was a comprehensive update, with no further actions required.

5 Mar to 15 Apr

AICC Meeting
Noted HPS issued guidance for consultation which states IPCT will carry out a review for every water infection. Notes do not specify what water organisms or high risk areas are to be included.

13 May

- Patients admitted on 20 May to Ward 6A.
- Multiple day care visits.
- Patients positive for Stenotrophomonas on 20 May, 21 May and 22 May.
- Patient had caught their line 2 weeks earlier causing trauma to the site.

20 May

- Patient admitted on 28 May to Ward 6A.
- Day visits to Ward 6A and OPD.
- Also attended Ninewells where they had positive culture for Pantaea Septica.
- Test repeated on arrival but negative so far.

27 May

1 Mar 2019

STM 6A → AB PICU → STM 6A → PanS 6A → EC 6A → IPC

31 May 2019

13 Apr

- Patient admitted on 13 Apr to Ward 6A.
- Day patient 15 days earlier.
- Positive for STM on 13 April, 14 April (twice) and 17 April.

Reported to:
16 Jul, 2 Sep, 12 Nov (draft) – **AICC** given update.
29 Jul – **BICC** **19 Aug and 28 Oct** (draft) – **BCGF**
20 Aug and **22 Oct** – **GGC Board** **Aug** and **Oct** HAIRT

PAG 16 Apr – no HIIAT

Acinetobacter baumannii

- Two cases identified on 21 Feb and 9 Mar. One patient died but AB not on death certificate.
- No link between cases.
- SPE audit section repeated as scored red.
- Ongoing surveillance monitoring by IPCT in place.

Reported to: 16 Jul – **AICC**

Reported to:
16 Jul, 2 Sep, 12 Nov (draft) – **AICC**
29 Jul – **BICC**
19 Aug and 28 Oct (draft) – **BCGF**
10 Jun and 5 Aug – **ACGC**
20 Aug and 22 Oct – **GGC Board**
Aug and Oct HAIRT

29 May

- Patient admitted on 14 May to Ward 6A.
- Positive for EC on 29 May.
- Transferred to PICU.

A43293438

Timeline for 2019 (June)

1 June 2019

31 June 2019

F&E

IMT on 19 and 25 June - HIIAT - AMBER

Gram Negative Bacteria PAG

- The PAG reviews the 2 STM, 1 PanS and 1 EC case detailed on the previous page (page 21) that had occurred in Ward 6A.

Actions taken

- The results of water samples from Ward 6A are awaited but provisional results found no GNB.
- Review of patient timeline shows patients have visited Theatre 6 and Interventional Radiology. Water samples to be taken from both locations. Drains will also be inspected and swabbed if evidence of grime build up – but were clear at time of PAG.
- Latest hand hygiene and infection control audits both scored 95%. No practice issues were noted by IPCN on the day of PAG.
- Patient isolates are sent for typing.
- Ward considered safe for new admissions.
- There had been some high fungal counts on ward but no water or moisture sources found to explain high counts. Portable filters to be checked for expiry and water fountain to be removed from Ward 6A meeting room.

IMT – Following on from the PAG on 3 June, a further case of Enterobacter cloacae (EC) on 12 June and one case of Mycobacteria chelonae (MC) isolated from a patient's chest wall around line site and also water sampling on Ward 6A. The IMT considers all cases from April. Of the total cases, 2 are HAI (possible source is patients own gut) and 4 are HCAI. Total of 6 cases in April.

Investigations performed

- There had been a case of MC in May 2018 during previous water incidents. Rare pathogen and only 4 adult cases and no paediatric cases reported by NHS GGC in the last decade. Confirmed new MC patient had no contact with unfiltered water.
- Drains in theatre and trough sinks clean but clinical wash had basins in anaesthetic room; clean and dirty prep room have heavy build up of grime.
- Water samples from theatre negative. Drains grew unique strains of Steno, Enterobacter and other organisms. Water sampling in Ward 6A with POUF off found MC in several areas. Significant reduction in gram negative bacteria noted.
- Drains dosed with Hysan disinfectant regularly and have no grime.
- Discussed recent leaks from chilled beams due to a boiler failure and leaking pipe with water ingress into ceiling space. Mould evident on ceiling tile.
- Noted that some areas within A&E, outpatients and theatres have no POUF on their CHWB.
- Three shower heads and Domestic Service Rooms (DSR) from 6A positive for MC. Samples from taps with filters removed show fungal growth.

Hypothesis – MC patient had contact with unfiltered water. Three ways this could have happened:

1) Aerolisation from drains when water from take hits drains.
2) Bio-film creep from staff washing hands in CHWB were aerolisation occurs.
3) Patient washing their hands and touching their lines afterwards.

Control measures taken

- Timeline for patients with MC to be developed to see if any contact with unfiltered water.
- HPS to research what instances other health boards have of MC so NHS GGC can compare own figures.
- Dosage of chlorine dioxide to be increased. MC isolate from patient and water samples to be sent for genome sequencing.
- MC now included on IPCT alert organism list.
- POUFs to be fitted in theatres, Interventional radiography and Out Patient Departments.
- Chill beams to be sampled as leaks reported within the last month. F&E to review all leaks from Ward 6A in last month to see if any commonality with patients.
- Air sample to be done in Ward 6A with water running into the sink to check for aerolisation of drains.
- Hand washing to be followed by gel sanitisation.
- Cleaning of drains in theatre.
- Water sampling in Ward 6A to be done with and without POUFs.
- Talk to POUF manufacturer to see if there is evidence that filters can prevent MC from entering water from the tap.
- Check previous water sample results for MC.

3 June

June

MC EC 6A

IPC

1 June 2019

3 June

12 June

30 June 2019

HIIAT status – Amber

- Patient admitted on 8 April to Ward 6A. New Patient. Tested positive for Enterobacter Cloacae on 12 June.
- Further patient also tested positive for MC which was isolated from lessons around the patient's line site on 19 June.

Reported to:
29 Jul - BICC – update given on this incident. **10 Jun and 5 Aug** – ACGC – minutes of 10 Jun state that incidents at QEUH are noted but not which ones. Minutes of 5 Aug make reference to 2 rare water borne bacteria. **16 Jul, 2 Sep and 12 Nov** (draft) **–** AICC give update. Minutes of 16 Jul note major problems in validating theatre in new ICE building but not why this is the case. **20 Aug and 22 Oct –** GGC Board **19 Aug and 28 Oct** (draft) – BCGF **August** and **October** HAIRT

Timeline for 2019 (July to August)

- The F&E compliance team commence a substantial exercise on Smartsheet (a computer database programme) to create electronic compliance dashboards for Senior Managers and Estates Managers to allow instant visibility of the compliance level of a site/sector and Board level for all Standard Compliance and Risk Tool topics, AE Audits, Water Risk Assessments and sustainability issues, along with all action plans supporting these reports. Evidence to support completed action is also held. The exercise was completed in 2020 and means that all compliance related documents and action plans are in one place rather than in several. Where action plans are not being followed or instigated, these can be followed up more quickly.

1 July 2019 — 31 Aug 2019

August onwards

F&E

IMT on 3 Jul – HIIAT AMBER

Pseudomonas Putida (PsP)

- Two further patients have tested positive for PsP and these have been classed as HAI. No new cases of MC. Total cases now 8.

Investigations performed

- Water results taken from a sink with a filter - the Arjo bathroom is positive for MC. This sample was subsequently found to have been mislabelled at the lab.
- The sink within the DSR cannot have a POUF fitted to it. Discussions with manufacturer to see if filter can be fitted retrofitted to the sink.
- Genome sequencing results are awaited.
- IPCT carried out SICP audit of Ward 6A – score 93%. Very few issues identified and practice was very good.
- Noted POUFs are being fitted everywhere along a patients' pathway and drain cleaning had been completed in theatres and CDU. Nuclear Medicine/MRI areas also to be done.
- TWG are looking into using a higher dose of chlorine dioxide to shock dose the water supply.

Hypothesis – unclear if gram negative bacteria numbers are normal background rate or if related to ward or outlying area environment. For MC cases, working on the basis that patient/staff had access to unfiltered water in another area.

Control measures put in place

- Sink in Arjo bathroom to be retested to ensure filter is working.
- Future water tests to be carried out for half the ward every 2 weeks then other half for following 2 weeks to give an overview of all water outlets in the whole ward.
- Arjo bath to be removed and reinstated once patients move back to Wards 2A/2B.
- Taps in an unused prep room to be replaced as a preventative measure since POUF cannot be fitted to them.

IMT on 1, 8, 14 and 23 Aug – HIIAT RED

IMT – PAG held on 3 June but with a further 1 case and 1 possible case as noted below, an IMT is set up. Total of 11 cases plus 1 possible case since April.
There was a change in LICD from Aug 2019.

Investigations performed

- Water tests from taps with POUFs are negative in Ward 6A and elsewhere. A sample of POUFs have been tested by manufacturer for integrity and all passed.
- Noted that chilled beams suffer from leaks and condensation. Samples show Pseudomonas oleovorans (PO) and Pseudomonas aeruginosa (PA) in the cold water. Swabs of grills on the beams show small growth of Acinetobacter, Klebsiella and Patoae species. Discussion held with HPS on where samples should be taken from.
- Water sample from plant room tests positive for Klebsiella and Psuedomonas Putida. It is not known if this a pre or post filter sample.
- Air samples from patient room en-suites show small counts of Aspergillus.
- Enhanced daily supervision by IPCT; HH and SICP audits continue and any issues identified are raised and actioned. Central line audit produces very good results.
- Clinicians express concerns that patients are in rooms with chilled beams but noted all rooms in hospital are same apart from Ward 4B. Options discussed are use of beds in Ward 4B, a further decant and use of a temporary mobile unit.
- There is disagreement amongst microbiologists with regards to the reliability of swabbing and also whether the level and nature of GNB being seen is unusual.
- Change of chair on 23 August. Chair notes asked to demit but IPCT advised that following a conversation between them about the complexities of being the Chair and an active participant, the Chair was in favour of another chair. Certain MBs/ICDs dispute this point and advise the LICD was not in favour of another Chair and was replaced after asking for MBs to attend IMT meetings.

Hypothesis – patients have either had contact with unfiltered water or the chilled beams are either leaking or dripping condensation onto patients.

Control measures put in place

- Admissions restricted from 2 Aug and new patients diverted to other NHS Boards.
- Patient timeline to be completed.
- Biocide is introduced to chilled beam system and subsequent testing is negative. Cleaning of grills increased to every 6 weeks rather than every 3 months.
- F&E to draw up dedicated action plan for chilled beams in Ward 6A and how Issues/services are managed.
- Cleaning of chilled beam grills increased to every month/6 weekly.
- Clinicians to speak to MD regarding alternative accommodation.
- Review to be done as to what patients could be moved to Ward 4B.
- HEPA filtration units to be installed in patients' en-suite bathrooms in ceiling void.
- All patients receiving ciprofloxacin.
- Chlorine dioxide dose to be increased.
- Change of sink in the domestic services room (DSR) to be completed as it has no POUF and one cannot be fitted.

PsP — 6A — Aug — EA — Ps — CH — EM — STM — EC — 6A — IPC

1 July 2019 — 31 Aug 2019

Reported to
29 Jul (PsP only) – BICC – given update.
5 Aug – ACGC – given update on incidents to date.
19 Aug and 28 Oct (draft) **– BCGF** - August HAIRT
20 Aug and 22 Oct – NHS GGC Board
2 Sep and 12 Nov (draft) **– AICC** Noted at 2 Sep meeting that the re-opening of Ward 2A/2B is due March/April 2020.
August and October 2019 **HAIRT**

- **Between 3 Jul and 1 Aug** –
  - 1 patient with Chryseomonas who also developed Pseudomonas a week later.
  - 1 patient with Enterobacter cloacae and Elizabethkinga Miricola.
- **Between 2 Aug and 8 Aug** –
  - 1 patient with Stenotrophomonas on 6 Aug, admitted 4 Aug.
  - 1 patient in at Raigmore in Inverness with Enterobacter Aeromonas who previously had Psuedomonas. This second patient is possibly linked to Ward 6A due to post transplant at RHC.
- Total cases now 11 plus 1 possible case which is patient admitted to Raigmore.

Timeline for 2019 (September)

AICC Meeting - A specialist sub group formed to look at ventilation in PICU. This group includes clinicians, IPCT, F&E and ventilation AE. PICU is non-compliant as it has a lower number of isolation rooms than required. An options appraisal was done and an option will be recommended to allow a derogation to be signed off and agreed so that the unit can operate in its current set up. This will be shared with HFS.

The work to address the recommendations of the 2018 DMA report is completed.

A review of NHS GGC's Water Safety Policy is conducted by an external consultant - a first draft is produced.

1 Sep 2019 — 2 Sep — Sep — Sep — 30 Sep 2019

F&E

IMTs held on 6, 13, 18 and 20 Sep. HIIAT starts as AMBER and reduced to Green on 18 Sep

IMTs continue. 12 + 1 new case of GNB to date. 3 patients remain as inpatient - one in Ward 6A, one in Ward 4B, and one in PICU. It is noted from this point that previous Chair of the IMT is not in attendance.

Investigations performed

- An SBAR is received from MBs outlining a number of concerns which include issues about 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. The issues and responses sent to the MBs discussed at the first IMT meeting in September. At the next IMT meeting on 13 Sep it is noted the Chair has received a response from the MB but this is not shared with the IMT.
- Enhanced supervision by IPCT; HH and SICPs audits continue and are achieving good scores.
- Environmental sampling in Ward 6A and Beatson is negative.
- Noted that the typing of the GNB organisms from sampling and from patients are different and unique.
- Discussions about patients feeling unwell due to the prescribing of ciprofloxacin.
- F&E visited Great Ormand Street to look at the water and air ventilation systems and will provide a report on their findings. F&E state all work is completed on the ward apart from installation of HEPA filtration units in patients' en-suite bathrooms which will be done in 6 weeks time when units arrive.
- Discussion on a number of epidemiology reports produced by MBs and HPS on the numbers and types of infections compared to other hospitals. The MBs conclude that the environment is safe but there is debate over methodology and whether measures are appropriate. Clinicians state there is an impasse between MBs and what is to be done to resolve this. These reports are to be submitted to the Executive Committee following further analysis being performed.
- An options paper is prepared by the clinicians for moving patients to alternative accommodation and is submitted to the Executive Committee, MD and CEO. Agreed to be used if further problems occur.
- On 18 Sep the Chair reduces the HIIAT to Green based on above data but clinicians and SG express concerns. Chair asks HPS to explain to SG the level of detail considered by the IMT and that Green rating is based on the decision to lift restrictions.

Control measures in place

- Confirmation that patients transferred from other hospital did not have positive blood cultures.
- Timeline to be created for new patients.
- Restrictions on admissions continue.
- Weekly enhanced supervision by IPCT to continue.
- Detailed review of all confirmed (12) and possible (1) cases to be done.
- Full microbiological analysis and root cause analysis (RCA) to be performed on all cases going forward.
- SOP developed for obtaining regular water, environmental and chilled beams sample. HPS to help with this.
- Central line infection triggers to be put in place so if reached action can be taken.
- Consideration of how IMTs are triggered, i.e. NHS GGC suggest 2 cases of same infection in 2 week period (proposed by NHS GGC) or 2 infections regardless of type (proposed by HPS). Paper to be circulated for comment and approved on basis of discussion.

1 patient admitted on 22 Sep tested positive for Achromobacter spp on admission.

1 patient admitted on 27 Sep tested positive for Stenotrophomonas maltophila on 29 Sep.

GNB — 6A — Sep — 22 Sep — AC — 6A — STM — 6A — 29 Sep — IPC

1 Sep 2019 — 3 Sep — 30 Sep 2019

1 patient admitted on 2 Sep has a positive culture next day. Details not provided but there were multiple organisms. Patient was in Ward 3B, then 6A mid Aug and then day care. Line accessed at day care on 27 Aug in Beatson and 28 Aug in Ward 6A. Patient was home between mid and late Aug.

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Reported to:
28 Oct (draft) **–** BCGF - August HAIRT
22 Oct – NHS GGC Board
12 Nov (draft) **–** AICC
October 2019 HAIRT

Reported to:
7 Oct and **11 Nov**– ACGC – update. **22 Oct –** NHS GGC Board – noted the 3 work streams commissioned in Feb are nearly complete. **28 Oct** (draft) **–** BCGF - through HAIRT. **12 Nov** (draft) **–** AICC – ongoing reporting of these incidents. **Oct** HAIRT

Timeline for 2019 (October)

1 Oct 2019 — 31 Oct 2019

F&E

IMTs held on 8, 11 and 25 Oct - HIIAT AMBER then GREEN on 25 Oct

IMTs continue and SG representatives join the first IMT following its and clinicians' concerns on the lifting of ward restrictions. Agreed at meeting that these should continue.

Investigations performed

- Discussion and development of the RCA started in Sep to include detail on patient pathways when outside ward and what they do. Noted lines are accessed in multiple areas e.g. ward, OPD, Beatson, oncology, patient's home etc.
- Debate on case definition and if informed by the past or is more forward looking. Agreed aim is to identify common source, link and route of transmission but accept definition evolves over time.
- Noted water sampling results are reported through TWG. August results show some very low and some high levels of coliforms but sequence testing was negative. September results show DA and STM but retest results are awaited. Noted HPS/HFS sit on TWG but currently no MB sits on both TWG and IMT. Noted previous chair had been this liaison.
- A leak in the ward kitchen (which was being used to store patient food) has been repaired and is now open. The leak was from a tap fitted in August and corrosion of the pipe work has been found. The tap was replaced with one compatible with a POUF. Questions raised over what reassurances there are that no other taps are leaking. F&E Director advises they rely on visual inspection and that any leaks behind panes would be a major undertaking as over 120 water outlets are in each ward. IMT agree this check would not be done at this time. If the integrity of the wall and ceiling are intact then there is no evidence of water seepage through the water ingress. It is later found that the leak is from the hydro unit and not the tap.

Control measures put in place

- Ciprofloxacin only to be given to inpatients and not day case patients.
- Seek external advice on recommendations made when patients go home.
- Smart site hubs to be tested. Normally replaced weekly but will now be replaced when contamination spotted.
- Agree the use of a multi disciplinary team for cases going forward.

Hypothesis – new hypothesis from RCA that infections may be from Smart Site Hubs which allow needleless injections of medication into patient line.

- In October 2019, NHS GGC requested HPS to provide independent support to review the data being used to inform their risk assessment and decision making in relation to Wards 6A and 4B at QEUH. At this point the wards were closed to new admissions. This request resulted in an HPS report entitled "Review of NHSGG&C paediatric haemato-oncology data" in Oct 2019. The report was published in Nov 2019.
- The report states its key objective was to assess NHS GGC's datasets and ensure assurance data provided an accurate reflection of the current epidemiological situation in this patient population and, where differences existed, to understand reasons and assist with interpretation. The report also sought to review the environmental gram negative blood cultures and whether there had been a change in the type reported.
- The review compared different sources of data (3 datasets from NHS GGC and one from HPS) on positive blood samples from haemato-oncology patients. Blood samples were divided into four groups - GNB, GPB, Environmental Bacteria and Environmental Bacteria including Enteric Bacteria (those found in the gut). Analysis covered the period between July 2013 and September 2019.

Conclusions of report – these were as follows:

- The analysis presented did not provide evidence of a single point of exposure causing bloodstream infections.
- Admissions should be reconsidered but the analysis also underlined the need to continually monitor risk in this patient population.
- The results suggested the NHS GGC datasets were broadly consistent with national data held by HPS and were suitable for ongoing monitoring. Statistical analysis highlighted months where positive blood sample rates were higher than expected – the purpose of this analysis was to prompt further investigation and to ensure any appropriate action is taken.
- Analysis of different types of bacteria showed some changes, but numbers in each group were small, meaning the significance of this was not fully understood and should be part of the ongoing monitoring.

Recommendations from the report – for NHS GGC to consider were as follows:

- Systematically collect clinical data on cases to describe the risks in this patient population and ensure ongoing monitoring is in place.
- Categorising cases in terms of "person" and "place" to identify when there are more cases than normally expected.
- Consider the epidemiological characterisation of cases in the context of environmental risks, e.g. water and ventilation testing results.
- Consider the data provided in the context of the findings from the action plan.
- Consider lifting the restrictions on admissions as based on HPS review of the data there is no evidence to support this continuation.
- The report also notes recommendations for HPS including review of categorisation of environmental organisms for inclusion in the new Chapter 4 of the IPCM, along with development of appropriate triggers for ongoing monitoring.

Oct

DA **6A**

IPC

1 Oct 2019

1 Oct

- 1 patient who had a line inserted on 24 Sep, came in for treatment on 1 Oct and tested positive for Delftia acidovorans (DA).
- The total is now 3 cases and 1 possible case.

Reported to:
7 Oct and **11 Nov**– **ACGC** – update.
22 Oct – NHS GGC Board – noted the 3 work streams commissioned in Feb are nearly complete. **28 Oct** (draft) **– BCGF** - through HAIRT. **12 Nov** (draft) **– AICC** - ongoing reporting of these incidents.
Oct HAIRT

1 Oct 2019 — 31 Oct 2019

Timeline for 2019 (November)

1 Nov 2019 — 30 Nov 2019

F&E

IMTS on 5, 11 and 14 Nov when incident closed. HIIAT GREEN

- IMTs continue into November with incident finally closed on 14 Nov. A report by HPS notes there is no clinical reason to keep restrictions in place and no single source of infection has been identified. HPS give formal agreement to lift restrictions.
- Genetic sequencing of Enterobacter cases shows there are no links and source is likely to be patient's own gut. Cases are removed from RCA.
- RCA is finalised with SG and HPS.
- New procedure for cases is agreed as follows:
  - RCA to be done for all cases;
  - PAG set up if there are 2 GNB cases in 30 days or upper warning limits of SPC charts are met;
  - Escalation to IMT will be based on Board's standard outbreak procedures;
  - If immediate source not identified, external advice will be sought early;
  - Findings of PAG will be reported to Clinical Review Group;
  - Data collection form, developed with help of HPS, to be used by multi disciplinary team to collect the relevant data.
- Water results are noted as being pristine with very low TVCs.
- Patients to be given Taurolock rather than Ciprofloxcin.
- Enhanced surveillance by IPCT is still ongoing with education being given to parents on HH which scored very poorly.
- Agreed increased portering, nursing, potential housekeeper resource & water testing will provide reassurance to patients/parents.

19 Nov - HIIAT GREEN

- IMT convened to review 2 PsA cases in PICU noted below to asses if HAI or not. Medical history of patients discussed and it was agreed that it is HAI.
- Noted that typing results do not match.
- Both had treatment on an ECMO machine on 21 Sep and 7 Nov respectively. ECMO has disposable circuits and is sterilised weekly and after patient use. Water in machine is tested after each patient and has been negative.
- Also both used haemofiltration unit which has disposable circuits - not sure if this was tested.
- Noted that patient 1 came from NHS Ayrshire and Arran. No samples taken so unclear where infection is from. Suspect infection already present given rate of deterioration.
- Patient 2 was negative before going on ECMO.

Actions taken

- ECMO out of use pending results of water samples taken last week. Water samples to be taken from NICU and Theatre 8 as patient 2 was in both. If all negative, ECMO can be used.
- HH education to be put in place and IPCT to do an audit.
- Trial of BD Pure Hub sites as these now used in Ward 6A after a successful trial.
- Lead Nurse and SCN agreed to carry out peer hand hygiene reviews.
- No water checklist or domestic issues were highlighted.

- IMT convened to review an **SM** case (noted below) and discuss cases since 5 Oct for **AB** and **PsA**. Noted case of **PsA** reported 27 Nov which is still to be investigated and may be a transfer in.

Investigations performed

- Water samples taken with filters removed were negative. Noted that only connection is between the first two PsA cases - Theatre 8 which has tested clear.
- Noted no recent cases of SM to compare typing. Last reported in Aug 2019. A retrospective case mentioned at IMT for Ward 6A is mentioned but no details provided in minutes. HH education is ongoing and ward is getting excellent HH results despite lots of visiting doctors.
- Observation of bronchoscope investigation to gain sample from lower airways (BBAL) procedure noted no issues.
- Weekly assurance checklists for equipment are being completed and new keyboards ordered that can be immersed in water.
- Discussion around sinks and little-used outlets and uncertainty about changing style of sink. Agreed this would be looked at separately.

Hypothesis –SM is likely a sporadic case in a susceptible patient. No hypothesis noted in relation to other cases.

Control measures being performed

- Patient equipment control measures to be tightened up. A plan on splash risk at sinks to be developed.
- Discussion with domestic staff around who is responsible for cleaning the relatives' room to be taken forward. Parent education to be provided.
- Environmental sampling of frequently touched surfaces is being done.
- SM case to be sent for typing.
- To look to address visiting doctors from a HH perspective.

November — 19 Nov - HIIAT GREEN — 27 Nov HIIAT GREEN

AB | PICU | PsA | PICU | PsA | PICU | SM | PICU | IPC

1 Nov 2019 — 30 Nov 2019

PAG 5 Nov — PAG 12 Nov – HIIAT GREEN — PAG 21 Nov – HIIAT GREEN — 24 Nov

- PAG held after 3 cases (5, 9 and 17 Oct) of AB over a 12 day period. HAI trigger is 3 cases in 2 weeks.
- Two patients in same bed bay so cross transmission suspected. These match the patient in Aug but patient in PICU on 16 Sep.
- **Actions –** use of checklist to ensure weekly cleaning of shared patient equipment after issues found, enhanced IPC surveillance, HH and IPCAT audits to be repeated.

- PAG held on 12 Nov following 2 cases of PsA.
- First identified on 21 Sep was community acquired. Patient died on 27 Sep and PsA noted on part 1b of the death certificate.
- Second identified on 7 Nov was a HAI and patient died on 9 Nov but PsA not stated on the death certificate.

- PAG held following another case of PsA Identified from a bronchoscope investigation to gain sample from lower airways (BBAL) on 18 Nov. Patient transferred from Crosshouse Hospital on 29 Sep.
- HH education being coordinated and further audits and IPCT to observe procedure for BBAL.
- No domestic or water checklist issues identified.
- Water samples taken on 14 Nov are negative.

- Case of Serratia marcescens on 24 Nov. Patient died on 25 Nov.
- SM not cited on provisional death certificate but now retracted and post mortem to be performed.
- Transferred from NHS Highland.

Timeline for 2019 (December)

- Since the appointment of the Director of F&E, the structure of the F&E team has been changing and this is still the case in 2020. The date this reorganisation started is not clear but F&E activities have been separated where previously they were both the responsibility of a sector general manager. There are now a separate Associate Directors in charge of Estates and of Facilities. There is also greater definition around each role as well as specific allocation of responsibilities to allow individuals to develop expertise in specific areas.

1 Dec 2019 — Dec???? — 31 Dec 2019 — **F&E**

- SG advise that the last 3 incidents in PICU are investigated together retrospectively and prospectively using the HPS case definition used in relation to the recent GNB incident in Ward 6A.
- The IMT consider each infection category and come up with 3 separate hypotheses as follows:
- Pseudomonas – 3 cases reviewed by IMT on 19 Nov. Noted that case 1 was sepsis as per death certificate and not a bacteria as per the minutes. Patient had 5 negative blood cultures. Hypothesis was that, as cases 1 and 2 had both attended Theatre 8, there had been transmission. There was no link for case 3.
- Serratia – 1 case was referred to procurator fiscal as unable to establish cause of death. Noted IMT hypothesis was a possible water transmission.
- Acinetobacter – 3 cases; hypothesis was cross transmission between cases 1 and 3 as typing was identical. Noted typing also matched a case in Aug 2019. Noted appropriate controls were in place.
- Water samples from PICU, Theatre 8 and NICU are negative. HH and IPCAT audits also reviewed with deficiencies noted in SPE section.

Additional control measures put in place

- Weekly Safe Patient Environment audits to be put in place.
- Weekly swabbing of POUFs, drains and CHWBs and water sampling for GNB over a 4 week period. Monthly water sampling for Mycobacterium.
- Drains will have weekly Hysan dosing.
- A SPC chart for all Gram negatives in PICU with bed days to be supplied.
- Trigger is 2 GNB in 30 days or 2 HAIs in a 2 week period - RCA to be completed.
- Retrospective look back of a 6 month period and RCA completed for 2 cases In that period.

- IMT noted that GNB cases were to be investigated collectively but this was complicated by different case definitions applied when GNBs were being reviewed separately.
- Agreed that SPC chart for blood cultures is to be used going forward as well as normal triggers.
- Noted that robust definitions for the above were required to ensure consistent reporting.
- Clinical review of all cases is suggested to allow for a more descriptive picture of the situation. Agreed that SPC will be completed first, then RCA on patterns identified and then patterns will be discussed.
- Noted a new case of Serratia on 10 Dec. Not HAI based on review by clinical team.
- Tests in Theatre 8 were all negative. All water sources tested against PsA, SM and AB on 10 Dec including inside filters, trough sinks and HH sinks in peripheral rooms.
- Environmental screens picked up a number of organisms in drains including SM in trough sink adjacent to bed space. Sent for typing and re-swabbed this morning.
- Hypotheses updated as follows:
  - AB – patient to patient transmission, all in same bed space with index case being Aug 2019. One sporadic case. IPC continue surveillance monitoring, ensuring shared equipment is clean and all TBPs are in place.
  - PsA – potentially Theatre 8 for cases 1 and 2 but water/environment samples show no links so water hypothesis now closed.
  - SM – 2 cases with different typing. First patient died, second patient came in colonised. Water hypothesis now closed. New hypothesis about drains as a positive sample was found in the room the patient was nursed in. IMT agreed that patient colonisation status should be reviewed.

Additional control measures put in place

- Clinical Review Group set up for Ward 6A and suggest same done for PICU. Should meet weekly and include directorate management, F&E, IPC, Clinical Staff and Deputy Director of Nursing.
- Results as to why staff fail HH audits should be recorded.
- SPC to be developed for first isolates of any other clinical sample, e.g. wounds, BAL etc. Noted that this should be sample type specific for every GNB and to use 3 organisms PsA, AB, SM. Noted that patient pathway also needs to be considered as BAL could be done in theatres as well as PICU.

- Fourth case of AB since 5 Oct.
- Environmental samples (including drains) taken on 11 and 19 Dec are negative.
- IPCT contacting Wishaw to see if patient had any historic organisms.
- Work in Oct/Nov to upgrade ventilation with all 4 bedded rooms complete and few cubicles still to be completed.

Hypothesis – sporadic case as no overlap in time and place or equipment. No AB isolated in environment, water, Theatre 8 or in specific rooms tested. Possibly transmitted by hand but awaiting typing results. No further IMT arranged but will be held if another new case or trigger activated.

Control measures put in place

- Patient being isolated in single room.
- Enhanced IPCT supervision weekly.
- HH scored 90% the same day.
- SPC regarding BC and BAL specimens from PICU being drawn up for submission to to Clinical Review Group once IMT closed.
- Facilities will survey PICU to check for leaks and dampness.
- Water samples of all water outlets in 4 bedded areas and also room 17 to be done.

1 Dec 2019 — **SM** — **PICU** — 10 Dec — 17 Dec — 30 Dec — **IPC** — 31 Dec 2019

10 Dec

- Second case of Serratia (SM) reported from a blind BAL sample. Patient discharged to Ward 2C on 16 Dec.
- Typing was different from any seen in the hospital so far.
- Patient transferred from Crosshouse Hospital.
- Clinical team consider not HAI on review of the case.

23 Dec

- Case of AB on 23 Dec taken from a blind BAL.
- Patient admitted on 28 Nov from Wishaw General Hospital.

Section 8
Timeline for Water Groups

Technical Water Group Timeline for 2018 (January to May)

- To understand where bacteria is located water samples were taken from all parts of the water system. Results showed each floor had some contamination indicating that problem is widespread.
- Positive results were returned from water coolers (which are maintained by a third party) and were disinfected.
- Group agrees that POUF will only be fitted to high risk areas rather than the whole campus.
- Discussions held with tap manufacturer who advises issues with Pseudomonas in the flow straightener are known but not other organisms. Manufacturer notes these should be decontaminated and replaced as required. Taps are sent for further analysis to determine if source, but replacement of taps is also discussed.
- Discussions held on how long bio-film takes to develop – opinions vary from a very short period to up to a year.
- The TWG minutes of 27 April 2018 record that a report from water expert (Sarah Lees) notes it likely that system was contaminated before handover and that fluctuations in the water temperature experienced since opening were also a likely contributing factor. Fungus in the system is thought to be due to dust levels around the site during construction and demolitions. Noted air tests carried out during the works were all recorded within parameters. Visits by further expert – Tom Makin - is planned.
- Discussions about plans to review information on water temperature to identify trends but advised majority of data has been lost due a system failure. Some manual records can be reviewed but these are not extensive.
- Group discuss long terms solutions. Options include shock dosing, thermal cleaning and chemical cleaning (including chlorine dioxide). Each option will require investigation into the impact on the water system, effectiveness against organisms and bio-film, and impact on hospital. Paper on all options to be prepared and presented to group. Noted that whatever option is selected a full risk assessment would be required and options selected that would cause minimum disruption to wards/patient care

South and Clyde Sector Water Group (SCSWG) Meeting

- Update given to group on the "water incident" at QEUH.
- Noted over 2000 water samples taken and mapped to floor plans and within schematic diagrams concluding there was a bio-film build up in the system which requires to be eradicated and preventative measures put in place.
- Water dispensers were removed from RHC.

BICC Meeting

- ToRs for the TWG are now included in the IPCT work plan.
- MD asks that lessons learned from recent water issues are reviewed and a plan prepared to address these for review by the TWG and then BICC.

6, 13, 20 and 27 Apr

16 May

23 May

1 Jan 2018

6 Mar

28 Mar

4, 11 and 18 May

31 May 2018

Board Water Safety Group (BWSG) Meeting

- Given an update on the "water incident" in Ward 2A.
- Noted the need to identify if problem was elsewhere to determine if there was an issue with the cleaning regime or simply the implementation of the cleaning regime in that ward.
- Noted the need to be proactive with this situation given nature of patients. Agreed a different practice (not stated what this is) for this ward would be needed and this should be reflected in the written scheme.
- Use of disposable shower heads was discussed.
- ICD recommends water sampling on the ward is increased to monthly and on instruction from ICT.

BICC Meeting

- A copy of the Terms of Reference (ToR) for the TWG were issued with the agenda and noted.
- Agreed that these would be reviewed as part of the IPCT annual work plan and ToR should set out how TWG reports to BICC and Health and Safety Group. It will also take account of any local or national advice on water safety.
- Chair of the TWG to keep the executive team and Board updated on Progress.

- The Group decided that chemical cleaning is more appropriate than thermal disinfection (which raises the water temperature in the system to 90 degrees to pasteurise the water) due to risk of scalding and other safety concerns. In addition, raising the temperature in cold water systems is not always possible due to the lack of a mechanism to raise the temperature and impact on the system as pipework expands because of the temperature differential.
- The Group decided they will start with continual dosing followed by a shock dose and then revert back to continual dosing. Water will not be available during the shock dose. The process for shock dosing is to be written up and a risk assessment performed.
- The TWG minutes of 11 May 2018 record that a meeting was held with another water expert (Tom Makin) who concluded chlorine dioxide (CD) is the best choice for striping bio-film. The TWG minutes also record that the expert noted there are issues with new builds and method of construction – many sealed buildings are now showing water issues never previously seen in hospital buildings. Agreed input of experts should be continued going forward.
- Manufacturers being contacted to determine the appropriate doses of CD and what impact this will have on pipes.
- Agreed that flow straighteners are replaced on a 3 monthly basis and taps are steam cleaned and put back with POUFs in place. Noted that, until replaced, caution must be taken that taps do not re-cede the system. Suggested flow straighteners are analysed. Taps will be replaced in Wards 2A and 4B and rest of the RHC and QEUH will be monitored.
- Group agreed that acceptable sample levels need to be agreed going forward.
- Efforts are being made to locate water certification sign off at time of handover.

Technical Water Group Timeline for 2018 (June to July)

• Group confirmed chlorine dioxide (CD) dosing is their recommended option. NHS GGC Board to be informed of the process and financial implications. It is noted in the minutes that the potential impact on the pipework is unclear but the level of the doses which are anticipated to be applied will not affect pipework warranty. It is noted that various checks will be performed during the CD process to monitor any impact and it was important to note that the Board will be kept informed. The water sample testing regime to be performed following implementation of CD is discussed.
• Purchase of dosing plant will be by an accelerated tender process and plant will be placed by Oct/Nov with continual dosing starting on 1 November.
• A work programme setting out the logistics for the implementation of the shock dosing is discussed as water will be turned off. Discussion includes use of portable wash hand basins, bottled water, flushing of system after shock dose, and impact on patients and wards. Noted a better system is required to record and audit flushing regimes by domestics. Noted Board Water Safety Group and South Sector Water Group should assess risk assessment outcomes and be involved in the work plan. Noted that POUFs will need to be changed after shock dosing.
• Following discussions with experts a replacement tap (the Marwick with Bio Guard) is selected for high risk areas. The tap chosen requires the flow straightener replaced every 3 months. Raw and bulk water tanks and one section of the filtration plant are sanitised during this month (with rest to be completed in July). Debris is found in a tank (which one not stipulated) which looks like sponges and this has been sent for analysis.
• Cleaning of drains and replacement of flow straighteners in high risk areas is ongoing. Water coolers also removed from Wards 2A and 2B. HFS informed of debris found in drains as this is a potential national issue.
• Noted that commissioning validations record data cannot be found and contacting project advisers, Director and IPC to see if they can provide any clarification on what was done and signed off. Some flushing carried out at time but not all for the period after handover or records from main contractor on its flushing regime.

8, 15, 22 and 27 June

1 June 2018

5 June

BWSG Meeting

• Noted no legal requirement for Scottish Water to supply water at a particular temperature which is an issue as water supplied is at a higher temperature than that required for a hospital setting.
• Discussion on possible causes of the issues in new buildings being created by the temperature of water increasing from the inlet to the actual user. When new buildings are being constructed, consideration should be given to ensuring there is sufficient space to include chillers to ensure temperature of water remains stable until the last user outlet.

19 June

AICC Meeting

• Advised that a TWG has been set up which will report to the BICC and is looking to resolve long term issues on tap replacements, implementation of water dosing on the full campus and ongoing HPV cleaning of patient rooms in Wards 2A/2B.
• The ToRs for this group will be confirmed at the next BICC meeting.

6,11, 13, 20 and 27 July

31 July 2018

• Group discussed for how long continuing dosing should be performed before a shock dose is administered and if latter is required. Agreed position will be monitored through test results and if counts do not fall to below acceptable levels, shock dosing will be undertaken.
• Development of the work plan continues and looks at impacts on clinical services and the detailed logistics that need to be in place for the shock dosing.
• Group discussed options for taps in other parts of the hospital. Options are for the existing taps to be retained with tap being modified and regulator removed, or to regularly replace the flow regulator or completely replace the taps. Modification of the current tap is not viable. Other taps on the market would need to be modified to contain a bio guard making the tap either not compliant or creating separation of components which is not recommended. A Delaby tap is to be investigated as it has smooth surface and disposable parts that can be changed. It has a disposable spout and a built in POUF. Discussion with manufacturers and guidance was being sought from HFS/HPS.
• Regulators that were sampled have counts but no bio-film. Replacement regulators are not individually sealed and also show counts when they arrive. This means they have to be sanitised before being put in place. Re-cycling also considered through use of a ultrasonic bath and then soaking in a sanitising agent.
• Advice being sought from HFS/HPS on whether drains are to be cleaned and if so what agent to use. Cleaning is against national policy but agreed that this should continue in high risk areas. Drain parts affected by cleaning are being replaced. Debris noted down the drains and this is to be addressed with nursing staff.

Technical Water Group Timeline for 2018 (August to September)

SCSWG Meeting

- Noted that water temperature coming into QEUH is above acceptable levels.
- Noted that there were similar issues at the GRI site.
- Noted a large increase in daily water usage at QEUH and 23 dump values to dump water were constantly open to try and resolve issue. Consumption being monitored.
- Noted that flushing was being undertaken and POUFs would remain in place.
- Hoped that drop in external temperature will significantly reduce water consumption.

- Air sampling in tank room found fungi. Leak found in one tank and manhole cover are both repaired. Room being monitored and HEPA filters installed.
- Timeline agreed for CD system. Monitoring system to be put in place to give indication of strength of the CD in different parts of the system and give early warning of any issues. Drawings will map the efficacy of CD around the site and allow dosage to be adjusted. Noted it can take 3 years for CD to be effective but as pipework is new it will not provide any resistance to CD, so effect may be quicker. Noted taps may need to be removed and cleaned separately.
- Updated on incident with drains in Ward 2A and the need to understand where this is coming from. CCTV survey suggested to rule out blockages. Agreed drains are to be cleaned weekly with CD and mechanical agitation monthly. Shower drains pooling and this is to be investigated. A German product which does a thermal clean of drains and is fitted to the pipework to be researched. There are concerns around scalding and damage to pipework but would elevate the effect of chemicals on seals.
- Group also reviewed progress to date and decisions taken. No guarantee CD will work but water experts, MB, Department of Health and other agencies indicate best option. Other options were Clorus2 but this has not been proven, as CD was, in a healthcare environment. Copper silver and hydrogen peroxide were proven not to work. Shock dosing ruled out after discussion with clinicians due to smell, effects on pipework, and the need to decant hospital.
- Discussion held on work needed in Ward 2A/2B with regard to pipework, drains and ventilation. Agreed taps will not be changed as no suitable alternative. Cause of issues discussed and if it is water, drains, ventilation, combination or simple hand washing. Decant will allow full investigation. Noted that only Haemato-oncology but not BMT patients were affected even though bio-film was found in both areas.

1 Aug 2018

15 Aug

7 and 20 Sep

30 Sep 2018

3, 10, 17 and 31 Aug

- Following further discussion it was agreed that shock dosing would be difficult to deliver given the extent of disruption. Agreed continual dosing would be done with increasing amounts of CD being injected into the system and results will be monitored. The initial dose would be 1ppm increasing in 0.5ppm stages up to 2ppm for a 3 month period. If the results were still not within limits, a risk assessment would be required. This option is more flexible and allows fine tuning of dosage as and when required.
- Noted that in hot water system CD will become a gas and could lead to corrosion of pipes which will invalidate warranty. Noted that dosing will be within manufacturer recommendations but Board has little choice and will incur the cost of any adverse impact.
- Tender process for CD system has resulted in only 1 bidder with 2 possible bidders withdrawing due to lack of resources. Remaining bidder has proven track record and process is accelerated so contract can be placed. First meeting is to take place 3 September and timelines for work to be agreed. CEO to be notified of timeline. Anticipate dosing of RHC will occur mid October.
- Testing of flow straighteners shows that bio-film has built up after a month. Consider whether filters can be fitted further up the taps but this is against regulations. Not clear whether flow straighteners are the issue or water supply. Agreed that once CD in place, could review and then plan a maintenance programme if the former is the issue.
- POUFs will remain in place for at least 6 months after dosing starts to catch any bio-film dislodged. POUF will only be in high risk areas as organisms only harmful to these patients. Sampling will occur every 4 weeks to obtain a baseline before CD implemented. Work ongoing to determine monitoring points in system once CD is in place to monitor counts. Automatic and manual testing will be done – former will give early warning if results are not within limits.
- Water testing of tank room shows water mostly negative post filtration but raw water tanks have positive results from drain connections which are not capped or sanitised. This action is to be progressed. Bulk storage tanks also positive - believed to be due to environmental conditions – noted to be cockroaches, fungal odour, room not ventilated, water ingress and dried algae on floor. Area to be disinfected, repainted with anti-fungal paint, repairs made and pest control called in. Testing to be done once work completed.
- HPS noted build up of grime in drains in Ward 2A/2B despite only recently being cleaned. Investigated and believe silicone washer is the source. Speaking to manufacturer to see if it can be re-designed and also whether it can cope with CD.

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4 Sep

BWSG Meeting

- Noted that TVC guidance is likely to be changed nationally to include GNB testing but this cannot be introduced until this is confirmed.
- Noted that this specifically is an issue for immunocompromised patients and this is why POUFs are currently in place in these high risk areas in RHC in particular.
- BWSG noted it is taking the correct approach as this is based on information received from clinical, water experts and HPS.
- Noted there needs to be careful management of placement of patients in a hospital setting but this is ultimately for clinical decision and determination.

Technical Water Group Timeline for 2018 (October to November)

- Timescales for CD system are agreed with the contractor. Work will start on 22 October and anticipated that dosing of RHC will begin on 19 November. Anticipated work will be concluded by 21 December at latest, so patients would not be back until January 2019.
- The impact of the work is considered by the group and discussions are held with clinicians to decide when the work involving the installation of the CD system can be done so that it limits the disruption to clinical services.
- A work plan is developed detailing all work to be performed in Wards 2A/2B and to progress procurement of the necessary materials and contractors. Costs of the work are also obtained so that budget can be approved. This also includes alterations to the treatment and prep rooms as discussed by the IMT and also the removal of certain sinks including trough sinks.
- Agreed by group that clinical sinks are to be replaced with ones that have a trap type to prevent material going down the drain. Chosen sink is Contour 21 which is easy to maintain.
- Various different taps for Wards 2A/2B are assessed and discussed by the group and a final decision is taken to fit a tap called Marwick 21.
- Testing of a sample of POUFs is done following two POUF testing positive for rust. Test for integrity is passed and it is unclear where the rust originates from. Agree to check with domestic supervisors that this not due to cleaning issues.
- Reports are received on the survey of the drainage and ventilation system. The report on drains finds nothing of concern that would impact Ward 2A/2B. The ventilation report shows the system does not have as much capacity as initially thought. Currently there is negative pressure in the ward which is not suitable for immunocompromised patients as the pressure needs to be positive. A meeting will be held to review the findings and discuss what options are available to address this issue and what work will be required – this is likely to be extensive.
- Drains were checked and rated for level of contamination by domestic staff. Clinical drains score the worst.

BICC Meeting

- Provided with an update of the ongoing work in Ward 2A/2B. A list of remedial actions had been drawn up and this includes changing the clinical taps, lights and flooring - work will be completed in December.
- Advised that ventilation system is also being looked at and the implication for this; discussions are ongoing with clinicians.
- Noted that with regards to CD there is a wider plan to carry this out in the adult hospital on 24 and 27 January, where the water system will need to be shut down.
- Advised that the SG are being kept informed of the work and communications are ongoing.

1 Oct 2018

5, 12, 19 and 26 Oct

28 Nov

30 Nov 2018

16 Oct

26 Oct

9, 16 and 23 Nov (note meeting also on 30 Nov but minutes not provided)

Board Meeting

- Board is advised that a detailed investigation of the water systems in Wards 2A/2B is currently being performed by an expert external company.
- Director of F&E advised that plans to dose the water supply with CD continue and a mobile dosing plant would be installed by the end of the week. There are also plans to remove wash hand basins and taps and to replace the drainage systems which are being taken forward. This work would result in the requirement for extensive flooring repairs and redecorating.
- Board members ask about the frequency of these incidents in similar facilities but are advised that they do not appear to be common.

AICC Meeting

- AICC were updated on the programme for the water dosing being introduced to the QEUH and RHC hospitals.
- Advised that there will be a period where there will be no running water for 4 hours and no hot water for 24 hours.
- Guidance has been written for staff/patients which is currently being reviewed and will be issued once it has been agreed.
- The water dosing of the two hospitals is planned to be completed by 12 Jan 2019.
- AICC advised that F&E will arrange for portable toilets, mobile hand washing sinks and bottled water to be provided to each of the wards in advance of the water being turned off.

- Updates on the installation of the CD system - CD starts to be fed into the system on 12 Nov. It is noted that there are issues with connecting the tanks to the CD system and that existing pipework requires modifications. Incorrect parts were ordered meaning the deadline may extend beyond 29 Nov. A temporary dosing plant is put in place for Wards 2A/2B but there is less control over dosing. Once CD is embedded, water testing can begin. If deadline of 29 Nov is met then whole site will be dosed by 25 Jan 2020. Impact on clinical services continues to be managed and discussed with clinicians.
- Main contractor who built the hospital has been asked to provide certificates for pipework to show this is WRAS approved to give assurance it can cope with CD. Current contractors on site (who previously worked with main contractor) advise that water was in the system for 9 months during construction but no flushing was done. Group advised that while installing CD system in Ward 2A some corrosion of values was noted and could be the reason for metal findings in recent water tests, although noted this is within parameters. Group considered whether these issues could be the cause of the increase in bacteria.
- New shower heads and hoses sent through by PAL (filter manufacturer) are being trialled in staff changing area. Only require one part to be replaced. MBs note that, while effective, once contaminated they become less so. Literature and research is gathered and members asked to comment. Group agree high risk areas should continue with disposable shower heads and hoses but PAL ones could be used for other parts of the hospital depending on trial results.
- Discussion and review of ventilation report highlights problems with pressure and air changes. Air changes were recorded during commissioning but not air pressure. Derrogation was made from 6 to 3 air changes and this applied everywhere apart from BMT areas. Noted that the Project Board did not have the capability to challenge the impact of this change. This was not a deliberate error but was just not picked up. Report also highlights that the dirty and clean extractor fans are connected which means dirty air could be re-circulated, potentially causing the problems with bacteria.
- A variety of solutions to address the recommendation made in the ventilation report are discussed but none are thought to be a viable solution. A ventilation specialist is to be engaged to complete a design feasibility study but this will delay the move back to Wards 2A/2B. Clinicians are advised that it may be end of Jan/beginning of Feb before patients can move back.

Technical Water Group Timeline for 2018 (December)

ACGC Meeting

- ACGF are advised that investigation into the water issue in Ward 2A has uncovered a ventilation issue which will require significant infrastructure change and will prolong the current decant arrangements.

10 Dec

- Further updates are provided on work plan for Wards 2A/2B and noted that work is progressing.
- First set of water samples retuned with good results. No legionella returned and all results are within parameters. Samples were taken from tank room, sentinel points at start and end of ward, and shower points. The Group agreed that this would indicate that the taps have held the bio-film.
- The Group noted that tests later in the month from 13 Dec are clear but indicate fungi, though not in Wards 2A/2B. Noted this appears to have increased from first samples but also noted that fungi are difficult to overcome and CD would take longer to take effect. Also noted increase may be due to CD breaking the bio-film down and ICD to be asked for their opinion. Group agreed to not have a "knee jerk" reaction to this result as data was still being gathered but it should be recorded that an increase had occurred.
- Testing to be extended to whole of hospital to get a baseline to compare to once CD dosing commences throughout campus. Labs would not be able to cope over Christmas with additional samples so this would be commenced but suspended over the Christmas break.
- Noted that more flushing has been performed to get the CD through and for it to penetrate.
- Dosing of the water tanks begins this month with further dosing to be carried out in January. Go live date for whole system is now 4 Feb 2019.
- Decision taken not to fit new taps in Wards 2A/2B until 3 consecutive water results are negative and would be left until after the holiday period.
- Scope of work is being progressed for the ventilation specialist. It is noted that there are challenges in the size of the duct work that need to be overcome for any alterations that may be needed.

10 and 20 Dec

1 Dec 2018

4 Dec

BWSG Meeting

- A sector update noted disposable shower heads are being considered for the QEUH campus.
- Update also noted there was an increase in the incoming water temperature to above what is acceptable over the summer period which has been flagged to HFS.
- QEUH has dump valves with an associated cost to dump water.
- The minutes note that water expert Suzanne Lee had advised that biocide could be utilised to sanitise the water as there is difficulty in cooling the water temperature, which HFS are also aware of.
- Noted a discussion is required with HFS and HPS to resolve this issue as it is not Board Policy to install cooling equipment at the water inlet.
- Discussion required with IPC colleagues regarding impact on patient safety.

11 Dec

CCGC Meeting

- Advised CCGC that installation of the CD system to dose the water supply is now complete. An additional 12 localised dosing sites were also being installed in the next few weeks and work would be completed by January 2019.
- Ongoing reviews of the efficacy of the dosing would be undertaken.
- HIS, HFS and external advisors continue to investigate the cause of the contamination.
- CCGC advised that an extensive replacement programme was being undertaken including replacement of basins, taps, drainage outlets, with additional work being done 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.
- Committee members raised questions about the original design of the facility. CCGC were advised that work was underway to consider all of the identified issues across the site in relation to the original specification requirements for the building.

31 Dec 2018

Technical Water Group Timeline for 2019 (January to February)

AICC Meeting

- AICC advised that upgrading of the ventilation system in Ward 2A is required to bring the system up to the standard required for these patients
- Advised that the work will take 12 months to complete.
- Patients are to remain in the adult hospital in Ward 6A while the work is being performed.
- AICC advised that there had been no cases associated with water since the ward moved to the adult hospital.
- Clinicians noted that the communication from F&E had been really good and no issues were reported when wards were without water during transition to the water dosing system.

7 Jan

- Update on work plan for Ward 2A/2B was given. CD run through RHC system since 22 Nov and by end of Jan work is complete with 4 CD units in place for hot and cold water systems.
- Water results for Ward 2A/2B show some out of spec, some very low level counts which is acceptable, some fungal counts and 4 CU counts. Pre CD results were much higher. One consultant room in Ward 2B and treatment rooms show higher counts. The latter is being modified and sanitised. Playroom wash hand basin and sink show positive on cold water. Agreed to address issues, retest and if still an issue CD level will be increased. If fungi levels are acceptable new taps can be fitted. When taps are fitted they all leak which is resolved by adjusting the connection. Tap must also be aligned manually to prevent a splash risk but noted it could still be easily knocked and create this risk.
These issues are taken up with manufacturer. Ventilation review is postponed as ward is used for low risk patients due to winter pressures.
- Discovery that Slop sinks used to dispose of clinical waste have flexible hoses which is against guidance.
These are all over hospital and ICT had advised not to use them. Group will talk to nursing staff to ask if used. If so, they will be included in flushing regime and if not, they will be removed.
- CD is now embedded in RHC and cold water system for rest of campus and will next be introduced into the hot water system.
- Noted that across campus, 240 water samples were taken with only 30 showing issues. Both hot and cold systems tested to indicate where issues are and allow these to be targeted. Monthly samples being taken but will increase to weekly when system fully up and running.
- Water meters are corroding (prior to introduction of CD). Manufacturer to be asked about this before deciding if they are to be replaced. Higher spec meters will be obtained for drinking water so impact of CD can be assessed on this water.

11 and 25 Jan

BICC Meeting

- Advised there is bacteria in the water system in RHC but there have been no water related cases since September 2018.
- Following advice from HPS, HFS and national water experts a CD system had been installed in RHC and will be completed in QEUH by end of March 2019.
- Chair of the TWG advised that the group will not be stood down until TVCs are at an acceptable level but the results appear to be better than anticipated and the TWG continue to meet fortnightly.
- One clinician notes there is debate about the number of sinks that need to be changed and is concerned regarding the implications for patients. The ICD advises that there is agreement to reduce the number of sinks and remove the trough sinks but there will still be sinks available.
- Noted that a meeting will be arranged with senior clinicians and TWG to discuss the plans regarding the ventilation and sinks.

28 Jan

1 Jan 2019

14 Jan

ACGC Meeting

- Sector update advises that water and ventilation issues found in Ward 2A will now take up to 12 months to address.
- Sector also advises that to address the ongoing water quality issues at QEUH and RHC, chlorine dioxide dosing will commence in December/January to bring the system under control and allow removal of filters which were a short term control measure only.

8 and 22 Feb

- CD is introduced into the hot water system and monitoring system goes live. All work will be completed by 15 Mar.
- At start of month, out of a total of 142 water tests, only 12 were positive for fungal yeast. These have gone for typing. Later in the month good results are being seen but there are 3 legionella results which may be due to bio-film being removed. Decided resampling of the area is to be conducted, test area is to be extended to ensure it's not further afield, taps and shower heads are removed and tested, as are rooms on either side. Both hot and cold outlets are tested.
- Tender process for ventilation has recommenced and review identified one preferred bidder. Purchase order being raised and tender and design phase will take 3 to 4 months to complete.
- Issues identified with taps last month were discussed with manufacturer. The leak is due to a production fault and being addressed. The movement of the tap is thought to be due to a stress or corrosion crack through incorrect fitting. Manufacture is attaching a locking mechanism to the tap and providing training on installation and working with tap.
- A TVC protocol document is agreed setting out when POUFs could be removed. This would be after 4 week of consecutive clear tests, then moving to monthly and then quarterly for 3 consecutive acceptable results to confirm control values are maintained long term. Noted that getting below thresholds may not happen and may need to accept results are as good as can get. Monthly checks will remain in the high risks areas for Legionella and Pseudomonas.
- Communication and protocol for reporting little used outlets is developed and shared with nursing staff to ensure such outlets are reported and actioned, and not left. This includes escalation if report is made to senior nurses and F&E but no response is received. To be ratified by Board Water Safety Group.
- Manufacturer confirms water meters will be affected by CD and should be removed when system is sanitised. Not practicable with continual dosing. Guidance from HPS being sought.
- Following a review of the options for shower heads and hoses, conclusion is hose is the issue and none on market are better than replacing a hose on a regular basis. With CD in place, Group agreed that replacement can be reduced to 3 times a year instead of every 43 days but in high risk areas this remains at 62 days.

25 Feb

South and Clyde Sector Water Group (SCSWG)

- Noted that written scheme is being updated to reflect the installation of the CD plant.
- Confirmed to group that both the QEUH and RHC are both receiving CD dosing with good positive results.
- Group noted that installation of the CD will make a good impact on quality if correct dosage is utilised.

28 Feb 2019

Technical Water Group Timeline for 2019 (March to April)

- Remedial work has been completed to address the Legionella results from Feb and test results are clear. The Feb 2019 results showed Ward 2A had CU in certain rooms. This ward has received the most exposure to CD but Is the only one showing CU. CD dosage to be increased for this area. Noted that if this does not solve issue then further works will be required to look at potential engineering issues.
- Report on water meters shows that paintwork on cases is unevenly applied and affected by water with damage caused prior to CD implementation - it does not meet healthcare quality requirements. Report to be sent to HFS who advise consulting WRAS to see if approval process covers paintwork. WRAS confirms testing does not cover coatings and paint coverings. NHS GGC to request HPS to update national guidance on this basis.
- The CD installation will be completed this month with only 6 hot water systems still to go live.
- Ventilation tender has been awarded and a pre-start meeting is held this month to discuss feasibility works. The full design and feasibility work will take 4 months and construction work will be phased over 6 months.
- Slop hoppers found to be in dirty utilities and not used for disposable waste. Hopper to be disconnected, capped and sanitised, then covered to make a work surface – where these are not used.
- Water results for March show only one sample has Legionella count of over 200 counts. This area was serviced and sanitised and results are awaited. Group agreed to sample a few rooms either side and check pipework to determine if testing was required as far as the pipework runs.
- Complaints received about odour and taste of water. Noted this may be due to bio-film breakdown which can cause odour and taste issues for short 24-48 hour period. Investigate to see if test can be carried out to determine.
- Second report in connection with tap connection failure notes that a chemical reaction with ammonium compound may have caused the failure. This chemical had been used many times before to disinfect but manufacturer will propose an alternative.

8 and 29 Mar

1 Mar 2019

12 Mar

AICC Meeting

- Update that CD installation is scheduled for completion by end of Mar 2019 and will service both QEUH and RHC.
- F&E staff continue to undertake drain cleaning arrangements with areas specified by IPCT colleagues.
- Domestic service staff will perform flushing as part of their duties and a SOP has been developed and will be implemented to inform domestic staff on how flushing is performed.
- Water coolers/dispensers are being removed from high risk areas across NHS GGC.

18 Mar

ACGC Meeting

- Now confirmed that the the water and ventilation issues found in Ward 2A will take up to 12 months to address.

25 Mar

BICC Meeting

- ICD reported that the taps and sinks in Ward 2A/B were changed and the filters will be kept on long term in the Haematology unit as fungi was identified there.
- ICD also advised that low levels of Legionella were picked up but levels are not clinically significant.
- ICD also advised that discussions are underway to determine if the taps should be removed from other critical care areas.

8 Apr

BCGF Meeting

- Forum noted that installation of a continuous (low level) chlorine dioxide water treatment system had been completed in the QEUH and RHC.
- Forum noted that results have been extremely encouraging with no cases of bacteraemia associated with water in RHC since September 2018.

16 Apr

Board Meeting

- The report provided an update on the water and ventilation system at QEUH and RHC, and MD noted that installation of a continuous (low level) chlorine dioxide water treatment system was now complete and there had been no cases of bacteraemia associated with water since September 2018.

MD also advised that over 800 air samples had been taken in relation to Cryptococcus neoformans, however Cryptococcus had not been identified in air sampling since the end of January 2019. Air sampling continued and no incidence of infections had been identified since December 2018.

11 and 26 Apr

- Work is completed on the CD installation and snagging list is also addressed by the end of this month.
- Water tests for March show 16 fungal results but agree CD will eradicate these over time. High TVC counts recorded in the Acute Receiving Unit (ARU) which will be investigated. Feb E.coli results were in the porters' rest room and pipework was reconfigured to remove dead legs and 5 little used outlets.
- General results for RHC are good apart from certain areas in Ward 2A - Hospital at Night (HaN) tested positive for EC in cold water system and TCT rooms 3 and 6 routinely record fungi counts and Cuprividus Pauculis, respectively. Noted 2 water coolers, dead legs and a little used wash hand basin in HaN room were removed and automatic flushing of outlets was installed. Pipework configuration will be examined if followed by a high level CD treatment programme and resampling of whole area. If this does not work then further investigations will be required to see if this is an engineering problem.
- Complaints from staff about removal of all water dispensers – a preventative measure taken by the BWSG. Staff do not believe assurances that water is safe to drink. Matter to be raised at next BSWG.
- Noted that other products are in the water system that have the same coating as water meters. Given the concerns raised, a sample of these will be tested to assess condition and impact on water quality.
- Water meters designed to monitor and automatically dose the water based on volume are found to be underdosing the water system. Other sensors are still to be installed which may resolve this issue. Replacement of water meters would involve additional cost and shut down of the system and require senior management approval. Group agreed to defer decision until other sensors are in place.
- Group decided that they will meet monthly from now on and technical advisers will attend quarterly.
- Discussion held on replacement taps for all high risk areas given issues found in Ward 2A.
- Selection of taps for high risk areas is reviewed given issues found in Ward 2A. Agreed that Marwick 21 is still the tap of choice as it is fitted with a copper lined open orifice bio-guard antimicrobial flow straightener.

30 Apr 2019

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Technical Water Group Timeline for 2019 (May to June)

- Group advised of positive results from Ward 6A of STM and MC. Discussion centres on investigation of other sources, not just water, i.e. patients, equipment used for treatment or from other hospitals. Agreed that water samples from filtered and non-filtered outlets, and other areas of the hospital visited by patients will be taken and analysed.
- Noted that a large dose of CD can be added to the bulk storage water tanks but water will not be drinkable and could adversely affect pipework. Only to be done if water was considered the root cause and other potential sources, as noted above, had been ruled out. A strategic risk assessment would be needed and a communication plan to inform staff but a small CD increase could be done now.
- Noted that CD is killing off the bacteria and may be breaking up the bio-film allowing the more resistant bacteria room to grow. Noted it can be 3 -4 years before results are clear.
- A review of products (all WRAS approved) in the water system found that those made of cast metal or had paint treatment showed signs of corrosion and bio-film, while brass and stainless steel products did not. Noted products affected need to be replaced. Alternative products are to be investigated and HFS also asked to provide advice.
- Noted that continual fungi results from water tanks but it was possibly due to cross-contamination during the sampling process which has now been modified to ensure this does not occur. Noted smell of mustiness from sprinkler tap room which was used as a storage room. Agreed area is to be cleaned and sanitised, tanks repaired and sealed to the floor. Air samples show fungus and air filtering discussed but noted area open to outside and air contains fungus. Agreed that area did not need to be clean to clinical standards.
- Mould found in IPS panels in Ward 2A and, due to either defective joint fitting or design of room floor and wall joint, water samples show shower heads are leaking lead leachate – manufacturer advised this is normal for some during run in process, and although counts are unusually high these will return to below accepted levels. The minutes note that the Group thought these unusually high counts are the product of stress corrosion, new fittings that were added and the previous shower cleaner which had a causative catalyst and was no longer being used.
It is also noted in the minutes that this high count level is not expected to recur and that this issue is not considered to pose a risk. Shower heads are to be sanitised and waiting for manufacturer to advise what chemical should be used.
- High risk areas for tap replacement now identified and the replacement programme will take 12 months to complete.

21 June

1 May 2019

May

No meetings are held this month and the next is in June.

3 June

BICC Meeting

- Chlorine dioxide dosing of the water is now in place.
- Filters are now on all outlets where high risk patients are located.
- Planned tap replacement programme ongoing.

30 June 2019

Technical Water Group Timeline for 2019 (July to August)

- At the previous month's meeting it was decided that the sprinkler water system on the helipad should be treated with CD but manufacturer information reveals this cannot be used with aluminium which houses the system. A SOP is to be developed to ensure there is sufficient turn over of the water in this system. The firefighting water tank can have CD treatment but clarification on the dose is being sought.
- DMA are commissioned to carry out a survey of the products in the water system that are cast iron or have paint treatment but no replacement is to be carried out. Noted that only able to survey accessible products but it will help to develop a plan for replacement and what would be involved.
- The work to address the mould in the water tank has been carried out but a visit yesterday found that there was standing water and hoses left on the floor. The room will be checked and a message relayed to those using the room that it should be left in a clean and tidy state.
- Following the reports of STM in Ward 6A in April/May, a sweep of tests were performed on outlets but the results from these are all negative.
- Weekly testing will commence from first week in August as the CD is now embedded into the domestic hot water supply. Commencement of weekly testing is dependent on the "residual" values reaching a certain level across all water systems. These "residuals" are the elements such as bacteria and particles being extracted from water.
- The automatic flushing has been stopped in Ward 2A as this is thought to have exacerbated the mould found in the IPS panel. Investigation being carried out in other areas of the hospital to check if this is just located in 2A or further afield.
- Following installation of sensors, the issue with water meters under-dosing the system is resolved.
- Noted tap replacement in 12 high risk areas will take 2 months to complete.

BICC Meeting

- BICC advised that after positive pre filter water results being returned for Ward 6A, the CD dose to the water supply was increased but remains within WHO standards.
- A shock dose treatment to Ward 6A water is being considered but post water results are negative.
- Current samples taken on 8 July are looking specifically for Mycobacterium but results will not be available until mid August.
- BICC advised that one theory as to why Mycobacterium is showing up is that it is resistant to chlorine and with the introduction of CD has eliminated other types of organisms which is allowing more unusual types of bacteria to grow.
- TWG to work with IPCT and Public Health Consultant to research public literature to see what advice and guidance is available.

ACGC Meeting

- Advised that the estimated completion date for the work to address the water and ventilation issues on Wards 2A/2B is now March 2020.

Board Meeting

- Following a briefing on the incidence of unusual GNB being found on Ward 6A Board members ask how long children would be accommodated in ward 6A. The Director of F&E advised that while Wards 2A/2B were being renovated patients would remain in Ward 6A. The work on Wards 2A/2B is expected to be completed by March 2020.

AICC Meeting

- AICC informed that the QEUH chlorination system is fully fitted and there have been good results. Gram negative count has reduced significantly, however the mycobacteria issue has recently appeared and is resistant to chlorine at the original used levels. It is noted that the increase in mycobacteria may be due to existing bio-film or it is being selected out and proliferating because it is resistant to chlorine.
- AICC are advised that the initial step is a slight increase in the chlorine levels, and that the level is still within the WHO guidelines. AICC are advised that if this measure is not successful then shock dosing may be considered but this would have a significant impact on all clinical areas (water would have to be closed down for a period of time).
- The Water Technical Group continues to meet and support the QEUH.
- The Board also continue to have international water experts on retainer for advice as required.
- The issue of bottled water coolers has been discussed at the BSWG and there is a current National Directive that all bottled water coolers irrespective of location, should be removed. This will be discussed at the next BWSG meeting.

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- SOPs for sprinkler and helipad firefighting water tanks have been drafted and further information is awaited on the dose of CD to be applied to the latter. A CD dosing apparatus will not be installed for these tanks due to cost and ongoing maintenance requirements. Manual dosing will be performed.
- External contractor appointed to perform tap replacement and a survey was performed for establish the scope of work and approximate costing - this will be provided next week.
- Water tank room now in good order. The new CD apparatus has an ongoing leak making the floor wet. Leak is being managed on an ongoing basis until principle contractor has remedied the defect.
- Group advised that there was MC in the water and whether the CD should be increased further was discussed. Dose currently 0.5 ppm and increase to 0.7 ppm suggested. Noted by one member this was unlikely to have a major effect based on literature read and dose of 1.2ppm should be considered. Group considered this not feasible given engineering challenges and potential impact on services.
- Testing showed positive results for Ps and coliforms from the main water tank room. Two filtered water tanks and an outlet downstream of the tanks in the children's OPD on ground floor were sampled and have been submitted to lab. Noted that water sampling is identifying consistent activity for mould and yeast which have been sent for typing. Noted that where counts are low this is often due to dirty taps or sampling errors. Need to know coliform counters and results of nearby outlets upstream and downstream, and results following disinfection and resampling. The ongoing issues in the basement plant room in terms of yeast and mould need to be further investigated, including broadening of the scope to include air sampling.
- Noted that issues with mould identified in Ward 2A are only in this area and not further afield. Work to be added to ventilation upgrade project.

Technical Water Group Timeline for 2019 (September to October)

- SOP for sprinkler system and fire tanks now completed as CD for fire tanks has been provided by manufacturer. DMA are currently draining and flushing these tanks so they do not become a little used outlet.
- Basement tank is found to be leaking and repairs are instigated.
- Discussion on whether air quality testing should be performed in tank rooms and areas outside as this would indicate if any mould spores are in the humid air. After further discussion it was decided this instruction would have to come from an IC representation and this decision would be taken outside of the meeting.
- A review of sample results of failures showed there was an increase initially but then a steady decrease over the following weeks. These results are only showing yeast and moulds – initially results had shown coliforms and E.coli, but no Legionella or Psuedomonas had ever been found. The group discussed the possible environmental impact as it was noted the results had been higher during a period of wet weather. Thought that a look back might reveal increases during wet periods of weather and lesser numbers or none during warm weather.
- Cost of tap replacement is £3m which includes replacement of sinks, reduction of pipework and replacement of taps and IPS panels, including any additional work required. The decision to progress has not yet been made and there is likely to be a phased implementation. Taps will be replaced with Marwick - although issues have been noted with these taps in other areas, it removes the Optitherm taps which giving cause for concern in other areas.
- Showers in Ward 2A are now being manually flushed and funding is available to remove and resolve the mould issue within this ward. Will investigate market to obtain options to resolve this issue.
- Noted that some rooms in Ward 2A had high humidity at 15% (12% is the accepted limit).
- Agreed that water sampling would stop in Ward 2A as there are no patients and flushing of system is continuing. Testing will be recommenced once work is completed and patients are due to return to the ward.

13 Sep

1 Sep 2019

2 Sep

AICC Meeting

- Advised that further sampling for Mycobacteria had been carried out across QEUH to find out how widespread the issue is and the results are expected within 4-6 weeks.
- The dosage applied to the water supply for Wards 2A/2B is to be increased from 0.5ppm to 0.7ppm - this is to be monitored for a period of time to review its impact on water results.
- The increase is within the WHO guidelines and has been approved by the TWG and IMT.
- The TWG continues to meet, support the QEUH and continue to have international water experts on retainer for advice as required.

BCGF Meeting

- Advised that the work to address the background water/ventilation issues in Ward 2A/2B is estimated to be completed by March 2020.

28 Oct

25 Oct

31 Oct 2019

- Tests of flow straighteners for last 3 months show no Ps or bio-film. Conclusion is that CD is keeping these clean but this needs to be confirmed by experts. Agreed periodic testing should continue as agreed to allow any changes to be noted quickly and actioned. Agreed to re-run test and previous results are to be reviewed by the expert group.
- Testing of basement tanks post filter shows Delftia in one tank and room. One Ps found in the drain points and TVCs are showing in raw water tank but only in certain lines. Noted that room has high level of humidity and musty smell. Air sampling to be done in the room and corridor to see if any spore counts and justify a dehumidifier being installed.
- Out of 142 samples from campus only one shows bacteria. Noted that samples over the last couple of months are clearer and clearer. However minutes also note a minor TVC and one coliform was found. The DSR and dirty utilities had positive results (agreed that this is not surprising) and adult first floor critical treatment room recorded a repeat coliform failure and high TVCs which need to be investigated.
- View of Scottish Water around coliform failures in August and September is that, based on the pattern of results, this is due to either tap hygiene or lab issue, but probably a sampling issue. Advised length of flushing time should be increased given the size of campus. Offered to review NHS GGC SOP and carry out observation of practice for water sampling - this was agreed as a good way forward.
- Meeting discusses what information IMTs want from this group and it was agreed that the following was needed:
  - Visibility of any current positive water samples;
  - Local water groups are to discuss any issues with IC and F&E are to be present at these meetings;
  - Any positive results are to be reported to IC and patient pathways followed to identify any issues;
  - Written statement of process to be followed when positive results found (currently only for Legionella and Ps);
  - Agree to carry out more than usual sampling on QEUH and this would include yeast and mould samples; and
  - Statement on the water quality and potability and also on status of flow straighteners.

Technical Water Group Timeline for 2019 (November to December)

- Meeting unclear whether air sampling of the basement tank room was performed - will check and results will be reviewed in January. Sampling of the air vents at top of tanks to be performed to see if anything there which might Infect tanks. Discussion will also be held with F&E to see what options there are to increase ventilation which is an issue. Re-sampling also to be done to determine if air in room is infecting the tank.
- Discussion of the results returned from Ward 6A that had led to the conclusion of contamination and also around method of sampling which had led to this result. This had been shared with people within the Board. This conclusion was contrary to what was previously reported and that the water was safe. It is not clear whether the results were expected or this was just a spurious result, but it has now led to ongoing discussion with SG. A number of observations were made that sampling methods may vary and that there had been reactive reactions to all issues with no closing off of actions, no reporting of conclusions or understanding or knowing why actions were taken. There was a need to shut down and conclude on the outcome of the samples. The use of technology to review, action and understand the sample results should also be used. It is noted that national guidance is needed in this area, but Group agrees the following actions going forward:
  - Use of flop swabs for sampling and systematic procedures to be put in place for sampling. SOP to be developed to ensure all areas tested in the same way using the same technique;
  - Cognisant of any changes to baselines and impact to ICT results;
  - Other opportunities to prevent infections – patient information, nursing methods;
  - Better analysis of data - are the bugs in the drains the same as in patients, are they harmful to patients, test to look for failures in the system i.e., tanks, testing to reassure of system safety. Statistician to look at data going forward to determine if results show trends, focus on recurring incidents and allow appropriate reactions; and
  - Consider what can be done with information that is produced to allow clinical teams to remove POUF.

12 Dec

1 Nov 2019

Nov

No meetings are held this month and the next is in December.

31 Dec 2019

Water Testing Process

F&E has provided further detail on the water testing that is performed and copies of spreadsheets showing the results of tests that have been performed in late 2019 and early 2020.

Testing Process

- F&E advised they maintain a register of the total ongoing sampling that is being conducted at the QEUH on a weekly basis. 142 tests are taken from 71 designated points throughout the QEUH and RHC. Two samples are taken from each designated point such as a tap or shower and an outlet to a drain.
- The results are recorded on a 'sample matrix ' for the QEUH which F&E receive on a regular basis. Any time samples are taken, the matrix is updated by a specialist water consultant. This means the frequency of getting this matrix varies depending on the sample being taken and analysed. This matrix covers the 'full sampling regime' across the Adult and Childrens Hospitals.
- From this sampling grid the operational estates team reviews two specific areas (as required by SHTM04-01) - Legionella and TVCs at a water temperature of 37 and 22 degrees centigrade . If these results are found to be 'out of spec' then the results are uploaded onto a further spreadsheet and actioned accordingly. The spreadsheet lists the sample reference and actions taken to address the out of specification issue.
- All other bacteria found in the samples are reviewed by the ICD and if action is required to be taken then the ICD discusses this with F&E. These other bacteria are:
    - Coliforms
    - LP Sero Group
    - Psuedomonas
    - SAB at a water temperature of 30 and 22 degrees centigrade
    - Cupriavidus
    - AMS
    - Other (which includes GNB)
- Samples of these spreadsheets were provided by F&E. The below spreadsheet covers the period from 7 Jan 2020 to 6 April 2020. The spreadsheet also pulls out into a separate tab those results that are out of specification. A summary of the results is given is in the table below.

Month and Year	Total number of samples	Samples not received	Samples awaiting results	Results returned	Out of spec samples
January 2020	347	-	-	347	14
February 2020	352	2	4	346	21
March 2020	357	-	27	330	3
April 2020	55	-	52	3	0
Total for period 7 Jan to 6 April 2020	**1,111**	**2**	**83**	**1,026**	**39**

- Although 39 samples were out of specification, some samples had counts of more than one type of organism. In total there were 62 organisms classified as follows:

Organism	January	February	March	Total
TVC at 22 degrees centigrade	2	4		6
TVC at 37 degrees centigrade	2	6	-	8
SAB at 22 degrees centigrade	3	4	-	7
SAB at 30 degrees centigrade	6	6	1	13
Psuedomonas	2	9	-	11
Cuprividus	1	3	1	5
Coliforms	2	-	2	4
Enterobacter cloacae	2	-	-	2
Other	-	6	-	6
Total	**20**	**38**	**4**	**62**

- The Other category is made up of a number of GNB organisms which are
    - Aeromonas Media (1)
    - Sphingobium Xenophagum (1)
    - GNB Enviro (1)
    - Delata Acidovorans (2)
    - Chryseobacterium Indologenes (1)
- The sample spreadsheet provided by F&E also shows actions that have been taken in relation to out of spec samples.
- SOP was developed in December 2019 in respect of the sampling that was required to be undertaken and what action should be performed, once the sample matrix is received, around those samples that are out of specification.
- While the overall number of samples that are out of spec seems relatively low, there is a lack of context around these results to allow any meaningful conclusions to be drawn. This highlights the need for a more statistical approach to the analysis of these results to identify trends over a period of time and whether there are "hot spots" within the campus where bacteria is located.
- It is noted in the December 2019 minutes for the TWG that statistical analysis was being proposed and NHS GGC have advised that data has been shared and discussed with HPS and a software company. However, Covid-19 has halted work on the analysis. It is suggested that this work is revived as soon as practicable to ensure that there is a continuing trend downwards in respect of all bacteria across the RHC and QEUH and ensure the CD is adjusted accordingly for "hot spots" identified by such analysis.

Section 9
Heat Map of Infections

Summary Table of Incidents

The following table provides a summary of the incidents which are set out in the timeline which is based on the information sources set out in the Introduction at Section 1. The table brings together in one place the different types of GNB and Fungal organisms that were reported, the month and year they were reported, the ward and number of patients affected. The table aims to show the spread of these incidents across the RHC and QEUH (but only after patients from Ward 2A/2B were transferred) and also the variety of organisms identified. It should be noted that the table does not detail the organisms by strain or typing or whether they were related – the information in this respect was limited in the documentation that was reviewed. The table is therefore not an epidemiological analysis of the incidents which occurred.

Ward/Year	2015	2016	2017	2018	2019
Ward 1E - RHC			AB (Nov) (1)		
Ward 2A – RHC		A (Aug) (1) CU (Feb) (1) NUO (Jul 2016 to Feb 2017) (???)	EM (Sep 2016 to Feb 2017) (3) A (Mar/Apr) (3) STM (Jul) (2) CU (Sep) (1) A (Oct) (1)	STM (Mar) (5) CU (Mar) (1) PsA (Mar) (1) Pan (May) (1) AB (Jun) (2) CU (Jun) (1) GNB (Sep) (5) SM (Sep) (1) Ps (Mar) (2) FG (Mar) (1) EC (Jun) (6) STM (Jun) (9) Ps (Jun) (4) STM (Sep) (1) Ward Closes 26 Sep	
Ward 3A – RHC			AB (Oct) (4)		
Ward 6A - RHC					CN (Dec 2018 – Jan 2019) (2) PsA (Jan) (5) STM (Apr) (1) PanS (May) (1) STM (May) (1) MC (Jun) (1) EC (May/Jun/Aug) (3) PsP (Jul) (8) CH (Aug) (1) EM (Aug) (1) EC (Aug) (1) EA (Aug) (1) Ps (Aug) (1) STM (Aug/Sep) (2) GNB (Sep) (Multiple) AC (Sep) (1) DA (Oct) (1)
PICU - RHC	PsA (Dec) (2)	AB (Jun) (2) SM (Sep/Oct) (6)	SM (Feb) (?) Ps (Aug) (2) AB (Nov) (1) SM (Mar) (3) SM (Oct) (4)	PsA (Jan) (4) AB (Feb/Apr/May) (6)	AB (Jan/Feb) (2) Ps (Jan/Feb) (2) SM (Jan/Feb) (1) AB (Apr) (2) AB (Nov) (3) SM (Nov/Dec) (2) PsA (Nov) (3) AB (Dec) (1)
Ward not identified			MA (Jul?) (?)		
Theatre 6 - RHC				PsA (Nov) (5)	

Key

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(17) – the numbers in brackets are the number of patients that were identified with this organism.
(??) – the number of patients that were identified with this organism is not known

Key for Summary Table of Incidents

Gram Negative Bacteria

- AB - *Acinetobacter baumanii*
- AC - *Achromobacter*
- CH - *Chryseomonas*
- CU - *Cupriavidus*
- DA - *Delftia acidovorans*
- EA - *Enterobacter aeromonas*
- EC - *Enterobacter cloaecae*
- EM - *Elizabethkingia miricola*
- Pan - *Pantoea*
- PanS - *Pantoea septica*
- Ps - *Pseudomonas*
- PsA - *Pseudomonas aeruginosa*
- PsP - *Pseudomonas putida*
- SM - *Serratia marcescens*
- STM - *Stenotrophomonas matophilia*
- GNB - *Gram Negative Bacteria not yet identified*
- NUO - *Numerous unidentified organisms*

Fungal Infections

- A - Aspergillus
- CN - *Cryptococcus neoformans*
- FG - *Fungal Growth*

Gram Positive Bacteria

- MA - *Mycobacteria abscessus*
- MC - *Mycobacteria chelonae*

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Summary Table of Incidents

The previous slide provides a pictorial representation of all the incidents contained in the timeline by location, month they occurred, the type of organism involved, and the number of patients that were identified with this organism. It should be noted that this does not represent the total number of patients affected as some patients had more than one organism at any given time.

There are a number of observations that can be drawn from this table and from the narrative within the timeline, as follows:

Development of water contamination hypothesis and timing of incidents

The table shows that the incidents started to appear in 2017 but were more numerous in the subsequent years. Although there appears to be an increase in incidents from 2018 onwards, as already mentioned, NHS GGC advised that this was a direct result of update to the NICPM in June 2017 which resulted in environmental organisms being added as alerts.

It will be noted from the timeline that the hypothesis that the incidents were due to contamination of the water system started to develop in 2018. Actions, such as replacement of taps or removals of basins, were precautionary measures or ones where a definite link had been identified to the tap or wash hand basin, rather than indicating a real concern about the quality of the water.

Some GNBs can originate in water so the development of the hypothesis that water was the source was not an unreasonable one. However, and importantly, while some GNBs are contained throughout the environment and others are contained in the human body, they generally remain harmless and do not affect a normal healthy individual. Those such as haemato-oncology patients are, however, at greater risk from GNBs as their immune system is compromised and, as a result, they are more susceptible to infections from these organisms. Such infections can therefore be obtained either from organisms in the patient's own body or from an external source. NHS GGC have advised that endogenous infections, i.e. from the patient's own flora (body), are very common in patients whose immune system is compromised.

Although the development of the hypothesis around water began in 2018, other avenues of investigation and hypotheses as to the cause were pursued, both at the time and prior to this:

- levels of hand hygiene and ward cleanliness;
- operating practices;
- issues with drains – although it is noted in the timeline that a survey revealed that no issues had been found with the drainage system for either hospital. However, certain MBs/ICDs note the survey did not, and could not, look at issues with drains detected at the back of sinks, such as evidence of corrosion and heavy bio-film and pools of stagnant water;
- issues with ventilation systems and leaking chilled beams (in relation to the fungal incidents);
- investigation of water leaks and ingress – especially in relation to a long standing slow leak in the ward kitchen;
- the work undertaken in respect of line infections (CLABSI work which did lead to a reduction in infection rates); and
- analysis of patient pathways to identify other potential sources of these infections.

Given that some GNBs are contained throughout the environment and others are contained in a patient's own flora and considering the risks in terms of transmission and wider spread of such organisms, it would appear reasonable that these other lines of investigation were pursued as well as those relating to the water supply.

It is noted in the timeline and was ascertained through the HPS/HFS investigation in 2018 that prior to the hospital being handed over there was water testing performed by the main contractor which returned high TVC counts in some locations. These areas were sanitised and retested but it was noted that not all locations passed the second test and HPS noted that the records were not clear as to whether these areas subsequently passed.

IA senior estates manager instructed two members of his team to conduct water sampling following the building being handed over. An interview with one of these staff members revealed that only tests for Legionella were conducted and they and their colleagues had no training in taking water samples. Where positive results were identified these areas were sanitised and retested. Only once three consecutive negative results had been obtained was no further action taken – if positive results were obtained, then further sanitisation was performed.

The HPS report and the findings of water experts engaged in 2018 concluded that contamination was likely to have occurred during the building of the hospitals and it led to the build up of bio-film and consequently the organisms that were seen. The water experts also concluded that the advent of fungal bacteria was the result of temperature fluctuations of water. The temperature is controlled by the Energy Centre and there have been issues with this building since it first opened.

Certain MBs/ICDs have advised that they raised concerns over the water system prior to the hospital opening and then repeatedly since 2017. The review of the information sources used to create the timeline does not contain any record of these concerns being raised, other than the SBAR in September 2017 and again in September 2019. Certain MBs/ICDs advise that these SBARs highlight the importance of ICDs requesting water testing as this is a key measure in the investigating and managing of the incidents included in this timeline. It is noted in the timeline that an action plan was put in place to address the concerns raised in 2017 but the MBs/ICDs advise that this was not agreed with them and it contained inaccuracies and misrepresentations – although this is not noted in any of the various committee or Board minutes.

The report generated by DMA in 2015 should have been a key indicator that there were issues with the water system but this report seems to have been "lost" amongst the host of other issues that were being experienced in both hospitals following handover. The extent of the issues being identified with the hospitals and the level of work still to be completed resulted in this report not being actioned due to the firefighting that was being performed at that time by the F&E team.

It can be seen that the "loss" of the DMA report and the main contractor not informing the project board that there had been high TVC counts noted, resulted in the opportunity to address any issues in the water system being lost. In addition, if the findings in the DMA report had been known at the time together with the concerns raised by certain MBs/ICDs prior to the hospital opening, then the actions taken during the incidents noted in the timeline and the various hypotheses pursued may have been different.

NHS GGC advised that the hypothesis around the water system causing the incidents highlighted in the timeline has never been proven and cannot be taken as fact. NHS GGC also advised that the reference laboratory analysed all patient samples from 2018 onwards and linked none of them to the positive water samples. The results of these patient samples have not been provided or reviewed during the course of constructing the timeline.

It should also be acknowledged that the HPS report dated October 2019 entitled "Review of NHSGG&C haemato-oncology data" stated that its review did not provide evidence of a single point of exposure causing the bloodstream infections. However, one of its recommendations was that consideration should be given to the epidemiological characterisation of cases in the context of environmental risks, e.g. water and ventilation testing results.

Certainly the 2015 and 2017 DMA reports and 2018 HPS report and results of the water testing performed by the TWG would indicate that there are, or were, issues with the water system. The tests performed by the TWG showed that contamination was wide spread and there was a build up of bio-film in the system. While this was a key milestone in confirming that there were issues with the water system, it is less clear whether these contributed to or were the cause of the incidents seen in the haemato-oncology population in Wards 2A and 6A.

Location of incidents

The table on page 40 shows that these are predominantly in Ward 2A until 2019 when Ward 6A starts to display the most organisms. It is noted that Ward 6A, prior to accommodating the patients from Ward 2A, was a general adult ward and therefore any incidents which occurred in that ward prior to the transfer have not been reviewed as part of this timeline.

It is noted from a review of the TWG minutes that initial water testing found that there were organisms located throughout both hospitals and this was consequently a widespread problem. The results from the water testing would therefore support the hypothesis around contamination of the water supply. The TWG minutes also record that issues with the ventilation system were also noted in this ward.

It is also noted that PICU had a number of GNB incidents during the period from 2015 to 2019 with 2019 having the most incidents. In this case, however, the type of GNB is much more restricted and is confined to either Ps/PsA, AB or SM bacteria.

Typing of organisms

It is noted throughout the timeline that the organisms were sent for typing to see if the strain of each positive sample was the same, thereby indicating either a common source, or cross transmission. In some cases this would be the same but in many instances these were unique both in terms of the cultures taken from patients but also from those taken from water outlets and drains.

While there may be sound epidemiological reasons for analysing bacteria by unique strain, the focus on this alone seems to have detracted from the investigation of the cause of these bacteria in the first place. It may also have been more helpful to look at the incidents as a whole rather than by individual strain. This was a suggestion made by SG in late 2019 when they advised that NHS GGC should investigate the last 3 incidents together.

This also appears to be advocated by the HPS 2019 report which recommends characterisation of cases in terms of "person" and "place" to support identification of times when there are more cases than normally expected, as well as its recommendation about considering the epidemiological characterisation of cases in the context of environmental risks (such as water and ventilation testing results). While it is important to know whether cross transmission has occurred, it should not detract from the overall question of why and what the cause is of multiple different strains of bacteria. This point is not meant to question, or indeed contradict the need for, the science of determining the type of organisms, but rather it should compliment it.

The need for national guidance

During the time period covered by the timeline there was no apparent guidance available around the management, control and investigation of GNB and water borne organisms. HPS is currently working on such guidance and produced an aide memoire on the "Prevention and management of healthcare water associated infection incidents/outbreaks". Another aide memoire for infections/outbreaks associated with ventilation was also produced. It is noted that both areas are to be covered in a new chapter of the Infection Control Manual but currently the aide memoires are the only guidance available on water and ventilation associated infections/outbreaks. This highlights the lack of expertise available to NHS GGC during the course of 2015 to 2019. Throughout this period NHS GGC drew on the expertise of HFS, HPS, water experts (Sarah Lees and Tom Makin), Public Health in England, and the experience of other health boards in Scotland and England, and even from hospitals abroad. Reviews of available literature were also performed to inform thinking and investigation. It is clear that from 2018 NHS GGC were seeking outside assistance in trying to resolve the issues they were facing.

The minutes of the TWG on 11 May 2018 record that one water expert noted that there are issues with new build hospitals and the method of their construction. These buildings are hermetically sealed and many are now showing water issues never previously seen in hospital buildings. On this basis it would seem clear that a further level of expertise is required to deal with such incidences and further guidance is needed.

The question arises as to whether further national research is required into these bacteria and how they develop and are transmitted in such environments, including both water and ventilation systems, particularly in new build hospitals. It is also necessary to know how these organisms should be monitored and, if detected, what appropriate action should be taken. The NIPCM is currently being extended to cover more organisms but it has not yet been issued and it is not clear whether it will take account of the experiences and actions taken by other new build hospitals in dealing with similar issues. Certainly the experience and lessons learned by NHS GGC from these incidents should be captured and inform the guidance to be issued by HPS.

In addition, the knowledge and experience related to these incidents gained by IPCT, MBs, LICD, ICDs and F&E staff at NHS GGC should not be lost. It is important to ensure that this knowledge and experience is retained and capitalised on. To that end consideration should be given to setting up an expert group that includes ICD and F&E staff so that, if further incidents occur at the RHC or QEUH for this patient cohort, they are referred to this group for investigation as the knowledge and expertise they have already gained can be utilised. This should quicken the process of investigation as the group will have a better idea of what to look for and what to consider in these circumstances.

Queen Elizabeth University Hospital
and Royal Hospital for Children

Case Note Review Overview Report

March 2021

Contents

EXECUTIVE SUMMARY

In November 2019, NHS Greater Glasgow and Clyde (NHS GGC) was escalated to Stage 4 of NHS Scotland's National Performance Framework as a result of a continuing series of infection incidents at the Queen Elizabeth University Hospital (QEUH) and the Royal Hospital for Children (RHC). An Oversight Board was established by the Director-General of Health and Social Care in the Scottish Government and Chief Executive of NHS Scotland to address critical issues arising from the operation of infection prevention and control, governance, and communication and engagement at the QEUH and the RHC. In parallel, in her statement to Parliament on 28 January 2020, the Cabinet Secretary for Health and Sport commissioned a Case Note Review, to be undertaken by a panel of independent experts. The period defined for our review was from the time the paediatric haematology oncology service moved into the new RHC in 2015, to the end of 2019.

We were pleased to accept the invitation to undertake this work and at the heart of our report lies a shared concern for the safety of children and young people under the care of the Paediatric Haematology Oncology service at the Royal Hospital for Children in Glasgow.

Concerns about risk of infection emerged after the hospital moved from its old site at Yorkhill to the new Queen Elizabeth University Hospital in June 2015. Views about deficits in the design, commissioning and maintenance of the buildings have been aired in other publications and will continue to be addressed in the future. Our task, however, has been to determine how many children and young people with cancer, leukaemia and other serious conditions were affected by a particular type of serious infection, caused by Gram-negative environmental (GNE) bacteria, from 2015 to 2019; to decide, as far as it is possible so to do, whether these infections were linked to the hospital environment; and to characterise the impact of the infections on the care and outcome of the patients concerned. Our full Terms of Reference are set out in Chapter 2. These also include a responsibility to offer, based on our exploration of the issues, recommendations that may strengthen infection prevention and control in future.

An agreed database was used to identify patients eligible for our review. Using healthcare records provided by NHS GGC, we extracted relevant clinical and microbiological information to create an individual timeline for each episode of infection in the included patients. We supplemented this by an assessment of data relating to the location of the patient’s care; results of microbiological surveillance of the environment; detail of any building repairs or maintenance activity taking place in the vicinity; and information about additional investigations undertaken at the time. This approach allowed us to build up an individual picture of the factors that could indicate the origin of an infection, and to assess the impact it had on patient care and outcome.

For every episode, we answered a predefined set of questions to help us determine the likelihood that an infection could be linked to the hospital environment; to quantify key measures of the impact on the child/young person affected; and to do so in a structured and consistent way. We formally reviewed all infection episodes included

in the Review twice and, in some episodes, more frequently until we were content that we had been able to access as much of the data we needed as was available.

We also looked at the manner in which NHS GGC had itself assessed, responded and reported the situation at the time, and looked for evidence that common themes were identified and pursued during its investigations. We critiqued the quality and adequacy the information provided to us and formed an assessment of the availability and integration of relevant data within existing NHS GGC systems.

We had access to several hundred documents. We held meetings with individuals and groups of individuals, in particular, staff at NHS GGC. We generated, received and saw many emails, all of which provided additional and/or complementary information. Although we experienced frustrations in access to NHS GGC systems, and were critical of their ability to readily provide data we considered key to our investigation of the hospital environment, our requests to them for access to documents and other data were met with courtesy and helpfulness.

A small number of families availed themselves of the opportunity to provide reflections or questions about their child's care and, where they did, we reviewed these alongside our other assessments.

Our main findings in relation to the children and young people and the nature of their infections are as follows:

- 84 children and young people between them experienced 118 episodes of infection which fulfilled the criteria set for inclusion in our review.
- Their age ranged from 3 months to 18 years 10 months at the time of their first infection.
- The great majority had a diagnosis of cancer or leukaemia but a small minority had other forms of serious blood disease or another condition requiring the expertise of a haematologist or oncologist.
- Although over three quarters of patients experienced only one episode of infection, ten had two episodes and several had three or more episodes, up to total of eight episodes in one patient.
- Using an approach that we describe in detail in our report, we determined that whilst eight episodes were unrelated to the hospital environment, and in one case we were unable to determine the relationship, of the rest 76 (70%) could possibly relate to the hospital environment and 33 (30%) probably did. We were unable to identify evidence that unequivocally provided a definite relationship between any infection episode and the environment. There are complex reasons for this which we discuss in more detail in the body of the report.
- In the absence of a definitive link to the environment, we nevertheless felt the possibility of a link remained strong. We grouped episodes we had defined as 'Strong Possible', 'Probable' & 'Strong Probable' into a single group which we felt might reasonably be considered to be 'Most Likely' linked to the environment. This constituted 37 (34%) of all episodes and included an excess of one particular bacterium (Stenotrophomonas). There was also an increased likelihood that the infections constituting the 'Most Likely' group had occurred in 2018: this may well be related to the particular excess of Stenotrophomonas bacteraemias in that year.
- We designed a framework for assessing the overall impact of an infection on a patient. This framework included consideration of various factors including the

duration of hospitalisation attributable to the infection; duration of antibiotic therapy; the necessity to remove the patient's Central Venous Line (CVL) to resolve the infection; the need for admission for intensive care (PICU); the need to modify the planned delivery of cancer treatment; and death. This allowed us to score overall impact on a five point scale from None to Critical. Only 6 (5%) of evaluable episodes were assessed as having no or minor impact whilst 44 (38%) scored as major or critical. The breakdown of these individual factors can be summarised as follows:
    - 57 (58%) episodes involved an additional hospital stay of over 2 weeks.
    - 78 (68%) episodes resulted in the removal of the patient's CVL.
    - 12 (11%) episodes required admission to PICU.
    - 60 (48%) assessable episodes resulted in a delay to planned cancer treatment of which 12 (12%) were for more than 2 weeks.
- We found that the deaths of 2 of the 22 children and young people who had died by the time of the publication of this report were, at least in part, the result of their infection. Both of these children also had other serious medical problems and it is our view that, even without the infection, their survival would still have been uncertain. Within the constraints necessary to protect individual patient identity, we discuss these deaths in more detail in the body of our report.

We recognise that nothing we have been able to measure can truly reflect the broader impact of these infections on the lives of the children and young people who were affected, and their families. Unplanned or prolonged admission, or both, will contribute to the already significant impact that their disease and its treatment has on their lives. It further disrupts schooling, social life, parental work, and the care of siblings or dependent relatives. It contributes to additional anxiety because families are well aware that infection is a risk, can be serious and may be life threatening; also, families are anxious about the consequences of delays to treatment. In this respect, our findings underline the very significant additional burden that these infections, whatever their cause, must have had on the children and young people concerned, and their families.

In respect of the wider issues, we identify a number of areas that have caused us concern in Chapter 8 of the report. These are summarised as follows:

- We have documented our challenges with NHS GGC over access to data systems but, more importantly, over the time taken to provide us with data we had requested about the microbiological surveillance of the hospital environment and the extent of building, repair and maintenance work that took place in relevant clinical areas during the period of our review. This delay, and others regarding our access to the laboratory information systems, necessitated us to undertake a second complete review of the entire series of infection episodes so as to incorporate information received late in our work schedule. Perhaps most significantly, however, it raised questions for us about how NHS GGC had been able to make effective use of such data in its own investigations of the GNE bacteraemias as they had occurred.
- We are critical that, despite over five years of experience in investigating outbreaks of GNE bacteraemia and concerns about the hospital environment, NHS GGC had not established an electronic database of microbiological typing results (a key strategy in the ability to link bacteria identified in one person or place with that from another person or place) and consequently had no ability to

easily relate potentially linked bacterial isolates. We recognise that this work is now ongoing, and we also acknowledge the considerable amount of work required by NHS GGC staff to provide us with the data that was available. However, the fact that there were too many gaps in terms of which isolates were included in these analyses, together with an inconsistent approach to environmental sampling, led us to conclude that we were unable to interpret the true extent of relatedness between patient and environmental isolates, even with the provision of some data using state of the art Whole Genome Sequencing (WGS) methodology which has more recently been brought into use.

- ICNet is an electronic patient management system used by the Infection Prevention and Control Team (IPCT) to manage patients identified with possible or confirmed infection. It relies on data being exported from Telepath (the laboratory information management system) and if a microorganism is identified as one of a pre-defined list of 'alert' organisms, it will automatically alert the Infection Prevention and Control Team. The National Infection Prevention and Control Manual provides a nationally-agreed minimum list of alert organisms, the purpose of which is to alert NHS Boards to situations that may require further investigation. The guidance states: "the list is not exhaustive and specialist units … will also be guided by local policy regarding other alert organisms not included within these lists". We found little evidence, even as late as 2019, that (and despite assurance from NHS GGC) the alert list had been modified in light of the evolving experience with GNE bacteraemias. This resulted in frequent absence of alerts being triggered within ICNet, and the subsequent absence of IPCT input in some episodes of the GNE bacteraemia we reviewed.
- We examined how possible outbreaks of infection were investigated and managed within NHS GGC. We found the process involving the PAG (Problem Assessment Group) and IMT (Incident Management Group) structure to have been inconsistent. We were particularly concerned that, despite the continuing existence of concern about GNE bacteraemias over several years, there was less evolution in the approach to the recognition of an outbreak than we might have expected. We believe there was too much emphasis on standard definitions, inappropriate reassurance from the use of SPC methodology and even an unwillingness to accept that there was a problem. All of this is further clarified in our report.
- IMT minutes were not always easy to understand in retrospect. Action logs were rarely apparent either within the minutes or separately, which must have limited the ability to track completion or evolution of actions from one meeting to the next - either within an IMT sequence or between consecutive IMT sequences. This suggested a fragmentation of approach and we believe it limited the chance of learning for the future. We did not find final reports at the close of a series of IMT meetings despite this being mandated in the NHS GGC Standing Operational Procedure for Infection Outbreaks. This was despite the fact we saw examples of such documents from IMTs in other clinical areas within NHS GGC, raising questions about consistency in practice across the organisation.
- Our observations suggested to us that the communication between microbiologists, the infection control doctors and the rest of IPCT may not have been as robust or cohesive as it should be. It seemed that the teams appeared to

work independently and that communication between these staff groups was sometimes not as good as would be required for effective IPC.

- We have recommended a systematic and structured approach to the investigation of all future bacteraemias using Root Cause Analysis methodology. We recognise that this approach was introduced in NHS GGC at the end of 2019 but it is hard to see why, given the experience of repeated GNE bacteraemias over five years, this was not introduced earlier.
- In our report we have highlighted an example of upward reporting to the NHS GGC Board which, we believe, demonstrates an inconsistency in the process and purpose of reporting; it also raised our concern that this could be an organisation that promotes a focus on process (i.e. that a report was received) rather than ensuring clarity about the cause or consequences of a situation.
- We used the Paediatric Trigger Tool (PTT) to identify Adverse Events in the care of the patients we reviewed and compared this with findings from NHS GGC's own incident reporting system, Datix. It is quite clear that reporting to Datix is incomplete and incidents were sometimes inaccurately categorised and under scored for severity. Yet the data acquired from the use of the PTT allowed us to show that NHS GGC compared favourably with other paediatric institutions and we recommend the continuing use of the PTT in the future.
- We identified significant inconsistencies in the way patient healthcare records were stored and organised within NHS GGC's Clinical Portal system. This not only added to the complexity of our task but, more importantly, the management of records to ensure they are clear and easy to follow is ultimately an issue for patient safety.

There were of course positive findings, in particular:

- We found that clinical records kept by the medical and nursing teams were detailed and comprehensive; that there was good communication between the microbiologists and the haematology oncology team about the diagnosis and management of infections; and that communications with parents were generally well documented and of a high standard, despite some parents raising concerns in this respect.
- We particularly commend the work achieved by the Quality Improvement Group established in 2017 to drive down (the then very high) central line associated line infection (CLABSI) rates. The latest data we have seen show these to have fallen to low levels consistent with international best practice. We should emphasise in this context that a substantial reduction in CLABSI rates does not negate the possibility of an environmental risk for GNE bacteraemia and that continuing surveillance is required.

Our report makes 43 recommendations within 15 separate themes. We recognise that work has already commenced in some areas, some of which represent themes highlighted in previous reports including the November 2019 HPS report. Most of our recommendations apply to NHS GGC but some may have wider relevance to NHS Scotland and to the Managed Service Network for Children and Young People with Cancer.

Overall, we urge NHS GGC to take immediate steps to ensure greater consistency in the way it monitors and investigates GNE infections in Paediatric Haematology

Oncology patients as the work to date has been fragmented and incomplete. In responding to this report and our recommendations, NHS GGC should assure patients, families and staff of a new approach. It is particularly important that it does so before the Paediatric Haematology Oncology service returns to Wards 2A and 2B. In this way, it will be seen that change has been implemented and that risk will be effectively monitored in the return to the upgraded environment.

We recognise that some families will be disappointed at our ability to identify a links between their child's infection and the hospital environment with greater certainty than has been possible. This not only represents the limits of a retrospective review and the shortcomings we have described in the data we were able to access, but also highlights the fundamental challenge of identifying a specific source in all such infections. However, the purpose of continuing to try to do so is to further reduce risk to patients in the future.

Whilst it is not our task to determine whether the environment at NHS GGC is now safe from the risk of hospital acquired infection for these patients, we wish to acknowledge the steps the organisation has taken to date to respond to what was an extremely challenging situation.

We would like to thank our Review Team for their outstanding work; the Oversight Board for its guidance; and the many individuals within and without NHS GGC who played their part in informing our Review and in the preparation of this report.

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GLOSSARY

A	
Adverse Event (AE)	An adverse event is defined as an event that could have caused harm, or resulted in harm, to people within the healthcare system.
ARHAI	National Antimicrobial Resistance and Healthcare Associated Infection (ARHAI) Scotland is responsible for the coordinating of national surveillance and reporting of healthcare associated infections and the monitoring of antimicrobial resistance and antimicrobial prescribing. It forms a part of NSS (National Services Scotland)
B	
Bacteria (plural) / Bacterium (singular)	Microscopic, single-celled organisms. They thrive in many different environments and may or may not be the cause of illness in humans
Bacteraemia	The presence of bacteria in the blood, detected by a blood culture test. Bacteraemia may result in sepsis which is when clinical illness results from bacteria entering the blood stream. This can be very serious and potentially fatal.
Blood Stream Infection (BSI)	This describes infections present in the blood**.** Blood is normally a sterile environment, so the detection of microorganisms in the blood is always abnormal.
Bundle (of Care)	A small set of evidence-based practices that, when performed collectively and reliably, have a greater effect on patient outcomes if done together, rather than separately
C	
Central Venous Line (CVL) / Central Line	A soft plastic tube placed in a large vein to allow frequent access to the blood stream, to take samples for tests and to give fluids, medications or blood product transfusions. If required for longer periods of time, these are usually inserted into a vein in the neck via a short tunnel under the skin of the chest, emerging for a short distance and sealed with a cap. See also Port.
Chilled beam	A type of radiation/convection heating, ventilation, and air conditioning system designed to heat and cool buildings.

CLABSI	Central Line Associated Blood Steam Infection - defined as a laboratory-confirmed blood stream infection in a patient with a central line which is not related to an infection at another site.
Clinical Portal	The electronic system used by HNS GGC that integrates and allows access to all relevant patient information (e.g. clinical notes; laboratory tests and results; radiology tests and results).
Cluster	Refers to suspected linked cases (linked in time or place).
Cryptococcus	A fungus widely found in the environment. The species '*C. neoformans*' is the major human pathogen, most commonly affecting patients with compromised immunity.
D	
Datix	Data collection system used by NHS Greater Glasgow and Clyde for clinical and non- clinical incident reporting.
E	
Endogenous	Infections that arise from within the patient him/herself.
Epidemiology / Epidemiological	The branch of medicine which deals with the incidence, distribution, causation and approaches to the control of diseases and other factors relating to health.
Exogenous	Infections caused from sources in the external environment. This includes the environment experienced by the patient both inside and outside the hospital building.
F	
Febrile	Having or showing the symptoms of a fever.
G	
Genetic Fingerprinting	A way to define the identity of a microorganism by describing the sequence of the 'building blocks' that make up its DNA (its genetic code). This can be used to determine how closely microorganisms are related to each other.
Genus	The name for a class, or group of bacteria marked by common characteristics or by one common characteristic

	A genus usually consists of more than one species.
Gram-negative (bacteria)	This is a way of classifying bacteria by their appearance under the microscope when stained in a particular way. Gram-negative bacteria are more resistant to antibiotics and can cause serious infections both in the blood stream and at other sites in the body.
Greater Glasgow and Clyde Health Board (NHS GGC)	The body responsible for the delivery of health care services in the Greater Glasgow and Clyde region.
Gut Translocation	The ability for bacteria normally resident in the gut to pass into the blood stream. This usually occurs when the lining of the gut is damaged by, for example, chemotherapy.
H	
Haematology Oncology	The medical sub-specialties concerned with the diagnosis and treatment of blood diseases (Haematology), including leukaemia, and of other malignant (cancer) diseases (Oncology)
HAI	Originally used to mean ‘hospital acquired infection’, but the official Scottish Government term is now ‘Healthcare Associated Infection’. These are considered to be infections that were not present prior to contact with a healthcare facility or whilst undergoing a healthcare intervention.
HAIRT	Healthcare Associated Infection Reporting Template. The format used to provide regular reports to the NHS GGC Board about Infection Prevention and Control issues.
HAI-SCRIBE	Healthcare Associated Infection System (for) Controlling Risk in the Built Environment. The procedure by which staff in hospitals work together to identify, manage and mitigate issues posing a risk to infection that may arise in the built environment as a result of building work, repairs or maintenance activities.
Hard Surface Sample	Hard surface sample in this context refers to samples taken for microbiological examination from environmental surfaces in the hospital environment. Examples would include samples taken from equipment, floors, chilled beams, sinks, and drains.

HCAI	Healthcare Associated Infection.
Healthcare Infection Incident Assessment Tool (HIIAT)	Healthcare Infection Incident Assessment Tool (HIIAT). An infection assessment and reporting tool found in the Scottish National Infection Prevention and Control Manual, used to gather epidemiological data and clinical information on the patient's condition.
Healthcare Infection Incident and Outbreak Reporting Template (HIIORT)	Healthcare Infection Incident and Outbreak Reporting Template (HIIORT) – more detailed assessment and reporting of an incident within the Scottish National Infection Prevention and Control Manual.
Health Facilities Scotland (HFS)	Provides operational guidance to NHS Scotland bodies on a range of healthcare facilities topics.
Health Protection Scotland (HPS)	Health Protection Scotland is the organisation that co-ordinates health protection in Scotland. It is part of Public Health Scotland.
HIS	Healthcare Improvement Scotland. The purpose of Healthcare Improvement Scotland is to enable the people of Scotland to experience the best quality of health and social care.
I	
ICNet	The software system used at NHS GGC that supports the IPC nurses/team in advising and following up infections in the hospital environment.
Immunocompromised	A person who is incapable of developing a normal immune response making them more susceptible to infection: in this context this is as a result of disease or its treatment.
Incident Management Team (IMT)	An Incident Management Team comprises clinicians, the IPC Team, public health clinicians, and colleagues from estates and facilities**.** They meet to investigate potential causes of the infection(s) under consideration and to agree and direct necessary infection control measures.
Infection Prevention Control (IPC)	The clinical discipline and the collection of interventions aimed at preventing and controlling healthcare associated infections.

Information Governance	Handling information in a confidential and secure manner to appropriate ethical and quality standards.
Information Sharing Agreement (ISA)	An agreement that sets out the basis for the use of personal data by the public sector for the protection for the individuals concerned.
IPCN /T/D/M	Infection Prevention & Control Nurse / Team / Doctor / Manager

M

Malignant	A term for diseases in which abnormal cells divide without control, can invade nearby tissues, or spread to other parts of the body through the blood and lymph systems. Also called cancer. Children and young people with these diseases are cared for by Haematologists and Oncologists. Note also that some conditions (typically some kinds of brain tumour) may not be truly malignant but remain capable of causing serious disease/damage/death and require treatment of a similar nature.
Medical Microbiology	The clinical and laboratory discipline that diagnoses, treats and prevents infections.
Microorganisms (Microbes)	Organisms that are too small to be seen by the naked eye and are found everywhere. They may exist in a single-celled form or in a colony of cells. They can live in water, soil, or in the air. The human body is home to millions of these: some can cause sickness, while others are critical for health.
Mortality and Morbidity Reviews/ Meetings (M&M)	Mortality and morbidity meetings support a systematic approach to the review of patient deaths or care complications to improve patient care and provide professional learning.

N

NHSS	The National Health Service (NHS) in Scotland
National Services Scotland (NSS)	Is a Non-Departmental Public Body which provides advice and services to the rest of NHS Scotland. Accountable to the Scottish Government, NSS provides national strategic support services and expert advice to NHS Scotland.
Neutropenia (Neutropenic)	A blood condition characterised by low levels of neutrophils, which are white blood cells that protect the body from infections. Having neutropenia

	increases the risk of all types of infection, especially from bacteria. This is a common side effect of chemotherapy but may also occur as a result of disease (like leukaemia) affecting the bone marrow (the site of production of neutrophils in the body).
Non-Malignant	A tumour that is not cancerous. Non-malignant tumours or conditions can nevertheless sometimes cause serious problems and require treatment by Haematologists and Oncologists.
O	
Outbreak	Two or more linked cases with the same infectious agent associated with the same healthcare setting over a specified time period or, a higher than expected number of cases of HAI in a given healthcare area over a specified time period.
P	
Paediatric Trigger Tool (PTT)	A structured case note review tool that identifies and measures the rate of adverse events in a hospital setting using paediatric-specific triggers.
PICU	Paediatric Intensive Care Unit – a specialist ward that provides treatment and monitoring for children and young people who are very ill, often requiring artificial ventilation or other organ support.
Polymicrobial	The presence of several species of microorganisms in the same bacterial culture.
Port	A port is a small chamber or reservoir that sits under the skin at the end of a central venous line. The other end of the line sits in a large vein. You can feel the chamber of the port under the skin but the system is completely sealed and requires a special needle to access the port and obtain blood samples, give fluids, medication or blood products.
Problem Assessment Group (PAG)	A team of specialists who come together to undertake an initial assessment of a potential infection outbreak and determine if an Incident Management Team should be established.
Q	
QEUH	Queen Elizabeth University Hospital

R

RHC	Royal Hospital for Children. It is located adjacent to the QEUH and replaces the former Royal Hospital for Sick Children located in Yorkhill.
Root Cause Analysis (RCA)	A structured approach to problem solving used for identifying the root causes of (in this context) infections.

S

SBAR	Situation, Background, Assessment, Recommendation. A structured reporting tool often used to describe clinical situations.
Sepsis	Sepsis (sometimes called septicaemia) is the body's extreme response to an infection. It is a life-threatening medical emergency. Sepsis happens when an infection that is already present triggers a chain reaction throughout the body. Without timely treatment, sepsis can rapidly lead to tissue damage, organ failure, and death.
Serious Adverse Event (SAE)	An event that may have contributed to, or results in permanent harm to a patient. It includes (but is not restricted to) situations where there is unexpected death or the need for intervention to sustain life. This is defined by the Scottish National Framework as a Category I adverse event.
Species	Groups of similar organisms within a genus.
Standard Infection Control Precautions (SICP)	Basic guidelines for the prevention and control of infection in the hospital environment. They include: hand washing; using protective barriers like gloves and masks; handling infectious waste material properly; and keeping the environment clean.
Standard Operating Procedure (SOP)	A set of step-by-step instructions compiled by an organisation to help workers carry out complex routine work in a consistent way.

T

Telepath	Telepath is the Laboratory Information Management System (LIMS) used by NHS GGC. The system is used to store laboratory sample results for patients and has the capacity to store patient notes recorded by microbiologists.

Terms of Reference (ToR)	Define the purpose and structures of a project (committee, meeting etc.) to accomplish its objectives.
TraKCare	Is the Patient Management System for NHS GGC. All patient episodes (Outpatient, Inpatient and Emergency) are recorded and managed on TrakCare.
(Microbiological) Typing	Laboratory technique(s) to assign a microorganism to a predefined group (type). These groups can be wide or narrow; the narrower the group, the more confidence there is that microorganisms in this group are related. See also: Genetic Fingerprinting

W

Water Sample	Water samples can be taken from a wide variety of sources in the water supply and delivery system for the hospital - for example: taps; showers; and tanks.

1. BACKGROUND TO THE CASE NOTE REVIEW

The events that have occurred since the move of the Children's Hospital from its previous site at Yorkhill, to its new home on the QEUH campus in the summer of 2015 have been numerous and complex. The concern that infections in children and young people under the care of the Paediatric Haematology Oncology service have arisen from microbiological contamination of the hospital environment is a story that derives from many interwoven threads. It is not our task to create a comprehensive historical account but we are cognisant that much of what has gone before bears on the presentation and interpretation of the data we have sought to evaluate in the course of our Review.

Section 1.1 is a timeline of dates that has helped the Panel understand the evolving story, before and through, the period of the Review. We recognise that there have been other elements to this story which carry a sense of greater or lesser importance to other stakeholders depending on their perspective of the events.

We have also reviewed the timeline document prepared for the Oversight Board and published in the annex to its Final Report which provides a narrative timeline from January 2015 to 2019 (in fact this also includes data collected up to March 2020). This is a timeline of the infection incidents which occurred in Wards 2A and 2B in RHC and latterly in the QEUH (Wards 4B and 6A only). It was created to assist in the understanding of the sequence of incidents that occurred, the control measures put in place and the various hypothesis that were investigated to identify the source of the incidents. The timeline also considers incidents which occurred in other wards in the RHC (as patients could be temporarily accommodated in other parts of the RHC due to the severity of their illness) but also to demonstrate exactly where all of the incidents reported actually occurred. The timeline does not cover any such incidents reported in the QEUH other than following the transfer of patients to Wards 6A and 4B.

The report published by Health Protection Scotland (HPS) in November 2019[1] provides an insight into the creation of an agreed microbiology definition for the cohort selected for our review. We comment further on this report in Chapter 8 (section 8.2.3).

We also recognise that blood stream infection in Paediatric Haematology Oncology patients is a known hazard that derives from several factors relating both to disease and its treatment. It seemed relevant, therefore, that we should incorporate a brief summary from published literature to set the scene about what is already known and understood in this area. This is set out in section 1.2.

[1] Review of NHSGG&C Paediatric Haemato-oncology Data. Health Protection Scotland. November 2019 https://www.hps.scot.nhs.uk/web-resources-container/review-of-nhsggc-paediatric-haemato-oncology-data/

1.1 Timeline of key dates leading up to the Case Note Review

27 January 2015	Handover of QEUH and RHC buildings to NHS GGC
10 June 2015	Move from Royal Hospital for Sick Children (Yorkhill) to Royal Hospital for Children (Govan).
7 July 2015	Having previously identified concerns about the safety of the new environment for patients (adults and children) undergoing stem cell transplantation, the Infection Control Doctor resigned over the approach being taken to their resolution.
February 2016	Infection of a child with *Cupriavidis pauculus*[2]. Investigation linked the infection to a sink in the aseptic pharmacy suite.
March 2017	Concern emerging within NHS GGC about increased bacteraemia rates in Paediatric Haematology Oncology patients. The first Problem Assessment Group (PAG) for a Gram-negative environmental bacteraemia is convened. Concern also emerged about incidence of *Aspergillus* spp. infections at the same time. Quality improvement group established to work on reducing CLABSI (Central Line Associated Blood Steam Infection) rates.
September 2017	Microbiology staff raised concerns about the facilities in the QEUH and RHC and the structure of IPCT Service in NHS GGC. (SBAR in October 2017).
March 2018	Health Facilities Scotland (HFS) and HPS were asked by NHS GGC to investigate ongoing issues with the water supply.
2 March 2018	Water Incident Management Team IMT convened.
26 March 2018	CNO invoked the National Framework: this offers additional support to to NHS Boards in responding to HAI incidents/outbreaks and ensures assistance from HPS.
26 September 2018	All services from RHC Wards 2A and 2B are transferred to QEUH Ward 4B and Ward 6A due to concerns over facilities.

[2] Both the February 2019 HPS report and the 2020 Independent Review report state that this child was a patient on Ward 2A, in which case he/she would have been included in our Review. This was not the case and ARHAI have since confirmed that this child was not a patient on Ward 2A.

Autumn /Winter 2018/19	Additional chlorination of the water supply implemented.
22 January 2019	Paediatric Haematology Oncology patients transferred out of Ward 6A due to concerns relating to Cryptococcus and the sealant used in the ensuite shower rooms (they were returned on 11 February 2019).
22 January 2019	The Cabinet Secretary for Health and Sport announced in Parliament plans for an Independent Review.
22 February 2019	HPS publish its report: Summary of Incidents and Findings of the NHS Greater Glasgow and Clyde: Queen Elizabeth University Hospital/Royal Hospital for Children Water Contamination Incident and Recommendations for NHS Scotland[3]**.**
March 2019	HFS finalised (although never published) its report: Water Management Issues Technical Review: NHS Greater Glasgow and Clyde - Queen Elizabeth University Hospital/Royal Hospital for Children.
5 March 2019	Drs Fraser and Montgomery appointed to lead the Independent Review.
2 August 2019	Admissions to Ward 6A restricted and new patients diverted to other NHS Boards due to concerns over facilities.
29 August 2019	SBAR issued by Consultant Microbiologists raising persisting concerns about the microbiological safety of Ward 6A: subsequently reviewed at IMT 6.9.2019 and options for resolution were discussed (also in relation to the refurbishment of Ward 2A).
September 2019	Closed Facebook group established for patients and families associated with the Paediatric Haematology Oncology service.
4 October 2019	Cabinet Secretary for Health and Sport appoints Professor Craig White to review concerns articulated by families and liaise with families as appropriate.
21 November 2019	Ward 6A re-opened to new admissions.

[3] https://www.hps.scot.nhs.uk/web-resources-container/summary-of-incident-and-findings-of-the-nhs-greater-glasgow-and-clyde-queen-elizabeth-university-hospitalroyal-hospital-for-children-water-contamination-incident-and-recommendations-for-nhsscotland/

22 November 2019	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.
26 November 2019	HPS published its report: Review of NHS GG&C Paediatric Haematology Oncology Data (see section 1.2 for further commentary).
28 January 2020	The Cabinet Secretary for Health and Sport announced in Parliament the plans for a Case Note Review.
24 February 2020	The Case Note Review commenced.
June 2020	Independent Review report published.
15 June 2020	ToR 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.
21 December 2020	The QEUH/NHS GGC Oversight Board published its Interim Report.
January 2021	Completion of the review of cases and episodes within the Case Note Review.
March 2021	Case Note Review Overall Report and QEUH/NHS GGC Oversight Board Final Report both published.

1.2 Blood Stream Infections in Paediatric Haematology Oncology patients

Long-term survival of children with cancer has improved dramatically due to multiple medical advances, including the delivery of intensive chemotherapy. This aggressive therapy alongside disease-related bone marrow aplasia, prolonged courses of high-dose steroids, treatment induced mucositis and the requirement for long-term central venous access, puts children with cancer at increased risk of blood stream infections (BSI) and severe sepsis. Sepsis is the leading cause of Paediatric Intensive Care Unit (PICU) admission, morbidity and mortality among children with cancer[4,5,6].

[4] Pizzo PA. Management of Patients With Fever and Neutropenia Through the Arc of Time: A Narrative Review. Ann Intern Med. 2019 Mar 19;170(6):389-397. doi: 10.7326/M18-3192. Epub 2019 Mar 12. PMID: 30856657.

[5] Aljabari S, Balch A, Larsen GY et al. Severe Sepsis-Associated Morbidity and Mortality among Critically Ill Children with Cancer. J Pediatr Intensive Care. 2019; 8(3): 122-129. doi: 10.1055/s-0038-1676658

[6] Levene I, Castagnola E, Haeusler G. Antibiotic-resistant Gram-negative Blood Stream Infections in Children with Cancer: A Review of Epidemiology, Risk Factors, and Outcome. The Paediatric Infectious Disease Journal: 2018; 37(5): 495-498. doi: 10.1097/INF.0000000000001938

Overall mortality from febrile neutropenia (the commonest side effect after most forms of chemotherapy) is frequently quoted as less than 1%[7]. Bacteraemia is, however, identified in 5-38% of all paediatric cancer patients with febrile neutropenia and the early use of broad-spectrum antibiotics is crucial to prevent harm[8,9,10]. The mortality rate from severe sepsis in children with cancer ranges from 8% to as high as 41%, reported in a recent multinational study[11].

One study demonstrated that 45% of all Paediatric Haematology Oncology patients required at least one admission due to concerns about sepsis and 8% of those admitted required paediatric intensive care of whom, 34% of those with severe sepsis developed multiple organ dysfunction and/or died. Children with leukaemia and related diagnoses were more likely to require intensive care treatment than those with other types of cancer, however the type of diagnosis did not affect the ultimate outcome[3].

Other studies have demonstrated a lower overall intensive care mortality rate but also showed that this was significantly higher in patients with a history of haematopoietic stem cell transplantation (HSCT) and varied depending on the causative pathogen, greater for fungal sepsis than for Gram-negative bacterial sepsis[12,13].

BSI in Paediatric Haematology Oncology patients are most commonly associated with indwelling central venous access devices, most commonly Hickman lines. Prospective surveillance studies report overall incidence rates for central-line associated infections per 1000 central venous catheter (CVC) days, and rates of about 1 BSI/1000 CVC days are where best practice should aim to lie[14].

[7] Hann I et al. "A comparison of outcome from febrile neutropenic episodes in children compared with adults". British Journal of Haematology, vol. 99, no. 3-I, December 1997, pp. 580-588

[8] Asturias EJ, Corral JE, Quezada J et al. Evaluation of six risk factors for the development of bacteraemia in children with cancer and febrile neutropenia. Curr Oncol. 2010; 17(2): 59-63. doi: 10.3747/co.v17i2.453

[9] Al-Mulla NA, Taj-Aldeen SJ, Shafie S E et al. Bacterial blood stream infections and antimicrobial susceptibility pattern in pediatric hematology/oncology patients after anticancer chemotherapy. Infect Drug Resist. 2014; 7: 289-299 doi:10.2147/IDR.S70486

[10] Duncan C, Chisholm JC, Freeman S et al. A prospective study of admissions for febrile neutropenia in secondary paediatric units in South East England. Pediatr Blood Cancer. 2007; 49(5):678-81.doi: 10.1002/pbc.21041.

[11] Weiss SL, Fitzgerald JC, Pappachan J et al. Sepsis Prevalence, Outcomes, and Therapies (SPROUT) Study Investigators and Paediatric Acute Lung Injury and Sepsis Investigators (PALISI) Network. Global epidemiology of paediatric severe sepsis: the sepsis prevalence, outcomes, and therapies study. Am J Respir Crit Care Med. 2015;191(10):1147-57. doi: 10.1164/rccm.201412-2323OC.

[12] Fiser RT, West NK, Bush AJ et al. Outcome of severe sepsis in pediatric oncology patients Pediatr Crit Care Med. 2005;6(5):531-6. doi: 10.1097/01.pcc.0000165560.90814.59.

[13] Akinboyo IC, Young RR, Spees LP, Heston SM, Smith MJ, Chang YC, et al. Microbiology and Risk Factors for Hospital-Associated Blood stream Infections Among Pediatric Hematopoietic Stem Cell Transplant Recipients. Open Forum Infect Dis. 2020;7(4):ofaa093

[14] Simon A, Fleischhack G, Hasan C et al. Surveillance for nosocomial and central line-related infections among pediatric hematology-oncology patients. Infection Control and Hospital Epidemiology 2000;21:592-6

Bacterial BSI are also more common in those who have undergone HSCT, occurring in 20 to 45% of patients in some series, with the majority of infections occurring prior to engraftment[15]. Post transplant BSI remains a risk and may be associated with a higher mortality depending on confounding factors such as the presence of graft versus host disease and extended use of steroid therapy.

The profile of microorganisms causing BSI in children with cancer has evolved over the years. In the early years of modern therapies, Gram-negative organisms were the predominant concern. This was followed by a sustained increase in Gram-positive infections but, more recently Gram-negative organisms are re-emerging, accounting, in some reports, for approximately half of all BSI.

Gram-negative bacteria are associated with significantly higher mortality rates and there is growing concern about antibiotic resistance[16]. Particular concerns have been raised in several studies about extended-spectrum β-lactamase (ESBL) producing Enterobacteriaceae, fluoroquinolone-resistant Gram-negative bacteria, carbapenem-resistant Pseudomonas aeruginosa and multidrug resistant organisms [4,12].

A systematic review of risk factors in the development of antibiotic resistant Gram-negative bacteriaemia in children with cancer concluded that hospitalisation for 48 hours or more increases the probability of antibiotic resistance as does recent antimicrobial exposure, including prophylaxis with ciprofloxacin, which may increase the risk of developing antibiotic resistant Gram-negative bacteraemia[14]. Consensus guidelines about antibiotic prophylaxis in this setting have recently been published[17].

Antimicrobial resistance and the paucity of new antibiotics could be a particular threat to Paediatric Haematology Oncology patients with severe sepsis in future. Prevention remains key and it is recommended that infection control ‘bundles’ are adapted alongside the careful oversight of antibiotic use. Knowledge of the local epidemiology of pathogens and patterns of antibiotic resistance is essential to guide management.

[15] Youssef A, Hafez H, Madney Y et al. Incidence, risk factors, and outcome of blood stream infections during the first 100 days post-pediatric allogenic and autologous hematopoietic stem cell transplantations. Pediatr Transplant. 2020; 24(1):e13610

[16] Haeusler GM, Levene I. Question 2: What are the risk factors for antibiotic resistant Gram-negative bacteraemia in children with cancer? Archives of Disease in Childhood 2015;100:895-898

[17] Lehrnbecher T, Fisher BT, Phillips B, Alexander S, Ammann RA, Beauchemin M, Carlesse F, Castagnola E, Davis BL, Dupuis LL, Egan G, Groll AH, Haeusler GM, Santolaya M, Steinbach WJ, van de Wetering M, Wolf J, Cabral S, Robinson PD, Sung L. Guideline for Antibacterial Prophylaxis Administration in Pediatric Cancer and Hematopoietic Stem Cell Transplantation. Clin Infect Dis. 2020;71(1):226–36. https://doi.org/10.1093/cid/ciz1082.

2. TERMS OF REFERENCE AND MEMBERSHIP OF THE EXPERT PANEL

This chapter presents the Terms of Reference for our Review as written for, and agreed by the Review's Core Project Team and the QEUH/NHS GGC Oversight Board in March 2020.

We have added notes to indicate where we have made important adjustments to the original text and have added links to other sections of our report where appropriate. Otherwise the language, including tense, is was written in the original document. Other than those with overall leadership and accountability, who are named in the text, the names of all those who contributed to the Case Note Review are given in the Acknowledgements section elsewhere in this report.

2.1. Introduction

As a result of continuing problems arising from infection incidents on the QEUH campus, on 22 November 2019, the Scottish Government's Health and Social Care Management Board escalated NHS GGC to 'Stage 4' of its escalation ladder. That stage represents a level where there are "significant risks to delivery, quality, financial performance or safety, and senior level external transformational support [is] required." As a result, a new Oversight Board under the chair of the CNO, Professor Fiona McQueen, has been set up to address two specific sets of issues that led to escalation: infection prevention and control and associated governance with respect to the QEUH; and communications and engagement with affected families.

As part of the work of the Oversight Board, the Cabinet Secretary for Health and Sport set out plans for a Case Note Review in a Parliamentary statement on 28 January 2020. The Case Review team would review the case notes of Haemato-Oncology paediatric patients in the RHC and the QEUH from 2015 to 2019 who have had a Gram-negative environmental pathogen bacteraemia (and selected other organisms) identified in laboratory tests. The following sets out the ToR for this work, specifically:

- its purpose and authority;
- the outputs/deliverables;
- key elements of its methodology, particularly the identification of cases for review, the use of the Paediatric Trigger Tool and the epidemiological review;
- communications and engagement of the Review and its outputs;
- key responsibilities;
- timelines for different phases of work; and
- risk management.

2.2 Purpose

The Case Note Review will review the medical records of all children (and young people) diagnosed with qualifying infections (see definition below) and who were

cared for at RHC between 1.5.15 and 31.12.19[18] to establish several key issues: the number of children – in particular, immunocompromised children – who were likely to have been put at risk because of the environment in which they were cared; and how that infection may have influenced their health outcomes. Such work will be vital in determining the number and nature of the children affected, providing assurance and identifying improvement actions, not just for NHS GGC, but more widely across NHS Scotland, including Health Protection Scotland (HPS), and the Scottish Government. It is also an important element in improving the communications and engagement with families and affected patients.

The Review will consider the following set of specific questions:

- How many children in the specified patient population have been affected, details of when, which organism etc.?
- Is it possible to associate these infections with the environment of the RHC and the QEUH?
- Was there an impact on care and outcomes in relation to infection?
- What recommendations should be considered by NHS GGC – and, where appropriate, by NHS Scotland, more generally – to address the issues arising from these incidents to strengthen infection prevention and control in future?

Through Professor Marion Bain (Director of Infection Prevention and Control NHS GGC and Senior Medical Consultant, NHS National Services Scotland (now Deputy Chief Medical Officer)) the Review will report directly to Professor Fiona McQueen as Chair of the Oversight Board.

2.3 Outputs/Deliverables

There are two specific sets of outputs, described in more detail below:

- reporting to the Oversight Board; and
- specific feedback to patients and families.

2.3.1 Reporting to the Oversight Board

The Expert Panel (see section 2.9) will be responsible for providing a Final Report to Professor Bain and the Oversight Board, which should include:

- a description of the approach and methodology to the Review;
- a description of the patients included in the Review;
- a description of the cases according to specified data types;
- analysis to answer the questions set out in the Purpose section above; and
- recommendations for NHS GGC and NHS Scotland, based on this analysis.

Individual case details will not be set out in the Report and the cases will be anonymised. The Final Report will be provided to the Cabinet Secretary for Health and Sport thereafter. The Final Report will be published by the Scottish Government.

[18] We have only included infections that arose after attendance/ admission to the new QEUH/RHC site.

Reporting on progress to the Oversight Board will be undertaken by Professor Marion Bain, which may include the provision of an interim report, subject to agreement between her and the Chair.

2.3.2 Reporting to Patients and Families

The Expert Panel will provide individual reporting to patients and families that request a description of the results of their individual patient case review[19]. Patients and families will be invited to take up the offer of engagement with the Panel through Professor Craig White, Chair of the Oversight Board's Communications and Engagement Subgroup. The format of reporting will accommodate, as far as practicable, the wishes of the family, and will be decided in conjunction with the Expert Panel. All reporting will be carried out within three months of the submission of the Final Report to the Oversight Board.

Arrangements for engaging with patients and families, the format of individual reporting and the timetabling of any meetings will be determined by the Expert Panel with Professor Bain and Professor White.

2.4 Methodology

In its overall approach to developing a methodology for the Case Note Review, these terms of reference set out key elements for how the Review should be conducted. Its overarching principles will be:

- respect and sensitivity to individual patients and their families in the handling of data and the conduct and reporting of results;
- rigorous handling, recording and storage of data, respecting patient confidentiality and family sensitivity; and
- use of internationally-respected and clearly-explained methodological tools and data sources, which will be documented for the Final Report.

A range of information will need to be gathered for the Expert Panel analysis and reporting. This includes several key elements, described in more detail below:

- the epidemiological and clinical outcomes review;
- the use of the Paediatric Trigger tool; and
- the gathering of other key data.

2.4.1 Identification of Cases

Health Protection Scotland (HPS) [20] has undertaken an analysis of a variety of options to define the sample. The Expert Panel has agreed the following cohort definition, but will continue to review the sample as the Review progresses.

- The cohort currently consists of 85 patients[21] (and a larger number of infection episodes):

[19] We will issue individual reports to all families

[20] This involved staff from National ARHAI Scotland, NSS

[21] This was the initial cohort – see Chapter 4, section 4.1 for detail of subsequent exclusions

- patients with blood cultures of a Gram-negative environmental pathogen (including enteric pathogens associated with the environment) (there are 81 patients that meet this inclusion criteria);
- patients with a M. chelonae (Acid Fast Environmental) infection (there are 3 patients that meet this criteria – 2 with bacteraemia, and 1 with a skin infection); and
- patients included for other reasons: this includes one child with a Gram-negative infection (not blood stream detected) and Aspergillus.

2.4.2 Epidemiological and Clinical Outcomes Review

An epidemiological and clinical outcomes review of the cases is required to collect patient, outcome and risk data systematically using agreed definitions and for the findings to support the incident investigation. The objectives of this epidemiological investigation are to:

- determine a timeline for each of the cases;
- characterise the cases in terms of time, place and person:
    - time: describe the episodes of blood stream infection (BSI) over time and create a timeline for outbreak, including plotting of control measures against number of cases,
    - place: describe the location of patients (hospital, ward, bed/bay) and describe their movements in the hospital, and
    - person: characterise the patients with infection in terms of intrinsic and extrinsic risk factors; outcomes; antimicrobial prophylaxis and treatment; and individual infection prevention and control measures in place; and
- describe the cases in the context of environmental risks and incidents (where possible).

The epidemiological components of the review will be carried out by HPS staff and data items to inform clinical outcomes will be extracted in collaboration with the Clinical Team responsible for the Paediatric Trigger Tool work (see below). A full description of the agreed data set is provided in the separate Epidemiological and Clinical Outcomes Protocol[22].

2.4.3 Paediatric Trigger Tool

The review of the case notes is set against the background of Healthcare Improvement Scotland's document, 'Learning from adverse events through reporting and review – A national framework for Scotland: July 2018'. The aims of the national approach to learning from adverse events are to:

- learn locally and nationally to make service improvements that enhance the safety of the care system for everyone;
- support adverse event management in a timely and effective manner;

[22] See Appendix D for the full dataset

- support a consistent national approach to the identification, reporting and review of adverse events, and allow best practice to be actively promoted across Scotland;
- present an approach that allows reflective review of events which can be adapted to different settings; and
- provide national resources to develop the skills, culture and systems required to effectively learn from adverse events to improve health and care services across Scotland.

The national approach seeks to ensure that no matter where an adverse event occurs in Scotland:

- the affected person receives the same high quality response;
- organisations are open, honest and supportive towards the affected person, apologising for any harm that occurred;
- any staff involved are supported in a consistent manner;
- events are reviewed in a consistent way; and
- learning is shared and implemented across the organisation and more widely to improve the quality of services.

The intention of using an adapted Paediatric Trigger Tool (PTT) in the study of NHS GGC is not to determine preventable or non-preventable harm but to create opportunities to learn from the triggers and adverse events identified. It forms only part of the overarching case review process and it is anticipated the information from the PTT will underpin the epidemiological and clinical outcome review and the contextual organisational data and reports. The PTT methodology will examine harm in the processes of healthcare in the group of patients selected for Case Note Review and its objectives are to contribute to the overall aim of the Case Note Review by:

- identify all triggers and adverse events in the cohort of patients identified by the epidemiological review using an adapted PTT; and
- describe the rate and severity of harm occurring in hospitalised children in the cohort group.

The PTT would be amended for use for this patient population[23].

2.4.4 Other Data Collection

The Epidemiological and Clinical Outcomes Review and the PTT may not provide all the data that the Expert Panel requires to conduct its work. The Expert Panel will review its data requirements on a continuing basis and request these through the Clinical and Support Team leads as well as Professor Bain as required.

2.5 Communications and Engagement

Communications and engagement is distinct from reporting, as described above. There are key ‘audiences’ whose communication needs should be supported through the work of the Case Note Review. Key among these are:

[23] See section 3.4.3

- patients and families, both those who will be part of the Case Note Review and those who may want to know more, or feel they should be part of the Review; and
- the staff of the relevant parts of the RHC and the QEUH.

More detailed work on communications and engagement will be reflected in the Programme Plan for the work.

Patients and Families: Initial communication with patients and families – setting out which cases would be reviewed has now taken place. That set out the purpose and details of the Case Note Review, and invited any questions and issues to be raised through the signatories of the letters[24], Professor Bain and Professor McQueen.

Progress reporting on the Case Note Review as a whole will be conducted through the NHS GGC web pages and the 'closed' Facebook page to the affected families.

Specific engagement with families wishing to discuss their particular cases will be handled on a case-by-case basis through Professor Bain and Professor White.

Staff: The medical, nursing and other relevant staff of the relevant parts of the RHC and the QEUH (including the NHS GGC Board and relevant committees) will want to be kept appraised of the progress of the Review. Professor Bain will organise:

- an initial overview session of the methodology/approach of the Review to reviewing the cases;
- regular progress reports from representatives of the Expert Panel, ideally delivered in face-to-face meetings; and
- a final 'debrief' of the key results and recommendations of the Final Report.

2.6 Key Responsibilities

As Executive Lead for Infection Prevention and Control within NHS GGS, as appointed by Professor McQueen, Professor Bain will have oversight of the project as a whole. She will be responsible for its progress and reporting to Professor McQueen, including advice – provided by the Expert Panel and other members of the team below – for any necessary change in key elements of these Terms of Reference.

2.6.1 The Expert Panel

The Expert Panel will be responsible for:

- agreeing, within the scope of these Terms of Reference, the definitions used to select patients for the review; the scope and direction of the data collection; and the methodological tools required;
- overseeing and interpreting the analysis of data obtained and developing the Final Report (and, in discussion with Professor Bain, the provision of any agreed interim reporting);
- progress reporting to relevant audiences, including the RHC/QEUH staff; and

[24] These letters were sent on 4th March 2020. In fact, specific engagement with families was (and remained) the remit of Professor Craig White (this text was that of the original Terms of Reference and in this respect does not reflect the agreed position of Professor White).

- providing reporting to individual patients and families.

2.6.2 Clinical Team

The Clinical Team[25] will be responsible for:

- undertaking the data collection, storage and submission of Case Note Review material to the Expert Panel;
- resolving data/sampling issues with Professor Bain, the Support Team and the Expert Panel; and
- supporting the analysis and reporting of the Case Note Review through the Expert Panel.

All handling of patient data will be covered by relevant data-sharing agreements and protocols.

2.6.3 Support Team

The Support Team will be responsible for:

- resolving practicalities and resourcing issues;
- undertaking key communication and engagement functions;
- developing and maintaining the Review workplan;
- providing secretariat and related functions to the Expert Panel; and
- ensuring submission of Final Report to the Cabinet Secretary and publication.

2.7 Timelines

The timelines for the Review will be reviewed on an ongoing basis by Professor Bain in conjunction with the heads of the Expert Panel, the Clinical and Support Teams, and Professor McQueen. They will be encapsulated in the workplan to be developed and maintained by the Support Team. The Review is currently anticipated to provide a final report to the Oversight Board in summer 2020[26], but timelines will necessarily continue to be reviewed in light of the impact of COVID-19.

2.8 Risk Management

Risks will be identified and actively managed by the Programme Manager on an ongoing basis and discussed regularly with Professor Bain.

[25] This implies both the clinical and epidemiological team. See the detail of our approach in section 3.6

[26] This was an ambitious target, declared before the full complexity of the task and the impact of the COVID-19 pandemic were apparent. See section 3.1 for detail of the constraints on the progress of the Review

2.9 Members of the Expert Panel:

Professor Michael Stevens (Emeritus Professor of Paediatric Oncology at the University of Bristol), who will be Head of the Expert Panel and report to Professor Bain.

Gaynor Evans (Clinical Lead for the Gram-negative Blood stream Infection Programme at NHS Improvement/England).

Professor Mark Wilcox (Professor of Medical Microbiology at the University of Leeds).

3. METHODOLOGY

In this chapter we set out the approach we developed to access, collect and assess the data we believed were necessary for us to address the ToR governing our Review.

Data systems within NHS GGC were identified, access was negotiated and sources of other potentially important information sought and requested. Two data collection teams were formed to work in a complementary way to identify and extract different components of the clinical and microbiological information required to create a detailed timeline of clinical care for each eligible bacteraemic episode for every patient included in the Review. We created processes for documenting, collating and summarising data from multiple sources so as to inform the Panel discussions which assessed and determined outcomes.

Section 3.1 presents an overall timeline and also describes some of the constraints we encountered in our work. Sections 3.2 to 3.6 describe each of the steps in our processes and section 3.8 describes our approach to communication with stakeholder groups.

3.1 Overall timeline for the work undertaken for the Case Note Review

The overall process of the Review and the work of the Panel is summarised in the diagram provided as Appendix A.

There was an early assumption that the overall timeline to complete the work for the Case Note Review would begin in March 2020 and end in the summer of 2020. This view was held not only before the impact of COVID-19 became apparent but also before data collection commenced and we had begun to understand the challenges that lay ahead.

Communication and engagement with NHS GGC, requesting critical data for Panel consideration, began on 7.4.2020 and continued until a final set of data was received on 21.12.2020. A final meeting with NHS GGC was held on 4.2.21 to discuss late concerns about the data available to us.

Throughout the Review our aim was to communicate progress, and delays, to stakeholders by means of written updates and virtual meetings. The timeline illustrates these occurrences from March 2020 to February 2021 however the communication element of the Review will continue beyond publication of this report, particularly with patients and families (discussed further in Chapter 7).

3.1.1 Constraints on the work of the Panel

In planning for this Review, in February 2020, a number of individuals were being identified to work directly on aspects of the work but, by the end of May 2020, as a result of the competing demands of the COVID-19 pandemic, the number of those still available for the Review Team was significantly reduced. The 3 members of the Expert Panel had also each identified reduced capacity because of varying commitments to support COVID-19 related work in NHS England. At this point, the Review had reached a critical point: data extraction had been successfully established and Panel reviews of patient records were just starting. The last full meeting of the Panel had been on 26.5.2020 when the issue was discussed by the

Core Project Team on 2.6.20. It was decided at that meeting to pause further Panel meetings for a period of time, but that data extraction could continue.

This became, however, a relatively short-term issue and by the second half of 2020, resource was adequate to fulfil the ToR for the Review (with, as is noted in section 8.1.3, the later appointment of additional IPC support). Panel meetings recommenced on 29.7.2020 although initially without full membership and by the time of the next meeting on 6.8.2020, the extent of data not yet available from NHS GGC to support the Review process was becoming fully apparent. This was discussed at the Core Project Team on 11.8.2020 and a mitigation plan agreed that resulted in the Panel scheduling Review meetings every week from 25.8.2020 to 15.12.20. Engagement with NHS GGC was increased to reinforce and clarify previous requests for data (see also section 8.1).

The Panel completed its primary review of all cases on 15.12.2020 but, by then, the need for a second review to assimilate late data received from NHS GGC had become apparent. This was completed in January 2021, but concerns emerged at the end of that month that there might be additional, potentially relevant data held by NHS GGC to which the Panel had not had access. Although this was subsequently not felt to be the case in relation to our ability to assess individual patients and episodes of infection, progress on the completion of the report was affected whilst this was investigated; a further additional short delay in the publication of this Report was therefore agreed with the Core Project Team on 10.2.21.

3.2 Selection criteria for inclusion of patients in the Review

The selection criteria for cases to be included in the Review were drafted and agreed by the Core Project Team after also inviting parents of the children and young people in the Review to comment on the proposals. These were approved by the Oversight Board and set out in a protocol document[27]. This defined that the study population should include all patients cared for in the Paediatric Haematology Oncology service at the Royal Hospital for Children, NHS GGC who met one of the following criteria between May 2015 and December 2019:

- at least one positive blood culture of a Gram-negative bacterium associated with the environment (Group 1)
- at least one positive culture of an atypical *Mycobacterium* spp. (acid-fast environmental bacteria (Group 2).

It was nevertheless agreed that a flexible approach should be retained, and one patient who did not meet these criteria, but who nevertheless experienced severe infection with a Gram-negative environmental microorganism, although without proven bacteraemia, was included at the request of the family (Group 3).

All families were informed, in a letter sent from NHS GGC on 4.3.2020, of the inclusion criteria agreed by the Panel. Only one family responded to say they did not wish their child to be included in the Review.

[27] Case Note Review. Paediatric Haemato-Oncology Patients, Royal Hospital for Children NHS Greater Glasgow and Clyde. Epidemiology and Clinical Outcomes Protocol; April 2020 v1.0

3.2.1 Datasets and definitions used to identify patients for inclusion in the Review

The combined dataset used in a previous review by staff in HPS published in October 2019[28] (and now ARHAI Scotland) formed the basis by which patients were identified to be included in the Review. For the HPS work, qualifying infection episodes were extracted from the following datasets:

- HPS dataset - Electronic Communication of Surveillance in Scotland (ECOSS) extract;
- NHS GGC Central Line Associated Blood stream Infection (CLABSI) Surveillance System;
- NHS GGC ECOSS extract; and
- NHS GCC Microbiology laboratory information management system (LIMS).

The data extract utilised for the previous HPS publication was extended to December 2019 and the final patient/episode list was cross-checked with NHS GGC before the start of the Review.

Positive blood cultures were identified for micro-organisms from the environment including enteric bacteria group. This included all species of the following: Achromobacter; Acinetobacter; Aeromonas; Brevibacillus; Brevundimonas; Burkholderia; Cedecea; Chryseobacterium; Chryseomonas; Citrobacter; Clavibacter; Comamonas; Cupriavidus; Delftia acidovorans; Elizabethkingia; Enterobacter; Flavimonas; Gordonia; Klebsiella; Pseudomonas; Pantoea; Pseudoxanthomonas; Psychrobacter; Ralstonia; Rhizobium; Rhodococcus; Roseomonas; Serratia; Sphingomonas; Stenotrophomonas and atypical mycobacteria.

A full breakdown of the grouping is detailed in Appendix B.

3.2.2 Case definition

In order to consider the diversity of bacteria likely to be identified if there is an environmental source, and to account for polymicrobial episodes, the following case definitions were used.

At the Species level - a positive blood culture of a single bacterium that has not been previously isolated from the patient's blood within the same 14-day period (i.e. 14 days from date last positive sample obtained).

At the Episode level - a positive blood culture for an environmental including enteric bacteria group that has not been previously isolated with same or other environmental including enteric bacteria group organism in the patient's blood within the same 14 day period.

In line with the case definition, and to align with other national bacteraemia surveillance, a standard 14 day rolling deduplication was applied to the HPS ECOSS dataset, and these episodes were cross-checked with NHS GGC data sets supplied.

All positive blood cultures were included with the exception of post-mortem blood, any quality test samples, foetal samples or non-human samples.

[28] Review of NHSGG&C Paediatric Haemato-Oncology Data. Health Protection Scotland; November 2019. https://www.hps.scot.nhs.uk/web-resources-container/review-of-nhsggc-paediatric-haemato-oncology-data/

3.3 Epidemiology data collection

3.3.1 Objectives

The objectives of the epidemiological investigation were to:

- determine a timeline for each of the cases identified for review;
- characterise the cases in terms of time, place and person
    - Time: describe the episodes of blood stream infection over time and create a timeline for outbreak, including plotting of control measures against number of cases
    - Place: describe the location of patients (hospital, ward, bed/bay) and describe their movements in the hospital
    - Person: characterise the patients with infection in terms of intrinsic and extrinsic risk factors; outcomes; antimicrobial prophylaxis and treatment; and individual infection prevention and control measures in place; and
- describe the cases in the context of environmental risks and incidents including the use of environmental microbiological data and Healthcare Associated Infection – System for Controlling Risk in the Built Environment (HAI-SCRIBE)/other facilities data provided by NHS GGC.

3.3.2 Data extraction

A data extraction form was created to capture the data fields identified in a dataset agreed by the Core Project Team[29] (this is shown in Appendix D).

Dates of inpatient, outpatient and day care attendance were provided by the NHS GGC TrakCare system, including bed location and movement data for inpatient stays. Extracts were linked with patient infection episodes and species level data and a bespoke MS Access database was built which incorporated these datasets.

Patient data were reviewed through direct access to NHS GGC Clinical Portal providing information from medical notes, nursing notes and observation charts, surgical procedures, drug charts, laboratory information and correspondence.

The process by which more detailed extraction of clinically relevant information required by the Panel, and by which the PTT was implemented, is described in section 3.4.

Microbiology management data and infection control actions were separately obtained from the NHS GGC Telepath and ICNet systems (section 3.5).

Although the time period of the Review was from May 2015 to December 2019, when necessary, patient records were reviewed outwith this period in order to obtain diagnostic information and other clinical details relevant to the Review, including accessing electronic notes that had been scanned into the patient record at a later date.

Data from the database were extracted and processed using R software[30] to generate a report for each patient for review by the Panel.

[29] Expert Panel Dataset v1.0. 17.04.20

[30] v 3.5.1 (2018-07-02). The R Foundation for Statistical Computing

3.3.3 Timelines

Timelines were created using data visualisation software (Tableau 2019.1). These were viewed via an online platform called Eviz, a secure Tableau server web space managed by National Services Scotland. Panel members were provided with individual password protected log-in details for access.

The timelines created were used to display:

- Patient admission/bed location with infection episodes. This allowed the species level microorganism list to be filtered so that all or only selected bacteria could be reviewed. Patients could be searched individually or collectively and locations of care could be separated by ward and room.
- Environmental water sample data provided by NHS GGC. This allowed the results to be filtered by positive and negative findings, by all or selected microorganisms and, where available, location could be searched at room level.
- Environmental 'hard surface' (this includes surfaces on items such as medical equipment, bathroom fittings and drains, and air conditioning units) sample data provided by NHS GGC. This allowed the results to be filtered by positive and negative findings, by all or selected organisms and, where available, location could be searched at room level.
- Facilities maintenance data provided by NHS GGC. This allowed maintenance activity to be viewed by clinical area, down to room level where available, and by type of work.

Time filters allowed data to be reviewed for the entire period of the Case Note Review or for selected periods within this.

3.4 Adverse Events and the Paediatric Trigger Tool

3.4.1 Background to national and NHS GGC Policy

It is internationally recognised that between 10-25% of episodes of healthcare (in general hospital, community hospital and general practice) are associated with an adverse event[31].

Since 2013, NHS Scotland has used the National Reporting Framework for adverse events[32]. The category I to III classification framework was in place since 2013, although the regulatory requirement to report all Significant Adverse Event Reviews commissioned for Category I events to Healthcare Improvement Scotland (HIS) was only applied in January 2020.

The NHS GGC Incident Management Policy (2020) details the organisational system to record and address adverse events and near misses. It covers all incidents, whether they involve patients, relatives, visitors, staff, contractors, volunteers or the general public, and indicates that a robust investigation will be conducted into all

[31] The Health Foundation. Evidence scan: Levels of Harm 2011 [Available from: www.health.org.uk/publications/levels-of-harm/.

[32] Healthcare Improvement Scotland. Learning from adverse events through reporting and review. A national framework for Scotland: 2019 http://www.healthcareimprovementscotland.org/our_work/governance_and_assurance/management_of_adverse_events/national_framework.aspx.

Significant Clinical Incidents. The purpose of the investigation is to determine whether there are learning points, locally or for the wider organisation.

The main route for reporting adverse events within NHS GGC is through Datix (a web-based incident reporting and risk management software for healthcare and social care organisations). A trigger list categorises adverse events in line with the national guidance and a risk assessment is undertaken to inform initial notification and its escalation. A risk matrix is used to determine the incident's grade based on its impact and the likelihood of recurrence. The grades used by the matrix are designated: Insignificant, Minor, Moderate, Major and Extreme.

When an incident is scored Major or Extreme there must be an investigation, which investigates causation: one approach to this is Root Cause Analysis[33]. If the severity is Moderate, there should at least be a local investigation, led by the line manager also using, if appropriate, a root cause analysis type approach.

We chose to explore the occurrence of adverse events by considering data both from the NHS GGC Datix system and from a tool specifically developed to detect adverse events in paediatric care (the PTT).

3.4.2 The Paediatric Trigger Tool (PTT)

A trigger tool is a method for identifying adverse events (AE). In adults, the rate of detection of AE with a trigger tool is typically ten-fold greater than the rate detected through spontaneous reporting systems[34,35]. Similar results have been reported with paediatric trigger tools in general wards[36] and neonatal intensive care units[37].

In 2014, the UK PTT was developed with the support of clinicians in nine hospitals across the UK in order to detect AE in paediatric care provided in district general hospitals, acute teaching hospitals and specialist paediatric centres[38].

The intention of using the PTT as part of the methodology chosen for the Case Note Review was not to determine preventable or non-preventable harm but to create opportunities to learn from the AEs identified. The aims were to:

[33] Root cause analysis offers a structured approach to the investigation of patient safety incidents and facilitate organisational learning

[34] Classen DC, Resar R, Griffin F, et al. 'Global trigger tool' shows that adverse events in hospitals may be ten times greater than previously measured. *Health Aff (Millwood)* 2011;30(4):581-9. doi: 10.1377/hlthaff.2011.0190 [published Online First: 2011/04/08]

[35] Cullen DJ, Bates DW, Small SD, et al. The incident reporting system does not detect adverse drug events: a problem for quality improvement. *Jt Comm J Qual Improv* 1995;21(10):541-8. doi: 10.1016/s1070-3241(16)30180-8 [published Online First: 1995/10/01]

[36] Solevåg AL, Nakstad B. Utility of a Paediatric Trigger Tool in a Norwegian department of paediatric and adolescent medicine. *BMJ Open* 2014;4(5):e005011. doi: 10.1136/bmjopen-2014-005011 [published Online First: 2014/05/21

[37] Sharek PJ, Parry G, Goldmann D, et al. Performance characteristics of a methodology to quantify adverse events over time in hospitalized patients. *Health Serv Res* 2011;46(2):654-78. doi: 10.1111/j.1475-6773.2010.01156.x [published Online First: 2010/08/21]

[38] Chapman SM, Fitzsimons J, Davey N, et al. Prevalence and severity of patient harm in a sample of UK-hospitalised children detected by the Paediatric Trigger Tool. *BMJ Open* 2014;4(7):e005066. doi: 10.1136/bmjopen-2014-005066 [published Online First: 2014/07/06]

- identify all triggers and adverse events in all patients included in the Review;
- to describe the rate and severity of harm occurring in hospitalised children in this cohort; and
- to compare the rate and severity of harm occurring in the cohort with evidence from published studies

3.4.3 Adaptation of the UK PTT and its use in the Case Note Review

The checklist used for the implementation of the UK PTT is shown in Appendix C.

In preparation for the Review, the UK PTT was reviewed by Professor Hamish Wallace (Consultant Paediatric Oncologist at the Royal Hospital for Sick Children, Edinburgh and previously National Clinical Director of the Managed Service Network for Children and Young People with Cancer in Scotland); and by Professor George Youngson CBE (Emeritus Professor of Paediatric Surgery, Aberdeen University), a UK leader in patient safety practice. Following their review three additional triggers were recommended. These additions (PG12* Pain Score >7; PM9* Missed Doses; PM10* Antifungal treatment) were discussed and agreed by the Core Project Team.

The UK PTT is the same as the Canadian PTT. The validation study for the CPTT showed that inter-rater reliability was high when triggers were identified by a nurse and adverse events confirmed by a doctor[39]. This is the method that we used. The positive predictive value of the additional triggers in the adapted PTT was high[40] and we do not believe there is any reason to question the validity of the adapted UK PTT for detection of adverse events.

3.4.4 Data collection

The adapted UK PTT was applied to any episode of care for which the patient was an inpatient in QEUH/RHC for at least 24 hours. A systematic structured process was used to review the entire healthcare record. The process searched for 'triggers' within each episode of care as determined by the PTT check list. Once a trigger was identified, the reviewer used clinical expertise to examine the records in more detail to understand the circumstances around the event and record additional contextual narrative details. A second reviewer (a physician) reviewed, confirmed and validated all of the AE identified, recording the details within the PTT checklist and in accompanying additional narrative notes.

NHS GGC were asked to provide copies of all Datix reports for patients included in the Review, for the duration of the Review.

The National Framework in Scotland for learning from adverse events through reporting and review recommends that the following categories (and definitions) should be used to group adverse events:

- Category I – events that may have contributed to or resulted in permanent harm, for example unexpected death, intervention required to sustain life, severe financial loss (£>1m), ongoing national adverse publicity (likely to be graded as major or extreme impact on NHS Scotland risk assessment matrix, or as Category

[39] Matlow AG, Cronin CMG, Flintoft V, et al. Description of the development and validation of the Canadian Paediatric Trigger Tool. *BMJ quality & safety* 2011;20(5):416-23.

[40] Details are provided in a separate, more detailed, report of the use of the PTT and its findings requested by the Chief Nursing Officer.

G, H or I on National Coordinating Council for Medical Error Reporting and Prevention (NCC MERP) index[41]).

- Category II – events that may have contributed to or resulted in temporary harm, for example initial or prolonged treatment, intervention or monitoring required, temporary loss of service, significant financial loss, adverse local publicity (likely to be graded as minor or moderate impact on NHS Scotland risk assessment matrix, or Category E or F on NCC MERP index).
- Category III – events that had the potential to cause harm but no harm occurred, for example near miss events (by either chance or intervention) or low impact events where an error occurred, but no harm resulted (likely to be graded as minor or negligible on NHS Scotland risk matrix or Categories A, B, C or D on NCC MERP index).

The PTT uses the NCC MERP index, whereas Datix uses the NHS Scotland risk matrix to classify adverse events. We therefore converted these classes into the three categories advised by the National Framework for Scotland. We also applied these categories to data from published papers that use the NCC MERP index. An analysis and interpretation of the findings is given in section 8.6.

3.4.5 Literature review to obtain comparative data

Evidence from the literature about detection of AEs in paediatric inpatients using trigger tools was identified through searches in PubMed and Medline. Additional records were identified from published reviews and by searching bibliographies of full text articles. (Details of the literature search strategy, screening of articles and the studies included are in a report on Adverse Event Detection with the UK PTT separately submitted to the Chief Nursing Officer for Scotland.)

In comparing data with NHS GGC, hospitals identified from the literature review were classified according to the nature of the clinical services offered (secondary, tertiary).

As published studies used trigger tools in random samples from all admissions, for the comparison of event rates in NHS GGC with the published evidence, we only included adverse events that were not directly related to the infections causative of their inclusion in the Review.

3.5 Data relating to microbiology management and infection prevention and control

Telepath is the Laboratory Information Management System (LIMS) used by NHS GGC. The system is used to store laboratory sample results for patients (microbiology) and has the capacity to store patient notes (in the patient note pad - PNP) recorded by microbiologists. Communication between microbiologists and clinical teams are recorded in the PNP chronologically by date as a record of any discussions regarding advice provided by the microbiology team. This function allows any microbiologist to access the records and review previous conversations regarding patient specific issues relating to current or previous admissions, or positive samples.

ICNet is an electronic patient management system used by the Infection Prevention and Control Team (IPCT) to manage patients identified with possible or confirmed

[41] https://www.nccmerp.org

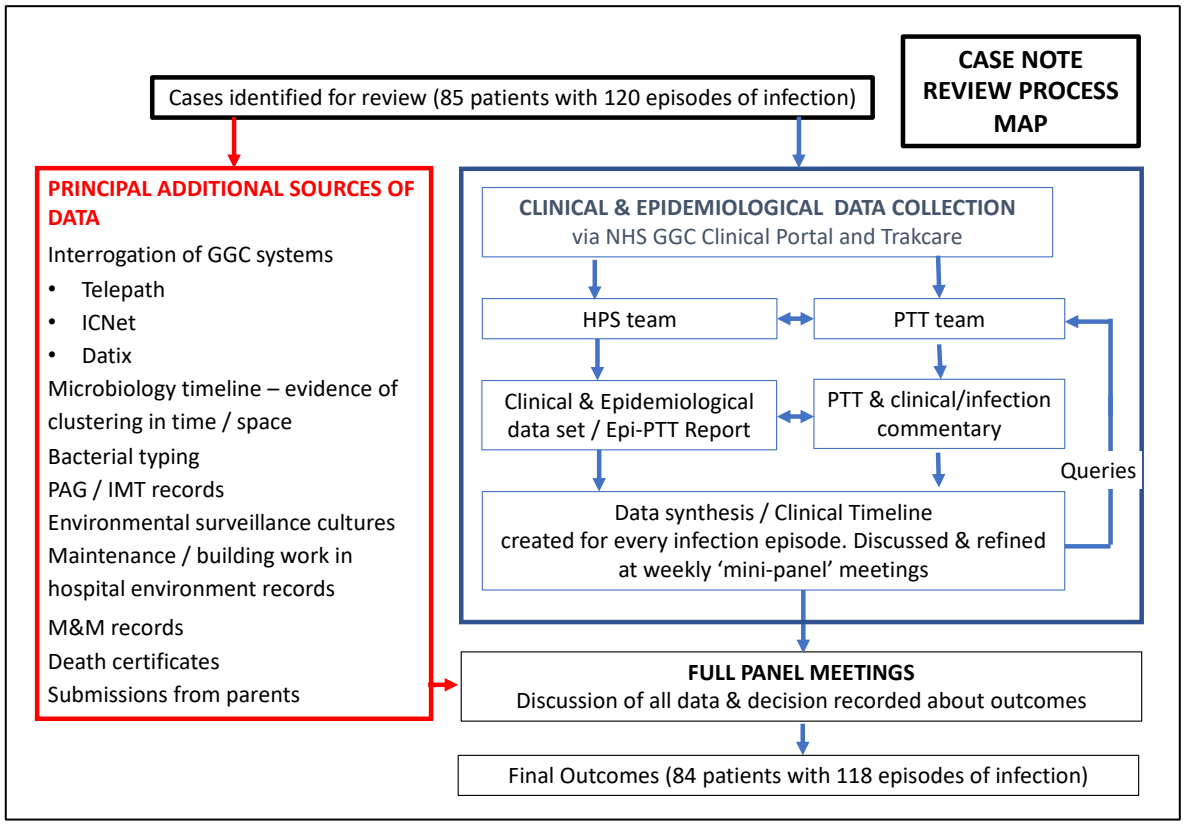
infection. The Telepath system sends microbiology results to the ICNet system every 15 minutes. This provides timely reporting to the IPCT.

The ICNet system has a pre-defined list of alert organisms (based on the list of alert organisms in chapter 3 of the national manual[42]) which, if identified from the data transfer from Telepath, will automatically create a case in the ICNet system. This case alerts the local IPCT of a new referral to be reviewed and assessed. The IPCT also have the ability to create a case manually should the ward clinicians report patients with a possible infection where no microbiology results are available, or if separately alerted by a microbiologist. Once a case is created, the local IPCT would review the patient and assess the IPC needs in the same way as an automatically generated case. The ICNet system also receives regular information 'pushes' from the NHS GGC patient information system which allows the IPC team to identify patient location in the hospital during their stay. This is particularly helpful to assess any possible infection cross transmission risks and avoids the need to navigate multiple systems.

3.6 Expert Panel Review Process

Our overall process is summarised in Figure 3.2.

Figure 3.2: Case Note Review Process Map



3.6.1 Anonymisation of patient data

Patients included in the Review were not identified to the Panel by name. A unique patient identifier (UPI) was created to link to the patient's Community Health Index

[42] National Infection Prevention and Control Manual. NHSScotland

(CHI) number and was used by the data collection teams to present information to the Panel from each of the data sources accessed.

Data that came direct from NHS GGC (for example, environmental microbiology and facilities maintenance data) were anonymised by the substitution of patient identifiers with the UPI before being presented to the Panel.

3.6.2 Data collection

Two teams (the clinical/PTT team and the epidemiology team) accessed the NHS GGC Clinical Portal to view patient case note records. Access to other GGC systems was also required to collect further data required for the epidemiology data collection (section 3.3.2) and for the PTT and augmented clinical data collection (section 3.4). These data were collated into a single document created for each patient (case) and each infection/bacteraemia (episode). This was usually supplemented by a second document that provided narrative comments about clinical care and the microbiological management of the infection.

3.6.3 Data Synthesis

The data provided by the two collection teams were reviewed and integrated into a Data Synthesis file, which was created separately for each infection episode. The Data Synthesis File had three components: Dataset; Summary; and Conclusions.

The Dataset component recorded data obtained for the data items defined in the Expert Panel Dataset and was structured to allow queries to be raised about missing data or data requiring clarification.

The Summary component included the creation of a Clinical Timeline which set out the chronology of events around the infection episode. This component also included sections for completion by the Panel in relation to data provided from additional data sources.

The Conclusions component provided a framework to structure the Panel's response to the key questions required of the Review.

The Data Synthesis files were reviewed at a weekly 'mini Panel' meeting with the data collection teams to identify and resolve queries before being passed on for full Panel review.

A copy of the Data Synthesis template is included at Appendix D.

3.6.4 Expert Panel Review

Once complete, Data Synthesis files were provided to us for review at a scheduled Panel Review meeting. All data were made available in individual files for each patient, identified by their UPI and stored in a secure MS Teams channel. In preparation for the Review meeting, in addition to the Data Synthesis file for each infection episode, we also had access to the source material utilised to create the clinical timeline; the Epidemiology timelines (via EViz - section 3.3.3); and to extracts from additional data sources (for example, extracts from the Telepath, ICNet and Datix systems).

Parents of the children involved in the Review had been invited to make submissions to the Panel if they wished, and a small number did so. When this was the case, these submissions also formed a part of the material made available to us as part of our Review.

Each case was first reviewed individually by one of us, to assess the adequacy of the data available and to make a provisional judgment on source/causality, impact and lessons learned. This initial assessment was shared and discussed amongst us at the Panel Review meeting when, after detailed review of the evidence, a consensus decision could usually be reached. In some cases, a decision could not be made pending the need for further information, in which case a further review took place at a subsequent meeting once all the information that could be obtained was available.

Some data (in particular, the results of environmental microbiology sampling, bacterial typing and facilities maintenance activity) only became available to us in a useful form in the later stage of the Review process. The reasons for this are further discussed in Chapter 8. As a consequence, we had to re-review all cases to ensure that our assessments were as informed as possible according to the information finally available. We also utilised the second review process to check for standardisation of our approach, and to review the basis of our initial decisions in the light of an evolving understanding of the issues we had been considering.

We recognised from the outset that we should need to use our judgement to assess and interpret the information available. We agreed, therefore, that our decisions should be justified by using the principle of the 'balance of probabilities,' i.e. that, on the evidence available, the conclusions we reached in the review of each case/episode were more likely to apply than not.

3.6.5 Final Outcome Reports

We recorded our final outcome within the data synthesis template for each episode of infection. In some cases, with more than one infection episode, one or more episodes were evaluated together, usually because of close time relationship and sometimes similar causative bacteria.

Prior to commencing our review meetings, we had defined the questions we needed to answer after reviewing each episode of infection. These were as follows:

1. Are the data provided sufficient to complete the review as intended and to reach a conclusion?

   Answers: Yes; No

2. Does the infection episode fit within the criteria for the Review?

   Answers: Yes; No

3. Is it possible to link this infection episode with the environment of the RHC/QEUH?

   Answers: Unrelated; Possible; Probable; Confirmed; Unable to determine

   The criteria we considered in determining the likelihood of a link between an infection episode and the environment of the hospital are discussed in section 3.6.6

4. Was there an impact on patient care and outcome in relation to the infection?

   Answers: Yes; No; Unable to determine

5. If so, grade severity

Answers: These were initially scored by the Panel as None, Minor; Significant; Severe; Critical but for analysis were directly converted to Negligible, Minor, Moderate, Major, Extreme as used by the NHS Scotland Risk Assessment Matrix

We created a framework to assure a consistent approach in the allocation of a grade of severity (section 3.6.7).

6. What lessons might be learned from this case?
   a) To strengthen IPC measures in the future?
   b) In any other respect?
7. Are there any other points arising from this review?
8. The Panel's response to any questions or comments raised by patient / family.

The data from the final outcome reports for all patients were entered into a data analysis spreadsheet to allow descriptive reporting of characteristics from the whole cohort of cases and episodes.

3.6.6 Categorising the likelihood of an environmental source for an infection

In considering the likelihood of the hospital environment being the source of each bacteraemia, we took into account all available (i.e. that which was provided to us) patient, clinical, infection prevention and control, microbiology, local investigations (including Datix and IMTs where available) and hospital environmental data.

The standard epidemiological way of determining causality of, and potential links between infections is according to 'time, place and person' information[43]. The levels of certainty we agreed about a common source of infection (i.e. potentially from the hospital environment) were markedly influenced by whether clusters of episodes caused by the same bacterium occurred over successive days/weeks/months (time), affected different children (persons) in the QEUH and RHC (place). This was most pertinent for either large clusters (in time) and/or bacteraemias due to relatively uncommon bacteria.

We decided to categorise episodes into one of four levels of likelihood that the hospital environment was the source of a bacteraemia: Unrelated, Possible, Probable or Definite. This approach is discussed further in Chapter 5, section 5.6. In some cases, we thought we might be unable to determine likelihood because of inadequate or conflicting data. The allocation of these descriptors inevitably represented a position taken along a continuum of certainty and, for the two largest groups (Possible and Probable) we attempted to refine our position by further extending our categorisation into Weak Possible, Possible, Strong Possible, Probable and Strong Probable groupings. We did not feel we were able to distinguish between Probable and Weak Probable.

For the hospital environment to be classified as a Definite source of a bacteraemia, we required not only time, place and person data to confirm the opportunity for infection to be derived from the hospital environment, but also bacterial typing data (noting the limitations set out below) that matched a patient blood culture isolate to the same microorganism recovered from water or surface samples.

[43] Principles of Epidemiology in Public Health Practice, Third Edition: An Introduction to Applied Epidemiology and Biostatistics. https://www.cdc.gov/csels/dsepd/ss1978/lesson1/section6.html

For cases that we considered to be Unrelated to the hospital environment, we agreed either that key issues such as a (relative) lack of opportunity to acquire bacteria from the hospital environment over a period of time consistent with the development of bacteraemia, and/or strong alternative hypotheses about the origin of the bacteraemia, had to be present. For example, if there was strong evidence of an endogenous source, including significant mucositis or typhlitis (both descriptors of damage to/inflammation of the bowel), in the absence of clear clusters of bacteraemias caused by the same bacterial species. Mucositis and typhlitis are known to be associated with an increased risk for the passage of bacteria from the bowel, where many different Gram-negative bacteria can be found, into the blood stream.

We found, as anticipated, that a distinction between the hospital environment being classified as a Possible or a Probable source of a bacteraemia was not straightforward. For a bacteraemia to have a Probable environmental source, we agreed that the information available supported a view that the environment was likely the source (on the grounds of probability), using a standard infection prevention and control assessment of the available data/information. In routine practice, such a conclusion would be made until/unless it was possible to confidently arrive at an alternative hypothesis for the cause/source of infection.

Clustering of cases caused by the same bacterial species was often a key factor in reaching a Probable conclusion – we discuss this further in section 4.3. Other factors included multiple/prolonged opportunities for contamination of intravascular catheters (which is a recognised cause of hospital acquired infection); bacteria that are uncommon causes of bacteraemia; repeated recovery of the same bacterial species from hospital environmental samples around the time of the bacteraemia(s), especially if such samples were taken close to where the patient was managed. The latter point was complicated by the often multiple placements (wards, units and rooms) used for both inpatient and outpatient care of each patient (including leave ‘on pass’ from in patient care). Given our remit, we focused on potential hospital sources of infection, but we acknowledge that community sources of infection were possible; we did take into account the extent of out of hospital exposure prior to a bacteraemia when assessing infection source likelihood.

The more of these criteria were present, the greater was our confidence in concluding a Probable environmental source of infection.

We also recognise that the chance of finding/proving that a microbe in the environment is the source of human infection is directly related to the frequency with which it is sought. This raises two issues: how commonly/systematically is the environment sampled, and are the samples obtained examined specifically for a microbe of interest, or simply to determine the overall number of microbes and/or whether one of a few commonly sought bacteria are present? It is therefore the case that not finding a bacterium in the hospital environment does not exclude the possibility that the latter could have been the source.

Different typing methods are used by reference laboratories to characterise different microbiological isolates and can be used to compare strains of the same bacterium taken from two or more different people or sites. However, it is also necessary to take into account the bounds of possibility around the observation that one strain is the same or closely related to another, given that bacterial DNA can vary in time. Thus, it is standard practice when considering such data, to ascribe limits of

differences between strains under comparison, before concluding they are identical, indistinguishable or very closely related (making it highly likely that these are 'the same' bacterium) or distinct. One caveat, however, is that where reference laboratory reports merely state that an isolate/strain is 'unique', the interpretation depends on the knowledge of what the isolate in question was compared with – is it unique amongst two or amongst a much larger number of strains of the same bacterial species to which it had been compared?

We recognise there are well known constraints affecting any attempt to assess causality, i.e. the possibility that an association might be affected by chance, bias or confounding: we weighed up all these issues in considering the data presented for our assessment.

3.6.7 Standardising the assessment of the impact of infection on patient outcome

Assessing the consequences of the infection represented an important element of our work. In order to do so, we requested data related to the following specific areas:

1. Length of hospitalisation
2. Duration of antibiotic therapy
3. Removal of Central Venous Line (CVL)
4. Admission for intensive care (PICU)
5. Modification of the planned delivery of cancer treatment
6. Evidence of persisting toxicity
7. Death

We also considered

8. Any other impact on care highlighted by the PTT analysis or identified from the narrative of the case note records
9. Statements and insights submitted by parents about their perception of the impact of the infection episode on their child and themselves.

In order to standardise the approach taken, and to allow the generation of descriptive statistics for the final report, we developed a framework that defined a measure of the overall impact of each infection episode on an individual patient[44].

The framework was informed by the approach taken by NHS Scotland to the categorisation of adverse events and to the definition of the impact/consequences that follow[45], but it was tailored to utilise the specific outcome criteria we selected for use in the Case Note Review.

Early experience with data collected for the first 18 patients (24 episodes) in the Review was used to pilot a framework which related individual consequences to an overall category of severity. All the pilot episodes had been scored during the early phase of the review process by allocating an overall impact grade on a scale of 0–4

[44] RHC Case Note Review – Defining the impact of the infection episode v1.0. 27.8.20

[45] Healthcare Improvement Scotland. Learning from adverse events through reporting and review: A national framework for Scotland. December 2019.

(initially defined[46] as: 0 = None, 1 = Minor, 2 = Serious, 3 = Severe, 4 = Critical impact). These overall scores were plotted into a grid against the observed occurrence of the items numbered 1-7 in the list above. A single score allocation was then adjusted to achieve a degree of consistency across the differing measures of impact experienced by the whole pilot group. In the course of this, evidence for persisting toxicity (item 6 on the list above) was excluded from the model as data to define this was only readily identifiable in one case which, for other reasons, already met the grade of Critical impact.

The final version of the impact framework subsequently used to score all cases in the final outcome reports is shown in Figure 3.3. In utilising the framework, the occurrence of the specified outcome criteria for each infection episode were plotted onto the grid but could only be allocated into an unshaded field.

Figure 3.3 Impact assessment Framework

	Admission resulting from infection			CVL removed	Treatment disrupted			PICU admission		Death
Impact grade	Not evaluable or <= 7 days	8 to <= 14 days	>=15 days	Yes	Not evaluable, none or <= 7 days	>7 days	>=14 days	<=3 days	>3 days	Infection likely to have contributed
1 Minor										
2. Significant										
3. Severe										
4. Critical										

The overall impact was determined by the level of the highest impact grade recorded for each episode. For example, no patient who had their CVL removed as result of the infection could be graded as experiencing a ‘Minor’ impact; and no patient who was admitted to PICU because of the infection for >3 days could be graded as having anything less than ‘Critical’ impact.

Whilst the framework offered a standardised approach to allocating an impact grade, we retained flexibility to moderate the grade (up or down) by considering any other relevant information available at the time of our review.

Although the grade allocated implies a numerical level of impact on a 5-point scale, we also attributed a short descriptive identity to each, as follows: (this shown as our original descriptor with the NHS Scotland descriptor in brackets):

Grade 1: None (Negligible) – there is no discernible impact of the infection on the patient’s experience, or outcome.

[46] The terminology was subsequently adjusted by the Panel to match that used by the NHS Scotland Risk Assessment Matrix (Negligible, Minor, Moderate, Major, Extreme)

Grade 2: Minor (Minor) - whilst the infection had the potential to cause harm, the impact on the patient was limited to a short additional admission and / or to a non-significant delay to planned cancer treatment.

Grade 3: Significant (Moderate) - the infection may have contributed to or caused temporary harm including any of the following: prolonged admission >7<15 days; removal of CVL; >7 day disruption to planned cancer treatment but without likelihood of long-term adverse consequences.

Grade 4: Severe (Major)[47] – the infection caused significant disruption to patient experience and / or treatment with the potential for long term consequences. This includes any of the following: prolonged admission >14 days; >14 day disruption to planned cancer treatment; short (<3 day) PICU admission for higher level support.

Grade 5: Critical (Extreme) – this applied when the infection resulted in prolonged (>3 day) admission to PICU and/or if the infection is likely to have contributed to the patient's death.

Finally, and importantly, we recognise that applying a numerical grade to define our assessment of the impact attributed to an infection episode may not necessarily reflect the 'lived experience' of the patient and family who were affected. In offering feedback to individual families at the end of the Review process (see section 7.2), emphasis will be placed as much on the descriptive detail of what we have observed as on the allocated grade.

3.7 Communication with stakeholders

This section provides more detail on who the stakeholders are (acknowledging differences within each group); what information was shared about the Review; the desired methods of communicating with them; and the sensitivities we considered when doing so. It also acknowledges and includes those who have indicated their preferences to not receive communications from the Review.

A summary of the meetings and other communications activity undertaken during our Review is shown the timeline in Appendix A.

3.7.1 Children, Young People, Parents and Families

Addressing individual questions from children, young people, their parents and families was a key driver for the Review. This section focuses on how we tried to understand individual circumstances and to ensure that our response took this into consideration.

There are different levels of engagement within this group; for example, some families did not want to receive communications about the Review. We also recognised the sensitivity required to address differences in perspective. For example, some families are affected by the death of their child whether or not this was thought to be related to infection or not. Others may feel their previously expressed concerns have not been 'heard' and/or still have unresolved questions relating to their child's care. Others still may feel that their previous questions were not addressed in ways that instilled confidence or assured them that their concerns

[47] The description used here of Grade 4 (Major) impact is that used for the Patient Experience descriptor (rather than the Injury descriptor) in Healthcare Improvement Scotland. Learning from adverse events through reporting and review. A national framework for Scotland 2019.

or dissatisfaction were understood. We recognise too that these positions may each overlap.

This section acknowledges the different elements to the communications work:

- introducing and setting out the background to the Review;
- contacting families and setting out the basis for case selection;
- providing families with the opportunity to highlight questions, issues or observations that they wished to make known to the Panel;
- addressing individual questions and providing appropriate updates on overall progress;
- ensuring that preferences for updates and discussion of the individual outcome for their child were elicited and delivered;
- communicating specific findings and responses to questions to those families/patients that wish to receive these; and
- ensuring that the core narrative supporting this Review was consistently reflected in communications and engagement – particularly reflecting Ministerial commitments to full, open, transparent and respectful engagement with parents and families.

Considerable engagement had already taken place with this group prior to the start of the Review, in particular, by information coming from NHS GGC and the clinical team working closely with the patients/families, supported by the Paediatric Haemato Oncology Closed Facebook page. Engagement has also been supported through the Scottish Government Oversight Board Communications and Engagement subgroup led by Professor Craig White, with the support of Patient and Family Representative, Professor John Cuddihy, and with whom we agreed a process for communication with families.

We were able to harness the established communication and engagement processes, to provide patients and families with quarterly written updates on the progress of the Review, to receive questions and information from families for consideration by the Panel, and to provide responses. Further information on information sent by families to the Panel is discussed in Section 7.1.

3.7.2 Core Project Team

The Core Project Team meetings, chaired by Professor Marion Bain, provided governance oversight for the Case Note Review. These meetings received an update on the progress of our work and provided an opportunity to discuss risks and issues arising from the Review process itself. These meetings also acted as the conduit to provide updates and escalate risks and issues to the Oversight Board.

3.7.3 NHS GGC Clinical and Medical Staff

This area of communications and engagement had been recognised as a particular risk in the Review. This group had been concerned with the appropriateness of (some of) the methods being applied for the Review, and there were particular sensitivities expressed with respect to any focus on the quality of care provided to these patients.

Steps were taken to address these concerns as far as was realistically achievable. This included quarterly virtual update meetings to which senior medical, nursing and management staff from the Paediatric Haematology Oncology service and RHC were invited. On occasions, a senior member of the Core Project Team also attended with a view to providing opportunities to raise concerns and ask questions.

3.7.4 NHS GGC Senior Management

Senior members of the NHS GGC Senior Leadership Team were appraised through the work of the Oversight Board to which Professor Marion Bain provided updates on progress of the Review following Core Project Team meetings while she was Director of Infection Prevention and Control at NHS GGC. In addition, we engaged frequently with the Head of Corporate Governance and Administration at NHS GGC regarding meetings to request and discuss data submissions for the Review.

3.7.5 Other NHS GGC staff

Through and with members of the wider Review team, we and other NHS GGC staff communicated frequently from April 2020 to December 2020 over requests for NHS GGC data, and to clarify data received. This spanned across various divisions in NHS GGC, for example, Estates and Facilities, Microbiology, Infection Prevention Control and Paediatric Haematology and Oncology.

3.7.6 Others

In line with the independent nature of the Case Note Review, we asked for meetings with, or sought written clarification from, a number of individuals who held technical, advisory or clinical positions within Scottish Government, HFS and NHS GGC. The purpose was to discuss background information and to clarify our understanding of specific points identified in our review. These meetings took place between November 2020 and January 2021.

4. DESCRIPTION OF CASES AND EPISODES INCLUDED IN THE REVIEW

4.1 Overview

The criteria for the inclusion of patients in our Review were defined in our ToR (Chapter 2), and the associated methodology for identification of these cases is further described in Chapter 3, section 3.2. The work undertaken using these criteria before we began our work suggested that 85 patients, who had experienced 120 infection episodes, were eligible for review. In the course of our work, however, we identified some adjustments.

1. We identified one patient who had had two episodes of eligible infection, the earliest of which had occurred shortly before the move of the Children's Hospital from Yorkhill to the new QEUH campus. As this fell outside the timeline of the Review and did not relate to the QEUH/RHC site, we considered that this first episode was ineligible for inclusion. However, the patient remained in the review by virtue of a second qualifying episode.
2. We subsequently identified a patient who had been identified for the Review with a single episode of bacteraemia caused by *Moraxella catarrhalis*. This is a Gram-negative bacterium, but is not considered to be environmental and spreads predominantly from person-to-person by droplet contamination. We considered this ineligible for inclusion and both the patient and the episode have been excluded from our analysis. However, as the family had been notified of, and subsequently agreed for the Case Note Review, we reviewed this child's records and will provide the family with an individual report.
3. One further patient, who otherwise fulfilled the criteria for the Review, was not included at the family's request. This patient had had four episodes of infection and although no other records were extracted or reviewed by the Panel, the timings and types of these infections were included in the microbiology data provided to the Panel because this could have contributed to our understanding of any clustering with other cases with similar infections.

In summary, in this report we provide findings for 84 patients who, between them, had 118 episodes of infection and were eligible for the Review.

4.2 Demographic and Clinical Profiles of Patients included in the Review

The characteristics of the patients included in the Review are summarised in Table 4.1.

Table 4.1 Demographic and Clinical characteristics of cases included in the Review

Total no. of cases	84	100%
Gender	Male 32 Female 52	38% 62%
Diagnosis	Leukaemia 36 Lymphoma 7 CNS tumour 11 Solid tumour 23 Non-malignant Disease 7	43% 8% 13% 27% 8%
Age at diagnosis	Median (Range): 3y 9m (Birth–18y 4m)	
No. of infection episodes in the Review	One episode 65 Two episodes 10 Three or more episodes 9 *(n=3 in 6; n=4 in 2; n=8 in 1)*	77% 12% 11%
Age at first episode of infection	Median (Range): 5y 11m (3m–18y 10m)	
Alive* at the time of the publication of this report	62	74%

*Further discussion of patients who have died is provided in section 6.2.

4.2.1 Gender

The observation that 62% of the cases in this series were female is of interest. Age Standardised Rates for cancer in children to the age of 15 in northern European countries (and in most developed countries) indicate a slight excess of boys with a M:F ratio in the range of 1.1-1.2. The ratio in older teenagers and young adults is closer to 1.0. This is confirmed in the most recent publication of data for cancer in children and young people in Scotland[48], which states "In the ten year period 2009-2018, 1,298 children (aged 0-14, 53% male) were diagnosed with cancer and 1,996 young people (aged 15-24, 51% female) were diagnosed with cancer".

The great majority of patients in our Review were aged under 15 years at diagnosis and we are not able to offer any obvious explanation for the reversal of the expected gender balance. There is no reason to believe that gender should influence the risk of infection at this age, and the finding of a female excess is unexpected. As the number of cases in this series is relatively small, the likelihood of this being a real effect is also small. It would nevertheless be appropriate for the staff in the Paediatric Haematology Oncology service at NHS GGC to audit gender patterns of all bacteraemias in children under their care to assess this further.

[48] Children and Young People with Cancer in Scotland 2009-2018. Public Health Scotland 2020. https://beta.isdscotland.org/find-publications-and-data/conditions-and-diseases/cancer/children-and-young-people-with-cancer-in-scotland/

4.2.2 Age

The patients included in the Case Note Review were young, both at the diagnosis of their cancer or other condition (median age 3 years 9 months) and at the time of their first Gram Negative Environmental (GNE) infection (median age 5 year 11 months). The young median age at diagnosis is not unexpected and reflects the peak of diagnosis of the commonest form of childhood leukaemia, and some solid tumours, seen in the pre-school age range.

We consider the distribution of diagnoses in patients included in the Case Note Review to be representative of the age range expected to be under treatment in the Paediatric Haematology Oncology service at NHS GGC.

4.2.3 Diagnosis

The classification of cancer in children and young people uses a different system to that applied in adults. Individual diagnoses may be very rare and analyses typically group patients into four main groups – leukaemias, lymphomas, central nervous system (CNS) tumours, and solid tumours. The data shown in Table 4.1 for the distribution of diagnoses amongst patients included in the Review are broadly in line with that expected, although there is a small excess of leukaemia (43% of the cases in the Review group *vs* 31% in the Scottish data for 2009-2018) and a corresponding deficit of both CNS (13% *vs* 27%) and solid tumours (27% *vs* 34%). The proportion of children with lymphoma is as expected (8% *vs* 8%).

The leukaemia excess is consistent with two observations: i) almost all children with leukaemia require periods of intensive treatment with chemotherapy, and are therefore more susceptible to infection; and ii) NHS GGC is the national center for paediatric bone marrow stem cell transplantation (SCT) in Scotland and receives referrals of patients with high risk leukaemia and other blood disease from other centres. SCT patients are especially at risk of serious infection.

The small number of children in the Review with non-malignant diagnoses included those with serious blood diseases such as aplastic anaemia and other bone marrow failure syndromes (n = 5), haemophilia (1), and two patients who had initially been diagnosed with a malignant condition but were subsequently shown to have alternative but nevertheless serious non-malignant conditions.

An additional factor to consider is that the Paediatric Haematology Oncology service at NHS GGC is the designated national bone marrow stem cell transplant service for children in Scotland. Some of the children in the series had been referred for stem cell transplantation after initial treatment elsewhere. The requirement for such treatment is typically seen amongst children with high risk, including relapsed, leukaemia and those with severe bone marrow failure syndromes. Overall, however, we consider the population of patients seen in the Case Note Review to be representative of the case mix expected to be under treatment at NHS GGC.

4.2.4 Frequency of infection episodes

It is noteworthy that although the large majority (77%) of patients included in the Review had only one episode of GNE infection, almost one quarter had more than one, and several patients had >2 episodes. We believe this indicates the persistence of risk in this population, with the continuing presence of a central venous line and, in most, ongoing exposure to chemotherapy. It may also imply the persistence of environmentally associated risk.

Further detail about the frequency and type of organisms causing the bacteraemias in the whole case series is discussed in section 4.3.

4.3 Microbiology profile of the isolates identified in the Review

We have described (section 3.2) how cases were selected for the Case Note Review and have identified the adjustments we made to arrive at the final figures of 84 cases and 118 infection episodes eligible for our Review (section 4.1).

Table 4.2 provides a summary of all bacteraemias at genus level. Table 4.3 provides a summary of the same data but at the species level. Note that data from 2015 represent only a partial year (from May 15th 2015[49]) and that the isolates from the patient who was eligible but whose family did not wish them to be part of the Review (patient 3 discussed in section 4.1) are included within these data. Note also that, as some episodes were polymicrobial (i.e. more than one bacterium was identified in the same blood culture), the totals given in these tables exceed the total number of episodes considered in the Review.

Table 4.2 Frequency of infection by organism (defined at genus level) and year

Organism by genus	2015	2016	2017	2018	2019	Total
Achromobacter					1 (3.6%)	1 (0.6%)
Acinetobacter		2 (7.7%)	6 (11.8%)	2 (4.2%)	1 (3.6%)	11 (7.1%)
Aeromonas		1 (3.8%)			1 (3.6%)	2 (1.3%)
Brevundimonas			1 (2.0%)			1 (0.6%)
Burkholderia			1 (2.0%)	1 (2.1%)		2 (1.3%)
Chryseobacterium		1 (3.8%)	1 (2.0%)	2 (4.2%)	1 (3.6%)	5 (3.2%)
Citrobacter			3 (5.9%)	2 (4.2%)		5 (3.2%)
Cupriavidus			1 (2.0%)	1 (2.1%)		2 (1.3%)
Delftia			2 (3.9%)		1 (3.6%)	3 (1.9%)
Elizabethkingia		2 (7.7%)	3 (5.9%)		1 (3.6%)	6 (3.9%)
Enterobacter		1 (3.8%)	8 (15.7%)	10 (20.8%)	8 (28.6%)	27 (17.4%)
Herbaspirillum			1 (2.0%)			1 (0.6%)

[49] Although data collection limits were set from 15.5.2015 to 31.12.2019, we recognise that patient transfer did not take place until June and no infections were included before that date. In fact, the first infection included in the Review was identified on 21.10.2015.

Klebsiella	1 (50.0%)	10 (38.5%)	10 (19.6%)	7 (14.6%)	2 (7.1%)	30 (19.4%)
Mycobacterium		1 (3.8%)		2 (4.2%)	1 (3.6%)	4 (2.6%)
Pantoea			1 (2.0%)	1 (2.1%)	1 (3.6%)	3 (1.9%)
Pseudomonas	1 (50.0%)	3 (11.5%)	3 (5.9%)	6 (12.5%)	4 (14.3%)	17 (11.0%)
Raoultella		1 (3.8%)	1 (2.0%)			2 (1.3%)
Rhizobium		1 (3.8%)				1 (0.6%)
Roseomonas			1 (2.0%)			1 (0.6%)
Serratia		2 (7.7%)	1 (2.0%)	2 (4.2%)	2 (7.1%)	7 (4.5%)
Sphingomonas			1 (2.0%)			1 (0.6%)
Stenotrophomonas		1 (3.8%)	6 (11.8%)	12 (25.0%)	4 (14.3%)	23 (14.8%)
Totals	**2**	**26**	**51**	**48**	**28**	**155**

Table 4.3 Frequency of infection by organism (defined at species level) and year

Organism by species	2015	2016	2017	2018	2019	Total
Achromobacter spp.					1 (3.6%)	1 (0.6%)
Acinetobacter baumannii		1 (3.8%)	3 (5.9%)			4 (2.6%)
Acinetobacter baumannii complex			1 (2.0%)			1 (0.6%)
Acinetobacter ursingii		1 (3.8%)	2 (3.9%)	2 (4.2%)	1 (3.6%)	6 (3.9%)
Aeromonas hydrophila		1 (3.8%)				1 (0.6%)
Aeromonas spp.					1 (3.6%)	1 (0.6%)
Brevundimonas spp.			1 (2.0%)			1 (0.6%)
Burkholderia cepacia			1 (2.0%)	1 (2.1%)		2 (1.3%)
Chryseobacterium indologenes		1 (3.8%)	1 (2.0%)	1 (2.1%)	1 (3.6%)	4 (2.6%)
Chryseobacterium spp.				1 (2.1%)		1 (0.6%)
Citrobacter braakii			1 (2.0%)			1 (0.6%)

Citrobacter freundii			1 (2.0%)	1 (2.1%)		2 (1.3%)
Citrobacter koseri				1 (2.1%)		1 (0.6%)
Citrobacter youngae			1 (2.0%)			1 (0.6%)
Cupriavidus pauculus			1 (2.0%)	1 (2.1%)		2 (1.3%)
Delftia acidovorans			2 (3.9%)		1 (3.6%)	3 (1.9%)
Elizabethkingia meningoseptica		2 (7.7%)	1 (2.0%)			3 (1.9%)
Elizabethkingia miricola					1 (3.6%)	1 (0.6%)
Elizabethkingia spp.			2 (3.9%)			2 (1.3%)
Enterobacter cloacae		1 (3.8%)	7 (13.7%)	7 (14.6%)	6 (21.4%)	21 (13.5%)
Enterobacter cloacae complex				1 (2.1%)	2 (7.1%)	3 (1.9%)
Enterobacter cloacae ESBL				1 (2.1%)		1 (0.6%)
Enterobacter hormaechie			1 (2.0%)	1 (2.1%)		2 (1.3%)
Herbaspirillum spp.			1 (2.0%)			1 (0.6%)
Klebsiella oxytoca	1 (50.0%)	4 (15.4%)	2 (3.9%)	1 (2.1%)	1 (3.6%)	9 (5.8%)
Klebsiella pneumoniae		6 (23.1%)	8 (15.7%)	6 (12.5%)	1 (3.6%)	21 (13.5%)
Mycobacterium chelonae		1 (3.8%)		2 (4.2%)	1 (3.6%)	4 (2.6%)
Pantoea septica					1 (3.6%)	1 (0.6%)
Pantoea species			1 (2.0%)	1 (2.1%)		2 (1.3%)
Pseudomonas aeruginosa		1 (3.8%)	1 (2.0%)	5 (10.4%)	2 (7.1%)	9 (5.8%)
Pseudomonas putida	1 (50.0%)	2 (7.7%)	1 (2.0%)	1 (2.1%)	2 (7.1%)	7 (4.5%)
Pseudomonas stutzeri			1 (2.0%)			1 (0.6%)
Raoultella planticola		1 (3.8%)	1 (2.0%)			2 (1.3%)
Rhizobium radiobacter		1 (3.8%)				1 (0.6%)
Roseomonas mucosa			1 (2.0%)			1 (0.6%)
Serratia liquefaciens				1		1

				(2.1%)		(0.6%)
Serratia marcescens		2 (7.7%)	1 (2.0%)	1 (2.1%)	2 (7.1%)	6 (3.9%)
Sphingomonas paucimobilis			1 (2.0%)			1 (0.6%)
Stenotrophomonas maltophilia		1 (3.8%)	6 (11.8%)	12 (25.0%)	4 (14.3%)	23 (14.8%)
Totals	**2**	**26**	**51**	**48**	**28**	**155**

In the following sections, we briefly consider the frequencies and distributions of bacteraemias caused by 4 particularly common GNE species groups.

4.3.1 Enterobacter spp.

In total, there were 38 bacteraemias in 31 children. In 2017, between mid-July and mid-December, there were 7 episodes in 6 children. In 2018, of the 10 affected children, all occurred in a 6-month period (February–August 2018). Similarly, in 2019, 11 children had bacteraemias, but none after May 2019.

4.3.2 Stenotrophomonas spp.

21 bacteraemias occurred in 19 children. There were 12 episodes of S. maltophilia bacteraemia in 11 children during 2018, but none after September 2018, until the first of 5 episodes in 5 children between April - September 2019.

4.3.3 *Klebsiella* spp.

22 children had a Klebsiella spp. bacteraemia. In 2016, there were 9 episodes affecting 8 children; all except one of these bacteraemias occurred in between June-November 2016. In 2017, 9 bacteraemias occurred in 7 children, with all except one occurring in a 5-month period (July-December). In 2018, 6 children had a Klebsiella spp. bacteraemia, 5 of which occurred between late January and mid-May.

4.3.4 *Pseudomonas* spp.

16 bacteraemias occurred in 14 children; in 2018, all 5 episodes (in 4 children) occurred between February-June. Similarly, in 2019, there were 4 bacteraemias in 4 children; with respect to time, there were two pairs, one five days apart in March and the others 16 days apart in June.

4.3.5 Conclusions

The above observations demonstrate two notable points. Firstly, while it is not possible to state this with certainty, the frequency of these bacteraemias caused by GNE appears to be higher than would be expected, particularly for the infections caused by *Enterobacter* spp. and *Stenotrophomonas* spp.. As *Klebsiella* spp., and *Pseudomonas* spp are the second and third most common Gram-negative bacteria (after *Escherichia coli*) causing blood stream infections, it is less clear that the frequencies of these two bacteria are higher than would normally be expected.

The second notable point is the clustering of bacteraemias in time; by virtue of this Review they are all broadly clustered in place. We consider the chances of the cluster patterns identified above occurring by chance is small.

Thus, we conclude from this simple analysis of the epidemiology of a large proportion of the bacteraemias in this Review that there is evidence for both increased frequency of specific GNE bacteraemia and episode clustering in time (and place). Neither phenomena prove that some of the bacteraemias had hospital environment sources, but the observations are consistent with this hypothesis.

5. THE ROLE OF THE HOSPITAL ENVIRONMENT AS A SOURCE OF INFECTION

5.1 Context

Concerns about the QEUH/RHC hospital environment have been widely discussed. They were discussed in detail the Independent Review undertaken by Dr Andrew Fraser and Dr Brian Montgomery, published in June 2020[50], and will be further addressed by the Oversight Board whose final report is to be published at the same time as the publication of our own report.

Reported deficits in the hospital environment include (but not are not limited to) issues such as: the design and maintenance of the water system[51]; lower than required air exchange in patient rooms and inadequate positive pressure protection of patient rooms; the lack of provision of particulate (HEPA) filtration in some higher risk patient areas; and uncertainties around the appropriate utilisation of chilled beams for temperature control in rooms used for immunocompromised patients[52].

The focus of the Independent Review was explicitly on the built environment of the QEUH and problems related to infection prevention and control. Its ToR state that it was charged "to establish whether the design, build, commissioning and maintenance of the Queen Elizabeth University Hospital and Royal Hospital for Children has had an adverse impact on the risk of Healthcare Associated Infection and whether there is wider learning for NHS Scotland".

It is not the remit of the Case Note Review to revisit that objective but, in addressing our task to consider how many children in the specified patient population had been affected by the defined types of infection over the period from May 2015 to December 2019, and to answer the question whether it is possible to associate those infections with the environment of the RHC and the QEUH, it is inevitable that we have had to place our considerations in that context.

The remit of the Scottish Hospitals Inquiry now being undertaken by the Right Hon. Lord Brodie is much broader. Its overarching aim is "to consider the planning, design, construction, commissioning and, where appropriate, maintenance of both the Queen Elizabeth University Hospital Campus (QEUH), Glasgow and the Royal Hospital for Children and Young People and Department of Clinical Neurosciences (RHCYP/DCN), Edinburgh. The Inquiry will determine how issues relating to adequacy of ventilation, water contamination and other matters adversely impacting on patient safety and care occurred; if these issues could have been prevented; the impacts of these issues on patients and their families; and whether the buildings provide a suitable environment for the delivery of safe, effective person-centred care"[53].

[50] Queen Elizabeth University Hospital Review Report. Scottish Government. June 2020

[51] Water Management Issues Technical Review. NHS Greater Glasgow and Clyde – Queen Elizabeth University Hospital and Royal Hospital for Children. Health Facilities Scotland. March 2019

[52] Issues summarised in: Potential infection control risks associated with chilled beam technology: experience from a UK hospital. T Inkster, C Peters, H Soulsby. J Hosp Inf, 2020;106:613-616

[53] Scottish Hospitals Inquiry. https://www.hospitalsinquiry.scot

We recognise, therefore, that our work and conclusions are not only informed by the findings of the Independent Review but also will be of relevance to the work of the Scottish Hospitals Inquiry.

The conclusions of the Independent Review record that there were, amongst many other findings, examples of non-compliance in the design of the water and ventilation systems at QEUH. The report also concluded that, at commissioning, there was a lack of documentation to prove the water and air ventilation systems in Royal Hospital for Children (RHC) wards 2A and 2B and QEUH 4B (ultimately to become the location of the adult bone marrow transplant (BMT) service, and currently offering accommodation for the paediatric BMT service whilst the deficits identified in wards 2A and 2B are being rectified) were compliant with specification.

In a succinct summary of the challenges identified with the water system, Drs Fraser and Montgomery wrote that 'the water system of the hospital became, from within one year of admitting patients, the emerging source of infections that entered the blood streams of a substantial number of child patients with haematological cancers. The Health Protection Scotland report (2018)[54] states that they were investigating a 'contaminated water system'; the entire new hospital was affected and, after immediate local action in the vicinity of the affected patients, the remedy became a new system of additional chemical disinfection for the hospital water supply'.

A key statement made in the Executive Summary of the Independent Review, and relevant to the work of our Review, reads as follows:

'Patients, staff and visitors who are vulnerable due to immuno-suppression, or who are in proximity to patients with certain highly infectious communicable diseases, have been exposed to risk that could have been lower if the correct design, build and commissioning had taken place'.

Nevertheless, the two high level findings reported by the Independent Review read as follows:

1. In the course of the Review, through examination of documentation, listening to witnesses, discussion with experts and input from the Review's expert advisers, and site visits, we have not established a sound evidential basis for asserting that avoidable deaths have resulted from failures in the design, build, commissioning or maintenance of the QEUH and RHC.

2. The QEUH and RHC combined 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.

We suggest that these two, more positive conclusions stand in some contrast with the immediately previous statement we have quoted, and with the considerable detail of adverse findings in the hospital environment highlighted elsewhere in the Independent Review. This places the relevance of our work into sharper focus and, whilst we acknowledge that considerable work has been undertaken within NHS GGC to address or mitigate the risk associated with the environmental concerns

[54] Summary of the Incident and Findings of the NHS Greater Glasgow and Clyde: Queen Elizabeth University Hospital/ Royal Hospital for Children water contamination incident and recommendations for NHSScotland. Health protection Scotland. December 2018

described by the Independent Review, we are aware that some staff expressed a view that these concerns remained unresolved even as late as the second part of 2019[55].

This chapter provides our observations on the maintenance of the hospital environment and its microbiological surveillance, and on the inferences we derive for the risk of environmentally acquired infection.

5.2 The built environment and its maintenance

Regular maintenance and repair of the building, its equipment and fixtures and fittings is a normal, and essential, part of the life of any hospital. Nevertheless, the nature and frequency of interventions by Facilities department maintenance staff or other contractors provides the potential for environmentally acquired infection, despite the fact that any work of this nature must be risk assessed and mitigated in compliance with HAI-SCRIBE requirements[56,57]. Furthermore, the nature of any incident they are called to resolve may itself be evidence that a potential source of infection exists in the environment (for example, the risk posed by a blocked sink or shower drain).

We have therefore undertaken a retrospective review of a large database of logs and documents provided by NHS GGC that offered data related to the maintenance of the clinical environment with a particular focus on Wards 2A and 2B and 6A and 4B.

This has not been straightforward. Initially we found it difficult to interrogate the large amount of data related to facilities management because of the way this information was structured and presented. Nor did the initial data submissions from NHS GGC allow us to readily link a maintenance action to a specific clinical location; frequently these initial records identified only the ward and not the individual room. They also did not provide the precise date work was undertaken, more often indicating a range of days between the requisition and the completion of the work. This experience suggested to us that the data systems used within NHS GGC to record facilities maintenance activity are better designed to manage workload than to provide information of potential relevance in the management of clinical situations, particularly IPC events.

Latterly, further work by NHS GGC to clarify the data and reformat its presentation provided a more workable solution to better allow us to investigate links between patients and maintenance activity in their care environment. However, even the later database did not always reflect the location of work undertaken with sufficient detail for the information to be useful. Subject to these constraints, however, we found very few examples where work undertaken in close temporal and physical relationship to the care environment of a patient could be linked to the occurrence of a specific infection, or to potential outbreaks of infection.

Overall, however, it was apparent to us that there were large numbers of requisitions for Estates and Facilities department interventions in the Haematology Oncology

[55] SBAR – Ward 6A environment. Microbiology dept QEUH. 26/8/2019.

[56] Healthcare Associated Infection – System for Controlling Risk in the Built Environment: a system used to identify, manage and record built environment infection control.

[57] SHFN 30 Part B: HAI-SCRIBE Implementation strategy and assessment process. Health Facilities Scotland 2014.

wards and that those relating to plumbing and drainage seemed particularly evident (although we have no suitable comparative data with which to compare these observations). These problems include 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.

We have not been able to ascertain with clarity what planned programme of inspection and preventative maintenance existed or was actually undertaken on a routine basis, particularly with regard to the chilled beam system (outside that suggested as part of actions agreed at IMT).

5.3 Cleaning and Standard Infection Prevention and Control Measures (SICP)

Effective cleaning and IPC practice make a significant contribution to ensuring patient safety within the hospital environment. A cycle of audit and subsequent improvement in practice contributes to the ethos of a learning organisation.

To investigate the potential link between cleaning standards, infection prevention practice and the incidence of bacteraemia, we reviewed the IPC data and the relevant national and local policies commensurate with the time period of our Review.

5.3.1 IPC audits

Infection prevention safe practice in acute care audits looks at a wide range of factors including environment, isolation, equipment, hand hygiene, personal protective equipment, linen, waste and indwelling devices, including intravenous lines. Where suboptimal practice is identified, remedial action should be instigated through a systematic action/implementation plan, work execution and recording of completion.

The National Infection Prevention and Control Manual (NIPCM)[58] specifies standards for infection prevention and control and includes an audit tool for each of the SICP, which should be performed monthly by the Senior Charge Nurse (SCN)[59]. Non-compliance with SICP audits should be resolved locally by the SCN working with their team. On occasion SICP audits may be performed by the IPCT during incidents or outbreaks to ascertain practice against national guidance. Any non-compliance should be recorded and an action plan implemented for improvement. NHS GGC used an audit tool based on the national guidance in place when QEUH/RHC opened.

We reviewed reports of IPC audits and SICP audits undertaken at NHS GGC between 2016 and 2019. These were based on the NHS GGC IPC audit tool as part of a planned audit cycle. SICP audits formed part of an audit cycle that appeared to have commenced in 2017. The overall score from an IPC audit then defines when a

[58] National Infection Prevention and Control Manual. NHSScotland http://www.nipcm.scot.nhs.uk

[59] A National Monitoring Framework to Support Safe and Clean Care Audit Programmes . An Organisational Approach to Prevention of Infection Auditing. NHS National Services Scotland 2018. https://hpspubsrepo.blob.core.windows.net/hps-website/nss/2678/documents/1_national-monitoring-framework.pdf

re-audit is due and the report generates an action plan for any non-compliance or if standards are not met.

We have reviewed the domestic and estates facilities management tool audits made available from 2015 to 2019. All the audits we reviewed demonstrate high compliance to the standards set in the National Cleaning Services Specification[60].

Compliance against an audit resulted in a RAG + Gold rating according to criteria shown in Table 5.1

Table 5.1 RAG + Gold rating criteria for IPC audit

RAG + Gold score	% compliance obtained	Re-audit interval
Red	0-65%	3 months
Amber	66-79%	6 months
Green	80-90%	12 months
Gold	91-100%	12 months

During 2017 IPC audits in ward 2A were undertaken monthly from May to September and then twice monthly in October and December of the same year. We noted that whilst a score may be classified as Gold, the highest rating, some elements may have less satisfactory compliance. For example, an audit might score 91% overall and yet the environment score could be 67% and equipment 75%. The Gold outcome would indicate that a re-audit was not required for 12 months despite there being obvious areas for improvement: in such situations we would expect to see a focused plan for improvement in areas that were not compliant. Significantly the guidance within the NIPCM about audit includes a statement about the use of RAG scores: '…although RAG status can be useful; where it is used there should also be structures in place which weights the risk associated and not necessarily concentrates on the percentage score'.

In 2018, there were monthly audits for Ward 2A (until it closed in September and patients were transferred to Ward 6A). We noted again that an overall Gold rating could be achieved but with some sections (usually environment and equipment) achieving non-compliant scores, demonstrating no sustained improvement. As an overall Gold standard was reached, the next scheduled audit would not have been required for 12 months. This is not indicative of a culture that was thinking carefully enough about quality improvement and we are not convinced that the data shown in Table 5.2 are sufficient to tell the whole story.

[60] NHSScotland National Cleaning Compliance Report Domestic and Estates Cleaning Services Performance 2015/2016. Health Facilities Scotland 2016. https://nhsnss.org/media/4966/1479909664-2015-16-cleaning-monitoring-report-quarter-4-v10-published.pdf

Table 5.2. Summary of overall scores for NHS GGC IPC & Safe Practice in Acute Care audits

Ward	2016	2017	2018	2019
2A	91%	94%	96%	
2B	95%	92%	98%	
6A			95%	96%
4B				94%

There is insufficient evidence from documentation we have reviewed to assure us that the improvement actions were robustly and continuously undertaken and we were unable to ascertain the governance process underpinning action plans.

5.3.2 Enhanced Supervision

A process of Enhanced Supervision was used by NHS GGC to support ward 2A to monitor and drive improvement with IPC. The aim of the supervision was to support staff and provide real time education to the clinical teams. The process involves review of areas such as equipment, cleaning, clinical wash hand basins, PPE and hand hygiene. If standards were not adequate, the issue was referred to the nursing manager for action. It is not clear to us, from the documents we have received, how actions were pursued or how improvement and learning was shared and sustained.

During 2017, there were six such interventions in Ward 2A but the Enhanced Supervision appears to have ended prior to assurance that all the standards had been achieved.

During 2018, Enhanced Supervision was undertaken from March to December (the period from late September relating to Ward 6A) and we observed that standards were often under achieved.

Enhanced Supervision was undertaken again in Ward 6A during 2019, and yet our observations were that the standards were again often not compliant. This leaves us to question whether this approach offered a reliable improvement intervention and we are uncertain where the accountability lay for the assurance it provided in relation to IPC.

5.3.3 Hand Hygiene

Hand hygiene is considered an important practice in reducing the transmission of infectious agents that cause healthcare associated infections. It is one of the core SICPs. Hand hygiene refers not only to hand washing using the established technique but also to the appropriate use of alcohol based hand rubs at point of use. The NIPCM for Scotland has a framework for hand hygiene to support a safe and clean care audit programme. We reviewed hand hygiene audit results undertaken by the NHS GGC hand hygiene coordinators. The information we received for audits between 2015 and 2019 did not appear have a consistent frequency, and it was unclear to us how a lower compliance score triggered an improvement response and re-audit.

The audit is measured as a percentage of opportunities taken for hand hygiene and compliance with correct procedure. It then provides a combined score to give an overall indication of hand hygiene practice. From the data we have seen, it is not

clear how many hand hygiene opportunities were observed for each audit or which staff groups were represented in the audit, although circumstances relating to non-compliance were occasionally described in IMT minutes.

Regarding the use of improvement plans for improving hand hygiene, we saw, for example, that in 2017 there was a programme of ward-based hand hygiene education, but we were unable to link the impact with subsequent improvement in compliance or any effect on the incidence of infection episodes. We also saw data pertaining to Enhanced Supervision of ward 2A during 2017 but only one question related to hand hygiene. Where inconsistencies or non-compliance were observed, the ward manager was informed but we have not been able to identify records of improvement actions.

In addition, data provided by hand hygiene audits were also included as a part of the SICP audit programme. This audit records only a yes/no response and from the data we received we were unable to identify how regular hand hygiene audit was used as a tool to contribute to sustainable improvement in the provision of care.

We would have expected to see more frequent hand hygiene audits in the ward environments, particularly during the periods where continuing concerns regarding the increased occurrence of bacteraemia were under investigation by an IMT. Example 5.1 provides one situation to illustrate our concern:

EXAMPLE 5.1

The minutes of a PAG meeting in early June 2019, called because of 2 recent Stenotrophomonas infections, and 2 further GNE isolates in May that year, document that the last hand hygiene audit on Ward 6A had been held in October 2018 and the last Infection Control audit in November 2018.

The infrequency of these audits seems surprising, as was a statement that enhanced supervision of environmental cleaning was discontinued in April 2019 on the basis that practice observed was of a consistently high standard.

5.3.4 Conclusion

Given the continuing focus on a possible link between bacteraemia (particularly due to GNE bacteria) and the hospital environment and its water supply, we cannot find consistent reference to IPC audits in the IMT process.

The documentation we have reviewed does not assure us there was a robust enough culture of continuous improvement for IPC within the organisation during the period of our Review or that the Enhanced Supervision process for IPC had sustained impact.

We were unable to determine a strong governance and assurance process for IPC and formed a view that the focus of the organisation appeared to be directed more towards the task of audit than to the achievement of quality improvement outcomes.

5.4 Environmental microbiological surveillance

In contrast to water sampling (section 5.5), we recognise that routine microbiological sampling of so called ‘hard surfaces’ offers little to routine IPC practice but we consider it relevant in the investigation of outbreaks of specific or unusual infection providing it is undertaken systematically.

We have had access to a database, provided by GGC, of 'hard surface' samples taken during the period of our Review. This also included samples taken from drains. Initially these data were subject to the same limitations as those for facilities maintenance in that the information supplied frequently failed to link samples to a recognisable clinical location. Later in the Review, reprovision of the data allowed us to investigate links more readily between the location of patient care and environmental microbiology samples. In reality, however, it proved difficult to link environmental samples taken from patient rooms to dates of specific bacteraemia, not least because samples (we had the results for both positive and negative samples) were infrequent and, when taken, seemed not to be taken in a systematic way. It was also often not clear to us which microorganisms had been sought/identified during laboratory processing of samples.

There were, however, occasions when samples requested by the IMT were reported positive for an organism under investigation. A good example of this would be the identification of Enterobacter in drains on ward 6A during a cluster of *Enterobacter* spp. bacteraemias in 2019. Even here, however, positive samples came from different areas of the ward and were not specifically found in the rooms previously occupied by the patients who developed bacteraemia. This does not, in our view, diminish the argument that the environment was the potential likely source but limits our ability to strengthen the observation that it was.

The further specific significance of microbiological typing to consolidate a relationship between isolates from different sources is discussed in Chapter 8, section 8.3.1.

In other IMT records, where actions recorded that environmental samples should be taken, evidence was not always available to confirm that this had been done (and whether this was a single sampling exercise or was repeated) or, if it had been done, the outcome had not been recorded.

Overall, we were unable to conclude that the organisation had a systematic approach to environmental sampling in the context of either a specific, unusual infection or an outbreak of a more commonly seen infection.

5.5 Water safety

5.5.1 Water testing policies and practice

Following increasing evidence relating to outbreaks and incidents of *Pseudomonas aeruginosa* in augmented care units, and notably a cluster of infections in a neonatal unit in Belfast, the Department of Health (England) published 'Water sources and potential *Pseudomonas aeruginosa* contamination of taps and water systems: advice for augmented care units' in 2012. An addendum to Health Technical Memorandum 04-01 was also published in 2013 and superseded the 2012 document[61].

This guidance is concerned with controlling/minimising the risk of morbidity and mortality due to *P. aeruginosa* associated with water outlets. It provides guidance on: assessing the risk to patients when water systems become contaminated with *P. aeruginosa* or other opportunistic pathogens; remedial actions to be taken when water systems are contaminated; protocols for systematic sampling, testing and

[61] https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/140105/Health_Technical_Memorandum_04-01_Addendum.pdf

monitoring of water for *P. aeruginosa*; and forming a Water Safety Group and developing water safety plans. The guidance is aimed at Estates and Facilities departments and IPC teams and is directed towards healthcare organisations providing patient care in augmented care settings. These include patients:

- who are severely immunosuppressed because of disease or treatment: this will include transplant patients and similar heavily immunosuppressed patients during high-risk periods in their therapy;
- cared for in units where organ support is necessary, for example critical care (adult paediatric and neonatal), renal, respiratory (may include cystic fibrosis units) or other intensive care situations; and
- those patients who have extensive breaches in their dermal integrity and require contact with water as part of their continuing care, such as in those units caring for burns.

NHS Scotland did not adopt a similar approach to water testing in augmented care units until 2018[62] and was provided in an addendum from HPS to advice directed at neonatal units and adult and paediatric intensive care units[63].

5.5.2 Water testing at NHS GGC

We set out the summary of the policy above because, whilst the timing of the guidance issued in Scotland means that water systems in Haematology Oncology wards at NHS GGC were not required to be tested for *P. aeruginosa* contamination, there must have been professional and managerial awareness that such guidance was in place elsewhere in the UK. This ought to have further strengthened the need for regular, systematic sampling/testing of water given the emerging concerns over this timeframe about possible environmental sources for paediatric bacteraemias. NHS GGC informed us that they had in fact implemented testing for *P. aeruginosa* in 2016 and we have confirmed this by reference to the risk assessment undertaken for that year. However, we found that their SOP for Minimising the risk of *Pseudomonas aeruginosa* infection from water is confusing: even the 2019 version is still headed 'Applicable in all adult and paediatric intensivecare units and neonatal units' and makes no reference to other high risk areas such as transplant units. This is important as critical control of this issue is not just about water testing but also about flushing regimes and alert surveillance.

The investigation undertaken by HFS[64] and the findings of the Independent Review[65] have each confirmed that there were serious issues about the design and commissioning of the water system. The response of the organisation to the point at which additional whole system chlorination was introduced, suggests that these issues were accepted. Yet we have been told that there was a lack of a robust water

[62] https://hpspubsrepo.blob.core.windows.net/hps-website/nss/1989/documents/3_psuedomonas-water-testing-v1.0.pdf

[63] https://www.hps.scot.nhs.uk/web-resources-container/guidance-for-neonatal-units-nnus-levels-1-2-3-adult-and-paediatric-intensive-care-units-icus-in-scotland-to-minimise-the-risk-of-pseudomonas-aeruginosa-infection-from-water/

[64] Water Management Issues Technical Review. NHS Greater Glasgow and Clyde – Queen Elizabeth University Hospital and Royal Hospital for Children. Health Facilities Scotland. March 2019

[65] Queen Elizabeth University Hospital Review Report. Scottish Government. June 2020

testing strategy from the point at which the new hospital building was commissioned, including assurance that the system was fit for purpose.

From the information with which we have been provided, it has proved difficult to understand the rationale for how water sampling/testing took place, in particular to assure the organisation that water systems/sources were not related to the observed GNE bacteraemias in children. 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/uncommon) GNE bacteria. We are not assured that there was adequate communication about what sampling and testing occurred and the results obtained. We have been told that some key staff involved in IPC at NHS GGC were denied access to water sampling/testing information despite multiple requests. As the concerns increased about whether the bacteraemias occurring in children on the Haematology Oncology wards at NHS GGC might be related to environmental/water contamination, the lack of a clear step change in the organisation's approach to water sampling, testing, reporting and strategy is of concern.

After repeated requests for information on what water system sampling testing took place, we were provided with data that frequently did not specify the precise location from where a sample was obtained, and/or precisely which bacteria were sought and identified in the laboratory. It is possible that water samples were examined to determine only the burdens (total numbers) of bacteria present, without formal identification of the bacteria present; conversely, samples may have been taken to look for specific bacteria (e.g. in relation to bacteraemias caused by uncommon microorganisms). Specific bacteria may have been sought in some samples, but this does not mean that all bacteria present were identified. Also, searching once or only occasionally for specific bacteria, and from only a limited number of sites, limits the confidence that a bacterium of concern was not contaminating a water point/system and thus could have been the source of one or more bacteraemias. Example 5.2 illustrates some of our concerns.

EXAMPLE 5.2

We summarise here the results provided in a file provided to us labelled '2018 Potable Water Master File Complete 13.11.20'.

Despite the electronic title referring to 'potable', the samples were actually taken from a mixture of sources including water tanks, taps and showers. The Excel spreadsheet contains detailed information about the samples (n = 2864), dates, investigations and results. At first glance it appears to represent a comprehensive set of sampling/testing information. However, for over 70% of the listed water samples, Cupriavidus is stated as the target microorganism. As such, there appears to have been limited testing for other bacteria performed on these samples.

The file contains results from multiple locations/buildings but 336 are stated as coming from water sources on Ward 2A. Of note, however, with the exception of 22 (dated during September 2018), almost all the samples were taken during one of two adjacent months (i.e. March or April 2018). For Ward 2B we see a similar time constrained sampling pattern, but for only 27 samples; 16 were in March, 2 in May and 9 in September 2018.

We emphasise that 2018 was a year of heightened concern about the possibility of contamination of water sources.

We conclude that these data do not support a systematic approach to water sampling (i.e. frequent, repeated sample collection) certainly for wards 2A and 2B and in the context of concern regarding possible environmental sources of bacteraemias.

In summary, and crucially, without any other clear account of which water points/systems were/were not sampled, when and how often sampling occurred, and which bacteria were specifically sought, we frequently could not confidently exclude these as potential point sources for bacteraemias caused by GNE bacteria that are known to be associated with such environments.

5.6 The likelihood that infections were linked to the hospital environment

Chapter 3 addresses the methodology utilised for the work of the Panel and section 3.6.6 describes the principles we used in reaching our conclusions about the likelihood of an environmental source for an infection in each episode of infection. That section also describes the cautions and limitations we had to consider in making our decisions. Table 5.3 summarises our overall findings.

Table 5.3: Panel assessment of the likelihood that infection episodes were linked to the hospital environment

Likelihood of a link to the hospital environment	No. of Episodes	Proportion
Unrelated	8	7%
Weak Possible	17	14%
Possible	55	47%
Strong Possible	4	3%
Probable	30	25%
Strong Probable	3	3%
Definite	0	0%
Unable to Determine	1	1%
Total	**118**	**100%**

Whilst we classified 8 episodes as being unrelated to the hospital environment, and 1 we were unable to determine, of the rest of the episodes (n=109), 76 (70%) fell into the Possible group and 33(30%) into the Probable group.

Our decisions reflected our judgements based on the balance of probability when considering all the data we had available. They also reflect the complexity of drawing such distinctions in a population of patients who, by the nature of their diagnoses and treatments, are susceptible to serious infection. Many of these infections can arise both from endogenous (within the patient him/herself) and exogenous (from the external environment) sources. Exogenous sources include not only the environment of the hospital but also all environments encountered by the patient outside the hospital.

The lack of any episodes being classified as Definite[66] reflects the tight criteria, agreed before we started our Review, that were required to achieve this descriptor. Decisions at this level were also influenced by the inconsistency with which our investigation and evaluation could be informed by data systematically investigating the microbiological environment (section 5.4), the water system (section 5.5.2), and the likelihood that, by using typing methodologies, different bacterial isolates were linked (Chapter 8, section 8.3). Microbiological information alone was insufficient for us to reach our conclusions and we also looked carefully at clinically relevant information. Above all, the complexity of the challenge we faced was in the retrospective acquisition of adequately informative data.

The distinction between classification as 'Strong Possible' and 'Probable' was often relatively subtle, as was that between 'Probable' and 'Strong Probable', and by linking these three categories we believe we can reasonably create a group of infections with the closest likelihood of a link to the hospital environment ('Most likely' to be associated with the hospital environment). In total, these three groups constituted 37 (34%) of those designated as either possibly or probably related (and accounted for 31% of the whole series). Table 5.4 describes the profile of bacteria encountered in this 'Most likely' group of episodes, compared to that of all other episodes.

Table 5.4 Microbiological profile of infections in the group 'Most likely' to have been associated with the environment vs the rest

Organism	**Seen in 'Strong Possible', 'Probable' & 'Strong Probable' groups** **'Most Likely' (n = 37 episodes)**	**Seen in all other episodes** **(n = 81)**
Stenotrophomonas spp	14	7
Klebsiella spp	10	18
Enterobacter spp	7	18
Pseudomonas spp	4	13
Acinetobacter spp	3	7
Cupriavidus spp	2	0
Serratia spp	1	6
Elizabethkingia spp	1	5
Chryseobacterium spp	1	4
Mycobacterium chelonae	1	3
Other	0	21
TOTAL	**44[1]**	**103[2]**

[1]6 and [2]14 episodes were polymicrobial (i.e. they involved more than one bacteria)

[66] Although NHS GGC told us that they had been able to link one of the three cases of Mycobacterium chelonae in our Review to the environment (see also section 8.3.1), we have not seen the confirmatory data and, without which, we have not classified the case as Definite.

There is a striking excess of *Stenotrophomonas* spp. in the ‘Most likely’ group which is significant (Chi square test 14.80; $p<0.05$) but differences in the frequency of all other bacteria are less obvious. Other characteristics of the ‘Most likely group’ are discussed in Chapter 6.

We also looked at the frequency with which we identified episodes as ‘Most likely’ in relation to the year of infection. We did this in case there might have been a shift in the amount of data available to us over the era of the Review. We found that there was a substantially greater proportion of ‘Most likely’ episodes in 2018 but concluded that this probably reflected the fact that most isolates of Stenotrophomonas (11/21) occurred in that year.

In closing this chapter, we offer one further observation. Whilst we are not reassured about the adequacy of the systems in place to monitor the environment during the period of our Review, and believe that about one third of the episodes we reviewed were ‘Most likely’ linked to the hospital environment, we suggest NHS GGC must also have recognised that some links with the environment were likely to exist. Acting with the support of external advisers, they introduced significant interventions and control measures and it is difficult to consider the actions they took – such as the closing of Wards 2A and 2B (with relocation of services to Ward 6A and 4B); the addition of point of use filters for water outlets; augmented chlorination of the entire water supply; and additional decontamination of the healthcare environment - would have all taken place, primarily to address public confidence (important though that would be), if there was not also some acceptance of environmental risk.

6. THE IMPACT OF INFECTION ON PATIENT OUTCOMES

6.1 Background

Our ToR charged us with defining: a) how many children were affected by GNE bacterial infection (addressed in Chapter 4); b) whether it is possible to associate these infections with the environment of the QEUH/RHC (Chapter 5); and c) was there an impact on care and outcomes in relation to infection? This chapter addresses this third question.

The findings described in this chapter will also inform the final question asked of us: d) what recommendations should be considered by NHS GGC and, where appropriate, by NHS Scotland more generally to address the issues arising from these incidents to strengthen infection prevention and control in future? Our overall recommendations are given in Chapter 10.

The approach we took towards defining and assessing the impact of infection is described in Chapter 3, section 3.6.7. We address issues relating to aspects of clinical care in section 6.2: these are the principal items that contributed to the scoring framework we used to assess the impact of the infection. In section 6.3 we will discuss information about the 22 children known to have died by the time of the publication of this report. Our approach to the collection and grading of adverse events is described in section 6.4 and in section 6.5, we try to bring these various themes together in a narrative summary of impact.

The themes raised by families in their submission to the Panel are dealt with in Chapter 7.

6.2 Items relating to aspects of clinical care

Details of the specific items identified in this section were sought in the data collection process and included the Data Synthesis files created to inform Panel review (as described in section 3.6). The data in this section are presented in two ways, first for all episodes in the Review (correcting the numbers for those which were not evaluable); and second, comparing the episodes we considered ‘Most likely’ to have been linked to the hospital environment with the remaining episodes (as described in section 5.6).

6.2.1 Overall impact

We have described the approach taken to agree an overall impact score for each infection episode (section 3.6.7). The distribution of these scores for evaluable episodes of infection is summarised in Table 6.1 which presents the data both as the impact grade used for the panel review and as the equivalent NHS Scotland Risk Assessment Matrix score.

Table 6.1. Overall impact grade allocated in each episode of infection

Panel Impact Grade	NHSS Risk Assessment Matrix score	Whole Group (No. evaluable = 115)	Most Likely linked (No. evaluable = 36)	Least Likely linked (No. evaluable = 79)
None	1. Negligible	1 (1%)	0 (0%)	1 (1%)
Minor	2. Minor	5 (4%)	1 (3%)	4 (5%)
Significant	3. Moderate	65 (56%)	21 (58%)	44 (56%)
Severe	4. Major	40 (35%)	12 (33%)	28 (35%)
Critical	5. Extreme	4 (3%)	2 (6%)	2 (2%)
*Non evaluable		3	1	2

*Three patients were not evaluable for an overall impact grade because of the circumstances of their admission and complications of their disease.

6.2.2 Length of hospitalisation

We requested data for the duration of the whole admission during which each infection episode took place and/or was treated. We also collected details of all antibiotics used and the duration of antibiotic treatment. It became clear to us, however, that whilst the duration of the entire admission and/or the duration of antibiotic treatment was easiest to define, the best measure of the overall impact (burden) of the infection was the length of an inpatient admission that could, as far as it was possible to assess, be attributed to the treatment of the infection. Making this distinction was not always easy: in many patients, the duration of admission was extended either because of other toxicities, including other infections, or because the patient stayed in hospital to continue or restart treatment. In others, antibiotics were continued for several days (and occasionally significantly longer) after the patient had been discharged from inpatient care. However, by considering the details collected from the case notes to inform the patient's clinical timeline, we found it was generally possible to make a reasonable assessment of the length of an admission that could be accounted for principally because of the occurrence of the GNE infection (Table 6.2).

Table 6.2 Length of hospital stay attributed to the infection

Duration	Whole Group (No. evaluable = 115)	Most Likely linked (No. evaluable = 36)	Least Likely linked (No. evaluable = 79)
1-7 days	15 (13%)	9 (25%)	6 (8%)
8-14 days	43 (37%)	11 (30%)	32 (40%)
15+ days	57 (50%)	16 (44%)	41 (52%)
Not evaluable	3	1	2

6.2.3 Removal of the central venous line

Patients with indwelling venous access devices (lines and ports) are especially susceptible to blood stream infections. It is frequently necessary to remove the device in order to eradicate a blood stream infection although there are often good clinical justifications to try to 'salvage' the line (or port) with antibiotic treatment in order to facilitate continuing care in a challenging clinical situation. This may be

possible by extending antibiotic treatment and by using antibiotic 'locks' (instillation of a high concentration of an antibiotic into the catheter lumen, and allowing it to remain for a period of time), but may also be associated with risk if the strategy fails.

The removal of a central line in a child almost always requires a short anaesthetic and, under most circumstances, a replacement line will be required once the infection has been treated. This contributes a degree of further risk and an added logistical challenge to the delivery of care.

The data we collected are summarised in Table 6.3.

Table 6.3 Infection episodes requiring removal of the central line

CVL removed?	Whole Group (No. evaluable = 115)	Most Likely linked (No. evaluable = 36)	Least Likely linked (No. evaluable = 79)
Yes	78 (68%)	26 (72%)	52 (66%)
No	37 (32%)	10 (27%)	27 (34%)
No CVL in situ	2	1	1
Not evaluable	1	0	1

6.2.4 Admission for Intensive Care

Bacteraemia of any kind can result in severe illness, but many GNE bacteria can be virulent pathogens (with the potential for endotoxic shock) which may cause rapid clinical deterioration and risk of death. Admission to PICU is therefore an important measure of the severity of infection and its impact on the patient.

All infections which merit admission to PICU are serious but there are occasions when patients who might sometimes be managed satisfactorily in the normal ward environment are admitted to PICU because of the opportunity for closer and more intensive monitoring and, perhaps, short term life support. There are others whose deterioration is more profound and who may require prolonged support. Empirically, we therefore divided admissions to PICU into two groups - those of up to 3 days and those with longer stays - as a way of trying to reflect this distinction (Table 6.4). We also recognised that some patients required PICU support for other problems at the time of the bacteraemia but not, in our judgement, specifically because of the bacteraemia.

Table 6.4 Admission to PICU

PICU admission at the time of the bacteraemia	Whole Group (No. evaluable = 114)	Most Likely linked (No. evaluable = 37)	Least Likely linked (No. evaluable = 77)
Yes, for 1- 3 days	9 (8%)	6 (16%)	3 (4%)
Yes, for >3 days	3 (3%)	2 (5%)	1 (1%)
No	102 (89%)	29 (78%)	73 (95%)
Yes, unrelated to infection	3	0	3
Not evaluable	1	0	1

6.2.5 Cancer treatment disruption

Children and young people with cancer are most often treated with a predefined plan (protocol) for treatment which is shaped by the details of their diagnosis and is based on the outcome of prior experience of the same condition or by a clinical trial. These

protocols represent an ‘intent to treat’ strategy which incorporate combinations of different elements of therapy (chiefly chemotherapy and/or radiation therapy and/or surgery according to diagnosis). This is delivered according to a schedule that has either been achieved in the past with defined results, or represents an ambition based on preliminary or pilot data but may still be under evaluation in a current trial. The reality, however, is that many patients are not able to adhere to the intended plan at some or other stage in their treatment, with the result that therapy has to be paused or modified, or both.

The circumstances leading to a decision to pause or modify treatment will vary but generally these relate to the extent to which the patient already manifests side effects from the therapy delivered to date. This includes, for example: the severity of bone marrow suppression with consequent low blood counts; infection; nutritional deterioration; other organ toxicity (e.g. liver or kidney function problems); and the psychological state of the patient and/or family. The oncologist treating the patient continually monitors these factors and must judge whether, and when, a pause in treatment is required, and if treatment needs to be modified in the future (for example, reduction or omission of a planned chemotherapy dose or the deferral of the start of a course of radiation therapy). This constitutes the ‘art’ as well as the ‘science’ of oncology care. Clinical trial protocols, however, usually include rules that set out whether, when and how treatment should to be modified in relation to specific toxicities.

It is to be expected that most parents and clinicians would agree that adherence to the intended treatment protocol leads to a better chance for long term disease control and cure. However, there are remarkably few peer reviewed publications that explore the impact of treatment adjustment and treatment delay on outcome. From an entirely pragmatic perspective, minor (up to one week) delays in treatment are common in practice and there is no evidence that this makes a material difference to outcome. Longer delays are, however, sometimes necessary and whilst the impact is also uncertain, this is more undesirable and would generally be avoided if circumstances permit. It is also generally the case that avoiding delay in the early phase of treatment after a new or recurrent diagnosis is more important than at later stages in treatment.

In order to explore the impact of infection on the continuity of cancer treatment, we tried to define, from the clinical records, the extent to which treatment was disrupted specifically in relation to the GNE infection. We looked principally for evidence that chemotherapy had been delayed on the basis of the infection although this was not always clear and often compounded by the fact that, for example, blood count recovery was insufficient to allow chemotherapy to proceed with safety. Complexity in attributing a causal effect is compounded when one considers that whilst infection may itself contribute to delayed bone marrow recovery, this can also happen without infection.

It was more difficult to identify where drug doses had been subsequently modified but dose reduction as a result of an infection is less likely to be required in the short term than a delay in re-starting treatment. We also recognised that not all patients were receiving chemotherapy at the time of their infection and we therefore also looked for evidence that other elements of treatment had been deferred. The data in Table 6.5 represent our best estimates of all types of treatment delay.

Table 6.5. Delay to treatment attributed to the infection

Duration of delay	Whole Group (No. evaluable = 101)	Most Likely linked (No. evaluable = 32)	Least Likely linked (No. evaluable = 69)
None	53 (53%)	18 (56%)	35 (50%)
1 - 7 days	19 (19%)	6 (19%)	13 (19%)
8 – 14 days	17 (17%)	5 (16%)	12 (17%)
15+ days	12 (12%)	3 (9%)	9 (13%)
Not evaluable*	17	5	12

*9 episodes of infection were experienced by patients with non-malignant diagnoses for whom we did not attempt to determine the impact of the infection on treatment; 3 patients were not evaluable because the data were insufficient; 3 were excluded because treatment was delayed by other toxicities and we were unable to separate the specific impact of the infection; treatment was discontinued after infection in 1 patient because of concurrent evidence of progressive disease; and in 1 patient treatment had already been completed after stem cell transplantation.

6.3 Details of the children and young people who have died

At the time of the publication of this report, we were aware of the deaths of 22 patients (6 male and 16 female) who had been included in our Review.

Dates of their death ranged from November 2016 to January 2021. The primary diagnoses were: Solid Tumour (n=7); Leukaemia (6); CNS Tumour (6); Lymphoma (2); and non-malignant condition (1).

Median age at death was 6 years 6 months with a range from 1 year 8 months to 16 years 3 months. The median interval from the last GNE infection episode to the date of death was 10 months (range 1 day to 3 years 8 months).

Three patients died within 28 days of a GNE infection episode. Two of these died from tumour related causes and their deaths were not linked to the prior infection; in one of these cases we decided that the preceding infection was Unrelated to the hospital environment and in the other that it was Probably related to the hospital environment.

The third child in this early post infection group died in PICU 6 days after the last positive culture was taken. This occurred in the very early phase of a stem cell transplant undertaken in the context of rapidly progressive disease. Although disease progression was a major factor, we judged that the GNE bacteraemia was a significant factor in the cause of death and noted that sepsis was also identified as the principal cause of death on the death certificate issued by NHS GGC. We determined that this bacteraemia infection was Probably related to the hospital environment.

One further child, whose infection we had similarly determined was Probably linked to the hospital environment, also died relatively early (within 6 weeks) of the infection episode. Death occurred in PICU 36 days after the last positive culture. There were a number of other serious contributory factors but we judged that the GNE bacteraemia was implicated in the cause of death; this was also recorded as a possible contributory factor on the death certificate issued by NHS GGC.

Overall, death certificate information was obtained for 19 of the 22 patients – it was unavailable in one because the patient had died abroad and in the other two because there was insufficient time from the notification of death to the completion of this report.

In summary, based on death certificates and clinical information, we decided that infection was implicated as a cause of death in 2 patients (discussed above) whilst; 19 had died of their underlying disease (all cancer) and 1 died from other causes unrelated to infection.

6.4 Adverse Events

The approach we took to the detection of Adverse Events (AE) by the use of the PTT and interrogation of the Datix system at NHS GGC is described in chapter 3, section 3.4.

6.4.1 PTT data

In addition to the 115[67] GNE bacteraemias occurring in the 83 patients eligible for the PTT analysis (all of which were defined as an AE), the PTT review separately identified 386 other AE. Of these 24 (5%) were classified as Category I[68,] according to the National Framework[69] (discussed in section 3.4.4) and occurred in 17 (14%) of the 117 episodes.

All unplanned admissions to PICU were classified as Category I AE and occurred in 16 episodes[70], accounting for 67% of all Category I AE. Moreover, 7 of the remaining Category I events occurred in 2 of the same 16 episodes. The only Category I event to be recorded in an infection episode with no PICU admission occurred in a patient who was resuscitated for sepsis on the ward but whose condition stabilised sufficiently to avoid PICU admission. These data suggest that admission to PICU is an obvious way of identifying patients with the greatest risk of the most serious category of AE for audit and review.

[67] Of the total of 118 episodes evaluated in the Review, 3 were excluded from the count of bacteraemias: one involved sepsis with Pseudomonas aeruginosa which was isolated from other sites but not from blood cultures; a second involved a culture proven disseminated infection with Mycobacterium chelonae but without positive blood cultures; and a third patient was excluded as although this patient had a gram negative environmental bacteraemia, this was detected and managed at another hospital after previously attending NHS GGC.

[68] Category I events are those that may have contributed to or resulted in permanent harm, for example unexpected death, intervention required to sustain life, severe financial loss (£>1m), ongoing national adverse publicity. These are likely to be graded as major or extreme impact on NHSScotland risk assessment matrix, or Category G, H or I on National Coordinating Council for Medical Error Reporting and Prevention (NCC MERP) index.

[69] Healthcare Improvement Scotland. Learning from adverse events through reporting and review. A national framework for Scotland: December 2019 2019: http://www.healthcareimprovementscotland.org/our_work/governance_and_assurance/management_of_adverse_events/national_framework.aspx

[70] 12 PICU admissions for infection related AE; 4 for AE unrelated to infection; and 3 with PICU admissions that were not classified as AE.

There were 362 Category II[71] AE of which 78 (22%) related to removal of the central line.

Overall, of the 501 AEs detected by the PTT, only one fifth (91 (18%)) were unrelated to management of the infections. Six of these were Category I – four of the admissions to PICU, one pulmonary embolus and one case of pressure ulcers.

We recognise that some of the triggers identified by the PTT relate to expected complications of chemotherapy or represent support measures commonly required by this group of patients. Nevertheless, the use of the PTT could provide a useful audit tool to monitor trends in the occurrence of AE that occur during care.

6.4.2 Datix system data

In total, 174 incidents were recorded in Datix in 65 (76%) of the 84 patients included in the Review (collected during the period of review) with a median of 2 (range, 1-6) incidents per patient. In 23 of these patients a total of 31 Datix reports were made during an admission that incorporated one or more episodes of Gram-negative environmental infection. The other 143 Datix reports were made during admissions that occurred either before (n=84) or after (n=59) the admissions with infection episodes.

Of the total 501 AEs detected with the PTT, only 6 (1%) were reported in Datix, which included 2 (8%) of the 24 Category I AEs. One of these patients had severe sepsis and died in PICU; this was correctly classified in Datix as Category I (Extreme). The second patient had a PICU admission for toxic megacolon due to *C difficile*, but this was incorrectly scored as Moderate (Category II – should have been Category I) on Datix.

The 6 AE common to both systems included 2 incidents that were categorised as infection control in Datix: septic shock associated with GNE bacteraemia and the *C difficile* infection (mentioned above). The other 4 incidents common to both systems were pressure ulcers, bacterial contamination of infused donor bone marrow cells, and 2 pain control incidents.

The 23 patients with Datix reports made during an admission that incorporated one or more episodes of Gram-negative environmental infection had a total of 36 incidents. However, 9 (29%) of these were recorded as Negligible risk, i.e. Category III[72] incidents that were not associated with harm, whereas the PTT review only included Category I and II incidents. However, one of the Datix incidents that was graded as Negligible risk was one of the two deaths we identified as being associated with infection. The reason given in Datix for reporting this death was (correctly) that it had occurred within seven days of receiving donor stem cells. Whether or not the stem cell transplant *per se* contributed to death is not the issue we raise; it is rather that, as the incident was an unexpected death, this should have been reported as Category I.

[71] Category II events are those that may have contributed to or resulted in temporary harm, for example initial or prolonged treatment, intervention or monitoring required, temporary loss of service, significant financial loss, adverse local publicity. These are likely to be graded as minor or moderate impact on NHSScotland risk assessment matrix, or Category E or F on NCC MERP index

[72] Category III events are those that had the potential to cause harm but no harm occurred, for example near miss events (by either chance or intervention) or low impact events where an error occurred, but no harm resulted. These are likely to be graded as minor or negligible on NHSScotland risk matrix or Category A, B, C or D on NCC MERP index

In addition to the Extreme incident (Category I - death in PICU), there was only one other incident reported in Datix as Major in any of these patients throughout the period of the Review, and this was unrelated to an infection episode.

Of the total of 174 Datix incidents, 124 (71%) were classified as Minor or Negligible. Only 5 of the total 174 incidents were coded as relating to infection control for the entire period of the Review, and only 2 of these were documented as such during an infection episode. However, some Datix reports that were classified as 'Other' clearly described an infection control incident (e.g. bacterial contamination of donor stem cells) and should have been coded as such.

We concluded that Datix reporting significantly underestimated the number of AE experienced by this group of patients and that, even when reported, some incidents were incorrectly classified and under scored in terms of their severity.

6.5 Summary

In this chapter we have tried to set out measures of the burden of the GNE infections experienced by the patients we have reviewed. Our data provides an insight into the overall experience of children and young people with cancer (these were, in the great majority, children and young people with leukaemia and other forms of cancer) who experience such infections.

In the course of our review, we used selected clinical indices to express our overall assessment of the impact of an infection episode on the patient (section 3.6.7). In so doing, we identified that over one third (38%) had experienced an overall severe or critical impact and only 5% of the whole group experienced no or minor impact.

Whilst accepting the limitations on our ability to define the length of hospital admission directly attributable to infection, our estimate suggests that additional hospitalisation of 15 days or more was required in approximately half of the episodes reviewed.

Removal of a central line was required in two thirds of these episodes for the management of the infection, which implies that, in almost all those patients, a further anaesthetic and surgical procedure would have been required to insert a replacement.

Twelve patients (11%) required admission to PICU specifically for the consequences of their infection although admissions were short (1-3 days) in the majority of cases.

Finally, infection is an important reason for treatment to be disrupted in this clinical context and we estimated that approximately 30% of episodes were associated with a delay in planned treatment of over 1 week, and in 12% for over 2 weeks.

Tables 6.1 to 6.5 also analyse the data according to two groups: those with the GNE infections we determined were 'More likely' to have been acquired from the hospital environment (defined in section 5.6) and those for whom we did not find strong evidence for an association (labelled as 'Less likely').

There is, in fact, little difference between the two groups except for the frequency with which patients were admitted to PICU: 8/37 in the 'More likely' group *vs* 4/77 in the 'Less likely' group. This difference is significant (Relative Risk 4.16 (95% CI 1.34–12.94)) and whilst it may be unwise to speculate too much on a single variable in an analysis of this kind, variation in the type and pathogenicity of organisms contributing to these two groups may be the relevant factor. Table 5.4 shows that

there was a significant excess of *Stenotrophomonas* spp. in the ‘More likely’ group of infection episodes. This may be relevant and, perhaps, a predictive factor for greater risk of severe illness.

GNE was implicated in the deaths of 2 of the 22 patients known to have died; this was the primary cause of death in one and an important contributory factor in the second. Both were infected with *Stenotrophomonas maltophilia*.

The use of the PTT identified that 5% of 501 AE identified in the whole population included in the Review were Category 1 events (classified as Major or Extreme in the NHS Scotland risk assessment matrix). Comparison of PTT data with Datix incident reporting suggests that the NHS GGC reporting system had significantly underestimated the true extent of such events and, where reported, may underestimate their severity.

Finally, we recognise that nothing analysed in this chapter measures the broader implications of infection on the lives of the children and young people affected, and their families. Unplanned or prolonged admission, or both, will contribute to the already significant impact they experience in their lives. It further disrupts schooling, social life, parental work, and the care of siblings or dependent relatives. It contributes to additional anxiety both because families are well aware that infection is a risk, can be serious and may be life threatening; and because families are anxious about the consequences of delays to treatment.

We have been able to characterise part of the physical impact of infection but wish to emphasise that the emotional, social, financial and psychological costs can also be significant.

7. COMMUNICATION WITH THE FAMILIES

7.1 Overview

At the heart of this report lies our responsibility to the children and young people who experienced the GNE infections included in our review, and to their families. Throughout the Review we have tried to address the ToR with which we were charged as fully and accurately as we have been able, with the information provided to us. We have also recognised our responsibility to keep families informed about the Review and its progress. In order to do so, the following principles were adopted:

1. Clarity about the purpose of, and eligibility for the Review – this was addressed by an initial communication sent on 4th March 2020 to all families from Professor Fiona McQueen, CNO, and Professor Marion Bain, Director of IPC NHS GGC and Senior Medical Consultant, NHS National Services Scotland (now Deputy Chief Medical Officer), setting out the criteria for inclusion in the review and its ToR.
2. A commitment to regular progress reporting – this has been undertaken in collaboration with Professor Craig White (Communications and Engagement Lead, Scottish Government) and Professor John Cuddihy (Patient and Family Representative for the Case Note Review and the QEUH/NHS GGC Oversight Board) with whom meetings have been held regularly (as shown in Appendix A) during the review process, and through whom we provided written updates to the families in July, October and December 2020.
3. The opportunity for families to submit written comments to us in relation to their own child was made clear at the outset and was reiterated in subsequent progress updates; a summary of the responses we received is shared in section 7.2.

In line with our ToR, we have given an undertaking that, in addition to this overview report, we will provide an individualised report for each patient/family describing our assessment of the infection episode(s) experienced. Our plans for doing this are set out in section 7.3.

In our previous communications with families, we have made two important points. First, given that we have had to make judgements on retrospectively acquired data, we have used the principle of the 'balance of probability' in reaching our conclusions. This means that, based on the evidence available to us, our conclusion about an event is more likely to apply than not. Second, that our report will not include the case details of individual patients in a way that would readily allow them to be identified by others.

7.2 Information received from families about the Case Note review

All information and updates to and from families has so far been coordinated through NHS GGC. Communications from families were received by NHS GGC in the first instance, and then passed on to us via Professor Craig White for consideration in the Review.

Of the 86 patients initially identified as eligible for inclusion in our review, NHS GGC received communication from one family requesting that their child be excluded: we undertook no consideration of the clinical circumstances of this case.

A further 9 written communications were passed on to us for consideration. One raised specific concerns relating to nursing care which was considered out of scope but we will acknowledge and explain this in the individual report to that family; 1 requested a copy of their child's medical notes from NHS GGC and a copy of any reports about their child; (this is outwith our remit); and 7 included specific concerns relating to their child's infection.

The main themes addressed by these 7 communications can be summarised as follows (note that some families raised several points and the number of families addressing each theme is given in brackets):

- lack of clear communication about the nature of the infection(s) (6)
- questions raised about medication prescribed for and/or to prevent infection(s) (3)
- describing the impact the infection had had on their child/themselves, including delay in treatment (3)
- concern about the length of time before the central venous line was removed (1)
- concern about the timing and interpretation of microbiological typing results from the reference laboratory (1)

We intend to respond to these points as fully as we can in our individual written reports to the families concerned.

7.3 Individual Reporting to Families

After the publication of this report, we will prepare individual written reports for each of the infection episodes included in our review for every patient. These will summarise our findings in line with the framework to which we worked during the review process (section 3.6).

We view these as private reports from the Panel to the patient and family concerned. The Review Team will therefore take responsibility for distributing the reports having first worked with NHS GGC to ascertain up to date contact details and communication preferences for the patients and families concerned, and to confirm the updated status of all patients.

The process by which this will be effected has been the subject of discussions between ourselves, representatives of NHS GGC, Professor White and Professor Cuddihy. It is agreed that families will receive written information about the process approximately 4 weeks before the reports are distributed. This will explain the timescale and offer the opportunity for patients and families to meet with members of the Panel after receiving their report, if they wish to do so. They will also receive information about the support available to them should they find the details of the report distressing or if it raises other concerns about their treatment experience and its consequences. We will ensure that those families who have been bereaved by the death of their child will be able to access appropriate support.

Whilst we believe that the individual report should be 'owned' by the patient/family, we also believe it is appropriate, subject to the consent of the patient/family, that a copy of the report is made available to the clinical team who was, or may still be

responsible for the care of each patient. The opportunity to share the report with the relevant clinical team will be set out in the advance letter to the families.

When we send families their reports, we will also send an information sheet and consent form requesting consent to share the report with the relevant clinical team. Families will then be able to contact the Review Team to make an appointment for a meeting with the Panel should they wish to do so.

To further facilitate direct contact with the Review Team, a specific electronic mailbox has been set up and will be in operation prior to the distribution of individual patient reports. It will be manned until the process is complete. A contact telephone number will also be provided for families to use if preferred.

A written summary of the meeting held with a family will not be prepared but families will be able to bring an additional person with them to the meeting to act as a supporter who may, if wished, also keep notes for the family during the discussion. Any agreed action points that emerge from the discussion will however be documented and shared in writing with the family after the meeting. This will include an indication of how and by when it is hoped these can be addressed.

We will treat the proceedings of the meetings as confidential and we will not share the content of the discussion with any other person or organisation unless specifically requested and agreed by the family.

At the completion of the process, the dates of all meetings held with families will be notified to the Oversight Board, NHS GGC and Scottish Government. This will indicate that the Case Note Review is complete.

8. AREAS OF CONCERN

In this chapter we bring together issues encountered in the course of our Review that have caused us concern or otherwise wish to comment. We have separately identified examples of the good practice we observed which we discuss in chapter 9.

We address concerns about data availability and its quality in section 8.1 and offer a detailed analysis of our observations about the management, investigation and reporting of infection outbreaks in section 8.2: this is the longest section in this chapter and, we believe, provides a context against which the previous recognition and investigation of GNE bacteraemia within NHS GGC can be viewed. Section 8.3 looks at microbiology and IPC information systems and includes some important observations about how data relating bacterial typing were collated and stored. Section 8.4 addresses issues about clinical records and section 8.5 looks in more detail at Adverse Event reporting. Sections 8.6–8.8 address selected aspects of clinical practice.

Some of these observations create opportunities for changes to policy and practice, and all, we believe, offer learning for the future.

8.1 Data Availability and Data Quality

The concurrence of the COVID-19 pandemic with the period of the Review created additional challenges both for NHS GGC and for the Review Team, with pressures on staff resource and the necessity to work remotely. There were, nevertheless, areas in which NHS GGC's response to the Panel's need for access to data was unsatisfactory and where we encountered difficulties in its presentation.

8.1.1 Access to NHS GGC information systems

In March 2020, an Information Sharing Agreement (ISA) was approved between Scottish Government and NHS GGC as the designated data controllers for the project. This provided permissions for individuals named on the agreement to access specified NHS GGC IT systems, and set out the principles governing the use of the information obtained from those systems. A process was established whereby any amendments required to the ISA would be raised with Scottish Government and with NHS GGC Information Governance by email and subsequently submitted to the NHS GGC Caldicott Guardian for approval.

As resource assigned to the Review, particularly in relation to IPC expertise, had been re-directed to COVID-19 related work, changes to those contributing to the Review Team became inevitable, requiring amendment of the ISA. The response time from making such requests to NHS GGC Information Governance to receipt of approval was often slow. It became common that repeated emails were required to generate a response. One example was a request to add an individual to the ISA on 23 October 2020 which, despite twice chasing for a response and escalating the matter to a member of the NHS GGC Senior Executive Team, was not approved until 9 November 2020. Given the time constraint under which the Review Team was working, this caused delay to planned work.

Finally, there were several instances when the access of all members of the Review Team who had access to NHS GGC IT systems was unexpectedly suspended. For example, on 4 September 2020 the Review Team requested account extensions beyond the existing agreement to the end of that month. Despite this, all accounts

were still suspended on 30 September 2020. This caused delays in retrieving the information required for us to carry out the review.

8.1.2 Environmental Microbiology and Facilities Maintenance Work data

By April 2020, the Review Team had identified the need for additional data which were not available from the access already granted to the clinical records. We needed to be able to consider environmental data for the QEUH/RHC buildings; NHS GGC was asked to supply results relating to environmental microbiology sampling and the records of facilities department maintenance work for the duration of our review. We have discussed the significance of such records in Chapter 5, specifically, sections 5.2, 5.4 and 5.5; notably, we needed data that could be related in time and place to the locations of care of the patients within the review. We initially requested 'all environmental microbiology sampling results that are available' in an email on 7 April 2020. Thereafter difficulties were encountered over the supply and quality of these data.

The first merged data were received on 11 May 2020 were for water samples only; we later discovered drain samples were not included. We found that the data appeared to be incomplete and inconsistent. For example, a large number of samples listed in the database provided were recorded to have 'No DMA[73] Record' and, for samples that had such a record, either no sample location was provided or it was identified only at the level of the ward and not by the patient room or other designated location.

In line with our initial request, the facilities maintenance data provided to us first came as HAI-SCRIBE[74] records. We subsequently recognised that our requirements would be better addressed by focusing on the work actually carried out in the Paediatric Haematology Oncology wards, and not on the HAI-SCRIBE risk assessments. Further communication with staff in NHS GGC Estates and Facilities provided these data on 1 June 2020 but with similarly limited location information which did not permit us to relate, for example, the visit of a plumber to Ward 2A to deal with a blocked drain, to any specific room or drain.

During June-September 2020, further attempts were made to communicate with NHS GGC to discuss the data received, its incompleteness and the lack of location identification, as well as to clarify additional data the Panel would require for review.

At a meeting on 1 October 2020 we began to understand for the first time that NHS GGC did not have data available in the form we needed or, it seemed in one place. Consequently, NHS GGC had to undertake significant work to generate an appropriate data set from source records. At the beginning of December 2020, as we were coming to the end of our initial review process, we received what we now believe to be the complete records available for water samples, environmental 'hard surface' samples (which included the drain samples) and maintenance data.

[73] DMA was the private contractor employed by NHS GGC to undertake water sampling

[74] Healthcare Associated Infection – System for Controlling Risk in the Built Environment: a system used to identify, manage and record built environment infection control.

This delay, and others regarding our access to the laboratory information systems (section 8.1.3), necessitated us to undertake a second complete review of the entire series of infection episodes so as to incorporate this additional information.

8.1.3 Laboratory information systems

In Chapter 3, section 3.5, we have discussed the relevance of our access to both the Telepath and ICNet systems. Although access to ICNet was agreed in the ISA in March 2020, by August 2020 it had become evident that we had no access to the system. When exploring this with the NHS GGC IPC Team, we were initially advised that we would not require direct access and that any information could be requested from them as required. We rejected this suggestion and escalated the matter to senior members of the NHS GGC Executive Team who rapidly resolved the issue. In the meantime, however, the IPC Team provided us with extracts from ICNet for five patients scheduled for imminent Panel review. Our review of these extracts suggested that, in four of the five cases, potentially relevant information was lacking but we were unable to ascertain if this was because it was not available or had not been included – emphasising our need for direct access to the system itself.

It was only at this time that we became aware of the Telepath system. Initially, we received copies of entries in its Patient Note Pad function from NHS GGC. This part of the system records information relevant to our review as it documents the dialogue between microbiology and clinical staff and provides information about, for example, the identification and antibiotic sensitivity profile of the organism concerned; the advice given about the type and duration of treatment; and the necessity (or otherwise) to remove a central line. Our initial request to be provided with material recorded in Telepath within a period of 1 month either side of the date of an infection episode proved unsatisfactory as a wider perspective seemed likely to be helpful. We also recognised that we would benefit from independent IPC expertise to interrogate both this and ICNet.

By late September 2020, we had identified the IPC resources required to support our work and made arrangements via NHS GGC Information Governance for access to both systems. However, the access level set in Telepath provided limited functionality; this meant that it was not possible to copy or download information from the system, requiring data to be transcribed into a separate Word document for us to use in our review.

These issues contributed to impede and delay our ability to assess and integrate relevant information into our case note reviews.

8.1.4 IMT and PAG meeting records

In assessing causation in relation to specific infection episodes, we began to look for data utilised in NHS GGC's internal processes for investigating and responding to infections in real time. We requested, and from September 2020 began to receive, minutes from PAG and IMT meetings. The relevance and agreed process for implementing such meetings is defined in NHS GGC's SOP for Outbreaks/Incidents in hospitals.

We initially noted that, for some of the 2018 IMT minutes, environmental microbiology sample results were given with details of sample location. This prompted us to undertake an exercise to cross check some of the sample results found in IMT minutes against the data we had received. An example of the inconsistency we encountered is shown as Example 8.1:

EXAMPLE 8.1

"Subsequently, the colonised patient and one of the cases were nursed sequentially in Room 12, which is the only room with water results positive for Stenotrophomonas." **(IMT Minute, 23 March 2018)**

Our investigation of the environmental water sample results received from NHS GGC in May 2020, showed that a water sample positive for Stenotrophomonas could be identified, but no sample location was recorded.

This experience challenged our confidence about how records of data utilised in IMT meetings were located and stored. We began to reflect whether, on the basis of what we had seen, NHS GGC had systems in place to ensure comprehensive reporting and recording of data relevant to the IMT process.

We reassured ourselves that the quality of the environmental microbiology sampling data received in December 2020 had improved by undertaking a further cross checking exercise from which, for example, the sample results highlighted in Example 8.1, shown above, could now be identified. Unfortunately, inconsistent coding characterised this final data set and made it difficult for Data Managers to present the data in a usable and searchable format for the Panel to review. Substantial further manual checking and data cleaning were required before this could be achieved, resulting in an additional delay at a point when we were under considerable pressure to complete our second round of reviews.

8.2 Managing, investigating and reporting infection outbreaks

We examined the notes of investigations into outbreaks of infection undertaken by NHS GGC, to help our consideration of the likelihood of a hospital environmental source for the Gram-negative environmental infections under our review.

The process used for investigating a possible outbreak of infection is outlined in NHS GGC's SOP for Outbreaks of Communicable or Alert Organisms in Healthcare Premises. This advises on the safe systems and processes required to identify and manage a potential outbreak/cluster of infections, and for convening a formal investigation into an increase in infections that can be linked by time, place and person: we make some observations about the SOP in section 8.2.1. In section 8.2.2. we look at evidence for compliance with the process.

In section 8.2.3 we provide our own critique of the HPS 2019 report. This is relevant as it addressed the recognition of outbreaks and provided guidance for future monitoring.

8.2.1 Recognising and Investigating an Outbreak: the NHS GGC Standard Operating Procedure

Our understanding of the process is that, once the possibility of an infection incident has been raised, a member of the IPCT should make an initial assessment; criteria are given in the SOP to guide the calling of a PAG[75] to further assess the situation. The framework mandated for use in the initial risk assessment is the Healthcare Infection Incident Assessment Tool (HIIAT). Whether or not the HIIAT is formally recorded at the earlier stage, the practice we have seen at NHS GGC has been for it

[75] The PAG was added to the process as part of the update to the NHS GGC Outbreak SOP in 2019

to be completed (or confirmed) and documented once a PAG meeting has been convened.

The SOP also provides guidance for the institution of an IMT (Incident Management Team) which serves to further assess and manage the situation. Once the process is complete, a final report (in the form of a 'Hot Debrief' or a full IMT report) should be prepared by the IMT chair, agreed by the members and escalated up the organisation by a defined reporting pathway. Once the IMT process is complete and the report approved by its members, the SOP states that the incident should be reported on Datix.

We have reviewed the sequential SOPs during the era of our review (versions 2015, 2017, 2019) as well as that released in 2020. The SOP appears to be commensurate with the guidance published in the NIPCM[76].

The main changes to the 2017 version of the SOP included an update to organisational roles and responsibilities, as described in recommendation 16 of the Vale of Leven Hospital Enquiry[77], and the addition of a recommended agenda template from Chapter 3 of the NIPCM.

The SOP was further updated in October 2019. This update occurred at the end of the period of our review but incorporated reference to an Acting Chief Nursing Officer publication earlier in 2019[78] which reiterated guidance on ensuring robust communication with patients and their families during infection incidents and outbreaks. This revision also expanded the documentation required, stating that each meeting 'will have an action log and a data collection tool presented at each meeting. Each agenda item will be listed in the action log and must document the discussion and rationale for each decision made. It is not enough to record actions; the relative risks and options and why the final decision was made must also be part of the documentation of the event (Civil Contingencies Act 2004)'. Whilst we saw this as welcome step to strengthen future responses to outbreaks of infection, the previous versions of the SOP had nevertheless indicated a requirement for minutes to be kept and actions to be recorded and justified.

8.2.2 Compliance with the process

We reviewed PAG and IMT documentation between 2016 and 2019 to assess the recognition, analysis, and action taken in relation to the GNE infection episodes included in our Review; and for evidence of compliance with the SOP.

8.2.2.1 Triggering an investigation**.** PAG and IMT reports covering incidents between 2016 and 2019 (no such documentation was available for 2015) identified the investigation of infections (relevant to our Review) caused by Stenotrophomonas, Cupriavidus and Enterobacter, whilst some IMTs were convened to address a more general increase in Gram-negative bacteraemia. Not all outbreaks which may appear relevant retrospectively were investigated at the time, and not all incidents/outbreaks progressed to IMT status.

[76] National Infection Prevention and Control Manual. NHSScotland http://www.nipcm.scot.nhs.uk

[77] The Vale of Leven Hospital Inquiry Report. November 2014.

[78] HAI-related incidents, outbreak/incidents and data exceedance: Assessment, and reporting requirements and communication expectations. ACNO February 2019.

The NHS GGC SOP defines outbreaks/incidents in line with the NIPCM. This defines a healthcare associated infection outbreak as:

- two or more linked cases with the same infectious agent associated with the same healthcare setting over a specified time period; or
- a higher than expected number of cases of HAI in a given healthcare area over a specified time period.

We note that the NHS GGC SOP does not define the term HAI which we have seen used both to mean Hospital Acquired Infection and Healthcare Associated Infection. This may be important as distinctions between the two[79] sometimes appear in the PAG/IMT records in the discussion of the significance of a reported bacteraemia. It is clear to us that the utility of the distinction offered by these two definitions is less informative in a clinical setting where, in addition to inpatient episodes, patients are attending for day care or outpatient appointments at the very high frequency seen in this patient group.

We also read accounts of discussions at IMTs where analyses prepared by different individuals were used to confirm or refute the reality of an increase in GNE infection over the period of our review.

We have reservations about the reliability of SPC charts used in this setting (although GGC followed a process as recommended by HPS). First because it is necessary to establish a prior baseline and it can be argued that the use of data for the incidence of GNE infections when the hospital was located at Yorkhill merely swaps one environmental baseline for another. Neither are we sure this is the most reliable approach when dealing with small numbers of incidents – and we note that the HPS 2019 report also advises caution in using this methodology with small numbers. We therefore also found it helpful to look at simple timelines to identify possible clusters of individual GNE bacteraemias, particularly those reported to be of the same genus/species (section 4.3). Example 8.2 provides a context for this point.

EXAMPLE 8.2

There was no investigation into an increasing number of Klebsiella bacteraemias encountered between 2016 and 2018. Whilst Klebsiella bacteraemia is not infrequently seen in this patient population, and may be endogenously as well as environmentally acquired, we would have expected the evidence apparent to us for an increasing number of infections, to have triggered a formal investigative process.

Section 4.3.3 of our Report points out that, of 22[80] Klebsiella infections identified in the Review, 9 episodes (affecting 8 patients) were noted from June to November 2016; 9 (7 patients) between July and December 2017; and 5 episodes (5 patients) between January and May 2018.

[79] The definitions used in the Protocol agreed for the Case Note Review were: Hospital associated infection (HAI) – positive blood culture in a patient who has been hospitalised for at least 48 hours and Healthcare associated infection (HCAI) – positive blood culture in patient within 48 hours of admission but who has had specified healthcare contact or intervention in the prior 30 days. In the event, we did not find this distinction useful in our review.

[80] Note that the numbers of Klebsiella isolates exceed the number of patients because some episodes were polymicrobial.

We would have expected the number of infections to have attracted greater attention within NHS GGC at the time. We were informed by NHS GGC that *Klebsiella* spp. had been added to the list of alert organisms in 2018 but neither of the 2 Klebsiella infections seen in 2019 had had a case created on ICNet, raising concern that the alert was not active.

We perceive that part of the problem confronting NHS GGC was a relatively small number (small in relation to the overall IPC workload) of patients presented with unusual infections and our concern is that opportunities to instigate early investigation may have been missed because of too great an emphasis on 'standard' definitions for an outbreak.

8.2.2.2 Appropriate investigation and recording of action taken. Retrospective review of the records we received for the period within our Review did not always provide clarity that the governance and assurance required to establish an outbreak had been appropriately investigated and subsequently managed appropriately.

Root Cause Analysis (RCA) methodology was only agreed as the basis for future IMT investigation in late 2019 and applied prospectively in two patients in our Review. We have seen the template subsequently created to support RCA for bacteraemias in Haematology Oncology patients. This includes many of the data items we had identified as necessary for our own investigation. The template (appropriately, we believe) goes beyond the HPS Outbreak/Incident Data Collection Tool provided as an appendix to the NHS GGC outbreak SOP.

We found it surprising that a requirement (or even a recommendation) for the use of a structured process in line with the RCA approach does not feature in the 2019 SOP. It is difficult to understand why, given the experience of repeated GNE infection over a period of five years, this would not have been introduced earlier or more generally. We are, however, also aware that recommendations for use of a more detailed approach to the investigation of infection using RCA methodology do not feature in the NICPM[81].

We identified a consistent concern that action logs from individual IMT meetings were either not systematically created, or if they had been, were only rarely apparent to us. These were not routinely referenced within the minutes of the IMT meetings or provided to us separately. We could not identify a clear and contemporaneous record of all outbreak management actions to span the entire timeline of an IMT investigation.

We found several examples, particularly in earlier IMT meetings, where actions were not assigned, reviewed or recorded as completed or, if completed, there was any form of assurance that the actions had been sustained. Where logs were provided, we saw that some had outstanding actions for which we could find no closure. Overall, however, this improved in the incidents we reviewed from later in 2018 and 2019.

Example 8.3 illustrates a range of our concerns about: delay in escalating concerns identified at a PAG meeting to a full IMT; underestimation of HIIAT score; lack of documentation about follow through of actions agreed; failure to link to the wider context i.e. that two PAG meetings on the same day were addressing fundamentally

[81] http://www.nipcm.scot.nhs.uk

the same problem of increased GNE infection; and the premature discontinuation of planned IMT meetings.

EXAMPLE 8.3

Between 28.4.2018 and 20.8.2018, 8 isolates of *Enterobacter cloacae* were identified in 7 patients (one was infected twice) and including 2 isolates in separate patients on the same day.

A PAG was convened on 18.5.2018 (at this stage there had been 4 cases in 16 days). Only one patient had symptoms consistent with gut translocation and the minutes of the PAG meeting record concerns about cleanliness, 'clutter' in patient rooms and too many people on the ward. The latest hand hygiene combined compliance score was 85%. Surprisingly, the HIIAT only scored minor/moderate (Amber).

A separate PAG was held on the same day to discuss simultaneous concern about an increased incidence of *Stenotrophomonas* spp. isolates but no cross reference was made in the records of the two meetings and a separate HIIAT also scored Amber.

An IMT was not held until 29.5.2018 after a 5th isolate of *Enterobacter* spp. bacteraemia. The minutes record that various actions in relation to cleaning were to be implemented and a plan was made to sample drains. The HIATT score remained Amber and no further meetings were planned 'unless further isolates'.

There are further examples in 2018 where the IMT was closed or stood down despite continuing outstanding actions and with no clear process in place to continue to monitor the situation or measure the impact of interventions made.

We could find no evaluation in the IMT minutes of recommendations implemented that impacted the risk of infection to patients; for example, the installation of point of use water filters to taps and linking these to the results of water testing. This is illustrated in Example 8.4 which follows the continuing evolution of the *Enterobacter cloacae* outbreak already identified in Example 8.3 above.

EXAMPLE 8.4

Despite the suspension of the IMT on 29.5.18, it was appropriately reinstated on 4.6.18 after swabs from drains on Ward 2A were shown to have grown a range of Gram-negative bacteria including *Enterobacter cloacae, Pseudomonas aeruginosa, Sphingomonas* spp*., Cupriavidus pauculus, Acinetobacter ursingii* and *Klebsiella oxytoca*. It was concluded that the recent *Enterobacter* spp. bacteraemias were associated with the contaminated drains.

The actions taken at this time included drain cleaning and Actichlor (chlorine containing disinfectant) treatment; filters on taps; and antibiotic prophylaxis for all children/young people with a central venous line.

Surprisingly, however, the IMT was discontinued again after meeting on 21.6.18 despite ongoing actions and did not meet again until 5.9.18 notwithstanding two further isolates of *Enterobacter cloacae* in July and August.

Although the parallel water review group continued to meet during this time, these meetings did not summarise the clinical situation, directly address patient management or record evaluation of the impact of interventions.

8.2.2.3 Adequacy of IMT meeting records. In reviewing IMT meeting minutes, we did not receive any supplementary appendices or microbiology reports that would have been necessary to have influenced critical recommendations. For example, we would have expected water and other environmental microbiology results to have been shared at IMT meetings in a format that allowed link to patient location, and for IPC audit reports to have been referenced and utilised in the decision-making process and risk assessments.

We pursued the issue of documentation for the IMT process in discussions with NHS GGC. Ultimately, we concluded that the records relating to each IMT meeting do not consist of a comprehensive written collation of all the information that may have been considered and/or shared at the meeting. It seems that certain pieces of information (for example, data relating to environmental microbiology results or bacterial typing) may be brought to the IMT by different individuals and are not stored centrally in the Infection Control Shared Drive as we had envisaged. We acknowledge that whilst such data may have been both shared and discussed, there is a limited audit trail of the evidence used to support conclusions made or action taken.

IMT minutes were not always easy to understand in retrospect: patients may not have been identified in a way that allowed them to be tracked across a series of meetings; staff were not always identified by their role, making it difficult to see if the attendance was appropriate in terms of relevant expertise; the structure of the documents varied and the style was sometimes informal. A short, written assessment of an IMT record dating from July 2019 and taken from our own records of a Panel meeting, is shown in Example 8.5.

EXAMPLE 8.5

(This case was) Not specifically identified at IMT meetings, and minutes are not precise; for example (IMT) on 3.7.2019 identifies 6 Gram-negative bacteraemias in Ward 6A but these isolates are not dated or named and minutes go on to state *"All Gram-negative bacteraemia have unique strains. This rules out cross transmission between staff/patients but not from water/drains which has tested positive for the organisms".* No detail of samples/results from water or drains is given.

These IMT minutes include a statement about the implications of typing results which does not seem correct and our comments illustrate the difficulty we had in linking IMT records to individual patients and to investigations undertaken.

In respect of investigations, we found it difficult to understand how requests for environmental samples were consistently agreed, implemented and reported to inform IMT discussions.

Example 8.5 (above) suggests that the IMT did not record results of environmental samples taken yet we know that this meeting referred to at least one of a series of 8 isolates of *Enterobacter cloacae* that occurred in 7 patients from 15.1.19 to 31.12.19. We have also ascertained from the data we received that there are no records to show any 'hard surface' (including drain) samples were positive for *Enterobacter* spp. in 2019. Water samples positive for *Enterobacter* spp. in the same period were identified from an anaesthetic kitchen and basement water tank on 27.3.2019 and from toilets in 3 patient rooms in Ward 6A on 24.6.2019. 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. This possible connection was not documented in the IMT minutes.

8.2.2.4 Upward reporting from IMT meetings. We have seen no 'Hot Debrief' or full reports at the close of a series of IMT meetings relating to cases included in the review despite this being mandated in the GGC outbreak SOP. Examples of such documents have however been provided to us from IMTs in other clinical areas within NHS GGC, raising questions about consistency in practice across the organisation.

The SOP also indicates that these reports should be signed off by members of the IMT and sent to the Acute Infection Control Committee from which upward reporting to the NHS GGC Board is expected. There is little or no documented evidence that IMT members were asked to approve such reports.

Whilst it is evident from NHS GGC Board papers that reports about the problems encountered within Wards 2A/B, and subsequently 6A, were provided at Executive level, we are concerned that the significance and scale of what was happening may not have been adequately expressed. Example 8.6, describes a HAIRT (Healthcare Associated Infection Reporting Template) report made to the NHS GGC Board at the first meeting held following the death of a child after GNE bacteraemia[82].

EXAMPLE 8.6

"*Two cases of …..bacteraemia were identified over an 8- day period….. A Problem Assessment Group (PAG) was held ….. HPS were notified and a Healthcare Incident Infection and Outbreak Reporting Template (HIIORT) was completed. No further cases were identified and the two cases were later confirmed to be different types"*.

We do not understand why it was important for the Board to hear that there had been two infections, that they had been appropriately reported and that they were considered to be of different types but not to be told that one of the children had died. We have since been told by NHS GGC that these infections and the death were reported as far as the Board Infection Control Committee but that, as the Board is a public meeting, there was a need to ensure awareness of infections but no requirement to discuss individual patient details (for patient confidentiality and Data Protection reasons). However, we note that the occurrence of another bacteraemia, caused by the same organism, earlier in the same year, following which the child also died, was not reported to the Board. It is not clear to us what was or was not expected to be reported to the Board. We conclude this shows an inconsistency in the process and purpose of reporting and may represent an organisational culture which promotes a focus on process (i.e. that a report was received) rather than being clear what the cause or consequences were.

8.2.2.5 Clinician concern. We noted that the there are occasions when the minutes record that clinicians present at an IMT meeting directly questioned if the environmental risks had been reported to senior management within NHS GGC (this was mainly in 2018 and 2019 and while there is an unsubstantiated suggestion that this could also have been in 2017, the Panel have not seen written evidence for this). It was interesting for us to hear, at a meeting with RHC clinicians in February 2020, the IMT process described as 'lacking integration and fails to recognise patterns'. This simple statement reflects the overall impression of the Panel.

[82] Dates and some detail of the infections have been omitted from this quote to protect patient identity

8.2.3 Review of NHS GGC Paediatric Haemato-oncology data (HPS October 2019)[83]

The context for the report is that, having supported NHS GGC in dealing with cases of blood stream infection in patients in Wards 2A and 2B, associated with concerns about the contaminated water supply in 2018, HPS were asked to assist when concerns emerged about a suspected increase in Gram-negative environmental (GNE) bacteraemias in patients on Ward 6A during the summer of 2019.

We had not intended to provide a critique of this report as we saw it as one of a number of previous investigations, the results of which should not influence our own. However, its significance loomed large in our discussions with NHS GGC and we have therefore added this short section summarising our view of the reports findings.

The aims of the report were to describe any differences in the datasets being used to explore the situation; to review the GNE infections; and to identify if there had been a change. The principal methodology used was the creation of Statistical Process Control (SPC) charts which were used to explore the data collected from July 2013, before the move of patients to the new site at QEUH/RHC, until September 2019. Changes in hospital activity data for the Paediatric Haematology Oncology service were explored in parallel and, finally, comparisons were made between data for the whole of RHC, for the period June 2015 to September 2019, with similar data for the Royal Hospital for Sick Children, Edinburgh and Royal Aberdeen Children's Hospital.

In summary, the report identified periods at which there were upward shifts, trigger points (above the Upper Warning Limit) and outliers (above the Upper Control Limit) in the SPC plots of bacteraemia identified since the move to the new hospital. Overall, however, patterns showed no consistent trend. There were also differences between NHS GGC and the data from Edinburgh and Aberdeen. This showed higher rates for environmental with enteric bacteria over the whole time period at NHS GGC, but lower rates for Gram-positves and no difference for Gram-negatives and environmentals alone. Various subgroup analyses showed no consistent message.

As far as we are able to ascertain from our own assessment of the data presented in the report, we agree: a) that the dataset used was providing an accurate reflection of the situation at NHS GGC; b) that there were episodes of variation in the SPC data (the latest occurring in September 2019) but that this alone did not provide clarity about its cause or significance; and c) that the caution expressed about small numbers in the analysis of some subsets of the data, is justified.

We do not see that this report would have provided any clear message of either reassurance or concern about past events. Nor do we see that it offered a clearly interpretable and favourable comparison with other Scottish children's hospitals (not least because the size of the paediatric haematology oncology services in these three hospitals varies very substantially – NHS GGC being easily the largest).

From our perspective, the most useful output of the HPS report lies in the clarity of its recommendations for the future, some of which align with our own. We would particularly emphasise the points made that, going forward, interpretation of these data requires the systematic collection of clinical data; must be set in an

[83] Review of NHS GGC Paediatric Haemato-oncology data. Health Protection Scotland. October 2019

environmental context; and requires continual monitoring. NHS GGC accepted the need for the ongoing monitoring.

8.3 Microbiology and IPC information systems

We have already discussed issues over our access to the Telepath and ICNet systems (section 8.1.3). In this section we discuss the constraints encountered in using the systems and focus on two particular issues: the challenges we experienced in accessing and interpreting data on bacterial typing; and the concerns we identified about the alert system used for ICNet.

8.3.1 Telepath and Bacterial Typing

The Telepath LIMS is used across all laboratories within NHS GGC. The system provides listings of all microbiological samples, detailing the laboratory processing and results for these, in addition to a Patient Note Pad (PNP) option for a given patient, which allows microbiologists to record free text information related to any positive isolates/infection episodes of key interest (which typically includes isolates from sterile sites, including blood cultures). The PNP is also used to record information obtained from communications with ward based clinical teams, and any advice provided to these.

We found that the PNP generally provided very good evidence of frequent engagement and information sharing between the microbiology and ward based clinical teams, including recommendations for choice and duration of antibiotic treatment, based on laboratory derived susceptibility testing, and associated infection management (for example, removal of sites of infection such as intravascular catheters), and follow on diagnostic sampling/testing. This information was helpful to us in understanding more about the nature of the infections we reviewed and their management.

Notably, however, the Telepath system did not systematically offer the basis for recording the results of typing bacterial isolates (mainly derived from reports provided by the Public Health England reference laboratory at Colindale, London but some data also from the Scottish Microbiology Reference Laboratories), either by annotating the original specimen results page or within a patient's results at a later date (when the typing information was received).

We found that typing results were also not routinely entered into the PNP, although some results were referenced and, where so, the results were most frequently reported as 'unique'. Some were also referenced with the statement that a full report could be found on the Clinical Portal (the electronic clinical patient records system). We were able to access the typing results on the Clinical Portal, but these reports were similarly vague, reporting isolates as 'unique' but without any crucial context of which bacterial strains it had been compared with (what strains, their origin and how many other strains?).

Discussion with NHS GGC about bacterial typing revealed that, hitherto, there had been no electronic database of typing results. Generally, results from PHE Colindale had been received as pdf documents which were filed as such, either in paper form or, more recently, electronically. Consequently, the organisation had no ability to search a database in order to relate potentially linked bacteria whether these came from a patient or the environment. Useful linkage searches would involve several items of data about the bacterial isolate: the date it was obtained, the patient sample

or environmental site from which it derived, and the physical location within the hospital environment from which it was obtained.

This is precisely what we had hoped we might have been able to achieve to support our Review and we were surprised that, despite over five years of experience with outbreaks of GNE bacteraemia and concerns about the hospital environment, a database with this functionality had not been created by the time the Case Note Review had been commissioned. It appeared from our discussions with NHS GGC that work had commenced but a considerable amount of work was needed for staff to collate information held in different systems in order to provide us with the data we requested.

Most of these data were not received by us until December 2020. Databases identifying bacterial typing by year from 2015-2019 were supplemented by additional data relating to more sophisticated analyses using Whole Genome Sequencing (WGS) methodology in specific types of bacteria. The year-related databases were very large and appeared to include all typing done within NHS GGC for that year, i.e. for patients of all ages, at all clinical sites and involving many different clinical samples other than blood cultures. It was not clear, even in 2019, that all isolates from patients within our Review had been typed but, in general terms, we were not able to ascertain evidence of a direct links between bacterial isolates obtained from children in our review and other specimens.

However, the number of environmental samples in these databases were limited. For example, the 2019 database (being the database we assumed would be most likely to be complete) listed almost 550 samples but included only 6 water samples, of which 3 could not be typed. There were approximately 140 other samples from environmental sites but none had complete location information rendering it impossible to relate to sites of patient care.

WGS is the state of the art fingerprinting method for the comparison of microorganisms. Its strength lies in its ability to help determine how closely microorganisms are linked. However, the interpretation of WGS derived data in linking bacterial isolates has significant challenges given the way the genetic code evolves/mutates. Differences between microorganisms can be measured as SNPs (Single Nucleotide Polymorphisms) each representing an individual DNA building block. There is a risk that defining difference by an absolute number of SNPs (for example, by saying anything more than a 25 SNPs difference is not significant when comparing two samples of the same bacteria isolated from different patients/places) may result in an oversimplification. It is likely that bacteria found in environmental locations may exist as multiple types and it may best to say that whilst the demonstration of a close relationship between a patient specimen and an environmental isolate of the same bacteria is strongly indicative of a relationship, the reverse does not necessarily apply.

The WGS was carried on three groups of isolates: *Enterobacter* spp., *Stenotrophomonas* spp. and *Cupriavidus* spp..

The *Enterobacter* spp. (n=42) comprised 36 clinical/patient isolates and 6 environmental isolates. However, isolates from 5 of the children with *Enterobacter* spp. bacteraemia were not included. Similarly, the records of water and surface sampling show a total of 25 *Enterobacter* spp. isolates during the review period, and thus approximately three-quarters of these were not included in the WGS exercise.

The *Stenotrophomonas* spp. (n=84) included n=15 isolates from patients in our Review, 10 from other patients and 59 environmental strains, 11 of which were from 2020. Five children in our series with *Stenotrophomonas* spp. bacteraemia were not included.

There were 263 isolates of *Cupriavidus* spp. from water or surface sampling in the review period but only 18 samples were included in this exercise. As far as being informative for the Case Note Review, this included one patient from Ward 2A with a sample dated 25.2.18 (which doesn't match the date of infection for either of the patients with Cupriavidus in the CNR) and 7 environmental samples from ward 6A taken on three dates 18.11.2019, 7.1.2020, 14.1.2020. This is far from an adequate sample to exclude an environmental source.

NHS GGC told us that it was possible to definitively link the environment to infection in only two patients; firstly, in 2016 when *Cupriavidus* spp. was identified in the Aseptic Dispensing Unit[84], and secondly a case of *Mycobacterium chelonae* included in our Review. However, we concluded from our investigations (above) that there are too many gaps in terms of which isolates were included (alongside the inconsistent environmental sampling – Chapter 5) to be able to interpret the true extent of relatedness between patient and environmental isolates from these WGS results.

8.4.2 ICNet and IPC Alerts

The ICNet system relies on data being exported from Telepath at regular intervals. If a microorganism is identified as one of a pre-defined list of 'alert' microorganisms, it will automatically create a 'case'. This case will alert the IPC Nurse/Team responsible for that hospital site, who will then review the situation, ascertain if there is an infection risk to the clinical area or patient population and advise on the appropriate care for that patient.

The IPCN is then required to complete a question set, which will determine if the infection is hospital acquired for the purposes of local surveillance. The questions also confirm what written information should be provided for the alert microorganism such as care plans, care bundles or patient information leaflets. Following the initial assessment, the IPCN has the opportunity to close the case if no infection risk is identified, or to keep the case open to monitor the patient's condition until they are discharged or no longer an infection transmission risk. There is a patient notes function within the ICNet system, which allows IPCNs to record any communication with the clinical team or microbiologists. NHS GGC/IPCT policy is that patients with open ICNet cases should be reviewed weekly as a minimum.

The NIPCM provides a nationally agreed minimum list of alert organisms/conditions; this informs NHS Boards of those alert organisms/conditions that may require further investigation. The guidance states 'The list is not exhaustive and specialist units, for example those managing patients with cystic fibrosis, will also be guided by local policy regarding other alert microorganisms not included within these lists.'

As part of our review, we assessed information provided to us from ICNet and identified whether cases were created or not. We found little evidence, even as late as summer 2019, that the GGC alert list had been modified in light of the evolving experience with bacteraemias caused by Gram-negative environmental infections. This resulted in frequent absence of alerts being triggered within ICNet and the

[84] This patient was not included in our review

subsequent absence of IPCN input into cases under our review. Example 8.7 provides brief details of two different situations.

EXAMPLE 8.7

a) In late July 2019, a patient presented with an *Enterobacter cloacae* bacteraemia.

This was the seventh isolate of this organism in the Paediatric Haematology Oncology population in 6 months. An IMT had been initiated in May because of concerns about the frequency of this type of bacteraemia (see also Example 8.2) but no alert was raised in ICNet for this next case despite the previous experience. Why?

Although NHS GGC told us that Enterobacter had been added to the alert list in 2018. However, we reviewed 8 episodes of Enterobacter spp. bacteraemia in 2019 and none had an alert created in ICNet. This suggests that the alert was not active.

b) In late September 2019, a patient presented with bacteraemia associated with *Achromobacter* spp. which is a particularly unusual bacterium.

In this case, however, an alert was triggered on ICNet, not because of the specific nature of the bacterium, but because the system had by then been adjusted to trigger an alert should two or more positive blood cultures be reported on Ward 6A within 14 days.

This coincided with a period of great concern about the safety of Ward 6A and limitations being placed on admissions. Why was this change not implemented previously?

We have heard that requests from some microbiologists for the list of microorganisms on the ICNet alert list to be augmented were not heeded.

We understand, however, that when cases are not identified by alerts in ICNet, there is still capacity within the system for IPCNs to manually create a case for any patient - if they are alerted to the identification of a microorganism of concern. We have been told that some microbiologists did make direct contact with IPCNs to alert them in this way and under certain circumstances, but we have also seen evidence that Infection Control management within NHS GGC sought to discourage this. This seems entirely inappropriate as it would have excluded the IPC nurses from the management of some GNE infections at NHS GGC, which, at the very least, would have limited wider awareness of the problem.

Overall, however, our observations suggest to us that the communication between microbiologists, the infection control doctor and IPC nursing team is not as robust or systematic as it should be. The teams often appear to work independently and communication between these staff groups appears to occur on an adhoc basis: referral of patients with alert organisms on the basis of an automated electronic process (where it happens) is not direct communication.

8.4 Clinical records

This commentary is based on the experience of reviewing the health care records for 83 patients with 117 episodes of infection[85]. It highlights the challenges we

[85] Records were not reviewed for one patient as the bacteraemia was identified and managed at another hospital after day case attendance at NHS GGC.

experienced in extracting relevant information from the case records, focusing particularly on inpatient medical records.

8.4.1 The Clinical Portal

The Clinical Portal is the web-based application that presents patient clinical data from various NHS clinical systems. It is widely accessed by a range of medical, nursing, AHP and administration staff, as well as by GPs and other Health Professionals, and has largely replaced paper-based case records at most NHS Scotland locations.

In general, the review team found that the medical and nursing care for each patient was identifiable in the Clinical Portal, and was recorded routinely and reliably on a day to day basis. The challenge, however, was locating the specific information required as there are wide variations in the way that parts of the clinical record are scanned into and filed within the Clinical Portal.

Daily recordings of In-patient medical care were found in 3 different areas in the Portal:

- written and scanned in a sub section tab of Clinical Notes detailed as “In-patient Medical Notes”
- embedded in the “Nursing Assessment” tabs on a generic continuation sheets continuous with the nursing records and not necessarily recorded as a medical record of care
- digitally recorded in the “Clinical Notes”

Nursing care is reliably recorded and stored in the nursing assessment tabs. These records are exemplary with dated, signed entries of the elements of care recorded. In particular, standardised elements of care (for example CEWS[86] and CVC/PVC bundle[87] care) are reliably recorded in the dedicated record segments.

Medications are recorded in a wide range of documents/places within the medical and nursing records in narrative form when administered or considered for change as instructed by medical staff.

All laboratory results are reliably entered into the associated test carried out under the separate laboratory headings.

When a procedure was undertaken, such as the insertion or removal of a central line, the information was usually recorded in dedicated records for “Interventions” under the sub tabs of “Anaesthetics” and “Operation Notes”. In some cases, the records for the same procedure were not dated correctly or signed. Mentions of the procedures/interventions are also recorded in the medical and nursing records.

Admission and Transfer information was embedded in the nursing and medical records and in the “Patient Notes” sections. Transfers of care within the hospital system are difficult to identify, as Medical PICU admission and discharge summaries were often scanned and embedded within nursing notes within the Nursing

[86] Children’s Early Warning Score. This identifies paediatric patients at risk for clinical deterioration.

[87] A ‘Bundle’ is a structured way of improving processes of care and patient outcomes; in this context in relation to central and peripheral venous catheters

Assessment section; and not all patients had an immediate discharge or final discharge letter prepared and stored.

It was challenging to find all components of the records, although knowledge and frequent use of the system enabled easier navigation of the anomalies. Some records were scanned in long sections, representing one document with a variety of records within. Some records were scanned in with dates many months or years after discharge. Scanned records for each episode did not necessarily have the correct care episode date. Scanned pages within the records, particularly for patients with extended in-patient stays and/or multiple episodes of care were often the most problematic. We found that many cases had pages of the records scanned in reverse order and had multiple admission episodes within the same scanned document, and not necessarily in date/time order.

8.4.2 Inpatient Medical Records

We focused on an analysis of in-patient medical records - both the scanned hand written records and the digital notes - as these related directly to the management of the bacteraemia.

1.4.2.1Scanned Hand Written Notes. For the 117 infection episodes, we found completed written notes for 76 (65%), incomplete notes for 22 (19%) and no written notes for 19 (16%). Only 60% of the written notes were filed under the date of discharge; others were filed up to 14 months after the date of discharge.

Standards varied to a considerable extent. One patient, who experienced multiple episodes of GNE infection, had 906 pages of hand written notes covering 418 days of admission, which were complete, in order and with no irrelevant information. In contrast, another patient had 139 pages of hand written notes covering care after a GNE bacteraemia, but many of the pages were undated or were not filed in chronological order; the notes commenced one week after the bacteraemia and contained very few details regarding the clinical management of the bacteraemia itself. However, further hand written medical notes with critical information about bacteraemia management, including discussions with parents, were found filed in the nursing records.

8.4.2.2 Digital Notes. Digital medical records may be filed in three separate areas within Clinical Notes - Generic Continuation, Patient Notes and Pharma Care Plan. When filed under Generic Continuation, notes were not linked to specific admissions and contained diverse inpatient and outpatient records from a range of clinical disciplines and specialties. When Generic Continuation records were labelled Paediatrics, we found those to contain digital inpatient medical notes. These were detailed and fully electronic, which enabled word searching but might cover several admissions.

Patient Notes were labelled by medical (e.g. Haematology) or AHP (e.g. Dietetics) specialty. Most Patient Notes were outpatient contacts covering a clinic appointment, home visit or telephone call. However, there were some notes about inpatient contacts.

Pharma Care Plan notes are stored within a standardised care plan exclusively recording information about medicines.

We found digital notes (to any degree) for a minority (37%) of episodes. There was no trend to show the increasing use of digital records over time suggesting that there was no planned evolution to full digital record keeping over the period of the review.

8.4.3 Completeness of Inpatient Medical Records

Overall, we were able to locate complete inpatient medical records for 111 (95%) of all episodes. However, only 46 (39%) of all episodes had complete medical records filed by the date of discharge for the episode concerned. Finding medical records for 61% episodes required searching through written records for up to 14 months and digital records for up to 35 months after the date of discharge for the episode.

Both written and digital notes were found for 28 (24%) of 117 episodes, but these were not duplicate records and sometimes included separate, important information about the same day of the episode. For example, inpatient medical notes for one patient were correctly filed under the date of discharge but in fact only contained records for 2 of the 18 days of the admission: records were ultimately identified for every day of this admission but were filed within different areas of the Clinical Oncology, Haematology and Paediatrics Patient Notes sections of the record. For another patient, we found inpatient records relating to a single 24 hour period in three different locations in the clinical portal system.

We found no written or digital medical notes for three episodes

8.5 Patient location records

The locations of patients during hospital attendance and inpatient stays were obtained from TrakCare, the Patient Management System used by NHS GGC. All patient episodes (Outpatient, Inpatient and Emergency) are recorded and managed on TrakCare. In the course of our Review, we found that a specific bed was identified for almost all inpatient stays, but the system did not provide location (to the level of a specific bed space) when patients were receiving day care in ward 2B or, subsequently, in ward 6A. This limited the sensitivity by which we could assess location of care as a risk factor for infection.

One singularly unexpected issue was the coding of Haematology Oncology Day Care patients as attending Ward 2B after the date on which both wards 2A & 2B had been closed in September 2018.

This occurred inconsistently within individual records; although we were made aware that ward 2B was used for the RHC pre-assessment service from 29.4.2019 to 15.11.2019, we have been assured that no Haematology Oncology patients attended that area during this period. It seems self-evident for the benefit of tracking purposes that patients should never be coded to an area other than that to which they physically attended.

It was also often difficult to identify from the clinical records in which operating theatre surgical procedures took place. It also seems likely that procedures (e.g. bone marrow sampling and lumbar puncture procedures) were undertaken in anaesthetic rooms, also without a record of the location.

Attention needs to be paid to the accuracy with which patient location is defined, should a review of this kind be required again, or if support to an internal investigation of linked episodes of infection is required.

8.6 Adverse Event Reporting

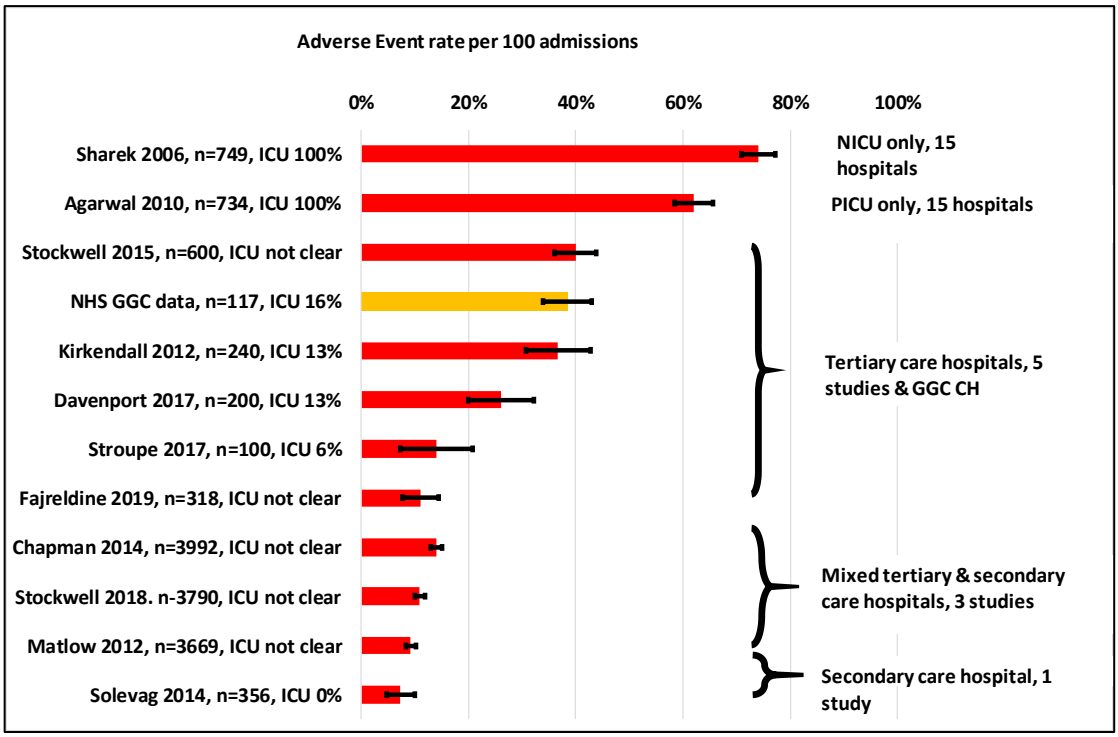
We have already discussed data derived from AE reporting, whether from the PTT or Datix notifications, in Chapter 6, section 6.4. In this section, we compare AE rates in the Haematology Oncology patients we have reviewed at NHS GGC with data available from the literature from other paediatric hospitals, and offer some further reflections about issues we have identified.

8.6.1 Comparison of AE rates at NHS GGC with other paediatric hospitals

A literature search identified 11 studies involving 15,153 paediatric inpatients from 104 hospitals in five countries (Argentina, Canada, Norway, the UK[88] and the USA). This is summarised in Figure 8.1. These studies only included data from randomly selected patients but, for comparison, the event rate at NHS GGC was calculated using the PTT data from the 45 inpatient episodes with one or more AE that were not related to the management of infection in these 117 admissions. The proportion of patients receiving intensive care was calculated using all PICU admissions.

The reported AE rate ranged from 7% to 74%, but much of this variation can be explained by the different settings in which data were collected (shown in Figure 8.1) which confirms that: the highest AE rates were in the two studies that only included patients from ICUs; studies that only included tertiary care hospitals had higher AE rates; and in tertiary care hospitals, a higher proportion of ICU patients was associated with higher AE rates.

Figure 8.1: Adverse events per 100 admissions in 11 studies of paediatric inpatients and at NHS GGC.



[88] Chapman SM, Fitzsimons J, Davey N, et al. Prevalence and severity of patient harm in a sample of UK-hospitalised children detected by the Paediatric Trigger Tool. *BMJ Open* 2014;4(7):e005066. doi: 10.1136/bmjopen-2014-005066 [published Online First: 2014/07/06]

Bars show 95% CI of event rates. The numbers for each study are the total number of admissions and the % of admissions that included admission to the ICU.

Eight of these studies used the NCC-MERP classification of harm[89] to assign severity to AEs; this is also the classification used in the UK PTT. The median proportion of Category I events from those studies was 11%, range 2-22%; in comparison, 5% of AEs at NHS GGC were category I.

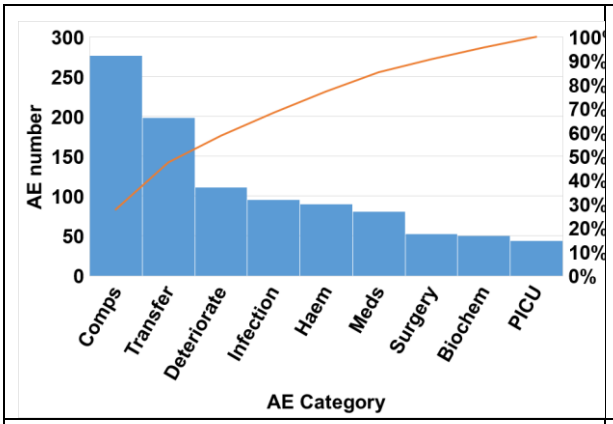
Appendix C shows the PTT score sheet used in our Review. For ease of analysis, the adverse events that derive from searching for these triggers can be grouped as shown in Figure 8.2.

Table 8.1 Adverse Event Categories (adapted from Matlow 2012 and Stroupe 2017).

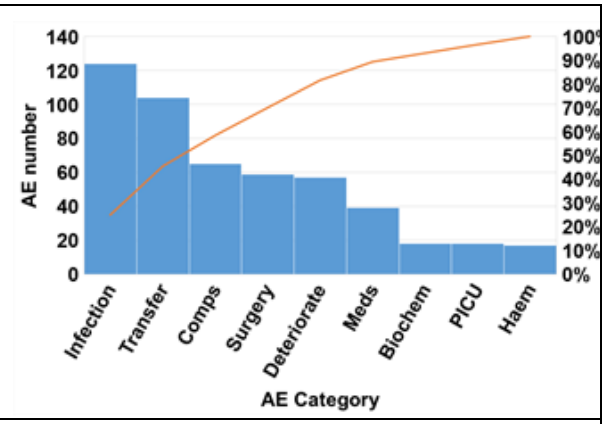
Biochem	Biochemistry	Intervention for increased creatinine; high/low potassium, sodium, sugar
Comps	Care complications	Intervention for tissue damage, thrombosis, other complication (e.g. adverse drug reaction, central line infection) or pain
Deter	Deteriorating patient	Delayed response to Early Warning Score; intervention for cardiac/respiratory arrest, hypoxia or hypovolaemia
Haem	Haematology	Intervention for anticoagulation, anaemia, thrombocytopenia or neutropenia
Infection	Infection	Intervention for infection causing admission or occurring >48h after admission, bacterial or fungal
PICU	PICU	Unplanned transfer to PICU
Meds	Medication	Intervention with naloxone, chlorpheniramine, glucagon; unplanned anti-emetic; interruption of planned treatment
Surgery	Surgery	Returned to theatre for unplanned procedure
Transfer	Transfer to/from hospital	Readmission, unplanned admission, delayed discharge

[89] https://www.nccmerp.org

Figure 8.2 Pareto charts plotting the pattern of AE at NHS GGC compared with those of large study at other UK hospitals.



Chapman 2014. Data from 1001 AE from 25 UK hospitals (9(36%) were tertiary care)



NHS GGC. Data from all 501 AE identified from the PTT

The NHS GGC data are dominated by AE classified as Infection and Transfer, which is much as would be expected from the nature of the group selected. It is reassuring, however, that although nearly one third of 'Deteriorating patient' AE in the Chapman study were caused by failure to do or to respond to Early Warning Scores, this was not identified in any of the NHS GGC episodes. In contrast, 74% of these AEs in the NHS GGC data were in patients who were given fluid resuscitation on the ward in response to symptoms of their bacteraemia – in itself, this is indicative of the serious nature of such infections.

8.6.2 Learning for the future

Using the data derived from the PTT to identify AE, we saw that most were related to the appropriate management of the serious infections under our Review. The analysis illustrated in Figure 8.1 suggests that overall AE rate in this population of patients at NHS GGC is comparable with reports from other tertiary care hospitals. It was clear to us, however, that Datix reporting significantly underestimated AE rates and that individual AE were sometimes incorrectly classified and under scored for their significance (section 6.4.2). We also have concerns about their identification and suggestions for learning from incidents.

Only one of the Category I events identified via the PTT was reported as risk level 4/5 on Datix; and there was only one other risk level 4/5 incident reported on the entire patient cohort from 2015-2019. The NHS GGC Incident Management Policy is clear that these events should be reported on Datix and "will be considered potential Significant Clinical Incidents and subject to screening using the appropriate tool to support decision making as to whether the incident should be confirmed as an SCI. Our data suggest that this was not done.

Of the 17 episodes with one or more Category I events, 14 included a PICU admission. The only exception was a patient who was resuscitated for sepsis on the ward but did not require PICU admission. Therefore, 94% of the patients with Category I events could have been identified from routine data (PICU admission

within 28 days of their bacteraemia). This illustrates a way to use routine data to identify patients for review. Other opportunities to use routine data to identify Category I events might include, for example, deaths within 7 days of stem cell transplant or within 30 days of chemotherapy.

Our analysis suggests that Category II events will occur in 20-40% of children in tertiary care, but we are not clear how incidents are selected for reporting, review and audit within NHS GGC. An advantage of looking for AE in random samples of patients is that it provides a systematic approach to the identification and classification of events in an unselected setting. In addition, reviewing a random sample of patients rather than starting with an incident provides a better opportunity to identify and feedback on good practice. We recognise, however, that many of the episodes we have reviewed are of very long duration, and so consideration could be given to focusing such reviews on a limited period within an admission (for example, within 28 days of admission or 28 days of a bacteraemia).

8.7 Morbidity and Mortality Reports

In Chapter 6, we have looked at the characteristics of the 22 children and young people included in our review who had died by the time of the publication of this Report (section 6.3). Cause of death was assessed from the clinical records in all cases, and validated from death certificates in the 19 cases for whom these were available.

We were provided with 17 Morbidity and Mortality (M&M) reviews (also known as Paediatric Review and Assessment Meetings (PRAM)), all from amongst the patients who had died. Two of these reviews were about patients who died and where the infection was attributed, at least in part, as the cause of death and two others were deaths within 28 days after discharge following an infection episode.

In one of these four patients, both the PICU M&M review and the cardiac death audit referred to the infection which was also recorded as a contributory factor on the death certificate. At the request of NHS GGC management, an additional review was undertaken of this patient by a paediatric intensive care consultant, over two years after the child died. The death had been correctly reported on Datix as an Extreme incident.

The other three M&M reviews of deaths that related in time to infection episodes were all initiated by clinical staff. None of these reviews included a discussion of the Gram-negative environmental infection but they did identify other significant discussion points, including death within 30 days of chemotherapy and the very large resource implications of transferring a ventilated patient from PICU to another hospital for other treatment. None of these issues were reported on Datix and the M&M reports do not include action plans.

Much of the content of the other M&M reports related to the chronology of the patient’s underlying disease, its treatment, and to aspects of end of life care. There was no reference to Gram-negative environmental infection. The M&M reports we have seen were limited to patients who died, but the Scottish Mortality and Morbidity

Programme[90] clearly states that such reports should include review of care complications in addition to patient deaths.

Some of the M&M reviews were presented by Specialist Trainees. Audit and quality improvement are Outcome 8 in the RCPCH Paediatric Training Curriculum, and this is one of nine areas for assessment of applicants for Specialist Training, with clearly described indicators of involvement in audit/quality improvement and learning from this[91,92]. We could not identify a systematic approach to how the use of incident reporting or M&M review was used either to improve patient care or to provide professional learning. Some of the M&M reviews clearly identified important issues. If these were cross referenced to, or entered as reports on Datix, this would create an opportunity to engage more widely with the organisational response and in creating action plans and auditing improvement.

8.8 Central Venous Line Care

We have looked at aspects of central venous line (CVL) care in the patients in our review. CVLs, like other indwelling medical devices, present a clear risk for infection but are intrinsic to the delivery of many aspects of the complex care required by children and young people undergoing chemotherapy or treatment for other serious blood diseases.

We assessed central line care in 81[93] patients who had 115 episodes of central line associated infection that were treated as an inpatient in the GGC Paediatric Oncology Unit. We collected information from written and digital inpatient medical and nursing records, and from the Patient Note Pad section in Telepath.

8.8.1 NHS GGC policies

The antibiotic policy for Paediatric Haematology Oncology patients with febrile neutropenia incorporates detailed recommendations about antibiotic treatment and addresses aspects of CVL usage in the context of presumed line related infection. This has been regularly updated from v1.0 dated 2010, to v4.0 dated March 2020. The policy includes a recommendation to document the central line insertion site in febrile patients and cautions that if a child deteriorates with flush or continuing use of the line, consideration should be given to siting a peripheral cannula and discontinuing use of the line, with further consideration given to adjusting the antibiotic regimen. There are otherwise no specific recommendations for resting, removing or challenging lines.

[90] Healthcare Improvement Scotland. Scottish Mortality and Morbidity Programme [Available from: http://www.healthcareimprovementscotland.org/our_work/patient_safety/scottish_mortality__morbidity.aspx.

[91] Royal College of Paediatrics and Child Health. Paediatric ST4 Recruitment 2020 – R2R Self-assessment Framework & Guidance [Available from: https://www.rcpch.ac.uk/sites/default/files/2020-07/st4_recruitment_2020_round_2_readvert_self-assessment_framework_0.pdf

[92] Royal College of Paediatrics and Child Health. Paediatric ST1 Recruitment 2020-2021 Application Scoring Framework & Guidance [Available from: https://www.rcpch.ac.uk/sites/default/files/2020-11/ST1%20Application%20Form%20Scoring%20Framework%20v.3b%20JAC%20291020_0.pdf

[93] Three patients were excluded because they did not have central line associated bacteraemia treated in GGC (two had no central line in place during the episode of infection, and one was not an inpatient in GGC during the infection episode).

The Patient Note Pad notes in Telepath frequently state that microbiology advice is based on evidence from the IDSA (Infectious Diseases Society of America) guidelines on management of intravascular catheter related infection[94]. Overall recommendations for GNE bacteraemia in patients with long term catheters are:

- If the line is removed, treat with 7-14 days antibiotics.
- For line salvage, use systemic and antibiotic lock therapy for 10-14 days.

Specific recommendations from the IDSA guidelines provide more detailed advice about criteria for line removal, treatment without line removal and about management of infection in paediatric patients. The IDSA guidelines do not mention line challenge.

8.8.2 Observed CVL management

The appearance of the line site was recorded when the patient became symptomatic in 94 (82%) episodes and was documented as clean in 84 (89%) of these records.

The line was rested in 51 (45%) episodes and subsequently challenged in 21 (18%) episodes. Signs and symptoms of sepsis occurred after 9 (43%) of those line challenges and, in one case, resulted in a patient who experienced rigors, became cyanosed, tachycardic and had limited response to bolus fluid infusion, being admitted to PICU.

The Chief Nurse for Paediatric and Neonatal Services at NHS GGC provided us with this information about central line challenges: “Challenging the lines was a rather historic practice where if a child had a pyrexia they would stop using the line, insert a cannula and use that, then a few days later ‘challenge’ the line by taking more blood cultures and flushing, gradually using for fluids and medications. This practice was discussed at the QI group (set up in May 2017) and we worked from there towards a change. Microbiology and other representatives within the group agreed to continue to use a line or remove a line depending on the clinical and microbiological status of the child”.

However, the frequency of line challenges did not appear to reduce with time and was identified in 5 (14%) of 36 episodes occurring up to May 2017 versus 16 (20%) of 79 episodes from June 2017 onwards. The latest line challenge we noted in our Review was for a bacteraemia diagnosed in March 2019.

Patient Note Pad notes do not document any microbiology concerns about plans to challenge the line where this is explicitly mentioned.

Data in section 6.2.3 looks at the removal of a CVL in response to GNE infection. This occurred in 78 (68%) of episodes. We found that the PNP notes consistently recorded when line removal was considered to be the optimal microbiology advice but, recognising this was not always clinically optimal for continuing patient management, when line salvage was attempted, there was regular advice from microbiology about systemic and antibiotic lock therapy, with frequent reference to IDSA guidelines. We were, however, concerned to see that when a decision was reached to remove a line, there were delays in its implementation. We were not able to investigate this in detail but recognise that this may be a consequence of

[94] Mermel LA, Allon M, Bouza E, et al. Clinical Practice Guidelines for the Diagnosis and Management of Intravascular Catheter-Related Infection: 2009 Update by the Infectious Diseases Society of America. *Clin Infect Dis* 2009;49(1):1-45. doi: 10.1086/599376

competing priorities for operating theatre and anaesthetic time. Nevertheless, we believe that delay in removal of an infected line carries risk and so that removal should be prioritised accordingly.

8.8.3 Conclusions

We have seen that CVL care was well documented by the nursing staff and that good advice was provided by the microbiologists in the context of bacteraemia. We acknowledge that considerable work was being undertaken within NHS GGC during the period of our Review to reduce the incidence of central line associated blood stream infections (CLABSI) through a Quality Improvement framework. We are, however, concerned both about the practice of 'line challenge' and the lack of documentation in the medical records when attempts to continue to salvage a line were preferred over advice from microbiology to remove it.

Episodes of central line associated bacteraemia present an opportunity as much to learn from its management as from the analysis of its causation.

8.9 Other aspects of clinical care

Two other issues have arisen in our review that we discuss briefly here.

8.9.1. Antimicrobial prophylaxis

The prophylactic (preventative) use of antibiotics, antifungal and antiviral drugs to reduce the risk of infection in patients who are at high risk by virtue of their disease and/or treatment is well established in Paediatric Haematology Oncology care. The evidence base varies according in relation to diagnosis, treatment and age. In practice, consistency is often addressed by guidance incorporated within established treatment schedules and clinical trial protocols.

Concern about the incidence of GNE bacteraemia at NHS GGC raised an understandable question for the clinical and microbiological teams about the use of antibiotic prophylaxis (i.e. whether its use should be extended beyond the settings in which it would normally have been considered). The use of fluoroquinolone antibiotics is a particular focus because of concern that this can contribute to selection of antibiotic resistance and to the risk of *Clostridium difficile* infection. Its use in the context of preventing neutropenic sepsis has recently been reviewed by the National Institute for Health and Care Excellence[95], but whether use of fluoroquinolone prophylaxis is useful in a setting where there is concern about a possible environmental focus for infection is unclear. Furthermore, once a policy of this kind has been initiated, it is understandably difficult to know when to de-escalate.

We are not critical of the use of fluoroquinolone prophylaxis in this context and recognise from what we have since been told that the matter was carefully considered at the time. We note that the continuation of its use was reviewed in an SBAR written by Dr Andrew Murray, Medical Director, NHS Forth Valley and Co-chair, Scottish Managed Service Network for Children and Young People with Cancer in December 2019 (on behalf of the Oversight Board).This concluded that the continuing use of fluoroquinolone prophylaxis should be on the basis of individual patient assessment; no indication was given for criteria against which such individual assessment should be effected but consensus guidelines for the use of antibiotic

[95] 2020 exceptional surveillance of neutropenic sepsis: prevention and management in people with cancer (NICE guideline CG151)

prophylaxis in Paediatric Haematology Oncology practice have recently been published and should be reviewed for their use in NHS GGC[96]. We have not sought information about audit of ongoing use of antibiotic prophylaxis but best practice would anticipate this is being undertaken.

8.9.2 The impact of the organisational response on the delivery of clinical care

In Chapter 6 we have tried to share data we obtained or derived from our Review in order to demonstrate the impact of GNE bacteraemia on individual patients. We were less able to form a view of the overall effect on the clinical service although it was obvious that disruption was substantial, particularly in relation to the decisions to close Ward 2A and 2B in September 2018, to move patients out of Ward 6A for a short period at the beginning of 2019, and to limit admissions to Ward 6A in the summer and early autumn of that year.

Throughout our Review we had not seen any document prepared by the clinical team, by NHS GGC management or by the Managed Service Network that set out an analysis of how these decisions affected the overall delivery of Paediatric Haematology Oncology care. Measures that would have been of interest are, for example, timeliness in delivering planned chemotherapy; deferral of planned treatment (e.g. surgery, radiotherapy, stem cell transplantation); use of shared care; and transfers to other units.

We questioned the availability of evidence of this kind at a meeting with the Haematology Oncology clinicians in December 2020 and have since seen two documents. One is an audit of admissions with bacteraemia from 1.7.2017 to 31.8.2018. This looked at characteristics of patients affected by age, gender, diagnosis and the profile of the microorganisms causing infection and their antibiotic sensitivities (this was not restricted to Gram-negative environmentals). The main focus of the audit seemed to be on defining the optimal choice of empirical antibiotics. It did not attempt to look at the observed frequency of bactaeraemia against that which might have been expected, but it is possible to see that 7 out the 8 most frequent bacteria identified in the series fell into the Gram-negative environmental group. We do not know where these data were presented within the organisation or what response was made.

The second document presents an analysis of episodes of care transferred to other Wards/Hospitals/Health Boards for delivery of chemotherapy and relates to data collected from 29.7.2019 to 4.11.2019, during the period when there were restrictions on admission to Ward 6A. In summary, this showed that 8 children (9 episodes of treatment) were transferred to Edinburgh during this period; 4 children (5 episodes) to Aberdeen; 1 child (1 episode) to Newcastle; and 1 young person (2 episodes) to the Young Person's Unit at the Beatson West of Scotland Cancer Centre. Internally, accommodation was found within Ward 4B for 11 children (17 episodes) in addition to the ongoing Paediatric Stem Cell Transplant activity planned to be delivered in that ward. We have also been informed that shared care[97] activity

[96] Lehrnbecher T, Fisher BT, Phillips B, Alexander S, Ammann RA, Beauchemin M, Carlesse F, Castagnola E, Davis BL, Dupuis LL, Egan G, Groll AH, Haeusler GM, Santolaya M, Steinbach WJ, van de Wetering M, Wolf J, Cabral S, Robinson PD, Sung L. Guideline for Antibacterial Prophylaxis Administration in Pediatric Cancer and Hematopoietic Stem Cell Transplantation. Clin Infect Dis. 2020;71(1):226–36. https://doi.org/10.1093/cid/ciz1082.

[97] Shared care is the arrangement by which the specialist haematology oncology centre (in this case NHS GGC) continues to direct overall patient management but works with a general hospital local the

increased during this time and has since been maintained although we have seen no data.

Short term adjustment to patient flow is expedient under such circumstances and it was good that these transfers were able to take place to limit delay to treatment. It seems, however, that there may also have been some more permanent change to shared care activity as a result of the impact of these infections. The wider development of shared care with local hospitals may have been helpful to individual families in offering more care, closer to home but appropriate structures and processes are needed to ensure that a shared care network is both supported and safe. We have not seen evidence that the issues that arose at NHS GGC were supported by any action from the Managed Service Network[98].

patient's home to deliver aspects of care, for example, less complex courses of chemotherapy, blood product transfusion, nutritional support.

[98] The MSN is charged with delivering the Scottish Governemnt's vison for cancer services for children and young people – to attain the best possible outcomes; ensure access to appropriate, safe and sustainable specialist services as locally as possible; and that pathways of care are as equitable as possible across the country. https://www.youngcancer.scot.nhs.uk/managed-service-network/about-us/about-the-network

9. Evidence of Good Practice

In the course of our Review we identified areas of Good Practice which we briefly summarise here.

9.1 Nursing Care Records

Nursing records were especially comprehensive and clearly written. There was almost universal completion of vital signs and central venous line and peripheral venous catheter documentation.

9.2 Medical Care Records

Notwithstanding our criticism of the organisation of the medical records, the medical care notes were generally comprehensive and frequently very detailed in their account of specific clinical issues. Reading these notes gave a picture of good communication between junior and senior medical staff and clear evidence of consultant led care.

9.3 Communication with families

Although we are aware of complaints from some families about standards of communication, we saw examples where communication with individual families about clinical care was particularly carefully recorded and, in respect of professional Duty of Candour, this included cases where an adverse event had occurred.

We also saw evidence of joint consultations with parents by Consultant Haematologists/Oncologists and Consultant Microbiologists to discuss specific aspects of the causes and treatment of difficult to treat infection.

9.4 CLABSI surveillance and incidence

Despite the fact this Review has been initiated because of concern about bacteraemia, we are also aware of the work done by the Quality Improvement group established in 2017 to reduce central line associated blood stream infection. We have seen data which illustrates the impact of their interventions, currently achieving rates at 0.77/1000 line days. We also recognise the openness with which the group acted to ensure comparison was made between NHS GGC and other institutions nationally and internationally to establish a benchmark for future care.

9.5 Infection Prevention Control Nursing practice

Where ICNet generated a case in response to a positive laboratory test result, there was evidence of good record keeping and a detailed information of the IPC nurse response and intervention.

During IMT investigations the IPC nursing response was seen to generate appropriate infection prevention and control support measures, often undertaking an enhanced review of basic IPC practice and actions.

9.6 Microbiology advice

The advice provided to the Haematology Oncology Team by the microbiologists was well documented in Telepath and shows that frequent and clear advice was provided

about the identification of the infecting organism; antibiotic sensitivities; choice and duration of antibiotic treatment; and removal of the central venous line.

10. Summary of findings and recommendations for action

This chapter is structured to answer the questions we were asked to address at the outset of our Review and offers recommendations for consideration and action by NHS GCC, and other organisations.

10.1 How many children in the specified patient population have been affected, details of when, which organism etc.?

The work undertaken to define the number of patients and infection episodes that would be the subject of our Review appears comprehensive. We are not able to ascertain with complete certainty that any patients/episodes that should have been included were omitted in error, but we have no reason to believe this to be the case. We identified only two episodes and one patient we deemed ineligible, resulting in a final population of 84 patients and 118 episodes of infection in our Review.

We found that the patients broadly represented the population of patients we would expect to be under the care of the Paediatric Haematology Oncology service at NHS GGC, given that it also houses a unit for Teenagers and Young Adults. Their ages ranged from 3 months to 18 years 10 months at the time of their first infection episode, with a median age of 5 years 11 months. There was an unexpected excess of female patients which we suggest is investigated further, but this may still be a chance finding. The great majority of the patients had a diagnosis of leukaemia (as expected, the largest subgroup) or other cancer but a minority had other forms of serious blood disease or a non-malignant condition.

Although, over three quarters of patients experienced 1 episode of infection, 10 had 2 episodes and several had 3 or more episodes, up to a maximum of 8 episodes in one patient.

10.2 Is it possible to associate these infections with the environment of the RHC and the QEUH?

We were able to conclude that bacteraemia was Unrelated to the hospital environment in only 8 (7%) episodes and, for reasons we have discussed in detail, we were not able to identify any episodes that were Definitely linked to the environment (as discussed in section 5.6). The remainder of the episodes were graded, in varying degrees, as Possible or Probable in their relationship to the hospital environment.

This is not as satisfactory a conclusion as many will have hoped we would be able to reach but we have described the standards of proof we required and discussed the complexity of attributing cause/origin in this population of patients.

It is without question, however, that our decision making was affected by the inconsistencies we encountered in the data we received from NHS GGC: data that, we had hoped, would clarify concerns about the maintenance and surveillance of the environment, the water system, and the use of typing methodologies to link different bacterial isolates.

We conclude that the difficulty the organisation had in locating, collating and presenting these data to us supports our belief that this information may not have been readily and/or consistently available in real time for their own investigations

over the period of our Review. The very fact that, in late 2020, such data remained difficult to provide to us suggests that the previous years of concern and investigation of Gram-negative environmental bacteraemia had not translated into clear evidence that good quality data about the control of the environment were being sought, interrogated and stored in a retrievable format for future use.

We have, nevertheless, identified 37 (32%) of the bacteraemias in the Review as being 'More likely' to be linked to an environmental origin. These infection episodes are characterised by a particular excess of *Stenotrophomonas* spp. but do not otherwise appear to be related to any distinctive microbiological profile or to have occurred more than expected in any particular period in the years covered by our Review.

We are surprised that the evidence for an excess of GNE bacteraemia in the Paediatric Haematology Oncology patients was challenged by some within the organisation. By 2018, we suggest that simple observation should have identified a disturbing pattern characterised by the occurrence of bacteraemias caused by some very unusual microorganisms and apparent clusters of some of those more commonly encountered. The widespread contamination of the water system seems to have been accepted operationally and NHS GGC's response, notably its decision to close and relocate an entire clinical unit in September 2018, must be interpreted as evidence of the organisation's acceptance that the environment presented a risk of serious infection to a vulnerable group of patients. Although the investigations undertaken to that date had failed to identify a single cohesive hypothesis for the origin of many of the infections, the approach taken to surveillance thereafter did not appear to match the severity of what had already occurred.

10.3 Was there an impact on care and outcomes in relation to infection?

First, it should be recognised that infection occurs in Paediatric Haematology Oncology patients and carries risk, regardless of its likely origin. We have characterised the impact of all the GNE infection episodes experienced by the whole group within our Review and then looked separately to determine if these were different in those episodes we judged to be 'More likely' to be associated with the hospital environment.

We created a 5-point scale by which we defined the overall impact of each infection on the patient. This was based on a number of specific criteria which we shall highlight separately. In summary, we identified only 5% of episodes with a Negligible or Minor overall impact whilst 38% of episodes were associated with a Major or Critical overall impact.

In looking at the individual components of the impact assessment, we identified that 87% patients experienced a hospital admission of more than 7 days directly as a result of their infection, and this was greater than 14 days in 50%. Seventy-five (68%) of infection episodes required removal of the central line to control the infection; this is a striking finding because it also conveys an additional risk of general anaesthesia, first to remove the line and then (in almost all cases), to insert another one. This also carries a significant logistic and resource cost in the additional operating theatre utilisation required.

Twelve patients (11% of those evaluable) required admission to the intensive care unit solely or principally because of their infection, of whom the majority (75%) could be discharged to the ward within 3 days. This statistic tells its own story in relation to how sick these patients may become and illustrates again the resource burden that GNE bacteraemia imposed.

Treatment disruption was, as we have discussed, more difficult to characterise but we estimated that treatment delays of more than one week were seen in 29% patients (and for more than 2 weeks in 12%). It is not possible to ascribe clear significance to such observations because many other factors are involved and delays in treatment are common during cancer care. We believe most clinicians would accept that, under most circumstances, a delay of 1 week is very unlikely to be significant in terms of patient outcome. However, it also seems logical to accept that the longer the delay beyond that point, the more likely there could be an impact on disease control.

These are not trivial findings and indicate the scale of the impact of GNE infections within the whole group. When we looked separately at the 37 episodes we deemed 'More likely' to be associated with the hospital environment, the pattern of impact was generally similar except for an increase in risk of admission to intensive care. This may link to the excess of *Stenotrophomonas* spp. infections seen in this group.

We measured AE using two different approaches – first by exploring incident reporting through NHS GGC's Datix system, and second by using the Paediatric Trigger Tool (PTT). Although many of the triggers identified by the PTT relate to expected complications of chemotherapy or represent other support measures commonly required by this group of patients, the incidence of adverse events identified in this way far exceeds the evidence available from Datix reports. Furthermore, it was apparent that when incidents recognised as adverse events were entered into Datix, there was a clear possibility that the situation might be misclassified and/or its risk underestimated. The principal lesson here is that, used appropriately, the reporting of events into Datix could provide a valuable tool for auditing patient safety in this group of high risk patients, as it is intended to do.

The work using the PTT also provided an opportunity to compare the overall incidence of adverse events in these patients at NHS GGC with paediatric populations in other hospitals: our conclusions are that, when comprehensive data were used, NHS GGC performed in line with that of other comparable institutions.

We found that the deaths of 2 of the 22 patients who had died by the time of the publication of this report were, at least in part, the result of their infection. Both also had other serious medical problems and it is our view that, even without the infection, their survival would still have been uncertain. In one child, who died in PICU 6 days after the last positive culture, sepsis had been implicated at the time as the principal cause of death and was recognised as such on the death certificate issued by NHS GGC. The second child died in PICU at a longer interval (36 days) after the last positive culture and a number of other contributory factors were present. We decided that the bacteraemia was contributory to the cause of death and this was reflected in the death certificate issued by NHS GGC. In both cases we had determined that the infections were both Probably related to the hospital environment and fell within our 'Most likely' to be related to the environment group. Of the remainder, 19 had died of their underlying disease (all leukaemia/cancer related); and 1 from other causes unrelated to infection.

10.4 What recommendations should be considered by NHS GGC – and, where appropriate, by NHS Scotland, more generally – to address the issues arising from these incidents to strengthen infection prevention and control in future?

In our work in undertaking this Review, we have explored data pertinent to an understanding of the nature of each infection and to the factors at play in determining its likely origin, subsequent management and influence on patient outcome. We also reviewed the IPC processes in place, and the approach taken to the investigation of these infections when identified internally as an infection incident or outbreak. We identified specific concerns that we have discussed in Chapter 8.

NHS GGC should take immediate steps to ensure greater consistency in the way the organisation monitors and investigates GNE infections in Paediatric Haematology Oncology patients. The approach hitherto has been fragmented and incomplete. In responding to this report and our recommendations, NHS GGC should assure patients, families and staff of a new approach. It is particularly important that it does so before the Paediatric Haematology Oncology service returns to Wards 2A and 2B. In this way, it will be seen that change has been implemented and that risk will be effectively monitored in the return to the upgraded environment.

Recommendations.

1. Overall Management of Gram-negative environmental infection in Paediatric Haematology Oncology

1.1 Every GNE bacteraemia occurring in a Paediatric Haematology Oncology patient at NHS GGC should be comprehensively investigated using RCA methodology, whether or not it is considered at the outset to be related to the hospital environment or thought to be part of a potential outbreak. This will ensure that future consideration of the underlying issues can be informed by consistent, comprehensive and prospectively collected data.

1.2 A multi-professional group, with a defined and consistent membership representing all appropriate skills and backgrounds, should be established with responsibility for continuing oversight of these data: for assessment of its quality, and completeness, and for its analysis and reporting. The intent is that this group, which should have external representation, will grow in collective expertise and knowledge; have a shared understanding of the history and challenges encountered since the opening of the new QEUH/RHC site; and will be able to define and guide the organisation’s response to future concerns about environmentally acquired infection in this group of patients. The group should report directly to the IPC Manager and Lead Infection Control Doctor and its findings form a standard part of upward reporting of IPC issues within NHS GGC.

2. Demographic profile of patients

Given the unexplained but significant excess of female patients in the Case Note Review, the Paediatric Haematology Oncology service should audit all bacteraemias for a sufficient period either to reassure that there is no real gender effect, or to investigate further if this proves to be the case.

3. Environmental surveillance

3.1 The data systems used to document facilities maintenance activity in clinical areas need to consistently capture the exact location of the work done; the date(s) on which the work was actually done; and be accessible to inform the IPC process, including the investigation of clusters and outbreaks.

3.2 The frequency with which facilities maintenance activities occur in specific ward areas should be reported on a regular basis in a way that informs wider awareness of the vulnerability of the environment and tracks changes in the pattern of such activity.

3.3. The precise location of any swab or water sample taken for microbiological surveillance, and the date on which it was obtained, must be recorded and the results made accessible to inform the IPC process, including the investigation of clusters and outbreaks.

3.4 When a suspected infection outbreak is being investigated, the plans agreed for environmental sampling of the relevant area must demonstrate a systematic approach appropriate to the circumstances of the investigation.

3.5 When the Chair of an IMT (or similar future structure) identifies that environmental samples are required to inform an investigation, these should be taken, reported back promptly and evidenced in the IMT minutes.

4. Water testing

4.1 A systematic, fit for purpose, routine, microbiological water sampling and testing system is required to provide assurance going forwards. How the results from such sampling/testing are recorded, accessible and used to highlight concerns should be reviewed, including to ensure that investigations of possible links between clinical isolates and water/environment sources can be informed in a timely way. In addition, investigations of possible links between clinical isolates and water/environment sources should consider whether (short or medium/long term) changes to the routine microbiological water sampling and testing system are required.

4.2 NHS GGC should ensure that the SOP for Minimising the Risk of Pseudomonas aeruginosa infection from water explicitly states whether this also applies to high risk areas other than adult and paediatric intensive care units and neonatal units.

5. Infection Prevention Control Practice and Audits

5.1 NHS GGC should review the current approach to IPC audit: a) to ensure that the component elements are addressed individually and that the RAG rating is not determined only by an overall score; and b) to show that the governance and assurance process relating to improvement action plans can demonstrate if interventions have been effective. Quality improvement methodology should be used to drive and sustain improvement.

5.2 The current status of IPC audit should form a routine and documented component of IMT assessment.

5.3 Greater effort should be made to ensure that deficits identified by IPC audits are remedied, re-audited, linked to measures of ongoing quality improvement/compliance, and clearly documented.

5.4 Greater attention should be paid to the evidence for benefit from Enhanced Supervision by demonstrating sustained improvement in standards where this approach is introduced to a clinical area.

5.5 The validity of Hand Hygiene audits should be strengthened by ensuring the staff sample audited is sufficiently representative in terms of numbers and types of staff; and that effectiveness of the interventions are monitored to demonstrate sustained improvement.

5.6 The frequency of Hand Hygiene audits should be increased when there are concerns about infection rates potentially related to the environment

6. Infection Prevention Control Communication

NHS GGC should ensure better communication between the Microbiology and IPC teams. We recommend a forum by which sharing of information and actions occurs in real time to support and improve quality of care to patients, maintain progress and discuss action for any potential change in a patient's condition or linked infections.

7. ICNet Alerts

NHS GGC should review the ICNet alert organism list to ensure that, at a minimum, it reflects the advice in the Scottish NIPCM and to ensure that it is further updated to reflect experience with GNE bacteraemias.

8. Infection Incident and Outbreak Policy

8.1 NHS GGC should review its Standing Operating Procedure regarding the use of the term HAI to make it clear whether this includes all Healthcare Associated Infections. This is a specific issue in the context of patients who, like those in Paediatric Haematology Oncology, frequently and repeatedly attend the hospital as outpatients, day patients and inpatients and for whom the distinction between Hospital Acquired Infection (HAI) and Healthcare Associated Infection (HCAI) is unlikely to be useful.

8.2 NHS GGC should revisit how they will monitor and, if necessary, trigger concerns about future outbreaks of Gram-negative environmental infections. Relaince on SPC charts to determine if episodes of infection caused by unusual/uncommon microorganisms are significant should be re-evaluated. The process in place for much of the Review period appears to have been insensitive to identifying clusters that should have raised earlier concerns about potential for a common/environmental source of infection.

8.RCA methodology should become the standard approach to the investigation of serious infections in Paediatric Haematology Oncology patients.

8.4 NHS GGC should consider the further and consistent use of the RCA process across the organisation a) to identify evidence of common themes as a cause of infection over time; and b) what can be extracted from the RCA process for organisational learning and improvement.

8.5 NHS Scotland should consider if this approach should become a recommendation in the NIPCM.

9. IMT Process

9.1 The IPC Team should ensure IMT minutes are filed with all supporting papers so that a complete record of the discussions held, evidence presented, actions agreed

and the overall report concluding the process, is available and accessible in a single place.

9.2 The IMT action log should be a continuous and evolving document throughout all meetings in an IMT series. The log should be reviewed and updated at each meeting so that there is a clear record of actions agreed, responsibility held and tasks completed. The IMT should not be closed if there are actions which have not been completed.

9.3 The absence of IMT reporting at the closure of an IMT sequence is a breach of NHS GGC's own policy. This should be remedied so that practice complies with policy.

9.4 In addition to confirming that due process has been followed in line with organisational policy, IMT and other IPC reports intended for upward reporting within the organisation should more fully describe the scale and significance of the incident that has been investigated from the patient perspective.

9.5 NHS GGC should assure that the governance of the IMT process, its reporting and escalation to Board level, is clearly defined and followed; and that an audit trail of all evidence related to any suspected or actual outbreak is clearly documented and fully reported.

10. Bacterial typing data / Reference laboratory reports

10.1 NHS GGC must (continue to) develop a comprehensive and searchable database that allows details of microbiology reference laboratory reports to be compared between samples of the same bacteria obtained from different patients or environmental sites.

10.2 The system for integrating microbiology reference laboratory reports into the patient microbiology record needs to be reviewed and strengthened. Similarly, the system for ensuring that microbiology reference laboratory information is available to and used by the IMT process, including the investigation of clusters and outbreaks, needs to be reviewed and strengthened.

11. Patient Records

11.1 NHS GGC should undertake a review of the current effectiveness of the system for collating, storing and integrating both scanned hand written records and digitally recorded records and how this achieves an accurate, accessible and chronologically accurate health record for each patient.

11.2 NHS GGC should clarify their strategy for further evolution towards fully digital records

11.3 Consideration should be given to the integration of the microbiology recommendations regarding the diagnosis and management of infections, as currently documented in the Telepath patient notepad, into the patient clinical record.

12. Patient location coding

It should not be possible to code patient activity to a clinical area in which the patient was not present: this should be addressed.

13. Adverse Events

13.1 The Paediatric Haematology Oncology service should engage with regular reporting and analysis of adverse events. Admission to PICU is an obvious way of

identifying, for audit purposes, the patients most likely to have the most serious (Category I) AE.

13.2 The PTT offers a useful tool to identify and monitor trends in the occurrence of adverse events that occur during care.

13.3 NHS GGC should assure and report consistent utilisation of the Datix system, and audit the validity of the classification and risk categorisation given to incidents by its staff.

14. Central Venous Line Care

14.1 The Paediatric Haematology Oncology service should review the practice of 'challenging' central venous lines in line with evidence for its risks and benefits.

14.2 When it is agreed that a central line should be removed for optimal management of a patient's infection, operating theatre and anaesthetic resources must be made available to ensure its prompt removal (within 24 hours).

14.3 The Paediatric Haematology Oncology service should ensure that a decision not to remove a central venous line contrary to the advice of the microbiologists is always documented in the medical record.

15. Other aspects of Clinical Care

15.1 The Paediatric Haematology Oncology service should ensure that Morbidity and Mortality reports are not restricted to a review of patients who die. Future GNE infections should be used as a trigger for an M&M review; to assess management and outcome; and with the inclusion of an action plan to identify approaches to reduce risk and improve care.

15.2 International consensus guidelines have recently been published for use of antibiotic prophylaxis in Paediatric Haematology Oncology. These should be reviewed by both the service and by the Managed Service Network, and local and network policy and practice should be amended accordingly.

15.3 The Paediatric Haematology Oncology service should audit the use of antibiotic prophylaxis against the new policy once implemented.

15.4 The Managed Service Network and NHS GGC should review any changes to the use of shared care that have evolved as a result of the service disruption experienced in recent years, and ensure the structures and processes in place adequately address patient safety and staff support across the shared care network.

11. REFERENCES AND RESOURCE MATERIAL

This chapter lists the documents to which we had access. Not all turned out to be relevant but we list them here for completeness. Not all documents were dated or had an identified author / origin.

Section 1 relates to documents that are principally internal to NHS GGC and are ordered within themes.

Section 2 summarises external documents/reports and are listed against the originating organisation.

In addition, we held meetings with individuals and groups of individuals (see Appendix A) and generated, received and saw many emails; all of this activity provided additional and/or complementary information.

SECTION 1

11.1 Environmental Microbiology

Water Sampling

Potable Water Master Files: 2015/2016/2017/2018/2019

Positive results: January-March 2017

QEUH DMA Sample Results: 2017

TPATH Master Record:2017

Potable water- combined TPATH & DMA- final version for GGC Review: 2017

QEUH DMA Sample results: 2018

TPATH Master Record: 2018

QEUH DMA Sample Results: January-June 2019

QEUH DMA Sample Results: July-December 2019

Potable Water- combined TPATH & DMA Data- Final draft for GGC Review: 2019

QEUH DMA Sample Results Retained: 2019

Sampling Schedule- QEUH Campus: 2020

Water Flushing

SOP Weekly Water Flushing Review: 25 February 2020

Water Flushing Record Supervisors Report: November 2020

QEUH & RHC Ward Flushing Record examples: November 2020

Water Flushing Compliance Record: 9 November 2020

Water Flushing Compliance Record: 16 November 2020

Water Flushing Compliance Record: 24 November 2020

Water Flushing Compliance Record: 01 December 2020

QEUH Water Flushing Tool Box Talk Domestic Services - 16 March 2020

Water Risk Assessments

Risk Assessment pre-Occupancy L8 Risk Assessment - 2015

Risk Assessment Water Supply: March 2015

Risk Assessment Water Safety: August 2016

Risk Assessment Water Safety- Draft: April 2017

Risk Assessment Water Safety- version 4: July 2017

Risk Assessment Water Safety pa v6 Interim report: June 2018

Water Policies

NHSGGC SOP for Minimising the Risk of Pseudomonas Aeruginosa Infection from Water. Versions dated: 2015, 2017, 2018, 2019

Controlling the Risks of Exposure to Legionella & other harmful bacteria. Written scheme: 2019

External Reports

2015 DMA Report (version 3)- Review of recommendations and actions arising from the Draft meeting report by Dr Susanne Lee, Leegionella Ltd - 25 April 2018

Investigation into Contamination of flow straighteners - 11 July 2018

Reports on water systems at QEUH and RHC - 'Pre-occupancy risk assessment': published 16 December 2018

2015 DMA Report (version 3)- Further review of recommendations and actions arising from the reports on water systems at QEUH and RHC (version 3) - 'Pre-occupancy Risk Assessment': published 29 November 2019

Hard Surface

Hard Surface samples- master file: 2015-3 March 2020

6A Hard Surface samples: 1 June 2019-23 December 2019

Other

6A Air Samples: 1 June 2019-19 December 2019

11.2 Microbiological Typing

Standard

2015 Referred Gram negative isolates QEUH (inc. Water). Complete Final Record 16.12.20

2016 Referred Gram negative isolates QEUH (inc. Water). Complete Final Record 16.12.20

2017 Referred Gram negative isolates QEUH (inc. Water). Complete Final Record 16.12.20

2018 Referred Gram negative isolates QEUH (inc. Water). Complete Final Record 16.12.20

2019 Referred Gram negative isolates QEUH (inc. Water). Complete Final Record 16.12.20

Master Timeline – Gram negative blood cultures updated May Nov 2019

Timelines for selected cases (GGC fingerprinting)

Whole Genonome Sequencing (WGS)

Stenotrophomonas spp. WGS files 2020

Enterobacter spp. WGS files 2020

Cupriavidus spp. WGS files 2020

11.3 Facilities Maintenance Work

FMT Audits RHC ward 2A Audits: 2015-2018

FMT Audits QEUH ward 6A Audits: 2018-2019

HAI-SCRIBEs: 2016-2018

HAI-SCRIBEs: 2019

Completed Estates work (old data): 2015-2019

HAI-SCRIBE (old data)- Risk Assessment of work done

6A Maintenance Data: January 2019-October 2020

Domestic FMT Scores: 2015-2018

Estates FMT Scores: 2015-2018

FMFirst Information Ward 2A: 2015-2018

SCRIBE Summary Document: 2016-2018

Ward 2A & 2B Floor Plan

Ward 2A Data final- Facilities Monitoring Tool Information: 2015-2018

Ward 6A Data final: 2018-2020

11.4 Infection Prevention & Control Activity

IPCAT audits

2016 - 2A/2B- Audits

2017 - 2A/2B- IPCAT Audit Actions

2018 - 6A-IPCAT Audit Actions

2018 - 6A- Audits

2018 - 2A- IPCAT Audit Actions

2018 - 2B- IPCAT Audit Actions

2019 - QEUH 6A DCU (RHC 2B) IPCAT Actions

2019 - QEUH 4B BMT IPCAT Actions

2019 - QEUH 6A (RHC 2A) IPCAT Audit Actions

SICP audits

2015 – 2019 Hand Hygiene audits

Ward 2A- Weekly ward reports:

2017 May – October, and December

2017 September SICP Action Plan Completion report

2018 January, March - August

Ward 6A
2018 December

2019 March, May, September, November and December

Ward 6A CAIR Report- Audit of IC Standards (Scoresheet): October 2019

CIP Action Plan Completion: 16 December 2019

Ward 6A CAIR Report: December 2019

Enhanced Supervision audits

2017- Ward 2A
Master Enhanced Supervision - template

June, July

2018- Ward 2A
March – December

2019- Enhanced Supervision Ward 6A (ward 2A) Audits
January - April

August - December

Copy of 6A Walk Round: 6 August 2019

Hand Hygiene Audit Summary Report

11.5 IMT & related Activity

2016 Meetings:

PAG-HAI Asperguillus cases in paediatric haematology: 4 August 2016

IMT Aspergillus Schiehallion IMT minutes: 5 August 2016

NHS GGC HAIORT Aspergillus Royal Hospital for children - Incident form: 5 August 2016

Timeline April v2: August 2016

Aspergillus email: 16 August 2016

Acinetobacter baumanii in Ward 1a-: 28 June 2016

Summary of HIIORT: 2015-2019

2017 Meetings:

Appendix 4- Summary of Incidents & outbreaks on ward 2A: 1 March 2017- May 2017

PAG increase in fungal pathogens in Haematology: 3 March 2017

Minutes- IMT Aspergillus Ward 2A: 7 March 2017

PAG: 12 April 2017

IMT minutes action points ward 2A Rotavirus: 13 April 2017

Minutes Ward 2A Rotavirus Astro Virus: 17 April 2017

PAG-URE 2A: 28 April 2017

Line listing v ward 2A, RHC: April 2017

PAG- Norovirus 2A: 31 May 2017

Stenotrophomonas (1): 26 July 2017

PAG Aspergillus Ward 2A RHC: 27 October 2017

NIPCM Debrief report VRE Rotavirus Astrovirus final

2018 Meetings:

Final PAG Cupriavidus: 15 February 2018

IMT Water Contamination Ward 2A: 2 March 2018- 27 March 2018

Healthcare Infection Incident & outbreak reporting (2): 1 March 2018

VRE PAG Ward 2A: April 2018

PAG E Cloacae final: 18 May 2018

PAG Increased incidence - Enterobacter Cloacae in Blood Cultures: 18 May 2018

PAG Increased incidence - Stenotrophomonas maltophilia in blood cultures: 18 May 2018

IMT Water Contamination Ward 2A: 29 May 2018

Healthcare Infection Incident & outbreak reporting: 4 June 2018

IMT Water Contamination Ward 2A: 4 June-21 June 2018

PAG Aspergillus final: 20 July 2018

IMT x3 Gram Negative bacteraemia associated with Haemoncology patients Ward 2A: 5 September 2018, 10 September 2018 & 13 September 2018

Weekly summary information: 5 September 2018 & 12 September 2018

IMT Action list - 5 September 2018-13 September 2018

IMT Water Contamination Ward 2A: 14 September -28 September 2018

Ward 6A pre Decant inspection completed on 21 September 2018

October- IMT Water Contamination Ward 2A: 5 October-26 October 2018

IMT Water Contamination Ward 2A: 2 November: 30 November 2018

Communication with patient families and staff as a result of IMT actions in 2018-2 March 2018. 30 November 2018

PAG Cryptococcus neoformans: 18 December 2018

2019 Meetings:

Ward 6A weekly shower checks 28 January 2019

PAG- Gram Negative 6A: April-May 2019

PAG-Steno cases: April- May 2019

IMT Ward 6A Gram Negative Blood Cultures: June - November 2019

IMT Action list (version 2): 19 June - 25 June 2019

IMT Action List: 19 June - 25 June 2019

IMT Teleconference notes ward 6A Gram Negative blood cultures: 20 September 2019

Communication with patient families and staff as a result of IMT actions in 2019

IMT PICU Pseudomonas Aeruginosa: 19 November 2019

Water Group Meetings:

Monthly meeting minutes from April - December 2018

Monthly meeting minutes from January - December 2019 (excluding May & November)

QEUH Campus Water Systems Written Scheme - Controlling the Risks of Legionella &n other Harmful bacteria in Water Systems - NHS GGC & QEUH Oversight Board report. 2019

QEUH Water Sampling Programme 2020, version 4 - NHS GGC & QEUH Oversight Board report

Risk Assessment Water Safety (interim report): 6 June 2018

NHSGGC Water Actions & reviews: 2015-2019

Water Testing in QEUH Campus 2015-2017

HIIATS:

HIIATS Red & Amber RHC 2018 - 2020

HIIORTS:

Review of Healthcare Infection Incident & Outbreak Reporting Templates (HIIORTS) 2015 -2019

Hot Debriefs:

Hot debrief - Serratia Marcescens Outbreak report NICU- March 2011

Hot debrief - Outbreak Report completed: 12 May 2016

Hot debrief - Outbreak Report PICU RHC: 27 October 2016

Hot debrief - Rota Astro ward 2A: April 2017

Hot debrief - Aspergillus- March: April 2017

Hot debrief - March/April 2018

Hot debrief - Stobhill GAS: 19 February 2019

Hot debrief - Ortho SSI Rates: 29 July 2020

Hot debrief - PRM MSSA 2019 (final draft): 30 July 2020

Root Cause Analyses (RCA)

Root cause analysis of gram negative bacteraemia in a cohort of paediatric Haematology/oncology patients at the Royal Hospital for Children, October 2019.

Template RCA document for Haem Onc 2019

Completed examples of RCA: 2019 (2); 2020 (10)

Other IMT's

Meeting records for Cryptococcus December 2018-February 2019

Analysis Documents and Other Data

NHSGGC report on IPC response to 2017 Infections in RHC

Indexed comparison of changes in bed days haem/onc v Rest of RHC: July 2013-July 2018

Descriptive Analysis of Five year trends in bacteraemia rates for selected Gram Negative Organisms: July 2013-July 2018

Bacteraemia rates and Resistance Paediatric Haemato –oncology 2014 -2018- Dr Christine Peters & Kathleen Harveywoods

QEUH Sampling OOS Parameters IP- Microbiological monitoring QEUH/RHC during & post chlorine dioxide installation: 20 November 2018- Dr Teresa Inkster

Timeline with Reference to HFS Water Management Issues Technical Review- NHSGGC-QEUH & RHC- 2018

Timeline of Events & Actions relating to RHC wards 2A/2B Water Incident: March- November 2018

RHC Gram Negative Descriptive Epidemiology- Dr Iain Kennedy July 2019

PHPU Epidemiological Curve & Summary of Organisms- updated: July 2013-September 2019

SBAR 6A Incident Data & Epidemiology – Dr Teresa Inkster & Dr Christine Peters: 7 October 2019

SBAR- Review of 2017 Mortalities in which Stenotrophomonas was isolated, by Alan Mathers, Chief of Medicine, W&C - November 2019

Report on the Clinical aspects of the management of patients with documented Blood stream infection with an environmentally classified Gram Negative organism in the Paediatric Oncology Service, NHSGGC between June 1st 2015 and September 30th 2019. - TJ Beattie, January 14 2020

NHSGGC Infection Control presentation: 16 January 2020

Paed Haem-Onco SPCs Blood Cultures: 5 August 2020, by Ann Kerr

SPC Charts Gram Negative Blood Cultures Paediatric Haem-Onc: August 2020

Paediatric- Haemato-Oncology (QEUH 6A & 4B BMT)- Blood Cultures- Gram Negative Environmental Bacteria Group & Environmental Enteric Bacteria Group: September 2020, by Ann Kerr

SPC Chart- Gram Negative RHC/QEUH- Paediatric Haemato-Oncology blood cultures: October 2020

Policies

NHSGGC Outbreaks in Hospitals- versions dated: November 2015, 2017, 2019, 2020 (v9)

NHS GGC SOP Environmental Organisms in High Risk Areas. November 2018 (final v1)

11.6 Clinical Care

Central Line Care

Audit report: Gram Negative Sepsis & CVL Removal

Rate of Central line associated blood stream infections (CLABSI) per 1000 central line days- updated to December 2020

Antibiotic Policies and Practice:

Management of Neutropenia & Fever Antibiotic Policy 2010, 2015, 2017, 2020

Clinical Guideline- Empirical Antibiotic Therapy in Children, November 2017

SBAR- Review of Prescribing in Haemato-Oncology Patients RHC Glasgow: 12 December 2019

Adverse Events

Datix system reports for cases included in the Case Note Review

NHS GGC Policy on the Management of Serious Adverse Events: August 2020

Information about Deaths

Death certificates (19 patients)

NHS GGC PRAM / Morbidity & Mortality Meeting reports (17 patients)

NHS GGC Guidelines for Morbidity & Mortality Review Meetings

NHS GGC M&M participant Analysis Tool

NHS GGC M&M Principles of Practice- Code of Conduct- paper by Karon Cormack, Head of Clinical Risk

NHS GGC Morbidity & Mortality Review Process - January 2018

NHS GGC Morbidity & Mortality Reviews, An analysis

Other

Clinical Review Group Terms of Reference

Ward 6A Reopening Bundle: 8 November 2019

CRG Minutes Ward 6A: 17 February 2020

Episodes of care- Transferred to other wards/hospitals/Health Boards for delivery of Chemotherapy – July–November 2019.

SECTION 2

11.7 Health Facilities Scotland:

Water Management Issues Technical Review-NHSGGC-QEUH & RHC. March 2019

SBAR for Health Facilities Scotland Water Management Issues Technical Review report dated March 2019; published 19 February 2020

11.8 Healthcare Improvement Scotland:

Learning from Adverse Events through reporting & review - A national framework for Scotland - December 2019

Adverse Events: Guidance on national notification data - March 2020

11.9 Health Protection Scotland:

HPS Pseudomonas Guidance (Post Consultation):13 December 2012

Water Report - Summary of Incident & Findings of the NHS GGC: QEUH/RHC for Children Water Contamination Incident & Recommendations for NHS Scotland: 20 December 2018

Health Protection Scotland - Review of NHSGGC Paediatric Haemato-Oncology Data: October 2019

Mandatory NHS Scotland Alert Organism/Condition list: November 2019

Guidance for Neonatal Units (NNUs) (Levels 1,2 & 3) adult & Paediatric Intensive Care Units (ICUs) in Scotland to Minimise the risk of Pseudomonas Aeruginosa infection from water 2018

Pseudomonas aeruginosa routine water sampling in augmented care areas for NHS Scotland- Report by Health Protection Scotland September 2018

Prevention and management of healthcare ventilation system-associated infection incidents/outbreaks – 16 October 2019

Prevention & Management of Healthcare Water Associated Infection Incidents/Outbreaks: August 2019 v1.0

HPS Infection Incident Assessment Tool

11.10 NHS Scotland

The Risk Management of HAI: A Methodology for NHS Scotland- Healthcare Associated Infection Taskforce, November 2008

National Infection Prevention & Control Manual- Healthcare Infection Incidents, Outbreaks & Data Exceedance- http://www.nipcm.scot.nhs.uk/chapter-3-healthcare-infection-incidents-outbreaks-and-data-exceedance/#a1744

11.11 Other Healthcare Reviews:

The Vale of Leven Hospital Inquiry Report- November 2014

QEUH Independent Review- Review report- Fraser & Montgomery- June 2020

Terms of Reference for the Brodie Inquiry: June 2020

11.12 Oversight Board

Procedures in the event of out of specification sample for Legionella & other

monitored bacteria, moulds etc- NHS GGC & QEUH Oversight Board report

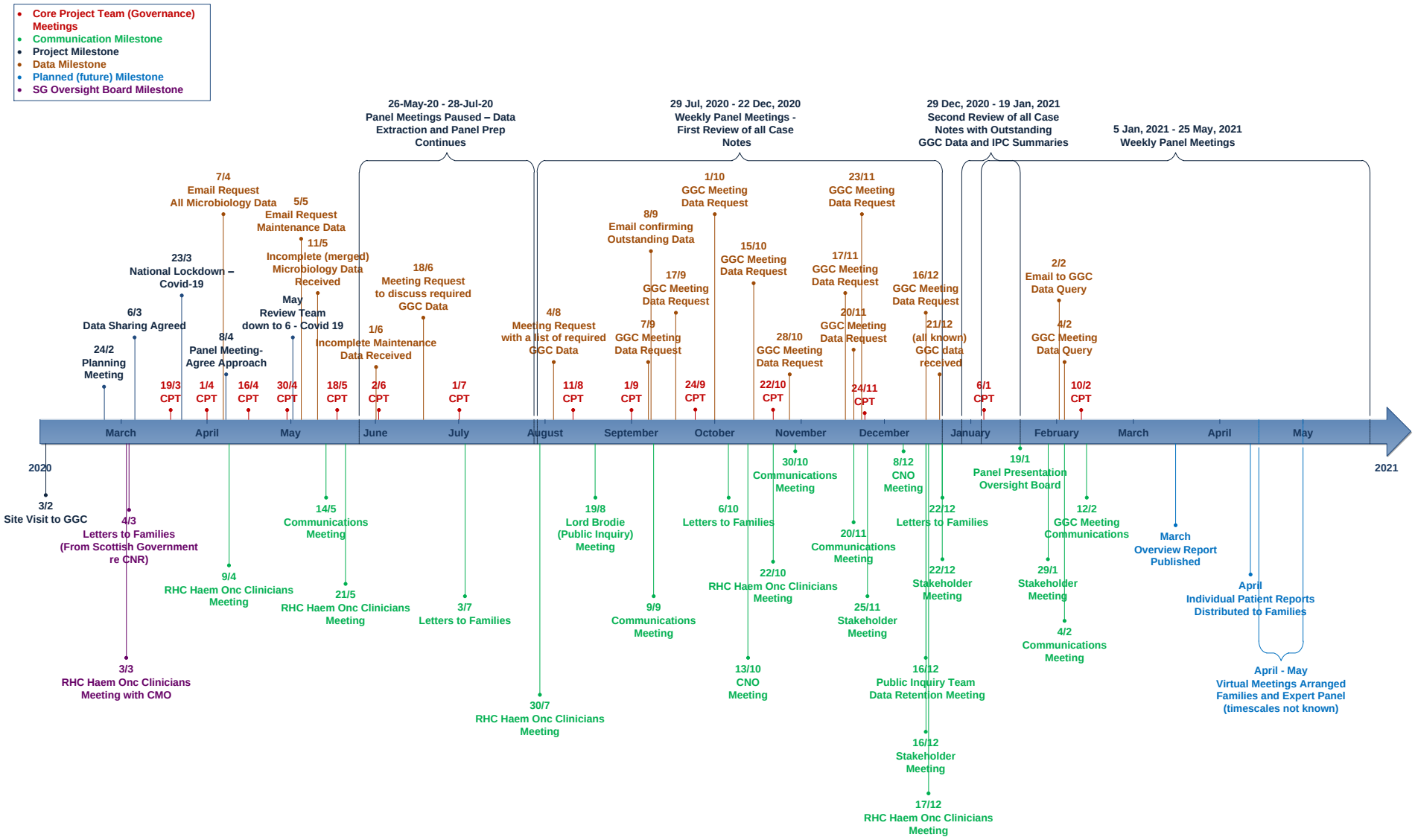
Timeline of Incidents for period 2015-2019 (‘Super Timeline’) 2020

NHSGGC Oversight Board Infection Prevention & Control & Governance Subgroup- Report of the Peer Review: June 2020.

NHSGGC- QEUH Oversight Board- Management of Infection Control Incidents in Wards 2A/RHC during 2017. 31 August 2020

The QEUH/NHS Greater Glasgow & Clyde Oversight Board- Interim Report: Progress & Findings- December 2020

Appendix A: Timeline of the Work of the Review



Appendix B: Organisms Selected for Inclusion

Gram-negative Environmental/Enteric grouping	
Genus	**Species**
Achromobacter	*Achromobacter species*
Acinetobacter	*Acinetobacter baumannii* Acinetobacter baumannii complex *Acinetobacter ursingii*
Aeromonas	*Aeromonas hydrophila* *Aeromonas species*
Brevundimonas	*Brevundimonas species*
Burkholderia	*Burkholderia cepacia*
Chryseobacterium	*Chryseobacterium indologenes* *Chryseobacterium species*
Citrobacter	Citrobacter braakii Citrobacter freundii Citrobacter koseri Citrobacter youngae
Cupriavidus	*Cupriavidus pauculus*
Delftia	*Delftia acidovorans*
Elizabethkingia	*Elizabethkingia meningoseptica* *Elizabethkingia miricola* *Elizabethkingia species*
Enterobacter	*Enterobacter cloacae* Enterobacter cloacae complex Enterobacter cloacae ESBL Enterobacter hormaechie
Herbaspirillum	*Herbaspirillum species*
Klebsiella	Klebsiella oxytoca Klebsiella pneumoniae
Pantoea	*Pantoea septica* *Pantoea species*
Pseudomonas	*Pseudomonas aeruginosa* *Pseudomonas putida*

	Pseudomonas stutzeri
Raoultella	*Raoultella planticola*
Rhizobium	*Rhizobium radiobacter*
Roseomonas	*Roseomonas mucosa*
Serratia	*Serratia liquefaciens* *Serratia marcesens*
Sphingomonas	*Sphingomonas paucimobilis*
Stenotrophomonas	*Stenotrophomonas maltophilia*
Acid Fast Environmental (AF ENV)	
Mycobacterium	*Mycobacterium chelonae*

Appendix C: Paediatric Trigger Tool Score Sheet

PAEDIATRIC TRIGGER TOOL

www.institute.nhs.uk/safercare/portal

Trigger Tool Paediatrics

Patient Age _____ years, months

Date Of Discharge: _____

Length Of Stay: _____ days

NHS Institute for Innovation and Improvement

		Full Description	Trigger	Adverse Event	Severity of Adverse Event	Comment on this trigger
General	PG1	EWS or baseline obs missing or incomplete OR score/observation requiring response	○ No ○ Yes	○ No ○ Yes	N/A E F G H I	
	PG2	Tissue damage or pressure ulcer	○ No ○ Yes	○ No ○ Yes	N/A E F G H I	
	PG3	Readmission to hospital within 30 days	○ No ○ Yes	○ No ○ Yes	N/A E F G H I	
	PG4	Unplanned admissions	○ No ○ Yes	○ No ○ Yes	N/A E F G H I	
	PG5	Cranial Imaging	○ No ○ Yes	○ No ○ Yes	N/A E F G H I	
	PG6	Respiratory/Cardiac arrest/crash call	○ No ○ Yes	○ No ○ Yes	N/A E F G H I	
	PG7	Diagnostic imaging for embolus/thrombus +/- confirmation	○ No ○ Yes	○ No ○ Yes	N/A E F G H I	
	PG8	Complication of procedure or treatment	○ No ○ Yes	○ No ○ Yes	N/A E F G H I	
	PG9	Transfer to higher level of care (inc admission to specialist unit, ICU/ HDU)	○ No ○ Yes	○ No ○ Yes	N/A E F G H I	
	PG10	Hypoxia O_2 sat <85%	○ No ○ Yes	○ No ○ Yes	N/A E F G H I	
	PG11	Cancelled elective procedure/ delayed discharge	○ No ○ Yes	○ No ○ Yes	N/A E F G H I	
Surgical	PS1	Return to theatre	○ No ○ Yes	○ No ○ Yes	N/A E F G H I	
	PS2	Change in planned procedure	○ No ○ Yes	○ No ○ Yes	N/A E F G H I	
	PS3	Surgical site infection	○ No ○ Yes	○ No ○ Yes	N/A E F G H I	
	PS4	Removal/Injury or repair of organ	○ No ○ Yes	○ No ○ Yes	N/A E F G H I	
ITU	IP1	Readmission to ICU or HDU	○ No ○ Yes	○ No ○ Yes	N/A E F G H I	

Adverse Event Score (Measure of Harm)

E	Temporary harm to the patient and required intervention	G	Permanent patient harm
F	Temporary harm to the patient and required initial or prolonged hospitalisation	H	Intervention required to sustain life
		I	Patient death

PTO

		Full Description	Trigger	Adverse Event	Severity of Adverse Event	Comment on this trigger
Medication	PM1	Vitamin K given (except for routine neonatal dose)	No Yes	No Yes	N/A E F G H I	
	PM2	Naloxone given	No Yes	No Yes	N/A E F G H I	
	PM3	Flumazenil given	No Yes	No Yes	N/A E F G H I	
	PM4	Glucagon or glucose ≥ 10% given	No Yes	No Yes	N/A E F G H I	
	PM5	Chlorphenamine given	No Yes	No Yes	N/A E F G H I	
	PM6	Anti-emetic given	No Yes	No Yes	N/A E F G H I	
	PM7	IV Bolus ≥ 10ml/kg colloid or crystalloid given	No Yes	No Yes	N/A E F G H I	
	PM8	Abrupt medication stop	No Yes	No Yes	N/A E F G H I	
Laboratories	PL15	Thrombocytopenia (<100)	No Yes	No Yes	N/A E F G H I	
	PL1	High INR (>5) or APTT > 100 sec	No Yes	No Yes	N/A E F G H I	
	PL2	Transfusion	No Yes	No Yes	N/A E F G H I	
	PL3	Abrupt drop in Hb or Hct (>25%)	No Yes	No Yes	N/A E F G H I	
	PL4	Rising urea or creatinine (>2x baseline)	No Yes	No Yes	N/A E F G H I	
	PL5	Na^+ <130 or >150	No Yes	No Yes	N/A E F G H I	
	PL6	K^+ <3.0 or >6.0	No Yes	No Yes	N/A E F G H I	
	PL7	Hypoglycaemia (<3mmol/l)	No Yes	No Yes	N/A E F G H I	
	PL8	Hyperglycaemia (>12mmol/l)	No Yes	No Yes	N/A E F G H I	
	PL9	Drug level out of range	No Yes	No Yes	N/A E F G H I	
	PL10	MRSA bacteraemia	No Yes	No Yes	N/A E F G H I	
	PL11	C. difficile	No Yes	No Yes	N/A E F G H I	
	PL12	Vanc resistant enterococcus	No Yes	No Yes	N/A E F G H I	
	PL13	Nosocomial pneumonia	No Yes	No Yes	N/A E F G H I	
	PL14	Positive Blood Culture	No Yes	No Yes	N/A E F G H I	
	PO1	Other (specifiy)	No Yes	No Yes	N/A E F G H I	
		TOTALS				**Completed portal entry**

Appendix D: Data Synthesis Template

Part 1- Dataset:

UPN (GC)	EPISODE	DATES OF PANEL REVIEW	
DATASET ITEM Ref No.	DATA ITEM DESCRIPTION	FINDINGS & COMMENTARY	ACTION REQUIRED / ADDITIONAL INFO.
OTHER			
3.0	GENDER		
4.0	DOB		
CANCER DIAGNOSIS			
5.0	DIAGNOSIS NAME		
6.0	DATE OF DIAGNOSIS		
7.0	AGE AT THIS DIAGNOSIS		
8.0	TREATMENT PROTOCOL		
9.0	DATE TREATMENT ON THIS PROTOCOL FIRST STARTED		
10.0 & 10.1	DELIVERY OF TREATMENT FOR CANCER IN THE PAST 30 DAYS PRIOR TO INFECTION / CLARIFICATION		
MICROBIOLOGY			
11.0	ORGANISM		
12.0	CATEGORY FOR INCLUSION IN REVIEW (Group 1, 2 or 3)		
13.0 & 14.0	DATE (& Time) CULTURE TAKEN (Defines date of infection)		
15.0	SITE OF CULTURE		
16.0 & 16.1	WHY WAS CULTURE TAKEN?		
17.0 & 17.1	ORIGIN OF INFECTION (HAI, HCAI, Community, Other)		
18.0	OTHER POSITIVE CULTURES (30 days pre or post index infection)		
18.1	DATE OF SPECIMEN		
18.2	ORGANISM		
18.3	SITE		
INFECTION EPISODE			
19.0	DATE OF ADMISSION (Relates to date infection was recognised and / or treated)		
20.0	PLACE ADMITTED FROM		
21.0	REASON FOR ADMISSION		
22.0	DATE OF ONSET OF SYMPTOMS		
23.0 & 23.1	DATES OF ADMISSION & DISCHARGE FOR PREVIOUS IN PATIENT STAY AT RHC/QEUH IN PREVIOUS 30 DAYS		
23.2	DISCHARGE DESTINATION AFTER PREVIOUS IN PATIENT STAYS AT RHC/QEUH		
24.0	DATE OF PREVIOUS ATTENDANCE AT RHC/QEUH CLINIC OR DAY CARE IN PREVIOUS 30 DAYS		
25.0	WARD & BED LOCATION ON DATE OF ONSET OF SYMPTOMS		
25.1	ISOLATION / PROTECTION PRECAUTIONS IN PLACE AT THAT LOCATION		
26.0	WARD & BED LOCATION ON DATE OF INFECTION		
26.1	ISOLATION / PROTECTION PRECAUTIONS IN PLACE AT THAT LOCATION		
27.0	CLINIC, DAY CARE AND WARD & BED LOCATION IN PREVIOUS 30 DAYS		
27.1	ISOLATION / PROTECTION PRECAUTIONS IN PLACE AT THAT LOCATION		
28.0	AGE AT DATE OF INFECTION		
29.0	NEUTROPENIC ON DATE OF INFECTION		
30.0 & 30.1	ANTIBIOTIC PROPHYLAXIS (at time of infection or in previous 30 days)		
31.0	DATE ANTIBIOTICS COMMENCED		
32.0	FIRST LINE ANTIBIOTIC THERAPY		
32.1	IN LINE WITH LOCAL POLICY / MICROBIOLOGICAL ADVICE		
33.0	SECOND OR SUBSEQUENT LINE ANTIBIOTIC THERAPY		
33.1	DATE SECOND OR SUBSEQUENT LINE ANTIBIOTICS COMMENCED		
33.2	IN LINE WITH LOCAL POLICY / MICROBIOLOGICAL ADVICE		
34.0	DATE ALL ANTIBIOTICS DISCONTINUED		
35.0	CENTRAL VENOUS ACCESS DEVICE IN SITU		
35.1	DATE INSERTED		
36.0	PROBLEMS WITH DEVICE (Recorded within 30 days prior to date of infection)		
37.0 & 37.1	DATE REMOVED FOR THIS INFECTION		
38.0	OTHER DEVICE IN SITU		
38.1	DESCRIPTION		
39.0	DATE OF PRIOR SURGICAL PROCEDURE		
39.1	DESCRIPTION		
39.2	THEATRE LOCATION		
40.0	DATE OF DISCHARGE		
41.0	DISCHARGE DESTINATION		
42.0	DURATION OF ADMISSION		
PAEDIATRIC TRIGGER TOOL			
43.0 & 44.0 & 45.0	TRIGGER CODE/DESCRIPTION		
46.0 & 46.1	ADVERSE EVENT? / SCORE		
OUTCOMES			
47.0	REQUIRED PICU ADMISSION		
47.1	DATE ADMITTED		
47.2	DATE DISCHARGED		
47.3	DAYS IN PICU		
48.0	DATE NEXT SCHEDULED CANCER TREATMENT WAS DUE TO START		
48.1	CLARIFICATION		
49.0	DATE ACTUAL START		
50.0	DURATION OF DELAY		
51.0	TREATMENT MODIFICATION REQUIRED		
51.1	CLARIFICATION		
52.0	EVIDENCE OF PERSISTING SEVERE TOXICITY		
52.1	DESCRIPTION		
DEATH			
53.0	DATE OF DEATH		
54.0	CAUSE OF DEATH - HOSPITAL		
55.0	CAUSE OF DEATH - DEATH CERTIFICATE		
56.0	AGE AT DEATH		
57.0	TIME FROM DATE OF INFECTION		
58.0	PLACE OF DEATH		

Part 2- Summary:

UPN	EPISODE	DATES OF PANEL REVIEW
CLINICAL TIME LINE:		
DATE	EVENTS	
TABLEAU TIMELINE (Infection clustering in relation to date and location of care):		
ICNET:		
TELEPATH:		
IMT & PAG MINUTES:		
DATIX:		
ENVIRONMENTAL MICROBIOLOGY (Surveillance cultures):		
HAI-SCRIBE (Maintenance / Building activity):		
OTHER INFORMATION / OBSERVATIONS:		

Part 3- Conclusions:

UPN	EPISODE	DATES OF PANEL REVIEW
1. Are the data provided sufficient to complete the review as intended and to reach a conclusion?		
2. Does the infection episode fit within the criteria for the review? (Yes / No)		
3. Is it possible to link this infection episode with the environment of the RHC/ QEUH? (Unrelated / Possible / Probable / Confirmed / Unable to determine)		
4. Was there an impact on patient care and outcome in relation to the infection? (Yes / No / Unable to determine)		
5. If so, grade severity (Minor; Significant; Severe; Critical)		
6. What lessons might be learned from this case? a) To strengthen IPC measures for the future		
b) In any other respect		
7. Are there any other points arising from this review?		
8. Panel's response to questions or comments raised by patient / family		

Acknowledgements

We are very grateful for the information, advice and support we have received from the many people with whom we have been in contact, directly and indirectly, in undertaking our Review and delivering this Report.

Many staff at NHS GGC have been involved in locating and collating data, sourcing and providing documents, and advising on policy and process. We thank them all but would like to acknowledge the coordinating role played by Elaine Vanhegan, Head of Corporate Governance and Administration, through whom so many of our requests, queries and challenges were directed.

We have benefited from the wisdom and advice of members of the NHS GGC Oversight Board, but particularly wish to acknowledge the support of Professor Marion Bain and the active engagement and encouragement of Phil Raines whose encyclopaedic knowledge of the story of the QEUH/RHC has been invaluable in helping us understand so much of the context to our work, and in pointing us to sources of data without intruding on our independence.

We have valued the advice and guidance of Professor Craig White and Professor John Cuddihy who have so carefully helped us understand the needs and sensitivities of the families affected by the infections that resulted in the need for our Review, and who have provided us with a communication link with the families themselves.

Scottish Government staff, including Carole Campariol-Scott, Jim Dryden and, more recently, Martina Fluke and Shalinay Raghavan have provided important support and kept processes moving in the background.

However, this Review and our Report would not have been possible without the skills and commitment shown by the following members of the wider Review Team, who have showed extraordinary commitment to the work involved despite the challenges encountered:

Dr Julie Aitken, Scottish Clinical Leadership Fellow with the Scottish Government in the Office of the CMO and Healthcare Improvement Scotland; ST6 Paediatric Registrar. (Data synthesis and literature review);

Marie Brown, Programme Manager, Programme Management Services, NHS National Services Scotland (Programme management);

Professor Peter Davey, University of Dundee (Clinical data extraction and assessment, and PTT);

Linda Dempster, Infection Prevention and Control Adviser Safety Support, NHS England and NHS Improvement (IPC adviser);

Hayley Kane, Infection Control Manager, Scottish National Blood Transfusion Service (Telepath and ICNet data extraction);

Emma Mackay, Project Support Officer, Programme Management Services, NHS National Services Scotland (Management support);

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Dr Fiona Murdoch, Lead Healthcare Scientist, National ARHAI Scotland (Clinical and epidemiological data lead; data analysis and presentation); and

Dr Pat O'Connor, Honorary Professor, University of Stirling, Faculty of Healthcare Sciences and Sport (PTT lead and clinical data extraction).

We thank them for their professionalism, hard work and good humour. Some will continue to work with us as we enter the second phase of our work in delivering individual reports for all families of children included in our Review.

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

CONFIDENTIAL NOT FOR ONWARD DISTRUBUTION

Final Draft 05/04/2022

Full: NOT redacted

Contents

Summary of Findings

Hypothesis number 1: Plantroom (PR) air (particularly on Level 12, QEUH).

The Hypothesis was that *Cryptococcus neoformans* spores, (and those of *Cryptococcus* species) if present, could get into the Air Handling Unit (AHU) during a Final Filter change with the belief that without the presence of the Final Filter (to protect and remove), the air from the Plant room (presumed to have spores of *C. neoformans* in it) would gain entrance to the duct work and thence to the patients. Importantly, it was discovered that during a Final Filter change **the air from the duct work comes forcefully BACK UP the duct and pushes out INTO the Plant room. This is thought to be a 'thermal effect'.**

1. There have been more than 3000 air samples taken and *Cryptococcus neoformans* has never been found in any room, ward or in any of the samples taken from the air circulating inside or outside the Hospitals.
2. Non-neoformans Cryptococci have been found in air samples not only in areas served by AHUs on Level 12 but also in different levels of the QEUH and RHC, AND also found in air in the Laboratory Building. It should be noted that the Laboratory building and their associated Plant rooms are completely separate from those in QEUH/RHC. It is also important to note that these Plant rooms in the Lab building showed absolutely no evidence of either ingress of pigeons or pigeon guano.
3. The above is highly suggestive of the presence of the Cryptococci in the 'outside air' as it was also still present after months of active pest control, inspection and cleaning of the QEUH/RHC Plant rooms.

This Hypothesis was therefore deemed UNFEASIBLE

Please, also note, that in this part of the Report a discussion concerning the issues of damp/wet pigeon guano takes place, i.e., spores less easily aerosolised and larger spore size.

Hypothesis number 2: Outside Air Source

1. Wards [redacted] had F7 standard air filters but did not have HEPA filters therefore would allow through a percentage of *C. neoformans* spores if present in the outside air.
2. The investigations and finding detailed above in hypothesis 1 informed the consideration of hypothesis 2.

Thus Hypothesis 2 was therefore deemed 'POSSIBLE'.

Hypothesis number 3: Lack of 'Protective Isolation'

'Protective Isolation' requires 3 things:

- Air should be HEPA filtered.
- Patient's room must be positively pressurised to its surroundings.
- Air in room must uniformly leak outwards.

This is to prevent ingress of non-HEPA filtered air – 'dirty air' that may carry, e.g., fungal spores including *C. neoformans*.

Following extensive air sampling, pressure and flow testing, the following was concluded:

- [redacted] with HEPA filtered air, but lacks control of the air particularly around one of its entrances. It should however be noted that the rooms in [redacted] are HEPA filtered but not in the corridor and this would in turn make control less effective.
- [redacted] does not have HEPA filtered air, but surprisingly has best control of the air around it.
- [redacted] does not have HEPA filtered air and has poor control of the air around it.

List of mitigations taken to address some of these issues is contained in each section of the report.

In all these wards the above is related to the air sampling results.

The Bone Marrow Transplant Unit (BMTU) is situated within [redacted], even though one might think that this patient population are likely to be the most 'at risk' of *C. neoformans* infections, in fact, the literature would suggest otherwise, with very few cases reported in BMT patients. No one has yet elucidated why this is the case.

[redacted] also houses the Renal Transplant patients. Air sampling showed that air movement around/within this ward is controlled best, but it is not HEPA-filtered. This ward carries out 140 Renal Transplants per year. These patients are among those identified in the literature as 'at risk' of getting infections with *C. neoformans* however following review of this patient cohort, no cases have ever been identified. [redacted]

[redacted]. Please also note, that again, there is no HEPA filtration in this area and real issues with control of the air around both of its entrances, particularly the main entrance. This is fully explained and discussed in the report.

Hypothesis – number 3: 'lack of protective isolation' deemed POSSIBLE, [redacted]

[redacted]

Hypothesis number 5: Helipad

'In the Computational Fluid Dynamics simulations undertaken, they demonstrate that the air arriving at the AHU intake locations does not originate in the region beneath the Helipad for any of the scenarios considered. As a result of this conclusion, it is therefore *unlikely* that debris from the Helipad area is being carried into the hospital ventilation system(s), so anything drawn into the AHU's intakes is coming from the wider environment and not affected by the shape of the building or the presence of a helicopter'

Hypothesis Number 5 is rejected as an unlikely route.

a) See report from Experts
b) REJECTED as cause, by Group

Hypothesis number 6: Specimen Transport System (POD)

POD system AKA 'pneumatic tube system'

This system is used to move specimens from a ward to the labs (and back the other way) via compressed air drawn from either the Plant room (PR 31 – not a PR on Level 12) or the ward area. This is via an enclosed tube system. These PODS then discharge the air into the ceiling void above the Ward Treatment Rooms on their return to them.

The worry was that unfiltered air, particularly from the Plant room might get into the prep/ treatment rooms on the ward.

Deemed by Group as an UNLIKELY route

Hypothesis number 7: Dormancy/Reactivation (complex)

That the cases acquired the *Cryptococcus neoformans* prior to their admission to the QEUH/RHC. The infection lay dormant until their immune system was sufficiently compromised by their co-existing conditions.

The literature review supports this hypothesis. However as reported in many other cases within the literature, due to the length of time that may have elapsed since first exposed and the complexity of how reactivation occurs, this is very difficult to prove.

VERY POSSIBLE [redacted] but likely to be VERY DIFFICULT TO PROVE.

IMPORTANT FINDINGS OF OTHERS AND SOME QUESTIONS TO CONSIDER

1. **Marr, KA et al, (2020)[0].** Important to note that Haemato-oncology patients with particularly lymphoreticular malignancies ([redacted]) are not the only patients at risk of infections with *C. neoformans.* See above paper, there are a wide variety of other diseases that predispose to this infection noting that the QEUH/RHC is the biggest acute hospital in Scotland and will contain many patients who are/were at risk.

2. Note that children very rarely contract infections with *C. neoformans* (this is already a rare disease in adults with only the 17 cases in GGC area in 10 years, 2009-2018) [redacted]

   Again, no one understands why this is so much rarer in children.

3. Note that very few cases, of what is believed to have been, 'hospital-acquired' see Farrer, RA *et al*. (2021)[1] – who quote only one: **Vallabhaneni, S *et al*. (2015)[2]** in Arkansas, USA. There are only, perhaps, a few more cases of hospital-acquired cases in the literature.

4. Note that the literature also suggests that adult males have *C. neoformans* infection about twice as frequently as adult females – this was observed over 50 years. See **Guess, TE et al. (2018)[3]**. Also see cases in GGC, 2009-2018 – 18 cases: 6 Female and 12 Male. [redacted]

5. Other question regards [redacted] Renal Transplants – who are 'at risk' but so far, no cases with approximately 140 transplants per annum (in QEUH). [redacted]

6. Genomics. These were carried out in Boston (USA) on the isolates from the two patient cases in QEUH and also two 'community- acquired' cases from 2018. This was published by Farrar, RA et al. (2021) [1].

The findings were that [redacted], but no environmental *C. neoformans* isolates had (so far) been isolated (by us) in Glasgow. The only guano specimen from the QEUH/RHC site had grown *Cryptococcus uniguttulatus* (from the Helipad).

All of the above will be discussed further in the main report.

Introduction

In November and December 2018, the microbiology laboratory in the Queen Elizabeth University Hospital campus confirmed that they had identified *C. neoformans* [redacted]

This was considered an exceptional infection episode and was therefore reported to Health Protection Scotland (HPS) as per Chapter 3 of the National Infection Prevention and Control Manual. This incident was first reported to HPS on the 20th December 2018 and incident updates continued until the incident was declared over on the 15th February 2019.

There was an initial Problem Assessment Group meeting held on the 18th December 2018. This was followed by 12 Incident Management Team (IMT) Meetings, the first of which was held on the 20th December 2018 and the last one on 15th February 2019. At this time the main hypothesis was, that cryptococcal spores (from pigeon guano) were being aerosolised into the Plant room air, then getting into the Air Handling Units (AHUs) during routine maintenance, i.e. during shut down, opening and final filter change, then onwards to the patients down the duct.

On 20th February 2019 the IMT was stood down by the Infection Control Doctor (IMT Chair). There had been no additional cases since and control measures had been put in place.

One of the actions from the IMT was to commission a review from a group of experts to investigate all possible hypotheses suggested by the IMT and any subsequent hypothesis developed by the Cryptoccocal IMT Expert Advisory Sub Group to determine, if possible, the route(s) of transmission of these rare but significant infections with findings presented in a report format. Membership included representatives from Health Protection Scotland (HPS), Health Facilities Scotland, National Infection Service Reference Laboratory (Public Health England - Colindale) and clinical experts and engineers from NHS Greater Glasgow and Clyde.

The Cryptoccocal IMT Expert Advisory Sub Group chaired by Dr J. Hood was established in February 2019. By 18th November 2019, over 3300 air tests had been conducted since 5th December 2018, air sampling continued until February 2020. The report will be submitted to the Chair of the IMT and the relevant governance groups within GGC including the Board Infection Control Committee, Acute Clinical Governance and Board Clinical Governance Forums and the NHS Board.

Background

C. neoformans is a fungus that lives in the environment (including soil, some trees including decaying wood) throughout the world. It has a known, although complex, association with the guts of pigeons and other birds. Although most people who are exposed to the fungus do not get sick from it, a small number of people can become infected after breathing in the spores. Only one outbreak associated with a hospital has ever been previously reported in the literature Vallabhaneni, S *et al* (2015)[2].

C. neoformans infections are very rare in people who are otherwise healthy; most people affected are immunocompromised (weakened immune system). Classically it occurs in patients with advanced HIV/AIDS, however the incidence in this group depends on where you are in the world and the access to antiviral medication. There are large numbers of cases reported in sub-Saharan Africa where HIV therapies are not readily available.

Please, also, refer to the work of Goldman *et al* (2001)[4] and Kao & Goldman, (2016)[5], on Children and *C. neoformans* infections. 'According to this model, infection is acquired early in life, but remains latent only to be re-activated in the context of immunosuppression. Primary progressive infection also appears to occur as indicated by 'outbreak' reports and the demonstration of recent acquisition of infection from the local environment.'

This is the concept of latency or dormancy. This adds to the complexity of investigating the source of the infection. *C. neoformans* has a known, although complex association with the gut of pigeons and other birds.

The issues of latency and dormancy are fully explored in the hypothesis section of this report, i.e. it is, usually, not possible to determine exactly when patients have been exposed to the *Cryptococcus neoformans*.

Introduction to *C. neoformans* and pigeons plus a little on the exposure to *C. neoformans* and the immune response to it.

Lin, X & Heitman, J (2006)[6] The Biology of *C. neoformans* Species Complex, *Annu. Rev. Microbiol*. 60: 69-105.

This is a useful introduction even if from 2006 but as you will see much more has been learnt since. Page 76: '*Pigeons*. *C. neoformans* serotypes A and D have been isolated from various sources in nature. Their association with pigeon guano is well established, and the fungus has also been less commonly isolated from droppings of other avian species such as chicken, goose, duck, eagle, owl, peacock and parrot. Although cryptococcosis has been associated with birds for almost 50 years, pigeons, however, do not acquire cryptococcosis and point sources for infection have not been identified'.

'Substantial evidence establishes a link between the worldwide distribution of *C. neoformans* and pigeons. However, whether pigeons are infected or serve as carriers for *C. neoformans* is debatable. Most evidence thus far does not support the hypothesis that pigeons themselves are infected; rather they are likely carriers of the fungus.'

'First, although there is an established association between pigeon guano and *C. neoformans* strains, few studies have found *C. neoformans* within the body of birds. The pathogen, however has been cultured from the surface of birds including beaks, feathers and legs, possibly because their habitats (with their guano) are contaminated and enriched for the fungus'.

'Second, aged pigeon guano and the dirt and dust surrounding the guano are more likely to be positive for *C. neoformans* than are fresh droppings, suggesting either that the fungus could originate in the soil and flourish in this particular environment after the soil is contaminated with bird guano, or that the few cells originally in the guano could amplify better in the exposed environment. Because airborne *C. neoformans* cells have been collected from the air above bird guano collected from soil, but not from air above guano deposited on a large adjacent asphalt area, it is less likely that the fungus was originally present in the guano. Population densities of *C. neoformans* in excreta samples are usually significantly higher than those from other sources, such as plant samples, suggesting that avian droppings offer suitable conditions and possibly less competition for the growth of the fungus. It has been documented experimentally that the fungus multiplies well in sterilized pigeon or chicken guano. Dry excrement is a more favourable substratum because it has fewer bacteria and therefore less competition for growth, which could help explain the higher population density found in this substratum.'

'Third, the host environmental conditions in birds are not suitable for the growth of *C. neoformans*. The internal temperature of pigeons is as high as 42 degrees C, and most *C. neoformans* strains cannot survive at this elevated temperature. When a large number of *C. neoformans* cells were fed to birds, viable cells could be recovered shortly after the feeding but no viable cells of *C. neoformans* were detected in the droppings after longer incubation, suggesting that birds can effectively clear fungal cells from their body. In addition, bacterial flora isolated from the intestinal contents of apparently healthy pigeons inhibits the growth of *C. neoformans in vitro*.'

'These lines of evidence indicate that the environment in the gastrointestinal tract of pigeons does not favour multiplication of the fungus, and pigeons are not likely to be systemic carriers of *C. neoformans* in nature. Isolation of *C. neoformans* from avian environments may reflect colonization by enrichment due to the favourable conditions of guano-contaminated soil. However, this does not necessarily mean that birds do not play an active role in dissemination of *C. neoformans* in nature, since they could either pass the fungus through their body or carry the fungus on their surface and could readily transport the cells for a long distance. Birds, most notably pigeons, still remain the most probable vector for worldwide dissemination of this fungus.'

As well as the above paper there are several Review articles which are very informative and are contained, mostly, in the Bibliography section of this report.

Important quote from Maziarz & Perfect (2016)[7] 'The many factors in the immunologic responses to *C. neoformans* cannot be covered completely in this review, but several observations can be made:'

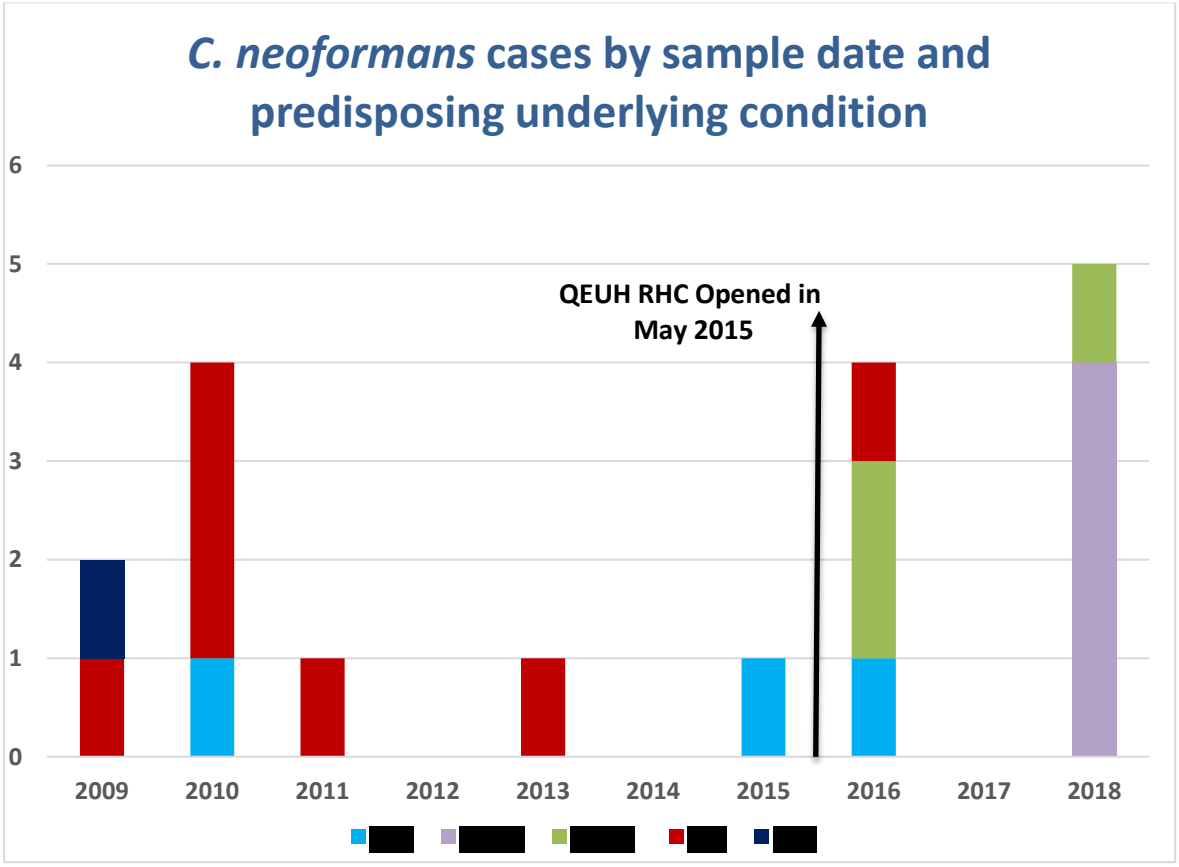
'First: exposure is frequent, and the healthy immunocompetent individual is generally resistant to cryptococcal disease. In fact, even in this group, some apparently normal hosts with cryptococcosis have been found to possess anti-granulocyte macrophage colony stimulating factor antibodies as a potential immune defect.'

'Second: the effective immune response is through a helper T cell-supported reaction and anything that weakens it may let cryptococci survive and thrive. This includes destruction of CD4 + cells by HIV, reduction of TNF activity by anti-TNF inhibitors, or the multifaceted immune suppressant effect of corticosteroids. From activated macrophages to the development of protective antibodies over non-protective antibodies, immunity changes over the course of cryptococcal infections. In fact, even some of our protective host mechanisms might be used against us, as surfactant D may be co-opted by Cryptococcus to gain entry into the lung. Clearly, cryptococcosis emphasizes the Goldilocks paradigm of immunity. It produces disease when immunity is too little or too much, but when the human host immunity is just right, disease does not appear.'

Local Epidemiology

The numbers below represent all cases of *C.neoformans* that have occurred in the Greater Glasgow and Clyde Health Board (GGCHB) area between 2009 and 2018.

Figure 1



The distribution of cases over time across all of Greater Glasgow and Clyde Health Board. This includes cases in other hospitals and the community. (U/K is unknown)

In summary:

- Disease caused by *C. neoformans* is rare, with only 18 cases over ten years in the GGCHB area (see Figure 1).
- In the earlier part of Figure 1, the cases are dominated by patients with HIV.
- In recent years the picture is mixed.
- 2018 had the highest number of cases [redacted] with cases clustered in the second half of the year. The second highest incidences were in 2010 [redacted] and 2016 [redacted].
- [redacted]
- Cases were identified in both, other hospitals and in the community, but only [redacted] cases believed to be possibly hospital-acquired.

Table 1

Underlying Condition	Number
[redacted]	[redacted]
[redacted]	[redacted]
[redacted]	
[redacted]	[redacted]
[redacted]	[redacted]
[redacted]	[redacted]
[redacted]	
[redacted]	[redacted]
[redacted]	[redacted]
[redacted]	[redacted]
[redacted]	[redacted]
[redacted]	[redacted]
[redacted]	[redacted]

[redacted]

Hypotheses

Of the seven hypothesis which were considered by the IMT five were excluded after investigation. Two were taken forward by the sub group (highlighted in bold below):

- **Ingress of pigeons into the Plant room (s) with contamination of the Plant room (s) (PR) with their guano (? containing spores of *C. neoformans*). These spores then gained entry to the air of the PR and then into the Air Handling Units serving specifically the case-patients and others.**
- **Ingress of cryptococcal spores (if present) with the outside air, a small proportion of which would not be removed by the F7 filters, to all areas of the hospital (s), including the Laboratory Block etc. Except where the ventilation system was specialised, e.g. with HEPA filtered air such as the Bone Marrow Transplant Unit (please refer to hypothesis 2) or ultraclean operating theatres.**
- Patient to patient contact – excluded – no links identified.
- Aseptic pharmacy – excluded – no links identified.
- Lab contamination – processes reviewed and hypothesis excluded.
- Stores becoming contaminated outside prior to delivery – process reviewed and no evidence found. Excluded.
- Windows not sealed – after review – Excluded.

The C. *neoformans* IMT Expert Advisory Sub Group reviewed the two hypotheses considered by the IMT in addition to a further five generated by this group following evidence review and investigations undertaken as described in this report.

Hypothesis – Number 1 – Plant Rooms

Pigeon ingress and then fouling in Plant rooms leading to cryptococcal spores (if present) entering the Plant Room air (on for example, Plant rooms on Level 12 QEUH) and then gaining access to the Air Handling Units (AHU's) ventilating the rooms/wards where the case - patients were.

The theory was that when the AHU was shut down, opened, with the final filter removed and changed, there was - believed at that time - the opportunity for *C. neoformans* spores (if present in Plant room air) to be 'sucked' into the open AHU, then into the duct and then down it to the 'at risk' patients.

This would need to have happened when the AHU was shut down, in order to carry out routine maintenance such as removal and or changing, of the final F7 filter, thus possibly allowing spores (if present) from the Plant Room air to get into the duct and then to the patient.

Firstly

AHUs in Plant rooms related to case patient rooms/wards were not opened when the case patients were in these rooms/wards. [redacted]

Secondly

Initial Plant room air samples were taken on the 21st December 2018. These were sent to the laboratory at Glasgow Royal Infirmary and were reported as *C. albidus* (8*/32). When these samples were sent to the National Reference Laboratory (NRL for Fungi, Bristol) it was subsequently found that 7/8* were in fact *C. diffluens* and only one was confirmed to be *C. albidus.* This is important, in that the initial advice from the NRL in Bristol was that *C. albidus* could be employed as a surrogate marker for *C. neoformans,* advice that was later altered after review by NRL. Their experience was also that *C. neoformans* appears to be very difficult to grow from air samples.

On reflection we may have failed to grow C. *neoformans* from outside air (if it was present) due to the presence of significant numbers of other fungi, especially *Aspergillus* spp. This is likely to make spotting it difficult. Perhaps we should have employed Staib's Medium (Bird Seed Agar). However, since we had success in isolating 96 times, 5 different *Cryptococcus* spp., in 12 months of indoor ward sampling, it may have been that *C. neoformans* was simply not present in these air samples.

Thirdly

The Finding of Pigeon Ingress and Fouling on Level 12, QUEH in Late November/Early December 2018.

In late November / early December 2018, pigeon ingress and fouling were found in Plant Room number 123D (Level 12, QEUH). The AHUs in this Plant room serves wards ending in D e.g., 4D, 5D, 6D, 7D etc. [redacted]. It is also worth noting that the time at which you would expect spores to be at their highest level (in the above Plant room air scenario) would be when the cleaning up of the pigeon fouling, was in progress – with the possible risk of aerosolisation into the surrounding air. These areas, in PR 123, were cleaned on the 6th & 7th December 2018.

Fourthly

Note that AHU 123-07 was opened in PR123 on 29th November 2018. [redacted]

[redacted]

[redacted]

[redacted]

The above should give the reader a hint of the complexities of the possible air movements within this hospital. Please see Hypothesis 3, Lack of 'Protective Isolation'.

Fifthly

The Hypothesis was that air from a Plant Room (postulated to contain aerosolised spores of *Cryptococcus neoformans*, from the postulated presence of pigeon guano) could possibly gain access to the patients via the Air Handling Units (AHUs) when they were shut down and opened to replace the Final Filter – thus allowing aerosolised spores (if present in the Plant Room air) down the then 'filter-less' duct. The theory was that the air would be 'pulled' into the AHU through its open door and proceed down the duct to the patients.

In reality the OPPOSITE happens. When the AHU is shut down and the door opened – and the Final Filter removed - air is driven, at some force, OUT of the duct and INTO the Plant Room – a presumed thermal effect – NOT down the duct to the patients.

[redacted]

Sixthly

It is also important to point out that when the ventilation system is operational (i.e., when the AHU is ON) that the part of the AHU from the fan onwards (about half way down the unit) is all under positive pressure i.e., the air within the unit can leak OUT but air (i.e., Plant room air) CANNOT leak IN. Next, the air goes through the fine filter (Final Filter) prior to entering the duct work which takes the air to the wards and rooms that it serves.

It is also important to realise, that from that fine filter (Final Filter) in the AHU to the Ward/Rooms themselves - that the duct work is also under positive pressure. Therefore, as above, filtered air can leak OUT of the duct, BUT air (including unfiltered air) cannot leak INTO the duct.

Therefore: both the outside air via the air intakes and any ingress of Plant Room air gaining access prior to the fan in the AHU (as this part of the AHU is under negative pressure, so air can leak IN) – air from *BOTH the above* will be met by the same Final Filter. Air, after passing the Final Filter and entering the duct work, is under positive pressure, so that air will always leak OUT not IN and therefore this gives the protection of preventing ingress of unfiltered air into all of that duct work.

We also continued to find the intermittent presence of *Cryptococcus* spp., mainly *C. diffluens*, in room/corridor air samples (but never *Cryptococcus neoformans*). We have found these (non-*C. neoformans* cryptococci) in air samples not only from rooms in QEUH/RHC but also in rooms/areas of the Lab Block (which is in a completely separate building, which also contains its own separate Plant rooms from those serving the QEUH or RHC).

These (Lab block) positive air samples were NOT related to obvious pigeon ingress / faecal contamination of any of the supplying Plant Rooms, all of which have had routine inspection and routine cleaning since late December 2018 / early January 2019.

CONCLUSIONS

We can, therefore, say that the presence of non-*C.neoformans* cryptococci in Ward areas of the QEUH, RHC and Lab Block is highly unlikely to be related to pigeon fouling in the Plant rooms/AHUs for the following reasons:

Firstly, we have never found *C. neoformans* either from samples of Plant room air or from any room/ward air at any time, but it should also be noted that *C. neoformans* has never been isolated from any air sample in this study (>3000 samples). *Cryptococcus* spp. (*not C.neoformans*) have been found in Plant Room air but only once from outside air (QUEH roof, with a *Cryptococcus curvatus* in December 2018). We have also found in ward/room air samples in QEUH/RHC between late 2018 to December 2019 some 96 isolates of a varying *Cryptococcus* spp., but again not *C. neoformans* (Table 2).

Secondly, we continued to find these non-*C. neoformans* cryptococci, not only in areas served by AHUs on Level 12 but also on different levels of QEUH/RHC and also in areas in the LABORATORY BUILDING, served by Plant rooms/AHUs which are in a completely separate building from those in the QEUH/RHC and they also had NO evidence of pigeon ingress/guano.

Thirdly, it should also be noted that these non-*C. neoformans* cryptococci were still present in air samples taken after months of active pest control inspection, cleaning and prevention.

This all suggests that these *Cryptococcus* species are/were present in the outside air and some were coming in through the F7 filters and/or due to ingress of unfiltered outside air (due to, lack of 'protective isolation', see later) and not related to any pigeon ingress and pigeon guano contamination of any Plant room.

Table 2*: Cryptococcal* species isolates from air sampling 21 Dec 2018 to end Dec 2019

	C.diffluens *(N. diffluens)*	*C.albidus* *(N.albida)*	*C.albido-similis* *(N.albido- similis)*	*C.uniguttulatus* *(F.uniguttulata)*	*Crypto.curvatus* *(Cutan.curvatus)*	TOTAL
Dec 21st2018 N=53	14	0	1	0	1 Roof	**16**
Jan 2019 N=422	24	3	0	0	0	**27**
Feb 2019 N= 440	0	0	0	1	0	**1**
March 2019 N= 320	4	0	0	1	0	**5**
April 2019 N= 334	2	0	0	0	0	**2**
May 2019 N=420	7	3	0	3	0	**13**
June 2019 N=448	8	0	0	0	0	**8**
July 2019 N=419	3	0	0	2	0	**5**
August 2019 N=150	3	0	0	1	9	**13**
Sept 2019 N=98	2	0	0	0	0	**2**
Oct 2019	0	0	0	0	0	**0**
Nov 2019	0	0	0	2	0	**2**
Dec 2019	2	0	0	0	0	**2**
Total so far	**69**	**6**	**1**	**10**	**10**	**96**

Summarising: the hypothesis was that cryptococcal spores, if present in the Plant Room air, could get into the AHU during a filter change when the AHU door was open and the final filter removed. The spores would then get into the AHU and then down the duct, to the patients. **In reality this is/was clearly, NOT the case.**

When the AHU was shut down and the Final Filter was removed, air was, in fact, forcefully pushed **OUT of the duct BACK INTO the AHU and then OUT OF THE AHU INTO the Plant Room**. This was believed to be, a thermal effect.

Therefore, the air of the Plant Rooms on Level 12 (or any other Plant Room) **is an unfeasible** source/route for *Cryptococcus neoformans* spores (from pigeon guano, if present) via the AHU(s) during shut down and change of the Final filter.

[redacted]

Implications of Wet Pigeon Guano

From the pictures of PR 123D, it is clear that the guano and the area containing it have been wet and possibly were **still** damp/wet.

Firstly, damp or wet pigeon guano will make aerosolisation of the cryptococcal spores much more difficult. Aerosolisation is more likely only to take place easily from **dry** pigeon guano/soil mixture.

Secondly, the size of the cryptococcal spores is critical, we are looking at sizes of probably 1 to 3 microns in diameter to get deep lung deposition i.e., into the alveoli of humans and then cause infection. Much of this work was carried out in the 1970s and 1980's by a Group working in Oklahoma., Ruiz, Bulmer, Fromtling, Neilson[8,9,10,11,12] and others who studied *C.neoformans* in natural habitats i.e., soil, which is believed to be a significant habitat of *C. neoformans*.

In 1981, these workers looked at large piles of pigeon guano compared to loosely scattered dry guano on the floor of a pigeon infested tower. They found that large piles of guano contained <0.3% of the number of viable *C.neoformans* cells compared to the *C.neoformans* cells grown from the average samples of floor material. They concluded that 'These findings may be important in the epidemiology of cryptococcosis because the finer, looser and drier material would be more easily aerosolised and therefore, may represent a greater potential health hazard.' Ruiz *et al* (1981) [8]

Thirdly, the same group, Neilson *et al* (1977)[12] also noted the importance of the size of the capsule of the *C. neoformans* cells in the environment. They found that the capsule size was 'intimately' linked to the amount of water present. They felt it was logical that capsule production may be an 'on/off affair' depending on the environmental conditions, e.g., after rain the amount of moisture and transported nutrients in the soil would increase dramatically with perhaps capsule production being 'turned on' with a subsequent increase in size of the cell, making it less likely of deposition in the alveoli.

They also found the opposite happened when *C. neoformans* cells were grown in dry soil; the longer the incubation period the smaller the cells, so the more likely they could be aerosolised and the more likely their deposition in the alveoli.

They also noted in this paper that 'this further substantiated their earlier observations that in nature many cells (of *C. neoformans*) may exist in a relatively small non-encapsulated state. Such particles may be the true infectious particles in cryptococcosis'

Fourthly, Bacterial decomposition, the effect on *C. neoformans* in fresh or wet pigeon droppings:

Staib, F (1963)[13] commented on the growth *of C. neoformans* in either fresh or wet pigeon guano. 'I stated that solutions of fresh bird manure offer favourable conditions for only about 24hrs. The bacterial decomposition of bird-manure substances can cause a strong alkalinization within 3-4 or 5 days '.

The growth of *C. neoformans* can be stopped and even isolation of *C. neoformans* is not then possible. This alkalinisation depends on the proportion of faeces and urine and the degree of *moistening*. After saving dry *C. neoformans* – containing canary-bird and pigeon manure for one year *C. neoformans* remained able to grow in this dry hard manure. Ruiz *et al* (1982).[11]

Abou-Gabal, & Atia (1978)[14] they noted that: Under: 'Effect of pigeon intestinal bacterial flora on *C. neoformans* – seven different species of bacteria were recovered from the intestinal contents of pigeons. They were: *Staphylococcus albus, Streptococcus faecalis, Bacillus subtilis, Escherichia coli, Pseudomonas aeruginosa, Proteus mirabilis and Klebsiella aerogenes*.

The suspension comprising these isolates exhibited a complete inhibitory effect on the growth of *C. neoformans* and no viable cells of any of the tested strains were detected after one week's incubation period. In the control bacteria-free tubes, the average numbers of viable *C. neoformans* counted reached 96 x 10^4 per gram.'

They concluded that: 'It seems a greater likelihood that initial inoculum for colonization of pigeon droppings by *C. neoformans* may originate from other sources, most probably the soil. Isolation of the fungus from soil, free of pigeon guano, is well documented (quoting 8 papers). The coincidence of accumulated pigeon droppings in nature besides other favourable environmental conditions may support the increased prevalence of *C. neoformans* in such locations.'

Kwong-Chung, KJ & Bennett, JE (1992)[15] quote Staib above – and go on to say: '*C. neoformans* cells are highly resistant to desiccation. When the weathered droppings are diluted and plated on agar media as many as 5 x 10^7 viable *C. neoformans* cells may be found per gram of faecal material. Fresh pigeon droppings or wet droppings on the other hand, infrequently contain *C. neoformans*. The bacterial decomposition of wet bird droppings causes a strong alkalinisation, and *C. neoformans* stops growth on the substrate with alkaline pH.'

Therefore, the four points above suggest that the damp pigeon guano in PR 123 did not result in as a significant risk as was originally postulated, therefore another reason for ruling out this hypothesis.

The role of water (e.g., rain) and its effect on the pathogenesis of infection with *C. neoformans*, specifically on aerosolization and size of capsule etc, should also be viewed on its likely effect on *C. neoformans* in its environmental sources (soil and guano).

This is, perhaps, one of the reasons that there are significantly fewer cases in the West of Scotland than say in the Southern States of the USA, likely to be due to the different weather/climatic conditions here and perhaps, particularly the frequency of rain fall, humidity etc.

Quote from Bratton, EW *et al* (2012)[16].

In this paper: 'Under Limitations': 'this review was limited to a single tertiary care centre and teaching hospital. Our medical centre averaged nearly 15 cases of cryptococcosis per year and this likely reflects both an endemic exposure to this yeast in the environment within the Southeastern USA and an enriched population of immunosuppressed individuals due to our hospital's care patterns. The actual number of cases seen in a particular medical centre certainly varies within the U.S.'

Therefore, Duke University Medical Centre (between 1996 and 2009) saw an average of 15 cases of *C. neoformans* per year compared with the Greater Glasgow and Clyde Health Board Area (between 2009 and 2018 – a 10-year period) who saw an average of only 1.8 cases per year.

Fifthly, where is the soil? On reflection of the presence of pigeon guano on the floor on PR123 and also e.g., guano on the helipad – there is NO actual 'soil' present as there would be in the natural environment (but admittedly, there may have been some dust, but I would think that the Plant room floors were more like an 'asphalt area' noted below).

See quote from: **Lin, X and Heitman (2006)[6]**, Page 76: **'Second**, aged pigeon guano and the dirt and dust surrounding the guano are more likely to be positive for *C. neoformans* than are fresh droppings, suggesting either that the fungus could originate in the soil and flourish in this particular environment after the soil is contaminated with bird guano, or that the few cells originally in the guano could amplify better in the exposed environment. Because airborne *C. neoformans* cells have been collected from the air above bird guano collected from soil, but not from air above guano deposited on a large adjacent asphalt area, it is less likely that the fungus was originally present in the guano. Population densities of *C. neoformans* in excreta samples are usually significantly higher than those from other sources, such as plant samples, suggesting that avian droppings offer suitable conditions and possibly less competition for the growth of the fungus. It has been documented experimentally that the fungus multiplies well in **sterilized** pigeon or chicken guano. Dry excrement is a more favourable substratum because it has **fewer bacteria** and therefore less competition for growth, which could help explain the higher population density found in this substratum.' **NB more of this paper is quoted on Pages 8 & 9 of this report.**

Therefore, the Plant room floor or the helipad platform are **not** mimicking what is going on in the natural environment, i.e., it is likely that it is the 'soil' itself that may contain the *C. neoformans* (? less likely to be present in the pigeon guano) see paragraph entitled '**Third'** in **Lin & Heitman (2006)[6].**

Therefore, the above gives another reason (in addition to the evidence of water on the Plant room floor) that the Plant room was a very unlikely source of, functioning and aerosolized, *C. neoformans* spores.

It should be noted (again) that what pigeon guano samples were taken from the QEUH site did not grow *C. neoformans,* these were from the Helipad and sent to the Veterinary microbiologists. They grew *Cryptococcus uniguttulatus*. Interestingly, this finding was the same as that of the Swedish workers - **Matteson, R *et al.* (1999).[17]**

Action taken by NHSGGC to mitigate this potential risk:

- Regular cleaning and inspection plant rooms.
- Pest control measures implemented to reduce the numbers of birds throughout the campus.
- Paediatric Radiology Courtyard. The area has been netted across the top of the courtyard to prevent any birds roosting in this area.
- F7 filters on AHUs were changed to F9 in all AHUs [redacted]
- Tackmats were installed at helipad lift to remove any contamination brought in on trolley wheels. These Tackmats are monitored by the security and portering team and changed as required.

- Quarterly inspections are carried out to ascertain if filters on AHU(s) need to be changed.

Therefore, the Plant Rooms on Level 12 (or any other Plant Rooms) are unfeasible to have been the source of *C. neoformans* spores (from pigeon guano) in a Plant room - by this postulated route, over the timeframes noted above.

Hypothesis Number 1 – Unfeasible.

Hypothesis Number 2 - Outside Air Source (External Air)

C. neoformans present in the outside air entered the AHU ventilating the rooms/wards where the case - patients were.

Cryptococci (including *C. neoformans*) are most likely to be periodically present in the outside air (but impossible to prove definitively as we have not been able to grow *C. neoformans* from extensive air sampling either external or internal) and so may enter the AHU's and then subsequently may still be present in the filtered air delivered to the ward areas.

But note, testing only a few times monthly and a relatively small sample size (volume: 500L and time: 3 minutes). Filtration of air destined for 'general wards' (is of F7 standard (?80% filtered), i.e. NOT of the standard required for patients needing 'protective isolation' (which is HEPA filtered air). Please note however, that many hospitals will not even have filters of F7 standard in general wards as the QEUH/RHC does.

In areas where 'protective isolation' is required e.g. , filtration should be of a HEPA filter standard, i.e. 99.9%. Please also note that 'protective isolation' not only requires HEPA filtered air but also requires positive pressure within the room and with the air uniformly leaking outwards.

FINDINGS

When sampled (>3000 samples) (21st December 2018 to January 2020) the had only 8 isolations of *Cryptococcus* spp. compared to 88 isolations found in the rest of the hospital) from non-HEPA filtered environments. *Cryptococcus* spp. continues to be isolated from patient care wards and in other areas on site but never *C. neoformans.*

Therefore, a possible route is that cryptococcal spores are entering through the outside air. The F7 filters are NOT sufficient to, nor intended to, remove all of them, not only all the cryptococcal spores, but also many other fungal spores such as those of *Aspergillus* spp ( ). This is clearly seen in the air sampling results (See Tables 3a, 3b, 4 & 5 in Hypothesis 3 below).

It should be noted, again, that in December 2018/January 2019 there were widespread positive air samples with *C. diffluens,* not only in areas served by Plant rooms on level 12 (A, B, C and indeed also D, when checked) [redacted]. Subsequently, when air tested, *C. diffluens* was found in many areas of the Laboratory Block which is remote from the Plant Rooms (PRs) in QEUH/RHC. The Lab Block PRs were not known to have/had any issues with pigeon ingress. Also, subsequently, we continued to grow cryptococcal species [redacted], despite regular inspection and routine cleaning of these Plant Rooms serving the QEUH/RHC.

The above findings (in the Lab Block) are highly suggestive that cryptococci (and specifically *C. diffluens* and other *Cryptococcus* spp.) are likely to often be present in the outside incoming air and their presence is not likely to be related to the presence of pigeons in these Plant room(s). Note that *C.diffluens* was also grown from two air samples (from 2 bathrooms) recently (late 2019) in Ward B7 of the Beatson Cancer Centre (at Gartnavel General Hospital). Prior to December 2018 these would not have been identified. What this shows is that in another hospital (2 miles away) *C. diffluens* was also present in air samples (and ironically where the adult BMTU and Haemato-oncology Unit had been previously).

Please see Table 3a and 3b below in Hypothesis 3 (note that this was originally in Minute no 27, 26th February 2020) showing *Cryptococcal* species isolates from air sampling: 21st December 2018 to end December, 2019*, [redacted] Although the QEUH Bone Marrow Transplant Unit [redacted] results are significantly lower than the rest of the hospital it is an indicator (we should be expecting more 0,0 counts here) even in a BMT with HEPA filtered air and positively pressured rooms. Therefore, there are still issues that need to be addressed, however, it should also be noted that the corridors in [redacted] are not specially ventilated, i.e. the reason for positive samples in this area could be that the BMTU does not have HEPA filtered air in the corridor.

Action taken by NHSGGC to mitigate this potential risk:

- F7 filters on AHUs were changed to F9 in all AHUs [redacted]
- Quarterly inspections are carried out to ascertain if filters on AHUs need to be changed.
- Mobile HEPA filters were located in areas throughout [redacted].
- As an additional risk reducing measure within [redacted], recirculation air scrubber fans were installed (Camfil Camcleaner 400 concealed fan units) within the ceiling space of each ensuite on [redacted], then each space was validated to quantify the improvements achieved. The Cam cleaner consists of a pre-filter (bag) and a secondary HEPA filter.
- Routine air sampling is undertaken in ward [redacted] and results are reviewed by ICD/Microbiologist.
- Ongoing surveillance of infections linked to air as per the National Infection Prevention and Control Manual is in place.

The Cryptococal IMT Expert Advisory Sub Group was unable to prove this hypothesis as ***none*** of the extensive air sampling yielded a positive result for *C. neoformans*. The limitations of the

tests and the difficulty in isolating the organism are discussed in the first section and apply to all air sampling results.

Hypothesis Number 2 is possible.

Hypothesis Number 3 – Lack of 'Protective Isolation'

The possibility that unfiltered air from the Plant rooms could, via mechanical or electrical risers and or service voids, get into the rooms/wards where the 'at risk' patients were and an explanation of the varying degrees of the 'lack of control' of air movements around the entrances and exits of [redacted] and even [redacted]

*There are no 'protective isolation' rooms in the general wards in QEUH [redacted]. Rooms in these wards **do not have**: HEPA filtered air, positive pressure within the room and with the air uniformly leaking outwards. Indeed, there are also a few issues with 'protective isolation' in [redacted]

(But please note that there are **no** Standards or Guidelines for 'Protective Isolation')

**The lack of these 3 crucial controls means that it is possible that unfiltered air may gain access to the patient rooms/areas of these wards, e.g., from mechanical risers, electrical risers and service voids etc and also (importantly) any 'lack of control' of the air movements around the entrances/exits to these wards (please refer to mitigations implemented to address this further on in this report).

FINDINGS

[redacted] with F7 filtration (? less than 80%). Investigation, of these areas, showed that the ventilation was 'dilution' only. The aim of ventilation, in 'protective isolation', should be dilution **and** exclusion (of unfiltered/dirtier air). **See paragraph above.

Some may point out that [redacted] have portable HEPA filters in both rooms and corridors and indeed some in the toilet areas. It is important to realise that these cannot remotely remedy the lack of proper 'protective isolation' noted. This is borne out by the air sampling results. Again, please note these are general ward areas and not specially ventilated wards.

Air testing has also revealed the presence of other types of fungi, e.g., *Aspergillus* species (see Table 5, below) which are known to affect BMT patients, however it should be noted that, there is limited evidence that *C. neoformans* actually poses a significant risk to this patient group (BMT patients) with only, about, 20 cases reported in the literature, **Firacative, C *et al*. 2020[18].** It should be noted, that this is the case, and that neither it has been explained nor understood.

[redacted] that the BMT Unit **does** have HEPA-filtered air in the rooms which **also** 'uniformly

leaks outwards'. Note however, that there are still issues, as [redacted] does not have ventilation in the corridor (air pushed out from rooms only) nor does the corridor have a solid ceiling. A major issue (see later) in [redacted] corridor is that at its interface with [redacted] corridor, periodically, air moves from this area [redacted] into [redacted] i.e., there is lack of 'protective isolation' in the corridors.

We will relate the air sampling results in [redacted] and also relate the results to: the voids/risers and the control of the air (or lack of it) in and around these wards.

Table 3a

This compares **fungal** air samples taken in individual rooms of [redacted] The corridors of [redacted], [redacted] and [redacted] and individual rooms of Beatson B8 & B9 (Air samples from time prior to move into QEUH, in years 2016 to 2018).

WARD	Total (paired) AIR samples	Total counts	Mean count (95% CI)	Median count	No (%) of samples with counts of 0,0	No (%) of samples with counts of >0,0
[redacted]	217	238	1.10 (0.80 – 1.40)	0	135 (62%)	82 (38%)
[redacted]	47	153	3.25 (2.73 - 3.77)	2	10 (21%)	37 (79%)
[redacted]	126	325	2.58 (1.54 – 3.62)	1	51 (40%)	75 (60%)
[redacted]	22	112	5.09 (3.44 - 6.74)	2	3 (14%)	19 (86%)
[redacted]	239	1181	4.92 (3.98 – 5.86)	2	48 (20%)	191 (80%)
[redacted]	240	1526	6.33 (3.41 – 9.25)	2	48 (20%)	192 (80%)
[redacted]	24	345	14.4 (10.95 – 17.87)	13	0%	24 (100%)
Beatson	218	120	0.55 (0.24 - 0.86)	0	172 (79%)	46 (21%)

[redacted]

Table 3b

[redacted]	292	1215	-	-	54 (18.5%)	238 (81.5%)
[redacted]	28	358	-	-	1 (3.7%)	27 (96.4%)

Table 4

WARD	NO of Paired AIR Samples	Paired samples with *Crypto* spp.	% with *Crypto* spp.
[redacted]	264	4	1.5%
[redacted]	148	11	7.4%
[redacted]	320	36	11.3%

[redacted] samples taken between 21st December 2018 and 31st August 2019.
[redacted]

Table 5

WARD	No of Paired AIR Samples	Paired samples with *Aspergillus* spp.	% with *Aspergillus* spp.
[redacted]	264	6	2.3%
[redacted]	148	7	4.7%
[redacted]	320	37	11.6%

[redacted] samples taken between 21st December 2018 and 31st August 2019.
[redacted]

Please note the following:

1. We employed as a reference point for the room air samples with about 3 years air counts taken in the BMTU, at the Beatson Cancer Centre (when still operational), between 2016-2018. This Unit was acknowledged as a Unit that was partly designed, by an expert, Andrew Streifel of Minneapolis, and therefore built to a high US standard in terms of its ventilation and 'protective isolation'.

2. Each Ward; [redacted] were compared to each other (the Beatson BMTU only compared with paired fungal air samples*) in three ways:
   a. Number of paired air samples with fungal counts of 0,0* (Tables: 3a and 3b)
   b. Number of paired air samples with isolation of *Cryptococcus* spp. (nos and %) (Table 4)
   c. Number of paired air samples with isolation of *Aspergillus* spp. (nos and %) (Table 5)

It is quite clear that looking at the results of these [redacted] wards that there is a consistency between them:

In terms of % of 0,0 counts going from best to worst is: **Beatson** with 79% of 0,0 counts; [redacted] with 62% of 0,0 counts; [redacted]

Please see Tables 4 & 5 (excluding the Beatson) which both concur, when comparing counts for *Cryptococcus* spp. or *Aspergillus* spp., that the best to the worst is [redacted]

The questions to be asked are: why is [redacted] not of the standard of the Beatson (please refer to the section on the decision-making processes/rationale for the move from the Beatson to QEUH), [redacted]

We will now look at why these specific wards have issues with their air quality: in terms of their ventilation, the control (or lack of it) of the air movements around them and the possible role of their voids and risers. **i.e., their ability to provide 'protective isolation'.**

Ward [redacted]

It should be noted that in [redacted], all the rooms were under positive pressure of between 9 to10 Pascals (Pa) to the corridor with the room door closed. But note that there is no ventilation of the corridor, just 'spill over' from the rooms and the corridor does not have a solid ceiling. Normally a BMTU would have both of these. Consequently, these latter two points have implications in providing 'protective isolation'.

Peter Hoffman noted in Minute no 7 of 10 April 2019 and emphasised the need for solid ceilings in these critical areas 'A false ceiling adds a level of instability to pressure control (positive pressure) of such a room, and such pressure is crucial (along with HEPA filtration of the air).'

Voids

Specifically looking at the IPS (Integrated Plumbing System) panels, which behind them carry the water pipes to the wash hand basins in both the patient rooms and the toilets and to the toilet itself. Importantly, [redacted] had also all its IPS panels sealed with silicone, therefore no movement of air either in or out of the void was therefore possible (up to a point, as the seal will eventually degrade).

Risers

[redacted] had the Risers sealed above and below the ward. Therefore, no ingress of e.g., 'dirty air' from a Plant Room possible by this route.

The Mechanical and Electrical Risers (small rooms) in [redacted] were investigated by JH and IP (Ian Powrie) on 10 May 2019.

Findings:

i. Doors to the Risers are kept locked
ii. Visually they *all* appeared well sealed and smoke testing showed no ingress or egress of air.
iii. All Risers were found to be under *negative pressure* to the Ward with air moving into the Risers, from the Ward, at between 1.7 to 4Pa

Air testing was carried out in the Risers.

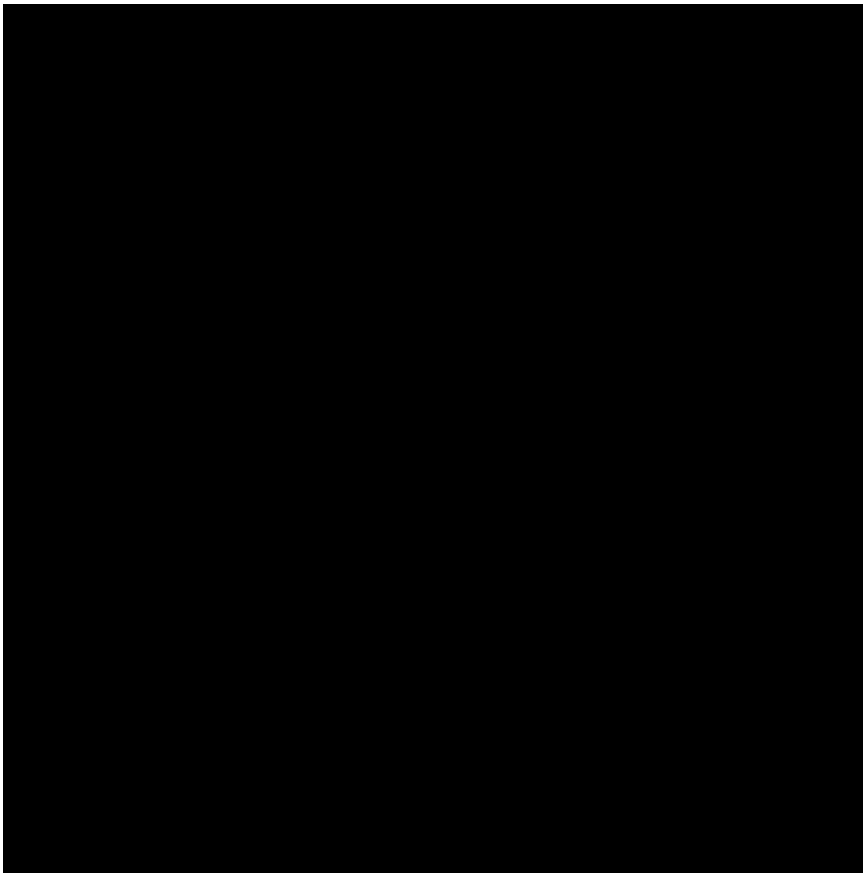
Table 6

Riser	Fungal Counts	Isolates
HOW-038 Mech	0,3	1 each of: *Penicillium* spp. *H. hyphomycete* *Cladosporium* spp.
HOW-200 Elect	1,0	*Cladosporium* spp.
HOW-207 Mech	0,1	*Aspergillus fumigatus*
HOW-035 Elect	1,1	*H. hyphomycete* x2

Therefore, air all moving in correct direction and counts low (but note, more an indication of counts in the corridor)

Control of air around Entrances

The important issue in [redacted] is the 'lack of control' of the air at the interface of the entrance at Room [redacted] which is directly opposite to the entrance/exit from [redacted] It should be noted that this exit from [redacted] is purely used as a Fire Escape route, therefore it was neither completely sealed nor locked. On the left is a Room used by [redacted] Medics and a door from this Room out onto the Roof on Level 4. On the right coming out of [redacted] exit is a corridor (which becomes the Facilities corridor) and immediately off this (on both the left and right) are Bed/Patient Lift lobby Core C and FM Lift lobby Core C. There is also the complication that on the immediate left before Bed/Patient Lift lobby Core C is an Inter-departmental Corridor that runs straight up to the Controlled (main) Entrance to [redacted]



In early May 2019 Ian Powrie (Senior Estates Officer)/John Hood (Chair of the Cryptococcal IMT Expert Advisory Sub Group) measured the pressure differences across the entrance to [redacted] opposite the entrance to [redacted] With both doors shut we found a differential pressure of 4Pa going from [redacted] out to the Corridor and a differential pressure of 10Pa going out to the Corridor from [redacted] i.e., towards the 'entrance' to [redacted]

On 10th May 2019 we checked these results. Again, with both [redacted] and [redacted] doors shut, we found 4Pa going out from [redacted] and 10Pa going out from [redacted] However, if we then ***opened*** the door from [redacted] this resulted in [redacted] going from 4Pa out, *to* ***going negative*** and pulling 1.5 Pa INTO the bottom of [redacted] Indicating a failure to control the air movements around that entrance of [redacted] Therefore, 'dirty' non-HEPA filtered air was intermittently being pulled into the bottom Corridor of [redacted]

The air sampling results for [redacted] for 2019 would support this likely intermittent issue (and 'lack of control' of the air) at the bottom of [redacted]

Air sampling results

Ward [redacted] air sampling results from 21 December 2018 to 17 January 2020 grew in air sampling only a total of 8 isolates of *Cryptoccoccus* spp. The first being in May 2019 and the last in January 2020.

The main entrance to [redacted] is controlled, so does not allow entry without agreement and therefore the door should not be left open for long periods of time. The beds from this entrance go from 99 to 89 – there was only a single isolation of *Cryptococcus* spp. in Room 90. Going round to the opposite side of the ward from Rooms 85 to 80, again there is only a single isolation of *Cryptococcus* spp. in Room 81. In Rooms 79 to 76 (noting that Room 76 is the last Room prior to the 'closed' exit) there were a total of 6 isolates of *Cryptococcus* spp. in this area; 3 positives in the Corridor near Rooms 77 & 78 with 2 positives from Room 78 and 1 positive from Room 77. Reiterating: this gives a total of 6 isolates at the end of this corridor (with only 2 from the rest of the Ward) where we know that intermittently air (which is not HEPA-filtered) from outside the Ward is almost certainly getting into that part of [redacted]

Therefore, the above is the likely explanation of the 'lack of control' of the complex air movements around that entrance to [redacted] at Room 76.

The reasons for retrofitting the BMTU into the QEUH and the governance approving this move are listed below:

In July 2013 the Quality and Performance Committee in GGC approved a paper outlining the background and clinical reason for transferring BMT services from Beatson Oncology Centre (BOC) to QEUH. The following is a summary of this paper:

In June 2013, there were 52 designated Haematology inpatient beds across NHS Greater Glasgow & Clyde: 38 at Beatson West of Scotland Cancer Centre (BWOSCC) and 14 at the Southern General Hospital. The wards at the Beatson Oncology Centre managed acute and non-acute haematology patients, chronic and acute leukaemia, inpatient chemotherapy, inpatient radiotherapy, and housed both the Scottish Unrelated Donor Bone Marrow Transplant service and the West of Scotland Sibling Donor transplant programme.

Following a series of clinical meetings for the Clinical Service Review, the haematologists expressed the view that the new service model should split acute and non-acute haematology, with preference for maintaining all acute services at the New South Glasgow Hospital, due to the on-site availability of ITU. This would allow future-proofing of the service against changes in patient populations (e.g., paediatric sickle cell patients graduating to adult care) and fluctuations in activity.

The clinical drivers for the move from BWOSCC to QEUH were:

- To ensure 24/7 on-site ITU cover and to meet clinical standards
  For Bone Marrow Transplantation (all forms), services require JACIE accreditation which already stipulates that there must be robust and reliable access to ITU-level care. This is currently available on the Gartnavel site, supported by ITU at the Western Infirmary, but is unlikely to be maintained at existing levels after 2015.

  The Beatson WOSCC is the only UK transplant centre which does not have full ITU access on-site, and it is expected that future iterations of the JACIE standards may make this an explicit requirement.

The existing NICE and British Society of Haematology standards for the management of acute haemato-oncology patients specify on-site access to HDU, ICU, central line insertion facilities, dialysis or haemofiltration and interventional radiology. After 2015, the New South Glasgow Hospital will be the only site which can fulfil these requirements, as all inpatient Renal services will also be on Level 4, NSGH.

- Out-of-hours care
  At present, haematology out-of-hours is covered by multiple high-intensity (1 in 2 to 1 in 4) rotas at consultant level. This model would allow a single specialist rota, based at nSGH (new Southern General Hospital). All out-of-hours admissions would be to that site.

This proposal was approved in July 2013.

[redacted]

Voids
Early on, 5th February 2019 we checked the Voids related to the IPS panels in [redacted]

Findings:
As above, unlike [redacted], these panels had not yet been sealed with silicone. (See [redacted] and IPS panels above). However, it was *impossible* to get the pressure probe between the joins in these panels (such was the tight fit) and importantly, smoke was neither sucked into nor blown out of the Void. On removing these panels, smoke testing did show that the Void was, however, under positive pressure to the Room, with smoke moving into the Room. However, it was unlikely that the Voids in [redacted] were an issue as although not sealed with silicone there was no movement of air from the voids to the Room, until the IPS panels were actually removed.

Risers
The Risers were found not to be sealed above and below as in [redacted]

Table 7

No	Riser Name	Direction of flow	Fungal Counts
1	RENW 178 (Elect)	*Riser to Corridor: 0.1 to 0.2 Pa	5,1
2	RENW 212 (Mech)	Corridor to Riser: 18Pa	9,11
3	RENW 220 (Elect)	Corridor to Riser: 0.2Pa	1,1
4	RENW 223 (Mech)	Corridor to Riser: 15 to 16Pa	2,4

Comment: On the face of it [redacted] Risers are an unlikely issue with only one (no 1) with hardly any positive pressure **out to** the corridor and two risers with >15Pa pushing **into** the Risers.

Control of air around Entrances

As noted above, at [redacted] interface, [redacted] is pushing air out of the Ward (by Room 75) at +10Pa therefore this gives very good control of **keeping out** the air from around this complex area (see [redacted] control of air around entrances).
Similarly, at the [redacted] interface (checked on 3rd September 2019): [redacted] is pushing air out towards [redacted] at approx. +12Pa, **with all doors shut.** [redacted] is pushing out towards [redacted] at +6Pa, with door to **Lift lobby open.** [redacted] is pushing air out towards [redacted] at approximately + 10 Pa with all doors shut.

Importantly, no configuration of opened doors at the [redacted] interface or [redacted] interface, resulted in air being pushed *into* [redacted] Therefore, the above suggests that the Control of the Air around both entrances to [redacted] is reasonable compared to [redacted] and [redacted] (just not HEPA–filtered like [redacted]).

Air sampling results

[redacted]

Voids

[redacted]

Findings:
As above, unlike [redacted] these panels had not yet been sealed with silicone. (See [redacted] Voids and IPS panels above). However, it was *impossible* to get the pressure probe between the joins in these panels, such was the tight fit, and importantly, smoke was neither sucked into nor blown out of the Void. On removing these panels, smoke testing did show that the void was, however, under positive pressure to the Room, with smoke moving into the Room.

However, it was unlikely that the Voids in [redacted] were an issue as although not sealed with silicone there was no movement of air from the voids to the Room, until the IPS panels were actually removed [redacted]

Risers

As with [redacted], the Risers were **not** sealed above or below the Ward as in [redacted]

Table 8

No	Riser Name	Direction of Flow	Fungal Counts
1	GENW1-068 (Mech)	Corridor to Riser: 5Pa	2,0
2	GENW1-054 (Elect)	Corridor to Riser: 0.1Pa	13,7
3	GENW1-082 (Mech)	**Riser to Corridor: by smoke only**	1,0
4	GENW1-085 (Elect)	Just positive to Just negative	62,30
5	**CA6-006 (Mech)**	**Riser to Corridor: 3Pa**	0,0

Comment: Clear issue with consistent movement of air from CA-006 riser, very near to [redacted] entrance opposite [redacted]. Note that this Riser is opposite [redacted]

Control of air around Entrances

Interface of [redacted] and Lifts (Sept 2019)

1. **All doors shut**: [redacted] is **negatively** pressurised i.e., pulling air into ward from this area ([redacted] and Lifts) at, – 3.5 Pa
2. **Door to lifts open**: [redacted] **still negatively** pressurised but less so at – 1.9Pa
3. **Door to [redacted] open**: [redacted] **more negatively** pressurised at - 9.3Pa
4. **Both above doors open**: [redacted] **negatively** pressurised at – 7.4 Pa

Interface of [redacted] and Facilities Corridor (Sept 2019)

1. **All doors shut**: [redacted] positively pressurised at + 0.3 to +1Pa
2. **Door to [redacted] open**: [redacted] negatively pressurised to -1.9 to -2 Pa
3. **[redacted] door open**: [redacted] positively pressurised to + 3Pa, i.e., air being pushed out of [redacted]
4. **Doors to [redacted] and door to [redacted] open**: [redacted] positively pressurised at +2.3 to + 4Pa, i.e., air being pushed out of [redacted]

The important findings here are that, firstly, there is poor control of air movement around the [redacted] interface with air being pulled into [redacted] between 1.9 to 9.3Pa depending on which of the doors are open. Therefore, we can clearly see the complexity and poor control of air around [redacted], particularly at the [redacted] interface, while it is not so bad at the [redacted] interface. At the [redacted] interface, depending on which doors are open, between +0.3 to +4Pa of air is being pushed out of [redacted] to about 2Pa being pulled in.

Air Sampling Results

[redacted] had 36 isolations of *Cryptococcus* spp. (from air sampling) between 21st December 2018 and 16th January 2019 and between 12th February 2019 and 31st August 2019, see Tables 3a, 3b and 4. None of these were *Cryptococcus neoformans*.

These cryptococcal isolations support, 'the lack of control' of the movement of air at the [redacted] interface (with air being pulled into [redacted] between 1.9 to 9.3Pa, depending on the configuration of opened doors) and also Riser CA6-006 pushing air out into the corridor at +3Pa.

Table 9 -The air sampling results for [redacted] are as follows:

Room No	No of Crypto Isolates
1	4
2	3
3	1
4	1
5	2
6	2
7	0
8	2
9	1
10	1
11	0
12	0
20	1
21	1
22	0
23	1
24	2
25	1
26	2
27	1
Room no/Corridor/Riser	No of Crypto Isolates
Corridor by Nurses Station Opposite Room 5	9
Clean Utility, between Rms 8 & 20	2
GENW1-085 Riser	1
	Total Crypto Isolates 38

We can clearly see that air is being pulled into this end of [redacted] perhaps most of the time. This air will be a mixture of unfiltered air due to its 'lack of control', particularly with that from Riser CA6-006 (and note that this Riser is directly opposite Room 1). Room 1 is also the first room in [redacted] after the entrance to [redacted] from Core A lobby which has the entrance to [redacted] opposite and the Lift lobbies on the left.

The results support the theory that there is poor control of the air movement around Ward [redacted] entrances – *particularly the entrance opposite* [redacted] *(see above).* There are 13 positive *Cryptococcus* spp. results in Rooms 1 to 6.
There are also 9 *Cryptococcus* spp. positive results at the Nurses station, in the Corridor opposite Room 5 (Case-patient Room). There are only 9 positive *Cryptococcus* spp. results in Rooms 20 to 27 at the other entrance to [redacted] This clearly supports the hypothesis that the problem is due to the pulling in of 'dirty' air into [redacted] at the Entrance at Room 1 coupled with

the issue of a Riser opposite Room 1 with likely 'dirty' air coming out of this Riser into [redacted] at +3Pa.

I will finish with my (John Hood) 'Take Home Message' from the Minute of 18th December 2019: 'That now we know how complex the air movements are around these wards ([redacted] we could spend much time collecting more DATA on this, essentially trying to understand the complexities of it (it would be hugely time consuming), but…. the point is that we know this is happening, at least intermittently….and we must mitigate its effect i.e., stopping the ingress of unfiltered or dirtier air getting into these areas'. Noting: 'lack of HEPA filtration in [redacted] with only 3 ACH, lack of solid ceilings and no ventilation in [redacted] corridor (only spill over from the rooms) …to name but a few…'

Therefore, there are clearly failures/lack of 'protective isolation' in all [redacted] wards including in [redacted]

Action taken by NHSGGC to mitigate this potential risk:

- F7 filters on AHUs were changed to F9 in all AHUs serving Ward [redacted]
- Quarterly inspections are carried out to ascertain if filters on AHU need to be changed.
- Plant re-calibration and ventilation system re-balance to change ward [redacted] Room Differential pressures to corridor to be nominally positive (+ve).
- Deployment of mobile city M HEPA air scrubbers to assist in reducing the existing particulate within the Air in wards [redacted]
- CVG (Ceiling Ventilation Grilles) removed and replaced with a standard ceiling tile to reduce the risk of particulates moving from the corridor ceiling void into the corridor transfer area and rooms in [redacted]
- [redacted], installation of recirculation air scrubber fans.
- Enhanced supervision in place in [redacted] where any issues regarding the ward estate is noted, escalated and actions put in place. (Monthly).
- Chilled beams are cleaned every 6 weeks in [redacted] and the recommendation is that this should be done yearly.
- Ongoing surveillance – clinicians and microbiologists will consider as part of differential diagnosis and send serum antigen and blood cultures.
- All windows in the affected wards were checked to confirm that there is no ingress (directly) of air from the outside.
- As an additional risk reducing measure within ward [redacted], recirculation air scrubber fans were installed (Camfil Camcleaner 400 concealed fan units) within the ceiling space of each ensuite on [redacted] then each space was validated to quantify the improvements achieved. The Cam cleaner consists of a pre-filter (bag) and a secondary HEPA filter.
- Adjust door seals to Gruffalo corridor light well, door seals adjusted to minimise air passage from outside environment.
- All IPS panels [redacted] to be sealed with silicone.
- Door risers were sealed in [redacted]
- Door seals between [redacted] were adjusted to reduce the passage of air between the spaces.

- Routine air sampling is undertaken in ward [redacted] and results are reviewed by ICD/Microbiologist.
- Ongoing surveillance of infections linked to air as per the National Infection Prevention and Control Manual.

NB this list is not exhaustive.

It should however, be noted, that a move from the Top Floor of the Beatson Cancer Centre - which had one of the best built Units in the UK (in terms of ventilation, including HEPA filtration and strict control of air movement etc) - was suddenly required (see page 29). The organisation then had to provide an adult BMT Unit and adult Haemato-oncology Wards on the QEUH site, due to the lack of an ITU on the Gartnavel General Hospital campus (which the Beatson is on). This issue arose sometime after the design stage of the QEUH. Therefore, it was never likely to be possible for them to replicate the Top Floor of the Beatson in the QEUH in the timescale required, *at such short notice.*

[redacted]

[redacted]

Hypothesis Number 4 - [redacted]

[redacted]

[redacted]

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Hypothesis Number 5 – Helipad

That the down draft from Helipad was aerosolising cryptococcal spores from pigeon guano dust into the air intakes and thence the AHUs providing ventilation into the patient areas.

FINDINGS

Computational Fluid Dynamics (CFD) model was commissioned by GGC. The report concluded:

Comments from Minute of 6 June 2019. 'In the CFD simulations undertaken they demonstrate that the air arriving at the AHU intake locations does not originate in the region beneath the helipad for any of the scenarios considered. As a result of this conclusion, it is therefore, *unlikely* that debris from the helipad area is being carried into the hospital ventilation system(s), so anything drawn into the AHU's intakes is coming from the wider environment' and not affected by the shape of the building or presence of a helicopter. 'Whilst it is not possible to determine how far away potential contamination will originate, it should be noted that anything carried in the flow will be lightweight, since heavier matter will fall out due to gravity.' (See Appendix 3 for full report).

'Peter Hoffman asked if there are louvres on the Plant rooms. Althea explained that there are louvres, but are angled, dropping vertically, so that nothing can fall into the vents. Ian Powrie confirmed there are louvres on the external of the building. The AHU is attached to the louvres with a plenum. Peter Hoffman further asked about the louvres, not the AHU, if the downflow from the Helipad could push the air down into the Plant rooms? Ian Powrie stated that this was not impossible, but is unlikely because the louvres are fitted with sealed insulation boards. Peter Hoffman stated that it would therefore be difficult for air to get into the Plant rooms by this route. Ian Powrie stated that the only issue would be if any of the insulation panels were damaged or dislodged or if there was any movement.'

'There was some discussion after the presentation and Peter Hoffman stated it is unlikely to have been a build-up of aerosolisable material e.g., pigeon faeces as it would be regularly scoured by the helicopter.'

<u>Hypothesis Number 5 is rejected as an unlikely route.</u>

Hypothesis Number 6 - Specimen Transport System (POD)

AKA the 'pneumatic tube system'. This system is used to move specimens from wards to labs (and back the other way) via compressed air drawn from either the Plant room (PR 31 – not a PR on Level 12) or the ward area. These PODs then discharge the air into the ceiling void above Ward Treatment Rooms (on return to them).

FINDINGS

Discussed at length in Expert Group the consensus of which was that the 'risk related to the pneumatic tube system is likely to be small'. Peter Hoffman view: 'Felt that a small amount of unfiltered air coming into a Prep/Treatment room would have little effect on the air quality in a patient room.' 'He thought that this was an insignificant source if the *C. neoformans* was getting to patients by the air.'

Susie Dodd: 'stated that if this was a significant ingress of unfiltered air it would occur in all other Treatment/Prep rooms, thinking that we would be seeing infective consequences related to these other Treatment/Prep rooms as well' Minute of 2nd September 2019'

Hypothesis Number 6 is unlikely

Hypothesis Number 7- Dormacy/Latency/ Re-activation, and therefore often an unknown time of Exposure (and therefore an unknown Incubation Period)

This Hypothesis suggests that both patients could have been exposed to *C. neoformans prior* to their QUEH/RHC hospital admission.

One of the key papers on Dormancy/Latency is: Epidemiological Evidence for Dormant *C. neoformans* Infection (1999). Garcia-Hermoso, GJ *et al*. *J. Clin. Microbiol.* 37: 3204-3209[19]. They state: 'Several observations converge towards the hypothesis that the infectious particles can be acquired long before the infections develop and is diagnosed. First: a high percentage of healthy subjects have anti-cryptococcal antibodies which suggests prior contact with the fungus. Second: patients coming from tropical areas can be diagnosed with *C. neoformans var gattii* long after they have left these countries. Finally, unlike French patients, African patients living in France and diagnosed with cryptococcosis are rarely infected with *C. neoformans var neoformans'* (Serotype D). But a common serotype and cause of infection in France.

'In this study, we addressed the question of the time of acquisition of the infecting organism, an issue that had never before been raised. Using control samples of environmental isolates and two typing methods capable of clustering strains based on their geographical origins, we were able to demonstrate that patients diagnosed with cryptococcosis in France but born in Africa, had acquired their infectious strains a long time ago prior to emigrating from their countries of origin.'

In the discussion they went on to say: 'Based on the RAPD profiles obtained, we showed that the distribution of clinical isolates from nine African patients diagnosed with cryptococcosis in France was significantly different from that of the clinical isolates recovered from the 17 European patients ($p < 0.0005$). Furthermore, a second, independent typing method (CNRE-1

RFLP) confirmed the results, showing two clusters that contained the isolates from eight of nine African patients. This finding suggests that the infecting organism can be acquired long before the infection develops, since these patients had been living in France a median of 110 months, and had not been in contact with the African environment for as long as 13 years. That the African patients were infected with African isolates strongly suggests that these isolates had been sequestered and contained somewhere in the body, most likely in the alveolar macrophages. Then as soon as some kind of immune system defect occurred, which in most cases was AIDS, the fungus could multiply, disseminate and cause infection'.

'The clinical histories of these patients and the demonstration of a geographical clustering of isolates based on the generated profiles, are consistent with a dormant phase of *C. neoformans* within all individuals.'

The most recent review article on Dormancy and latency was published in July 2020: Dormancy in *C. neoformans*: 60 years of accumulating evidence. Alanio, A (2020)[20]. *Journal of Clinical Investigation*; 130: 3353-3360. This is another key paper which not only goes into the history but discusses the latest research on the biology of dormancy and reactivation. But it will give you an idea of the complexities.

'In summary *C. neoformans* can adapt fantastically to various environments, even very drastic ones, such as 8 days of complete anaerobiosis (no oxygen) without extracellular nutrients. *C. neoformans* uses strategies to resist these conditions. It is first perfectly able to enter quiescence in nutrient starvation conditions (stationary phase) or to be pushed into dormancy under additional anaerobiosis exposure. In vivo, one can imagine that viable but non-culturable cells (VBNCs)/dormant yeasts are most likely hidden in the innate immune cells for years before being able to reactivate and multiply in the body of immunocompromised patients but also in the environment. This makes *C. neoformans* the first relevant pathogenic organism in which to study fungal dormancy and its role in pathogenesis in humans.'

DIFFICULTY IN DETERMINING THE ACTUAL TIME OF EXPOSURE TO *C. neoformans* AND RELATING THAT TO WHEN THE SYMPTOMS OF THE DISEASE FIRST OCCUR i.e., THE INCUBATION TIMES

HIV/AIDS

Fessel, WJ. (1993)[21]. Two patients, who were, HIV positive had 'unusually intense exposures' to pigeons/old aviary demolition. Both developed cryptococcal meningitis and were asymptomatic until meningitis developed. The first patient helped dismantle an aviary that had been unused for about 10 years. The wooden floor was rotten and removing it produced clouds of dust and removing the rest of the wood with a chainsaw produced more dust. The demolition took about 2 hrs to complete. Seven weeks later he had first symptoms of Cryptococcal meningitis. Second patient was a 38yr old man whose office had no windows. One wall of the office faced an alley infested with pigeons. The bricks on the outside of this wall were loose; pigeons found their way through the wall and nested in the ceiling above the man's desk. Each day the patient had to remove from his desk the debris that had fallen from the pigeons' nest in the ceiling above. Cryptococcal meningitis developed about 10 weeks after this exposure to pigeons began.'

The author concluded that on the basis of the above case histories 'it is possible that the incubation period of cryptococcal disease is between 6 to 10 weeks. But noted 'that other

sources of infection could not be ruled out, because *C. neoformans* is widespread in nature' and they had not any samples from the environment in either case.

Varying Incubation times in Solid Organ Transplants (SOT).

Ooi, *et al*. (1971)[22] Renal transplant with donor discovered to have cryptococcal granulomas in the other (non-transplanted) kidney on day 5. Patient happy for graft to remain. Cryptococcus not found in urine until day 18 (Treated from day 20).

Sun, H-Y *et al*. (2010)[23]. 175 SOT's. Very early onset in 9/175. 5/9 were Liver transplants. Mean of 5.7 days post-transplant. Two early cases of day 1 onset – undetected pre-transplant infections, plus another 5 cases the likely result of donor acquired disease.
They split the cases into those occurring in less than 30 days and those after 30 days. In the group of 'less than 30 days to diagnosis' there were 2 cases on day 1, and 2 cases on day 25 and one case each on days: 3, 10, 21, 26 & 30.

They commented that 'most post-transplant cryptococcosis is considered to represent re-activation of latent or quiescent infection in the recipient. Assessment of pre-transplant serum samples for cryptococcal specific antibodies exhibited serological evidence of infection before transplantation.' Quoting: Saha et al (2007)[24]. 'Although these patients developed cryptococcal disease significantly earlier after transplantation than those without serological evidence of infection, the median time to onset of disease in patients with prior antibody reactivity was still 5.6 months. Development of cryptococcosis 1 month after transplantation is therefore unusual.'

MacEwan, CR *et al*. (2013)[25] Renal transplant secondary to diabetic nephropathy. Donor believed to have presumed bacterial meningitis. Given basiliximab at induction followed by tacrolimus, mycophenolate and reducing prednisolone. Five days later the team was informed that donor had died of *C. neoformans,* grown from CSF and blood. Donor was HIV negative with no known risk factors and no exposure to steroids or other immunosuppressants. Fluconazole prophylaxis 'not recommended' - due to rarity of *C. neoformans* infection in SOT and issues with interaction with tacrolimus – alters its pharmacokinetics. Recipient, discharged home, on tacrolimus and mycophenolate. Nine weeks post-transplant re-admitted with vomiting and severe frontal headache, also admitted to 3 weeks of frontotemporal headache, with no other signs of meningitis, and felt otherwise well. Therefore, the likely incubation period of 6 to 9 weeks

Baddley *et al*, (2013)[26]. 3 Cases: 1 liver transplant and 2 renal transplants. All 3 on tacrolimus.

Liver Transplant: 2 weeks post-transplant, splenectomy and liver biopsy. Both organs showed *C. neoformans* as did the blood culture.
Incubation period <14 days

Renal Transplant 1: IgA nephropathy and previous Renal Tx. Got anti-lymphocyte globulin and steroids at induction, then maintenance with tacrolimus and mycophenolate and prednisolone. Day 17 post-transplant, malaise and fever – Blood cultures positive with *C. neoformans*, CSF normal.
Incubation period 16 days

Renal Transplant 2: Alport's syndrome. End stage renal disease. Had basiliximab and steroids at induction and then onto tacrolimus, mycophenolate and prednisolone. Admitted 24 days post Tx with fever and neck stiffness. Blood culture and CSF both with *C. neoformans.*
Incubation period 24 days

Chang, Chun-Min *et al*, (2014)[27] Described a donor derived cryptococcal disease in a liver transplant patient. Recipient was 63-year-old female with hepatitis C related cirrhosis complicated by massive ascites and hepatocellular carcinoma. Donor was 48-year-old male with a massive haemorrhage in his left thalamus and ventricles. Recipient's post-operative course was uncomplicated and extubated on post-operative day (POD) 2.

Bilirubin gradually going up from POD 1 to POD 6. Temperature 38.5 on POD 6 with dyspnoea, respiratory failure and was re-intubated. She was commenced on fluconazole on POD 9 for a *Candida tropicalis* in her blood cultures. She had a liver biopsy on POD 14 due to her persistently elevated bilirubin (around 171 micromoles/L). This revealed a 'few cryptococcal – like encapsulated yeasts', 'found incidentally'. The blood culture also taken on POD 14 was also positive for *C. neoformans*. 'Nothing was found in her native liver and or pretransplant donor liver biopsy.'

Incubation period – Chang *et al*. (2014)[27] do not themselves give this but Camargo, JF *et al*. (2018)[28] in their review of all 14 cases (Table 1) – have it at <14 days.

Camargo, JF *et al*, (2018)[28] A cluster of donor-derived *C. neoformans* affecting lung, liver and kidney transplant recipients: case report and review of the literature.
These patients, all three, received their organ from the same donor at around the same time. They were done at different centres and the donor was from a different centre also.

The donor centre did not inform the 3 centres that the donor was found to have *C. neoformans* in blood, identified 8 days post transplants. 'Remarkably, the onset of illness in the kidney and liver recipients occurred more than 8 to 12 weeks after transplantation, which is beyond the incubation period previously reported from donor-derived cryptococcosis.

'None of these patients received antifungal prophylaxis that could have influenced the timing of presentation.' The authors also point out that all three recipients were on either tacrolimus or cyclosporine and that 'one possibility is that clinical presentation was delayed because of the anti-cryptococcal activity attributed to calcineurin-inhibitors. However, this is less likely since in the report by Baddley *et al* (2013)[26] – no 4 above – 'all the recipients were receiving tacrolimus at the time of presentation.'

Quotes from the Discussion: *'Thus the time from transplantation to symptomatic disease is variable and the incubation period, in some cases might be longer than previously described.'

*'The clinical presentation of cryptococcosis can also vary significantly depending on the individual patient's immune response which may contribute to variability in the timing and severity of the presentation. Based on the cases reviewed here the incubation period can range from a few days to more than 3 months.'

Incubation period in lung transplant was 5 days
Incubation period in kidney transplant was 60 days
Incubation period in liver transplant was 102 days

Therefore, knowing the actual time of exposure (i.e., the date of transplant), the range of Incubation Periods (in days of the 14 cases above) is **wide**. The range is: 3, 5, 10, <14 (2), 16, 18, 21, 24, 25, 30, 60, 63, 102 days. The explanation of this is perhaps that outlined by Camargo *et al*. (2018)[24] and marked with the * above.

While this work is on Solid Organ Transplant patients, it shows how variable and complex the incubation period in *C. neoformans* can be and [redacted]

Quote from **Kaplan, MH *et al* (1977)[29]**. 'The true duration of infection (of *C. neoformans*) **is unknown because there is no way to determine when the infection was actually acquired**. (Apart from donor-derived in SOT - as above).

Hypothesis Number 7 is therefore possible, [redacted] **, but: highly likely to be impossible to prove.**

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OTHERS AT RISK FROM INFECTION WITH *CRYPTOCOCCUS NEOFORMANS*

Marr, KA *et al*. (2020)[0] 'Cryptococcosis has decreased in incidence in HIV infected patients, but disease and related mortality are increasing in other immunosuppressed populations. We undertook this longitudinal cohort study as an NIH intramural-extramural effort, positioning 25 centres to identify cases and report longitudinal outcomes. Longitudinal assessment enabled depiction of clinical presentations and outcomes over time, incorporating functional assessments that were not clinical practice.' 'Underlying diseases in the cohort generally reflect other population-based analyses quoting George, IA *et al*. (2018)[37] Results reflect an increasing trend in targeted biological therapies (anti TNFa and interleukin 6).'

'Patients with haematological malignancies had frequently received targeted monoclonal antibodies and small-molecule signalling inhibitor, anti CD20 ([redacted] etc'
'A sizeable proportion of people had decompensated liver disease as a sole risk, consistent with other reports, and potentially indicative of complex immunodeficiency.'

'Prior serologic studies have shown that many in certain geographic areas are infected with *C. neoformans* early in life, and a substantial proportion of cases that are recognised after SOT (solid organ transplant) reflect reactivation of latent infection' (quoting: Saha *et al* (2007)[24] and Davis *et al*[38] (2007) 'Paradoxical worsening in HIV-negative patients is associated with defective alternative (M2) macrophage activation, pro inflammatory cytokine release, and intrathecal T-cell activation, with resultant axonal damage.'

'In this heterogeneous cohort of people without HIV infection, survival rates were, not surprisingly, lowest in people with CNS (Central Nervous System, JH) disease. Low risks of death were noted among SOT recipients and people with haematological malignancy.' But note only 17 cases of haematological malignancy out of 145 patients. They found that patient age of >60yrs was associated with higher risk of death. They also pointed out that 'The cohort design also has limitations. While it enables assessment of long-term outcomes in a limited cohort of people, it cannot generate estimates of prevalence or geographic distribution, because this is also influenced by site selection.' While bearing this in mind I wish to describe, within their cohort, the various underlying diseases that they found in these 145 patients.

Underlying Disease: no (% of 145)

1. Solid Organ Transplant (SOT)

n = 49 (33.8%)

Kidney Tx	24
Liver Tx	10
Heart Tx	8
Kidney/Panc Tx	3
Lung Tx	3
Kidney/Heart Tx	1
Total	49

2. Haematological malignancy (without haematopoietic stem cell transplant, HSCT)

n = 17 (11.7%)

Lymphoma	7
CLL	4
Myelodysplastic Syndrome /AML	3
Myeloma	2
ALL	1
Total	17

3. HSCT

n = 2 (1.3%) One autologous and one allogenic

Total	2

4. Autoimmune syndromes

n =23 (15.9%)

SLE	3
Rheumatoid arthritis	2
Eosinophilic Syndromes	2
Sarcoidosis	2
Myasthenia gravis	2
Inflamm colitis	2
Autoimmune hepatitis	1

5. Autoimmune syndromes (contd)

PBC	1
Multiple sclerosis	1
Idiopathic thrombocytopenia	1
Polyarteritis nodosa	1
Polymyositis	1
Wegener's	1
Polyarthropathy	1
Psoriasis	1
Unknown	1
Total	23

6. Decompensated liver disease

n = 14 (9.7%)

Total	14

7. Solid tumours

n = 8 (5.6%)

Lung	3
Breast	2
Prostate	1
Rectal	1
Liver	1
Total	8

8. Primary Immunodeficiency

n = 3 (2.1%)

Idiopathic lymphocytopenia	2
Amylogenesis Imperfecta	1
Total	3

9. Miscellaneous

n = 4 (2.8%)

Diabetes mellitus	2
Steroid receipt after pneumonia presentation	2
Total	4

10. None

n = 25 (17.2%)

Total	25

11. Grand Total: 145

IMMUNOSUPPRESIVE MEDICATIONS IN THIS COHORT (n = 145)

1. Glucocorticoid therapy
   n = 69 (47.6%)

2. Cytotoxic chemotherapy
   n = 60 (41.4%)

3. Calcineurin/mTOR inhibitors
   n = 42 (29.0%)

4. Antimetabolites
   n = 36 (24.8%)

5. Targeted antibodies
   n = 10 (6.9%)

6. Other
   n = 6 (1.3%)

This essentially shows the wide range of patients that are potentially at risk (e.g., in the QEUH) from *C. neoformans*, [redacted]

Genomics

Farrer, RA, Borman, AM, Inkster, T, Fisher, MC, Johnson, EM & Cuomo, CA (2021). Genomic epidemiology of a Cryptococcus neoformans case cluster in Glasgow, Scotland, 2018. *Microbial Genomics*, DOI 10.1099/mgen0.000537

[redacted]

[redacted]

[redacted]

[redacted]

CONCLUSIONS:

Reasons why [redacted] unlikely to have contracted *C. neoformans* infection while in QEUH/RHC.

1. [redacted]

2. Note that Nosocomial (hospital-acquired cases) cases are very very rare (worldwide). Please see: *Farrer et al*, 2021 & *Vallabhaneni et al*, 2015.
   Quote from Farrer *et al*, 2021 commenting on *Vallabhaneni et al*, 2015:'[redacted]. In Arkansas in 2013, six patients in a community hospital developed blood stream and respiratory infections. Bird habitats at the hospital and staff who had contact with birds were investigated, but no definitive source was established, and environmental sampling was negative. Isolates from the clinical cases appeared genetically diverse, as three separate MLST (multilocus sequence typing) types were identified.'
   [redacted]

3. Please also note the very significant issue of dormancy and reactivation - [redacted]. Please see pages 6 & 8 of the Report. Please also see: *Goldman, DL et al*, 2001 & *Kao, C* & *Goldman*, *DL*, 2016.

4. [redacted] showed 4 completely different Genotypes.

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

6. Infection caused by *Cryptococcus neoformans* is a rare disease in Adults [redacted]. Commoner in Males than Females - twice as common in Males than Females (see page 6 of the Report and *Guess, TE et al*. 2018). [redacted]

7. [redacted]

[redacted]

[redacted]

9. Opening of AHUs (Air Handling Units) [redacted]. Please see Hypothesis Number 1, Plant Rooms – pages 12 to 21.

Theory: 'Pigeon ingress and then fouling in Plant Rooms leading to cryptococcal spores (if present) entering the Plant Room air and then gaining access to the Air Handling Units (AHUs) ventilating the rooms/wards [redacted]
The theory was that when the AHU was shut down, opened, with the final filter removed and changed, there was – believed at that time – the opportunity for *C. neoformans* spores (if present in the Plant Room Air) to be 'sucked' into the open AHU, then into the duct and then down it to the 'at risk' patients.'

Findings:

[redacted].

Fifthly: The Hypothesis was that air from a Plant Room (postulated to contain aerosolised spores of *Cryptococcus neoformans*, from the postulated presence of pigeon guano) could possibly gain access to the patients via the AHUs, when they were shut down and opened to replace the Final Filter – thus allowing aerosolised spores (if present in the Plant Room air) down the then 'filter-less' duct. The theory was that the air would be 'pulled' into the AHU through its open door and proceed down the duct to the patient(s).

In reality the OPPOSITE happens. When the AHU is shut down and its door opened – and the Final Filter removed – air is driven, at some force OUT of the duct and into the Plant Room – a presumed thermal effect – NOT down the duct to the patients.

[redacted]

Membership of the group

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Ian Storrar, Health Facilities Scotland

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Tom Steele, Director of Facilities and Estates, NHS Greater Glasgow and Clyde

Dr A Seaton, Infectious Disease Consultant NHS Greater Glasgow and Clyde (only at First Meeting)

S Devine, Associate Nurse Director, Infection Prevention and Control.

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S Dodd, Nurse Consultant ARHAI

Darryl Conner, Sector Estates Manager NHS Greater Glasgow and Clyde

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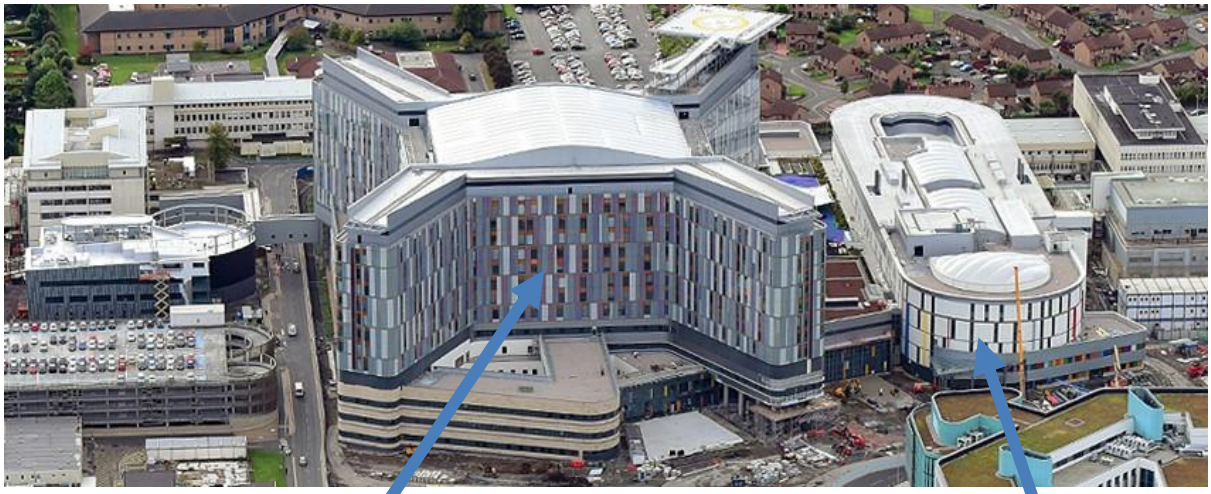
Appendix 1 – Site Map



Appendix 2 – Report helipad

Report on the Computational Fluid Dynamics Simulation of the External Flow Around Queen Elizabeth University Hospital by Quesada Solutions Ltd. - 14th June 2019. Report is detailed below.

21.06.19 - Revised CFD Model - QS Repo

Appendix 3 – Literature Review

Literature Review carried out by Antimicrobial Resistance and Healthcare Associated Infection (ARHAI) – June 2021. Report is detailed below.

Cryptococcus Literature Review_V1

Glossary of Terms

ACH	Air Changes per hour
AHU	Air Handling Units
CFU	Colony-forming unit. In microbiology, a colony-forming unit (CFU, cfu, Cfu) is a unit used to estimate the number of viable bacteria or fungal cells in a sample. Viable is defined as the ability to multiply via binary fission under the controlled conditions.
HEPA	High Efficiency Particulate Absorbing
F7 Filters	The F7 **Pleated Panel Filter** is from the HVDS F7 HVAC panel filter range, and is designed for use in HVAC systems. Offering superior performance and more energy efficient than standard panel filters.
NIPCM	National Infection Prevention and Control Manual.

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Application of whole genome sequencing to identify relationships among isolates of *Cupriavidus* spp., *Enterobacter* spp., and *Stenotrophomonas* spp. isolated from clinical samples and from water and drainage associated sources within the healthcare environment.

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Background

Early in 2018, *Cupriavidus pauculus* was isolated from the bloodstream of an immunosuppressed patient in a large, recently opened, Glasgow hospital. This triggered a period of intensive environmental sampling, particularly of the water system, and the investigation developed to include any paediatric haemato-oncology patient with a bacteraemia secondary to an organism found in the water or drainage system (Inkster *et al.*, 2021). Infections were classified into hospital-acquired infection (acquired after 48 hours of admission (HAI)) and healthcare-associated infection (contact with healthcare in the preceding 30 days (HCAI).

In addition to the initial *Cupriavidus* bacteraemia case, the extension of the case definition came to include cases of bacteraemia involving *Acinetobacter ursingii*, *Enterobacter cloacae*, *Klebsiella oxytoca*, *Pseudomonas fluorescens*, *Serratia marcescens*, and *Stenotrophomonas maltophilia.*

This current project was initiated to investigate the genetic variability of *Cupriavidus* spp., *Enterobacter* spp., and *Stenotrophomonas maltophilia* isolated from potable water and environmental sources, and to determine, from the samples available, whether there is evidence of possible transmission events between the environment and patients.

Laboratory investigations were carried out by the pathogen sequencing service within the Scottish Microbiology Reference Laboratory (SMiRL) which operates under UKAS accreditation in accordance with International Standard ISO 15189:2012 (UKAS Certificate Number 8514).

The genus *Cupriavidus*:

The genus *Cupriavidus* are Gram-negative, aerobic, non-fermentative bacilli that have been isolated from diverse environmental and human clinical sources (Cuadrado *et al.,* 2010). The genus is currently comprised of 18 validly published species listed in the LPSN database (List of Prokaryotes with a Standing in Nomenclature - Euzéby, 1997; https://lpsn.dsmz.de/genus/cupriavidus (accessed 2021-09-01)). Human infection is generally related to contaminated infusates or an immunocompromised status in the host and has been found to be the cause of rare hospital outbreaks, especially in intensive care units (Yahya & Mushannen, 2019). *Cupriavidus gilardii*, *Cupriavidus pauculus* and *Cupriavidus metallidurans* are involved in invasive human infections, such as bacteraemia and pneumonia, most of which (though not exclusively) occur in immunocompromised patients (Bianco *et al*., 2018; Kobayashi *et al*., 2016; D'Inzeo *et al*., 2015). Additionally, *Cupriavidus* species, *Cupriavidus respiraculi* in particular are increasingly identified in patients with cystic fibrosis (Coenye *et al. 2005)*.

The genus *Enterobacter*:

This organism is a Gram-negative, facultatively anaerobic bacillus. The genus is currently comprised of 46 validly published species listed in the LPSN database (List of Prokaryotes with a Standing in Nomenclature - Euzéby, 1997; https://lpsn.dsmz.de/genus/enterobacter (accessed 2021-09-01)). The nomenclature and taxonomy of the genus is complex, particularly as traditional phenotypic methods are unreliable and difficult to reproduce. Among these are the species of the *Enterobacter cloacae* complex (Ecc) which are regarded as part of the normal human gut flora, and is ubiquitous in the environment, water, soil and sewage (Sanders *et al.*, 1997). *E. cloacae* has also emerged as a common nosocomial pathogen in neonatal units (Dalben *et al.*, 2008). The Ecc includes *E. cloacae* subsp. *cloacae, E. asburiae*, *E. kobei, E.*

hormaechei, *E. ludwigii, E. mori* and *E. nimipressuralis, E. xiangxfangensis* (Chavda *et al.*, 2016). The organism is recognised as an important opportunistic pathogen responsible for infections involving the gut, lower respiratory tract, urinary tract and bacteraemia. The identification at a species level of *E. cloacae* complex is very difficult, thus these outbreaks might be falsely identified as *E. cloacae*. The increasing use of matrix assisted laser desorption ionisation-time of flight (MALDI-TOF) technology in clinical microbiology laboratories for bacterial identification did not resolve this issue because it cannot discriminate at the species level inside the *E cloacae* complex (Pavlovic *et al.*, 2012).

***Stenotrophomonas maltophilia*:**

S. maltophilia is a species of Gram-negative, aerobic, non-fermentative bacteria. The organism is ubiquitous in aqueous environments, soil, and in plants. It is a rare, opportunistic pathogen in humans, occurring in the hospital environment and being implicated in bloodstream, respiratory, urinary tract, and surgical site infections in patients with impaired immune defences. Public Health England guidance states that "*S. maltophilia* does not readily spread between patients and is not a common cause of healthcare-associated infection. Hospital outbreaks for many pathogens, like *Acinetobacter baumannii*, are usually caused by a single strain. Apparent outbreaks attributed to *S. maltophilia* are frequently caused by multiple strains, implying acquisition from environmental sources as opposed to inter-patient spread." (Public Health England, 2013)

Laboratory Methods

Subculture and storage

Isolates were collected from three main sources; clinical isolates from patients, water isolates from the potable water system and environmental isolates, defined as organisms collected by swabbing from hard surfaces within the hospital, which includes swabs from surfaces, and drains. All available stored isolates of *Cupriavidus*, *Enterobacter* and *Stenotrophomonas* from the GRI environmental laboratory and the QEUH Microbiology Department were received as cultures on nutrient agar slopes. All identified isolates from March 2018 were stored as a matter of routine. Prior to this, isolates were stored on an *ad hoc* basis. On receipt, isolates were subcultured onto MacConkey Agar plates and incubated overnight at 37°C to check for purity. A single colony was taken from the purity plate and inoculated into 3 mls Brain-Heart Infusion (BHI) broth for DNA extraction and incubated at 37°C for 19-21 hours.

The original slope culture was stored at room temperature. An aliquot of the BHI broth culture was used to inoculate a Protect Cryo-bead Vial for storage at -80°C.

DNA extraction

For pre-extraction lysis, a 1500 ul aliquot of the overnight BHI culture was spun down and the supernatant discarded. Cell pellets were gently re-suspended in 220 µl ATL buffer (cell lysis) and 20 µl Proteinase K was added before incubation in a 54°C water bath for 30 mins. Four microliters RNase were added and the mix incubated at 37°C for 15 mins. A final heat inactivation step, at 105°C on a calibrated heating block for 20 mins, was carried out prior to extraction.

Tubes were transferred to a QiaSymphony SP automated extractor for DNA extraction using the QiaSymphony DSP DNA mini kit (Qiagen). Purified genomic DNA was eluted in a 100µl volume and stored at -20°C until processed for sequencing.

Library preparation and sequencing

Libraries were prepared using the Illumina® DNA Prep (M) library protocol according to the manufacturer's instructions. This protocol is compatible with DNA inputs of 1–500 ng or higher and uses a bead-transposome complex to tagment genomic DNA by fragmenting and adding adapter tag sequences in a single reaction step. After saturation with input DNA, the bead-based transposome complex fragments a set number of DNA molecules. This bead-based saturation allows the flexibility to use a wide DNA input range and delivers consistent, uniform fragment size distribution, as well as normalized libraries. Following tagmentation, a limited-cycle PCR step adds Nextera DNA Flex-specific index adapter sequences to both ends of a DNA fragment, enabling dual-indexed sequencing of pooled libraries. A subsequent bead-based cleanup step then prepares libraries for use on any Illumina sequencing platform. Pooling libraries combines equal volumes of the normalised libraries in a single tube. The pooled library is then denatured and diluted for sequencing with PhiX library as a sequencing control.

Sequencing was carried out on the Illumina MiSeq system using the Illumina MiSeq v3 (2 x 300bp) sequencing kit. Sequencing runs took 57 hours to complete and generated sequencing output comprising paired FASTQ files as detailed below.

Bioinformatic processing of sequence data

FASTQ Generation

Initial analysis of the raw sequencing data was carried out onboard the Illumina MiSeq. MiSeq Reporter software generates intermediate analysis files in the FASTQ format, which is a text format used to represent sequences. FASTQ files contain reads for each sample and their quality scores, excluding reads identified as inline controls and clusters not passing filter. FASTQ files are the primary input for alignment. The files are written to the "BaseCalls" folder (Data\Intensities\BaseCalls) in the MiSeqAnalysis folder, and then copied to the "BaseCalls" folder in the MiSeqOutput folder. Each FASTQ file contains reads for only 1 sample, and the name of that sample is included in the FASTQ file name.

FASTQ files were transferred to the SMiRL Linux computer for further analysis.

Quality Control

Quality control of the raw reads was conducted through fastQValidator, fastQC, ngsutils, and Trimmomatic. FastQValidator first confirmed the format of the raw read file (fastq format) to confirm that no file corruption occurred during file transfer. FastQC generated a report on basic quality metrics and determined how many reads were obtained by the sequencer. Ngsutils calculated similar statistics but with detailed quality score distribution across reads. Trimmomatic removed leading and trailing bases with a phred score below 30 (represents a 99.9% base calling accuracy rate), removed any remaining adapters that were not removed by Illumina's software, and removed any stretch of read from the 5' end which does not average a phred score of 25 across 10 base pairs. FastQValidator and fastQC were then run a second time to confirm that the trimmed reads are high quality and ready for further processing. Some of the further processing step have their own quality control tests.

Speciation

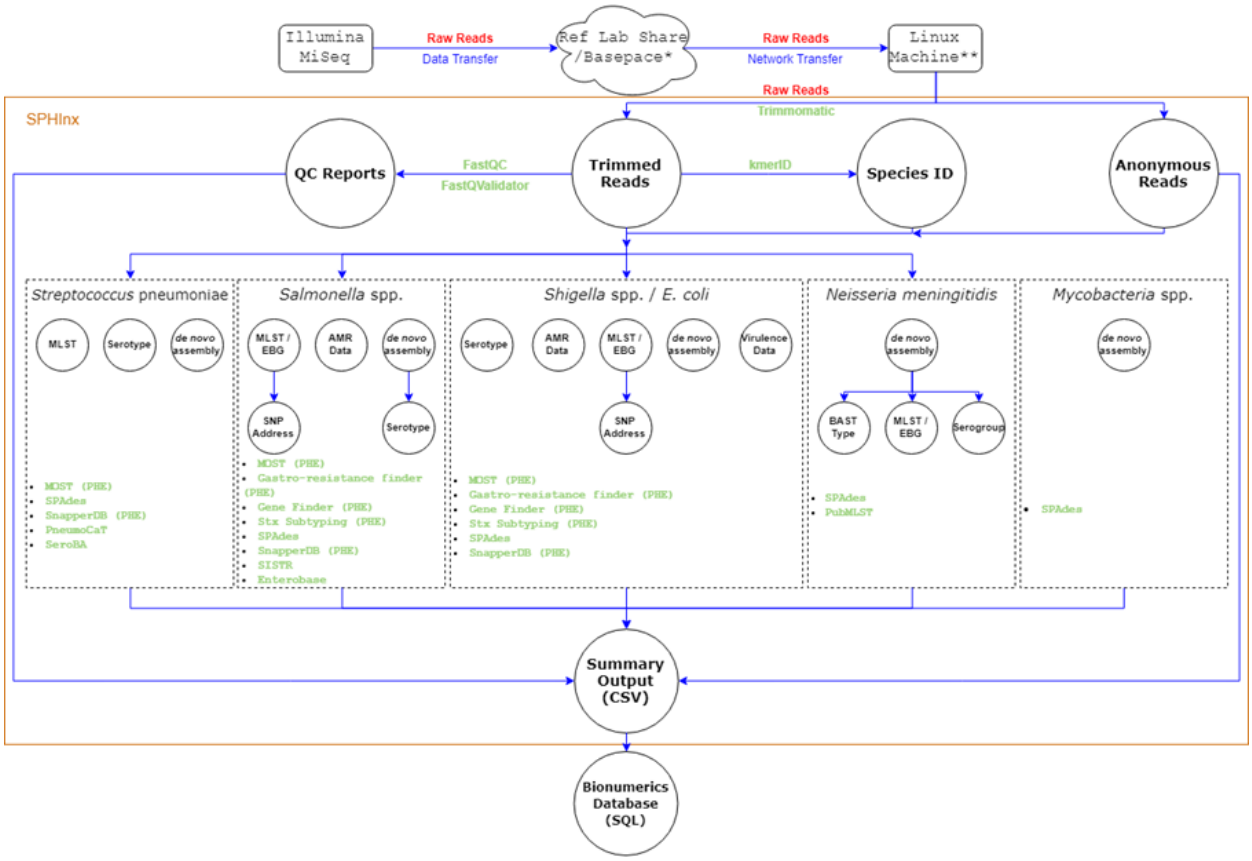
Speciation was performed using the kmerID tool developed by Public Health England (PHE). Using a kmer hashing method, it allows the determination of the bacterial species of the sample comparing it to a list of references, and detecting potential mixed samples.

Species Specific Typing

The routine SMiRL analysis pipeline, SMiRLWBP (Figure 1 below), deploys different tools depending on the species identified. After completion of these steps, a *de novo* assembly is run using SPAdes. This assembly is used to determine serotype genes for Salmonella using SISTR (Yoshida et al., 2016), and in conjunction with read mapping is used for Stx Subtyping for *Shigella*.

Neisseria meningitidis is processed differently in that only its assembly is performed locally. The sequence is then submitted to pubMLST where further analysis is carried out to extract ST, as well as finetyping antigens (porA VR1, VR2, and VR3 and FetA) and Bexsero Antigen Sequence Typing (BAST) (FHbp, NHBA and NadA).

Figure 1: Schematic representation of the routine bioinformatics analysis pipeline (SMiRLWBP) in use at SMiRL.



Ad hoc analyses

Other organisms, which for the purposes of this study included *Cupriavidus, Stenotrophomonas, Klebsiella* and *Enterobacter*, are not currently part of the routine remit of the pathogen sequencing service. The *ad hoc* sequence analysis of these organisms is carried out as for *Neisseria* and it is only QC and *de* novo assembly which are carried out locally.

A SPAdes assembly is not generated for unusual organisms that are not included in the SMiRLWBP (SPHinx) kmerID database. The assembly can be processed by altering the kmerID output for the sequence in question to a value greater than the 40% cutoff and rerunning the pipeline using the "SMiRLWBP –r" command. Once complete, the assembly FASTA file is available for downstream analysis.

Confirmation of species identity using the FASTA files is carried out using two third-party applications.

1. PubMLST (https://pubmlst.org/species-id) - Ribosomal Multilocus Sequence Typing (rMLST) is an approach that indexes variation of the 53 genes encoding the bacterial ribosome protein subunits (rps genes) as a means of integrating microbial taxonomy and typing. The *rps* gene variation catalogued in this database permits rapid identification of the phylogenetic position of any bacterial sequence at the domain, phylum, class, order, family, genus, species and strain levels (Jolley et al., 2012).

2. PathogenWatch (https://pathogen.watch/) – Speciator is a tool for assigning a species to an assembled genome. It combines searching the NCBI RefSeq genome database using mash (Ondov et al., 2016) with a search of a curated library of *Enterobacterales* genomes (github.com/rrwick/Bacsort).

3. PubMLST (https://pubmlst.org/organisms) - The PubMLST.org website hosts a collection of open-access, curated databases that integrate population sequence data with provenance and phenotype information for over 100 different microbial species and genera (Jolley *et al.*, 2018). PubMLST was used to provide multilocus sequence typing data (MLST), using established, curated databases, for *Stenotrophomonas maltophilia*, *Klebsiella aerogenes*, and *Enterobacter* spp.

Determination of relatedness of isolates using Single Nucleotide Polymorphism (SNP) analysis.

Strain typing by whole genome sequencing (WGS) based on SNPs can be performed via reference-based mapping of either reads or assembled contigs. Many studies choose to map sequencing reads against a reference genome (Reuter *et al*., 2013). The SNP approach can give very high resolution, but a reference genome must be used that is closely related to the sequenced samples. This reduces the chances of mismapping and increases the regions present in the reference genome to which reads will be mapped against. The chance of mismapping increases and the number of mapped bases decreases if a diverse set of samples is mapped against an arbitrary reference. Ideally, the analysed samples are also very closely related, which is the case in outbreak or intrapatient divergence studies. In this setting, one of a set of closely related samples may be assembled and used as reference against which all others can be mapped (Haley *et al.*, 2016).

For all isolates of *Cupriavidus* spp., *Enterobacter* spp. and for *Stenotrophomonas maltophilia,* SNP analysis was performed using the online software tool CSI Phylogeny v1.4 (https://cge.cbs.dtu.dk/services/CSIPhylogeny/). Reads were initially mapped to reference sequences (Table 1) using BWA v. 0.7.2 (Li & Durbin, 2009). The depth at each mapped position was calculated using genomeCoverageBed, which is part of BEDTools v. 2.16.2 (Quinlan & Hall, 2010). Single nucleotide polymorphisms (SNPs) were called using mpileup part of SAMTools v. 0.1.18 (Li et al., 2009). SNPs were filtered out if the depth at the SNP position was not at least 10x or at least 10% of the average depth for the particular genome mapping. The reason for applying a relative depth filter is to set different thresholds for sequencing runs that yield very different amounts of output data (total bases sequenced). SNPs were filtered out if the mapping quality was below 25 or the SNP quality was below 30. The quality scores were calculated by BWA and SAMTools, respectively. The scores are phred-based but can be converted to probabilistic scores, with the formula $10^{(-Q/10)}$, where Q is the respective quality score. The probabilistic scores will represent the probability of a wrong alignment or an incorrect SNP call, respectively. In each mapping, SNPs were filtered out if they were called within the vicinity of 10 bp of another SNP (pruning). A Z-score was calculated for each SNP. The depth requirements ensure that all positions considered are covered by a minimum amount of reads. The SNP quality and the Z-score requirements ensure that all positions considered are also called with significant confidence with respect to the bases called at each position. All genome mappings were then compared and all positions where SNPs was called in at least one mapping were validated in all mappings. The validation includes both the depth check and the Z-score check as for the SNP filtering. Any position that fails validation is ignored in all mappings. Maximum Likelihood trees were created using FastTree (Price et al., 2010).

Following completion of the analysis, results were download. The similarity matrix was downloaded as a .txt file, which was then saved as an Excel .xlsx file. The maximum likelihood trees were downloaded as .newick files and subsequently visualised and annotated in iTOL: Interactive Tree of Life (https://itol.embl.de/itol.cgi), before downloading as .pdf files (Letunic and Bork, 2021).

Table 1: List of reference genome sequences used for mapping and single nucleotide polymorphism analysis.

WGS Project Ref	**Species**	**GenBank Accession**	**Reference**
AHJE01 (OR16)	*Cupriavidus basilensis*	GCA_000243095.2	Cserhati *et al.*(2012)
AKXR01 (B-8)	*Cupriavidus basilensis*	GCA_000282815.1	Shi *et al.* (2013)
VLJN01 (J11)	*Cupriavidus gilardii*	GCA_007829435.1	Direct submission
(CR3)	*Cupriavidus gilardii*	GCA_001281465.1	Wang *et al*. (2013)
AXBU01 (H1130)	*Cupriavidus metallidurans*	GCA_000496715.1	Monsieurs *et al.* (2013)
BCZO01 (NBRC101272)	*Cupriavidus metallidurans*	GCA_001598775.1	Direct submission
(CH34)	*Cupriavidus metallidurans*	GCA_000196015.1	Direct submission
BBQN01 (KF709)	*Cupriavidus pauculus*	GCA_000974605.1	Watanabe *et al.* (2015)
CCUG 12507 (VZOW01)	*Cupriavidus pauculus*	GCA_008801835.1	Direct submission
K279a	*Stenotrophomonas maltophilia*	GCA_000072485.1	Crossman *et al.* (2008)
ATCC 13047	*Enterobacter cloaca* subsp. *cloacae*	GCF_001997105.1	Direct submission

Results

Cupriavidus spp.

A total of 155 isolates identified by the diagnostic laboratory between 2016 and 2021 as *C. pauculus*, *C. gilardii*, or *Cupriavidus* spp., were sequenced (Appendix 1). Of these, an acceptable identification was obtained by sequencing for 138 isolates - 85 isolates were confirmed as *C. pauculus*, 19 were confirmed as *C. gilardii*, 28 as *C. metallidurans*, 5 as *C. basilensis*, and one as *Cupriavidus* sp. 2SB. The remaining 17 isolates were identified as other organisms (*Bacillus* spp., *Priestia* spp., *Acidovorax* spp., *Microbacterium spp., Lysinibacillus massiliensis, Klebsiella pneumoniae*) or were unidentified. This demonstrates that conventional identification methods, as used in a diagnostic laboratory, are significantly less accurate compared to WGS.

Cupriavidus basilensis

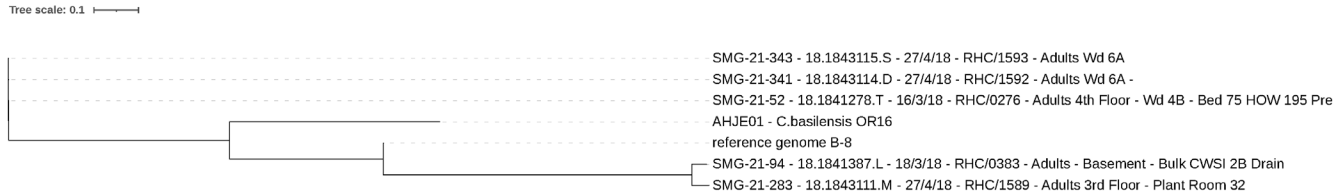
Five isolates, identified by the diagnostic laboratory as *C. pauculus*, were subsequently identified by rMLST and by mash as *C. basilensis*. All five isolates were obtained from water sources within the hospital between mid-March and the end of April 2018.

In the phylogeny generated (Figure 2), approximately 30,000 to 50,000 SNP differences were identified between the five isolates, and the two reference genomes used.

Two isolates recovered from Ward 6A on the same day were found to be the most closely related to each other, differing by 29 SNPs. Another isolate, recovered 6 weeks previously, and from ward 4B, was related to this group at between 75 and 78 SNPs.

Two other isolates recovered from different areas within the water system, with sampling on the same two days as the three isolates above, were over 4,000 SNPs apart from each other, but were not related to the isolates from Wards 4B and 6A, being almost 50,000 SNPs distant.

Figure 2: Maximum Likelihood Tree of *Cupriavidus basilensis* isolates generated from SNP analysis. Genome B-8 used as mapping reference sequence.



Cupriavidus gilardii

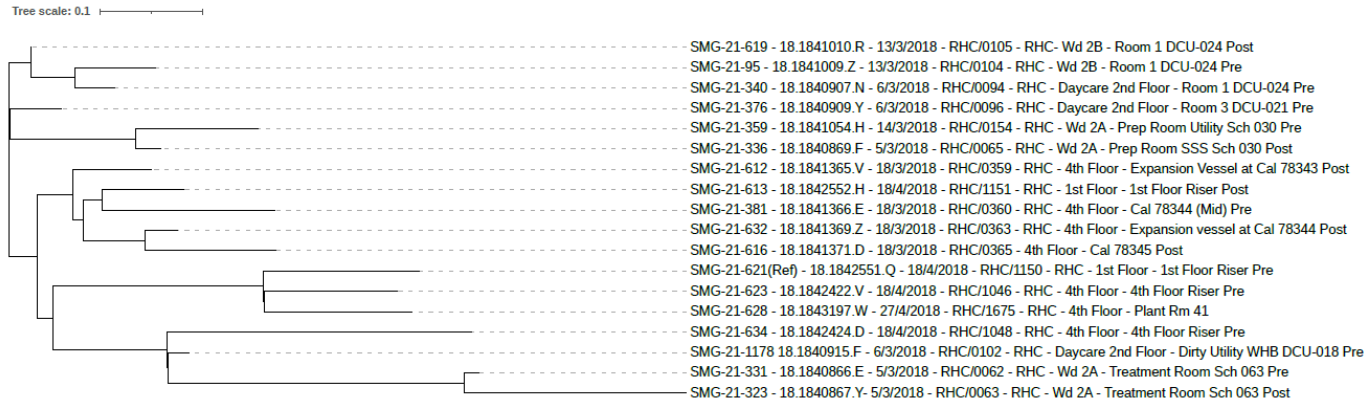
Nineteen isolates of *C. gilardii* were identified, all recovered from water sources within the hospital between February and the end of April 2018.

Initial mapping and comparison of the genomes with the reference genome CR3 provided a phylogeny (Figure 3) that indicated that all isolates displayed a relatively close relationship (<50 SNPs) apart from one isolate (18.1840723, recovered from Ward 2A Schiehallion/TCT Room 14 WHB Post in February 2018) which showed >26,000 SNP differences. This isolate was excluded from a re-analysis which utilised one of

the environmental isolates (SMG-21-621) as the mapping reference. By this approach, we were able to provide a more detailed tree showing the relationships between the isolates, with SNP distances ranging from 10 to 103 SNPs.

The limited diversity observed is likely to be representative of the population present within the water system over the sampling period.

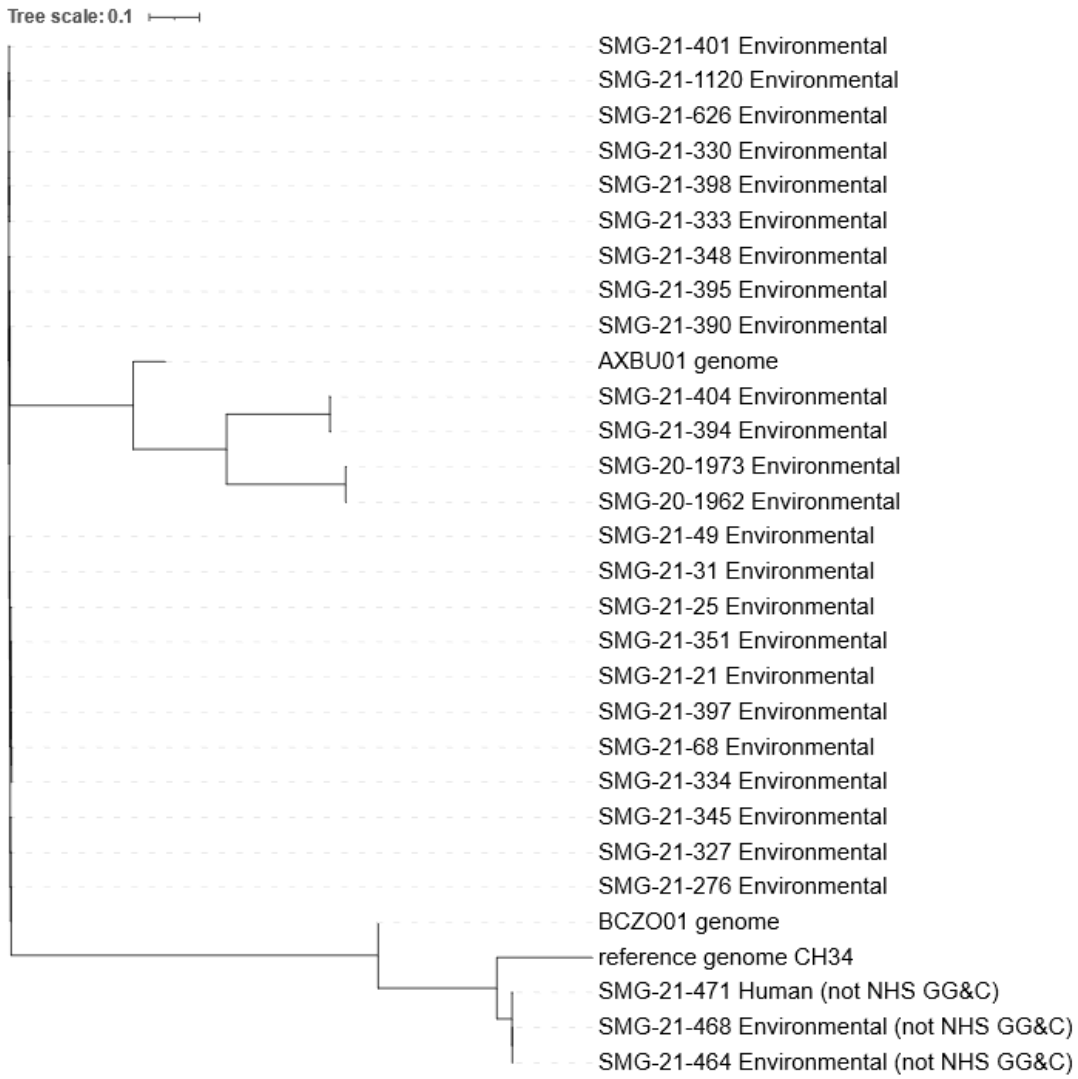
Figure 3: Maximum Likelihood Tree of *Cupriavidus gilardii* isolates generated from SNP analysis. Assembly contigs from strain SMG-21-621 used as mapping reference sequence.



Cupriavidus metallidurans

Twenty eight isolates of *C.metallidurans* were identified. Twenty five of these isolates had been recovered from water sources at the hospital between February 2018 and January 2020. In addition, a small number of isolates were sourced from another large hospital in Scotland, comprising two environmental isolates and one human blood isolate from early 2021. In the initial phylogeny generated (Figure 4) isolates were found to be highly diverse (0 to >50,000 SNPs), however, most isolates clustered relatively closely while there were three outlier groups.

Figure 4: Maximum Likelihood Tree of *Cupriavidus metallidurans* isolates generated from SNP analysis. Genome CH34 used as mapping reference sequence.



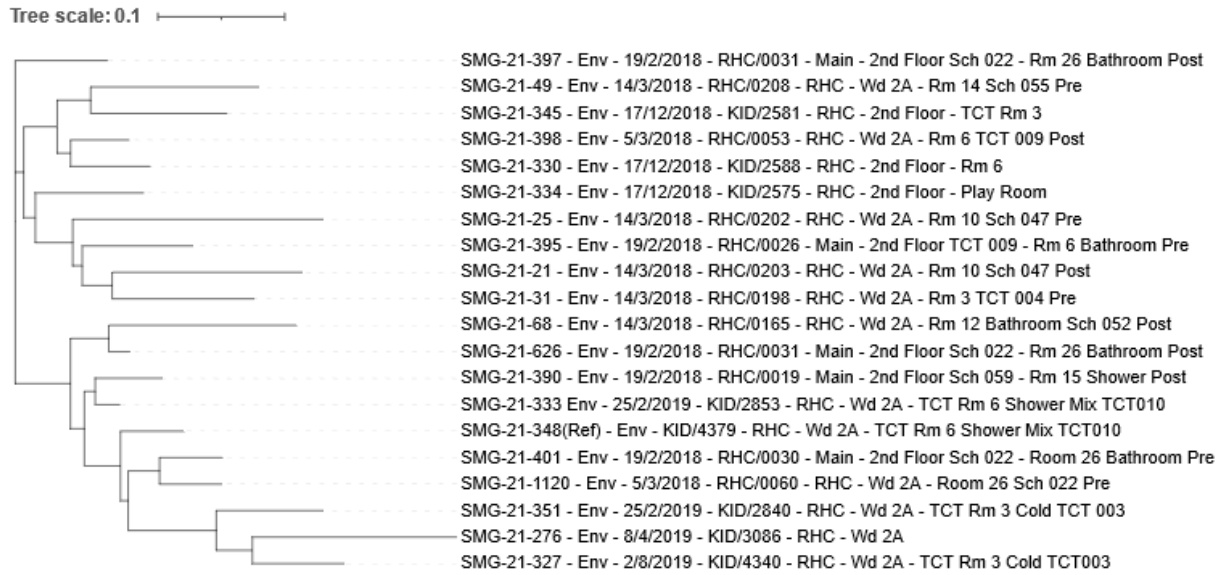
For one of these outliers (isolates SMG-21-394 and 404), both isolates were sampled from the wash hand basin in the same room (Room 3) at two different sampling times (Feb and Mar 2018). These isolates differed by 23 SNPs from each other but differed by approx. 38,000 SNPs from other isolates.

The second outlying group (SMG-20-1962 and 1973) contained two isolates from different wards (1D and 6A), sampled at different times (Dec 2019 and Jan 2020). These differed by 46 SNPs from each other, and almost 40,000 from most other isolates.

The third, and final, outlying group contained the three isolates from another Scottish hospital. These isolates were within 10 SNPs difference of each other but were >50,000 SNPs distant from those isolates from our study hospital.

As was previously done for *C. gilardii,* the outlying isolates were excluded from a re-analysis which utilised one of the water sequences as a mapping reference (Figure 5).

Figure 5: Maximum Likelihood Tree of *Cupriavidus metallidurans* isolates generated from SNP analysis. Assembly contigs from strain SMG-21-348 used as mapping reference sequence.



These isolates, all from between Feb 2018 and Feb 2019, showed a high degree of relatedness with <50 SNP differences between them. As with *C. gilardii*, there is little evidence of temporal differences over this period, and this indicates a small degree of diversity within a stable population.

Cupriavidus pauculus

Eighty-five isolates of *C. pauculus* were available for sequencing comprising water isolates from 2018, 2019 and 2020. A total of 9 human clinical isolates were also sequenced. These included two isolates from the original human case described by Inkster et al (2021), and 7 other human isolates from different hospitals in NHS GG&C, isolated between 2016 and 2021.

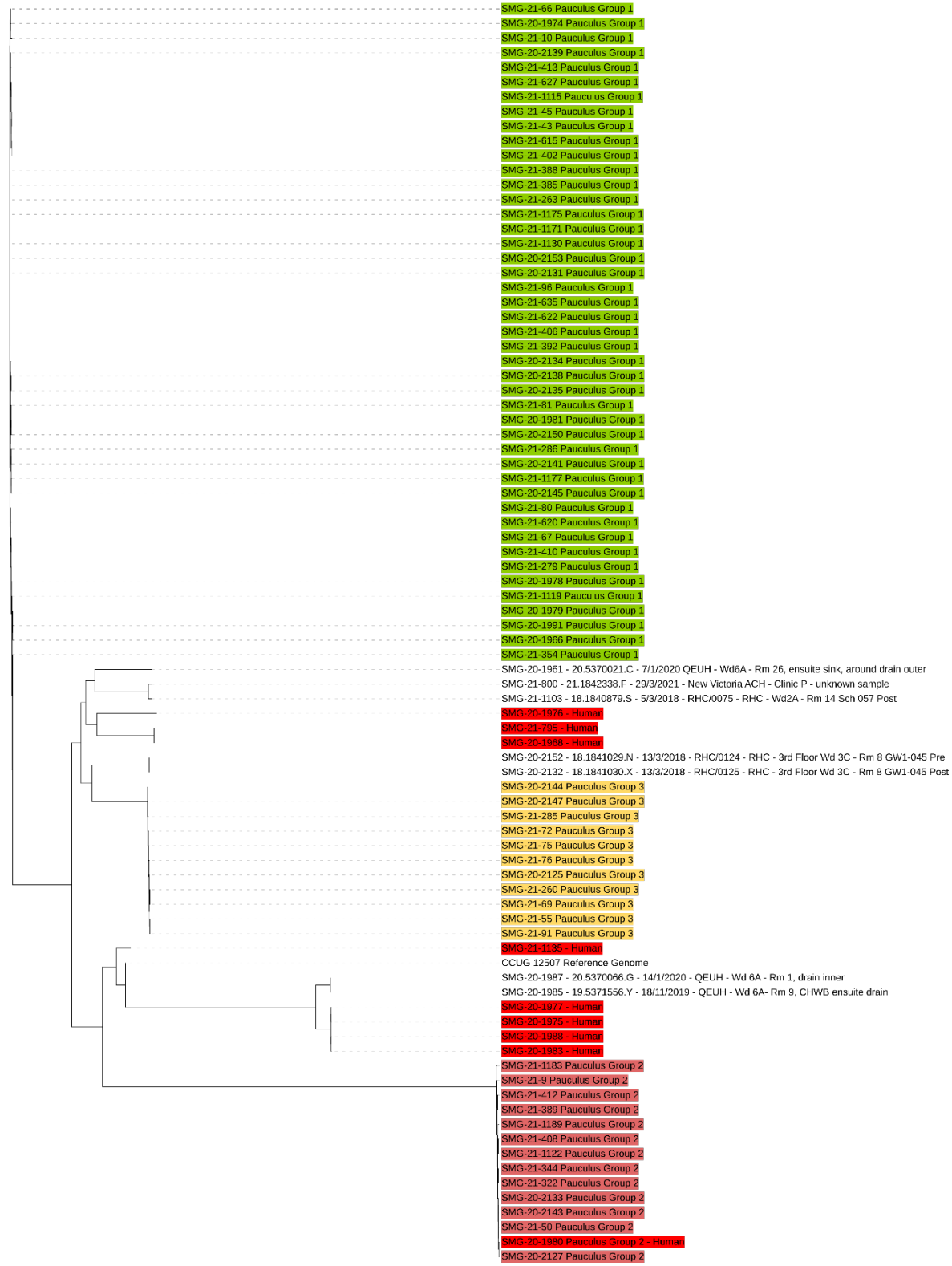
An initial phylogeny using *C .pauculus* CCUG 12507 highlighted the high degree of diversity within the collection of isolates (Figure 6).The number of SNP differences observed between isolates ranged from 0 to >65,000 and therefore too great to allow detailed evaluation of relationships. However, even at this low level of resolution, several key observations could be made:

1. Most water isolates were clustered in one of three groups. Clade 1 (45 members – highlighted in green) and Clade 3 (11 members - highlighted in yellow) contained exclusively water isolates. Clade 2 (14 members – highlighted in pink) included a single human clinical isolate dating from 2016. All clinical human isolates are highlighted in red.

2. The remaining human clinical isolates did not cluster closely with any of the water isolates sequenced in this study.

3. The two clinical isolates taken from the same patient from the 2018 case described by Inkster *et al.* (2021) differed from each other by 11 SNPs. The closest related isolates to these were another pair of isolates from an unrelated clinical human case in 2020. These two clinical isolates taken from the patient in 2020 differed from each other by 9 SNPs, and from the Inkster 2018 isolates by between 43 and 47 SNPs. The isolates from these two patients represents a new species that has not been described formally. As a new species it is not possible to say anything about the relatedness of these 4 isolates until we have an idea of how heterogeneous this species is. The formal taxonomic description of this new species is currently underway in SMiRL, Glasgow and Glasgow University. The closest related water isolates were almost 5,000 SNP differences distant.

Figure 6: Maximum Likelihood Tree of 85 *Cupriavidus pauculus* isolates (plus one reference genome) generated from SNP analysis. Genome CCUG 12507 used as mapping reference sequence. (Red – Human isolates; Green – clade 1; Pink – clade 2; Yellow – clade 3)

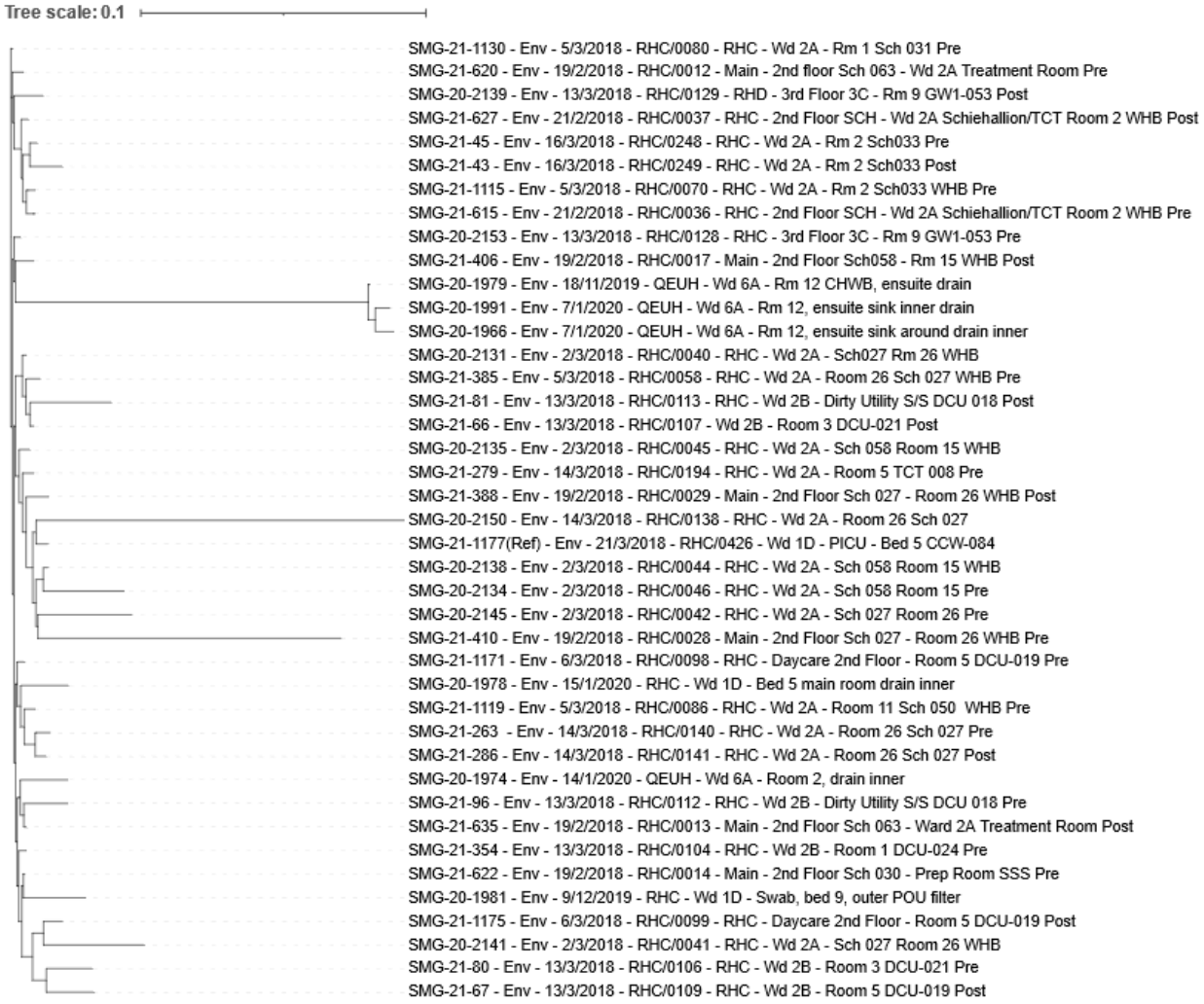


The phylogenies within clades 1, 2 and 3 were examined separately using reference genomes from within each individual group.

***C. pauculus* clade 1**

SNP analysis was carried out using SMG-21-1177 as the reference genome, resulting in a phylogeny with between 1 and 486 SNP differences. However, one isolate (SMG-21-10 – a water isolate from the main hospital under study, from March 2018) appeared to be an outlier, with the remaining isolates showing a difference of between 1 and 175 SNPs, with an average difference of 52 SNPs (Figure 7). Again, there is limited diversity observed within this group, indicating a stable population over the study period from early 2018 to 2019. A small group of isolates cluster closely together at <10 SNPs difference, while distinct from the main group of isolates. These were all isolated from water samples taken from a particular room on one ward between Nov 2019 and Jan 2020 and are therefore temporally and spatially distinct from other isolates in this group.

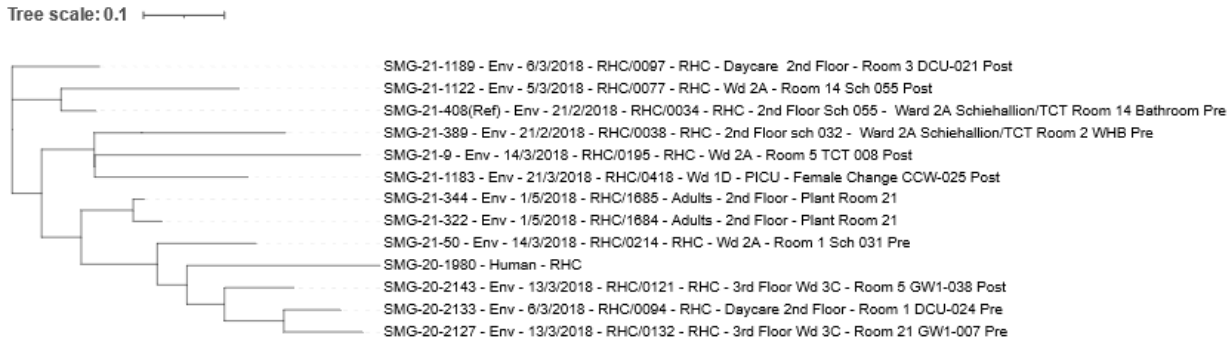
Figure 7: Maximum Likelihood Tree of *Cupriavidus pauculus* clade 1 isolates (excluding SMG-21-10) generated from SNP analysis. Assembly contigs from strain SMG-21-1177 used as mapping reference sequence.



***C. pauculus* clade 2**

SNP analysis was carried out using SMG-21-408 as the reference genome, resulting in a phylogeny with between 11 and 124 SNP differences with an average distance of 71 SNP differences (Figure 8). Water isolates were from Feb to May 2018 with a weak suggestion of spatial clustering (2nd floor, 3rd floor and Adults 2nd floor. A single human clinical case, dating from early 2016, was positioned within group 2 with a mean distance of 89 SNPs from the other group 2 isolates. It was not possible to determine whether there was any epidemiological linkages involved (see p.34 for further analysis).

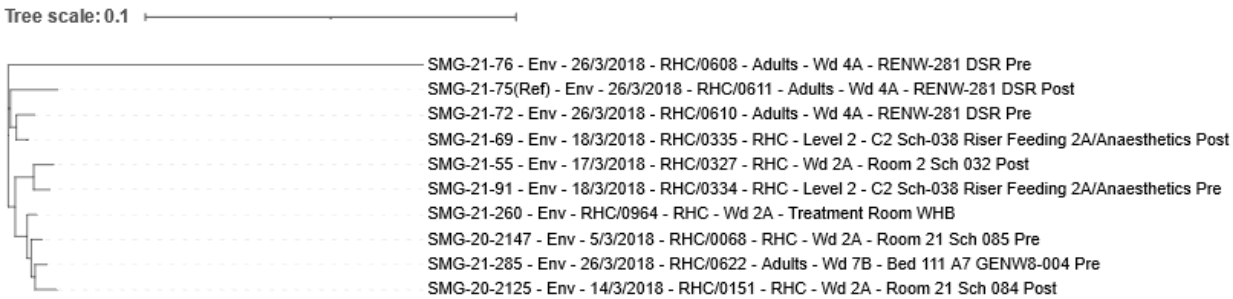
Figure 8: Maximum Likelihood Tree of *Cupriavidus pauculus* clade 2 isolates generated from SNP analysis. Assembly contigs from strain SMG-21-408 used as mapping reference sequence.



***C .pauculus* clade 3**

SNP analysis was carried out using SMG-21-75 as the reference genome, resulting in a phylogeny with between 13 and 1912 SNP differences. By excluding an outlier (SMG-20-2144), this range of diversity was reduced to between 13 and 216 SNP differences with an average distance of 64 SNP differences (Figure 9). These were all water isolates dating from Mar to Apr 2018. No evidence of temporal or spatial clustering could be determined due to the limited sample size/period.

Figure 9: Maximum Likelihood Tree of Cupriavidus pauculus clade 3 isolates generated from SNP analysis. Assembly contigs from strain SMG-21-75 used as mapping reference sequence.



Enterobacter spp.

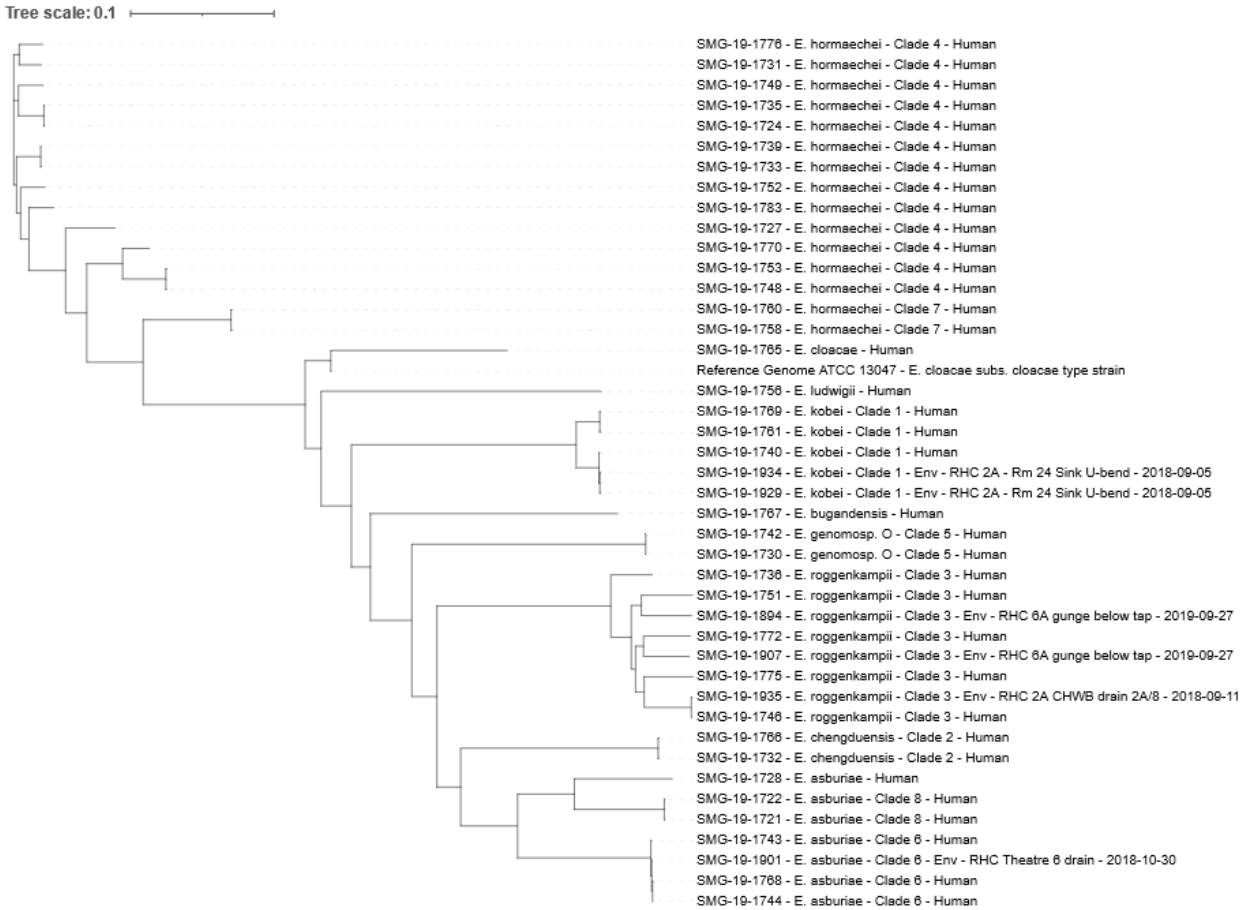
A total of 42 isolates (seven human clinical isolates from GRI from Jan to Sep 2019; six environmental isolates from QEUH/RHC from 2018/19; 29 human clinical isolates from 24 patients from QEUH/RHC between Jan 2016 and Jul 2019) identified by the diagnostic laboratory as *E. cloacae* were sequenced (Appendix 1). The six environmental isolates were from drains, sink u-bends, or from "gunge below tap". No isolates were available from water samples as there were only four instances where *Enterobacter* spp. were isolated from water over the five year period (2015-2020) and isolates were not routinely saved and stored.

Species identification was carried out from WGS sequence assemblies (FASTA files) using rMLST and Speciator as for *Cupriavidus* spp. above. Seven isolates were confirmed as *E. asburiae*, 1 as *E. bugandensis*, 1 as *E. cloacae* subsp. *cloacae*, 15 as *E. hormaechei*, 5 as *E. kobei*, 1 as *E. ludwigii*, 2 as *E. chengduensis* and 8 as *E. roggenkampii*. A further 2 isolates could only be identified as *Enterobacter* genomospecies O. The 7-gene MLST profile was obtained from PubMLST.

All of the species listed above were identified among the total of 38 human isolates. The six environmental isolates were identified as *E. asburiae* (1), *E. kobei* (2), and *E. roggenkampii* (3). An initial phylogeny using the genome from *Enterobacter cloacae* subsp. *cloacae* ATCC 13047 as reference highlighted the high degree of diversity within the collection of isolates (Figure 10).

The number of SNP differences observed between isolates ranged from 6 to >46,000 and was therefore too great to allow detailed evaluation of relationships. Further SNP analysis was undertaken on subsets of sequences corresponding to the species level groupings observed. These are shown in Figures 11 to 14.

Figure 10: Minimum spanning tree of *Enterobacter* spp. isolates generated from SNP analysis. Assembly contigs from *E.cloacae* subsp. *cloacae* strain ATCC 13047 used as mapping reference sequence. Clustering of isolates generally corresponds to the species.



Enterobacter hormaechei

This was a loose cluster of 15 human clinical isolates from 13 patients. SNP distances ranged between 115 and 68,200 differences. However, four pairs of isolates clustered at between 115 and 354 SNP differences. The remaining cluster distances were >19,000 SNPs.

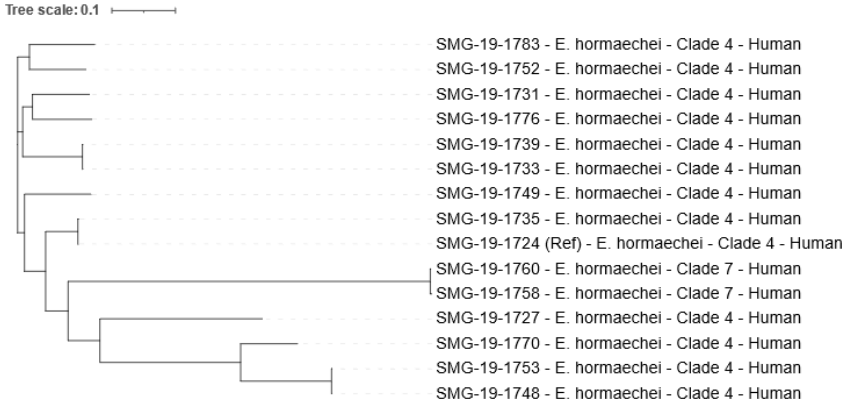
1. Two human isolates (SMG-19-1733 and SMG-19-1739) clustered with 115 SNP differences between them and were both ST45. These were from two different patients, one in RHC 2A in July 2017 and the other in RHC 2B in May 2018. This clustering is not evidence of transmission from a common source.

2. Two human isolates (SMG-19-1748 and SMG-19-1753) clustered with 117 SNP differences and were both ST143. This clustering is not evidence of transmission from a common source. These were from RHC 2A in July 2018 and from RHC 6A in Oct 2018. The RHC 2A isolate was from the same individual patient from whom one of the ST45 isolates described above had been isolated two months previously. The results from the two isolates from this patient, cultured 2 months apart, being different STs and differed by almost 50,000 SNPs were strongly indicative of a new infection.

3. Two human isolates (SMG-19-1724 and SMG-19-1735) clustered with 236 SNP differences, one being ST175, the other being a previously unrecognised single locus variant of ST175. One was from a patient in RHC 1D in March 2016, the other from a patient in RHC 2A in Jun 2018. This clustering is not evidence of transmission from a common source.

4. Two isolates (SMG-19-1758 and SMG-19-1760) from a single patient clustered at a distance of 354 SNP differences had been isolated three weeks apart.

Figure 11: Minimum spanning tree of *Enterobacter hormaechei* isolates generated from SNP analysis. Assembly contigs from *E. hormaechei* strain SMG-19-1724 used as mapping reference sequence.



	SMG-19-1724	SMG-19-1727	SMG-19-1731	SMG-19-1733	SMG-19-1735	SMG-19-1739	SMG-19-1748	SMG-19-1749	SMG-19-1752	SMG-19-1753	SMG-19-1758	SMG-19-1760	SMG-19-1770	SMG-19-1776	SMG-19-1783
SMG-19-1724	0	37783	20061	19413	236	19425	44041	20253	19897	43950	52023	51701	42456	20086	20762
SMG-19-1727	37783	0	41178	41416	37844	41445	53588	41255	41162	53551	67160	66973	45272	41250	41019
SMG-19-1731	20061	41178	0	20051	20096	20081	49760	21450	20582	49695	60639	60389	47540	20118	21921
SMG-19-1733	19413	41416	20051	0	19448	115	49583	21159	20458	49504	60457	60205	47448	20072	21767
SMG-19-1735	236	37844	20096	19448	0	19462	44109	20295	19937	44018	52133	51811	42528	20129	20797
SMG-19-1739	19425	41445	20081	115	19462	0	49600	21176	20490	49521	60478	60226	47467	20094	21788
SMG-19-1748	44041	53588	49760	49583	44109	49600	0	49859	49795	117	68200	68028	24700	50003	50083
SMG-19-1749	20253	41255	21450	21159	20295	21176	49859	0	21559	49796	60686	60439	47666	22061	22739
SMG-19-1752	19897	41162	20582	20458	19937	20490	49795	21559	0	49726	60607	60355	47541	21215	20881
SMG-19-1753	43950	53551	49695	49504	44018	49521	117	49796	49726	0	68168	67996	24750	49937	50010
SMG-19-1758	52023	67160	60639	60457	52133	60478	68200	60686	60607	68168	0	354	67373	60754	60928
SMG-19-1760	51701	66973	60389	60205	51811	60226	68028	60439	60355	67996	354	0	67201	60511	60674
SMG-19-1770	42456	45272	47540	47448	42528	47467	24700	47666	47541	24750	67373	67201	0	47857	47841
SMG-19-1776	20086	41250	20118	20072	20129	20094	50003	22061	21215	49937	60754	60511	47857	0	22479
SMG-19-1783	20762	41019	21921	21767	20797	21788	50083	22739	20881	50010	60928	60674	47841	22479	0
min: 115 max: 68200															

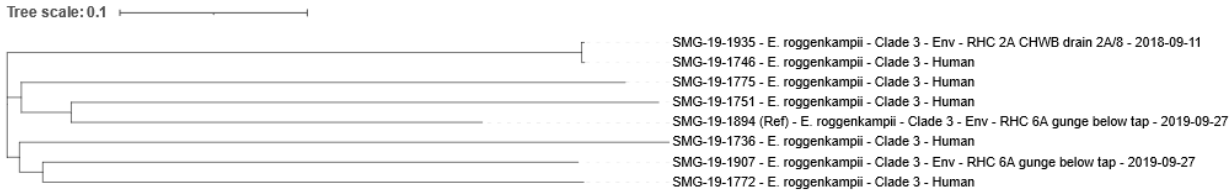
Enterobacter roggenkampii

Eight isolates (5 human and 3 environmental) formed a loose cluster with SNP distances of between 211 and 31,000 differences. MLST type could not be determined for two of these isolates. The other isolates belonged to 5 different STs.

Two isolates (SMG-19-1935 and SMG-19-1746), both ST997, formed a cluster at 211 SNP differences from each other, a human clinical isolate from RHC CDU in June 2018 and an environmental isolate from RHC 2A from September 2018. This clustering is not evidence of transmission from a common source. Remaining SNP distances were all >25,000 differences.

The two other environmental isolates were two separate isolates from the same specimen (M19.5371473.N). One of these was identified as ST272 while the other was a single locus variant of either ST172 or 984.

Figure 12: Minimum spanning tree of *Enterobacter roggenkampii* isolates generated from SNP analysis. Assembly contigs from *E. roggenkampii* strain SMG-19-1894 used as mapping reference sequence.



	SMG-19-1894_contigs	SMG-19-1736_contigs	SMG-19-1746_contigs	SMG-19-1751_contigs	SMG-19-1772_contigs	SMG-19-1775_contigs	SMG-19-1907_contigs	SMG-19-1935_contigs
SMG-19-1894_contigs	0	27303	26468	26121	26199	26825	26042	26460
SMG-19-1736_contigs	27303	0	30080	30955	29464	30326	29494	30074
SMG-19-1746_contigs	26468	30080	0	29420	28154	29057	28082	211
SMG-19-1751_contigs	26121	30955	29420	0	29245	30310	29055	29413
SMG-19-1772_contigs	26199	29464	28154	29245	0	28664	27533	28147
SMG-19-1775_contigs	26825	30326	29057	30310	28664	0	28580	29048
SMG-19-1907_contigs	26042	29494	28082	29055	27533	28580	0	28073
SMG-19-1935_contigs	26460	30074	211	29413	28147	29048	28073	0
min: 211 max: 30955								

Enterobacter asburiae

A total of eight isolates demonstrated a range of relatedness of between 56 and 73,000 SNP differences.

Four isolates, 3 clinical (SMG-19-1743, SMG-19-1744 and SMG-19-1768) and one environmental (SMG-19-1901), were all determined as MLST type 780 and formed a cluster at between 90 and approx. 600 SNP differences distance. The environmental isolate was at least 223 SNPs away from the closest human isolate. The human isolates were from RHC 3B in Jan 2016, RHC 1D in May 2017 and GRI Ward 67 in Aug 2019. The environmental isolate was from a drain swab from RHC theatre 6 in Oct 2018. The closest match was between SMG-19-1744 (RHC 3B - Jan 2016) and the SMG-19-1768 (GRI Ward 67 - Aug 2019) at 90 SNPs difference. This clustering is not evidence of transmission from a common source.

A second cluster of two human isolates (SMG-19-1721 and SMG-19-1722), isolated at RHC two weeks apart, showed 56 SNPs distance. The SNP distances between these two isolates, while not demonstrating a close relationship, would not preclude epidemiological linkage. Although genetically close these two isolates showed markedly difference antibiotic sensitivities with SMG-19-1721 being an ESBL producer whilst SMG-19-1722 was not and so there is no relatedness between these two isolates. The only environmental isolate was >50,000 SNPs away from these two clinical cases. No other environmental isolates of *Enterobacter asburiae* were isolated between 2015-20.

Figure 13: Minimum spanning tree of *Enterobacter asburiae* isolates generated from SNP analysis. Assembly contigs from *E. asburiae* strain SMG-19-1722 used as mapping reference sequence.

	SMG-19-1722_contigs	SMG-19-1721_contigs	SMG-19-1728_contigs	SMG-19-1743_contigs	SMG-19-1744_contigs	SMG-19-1768_contigs	SMG-19-1901_contigs
SMG-19-1722_contigs	0	56	46589	53000	52988	53012	52985
SMG-19-1721_contigs	56	0	46641	53043	53031	53055	53028
SMG-19-1728_contigs	46589	46641	0	73340	73296	73302	73283
SMG-19-1743_contigs	53000	53043	73340	0	602	600	571
SMG-19-1744_contigs	52988	53031	73296	602	0	90	243
SMG-19-1768_contigs	53012	53055	73302	600	90	0	223
SMG-19-1901_contigs	52985	53028	73283	571	243	223	0
min: 56 max: 73340							

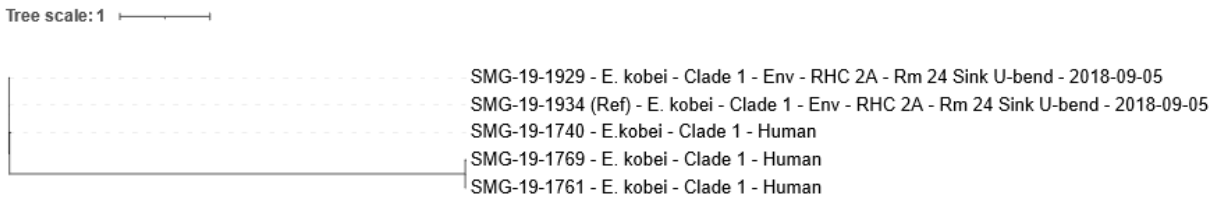
Enterobacter kobei

The number of SNP differences observed between the five isolates ranged from 23 to >21,000. The five isolates were split in two smaller clusters, separated by more than 21,000 SNP differences.

Two isolates recovered from a sink u-bend in RHC Ward 2A in Sept 2018 (SMG-19-1929 and SMG-19-1934), clustered at 23 SNPs distance from each other. These two also clustered with a human clinical isolate (SMG-19-1740), also from RHC 2A, isolated in August 2017, at a distance of 421 SNP differences. All three isolates were identified as MLST type 56. This clustering is not evidence of transmission from a common source.

A further two clinical isolates (SMG-19-1761 and SMG-19-1769), isolated in June and July 2019 and identified as ST 125, clustered at 252 SNPs distant from each other, but were from different hospitals. There was no identified epidemiological link between these cases.

Figure 14: Minimum spanning tree of *Enterobacter kobei* isolates generated from SNP analysis. Assembly contigs from *E. kobei* strain SMG-19-1934 used as mapping reference sequence.



	SMG-19-1934_contigs	SMG-19-1740_contigs	SMG-19-1761_contigs	SMG-19-1769_contigs	SMG-19-1929_contigs
SMG-19-1934_contigs	0	421	21199	21257	23
SMG-19-1740_contigs	421	0	21277	21236	424
SMG-19-1761_contigs	21199	21277	0	252	21204
SMG-19-1769_contigs	21257	21236	252	0	21262
SMG-19-1929_contigs	23	424	21204	21262	0
min: 23 max: 21277					

***Enterobacter* genomospecies O** (refer to Figure 10)

Two isolates (SMG-19-1730 and SMG-19-1742) from the same patient and isolated 3 months apart in 2016, demonstrated 18 SNP differences between each other.

Enterobacter chengduensis (refer to Figure 10)

Two isolates (SMG-19-1732 and SMG-19-1766) from different patients from RHC and GRI, 9 months apart in 2018/9, demonstrated 233 SNP differences between each other.

Stenotrophomonas maltophilia

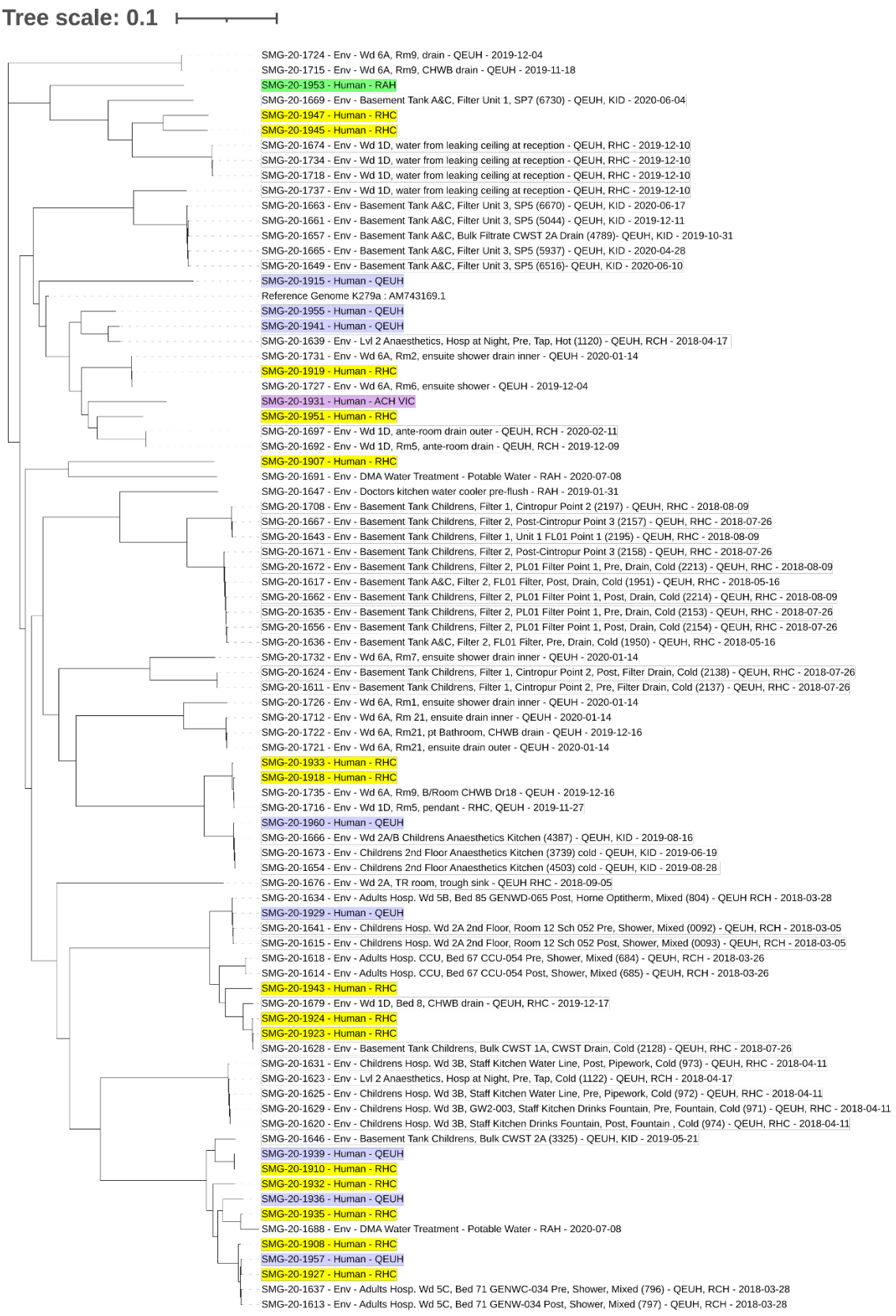
A total of 84 isolates identified by the diagnostic laboratory as *Stenotrophomonas maltophilia* were sequenced (Appendix 1). Species ID was confirmed for all isolates by sequencing. These included 25 human clinical isolates (23 from RHC/QEUH, 1 from RAH, and 1 from VIC ACH) collected between June 2015 and June 2020. Water and environmental isolates were collected from RHC/QEUH (56) and RAH (3) between Mar 2018 and Feb 2020 (Jul 2020 for 2 RAH samples).

An initial phylogeny of these isolates constructed using *S. maltophilia* K279 as reference genome highlighted the high degree of diversity within the collection of isolates (Figure 15). The number of SNP differences observed between isolates ranged from 0 to >55,000. Human isolates were represented across the entire phylogeny.

Groups of more closely related isolates were discernible within the tree and therefore, as for *Cupriavidus* spp., the phylogenies within these "clades" were examined separately using reference genomes from within each individual group.

In addition, it was possible to obtain a primary filter culture from a routine water sample collected in early 2021, and to sequence each of the individual colonies of *Stenotrophomonas maltophilia* present on that filter. This gives an estimate of the diversity between organisms from a single sample.

Figure 15: Maximum Likelihood Tree of *Stenotrophomonas maltophilia* isolates generated from SNP analysis. Assembly contigs from strain K279a used as mapping reference sequence. Coloured highlights indicate human strains

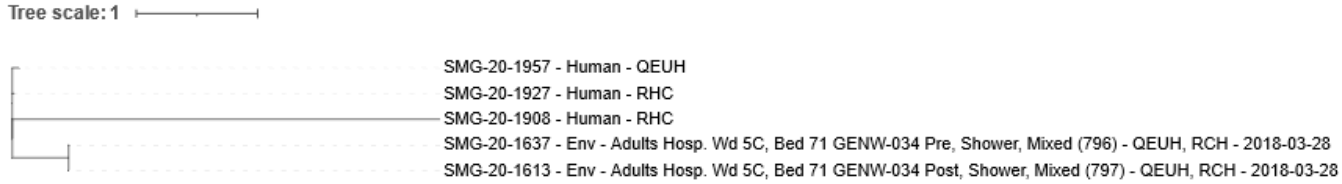


Yellow=RHC Blue=QEUH Green=RAH Purple=VIC ACH

***S. maltophilia* clade 1**

This clade contained three human isolates and two environmental isolates (Figure 16). The two environmental isolates, collected from the same site at the same time were very closely related at 8 SNP differences. Distance to the human isolates ranged from 645 to 1914 SNP differences. The human isolates were from 2017, 2018 and 2019, and were from different wards at RHC/QEUH. There was no evidence of a close relationships between the human isolates, with differences of between 144 and 1821 SNPs.

Figure 16: Maximum Likelihood Tree of *Stenotrophomonas maltophilia* clade 1 isolates generated from SNP analysis, together with table of SNP distances.



	SMG-20-1613	SMG-20-1637	SMG-20-1908	SMG-20-1927	SMG-20-1957
SMG-20-1613	0	8	1912	645	717
SMG-20-1637	8	0	1914	647	719
SMG-20-1908	1912	1914	0	1798	1821
SMG-20-1927	645	647	1798	0	144
SMG-20-1957	717	719	1821	144	0
min: 8 max: 1914					

***S. maltophilia* clade 2**

Clade 2 contained 7 isolates from water samples from the same area within the hospital over a 4 month period of May to Aug 2018 (Figure 17). A maximum of 47 SNP differences between isolates was found indicating a stable population with limited diversity over the sampling period.

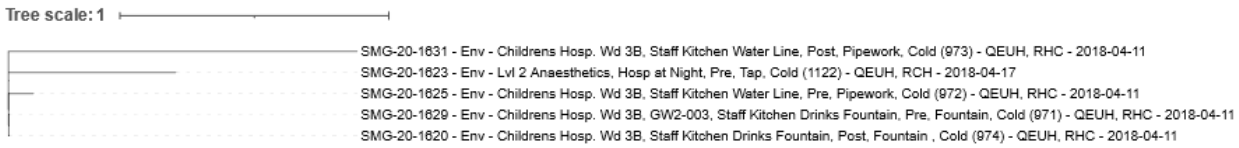
Figure 17: Maximum Likelihood Tree of *Stenotrophomonas maltophilia* clade 2 isolates generated from SNP analysis, together with table of SNP distances.

	SMG-20-1617	SMG-20-1635	SMG-20-1636	SMG-20-1656	SMG-20-1662	SMG-20-1671	SMG-20-1672
SMG-20-1617	0	11	11	9	4	39	12
SMG-20-1635	11	0	14	10	7	46	19
SMG-20-1636	11	14	0	6	7	46	9
SMG-20-1656	9	10	6	0	5	44	15
SMG-20-1662	4	7	7	5	0	39	16
SMG-20-1671	39	46	46	44	39	0	47
SMG-20-1672	12	19	9	15	16	47	0
min: 4 max: 47							

***S. maltophilia* clade 3**

Clade 3 contained 5 water isolates collected over a 1 week period in April 2018 from two areas within the hospital (Figure 18). A maximum of 23 SNP differences between isolates was found, indicating a stable population with limited diversity over the sampling period.

Figure 18: Maximum Likelihood Tree of *Stenotrophomonas maltophilia* clade 3 isolates generated from SNP analysis, together with table of SNP distances.

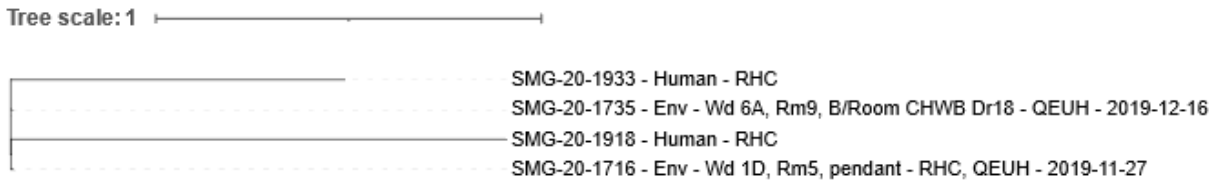


	SMG-20-1620	SMG-20-1623	SMG-20-1625	SMG-20-1629	SMG-20-1631
SMG-20-1620	0	11	2	0	14
SMG-20-1623	11	0	13	11	23
SMG-20-1625	2	13	0	2	16
SMG-20-1629	0	11	2	0	14
SMG-20-1631	14	23	16	14	0
min: 0 max: 23					

***S. maltophilia* clade 4**

Clade 4 contained 2 human isolates from RHC in Jun 2018 and Sep 2019, and 2 water isolates from Nov and Dec 2019 (Figure 19). The water isolates were 14 SNP differences apart. There was no evidence of association with either of the human isolates with SNP distances of about 500 to 1000 SNPs.

Figure 19: Maximum Likelihood Tree of *Stenotrophomonas maltophilia* clade 4 isolates generated from SNP analysis, together with table of SNP distances.



	SMG-20-1716	SMG-20-1735	SMG-20-1918	SMG-20-1933
SMG-20-1716	0	14	588	481
SMG-20-1735	14	0	586	479
SMG-20-1918	588	586	0	943
SMG-20-1933	481	479	943	0
min: 14 max: 943				

***S. maltophilia* clade 5**

Clade 5 contained a single human isolate from QEUH from Jan 2020, and 3 water isolates from one area within the hospital isolated in June and Aug 2019 (Figure 20).

The environmental isolates were closely linked with 4 – 5 SNP differences between them. The human case showed around 90 SNP differences from the environmental strains indicating no evidence of linkage.

Figure 20: Maximum Likelihood Tree of *Stenotrophomonas maltophilia* clade 5 isolates generated from SNP analysis, together with table of SNP distances.

	SMG-20-1654	SMG-20-1666	SMG-20-1673	SMG-20-1960
SMG-20-1654	0	4	5	92
SMG-20-1666	4	0	5	92
SMG-20-1673	5	5	0	93
SMG-20-1960	92	92	93	0
min: 4 max: 93				

***S. maltophilia* clade 6**

Clade 6 contained 5 water isolates collected from the same area within the water system between Oct 2019 and June 2020 (Figure 21). A limited degree of diversity was observed with between 6 and 19 SNP differences, possibly indicating a stable population with limited diversity over the sampling period.

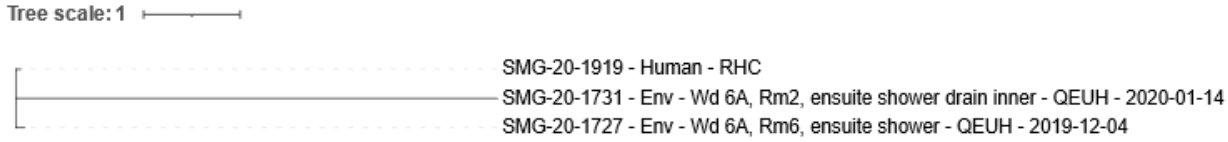
Figure 21: Maximum Likelihood Tree of *Stenotrophomonas maltophilia* clade 6 isolates generated from SNP analysis, together with table of SNP distances.

	SMG-20-1649	SMG-20-1657	SMG-20-1661	SMG-20-1663	SMG-20-1665
SMG-20-1649	0	15	19	18	17
SMG-20-1657	15	0	6	7	8
SMG-20-1661	19	6	0	11	12
SMG-20-1663	18	7	11	0	9
SMG-20-1665	17	8	12	9	0
min: 6 max: 19					

***S. maltophilia* clade 7**

Clade 7 contained a single human isolate from Sept 2017 and two drain environmental isolates from Dec 2019 and Jan 2020, both from the same ward (Figure 22). The environmental isolates differed from each other by about 450 SNPs. The human isolate differed from one of these (Dec 2019) by 52 SNPs. The human isolate from 2017 and environmental isolate from 2019 differ by 52 SNPs over a two year period. We would expect a maximum of 45 SNPs over this time period. Not only are the two isolates not epidemiologically linked in time, but they are also not linked in space, with the human isolate collected from 2A RHC whilst the environmental isolate was collected from 6A QEUH. Taken together there is no epidemiological link between the human and the environmental isolates.

Figure 22: Maximum Likelihood Tree of *Stenotrophomonas maltophilia* clade 7 isolates generated from SNP analysis, together with table of SNP distances.

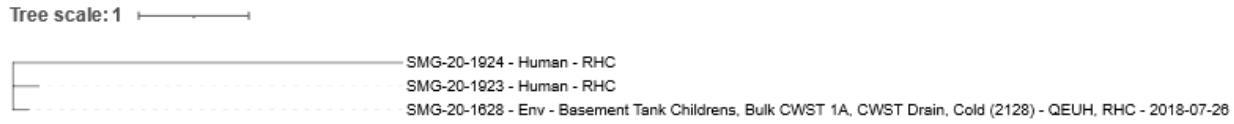


	SMG-20-1727	SMG-20-1731	SMG-20-1919
SMG-20-1727	0	453	52
SMG-20-1731	453	0	445
SMG-20-1919	52	445	0
min: 52 max: 453			

***S. maltophilia* clade 8**

Clade 8 contained two human isolates (one from the same patient as the human isolate in Cluster 7) collected in May and Jul 2017, and a single environmental isolate from Jul 2018 (Figure 23). No link was indicated between the human cases or the environmental isolate.

Figure 23: Maximum Likelihood Tree of *Stenotrophomonas maltophilia* clade 8 isolates generated from SNP analysis, together with table of SNP distances.



	SMG-20-1628	SMG-20-1923	SMG-20-1924
SMG-20-1628	0	92	316
SMG-20-1923	92	0	334
SMG-20-1924	316	334	0
min: 92 max: 334			

***S. maltophilia* clade 9**

Clade 9 contained two human isolates, one from 2017 and one from 2020, together with a reference human isolate sequence from 2013, obtained from a published study (Esposito *et al.*, 2017) (Figure 24). No close links were identified.

Figure 24: Maximum Likelihood Tree of *Stenotrophomonas maltophilia* clade 9 isolates generated from SNP analysis, together with table of SNP distances.

	SMG-20-1910	SMG-20-1939	SMG-20-1993
SMG-20-1910	0	183	764
SMG-20-1939	183	0	813
SMG-20-1993	764	813	0
min: 183 max: 813			

Outside of these clusters, there were no close linkages observed between any isolates.

Sequencing of multiple colonies recovered from a single water sample.

All seven single colonies were picked from the filter following overnight culture (Figure 25). Each colony was subcultured, extracted and sequenced individually. A level of diversity between 4 and 25 SNP differences was observed. Therefore, for *Stenotrophomonas* we used a conservative threshold of >25 SNPs as the level that we assigned strain differences. A level of < 25 SNPs or less between different strains has been used to signify possible transmission (Chung 2016, Steinmann 2018). A comparison of different analytical workflows for defining an outbreak of foodborne disease caused by *Salmonella* Enteritidis concluded that the threshold was variable, dependent on the workflow, with 14 SNPs or less denoting an outbreak from a point source (Coipan *et al*. 2020).

Figure 25: *Stenotrophomonas* colonies cultured from a single water sample

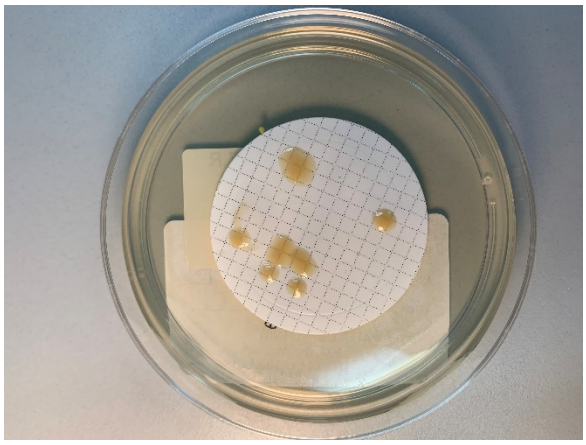


Figure 26: Maximum Likelihood Tree of seven individual *Stenotrophomonas maltophilia* colonies isolated from a single routine water sample, together with table of SNP distances.

	SMG-21-358	SMG-21-363	SMG-21-365	SMG-21-366	SMG-21-370	SMG-21-379	SMG-21-382
SMG-21-358	0	15	25	9	8	10	10
SMG-21-363	15	0	20	6	11	13	9
SMG-21-365	25	20	0	22	25	19	19
SMG-21-366	9	6	22	0	9	7	7
SMG-21-370	8	11	25	9	0	6	6
SMG-21-379	10	13	19	7	6	0	4
SMG-21-382	10	9	19	7	6	4	0
min: 4 max: 25							

We took the pragmatic decision to use the boundary of <25 SNPs to indicate strain similarity when analysing both *Cupriavidus* and *Enterobacter* species.

The majority of the sequenced organisms within this report are samples from the population in the water, a population which could have been resident for a significant length of time, collected over a 5 year period, and within which we would expect a level of sequence variation between isolates.

Estimating the rates at which bacterial genomes evolve is critical to understanding major evolutionary and ecological processes such as disease emergence, long-term host–pathogen associations and short-term transmission patterns. A study looking at 36 whole genome data sets from 16 species of bacterial pathogens found base substitution rates of between 10^{-5} substitutions per base per year for rapidly evolving organisms like *E. faecium*, *S. aureus* and *Acinetobacter baumanii*, down to 10^{-8} substitutions per base per year for *M. tuberculosis.* The average base substitution rate is around 10^{-6} to 10^{-7} substitutions per base per year (Duchene 2016).

Using this information and the average size of the organisms sequenced in this report it is possible to estimate the molecular clock rate of each genus.

The average genome size for strains of *Stenotrophomonas maltophilia* is around 4,800,000 base pairs. At 10^{-6} substitutions per base per year, this would equate to a molecular clock rate of 5 SNPs per year. For *Cupriavidus* spp. with an average genome size of 6,800,000 base pairs this equates to a molecular clock rate of 7 SNPs per year. For *Enterobacter* spp. with an average genome size of 4,800,000 base pairs this equates to a to a molecular clock rate of 5 SNPs per year.

Therefore, over a 5 year period (2016-2020) a sample from a single source, which could have a maximum SNP diversity of 25 SNPs across all the individual organisms found in that sample, would have produced progeny isolates that would have a maximum diversity of 75 SNPs from the original isolate, assuming a base substitution rate of 5 SNPs per year, or 115 SNPs for *Cupriavidus* spp., assuming a base substitution rate of 7 SNPs per year.

When analysed with a SNP difference of a maximum of 75 SNPs (for *S. maltophilia* and *Enterobacter spp*) or 115 SNPs (for *Cupriavidus* spp.), for the five year period (2016-2020), there is no difference in the conclusions of this report, except in one instance. There is a clinical isolate (from a blood culture) from a patient in 2016 that lies within the *C. pauculus* Clade 2. The patient was on total parenteral nutrition (TPN) and developed a bacteraemia. Around this time there was concern about contamination, with *C. pauculus,* of the water in the Aseptic Pharmacy Unit as described in the PAG 17.06.16. The human isolate was isolated in 2016 and co-locates with potable water isolates collected in 2018. Using the starting point of 25 SNPs distance within the initial 2016 population, after two years we would expect a maximum distance of 53 SNPs. There are 4 environmental potable water of these isolates which would fall within this cut-off (SMG20-2127, 20-2133, 20-2143 and 21-50). These isolates were all collected in early March 2018 from sites in RHC; Ward 3C (2 isolates), Ward 2A (single isolate) and the Day care Unit on the 2nd floor of RHC

(single isolate). As stated before (p.15) this could be interpreted that a stable population of Clade 2 organisms of *C.pauculus* exists within the water system.

The limitations of this process of defining the least number of SNPs to show identity are the assumptions being made. There is no data on the actual base substitution rates for the three genera sequenced in this report. Also, we do not know the diversity of the population in the water, or indeed the population in the patient sample, as only single colonies were taken and stored from clinical and potable water/environmental samples which may have had many colonies of growth apparent on the initial culture medium.

Limitations of this analysis

The main limitation within this analysis is the non-structured way the isolates were collected. The majority of saved water isolates relate to the period post March 2018 when water testing frequency was increased. Prior to March 2018 water testing was done less frequently and in a reactive fashion as part of Infection Control incident investigations (IMTs). Isolates that were collected from environmental swabs (drains, washhand basins, shower stalls etc) were not routinely saved and we have a paucity of isolates from these sources. Even if there were more isolates from these environmental sources, sequencing of these environmental isolates would not be able to infer any direction of transmission (patient to drain or drain to patient for instance).

As stated above we do not know the diversity of the population in the water, or indeed, the population in the patient sample, as only single colonies were taken and stored from the initial culture media, which may have grown many colonies on initial culture. Thus, there is potential that a heterogeneous population exists that is not reflected when only a single colony representative is stored and later sequenced. As reported in p.33-35 we have looked at this and have tried to project how SNPs may change in number (genetic distance) over a period of time to capture this.

In a number of cases, where reactive sampling as part of an Infection Control incident investigation did not grow any pathogen, or did not grow the pathogen of clinical interest, no water/environmental comparison could be made to the clinical isolate that was isolated from the patient.

In the case of *Enterobacter* spp. which are recognised to be part of normal human flora, analysis of a possible source in the QEUH and RHC is hampered by the low isolation frequency of *Enterobacter* spp. from the water tested. Between 2015-2020, out of 12,055 samples tested by the Environmental Laboratory at GRI, 4 *Enterobacter* species were isolated. No *Enterobacter* spp. were isolated from water sources in 2A/2B wards in RHC (QEUH water sampling dataset extract).

Summary conclusions

1. Sequencing of *Cupriavidus* spp., *Enterobacter* spp., and *Stenotrophomonas maltophilia* could be carried out using the routine validated protocols in existing use within SMiRL with minimal modifications.

2. While there are relatively few published and publically available genomes for *Cupriavidus* spp., it was possible to access suitable resources to allow for analysis and comparison.

3. Extraction of rMLST profiles from WGS sequence data using PubMLST SpeciesID was found to be a reliable method for the speciation of all isolates.

4. SNP analysis using mapping to reference genomes appropriate for the identified species was found to be a reliable method for subgrouping of isolate sequences for subsequent SNP analysis with a more relevant sequence assembly from within the group where required.

5. There was limited diversity observed for most isolates of *Cupriavidus* spp. within each of their species groups (*basilensis*, *gilardii* and *metallidurans*). For *C. metallidurans*, there was strong evidence of genetic linkage for environmental and human isolates with a small cluster lying within 10 SNP differences of each other. These linked isolates originated from a hospital in another region in Scotland and were not linked to any of the isolates from the Glasgow study.

6. There was more diversity observed for *C. pauculus,* and for *S. maltophilia* than for the other species, however this may reflect the larger number of isolates within those species in this study.

7. The environmental isolates *C .pauculus* could be subdivided into three distinct groups on the basis of SNP analysis, and these populations seemed stable over the study period. All human *C. pauculus* isolates included in the study, with the exception of one isolate (see p.34), were found to be markedly distinct from the environmental isolates examined as part of the study.

8. A single pair of human *Enterobacter asburiae* isolates were identified. The isolates were linked in time and space (RHC 2A/2B, 2 weeks separation) and differed by 56 SNPs. Although genetically close these two isolates showed markedly difference antibiotic sensitivities with one being an ESBL producer whilst the other was not. Thus there is no relatedness between these two isolates. *Enterobacter* spp. are a normal part of the human gut flora, which would be expected to contain a degree of diversity within individual types. No close relationships were established between the other human and environmental isolates from the samples taken. All environmental samples were from drain type sources rather than potable water sources.

9. There was no evidence implicating potable water as the source of the human *Stenotrophomonas* infections. The SNP differences between human isolates and water and environmental isolates were greater than that observed from groups of water and environmental isolates collected from the same area of the water system, even over a period of up to a few months.

10. Multiple colonies taken from a single water sample were found to display a level of diversity similar to that seen in isolates from sampling the same areas of the water system, even over time periods of months. This suggests that there is a stable resident population over a period of time.

11. A significant amount of diversity was observed for each of the three groups of organisms studied. While no clear evidence was found to implicate those organisms from the water and environment

directly in the human cases involved, it is evidently possible that the full diversity of the environmental population was not sampled as described in the limitations.

12. This study provides a valuable baseline on the genomic diversity of bacterial isolates from potable water and the environment within a healthcare setting. The diversity observed can be used to evaluate the significance of SNP differences observed in future outbreak/transmission analyses.

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Investigation and control of an outbreak due to a contaminated hospital water system, identified following a rare case of *Cupriavidus pauculus* bacteraemia

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SUMMARY

Background: *Cupriavidus pauculus* is rare cause of clinical infection. We describe an outbreak of *C. pauculus* and other Gram-negative bacteraemias in a paediatric haemato-oncology unit secondary to a contaminated water supply and drainage system.
Aim: To describe the investigation and control measures implemented for a waterborne infection outbreak in a new build hospital.
Methods: Extensive water testing from various points within the water system was undertaken. Taps, showerheads and components including flow straighteners underwent microbiological analysis. Drains were also swabbed. Surveillance for Gram-negative infections was established on the unit.
Findings: Water testing revealed widespread contamination of the water and drainage system. Outlets were also heavily contaminated, including flow straighteners. Drains were found to have underlying structural abnormalities. Water testing enabled us to detect high-risk components within the water system such as the expansion vessels and outlets and the results assisted with hypotheses generation. Review of commissioning data and risk assessments revealed extensive risks present within the water system prior to and after hospital opening.
Conclusion: Careful design, adequate control measures and maintenance are essential for hospital water systems in order to prevent infections due to waterborne organisms. We discuss what can be learned from this incident with a view to future prevention.

Introduction

Waterborne infections in hospitals are well described. Typically, they involve pathogens such as *Legionella* spp. and *Pseudomonas aeruginosa* for which guidance for investigation,

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prevention and control has evolved and is well established [1,2]. Whilst hospital water supplies are not expected to be sterile, careful design, installation of control measures and ongoing maintenance are the key to preventing waterborne infections. Contamination can occur at various points in a water system, and therefore it is important that the water system is appropriately designed, installed, commissioned, operated and maintained. Regular planned maintenance of the water system is important and formal risk assessments should be undertaken frequently to identify any ongoing risk. Whilst many waterborne pathogens do not present a risk to most individuals, patients with underlying immunosuppression have an increased susceptibility to infections caused by these organisms [3]. We describe the investigation and control of a contaminated water system in a new build hospital. Investigations were initiated following the isolation of a rare pathogen *Cupriavidus pauculus* from the bloodstream of an immunosuppressed patient.

Methods

Setting

The incident took place in 2018 at the Queen Elizabeth University Hospital (QEUH) campus involving two hospitals, the adult QEUH (1109 beds) and the attached Royal Hospital for Children (RHC) (256 beds). These new-build hospitals opened to patients in the Spring of 2015. Much of the incident centred on a 26-bedded paediatric haemato-oncology unit in the RHC situated on the second floor of the building adjacent to the aseptic pharmacy suite. This ward comprises 26 single rooms, eight of which are HEPA filtered positive-pressure rooms designated for bone marrow transplant patients. Each single room has a clinical handwash basin and the ensuite has a shower and a smaller hand hygiene sink. Bone marrow transplant rooms have the same configuration with the addition of a trough sink in the anteroom. The ward has ancillary support areas such as treatment and preparation rooms, each with sinks. Directly opposite is the haemato-oncology day care ward which patients attend frequently for Hickman line flushes and treatments.

Time course

The incident lasted from February to September 2018; however, at the time of writing, control measures remain ongoing.

Case definition

The case definition evolved during the incident and whilst initially focused on cases of *C. pauculus* it became 'any paediatric haemato-oncology patient with a bacteraemia secondary to an organism found in the water or drainage system'. Infections were classified into hospital-acquired infection (acquired after 48 h of admission (HAI)) and healthcare-associated infection (contact with healthcare in the preceding 30 days (HCAI)). We included the HCAI group due to the nature of this patient cohort who frequently attended the attached day unit for treatments and central line care/flushes.

Identification and laboratory methods

Water testing during the incident

Water testing was undertaken by an external contractor using an approved method statement for which all staff had received training.

On receipt in the local microbiology laboratory, 100-mL aliquot of each water sample were filtered on to the following agar plates; Membrane Lactose Glucuronide Agar (MLGA) (OXOID), Trypticase soy agar (TSA) (OXOID), Pseudomonas isolation agar (E&O) and Sabourauds (SAB) (OXOID) agar. MLGA plates were read at 24 h, TSA and Pseudomonas agar at 48 h and SABs after seven days. All plates were incubated at 36°C apart from SABs which were incubated at 22°C and 30°C. Oxidase-positive Gram-negative colonies were further identified using matrix assisted laser desorption ionization-time of flight (MALDI-TOF) mass spectrometry. Fungal isolates underwent preliminary identification locally and were sent to the mycology reference laboratory for confirmation. Total viable counts (TVCs) were reported for each outlet expressed as TVC/100 mL. If below 100 colony forming units (cfu) the results were quantified.

Taps and showerheads

Taps and showers from the haemato-oncology ward were sent to the local microbiology laboratory for analysis. Taps were dismantled and each component separately sampled. The thermostatic mixer valve (TMV) was only extracted from one tap as this required estates personnel to use an Allen key and a substantial amount of force to open. A sterile rayon swab was placed in fresh sterile water, then the area to be sampled was brushed over with the swab, covering as extensive an area as possible to maximize sensitivity.

Swabs were plated on to cysteine lactose electrolyte deficient agar (CLED) (E&O) and SAB plates. CLED plates were incubated at 37°C for 48 h and SABs for five days at 22° and 30°C. Non-lactose-fermenting coliforms were identified using MALDI-TOF mass spectrometry.

Flow straighteners

Flow straighteners were removed from a selection of taps on the hospital sites and microbiological analysis and bioburden assessment undertaken by an external laboratory.

For the microbiological analysis, 200 mL of sterilized deionized water was added to the sterile bag containing the flow straightener and the bag was agitated for 30 s. The 200 mL of liquid was then processed as a sample. One millilitre of the sample was used to create a serial dilution. Neat and one dilution was tested for TVCs. One 100-mL of sample was filtered and transferred to a TVC plate and a *P. aeruginosa* agar plate. All plates were incubated at 35°C for 48 h. Colonies were identified using MALDI-TOF mass spectrometry.

For bioburden assessment, a specialist Biofinder product was used. When sprayed on to a surface, the transparent yellow liquid reacts with catalase enzymes produced by microorganisms in biofilm and this creates an effervescent foam. Assessment of the levels of biofilm were made based on the strength and speed of the reaction with 0 = no reaction/no biofilm and 5 = strong instant reaction/large biofilm present.

Drains

Drains were swabbed *in situ* and components were also removed and sent for analysis. A sterile swab was inserted and rotated into each drain. Drain swabs were plated on CLED agar and incubated for 48 h at 37°C. Drain traps were visually inspected, and a biofilm test of the seal undertaken. Swabs were also taken from the metal fitting where the drain seal attached.

Results

Description of incident

Historical aspects

In 2016 our sterile aseptic pharmacy unit asked for input from the infection prevention and control team (IPCT) due to elevated TVCs from tap water from two sinks within the unit. The unit undertook frequent water testing and had prior agreed cut-off levels of <10 cfu/mL at 37°C and, <100 cfu/mL at 22°C. On several successive occasions, these control limits had been breached with counts of >300 cfu/mL reported. On analysis there was no evidence of legionella, *Escherichia coli* or *P. aeruginosa* to explain these high TVCs. A request was made by the infection prevention and control doctor to the laboratory to identify the organisms present in the samples as they were proving challenging to eradicate despite cleaning, descaling and regular flushing of taps. These bacteria were identified as *C. pauculus* from taps at both sinks. *Comamonas testosteroni* was also identified from one of the outlets. Following a review of the unit one of the sinks was classed as a little used outlet and subsequently removed. The other was dosed with silver stabilized hydrogen peroxide (Sanosil) and repeat samples were negative and remained so. A patient lookback exercise was undertaken and a patient with a *C. pauculus* bacteraemia who had received total parenteral nutrition (TPN) from the unit was identified. Typing of the isolates was undertaken by the antimicrobial resistance and healthcare associated infection (AMRHAI) reference laboratory and on pulsed-field gel electrophoresis (PFGE) the patient isolate matched the water isolate.

Incident – phase 1, February to April 2018

In February 2018, a child in our haemato-oncology unit presented with a *C. pauculus* bacteraemia. Having previously found this organism from outlets sampled in our aseptic pharmacy unit and given that the child had received products produced there, we focused initial testing on this area. Those results were negative with TVCs of 0 cfu/mL. We went on to sample numerous outlets (taps and showers) on the paediatric haemato-oncology ward. We included rooms that the patient had been in and shared areas such as the preparation and treatment rooms. On these initial tests we isolated *C. pauculus* in water samples from outlets in four patient bedrooms, preparation room and treatment room.

At this time, we had negative results from the aseptic pharmacy on the same floor and from the paediatric intensive care unit one floor down, thus it appeared to be an issue localized to the paediatric haemato-oncology ward. We also had negative samples from the cold water storage tanks serving the ward.

A review of our local epidemiology revealed three cases of *C. pauculus* bacteraemia from the date of hospital opening in 2015 onwards. There was one case in each year from 2016 to 2018, all of whom had been inpatients in the haemato-oncology ward.

The initial hypothesis at this stage was that the outlets (taps and shower heads) were a likely source. Taps, including flow straighteners, and showerheads were removed from the ward and sent to the microbiology laboratory for testing.

Between February 21st and April 5th 2018, we detected five cases of *Stenotrophomonas maltophilia* bacteraemia (one a mixed culture with *P. aeruginosa*) and a *P. fluorescens* bacteraemia (Figure 1). These organisms were also grown from water samples in the ward.

Water testing was expanded to include all Gram-negative organisms rather than just *C. pauculus*. During phase 1, further water testing took place on other units within both the adult and paediatric hospitals during the process of looking for a suitable decant option for the haemato-oncology patients. This decant would allow us to implement control measures safely and undertake a full review of the water system. It became apparent from the results that water contamination was extensive, it involved both hospitals and was therefore not just a localized problem. Following the implementation of control measures within the unit including application of point of use filters (POUF), and no further infections, the incident management team was stood down in April 2018. A subgroup, the water technical group continued to work on establishing the extent of contamination and implementation of long-term control measures.

Incident – phase 2 May–June 2018

In May of 2018 two separate problem assessment groups (PAG) were established to investigate increased incidences of *S. maltophilia* and *Enterobacter cloacae* on the haemato-oncology ward. During these meetings, staff reported visible black grime refluxing from drains into the clinical hand wash basins. A formal incident management team was re-established to investigate further. Water testing took place at outlets with (POUF) in situ, and this was negative. Swabs of the material from drains were undertaken. Inspection of the drains revealed the presence of visible black grime and corrosion of an aluminium spigot component. There was also evidence of occlusion of the drain as a result of adhesive, and some evidence of pooling of water noted at the back of the drain where it met the pipework. Between April and June 2018, we had 10 additional patient cases with bacteraemias with a greater diversity of bacteria which included *E. cloacae, S. maltophilia, P. putida, P. aeruginosa, Klebsiella pneumoniae, Pantoea agglomerans and Acinetobacter ursingii* (Figure 1) These organisms were also grown from drains and/or water. Three patients had mixed cultures and one patient had two separate episodes with different organisms during this time period. In addition, we reported a case of *Mycobacterium chelonae* infection in blood cultures from one patient. In terms of outbreak definitions, this case was reported as a possible case as we had not tested the water supply for atypical mycobacteria. Evidence of the drain issues described here were present across the sites and not localized just to the haemato-oncology ward. Drain-control measures were implemented and the incident management team was stood down for the second time in June 2018.

Incident – phase 3 August–September 2018

Between August 2nd and September 2018, a further six patients presented with bacteraemias that met the outbreak

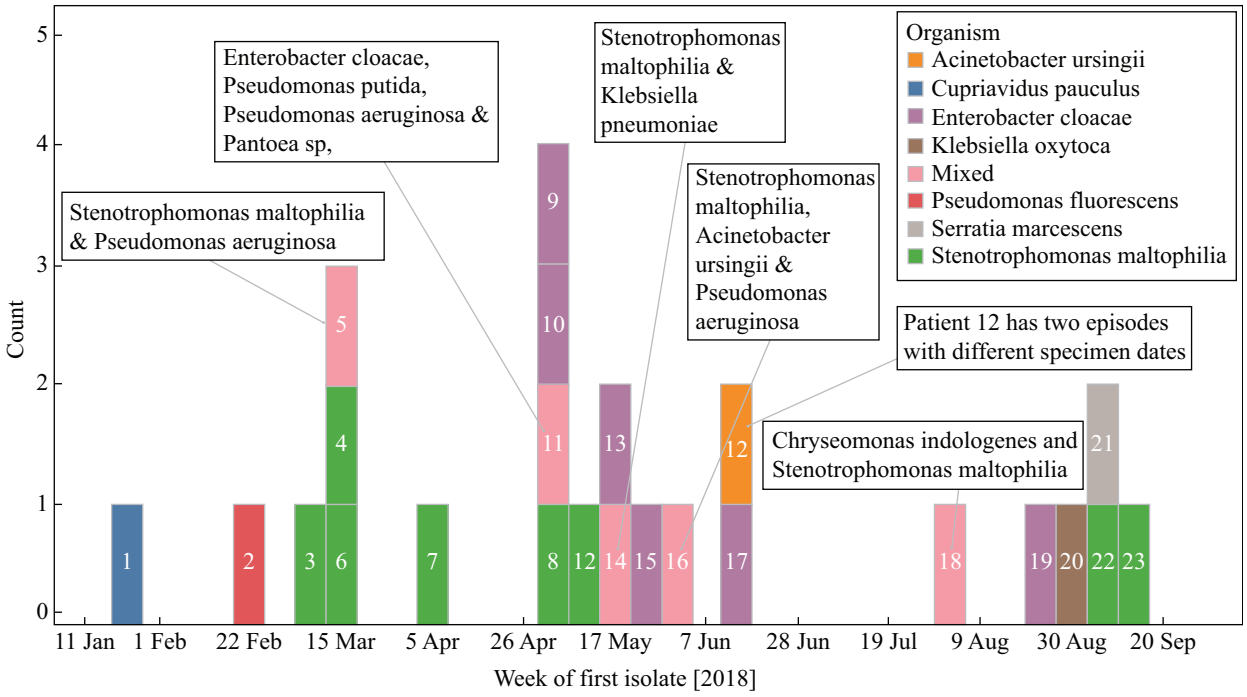

Figure 1. Epidemic curve.

case definition (Figure 1). This cohort included patients with *Serratia marsescens and Klebsiella oxytoca* bacteraemias. Nursing staff continued to report issues with the drainage system, specifically the larger trough sinks in the patent anterooms. A full drainage survey of the site was undertaken with no issues identified and the drain problems appeared to be localized to the back of the sink area and the sink traps. Despite extensive control measures there was an eventual decant of the paediatric haemato-oncology ward to another ward within the adult hospital. This was to allow for a full investigation and control measures such as shock dosing with chlorine dioxide, to be implemented safely, with no high-risk patients in the vicinity. During the initial ward decant, investigation of the ventilation system revealed evidence of abnormalities promoting mixing of dirty and clean air, lower air change rates due to chilled beam technology which is used to heat and cool large buildings, and lack of positive pressure. The initial proposal for a short term decant therefore had to be extended to enable a full ventilation upgrade.

In summary 23 confirmed cases and one possible case were considered by the Incident management team. All cases were paediatric haemato-oncology patients with either underlying haematological or solid tumour malignancy. All patients had Hickman lines *in situ* and required treatment with intravenous antibiotics and in most cases line removal. No fatalities occurred as a result of infection during the time period of this incident. Patients classified as HCAI all had frequent contact with the attached day unit where line flushes took place and treatments were administered.

Hypotheses

Hypotheses considered by the incident management team were as follows.

Route of transmission to patients

Either via (1) direct contact with water, e.g., hands, water splashing on to central line sites, showering in contaminated water, or (2) contact from a contaminated environment or equipment as a result of splashing, or contaminated hands of health care workers, or (3) contact with contaminated sinks and surrounding environments due to biofilm disruption from drains.

Contamination of the water system

Hypotheses considered for the contaminated water by the incident management team were: retrograde seeding of the water system from contaminated outlets, low-level seeding from the incoming supply contaminating outlets, and the possibility of contaminated pipework at installation.

Hypotheses for the drain problems were disruption and aerosolization of biofilm due to the application of filters on outlets where pre-existing structural abnormalities of drains were present.

Consideration was also given to the phenomenon of toilet plume and the potential role of the ventilation system abnormalities in the transmission of waterborne pathogens.

Results of microbiological investigations

Water results

During the course of this investigation, extensive water testing was undertaken by both local and external laboratories. Initially the focus of water testing was to detect *Cupriavidus* spp. As the incident evolved, identification of all Gram-negative bacteria was undertaken. Evidence of well-

established biofilm was detected with over 60 species of Gram-negative bacteria, fungi (including *Aspergillus* spp.) and atypical mycobacteria from water and system components (Table I). During the early stages of the incident in February and March 2018, 98 outlets were tested from the haemato-oncology unit with 75 of these testing positive for *C. pauculus* (76.5%); 37 of the 75 had counts in excess of 100 cfu/100 mL (49%). In total 1878 water samples were tested, and over 30% tested positive for each hospital (Figure 2).

Samples of the mains supply from Scottish Water were within normal limits for TVCs. Fungi were not tested for; the bacteria isolated were identified as *Ralstonia* spp. Samples taken from the bulk and filtered cold water storage tanks showed a small number of positive samples, three of which grew *C. pauculus* which was present in both. Testing of the expansion vessels, which are connected to the cold water feed to domestic hot water vessels, showed that 12 of 16 were positive containing *C. pauculus, C. gilardii, Delftia acidovorans* and various fungi.

Taps and showerheads

Visual inspection of the tap components showed discolouration and slime around the rubber seals of the flow directors and flow straightener, as well as green growth on the plastic components of the TMVs. Growth from taps and showerheads matched that which was found in the water. The first round of tests was undertaken before any chemical dosing and demonstrated predominantly *C. pauculus*. There was more diversity in the second set of samples which might reflect the dislodging of biofilm by silver hydrogen peroxide (Table I).

Flow straighteners

Seventeen flow straighteners were removed from taps, dismantled and tested. Figure A1 (supplementary data) shows the complexity of the flow straightener with eight components. Nine flow straighteners were visually soiled and 12 had heavy biofilm present on testing. Colony counts were high in all flow straighteners tested, ranging from 400,000 cfu/mL to >2 million cfu/mL. A total of 25 new and unused flow straighteners were tested for overall microbial load and biofilm. No biofilm was found on any of them and the total microbial load was very low compared with those tested after being in use. After one weeks' use, no biofilm was present; after one month of use, five of 10 tested (50%) showed some degree of biofilm. Those tested after one month showed biofilm contamination with 12 of 17 showing heavy biofilm present. For microbial load unused flow straighteners had an average of 242 cfu/straightener. Those tested after a week showed a 20-fold increase in microbial load, those at one month showed a 50,000-fold increase when compared to unused. After a month, there was a 500,000-fold increase (Figure 3). Bacteria isolated from flow straighteners *included S. maltophilia, Chryseobacterium sp, Sphingomonas paucimobilis, C. pauculus, Acidovorax temperans, Caulobacter spp. and Microbacterium laevaniformans* (Table I).

Drains

Two drain traps from sinks were sent for analysis. The drains showed significant evidence of solid contamination. The metal aluminium fitting at the base of the trap showed significant levels of corrosion to the surface. A rubber seal attached to the fitting was split and showed high levels of decay throughout the seal. Biofilm testing of the seal showed a strong reaction indicating the presence of large mature biofilm (Figure A2 – supplementary data) The estimated total organism count at the metal fitting was 210 × 106/cm^2. Bacteria grown from drain swabs are listed in Table I.

Other

Debris (Figure A3) and two sponges (Figure A4) were removed from the raw water and cold water storage tanks, respectively, and these also exhibited a strong reaction for biofilm formation. It was suspected that the sponges may have been in the tank for up to two years.

Control measures

Due to the high-risk nature of the haemato-oncology ward following the initial positive outlet results for *C. pauculus*, we elected not do any further sampling and moved straight to dosing with silver hydrogen peroxide (Sanosil),1000 ppm with 1-h contact time. Three separate doses were delivered between 2nd and 16th March 2018. Showers on the unit were placed out of use and patients were provided with wipes for hygiene purposes. Staff undertook hand hygiene followed by the use of alcohol gel. All patients were given sterile water for drinking. Bottled water was used for washing and tooth brushing unless the patient was a bone marrow transplant patient where sterile water was used as usual. Portable sinks were sourced and installed on the ward. These were stand-alone units and they ensured a supply of hot water. Ongoing surveillance of cases was established by the infection control team. Twice daily chlorine-based detergent (Actichlor plus) cleans were also undertaken. Increased cleaning took place on the unit and there was intensive input from the infection control team in relation to hand hygiene, Standard Infection Control Precautions (SICPs) and Transmission Based Precautions (TBPs) and central venous catheter line care management.

When it became apparent from repeat testing that Sanosil was proving ineffective, point of use filters (POUFs) were fitted. These were placed on all outlets in all high-risk units and along the haemato-oncology patient pathway.

During phases two and three, further control measures were implemented which included drain cleaning, and antibiotic prophylaxis with ciprofloxacin for patients. A standard operating procedure was developed for drain cleaning. On the haemato-oncology ward, drains were cleaned with Actichlor plus and the initial clean was performed with a wire brush to dislodge biofilm. Rooms were emptied to undertake this clean to minimize risk to patients from any dislodgement of biofilm. Sinks were cleaned afterwards and new POUFs were fitted, we also initiated a full hydrogen peroxide vapour (HPV) clean method of the room. Replacement of drain components was undertaken to ensure no obstruction or exposed metal. Education took place with regards sink hygiene, reminding patients, parents and staff not to decant products down drains and to keep sink surfaces free from toiletries. Enhanced environmental cleaning was maintained to address splash risk and a cleaning protocol for POUFs was developed.

Table I
List of bacteria and fungi found in water samples/drains/outlets

Organisms found in water samples:	Organisms found in drain samples:
Acromobacter spp.	*Acidovorax temperans*
Achromobacter xylosoxidans	*Acinetobacter haemolyticus*
Acinetobacter lowoffi	*Caulobacter spp.*
Acinetobacter ursingii	*Citrobacter spp.*
Bordetella bronchiseptica	*Cupriavidus pauculus*
Brevundimonas spp.	*Delftia acidovorans*
Brevundimonas versicularis	*Enterobacter cloacae*
Burkholderia cepacian	*Enterobacter hormaecechei*
Burkholderia spp.	*Klebsiella oxytoca*
Cedecea lapagei	*Microbacterium laevaniformans*
Chryseobacterium indologenes	*Pantoea agglomerans*
Chryseobacterium spp	*Pseudomonas aeruginosa*
Comamonas testeroni	*Pseudomonas fluorescens*
Cupriavidus gilardii	*Serratia marscesens*
Cupriavidus pauculus	*Sphingomonas paucimobilis*
Delftia acidovorans	*Stenotrophomonas maltophilia*
Environmental Gram negative rod	*Unidentified fungi*
Klebseilla pneumoniae	
Moraxella spp.	
Morganella morganii	
Mycobacterium chelonae	
Mycobacterium szulgai	
Pantoea agglomerans	
Paracocccus spp.	
Pseudomonas aeruginosa	Organisms found on outlet components:
Pseudomonas fluorscens	*Bordetella bronchiseptica*
Pseudomonas orzyhabitans	*Brevundimonas spp.*
Psuedomonas putida	*Burkholderia spp.*
Pseudoxanthomas Mexicana	*Candida guillermondii*
Pseudomonas chlororaphis	*Comamonas testosterone*
Ralstonia picketii	*Cupriavidus pauculus*
Rhizobium radiobacter	*Delftia acidovorans*
Serratia fonticola	*Ocromobacterium anthropic*
Shewanella putrifaciens	*Oxidase positive Gram-negative rod*
Sphingomonas melonis	*Serratia foniticola*
Sphingomonas thalophilum	*Sphingomonas paucimobilis*
Shingomonas xenophaga	*Rhodotorula spp.*
Stenotrophomonas maltophilia	
Fungi:	
Acremonium spp.	
Aspergillus spp.	
Aspergillus fumigatus	
Aspergillus versicolor	
Cladosporium spp.	
Dematiaceous hyphomycete	
Hyaline hyphomycete	
Mycelia sterilia	
Saprophytic fungi	
Unidentified fungi	

Peer audits with regular inspections were undertaken including a review of aseptic trolleys setup and line care. Traffic through the ward was reduced with minimal visiting staff from other departments able to enter. Following the decant of the ward to another unit within the adult hospital, no further cases that met the outbreak case definition were detected between September 2018 and April 2019. Prior to moving children into the adult hospital, extensive environmental control measures were implemented. Point of use filters were fitted to all outlets, drain components were replaced and cleaned and the unit underwent some refurbishment followed by extensive cleaning and use of hydrogen peroxide vapour.

Long term control measures

Due to the complexity of the incident and the extent of contamination a water technical group was established. This group was a subgroup of the incident management team comprised of estates colleagues, infection control, public health, external agencies and external water experts. Three main long-term control measures were implemented: a chlorine dioxide dosing system, recommendations to change taps and other fittings in high-risk areas, and continued long-term use of point of use filters until the water system became under control.

In addition, this group reviewed sources of water elsewhere in the hospital. These included: dishwashers (inline filters were placed where removal was not possible), hydro pools, baths (removed where possible), water coolers (removed). No ice machines were present. In the haemato-oncology group consideration was given to the waterless concept. It was agreed that not all sinks could be removed but unnecessary sinks in areas such as the playroom and pharmacy were removed. The risk from toilet plume was also considered and a recommendation was made to fit toilet seats.

Chlorine dioxide dosing system

Due to the size of the building and the complexity of the water system, expert input was sought to devise a hospital-

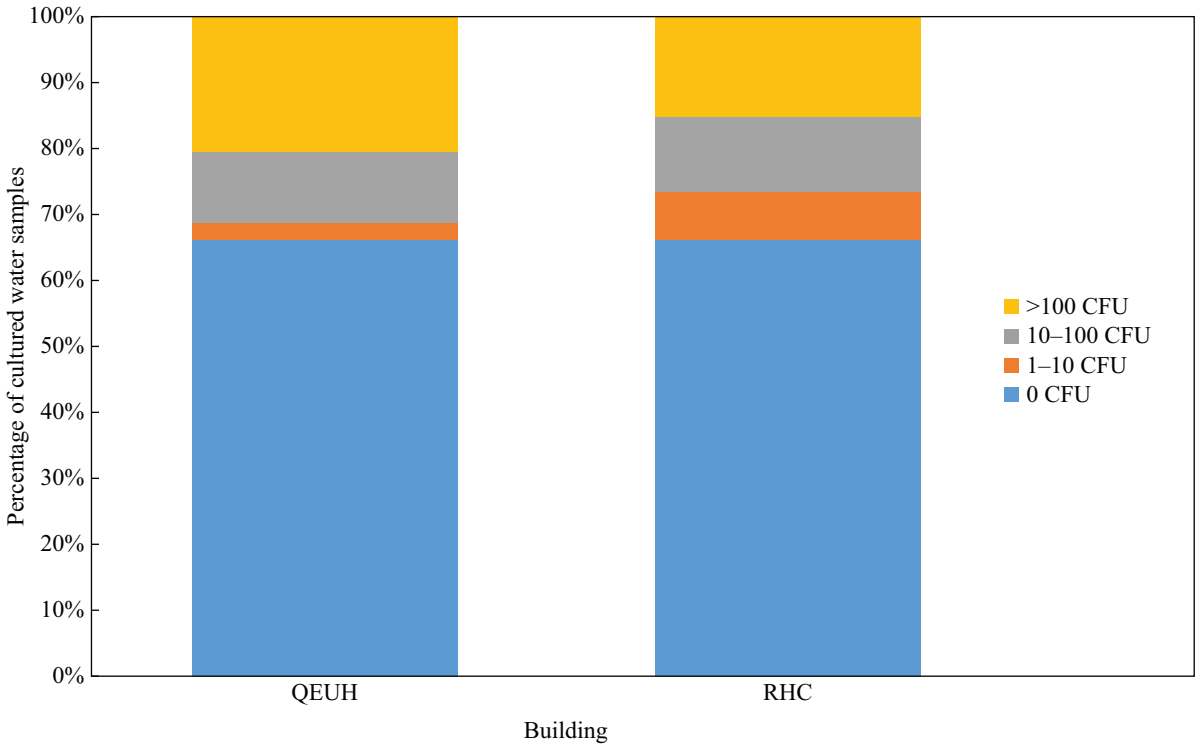

Figure 2. Percentage outlets positive and negative in each hospital. RHC, Royal Hospital for Children; QEUH, Queen Elizabeth University Hospital.

wide chlorine dioxide dosing regimen. On completion of each stage of the installation, chemical treatment of the domestic cold water system commenced at a level of 1.0 mg/L for 24–48 h. Manual monitoring of nominated sentinel points commenced after 24 h and trend logging of designated key locations commenced after a 48-h bedding-in period of the sensors and final recalibration. Once the residual level of chlorine dioxide reached 0.1 mg/L at each part of the system, microbiological monitoring commenced. Once the residual reached 0.2 mg/L at each part of the system, the associated plant output was

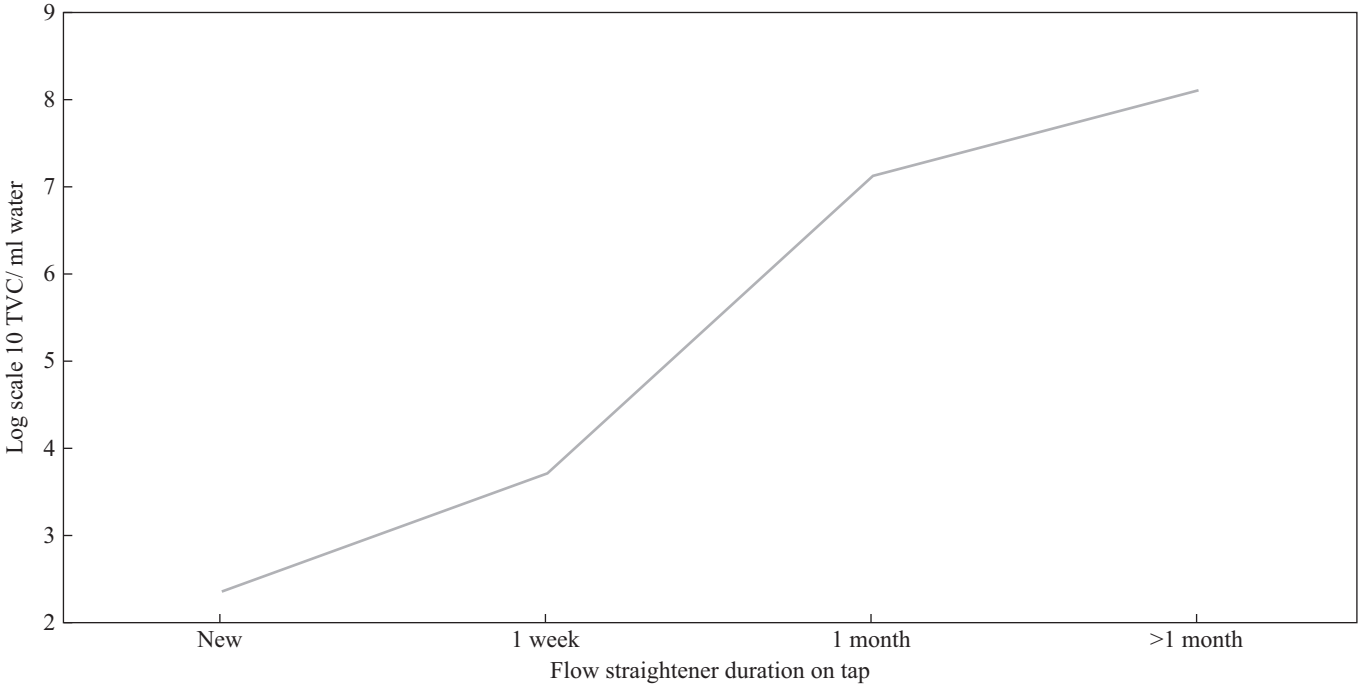

Figure 3. Flow straightener microbial load over time.

reduced in stages until the residual achieved 0.4 mg/L and the plant output was between 0.5 and 0.7 mg/L as a final continual water treatment baseline value.

The domestic hot water system presented an additional challenge as chlorine dioxide when exposed to high temperatures gasses off. Whilst beneficial in terms of impact on biofilm, it can result in difficulty in achieving the required residual levels to verify efficacy. Therefore, the treatment was set at 2—4 mg/L to achieve a residual of 0.5—1.0 mg/L at hot water outlets.

Once the minimal residual level was achieved, a servicing and sanitization programme for taps commenced to ensure that any disrupted biofilm was not caught within the components risking reseeding of the system.

New taps, sinks and drainage components were fitted to the children's haemato-oncology ward where it was possible to shock dose with higher strengths of chlorine dioxide due to the ward being vacant and higher levels of chlorine dioxide not coming into contact with users of taps and showers.

Investigations by external agencies

During the incident, investigations were undertaken by external agencies and reports from the time of hospital commissioning were accessed. These reports and investigations highlighted a range of issues dating back to the hospital opening in 2015 which included: elevated TVCs at the time of hospital handover, bypass of mains filtration, failure of temperature control, presence of dead legs, stagnation due to early filling of the water system, debris present in water tanks, installation of open-ended pipework, presence of flexible hoses, corrosion within the system, pressure testing of taps off site and suboptimal maintenance post-handover of the building. Components of the system were also found to be incompatible with silver/hydrogen peroxide.

Discussion

Hospital water systems are not sterile and will contain micro-organisms which are of minimal consequence to the majority of patients [3,4]. However, it is important that levels of micro-organisms are kept safe and that testing and additional precautions are implemented to prevent infections in patients who are immunosuppressed and more susceptible to waterborne infections. Patient groups most at risk are those with haematological malignancies, transplant patients, and those nursed in intensive care and burns units [2,3].

Hospital outbreaks of water-borne pathogens are well described. Causative pathogens include *Legionella* spp, *Pseudomonas* spp., other Gram-negative bacteria such as *S. maltophilia*, atypical mycobacteria and fungi [3,4]. Outbreaks due to multiple pathogens associated with water are more unusual. Sixteen patients were found to have *R. mannitolytica* in a renal dialysis centre due to a dysfunctional reverse osmosis filter resulting in water contamination. In addition to *R. mannitolytica, S. maltophilia, S. paucimobilis* and *C. pauculus* were found in the water but there were no associated patient cases [5]. In a paediatric haemato-oncology unit, eight children developed bacteraemias due to *P. aeruginosa* and *P. putida* with contaminated water outlets being the source [6]. Chlorination and filters were utilized initially with eventual control being achieved by creation of a water loop providing daily chlorinated and filtered water. Our outbreak included multiple pathogens and this likely reflects the maturity of the biofilm present within the water system.

The trigger for investigation of our incident was the isolation of *C. pauculus* from a patient's bloodstream. *C. pauculus* is ubiquitous in the environment, and is found in soil, water and plants [7]. It was formerly described as Ralstonia, a species of proteobacteria [8]. It is an aerobic Gram-negative motile bacterium which is catalase and oxidase positive [7]. Typical colonies are round, smooth and non-pigmented. It is nutritionally versatile and can tolerate harsh environments [7]. It was found in the international space station potable water supply during pre-consumption testing [9].

C. pauculus is a rare clinical pathogen, published case reports describe sepsis, abscesses, tenosynovitis, osteomyelitis, pneumonia and peritionitis [10]. Contaminated water sources such as hydro pools, extra-corporeal membrane oxygenation (ECMO) and bottled water have been reported. One study reported a pseudo-outbreak involving 27 patient samples which tested positive for *C. pauculus* due to contaminated swabs being rinsed in tap water in an outpatient clinic [7]. Of interest in this incident, four distinct PFGE strains were identified among the patient and tap-water samples [7]. A 2016 review paper cited a total of 32 cases of infection worldwide secondary to the organism [10]. For us to experience three cases in a short period was highly unusual and this was therefore considered a data exceedance and managed as an outbreak. Another *Cupriavidus* sp. was found in our water supply, *C. gilardii*, but there were no associated patient cases. It has been known to cause bacteraemia in immunosuppressed and immunocompetent individuals [11].

Whilst *C. pauculus* was the indicator organism for our outbreak, other pathogens were found in patients, water and drains during the course of the incident. These included *S. maltophilia, S. paucimobilis, E. cloacae, S. marcescens, Chyrseomonas indologenes, A. ursingii* and *P. putida*. These have all been previously implicated in waterborne outbreaks [3,6].

Waterborne infections can be due to either systemic contamination of hot and cold water systems or contamination of peripheral parts of the water system including taps and showers and sections of pipe proximal to these outlets. Our initial microbiological testing revealed contaminated tap and shower components. Our hospital was also a new-build and we did not anticipate finding well-established biofilm and systemic contamination in a building which had been open for less than three years. Further information was provided from analysis by an external lab regarding the degree of contamination found on flow straighteners from our taps. These were found to be heavily contaminated with evidence of significant biofilm and high TVCs. Outbreaks due to contaminated outlets and tap components are well described in the literature and these include flow straighteners. Flow straighteners are also referred to as aerators or rosettes. They sit in the end of the tap and their function is to modify the flow and generate an even stream of water [2]. A link to tap aerators and *P. aeruginosa* was first documented in 1961 following routine culture of sinks and aerators in a children's nursery [12].

In the 2011 *P. aeruginosa* outbreak in a neonatal unit in Northern Ireland, analysis of water taps revealed the presence of *P. aeruginosa*. Highest counts were associated with the

rosettes and their associated components [13]. The authors note that each time a tap is operated, the biofilm that is present on the rosette component is supplied with freshly oxygenated water and nutrients which potentiate it, and this is delivered at a temperature of around 41°C which is conducive to the growth of most waterborne opportunistic pathogens. This is due to the presence of a TMV. TMVs are routinely installed in most healthcare premises to prevent scalding but they help support the development of biofilm at outlets as they provide no downstream thermal control [13]. We were only able to analyse one TMV in which we found *S. paucimobilis*.

Other Gram-negative organisms have also been recovered from flow-straightener components. During the investigation of a cluster of *S. maltophilia* cases in a surgical intensive care unit, the organism was isolated from tap aerators present in the sinks. Multiple different strains were isolated from eight patients during this outbreak. PFGE revealed five strains colonizing patients and four different environmental isolates. In two cases, strains from patients matched those from tap aerators [14].

Typing of all patient isolates was undertaken during this incident and all were unique and not related to one another, thus ruling out patient to patient transmission. Whilst many water-related incidents demonstrate a link between patient and water isolates via typing, some water incidents can be complex with multiple strains being involved [7,4,15]. During an investigation of *P. aeruginosa* colonization in a medical intensive care unit, a total of 23 pulsotypes were identified from PFGE of 73 isolates from patients and tap water. The authors noted that genotyping was only performed from one colony on each positive culture plate which may have led to underestimation of the number of exogenous sources [16]. In a study investigating patterns of colonization by *P. aeruginosa* in intubated patients, four colonies from each plate were typed. This three-year analysis involved 1607 isolates and 35 different pulsotypes were obtained [17]. In a paediatric surgery unit, investigation of urinary tract infections secondary to *P. aeruginosa* included water testing. Fifteen different PFGE types from 18 isolates were identified illustrating the diversity of environmental strains [18]. This is particularly likely in the presence of significant contamination and well-established biofilm. In total, 1878 water samples were taken and this placed a huge strain on laboratory resources, therefore not all water samples were sent for typing. Neither did we select multiple colonies from each agar plate for typing. Several *C. pauculus* isolates could not be typed due to DNA degradation.

Whilst our initial focus was on outlets as the source of contamination, it became evident as the incident progressed that contamination was more widespread throughout both hospitals. We had evidence of contamination further back within the water system with positive results from risers, expansion vessels and cold water storage tanks. Over 30% of samples tested in each hospital were positive indicating a high-risk contaminated water system. In particular, expansion vessels were found to be a significant source of contamination with 16 of 20 testing positive. Expansion vessels are part of the hot water system and their purpose is to absorb pressure and protect pipework. Investigation revealed that these expansion vessels were of a type and material not recommended for hospital water systems [19].

During the latter part of the incident, further information became available from external agency reports who had reviewed commissioning data and Legionella risk assessments from the time of the hospital opening. The findings are complex but indicate multiple potential routes for contamination of the water system coupled with failures of temperature control and maintenance. It is likely that low levels of bacteria were introduced at the time of a documented bypass in mains filtration and that these may have proliferated on tap components following flushing of the system. Furthermore, there is evidence of pipe work installation where the pipes were uncapped, therefore providing the potential for contamination to be introduced via this route also. It is also possible that contaminated outlets led to retrograde contamination of the system. Raw and bulk water storage tanks and some outlets tested had fungal counts of >100 cfu/mL detected. The presence of high concentrations of fungi in our water samples may be as a result of construction work and demolition, with fungi entering the unprotected water system. These were two new-build hospitals, and thus this was a large building site with demolition of some parts of the retained state also taking place. Dust dampening measures were employed such as water spray but these may not have been sufficient to control the level of fungal spores. There were no fungal infections linked to water during the incident. Temperature control was the chosen method for managing the microbiological quality of the potable water but there is clear documentation that this was not achieved further enhancing the likelihood of proliferation of micro-organisms. Other risk factors included the presence of dead legs, filling of the water system prior to opening, and inadequate flushing, leading to stagnation. Taps were pressure tested at the factory of origin and this was not repeated on site. It is possible that they were contaminated on arrival or became contaminated whilst stored with Gram negative bacteria but we have been unable to determine this.

There are multiple routes of transmission of contaminated water to a patient but often these are not elucidated [4]. These include direct contact with contaminated water via the use of handwash basins or showering, whereby contaminated water can land directly on to central line sites. Other routes include via contaminated staff hands or contaminated environment/equipment as a result of splashing [4]. The exact route of transmission is not possible to determine but all of our patients had Hickman lines, thus direct contact with water via showering or splashing seems likely. It is important during a water-contamination incident to target all possible routes of transmission via implementation of infection control measures in addition to addressing the underlying water system contamination issue.

Initial infection control measures included provision of alternative sources of water and restriction of showering. These are well established preventative measures [3,4]. Local system dosing with silver hydrogen peroxide and application of point of use filters were also employed.

Silver hydrogen peroxide (Sanosil) was the initial biocide utilized. It has a rapid action, is effective at removing biofilms and will work at all temperatures [19,20]. Despite successive dosing, this biocide failed to reduce *C. pauculus* levels sufficiently. This is likely due to the extensive biofilm but also the potential for silver and other metal resistances which have been documented for some species of Cupriavidus [21,22]. The silver in Sanosil is important for inactivating catalase enzymes in biofilm and thus enabling hydrogen peroxide to function effectively as an oxidising biocide. Point of use filters were

fitted to all outlets including showers and taps. Point of use filters are a recognized control measure for the provision of safe potable water [23—25]. Whilst typically used as a short-term approach in response to an outbreak, they can be utilized as a long-term approach in high-risk units [25,26]. A disadvantage of this approach is the opportunity for biofilm to accumulate immediately upstream of the filter and the potential for retrograde contamination in the water pipes supplying the filtered outlet [25,27].

Unintended consequences of the use of point of use filters were issues that emerged with the drains. It must be noted that the drains had pre-existing abnormalities that were potentiated by the presence of filters. The application of filters reduced the gap between the tap outlet and drain leading to biofilm disruption and likely aerosolization from the drain biofilm. In some cases, there was visible reflux of biofilm material into sinks. Outbreaks due to sinks and drains are commonly described [28,29]. Poor placement of the taps can lead to disruption of biofilm in sink traps and splashing can enhance surrounding environmental contamination [28,30]. Contamination risk from sinks and drains can be exacerbated when inappropriate discard of liquids takes place as these can provide a nutrient-rich environment enabling biofilm to proliferate. Evidence of inappropriate discard of liquids and other materials such as small plastic toys were evident in our drains and education on sink hygiene was implemented. Patients were also discouraged from storing toiletries and cosmetic products on sink surfaces [31]. Shallow basins as were present in some of our en-suites have been shown to contribute to significant water splashing [32].

Our initial strategy for our drain issue included replacement of corroded spigots, biofilm disruption and cleaning and disinfection of drains. Later, whole sinks and drain components in the affected ward were removed and replaced. In a review of drain-related outbreaks involving carbapenemase-producing organisms 21 sites that reported outbreaks lasting greater than one month documented ongoing problems despite initial remediation activities. Fourteen of these sites reported subsequent replacement of sinks and other components. Complete sink replacement has been reported to be effective but may not always be successful particularly if contamination is further back in the water system involving the pipework [33].

Given the whole system water contamination it became evident that more aggressive long-term control measures would be required. This led to the development of a water technical group with representation from external agencies and water experts employed by the health board. Measures implemented included installation of a chlorine dioxide system serving both hospitals and replacement of sanitary fittings which commenced in the paediatric haematooncology unit. Several options are available for chemical disinfection of hospital water systems. These include: chlorine, copper/silver ionization, chlorine dioxide, monochloramine, ozone and ultraviolet irradiation [34,35]. Chlorine dioxide was chosen due to the complexity of the water system, degree of contamination, pH of water, efficacy and potential resistance of *Cupriavidus* spp. to metals. Chlorine dioxide is a selective oxide and is superior to chlorine alone. It has the ability to remove biofilm and is effective over a wide pH range. The main disadvantage is that chlorine dioxide and its by-products can be toxic therefore there is a legal requirement for levels not to exceed 0.5 ppm [19].

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. In the paediatric haemato-oncology ward shock dosing was undertaken with chlorine dioxide (in the absence of patients) and outlets, drains and sinks were replaced. It has not been possible to evaluate the efficacy of these measures as the ventilation system is being upgraded and the ward remains vacated.

During the incident-management process, we did assess whether we could move to a waterless unit. Reduced rates of Gram-negative bacilli in an intensive care unit were demonstrated after removal of sinks and introducing waterless patient care [36]. This was not deemed possible in the paediatric haemato-oncology patient cohort, but we did reduce the number of sinks on the unit and requested removal of those we felt were unnecessary. This measure was beneficial in that it reduced the number of little-used outlets and the associated risk from splashing.

Whilst we saw infections in our paediatric haemato-oncology patients, we saw only sporadic cases of infection due to environmental Gram-negative bacteria in our adult comparative population. It is postulated that this is due to a combination of behavioural and ventilation factors. There were specific observations made relating to the paediatric population. Children are smaller in stature and, as a result, when ambulatory, children's central line sites were in close proximity to outlets, drains and toilets. Furthermore, when washing hands children have a tendency to splash and often clap hands together generating more splash. We also found evidence of small toys pushed down drains. Hickman lines also have potential to dangle close to showers drains if not properly secured.

In conclusion, we describe a complex water and drainage system contamination incident which was detected following a rare *C. pauculus* bacteraemia in an immunosuppressed child. Water testing revealed evidence of extensive water contamination throughout our adult and paediatric hospitals with further patient cases detected during the course of the investigation. Through our investigations we also obtained evidence of contamination of outlets including taps and showerheads, particularly the flow straightener component of the tap. Drains exhibited structural abnormalities and extensive biofilm with evidence of disruption of biofilm, this was likely exacerbated by the installation of point of use filters on taps. Short-term control was achieved by application of point of use filters, provision of alternative water sources and drain cleaning/component replacement. Long-term measures remain ongoing and include installation of a chlorine dioxide dosing system, replacement of sinks and outlets and longer-term point of use filters.

The key learning points of this research are: (1) Infection control teams should play an active role in Water Safety Groups and be involved in the planning, and commissioning of hospital water systems from the outset. (2) For future new-build projects, early consideration should be given to methods of water control, including regular flushing of all outlets and continuous dosing of hot and cold water systems with an effective biocide. For larger, more complex sites, temperature control alone is unlikely to be sufficient, nevertheless recommended temperatures in hot and cold water systems should be maintained at all times. (3) Pipework should be capped to avoid contamination being introduced via this route. (4) Outlets should

be cleaned and disinfected prior to installation. (5) Water systems should be filled with water as late in the build as possible. They should be disinfected, flushed and kept flowing as if in full operational use to avoid stagnation. Records of flushing must be maintained and given to the building owner at handover. Where regular flushing is not practicable, consideration should be given to draining unused water systems and removing residual water with dry compressed air. (6) Patients and staff need to be regularly reminded of the importance of only using handwash basins for washing hands and not for the inappropriate disposal of materials. (7) Legionella risk assessments should be available to water safety groups and action plans developed with high-risk findings remedied prior to hospital opening. Consideration should also be given to maintenance and resources for such. (8) Taps, particularly in high-risk areas, should not be fitted with conventional flow straighteners, aerators, flow restrictors, or other devices fitted to tap outlets that can operate as an impediment to the flow of water and so support the development of biofilm. (9) Taps in healthcare premises should not be fitted with thermostatic mixing valves except where a scalding risk assessment indicates the need for such devices. (10) For hospitals housing high-risk units, such as haemato-oncology units, consideration should be given to additional precautions for these high-risk groups. These might include application of long-term point of use filters, local chemical dosing systems or point of use heating. (11) Infection control teams should be alert to more unusual Gram-negative organisms and atypical mycobacteria which might indicate a potential water source and consider the multiple factors that contribute to transmission.

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Conflict of interest statement
The authors have no conflicts of interest to declare.

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Appendix A. Supplementary data

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FACT-JACIE International Standards

for HEMATOPOIETIC ELLULAR THERAPY

Product Collection, Processing, and Administration

EIGHTH EDITION 8.1

FACT FOUNDATION FOR THE ACCREDITATION OF CELLULAR THERAPY

JACIE Joint Accreditation Committee ISCT | EBMT

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INTERNATIONAL STANDARDS FOR HEMATOPOIETIC CELLULAR THERAPY PRODUCT COLLECTION, PROCESSING, AND ADMINISTRATION

Eighth Edition
Version 8.1
December 14, 2021

NOTICE

These Standards are designed to provide minimum guidelines for programs, facilities, and individuals performing cellular therapy or providing support services for such procedures. These Standards are not intended to establish best practices or include all procedures and practices that a program, facility, or individual should implement if the standard of practice in the community or applicable governmental laws or regulations establish additional requirements. Each program, facility, and individual should analyze its practices and procedures to determine whether additional standards apply. Compliance with these Standards is not an exclusive means of complying with the standard of care in the industry or community or with local, national, or international laws or regulations.

The Foundation for the Accreditation of Cellular Therapy and the Joint Accreditation Committee – ISCT and EBMT expressly disclaim any responsibility for setting maximum standards and further expressly disclaim any responsibility, liability, or duty to member programs, directors, staff, or program donors or patients for any such liability arising out of injury or loss to any person by the failure of member programs, directors, or staff to adhere to the Standards or related guidance.

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INTRODUCTION

The *FACT-JACIE International Standards for Hematopoietic Cellular Therapy Product Collection, Processing, and Administration*, eighth edition, is the sixth collaboration to publish comprehensive quality-based Standards in cellular therapy between the Foundation for the Accreditation of Cellular Therapy (FACT) and JACIE, the Joint Accreditation Committee of ISCT and EBMT of the European Society for Blood and Marrow Transplantation (EBMT). FACT was founded in 1996 by the American Society for Transplantation and Cellular Therapy (ASTCT) and the International Society for Cell and Gene Therapy (ISCT), published the first edition of Hematopoietic Cell Standards that year, and initiated the North American inspection and accreditation program based on these Standards in 1997. JACIE was established in 1999, adopted the first edition of FACT Standards, and jointly reviewed the second edition in 2002. Subsequent editions of Standards have been jointly developed, approved, and published by FACT and JACIE.

The objective of the *FACT-JACIE International Standards for Hematopoietic Cellular Therapy Product Collection, Processing, and Administration* is to promote quality medical and laboratory practice in hematopoietic progenitor cell transplantation and therapies using hematopoietic-derived cellular products. FACT-JACIE Standards are unique in depth and breadth, being applicable to all phases of cell collection, processing, storage, transportation, and administration, and to all phases of clinical application including standard of care therapies and products, products administered under regulatory-approved clinical trials, and licensed (or other regulatory approval) products.

The scope of the FACT-JACIE Standards includes:

- Hematopoietic progenitor cells (HPCs), defined as self-renewing and/or multi-potent stem cells capable of maturation into any of the hematopoietic lineages, lineage-restricted pluri-potent progenitor cells, and committed progenitor cells, regardless of tissue source (bone marrow, umbilical cord blood, peripheral blood, or other tissue source).
- Nucleated cells or mononuclear cells from any hematopoietic tissue source (marrow, peripheral blood, umbilical cord, and placental blood) collected for therapeutic use other than as HPCs. These cells may be further enumerated, identified by CD designation or other methodology, or may be used in further manufacturing of cellular therapy products for administration.
- Immune effector cells (IECs), defined as cells, in vitro modified or not, that have differentiated into a form capable of modulating or effecting a specific immune response. This broad designation includes cellular therapy products with widely diverse manufacturing methods, constructs, clinical indications, and safety and toxicity profiles. Individual programs and responsible personnel must understand the immune effector cell products in clinical use, the spectrum and timing of potential and anticipated toxicities associated with each product or type of product, implement relevant risk evaluation and mitigation strategies, and apply these Standards appropriately to each situation.
- Genetically modified cells, defined as cells that have been modified by replacing a disease-causing gene with a health copy of the gene, inactivating a disease-causing gene that is not functioning properly, or introducing a new or modified gene into the body to help treat a disease.

For cellular therapy products derived from umbilical cord or placental blood, these Standards apply only to the clinical administration of the product, applying the relevant clinical and processing standards for product preparation and administration. Standards for cord blood collection and banking are available in a separate document, *NetCord-FACT International*

Standards for Cord Blood Collection, Banking, and Release for Administration, available at www.factwebsite.org.

STANDARDS DEVELOPMENT

All FACT Standards are developed by consensus of international experts in cellular therapy and are based on established evidence from the literature whenever possible. The Standards Committee includes experts in clinical administration, apheresis collection, cell processing, quality management, immune effector cells, and genetically modified cells.

The Standards development process includes initial consideration of advances in the field and feedback from the prior edition, and review of each current standard for retention, revision, or deletion. The resulting draft document is published for public comment, including comment from regulatory bodies. Each comment is reviewed by the Standards Committee, and revisions are made as indicated. FACT staff maintain consistency across the sections of each document and among the different sets of FACT Standards. Each new edition is approved by legal counsel and the Boards of Directors of FACT and JACIE (EBMT).

FACT-JACIE Standards also require compliance with other initiatives in the field. This includes assessment of clinical outcomes against published benchmarks, submission of complete and accurate data to a national or international registry, use of the Circular of Information (COI) donor testing and biohazard and warning label tables, and compliance with the ISBT 128 Standard. Links to these resources are available on the FACT website.

These Standards incorporate sound principles of quality medical and laboratory practice in cellular therapy. However, no standards can guarantee the successful outcome of such therapies. FACT-JACIE Standards are minimal guidelines that may be exceeded as deemed appropriate by the responsible personnel in individual facilities. Directors and Medical Directors assume responsibility for adopting FACT-JACIE Standards as appropriate to the program, and for setting more rigorous internal requirements where appropriate. Attempts have been made to conform these Standards to existing United States federal regulations and the requirements of the European Union Directives; however, compliance with these Standards does not guarantee compliance with all applicable regulations.

A detailed summary of major changes to the eighth edition of FACT-JACIE Standards is available on the FACT website at www.factwebsite.org. Significant additions to this edition include:

1. A tenet is a basic principle that is true throughout the Standards. A new tenet that any activity can be delegated to an appropriate designee (as currently defined) was added to permit flexibility in delegation of specific activities. The person appointing a designee retains ultimate responsibility. The phrase “or designee” was removed from individual standards throughout.

2. The terms chain of identity and chain of custody (as defined by the multi-stakeholder Chain of Identity/Chain of Custody working group of the Standards Coordinating Body) were added. Chains of identity and custody are necessary to permit tracking and tracing required by the Standards.

3. Due to increasing use of genetically modified cellular therapy products in FACT-accredited organizations, the term genetically modified cell was defined, and minimal requirements related to these cells were added, including appropriate training in administration of cells, review and analysis of clinical outcomes, and incorporation of a relevant biosafety plan

consistent with institutional and regulatory requirements for genetically modified products, including disposal.

4. The term GxP was introduced and defined as “good practice” following various quality standards and regulations. The “x” is a variable, with further definition of good practices defined by different Applicable Law and industry standards. The type of work performed defines which GxPs apply. Examples include good manufacturing practice, good documentation practice, good laboratory practice, good tissue practice, and others. Standards requiring annual training in applicable GxPs were added to collection and processing sections.

5. General standards were added to address risk management program requirements for Clinical Programs utilizing licensed (or equivalent regulatory approval) cellular therapy products for which such a program is required by Applicable Law or by the manufacturer. The intent is to require Clinical Programs to establish and follow policies and Standard Operating Procedures related to any mandated risk management program.

6. The College of American Pathologists (CAP) was approved as an accrediting organization appropriate to provide histocompatibility services for hematopoietic cellular therapy and is explicitly listed in the eighth edition of Standards.

7. The eighth edition language requires, rather than recommends, that family members not serve as interpreters or translators for donor consent. Guidance is provided that when rare languages or extremely limited resources necessitate, this practice is treated as a planned deviation and appropriate risk mitigation strategies are defined.

8. Data Management standards are enhanced in the eighth edition Standards. The Clinical Program is now required to submit autologous and allogeneic hematopoietic cell transplant data for a minimum of one year after cellular therapy product administration to a national or international registry. Non-transplant outcome data related to IECs should also be reported to a national or international database. In addition, programs should meet the data accuracy benchmark established by FACT, JACIE, and CIBMTR or EBMT. There must be policies or SOPs related to the data management processes, and data management staff should document continuing education annually.

The *FACT-JACIE International Standards for Hematopoietic Cellular Therapy Product Collection, Processing, and Administration*, eighth edition, version 8.1, is effective January 14, 2022.

ACCREDITATION

FACT and JACIE maintain separate and parallel accreditation processes based on documented compliance with the current edition of Standards through submitted documents and an on-site inspection. All inspections are conducted by persons qualified by training and experience in the area of cellular therapy they inspect, who have completed inspector training, have a working knowledge of the Standards and of their application to various aspects of the cellular therapy program, and who are affiliated with an accredited facility.

1) A clinical hematopoietic cellular therapy and transplantation program may apply for accreditation alone or in conjunction with the collection facility and the processing facility with which it is associated. A program must use a collection facility and a processing facility that meet FACT-JACIE Standards and have a clearly defined contractual or reporting relationship.

a) Clinical program accreditation may be for allogeneic transplantation, autologous transplantation, or both; for transplantation of adult patients, pediatric patients, or both; and for immune effector cellular therapy if provided in addition to transplantation.
b) All cellular therapy products within the scope of these Standards that are administered by the clinical program are included in the accreditation of that program.
c) A clinical program that provides other cellular therapy services in addition to transplantation requires only a single accreditation under these Standards.

2) A cellular therapy product collection facility or service (peripheral blood or bone marrow) may apply for accreditation as an integral part of a clinical transplant program, as an independent collection service providing cell collection services for one or more clinical transplant programs, or in conjunction with a cell processing facility if the services of collection and processing/storage are functionally linked. An accredited cell collection facility may provide services for clinical transplant programs that are or are not FACT or JACIE accredited but shall use a processing facility that meets FACT-JACIE Standards and have a clearly defined contractual or reporting relationship. All cellular therapy products collected by the facility are included under these Standards and this accreditation, regardless of the location or extent of further manufacturing.

3) A cell processing facility may apply for accreditation as an integral part of a clinical transplant program, as part of a collection service or facility, or as an independent cell processing facility that processes and stores products for clinical programs or collection facilities or for further manufacturing. An accredited processing facility may provide services for clinical transplant programs or collection services that are or are not FACT or JACIE accredited.

4) A clinical program that provides cellular therapy services other than hematopoietic progenitor cell transplantation may apply for FACT accreditation with a transplantation program provided that the definition of and requirements for a single clinical program are met. A program with common directorship, protocols, and staffing would meet this requirement.

5) A cell collection or processing facility that collects or processes hematopoietic progenitor cell therapy products in addition to other investigational products may apply for FACT accreditation for all activities and document compliance with the FACT-JACIE Standards.

6) If a facility does not collect or process hematopoietic cellular therapy products but wishes to apply for FACT accreditation, the facility personnel should consult the current edition of the *FACT Common Standards for Cellular Therapies*.

7) A program that administers only IECs and does not perform hematopoietic cell transplantation may apply for accreditation under the *FACT Standards for Immune Effector Cells.*

An accreditation cycle is three years for FACT and is four years for JACIE.

FACT or JACIE-accredited programs are listed on the websites of the respective organizations.

TERMINOLOGY, TENETS, ABBREVIATIONS, AND DEFINITIONS

PART A

PART A: TERMINOLOGY, TENETS, ABBREVIATIONS, AND DEFINITIONS

A1 TERMINOLOGY

For purposes of these Standards, the term “shall” means that the standard is to be complied with at all times. The term “should” indicates an activity that is recommended or advised, but for which there may be effective alternatives. The term “may” is permissive and is used primarily for clarity.

The phrase, “policies and Standard Operating Procedures,” is used for ease of reading. When referring to a single document, either a policy or Standard Operating Procedure is sufficient.

A2 TENETS

Basic tenets for compliance with these Standards include, but are not limited to:

A2.1 Where Applicable Law includes more stringent requirements than these Standards, those laws and regulations supersede the Standards. Conversely, when these Standards are more stringent than Applicable Law, the Standards must be followed.

A2.2 Any activity can be delegated to an appropriate designee (as defined). The person appointing a designee retains ultimate responsibility.

A2.3 Standards related to services not provided by the applicant do not apply to the applicant organization. The responsibility to demonstrate that a requirement is not applicable rests with the applicant organization.

A3 ABBREVIATIONS

The following abbreviations cover terms used in these Standards:

ABO	Major human blood group including erythrocyte antigens, A, B, O
AC	Accompany
AF	Affix
Anti-	Antibody to the antigen designated
APP	Advanced Practice Provider/Professional
ASHI	American Society for Histocompatibility and Immunogenetics
ASTCT	American Society for Transplantation and Cellular Therapy
AT	Attach
CAP	College of American Pathologists
CFR	Code of Federal Regulations
CIBMTR	Center for International Blood and Marrow Transplant Research
CIDR	Cellular Immunotherapy Data Resource
CMV	Cytomegalovirus
DLI	Donor lymphocyte infusion
DNA	Deoxyribonucleic acid
EBMT	European Society for Blood and Marrow Transplantation
ECP	Extracorporeal photopheresis
EFI	European Federation for Immunogenetics
EU	European Union

FACT	Foundation for the Accreditation of Cellular Therapy
FDA	U. S. Food and Drug Administration
GMP	Good Manufacturing Practice
GVHD	Graft versus Host Disease
HLA	Human leukocyte antigen
HPC	Hematopoietic progenitor cell
IEC	Immune effector cell
IRB	Institutional Review Board
ISCT	International Society for Cell & Gene Therapy
JACIE	Joint Accreditation Committee – ISCT and EBMT
MNC	Mononuclear cell
MSC	Mesenchymal stromal cell or mesenchymal stem cell
QM	Quality management
RBC	Red blood cell
Rh	Rhesus system of human red blood cell antigens; used in this document to refer to the Rh(D) antigen only, unless otherwise specified
SOP	Standard operating procedure
U.S.	United States

A4 DEFINITIONS

Accompany: To go, be together with, or be available to the appropriate individual(s) electronically, but not affixed or attached. Written or printed information that must accompany a cellular therapy product must be in a sealed package with, or alternatively, be attached or affixed to, the cellular therapy product container.

Accreditation cycle: The period of time from the awarding of accreditation until its expiration as set, and subject to change, by FACT or JACIE. At publication of these Standards, this period is three (3) years for FACT-accredited programs and four (4) years for JACIE-accredited programs.

Advanced practice provider/professional: Physician Assistant, Nurse Practitioner, or other licensed Advanced Practitioner authorized by the applicable legal authority to provide primary patient care with physician oversight. Physician Assistants are formally trained and licensed or certified by the applicable authority to provide diagnostic, therapeutic, and preventive health care services with physician supervision. Advanced Nurse Practitioner includes certified nurse anesthetists, nurse practitioners, certified nurse midwives, and clinical nurse specialists.

Adverse event: Any unintended or unfavorable sign, symptom, abnormality, or condition temporally associated with an intervention that may or may not have a causal relationship with the intervention, medical treatment, or procedure. Adverse reaction is a type of adverse event.

Adverse reaction: A noxious and unintended response suspected or demonstrated to be caused by the collection or administration of a cellular therapy product or by the product itself.

Affix: To adhere in physical contact with the cellular therapy product container.

Allogeneic: The biologic relationship between genetically distinct individuals of the same species.

Ambulatory care: A planned care system in which cellular therapy recipients at risk of prolonged neutropenia are based at home or in another specified accommodation. There should be specific safeguards to minimize the risk from potentially life-threatening complications of the preparative regimen.

Ambulatory setting: An environment of patient care outside of an inpatient hospital.

And/or: Either or both may be affected or involved.

Apheresis: A medical technology in which the blood of a donor is separated into its component parts, the desired component is removed, and the remaining components are returned to the donor.

Applicable Law: Any local, national, or international statute, regulation, or other governmental law that is applicable to cellular therapy product collection, processing, and administration that is relevant to the location or activities of the Clinical Program, Collection Facility, or Processing Facility.

Aseptic technique: Practices designed to reduce the risk of microbial contamination of cellular therapy products, reagents, specimens, recipients, and/or donors.

Attach: To fasten securely to the cellular therapy product container by means of a tie tag or comparable alternative. Any information required to be attached to a cellular therapy product container may alternatively be affixed.

Attending physician: The physician who is responsible for the delivery and oversight of care provided to cellular therapy recipients and who meets all qualifications defined in these Standards.

Audit: Documented, systematic evaluation to determine whether approved policies or Standard Operating Procedures have been properly implemented and are being followed.

Autologous: Derived from and intended for the same individual.

Calibrate: To set measurement equipment against a known standard.

CD34: The 115 kD glycoprotein antigen, expressed by 1-2% of normal bone marrow mononuclear cells, that is defined by a specific monoclonal antibody (anti-CD34) using the standardized cluster of differentiation (CD) terminology.

Cellular therapy: The administration of products with the intent of providing effector cells in the treatment of disease or support of other therapy.

Cellular therapy product: Somatic cell-based product (e.g., HPC, mononuclear cells, cord blood cells, immune effector cells, genetically modified cells, and others) that is procured from a donor and intended for processing and administration.

Chain of identity: The permanent and transparent association of a cell or gene therapy's unique identifiers from procurement of tissue or cells throughout the full product(s) lifecycle including post treatment monitoring.

Chain of custody: Concurrent, permanent, auditable documentation illustrating the guardianship of a cell or gene therapy product from its origin through its final disposition.

Chimerism: The coexistence of cells of more than one genotype in a single individual. In hematopoietic cell transplantation, chimerism generally refers to the presence of allogeneic donor hematopoietic and/or lymphoid cells in the transplant recipient.

Chimerism testing: Assessment of the presence of allogeneic donor cells in a transplant recipient using any assay of informative genetic markers that distinguishes donor from recipient cells.

Circular of Information: An extension of container labels that includes the use of the cellular therapy product, indications, contraindications, side effects and hazards, dosage, and administration recommendations.

Clinical Program: An integrated medical team housed in a defined location that includes a Clinical Program Director and demonstrates common staff training, protocols, Standard Operating Procedures, quality management systems, clinical outcome analysis, and regular interaction among clinical sites.

Collection: Any procedure for procuring and labeling a cellular therapy product regardless of technique or source.

Collection Facility: An entity providing the service of cellular therapy product collection.

Competency: Ability to adequately perform a specific procedure or task according to direction.

Complaint: Any written, oral, or electronic communication about a problem associated with a cellular therapy product; a service related to the collection, processing, storage, distribution, or administration of a cellular therapy product; or clinical care.

Continuum of care: The delivery of health care over a period of time. In patients with a disease, this covers all phases of illness from diagnosis to the end of life.

Cord blood: The whole blood, including HPC, collected from placental and umbilical cord blood vessels after the umbilical cord has been clamped.

Corrective action: Action taken to eliminate the root causes of an existing discrepancy or other undesirable situation to prevent recurrence.

Corrective Action Plan: A document describing the step-by-step plan of action to achieve a defined outcome or resolution of an identified occurrence or noncompliance.

Courier: An individual trained and competent in transport or shipping of cellular therapy products.

Critical: The quality of any element employed in cellular therapy product manufacturing to potentially change the identity, purity, potency, or safety of the cellular therapy product if altered or omitted. “Element” includes, but is not limited to, materials, equipment, personnel, documents, or facilities.

Cytokine release syndrome: A non-antigen-specific toxicity that occurs as a result of high-level immune activation.

Designee: An individual with appropriate education, experience, or expertise who is given the authority to assume a specific responsibility. The person appointing the designee retains ultimate responsibility.

Deviation: The action of departing from an established course of action or accepted practice.

Planned deviation: Allowed to occur with documented prior approval as the best course of action when adherence to the established course or accepted practice was not feasible or possible.

Unplanned deviation: The action of departing from an established course or accepted standard without intent.

Distribution: Any transportation or shipment of a cellular therapy product that has been determined to meet release criteria or urgent medical need requirements.

Donor: A person who is the source of cells or tissue for a cellular therapy product.

Donor advocate: An individual distinct from the cellular therapy recipient's primary treating physician whose main obligation is to protect the interests, well-being, and safety of the donor. The donor advocate may help the donor understand the process, the procedures, and the potential risks and benefits of donation.

Donor lymphocyte infusion (DLI): A therapy in which lymphocytes from the original cellular therapy product donor are given to a recipient who has received a hematopoietic progenitor cell transplant from the same donor.

Effective date: The day the new version of a document has been implemented and the previous version has been recalled or archived.

Electronic record: A record or document consisting of any combination of text, graphics, or other data that is created, stored, modified, or transmitted in digital form by a computer.

Critical electronic record: Electronic record system under facility control that is used as a substitute for paper, to make decisions, to perform calculations, or to create or store information used in critical procedures.

Eligible: An allogeneic cellular therapy product donor for whom all the donor screening and testing have been completed in accordance with Applicable Law and who has been determined to be free of risk factor(s) for relevant communicable diseases.

Engraftment: The reconstitution of recipient hematopoiesis with blood cells and platelets from a donor. It is recommended that cellular therapy programs use engraftment definitions from CIBMTR, EBMT, or another similar organization.

Errors and accidents: Any unforeseen or unexpected deviations from applicable regulations, standards, or established specifications that may affect the safety, purity, or potency of a cellular therapy product.

Establish and maintain: A process to define, document in writing (including electronically), implement, follow, review, and, as needed, revise on an ongoing basis.

Eurocode: The facility identification code (Center Code) and product coding assigned, published, and maintained by Eurocode International Blood Labeling Systems (IBLS).

Exceptional release: Removal of a product that fails to meet specified criteria from quarantine or in-process status for distribution through a defined approval process.

Extracorporeal photopheresis (ECP): A therapeutic procedure in which the buffy coat is separated from the patient's blood, treated extracorporeally with a photoactive compound (e.g., psoralens) and exposed to ultraviolet A light, then subsequently infused to the patient during the same procedure.

Facility: A location where activities covered by these Standards are performed, including but not limited to determination of donor eligibility or suitability, product collection, processing, storage, distribution, issue, or administration.

Genetically modified cell: A cell that has been modified by replacing a disease-causing gene with a healthy copy of the gene, inactivating a disease-causing gene that is not functioning properly, or introducing a new or modified gene into the body to help treat a disease.

Good Manufacturing Practice (GMP): The set of current practices followed by entities producing drug and biologic products, including cellular therapy products, to ensure that the products produced meet specific requirements for identity, strength, quality, and purity. Cellular therapy products that are extensively manipulated or that are used for non-homologous purposes are examples of products controlled under GMP regulations. In the US, GMPs are enforced under Section 501(B) of the Federal Food, Drug, and Cosmetic Act (21USC351). Similar requirements are delineated by the European Union as EU-GMP, and other countries such as United Kingdom, Australia, Canada, and Singapore have equally well-developed systems of regulations.

Good Tissue Practice: The methods used in, and the facilities and controls used for, the manufacture of cellular therapy products to prevent the introduction or transmission of communicable diseases, including all steps in collection, donor screening and testing, processing, storage, labeling, packaging, and distribution.

GxP: Good practice following various quality standards and regulations. The "x" is variable, with further definition of good practices defined by different Applicable Law and industry standards. The type of work that is being performed will define which GxPs should be followed.

Hematopoietic progenitor cells (HPC): A cellular therapy product that contains self-renewing and/or multi-potent stem cells capable of maturation into any of the hematopoietic lineages, lineage-restricted pluri-potent progenitor cells, and committed progenitor cells, regardless of tissue source (bone marrow, umbilical cord blood, peripheral blood, or other tissue source).

Hematopoietic progenitor cellular therapy: The administration of HPC product with the intent of providing effector functions in the treatment of disease or in support of other therapy.

Immune effector cell: A cell that has differentiated into a form capable of modulating or effecting a specific immune response.

Ineligible: An allogeneic cellular therapy product donor for whom all the donor screening and testing has been completed in accordance with the Applicable Law and who has identified risk factor(s) for relevant communicable diseases.

Institutional Review Board or Ethics Committee: A Board or Committee established by an institution in accordance with the regulations of the relevant governmental agency to review biomedical and behavioral research that involves human subjects and is conducted at or supported by that institution.

ISBT 128: A global standard for the identification, labeling, and information transfer of human blood, cell, tissue, and organ products published and maintained by ICCBBA.

Key position: A job category with responsibilities that significantly affect the provision of service or product safety and quality.

Label: Written, printed, or graphic material affixed to, attached to, or accompanying a cellular therapy product container or package. Labels must contain the information as defined by applicable standards, laws, and regulations.

Labeling: The process of creating and applying the cellular therapy product label, including confirmation of the presence and accuracy of the required information as defined in these Standards.

Late Effect: A health problem that occurs months or years after a disease is diagnosed or after treatment has been administered. Late effects may be caused by the primary disease or its treatment, and may include physical, mental, or social problems and/or secondary cancers.

Licensed health care professional: An individual who has completed a prescribed program of health care related study and has been certified, registered, or licensed by the applicable authority in the jurisdiction in which he or she is performing services to perform duties within the scope of practice of that certificate, registration, or license.

Manipulation: An ex vivo procedure(s) that selectively removes, enriches, expands, or functionally alters the cellular therapy product.

Minimally manipulated: Processing that does not alter the relevant biological characteristics of cells or tissues. For structural tissue, processing that does not alter the original relevant characteristics of the tissue relating to the tissue's utility for reconstruction, repair, or replacement.

More than minimally manipulated: Processing that does alter the relevant biological characteristics of cells or tissues. For structural tissue, processing that does alter the original relevant characteristics of the tissue relating to the tissue's utility for reconstruction, repair, or replacement. Products that are more than minimally manipulated are referred to as Advanced Therapy Medicinal Products in the European Union.

Unmanipulated: A cellular therapy product as obtained at collection and not subjected to any form of processing.

Manufacturing: Activity that includes, but is not limited to, any or all steps in the collection, processing, packaging, labeling, storage, or distribution of any human cellular or tissue-based product, and/or the screening and testing of a cell or tissue donor.

Marrow collection: Harvest of bone marrow for transplantation to achieve hematopoietic reconstitution in the recipient or for further cellular therapy product manufacture. This does not include marrow aspirations intended for diagnostic purposes.

Materials management: An integrated process for planning and controlling all steps in the acquisition and use of goods or supply items (materials) used for the collection or processing of cellular therapy products to determine whether these materials are of adequate quality and quantity and available when needed. The materials management system combines and integrates the material selection, vendor evaluation, purchasing, expediting, storage, distribution, and disposition of materials.

Microbial: Related to infectious agents including bacterial and fungal organisms.

New patient: An individual undergoing the specified type of transplantation (allogeneic, autologous, or syngeneic) for the first time in the Clinical Program, whether or not that patient was previously treated by that Clinical Program.

Occurrence: An instance in which an action or circumstance results in errors, accidents, deviations, adverse events, adverse reactions, or complaints.

Organizational chart: A graphic representation of the structure, function, and reporting relationships of key personnel within an organization.

Orientation: An introduction to guide one in adjusting to new surroundings, employment, or activity.

Outcome analysis: The process by which the results of a therapeutic procedure are formally assessed.

Packaging: Placing a cellular therapy product into an appropriate secondary or outer container for shipping or transportation.

Partial label at distribution for administration: A label that, because of the size of the product container or other constraints, does not contain all of the required information.

Periodic: Occurring at time intervals specifically defined by the organization as appropriate.

Physician-in-training: A physician in one of the postgraduate years of clinical training. Can be referred to as resident, fellow, registrar, or other designation, depending on the setting. The length of training varies according to the specialty.

Policy: A document that defines the scope of an organization, explains how the goals of the organization will be achieved, and/or serves as a means by which authority can be delegated.

Potency: The therapeutic activity of a product as indicated by appropriate laboratory tests or adequately developed and controlled clinical data.

Preparative (conditioning) regimen: The treatment(s) used to prepare a patient for hematopoietic progenitor cell transplantation or other cellular therapies (e.g., chemotherapy, monoclonal antibody therapy, radiation therapy).

Preventive action: Action taken to eliminate the root cause and prevent occurrence of a potential discrepancy or other undesirable situation.

Process: A goal-directed, interrelated series of actions, events, or steps.

Process control: The standardization of processes in order to produce predictable output.

Processing: All aspects of manipulation, labeling, cryopreservation, and packaging of cellular therapy products regardless of source, including microbial testing, preparation for administration or storage, and removal from storage. Processing does not include collection, donor screening, donor testing, storage, or distribution.

Processing Facility: A location where cellular therapy product processing activities are performed in support of the Clinical Program. A Processing Facility may be part of the same institution as the Clinical Program or may be part of another institution and perform these functions through contractual agreement.

Product code: An eight-character ISBT 128 code that comprises the Product Description Code, a Collection Type Code, and a Division Code. The product code makes each product from a collection unique.

Product sample: A representative quantity of product removed from the cellular therapy product; an aliquot.

**Products:* The ISBT 128 Cellular Therapy Class product database name and definition (format: type of cells, comma, source of cells) for products collected from hematopoietic sources are as follows:

Subcategory 1: At collection the product code will describe the composition of the cell therapy products. It can be HPC, NC, or MNC. These products may be collected for direct infusion without further manipulation, or may be further processed into other cellular therapy classes. If they are HPCs they would retain the class name if they are used as a source of hematopoietic progenitor cells. If these products undergo modification such as cryopreservation and thawing, the class will not change but the modification is added into the product description as an attribute.

CONCURRENT PLASMA, APHERESIS: Plasma collected from the donor as part of an apheresis cell collection procedure.

HPC, APHERESIS: A cell product containing hematopoietic progenitor cells obtained by apheresis.

HPC, CORD BLOOD: A cell product containing hematopoietic progenitor cells obtained from cord blood.

HPC, MARROW: A cell product containing hematopoietic progenitor cells obtained from bone marrow.

HPC, WHOLE BLOOD: A cell product containing hematopoietic progenitor cells obtained from whole blood.

MNC, APHERESIS: A cell product containing mononuclear cells obtained by apheresis.

NC, CORD BLOOD: A cell product containing nucleated cells obtained from cord blood.

NC, DECIDUA: A cell product containing nucleated cells obtained from the decidua.

NC, MARROW: A cell product containing nucleated cells obtained from bone marrow.

NC, WHOLE BLOOD: A cell product containing nucleated cells obtained from whole blood.

Subcategory 2: After enumeration or manufacture/processing of a collected product, the product is identified by the target cell population.

B CELLS, APHERESIS: A cell product containing B cells obtained by apheresis.

DC, APHERESIS: A cell product containing dendritic cells obtained by apheresis.

DC, CORD BLOOD: A cell product containing dendritic cells obtained from cord blood.

DC, MARROW: A cell product containing dendritic cells obtained from bone marrow.

DC, WHOLE BLOOD: A cell product containing dendritic cells obtained from whole blood.

INVESTIGATIONAL PRODUCT: A product for an investigational study that is accompanied by appropriate identifying study information. This class may be used for a specific product that may be part of a blinded comparison study. Products labeled as Investigational Product may include different doses or may include an active product or a placebo.

iPSC, CORD BLOOD: A cell product containing induced pluripotent stem (iPS) cells obtained from cord blood.

iPSC, WHOLE BLOOD: A cell product containing induced pluripotent stem (iPS) cells obtained from whole blood.

MALIGNANT CELLS, APHERESIS: A cell product containing malignant cells obtained by apheresis.

MALIGNANT CELLS, MARROW: A cell product containing malignant cells obtained from marrow.

MALIGNANT CELLS, TUMOR: A cell product containing, or derived from, malignant cells obtained from a tumor.

MALIGNANT CELLS, WHOLE BLOOD: A cell product containing malignant cells obtained from whole blood.

MNC, CORD BLOOD: A cell product containing mononuclear cells obtained from cord blood.

MNC, UMBILICAL CORD TISSUE: A cell product containing mononuclear cells derived from umbilical cord tissue.

MNC, WHOLE BLOOD: A cell product containing mononuclear cells obtained from whole blood.

MSC, ADIPOSE TISSUE: A cell product containing mesenchymal stromal cells derived from adipose tissue.

MSC, AMNIOTIC MEMBRANE: A cell product containing mesenchymal stromal cells derived from amniotic membrane.

MSC, CORD BLOOD: A cell product containing mesenchymal stromal cells derived from cord blood.

MSC, DENTAL PULP: A cell product containing mesenchymal stromal cells derived from dental pulp.

MSC, FETAL LIVER: A cell product containing mesenchymal stromal cells derived from fetal liver.

MSC, MARROW: A cell product containing mesenchymal stromal cells derived from bone marrow.

MSC, PLACENTA: A cell product containing mesenchymal stromal cells derived from placenta.

MSC, UMBILICAL CORD: A cell product containing mesenchymal stromal cells derived from umbilical cord.

MSC, WHARTON'S JELLY: A cell product containing mesenchymal stromal cells derived from Wharton's jelly.

NC, ADIPOSE TISSUE: A cell product containing nucleated cells obtained from adipose tissue.

NC, PLACENTA: A cell product containing nucleated cells obtained from placenta.

NC, UMBILICAL CORD: A cell product containing nucleated cells obtained from umbilical cord.

NC, UMBILICAL CORD VESSEL: A cell product containing nucleated cells obtained from umbilical vessels.

NK CELLS, APHERESIS: A cell product containing natural killer cells obtained by apheresis.

NK CELLS, CORD BLOOD: A cell product containing natural killer cells obtained from cord blood.

NK CELLS, MARROW: A cell product containing natural killer cells obtained from bone marrow.

NK CELLS, WHOLE BLOOD: A cell product containing natural killer cells obtained from whole blood.

T CELLS, APHERESIS: A cell product containing T cells obtained by apheresis.

T CELLS, CORD BLOOD: A cell product containing T cells obtained from cord blood.

T CELLS, MARROW: A cell product containing T cells obtained from bone marrow.

T CELLS, TUMOR: A cell product containing T cells obtained from a tumor.

T CELLS, WHOLE BLOOD: A cell product containing T cells obtained from whole blood.

Proficiency test: A test to evaluate the adequacy of testing methods and equipment and the competency of personnel performing testing.

Protocol: A written document describing steps of a treatment or procedure in sufficient detail such that the treatment or procedure can be reproduced repeatedly without variation.

Purity: Relative freedom from extraneous matter in the finished product, whether or not harmful to the recipient or deleterious to the product.

Qualification: The establishment of confidence that equipment, supplies, and reagents function consistently within established limits.

Qualified person: A person who has received training, is experienced, and has documented competence in the task assigned.

Quality: Conformance of a product or process with pre-established specifications or standards.

Quality assurance: The actions, planned and performed, to provide confidence that all systems and elements that influence the quality of the product or service are working as expected or exceed expectations individually and collectively.

Quality assessment: The actions, planned and performed, to evaluate all systems and elements that influence the quality of the product or service.

Quality audit: A documented, independent inspection and review of a facility's Quality Management activities to verify, by examination and evaluation of objective evidence, the degree of compliance with those aspects of the quality program under review.

Quality control: A component of a quality management program that includes the activities and controls used to determine the accuracy and reliability of the establishment's personnel, equipment, reagents, and operations in the manufacturing of cellular therapy products, including testing and product release.

Quality improvement: The actions, planned and performed, to implement changes designed to improve the quality of a product or process.

Quality management: The integration of quality assessment, assurance, control, and improvement in cellular therapy activities.

Quality management plan: A written document that describes the systems in place to implement the quality management program.

Quality management program: An organization's comprehensive system of quality assessment, assurance, control, and improvement. A quality management program is designed to prevent, detect, and correct deficiencies that may adversely affect the quality of the cellular therapy product or increase the risk of communicable disease introduction or transmission. May also be referred to by other terms.

Quality Unit: Personnel with responsibility for and authority to approve or reject in-process materials, cellular therapy product containers, packaging material, labeling, and cellular therapy products.

Quarantine: The identification or storage of a cellular therapy product in a physically separate area clearly identified for such use, or through use of other procedures such as automated designation to prevent improper release of that product. Also refers to segregated storage of products known to contain infectious disease agents to reduce the likelihood of cross-contamination.

Record: Documented evidence that activities have been performed or results have been achieved. A record does not exist until the activity has been performed.

Registry: An organization responsible for the coordination of the search for cellular therapy product donors (including cord blood) unrelated to the potential recipient.

Release: Removal of a product from quarantine or in-process status when it meets specified criteria.

Release criteria: The requirements that must be met before a cellular therapy product may leave the control of the Collection or Processing Facility.

Safety: Relative freedom from harmful effects to persons or products.

Shipping: The physical act of transferring a cellular therapy product within or between facilities. During shipping the product leaves the control of trained personnel at the distributing or receiving facility.

Sinusoidal obstruction syndrome (SOS): A distinctive and potentially fatal form of hepatic injury that occurs predominantly, if not only, after drug or toxin exposure; previously known as veno-occlusive disease (VOD).

Standard Operating Procedure (SOP): A document that describes in detail the process or chronological steps taken to accomplish a specific task. Also referred to as work instructions. An SOP is more specific than a policy.

Standard Operating Procedures (SOP) Manual: A compilation of policies and Standard Operating Procedures with written detailed instructions required to perform procedures. The SOP Manual may be in electronic or paper format.

Standards: The current edition of the *FACT-JACIE International Standards for Hematopoietic Cellular Therapy Product Collection, Processing, and Administration*, which may be referred to herein as “these Standards” or “the Standards.”

Storage: Holding a cellular therapy product for future processing, distribution, or administration.

Suitable: Donor or recipient suitability refers to issues that relate to the general health or medical fitness of the donor or recipient to undergo the collection procedure or therapy.

Syngeneic: The biologic relationship among genetically identical siblings.

Target cell population: A cell population that is expected to be affected by an action or that is believed to be mainly responsible for a given activity.

Third-party manufacturing: Outsourcing of part or all of the manufacturing of a cellular therapy product to a facility separate from the facilities primarily involved.

Time of collection: The time of day at the end of the cellular therapy product collection procedure.

Trace: To follow the history of a process, product, or service by review of documents.

Traceability: The ability to track any product through all stages of collection, processing, and administration so that tasks can be traced one step backwards and one step forward at any point in the supply chain.

Track: To follow a process or product from beginning to end.

Transplantation: The administration of allogeneic, autologous, or syngeneic HPC with the intent of providing transient or permanent engraftment in support of therapy of disease.

Transport: The physical act of transferring a cellular therapy product within or between facilities. During transportation the product does not leave the control of trained personnel at the transporting or receiving facility.

Unique: Being the only one of its kind or having only one use or purpose.

Unique identifier: A numeric or alphanumeric sequence used to designate a given cellular therapy product with reasonable confidence that it will not be used for another purpose.

Urgent medical need: A situation in which no comparable cellular therapy product is available and the recipient is likely to suffer death or serious morbidity without the cellular therapy product.

Validation: Confirmation by examination and provision of objective evidence that particular requirements can consistently be fulfilled. A process is validated by establishing, by objective evidence, that the process consistently produces a cellular therapy product meeting its predetermined specifications.

Verification: The confirmation of the accuracy of something or that specified requirements have been fulfilled.

Verification typing: HLA typing performed on an independently collected sample with the purpose of verifying concordance of that typing assignment with the initial HLA typing assignment. Concordance does not require identical levels of resolution for the two sets of typing but requires the two assignments be consistent with one another.

Viability: Living cells as defined by dye exclusion, flow cytometry, or progenitor cell culture.

Written: Documentation in human readable form.

*These definitions are as of the date of publication and use the current terminology as found in ISBT 128 Standard Terminology for Blood, Cellular Therapy, and Tissue Product Descriptions. For the most current list of definitions, see www.iccbba.org > Subject Area > Cellular Therapy > Standard Terminology.

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CLINICAL PROGRAM STANDARDS

PART B

PART B: CLINICAL PROGRAM STANDARDS

B1: GENERAL

B1.1 The Clinical Program shall consist of an integrated medical team that includes a Clinical Program Director(s) housed in a defined location(s).

B1.1.1 These Standards apply to all services provided by the Clinical Program.

B1.1.2 The Clinical Program shall demonstrate common staff training, protocols, Standard Operating Procedures, quality management systems, clinical outcome analyses, and regular interaction among all clinical sites.

B1.2 The Clinical Program shall use cell collection and processing facilities that meet FACT-JACIE Standards with respect to their interactions with the Clinical Program.

B1.2.1 If the Clinical Program or an intermediary facility receives cellular therapy products directly from a third-party provider, the following responsibilities shall be defined by a written agreement:

B1.2.1.1 Traceability and chain of custody of cellular therapy products.

B1.2.1.2 Cellular therapy product storage and distribution.

B1.2.1.3 Verification of cellular therapy product identity.

B1.2.1.4 Review and verification of product specifications provided by the manufacturer, if applicable.

B1.2.1.5 Readily available access to a summary of documents used to determine allogeneic donor eligibility.

B1.2.1.6 Documented evidence of allogeneic donor eligibility screening and testing in accordance with Applicable Law.

B1.3 The Clinical Program shall abide by Applicable Law.

B1.3.1 The Clinical Program shall be licensed, registered, or accredited as required by the appropriate governmental authorities for the activities performed.

B1.4 The Clinical Program shall have a designated transplant team that includes a Clinical Program Director, a Quality Manager, and a minimum of one (1) additional attending transplant physician. The designated transplant team shall have been in place and performing cellular therapy for at least twelve (12) months preceding initial accreditation.

B1.5 The Clinical Program shall comply with the minimum number of new patients for accreditation as defined in Appendix I.

B2: CLINICAL UNIT

B2.1 There shall be a designated inpatient unit of appropriate location and adequate space and design that minimizes airborne microbial contamination.

B2.2 There shall be a designated outpatient care area that protects the patient from transmission of infectious agents and allows, as necessary, for appropriate patient isolation; confidential examination and evaluation; and administration of intravenous fluids, medications, or blood products.

B2.3 When the preparative regimen, cellular therapy product administration, or initial post-transplant and cellular therapy care is provided in an ambulatory setting, there shall be a designated area with appropriate location and adequate space and design to minimize the risk of airborne microbial contamination.

B2.4 The Clinical Program shall document facility cleaning and sanitation and maintain order sufficient to achieve adequate conditions for operations.

B2.5 There shall be adequate equipment and materials for the procedures performed.

B2.6 There shall be provisions for prompt evaluation and treatment by an attending physician available on a 24-hour basis.

B2.7 There shall be access to an intensive care unit or emergency services.

B2.7.1 There shall be written guidelines for communication, patient monitoring, and prompt triage or transfer of patients to an intensive care unit, emergency department, or equivalent when appropriate.

B2.8 There shall be attending physician oversight if general medical physicians, physicians in training, or APPs provide care to cellular therapy patients. The scope of responsibility of general medical physicians or APPs shall be defined.

B2.9 There shall be a pharmacy providing 24-hour availability of medications needed for the care of cellular therapy patients.

B2.9.1 Pharmacies shall have prompt access to medications adequate to treat expected complications of cellular therapy, including cytokine release syndrome.

B2.10 There shall be access to renal support under the direction of nephrologists and trained personnel.

B2.11 There shall be 24-hour availability of CMV-appropriate and irradiated blood products or equivalent needed for the care of cellular therapy recipients.

B2.12 Clinical Programs performing allogeneic transplantation shall use HLA testing laboratories that are capable of carrying out DNA–based intermediate and high resolution HLA typing and are appropriately accredited by the American Society for Histocompatibility and Immunogenetics (ASHI), European Federation for Immunogenetics (EFI), College of American Pathologists (CAP), or other accrediting organizations providing histocompatibility services appropriate for hematopoietic cellular therapy transplant patients.

B2.13 Testing to monitor chimerism shall be performed in laboratories accredited for the techniques used.

B2.14 The Clinical Program shall be operated in a manner designed to minimize risks to the health and safety of employees, recipients, donors, visitors, and volunteers.

B2.15 The Clinical Program shall have a written safety manual that includes instructions for action in case of exposure, as applicable, to liquid nitrogen; communicable disease; and to chemical, biological, radiological, electrical, or fire hazards.

B2.16 All waste generated by the Clinical Program activities shall be disposed of in a manner that minimizes any hazard to facility personnel and to the environment in accordance with Applicable Law.

B2.17 Personal protective equipment, including gloves and protective clothing, shall be used while handling biological specimens. Such protective equipment shall not be worn outside the work area.

B3: PERSONNEL

B3.1 CLINICAL PROGRAM DIRECTOR

B3.1.1 The Clinical Program Director shall be a physician appropriately licensed to practice medicine in the jurisdiction in which the Clinical Program is located and shall have achieved specialist certification in one (1) or more of the following specialties: Hematology, Medical Oncology, Immunology, or Pediatric Hematology/Oncology. A physician trained prior to requirements for specialty training may serve as the Clinical Program Director if he/she has documented experience in the field of HPC transplantation extending over ten (10) years.

B3.1.2 The Clinical Program Director shall have a minimum of two (2) years of experience as an attending physician responsible for the direct clinical management of HPC transplant patients throughout the continuum of care.

B3.1.3 The Clinical Program Director shall be responsible for administrative and clinical operations, including compliance with these Standards and Applicable Law.

B3.1.4 The Clinical Program Director shall be responsible for all elements of the design of the Clinical Program including quality management, the selection and care of recipients and donors, and cell collection and processing, whether internal or contracted services.

B3.1.5 The Clinical Program Director shall have oversight of the medical care provided by all members of the Clinical Program.

B3.1.5.1 The Clinical Program Director shall be responsible for verifying competency of members of the Clinical Program annually.

B3.1.6 The Clinical Program Director shall participate in a minimum of ten (10) hours of educational activities related to cellular therapy annually.

B3.1.6.1 Continuing education shall include, but is not limited to, activities related to the field of HPC transplantation and other cellular therapies.

B3.2 ATTENDING PHYSICIANS

B3.2.1 Attending physicians shall be appropriately licensed to practice medicine in the jurisdiction of the Clinical Program and should be specialist certified or trained in one (1) of the following specialties: Hematology, Medical Oncology, Immunology, or Pediatric Hematology/Oncology.

B3.2.1.1 Clinical Programs performing adult transplantation shall have at least one (1) attending physician who has achieved specialist certification in Hematology, Medical Oncology, or Immunology.

B3.2.1.2 Clinical Programs performing pediatric transplantation shall have at least one (1) attending physician who has achieved specialist certification in Pediatric Hematology/Oncology or Pediatric Immunology.

B3.2.2 Clinical Programs performing pediatric transplantation shall have a transplant team trained in the management of pediatric recipients.

B3.2.3 Attending physicians shall participate in a minimum of ten (10) hours of educational activities related to cellular therapy annually.

B3.2.3.1 Continuing education shall include, but is not limited to, activities related to the field of HPC transplantation and other cellular therapies.

B3.3 TRAINING FOR CLINICAL PROGRAM DIRECTORS AND ATTENDING PHYSICIANS

B3.3.1 Attending physicians shall each have had a minimum of one (1) year of supervised training in the management of transplant and cellular therapy patients throughout the continuum of care.

B3.3.2 Clinical training and competency shall include the management of autologous and allogeneic transplant recipients and patients receiving immune effector cells or other cellular therapies.

B3.3.3 Clinical Program Directors and attending physicians shall each be assessed for competency on an annual basis.

B3.3.4 Clinical Program Directors and attending physicians shall have received specific training in each of the following areas as applicable to the Clinical Program's services:

B3.3.4.1 Indications for allogeneic and autologous HPC transplantation.

B3.3.4.2 Selection of suitable recipients and appropriate preparative regimens.

B3.3.4.3 Donor selection, evaluation, and management.

B3.3.4.4 Donor and recipient informed consent.

B3.3.4.5 Administration of preparative regimens.

B3.3.4.6 Administration of growth factors for HPC mobilization and for post-transplant hematopoietic cell reconstitution.

B3.3.4.7 Administration of cellular therapy products, including HPC, IEC, genetically modified cells, and other cellular therapies.

B3.3.4.8 Management of complications related to the administration of cellular therapy products.

B3.3.4.9 Management of neutropenic fever.

B3.3.4.10 Diagnosis and management of pulmonary complications.

B3.3.4.11 Diagnosis and management of fungal disease.

B3.3.4.12 Diagnosis and management of sinusoidal obstruction syndrome and other causes of hepatic dysfunction.

B3.3.4.13 Management of thrombocytopenia and bleeding, including recognition of disseminated intravascular coagulation.

B3.3.4.14 Management of hemorrhagic cystitis.

B3.3.4.15 Management of blood transfusion, including the use of CMV appropriate and irradiated (or equivalent) blood products.

B3.3.4.16 Monitoring and management of mucositis.

B3.3.4.17 Monitoring and management of gastrointestinal complications.

B3.3.4.18 Monitoring and management of pain.

B3.3.4.19 Monitoring and management of neurologic toxicity, including immune effector cell associated neurotoxicity syndrome (ICANS).

B3.3.4.20 Monitoring and management of cardiac dysfunction.

B3.3.4.21 Monitoring and management of renal dysfunction.

B3.3.4.22 Monitoring and management of anaphylaxis.

B3.3.4.23 Monitoring and management of infectious processes, including immunodeficiencies and opportunistic infections.

B3.3.4.24 Diagnosis and management of HPC graft failure.

B3.3.4.25 Diagnosis and management of dermatologic complications.

B3.3.4.26 Evaluation of post-transplant and other cellular therapy outcomes.

B3.3.4.27 Monitoring and management of cytokine release syndrome.

B3.3.4.28 Monitoring and management of tumor lysis syndrome and macrophage activation syndrome / hemophagocytic lymphohistiocytosis.

B3.3.4.29 Evaluation of late effects of cellular therapy.

B3.3.4.30 Documentation and reporting for patients on investigational protocols.

B3.3.4.31 Reporting responsibilities for adverse events according to Applicable Law.

B3.3.4.32 Palliative and end of life care.

B3.3.4.33 Age-specific donor and recipient care.

B3.3.5 Additional specific clinical training and competence required for physicians in Clinical Programs requesting accreditation for allogeneic HPC transplantation shall include:

B3.3.5.1 Identification, evaluation, and selection of HPC source, including use of donor registries.

B3.3.5.2 Donor eligibility determination.

B3.3.5.3 Methodology and implications of HLA typing.

B3.3.5.4 Methodology and implications of testing for chimerism.

B3.3.5.5 Management of patients receiving ABO incompatible HPC products.

B3.3.5.6 Diagnosis and management of acute and chronic GVHD.

B3.3.6 The attending physicians shall be knowledgeable in the following procedures:

B3.3.6.1 Apheresis collection procedures.

B3.3.6.2 Bone marrow harvest procedures.

B3.3.6.3 Cellular therapy product processing, including washing and diluting.

B3.3.6.4 Cellular therapy product cryopreservation.

B3.3.6.5 Cellular therapy product administration procedures.

B3.3.6.6 Extracorporeal photopheresis for GVHD.

B3.4 PHYSICIANS-IN-TRAINING

B3.4.1 Physicians-in-training shall be licensed to practice in the jurisdiction of the Clinical Program and shall be limited to a scope of practice within the parameters of their training and licensure and shall be appropriately supervised.

B3.4.2 Physicians-in-training shall receive specific training and develop competence in transplant and cellular therapy-related skills included within, but not limited to, those listed in B3.3.4 and B3.3.5.

B3.5 ADVANCED PRACTICE PROVIDERS/PROFESSIONALS (APPs)

B3.5.1 APPs shall be licensed to practice in the jurisdiction of the Clinical Program and shall be limited to a scope of practice within the parameters of their training and licenses.

B3.5.2 APPs shall have received specific training and maintain competence in the transplant and cellular therapy-related skills that they practice included within, but not limited to, those listed in B3.3.4 and B3.3.5.

B3.5.3 APPs shall participate in a minimum of ten (10) hours of educational activities related to cellular therapy annually.

B3.5.3.1 Continuing education shall include, but is not limited to, activities related to the field of HPC transplantation and other cellular therapies.

B3.6 NURSES

B3.6.1 The Clinical Program shall have nurses formally trained and experienced in the management of patients receiving cellular therapy.

B3.6.1.1 Nurses shall be trained in age-specific management of patients receiving cellular therapy.

B3.6.1.2 Clinical Programs treating pediatric recipients shall have nurses formally trained and experienced in the management of pediatric patients receiving cellular therapy.

B3.6.2 Nurses shall have received specific training and maintain competence in the transplant and cellular therapy-related skills that they practice including:

B3.6.2.1 Hematology/oncology patient care, including an overview of the cellular therapy process.

B3.6.2.2 Administration of preparative regimens.

B3.6.2.3 Administration of cellular therapy products, including HPC, IEC, genetically modified cells, and other cellular therapies.

B3.6.2.4 Administration of blood products, growth factors, and other supportive therapies.

B3.6.2.5 Care interventions to manage cellular therapy complications, including, but not limited to, cytokine release syndrome, tumor lysis syndrome, cardiac dysfunction, respiratory distress, neurologic toxicity, macrophage activation syndrome, renal and hepatic failure, disseminated intravascular coagulation, anaphylaxis, neutropenic fever, infectious and noninfectious processes, mucositis, nausea and vomiting, and pain management.

B3.6.2.6 Recognition of cellular therapy complications and emergencies requiring rapid notification of the transplant team.

B3.6.2.7 Palliative and end of life care.

B3.6.3 There shall be an adequate number of nurses experienced in the care of transplant recipients.

B3.6.4 There shall be a nurse/recipient ratio satisfactory to manage the severity of the recipients' clinical status.

B3.7 PHARMACISTS

B3.7.1 Pharmacists shall be licensed to practice in the jurisdiction of the Clinical Program and shall be limited to a scope of practice within the parameters of their training and licensure.

B3.7.2 Training and knowledge of designated pharmacists shall include:

B3.7.2.1 Hematology/oncology patient care, including the process of cellular therapy.

B3.7.2.2 Adverse events including, but not limited to, cytokine release syndrome and neurological toxicities.

B3.7.2.3 Therapeutic drug monitoring, including, but not limited to, anti-infective agents, immunosuppressive agents, anti-seizure medications, and anticoagulants.

B3.7.2.4 Monitoring for and recognition of drug/drug and drug/food interactions and necessary dose modifications.

B3.7.2.5 Recognition of medications that require adjustment for organ dysfunction.

B3.7.3 Designated pharmacists shall be involved in the development and implementation of controlled documents related to the pharmaceutical management of cellular therapy recipients.

B3.7.4 Designated pharmacists shall participate in a minimum of ten (10) hours of educational activities related to cellular therapy annually.

B3.7.4.1 Continuing education shall include, but is not limited to, activities related to the field of HPC transplantation and other cellular therapies.

B3.8 CONSULTING SPECIALISTS

B3.8.1 The Clinical Program shall have access to certified or trained consulting specialists and/or specialist groups from key disciplines who are capable of assisting in the management of recipients and donors requiring medical care, including, but not limited to:

B3.8.1.1 Cardiology.

B3.8.1.2 Dermatology.

B3.8.1.3 Gastroenterology.

B3.8.1.4 Infectious disease.

B3.8.1.5 Intensive care.

B3.8.1.6 Nephrology.

B3.8.1.7 Neurology.

B3.8.1.8 Obstetrics/Gynecology.

B3.8.1.9 Ophthalmology.

B3.8.1.10 Palliative and end of life care.

B3.8.1.11 Pathology.

B3.8.1.12 Psychiatry.

B3.8.1.13 Pulmonary medicine.

B3.8.1.14 Radiation oncology with experience in large-field (e.g., total body or total lymphoid) irradiation treatment protocols, if radiation therapy is administered.

B3.8.1.15 Radiology.

B3.8.1.16 Surgery.

B3.8.1.17 Transfusion medicine.

B3.8.2 A Clinical Program treating pediatric donors and recipients shall have consultants, as defined in B3.8.1, qualified to manage pediatric patients.

B3.9 QUALITY MANAGER

B3.9.1 There shall be a Clinical Program Quality Manager to establish and maintain systems to review, modify, and approve all policies and Standard Operating Procedures intended to monitor compliance with these Standards or the performance of the Clinical Program.

B3.9.2 The Clinical Program Quality Manager should have a reporting structure independent of cellular therapy product manufacturing.

B3.9.3 The Clinical Program Quality Manager shall participate in a minimum of ten (10) hours annually of continuing education activities.

B3.9.3.1 Continuing education activities shall include cellular therapy and Quality Management.

B3.10 DATA MANAGEMENT STAFF

B3.10.1 There shall be data management staff sufficient to comply with B9.

B3.10.2 Defined data management staff should participate in continuing education annually.

B3.11 SUPPORT SERVICES STAFF

B3.11.1 The Clinical Program shall have one (1) or more designated staff with appropriate training and education to assist in the provision of pre-transplant recipient evaluation, treatment, and post-transplant follow-up and care. Designated staff shall include:

B3.11.1.1 Dietary staff.

B3.11.1.2 Social Services staff.

B3.11.1.3 Psychology services staff.

B3.11.1.4 Physical therapy staff.

B4: QUALITY MANAGEMENT

B4.1 There shall be an overall Quality Management Program that incorporates key performance data from clinical, collection, and processing facility quality management.

B4.1.1 The Clinical Program Director shall have authority over and responsibility for ensuring that the overall Quality Management Program is effectively established and maintained.

B4.2 The Clinical Program shall establish and maintain a written Quality Management Plan.

B4.2.1 The Clinical Program Director shall be responsible for the Quality Management Plan.

B4.3 The Quality Management Plan shall include, or summarize and reference, an organizational chart of key positions, functions, and reporting relationships within the cellular therapy program, including clinical, collection, and processing.

B4.3.1 The Quality Management Plan shall include a description of how these key positions interact to implement the quality management activities.

B4.4 The Quality Management Plan shall include, or summarize and reference, policies and Standard Operating Procedures addressing personnel requirements for each key position in the Clinical Program. Personnel requirements shall include at a minimum:

B4.4.1 A current job description for all staff.

B4.4.2 A system to document the following for all staff:

B4.4.2.1 Initial qualifications.

B4.4.2.2 New employee orientation.

B4.4.2.3 Initial training, competency, and retraining when appropriate for all procedures performed, and in accordance with Applicable Law.

B4.4.2.4 Continued competency for each critical function performed, assessed annually at a minimum.

B4.4.2.5 Continuing education.

B4.5 The Quality Management Plan shall include, or summarize and reference, a comprehensive system for document control.

B4.5.1 There shall be identification of the types of documents that are considered critical and shall comply with the document control system requirements. Controlled documents shall include at a minimum:

B4.5.1.1 Policies, protocols, Standard Operating Procedures, and guidelines.

B4.5.1.2 Worksheets.

B4.5.1.3 Forms.

B4.5.1.4 Labels.

B4.5.2 There shall be policies or Standard Operating Procedures for the development, approval, implementation, distribution, review, revision, and archival of all critical documents.

B4.5.3 The document control system shall include:

B4.5.3.1 A standardized format for critical documents.

B4.5.3.2 Assignment of a numeric or alphanumeric identifier and a title to each document and document version regulated within the system.

B4.5.3.3 A system for document approval, including the approval date, signature of approving individual(s), and the effective date.

B4.5.3.4 A system to protect controlled documents from accidental or unauthorized modification.

B4.5.3.5 Review of controlled documents every two (2) years at a minimum.

B4.5.3.6 A system for document change control that includes a description of the change, version, the signature of approving individual(s), approval date(s), communication or training on the change as applicable, effective date, and archival date.

B4.5.3.7 Archival of controlled documents, the inclusive dates of use, and their historical sequence for a minimum of ten (10) years from archival or according to governmental or institutional policy, whichever is longer.

B4.5.3.8 A system for the retraction of obsolete documents to prevent unintended use.

B4.6 The Quality Management Plan shall include, or summarize and reference, policies and Standard Operating Procedures for the establishment and maintenance of written agreements.

B4.6.1 Agreements shall be established with external parties providing critical services that could affect the quality and safety of the cellular therapy product or health and safety of the donor or recipient.

B4.6.2 Agreements shall include the responsibility of the external party performing any step in collection, processing, testing, storage, distribution, or administration to maintain required accreditations and to comply with Applicable Law and these Standards.

B4.6.2.1 Agreements should include the responsibility of the external parties to provide clinically relevant information related to products or services.

B4.6.3 Agreements shall be dated and reviewed on a regular basis, at a minimum every two (2) years.

B4.7 The Quality Management Plan shall include, or summarize and reference, policies and Standard Operating Procedures for documentation and review of outcome analysis and cellular therapy product efficacy to verify that the procedures in use consistently provide a safe and effective product.

B4.7.1 Criteria for cellular therapy product safety, product efficacy, and the clinical outcome shall be determined and shall be reviewed at regular time intervals.

B4.7.2 Both individual cellular therapy product data and aggregate data for each type of cellular therapy product and recipient type shall be evaluated.

B4.7.3 Review of outcome analysis and/or product efficacy shall include at a minimum:

B4.7.3.1 For HPC products intended for hematopoietic reconstitution, time to neutrophil and platelet engraftment following cellular therapy product administration.

B4.7.3.2 For immune effector cells, including donor lymphocyte infusions, an endpoint of clinical function as approved by the Clinical Program Director.

B4.7.3.3 For genetically modified HPC products, an endpoint of clinical function as approved by the Clinical Program Director.

B4.7.3.4 Overall and treatment-related morbidity and mortality at thirty (30) days, one hundred (100) days, and one (1) year after cellular therapy product administration.

B4.7.3.5 Acute GVHD grade within one hundred (100) days after allogeneic transplantation.

B4.7.3.6 Chronic GVHD grade within one (1) year after allogeneic transplantation.

B4.7.3.7 Central venous catheter infection.

B4.7.4 Data on outcome analysis and cellular therapy product efficacy, including adverse events related to the recipient, donor, or product, shall be provided in a timely manner to entities involved in the collection, processing, and/or distribution of the cellular therapy product.

B4.7.5 The Clinical Program should achieve one-year survival outcome within or above the expected range when compared to national or international outcome data.

B4.7.5.1 If expected one-year survival outcome is not met, the Clinical Program shall implement a corrective action plan that meets FACT or JACIE requirements.

B4.7.6 The Clinical Program should set benchmarks for non-relapse mortality at one hundred (100) days after cellular therapy product administration and describe the rationale and process for review in the Quality Management Plan.

B4.8 The Quality Management Plan shall include, or summarize and reference, policies and Standard Operating Procedures for, and a schedule of, audits of the Clinical Program's activities to verify compliance with elements of the Quality Management Program and policies and Standard Operating Procedures, Applicable Law, and these Standards.

B4.8.1 Audits shall be conducted by an individual with sufficient knowledge in the process and competence in auditing to identify problems, but who is not solely responsible for the process being audited.

B4.8.2 The results of audits shall be used to recognize problems, detect trends, identify improvement opportunities, implement corrective and preventive actions when necessary, and follow-up on the effectiveness of these actions in a timely manner.

B4.8.3 Audits shall be performed annually at a minimum, and shall include at least the following:

B4.8.3.1 Audit of the accuracy of clinical data.

B4.8.3.2 Audit of the accuracy of the data contained in the Transplant Essential Data Forms of the CIBMTR or the Minimum Essential Med-A Forms of the EBMT.

B4.8.3.3 Audit of donor screening and testing.

B4.8.3.4 Audit of management of cellular therapy products with positive microbial culture results.

B4.8.3.5 Audit of safety endpoints and immune effector cellular therapy toxicity management.

B4.8.3.6 Audit of documentation that external facilities performing critical contracted services have met the requirements of the written agreements.

B4.8.3.7 Audit of verification of chemotherapy drug administered against the written order.

B4.8.3.8 Audit of the prescription ordering system against the protocol.

B4.9 The Quality Management Plan shall include, or summarize and reference, policies and Standard Operating Procedures for the management of cellular therapy products with positive microbial culture results that address at a minimum:

B4.9.1 Criteria for the administration of cellular therapy products with positive microbial culture results.

B4.9.2 Notification of the recipient.

B4.9.3 Recipient follow-up and outcome analysis.

B4.9.4 Follow-up of the donor, if relevant.

B4.9.5 Investigation of cause.

B4.9.6 Reporting to regulatory agencies if appropriate.

B4.10 The Quality Management Plan shall include, or summarize and reference, policies and Standard Operating Procedures for occurrences (errors, accidents, deviations, adverse events, adverse reactions, and complaints). The following activities shall be included at a minimum:

B4.10.1 Detection.

B4.10.2 Investigation.

B4.10.2.1 A thorough and timely investigation shall be conducted by the Clinical Program in collaboration with the Collection Facility, Processing Facility, and other entities involved in the manufacture of the cellular therapy product, as appropriate.

B4.10.2.2 Investigations shall identify the root cause and a plan for short- and long-term corrective and preventive actions as warranted.

B4.10.2.3 Occurrences shall be tracked and trended.

B4.10.3 Documentation.

B4.10.3.1 Documentation shall include a description of the occurrence, date and time of the occurrence, the involved individuals and cellular therapy product(s), when and to whom the occurrence was reported, and the immediate actions taken.

B4.10.3.2 All investigation reports shall be reviewed in a timely manner by the Clinical Program Director and Quality Manager.

B4.10.3.3 Cumulative files of occurrences shall be maintained and include written investigation reports containing conclusions, follow-up, corrective and preventive actions, and a link to the records of the involved cellular therapy products, donors, and recipients, if applicable.

B4.10.4 Reporting.

B4.10.4.1 When it is determined that a cellular therapy product has resulted in an adverse event or reaction, the event and results of the investigation shall be reported to the donor's and recipient's physician(s), as applicable, other facilities participating in the manufacturing of the cellular therapy product, registries, and governmental agencies as required by Applicable Law.

B4.10.4.2 Occurrences shall be reported to other facilities performing cellular therapy product functions on the affected cellular therapy product and to the appropriate regulatory and accrediting agencies, registries, grant agencies, sponsors, IRBs, or Ethics Committees.

B4.10.5 Corrective and preventive action.

B4.10.5.1 Appropriate action shall be implemented if indicated, including both short-term action to address the immediate problem and long-term action to prevent the problem from recurring.

B4.10.5.2 Follow-up audits of the effectiveness of corrective and preventive actions shall be performed in a timeframe as indicated in the investigative report.

B4.11 The Quality Management Plan shall include, or summarize and reference, policies and Standard Operating Procedures for cellular therapy product chain of identity and chain of custody that allow tracking from the donor to the recipient or final disposition and tracing from the recipient or final disposition to the donor.

B4.12 The Quality Management Plan shall include, or summarize and reference, policies and Standard Operating Procedures for actions to take in the event the Clinical Program's operations are interrupted.

B4.13 The Quality Management Plan shall include, or summarize and reference, policies and Standard Operating Procedures for qualification of critical manufacturers, vendors, equipment, software, supplies, reagents, facilities, and services.

B4.13.1 Qualification shall be required following any significant changes to these items.

B4.13.2 Critical equipment, software, supplies, reagents, and facilities used for the marrow or other cellular collection procedures shall be qualified.

B4.13.3 Qualification plans shall include minimum acceptance criteria for performance.

B4.13.4 Qualification plans, results, and reports shall be reviewed and approved by the Quality Manager and Clinical Program Director.

B4.14 The Quality Management Plan shall include, or summarize and reference, policies and Standard Operating Procedures for validation or verification of critical procedures.

B4.14.1 Critical procedures to be validated shall include at least the following: marrow or other cellular collection procedures, labeling, storage, distribution, preparation for administration, and infusion.

B4.14.2 Validation studies for a procedure shall be retained at a minimum until the procedure is no longer in use.

B4.14.3 Each validation or verification shall include at a minimum:

B4.14.3.1 An approved plan, including conditions to be assessed.

B4.14.3.2 Acceptance criteria.

B4.14.3.3 Data collection.

B4.14.3.4 Evaluation of data.

B4.14.3.5 Summary of results.

B4.14.3.6 References, if applicable.

B4.14.3.7 Review and approval of the plan, report, and conclusion by the Quality Manager and the Clinical Program Director.

B4.14.4 Significant changes to critical procedures shall be validated and verified as appropriate.

B4.15 The Quality Management Plan shall include, or summarize and reference, policies and Standard Operating Procedures for the evaluation of risk in changes to a process to confirm that the changes do not create an adverse impact or inherent risk elsewhere in the operation.

B4.15.1 Evaluation of risk shall be completed for changes in critical procedures.

B4.16 The Quality Management Plan shall include, or summarize and reference, policies and Standard Operating Procedures for obtaining feedback.

B4.16.1 Feedback shall be obtained from associated Collection and Processing Facilities.

B4.16.2 Feedback shall be obtained from donors and recipients or legally authorized representatives.

B4.17 The Clinical Program Director shall review the quality management activities with representatives in key positions in all elements of the cellular therapy program, at a minimum, quarterly.

B4.17.1 Meetings shall have defined attendees, documented minutes, and assigned actions.

B4.17.2 Performance data and review findings shall be reported to key positions and staff.

B4.17.3 The Clinical Program Director shall not have oversight of his/her own work if this person also performs other tasks in the Clinical Program.

B4.18 The Clinical Program Director shall annually review the effectiveness of the overall Quality Management Program.

B4.18.1 The annual report and documentation of the review findings shall be made available to key personnel, the Collection Facility Director, the Processing Facility Director, and staff of the program.

B5: POLICIES AND STANDARD OPERATING PROCEDURES

B5.1 The Clinical Program shall establish and maintain policies or Standard Operating Procedures addressing critical aspects of operations and management in addition to those required in B4. These documents shall include all elements required by these Standards and shall address at a minimum:

B5.1.1 Recipient evaluation, selection, and treatment across the continuum of cellular therapy care.

B5.1.2 Donor and recipient confidentiality.

B5.1.3 Donor and recipient informed consent related to treatment and cellular therapy product collection and storage.

B5.1.4 Donor search and selection, including screening, testing, eligibility determination, selection, and management.

B5.1.5 Management of donors and recipients who require central venous access.

B5.1.6 Administration of the preparative regimen.

B5.1.7 Administration of cytotoxic and immunosuppressive therapy.

B5.1.8 Administration of HPC and other cellular therapy products, including products under exceptional release.

B5.1.9 Management of ABO-incompatible products including indications for red blood cell or plasma reduction.

B5.1.10 Care of immunocompromised recipients.

B5.1.11 Administration of blood products.

B5.1.12 Management of cytokine release syndrome and central nervous system toxicities.

B5.1.13 Monitoring patients post IEC administration, including recognition of cellular therapy complications and emergencies requiring rapid notification of the responsible clinical team.

B5.1.14 Provision of appropriate long-term follow-up care.

B5.1.15 Duration and conditions of cellular therapy product storage and indications for disposal.

B5.1.16 Data management.

B5.1.17 Hygiene and use of personal protective equipment and attire.

B5.1.18 Disposal of medical and biohazard waste.

B5.1.18.1 When genetically modified cellular therapy products are utilized in the Clinical Program, the program shall incorporate or reference institutional or regulatory requirements relating to biosafety practices, including disposal.

B5.1.19 Cellular therapy emergency and disaster plan, including the Clinical Program response.

B5.2 The Clinical Program shall maintain a detailed list of all controlled documents including title and identifier.

B5.3 Standard Operating Procedures shall be sufficiently detailed and unambiguous to allow qualified staff to follow and complete the procedures successfully. Each individual Standard Operating Procedure shall include:

B5.3.1 A clearly written description of the objectives.

B5.3.2 A description of equipment and supplies used.

B5.3.3 Acceptable end-points and the range of expected results.

B5.3.4 A stepwise description of the procedure.

B5.3.5 Reference to other Standard Operating Procedures or policies required to perform the procedure.

B5.3.6 Age-specific issues where relevant.

B5.3.7 A reference section listing appropriate and current literature.

B5.3.8 Documented approval of each procedure by the Clinical Program Director or designated physician prior to implementation and every two (2) years thereafter.

B5.3.9 Documented approval of each procedural modification by the Clinical Program Director or designated physician prior to implementation.

B5.3.10 Reference to a current version of orders, worksheets, reports, labels, and forms.

B5.4 Controlled documents relevant to processes being performed shall be readily available to the facility staff.

B5.5 Staff review and, if appropriate, training and competency shall be documented before performing a new or revised Standard Operating Procedure or guideline.

B5.6 All personnel shall follow the policies and Standard Operating Procedures related to their positions.

B5.7 Planned deviations shall be pre-approved by the Clinical Program Director and reviewed by the Quality Manager.

B6: ALLOGENEIC AND AUTOLOGOUS DONOR SELECTION, EVALUATION, AND MANAGEMENT

B6.1 There shall be written criteria for allogeneic and autologous donor selection, evaluation, and management by trained medical personnel.

B6.1.1 Written criteria shall include criteria for the selection of allogeneic donors who are minors or older donors.

B6.2 ALLOGENEIC AND AUTOLOGOUS DONOR INFORMATION AND CONSENT TO DONATE

B6.2.1 The collection procedure shall be explained in terms the donor can understand, and shall include the following information at a minimum:

B6.2.1.1 The risks and benefits of the procedure.

B6.2.1.2 Tests and procedures performed on the donor to protect the health of the donor and the recipient.

B6.2.1.3 The rights of the donor or legally authorized representative to review the results of such tests according to Applicable Law.

B6.2.1.4 Alternative collection methods.

B6.2.1.5 Protection of medical information and confidentiality.

B6.2.2 Interpretation and translation shall be performed by individuals qualified to provide these services in the clinical setting.

B6.2.2.1 Family members and legally authorized representatives shall not serve as interpreters or translators.

B6.2.3 The donor shall have an opportunity to ask questions.

B6.2.4 The donor shall have the right to refuse to donate or withdraw consent.

B6.2.4.1 The allogeneic donor shall be informed of the potential consequences to the recipient of such refusal in the event that consent is withdrawn after the recipient begins the preparative regimen.

B6.2.5 Donor informed consent for the cellular therapy product donation shall be obtained and documented by a licensed health care professional knowledgeable in the collection procedure.

B6.2.5.1 Informed consent from the allogeneic donor shall be obtained by a licensed health care professional who is not the primary health care professional overseeing care of the recipient.

B6.2.6 In the case of a donor who is a minor, informed consent shall be obtained from the donor's legally authorized representative in accordance with Applicable Law and shall be documented.

B6.2.7 The allogeneic donor shall give informed consent and authorization prior to release of the donor's health or other information to the recipient's physician or the recipient.

B6.2.8 The donor shall be informed of the policy for cellular therapy product storage, discard, or disposal, including actions taken when an intended recipient no longer requires the cellular therapy product.

B6.2.9 Documentation of consent shall be available to the Collection Facility staff prior to the collection procedure.

B6.3 ALLOGENEIC AND AUTOLOGOUS DONOR SUITABILITY FOR CELLULAR THERAPY PRODUCT COLLECTION

B6.3.1 There shall be criteria and evaluation policies or Standard Operating Procedures in place to protect the safety of donors during the process of cellular therapy product collection.

B6.3.1.1 The Clinical Program shall confirm that clinically significant findings are reported to the prospective donor with documentation in the donor record of recommendations made for follow-up care.

B6.3.1.2 Allogeneic donor suitability shall be evaluated by a licensed health care professional who is not the primary health care professional overseeing care of the recipient.

B6.3.1.3 Autologous donors shall be tested as required by Applicable Law.

B6.3.2 The risks of donation shall be evaluated and documented, including:

B6.3.2.1 Possible need for central venous access.

B6.3.2.2 Mobilization for collection of HPC, Apheresis.

B6.3.2.3 Anesthesia for collection of HPC, Marrow.

B6.3.3 The donor shall be evaluated for the risk of hemoglobinopathy prior to administration of the mobilization regimen.

B6.3.4 Appropriate mobilization should be used for the disease being treated and for the donor being collected.

B6.3.5 A pregnancy test shall be performed for all female donors with childbearing potential within seven (7) days prior to starting the donor mobilization regimen or undergoing anesthesia, and, as applicable, within seven (7) days prior to the initiation of the recipient's preparative regimen.

B6.3.6 Laboratory testing of all donors shall be performed by a laboratory that is accredited, registered, certified, or licensed in accordance with Applicable Law.

B6.3.7 The Clinical Program shall inform the Collection Facility and Processing Facility of donor test results or if any testing was not performed.

B6.3.8 There shall be a written order from a physician specifying, at a minimum, anticipated date and goals of collection and processing.

B6.3.9 Collection from a donor who does not meet collection safety criteria shall require documentation of the rationale for his/her selection by the donor's physician.

B6.3.9.1 Issues of donor health that pertain to the safety of the collection procedure shall be communicated in writing to the Collection Facility staff prior to collection.

B6.3.10 There shall be written guidelines for communication between the Clinical Program and the Collection Facility or registry for the management of collection-related complications.

B6.3.11 There shall be policies or Standard Operating Procedures for follow-up of donors that include routine management and the management of collection-associated adverse events.

B6.4 ADDITIONAL REQUIREMENTS FOR ALLOGENEIC DONORS

B6.4.1 Written criteria shall include criteria for the selection of allogeneic donors when more than one (1) donor is available and suitable.

B6.4.2 Information regarding the donation process should be provided, including the considerations for donation, to the potential allogeneic donor prior to HLA typing.

B6.4.3 A donor advocate shall be available to represent allogeneic donors who are minors or who are mentally incapacitated, as those terms are defined by Applicable Law.

B6.4.4 Allogeneic donor infectious disease testing shall be performed using donor screening tests licensed, approved, or cleared by the governmental authority.

B6.4.5 Allogeneic donors and allogeneic recipients shall be tested for ABO group and Rh type using two independently collected samples. Discrepancies shall be resolved and documented prior to issue of the cellular therapy product.

B6.4.6 A red blood cell antibody screen shall be performed on allogeneic recipients.

B6.4.7 Allogeneic donors shall be evaluated for risk factors that might result in disease transmission from the cellular therapy product by medical history, physical examination, examination of relevant medical records, and laboratory testing.

B6.4.8 The medical history for allogeneic donors shall include at least the following:

B6.4.8.1 Vaccination history.

B6.4.8.2 Travel history.

B6.4.8.3 Blood transfusion history.

B6.4.8.4 Questions to identify persons at high risk for transmission of communicable disease as defined by the applicable governmental authority.

B6.4.8.5 Questions to identify persons at risk of transmitting inherited conditions.

B6.4.8.6 Questions to identify persons at risk of transmitting a hematological or immunological disease.

B6.4.8.7 Questions to identify a past history of malignant disease.

B6.4.8.8 The allogeneic donor shall confirm that all the information provided is true to the best of his/her knowledge.

B6.4.9 Allogeneic donors shall be tested for evidence of clinically relevant infection by the following communicable disease agents using tests required by Applicable Law:

B6.4.9.1 Human immunodeficiency virus, type 1.

B6.4.9.2 Human immunodeficiency virus, type 2.

B6.4.9.3 Hepatitis B virus.

B6.4.9.4 Hepatitis C virus.

B6.4.9.5 *Treponema pallidum* (syphilis).

B6.4.10 If required by Applicable Law, allogeneic donors shall also be tested for evidence of clinically relevant infection by the following disease agents:

B6.4.10.1 Human T cell lymphotropic virus I.

B6.4.10.2 Human T cell lymphotropic virus II.

B6.4.10.3 West Nile Virus.

B6.4.10.4 *Trypanosoma cruzi* (Chagas Disease).

B6.4.11 Blood samples for testing for evidence of clinically relevant infection shall be drawn and tested within timeframes required by Applicable Law.

B6.4.11.1 Blood samples from allogeneic donors of HPC, Apheresis or HPC, Marrow for communicable disease testing shall be obtained within thirty (30) days prior to collection.

B6.4.11.2 For viable lymphocyte-rich cells, including mononuclear cells and other cellular therapy products, blood samples from allogeneic donors shall be obtained within seven (7) days prior to or after collection, or in accordance with Applicable Law.

B6.4.12 Allogeneic donors shall be tested for cytomegalovirus (unless previously documented to be positive).

B6.4.13 Additional tests shall be performed as required to assess the possibility of transmission of other infectious and non-infectious diseases.

B6.4.14 Allogeneic donors and recipients shall be tested for HLA alleles by a laboratory accredited by ASHI, EFI, CAP, or other appropriate organization. Typing shall include at a minimum HLA-A, B, and DRB1 type for all allogeneic donors and also HLA-C type for unrelated allogeneic donors and related allogeneic donors other than siblings.

B6.4.14.1 DNA high resolution molecular typing shall be used for HLA typing.

B6.4.14.2 Verification typing shall be performed on the recipient and selected allogeneic donor using independently collected samples. Results shall be confirmed prior to administration of the preparative regimen, mobilization, or cellular therapy product collection, whichever is earliest.

B6.4.14.3 There shall be a policy or Standard Operating Procedure to confirm the identity of cord blood units if verification typing cannot be performed on attached segments.

B6.4.14.4 There shall be a policy or Standard Operating Procedure for anti-HLA antibody testing for mismatched donors and recipients.

B6.4.15 Allogeneic donor eligibility, as defined by Applicable Law, shall be determined by a licensed health care provider after history, exam, medical record review, and testing. The donor eligibility determination shall be documented in the recipient's medical record before the recipient's preparative regimen is initiated and before the allogeneic donor begins the mobilization regimen.

B6.4.16 Records required for donor eligibility determination shall be in English or translated into English when crossing international borders.

B6.4.17 The use of an ineligible allogeneic donor, or an allogeneic donor for whom donor eligibility determination is incomplete, shall require documentation of the rationale for his/her selection by the transplant physician, urgent medical need documentation, and the informed consent of the donor and the recipient.

B6.4.18 Allogeneic donor eligibility shall be communicated in writing to the Collection and Processing Facilities.

B6.4.19 There shall be a policy for the creation and retention of allogeneic donor records.

B6.4.19.1 Allogeneic donor records shall include donor eligibility determination, including the name of the responsible person who made the determination and the date of the determination.

B7: RECIPIENT CARE

B7.1 Recipient informed consent for the cellular therapy shall be obtained and documented by a licensed health care professional knowledgeable in the proposed cellular therapy.

B7.1.1 The informed consent process shall include information regarding the risks and benefits of the proposed cellular therapy.

B7.2 The attending physician shall confirm the availability and suitability of a donor or cellular therapy product prior to initiating the recipient's preparative regimen.

B7.2.1 The Clinical Program shall notify the Processing Facility prior to requesting a cellular therapy product from a cord blood bank, registry, or other facility.

B7.3 Records shall be made concurrently with each step of recipient care in such a way that all steps may be accurately traced.

B7.3.1 Records shall identify the person immediately responsible for each significant step, including dates and times (where appropriate) of various steps.

B7.4 There shall be policies addressing safe administration of the preparative regimen.

B7.4.1 The treatment orders shall include the patient's current height and weight, specific dates of administration, daily doses (if appropriate), and route of administration of each agent.

B7.4.2 Preprinted orders or electronic equivalent shall be used for protocols and standardized regimens. These orders shall be verified and documented by an attending physician.

B7.4.3 The pharmacist verifying or preparing the drug shall check and document the doses against the protocol or standardized regimen listed on the orders.

B7.4.4 Prior to administration of the preparative regimen, one (1) qualified person using a validated process or two (2) qualified persons shall verify and document:

B7.4.4.1 The drug and dose in the bag or pill against the orders and the protocol or standardized regimen.

B7.4.4.2 The identity of the recipient.

B7.5 There shall be policies addressing safe administration of radiation therapy.

B7.5.1 There shall be a consultation with a radiation oncologist prior to initiation of therapy if radiation treatment is used in the preparative regimen.

B7.5.2 The recipient's diagnosis, relevant medical history including pre-existing co-morbid conditions, and proposed preparative regimen shall be made available to the consulting radiation oncologist in writing.

B7.5.3 A documented consultation by a radiation oncologist shall address any prior radiation treatment the recipient may have received, any other factors that may increase the toxicity of the radiation, and include a plan for delivery of radiation therapy.

B7.5.4 Prior to administration of each dose of radiation therapy, the dose shall be verified and documented as per institutional radiation therapy standards.

B7.5.5 A final report of the details of the radiation therapy administered shall be documented in the recipient's medical record.

B7.6 There shall be policies addressing safe administration of cellular therapy products.

B7.6.1 There shall be policies for determining the appropriate volume and the appropriate dose of red blood cells, cryoprotectants, and other additives.

B7.6.2 There shall be policies for the infusion of ABO-incompatible red blood cells in allogeneic cellular therapy products.

B7.6.3 There shall be consultation with the Processing Facility regarding cord blood preparation for administration.

B7.6.3.1 Cord blood units that have not been red blood cell reduced prior to cryopreservation shall be washed prior to administration.

B7.6.3.2 Cord blood units that have been red blood cell reduced prior to cryopreservation should be diluted or washed prior to administration.

B7.6.4 Two (2) qualified persons shall verify the identity of the recipient and the product and the order for administration prior to the administration of the cellular therapy product.

B7.6.5 When administering cellular therapy products from more than one (1) donor, each cellular therapy product shall be administered safely prior to administration of subsequent cellular therapy products.

B7.6.6 There shall be documentation in the recipient's medical record of the unique identifier of the administered cellular therapy product, initiation and completion times of administration, and any adverse events related to administration.

B7.6.7 A Circular of Information for cellular therapy products shall be available to staff.

B7.7 There shall be policies or Standard Operating Procedures addressing appropriate follow-up of recipients after administration of preparative regimens and cellular therapy products, including, at a minimum, the management of the following elements:

B7.7.1 Management of nausea, vomiting, pain, and other discomforts.

B7.7.2 Monitoring of blood counts and transfusion of blood products.

B7.7.3 Monitoring of infections and use of antimicrobials.

B7.7.4 Monitoring of organ dysfunction or failure and institution of treatment.

B7.7.5 Monitoring of graft failure and institution of treatment.

B7.7.6 Regular assessment for evidence of acute GVHD using an established staging and grading system.

B7.7.7 Regular assessment for evidence of chronic GVHD using an established staging and grading system.

B7.8 There shall be policies and Standard Operating Procedures addressing the administration of immune effector cells and management of complications, if applicable.

B7.8.1 There shall be a consultation with the referring physician prior to initiation of immune effector cellular therapy to review the goal and plan of the treatment.

B7.8.2 There shall be regular assessment of the recipient to detect complications, including cytokine release syndrome and neurologic dysfunction.

B7.8.3 There shall be a written plan for rapid escalation of care, increased intensity of monitoring, and relevant workup to address complications.

B7.8.4 Communication to the clinical staff, intensive care unit, emergency department, and pharmacy shall be timely.

B7.8.5 The Clinical Program shall have written guidelines for management of complications, including the use of cytokine-blocking agents and corticosteroid administration.

B7.9 Clinical Programs administering licensed, authorized, or equivalent cellular therapy products with a mandated risk management program shall have policies and Standard Operating Procedures in place for the following as required:

B7.9.1 Training and competency.

B7.9.2 For each recipient of the cellular therapy product, availability of required medications to manage severe adverse events.

B7.9.3 Reporting of adverse reactions.

B7.9.4 Wallet cards or other means of communicating instructions to the recipient, caregivers, and other health care professionals who may provide care to the patient.

B7.10 There shall be policies or Standard Operating Procedures in place for planned discharges and provision of post-transplant care.

B7.10.1 When a recipient is discharged prior to engraftment, the Clinical Program shall verify that the following elements are available:

B7.10.1.1 A consult between the attending physician and the receiving health care professionals regarding the applicable elements in Standard B7.7.

B7.10.1.2 Facilities that provide appropriate location, adequate space, and protection from airborne microbial contamination.

B7.10.1.3 Appropriate medications, blood products, and additional care required by the recipient.

B7.10.2 The Clinical Program shall provide appropriate instructions to recipients prior to discharge.

B7.11 There shall be policies addressing indications for and safe administration of ECP if utilized by the Clinical Program.

B7.11.1 There shall be a consultation with the facility or physician that performs ECP prior to initiation of therapy.

B7.11.2 Before ECP is undertaken, there shall be a written therapy plan from an attending physician specifying the patient's diagnosis and GVHD grade, involved organs, timing of the procedure, and any other factors that may affect the safe administration of ECP.

B7.11.3 A report of the details of ECP administered, including an assessment of the response, shall be documented in the recipient's medical record.

B7.11.4 The facility performing ECP shall be qualified to meet FACT-JACIE requirements.

B7.12 There shall be an infrastructure and policies or Standard Operating Procedures in place for provision of appropriate long-term follow-up, treatment, and plans of care.

B7.12.1 There should be policies or Standard Operating Procedures in place for post-transplant vaccination schedules and indications.

B7.12.2 There shall be policies and Standard Operating Procedures for monitoring by appropriate specialists of recipients for post-cellular therapy late effects, including at a minimum:

B7.12.2.1 Endocrine and reproductive function and osteoporosis.

B7.12.2.2 Cardiovascular risk factors.

B7.12.2.3 Respiratory function.

B7.12.2.4 Chronic renal impairment.

B7.12.2.5 Secondary malignancies.

B7.12.2.6 Growth and development of pediatric patients.

B7.12.3 There shall be policies or Standard Operating Procedures describing the transition of long-term pediatric recipients to adult care as appropriate.

B8: CLINICAL RESEARCH

B8.1 Clinical Programs shall have formal review of investigational protocols and patient consent forms by a process that is approved under institutional policies and Applicable Law.

B8.1.1 Those Clinical Programs utilizing investigational treatment protocols shall have in place a pharmacy equipped for research activities, including a process for tracking, inventory, and secured storage of investigational drugs.

B8.1.2 There shall be a process to manage investigational cellular therapy products.

B8.2 Clinical research protocols shall be performed in accordance with institutional policies and Applicable Law.

B8.2.1 The Clinical Program shall maintain:

B8.2.1.1 Documentation of approval by the Institutional Review Board, Ethics Committee, or equivalent.

B8.2.1.2 If applicable, documentation of approval by the institutional Biosafety Committee or equivalent.

B8.2.1.3 Correspondence with regulatory agencies.

B8.2.1.4 Audits and any adverse events, including their resolution.

B8.3 For clinical research, informed consent shall be obtained from each research subject or legally authorized representative, in language he or she can understand, and under circumstances that minimize the possibility of coercion or undue influence.

B8.3.1 The research subject or legally authorized representative shall be given the opportunity to ask questions and to have his/her questions answered to his/her satisfaction, and to withdraw from the research without prejudice.

B8.3.2 Informed consent for a research subject shall contain the following elements at a minimum and comply with Applicable Law:

B8.3.2.1 An explanation of the research purposes, a description of the procedures to be followed, and the identification of investigational procedures.

B8.3.2.2 The expected duration of the subject's participation.

B8.3.2.3 A description of the reasonably expected risks, discomforts, benefits to the subject and others, and alternative procedures.

B8.3.2.4 A statement of the extent to which confidentiality will be maintained.

B8.3.2.5 An explanation of the extent of compensation for injury.

B8.4 There shall be a process in place to address the disclosure of any issues that may represent a conflict of interest in clinical research.

B9: DATA MANAGEMENT

B9.1 The Clinical Program shall collect and maintain complete and accurate data necessary to complete the Transplant Essential Data Forms of the CIBMTR or the Minimum Essential Data-A forms of the EBMT.

B9.1.1 Clinical Programs shall submit the data specified in B9.1 for allogeneic and autologous transplants to a national or international database.

B9.1.2 Clinical Programs shall collect the data specified in B9.1 for all patients for at least one (1) year following administration of the cellular therapy product.

B9.1.3 Clinical Programs should meet accuracy criteria established by FACT, JACIE, and CIBMTR or EBMT.

B9.2 The Clinical Program should collect and submit all data elements included in the Cellular Immunotherapy Data Resource (CIDR) forms of the CIBMTR or the Cellular Therapy Med-A forms of the EBMT.

B9.3 The Clinical Program shall define staff responsible for collecting data and, as appropriate, reporting data to institutional repositories and CIBMTR or EBMT.

B10: RECORDS

B10.1 Clinical Program records related to quality control, personnel training and competency, facility maintenance, facility management, complaints, or other general facility issues shall be retained for a minimum of ten (10) years by the Clinical Program, or longer in accordance with Applicable Law.

B10.1.1 Employee records shall be maintained by the Clinical Program in a confidential manner and as long as required by Applicable Law.

B10.1.2 Cleaning and sanitation records shall be retained for at least three (3) years or longer in accordance with Applicable Law or by a defined program or institution policy.

B10.2 Recipient and donor records including, but not limited to, consents and records of care, shall be maintained in a confidential manner as required by Applicable Law for a minimum of ten (10) years after the administration of the cellular therapy product, or, if not known, ten (10) years after the date of the distribution, disposition, or expiration, whichever is latest.

B10.3 Research records shall be maintained in a confidential manner as required by Applicable Law for a minimum of ten (10) years after the administration, distribution, disposition, or expiration of the cellular therapy product, whichever is latest.

B10.4 ELECTRONIC RECORDS

B10.4.1 The Clinical Program shall maintain a current listing of all critical electronic record systems. Critical electronic record systems shall include at a minimum systems under the control of the Clinical Program that are used as a substitute for paper, to make decisions, to perform calculations, or to create or store information used in critical procedures.

B10.4.2 For all critical electronic record systems, there shall be policies, Standard Operating Procedures, and system elements to maintain the accuracy, integrity, identity, and confidentiality of all records.

B10.4.3 There shall be a means by which access to electronic records is limited to authorized individuals.

B10.4.4 The critical electronic record system shall maintain unique identifiers.

B10.4.5 There shall be protection of the records to enable their accurate and ready retrieval throughout the period of record retention.

B10.4.6 For all critical electronic record systems, there shall be an alternative system for all electronic records to allow for continuous operation in the event that critical electronic record systems are not available. The alternative system shall be validated and Clinical Program staff shall be trained in its use.

B10.4.7 For all critical electronic record systems, there shall be written Standard Operating Procedures for record entry, verification, and revision.

B10.4.7.1 A method shall be established or the system shall provide for review of data before final acceptance.

B10.4.7.2 A method shall be established or the system shall provide for the unambiguous identification of the individual responsible for each record entry.

B10.4.8 For all critical electronic record systems, there shall be the ability to generate true copies of the records in both human readable and electronic format suitable for inspection and review.

B10.4.9 For all critical electronic record systems, there shall be validated procedures for and documentation of:

B10.4.9.1 Training and continued competency of personnel in systems use.

B10.4.9.2 Monitoring of data integrity.

B10.4.9.3 Back-up of the electronic records system on a regular schedule.

B10.4.9.4 System assignment of unique identifiers.

B10.5 RECORDS IN CASE OF DIVIDED RESPONSIBILITY

B10.5.1 If two (2) or more facilities participate in the collection, processing, or administration of the cellular therapy product, the records of each facility shall show plainly the extent of its responsibility.

B10.5.2 The Clinical Program shall furnish outcome data, related to the safety, purity, or potency of the cellular therapy product involved, to other facilities involved in the collection or processing of the cellular therapy product.

MARROW COLLECTION FACILITY STANDARDS

PART CM

PART CM: MARROW COLLECTION FACILITY STANDARDS

CM1: GENERAL

CM1.1 These Standards apply to all collection, storage, and distribution activities performed in the Marrow Collection Facility for cellular therapy products.

CM1.2 The Marrow Collection Facility shall use cell processing facilities that meet FACT-JACIE Standards with respect to their interactions with the Marrow Collection Facility.

CM1.3 The Marrow Collection Facility shall abide by Applicable Law.

CM1.3.1 The Marrow Collection Facility shall be licensed, registered, or accredited as required by the appropriate governmental authorities for the activities performed.

CM1.4 The Marrow Collection Facility shall have a Marrow Collection Facility Medical Director, a Quality Manager, and a minimum of one (1) additional designated staff member. This team shall have been in place and performing cellular therapy product collections for at least twelve (12) months preceding initial accreditation.

CM1.5 A minimum of one (1) marrow collection procedure shall have been performed in the twelve (12) month period immediately preceding initial accreditation, and a minimum average of one (1) marrow collection procedure per year shall be performed within each accreditation cycle.

CM2: MARROW COLLECTION FACILITY

CM2.1 There shall be secured and controlled access to designated areas for the collection procedure and for storage of equipment, supplies, and reagents.

CM2.1.1 The Marrow Collection Facility shall be divided into defined areas of adequate size to prevent improper labeling, mix-ups, contamination, or cross-contamination of cellular therapy products.

CM2.1.2 There shall be a process to control storage areas to prevent mix-ups, contamination, and cross-contamination of cellular therapy products.

CM2.1.3 There shall be suitable space for confidential donor examination and evaluation.

CM2.2 The Marrow Collection Facility shall provide adequate lighting, ventilation, and access to sinks for handwashing and to toilets to prevent the introduction, transmission, or spread of communicable disease.

CM2.3 Marrow Collection Facility parameters and environmental conditions shall be controlled to protect the safety and comfort of donors and personnel.

CM2.4 There shall be a written assessment of critical Marrow Collection Facility parameters that may affect cellular therapy product viability, integrity, contamination, or cross-contamination during collection.

CM2.4.1 The written assessment shall include temperature and humidity at a minimum.

CM2.4.2 Critical facility parameters identified to be a risk to the cellular therapy product shall be controlled, monitored, and recorded.

CM2.5 The Marrow Collection Facility shall document facility cleaning and sanitation and maintain order sufficient to achieve adequate conditions for operations.

CM2.6 There shall be adequate equipment and materials for the procedures performed.

CM2.7 There shall be access to an intensive care unit or emergency services.

CM2.8 The Marrow Collection Facility shall be operated in a manner designed to minimize risks to the health and safety of employees, donors, visitors, and volunteers.

CM2.9 The Marrow Collection Facility shall have a written safety manual that includes instructions for action in case of exposure, as applicable, to communicable disease and to chemical, biological, radiological, electrical, or fire hazards.

CM2.10 All waste generated by the Marrow Collection Facility's activities shall be disposed of in a manner that minimizes any hazard to facility personnel and to the environment in accordance with Applicable Law.

CM2.11 Personal protective equipment, including gloves and protective clothing, shall be used while handling biological specimens. Such protective equipment shall not be worn outside the work area.

CM3: PERSONNEL

CM3.1 MARROW COLLECTION FACILITY MEDICAL DIRECTOR

CM3.1.1 There shall be a Marrow Collection Facility Medical Director who is a licensed physician with a minimum of two (2) years postgraduate certification, with training and practical and relevant experience in cellular therapy product collection and transplantation.

CM3.1.2 The Marrow Collection Facility Medical Director shall be responsible for the following elements:

CM3.1.2.1 All technical procedures.

CM3.1.2.2 Performance of the marrow collection procedure.

CM3.1.2.3 Supervision of staff.

CM3.1.2.4 Administrative operations.

CM3.1.2.5 The medical care of allogeneic and autologous donors undergoing marrow collection.

CM3.1.2.6 Pre-collection evaluation of allogeneic and autologous donors at the time of donation.

CM3.1.2.7 Care of any complications resulting from the collection procedure.

CM3.1.2.8 The Quality Management Program, including compliance with these Standards and Applicable Law.

CM3.1.3 The Marrow Collection Facility Medical Director shall have performed or supervised ten (10) marrow collection procedures within his/her career at a minimum.

CM3.1.4 The Marrow Collection Facility Medical Director shall participate in a minimum of ten (10) hours of educational activities related to cellular therapy annually.

CM3.1.4.1 Continuing education shall include, but is not limited to, activities related to the field of HPC transplantation and other cellular therapies.

CM3.2 QUALITY MANAGER

CM3.2.1 There shall be a Marrow Collection Facility Quality Manager to establish and maintain systems to review, modify, and approve all policies and Standard Operating Procedures intended to monitor compliance with these Standards or the performance of the Marrow Collection Facility.

CM3.2.2 The Marrow Collection Facility Quality Manager should have a reporting structure independent of cellular therapy product manufacturing.

CM3.2.3 The Marrow Collection Facility Quality Manager shall participate in a minimum of ten (10) hours annually of continuing education activities.

CM3.2.3.1 Continuing education activities shall include cellular therapy, cell collection, and Quality Management.

CM3.3 STAFF

CM3.3.1 The Marrow Collection Facility shall have access to licensed health care professionals who are trained and competent in marrow collection.

CM3.3.2 The number of trained collection personnel shall be adequate for the number of procedures performed and shall include a minimum of one (1) designated trained individual with an identified trained backup individual to maintain sufficient coverage.

CM3.3.3 For Marrow Collection Facilities collecting cellular therapy products from pediatric donors, physicians and collection staff shall have documented training and experience with pediatric donors.

CM3.3.4 Physicians and collection staff shall have annual training in current GxP appropriate to the processes performed in accordance with Applicable Law.

CM3.3.5 There shall be attending physician oversight if general medical physicians, physicians in training, or APPs provide care to the cellular therapy donors.

CM3.3.5.1 The scope of responsibility of general medical physicians or APPs shall be defined.

CM4: QUALITY MANAGEMENT

CM4.1 The Marrow Collection Facility shall comply with B4 if it operates independently of a Clinical Program.

CM4.1.1 Agreements shall be established when the Marrow Collection Facility provides critical services to external parties.

CM5: POLICIES AND STANDARD OPERATING PROCEDURES

CM5.1 The Marrow Collection Facility shall establish and maintain policies or Standard Operating Procedures addressing critical aspects of operations and management in addition to those required in CM4. These documents shall include all elements required by these Standards and shall address at a minimum:

CM5.1.1 Donor and recipient confidentiality.

CM5.1.2 Donor informed consent for cellular therapy product collection.

CM5.1.3 Donor screening, testing, eligibility and suitability determination, and management.

CM5.1.4 Donor age-specific and size-specific issues where relevant.

CM5.1.5 Cellular therapy product collection.

CM5.1.6 Administration of blood products.

CM5.1.7 Prevention of mix-ups and cross-contamination.

CM5.1.8 Labeling (including associated forms and samples).

CM5.1.9 Cellular therapy product expiration dates.

CM5.1.10 Cellular therapy product storage.

CM5.1.11 Release and exceptional release.

CM5.1.12 Packaging, transportation, and shipping.

CM5.1.12.1 Methods and conditions to be used for distribution to external facilities.

CM5.1.12.2 Use of additives for long duration of shipment.

CM5.1.13 Critical equipment, reagent, and supply management including recalls and corrective actions in the event of failure.

CM5.1.14 Hygiene and use of personal protective equipment and attire.

CM5.1.15 Disposal of medical and biohazard waste.

CM5.1.16 Cellular therapy emergency and disaster plan related to the marrow collection procedure.

CM5.2 The Marrow Collection Facility shall comply with B5.2 if it operates independently of a Clinical Program.

CM5.3 Standard Operating Procedures in CM5.1 shall be sufficiently detailed and unambiguous to allow qualified staff to follow and complete the procedures successfully. Each individual Standard Operating Procedure shall include:

CM5.3.1 A clearly written description of the objectives.

CM5.3.2 A description of equipment and supplies used.

CM5.3.3 Acceptable end-points and the range of expected results.

CM5.3.4 A stepwise description of the procedure.

CM5.3.5 Reference to other Standard Operating Procedures or policies required to perform the procedure.

CM5.3.6 A reference section listing appropriate and current literature.

CM5.3.7 Reference to a current version of collection orders, worksheets, reports, labels, and forms.

CM5.3.8 Documented approval of each procedure by the Marrow Collection Facility Medical Director prior to implementation and every two (2) years thereafter.

CM5.3.9 Documented approval of each procedural modification by the Marrow Collection Facility Medical Director or designated physician prior to implementation.

CM5.4 Controlled documents relevant to processes being performed shall be readily available to the facility staff.

CM5.5 Staff training and, if appropriate, competency shall be documented before performing a new or revised Standard Operating Procedure.

CM5.6 All personnel shall follow the policies and Standard Operating Procedures related to their positions.

CM5.7 Planned deviations shall be pre-approved by the Marrow Collection Facility Medical Director and reviewed by the Quality Manager.

CM6: ALLOGENEIC AND AUTOLOGOUS DONOR EVALUATION AND MANAGEMENT

CM6.1 There shall be written criteria for allogeneic and autologous donor evaluation and management by trained medical personnel.

CM6.2 ALLOGENEIC AND AUTOLOGOUS DONOR INFORMATION AND CONSENT FOR COLLECTION

CM6.2.1 The collection procedure shall be explained in terms the donor can understand, and shall include the following information at a minimum:

CM6.2.1.1 The risks and benefits of the procedure.

CM6.2.1.2 Intent of the collection for treatment or research.

CM6.2.1.3 Tests and procedures performed on the donor to protect the health of the donor and the recipient.

CM6.2.1.4 The rights of the donor or legally authorized representative to review the results of such tests according to Applicable Law.

CM6.2.1.5 Protection of medical information and confidentiality.

CM6.2.2 Interpretation and translation shall be performed by individuals qualified to provide these services in the clinical setting.

CM6.2.2.1 Family members and legally authorized representatives shall not serve as interpreters or translators.

CM6.2.3 The donor shall have an opportunity to ask questions.

CM6.2.4 The donor shall have the right to refuse to donate or withdraw consent.

CM6.2.4.1 The allogeneic donor shall be informed of the potential consequences to the recipient of such refusal in the event that consent is withdrawn after the recipient has begun the preparative regimen.

CM6.2.5 Donor informed consent for the cellular therapy product collection shall be obtained and documented by a licensed health care professional knowledgeable in the collection procedure.

CM6.2.5.1 Informed consent from the allogeneic donor shall be obtained by a licensed health care professional who is not the primary health care professional overseeing care of the recipient.

CM6.2.6 In the case of a donor who is a minor, informed consent shall be obtained from the donor's legally authorized representative in accordance with Applicable Law and shall be documented.

CM6.2.7 The allogeneic donor shall give informed consent and authorization prior to release of the donor's health or other information to the recipient's physician or the recipient.

CM6.2.8 The donor shall be informed of the policy for cellular therapy product storage, discard, or disposal, including actions taken when an intended recipient no longer requires the cellular therapy product.

CM6.2.9 Documentation of consent shall be verified by the Marrow Collection Facility staff prior to the collection procedure.

CM6.3 ALLOGENEIC AND AUTOLOGOUS DONOR SUITABILITY FOR CELLULAR THERAPY PRODUCT COLLECTION

CM6.3.1 There shall be criteria and evaluation policies or Standard Operating Procedures in place to protect the safety of donors during the process of cellular therapy product collection.

CM6.3.1.1 The Marrow Collection Facility shall confirm that clinically significant findings are reported to the prospective donor with documentation in the donor record of recommendations made for follow-up care.

CM6.3.1.2 Allogeneic donor suitability shall be evaluated by a licensed health care professional who is not the primary health care professional overseeing care of the recipient.

CM6.3.1.3 Autologous donors shall be tested as required by Applicable Law.

CM6.3.2 The risks of donation shall be evaluated and documented, including anesthesia for marrow collection.

CM6.3.3 The donor shall be evaluated for the risk of hemoglobinopathy prior to administration of the mobilization regimen, if utilized.

CM6.3.4 A pregnancy test shall be performed for all female donors with childbearing potential within seven (7) days prior to starting the donor mobilization regimen (if mobilized donor is used) or undergoing anesthesia, and, as applicable, within seven (7) days prior to the initiation of the recipient's preparative regimen.

CM6.3.5 Laboratory testing of all donors shall be performed by a laboratory that is accredited, registered, certified, or licensed in accordance with Applicable Law.

CM6.3.6 The Clinical Program shall inform the Collection Facility and Processing Facility of donor test results or if any testing was not performed.

CM6.3.7 Collection from a donor who does not meet collection safety criteria shall require documentation of the rationale for his/her selection by the donor's physician. Collection staff shall document review of these donor safety issues.

CM6.3.7.1 There shall be written documentation of issues of donor health that pertain to the safety of the collection procedure available to the Marrow Collection Facility staff. Collection staff shall document review of these issues prior to collection.

CM6.3.8 There shall be policies or Standard Operating Procedures for follow-up of donors that includes routine management and the management of collection-associated adverse events.

CM6.4 ADDITIONAL REQUIREMENTS FOR ALLOGENEIC DONORS

CM6.4.1 A donor advocate shall be available to represent allogeneic donors who are minors or who are mentally incapacitated, as those terms are defined by Applicable Law.

CM6.4.2 Allogeneic donor infectious disease testing shall be performed using donor screening tests licensed, approved, or cleared by the governmental authority.

CM6.4.3 The Marrow Collection Facility shall comply with B6.4.8 through B6.4.8.8 when primarily responsible for donor screening for transmissible disease.

CM6.4.4 The Marrow Collection Facility shall comply with B6.4.9 through B6.4.13 when primarily responsible for infectious and non-infectious disease testing of HPC donors.

CM6.4.5 The Marrow Collection Facility shall comply with B6.4.4, B6.4.5, B6.4.6, and B6.4.14 through B6.4.14.4 when primarily responsible for testing for the selection of allogeneic donors.

CM6.5 There shall be a policy covering the creation and retention of donor records including at a minimum:

CM6.5.1 Allogeneic donor eligibility determination, including the name of the responsible person who made the determination and the date of the determination.

CM6.5.2 Donor identification including at least name and date of birth.

CM6.5.3 Age, gender, and medical history, and, for allogeneic donors, behavioral history.

CM6.5.4 Consent to donate.

CM6.5.5 Results of laboratory testing.

CM7: CODING AND LABELING OF CELLULAR THERAPY PRODUCTS

CM7.1 ISBT 128 AND EUROCODE CODING AND LABELING

CM7.1.1 Cellular therapy products shall be identified by name according to ISBT 128 standard terminology or Eurocode.

CM7.1.2 Coding and labeling technologies shall be implemented using ISBT 128 or Eurocode.

CM7.2 LABELING OPERATIONS

CM7.2.1 Labeling operations shall be conducted in a manner adequate to prevent mislabeling or misidentification of cellular therapy products, product samples, and associated records.

CM7.2.2 Pre-printed labels shall be held upon receipt from the manufacturer pending review and proofing against a copy or template approved by the Marrow Collection Facility Director to confirm accuracy regarding identity, content, and conformity.

CM7.2.2.1 A system of label reconciliation shall be used to ensure the final disposition of all labels allocated to a specific product is documented.

CM7.2.2.2 Stocks of unused labels representing different products shall be stored in a controlled manner to prevent errors.

CM7.2.3 Label systems shall be validated to confirm accuracy regarding identity, content, and conformity of labels to templates approved by the Marrow Collection Facility Director.

CM7.2.4 A system for label version control shall be employed.

CM 7.2.4.1 Obsolete labels shall be restricted from use.

CM7.2.4.2 Representative obsolete labels shall be archived minimally for ten (10) years after the last cellular therapy product was distributed with inclusive dates of use or as defined by Applicable Law, whichever is longer.

CM7.2.5 A system of checks in labeling procedures shall be used to prevent errors in transferring information to labels.

CM7.2.5.1 The information entered on a container label shall be verified by one (1) qualified staff member using a validated process or two (2) qualified staff members.

CM7.2.5.2 A controlled labeling procedure consistent with Applicable Law shall be defined and followed if container label information is transmitted electronically during a labeling process. This procedure shall include a verification step.

CM7.2.5.3 Cellular therapy products that are subsequently re-packaged into new containers shall be labeled with new labels before they are detached from the original container.

CM7.2.6 When the label has been affixed to the container, a sufficient area of the container shall remain uncovered to permit inspection of the contents.

CM7.2.7 Labeling elements required by Applicable Law shall be present.

CM7.2.8 All data fields on labels shall be completed.

CM7.2.9 All labeling shall be clear, legible, and completed using ink that is indelible to all relevant agents.

CM7.2.10 Labels affixed directly to a cellular therapy product bag shall be applied using appropriate materials as defined by the applicable regulatory authority.

CM7.2.11 The label shall be validated as reliable for storage under the conditions in use.

CM7.3 PRODUCT IDENTIFICATION

CM7.3.1 Each cellular therapy product collection shall be assigned a unique numeric or alphanumeric identifier by which it will be possible to trace any cellular therapy product to its donor, all accompanying records, and its recipient or final disposition.

CM7.3.1.1 The cellular therapy product, product samples, and concurrently collected samples shall be labeled with the same identifier.

CM7.3.1.2 If a single cellular therapy product is stored in more than one (1) container, there shall be a system to identify each container.

CM7.3.1.3 Supplementary identifiers shall not obscure the original identifier.

CM7.3.1.4 The facility associated with each identifier shall be named in the documents to accompany the cellular therapy product.

CM7.4 LABEL CONTENT

CM7.4.1 At the end of the cellular therapy product collection, the cellular therapy product label on the primary product container shall bear the information in the Cellular Therapy Product Labeling table in Appendix II.

CM7.4.2 Labeling of the cellular therapy product shall occur prior to removal of the product from the proximity of the donor.

CM7.4.2.1 The identity of the donor shall be verified against the label information prior to removing the cellular therapy product from the proximity of the donor.

CM7.4.3 Each label shall bear the appropriate biohazard and warning labels as found in the Circular of Information for the Use of Cellular Therapy Products, “Table 2. Biohazard and Warning Labels on Cellular Therapy Products Collected, Processed, and/or Administered in the United States.”

CM7.4.3.1 For cellular therapy products not collected, processed, or administered in the U.S., the appropriate Biohazard and Warning Labels shall follow Applicable Law.

CM7.4.4 A cellular therapy product collected in or designated for use in the U.S. shall be accompanied by the elements listed in the Accompanying Documentation table in Appendix IV at the time it leaves the control of the Marrow Collection Facility.

CM7.4.5 Any container bearing a partial label at the time of distribution shall be accompanied by the information required by the Cellular Therapy Product Labeling table in Appendix II. Such information shall be attached securely to the cellular therapy product on a tie tag or enclosed in a sealed package to accompany the product.

CM7.4.6 For cellular therapy products distributed before completion of donor eligibility determination, there shall be documentation that donor eligibility determination was completed during or after the use of the product.

CM7.4.7 Cellular therapy products distributed for nonclinical purposes shall be labeled with the statement, “For Nonclinical Use Only.”

CM8: PROCESS CONTROLS

CM8.1 Collection of cellular therapy products shall be performed according to written Standard Operating Procedures.

CM8.2 There shall be a process for inventory control that encompasses equipment, containers for transport and shipping, supplies, reagents, and labels.

CM8.2.1 There shall be a system to uniquely identify and track and trace all critical equipment, supplies, reagents, and labels used in the collection of cellular therapy products.

CM8.2.2 Each supply and reagent used to collect cellular therapy products shall be visually examined at receipt and prior to use for damage or evidence of contamination.

CM8.2.2.1 Supplies and reagents shall be quarantined prior to use until verified to have met acceptance criteria.

CM8.2.3 Supplies and reagents coming into contact with cellular therapy products during collection shall be sterile and of the appropriate grade for the intended use.

CM8.3 There shall be a process for equipment management that encompasses maintenance, cleaning, and calibration.

CM8.3.1 Equipment used in collection of cellular therapy products shall be maintained in a clean and orderly manner.

CM8.3.1.1 Maintenance and cleaning shall be performed according to established schedules as described in Standard Operating Procedures and in accordance with the manufacturer's recommendations.

CM8.3.1.2 The equipment shall be inspected for cleanliness and documented to be clean prior to use.

CM8.3.1.3 The equipment shall be verified and documented to be in compliance with the maintenance schedule prior to use.

CM8.3.2 All equipment with a critical measuring function shall be calibrated against a traceable standard, if available. Where no traceable standard is available, the basis for calibration shall be described and documented.

CM8.3.2.1 Calibration shall be performed according to established schedules as described in Standard Operating Procedures and in accordance with the manufacturer's recommendations.

CM8.3.2.2 When equipment is found to be out of calibration or specification, there shall be a defined process for action required for cellular therapy products collected since the last calibration.

CM8.3.3 Equipment, supplies, and reagents for the marrow collection procedure shall conform to Applicable Law.

CM8.4 Autologous or CMV-appropriate and irradiated blood products or equivalent shall be available during the marrow collection procedure for all donors.

CM8.4.1 Allogeneic blood products administered to the donor during marrow collection shall be CMV-appropriate and irradiated or equivalent prior to transfusion.

CM8.5 There shall be a written order from a physician specifying, at a minimum, anticipated date and goals of collection.

CM8.6 There shall be peripheral blood count criteria to proceed with collection.

CM8.7 There shall be written documentation of an assessment of donor suitability for the collection procedure performed by a qualified person immediately prior to each collection procedure.

CM8.8 General or regional anesthesia, if required, shall be performed or supervised by a licensed, specialist-certified anesthesiologist.

CM8.9 Administration of mobilization agents shall be under the supervision of a licensed health care professional experienced in their administration and management of complications in persons receiving these agents.

CM8.10 The Marrow Collection Facility shall utilize a process for assessing the quality of cellular therapy products to confirm product safety, viability, and integrity and to document that products meet predetermined release specifications. Results of all such assessments shall become part of the permanent record of the product collected.

CM8.10.1 Methods for collection shall employ procedures that minimize the risk of microbial contamination and be validated to result in acceptable cell viability and recovery.

CM8.11 Collection methods shall employ appropriate age and size adjustments to the procedures.

CM8.12 Cellular therapy products shall be packaged in a closed sterile transfer pack appropriate for blood or marrow products.

CM8.13 HPC, Marrow products shall be filtered to remove particulate material prior to final packaging, distribution, or administration using filters that are non-reactive with blood.

CM8.14 Records shall be made concurrently with each step of collection of each cellular therapy product in such a way that all steps may be accurately traced.

CM8.14.1 Records shall identify the person immediately responsible for each significant step, including dates and times, where appropriate.

CM9: CELLULAR THERAPY PRODUCT STORAGE

CM9.1 Marrow Collection Facilities shall control and secure storage areas to prevent mix-ups, deterioration, contamination, cross-contamination, and improper release or distribution of cellular therapy products.

CM9.2 Marrow Collection Facilities shall establish policies for the duration and conditions of short-term storage prior to distribution to a Processing Facility or Clinical Program.

CM9.2.1 Conditions and duration of storage of all cellular therapy products shall be validated.

CM9.2.2 Marrow Collection Facilities collecting, storing, or releasing cellular therapy products for administration or further manufacturing shall assign an expiration date and time.

CM10: CELLULAR THERAPY PRODUCT TRANSPORTATION AND SHIPPING

CM10.1 Standard Operating Procedures for transportation and shipping of the cellular therapy product shall be designed to protect the integrity of the product and the health and safety of individuals in the immediate area.

CM10.1.1 Additives to the cellular therapy product should be used for shipping over a long duration of time.

CM10.2 The primary cellular therapy product container shall be placed in a secondary container that is sealed to prevent leakage.

CM10.3 The cellular therapy product shall be transported or shipped to the Processing Facility in a validated container at a temperature defined in a Standard Operating Procedure.

CM10.3.1 Cellular therapy products that are transported or shipped from the collection site to the Processing Facility shall be in an outer container made of material adequate to withstand leakage of contents, impact shocks, pressure changes, temperature changes, puncture, and other conditions incident to ordinary handling.

CM10.3.2 The Collection Facility shall perform a risk assessment to evaluate the need for continuous temperature monitoring during transportation or shipment of cellular therapy products.

CM10.3.3 If the intended recipient has received high-dose therapy, the cellular therapy product shall be transported.

CM10.4 The cellular therapy product shall be transported or shipped with required accompanying records as defined in the transportation and shipping Standard Operating Procedure and in compliance with CM7.4.4 and CM7.4.6.

CM10.5 There shall be a record of the date and time of cellular therapy product distribution.

CM11: RECORDS

CM11.1 The Marrow Collection Facility shall comply with B10 if it operates independently of a Clinical Program.

CM12: DIRECT DISTRIBUTION TO CLINICAL PROGRAM

CM12.1 Where cellular therapy products are distributed directly from the Marrow Collection Facility to the Clinical Program for administration or subsequent processing, the Standards related to labeling, documentation, distribution, transportation, and record keeping in Sections D7, D10, D11, D13, and the Appendices apply.

APHERESIS COLLECTION FACILITY STANDARDS

PART C

PART C: APHERESIS COLLECTION FACILITY STANDARDS

C1: GENERAL

C1.1 These Standards apply to all collection, storage, and distribution activities performed in the Apheresis Collection Facility for cellular therapy products.

C1.2 The Apheresis Collection Facility shall use cell processing facilities that meet FACT-JACIE Standards with respect to their interactions with the Apheresis Collection Facility.

C1.3 The Apheresis Collection Facility shall abide by Applicable Law.

C1.3.1 The Apheresis Collection Facility shall be licensed, registered, or accredited as required by the appropriate governmental authorities for the activities performed.

C1.4 The Apheresis Collection Facility shall have an Apheresis Collection Facility Director, an Apheresis Collection Facility Medical Director, a Quality Manager, and a minimum of one (1) additional designated staff member. This team shall have been in place and performing cellular therapy product collections for at least twelve (12) months preceding initial accreditation.

C1.5 A minimum of ten (10) cellular therapy products shall have been collected by apheresis in the twelve (12) month period immediately preceding initial accreditation, and a minimum average of ten (10) cellular therapy products shall have been collected by apheresis per year within each accreditation cycle.

C2: APHERESIS COLLECTION FACILITY

C2.1 There shall be secured and controlled access to designated areas for the collection procedure and for storage of equipment, supplies, and reagents.

C2.1.1 The designated area for collection shall be in an appropriate location of adequate space and design to minimize the risk of airborne microbial contamination.

C2.1.2 The Apheresis Collection Facility shall be divided into defined areas of adequate size to prevent improper labeling, mix-ups, contamination, or cross-contamination of cellular therapy products.

C2.1.3 There shall be a process to control storage areas to prevent mix-ups, contamination, and cross-contamination of cellular therapy products.

C2.1.4 There shall be suitable space for confidential donor examination and evaluation.

C2.2 The Apheresis Collection Facility shall provide adequate lighting, ventilation, and access to sinks for handwashing and to toilets to prevent the introduction, transmission, or spread of communicable disease.

C2.3 Apheresis Collection Facility parameters and environmental conditions shall be controlled to protect the safety and comfort of donors and personnel.

C2.4 There shall be a written assessment of critical Apheresis Collection Facility parameters that may affect cellular therapy product viability, integrity, contamination, or cross-contamination during collection.

C2.4.1 The written assessment shall include temperature and humidity at a minimum.

C2.4.2 Critical facility parameters identified to be a risk to the cellular therapy product shall be controlled, monitored, and recorded.

C2.4.3 If using collection methods that may result in contamination or cross-contamination of cellular therapy products, critical environmental conditions shall be controlled, monitored, and recorded for air quality and surface contaminants.

C2.5 The Apheresis Collection Facility shall document facility cleaning and sanitation and maintain order sufficient to achieve adequate conditions for operations.

C2.6 There shall be adequate equipment and materials for the procedures performed.

C2.7 There shall be access to an intensive care unit or emergency services.

C2.8 The Apheresis Collection Facility shall be operated in a manner designed to minimize risks to the health and safety of employees, donors, visitors, and volunteers.

C2.9 The Apheresis Collection Facility shall have a written safety manual that includes instructions for action in case of exposure, as applicable, to communicable disease and to chemical, biological, radiological, electrical, or fire hazards.

C2.10 All waste generated by the Apheresis Collection Facility's activities shall be disposed of in a manner that minimizes any hazard to facility personnel and to the environment in accordance with Applicable Law.

C2.11 Personal protective equipment, including gloves and protective clothing, shall be used while handling biological specimens. Such protective equipment shall not be worn outside the work area.

C3: PERSONNEL

C3.1 APHERESIS COLLECTION FACILITY DIRECTOR

C3.1.1 There shall be an Apheresis Collection Facility Director with a medical degree or degree in a relevant science, with two (2) years of postgraduate training and experience in cellular therapy product collection procedures at a minimum.

C3.1.2 The Apheresis Collection Facility Director shall be responsible for all Standard Operating Procedures, technical procedures, performance of the collection procedure, supervision of staff, administrative operations, and the Quality Management Program, including compliance with these Standards and Applicable Law.

C3.1.3 The Apheresis Collection Facility Director shall have performed or supervised a minimum of five (5) cellular therapy product apheresis collection procedures in the twelve (12) months preceding initial accreditation and a minimum average of five (5) cellular therapy product apheresis collection procedures per year within each accreditation cycle.

C3.1.4 The Apheresis Collection Facility Director shall participate in a minimum of ten (10) hours of educational activities related to cellular therapy annually.

C3.1.4.1 Continuing education shall include, but is not limited to, activities related to the field of HPC transplantation and other cellular therapies.

C3.2 APHERESIS COLLECTION FACILITY MEDICAL DIRECTOR

C3.2.1 There shall be an Apheresis Collection Facility Medical Director who is a licensed physician with a minimum of two (2) years postgraduate certification, with training and practical and relevant experience in cellular therapy product collection and transplantation.

C3.2.2 The Apheresis Collection Facility Medical Director shall be responsible for the medical care of donors undergoing apheresis, including the pre-collection evaluation of the donor at the time of donation and care of any complications resulting from the collection procedure.

C3.2.3 The Apheresis Collection Facility Medical Director shall have performed or supervised a minimum of five (5) cellular therapy product apheresis collection procedures in the twelve (12) months preceding initial accreditation and a minimum average of five (5) cellular therapy product apheresis collection procedures per year within each accreditation cycle.

C3.2.4 The Apheresis Collection Facility Medical Director shall participate in a minimum of ten (10) hours of educational activities related to cellular therapy annually.

C3.2.4.1 Continuing education shall include, but is not limited to, activities related to the field of HPC transplantation and other cellular therapies.

C3.3 QUALITY MANAGER

C3.3.1 There shall be an Apheresis Collection Facility Quality Manager to establish and maintain systems to review, modify, and approve all policies and Standard Operating Procedures intended to monitor compliance with these Standards or the performance of the Apheresis Collection Facility.

C3.3.2 The Apheresis Collection Facility Quality Manager should have a reporting structure independent of cellular therapy product manufacturing.

C3.3.3 The Apheresis Collection Facility Quality Manager shall participate in a minimum of ten (10) hours annually of continuing education activities.

C3.3.3.1 Continuing education shall include cellular therapy, cell collection, and Quality Management.

C3.4 STAFF

C3.4.1 The number of trained collection personnel shall be adequate for the number of procedures performed and shall include a minimum of one (1) designated trained individual with an identified trained backup individual to maintain sufficient coverage.

C3.4.2 For Apheresis Collection Facilities collecting cellular therapy products from pediatric donors, physicians and collection staff shall have documented training and experience with pediatric donors.

C3.4.3 There shall be attending physician oversight if general medical physicians, physicians in training, or APPs provide care to the cellular therapy donors.

C3.4.3.1 The scope of responsibility of general medical physicians or APPs shall be defined.

C4: QUALITY MANAGEMENT

C4.1 There shall be a Quality Management Program that incorporates key performance data.

C4.1.1 The Apheresis Collection Facility Director shall have authority over and responsibility for ensuring that the Quality Management Program is effectively established and maintained.

C4.2 The Apheresis Collection Facility shall establish and maintain a written Quality Management Plan.

C4.2.1 The Apheresis Collection Facility Director shall be responsible for the Quality Management Plan as it pertains to the Apheresis Collection Facility.

C4.3 The Quality Management Plan shall include, or summarize and reference, an organizational chart of key positions, functions, and reporting relationships within the Apheresis Collection Facility.

C4.3.1 The Quality Management Plan shall include a description of how these key positions interact to implement the quality management activities.

C4.4 The Quality Management Plan shall include, or summarize and reference, policies and Standard Operating Procedures addressing personnel requirements for each key position in the Apheresis Collection Facility. Personnel requirements shall include at a minimum:

C4.4.1 A current job description for all staff.

C4.4.2 A system to document the following for all staff:

C4.4.2.1 Initial qualifications.

C4.4.2.2 New employee orientation.

C4.4.2.3 Initial training, competency, and retraining when appropriate for all procedures performed, and in accordance with Applicable Law.

C4.4.2.4 Continued competency for each critical function performed, assessed annually at a minimum.

C4.4.2.5 Annual training in applicable current GxP appropriate to the processes performed in accordance with Applicable Law.

C4.4.2.6 Continuing education.

C4.5 The Quality Management Plan shall include, or summarize and reference, a comprehensive system for document control.

C4.5.1 There shall be identification of the types of documents that are considered critical and shall comply with the document control system requirements. Controlled documents shall include at a minimum:

C4.5.1.1 Policies and Standard Operating Procedures.

C4.5.1.2 Worksheets.

C4.5.1.3 Forms.

C4.5.1.4 Labels.

C4.5.2 There shall be policies or Standard Operating Procedures for the development, approval, implementation, distribution, review, revision, and archival of all critical documents.

C4.5.3 The document control system shall include:

C4.5.3.1 A standardized format for critical documents.

C4.5.3.2 Assignment of a numeric or alphanumeric identifier and a title to each document and document version regulated within the system.

C4.5.3.3 A system for document approval, including the approval date, signature of approving individual(s), and the effective date.

C4.5.3.4 A system to protect controlled documents from accidental or unauthorized modification.

C4.5.3.5 Review of controlled documents every two (2) years at a minimum.

C4.5.3.6 A system for document change control that includes a description of the change, version, the signature of approving individual(s), approval date(s), communication or training on the change as applicable, effective date, and archival date.

C4.5.3.7 Archival of controlled documents, the inclusive dates of use, and their historical sequence for a minimum of ten (10) years from archival or according to governmental or institutional policy, whichever is longer.

C4.5.3.8 A system for the retraction of obsolete documents to prevent unintended use.

C4.6 The Quality Management Plan shall include, or summarize and reference, policies and Standard Operating Procedures for the establishment and maintenance of written agreements.

C4.6.1 Agreements shall be established with external parties providing critical services that could affect the quality and safety of the cellular therapy product or health and safety of the donor or recipient.

C4.6.2 Agreements shall include the responsibility of the external party performing any step in collection, processing, testing, storage, distribution, or administration to maintain required accreditations and to comply with Applicable Law and these Standards.

C4.6.3 Agreements shall be established when the Apheresis Collection Facility provides critical services to external parties.

C4.6.4 Agreements shall be dated and reviewed on a regular basis, at a minimum every two (2) years.

C4.7 The Quality Management Plan shall include, or summarize and reference, policies and Standard Operating Procedures for documentation and review of outcome analysis and cellular therapy product efficacy to verify that the procedures in use consistently provide a safe and effective product.

C4.7.1 Criteria for cellular therapy product safety, product efficacy, and the clinical outcome shall be determined and shall be reviewed at regular time intervals.

C4.7.2 Both individual cellular therapy product data and aggregate data for each type of cellular therapy product shall be evaluated.

C4.7.3 For HPC products intended for hematopoietic reconstitution, time to neutrophil and platelet engraftment following cellular therapy product administration shall be analyzed.

C4.8 The Quality Management Plan shall include, or summarize and reference, policies and Standard Operating Procedures for, and a schedule of, audits of the Apheresis Collection Facility's activities to verify compliance with elements of the Quality Management Program and policies and Standard Operating Procedures, Applicable Law, and these Standards.

C4.8.1 Audits shall be conducted by an individual with sufficient knowledge in the process and competence in auditing to identify problems, but who is not solely responsible for the process being audited.

C4.8.2 The results of audits shall be used to recognize problems, detect trends, identify improvement opportunities, implement corrective and preventive actions when necessary, and follow-up on the effectiveness of these actions in a timely manner.

C4.8.3 Audits shall be performed annually at a minimum, and shall include at least the following:

C4.8.3.1 Audit of documentation of interim assessment of donor suitability and eligibility prior to the start of the collection procedure.

C4.8.3.2 Audit of documentation of donor eligibility determination prior to start of the collection procedure.

C4.8.3.3 Audit of management of cellular therapy products with positive microbial culture results.

C4.8.3.4 Audit of documentation that external facilities performing critical contracted services have met the requirements of the written agreements.

C4.9 The Quality Management Plan shall include, or summarize and reference, policies and Standard Operating Procedures for the management of cellular therapy products with positive microbial culture results that address at a minimum:

C4.9.1 Notification of the recipient's physician and any other facility in receipt of the cellular therapy product.

C4.9.2 Investigation of cause.

C4.9.3 Follow-up of the donor, if relevant.

C4.9.4 Reporting to regulatory agencies, if appropriate.

C4.10 The Quality Management Plan shall include, or summarize and reference, policies and Standard Operating Procedures for occurrences (errors, accidents, deviations, adverse events, adverse reactions, and complaints). The following activities shall be included at a minimum:

C4.10.1 Detection.

C4.10.2 Investigation.

C4.10.2.1 A thorough and timely investigation shall be conducted by the Apheresis Collection Facility in collaboration with the Processing Facility, the Clinical Program, and other entities involved in the manufacture of the cellular therapy product, as appropriate.

C4.10.2.2 Investigations shall identify the root cause and a plan for short- and long-term corrective and preventive actions as warranted.

C4.10.2.3 Occurrences shall be tracked and trended.

C4.10.3 Documentation.

C4.10.3.1 Documentation shall include a description of the occurrence, date and time of the occurrence, the involved individuals and cellular therapy product(s), when and to whom the occurrence was reported, and the immediate actions taken.

C4.10.3.2 All investigation reports shall be reviewed in a timely manner by the Apheresis Collection Facility Director, Medical Director, and Quality Manager.

C4.10.3.3 Cumulative files of occurrences shall be maintained and include written investigation reports containing conclusions, follow-up, corrective and preventive actions, and a link to the records of the involved cellular therapy products, donors, and recipients, if applicable.

C4.10.4 Reporting.

C4.10.4.1 When it is determined that a cellular therapy product has resulted in an adverse event or reaction, the event and results of the investigation shall be reported to the donor's and recipient's physician(s), as applicable, other facilities participating in the manufacturing of the cellular therapy product, registries, and governmental agencies as required by Applicable Law.

C4.10.4.2 Occurrences shall be reported to other facilities performing cellular therapy product functions on the affected cellular therapy product and to the appropriate regulatory and accrediting agencies, registries, grant agencies, sponsors, IRBs, or Ethics Committees.

C4.10.5 Corrective and preventive action.

C4.10.5.1 Appropriate action shall be implemented if indicated, including both short-term action to address the immediate problem and long-term action to prevent the problem from recurring.

C4.10.5.2 Follow-up audits of the effectiveness of corrective and preventive actions shall be performed in a timeframe as indicated in the investigative report.

C4.11 The Quality Management Plan shall include, or summarize and reference, policies and Standard Operating Procedures for cellular therapy product chain of identity and chain of custody that allow tracking from the donor to the recipient or final disposition and tracing from the recipient or final disposition to the donor.

C4.12 The Quality Management Plan shall include, or summarize and reference, policies and Standard Operating Procedures for actions to take in the event the Apheresis Collection Facility's operations are interrupted.

C4.13 The Quality Management Plan shall include, or summarize and reference, policies and Standard Operating Procedures for qualification of critical manufacturers, vendors, equipment, software, supplies, reagents, facilities, and services.

C4.13.1 Qualification shall be required following any significant changes to these items.

C4.13.2 Reagents that are not the appropriate grade shall undergo qualification for the intended use.

C4.13.3 Qualification plans shall include minimum acceptance criteria for performance.

C4.13.4 Qualification plans, results, and reports shall be reviewed and approved by the Quality Manager and Apheresis Collection Facility Director.

C4.14 The Quality Management Plan shall include, or summarize and reference, policies and Standard Operating Procedures for validation or verification of critical procedures.

C4.14.1 Critical procedures to be validated shall include at least the following: collection procedures, testing, labeling, storage, and distribution.

C4.14.2 Each validation or verification shall include at a minimum:

C4.14.2.1 An approved plan, including conditions to be assessed.

C4.14.2.2 Acceptance criteria.

C4.14.2.3 Data collection.

C4.14.2.4 Evaluation of data.

C4.14.2.5 Summary of results.

C4.14.2.6 References, if applicable.

C4.14.2.7 Review and approval of the plan, report, and conclusion by the Quality Manager and the Apheresis Collection Facility Director.

C4.14.3 Significant changes to critical procedures shall be validated and verified as appropriate.

C4.15 The Quality Management Plan shall include, or summarize and reference, policies and Standard Operating Procedures for the evaluation of risk in changes to a process to confirm that the changes do not create an adverse impact or inherent risk elsewhere in the operation.

C4.15.1 Evaluation of risk shall be completed for changes in critical procedures.

C4.16 The Quality Management Plan shall include, or summarize and reference, policies and Standard Operating Procedures for obtaining feedback.

C4.16.1 Feedback shall be obtained from associated Clinical Programs and Processing Facilities.

C4.16.2 Feedback shall be obtained from donors or legally authorized representatives.

C4.17 The Apheresis Collection Facility Director shall review the quality management activities with representatives in key positions in all elements of the cellular therapy program, at a minimum, quarterly.

C4.17.1 Meetings shall have defined attendees, documented minutes, and assigned actions.

C4.17.2 Performance data and review findings shall be reported to key positions and staff.

C4.17.3 The Apheresis Collection Facility Director shall not have oversight of his/her own work if this person also performs other tasks in the Apheresis Collection Facility.

C4.18 The Apheresis Collection Facility Director shall annually review the effectiveness of the Quality Management Program.

C4.18.1 The annual report and documentation of the review findings shall be made available to key personnel, the Clinical Program Director, the Processing Facility Director, and staff of the program.

C5: POLICIES AND STANDARD OPERATING PROCEDURES

C5.1 The Apheresis Collection Facility shall establish and maintain policies or Standard Operating Procedures addressing critical aspects of operations and management in addition to those required in C4. These documents shall include all elements required by these Standards and shall address at a minimum:

C5.1.1 Donor and recipient confidentiality.

C5.1.2 Donor informed consent for cellular therapy product collection.

C5.1.3 Donor screening, testing, eligibility and suitability determination, and management.

C5.1.4 Donor age-specific and size-specific issues where relevant.

C5.1.5 Management of donors who require central venous access.

C5.1.6 Cellular therapy product collection.

C5.1.7 Administration of blood products.

C5.1.8 Prevention of mix-ups and cross-contamination.

C5.1.9 Labeling (including associated forms and samples).

C5.1.10 Cellular therapy product expiration dates.

C5.1.11 Cellular therapy product storage.

C5.1.12 Release and exceptional release.

C5.1.13 Extracorporeal photopheresis if performed by the Apheresis Collection Facility.

C5.1.14 Packaging, transportation, and shipping.

C5.1.14.1 Methods and conditions to be used for distribution to external facilities.

C5.1.14.2 Use of additives for long duration of shipment.

C5.1.15 Critical equipment, reagent, and supply management including recalls and corrective actions in the event of failure.

C5.1.16 Equipment operation, maintenance, and monitoring including corrective actions in the event of failure.

C5.1.17 Cleaning and sanitation procedures, including beds and chairs and the identification of the individuals performing the activities.

C5.1.18 Hygiene and use of personal protective equipment and attire.

C5.1.19 Disposal of medical and biohazard waste.

C5.1.20 Cellular therapy emergency and disaster plan, including the Apheresis Collection Facility response.

C5.2 The Apheresis Collection Facility shall maintain a detailed list of all controlled documents, including title and identifier.

C5.3 Standard Operating Procedures shall be sufficiently detailed and unambiguous to allow qualified staff to follow and complete the procedures successfully. Each individual Standard Operating Procedure shall include:

C5.3.1 A clearly written description of the objectives.

C5.3.2 A description of equipment and supplies used.

C5.3.3 Acceptable end-points and the range of expected results.

C5.3.4 A stepwise description of the procedure.

C5.3.5 Reference to other Standard Operating Procedures or policies required to perform the procedure.

C5.3.6 A reference section listing appropriate and current literature.

C5.3.7 Reference to a current version of collection orders, worksheets, reports, labels, and forms.

C5.3.8 Documented approval of each procedure by the Apheresis Collection Facility Director or Medical Director, as appropriate, prior to implementation and every two (2) years thereafter.

C5.3.9 Documented approval of each procedural modification by the Apheresis Collection Facility Director or Medical Director, as appropriate, prior to implementation.

C5.4 Controlled documents relevant to processes being performed shall be readily available to the facility staff.

C5.5 Staff training and, if appropriate, competency shall be documented before performing a new or revised Standard Operating Procedure.

C5.6 All personnel shall follow the policies and Standard Operating Procedures related to their positions.

C5.7 Planned deviations shall be pre-approved by the Apheresis Collection Facility Director or Medical Director, and reviewed by the Quality Manager.

C6: ALLOGENEIC AND AUTOLOGOUS DONOR EVALUATION AND MANAGEMENT

C6.1 There shall be written criteria for allogeneic and autologous donor evaluation and management by trained medical personnel.

C6.2 ALLOGENEIC AND AUTOLOGOUS DONOR INFORMATION AND CONSENT FOR COLLECTION

C6.2.1 The collection procedure shall be explained in terms the donor can understand, and shall include the following information at a minimum:

C6.2.1.1 The risks and benefits of the procedure.

C6.2.1.2 Intent of the collection for treatment or research.

C6.2.1.3 Tests and procedures performed on the donor to protect the health of the donor and the recipient.

C6.2.1.4 The rights of the donor or legally authorized representative to review the results of such tests according to Applicable Law.

C6.2.1.5 Protection of medical information and confidentiality.

C6.2.2 Interpretation and translation shall be performed by individuals qualified to provide these services in the clinical setting.

C6.2.2.1 Family members and legally authorized representatives shall not serve as interpreters or translators.

C6.2.3 The donor shall have an opportunity to ask questions.

C6.2.4 The donor shall have the right to refuse to donate or withdraw consent.

C6.2.4.1 The allogeneic donor shall be informed of the potential consequences to the recipient of such refusal in the event that consent is withdrawn after the recipient has begun the preparative regimen.

C6.2.5 Donor informed consent for the cellular therapy product collection shall be obtained and documented by a licensed health care professional knowledgeable in the collection procedure.

C6.2.5.1 Informed consent from the allogeneic donor shall be obtained by a licensed health care professional who is not the primary health care professional overseeing care of the recipient.

C6.2.6 In the case of a donor who is a minor, informed consent shall be obtained from the donor's legally authorized representative in accordance with Applicable Law and shall be documented.

C6.2.7 The allogeneic donor shall give informed consent and authorization prior to release of the donor's health or other information to the recipient's physician or the recipient.

C6.2.8 The donor shall be informed of the policy for cellular therapy product storage, discard, or disposal, including actions taken when an intended recipient no longer requires the cellular therapy product.

C6.2.9 Documentation of consent shall be verified by the Apheresis Collection Facility staff prior to the collection procedure.

C6.3 ALLOGENEIC AND AUTOLOGOUS DONOR SUITABILITY FOR CELLULAR THERAPY PRODUCT COLLECTION

C6.3.1 There shall be criteria and evaluation policies or Standard Operating Procedures in place to protect the safety of donors during the process of cellular therapy product collection.

C6.3.1.1 The Apheresis Collection Facility shall confirm that clinically significant findings are reported to the prospective donor with documentation in the donor record of recommendations made for follow-up care.

C6.3.1.2 Allogeneic donor suitability shall be evaluated by a licensed health care professional who is not the primary health care professional overseeing care of the recipient.

C6.3.1.3 Autologous donors shall be tested as required by Applicable Law.

C6.3.2 The risks of donation shall be evaluated and documented, including:

C6.3.2.1 Mobilization for collection of HPC, Apheresis.

C6.3.2.2 Possible need for central venous access.

C6.3.3 The donor shall be evaluated for the risk of hemoglobinopathy prior to administration of the mobilization regimen.

C6.3.4 A pregnancy test shall be performed for all female donors with childbearing potential within seven (7) days prior to starting the donor mobilization regimen and, as applicable, within seven (7) days prior to the initiation of the recipient's preparative regimen.

C6.3.4.1 For collections without mobilization, a pregnancy test shall be performed within seven (7) days prior to cellular therapy product collection.

C6.3.5 Laboratory testing of all donors shall be performed by a laboratory that is accredited, registered, certified, or licensed in accordance with Applicable Law.

C6.3.6 The Clinical Program shall inform the Collection Facility and Processing Facility of donor test results or if any testing was not performed.

C6.3.7 If central venous access is required, the rationale shall be documented in the donor's records.

C6.3.8 Adequacy of central line placement shall be verified and documented.

C6.3.8.1 Adequacy of central line placement shall be verified and documented by the Apheresis Collection Facility staff prior to initiating each collection procedure.

C6.3.9 Collection from a donor who does not meet collection safety criteria shall require documentation of the rationale for his/her selection by the donor's physician. Collection staff shall document review of these donor safety issues.

C6.3.9.1 There shall be written documentation of issues of donor health that pertain to the safety of the collection procedure available to the Apheresis Collection Facility staff. Collection staff shall document review of these issues prior to collection.

C6.3.10 There shall be policies or Standard Operating Procedures for follow-up of donors that includes routine management and the management of collection-associated adverse events.

C6.4 ADDITIONAL REQUIREMENTS FOR ALLOGENEIC DONORS

C6.4.1 A donor advocate shall be available to represent allogeneic donors who are minors or who are mentally incapacitated, as those terms are defined by Applicable Law.

C6.4.2 Allogeneic donor infectious disease testing shall be performed using donor screening tests licensed, approved, or cleared by the governmental authority.

C6.4.3 The Apheresis Collection Facility shall comply with B6.4.8 through B6.4.8.8 when primarily responsible for donor screening for transmissible disease.

C6.4.4 The Apheresis Collection Facility shall comply with B6.4.9 through B6.4.13 when primarily responsible for infectious and non-infectious disease testing of donors.

C6.4.5 The Apheresis Collection Facility shall comply with B6.4.4, B6.4.5, B6.4.6, and B6.4.14 through B6.4.14.4 when primarily responsible for testing for the selection of allogeneic donors.

C6.4.6 The Apheresis Collection Facility shall confirm that allogeneic donor eligibility, as defined by Applicable Law, is determined by a physician after history, exam, medical record review, and testing before the donor begins the mobilization regimen.

C6.4.7 Records required for donor eligibility determination shall be in English or translated into English when crossing international borders.

C6.4.8 Collection of a cellular therapy product from an ineligible allogeneic donor, or from an allogeneic donor for whom donor eligibility determination is incomplete, shall require documentation of urgent medical need that includes the rationale for the selection and documentation of the informed consent of the donor and the recipient.

C6.4.9 Allogeneic donor eligibility shall be communicated in writing to the Processing Facility.

C6.5 There shall be a policy covering the creation and retention of donor records including at a minimum:

C6.5.1 Allogeneic donor eligibility determination, including the name of the responsible person who made the determination and the date of the determination.

C6.5.2 Donor identification including at least name and date of birth.

C6.5.3 Age, gender, and medical history, and, for allogeneic donors, behavioral history.

C6.5.4 Consent to donate.

C6.5.5 Results of laboratory testing.

C7: CODING AND LABELING OF CELLULAR THERAPY PRODUCTS

C7.1 ISBT 128 AND EUROCODE CODING AND LABELING

C7.1.1 Cellular therapy products shall be identified by name according to ISBT 128 standard terminology or Eurocode.

C7.1.2 Coding and labeling technologies shall be implemented using ISBT 128 or Eurocode.

C7.2 LABELING OPERATIONS

C7.2.1 Labeling operations shall be conducted in a manner adequate to prevent mislabeling or misidentification of cellular therapy products, product samples, and associated records.

C7.2.2 Pre-printed labels shall be held upon receipt from the manufacturer pending review and proofing against a copy or template approved by the Apheresis Collection Facility Director to confirm accuracy regarding identity, content, and conformity.

C7.2.2.1 A system of label reconciliation shall be used to ensure the final disposition of all labels allocated to a specific product is documented.

C7.2.2.2 Stocks of unused labels representing different products shall be stored in a controlled manner to prevent errors.

C7.2.3 Label systems shall be validated to confirm accuracy regarding identity, content, and conformity of labels to templates approved by the Apheresis Collection Facility Director.

C7.2.4 A system for label version control shall be employed.

C7.2.4.1 Obsolete labels shall be restricted from use.

C7.2.4.2 Representative obsolete labels shall be archived minimally for ten (10) years after the last cellular therapy product was distributed with inclusive dates of use or as defined by Applicable Law, whichever is longer.

C7.2.5 A system of checks in labeling procedures shall be used to prevent errors in transferring information to labels.

C7.2.5.1 The information entered on a container label shall be verified by one (1) qualified staff member using a validated process or two (2) qualified staff members.

C7.2.5.2 A controlled labeling procedure consistent with Applicable Law shall be defined and followed if container label information is transmitted electronically during a labeling process. This procedure shall include a verification step.

C7.2.5.3 Cellular therapy products that are subsequently re-packaged into new containers shall be labeled with new labels before they are detached from the original container.

C7.2.6 When the label has been affixed to the container, a sufficient area of the container shall remain uncovered to permit inspection of the contents.

C7.2.7 Labeling elements required by Applicable Law shall be present.

C7.2.8 All data fields on labels shall be completed.

C7.2.9 All labeling shall be clear, legible, and completed using ink that is indelible to all relevant agents.

C7.2.10 Labels affixed directly to a cellular therapy product bag shall be applied using appropriate materials as defined by the applicable regulatory authority.

C7.2.11 The label shall be validated as reliable for storage under the conditions in use.

C7.3 PRODUCT IDENTIFICATION

C7.3.1 Each cellular therapy product collection shall be assigned a unique numeric or alphanumeric identifier by which it will be possible to trace any cellular therapy product to its donor, all accompanying records, and its recipient or final disposition.

C7.3.1.1 The cellular therapy product, product samples, concurrent plasma, and concurrently collected samples shall be labeled with the same identifier.

C7.3.1.2 If a single cellular therapy product is stored in more than one (1) container, there shall be a system to identify each container.

C7.3.1.3 If cellular therapy products from the same donor are pooled, the pool identifier shall allow tracing to the original products.

C7.3.1.4 Supplementary identifiers shall not obscure the original identifier.

C7.3.1.5 The facility associated with each identifier shall be named in the documents to accompany the cellular therapy product.

C7.4 LABEL CONTENT

C7.4.1 At all stages of collection, the cellular therapy product shall be labeled with the proper name of the product and the unique numeric or alphanumeric identifier, at a minimum.

C7.4.2 Labeling at the end of collection shall occur before the cellular therapy product bag is disconnected from the donor.

C7.4.3 At the end of the cellular therapy product collection, the cellular therapy product label on the primary product container and concurrent plasma container shall bear the information in the Cellular Therapy Product Labeling table in Appendix II.

C7.4.4 Each label shall bear the appropriate biohazard and warning labels as found in the Circular of Information for the Use of Cellular Therapy Products, “Table 2. Biohazard and Warning Labels on Cellular Therapy Products Collected, Processed, and/or Administered in the United States.”

C7.4.4.1 For cellular therapy products not collected, processed, or administered in the U.S., the appropriate Biohazard and Warning Labels shall follow Applicable Law.

C7.4.5 A cellular therapy product collected in or designated for use in the U.S. shall be accompanied by the elements listed in the Accompanying Documentation table in Appendix IV at the time it leaves the control of the Apheresis Collection Facility.

C7.4.6 Any container bearing a partial label at the time of distribution shall be accompanied by the information required by the Cellular Therapy Product Labeling table in Appendix II. Such information shall be attached securely to the cellular therapy product on a tie tag or enclosed in a sealed package to accompany the product.

C7.4.7 For cellular therapy products distributed before completion of donor eligibility determination, there shall be documentation that donor eligibility determination was completed during or after the use of the product.

C7.4.8 Cellular therapy products distributed for nonclinical purposes shall be labeled with the statement, “For Nonclinical Use Only.”

C8: PROCESS CONTROLS

C8.1 Collection of cellular therapy products shall be performed according to written Standard Operating Procedures.

C8.2 There shall be a process for inventory control that encompasses equipment, containers for transport and shipping, supplies, reagents, and labels.

C8.2.1 There shall be a system to uniquely identify and track and trace all critical equipment, supplies, reagents, and labels used in the collection of cellular therapy products.

C8.2.2 Each supply and reagent used to collect cellular therapy products shall be visually examined at receipt and prior to use for damage or evidence of contamination.

C8.2.2.1 Supplies and reagents shall be quarantined prior to use until verified to have met acceptance criteria.

C8.2.3 Supplies and reagents coming into contact with cellular therapy products during collection shall be sterile and of the appropriate grade for the intended use.

C8.3 There shall be a process for equipment management that encompasses maintenance, cleaning, and calibration.

C8.3.1 Equipment shall be maintained in a clean and orderly manner.

C8.3.1.1 Maintenance and cleaning shall be performed according to established schedules as described in Standard Operating Procedures and in accordance with the manufacturer's recommendations.

C8.3.1.2 The equipment shall be inspected for cleanliness and documented to be clean prior to use.

C8.3.1.3 The equipment shall be verified and documented to be in compliance with the maintenance schedule prior to use.

C8.3.2 All equipment with a critical measuring function shall be calibrated against a traceable standard, if available. Where no traceable standard is available, the basis for calibration shall be described and documented.

C8.3.2.1 Calibration shall be performed according to established schedules as described in Standard Operating Procedures and in accordance with the manufacturer's recommendations.

C8.3.2.2 When equipment is found to be out of calibration or specification, there shall be a defined process for action required for cellular therapy products collected since the last calibration.

C8.3.3 Equipment, supplies, and reagents shall conform to Applicable Law.

C8.4 Autologous or CMV-appropriate and irradiated blood products or equivalent shall be available during the apheresis collection procedure for all donors.

C8.4.1 Allogeneic blood products administered to the donor during apheresis collection or used during priming procedures shall be CMV-appropriate and irradiated or equivalent prior to transfusion.

C8.5 There shall be a written order from a physician specifying, at a minimum, anticipated date and goals of collection.

C8.6 A complete blood count, including platelet count, shall be performed within 24 hours prior to each subsequent cellular therapy product collection by apheresis.

C8.7 There shall be peripheral blood count criteria to proceed with collection.

C8.8 There shall be written documentation of a daily assessment of donor suitability for the collection procedure performed by a qualified person immediately prior to each collection procedure.

C8.9 Administration of mobilization agents shall be under the supervision of a licensed health care professional experienced in their administration and management of complications in persons receiving these agents.

C8.9.1 Appropriate mobilization should be used for the disease being treated and for the donor being collected.

C8.10 The Apheresis Collection Facility shall utilize a process for assessing the quality of cellular therapy products to confirm product safety, viability, and integrity and to document that products meet predetermined release specifications. Results of all such assessments shall become part of the permanent record of the product collected.

C8.10.1 Methods for collection shall employ procedures that minimize the risk of microbial contamination and be validated to result in acceptable cell viability and recovery.

C8.11 Collection methods shall employ appropriate age and size adjustments to the procedures.

C8.12 Cellular therapy products shall be packaged in a closed sterile transfer pack appropriate for blood products.

C8.13 Records shall be made concurrently with each step of collection of each cellular therapy product in such a way that all steps may be accurately traced.

C8.13.1 Records shall identify the person immediately responsible for each significant step, including dates and times, where appropriate.

C8.14 There shall be policies addressing safe treatment with ECP, if applicable.

C8.14.1 Before ECP is undertaken, there shall be a written therapy plan from a physician specifying the patient's diagnosis and GVHD grade, involved organs, indication, timing of the procedure, proposed regimen, and any other factors that may affect the safe treatment with ECP.

C8.14.2 A final report of the ECP treatment, including procedure details, shall be documented in the patient's medical record.

C9: CELLULAR THERAPY PRODUCT STORAGE

C9.1 Apheresis Collection Facilities shall control and secure storage areas to prevent mix-ups, deterioration, contamination, cross-contamination, and improper release or distribution of cellular therapy products.

C9.2 Apheresis Collection Facilities shall establish policies for the duration and conditions of short-term storage prior to distribution to a Processing Facility or Clinical Program.

C9.2.1 Conditions and duration of storage of all cellular therapy products shall be validated.

C9.2.2 Apheresis Collection Facilities collecting, storing, or releasing cellular therapy products for administration or further manufacturing shall assign an expiration date and time.

C10: CELLULAR THERAPY PRODUCT TRANSPORTATION AND SHIPPING

C10.1 Standard Operating Procedures for transportation and shipping of the cellular therapy product shall be designed to protect the integrity of the product and the health and safety of individuals in the immediate area.

C10.1.1 Additives to the cellular therapy product should be used for shipping over a long duration of time.

C10.2 The primary cellular therapy product container shall be placed in a secondary container that is sealed to prevent leakage.

C10.3 The cellular therapy product shall be transported or shipped to the Processing Facility in a validated container at a temperature defined in a Standard Operating Procedure.

C10.3.1 Cellular therapy products that are transported or shipped from the collection site to a processing facility shall be in an outer container made of material adequate to withstand leakage of contents, impact shocks, pressure changes, temperature changes, puncture, and other conditions incident to ordinary handling.

C.10.3.2 The Collection Facility shall perform a risk assessment to evaluate the need for continuous temperature monitoring during transportation or shipment of cellular therapy products.

C10.3.3 If the intended recipient has received high-dose therapy, the cellular therapy product shall be transported.

C10.4 The cellular therapy product shall be transported or shipped with required accompanying records as defined in the transportation and shipping Standard Operating Procedures and in compliance with C7.4.5 and C7.4.7.

C10.5 There shall be a record of the date and time of cellular therapy product distribution.

C11: RECORDS

C11.1 GENERAL REQUIREMENTS

C11.1.1 A records management system shall be established and maintained to facilitate the review of records.

C11.1.1.1 The records management system shall facilitate tracking of the cellular therapy product from the donor to the recipient or final disposition and tracing from the recipient or final disposition to the donor.

C11.1.1.2 For cellular therapy products that are to be distributed for use at another institution, the Apheresis Collection Facility shall inform the receiving institution of the tracking system and requirement for tracking the product in writing or electronic format at or before the time of product distribution.

C11.1.2 Records shall be maintained to preserve their integrity, preservation, and retrieval.

C11.1.3 Records shall be accurate and legible.

C11.1.4 Written records shall be indelible.

C11.1.5 Safeguards to secure the confidentiality of all records and communications between the collection, processing, and clinical facilities, and health care providers and their recipients and donors, shall be established and followed in compliance with Applicable Law.

C11.2 The Apheresis Collection Facility shall define and follow good documentation practices.

C11.3 Apheresis Collection Facility records related to quality control, personnel training and competency, facility maintenance, facility management, complaints, or other general facility issues shall be retained for a minimum of ten (10) years by the Collection Facility, or longer in accordance with Applicable Law.

C11.3.1 Employee records shall be maintained in a confidential manner, as required by Applicable Law.

C11.3.2 Cleaning and sanitation records shall be retained for a minimum of three (3) years or longer in accordance with Applicable Law.

C11.3.3 Validation studies for a collection procedure shall be retained for the duration of the use of the procedure.

C11.4 Records to allow tracking and tracing of cellular therapy products shall be maintained for a minimum of ten (10) years after the administration, distribution, disposition, or expiration of the cellular therapy product, whichever is latest. These records shall include product code, unique numeric or alphanumeric identifier, and collection date and time; and donor and recipient identification as far as known.

C11.5 Recipient and donor records including, but not limited to, consents and records of care shall be maintained in a confidential manner as required by Applicable Law for a minimum of ten (10) years after the administration of the cellular therapy product, or, if not known, ten (10) years after the date of the distribution, disposition, or expiration of the product, whichever is latest.

C11.6 Research records shall be maintained in a confidential manner as required by Applicable Law or for a minimum of ten (10) years after the administration, distribution, disposition, or expiration of the cellular therapy product, whichever is latest.

C11.7 ELECTRONIC RECORDS

C11.7.1 The Apheresis Collection Facility shall maintain a current listing of all critical electronic record systems. Critical electronic record systems shall include at a minimum systems under the control of the Apheresis Collection Facility that are used as a substitute for paper, to make decisions, to perform calculations, or to create or store information used in critical procedures.

C11.7.2 For all critical electronic record systems, there shall be policies, Standard Operating Procedures, and system elements to maintain the accuracy, integrity, identity, and confidentiality of all records.

C11.7.3 There shall be a means by which access to electronic records is limited to authorized individuals.

C11.7.4 The critical electronic record system shall maintain unique identifiers.

C11.7.5 There shall be protection of the records to enable their accurate and ready retrieval throughout the period of record retention.

C11.7.6 For all critical electronic record systems, there shall be an alternative system for all electronic records to allow for continuous operation in the event that critical electronic record systems are not available. The alternative system shall be validated and Apheresis Collection Facility staff shall be trained in its use.

C11.7.7 For all critical electronic record systems, there shall be written Standard Operating Procedures for record entry, verification, and revision.

C11.7.7.1 A method shall be established or the system shall provide for review of data before final acceptance.

C11.7.7.2 A method shall be established or the system shall provide for the unambiguous identification of the individual responsible for each record entry.

C11.7.8 For all critical electronic record systems, there shall be the ability to generate true copies of the records in both human readable and electronic format suitable for inspection and review.

C11.7.9 For all critical electronic record systems, there shall be validated procedures for and documentation of:

C11.7.9.1 Systems development.

C11.7.9.2 Numerical designation of system versions, if applicable.

C11.7.9.3 Prospective validation of systems, including hardware, software, and databases.

C11.7.9.4 Training and continued competency of personnel in systems use.

C11.7.9.5 Monitoring of data integrity.

C11.7.9.6 Back-up of the electronic records system on a regular schedule.

C11.7.9.7 System assignment of unique identifiers.

C11.8 RECORDS IN CASE OF DIVIDED RESPONSIBILITY

C11.8.1 The Apheresis Collection Facility shall furnish to the facility of final disposition a copy of all cellular therapy product records relating to the collection procedure.

C11.8.2 If two (2) or more facilities participate in the collection, processing, or administration of the cellular therapy product, the records of each facility shall show plainly the extent of its responsibility.

C12: DIRECT DISTRIBUTION TO CLINICAL PROGRAM

C12.1 Where cellular therapy products are distributed directly from the Apheresis Collection Facility to the Clinical Program for administration or subsequent processing, the Standards related to labeling, documentation, distribution, transportation, and record keeping in Sections D7, D10, D11, D13, and the Appendices apply.

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PROCESSING FACILITY STANDARDS

PART D

PART D: PROCESSING FACILITY STANDARDS

D1: GENERAL

D1.1 These Standards apply to all processing, storage, and distribution activities performed in the Processing Facility on cellular therapy products.

D1.2 The Processing Facility shall abide by Applicable Law.

D1.2.1 The Processing Facility shall be licensed, registered, or accredited as required by the appropriate governmental authorities for the activities performed.

D1.3 The Processing Facility shall have a Processing Facility Director, a Processing Facility Medical Director, a Quality Manager, and a minimum of one (1) additional designated staff member. This team shall have been in place and actively performing cellular therapy product processing for at least twelve (12) months preceding initial accreditation.

D2: PROCESSING FACILITY

D2.1 There shall be secured and controlled access to designated areas for the processing procedure and for storage of equipment, supplies, and reagents.

D2.1.1 The designated area for processing shall be in an appropriate location of adequate space and design to minimize the risk of airborne microbial contamination.

D2.1.2 The Processing Facility shall be divided into defined areas of adequate size to prevent improper labeling, mix-ups, contamination, or cross-contamination of cellular therapy products.

D2.1.3 There shall be a process to control storage areas to prevent mix-ups, contamination, and cross-contamination of cellular therapy products.

D2.2 The Processing Facility shall provide adequate lighting, ventilation, and access to sinks for hand washing and to toilets to prevent the introduction, transmission, or spread of communicable disease.

D2.2.1 Oxygen sensors shall be appropriately placed and utilized in areas where liquid nitrogen is present.

D2.3 Processing Facility parameters and environmental conditions shall be controlled to protect the safety and comfort of personnel.

D2.4 There shall be a written assessment of critical Processing Facility parameters that may affect cellular therapy product viability, integrity, or contamination or cross-contamination during processing, storage, or distribution.

D2.4.1 The written assessment shall include temperature, humidity, air quality, and surface contaminants at a minimum.

D2.4.2 Critical facility parameters identified to be a risk to the cellular therapy product shall be controlled, monitored, and recorded.

D2.4.3 The Processing Facility shall qualify environmental control systems and validate cleaning and sanitation procedures appropriate for the environmental classification and degree of manipulation performed.

D2.5 The Processing Facility shall document facility cleaning and sanitation and maintain order sufficient to achieve adequate conditions for operations.

D2.6 The Processing Facility shall be operated in a manner designed to minimize risks to the health and safety of employees, visitors, and volunteers.

D2.7 The Processing Facility shall have a written safety manual that includes instructions for action in case of exposure, as applicable, to liquid nitrogen; communicable disease; and to chemical, biological, radiological, electrical, or fire hazards.

D2.8 There shall be a biosafety plan consistent with the institutional biosafety committee requirements that addresses genetically modified cellular therapy products in accordance with Applicable Law.

D2.9 All waste generated by the Processing Facility activities shall be disposed of in a manner that minimizes any hazard to facility personnel and to the environment in accordance with Applicable Law.

D2.10 Personal protective equipment, including gloves and protective clothing, shall be used while handling biological specimens. Such protective equipment shall not be worn outside the work area.

D3: PERSONNEL

D3.1 PROCESSING FACILITY DIRECTOR

D3.1.1 There shall be a Processing Facility Director with a medical degree, doctoral degree, or equivalent degree in a relevant science, qualified by a minimum of two (2) years training and experience for the scope of activities carried out in the Processing Facility.

D3.1.2 The Processing Facility Director shall be responsible for all Standard Operating Procedures, administrative operations, and the Quality Management Program of the Processing Facility, including compliance with these Standards and Applicable Law.

D3.1.3 The Processing Facility Director shall have performed or supervised a minimum of five (5) cellular therapy product processing procedures in the twelve (12) months preceding initial accreditation and a minimum average of five (5) cellular therapy product processing procedures per year within each accreditation cycle.

D3.1.4 The Processing Facility Director shall participate in a minimum of ten (10) hours of educational activities related to cellular therapy annually.

D3.1.4.1 Continuing education shall include, but is not limited to, activities related to the field of HPC transplantation and other cellular therapies.

D3.2 PROCESSING FACILITY MEDICAL DIRECTOR

D3.2.1 There shall be a Processing Facility Medical Director who is a licensed physician with a minimum of two (2) years postgraduate certification, with training and practical and relevant experience for the scope of activities carried out in the preparation and clinical use of cellular therapy products.

D3.2.2 The Processing Facility Medical Director shall be directly responsible for all medical aspects related to the Processing Facility.

D3.2.3 The Processing Facility Medical Director shall have performed or supervised a minimum of five (5) cellular therapy product processing procedures in the twelve (12) months preceding initial accreditation and a minimum average of five (5) cellular therapy product processing procedures per year within each accreditation cycle.

D3.2.4 The Processing Facility Medical Director shall participate in a minimum of ten (10) hours of educational activities related to cellular therapy annually.

D3.2.4.1 Continuing education shall include, but is not limited to, activities related to the field of HPC and other cellular therapies.

D3.3 QUALITY MANAGER

D3.3.1 There shall be a Processing Facility Quality Manager to establish and maintain systems to review, modify, and approve all policies and Standard Operating Procedures intended to monitor compliance with these Standards or the performance of the Processing Facility.

D3.3.2 The Processing Facility Quality Manager should have a reporting structure independent of cellular therapy product manufacturing.

D3.3.3 The Processing Facility Quality Manager shall participate in a minimum of ten (10) hours annually of continuing education activities.

D3.3.3.1 Continuing education activities shall include cellular therapy, cell processing, and Quality Management.

D3.4 STAFF

D3.4.1 The number of trained processing personnel shall be adequate for the number of procedures performed and shall include a minimum of one (1) designated trained individual with an identified trained backup individual to maintain sufficient coverage.

D4: QUALITY MANAGEMENT

D4.1 There shall be a Quality Management Program that incorporates key performance data.

D4.1.1 The Processing Facility Director shall have authority over and responsibility for ensuring that the Quality Management Program is effectively established and maintained.

D4.2 The Processing Facility shall establish and maintain a written Quality Management Plan.

D4.2.1 The Processing Facility Director shall be responsible for the Quality Management Plan as it pertains to the Processing Facility.

D4.3 The Quality Management Plan shall include, or summarize and reference, an organizational chart of key positions, functions, and reporting relationships within the Processing Facility.

D4.3.1 The Quality Management Plan shall include a description of how these key positions interact to implement the quality management activities.

D4.4 The Quality Management Plan shall include, or summarize and reference, policies and Standard Operating Procedures addressing personnel requirements for each key position in the Processing Facility. Personnel requirements shall include at a minimum:

D4.4.1 A current job description for all staff.

D4.4.2 A system to document the following for all staff:

D4.4.2.1 Initial qualifications.

D4.4.2.2 New employee orientation.

D4.4.2.3 Initial training, competency, and retraining when appropriate for all procedures performed, and in accordance with Applicable Law.

D4.4.2.4 Continued competency for each critical function performed, assessed annually at a minimum.

D4.4.2.5 Annual training in applicable current GxP appropriate to the processes performed in accordance with Applicable Law.

D4.4.2.6 Continuing education.

D4.5 The Quality Management Plan shall include, or summarize and reference, a comprehensive system for document control.

D4.5.1 There shall be identification of the types of documents that are considered critical and shall comply with the document control system requirements. Controlled documents shall include at a minimum:

D4.5.1.1 Policies and Standard Operating Procedures.

D4.5.1.2 Worksheets.

D4.5.1.3 Forms.

D4.5.1.4 Labels.

D4.5.2 There shall be policies or Standard Operating Procedures for the development, approval, implementation, distribution, review, revision, and archival of all critical documents.

D4.5.3 The document control system shall include:

D4.5.3.1 A standardized format for critical documents.

D4.5.3.2 Assignment of a numeric or alphanumeric identifier and a title to each document and document version regulated within the system.

D4.5.3.3 A system for document approval, including the approval date, signature of approving individual(s), and the effective date.

D4.5.3.4 A system to protect controlled documents from accidental or unauthorized modification.

D4.5.3.5 Review of controlled documents every two (2) years at a minimum.

D4.5.3.6 A system for document change control that includes a description of the change, version, the signature of approving individual(s), approval date(s), communication or training on the change as applicable, effective date, and archival date.

D4.5.3.7 Archival of controlled documents, the inclusive dates of use, and their historical sequence for a minimum of ten (10) years from archival or according to governmental or institutional policy, whichever is longer.

D4.5.3.8 A system for the retraction of obsolete documents to prevent unintended use.

D4.6 The Quality Management Plan shall include, or summarize and reference, policies and Standard Operating Procedures for the establishment and maintenance of written agreements.

D4.6.1 Agreements shall be established with external parties providing critical services that could affect the quality and safety of the cellular therapy product or health and safety of the donor or recipient.

D4.6.2 Agreements shall include the responsibility of the external party performing any step in collection, processing, testing, storage, distribution, or administration to maintain required accreditations, and to comply with Applicable Law and these Standards.

D4.6.3 Agreements shall be established when the Processing Facility provides critical services to external parties.

D4.6.4 Agreements shall be dated and reviewed on a regular basis, at a minimum every two (2) years.

D4.7 The Quality Management Plan shall include, or summarize and reference, policies and Standard Operating Procedures for review of outcome analysis and cellular therapy product efficacy to verify that the procedures in use consistently provide a safe and effective product.

D4.7.1 Criteria for cellular therapy product safety, product efficacy, and the clinical outcome shall be determined and shall be reviewed at regular time intervals.

D4.7.2 Both individual cellular therapy product data and aggregate data for each type of cellular therapy product shall be evaluated.

D4.7.3 For HPC products intended for hematopoietic reconstitution, time to neutrophil and platelet engraftment following cellular therapy product administration shall be analyzed.

D4.8 The Quality Management Plan shall include, or summarize and reference, policies and Standard Operating Procedures for, and a schedule of, audits of the Processing Facility's activities to verify compliance with elements of the Quality Management Program and policies and Standard Operating Procedures, Applicable Law, and these Standards.

D4.8.1 Audits shall be conducted by an individual with sufficient knowledge in the process and competence in auditing to identify problems, but who is not solely responsible for the process being audited.

D4.8.2 The results of audits shall be used to recognize problems, detect trends, identify improvement opportunities, implement corrective and preventive actions when necessary, and follow-up on the effectiveness of these actions in a timely manner.

D4.8.3 Audits shall be performed annually at a minimum, and shall include at least the following:

D4.8.3.1 Audit of documentation that external facilities performing critical contracted services have met the requirements of the written agreements.

D4.8.3.2 Audit of management of cellular therapy products with positive microbial culture results.

D4.9 The Quality Management Plan shall include, or summarize and reference, policies and Standard Operating Procedures for the management of cellular therapy products with positive microbial culture results that address at a minimum:

D4.9.1 Documentation and product labeling.

D4.9.2 Product quarantine.

D4.9.3 Criteria for cellular therapy product release.

D4.9.4 Identification of individuals authorized to approve release, including the Processing Facility Medical Director at a minimum.

D4.9.5 Notification of the recipient's physician, collection facility, and any other facility in receipt of the cellular therapy product.

D4.9.6 Investigation of cause.

D4.9.7 Reporting to regulatory agencies, if appropriate.

D4.10 The Quality Management Plan shall include, or summarize and reference, policies and Standard Operating Procedures for occurrences (errors, accidents, deviations, adverse events, adverse reactions, and complaints). The following activities shall be included at a minimum:

D4.10.1 Detection.

D4.10.2 Investigation.

D4.10.2.1 A thorough and timely investigation shall be conducted by the Processing Facility in collaboration with the Collection Facility, the Clinical Program, and other entities involved in the manufacture of the cellular therapy product, as appropriate.

D4.10.2.2 Investigations shall identify the root cause and a plan for short- and long-term corrective and preventive actions as warranted.

D4.10.2.3 Occurrences shall be tracked and trended.

D4.10.3 Documentation.

D4.10.3.1 Documentation shall include a description of the occurrence, date and time of the occurrence, the involved individuals and cellular therapy product(s), when and to whom the occurrence was reported, and the immediate actions taken.

D4.10.3.2 All investigation reports shall be reviewed in a timely manner by the Processing Facility Director, Medical Director, and Quality Manager.

D4.10.3.3 Cumulative files of occurrences shall be maintained and include written investigation reports containing conclusions, follow-up, corrective and preventive actions, and a link to the records of the involved cellular therapy products, donors, and recipients, if applicable.

D4.10.4 Reporting.

D4.10.4.1 When it is determined that a cellular therapy product has resulted in an adverse event or reaction, the event and results of the investigation shall be made available to the donor's and recipient's physician(s), as applicable, other facilities participating in the manufacturing of the cellular therapy product, registries, and governmental agencies as required by Applicable Law.

D4.10.4.2 Occurrences shall be reported to other facilities performing cellular therapy product functions on the affected cellular therapy product and to the appropriate regulatory and accrediting agencies, registries, grant agencies, sponsors, IRBs, or Ethics Committees.

D4.10.5 Corrective and preventive action.

D4.10.5.1 Appropriate action shall be implemented if indicated, including both short-term action to address the immediate problem and long-term action to prevent the problem from recurring.

D4.10.5.2 Follow-up audits of the effectiveness of corrective and preventive actions shall be performed in a timeframe as indicated in the investigative report.

D4.11 The Quality Management Plan shall include, or summarize and reference, policies and Standard Operating Procedures for cellular therapy product chain of identity and chain of custody that allow tracking from the donor to the recipient or final disposition and tracing from the recipient or final disposition to the donor.

D4.12 The Quality Management Plan shall include, or summarize and reference, policies and Standard Operating Procedures for actions to take in the event the Processing Facility's operations are interrupted.

D4.13 The Quality Management Plan shall include, or summarize and reference, policies and Standard Operating Procedures for qualification of critical manufacturers, vendors, equipment, software, supplies, reagents, facilities, and services.

D4.13.1 Qualification shall be required following any significant changes to these items.

D4.13.2 Reagents that are not the appropriate grade shall undergo qualification for the intended use.

D4.13.3 Qualification plans shall include minimum acceptance criteria for performance.

D4.13.4 Qualification plans, results, and reports shall be reviewed and approved by the Quality Manager and Processing Facility Director.

D4.14 The Quality Management Plan shall include, or summarize and reference, policies and Standard Operating Procedures for validation or verification of critical procedures.

D4.14.1 Critical procedures to be validated shall include at least the following: processing techniques, cryopreservation procedures, testing, labeling, storage, distribution, and preparation for administration.

D4.14.2 Each validation or verification shall include at a minimum:

D4.14.2.1 An approved plan, including conditions to be assessed.

D4.14.2.2 Acceptance criteria.

D4.14.2.3 Data collection.

D4.14.2.4 Evaluation of data.

D4.14.2.5 Summary of results.

D4.14.2.6 References, if applicable.

D4.14.2.7 Review and approval of the plan, report, and conclusion by the Quality Manager and the Processing Facility Director.

D4.14.3 Significant changes to critical procedures shall be validated and verified as appropriate.

D4.15 The Quality Management Plan shall include, or summarize and reference, policies and Standard Operating Procedures for the evaluation of risk in changes to a process to confirm that the changes do not create an adverse impact or inherent risk elsewhere in the operation.

D4.15.1 Evaluation of risk shall be completed for changes in critical procedures.

D4.16 The Quality Management Plan shall include, or summarize and reference, policies and Standard Operating Procedures for obtaining feedback.

D4.16.1 Feedback shall be obtained from associated Clinical Programs and Collection Facilities.

D4.17 The Processing Facility Director shall review the quality management activities with representatives in key positions in all elements of the cellular therapy program, at a minimum, quarterly.

D4.17.1 Meetings shall have defined attendees, documented minutes, and assigned actions.

D4.17.2 Performance data and review findings shall be reported to key positions and staff.

D4.17.3 The Processing Facility Director shall not have oversight of his/her own work if this person also performs other tasks in the Processing Facility.

D4.18 The Processing Facility Director shall annually review the effectiveness of the Quality Management Program.

D4.18.1 The annual report and documentation of the review findings shall be made available to key personnel, the Clinical Program Director, the Collection Facility Director, and staff of the program.

D5: POLICIES AND STANDARD OPERATING PROCEDURES

D5.1 The Processing Facility shall establish and maintain policies or Standard Operating Procedures addressing critical aspects of operations and management in addition to those required in D4. These documents shall include all elements required by these Standards and shall address at a minimum:

D5.1.1 Donor and recipient confidentiality.

D5.1.2 Cellular therapy product receipt.

D5.1.3 Processing and process control.

D5.1.3.1 Appropriate processing procedures for specific products, including cryopreservation and thawing.

D5.1.4 Processing of ABO-incompatible cellular therapy products to include a description of the indication for and processing methods to be used for red blood cell and plasma reduction.

D5.1.5 Prevention of mix-ups and cross-contamination.

D5.1.6 Labeling (including associated forms and samples).

D5.1.7 Cellular therapy product expiration dates.

D5.1.8 Cellular therapy product storage to include alternative storage if the primary storage device fails.

D5.1.9 Release and exceptional release.

D5.1.10 Packaging, transportation, and shipping, including methods and conditions within the Processing Facility and to and from external facilities.

D5.1.11 Cellular therapy product recall, to include a description of responsibilities and actions to be taken, and notification of appropriate regulatory agencies.

D5.1.12 Cellular therapy product disposal.

D5.1.13 Critical equipment, reagent, and supply management, including recalls and corrective actions in the event of failure.

D5.1.14 Equipment operation, maintenance, and monitoring including corrective actions in the event of failure.

D5.1.15 Cleaning and sanitation procedures including identification of the individuals responsible for the activities.

D5.1.16 Environmental control to include a description of the environmental monitoring plan.

D5.1.17 Hygiene and use of personal protective equipment and attire.

D5.1.18 Disposal of medical and biohazard waste.

D5.1.18.1 Processing Facilities utilizing genetically modified cellular therapy products shall incorporate or reference institutional or regulatory requirements related to the disposal of genetic material.

D5.1.19 Cellular therapy emergency and disaster plan, including the Processing Facility response.

D5.2 The Processing Facility shall maintain a detailed list of all controlled documents, including title and identifier.

D5.3 Standard Operating Procedures shall be sufficiently detailed and unambiguous to allow qualified staff to follow and complete the procedures successfully. Each individual Standard Operating Procedure shall include:

D5.3.1 A clearly written description of the objectives.

D5.3.2 A description of equipment and supplies used.

D5.3.3 Acceptable end-points and the range of expected results.

D5.3.4 A stepwise description of the procedure.

D5.3.5 Reference to other Standard Operating Procedures or policies required to perform the procedure.

D5.3.6 A reference section listing appropriate and current literature.

D5.3.7 Documented approval of each Standard Operating Procedure by the Processing Facility Director or Medical Director, as appropriate, prior to implementation and every two (2) years thereafter.

D5.3.8 Documented approval of each procedural modification by the Processing Facility Director or Medical Director, as appropriate, prior to implementation.

D5.3.9 Reference to a current version of orders, worksheets, reports, labels, and forms.

D5.4 Controlled documents relevant to processes being performed shall be readily available to the facility staff.

D5.5 Staff training and, if appropriate, competency shall be documented before performing a new or revised Standard Operating Procedure.

D5.6 All personnel shall follow the policies and Standard Operating Procedures related to their positions.

D5.7 Planned deviations shall be pre-approved by the Processing Facility Director and/or Medical Director, and reviewed by the Quality Manager.

D6: EQUIPMENT, SUPPLIES, AND REAGENTS

D6.1 Equipment, supplies, and reagents used to process cellular therapy products shall be qualified and used in a manner that maintains product function and integrity and minimizes risks of product mix-ups, contamination, and cross-contamination.

D6.2 There shall be adequate equipment and materials for the procedures performed.

D6.3 Supplies and reagents used in processing, testing, cryopreservation, and storage shall be controlled by a materials management system that includes requirements for the following at a minimum:

D6.3.1 Visual examination of each supply and reagent used to manufacture cellular therapy products for damage or evidence of contamination upon receipt and acceptance into inventory.

D6.3.2 Records of receipt that shall include the supply or reagent type, quantity, manufacturer, lot number, date of receipt, acceptability, and expiration date.

D6.3.3 Storage of materials under the appropriate environmental conditions in a secure, sanitary, and orderly manner to prevent mix up or unintended use.

D6.3.4 Use of supplies and reagents coming into contact with cellular therapy products during processing, storage, and/or administration that are sterile and of the appropriate grade for the intended use.

D6.3.4.1 Reagents shall undergo initial qualification for the intended use.

D6.3.4.2 Where there are no suitable clinical or pharmaceutical grade reagents available, reagents shall undergo lot-to-lot functional verification.

D6.3.4.3 Lot-to-lot functional verification shall include acceptance criteria to confirm that new lots perform as expected compared to the previous lots.

D6.3.5 Cleaning and sterilizing of non-disposable supplies or instruments using a procedure verified to remove infectious agents and other contaminants.

D6.3.6 Use of supplies and reagents in a manner consistent with manufacturer instructions.

D6.3.7 Process to prevent the use of expired reagents and supplies.

D6.4 There shall be a system to uniquely identify and track all critical equipment used in the processing of cellular therapy products. The system shall identify each cellular therapy product for which the equipment was used.

D6.5 Equipment used in cellular therapy product processing, testing, cryopreservation, storage, and distribution shall be maintained in a clean and orderly manner and located to facilitate cleaning, sanitation, calibration, and maintenance according to established schedules.

D6.6 The equipment shall be inspected for cleanliness and verified to be in compliance with the maintenance schedule prior to use.

D6.7 The equipment shall be standardized and calibrated on a regularly scheduled basis and after a critical repair or move as described in Standard Operating Procedures and in accordance with the manufacturer’s recommendations.

D6.7.1 All equipment with a critical measuring function shall be calibrated against a traceable standard, if available. Where no traceable standard is available, the basis for calibration shall be described and documented.

D6.7.2 When equipment is found to be out of calibration or specification, there shall be a defined process for action required for cellular therapy products manufactured since the last calibration.

D6.8 There shall be a Standard Operating Procedure that addresses the actions to take in the event of equipment malfunction or failure.

D6.9 Equipment shall conform to Applicable Law.

D6.10 Lot numbers, expiration dates, manufacturers of critical reagents and supplies, and key equipment used in each procedure shall be documented.

D6.11 The Processing Facility shall use an inventory control system to document the availability and identity of critical reagents and supplies. This shall include at a minimum:

D6.11.1 A system to uniquely identify and track all critical reagents and supplies used to manufacture cellular therapy products.

D6.11.2 A system to identify each cellular therapy product for which each critical reagent or supply was used.

D6.11.3 A system to maintain adequate stocks of reagents and supplies for the procedures to be performed.

D7: CODING AND LABELING OF CELLULAR THERAPY PRODUCTS

D7.1 ISBT 128 AND EUROCODE CODING AND LABELING

D7.1.1 Cellular therapy products shall be identified by name according to ISBT 128 standard terminology or Eurocode.

D7.1.2 Coding and labeling technologies shall be implemented using ISBT 128 or Eurocode.

D7.2 LABELING OPERATIONS

D7.2.1 Labeling operations shall be conducted in a manner adequate to prevent mislabeling or misidentification of cellular therapy products, product samples, and associated records.

D7.2.1.1 Stocks of unused labels representing different cellular therapy products shall be stored in a controlled manner to prevent errors.

D7.2.1.2 Obsolete labels shall be restricted from use.

D7.2.2 Pre-printed labels shall be held upon receipt from the manufacturer pending review and proofing against a copy or template approved by the Processing Facility Director to confirm accuracy regarding identity, content, and conformity.

D7.2.3 A system of label reconciliation shall be used to ensure the final disposition of all labels allocated to a specific product is documented.

D7.2.4 Label systems shall be validated to confirm accuracy regarding identity, content, and conformity of labels to templates approved by the Processing Facility Director.

D7.2.5 A system for label version control shall be employed.

D7.2.5.1 Representative obsolete labels shall be archived minimally for ten (10) years after the last cellular therapy product was distributed with inclusive dates of use or as defined by Applicable Law, whichever is longer.

D7.2.6 A system of checks in labeling procedures shall be used to prevent errors in transferring information to labels.

D7.2.6.1 Cellular therapy products that are subsequently re-packaged into new containers shall be labeled with new labels before they are detached from the original container.

D7.2.6.2 A controlled labeling procedure consistent with Applicable Law shall be defined and followed if container label information is transmitted electronically during a labeling process. This procedure shall include a verification step.

D7.2.7 When the label has been affixed to the container, a sufficient area of the container shall remain uncovered to permit inspection of the contents.

D7.2.8 The information entered on a container label shall be verified by one (1) qualified staff member using a validated process or two (2) qualified staff members.

D7.2.9 Labeling elements required by Applicable Law shall be present.

D7.2.10 All data fields on labels shall be completed.

D7.2.11 All labeling shall be clear, legible, and completed using ink that is indelible to all relevant agents.

D7.2.12 The label shall be validated as reliable for storage under the conditions in use.

D7.2.13 Labels affixed directly to a cellular therapy product bag shall be applied using appropriate materials as defined by the applicable regulatory authority.

D7.3 PRODUCT IDENTIFICATION

D7.3.1 Each cellular therapy product shall be assigned a unique numeric or alphanumeric identifier by which it will be possible to trace any cellular therapy product to its donor, all accompanying records, and its recipient or final disposition.

D7.3.1.1 The cellular therapy product, product samples, concurrent plasma, and concurrently collected samples shall be labeled with the same identifier.

D7.3.1.2 If a single cellular therapy product is stored in more than one (1) container, there shall be a system to identify each container.

D7.3.1.3 If cellular therapy products from the same donor are pooled, the pool identifier shall allow tracing to the original products.

D7.3.1.4 Supplementary identifiers shall not obscure the original identifier.

D7.3.1.5 The facility associated with each identifier shall be named in the documents to accompany the cellular therapy product.

D7.3.1.6 If the original identifier is replaced, documentation shall link the new identifier to the original.

D7.4 LABEL CONTENT

D7.4.1 At all stages of processing, the cellular therapy product shall be labeled with the proper name of the product and the unique numeric or alphanumeric identifier, at a minimum.

D7.4.2 The name and address of the facility that determines that the cellular therapy product meets release criteria and the name and address of the facility that makes the product available for distribution shall either appear on the product label or accompany the product at distribution.

D7.4.3 At the completion of processing and at distribution for administration, the cellular therapy product label on the primary product container and concurrent plasma container shall bear the information in the Cellular Therapy Product Labeling table in Appendix II.

D7.4.4 Each label shall bear the appropriate biohazard and warning labels as found in the Circular of Information for the Use of Cellular Therapy Products, “Table 2. Biohazard and Warning Labels on Cellular Therapy Products Collected, Processed, and/or Administered in the United States.”

D7.4.4.1 For cellular therapy products not collected, processed, and/or administered in the U.S., the appropriate Biohazard and Warning Labels shall follow Applicable Law.

D7.4.5 A cellular therapy product collected in or designated for use in the U.S. shall have the elements in the Accompanying Documentation table in Appendix IV accompany the cellular therapy product at the time it leaves the control of the Processing Facility.

D7.4.6 Any container bearing a partial label at the time of distribution shall be accompanied by the information required by the Cellular Therapy Product Labeling table in Appendix II. Such information shall be attached securely to the cellular therapy product on a tie tag or enclosed in a sealed package to accompany the product.

D7.4.7 For cellular therapy products distributed before completion of donor eligibility determination, there shall be documentation that donor eligibility determination was completed during or after distribution of the cellular therapy product and that the physician using the product was informed of the results of that determination.

D7.4.8 Cellular therapy products distributed for nonclinical purposes shall be labeled with the statement, “For Nonclinical Use Only.”

D8: PROCESS CONTROLS

D8.1 There shall be a process for controlling and monitoring the manufacturing of cellular therapy products so that products meet predetermined release specifications.

D8.1.1 The Processing Facility Director shall define tests and procedures for measuring and assaying cellular therapy products to assure their safety, viability, and integrity and to document that products meet predetermined release specifications. Results of all such tests and procedures shall become part of the permanent record of the product processed.

D8.1.2 There shall be a documented system for the identification and handling of test samples so that they are accurately related to the corresponding cellular therapy product, donor, or recipient.

D8.1.2.1 There shall be a mechanism to identify the individual obtaining the sample, the sample source, the date, and the time, if appropriate.

D8.1.2.2 Samples obtained for testing shall be representative of the cellular therapy product to be evaluated.

D8.1.3 There shall be the establishment of appropriate and validated assays and test procedures for the evaluation of cellular therapy products.

D8.1.3.1 For all cellular therapy products, a total nucleated cell count and viability measurement shall be performed.

D8.1.3.2 For HPC products intended for restoration of hematopoiesis, an assay measuring viable CD34 shall be performed.

D8.1.3.3 For cellular therapy products undergoing manipulation that alters the final cell population, a relevant and validated assay, where available, shall be employed for evaluation of the viable target cell population before and after the processing procedures.

D8.1.4 For tests required by these Standards performed within the Processing Facility:

D8.1.4.1 There shall be a process for monitoring the reliability, accuracy, precision, and performance of laboratory test procedures and instruments.

D8.1.4.2 New reagent lots shall be verified to provide comparable results to current lots or to give results in agreement with suitable reference material before or concurrently with being placed into service.

D8.1.4.3 Where available, controls shall be used each day of testing and shown to give results within the defined range established for that material.

D8.1.4.4 Function checks shall be performed for testing instruments prior to testing donor, recipient, or cellular therapy product samples.

D8.1.4.5 There shall be documentation of ongoing proficiency testing as designated by the Processing Facility Director. The results shall be reviewed by the Processing Facility Director and outcomes reviewed with the staff.

D8.1.5 Tests required by these Standards, not performed by the Processing Facility, shall be performed by a laboratory that is certified, licensed, or accredited by the appropriate laboratory regulatory agency.

D8.1.6 Infectious disease testing required by these Standards shall be performed using screening tests licensed, approved, or cleared by the governmental authority for cellular therapy product donors.

D8.1.7 Cellular therapy products that do not meet allogeneic donor eligibility requirements, or for which allogeneic donor eligibility determination is not yet complete, shall be distributed only if there is documented urgent medical need for the product. Documentation shall include, at a minimum, the approval of the recipient's physician and the Processing Facility Medical Director.

D8.1.8 Notification of the recipient's physician of nonconforming cellular therapy products and approval for their release shall be documented.

D8.2 There shall be a written request from the recipient's physician specifying the cellular therapy product type, recipient and donor identifiers, the type of processing that is to be performed, and the anticipated date of processing before a cellular therapy product is processed, shipped, or otherwise prepared for administration.

D8.3 For allogeneic cellular therapy products, information required by the Processing Facility prior to distribution of the product shall include:

D8.3.1 A statement of donor eligibility.

D8.3.2 For ineligible donors, the reason for their ineligibility.

D8.3.3 For ineligible donors or donors for whom eligibility determination is incomplete, documentation of urgent medical need and physician approval for use.

D8.4 Processing procedures shall be validated in the Processing Facility and documented to result in acceptable target cell viability and recovery.

D8.4.1 Published validated processes shall be verified within the Processing Facility prior to implementation.

D8.4.2 The Processing Facility shall use validated methods for preparation of cellular therapy products for administration.

D8.4.3 Cord blood units that have not been red blood cell reduced prior to cryopreservation shall be washed prior to administration.

D8.4.4 Cord blood units that have been red blood cell reduced prior to cryopreservation should be diluted or washed prior to administration.

D8.4.5 Preparation for administration of cellular therapy products manufactured by third parties shall follow the instructions provided by the manufacturer.

D8.4.5.1 The Processing Facility should verify the preparation procedures utilizing practice units similar to the cellular therapy product intended for administration when feasible.

D8.4.5.2 If relabeling of prepared third-party products is required, the label shall follow Applicable Law.

D8.5 Critical control points and associated assays shall be identified and performed on each cellular therapy product as defined in Standard Operating Procedures.

D8.6 Critical calculations shall be verified and documented where appropriate.

D8.7 Methods for processing shall employ aseptic technique and cellular therapy products shall be processed in a manner that minimizes the risk of cross-contamination.

D8.7.1 Where processing of tissues and cells involves exposure to the environment, processing shall take place in an environment with specified air quality and cleanliness.

D8.7.2 The effectiveness of measures to avoid contamination and cross-contamination shall be verified and monitored.

D8.8 The Processing Facility shall monitor and document microbial contamination of cellular therapy products after processing as specified in Standard Operating Procedures.

D8.8.1 The results of microbial cultures shall be reviewed by the Processing Facility Director in a timely manner.

D8.8.2 The recipient's physician shall be notified in a timely manner of any positive microbial cultures.

D8.9 Records shall be made concurrently with each step of the processing, testing, cryopreservation, storage, and administration or disposal/disposition/distribution of each cellular therapy product in such a way that all steps may be accurately traced.

D8.9.1 Records shall identify the person immediately responsible for each significant step, including dates and times, where appropriate.

D8.9.2 Records shall show the test results and the interpretation of each result, where appropriate.

D8.10 The Processing Facility Director shall review the processing record for each cellular therapy product prior to release or distribution.

D8.11 There shall be documented notification to the recipient's physician and the Processing Facility Medical Director of clinically relevant processing end-points not met and remedial actions taken.

D8.12 Processing using more-than-minimal manipulation shall only be performed in accordance with institutional policies and Applicable Law; and with the written informed consent of the donor, if applicable, and the recipient of the cellular therapy product.

D8.12.1 Documentation of approvals by the Institutional Review Board, Ethics Committee, or equivalent; and the Institutional Biosafety Committee, or equivalent shall be maintained.

D8.12.2 The Processing Facility shall adhere to GMP appropriate for the degree of cellular therapy product manipulation.

D8.13 For allogeneic cellular therapy products containing red blood cells at the time of administration:

D8.13.1 Results for ABO group and Rh type testing shall be available from two (2) independently collected samples. Discrepancies shall be resolved and documented prior to issue of the cellular therapy product.

D8.13.2 Results for a red blood cell antibody screen on the recipient shall be available.

D8.14 There shall be a Standard Operating Procedure to confirm the identity of cord blood units if verification typing cannot be performed on attached segments.

D8.15 One or more samples representing the cryopreserved cellular therapy product shall be stored under conditions that achieve a valid representation of the clinical product and in accordance with institutional Standard Operating Procedures.

D9: CELLULAR THERAPY PRODUCT STORAGE

D9.1 Processing Facilities shall control and secure storage areas to prevent mix-ups, deterioration, contamination, cross-contamination, and improper distribution of cellular therapy products.

D9.2 STORAGE DURATION

D9.2.1 Conditions and duration of storage of all cellular therapy products shall be validated.

D9.2.2 Processing Facilities processing, storing, or releasing cellular therapy products for administration shall assign an expiration date and time for non-cryopreserved products and for products thawed after cryopreservation.

D9.2.3 There shall be a written stability program that annually evaluates the viability and potency of cryopreserved cellular therapy products.

D9.2.3.1 Samples should include those representative of all processing methods and those representative of maximum storage duration.

D9.3 TEMPERATURE

D9.3.1 Storage temperatures shall be defined in Standard Operating Procedures.

D9.3.2 Noncryopreserved cellular therapy products shall be maintained within a specific temperature range to maintain viability and function, to inhibit infectious agents, and for a period of time not to exceed that specified in Standard Operating Procedures.

D9.3.3 Cryopreserved cellular therapy products shall be stored within a temperature range, as defined in Standard Operating Procedures, that is appropriate for the product and cryoprotectant solution used.

D9.3.4 Prior to receipt of a cellular therapy product from an external facility, there shall be confirmation that the product can be appropriately stored.

D9.4 PRODUCT SAFETY

D9.4.1 Materials that may adversely affect cellular therapy products shall not be stored in the same refrigerators or freezers as the cellular therapy products.

D9.4.2 For cellular therapy products immersed in liquid nitrogen, procedures to minimize the risk of cross-contamination of products shall be employed.

D9.4.3 Processes for storing cellular therapy products in quarantine shall be defined in Standard Operating Procedures.

D9.4.3.1 Quarantined cellular therapy products shall be easily distinguishable and stored in a manner that minimizes the risks of cross-contamination and inappropriate distribution.

D9.4.3.2 All cellular therapy products with positive infectious disease test results for relevant communicable disease agents or positive microbial cultures shall be quarantined.

D9.4.3.3 Processing Facilities storing cellular therapy products shall quarantine each product until completion of the donor eligibility determination as required by Applicable Law.

D9.5 STORAGE MONITORING

D9.5.1 Storage devices in which cellular therapy products are not fully immersed in liquid nitrogen shall have a system to monitor the temperature continuously and to record the temperature at least every four (4) hours.

D9.5.2 There shall be a mechanism to confirm that levels of liquid nitrogen in liquid nitrogen freezers are consistently maintained to assure that cellular therapy products remain within the specified temperature range.

D9.6 ALARM SYSTEMS

D9.6.1 Storage devices for cellular therapy products or reagents for cellular therapy product processing shall have alarm systems that are continuously active.

D9.6.2 Alarm systems shall have audible and visible signals or other effective notification methods.

D9.6.3 Alarm systems shall be checked periodically for function.

D9.6.4 If trained personnel are not always present in the immediate area of the storage device, a system shall be in place that alerts responsible personnel of alarm conditions on a 24-hour basis.

D9.6.5 Alarms shall be set to activate at a temperature or level of liquid nitrogen that will allow time to salvage products.

D9.6.6 Written instructions to be followed if the storage device fails shall be displayed in the immediate area of the storage device and at each remote alarm location.

D9.6.6.1 Instructions shall include a procedure for notifying processing personnel.

D9.6.7 Storage devices of appropriate temperature shall be available for cellular therapy product storage if the primary storage device fails.

D9.7 The storage device shall be located in a secure area and accessible only to personnel authorized by the Processing Facility Director.

D9.8 The Processing Facility shall use an inventory control system to identify the location of each cellular therapy product and associated samples. The inventory control system records shall include:

D9.8.1 Cellular therapy product unique identifier.

D9.8.2 Recipient name or unique identifier.

D9.8.3 Storage device identifier.

D9.8.4 Location within the storage device.

D10: CELLULAR THERAPY PRODUCT TRANSPORTATION AND SHIPPING

D10.1 Standard Operating Procedures for transportation and shipping of cellular therapy products shall be designed to protect the integrity of the product and the health and safety of individuals in the immediate area.

D10.2 The primary product container for non-frozen cellular therapy products shall be placed in a secondary container and sealed to prevent leakage.

D10.3 Cellular therapy products that require a temperature-controlled environment and that are transported or shipped over an extended period of time shall be transported or shipped in a container validated to maintain the appropriate temperature range.

D10.4 Conditions shall be established and maintained to preserve the integrity and safety of cellular therapy products during transport or shipping.

D10.5 Cellular therapy products that are shipped to another facility or transported on public roads shall be packaged in an outer container.

D10.5.1 The outer container shall conform to the applicable regulations regarding the mode of transportation or shipping.

D10.5.2 The outer container shall be made of material adequate to withstand leakage of contents, shocks, pressure changes, and other conditions incident to ordinary handling during transport or shipping.

D10.5.2.1 The temperature of the shipping container shall be continuously monitored during shipment of cellular therapy products.

D10.5.2.2 The shipping facility shall maintain a record of the temperature over the period of travel.

D10.5.3 The outer container shall be secured.

D10.5.4 The outer container shall be labeled as defined in the Cellular Therapy Product Labels for Shipping and Transport on Public Roads table in Appendix III.

D10.5.5 There shall be a document inside the outer container that includes all the information required on the outer container, in conformity with the Cellular Therapy Product Labels for Shipping and Transport on Public Roads table in Appendix III.

D10.5.6 The outer container shall be labeled in accordance with Applicable Law regarding the cryogenic material used and the transport or shipment of biological materials.

D10.6 Cellular therapy products transported internally shall be packaged in a closed and rigid outer container.

D10.6.1 The outer container for internal transport shall be labeled as defined in Appendix III B.

D10.7 The transit time shall be within time limits determined by the distributing facility in consultation with the receiving facility to maintain cellular therapy product safety.

D10.8 If the intended recipient has received high-dose therapy, the cellular therapy product shall be transported.

D10.9 There shall be plans for alternative means of transport or shipping in an emergency.

D10.10 Cellular therapy products should not be passed through X-Ray irradiation devices designed to detect metal objects. If inspection is necessary, the contents of the container should be inspected manually.

D11: RECEIPT AND DISTRIBUTION

D11.1 RECEIPT OF CELLULAR THERAPY PRODUCTS

D11.1.1 Standard Operating Procedures shall be established and maintained for acceptance, rejection, and quarantine of cellular therapy products.

D11.1.2 The receipt of each cellular therapy product shall include inspection to verify:

D11.1.2.1 The integrity of the cellular therapy product container.

D11.1.2.2 The appearance of the cellular therapy product for evidence of mishandling or microbial contamination.

D11.1.2.3 Appropriate labeling.

D11.1.3 There shall be Standard Operating Procedures to verify that the cellular therapy product was appropriately transported or shipped.

D11.1.3.1 The receiving facility shall document the temperature inside the container upon arrival if shipped or transported on public roads.

D11.1.3.2 For cryopreserved cellular therapy products, receiving facility records shall include documentation of the container temperature during shipping.

D11.1.4 The receiving facility shall review and verify cellular therapy product specifications provided by the manufacturer, if applicable.

D11.1.5 There shall be Standard Operating Procedures to maintain cellular therapy products in quarantine until they have been determined to meet criteria for release from quarantine.

D11.1.6 If the temperature of the cellular therapy product has been compromised, the Processing Facility Director shall give specific authorization to return the product to inventory.

D11.1.7 The receiving facility shall have readily available access to a summary of documents used to determine allogeneic donor eligibility.

D11.1.7.1 For cellular therapy products received from an external facility, there shall be documented evidence of donor eligibility screening and testing in accordance with Applicable Law.

D11.1.8 When cellular therapy products are returned to the Processing Facility after distribution for administration, there shall be documentation in the Processing Facility records of the events requiring return, the temporary storage temperature when at the clinical facility, the results of inspection upon return, and subsequent action taken to protect product safety and viability.

D11.1.8.1 The Processing Facility Director shall consult with the recipient's physician regarding reissue or disposal of the returned cellular therapy product.

D11.2 DISTRIBUTION CRITERIA

D11.2.1 The processing, collection, and transport or shipping records for each cellular therapy product shall be reviewed by the Processing Facility Director for compliance with Standard Operating Procedures and Applicable Law prior to product release or distribution.

D11.2.1.1 Records shall demonstrate traceability from the donor to the recipient and from the recipient to the donor.

D11.2.2 Each cellular therapy product shall meet pre-determined release criteria prior to distribution from the Processing Facility. The release criteria shall include donor eligibility determination for allogeneic products.

D11.2.2.1 The Processing Facility Director shall give specific authorization for release when the cellular therapy product does not meet technical release criteria.

D11.2.2.2 The Processing Facility Medical Director shall give specific authorization for release when the cellular therapy product does not meet clinically relevant release criteria.

D11.2.2.3 Documentation of agreement between the Processing Facility Medical Director and the recipient's physician to use any non-conforming product shall be retained in the processing record if such release is allowed by policies, Standard Operating Procedures, or package inserts of licensed products.

D11.2.3 Each cellular therapy product issued for administration shall be visually inspected by two (2) trained personnel immediately before release to verify the integrity of the product container and appropriate labeling.

D11.2.3.1 A cellular therapy product shall not be released when the container is compromised or recipient or donor information is not verified unless the Processing Facility Director gives specific authorization for the product's release.

D11.2.4 For each type of cellular therapy product, the Processing Facility shall maintain and distribute or make a document available to clinical staff containing the following:

D11.2.4.1 The use of the cellular therapy product, indications, contraindications, side effects and hazards, dosage, and administration recommendations.

D11.2.4.2 Instructions for handling the cellular therapy product to minimize the risk of contamination or cross-contamination.

D11.2.4.3 Appropriate warnings related to the prevention of the transmission or spread of communicable diseases.

D11.3 DISTRIBUTION RECORDS

D11.3.1 The cellular therapy product distribution records shall permit tracking and tracing of the cellular therapy product, and shall contain the following information at a minimum:

D11.3.1.1 The proper product name and identifier.

D11.3.1.2 Unique identifier of the intended recipient.

D11.3.1.3 Documentation of donor eligibility determination, as appropriate.

D11.3.1.4 Identification of the facilities that requested and distributed the product.

D11.3.1.5 Identity of the receiving facility.

D11.3.1.6 Date and time cellular therapy product was distributed.

D11.3.1.7 Date and time cellular therapy product was received.

D11.3.1.8 Identity of the transporting or shipping facility.

D11.3.1.9 Identity of personnel responsible for cellular therapy product transportation or shipping and of personnel responsible for receiving the product.

D11.3.1.10 Identity of the courier.

D11.3.1.11 Documentation of any delay or problems incurred during transportation or shipping.

D12: DISPOSAL

D12.1 Disposal of cellular therapy products shall include the following requirements:

D12.1.1 A pre-collection written agreement between the storage facility and the designated recipient or the donor defining the length of storage and the circumstances for disposal of cellular therapy products.

D12.1.2 The option to transfer the cellular therapy product to another facility if the designated recipient is still alive after the agreed upon storage interval.

D12.1.3 Documentation of no further need for the cellular therapy product before any product is discarded.

D12.1.3.1 For HPC products, this shall include documentation of the designated recipient's death, if applicable.

D12.1.4 Approval by the Processing Facility Medical Director in consultation with the recipient's physician for cellular therapy product discard or other disposition, and method of disposal.

D12.1.5 A method of disposal and decontamination that meets Applicable Law for disposal of biohazardous materials and/or medical waste.

D12.2 Processing Facilities, in consultation with the Clinical Program, shall establish policies for the duration and conditions of storage and indications for disposal.

D12.2.1 Recipients, donors, and associated Clinical Programs should be informed about policies for directed cellular therapy products as part of the informed consent process and before the cellular therapy product collection.

D12.2.2 If there is no pre-existing agreement describing conditions for cellular therapy product storage and/or discard or if the intended recipient is lost to follow-up, the storage facility shall make a documented effort to notify the donor, cellular therapy product manufacturer, or designated recipient's physician and facility about product disposition, including disposal or transfer.

D12.3 The records for discarded or transferred cellular therapy products shall indicate the product was discarded or transferred, date of discard or transfer, disposition, and method of disposal or transfer.

D13: RECORDS

D13.1 There shall be a records management system for quality and cellular therapy product record creation, assembly, review, storage, archival, and retrieval.

D13.1.1 The records management system shall facilitate the review of records pertaining to a particular cellular therapy product prior to distribution and for follow-up evaluation or investigation.

D13.1.2 The records management system shall facilitate tracking of the cellular therapy product from the donor to the recipient or final disposition and tracing from the recipient or final disposition to the donor.

D13.1.3 For cellular therapy products that are to be distributed for use at another institution, the Processing Facility shall inform the receiving institution of the tracking system and requirement for tracking the product in writing or electronic format at or before the time of product distribution.

D13.1.4 Records shall be accurate and legible.

D13.1.5 Written records shall be indelible.

D13.1.6 Records shall be maintained in such a way as to secure their integrity, preservation, and retrieval.

D13.1.7 Safeguards to secure the confidentiality of all records and communications between the collection, processing, and clinical facilities, and health care providers and their recipients and donors, shall be established and followed in compliance with Applicable Law.

D13.2 The Processing Facility shall define and follow good documentation practices.

D13.3 ELECTRONIC RECORDS

D13.3.1 The Processing Facility shall maintain a current listing of all critical electronic record systems. Critical electronic record systems shall include at a minimum systems under the control of the Processing Facility that are used as a substitute for paper, to make decisions, to perform calculations, or to create or store information used in critical procedures.

D13.3.2 For all critical electronic record systems, there shall be policies, Standard Operating Procedures, and system elements to maintain the accuracy, integrity, identity, and confidentiality of all records.

D13.3.3 There shall be a means by which access to electronic records is limited to authorized individuals.

D13.3.4 The critical electronic record system shall maintain unique identifiers.

D13.3.5 There shall be protection of the records to enable their accurate and ready retrieval throughout the period of record retention.

D13.3.6 For all critical electronic record systems, there shall be an alternative system for all electronic records to allow for continuous operation of the Processing Facility in the event that critical electronic record systems are not available. The alternative system shall be validated and Processing Facility staff shall be trained in its use.

D13.3.7 For all critical electronic record systems, there shall be written Standard Operating Procedures for record entry, verification, and revision.

D13.3.7.1 A method shall be established or the system shall provide for review of data before final acceptance.

D13.3.7.2 A method shall be established or the system shall provide for the unambiguous identification of the individual responsible for each record entry.

D13.3.8 For all critical electronic record systems, there shall be the ability to generate true copies of the records in both human readable and electronic format suitable for inspection and review.

D13.3.9 For all critical electronic record systems, there shall be validated procedures for and documentation of:

D13.3.9.1 Systems development.

D13.3.9.2 Numerical designation of system versions, if applicable.

D13.3.9.3 Prospective validation of systems, including hardware, software, and databases.

D13.3.9.4 Installation of the system.

D13.3.9.5 Training and continued competency of personnel in systems use.

D13.3.9.6 Monitoring of data integrity.

D13.3.9.7 Back-up of the electronic records system on a regular schedule.

D13.3.9.8 System maintenance and operations.

D13.3.9.9 System assignment of unique identifiers.

D13.3.10 All system modifications shall be authorized, documented, and validated prior to implementation.

D13.4 RECORDS TO BE MAINTAINED

D13.4.1 Processing Facility records related to quality control, investigational protocols, personnel training and competency, facility maintenance, facility management, complaints, or other general facility issues shall be retained for a minimum of ten (10) years after the creation of the cellular therapy product record, date of the cellular therapy product's distribution, disposition, or expiration, or, whichever is latest, or according to Applicable Law.

D13.4.1.1 Employee records shall be maintained in a confidential manner, as required by Applicable Law.

D13.4.1.2 Facility maintenance records pertaining to facility cleaning and sanitation shall be retained for at least three (3) years or longer in accordance with Applicable Law.

D13.4.1.3 Validation studies for a processing procedure shall be retained at a minimum until no cellular therapy products manufactured using that procedure remain in inventory.

D13.4.2 Records to allow tracing of cellular therapy products shall be maintained for a minimum of ten (10) years after administration, distribution, disposition, or expiration of the cellular therapy product, or as required by Applicable Law, whichever is latest. These records shall include collection and processing facility identity, unique numeric or alphanumeric identifier, collection date and time, product code, and donor and recipient information as found on the original container.

D13.4.3 All records pertaining to the processing, testing, storage, or distribution of cellular therapy products shall be maintained for a minimum of ten (10) years after the date of administration, or if the date of administration is not known, then a minimum of ten (10) years after the date of the cellular therapy product's distribution, disposition, or expiration, or the creation of the cellular therapy product record, whichever is most recent, or according to Applicable Law or institutional policy, whichever is latest.

D13.4.4 Research records shall be maintained in a confidential manner as required by Applicable Law or for a minimum of ten (10) years after the administration, distribution, disposition, or expiration of the cellular therapy product, whichever is latest.

D13.5 RECORDS IN CASE OF DIVIDED RESPONSIBILITY

D13.5.1 The Processing Facility shall maintain a listing of the names, addresses, and responsibilities of other facilities that perform manufacturing steps on a cellular therapy product.

D13.5.2 The Processing Facility shall furnish to the facility of final disposition a summary of records relating to the collection, processing, and storage procedures performed related to the safety, purity, or potency of the cellular therapy product involved.

D13.5.3 If two (2) or more facilities participate in the collection, processing, or administration of the cellular therapy product, the records of the Processing Facility shall show plainly the extent of its responsibility.

APPENDIX I

MINIMUM NUMBER OF NEW PATIENTS FOR ACCREDITATION

Clinical Programs shall transplant at least the following number of new patients[1] before initial accreditation and annually thereafter:

Transplant Population	Clinical Site(s)	Type of Transplant	Twelve (12) Months Prior to Initial Accreditation	Average Per Year Within Accreditation Cycle
Adult OR Pediatric (only one of these two)	Single Clinical Site	Autologous only	5 autologous	5 autologous
		Allogeneic and Autologous	10 allogeneic recipients	10 allogeneic recipients
	Multiple Clinical Sites	Autologous only	5 autologous recipients at each site	5 autologous recipients at each site
		Allogeneic and Autologous	• 5 allogeneic recipients at each applicable site[2] • 5 autologous at each applicable site[2]	• 5 allogeneic recipients at each applicable site[2] • 5 autologous at applicable each applicable site[2]
Combined Adult AND Pediatric	Single Clinical Site	Autologous only	• 5 adult autologous • 5 pediatric autologous recipients	• 5 adult autologous • 5 pediatric autologous recipients
		Allogeneic and Autologous	• 5 adult allogeneic recipients • 5 pediatric allogeneic recipients	• 5 adult allogeneic recipients • 5 pediatric allogeneic recipients
	Multiple Clinical Sites	Autologous only	• 5 adult autologous at each applicable site • 5 pediatric autologous recipients at each applicable site	• 5 adult autologous recipients at each applicable site • 5 pediatric autologous recipients at each applicable site
		Allogeneic and Autologous	• 5 adult allogeneic recipients at each applicable site • 5 pediatric allogeneic recipients at each applicable site • 5 adult autologous at each applicable site[2] • 5 pediatric autologous at each applicable site[2]	• 5 adult allogeneic recipients at each site • 5 pediatric allogeneic recipients at each site • 5 adult autologous at each applicable site[2] • 5 pediatric autologous at each applicable site[2]

[1]The term “new allogeneic patient” or “new autologous patient” includes only a patient who received his/her first transplant of that type during the period of time in question.

[2]Programs performing allogeneic and autologous transplantation that have more than one clinical site may or may not perform both types of transplant at each site. The requirement for five autologous transplant recipients per site only applies to those sites that do not perform allogeneic transplant.

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APPENDIX II

CELLULAR THERAPY PRODUCT LABELING
Each label shall include at least the elements detailed in the following table[1]:

Element[2]	Label at completion of collection	Label at completion of processing	Partial label at distribution for administration[4]	Label at distribution for administration
Unique numeric or alphanumeric identifier[3]	AF	AF	AF	AF
Proper name of product[5,6]	AF	AF	AF	AF
Product code[5]	AF	AF	AF	AF
Product attributes[5]	AC	AC	AC	AF
Recipient name and/or identifier	AT	AT	AC	AT
Identity and address of collection facility or donor registry	AT	AC	AC	AC
Date, time collection ends, and (if applicable) time zone	AT	AC	AC	AC
Approximate volume	AF	AF	AF	AF
Name and quantity of anticoagulant and other additives	AF	AF	AF	AF
Recommended storage temperature range	AF	AF	AF	AF
Donor identifier and (if applicable) name	AT	AT	AC	AF
Biohazard and/or Warning Labels (as applicable, see CM7.4, C7.4, D7.4)	AT	AT	AC	AT
As applicable: Statement "NOT EVALUATED FOR INFECTIOUS SUBSTANCES"	AT	AT	AC	AT
Statement "WARNING: Advise Patient of Communicable Disease Risks"	AT	AT	AC	AT
Statement "WARNING: Reactive Test Results for [name of disease agent or disease]"	AT	AT	AC	AT
Identity and address of processing and distribution facility(ies)	-	AC	AC	AC
Statement "Do Not Irradiate"	-	AT	AC	AF
Expiration Date (if applicable)	-	AC	AC	AF
Expiration Time (if applicable)	-	AC	AC	AC
ABO and Rh of donor (if applicable)	-	AC	AC	AC
RBC compatibility determination (if applicable)	-	-	AC	AC
Statement indicating that leukoreduction filters shall not be used	-	-	AC	AF
Statement "FOR AUTOLOGOUS USE ONLY" (if applicable)	AT	AT	AC	AF
Date of distribution	-	-	AC	AC

AF=Affix, AT=Attach or Affix, AC=Accompany, Attach or Affix

[1]Container and full package labeling requirements for licensed products or products under Investigational New Drug (IND) application shall follow Applicable Law. In the U.S., see 21 CFR 312.6(a).
[2]Full implementation of ISBT 128 labeling requires compliance with the ISBT 128 Standard for the location of information on the label and/or the accompanying documentation.
[3]Overlay labels for supplementary identifiers shall not obscure the original identifier.
[4]A partial label at distribution is a label that because of the size of the product container or other constraints, does not contain all of the required information.
[5]Product proper names and attributes must also be identified in words, and are listed in Chapter Three of the ISBT 128 Standard Terminology for Blood, Cellular Therapy, and Tissue Product Descriptions. Available at: www.iccbba.org > Subject Area > Cellular Therapy > Standard Terminology. This includes all potential attributes, in addition to the core attribute referenced in this table (Anticoagulant, Volume, Storage Temperature): Intended Use, Manipulation, Cryoprotectant, Blood Component from Third Party Donor, Preparation, Genetically Modified, Irradiation, Modification, Mobilization, Pooled Single, Cultured, Enrichment, and Reduction.
[6] Proper name of product is also referred to as class name in the ISBT 128 Standard Terminology.

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APPENDIX III

A: CELLULAR THERAPY PRODUCT LABELS FOR SHIPPING AND TRANSPORT ON PUBLIC ROADS

Each container for shipping and transport on public roads shall include a document on the inside of the container and a label on the exterior of the container with at least the elements detailed in the following table:

Element	Inner container document	Outer container label
Date of distribution	AC	AC
Time[1] of distribution, if appropriate	AC	AC
Statement “Do Not X-Ray” and /or “Do Not Irradiate”, if applicable	AC	AF
Statements ”Human Cells for Administration” or equivalent and “Handle with Care”	AC	AF
Shipper handling instructions	AC	AF
Shipping facility name, street address, contact person, and phone number	AC	AF
Receiving facility name, street address, contact person, and phone number	AC	AF
Biohazard and/or Warning Labels (as applicable, see CM7.4, C7.4, D7.4)	AC	-
If applicable: Statement “NOT EVALUATED FOR INFECTIOUS SUBSTANCES”	AC	-
Statement “WARNING: Advise Patient of Communicable Disease Risks”	AC	-
Statement “WARNING: Reactive Test Results for [name of disease agent or disease]”	AC	-

AC= Accompany, AF=Affix

[1]Time shall include the time zone when shipping or transport of the cellular therapy product involves crossing time zones.

B: CELLULAR THERAPY PRODUCT LABELS FOR INTERNAL TRANSPORT

Each container for internal transport shall include an internal transport label with at least the elements detailed in the following table:

Element	Internal transport label
Statements ”Human Cells for Administration” or equivalent and “Handle with Care”	AF
Emergency contact person name and phone number	AF

AF=Affix

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APPENDIX IV

ACCOMPANYING DOCUMENTATION

Products collected in or designated for use in the U.S. shall be accompanied upon leaving the control of the Collection or Processing Facility with at least the elements detailed in the following table[1]:

Documentation	Allogeneic Donor-Eligible	Allogeneic Donor-Ineligible[2]	Allogeneic Donor-Incomplete[2]
Statement that the donor has been determined to be either eligible or ineligible, based upon results of donor screening and testing	X	X	-
Summary of records used to make the donor-eligibility determination[3]	X	X	-
Name and address of the establishment that made the donor eligibility determination	X	X	-
Listing and interpretation of the results of all communicable disease testing performed	X	X	X
Statement that the communicable disease testing was performed by a laboratory meeting regulatory requirements[4]	X	If applicable	If applicable
Statement noting the reason(s) for the determination of ineligibility	-	X	-
Statement that the donor eligibility determination has not been completed	-	-	X
Statement that the product must not be transplanted or administered until completion of the donor eligibility determination, except under condition of urgent medical need	-	-	X
Listing of any required screening or testing that has not yet been completed	-	-	X
Results of donor screening that has been performed	-	-	X
Documentation that the physician using the cellular therapy product was notified of incomplete testing or screening	-	-	X
Instructions for product use to prevent the introduction, transmission, or spread of communicable diseases[1]	X	X	X
Instructions for reporting serious adverse reactions or events to the distributing facility[1, 5]	X	X	X

[1]For autologous cellular therapy products, instructions for product use to prevent the introduction, transmission, or spread of communicable diseases and for reporting serious adverse reactions or events to the distributing facility are always required for autologous products. Furthermore, a donor eligibility determination is not required by the FDA. However, if any donor screening or testing is performed and risk factors or reactive test results are identified, accompanying documentation shall be provided.

[2]May only be distributed after release by the Processing Facility Medical Director due to urgent medical need. For ineligible cellular therapy products or incomplete donor eligibility determination, the product shall be shipped in quarantine. For products distributed prior to completion of donor eligibility, determination shall be completed and the physician shall be informed of the results.

[3]Access (electronic or otherwise) to the source documents by the distributing facility and/or receiving facility is sufficient.

[4]This includes laboratories certified to perform such testing on human specimens under the Clinical Laboratory Improvement Amendments of 1988 or those laboratories that have met equivalent requirements as determined by the Centers for Medicare and Medicaid Services, or those that have met equivalent non-U.S. requirements. If communicable disease testing is not performed by a laboratory that meets regulatory requirements, the donor is ineligible. If a donor is ineligible for other reasons, but the testing was performed in a compliant laboratory, this statement must be included in the documentation.

[5]Access to the Clinical Program SOPs and forms could suffice when the distributing and clinical facilities are within the same institution.

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APPENDIX V

CHANGES TO EIGHTH EDITION STANDARDS

The table below outlines the changes made to the *FACT-JACIE International Standards for Hematopoietic Cellular Therapy Product Collection, Processing, and Administration* with each version of the eighth edition Standards.[1]

Version Number	Standard	Change
8.1[2]	B3.8.2	A Clinical Program treating pediatric donors and recipients shall have consultants, as defined in ~~B3.9.1~~B3.8.1, qualified to manage pediatric patients.
8.1[2]	B10.1.2	Cleaning and sanitation records shall be retained for at least three (3) years or longer in accordance with Applicable Law ~~applicable laws or regulations~~, or by a defined program or institution policy.
8.1[2]	C6.3.4.1	For collections without mobilization, a pregnancy test shall be performed within seven (7) days prior to cellular therapy <u>product</u> collection.

[1]This appendix does not include minor renumbering or reorganization changes that were a result of any substantive changes listed above.
[2]The effective date of version 8.1 is January 14, 2022.

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ACKNOWLEDGEMENTS

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Ref: Haem Onc/AH

Date dictated: 30/8/2019
Date typed: 30/08/2019

Dear Jane and Jennifer,

We, the clinicians of the Haematology/ Oncology Unit wish to express our concerns about the infection and environmental issues which have affected our Unit and as a consequence our immunocompromised patients, for the past 18 months.

We seek management's view on the safety/appropriateness of the environment in which our patients are being treated. A recurring theme of recent IMT's has been questioning of the magnitude and clinical significance of recently documented infections with environmental organisms. Control measures instituted previously have reduced the number of positive blood cultures, but those that remain are due to rare, environmental organisms, highlighting concerns about the safety of the hospital environment.

It is of concern that no definite source of these unusual infections has been identified, although a number of factors have been hypothesised over the past 18 months and control measures instituted. Some of these control measures, including additional antibiotic and antifungal prophylaxis, have caused toxicities to patients.

The absence of a confirmed source of these problems means that there is uncertainty that the control measures are adequate and hence it is difficult to reassure patients, family and staff of the safety of the environment.

At a recent IMT it was agreed that an external review would be essential and we would very much support this.

This review should be lead by an individual from outwith Scotland, who is a recognised paediatric Control of Infection Expert.

We ask that this be expedited.

In addition, prior to returning to ward 6A we seek absolute clarity of what will constitute further environmental failures.

The decision to resume normal practice and treat our patient population in the existing environment is not a clinical decision, but for the Infection Control Group. It is important to clarify responsibilities. Following advice from the Medical Defence Unions our understanding is:

1. Responsibility for delivering chemotherapy safely and according to national and international protocols/ guidelines lies with clinicians.
2. Responsibility for providing a safe environment in which to deliver this chemotherapy lies with GGC, lead by the Chief Executive.
3. Responsibility for advising on whether or not an environment is safe for delivering the chemotherapy to vulnerable patients lies with Control of Infection.
4. The IMT is there to act on advice given by Control of Infection

We would appreciate the opportunity to meet with you to discuss these issues.

Yours sincerely

Consultants in Paediatric Haematology/Oncology
Dr E Chalmers, Dr S Chaudhury, Dr AM Ewins, Prof B Gibson, Dr C Halsey, Dr N Heaney, Dr Murphy, Dr McIntosh, Dr Pinto, Dr M Ronghe, Dr J Sastry

Health Protection Scotland

NHS National Services Scotland

National Infection Prevention and Control Manual

Version: 2.3.1
Date: 20 June 2014
Owner/Author: Infection Control Team

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Version History:

This literature review and/or National Infection Prevention and Control Manual will be updated in real time if any significant changes are found in the professional literature or from national guidance.

Version	Date	Summary of changes	Changes marked
2.3.1	**June 2014**	**Local NHS Lothian Changes made to National Policy**	
2.3	April 2014	Wider Consultation changes SLWG appendix 14 and Section 2.4. Update and agreed content.	
2.2	October 2013	Insertion of Chapter 2, TBPs Add Appendix on Glove changes Add care homes consensus	
2.1	January 2013	Amended after Board (ICN Leads) Consensus Meeting 9 January 2013.	
2.0	December 2012	Amended after Board (ICN Leads) Consensus Meeting 1 November 2012.	
1.0	January 2012		

HPS ICT Document Information Grid	
Description:	This evidence based National Infection Prevention and Control (NIP&C) Manual for Scotland is intended to be used by all those involved in care provision. The manual currently contains information on Standard Infection Control Precautions (SICPs), Chapter 1 and Transmission Based Precautions (TBPs), Chapter 2. It is planned to further develop the content of the manual.
Update/review schedule:	Updated in real time with changes made to practice recommendations as new evidence emerges and/or legislation changes.
Cross reference:	**Standard Infection Control Precautions (SICPs) Literature Reviews** **Transmission Based Precautions (TBPs) Literature Reviews**

Contents

Introduction

The National Infection Prevention and Control Manual was first published on 13 January 2012, by the Chief Nursing Officer (CNO (2012)1): **http://www.sehd.scot.nhs.uk/cmo/CNO(2012)01.pdf**, and updated on 17 May 2012: **http://www.sehd.scot.nhs.uk/cmo/CNO(2012)01update.pdf.**

This national manual provides guidance to all those involved in care provision and should be adopted for infection prevention and control practices and procedures. The national manual is mandatory for NHS employees and applies to all NHS healthcare settings. In all other care settings the content of this manual is considered best practice.

The manual aims to:

- Make it easy for care staff to apply effective infection prevention and control precautions.
- Reduce variation and optimise infection prevention and control practices throughout Scotland.
- Help reduce the risk of Healthcare Associated Infection (HAI).
- Help align practice, monitoring, quality improvement and scrutiny.

The literature reviews that underpin and inform the practical application of the national manual and highlight implications for research are available at **http://www.hps.scot.nhs.uk/haiic/ic/standardinfectioncontrolprecautions-sicps.aspx**

Responsibilities for the content of this manual

HPS must ensure:

- that the content of this manual remains evidence based.

Responsibilities for the adoption and implementation of this manual

Organisations must ensure:

- the adoption and implementation of this manual in accordance with their existing local governance processes;
- systems and resources are in place to facilitate implementation and compliance monitoring of infection prevention and control as specified in this manual in all care areas. Compliance monitoring includes all staff (permanent, agency and where required external contractors); and
- there is an organisational culture which promotes incident reporting and focuses on improving systemic failures that encourage safe working practices

Managers of all services must ensure that staff:

- are aware of and have access to this manual;
- have had instruction/education on infection prevention and control through attendance at events and/or completion of training e.g. via **NHS Education for Scotland (NES)** and/or local board/organisation;
- have adequate support and resources available to enable them to implement, monitor and take corrective action to ensure compliance with this manual;
- with health concerns (including pregnancy) or who have had an occupational exposure are timeously referred to the relevant agency e.g. General Practitioner, Occupational Health or if required Accident and Emergency;
- have undergone the required health checks/clearance (including those undertaking Exposure Prone Procedures (EPPs); and
- include infection prevention and control as an objective in their Personal Development Plans (or equivalent).

Staff providing care must ensure that they:

- understand and apply the principles of infection prevention and control set out in this manual;
- maintain competence, skills and knowledge in infection prevention and control through attendance at education events and/or completion of training e.g. **NHS Education for Scotland (NES)** and/or local board/organisation;
- communicate the infection prevention and control practices to be taken by colleagues, those being cared for, relatives and visitors without breaching confidentiality;
- have up to date occupational immunisations/health checks/clearance requirements as appropriate;

- report to line managers and document any deficits in knowledge, resources, equipment and facilities or incidents that may result in transmission of infection; and
- do not provide care while at risk of potentially transmitting infectious agents to others. If in any doubt they must consult with their line manager, Occupational Health Department, Infection Prevention and Control Team (IPCT) or Health Protection Team (HPT).

Infection Prevention and Control Teams (IPCTs) and Health Protection Teams (HPTs) must:

- engage with staff to develop systems and processes that lead to sustainable and reliable improvements in relation to the application of infection prevention and control practices; and
- provide expert advice on the application of infection prevention and control in the care setting and on individual risk assessments as required.

Disclaimer

When an organisation e.g. NHS board or care home uses products or adopts practices that differ from those stated in this National Infection Prevention and Control Manual, that individual organisation is responsible for ensuring safe systems of work including the completion of a risk assessment.

Chapter 1: Standard Infection Control Precautions (SICPs)

Standard Infection Control Precautions (SICPs), covered in this chapter are to be used **by all** staff, **in all** care settings, **at all** times, **for all** patients[1] whether infection is known to be present or not to ensure the safety of those being cared for, staff and visitors in the care environment.

SICPs are the basic infection prevention and control measures necessary to reduce the risk of transmission of infectious agent from both recognised and unrecognised sources of infection. Sources of (potential) infection include blood and other body fluids secretions or excretions (excluding sweat), non-intact skin or mucous membranes and any equipment or items in the care environment that could have become contaminated.

The application of SICPs during care delivery is determined by an assessment of risk to and from individuals and includes the task, level of interaction and/or the anticipated level of exposure to blood and/or other body fluids.

To be effective in protecting against infection risks, SICPs must be used continuously by all staff. SICPs implementation monitoring must also be ongoing to ensure compliance with safe practices and to demonstrate ongoing commitment to patient, staff and visitor safety.

Further information on using SICPs for Care at Home can be found at **http://www.nes.scot.nhs.uk/education-and-training/by-theme-initiative/healthcare-associated-infections/training-resources/preventing-infection-in-care-@-home.aspx.**

There are ten elements of SICPs:

1.1. Patient Placement/Assessment for infection risk

Patients must be promptly assessed for infection risk on arrival at the care area (if possible, prior to accepting a patient from another care area) and should be continuously reviewed throughout their stay. This assessment should influence placement decisions in accordance with clinical/care need(s).

Patients who may present a cross-infection risk include those:

- With diarrhoea, vomiting, an unexplained rash, fever or respiratory symptoms.
- Known to have been previously positive with a Multi-drug Resistant Organism (MDRO) e.g Meticillin Resistant *Staphylococcus aureus* (MRSA), Carbapenamase Producing Enterobacteriaceae (CPE).
- Who have been hospitalised outside Scotland in the last 12 months.

For assessment of infection risk see Section 2.1: Transmission Based Precautions.

Further information can be found in the patient placement literature review.

[1] The use of the word 'Persons' can be used instead of 'Patient' when using this document in non-healthcare settings.

1.2. Hand Hygiene

Hand hygiene is considered an important practice in reducing the transmission of infectious agents which cause HAIs.

Before performing hand hygiene:

- expose forearms;
- remove all hand/wrist jewellery (a single, plain metal finger ring is permitted but should be removed (or moved up) during hand hygiene);
- ensure finger nails are clean, short and that artificial nails or nail products are not worn; and
- cover all cuts or abrasions with a waterproof dressing.

To perform hand hygiene:

Alcohol Based Hand Rubs (ABHRs) must be available for staff as near to point of care as possible. Where this is not practical, personal ABHR dispensers should be used.

Perform hand hygiene:

- before touching a patient;
- before clean/aseptic procedures;
- after body fluid exposure risk;
- after touching a patient; and
- after touching a patient's immediate surroundings.

Wash hands with non-antimicrobial liquid soap and water if:

- hands are visibly soiled or dirty; or
- caring for a patient with a suspected or known gastro-intestinal infection e.g. norovirus or a spore forming organism such as *Clostridium difficile*.

In all other circumstances use ABHRs for routine hand hygiene during care.

Hand wipes **should not** be used by staff in the hospital or care home setting for hand hygiene unless there is no running water available. Staff may use hand wipes followed by ABHR and should wash their hands at the first available opportunity.

For how to wash hands see Appendix 1.

For how to hand rub see Appendix 2.

Skin care:

- Dry hands thoroughly after hand washing using disposable paper towels.
- Use an emollient hand cream during work breaks and when off duty.
- Do not use or provide communal tubs of hand cream in the care setting.

Surgical Hand Antisepsis

Surgical scrubbing/rubbing: (applies to persons undertaking surgical and some invasive procedures)

- Perform surgical scrubbing/rubbing before donning sterile theatre garments or at other times e.g. prior to insertion of vascular access devices.
- Remove all hand/wrist jewellery.

- Nail brushes (if used) must only be used for decontamination of nails. Nail picks can be used if nails are visibly dirty.
- Use an antimicrobial liquid soap licensed for surgical scrubbing or an ABHR licensed for surgical rubbing (as specified on the product label).
- ABHR can be used between surgical procedures if licensed for this use.

Follow the technique in Appendix 3 for Surgical Scrubbing.

Follow the technique in Appendix 4 for Surgical Rubbing.

Hand Hygiene posters/leaflets can be found at http://www.washyourhandsofthem.com/home.aspx

Further information can be found in the Hand Hygiene literature reviews:

- **Hand hygiene products in hospital settings**
- **Hand washing in hospitals settings**
- **Indications for hand hygiene in the hospital setting**
- **Skin care**
- **Surgical hand scrubbing/rubbing in the hospital setting**
- **Use of alcohol based hand rub in the hospital setting**

1.3. Respiratory and Cough Hygiene

Respiratory and cough hygiene is designed to minimise the risk of cross-transmission of respiratory illness (pathogens):

- Cover the nose and mouth with a disposable tissue when sneezing, coughing, wiping and blowing the nose.
- Dispose of all used tissues promptly into a waste bin.
- Wash hands with non-antimicrobial liquid soap and warm water after coughing, sneezing, using tissues, or after contact with respiratory secretions or objects contaminated by these secretions.
  - Hand wipes **should not** be used by staff in the hospital or care home setting for hand hygiene unless there is no running water available. Staff may use hand wipes followed by ABHR and should wash their hands at the first available opportunity.
- Keep contaminated hands away from the eyes nose and mouth.

Staff should promote respiratory and cough hygiene helping those (e.g. elderly, children) who need assistance with this e.g. providing patients with tissues, plastic bags for used tissues and hand hygiene facilities as necessary.

Further information can be found in the cough etiquette/respiratory hygiene in the hospital setting literature review.

1.4. Personal Protective Equipment (PPE)

Before undertaking any procedure staff should assess any likely exposure and ensure PPE is worn that provides adequate protection against the risks associated with the procedure or task being undertaken.

All PPE should be:

- located close to the point of use;
- stored to prevent contamination in a clean/dry area until required for use (expiry dates must be adhered to);
- single-use only items unless specified by the manufacturer; and
- disposed of after use into the correct waste stream i.e. healthcare waste or domestic waste.

Reusable PPE items, e.g. non-disposable goggles/face shields/visors must have a decontamination schedule with responsibility assigned.

Gloves must be:

- worn when exposure to blood and/or other body fluids is anticipated/likely;[2]
- changed immediately after each patient and/or following completion of a procedure or task;
- changed if a perforation or puncture is suspected; and
- appropriate for use, fit for purpose and well-fitting to avoid excessive sweating and interference with dexterity.

Double gloving is recommended during some Exposure Prone Procedures (EPPs) e.g. orthopaedic and gynaecological operations or when attending major trauma incidents.

For appropriate glove use and selection see Appendix 5.

Further information can be found in the Gloves literature review.

Aprons must be:

- worn to protect uniform or clothes when contamination is anticipated/likely e.g. when in direct care contact with a patient; and
- changed between patients and/or following completion of a procedure or task.

Full body gowns/Fluid repellent coveralls must be:

- worn when there is a risk of extensive splashing of blood and/or other body fluids e.g. in the operating theatre; and
- changed between patients and immediately after completion of a procedure or task.

Further information can be found in the Aprons/Gowns literature review.

[2] Scottish National Blood Transfusion Service (SNBTS) adopt practices that differ from those stated in the National Infection Prevention and Control Manual.

Eye/face protection (including full face visors) must be:

- worn if blood and/or body fluid contamination to the eyes/face is anticipated/likely e.g. by members of the surgical theatre team and always during **Aerosol Generating Procedures**. Regular corrective spectacles are not considered eye protection.

Further information can be found in the eye/face protection literature review.

Fluid repellent surgical face masks must be:

- worn if splashing or spraying of blood, body fluids, secretions or excretions onto the respiratory mucosa (nose and mouth) is anticipated/likely;
- worn to protect patients from the operator as a source of infection e.g. when performing an epidural or inserting a Central Vascular Catheter (CVC);
- well fitting and fit for purpose (fully covering the mouth and nose) (manufacturers' instructions must be adhered to ensure effective fit/protection); and
- removed or changed;
  - at the end of a procedure/task;
  - if the integrity of the mask is breached, e.g. from moisture build-up after extended use or from gross contamination with blood or body fluids; and
  - in accordance with specific manufacturers' instructions.

Further information can be found in the surgical face masks literature review

Footwear must be:

- non-slip, clean and well maintained, and support and cover the entire foot to avoid contamination with blood or other body fluids or potential injury from sharps; and
- removed before leaving a care area where dedicated footwear is used e.g. theatre.

Further information can be found in the footwear literature review

Headwear must be:

- worn in theatre settings/clean rooms e.g. Central Decontamination Unit (CDU);
- well fitting and completely cover the hair; and
- changed/disposed of between sessions or if contaminated with blood and/or body fluids.

For the recommended method of putting on and removing PPE see Appendix 6
Further information can be found in the headwear literature review

1.5. Safe Management of Care Equipment

Care equipment is easily contaminated with blood, other body fluids, secretions, excretions and infectious agents. Consequently it is easy to transfer infectious agents from communal care equipment during care delivery. Care equipment is classified as either:

- **Single-use** – equipment which is used once on a single patient and then discarded. Must never be reused even on the same patient. The packaging carries this symbol.

  - Needles and syringes are single use devices. They should never be used for more than one patient or reused to draw up additional medication.
  - Never administer medications from a single-dose vial or intravenous (IV) bag to multiple patients.
- **Single patient use** – equipment which can be reused on the same patient.
- **Reusable invasive equipment** - used once then decontaminated e.g. surgical instruments.
- **Reusable non-invasive equipment** (often referred to as communal equipment) - reused on more than one patient following decontamination between each use e.g. commode, patient transfer trolley.

Before using any sterile equipment check that:

- the packaging is intact;
- there are no obvious signs of packaging contamination; and
- the expiry date remains valid.

Decontamination of reusable non-invasive care equipment must be undertaken:

- between each use;
- after blood and/or body fluid contamination;
- at regular predefined intervals as part of an equipment cleaning protocol; and
- before inspection, servicing or repair.

Adhere to manufacturers' guidance for use and decontamination of all care equipment.

All reusable non-invasive care equipment must be rinsed and dried following decontamination then stored clean and dry.

Decontamination protocols should include responsibility for; frequency of; and method of environmental decontamination.

For how to decontaminate reusable non-invasive care equipment see Appendix 7

For an equipment decontamination status certificate; required if any item of equipment is being sent to a third party for e.g. inspection, servicing or repair see Appendix 8

For guidance prior to procuring, trialling or lending any reusable non-invasive equipment, see Appendix 9

Further information can be found in the management of patient care equipment literature review

1.6. Safe Management of the Care Environment

It is the responsibility of the person in charge to ensure that the care environment is safe for practice (this includes environmental cleanliness/maintenance). The person in charge must **act** if this is deficient.

The care environment must be:

- visibly clean, free from non-essential items and equipment to facilitate effective cleaning;
- well maintained and in a good state of repair; and
- routinely cleaned in accordance with the Health Facilities Scotland (HFS) National Cleaning Specification:
    - A fresh solution of general purpose neutral detergent in warm water is recommended for routine cleaning. This should be changed when dirty or at 15 minutes intervals or when changing tasks.
    - Routine disinfection of the environment is not recommended. However, 1,000ppm available chlorine should be used routinely on sanitary fittings.

Staff groups should be aware of their environmental cleaning schedules and clear on their specific responsibilities. Cleaning protocols should include responsibility for; frequency of; and method of environmental decontamination.

Further information can be found in the routine cleaning of the environment in hospital setting literature review

1.7. Safe Management of Linen

Clean linen should be stored in a clean, designated area, preferably an enclosed cupboard. If clean linen is not stored in a cupboard then the trolley used for storage must be designated for this purpose and completely covered with an impervious covering that is able to withstand decontamination.

Clean linen that is deemed unfit for re-use e.g. badly torn, should be disposed of locally or returned to the laundry for disposal.

Any linen used during patient transfer e.g. blankets, should be categorised at the point of destination.

For all **used linen** (previously known as soiled linen):

- Ensure a laundry receptacle is available as close as possible to the point of use for immediate linen deposit.
- Do not:
    - rinse, shake or sort linen on removal from beds/trolleys;
    - place used linen on the floor or any other surfaces e.g. a locker/table top;
    - re-handle used linen once bagged;
    - overfill laundry receptacles; or
    - place inappropriate items in the laundry receptacle e.g. used equipment/needles.

For all **infectious linen (this mainly applies to healthcare linen)** i.e. linen that has been used by a patient who is known or suspected to be infectious and/or linen that is contaminated with blood and/or other body fluids e.g. faeces:

- Place directly into a water-soluble/alginate bag and secure; then place into a plastic bag e.g. clear bag and secure before placing in a laundry receptacle. This applies also to any item(s) heavily soiled and unlikely to be fit for reuse.

- Used and infectious linen bags/receptacles must be tagged e.g. ward/care area and date
- Store all used/infectious linen in a designated, safe, lockable area whilst awaiting uplift. Uplift schedules must be acceptable to the care area and there should be no build-up of linen receptacles.

For how to manage linen at care area level see Appendix 10

Further information can be found in the safe management of linen literature review

1.8. Safe Management of Blood and Body Fluid Spillages

Spillages of blood and other body fluids may transmit blood borne viruses. Spillages must be decontaminated immediately by staff trained to undertake this safely. Responsibilities for the decontamination of blood and body fluid spillages should be clear within each area/care setting.

For management of blood and body fluid spillages see Appendix 11

Further information can be found in the management of blood and body fluid literature review

1.9. Safe Disposal of Waste (including sharps)

Scottish Health Technical Note (SHTN) 3: NHSScotland Waste Management Guidance contains the regulatory waste management guidance for NHSScotland including waste classification, segregation, storage, packaging, transport, treatment and disposal. The Health and Safety (Sharp Instruments in Healthcare) Regulations 2013 outline the regulatory requirements for employers and contractors in the healthcare sector in relation to the safe disposal of sharps.

Categories of waste:

- **Healthcare (including clinical) waste** – is produced as a direct result of healthcare activities e.g. soiled dressings, sharps.
- **Special (or hazardous) waste** – arises from the delivery of healthcare in both clinical and non-clinical settings. Special waste includes a range of controlled wastes, defined by legislation, which contain dangerous or hazardous substances e.g. chemicals, pharmaceuticals.
- **Domestic waste** – must be segregated at source into:
  - **Dry recyclates** (glass, paper and plastics, metals, cardboard).
  - **Residual waste** (any other domestic waste that cannot be recycled).

Waste Streams:

- **Black – Trivial risk**
  - Domestic waste or yellow and black stripes (small quantities of hygiene waste).Final disposal to Landfill. Clear/opaque receptacles may also be used for domestic waste at care area level.

- **Orange, Light Blue(laboratory) – Low risk**[3]
  - **Orange** - consists of items which are contaminated or likely to be contaminated with infectious blood and/or body fluids. Final disposal following heat disinfection is to landfill.
  - **Light Blue** – laboratory/microbiological waste that must be autoclaved before disposal via the orange stream.
- **Yellow– High risk**
  - Waste which poses ethical, highly infectious or contamination risks. This includes anatomical and human tissue which is recognisable as body parts, medical devices and sharps waste boxes that have red, purple or blue lids. Disposal is by specialist incineration.
- **Red – Special waste**
  - Chemical waste.

For care/residential homes waste disposal may differ from the categories described above and guidance from local contractors will apply. Refer to SEPA guidance http://www.sepa.org.uk/waste.aspx.

Safe waste disposal at care area level:

Always dispose of waste:

- immediately and as close to the point of use as possible; and
- into the correct segregated colour coded UN 3291 approved waste bag (either orange/yellow for healthcare waste or black/clear/opaque for domestic) or container (sharps box).

Liquid waste e.g. blood must be rendered safe by adding a self-setting gel or compound before placing in a healthcare waste bag.

Waste bags must be no more than 3/4 full or more than 4 kgs in weight; and use a ratchet tag/or tape (for healthcare waste bags only) using a 'swan neck' to close with the point of origin and date of closure clearly marked on the tape/tag.

Store all waste in a designated, safe, lockable area whilst awaiting uplift. Uplift schedules must be acceptable to the care area and there should be no build-up of waste receptacles.

Sharps boxes must:

- have a dedicated handle;
- have a temporary closure mechanism, which must be employed when the box is not in use;
- be disposed of when the manufacturers' fill line is reached; and
- be labelled with point of origin and date of closure.

For management of waste at care area level see Appendix 12

Further information can be found in the safe management of waste in the hospital setting literature review

[3] Not required for boards with an on-site incinerator facility. This applies only to NHS Borders.

1.10. Occupational Safety: Prevention and Exposure Management (including sharps)

The Health and Safety (Sharp Instruments in Healthcare) Regulations 2013 outline the regulatory requirements for employers and contractors in the healthcare sector in relation to: arrangements for the safe use and disposal of sharps; provision of information and training to employees; investigations and actions required in response to work related sharps injuries.

Sharps handling must be assessed, kept to a minimum and eliminated if possible with the use of approved safety devices. Manufacturers' instructions for safe use and disposal must be followed.

Needles must not be re-sheathed. [4]

A significant occupational exposure is:

- a percutaneous injury e.g. injuries from needles, instruments, bone fragments, or bites which break the skin; and/or
- exposure of broken skin (abrasions, cuts, eczema, etc); and/or
- exposure of mucous membranes including the eye from splashing of blood or other high risk body fluids.

There is a potential risk of transmission of a Blood Borne Virus (BBV) from a significant occupational exposure and staff must understand the actions they should take when a significant occupational exposure incident takes place.

For the management of an occupational exposure incident see Appendix 13

Further information can be found in the occupational exposure management (including sharps) literature review

[4] **Only** exception is local anaesthetic administration in dentistry.

Chapter 2: Transmission Based Precautions (TBPs)

Standard Infection Control Precautions (SICPs) may be insufficient to prevent cross transmission of specific infectious agents therefore additional precautions (TBPs) are required to be used by staff. SICPs must still be applied with these additional considerations.

TBPs should be applied when caring for:

- patients with symptoms of infection;
- asymptomatic patients who are suspected or incubating an infection; or
- patients colonised with an infectious agent.

TBPs are categorised by the route of transmission of infectious agents (some infectious agents can be transmitted by more than one route):

- **Contact** precautions: Used to prevent and control infections that spread via direct contact with the patient or indirectly from the patient's immediate care environment (including care equipment). This is the most common route of cross-infection transmission.
- **Droplet** precautions: Used to prevent and control infections spread over short distances (less than 3 feet (1 metre)) via droplets (>5µm) from the respiratory tract of one individual directly onto a mucosal surface or conjunctivae of another individual. Droplets penetrate the respiratory system above the alveolar level.
- **Airborne** precautions: Used to prevent and control infections spread without necessarily having close patient contact via aerosols (≤5µm) from the respiratory tract of one individual directly onto a mucosal surface or conjunctivae of another individual. Aerosols penetrate the respiratory system to the alveolar level.

Further information on Transmission Based Precautions can be found in the definitions of **Transmission Based Precautions literature reviews**.

2.1 Patient Placement/Assessment for Infection Risk

The potential for transmission of infection or infectious agents must be assessed at the patient's entry to the care area and should be continuously reviewed throughout their stay. The assessment should influence placement decisions in accordance with clinical /care need(s).

Patients who may present a cross-infection risk include those:

- With diarrhoea, vomiting, an unexplained rash, fever or respiratory symptoms.
- Known to have been previously positive with a Multi-drug Resistant Organism (MDRO) e.g MRSA, CPE.
- Who have been hospitalised outside Scotland in the last 12 months.

These patients should be prioritised for placement in a suitable area to minimise cross transmission pending investigation e.g.

- In a single room with a clinical wash hand basin; or
- Cohort area/room with a clinical wash hand basin.

Patients being transferred by ambulance should be transported on their own.

Isolation within a care home for a known/suspected infection may be necessary to prevent spread. In most cases this can be achieved in the persons' bedroom.

The clinical judgement and expertise of the staff involved in a patient's management and the Infection Prevention and Control Team (IPCT) or Health Protection Team (HPT) should be sought particularly for patient placement decisions such as the application of TBPs e.g. isolation prioritisation when single rooms are in short supply.

For patients with a suspected/known infectious agent. Appendix 14 provides details of the route of transmission, optimal patient placement, duration of isolation and type of precautions required.

Patient/Staff cohorting

If multiple patient cases of the same infection are confirmed or if single rooms are unavailable, cohorting of patients may be appropriate. Patients should be separated by at least 3 feet (1m) if cohorted.

Consider assigning a dedicated team of care staff to care for patients in isolation/cohort rooms/areas as an additional infection control measure (staff cohorting). This can only be implemented if there are sufficient levels of staff available (so as not to have a negative impact on non-affected patients' care).

Duration of isolation/cohort

Patient(s) should remain in isolation/cohort whilst they remain symptomatic and/or are considered infectious and the door must remain closed.

Before discontinuing isolation; individual patient risk factors should be considered (e.g. there may be prolonged shedding of certain microorganisms in immunocompromised patients); and the clinical judgement of those involved in the patient's management should be sought.

Avoid unnecessary transfer of patients within/between care areas.

All patient placement decisions and assessment of infection risk (including isolation requirements) must be clearly documented in the patient notes.

2.2 Safe Management of Patient Care Equipment in an Isolation Room/Cohort Area [5]

- Use single-use items if possible.
- Reusable non-invasive care equipment should be dedicated to the isolation room/cohort area and decontaminated prior to use on another patient.
- An increased frequency of decontamination should be considered for reusable non-invasive care equipment when used in isolation/cohort areas.

[5] Scottish Ambulance Service (SAS) and Scottish National Blood Transfusion Service adopt practices that differ from those stated in the National Infection Prevention and Control Manual.

For how to decontaminate non-invasive reusable equipment see Appendix 7

2.3 Safe Management of the Care Environment [5]

Routine environmental decontamination

Patient isolation/cohort rooms/area must be decontaminated **at least daily** using either:

- a combined detergent/disinfectant solution at a dilution of 1,000 parts per million available chlorine (ppm available chlorine (av.cl.)); or
- a general purpose neutral detergent in a solution of warm water followed by disinfection solution of 1,000ppm av.cl.

Increased frequency of decontamination should be incorporated into the environmental decontamination schedules for areas where there may be higher environmental contamination rates e.g.

- toilets/commodes particularly if patients have diarrhoea; and
- "frequently touched" surfaces such as door/toilet handles and locker tops, over bed tables and bed rails.

Equipment used for environmental decontamination must be either single-use or dedicated to the affected area then decontaminated following use e.g. mop and bucket.

Terminal decontamination

Following patient transfer, discharge, or once the patient is no longer considered infectious:

Remove from the vacated isolation room/cohort area, all:

- healthcare waste and any other disposable items (bagged before removal from the room);
- bedding/bed screens/curtains and manage as **infectious linen** (bagged before removal from the room); and
- reusable non-invasive care equipment (decontaminated in the room prior to removal) **Appendix 7**.

The room should be decontaminated using either:

- a combined detergent disinfectant solution at a dilution (1,000ppm av.cl.); or
- a general purpose neutral detergent clean in a solution of warm water followed by disinfection solution of 1,000ppm av.cl..

The room must be cleaned from the highest to lowest point and from the least to most contaminated point.

Manufacturers' guidance and recommended product "contact time" must be followed for all cleaning/disinfection solutions[6].

[6] Scottish Ambulance Service (SAS) and Scottish National Blood Transfusion Service adopt practices that differ from those stated in the National Infection Prevention and Control Manual.

2.4 Personal Protective Equipment (PPE): Respiratory Protective Equipment (RPE)

PPE must still be used in accordance with SICPs when using Respiratory Protective Equipment. See **Chapter 1.4 for PPE use for SICPs**.

Where it is not reasonably practicable to prevent exposure to a substance hazardous to health (as may be the case where healthcare workers are caring for patients with suspected or known airborne micro-organisms) the hazard must be adequately controlled by applying protection measures appropriate to the activity and consistent with the assessment of risk.

Respiratory Protective Equipment (RPE) i.e. FFP3 and facial protection, must be considered when a patient is admitted with a known/suspected infectious agent/disease spread wholly or partly by the airborne or droplet route and when carrying out aerosol generating procedures (AGPs) on patients with a known/suspected infectious agent spread wholly or partly by the airborne or droplet route.

For a list of organisms spread wholly or partly by the airborne (aerosol) or droplet routes see Appendix 14.

All tight fitting RPE i.e FFP3 respirators must be:

- Fit tested on all healthcare staff who may be required to wear a respirator to ensure an adequate seal/fit according to the manufacturers' guidance.
- Fit checked (according to the manufacturers' guidance) every time a respirator is donned to ensure an adequate seal has been achieved.
- Compatible with other facial protection used i.e. protective eyewear so that this does not interfere with the seal of the respiratory protection. Regular corrective spectacles are not considered adequate eye protection.
- Donned and removed in a safe area (e.g. outside the isolation/cohort room/area).

Further information regarding fitting and fit checking of respirators can be found on the Health and Safety Executive website at: **http://www.hse.gov.uk/respiratory-protective-equipment/basics.htm**

Powered respirator hoods are an alternative to tight-fitting FFP3 respirators for example when fit testing cannot be achieved.

FFP3 respirator or powered respirator hood:

- may be considered for use by visitors if there has been no previous exposure to the infected person or infectious agent; **but**
- must never be worn by an infectious patient(s) due to the nature of the respirator filtration of incoming air not expelled air.

Glossary

Abrasion – A graze. A minor wound in which the surface of the skin or a mucous membrane has been worn away by rubbing or scraping.

Aerosols – See Airborne Particles.

Aerosol Generating Procedures (AGPs) – Certain medical and patient care activities that can result in the release of airborne particles (aerosols). AGPs can create a risk of airborne transmission of infections that are usually only spread by droplet transmission. See **Appendix 14, footnote 3** for further information.

Airborne particles (aerosols) – Very small particles that may contain infectious agents. They can remain in the air for long periods of time and can be carried over long distances by air currents. Airborne particles can be released when a person coughs or sneezes, and during aerosol generating procedures (AGPs).

Airborne (aerosol) transmission – The spread of infection from one person to another by airborne particles (aerosols) containing infectious agents.

Alcohol based hand rub (ABHR) – A gel, foam or liquid containing alcohol that is rubbed into the hands as an alternative to washing hands with soap and water.

Alert organism – An organism that is identified as being potentially significant for infection prevention and control practices. Examples of alert organisms include Meticillin Resistant *Staphylococcus aureus* (MRSA), *Clostridium difficile* (C.diff) and Group A *Streptococcus*.

Alveolar – Refers to the alveoli which are the small air sacs in the lungs. Alveoli are located at the ends of the air passageways in the lungs, and are the site at which gas exchange takes place.

Antimicrobial – An agent that kills microorganisms, or prevents them from growing. Antibiotics and disinfectants are antimicrobial agents.

Antimicrobial hand wipes – Hand wipes that are moistened with an antimicrobial solution/agent at a concentration sufficient to inactivate microorganisms and/or temporarily suppress their growth.

Aseptic technique – A healthcare procedure designed to minimise the risks of exposing the person being cared for to pathogenic micro-organisms during simple (e.g dressing wounds) and complex care procedures (e.g. surgical procedures).

Asymptomatic – Not showing any symptoms of disease but where an infection may be present.

Autoclave – Machine used for sterilising re-usable equipment using superheated steam under pressure.

Body fluids – Fluid produced by the body such as urine, faeces, vomit or diarrhoea.

Blood Borne Viruses (BBV) – Viruses carried or transmitted by blood, for example Hepatitis B, Hepatitis C and HIV.

Carbapenemase Producing Enterobacteriaceae (CPE) - A group of bacteria that have become extremely resistant to antibiotics including those called carbapenems.

Care areas/environment – Any place where care is carried out. This includes hospital wards, treatment rooms, care homes and care at home.

Care staff – Any person who cares for patients, including healthcare support workers and nurses.

Central Decontamination Unit (CDU) – A large, centralised facility for the decontamination and re-processing of re-usable medical equipment e.g. surgical instruments.

Central Vascular Catheter (CVC) – An intravenous catheter that is inserted directly into a large vein in the neck, chest or groin to allow intravenous drugs and fluids to be given and to allow blood monitoring.

Chlorine – A chemical that is used for disinfecting, fumigating and bleaching.

Cleaning – The removal of any dirt, blood, sickness, etc by use of an appropriate cleaning agent such as detergent.

Clinical setting – Any area where a patient is observed or treatment is carried out such as a treatment room or hospital ward.

Clinical wash hand basin – A sink designated for hand washing in clinical areas.

***Clostridium difficile (C.diff)* –** An infectious agent (bacterium) that can cause mild to severe diarrhoea which in some cases can lead to gastro-intestinal complications and death.

Cohorting – Placing a group of two or more patients (a cohort) with the same confirmed infection in the same room or area.

Cohort area – A bay or ward in which two or more patients (cohort) with the same confirmed infection are placed. A cohort area should be physically separate from other patients.

Cohort nursing – A dedicated team of healthcare staff who care for a cohort of patients, and do not care for any other patients.

Colonisation – The presence of bacteria on a body surface (such as the skin, mouth, intestines or airway) that does not cause disease in the person or signs of infection.

Conjunctivae – Mucous membranes that cover the front of the eyes and the inside of the eyelids.

Contact transmission – The spread of infectious agents from one person to another by contact. When spread occurs through skin-to-skin contact, this is called direct contact transmission. When spread occurs via a contaminated object, this is called indirect contact transmission.

Contaminated – Dirty, soiled or stained.

Cross-infection/Cross-transmission – Spread of infection from one person to another.

Decontamination – Removing, or killing pathogens on an item or surface to make it safe for handling, re-use or disposal by cleaning, disinfection and/or sterilisation.

Detergent – A chemical cleansing agent that can dissolve oils and remove dirt.

Diarrhoea – 3 or more loose or liquid bowel movements in 24 hours or more often than is normal for the individual.

Direct contact transmission – Spread of infectious agents from one person to another by direct skin-to-skin contact.

Disinfectant – A cleaning chemical used to remove infectious agents from objects and surfaces.

Disinfection – A process, for example using a chemical disinfectant, to reduce the number of infectious agents from an object or surface to a level that means they are not harmful to your health.

Domestic waste – Waste produced in the care setting that is similar to waste produced in the home.

Droplet – A small drop of moisture, larger than airborne particle, that may contain infectious agents. Droplets can be released when a person talks, coughs or sneezes, and during some medical or patient care procedures such as open suctioning and cough induction by chest physiotherapy. It is thought that droplets can travel around 1 metre (3 feet).

Droplet transmission – The spread of infection from one person to another by droplets containing infectious agents.

Emollient – An agent used to soothe the skin and make it soft and supple.

En-suite – A room containing a sink and toilet and sometimes a shower/wetroom or bath.

Excretions – Waste products produced by the body such as urine and faeces (bowel movements).

Exposure – The condition of being exposed to something that may have a harmful effect such as an infectious agent.

Exposure Prone Procedures (EPPs) – Certain medical and patient care procedures where there is a risk that injury to the healthcare worker may result in exposure of the patient's open tissues to the healthcare worker's blood e.g the healthcare worker's gloved hands are in contact with sharp instruments, needle tips or sharp tissues inside a patient's body.

Fit testing – a method of checking that a tight-fitting facepiece respirator fits the wearer and seals adequately to their face. This process helps identify unsuitable facepieces that should not be used

FFP3 – Respiratory protection that is worn over the nose and mouth designed to protect the wearer from inhaling hazardous substances, including airborne particles (aerosols). FFP stands for filtering facepiece. There are three categories of FFP respirator: FFP1, FFP2 and FFP3. An FFP3 respirator or hood provides the highest level of protection, and is the only category of respirator legislated for use in UK healthcare settings.

Fluid repellent – Does not absorb liquid.

GP – 'General practitioner' (your family doctor).

Hand Hygiene – The process of cleaning your hands by using either alcohol based hand rub or liquid soap and water.

Health Protection Team (HPT) – A team of healthcare professionals whose role it is to protect the health of the local population and limit the risk of them becoming exposed to infection and environmental dangers. Every NHS board has a HPT.

Healthcare Associated Infection (HAI) – Infections that occur as a result of medical care, or treatment, in any healthcare setting.

Healthcare Waste – Waste produced as a result of healthcare activities for example soiled dressings, sharps.

Hygiene Waste – Waste that is produced from personal care. In care settings this includes feminine hygiene products, incontinence products and nappies, catheter and stoma bags. Hygiene waste may cause offence due to the presence of recognisable healthcare waste items or body fluids. It is usually assumed that hygiene waste is not hazardous or infectious.

Hypochlorite – A chlorine-based disinfectant such as bleach.

Immunisation – To provide immunity to a disease by giving a vaccination.

Immunocompromised patient/individual – Any person whose immune response is reduced or deficient, usually because they have a disease or are undergoing treatment. People who are immunocompromised are more vulnerable to infection.

Impervious – Cannot be penetrated by liquid.

Indirect contact transmission – The spread of infectious agents from one person to another via a contaminated object.

Infection – Invasion of the body by a harmful organism or infectious agent such as a virus, parasite or bacterium.

Infectious agent – Any organism, such as a virus, parasite, or bacterium, that is capable of invading body tissues, multiplying, and causing disease

Invasive device – A device which penetrates the body, either through a body cavity or through the surface of the body. Central Venous Catheters (central line), Peripheral Arterial Lines and Urinary Catheters are examples of invasive devices.

Invasive procedure – A medical/healthcare procedure that penetrates or breaks the skin or enters a body cavity.

Isolation – Physically separating patients to prevent the spread of infection.

Isolation suite/room – An isolation suite comprises a single-bed room, en-suite facilities and a ventilated entry lobby.

Microorganism (microbe) – Any living thing (organism) that is too small to be seen by the naked eye. Bacteria, viruses and some parasites are microorganisms.

Mode of transmission – The way that microorganisms spread from one person to another. The main modes or routes of transmission are airborne (aerosol) transmission, droplet transmission and contact transmission.

MRSA – Strains of the infectious agent (bacterium) *Staphylococcus aureus* that are resistant to many of the antibiotics commonly used to treat infections.

Mucous membranes/mucosa – The surfaces lining the cavities of the body that are exposed to the environment such as the lining of the mouth and nose.

Needle safety device – Any device designed to reduce the risk of injury from needles. This may include needle-free devices or mechanisms on a needle, such as an automated resheathing device, that cover the needle immediately after use.

Nitrile – A synthetic rubber material used to make non-latex gloves.

Non-sterile procedure – Care procedure that does not need to be undertaken in conditions that are free from bacteria or other microorganisms.

Occupational exposure – Exposure of healthcare workers or care staff to blood or body fluids in the course of their work.

Organism – Any living thing that can grow and reproduce, such as a plant, animal, fungus or bacterium.

Outbreak – When there are two or more linked cases of the same confirmed infection or illness or when there are more cases than the number expected.

Pathogen – Any disease-producing infectious agent.

Percutaneous injury – An injury caused by a sharp instrument or object such as a needle or scalpel, cutting or puncturing the skin.

Personal Protective Equipment (PPE) – Equipment a person wears to protect themselves from risks to their health or safety, including exposure to infections e.g. disposable gloves and disposable aprons.

Pyrexia – Fever. Rise in body temperature above the normal level >37.2°.

Respiratory droplets – A small droplet, such as a particle of moisture released from the mouth during coughing, sneezing, or speaking.

Respiratory Protective Equipment (RPE) – There are two main types of RPE: respirators and breathing apparatus. Respirators are devices worn over the nose and mouth or head and are designed to filter the air breathed in to protect the wearer from inhaling hazardous substances, including airborne particles (aerosols). Breathing apparatus provides a supply of breathing quality air from an external source such as a cylinder or an air compressor. The most commonly used item of RPE in healthcare settings is an FFP3 respirator.

Re-sheath – To put a needle or other sharp object back into its plastic sheath.

Sanitary fittings – Pieces of furniture that are in a bathroom, such as a toilet, bath etc.

Secretions – Any body fluid that is produced by a cell or gland such as saliva or mucous.

Segregated – Physically separating or isolating from other people.

Sharps – Sharp instruments used in healthcare settings such as needles, lancets and scalpels.

Sharps injury – See **percutaneous injury**.

Spore – A form that some types of bacteria take under certain environmental conditions. Spores can survive for long periods of time and are very resistant to heat, drying and chemicals.

Sterile – Free from live bacteria or other microorganisms.

Sterile procedure – Care procedure that is undertaken in conditions that are free from bacteria or other microorganisms.

Sterilisation – The procedure of making some object free of all germs, live bacteria or other microorganisms (usually by heat or chemical means).

Surgical face mask – A disposable fluid repellent mask worn over the nose and mouth to protect the mucous membranes of the wearer's nose and mouth from splashes and infectious droplets and also to protect patients.

Swan-neck – Way of closing bag by tying in a loop and securing with a zip tie to make a handle.

Terminal decontamination – Cleaning/decontamination of an area or room following transfer/discharge of patient or when they are no longer considered infectious to ensure the area safe for the next patient or for the person to go back into their room in a care home setting.

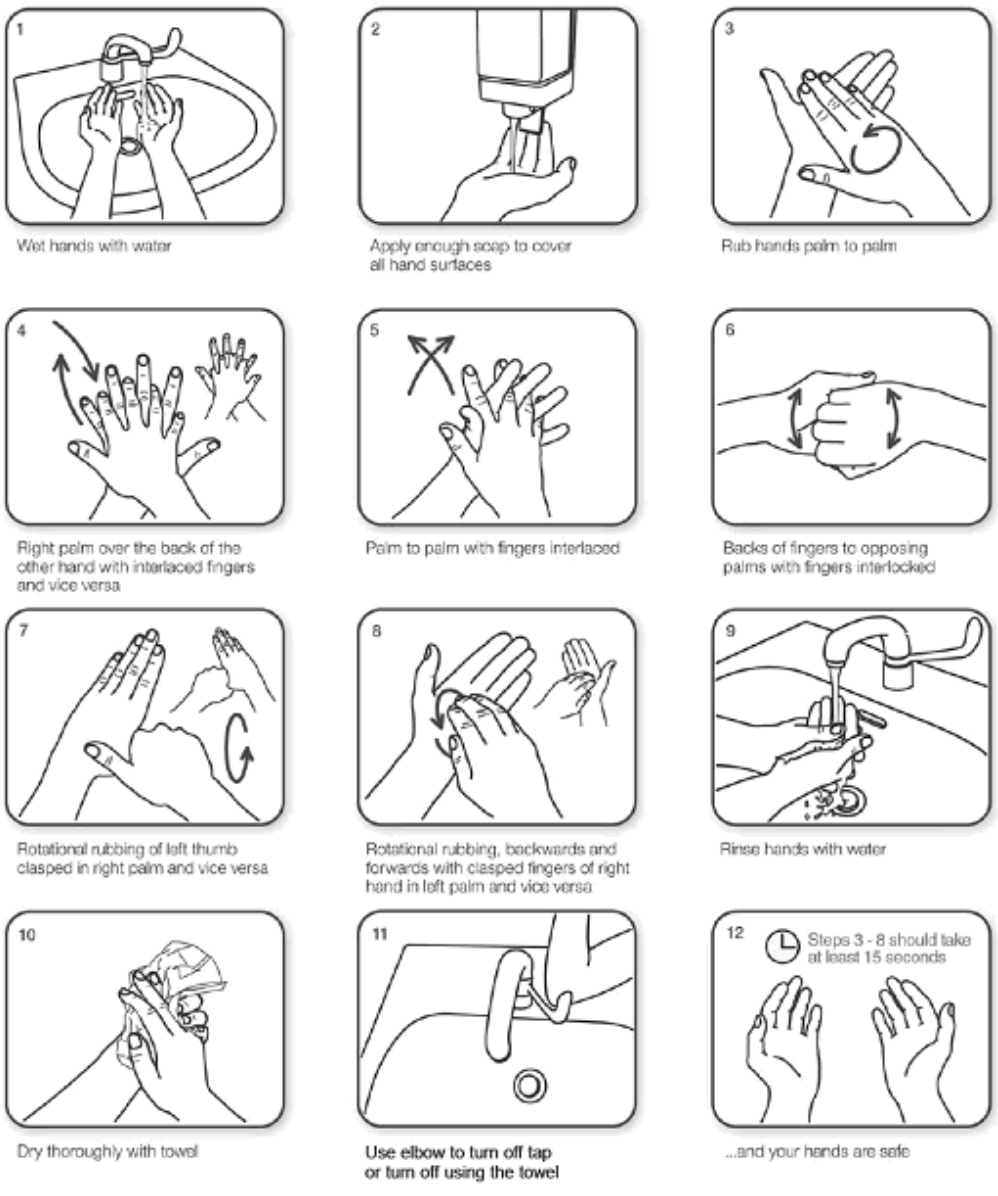
Vascular access devices – Any medical instrument used to access a patient's veins or arteries such as a Central Venous Catheter or peripheral vascular catheter.

Appendices

Appendix 1 – How to hand wash step by step images

Steps 3 – 8 should take at least 15 seconds

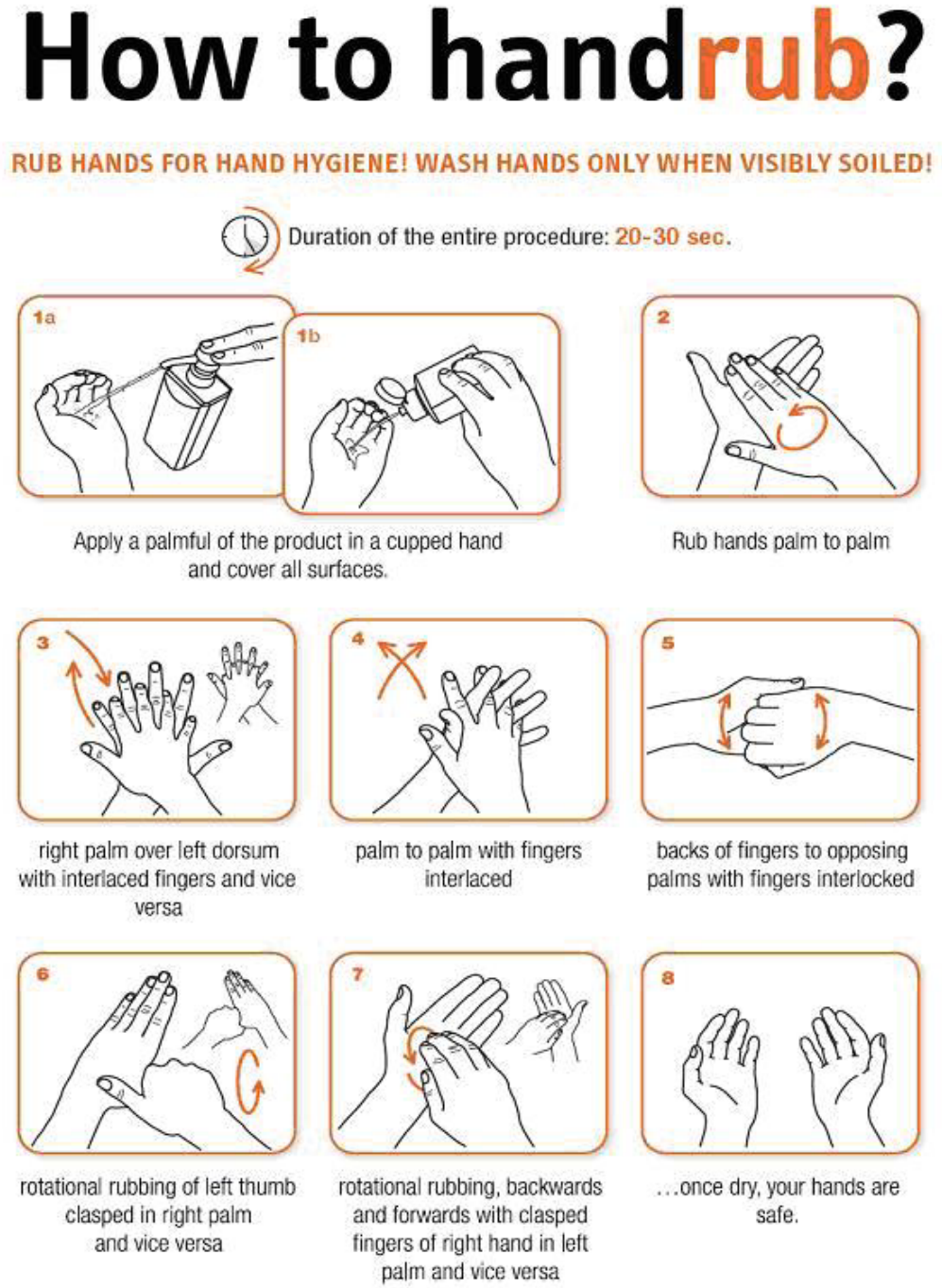
Source: World Health Organisation



Adapted from the World Health Organization

Germs. Wash your hands of them.

Appendix 2 – How to hand rub step by step images



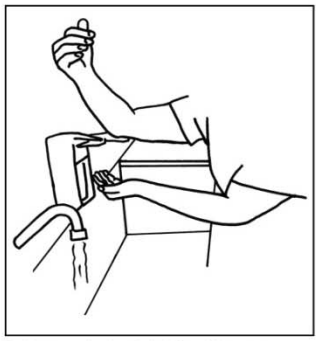
Adapted from the World Health Organization

NHS SCOTLAND

Germs. Wash your hands of them.

Appendix 3 – Surgical Scrubbing: surgical hand preparation technique using antimicrobial soap - step by step images

1. Wet hand and forearms.



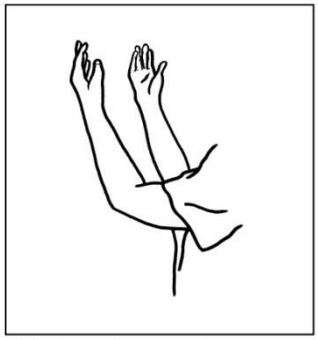
2. Put antimicrobial liquid soap onto the palm of each hand using the elbow of your other arm to operate the dispenser.

3. Scrub each side of each finger, between the fingers and the back and front of each hand for 2 minutes in total.

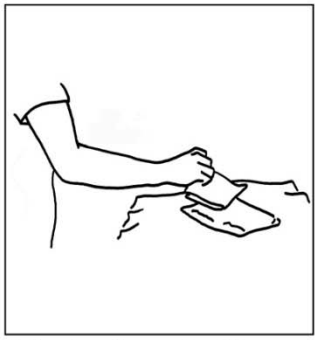
4. Put antimicrobial liquid soap onto the palm of your left hand using the elbow of your other arm to operate the dispenser. Use this to scrub the right arm for 1 minute keeping the hand higher than the arm at all times to prevent recontamination of the hands by water.

5. Repeat the process for the other arm keeping hands above elbows at all times.
If the hand touches anything at any time, the scrub must be lengthened by 1 minute for the area that has been contaminated.

6. Rinse hands and arms by passing them through the water in one direction only, from fingertips to elbow. Do not move the arm back and forth through the water.

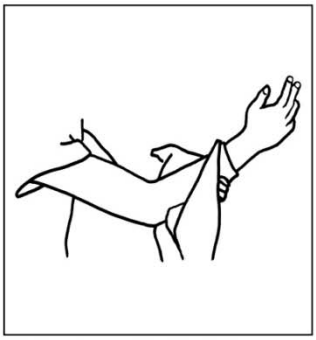


7. Hold hands above elbows.

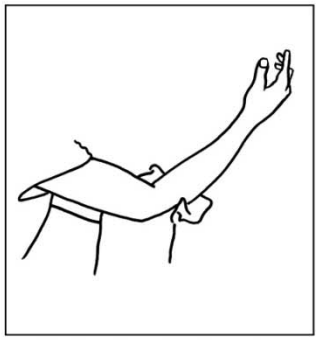


8. Hands and arms should be dried using a sterile disposable towel and aseptic technique before donning sterile gown and gloves.

9. The skin should be blotted dry with sterile disposable towels. Using one towel per hand work from fingertips to elbows.



10. Hands are dried firstly by placing the opposite hand behind the towel and blotting the skin – then using a corkscrew movement to dry from the hand to the elbow.



11. The towel must not be returned to the hand once the arm has been dried and must be discarded immediately.

Appendix 4 - Surgical rubbing: surgical hand preparation technique using alcohol based hand rub (ABHR) - step by step images

- **The hand rubbing technique for surgical hand preparation must be performed on clean, dry hands.**
- **On arrival in the operating theatre and after having donned theatre clothing (cap/hat/bonnet and mask), hands must be washed with soap and water.**
- **After the operation when removing gloves, hands must be rubbed with an alcohol-based formulation or washed with soap and water if any residual talc or biological fluids are present (e.g. the glove is punctured).**
- **Surgical procedures may be carried out one after the other without the need for hand washing, provided that the hand rubbing technique for surgical hand preparation is followed (Images 1 to 14)**

1.

Put approximately 5ml (3 doses) of alcohol-based hand rub in the palm of your left hand, using the elbow of your other arm to operate the dispenser.

2.

Dip the fingertips of your right hand in the hand rub to decontaminate under the nails (5 seconds).

3.

3. Images 3 – 7. Smear the hand rub on the right forearm up to the elbow. Ensure that the whole skin area is covered by using circular movements around the forearm until the hand rub has fully evaporated (10-15 seconds). Repeat for opposite hand and arm.

4.

5.

6.

7.

8.

Put approximately 5ml (3 doses) of alcohol-based handrub in the palm of your left hand, using the elbow of your other arm to operate the distributor. Rub both hands in the same time up to the wrists, and ensure that all the steps presented in images 9 – 14 are followed. Repeat for opposite hand and arm.

9.

Cover the whole surface of the hands up to the wrist with alcohol-based hand rub, rubbing palm against palm with a rotating movement.

10.

Rub the back of the hands up to the wrist with alcohol-based handrub, rubbing palm against palm with a rotating movement.

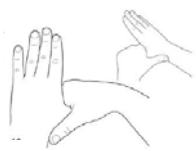
11.

Rub the back of the left hand, including the wrist, moving the right palm back and forth and vice-versa.

12.

Rub palm against palm back and forth with fingers interlinked.

13.



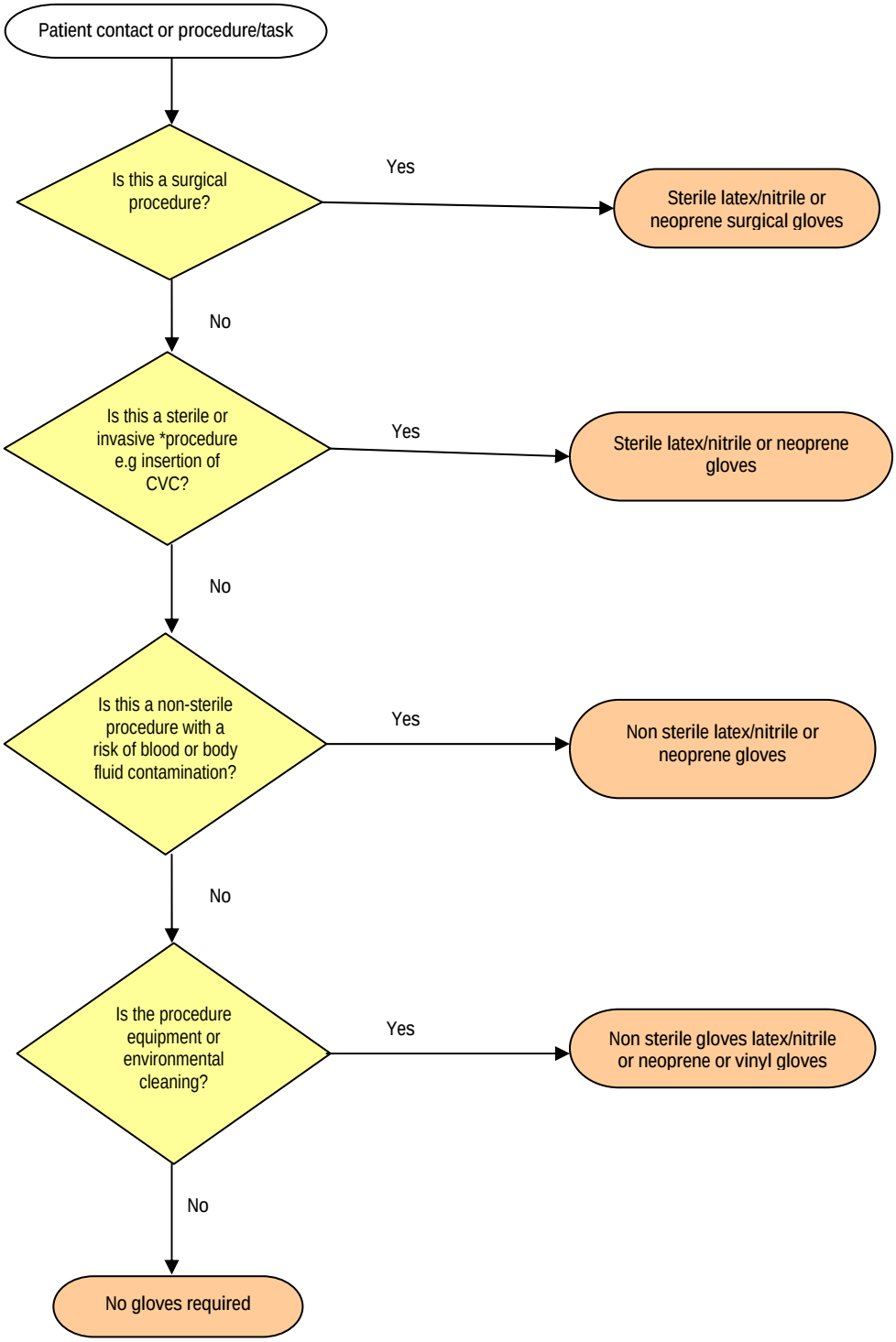
Rub the thumb of the left hand by rotating it in the clasped palm of the right hand and vice versa.

14.

When the hands are dry, sterile surgical clothing and gloves can be donned.

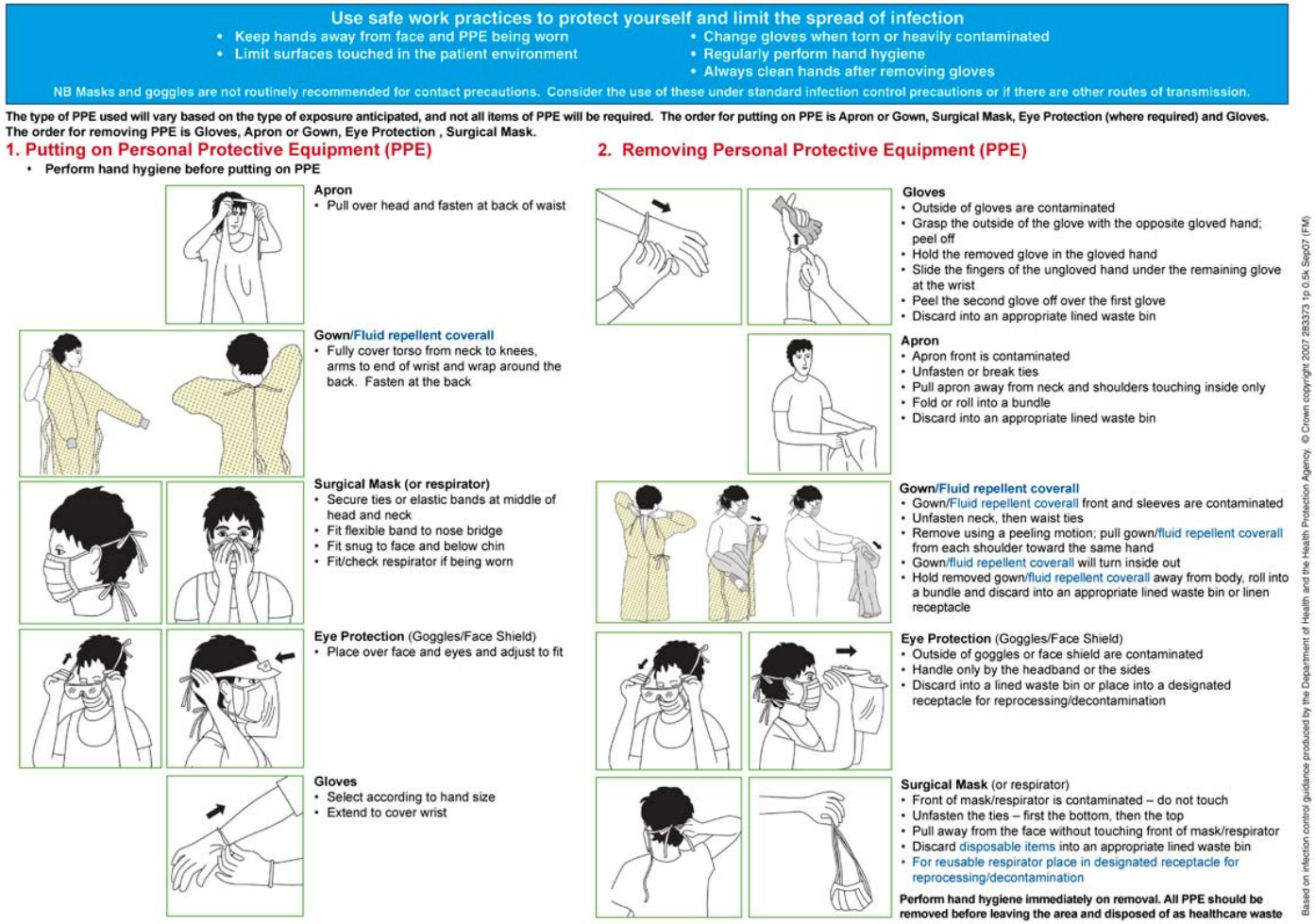
Adapted from World Health Organization

Appendix 5 – Glove use and selection

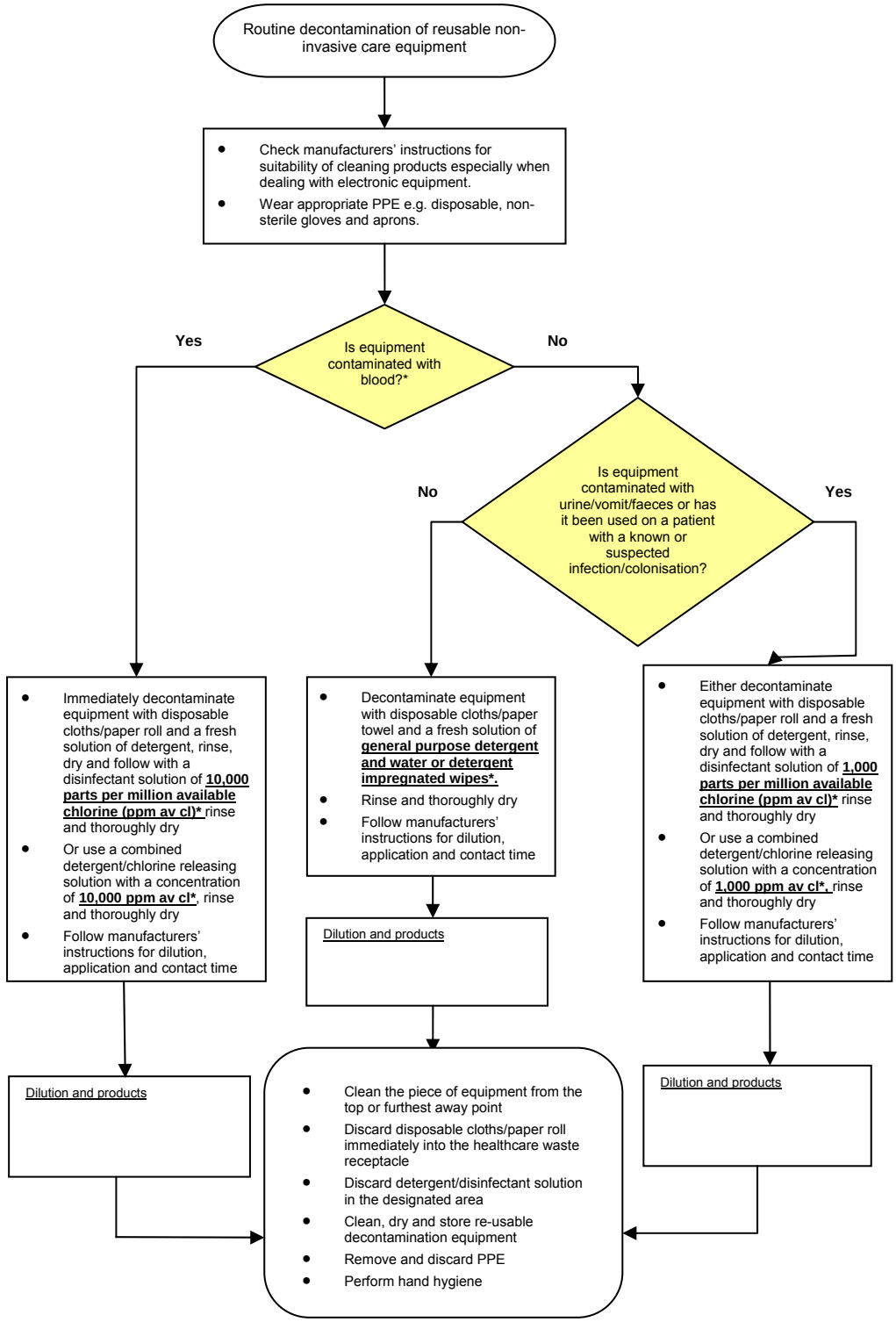


*sterile gloves are not required e.g for insertion of a PVC or obtaining blood cultures or when a safety device/technique is used

Appendix 6 – Putting on and removing PPE



Appendix 7 - Decontamination of reusable non-invasive care equipment



***** Scottish National Blood Transfusion Service and Scottish Ambulance Service use products that differ from those stated in the National Infection Prevention and Control Manual,

Appendix 8 - Decontamination status certificate

Please see supporting document for NHS Lothian's Medical Equipment Maintenance Request Form.

Further information can be found at http://www.hfs.scot.nhs.uk/services/incident-reporting-and-investigation-centre-iric/how-to-report-adverse-incidents/

Appendix 9 – Procuring, trialling or lending any reusable non-invasive care equipment

Please see supporting document for NHS Lothian's policy for New equipment purchase for NHS.

Appendix 10 – Management of linen at care area level

Lothian Laundry Users

CLASSIFICATION OF USED LINEN

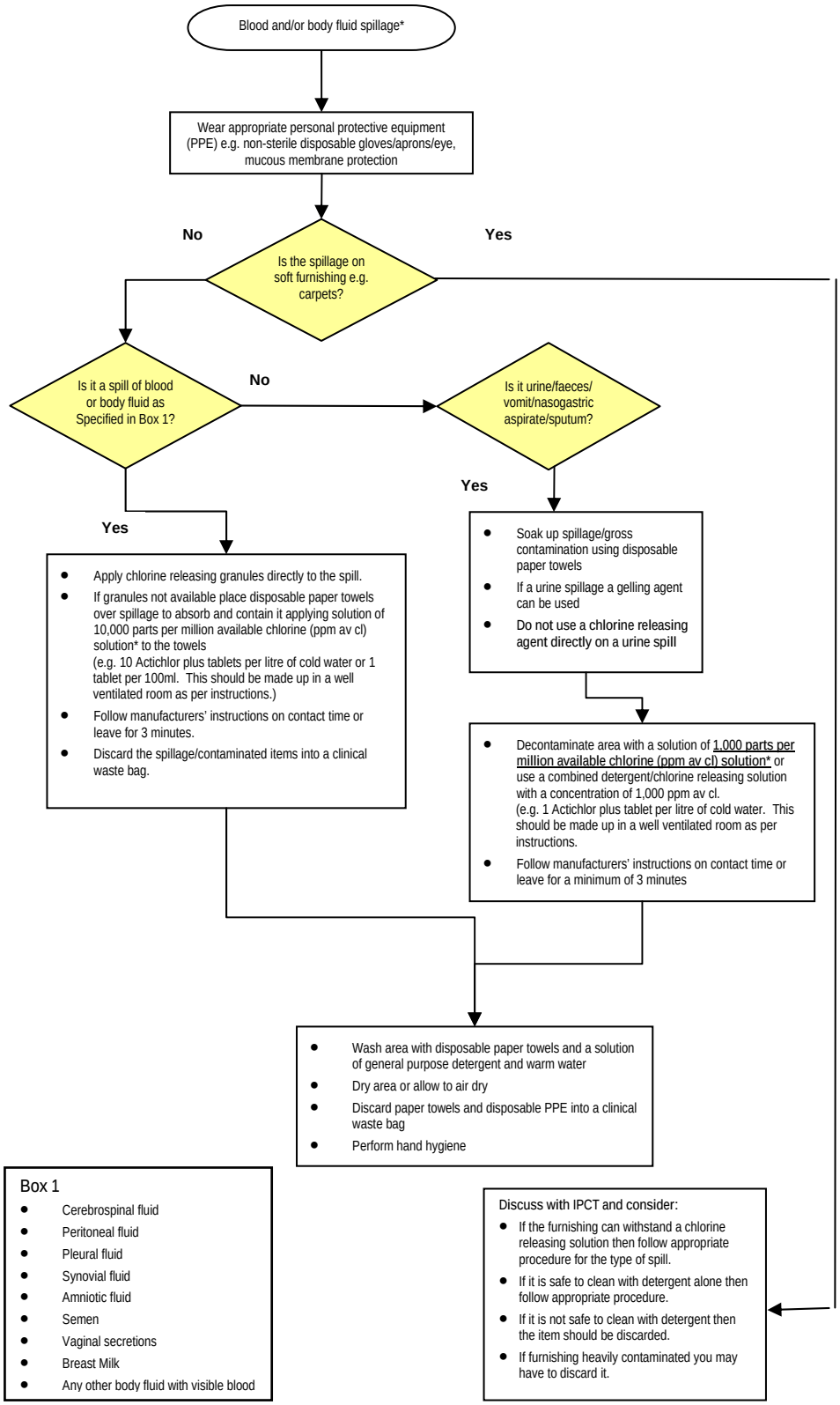
Categories	Laundry bag	Definition
Used	 White Linen Hamper	Linen that has been used but is not fouled, infected or infested
Fouled , Infected & Infested	 Water Soluble BAG Inside Red Linen Hamper	All linen & uniforms contaminated with blood, faeces , body fluids or from a patient known / thought to have an infection or infestation of lice, flees or scabies
Uniforms including theatre scrubs	 BLUE HAMPER	Uniforms that have been used but are not soiled, Infected nor infested
Curtains	 YELLOW HAMPER	Bed Screens & Window Curtains
Dry cleaning	 ORANGE HAMPER	Patients clothing to be Dry Cleaned
Personal Clothing and "return to user items " Eg. Hoist slings	See Local Arrangements (separate poster)	Personal Clothing may be damaged if treated as infected laundry. Patients personal clothing can be washed by relatives at home or processed by staff in an authorised hospital machine

NB linen bags must be labelled as to their source e.g. Hospital, ward/department, date/number and no heavier than 10kg

Do NOT send items other than linen / uniforms to the Laundry.

Do NOT use plastic bags when sending Linen to Laundry

Appendix 11 – Management of blood and body fluid spillages

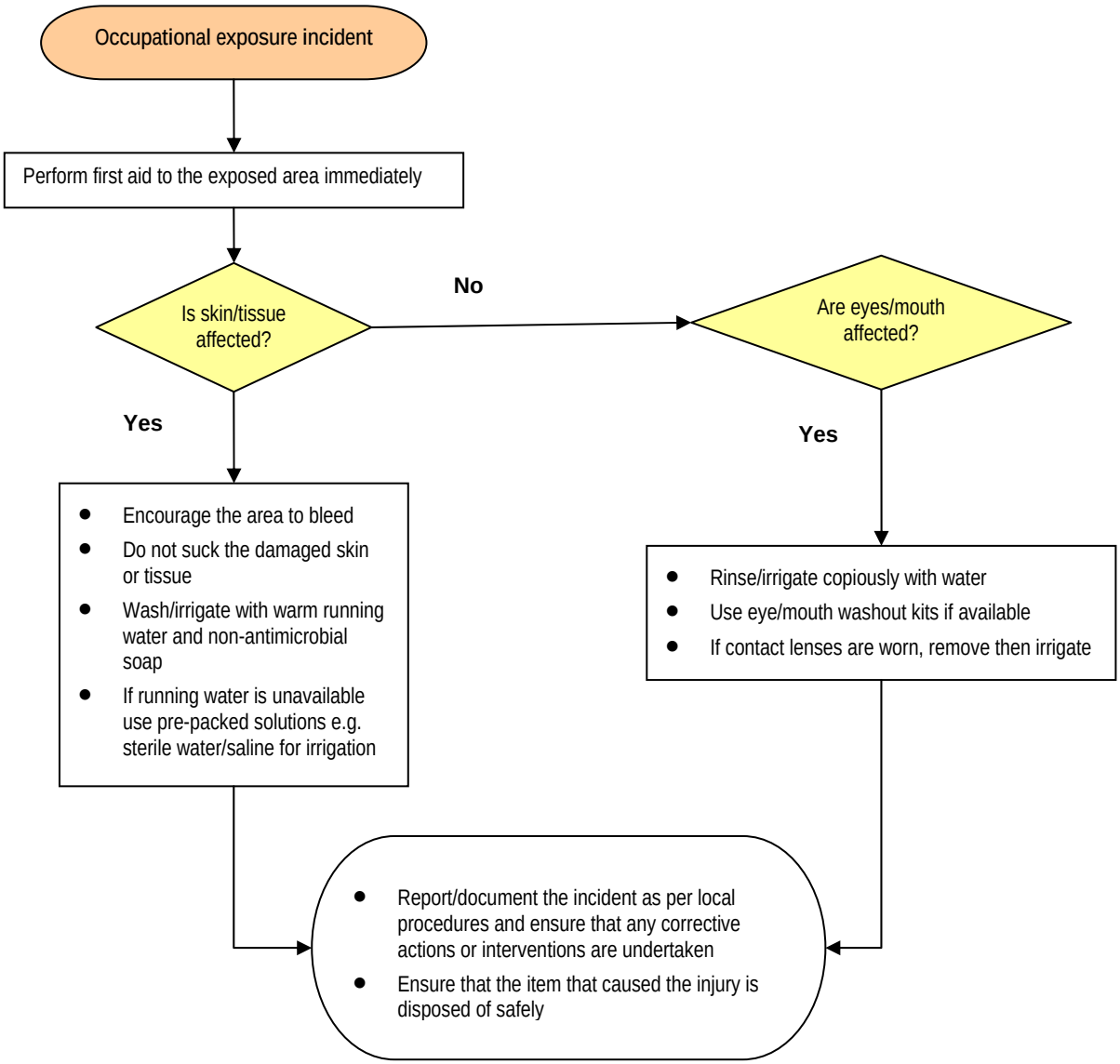


***** Scottish National Blood Transfusion Service and Scottish Ambulance Service use products that differ from those stated in the National Infection Prevention and Control Manual

Appendix 12 – Management of waste at care area level

Please see supporting document for NHS Lothian's Waste Policy.

Appendix 13 – Management of occupational exposure incidents



Appendix 14 – List of infectious agents and/or diseases that require Transmission Based Precautions (TBPs) in addition to SICPs.

The following table outlines:

1. Main route of transmission for a number of infectious agents/diseases;
2. Optimal patient placement whilst the patient is considered infectious; and
3. The appropriate RPE to minimise risk of infection to staff, patients and visitors. Clinical decisions made by staff regarding use/non-use of RPE will depend on a risk assessment which should include e.g. the risk of infection acquisition and the severity of the illness caused.

The clinical judgement and expertise of the Infection Prevention and Control Team or the Health Protection Team should be sought for novel, unusual or an increase in cases of known or suspected infectious agents in any care setting.

Apron and gloves to be routinely used and where noted additional precaution of facial masks/goggle and visor to be used if risk of exposure to mucous membranes (eyes/nose and mouth). Contact Infection Prevention and Control Duty Nurse (Extension 63373 or 0131 536 3373) for further clarification if required.

Pathogen	Disease	Main route of transmission	Notifiable (see footnote 4)	Optimal placement whilst patient is considered infectious		Respiratory and facial protection (RPE) for healthcare workers whilst patient is considered infectious		NHS Lothian Comments
				Single en-suite room	Isolation room with Negative Pressure	Surgical Facemask (If there is a risk of splashing or spraying of blood / body fluids from patient contact or procedure)	FFP3 respirator or Hood for AGPs	
Adenovirus (see footnote 1)	Upper +/- lower respiratory tract infection	Droplet		✓		✓	✓	Incubation period 4-12 days. Precautions can be lifted 24 hrs after the resolution of fever and respiratory symptoms.
	Conjunctivitis	Contact		✓		✓		Incubation period 4-12 days. Precautions can be lifted when patient asymptomatic.
Bordetella pertussis	Pertussis/ Whooping Cough	Droplet	✓	✓		✓	✓	Precautions can be lifted when patient received 5 days appropriate antibiotics.
Chlamydia pneumoniae	Pneumonia	Droplet		✓		✓	✓	Precautions can be lifted 24 hrs after the resolution of fever and respiratory symptoms.
Clostridium difficile	*Clostridium difficile* infection (CDI)	Contact	✓	✓		✓		Precautions can be lifted 48 hrs after the resolution of symptoms and a formed stool has been passed.

Pathogen	Disease	Main route of transmission	Notifiable (see footnote 4)	Optimal placement whilst patient is considered infectious		Respiratory and facial protection (RPE) for healthcare workers whilst patient is considered infectious		NHS Lothian Comments
				Single en-suite room	Isolation room with Negative Pressure	Surgical Facemask (If there is a risk of splashing or spraying of blood / body fluids from patient contact or procedure)	FFP3 respirator or Hood for AGPs	
Coronavirus (see footnote 1 and 5)	Acute respiratory syndrome *(Non-SARS & Non MERS)*	Droplet		✓		✓	✓	Precautions can be lifted 24 hrs after the resolution of fever and respiratory symptoms.
Corynebacterium diphtheriae	Diphtheria – Cutaneous	Contact	✓	✓		✓		Incubation period 2-5 days. Precautions can be lifted when patient asymptomatic.
Corynebacterium ulcerans	Diphtheria – Pharyngeal toxigenic strains	Droplet	✓	✓		✓	✓	Incubation period 2-5 days Precautions can be lifted 24 hrs after the resolution of fever and respiratory symptoms.
Gastrointestinal infections e.g salmonella, Cryptosporidium, Campylobacter, E.coli O157		Contact	✓ (some GI Infections are notifiable. Refer to guidance)	✓		✓		Discuss with IPCN when precautions can be lifted.

Pathogen	Disease	Main route of transmission	Notifiable (see footnote 4)	Optimal placement whilst patient is considered infectious		Respiratory and facial protection (RPE) for healthcare workers whilst patient is considered infectious		NHS Lothian Comments
				Single en-suite room	Isolation room with Negative Pressure	Surgical Facemask (If there is a risk of splashing or spraying of blood / body fluids from patient contact or procedure)	FFP3 respirator or Hood for AGPs	
Haemophilus influenzae type b	Epiglottitis	Droplet		✓				Incubation Period between 1-4 days. Precautions can be lifted when patient has received 24 hours of appropriate antibiotic.
	Meningitis	Droplet	✓	✓		✓	✓	
Herpes zoster (varicella-zoster) (see footnote 2)	Shingles (vesicle fluid)	Contact		✓		✓		Patient to remain in Isolation room if lesions cannot be covered and patient cannot reliably decontaminate hands. Precautions can be lifted when lesions crusted over.
	Shingles (lesions in the respiratory tract)	Droplet / airborne			✓	✓	✓	Patient to remain in Isolation room until clinical team has agreed with virologists that isolation is no longer required.

Pathogen	Disease	Main route of transmission	Notifiable (see footnote 4)	Optimal placement whilst patient is considered infectious		Respiratory and facial protection (RPE) for healthcare workers whilst patient is considered infectious		NHS Lothian Comments
				Single en-suite room	Isolation room with Negative Pressure	Surgical Facemask (If there is a risk of splashing or spraying of blood / body fluids from patient contact or procedure)	FFP3 respirator or Hood for AGPs	
Influenza virus (Endemic strains) (see footnote 5)	Influenza	Droplet	✓	✓		✓	✓	Incubation period 1-4 days. Precautions can be lifted 24 hrs after the resolution of fever and respiratory symptoms.
Measles virus (see footnote 2)	Measles (rubeola)	Droplet/ airborne	✓		✓	✓	✓ (see footnote 2)	If anyone presents with a rash in A&E/Outpatients should be isolated and contact IPCN Duty Nurse. Incubation period 7-18 days. Patient is infectious from 4 days before to 4 full days after the onset of rash.
Mumps virus (see footnote 2)	Mumps (infectious parotitis)	Droplet	✓	✓		✓ (see footnote 2)	✓	Incubation period 15-18 days. Precautions can be lifted 7 days after onset of symptoms.

Pathogen	Disease	Main route of transmission	Notifiable (see footnote 4)	Optimal placement whilst patient is considered infectious		Respiratory and facial protection (RPE) for healthcare workers whilst patient is considered infectious		NHS Lothian Comments
				Single en-suite room	Isolation room with Negative Pressure	Surgical Facemask (If there is a risk of splashing or spraying of blood / body fluids from patient contact or procedure)	FFP3 respirator or Hood for AGPs	
Mycobacterium tuberculosis	Extrapulmonary Tuberculosis	Contact	✓	✓		✓	✓	
	Pulmonary or laryngeal disease Tuberculosis	Airborne	✓		✓	✓	✓ and always if the patient has MDR or XDR TB	Patient to remain within negative pressure room until patient has received 14 days of appropriate antibiotics and noted clinical improvement. If patient is MDR or XDR TB positive to remain within isolation for duration of admission.
Mycoplasma pneumoniae	Pneumonia	Droplet		✓		✓	✓	Query Local Risk Assessment e.g. High Risk Area for immunocompromised patients (e.g. oncology, haematology and transplant) to be isolated.
Neisseria meningitides	Meningitis – meningococcal (Or presentation of clinical meningitis of unknown origin)	Droplet	✓	✓		✓	✓	Precautions can be lifted when patient has received 24 hours of appropriate antibiotics.

Pathogen	Disease	Main route of transmission	Notifiable (see footnote 4)	Optimal placement whilst patient is considered infectious		Respiratory and facial protection (RPE) for healthcare workers whilst patient is considered infectious		NHS Lothian Comments
				Single en-suite room	Isolation room with Negative Pressure	Surgical Facemask (If there is a risk of splashing or spraying of blood / body fluids from patient contact or procedure)	FFP3 respirator or Hood for AGPs	
Norovirus		Contact/ Droplet	✓	✓		✓		Incubation period 10-60 hours. Precautions can be lifted 72 hours after last symptoms. May be part of an outbreak follow outbreak precautions.
Parainfluenza virus (see footnote 1)	Upper +/- lower respiratory tract infection	Droplet		✓		✓	✓	Incubation period 1-4 days. Precautions can be lifted 24 hrs after the resolution of fever and respiratory symptoms.
Parvovirus B19 – (Erythema infectiosum – Erythrovirus B19)	Slapped cheek syndrome	Droplet		Not required if the rash+/- arthralgia has developed		✓	Not required if the rash+/- arthralgia has developed	Incubation period 4-20 days. Once the rash is present the patient is no longer infectious.
Respiratory syncytial virus (RSV) (see footnote 1)	Upper +/- lower respiratory tract infection	Droplet		✓		✓	✓	Incubation Period 5-8 days. Precautions can be lifted 24 hrs after the resolution of fever and respiratory symptoms.

Pathogen	Disease	Main route of transmission	Notifiable (see footnote 4)	Optimal placement whilst patient is considered infectious		Respiratory and facial protection (RPE) for healthcare workers whilst patient is considered infectious		NHS Lothian Comments
				Single en-suite room	Isolation room with Negative Pressure	Surgical Facemask (If there is a risk of splashing or spraying of blood / body fluids from patient contact or procedure)	FFP3 respirator or Hood for AGPs	
Rhinovirus (see footnote 1)	Upper +/- lower respiratory tract infection	Droplet		✓		✓	✓	Incubation Period 1-5 days. Precautions can be lifted 24 hrs after the resolution of fever and respiratory symptoms.
Rotavirus	Gastroenteritis	Droplet / contact		✓		✓		Incubation Period 24-72 hours. Precautions can be lifted 48 hrs after symptoms stop.
Rubella virus (see footnote 2)	German Measles	Droplet	✓	✓		✓	✓	The incubation period is 14-21 days. Patients with rubella are infectious from one week before symptoms appear to four days after the onset of the rash.
Staphylococcus aureus (Enterotoxigenic)	Scalded skin syndrome	Contact	✓	✓		✓		This condition is rare and requires individual risk assessment with IPCT.

Pathogen	Disease	Main route of transmission	Notifiable (see footnote 4)	Optimal placement whilst patient is considered infectious		Respiratory and facial protection (RPE) for healthcare workers whilst patient is considered infectious		NHS Lothian Comments
				Single en-suite room	Isolation room with Negative Pressure	Surgical Facemask (If there is a risk of splashing or spraying of blood / body fluids from patient contact or procedure)	FFP3 respirator or Hood for AGPs	
Meticillin resistant *Staphylococcus aureus* (MRSA)	Infection Colonisation (either swab positive or positive as per clinical risk assessment criteria)	Contact	✓	✓		✓		Precautions can be lifted after 3 negative sets of screening specimens
Streptococcus pyogenes (Group A Strep, Scarlet Fever)	Respiratory	Droplet		✓		✓	✓	Precautions can be lifted after 24 hours of appropriate antibiotics and clinical improvement in discussion with Microbiologist if required.
	Bacteraemia, meningitis, wound i.e. blood, cerebrospinal fluid or other normally sterile site	Contact	✓	✓		✓		Precautions can be lifted after assessment by IPCT. This usually requires at least 24 hours of appropriate antibiotics. Patients discharging pus or with necrotic tissue may require prolonged isolation. See Group A Strep chapter for details.

Pathogen	Disease	Main route of transmission	Notifiable (see footnote 4)	Optimal placement whilst patient is considered infectious		Respiratory and facial protection (RPE) for healthcare workers whilst patient is considered infectious		NHS Lothian Comments
				Single en-suite room	Isolation room with Negative Pressure	Surgical Facemask (If there is a risk of splashing or spraying of blood / body fluids from patient contact or procedure)	FFP3 respirator or Hood for AGPs	
Streptococcus pneumoniae	• Pneumonia • Meningitis	Droplet	✓	✓		✓	✓	Precautions can be lifted after 24 hours of appropriate antibiotics and clinical improvement in discussion with Microbiologist if required.
	Bacteraemia, meningitis, wound i.e. blood, cerebrospinal fluid or other normally sterile site	Contact	✓ (presence in the wound is not notifiable)	✓		✓		Precautions can be lifted after 24 hours of appropriate antibiotics and clinical improvement in discussion with Microbiologist if required.
Varicella virus (see footnote 2)	Chickenpox	Droplet/ airborne	✓		✓	✓	✓	Patients are infectious from day 9 to day 21 post exposure. Precautions can be lifted when the last vesicle crop has crusted.

Footnote 1
In routine clinical practice healthcare workers do not commonly wear masks when dealing with patients presenting with the "common cold" or "influenza – like illness". However, in a patient with undiagnosed respiratory illness where coughing and sneezing are significant features, or in the context of known widespread respiratory virus activity in the community or a suspected or confirmed outbreak of a respiratory illness in a closed or semi closed setting, the need for appropriate respiratory and facial protection to be worn should be considered.

"High risk environment for transmission includes clinical settings where AGPs are undertaken in open or communal patient areas. High risk environments for acquisition include areas where patients with severe immuno-suppression are being cared for." In these particular settings precautions should be discussed and agreed with the IPCT.

Footnote 2
In relation to childhood illnesses and use of masks, no vaccine offers 100% protection and a small proportion of individuals acquire/become infected despite vaccination. PPE i.e. facial/respiratory protection should be used as a means of protecting from the risks that remain. For those staff who are unaware of their IgG immunity or vaccination history a FFP3 respirator must be worn at all times during contact with the patient.

Footnote 3
Aerosol Generating Procedures (AGPs) can produce droplets <5 microns in size which may cause infection if they are inhaled. These small droplets, containing pathogens, can remain in the air, travel over a distance and still be infectious. AGPs procedures should only be carried out when essential. Where possible, these procedures should be carried out in well-ventilated single rooms with the doors shut. Only those healthcare workers who are needed to undertake the procedure should be present.

Aerosol Generating Procedures (AGPs) are defined as:

- Intubation, extubation and related procedures, for example manual ventilation and open suctioning.
- Cardiopulmonary resuscitation.
- Bronchoscopy.
- Surgery and post mortem procedures in which high-speed devices are used.
- Dental procedures.
- Non Invasive Ventilation (NIV) e.g. Bilevel Positive Airway Pressure Ventilation (BiPAP) and Continuous Positive Airway Pressure Ventilation (CPAP).
- High Frequency Oscillatory Ventilation (HFOV).
- Induction of sputum.

Footnote 4
A list of notifiable diseases can be found in the Public Health etc. (Scotland) Act 2008. Schedule 1 http://www.legislation.gov.uk/asp/2008/5/contents

Footnote 5
Additional guidance should be followed for known/suspected cases of novel influenza viruses, including avian influenza, MERS CoV.

SCOTTISH HOSPITALS INQUIRY

Bundle of documents for the Oral hearing commencing on 12 June 2023

Bundle 6 – Miscellaneous documents

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