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].

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[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:

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[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

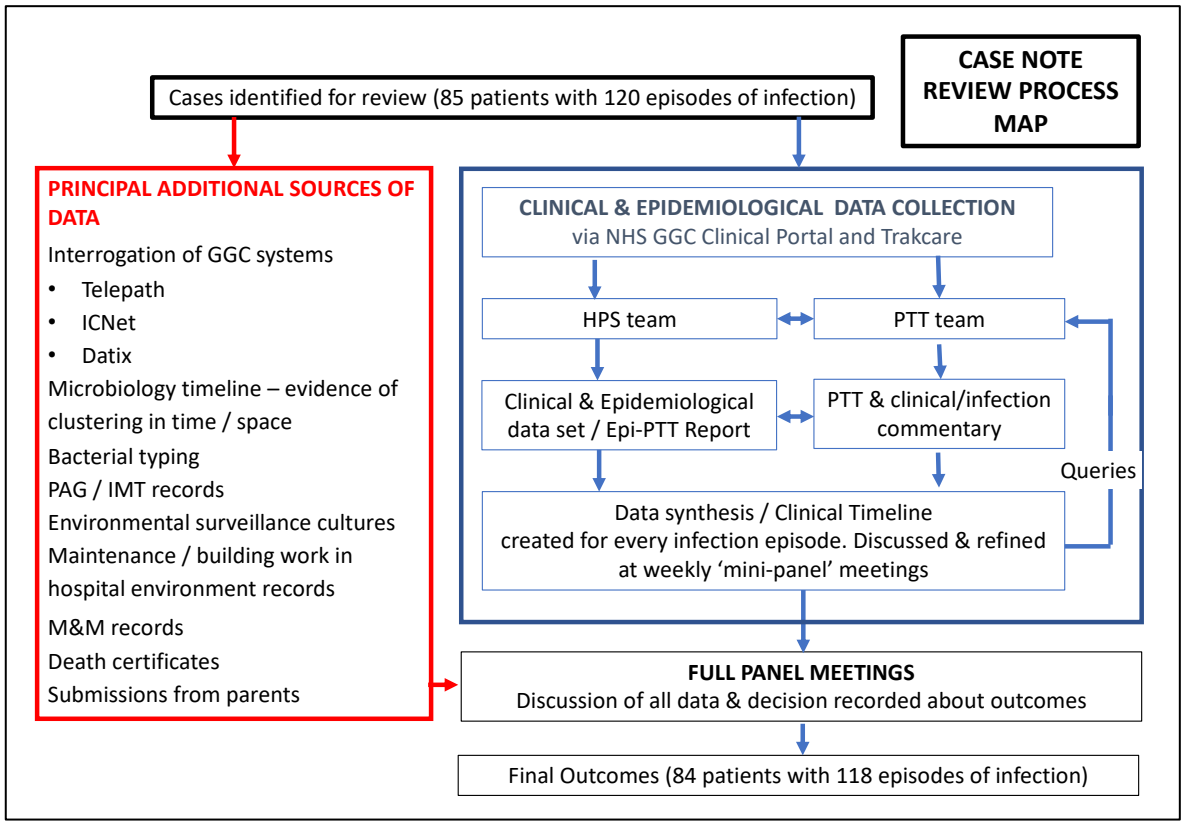
infection. The Telepath system sends microbiology results to the ICNet system every 15 minutes. This provides timely reporting to the IPCT.

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].

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[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.

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[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

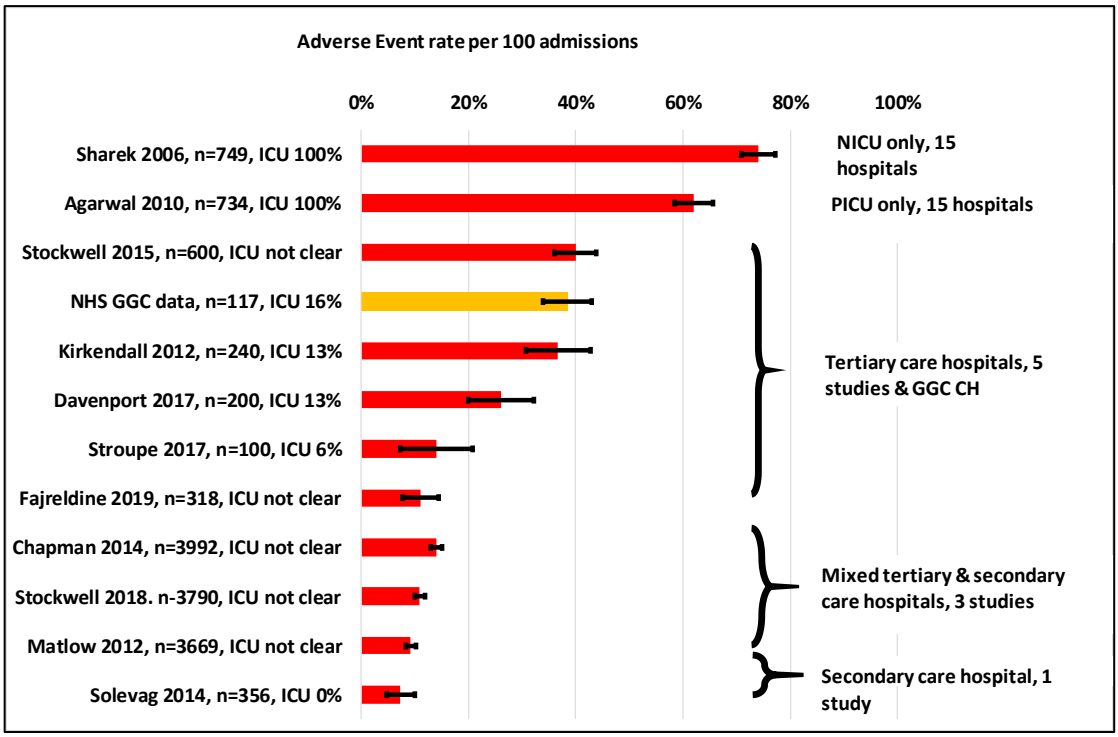
We have already discussed data derived from AE reporting, whether from the PTT or Datix notifications, in Chapter 6, section 6.4. In this section, we compare AE rates in the Haematology Oncology patients we have reviewed at NHS GGC with data available from the literature from other paediatric hospitals, 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.

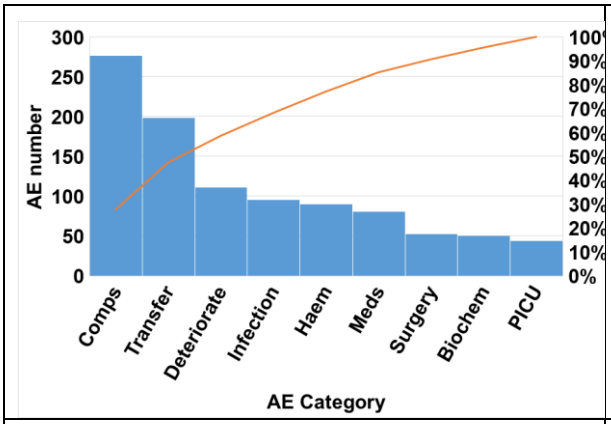
Appendix C shows the PTT score sheet used in our Review. For ease of analysis, the adverse events that derive from searching for these triggers can be grouped as shown in Figure 8.2.

Table 8.1 Adverse Event Categories (adapted from Matlow 2012 and Stroupe 2017).

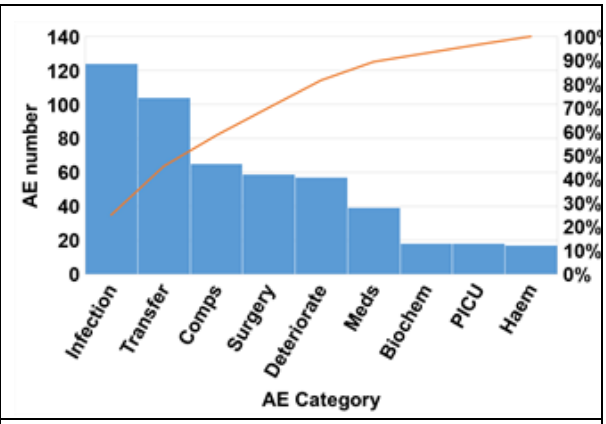
Biochem	Biochemistry	Intervention for increased creatinine; high/low potassium, sodium, sugar
Comps	Care complications	Intervention for tissue damage, thrombosis, other complication (e.g. adverse drug reaction, central line infection) or pain
Deter	Deteriorating patient	Delayed response to Early Warning 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.

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[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

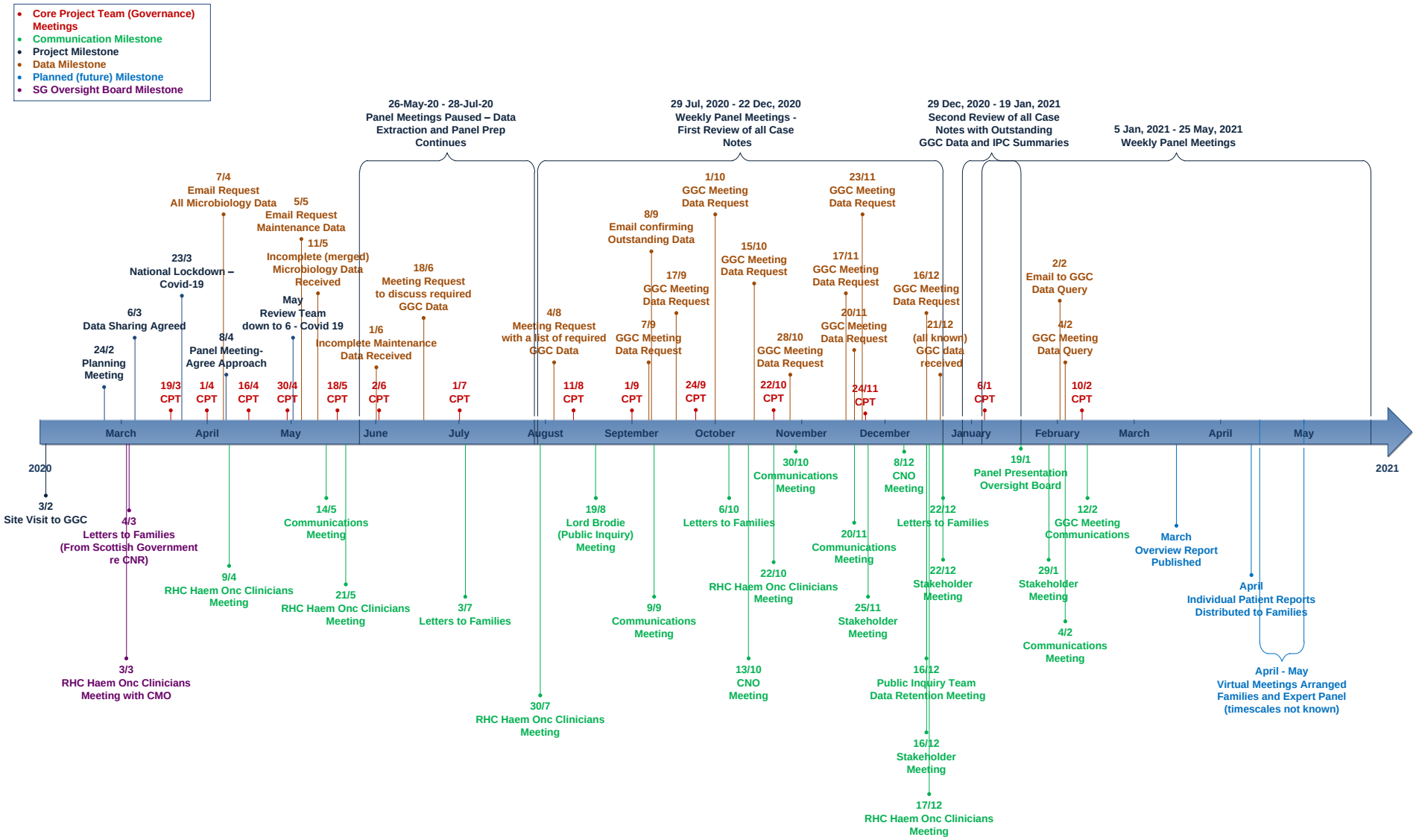
Timeline of Incidents for period 2015-2019 (‘Super Timeline’) 2020

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
- **F** Temporary harm to the patient and required initial or prolonged hospitalisation
- **G** Permanent patient harm
- **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		

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