Scottish Hospitals Inquiry
Witness Statement of
Professor Brenda Gibson

PERSONAL DETAILS

1. My name is Professor Brenda Elizabeth Simpson Gibson. I am a Consultant Paediatric Haematologist and Lead Clinician for the Haematology and Oncology service based in the Royal Hospital for Children (RHC) Glasgow, and the Departmental Lead for Systemic Administration of Chemotherapy (SACT). In these roles I am employed by Greater Glasgow and Clyde Health Board. I am also the Programme Director for Haematopoietic Stem Cell Transplantation (HSCT) which is a national service.

EDUCATION

2. I studied Medicine (MB ChB) at Aberdeen University. I went on to obtain the MRCP UK from the Royal College of Physicians and the MRCPath from the Royal College of Pathologists. I was appointed FRCP by the Glasgow Royal College of Physicians and Surgeons, FRCPath by the Royal College of Pathologists and FRCPCH by the Royal College of Paediatrics and Child Health. At Glasgow University I achieved a Diploma in Forensic Medicine and a Certificate in Law and Ethics in Medicine.

PROFESSIONAL BACKGROUND

3. My main areas of interest have always been leukaemia, particularly Acute Myeloid Leukaemia (AML), and Haematopoietic Stem Cell Transplantation (HSCT).

4. Latterly, at Yorkhill Children's Hospital, my primary duties were the care of children with leukaemia and those undergoing HSCT. I was responsible for the haematology laboratory and had responsibilities for patients with benign haematology on a rotational basis. I was the Lead for Haematology and Oncology services and the Programme Director for Haematopoietic SCT.

5. I was the President of the British Society of Haematology between 2007 and 2009, and Chair of the Managed Service Network for Children and Young People with Cancer in Scotland from 2011 to 2015.

6. Whilst at Yorkhill I established and supported a molecular laboratory to measure minimal residual disease (MRD) which is the main prognostic indicator of outcome for children with acute lymphoblastic leukaemia (ALL). This I did with endowment funds. Initially the prognostic value of MRD was tested within a national clinical trial and this laboratory provided a national service for Scotland and a service for Northern Ireland, Newcastle and Liverpool. When the importance of MRD was recognised, this service was integrated into the QEUH molecular service and remains a national service for Scotland. The current national ALL trial has a strict risk stratification which dictates the intensity of treatment and requires MRD measurement at several time points. Two methodologies will be used – molecular and flow cytometry. Departmental endowment funds will support flow cytometry MRD as a national service.

7. I have had representation on various National and International Committees, Colleges and Learned Societies. At present I am a Member of the Blood wise Strategic Advisory Committee, Member of National Cancer Research Institute (NCRI) Children's Cancer & Leukaemia Clinical Studies Group (CCLCSG) Leukaemia Sub-group, Member of SACDA DDRB, Expert for Acute Lymphoblastic Leukaemia (ALL) and AML on European Medicines Authority (EMA) Paediatric Committee on Medicine for Children, Member of European Bone Marrow Transplantation (EBMT) Paediatric Diseases Working Party, UK representative on the I BFM AML Steering Committee, Member of Childhood Leukaemia Research UK and Member of CCLG Bone Marrow Transplant Committee. Previously in my career I have been a member of Task Forces producing Guideline Documents and Advisory Committees, including a role as an External advisor to the London Paediatric Oncology Review.

8. I have been awarded 21 research grants between 1994 and 2016 and have been a reviewer for several Journals, Organisations and Annual Scientific Meetings. I have 181 publications spanning from 1986 to 2021. I have contributed to 17 chapters in textbooks and 93 presentations and abstracts.

CURRENT ROLE AND SPECIALISM

9. I am currently based in the RHC Glasgow as the Lead Clinician for the Haematology and Oncology service. My main responsibilities are provision of the West of Scotland Paediatric Leukaemia Service and Programme Director of the National Allogeneic Stem Cell Transplantation Programme. I have colleagues who specialise in Haemostasis and Thrombosis, Haemoglobinopathies and benign haematology.

10. My role changed slightly when we moved from Yorkhill. My primary duties remained the care of children with leukaemia and those undergoing HSCT. I devolved responsibilities for patients with benign haematology and more latterly for the haematology laboratory in favour of work in clinical trials. I remained the Lead for the Haematology and Oncology service and the Programme Director for Haematopoietic SCT. I am the departmental Lead for SACT but am demitting this role. I chair a number of Multidisciplinary meetings related to patient care including the Unit Multidisciplinary Meeting. I have a number of academic responsibilities. I am the Chief Investigator for an international trial in childhood AML which includes assessing serious adverse events and toxicities of patients entered into this trial. I am the Principal Investigator for a number of early phase I/II trials. I sit on several national and international committees where I represent Scotland or the UK. I peer review articles for publication and presentation at international scientific meetings and assess grant applications for national and international fund holders.

Clinical Trials

11. I have been asked by the Public Inquiry to clarify the difference between Phase I/II/III trials. Phase I trials are conducted to establish the maximum tolerated dose in children of a new / emerging drug.

12. All chemotherapy is associated with toxicity, but the maximum dose is the dose associated with acceptable toxicity. Phase II trials establish efficacy or not for a drug at this dose level. A Phase III trial will add a drug which has shown efficacy to an established chemotherapy regimen and compare it by randomisation to the established chemotherapy regimen. All trials aim to improve cure rates. Early phase trials – Phase I/II - are only open in a limited number of centres. Families will travel within the UK and indeed around the world to access these trials and gain access to new agents for their child. It is for this reason that we established an Early Phase Trial Unit in Glasgow in 2017 following a very successive year long fundraising campaign.

THE CANCER JOURNEY

Effect of Diagnosis

13. There is nothing more devastating for parents than the diagnosis of cancer in their child. Most fear the worst and although they may be overwhelmed by the prospect of intensive and prolonged chemotherapy, their real fear is that their child will not respond to treatment or will respond and then relapse and die. This fear overrides everything. The amount of time spent in hospital, the effect on other family members, the devastation to normal family life are initially of little consequence but gain importance with time.

14. Every cancer is associated with a different relapse risk, treatment related mortality and long-term outcome. After the diagnosis has been made the responsible Consultant will sit down with the parents and give them the precise diagnosis, discuss any necessary additional investigations, detail the treatment including the side effects, obtain informed consent and give a prognosis or explain what determines outcome. Written information is provided. Most children with cancer are treated on national or international trials or guidelines, and every effort is made to give families the comfort and reassurance that their child will receive the same treatment as every other child in the UK and indeed as every other child in the developed world. Consent is now taken on a UK wide consent form.

15. Most children have had symptoms for some time before diagnosis and many have had one or several General Practitioner (GP) or Emergency Department (ED) visits. Some parents feel that they were not listened to at these visits. However, childhood cancer is very rare and symptoms can be non-specific. Parents often express some relief that a diagnosis has now been made and that treatment will start. In children all treatment is initially given with curative intent. Whatever the predicted survival rates some parents will remember/concentrate on the number of children who remain in remission and do well, and others will concentrate on the number who relapse and do badly. However, the fear of relapse remains with all parents and indeed clinicians.

16. This diagnosis will change their child's life, their lives and that of siblings and other family members. The era of social media does mean that many search the internet for information and discuss issues on Facebook. We try to discourage them from doing this, because it is often not helpful and can be harmful, but we rarely succeed.

The Nature of the Different Types of Treatment for Cancer

17. Cancer is divided into leukaemias, lymphomas and a range of solid tumours, with the most common being brain tumours. The two most common cancers in children are leukaemia and brain tumours. Some patients require only surgery, others radiotherapy, chemotherapy, immunotherapy or a HSCT (haematopoietic stem cell transplant).

18. In terms of vulnerability to infection this relates to the depth and length of neutropenia (absence of healthy white cells) and the exposure to immunosuppressants, particularly steroid therapy. Leukaemia involves the bone marrow and therefore all patients with leukaemia are neutropenic (have no healthy white cells) until their disease goes into remission. One of the important drugs to achieve this is steroids, in particular Dexamethasone, which is a very potent steroid and immunosuppressant. Children with leukaemia may face profound neutropenia for four to six weeks after diagnosis and further periods of chemotherapy -related neutropenia throughout treatment. Only solid tumour patients with stage four disease have involvement of the bone marrow.

19. These patients have shorter periods of chemotherapy related neutropenia and are generally not treated with prolonged steroid /immunosuppressant therapy. The risk of serious infection is therefore much less for children with solid tumours than for children with leukaemia and those who undergo HSCT. The most vulnerable are transplant patients who have undergone a HSCT because they have prolonged and profound immunosuppression including steroid therapy. In summary it is those with disease which affects the bone marrow, who have profound and prolonged neutropenia and receive steroids/immunosuppression who are at greatest risk of overwhelming infection. This mirrors the reported incidence of infection or sepsis in the RHC cohort.

The Impact of Treatment on the Patient

20. The impact of treatment on the patient varies by the treatment and can be psychosocial as well as medical. Chemotherapy has generic side effects and drug specific side effects. The most serious generic side effect is infection or sepsis. All children receiving chemotherapy have a central line inserted to deliver chemotherapy and support them through treatment. This increases their risk of infection. The other main generic side effects of chemotherapy are anorexia, nausea, vomiting and mucositis (inflammation of the mouth) which are very difficult for children and parents. Older children may find it difficult to lose their hair. Different drugs have different specific side effects. In general, teenagers suffer a greater toll from chemotherapy toxicity than younger children.

21. Children may have a number of procedures, cannula insertion, lumbar punctures, bone marrows, trephine biopsies, nasogastric tubes; all except cannula insertion and nasogastric tubes are done under general anaesthesia although even the latter may also be inserted under general anaesthetic. It can be very difficult to place a cannula in children with small veins and this can be very distressing for children, particularly small children.

22. Different disease and treatment protocols carry a different risk of treatment related mortality. For example, in acute lymphoblastic leukaemia (ALL: the most common cancer in children treated with chemotherapy), the remission rate (chance of clearing disease morphologically after four weeks of chemotherapy) is between 95-98%. The results from the most recent trial reported a death rate during those four weeks of 0.7% and mainly from infection and a further 1.3% died in remission and again mainly from infection (courtesy of CI of UK ALL 2011). The most significant prognosticator of outcome is response to induction therapy which is now measured by residual leukaemia DNA. Children who respond best to induction treatment have a long-term relapse rate of around 4-5%. About 50% are salvaged with further treatment giving an overall survival rate of about 98% for this group. Therefore, even a treatment related mortality rate of 1-2% means that the chance of dying from infection or sepsis is almost as great as the chance of dying from disease in this group.

23. Children with ALL who respond less well to induction chemotherapy have a higher relapse risk, but infection remains a significant cause of death. In acute myeloid leukaemia (AML) the expected international treatment related mortality for those treated with chemotherapy alone is about 6%, again mostly from infection. Those with high-risk AML have a higher treatment related mortality. The treatment related mortality in transplantation is around 10-15% dependent on co morbidities, donor, and underlying disease. The treatment related mortality for solid tumours is much lower because of lack of involvement of the bone marrow in most patients, less neutropenia and generally absence of steroid/ immunosuppressant therapy. However, they have a higher relapse risk.

24. There is also a psychosocial impact. This includes hospitalisation and a lack of contact with peers, and inability to attend school can be difficult for teenagers. Separation from siblings and other close family members is hard for all children. Holidays and family events are restricted.

Vulnerability to Infection

25. Risk of infection for a cancer patient relates to depth and length of neutropenia, inclusion of steroid therapy in treatment, level of immunosuppression, and presence of a central line. This translates into transplant patients being at greatest risk > leukaemia patients > solid tumours. Patients with profound and prolonged neutropenia who are on immunosuppressive agents, particularly those who have a central line in situ, which is almost invariably the case, will always be at risk of bacterial and fungal infection. Measures such as good hand hygiene, good line care and prophylaxis will reduce the risk but not eradicate it.

26. There are two types of central lines, Hickman and Port-a-cath. Peripheral venous access includes cannulas and PICC lines. Plastic provides a nidus for bacteria. Port-a-cath and single lumen lines are associated with a lower risk of infection, but the choice of central line is disease and treatment dependent. The most common line related infections are gram positive organisms and are due to skin commensals. Good surgical skin preparation at the time of insertion and good line care afterwards may reduce the risk. Some gram-negative organisms create a biofilm in the line which prevents antibiotic penetration. These infections cannot be completely eradicated by antibiotics, and it is for this reason that some lines infected with gram negative bacteraemia require removal. Stenotrophomonas is an example of such an organism.

Treating infection

27. If a child has a temperature, blood cultures and samples for a viral screen are taken and sent to the microbiology / virology laboratory for investigation. If the patient has a central line in situ, blood cultures are taken from each lumen – single or double – and generally by nursing staff. Erythema around the line site suggests infection. Lines which are not aspirating normally, or malfunctioning, are at increased risk of becoming infected.

28. Broad spectrum antibiotics are started empirically before blood culture results are available because this may take 48 hours. The clinical team caring for the child will always discuss the choice of antibiotics for a child with a positive blood culture with the microbiologist and take advice on any change when sensitivities are available. However, generally, if the only symptom is fever, the antibiotics are chosen to cover gram-negative organisms initially because these are the most serious. If there is erythema, malfunctioning, persistence of fever despite gram negative cover or a gram-positive organism is cultured, the antibiotic cover will be broadened to cover gram positive organisms. Positive blood cultures are phoned directly to the ward by microbiology to allow a rapid change in antibiotics if required, but later reported on the IT system. Negative blood cultures are only reported after 48 hours of incubation. If the organism is one associated with biofilm formation, the line will be removed.

29. There is a duty to communicate to patients and families that they have an infection, the cause of the infection and the impact on health and treatment. Parents will know that their child has an infection because they will have had a temperature and parents understand what that means because it is something that is discussed with them in detail from the outset, due to its significance. The parents will know which antibiotics their child is receiving. This information will be given to parents on the daily ward round. If the organism is identified parents will be told what is causing the infection. If they require x-rays or scans to investigate the infection or assess organ involvement the need for these will be explained. If this is a serious infection, the parents will be told this. Parents will be made aware of any treatment interruptions.

The Impact of Infection

30. The risks of infection are sepsis, which can be life threatening, line removal, and treatment delay. Almost all children will have a temperature at some stage of treatment with temporary interruption of treatment. If a central line has to be removed and re–inserted this will interrupt treatment.

31. Patients require an anaesthetic for line removal and there is a risk with any anaesthetic. There is also a risk that, when the line is removed / pulled, bacteria will be showered into the bloodstream. Fungal infections in particular may significantly interrupt treatment because of the need to maintain a neutrophil count.

Surveillance, Monitoring and Reporting of Infection

32. When a patient is found to have an infection, the clinicians' focus will be on treating this, and monitoring, investigating, acting upon and reporting infection is the responsibility of Infection Control. Positive blood cultures are detected in the microbiology laboratory and the microbiologists who are members of the IC team would know about these infections before the patient's clinician. It is the responsibility of the Infection Control team to ascertain whether it was acquired in the hospital or elsewhere. A HAI is a Hospital Acquired Infection. I am not sure if there is a true distinction between Hospital Acquired Infection and Healthcare Associated Infection, but I am aware that in evaluating the significance / relationship of positive blood cultures to the environment, the IMT make a distinction based on whether the infection has occurred in a patient who could only have acquired the infection in hospital (inpatient for over 48 hours) and those who could have acquired the infection at home. The latter would include patients who had been at home in the previous 48 hours but may have attended the Day Care Unit as an outpatient during that time.

33. I think the procedures within the QEUH and RHC are very effective, and the IC team is strong.

Prophylaxis

34. Generally speaking, prophylaxis is given to prevent infection and can be primary or secondary. Primary prophylaxis is given to prevent infection because the risk for that group of patients is considered high, whilst secondary prophylaxis is given to a patient who has already had an infection, to prevent recurrence.

35. National and international protocols and guidelines may specify the use of antifungal and antibiotic prophylaxis where the patient group is either particularly vulnerable or the treatment protocol is particularly intensive and recognised to be associated with a high risk of serious infection, usually due to the inclusion of high dose steroids or profound and prolonged neutropenia. We know from experience and clinical trials the hierarchy of vulnerability: HSCT, Infant ALL, Relapsed AML, AML, Relapsed ALL, ALL (particularly those with Down syndrome). Protocols / guidelines for these patients will include recommendations for prophylaxis.

36. Out with such recommendations, local circumstances may indicate the use of prophylaxis, such as building works on site or outbreaks of infection. In summary, some prophylactics are mandated by protocol and some by perceived risk. There is no controversy around the prescription of prophylaxis in either context. Prophylaxis will be given for the duration for the risk period.

37. Standard antifungal prophylaxis prescribed in accordance with standard and national practice for certain high-risk groups would include drugs such as AmBisome, Caspofungin or Posaconazole. Septrin is routinely prescribed as prophylaxis against Pneumocystis Carnii Pneumonia (PCP) (now known as Pneumocystis Jiroveci Pneumonia) as per protocol to all children with leukaemia, during treatment and for 3 months after stopping treatment. It is also prescribed to post transplant patients as standard practice. Patients receiving very intensive chemotherapy and thought to be at particular risk of gram-negative bacteraemia because of poor immunity (which would include Down syndrome ALL and Infant ALL) often receive Ciprofloxacin prophylaxis. The next national ALL trial will have a subsidiary randomised trial to receive or not to receive Ciprofloxacin prophylaxis during induction.

38. As with all medications, there are possible side effects with prophylactic drugs. Septrin can be associated with myelosuppression, AmBisome can be associated with anaphylaxis and renal impairment, Caspofungin and Posaconazole can be associated with hepatic toxicity and Ciprofloxacin can cause gastro-intestinal symptoms. All drugs can upset hepatic or renal function.

The Importance of the Hospital Environment

39. The hospital environment clearly must be safe in terms of infection. The most vulnerable patients are those undergoing transplantation. Such patients should be nursed in an environment which protects them from microbial infection. This involves nursing these patients in High Efficiency Particulate Air (HEPA) filtered positive pressure rooms. HEPA filtration primarily protects against fungal infection. Whilst there are guidelines for hospital buildings, I am not aware of any specific national environmental guidelines for cancer patients who are not undergoing bone marrow transplantation. Even the Joint Accreditation Committee ISCT-Europe (JACIE) guidelines, which set out the standards for Transplant Units, set loose standards for the environment and merely state that patients should be nursed in an environment which protects them against microbial infection. They do not stipulate how this is achieved. The standard is loose to allow low- and middle- income countries to comply.

40. It is also important to understand that children who are treated on the Schiehallion unit have a range of underlying conditions which dictate their vulnerability to infection, for example, not all patients have malignancies; some have haemophilia or sickle cell disease. Patients with benign haematological conditions may have no predisposing factors. Many children with solid tumours are only neutropenic for a limited period of time and will receive no immunosuppressants although they will have a central line in situ. They are generally only in hospital for the delivery of chemotherapy which will only be given if they are not neutropenic. They are discharged home after completing chemotherapy and it is during this phase that they will become neutropenic. They will only be readmitted if they develop a temperature. These patients would be considered at low risk of significant sepsis. One can question the level of protection such patients require.

41. All rooms on the Schiehallion Unit are single rooms. These prevent spread of infection, particularly viral infection.

42. The hospital environmental should also be supportive of the children and their families. It should provide age-appropriate facilities and an area that parents can meet and draw support from each other.

The Specialised Nature of Care Required for Cancer Patients

43. Cancer patients require paediatric cancer trained staff across all disciplines. This includes consultant trained staff in paediatric haematology and oncology, nurses trained to give chemotherapy and importantly pharmacy staff with training and experience in cancer therapy. The latter is vital. Dedicated physiotherapy, dietetics, psychology and social work are important. Unique to paediatrics is the need for Play Therapists who help children cope with procedures.

The Cancer Journey – Impact on Patients and Families

44. There are psychosocial impacts on patients and families because of the cancer journey. Children do not attend school for a period of time. Normal activities and family life are suspended. Parents stop working for a period which can have significant financial implications. The public sector is generally very sympathetic, private sector less so. The self-employed suffer the greatest financial deficit. Social work advice is available but cannot always compensate. Siblings are not just separated from resident parents but feel less important.

45. The length of treatment varies by underlying disease. Children with the most common type of leukaemia, ALL, receive treatment for two to three years. Other children may just receive surgery or a few months of chemotherapy. However, many children will require prolonged periods of time or recurrent admissions to hospital, regular hospital attendances as an outpatient and regular procedures and investigations.

The Role of Communication and Trust in the Cancer Journey

46. Trust is essential and this is the greatest toll taken by issues being investigated by this Public Inquiry. Families deserve to believe that their child is receiving the best treatment. Children at RHC are receiving the best treatment delivered by an experienced and knowledgeable team but sadly publicity has questioned this.

47. Communication between clinicians and families is good. Families are given regular comprehensive information on diagnosis, prognosis, treatment and side effects. They are regularly updated on progress and future treatment. This is very much a consultant led and consultant delivered service. Sadly, families take to Facebook and the internet which often provides misinformation.

THE SCHIEHALLION UNIT

Overview

48. The Schiehallion Unit, wards 2A and 2B, of the Royal Hospital for Children is a paediatric haemato-oncology unit which aims to provide patient centred holistic care to the children and their families. This includes not just their medical care but psychosocial care and support. The type of treatment offered varies by disease. Within the unit there are dedicated teams - Pharmacy, Physiotherapy , Occupational therapy, Dieticians, Outreach Nurses to deliver some treatment at home and limit hospital visits, Psychologists and Social Workers for support and Play Therapists to help children cope with procedures.

49. Infection control is very important on the Schiehallion Unit but is equally important throughout the hospital and should not differ between wards. Staff, and indeed parents, are trained to recognise the early signs of infection to facilitate the early instigation of antibiotic treatment.

50. In the Schiehallion Unit, most children have a central line in situ which can act as a nidus for infection. Nursing staff are trained to access central lines (both Hickman lines and Port-a-caths) to deliver chemotherapy and antibiotics.

51. Patients undergoing Stem Cell Transplantation are nursed in positive pressure HEPA filtered rooms.

52. The unit has a Teenage Cancer Trust (TCT) facility.

53. The Unit has Play Specialists trained to help children cope with procedures. Many children and their families are resident in the ward for many weeks or indeed in some instances for months. The environment and ethos try to recognise this.

Senior Management in the Schiehallion Unit

54. All consultants report to the Clinical Director who is Dr Phil Davies, a Respiratory Physician. Although the Lead Clinician I have no management responsibilities and no budgetary control. Phil Davies reports to Alan Mathers who is the Medical Director (MD) and I believe that he in turn reports to Jennifer Armstrong, who is the MD at the Board. I simply sign off colleagues' annual leave, sort rota gaps, disseminate information to colleagues which has come to me as Lead Clinician and attempt to resolve minor issues within the department. Significant issues would be escalated to Service / General management.

55. The inpatient unit has two Ward Managers (previously referred to as Ward Sisters) who are full time managers, with no practical nursing duties, and whose role it is to manage the nursing staff and the ward. There is no comparable role for doctors. Any responsibilities doctors assume for the smooth running of the Unit (e.g. Lead Clinician) are merely absorbed into their day to day work. A significant issue on the ward would be referred from the Ward Manager to the Lead Nurse and up the managerial line to the Service or General Manager.

Standard Operating Procedures (SOPs)

56. Within the Schiehallion Unit, there are SOPs in place for many procedures and situations such as the Administration of Blood Products, and the Antibiotic Policy, which includes the investigation of infections, as well as appropriate antibiotics to administer. In fact, there are few situations for which there is not a SOP.

57. SOPs cover a wide range of situations. There are 131 SOPs related to the HSCT Programme and 62 non transplant related haemato-oncology SOPs.

58. SOPs are not just used in Schiehallion. They are used throughout the hospital and provide step-by-step guidance on various processes / procedures. There is a template for writing SOPs which starts with the background on the purpose of the SOP. It then explains who is authorised to carry out the process/ procedure, what equipment is needed, how the process/procedure is performed etc. It is written in such detail that anyone should be able to follow it and perform the procedure. SOPs provide consistency of care.

59. Numerous members of staff are responsible for writing SOPs, although the majority are written by medical staff. SOPs are wide ranging and written by the individuals most involved in that area. Those more relevant to nursing practice will be written by nurses and others may be written by Pharmacy, Data Management, Quality Management etc. Some SOPs are very specific to one area of practice, e.g. transplantation, but others are generic. For example the SOP on vomiting is generic and applicable to any child experiencing chemotherapy related nausea/vomiting irrespective of the situation. SOPs are very time consuming to write well and are updated every two years. They all follow a similar template. Each will have a lead author and then be reviewed by a number of individuals who may make additions or changes. Once finalised I will do the last check of any Schiehallion SOPs as the Programme Director or Lead Clinician and sign the SOP off along with the Quality Manager. The Quality Manager will then upload the SOP to “Q Pulse” which is a password protected IT system where SOPs and protocols are stored. All staff in the department have access to the SOPs for reference.

60. Many SOPs although not primarily written about environmental issues have relevance to the environment. There is a list on the NHS GGC Clinical guidelines website – ilnkA4316 – Haematology/Oncology (paediatric) – Guidelines – Standard Operating Procedures. This is the list that can be accessed on Q- Pulse.

61. Infection Control have their own SOPs.

JACIE standards

62. Transplant units have to adhere to JACIE standards and be accredited by JACIE. All of Europe adheres to the JACIE standards. The US and associated countries have a similar accreditation system – FACT. Standards relate to the whole transplant programme and are divided into 3 sections: 1) Collection of haematopoietic stem cells, 2) Clinical care and 3) Cell processing. The standards state that patients will be nursed in an environment which protects against microbial infections. The terminology is loose, non-specific and aims to be inclusive. There is also a standard which states that facilities should allow post- transplant outpatients to wait in a separate area from other outpatients who might pose an infection risk to them. The standards are stated below:

    JACIE Standard B2.1 There shall be a designated inpatient unit of appropriate location and adequate space and design that minimizes microbial contamination.

    JACIE Standard B2. There shall be a designated outpatient care area that protects the patient from transmission of infectious agents and allows as necessary, for appropriate patient isolation; confidential examination and evaluation; and administration of intravenous fluids, medications, or blood products.

63. When we moved to the new Schiehallion Unit we were told that the HEPA filtration which had been installed met the JACIE standards of protection against microbial infection. There was also a small waiting room in the Day Care Unit where transplant outpatients could be separated from other outpatients, so it appeared that the HSCT unit met the JACIE standards.

64. JACIE standards only apply to Transplant Units. Some hospitals have stand- alone Transplant Units; we do not. Our transplant cubicles are within the same ward as the rest of the Schiehallion patients. Only the rooms used for transplant require to meet JACIE standards.

65. In Yorkhill, the Transplant Unit was at the far end of the ward and was therefore semi-separated from the rest of the ward. The design of the current Schiehallion Unit is such that the Transplant cubicles are incorporated into the ward and there is no separation from other areas. Only the TCT is separated in any way from the rest of the ward and with hindsight that would have been the best area to have built the Transplant Unit.

66. We had intended to apply for JACIE re-inspection about 6 months after moving to the new site. The Quality Manager tried to get information in preparation for this application and requested details of the specification of the transplant cubicles, air handling, air sampling etc. I can't remember the details, other than it was difficult to get this information.

Benefits of a specialised unit

67. There are many benefits to a specialist unit dealing with haemato-oncology patients. Staff are trained in the early recognition of infection which is extremely important. Age specific facilities are important to children. Chemotherapy trained nurses are essential for the safe delivery of treatment. A nursing team which can deliver some treatment at home reduces hospital visits for families. Play therapists help children cope with procedures and are very important as is psychological support for children and parents.

68. There are occasions when some patients have to be nursed out with the Unit because of lack of bed capacity. When this happens, we prioritise children who are receiving chemotherapy and those who are most unwell to remain on the Unit. We would move children who are only in hospital for antibiotics or investigations. It would be an exceptional occurrence for chemotherapy to be given out with our Unit; for example, it might happen if the child is in PICU and has to receive chemotherapy in that setting. In such cases our chemotherapy trained nurses would deliver the chemotherapy in PICU. Chemotherapy treatment protocols are not available in other wards within the hospital and nor should they be. Staff on other wards don't have the experience to deliver chemotherapy and should not be doing so.

69. When children require to be nursed out with Schiehallion, there is no doubt that parents do not like this. They are unfamiliar with new staff and every ward does things slightly differently. However, the care they receive should not change irrespective of setting. The SOPs are available to all staff in the hospital. The same Schiehallion medical team see patients who are being nursed out with the Unit as part of their ward round. They remain a Schiehallion patient. If they need chemotherapy and it has to be given out with Schiehallion, our chemotherapy trained nurses do this. If they need a play therapist, or a psychologist, they still have access to this.

Views on The Schiehallion Unit when based at Yorkhill

70. The main advantage of the Schiehallion Unit at Yorkhill was that it accommodated everyone within the team, creating an atmosphere and culture of a cohesive team where all were equally important. It included accommodation not just for nursing and medical staff, but parents, pharmacy, social work, outreach nursing, data management and teachers. Like all units it would have outgrown the space in time as staff numbers increased, but other than that, it had everything we needed. Problems were minor.

71. I admit to having had strong emotional ties to Yorkhill. I had not only built the Schiehallion Unit in 1996 mainly from endowment funds but had overseen the service development from a two, and at times, single-handed consultant base in the 1980s to a large multidisciplinary team. I was very reluctant to move.

Views on the relocation to the new Royal Hospital for Children (RHC)

72. We didn't move from Yorkhill because of a problem with our Unit but because the whole hospital was relocated. We were promised and expected a state-of-the-art facility with like for like accommodation, but we didn’t get this.

73. When the relocation was discussed, I was not involved in any option appraisal. My recollection and understanding is that the relocation evolved from the decision to close the Queen Mothers Hospital because of the need to locate maternity services on the same campus as an adult ITU. The relocation of RHC followed.

74. As a Unit we had to move with other paediatric support specialities, particularly radiology and PICU.

75. I do not remember myself or my colleagues being asked for our views on the decision to re-locate. I did see some advantages of moving to the same site as the adult Transplant Unit. Unfortunately, because there were problems with the adult HSCT ward 4B the adult Transplant Unit didn't actually relocate from the Beatson until much later. The main adult haematology malignant hub is at the Beatson and most benign haematology, i.e. the Haemophilia Unit and facility for Haemoglobinopathy patients are at the Royal Infirmary Hospital. Apart from the Transplant Unit, we were not co-locating with specialised adult haematology services.

76. When we did move, I thought the problem was going to be that of inadequate accommodation for the multidisciplinary team. It never crossed my mind there would be a problem with either the ventilation or water supply. I would have assumed that Management, Estates, Facilities and IC would ensure that this was of an appropriate standard. Yorkhill was an old building, but in terms of our Unit we had a good facility, particularly because everyone could be accommodated within it and be readily available to patients and parents. It is difficult to describe how important and beneficial this is. Parents could knock on the office door of anyone whom they wanted to talk to – consultant, outreach nurse, social worker. Consultants were very close to the ward but are now accommodated in an Office Building about 10 minutes' walk from the ward. We had to adjust to a completely different culture, which was a deliberate decision by those designing the building. All space and all equipment are to be shared. When COVID came it became apparent how difficult this was. It was impossible for a Unit with our level of staffing for individuals to be two metres apart.

77. There were many people who thought the move to the new hospital was a good idea. However, opinions of most changed.

CHRONOLOGY OF EVENTS

Involvement in the planning the New Schiehallion Unit

78. From a clinical perspective, our requirement for the new Schiehallion Unit was that it should be a safe environment in which to deliver treatment and care for children with cancer. At a minimum we expected a like for like facility or a better facility than we had at Yorkhill.

79. As a clinician, I expected that the building, ventilation and water supply would meet all relevant standards, albeit I did not have knowledge of what regulations would apply.

80. The only input that my colleagues and I had into the planning of the new Schiehallion Unit was when we attended maybe three or four meetings with the Project Manager, Mairi MacLeod. We were shown the floor plan and allowed to input into how available space should be used. However, it was made very clear to us that there could be no increase in the available space irrespective of our concerns about the inadequacy.

81. We were told by the Project Manager that this was our allocated space and told very firmly that this could not be expanded. We could do anything we liked with the space we had been given, but that was all the space we would get. I assume Mairi MacLeod had probably been given an instruction from her superiors, but the meetings were extremely unpleasant.

82. We could decide on co-locations, e.g. where the preparation room used by nurses to make up drugs would best be situated. We left this type of decision to nursing staff.

83. We could comment on how many plug sockets were needed in any area, but again this decision was deferred to nursing staff. I think that we could have insisted on some accommodation for the multidisciplinary team, but we didn't want to lose patient accommodation because we knew from experience how difficult it was for patients and families to be boarded out with the ward, so as much as we wanted to maintain the multidisciplinary team that we had at Yorkhill, we prioritised patient accommodation, kept the optimal number of cubicles and sacrificed other things.

84. We had no staff room or seminar room in the new Schiehallion, both enormous losses. The pharmacy facilities were poor and the transplant administration facility was a narrow area with bench space for three individuals and their computers. There were no facilities for parents: no parent accommodation or rest area. There was very limited office accommodation, and except for ward nursing, almost all other staff could not be accommodated on the Unit or close to the ward. I do not know why these decisions were made.

85. As the Lead Clinician, I was asked to sign off the plans for the Unit. I refused to do so as I did not agree that we had adequate space to accommodate the patients, parents and multidisciplinary team in a manner which allowed us to operate optimally. We had gained nothing and lost much. I believed, and still believe, that in a Unit such as ours where children can become very unwell very quickly, senior medical staff should be accommodated on or close to the Unit and not a 10-15 minute walk away. Prior to the recent refurbishment, the accommodation allocated to consultants who wished to be present on the ward was a windowless room, which was probably intended as a storage cupboard, with benching and computers for four staff who were on call. There was no mobile phone reception.

86. I refused to sign off the plans. I'm not sure what happened in the end. Our Business Manager, Coral McGowan tells me that she has an email which states that she attended a meeting where it was said that the plans had been signed off by someone else. I don’t know who that person was. My refusal to sign off the plan was entirely in relation to the inadequate facilities. It was not because of concerns related to ventilation or the water supply, because I never dreamt that there would be a problem with either.

87. I am of the opinion that the cohesion of the Unit was destroyed. A lot of the families have talked about the family of Schiehallion, the “umbrella”, and the inadequacy of the new Unit challenged that.

88. My concerns were known to management. Jamie Redfern, the General Manager at the time, was aware of my concerns about the absence of a parents’ facility and in my opinion the poor pharmacy facility. However, it wasn’t necessarily within his gift to rectify this.

89. I was not asked my opinion on the suitability of the site. I would question why one would build a new hospital close to sewage works. I can’t justify this comment, but the smell can be pretty bad.

90. I was not involved in the commissioning or the validation stages of the new Schiehallion Unit.

Concerns about the environment pre-patient migration – 2015

91. When the hospital was built and before the patients were migrated, there were opportunities for myself and my colleagues to visit the new Unit. I visited two or three times, both very close to the time of relocation.

92. I have already stated my concerns about the inadequacy of space and facilities.

93. The Unit was gloomy with few rooms having windows with a view or exposure to day light. The most impressive area was the TCT unit which had been funded by the Teenage Cancer Trust. The TCT unit is outstanding and decorated to a very high standard. We decorated the rest of the Unit with the same interior design group using endowment funds. The difference would otherwise have been unacceptable.

94. I was particularly concerned by the lack of parent facilities and organised a small group of mothers to meet with myself and Jamie Redfern (GM). I had previously tried to negotiate a parents' kitchen / room and failed. I think this was because, by the time I raised it as an issue, the building work was already quite far on, and it would have taken a lot of work to convert the only room that was suitable. However, with the support of the mothers I was successful in getting agreement to convert the classroom to a parents' kitchen /room.

95. We also used endowment funds to fund two extra parent bedrooms in Marion House (CLIC parent accommodation) and the salary of a housekeeper. This was to compensate for the loss of parent bedroom facilities which we had had at Yorkhill. We had three bedrooms in Yorkhill and a sitting room for the parents. That was a nice facility because it meant parents didn't have to sleep in the same room as their child and could get a proper rest, without leaving the hospital. This was an important facility which we lost.

96. During a visit to the new hospital shortly before the planned move, the Quality Manager Alanna McVeigh and the Ward Manager Jean Kirkwood, were advised that HEPA filtration was not in place in the HSCT rooms. The casings were in place but not the HEPA filters. I cannot remember the precise date of this visit, but I think that it was within a few weeks of the transfer. This was rectified quickly before our transfer, and I was assured that the HEPA filtration met the required standard at the time of transfer. I can't remember who confirmed this, but at that time Professor Craig Williams was Lead ICD. We were told that everything was now in order and that there was no reason not to move. Everything was in place for the move, and it would have been very difficult to postpone.

97. The lack of HEPA filtration was a concern. My understanding is that when a building is handed over (something of which I have little experience) the Estates department check that the building has met the commissioned standards. I would expect this to be an ongoing process and was surprised that the omission of HEPA filters was detected at a late stage.

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98. I was told that the specification of the ward was to standard, and I trusted this guarantee. I expected Management / Estates to ensure that the building met necessary building standards and IC to ensure that it met all control of infection regulations. At the time of the move, I had no concerns about the safety of the environment in terms of ventilation and water safety. I expected a safe environment in which to treat children and never questioned that this would not be provided by those responsible.

99. I am aware of an email exchange between myself and Craig Williams, Consultant Microbiologist whom I believe was the Lead Infection Control Doctor (Lead ICD), shortly before relocation. Craig responded that it will be safe to start transplanting as soon as we move into our new Unit. I do not recall what I queried which prompted his response, but I obviously questioned something.

General views on the opening of RHC and Schiehallion Unit

100. Had I had a say around the design of the Schiehallion Unit on the QEUH campus I would have duplicated what we had at Yorkhill but made it a bit bigger to keep the team intact. Some consultants are very happy to embrace accommodation in an office block. I'm not, but that's a personal view. I have valued my proximity to patients and parents.

101. In the Schiehallion Unit only the transplant cubicles were HEPA filtered. The corridor was not HEPA filtered and the entry doors to the Unit were not air locked. At Yorkhill the corridor was HEPA filtered and the entry doors air locked. We were told (I cannot remember by whom) that it was not necessary to HEPA filter the corridors. I am a JACIE Inspector and have inspected most Transplant Units in the UK. Many are not completely HEPA filtered so it was hard to argue against this decision because it was not exceptional.

102. Following the recent refurbishment, we now have what is said to be the most highly spec'd ventilation system in the world. The entire Unit is HEPA filtered and the entry doors are air locked.

Upgrades to ward 2A between 2015 and 2018

103. Before the decant to ward 6A and the major refurbishment, there was a smaller refurbishment of some of the transplant cubicles on ward 2A. I think that this was done sometime in 2018 although I don't recall the detail.

104. I also recall that there was some refurbishment work carried out just after we first moved to the new hospital. I went to Australia for a month around July 2015 and I think it was around that time. Particle counts were being done regularly at that time and these may have been higher than expected. Craig Williams was the Lead ICD and when this was raised with him, his view was that the results were not reliable because the corridors weren't filtered. Smoke testing was carried out in the HSCT cubicles. The smoke testing showed that the air flow was in the wrong direction and that sockets and light fittings hadn't been properly sealed by the contractor. Everything had to be resealed.

105. The Unit has now been refurbished after a 3 and half year decant and at a cost of many millions of pounds. We are told that the ventilation is now of the highest possible standard and the water is as pure as it can be, although no water can be sterile. The Unit has been completely HEPA filtrated and airlock doors have been installed.

106. I don't know if the ward should have been built in 2015 to the current specification or not. As Clinicians we took advice from CI and Estates who are the experts and were assured at the time of relocation that the Unit met the necessary standards and was safe.

Common Issues

107. In the new hospital, there have been problems with cladding, windows falling out and an unpleasant odour from the sewage works.

108. I was aware of some common issues with the building in a peripheral manner, such as the temperature of rooms, blinds, TVs, Wi-Fi, adequacy/suitability of plug points and battery packs, power outages, the ward entry system, a sewage leak, the roof and the playpark. I could see that the blinds didn't work and neither did some of the TVs. I knew that the Wi-Fi didn't work particularly well because there were teenagers who wanted to use it. I was aware of these issues, but they weren't major issues compared to what eventually transpired.

109. It is important to remember that some families spend many weeks on the Unit. If you're only in hospital one night and your TV doesn't work, it's not the end of the world. If you're in for two months and your TV doesn't work, that is more challenging. When COVID arrived, it became even more challenging because patients/ parents couldn't leave their room and had to be entertained.

110. I was aware of the smell which was often very strong outside the hospital. I am not sure that I was that aware of the effect on nausea for patients undergoing chemotherapy. I knew nothing of the glazing panels until they fell out.

Cladding Issue and Prophylaxis

111. The cladding issue happened before the decant to ward 6A. The Lead ICD, Teresa Inkster, suggested that patients receive antifungal prophylaxis and that the entry to the hospital be re–directed whilst remedial works were being carried out. She provided written information for families which included how to enter the hospital using a different entrance.

112. As clinicians, we prescribe the prophylaxis, but the decision that patients should receive prophylaxis was taken at the IMT. I don't think that all patients received prophylaxis. Patients would fall into three groups - those who did not receive prophylaxis because they were considered at very low risk, those already on antifungal prophylaxis because that was mandated by their protocol or underlying disease, and those who would have been considered at risk and received prophylaxis because of the cladding associated risk.

113. Any kind of building work which disturbs soil can release fungus. There are many hospitals with building works on site. Giving patients prophylaxis is a very common practice in these circumstances.

Communication around the Cladding and Prophylaxis

114. I don't remember the exact details, but I know there was communication for staff and patients and families with reference to the cladding. Teresa Inkster wrote this. Communication was easiest for inpatients who could be given a written handout or who could be spoken to. Outpatients who attended regularly were also relatively easy to communicate with. Outpatients who attended irregularly were hardest to reach and communicate with and initially we were not particularly good at reaching this group. There was a period when Teresa Inkster would come to the Leukaemia Clinic on a Tuesday morning and offer to meet the parents. I don't remember if this was related to cladding associated antifungal prophylaxis or Ciprof loxacin for water related infection.

Flooding in en-suites

115. There was flooding in en-suite bathrooms in Schiehallion and the associated risk of infection concerned me. This also triggered parental concerns.

116. All problems detailed above caused inconvenience and concern to parents and children which made their stay in hospital more difficult than it need have been. The cladding was particularly concerning because entry to the hospital was compromised, and patients required prophylaxis.

Water Supply/ Concern about infection

117. I was not aware of any problems related to the water supply prior to relocation. I knew nothing of the DMA Canyon Ltd report of 2015 or indeed in any subsequent year.

118. After the relocation to RHC, we noticed an increased incidence of unusual organisms identified in blood cultures. Some were organisms which we had never met before, and we would ask microbiology colleagues if these were new organisms or renamed organisms. As clinicians we would expect microbiology colleagues to detect trends in positive blood cultures and escalate any concerns to IC. It is IC's responsibility to decide whether incidences are out with a natural variation and hence a true concern. I don't think that we questioned whether these organisms were environmental or that there was a cause for concern potentially linked to the environment until 2018.

119. Our clinical team has always worked closely with the microbiology team because of the significance of infection within our patient cohort. We have meetings every lunchtime either in person or by telephone. Many of our microbiology colleagues have roles in IC and they attend our clinical governance meetings as IC, so we have very close contact with them.

120. The increased incidence of unusual bacteria was discussed with microbiology from the outset, and whilst this was a matter of concern, there was no suspicion during the early period that there was any link to the hospital environment. As such, I do not believe there was any discussion with patients or parents about environmental issues associated with any infection diagnosed before the spring of 2018, although they would of course have been informed of any infections in their child and the treatment plan.

121. I do recall that Dr Penelope Redding, a Consultant Microbiologist, called me asking me for support for her concerns about the environment. I think she had retired by that time. I can't remember the detail of those concerns but my recollection is that they were about the hospital in general and not our Unit in particular. I don't remember when this contact happened. I am not sure what she thought I could do to help, and I don't think she ever came back to me.

122. My recollection is that, as clinicians, we first learned of a potential link between unusual infections and the water supply in the spring of 2018. I have some memory of a consultant meeting with Teresa Inkster, who was at that time the Lead ICD. She told us of her concerns about a blood culture positive for Cupriavidus in a patient on Ward 2A and gave us a brief history of previous positive Cupriavidus blood cultures in RHC. This was followed by an IMT on 2 March 2018- **A36690451 – IMT Water Incident Minutes – Ward 2A – Water Contamination – 2 March 2018 – Bundle 1 – page 54**. Cupriavidus was subsequently grown from several water outlets on Ward 2A, and Pseudomonas from another outlet. After Teresa Inkster raised the water issue in the spring of 2018, filters were fitted to the taps in March 2018. Thereafter we were advised by IC that these water filters were effective and that the tap water was clean. The water from taps post filters was tested for bacteria and was negative.

Concerns about Stenotrophomonas in 2017

123. The PI have informed me that around December 2018, Dr Anna-Maria Ewins and I raised concerns with Teresa Inkster about Stenotrophomonas infections we had seen in ward 2A in 2017. I don't remember this meeting although I do remember that when the issues with water related infection came to light in 2018, I looked back at infections in 2017 and questioned if the infections, including Stenotrophomonas, that we saw in 2017 were related to the water supply.

124. One of the Stenotrophomonas infections that I reflected on around this time was in a patient who died in 2017. [redacted] I had been very troubled by [redacted] death, and the way [redacted] had deteriorated despite all of our efforts to treat [redacted] infection. Stenotrophomonas is not the most common bacteria but we do see it from time to time. Usually if appropriate antibiotics are given and the central line is removed, the infection will be eradicated and the patient will survive. This was not the case with this patient.

125. I had many meetings with Teresa Inkster, and I got to know her very well during 2018. At some point I may have said to her that with the advantage of hindsight I thought that the problem started in 2017 and not 2018. It has been said that I had a database of positive blood cultures which I showed her. This is not true. Although upset by my patient's death in 2017 and aware of unusual infections I didn't suspect that there was anything wrong with the environment until 2018 when Teresa Inkster met with the consultant team and made this connection. I do remember a printout of positive blood cultures, but I am sure I did not create this.

126. We both approached Dr Alan Mathers in his role as MD with this printout. I don't remember the exact timeframe this covered. He acted on this information. He wrote an SBAR – **A39243760 – Email chain dated 4 March 2019 containing SBAR dated 1 March 2019 – Water Issues – RHC – 3 year retrospective – Bundle 4 – page 151** which he sent to Jennifer Armstrong. I received a copy. He then asked me to look at the patients on this list who had positive blood cultures and to determine what had happened to these children.

127. I asked one of my colleagues, Dr Shahzya Chaudhury to do this because she had only recently joined the department and I thought it was better that this be done by somebody who had not been involved in any of the cases. We agreed to try to identify the children who had died following infection and assess whether this was due to their underlying disease or infection.

128. Dr Chaudhury collated this information. I then reported this back to Dr Mathers in an email. This took longer than expected. Dr Chaudhury identified three children who had died: [redacted]; the second was the child who died in 2017; [redacted]

129. The latter two cases were the two deaths identified by Mike Stevens in the CNR. I'm not sure that I agree with Mike Stevens that the [redacted] death was due to infection. [redacted]

130. Of the three deaths, it was the death of my patient in 2017 which I was concerned might have been related to infection, Stenotrophomonas. I asked Dr Mathers whether [redacted] death should be externally reviewed because, although Stenotrophomonas is not that unusual an organism, what was unusual was [redacted] mode of death.

131. It's common that we as clinicians ask for an external opinion if we have concerns about a patient. We routinely do this informally at a national MDT. Often this is to reassure ourselves that nothing more could have been done and that everything that was done was done correctly.

132. With regard to the external review, I do know that there was a review, but I don't know if it was external. [redacted] the hospital did not carry out a SCI (Serious Clinical Investigation). My understanding is that either a review or a SCI was subsequently carried out by Dr Jim Beattie, retired Medical Director. I have never seen the outcome, but I'm told that Dr Beattie did not find anything of concern.

133. [redacted]

134 [redacted]

135 [redacted]

Water Incident on ward 2A – March to September 2018

136. The concerns around the water supply on ward 2A in 2018 arose because of the investigation of a blood culture which was positive for Cupriavidus, and subsequent sampling of water outlets on ward 2A from which Cupriavidus, Pseudomonas and fungus were isolated.

137. Other investigations included swabbing of taps and shower heads, which were also positive for environmental organisms. Later drains were swabbed and found positive. There were frequently workmen on the ward.

138. Corrective actions took place such as taps and showerheads being replac ed and water was initially dosed with silver hydrogen peroxide and then later, chlorine dioxide. Point of use filters were placed on taps. Water was turned off at times to allow dosing.

139. Various safety measures were brought in like alcohol gel, bottled water for washing and cleaning teeth, and sterile water for drinking. Patients were advised not to shower and to use wipes to clean their child and mobile sinks were in place for a period. Ciprofloxacin prophylaxis was recommended at an IMT on 16 March 2018 – **A36690477 – IMT Water Incident Minutes – Ward 2A and 2B – Water Contamination – 16 March 2018 – Bundle 1 – page 66**. Transplants were postponed in March 2018 until results of water testing, post fitting of PAL filters, were available and later to allow drains to be cleaned and Hydrogen Peroxide Vapor (HPV) cleaning of rooms to take place.

140. I can't remember the exact dates that different measures were brought in. However, the chronology of events and measures to resolve these are well documented in the IMT minutes as is the way knowledge and understanding evolved with time.

141. The main location of problems was ward 2A and 2B, but water outlets on 3C and PICU also tested positive for bacteria. This suggested that water throughout RHC might be affected. The water tanks were clear, suggesting that the water coming into the hospital was not the issue.

142. There was uncertainty about the risk of infection from the water supply. Gram-negative bacteria isolated from patient's blood cultures were often environmental and known to be associated with water.

143. Similar organisms were isolated from drains and water outlets in the unit. Sequencing did not identify these organisms as identical but suggested that they were different strains. I have no reason to doubt the view that bacteria could not breach the point of care filters.

Impact of corrective measures – Water issues

Water Incident Management Team (IMT) Meetings - 2018

144. My role at the IMT meetings was usually restricted to providing a clinical update to the group and reporting on the effect of remedial works on families and staff, and communicating information to colleagues, parents and patients as requested.

145. The point of an IMT was to identify the cause of any infection outbreak, form a hypothesis on aetiology and remediate it. The IMT investigated the issue thoroughly and put a number of remedial actions in place, but the issue was complex and repeated problems arose. It may have been impossible to resolve without a major refurbishment because nobody knew what the problem was.

146. I would say that the IMTs tried to resolve the problem with the environment, but serial issues arose and as each problem was dealt with another appeared. I remember that Teresa Inkster brought a tap to an IMT to show us the different parts and how they could trap bacteria. I could appreciate the problem but had no real knowledge of different types of taps and even less of chilled beams which I had previously never heard of until these meetings. There were also ancillary meetings which I didn't attend. For example, there was a Water Group meeting before the IMTs sometimes. As the IMTs progressed, particularly when held to deal with issues on ward 6A, the number of attendees increased. I remember large numbers of Infection Control Nurses (ICN) attending and presumably this was because problems were identified in wards that they had responsibility for.

Hypotheses

147. There were multiple causes/ hypotheses discussed at the IMT meetings. This included discussion about the inclusion of “straighteners” in taps which encouraged biofilm and very complex taps with mixing valves, which had been a subject of a SBAR in 2014. I was not involved in 2014 and knew nothing of this. Other theories considered were: (1) that the water outlets were contaminated, and bacteria was being spread by staff and parents. This was thought to be less likely when similar organisms were isolated on other wards; (2) Contamination of water outlets from drains; (3) low level contamination of main water supply which increased over time by the formation of a biofilm; and (4) contamination of water pipes and taps during commissioning. Whether the cleaners were cleaning properly and then whether the nurses and doctors were washing their hands properly was raised. This did not help morale.

148. As the IMT situation moved on, it became more apparent that a major refurbishment was needed as the problems were not being resolved. Cupriavidus was found in March 2018, and we moved out in September 2018, six months later. I don’t know if steps should have been taken to relocate the ward and start the refurbishment any earlier. Potentially corrective measures were put in place and time had to be allowed to see if they would work. An area for relocation also had to be identified.

Communication about the Water Supply Issues

149. I acknowledge that it is likely that the uncertainty or confusion on the part of clinicians impacted on our communications with patients and parents. However, there is no doubt in my mind that I was always absolutely honest with parents/families in my discussions of the nature of their child’s infection and in communicating what we knew about its source. At no time was I ever asked to hide, nor did I ever seek to hide, any information from them. Teresa Inkster and I regularly met with families to discuss these issues.

150. Often when a child was diagnosed with an infection, we would instigate the meeting, where we would advise the parents that there had been a positive blood culture, what the organism was, whether it was environmental or not, and would offer to answer any queries they might have. During these meetings we were often asked where the infection had come from. Teresa Inkster would tell the parents what she knew but usually she did not have a definitive answer.

151. Teresa Inkster and I also had meetings with parents whenever they requested this, and there were a number of occasions when we met with parents to discuss their concerns about what was happening on the ward even though their child had not been diagnosed with an infection. As the consultant responsible for their child's care, it was important for me to be present at these meetings, but Teresa Inkster tended to take the lead because she was better placed to answer questions about infection, and as the Lead ICD, she had the data from any testing of the water or drains. I cannot remember any occasion where Teresa Inkster was not honest with parents in communicating what she knew.

152. As I remember, the information provided from management to clinical staff came after IMTs. Staff were asked by the Chief Nurse to adopt many changes in practice agreed at the IMTs, such as the use of portable sinks and bottled water. When the IMTs first started, information came as a written statement from management after the IMT had taken place, and this was shared with staff and parents. I recall that Teresa Inkster produced information for families at the time of significant events such as around the cladding and the introduction of prophylaxis.

153. There was a person from the communication (Comms) team at most of the IMTs. When agreement was reached on the current situation and any necessary actions to be taken, the Comms person was responsible for writing the script. This is only my understanding; I don't exactly know what happened and wasn't involved in the writing of this information.

154. My understanding is that the script / communication would be approved at Board level. The written communication would then come to the ward for staff to disseminate to the families. This generally happened at about six o'clock at night and nearly always on a Friday. The nurses would be asked by Jamie Redfern, or Jennifer Rodgers the Chief Nurse, who were both very involved, to communicate the information to patients and families. Copies of the communication would be sent to the ward, and we would go round all of the parents and give them a copy and summarise the contents. I usually stayed to help as I didn't want the nurses to have to deal with any unhappy families, although generally families were understanding with ward staff.

155. There was no doubt that the scripted communication was the message from management, but it wasn't dishonest or inaccurate. It was just written in an unusual style and lacked meaningful information.

156. The communication to staff was limited but I think that was mainly due to the fact that neither the IMTs nor local or senior management understood the problem or knew how to resolve it. For this reason, staff felt that they were given limited guidance from management on what to say to patients and families.

157. When communicating information to patients and families, I do think that face-to-face meetings are better than a written script. As time moved on, I think management became aware that parents were dissatisfied with the level of communication and did try to improve this. The job of a communications team is to put a positive perspective on a situation whilst being honest. As staff, we couldn't really challenge the message being given to us because this was the only information we had.

158. Generally speaking, when information was given to the patients and families, they didn't come back asking for more information. They accepted the information that they were given even if they were concerned and not really satisfied. When there was dissatisfaction, particularly surrounding infections, Teresa Inkster and I tried to address this by having meetings with individual families.

159. There was at least one occasion when I was asked by Jane Grant, through Jamie Redfern, to phone a number of families, on a Saturday morning, with information. I don't remember the reason. This was either because something was about to appear in the press on the Sunday which they should be alerted to, or there was some restriction to access for treatment which was due to happen on the Monday, which they needed to know about. I was given a list of names and telephone numbers. I agreed to do this because I thought that it was better for families to get a phone call from somebody they could semi identify with rather that someone who was a stranger to them.

160. Most of the families were accepting, but others felt that this should have been the responsibility of management. I do think that the information was better coming from me as someone they knew or semi- knew and that it was the right thing to do.

Impacts from Water Supply Concerns

161. There were a number of impacts that arose in relation to the water supply, including work being carried out within the Unit, the closure of facilities and restrictions to the ability to wash/ shower. The parent's kitchen and the TCT communal area were closed. There was a period when families were asked not to shower but to use wipes to wash their children.

162. The presence of workmen on the ward was a constant reminder of the problem . If rooms were closed off for remedial work, a large orange screen was erected. An orange screen over a door is a huge indicator to families that work is ongoing. It didn't stop routine clinical work but did question trust. I suspect that the families probably thought that we knew more than we did. They were wrong, but I can understand why they might think this. The ward staff were the face of the hospital to them. Jamie Redfern and Jennifer Rodgers did visit the ward and were very approachable but were remote in comparison to the ward staff, who represented the hospital to families, and I suppose it's not unreasonable for them to assume that we knew what was going on, but that doesn't make it true.

163. Turning off water had an impact because no one could go to the toilet, and no one could wash their hands. We either had to gel our hands or have somebody pour water from a bottle over our hands to wash them.

164. In 2018, transplants were postponed until the results of water testing post fitting of PAL filters was available. The postponement was short and would not have impacted on patient care. If the postponement had impacted on patient care patients would have been referred to an alternative transplant centre. As clinicians we were at all times guided by the ICDs, who had the relevant expertise. Throughout the period, there was uncertainty on the part of the clinicians. We were advised by Teresa Inkster that there was a link between the hospital environment and the infections. We were later advised by Professor Alistair Leanord that the increased number of infections was likely not indicative of any water related problem but represented a natural fluctuation referred to as a "pseudo-outbreak ". He said that sequencing of the bacteria demonstrated that there is no proven link between these infections in almost all cases. . At the time of the problem, we had little or no direct face-to-face contact with him, but his views were relayed to us by management. There has therefore been uncertainty and confusion amongst clinicians throughout the period, and this continues to be the case even today.

165. Morale was particularly low amongst the nurses. Infections were thought to be line related and it was the nursing staff who were accessing lines. It was difficult to understand how bacteria got into the lines; there was much we didn't understand.

166. Comments have been made by witnesses and the Public Inquiry which suggest that there was a greater use of source isolation at times. I am not aware of this. Patients would be put in source isolation for viral infections e.g., Norovirus, Rotavirus, Astrovirus, rather than bacterial infection, except for Extended Spectrum Beta Lactamase (ESBL) in stools. This is a bacteria in your stool, which influences the choice of antibiotics patients might be given. There was an outbreak of Norovirus, and this might be the period being referred to. If there was a greater use of source isolation, I expect this would have been unrelated to any concerns with the water supply.

167. There was a change in the approach to hygiene and cleaning. Deep cleaning was more commonly used, but I think that Facilities and Nursing staff would be best placed to give this information. Rooms were closed for a number of reasons including cleaning and repairs. There were at times restrictions. At one point, which I can't remember, the ward was closed to siblings and visiting medical teams were asked to restrict numbers. Access was definitely restricted during COVID as it was to all other wards.

168. In relation to patients being boarded on wards other than Schiehallion, this has always happened due to limited bed capacity. I cannot say if this was a more common occurrence when work was being carried out because of the issues with the water supply. Rooms were closed for work to be carried out so it might have happened. When we moved to Ward 6A, the ward had a reduced number of beds and we had to accommodate our Day Care Unit within ward bed numbers. I don't know whether this led to more patients being boarded or not.

169. The nurses on wards other than Schiehallion may have had limited experience in accessing central lines, particularly Port-a-caths as they are not commonly used out with Schiehallion. If nurses on other wards did not have the necessary skills, nurses from Schiehallion would have attended to assist. Treatment would have been delivered according to national protocols and guidelines irrespective of where the patient was nursed, and Schiehallion nurses would have delivered this chemotherapy. SOPs would have been available to all staff on the GGC guideline website.

170. All of the above had an impact on staff and patients. The staff were anxious, demoralised and felt poorly informed and concerned about their role in events. Patients and families became angry at times.

Ventilation

171. The ventilation system has most relevance to the transplant unit. JACIE, which is the regulatory body for the transplant programme sets loose guidelines for the microbial protection of patients going through transplant.

172. Most Units employ positive pressure HEPA filtered rooms. The main aim is to prevent fungal infection, particularly Aspergillus present in the air. Ventilation is not about bacterial infection from the water.

173. There are no specific guidelines for a non-transplant haematology and oncology Unit that I am aware of. In Yorkhill the corridor was HEPA filtered and the entry doors air locked. This was not duplicated at RHC. At the time of relocation, we were assured that the ventilation system met building regulations and was appropriate for a haemato-oncology ward.

174. I am unable to comment on the different room types that were built on the Schiehallion Unit and had no involvement in the planning/ decisions.

Concerns about the ventilation

175. From early on I was aware that there were issues with the ventilation in the transplant cubicles on ward 2A. The electric sockets and light fitments hadn't been sealed properly within the HSCT rooms. This was identified around August 2015 not long after we moved in when Craig Williams was the Lead ICD. Steps were taken to remediate the issues when the problems first came to light. Some of the HSCT rooms were then upgraded before the decant to ward 6A, so this was before September 2018. My recollection is that not all the rooms were done at the same time. I recall two rooms being upgraded followed by another two. We allocated the upgraded rooms to patients at highest risk. Although we have eight HSCT rooms, four are at a higher specification than the others, and we would prioritise rooms of the highest specification to the patients at greatest risk of fungal infection. After the decant to ward 6A, we were told at a meeting by the Director, Kevin Hill, that a problem had been identified with the ventilation and this would be rectified during the decant.

176. Ventilation appears to have been a very large element of the major refurbishment and I understand that this is now of the highest standard.

177. I am unaware of Aspergillus in any of the transplant patients on ward 2A. Details of fungal infection out with transplant patients and from environmental screening can be confirmed with microbiology. Fungal infections are difficult to diagnose, and treatment is mostly empirical. Antifungals are usually prescribed when a patient's temperature doesn't resolve on antibiotics and the patient is considered to be at risk for fungal infection. There are fungal markers in the blood which can be useful but obtaining samples for culture can be difficult and biopsying the lesion a major procedure.

178. Transplant patients receive prophylaxis against Aspergillus and that is generally effective.

Technical aspects of ventilation

179. There was some discussion at IMTs in relation to the optimal number of air changes. My understanding is that there were three air changes in ward 2A before the refurbishment but six were said to be optimal at an IMT. Some would favour 10 air changes. As clinicians we would want the optimum number.

180. I cannot comment on chilled beams other than what I have read.

181. In the 13 November 2018 IMT, **- A36629308 – IMT Water Incident Minutes – Ward 2A – Water Contamination – 13 November 2018 – Bundle 1 – page 227** it was agreed that I would tell staff that ward 2A was getting a refurbishment with a specification for a Haematology/Oncology ward. As I have already said, at the time of moving to the new hospital in 2015, I was told that there was a technical team working with a GGC team and that the Unit would meet standards for a haemato-oncology ward.

182. I had no real knowledge of the technical aspects of building standards. I knew that you needed HEPA filtration for transplant cubicles. However, I didn't have any knowledge of the technicalities surrounding the ventilation or plant rooms. I put my faith in the people who were employed to deal with this.

Concerns being raised by Clinicians 2018-201

183. At the IMT on 6 March 2018 **- A36690471- Water Incident Ward 2A RHC IMT Minutes – Bundle 1 – page 56** - Dr Murphy and I raised concerns about the infections as they seemed to be environmental. We also expressed concerns that Teresa Inkster had already raised these concerns with senior management a couple of years earlier. Personally, I did not know whether Teresa Inkster had already raised these concerns.

184. These concerns continued following the decant to ward 6A and, as the IMTs continued into 2019, we as staff had little or no direct communication from senior (Board level) management and this left clinicians unclear as to whether the gravity of the situation was appreciated. I do not consider that it should be the role of clinicians to share concerns with the Senior Management Team (SMT). A situation of such gravity should have been escalated from local management or the MD to Jennifer Armstrong (Board MD) and to Jane Grant (Chief Executive). Teresa Inkster as Lead ICD would escalate concerns to the Board Lead for IC who I understood to be Jennifer Armstrong. However, the clinicians were close to the patients and parents and felt responsibility. We wanted some evidence that the Board knew about the issues and that the problem was being given their highest level of priority. Teresa Inkster had stated at the IMT on 6 March 2018 that she had highlighted concerns about environmental issues to GGC and Health Protect Scotland (HPS) via an SBAR two years earlier but had had no response.

185. Whilst we did not consider it our responsibility as clinicians to share our concerns with the SMT, we decided to do this, nonetheless. There was a general feeling of frustration and anxiety that the problems were evolving from one thing to the next with no resolution. As clinicians we were accustomed to seeking advice f rom external experts when we needed help and we felt that an external, independent expert with no vested interest in defending their own involvement in the hospital build, might be able to provide valuable input and advice.

186. When Professor Leanord expressed his view that we were not dealing with a real outbreak of gram-negative bacteria but with a pseudo-outbreak, we wrote as a consultant body (in August 2019) to Jane Grant to ask if she considered that we were facing a real outbreak or not and asked for an external review. Professor Leanord's view led to confusion within the consultant body, and we wanted clarity.

187. We had not escalated these concerns prior to 2019 because there was always someone from the SMT present at the IMT meetings. This included Directors, Scott Davidson (MD) and Jamie Redfern, GM. Jennifer Armstrong and Alan Mathers sometimes attended. I don't think there was any doubt that SMT knew the severity of the situation. This was often described to me as the worst thing that had happened in GGC in 20 years.

188. As consultants we had concerns about the safety of the environment in ward 6A and the need for long term prophylaxis.

189. I can't recall the full response to the letter we sent to Jane Grant, but the external review didn't happen in the way we expected. Experts were contacted by individuals who attended the IMT and their advice was followed. However, we expected something more extensive and transparent.

The Closure of ward 2A and 2B and the Move to Ward 6A and 4B – September 2018

190. I was present at IMTs in September 2018 when the decision to close wards 2A/2B and move to wards 6A/4B was discussed – **A36629302 – IMT Water Incident Minutes – Ward 2A – Water Contamination – 10 September 2018 – Bundle 1 – page 154**. By September 2018 many potentially remedial actions had taken place, but problems with infections persisted. Taps and sinks were to be replaced. Black material had been seen coming up drains and drains were being scoped and cleaned. Some pipes were to be replaced and rooms were to be HPV cleaned after chlorine dioxide dosing. A drain expert had been engaged and there was a plan to scope and investigate the drains.

191. Rooms were closed to allow works to take place and patients were being referred elsewhere where possible. Concerns persisted about the safety of the unit but primarily it was not thought practical to carry out the required remedial work whilst patients remained in the ward. We had never had any experience of the issues we were experiencing, or the work required to try and fix them, so we didn't know what it involved and had not anticipated the level of work required.

192. The rationale behind closing ward 2A and 2B was to allow necessary remedial works, which were extensive, to be carried out. However, the initial plan was that the decant would be short and we were told that we would be back in ward 2A and 2B for Christmas.

193. Ward 4B was selected as a decant location for HSCT patients, because it was the adult HSCT Unit. Consultants wanted to relocate everybody to 4B. I understand that there is some suggestion that, had the clinicians not wanted to relocate to ward 6A then another location would have been found. That is not strictly true. We didn't get to choose which ward we would relocate to.

194. There was an option appraisal which set out a few different options: (1) another ward at RHC was not an option because of a shared water supply; (2) a move to the Beatson would have meant no access to PICU; (3) a temporary, Army type facility, in the car park would have taken some time to construct.; (4) a transfer of patients to other Scottish Facilities, but there was not thought to be adequate capacity. We had sent some of our patients to Aberdeen and Edinburgh, but, despite the problems at RHC, patients who were sent to other centres were often critical of facilities in those centres and would not return; (5) the other option was a ward in QEUH.

195. I do not know why 6A was selected as I was not involved in the decision. Ward 4B was an obvious choice for the transplant patients because it is the adult transplant unit. I and my colleagues were not involved in any negotiations between the RHC and the adult hospital management teams to find a suitable ward.

196. We would have preferred for all of our patients to relocate to ward 4B, but I can understand that the adults didn't want to give up their transplant unit. They had only just moved there. I think that I remember a visit to ward 6A and was told that this was the only option. I know that a lot of parents felt that ward 6A was not suitable, but ward 4B also had its problems. Neither ward was optimal, but they were the best that could be provided and the decant was meant to be for a short time.

197. When we moved to wards 4B and 6A two wards had to be staffed, which stretched staffing capacity. Transplant patients on ward 4B required two nurses to be present on that ward at all times. This put a strain on nursing staff which would not have happened had all patients been nursed on the same ward. However, even more problematic was medical staffing. There were no paediatric doctors resident on ward 4B. If a patient was unwell or stem cells were being returned which required a medical presence, a doctor had to leave ward 6A and remain on ward 4B. The advantage of ward 6A was that there was always a medical presence.

198. I think that it was the IMT which made the decision that a decant was necessary to allow remedial work to take place. There were meetings out with the IMT to discuss the appraisal of the best option for decant. The meetings were organised by local management. Consultants and, I think, senior nursing staff were present, although I can't remember with certainty exactly who was present. My recollection is that Kevin Hill chaired these meetings of which I think there were two or three. I have already rehearsed the options and how the only possible/practical option was a ward in the QUEH. Our preference would have been to relocate all patient to ward 4B. We were not involved in the choice of ward 6A.

199. I did not consider that there were any risks involved in the physical movement of patients. The Service Manager, Lynne Robertson, was extremely diligent in planning and considered every eventuality. Patient pathways were put in place, phone numbers were retained, IT was secured, and SOPs were amended to acknowledge the different setting and facilities. I thought that the decant went well and was safely organised.

200. It was decided that we should move on the Wednesday after the September Bank Holiday weekend. I probably decided the order in which patients should be moved.

201. Ward 6A had been the Rheumatology ward and was not designed for immuno-compromised patients. Prior to the move it was painted and cleaned to make it as pleasant as possible. There was initially no HEPA filtration on ward 6A, but the cubicles on ward 2A for the use of non-transplant patients hadn't been HEPA filtered either. Later portable HEPA filtered Units were put in place after Cryptococcus was identified in January 2019. We expected to be on ward 6A for three or four months only, so, although it was not an ideal environment, it was probably acceptable for that short period.

202. Ward 4B was the adult transplant unit, and as such was considered fit for paediatric transplant patients.

Concerns about ward 6A

203. Facilities on ward 6A, particularly space, were challenging. Both ward 2A inpatients and ward 2B DCU patients had to be accommodated; an important concern was the distance from HAN (Hospital at Night), radiology and PICU, particularly PICU. PICU was on the 1st floor of RHC whilst we were on the 4th and 6th floors of QUEH. If we had a very sick child who was at risk of requiring PICU we would have all equipment ready on the ward, so that the PICU team only had to get to us, but everything would be prepared and available to them. PICU had passes which could give them priority for the lifts. Switchboard was challenged when asked to put out a paediatric arrest call to an adult ward.

204. After 10pm the wards are covered by a HAN medical team based at RHC with support from haematology–oncology Consultants on call, but at home. To have the HAN medical team in another hospital was concerning. We were fortunate in that initially after the decant our ANPs agreed to be present on ward 6A overnight, although this, in turn, diluted daytime staffing. Every effort was made to make the situation as safe as possible.

205. There were some positives about ward 6A. The patients' rooms had windows and there was a lot more natural light. The waiting area for the Day Care Unit was particularly bright. Children could play by a large window with views of the foyer. One of the 3 elevators for the whole hospital was dedicated to the ward. A separate lift for our children meant that they were not exposed to some adult patients inappropriate to children, but it did create problems for adult patients and their visitors in QUEH.

Communication about the decant to wards 6A/4B

206. There was communication to patients /parents in relation to the closure of wards 2A and 2B, and the move to wards 6A/4B. A letter was drafted by management. My recollection is that Teresa Inkster also drafted a letter about the need for drain cleaning and HPV.

207. I think that initially patients and families were accepting of the decant. Opinions changed with time.

Environmental Issues on Ward 6A

Cryptococcus and Mould

[redacted]

208. [redacted]

209. [redacted]

210. [redacted]

Concerns raised by the Clinicians – cryptococcus

211. When the issues with Cryptococcus arose, the clinicians on ward 6A became concerned about the safety of the ward. I sent an email to Jennifer Armstrong dated 8 January 2019- **A42506190- Email from Professor Gibson to Jennifer Armstrong dated 8 January 2019- Bundle 6 – page 43** expressing my concerns, and the concerns of my colleagues in relation to the safety of the environment and the steps we had been asked to take to protect patients, namely the introduction of portable HEPA filters and the use of prophylaxis. She did not meet with us, but I think she sent her deputy in CI, Marion Bain.

212. IMT decided that patients should receive prophylaxis against Cryptococcus. My colleagues and I had concerns about the prophylaxis that we were prescribing because of possible side effects but were told that this would be a short-term measure.

213. We faced a number of problems in delivering antifungals. Firstly, some patients reacted to AmBisome and we would normally have given these patients Caspofungin but Cryptococcus was not sensitive to Caspofungin. None of the "azole" drugs can be given to patients receiving vincristine as chemotherapy, which included all those with ALL.

214. The decision to use prophylaxis was more difficult for solid tumour patients than for those with AML and ALL who may have received prophylaxis on protocol.

215. I think that Jamie Redfern and Jennifer Rodgers did their best to meet with families, but the families expected to meet with more senior management.

Decant to Clinical Decisions Unit (CDU) – January 2019

216. When mould was identified on Ward 6A in January 2019 patients were decanted to ward 4B or Clinical Decisions Unit (CDU) based on needs and bed availability to allow remedial work to take place. We were only there for a few weeks and the transplant patients remained on ward 4B.

217. I felt that this additional decant was a significant disruption to services. Parents were anxious and frustrated and we were admitting patients on a case-by-case basis, with some patients being sent to other centres, depending on their needs. At the IMT of 4 February 2019 – **A36690558 – IMT Meeting Minutes – Ward 1D PICU – Cryptococcus – 4 February 2019 – Bundle 1 – page 303** - I made my concerns about the environmental risks and the disruption to services clear. At this meeting, I felt that the HIIAT score for impact to services, which was one of the 4 elements considered when scoring the HIIAT, should be Major and not Moderate as it was scored. This would have changed the overall HIIAT from Amber to Red. I was perhaps more affected by the disruption and understood better the effect on patients and families, hence my view on the score. Others at the IMT felt that it could be lowered to Amber. This happened because the score was a consensus. I don't know if there was a way to challenge or escalate disagreement about HIIAT scores, other than for it to be noted in the minute.

Concerns about HIIAT tool

218. I don't think that the HIIAT tool is a helpful tool. I understand that many countries have abandoned it. It wasn't that I thought that the HIIATs were wrongly scored, I just thought the HIIAT process was unhelpful. The impact of the illness to the patient was scored on their condition on the day of the IMT and not their condition when they were most unwell. I thought that the score for the patient should reflect the impact when they were most unwell. I know that Anwar Sarwar has said in parliament that the HIIATs were underscored. It was not the scores which were wrong. It is the method of scoring. The HIIAT guided the need for referral to SG and for a press statement release. Whilst Teresa Inkster was Chair of the IMT, I think that she was fair with HIIAT scoring even if I did not agree with how impact on patients was scored.

219. I understand that the HIIAT scoring system is under review.

220. I don't think that the HIIAT was the best tool in our unique scenario and an alternative approach may have been preferred. It is more appropriately used for outbreaks of rotavirus and norovirus. I refer you to Susie Dodd, Antimicrobial Resistance and Healthcare Associated Infection (ARHAI), who is dealing with a modification.

221. Our view as clinicians was that the problems that we encountered were generic to the hospital (building) but that our patient cohort had experienced the problems because they were immunocompromised.

Gram Negative IMT Spring/Summer 2019

222. After we moved back to ward 6A following the short decant to the CDU, things improved for a short time. Portable HEPA filters were in place. Later in 2019, I believe July, blood cultures positive for gram negative organisms were reported and IMTs resumed.

223. Initially Teresa Inkster was the chair of this IMT until a point in August 2019 when she was replaced as Chair by Emilia Crighton (Public Health). I recall attending an IMT chaired by Sandra Devine. I was unaware of the change in Chair and asked the reason. It was suggested that I ask the reason for the change in Chair to the Chair. Sandra Devine didn't give a clear answer. Emilia Crighton was the Chair thereafter.

224. I was at IMTs about the gram-negative bacteraemia in 2019 chaired by Teresa Inkster. Throughout 2019 I was aware that the hypotheses on the cause of infections were challenged, but I was not aware of major conflict between IMT members.

225. The PI tells me that I was at a reduced number of IMTs between August and December 2019. There was discussion about reopening the ward to new patients. My recollection is that the ward was never completely closed. Decisions were made on a case-by-case basis. New patients may have been referred to other centres but patients further into treatment who were returning for subsequent courses of treatment were given the option to go elsewhere, delay treatment or have it in on our Unit. As clinicians we were unhappy that whilst we had had little input to many previous decisions, we were asked to make these most difficult of decisions.

Hypotheses

226. The hypothesis before Teresa Inkster as Chair, was that the problems might be caused by the chilled beams leaking water. Professor Alistair Leanord and Professor Brian Jones became involved after Teresa Inkster demitted Chair and the hypothesis changed. Dr Iain Kennedy from Public Health spoke to us about the epidemiology and showed graphs of incidences of gram-negative blood cultures at Yorkhill and RHC by year. Professor Leanord told us that sequencing of organisms showed no commonality between organisms cultured from patients and those from water. I don't know if sampling was done at the same time as the blood cultures were taken and bacteria can mutate. I don't know the time intervals for mutation for these organisms.

227. Teresa Inkster as Chair tried to identify the problem, confirm the hypothesis and consider how this might be remediated. Emilia Crighton as Chair changed the emphasis to one of positivity. Teresa Inkster hypothesised that water was dripping from chilled beams. I had no knowledge of chilled beams and if the Director of Estates said that the chilled beams could not be involved, I could not contradict this with authority. I might ask why it can't happen, but I couldn't challenge it.

228. In terms of the IMTs throughout 2019, no solutions were forthcoming and the problems with infections continued. Enormous damage was done to the reputation of our Unit which as consultants we didn't feel was appreciated.

229. During the IMT on 8 August 2019 – **A37991958 – IMT Water Incident Minutes – Ward 6A – Gram Negative – Paediatric Haem Onc – 8 August 2019 – Bundle 1 – page 338** there was discussion of a further decant from Ward 6A to somewhere else. The role of leakage of water from chilled beam was discussed. Although these were thought to be a fully sealed system, swabs from the chilled beams grew gram negative organisms. Chilled beams are in place throughout the RHC and QEUH campus with the exception of adult transplant unit ward 4B. There was discussion around the suitability of chilled beams for a haemato-oncology unit and there was discussion around a second decant to a location with no chilled beams; temporary mobile unit or to the cardiac transplant ward in Golden Jubilee Hospital. However, this was not an option because we had to remain co-located with PICU. I can see from the minutes that an option appraisal was to take place on the Monday following this IMT, but I can't remember if this meeting took place or if I attended. I am only minuted as attending one further IMT on 6 September 2019, but I don't remember if I attended any others.

<u>Communication in relation to the Ward 6A IMTs</u>

230. Most communication in relation to the events on wards 6A and 4B between management and clinical staff came in the form of letters or statements from SMT after an IMT. The letter was written by Comms and presumably approved by SMT. The same information went to staff and families. The problem was that no one knew how to resolve the problem and therefore information had to be limited.

231. We have regular multidisciplinary Schiehallion Unit meetings. Local management and the Lead ICD are invited and did attend on a number of occasions to update staff, particularly at times of significant events. This is the meeting we asked Jennifer Armstrong to attend in our email in January 2019 and which Marion Bain attended in her place.

232. Information came down from the SMT to the clinical team. The families felt that they should have been spoken to directly by SMT. I did at one point suggest that SMT meet directly with the families but that was not accepted. I had taken this approach at Yorkhill at times of disquiet, and it had worked.

233. I was never asked to lie to patients and families. However, I think the answers we were giving to families were inadequate because no one knew the real answer.

234. I am aware that an IMT recorded that Jane Grant had sent two letters to parents which had not been reviewed by the IMT. I don't think I ever saw those letters; I am not sure what they said. I think this was in early 2019. The view was that no communication about environmental issues should go to families without being approved / reviewed by the IMT. I do know that Jane Grant wrote to families around the time of the Case Note Review, but I don't think that these were the same letters. This letter apologised to families but contained an apology for the care children had received. The Consultant team wrote to her to make their position clear. Her apology should be about the environment, which was the responsibility of management, and not the clinical care. She agreed to send an amendment, but I never saw the amendment.

November 2019 onwards

235. One of the difficulties that we faced in wards 6A and 4B was that we had to staff two wards. During the COVID era we had to comply with the restrictions imposed by the adult HSCT Unit. The risk to life for an adult undergoing transplant from COVID is much greater than that of a child. As a result, our families were much more restricted than families on other paediatric HSCT Units in the UK.

236. This was incredibly stressful for staff and for a parent who might find themselves confined to a cubicle with a toddler for 28 days or more and not allowed to leave that cubicle.

The New Ward 2A/2B

237. We are now back in the refurbished ward 2A/2B and there have been changes made to the ward environment. The ventilation has been upgraded. Filters remain on taps. The décor is lighter. Some accommodation has been provided for staff adjacent to the Unit. Pharmacy facilities are much improved. A cubicle has been turned into play accommodation for 8-12-year-olds.

238. I think that confidence has been restored. New patients who have not experienced the previous problems seem impressed and I have not heard of any complaints about the environment.

239. There is never enough accommodation in an expanding Unit.

240. Since returning to the refurbished ward, infections have reduced dramatically. If this was a pseudo-outbreak/ natural variation, the variation has come to an end, which I suppose all natural variations do, or alternatively if there was a problem, this has resolved. Many measures have been put in place and I don't know which led to the improvement. Regardless, we can't deny that we have observed a change.

INFECTION CONTROL

Concerns about infection

241. The reason that concern was raised over the infections on ward 2A and then ward 6A, was that many would be considered environmental.

242. Organisms isolated from patient's blood cultures were also isolated from water outlets before point of care filters were fitted and then from drains. However, unless the sequencing of these organisms is similar my understanding is that it cannot be confirmed that the water and drains were the source of the infection in the patients. Whilst staff had concerns of a potential link, they deferred to IC colleagues who were the experts in this field. I remain unclear as to the true position and continue to rely on the advice of the specialists. The latest information we have received has been from Alistair Leanord, whose position is that there is no evidence to support a link to the environment. My understanding is that he is referring to the whole period of the incident from 2017 onwards.

243. There was disagreement amongst the microbiologists in relation to the epidemiology and perhaps significance of the sequencing.

244. I have no knowledge of how or when concerns were escalated to the Board. There were a number of presentations about the incidence and type of organism s by year after relocation to RHC compared to Yorkhill from Iain Kennedy , Public Health. I believe that the SMT and Board would have been aware of this information.

245. The IMT recommended escalation to HPS, Health Facilities Scotland (HFS), and SG. These bodies have data from all over Scotland and are in the best position to make comparisons.

246. The IMT did receive reports from HPS but some were slow to be produced. Annette Rankin was the representative of HPS and would have had information on infection rates and organisms across Scotland. This information would have put our Unit in context.

Management and Control of Infection

247. There was good and frequent interaction between clinicians and IC. IC Nurses were frequently on the ward. The Lead ICD met with parents along with their consultant and was available.

248. There were frequent Hand Hygiene audits and inspection of the ward in terms of cleanliness. Root Cause Analysis (RCA) was carried out by ICNs on all new gram - negative organisms, although I can't remember when this started. The RCA will include tracking a patient through the different locations they visited in addition to the ward e.g. radiology and theatre. The ICNs will note the rooms occupied by a patient and whether more than one patient with the same infection had been in the same room. The ICN will also consider whether the patients could have acquired the infection at home, or whether it must have been acquired in hospital.

249. The ICNs will report to the ICD. The IPCT have guidelines that they work to. If I am correct, one gram-negative organism would trigger a Problem Assessment Group (PAG) meeting whilst two gram-negative infections would trigger an Incident Management Team meeting (IMT). The responsibility of informing management would lie with the ICD.

250. The need for good hand hygiene was stressed and from my observations was of a high standard. Other measures taken to control infection included asking parents not to pour coffee etc. down sinks in their rooms because this encouraged a biofilm and to try to unclutter the rooms so that the cleaning of surfaces was easier. The inspections of cleanliness, frequency of cleaning, was the remit of ward nursing staff and ICNs. Specific measures related to the handling of central lines were introduced. The management of each episode of bacteraemia was discussed with microbiology. The use of prophylaxis was discussed with microbiology / IC and generally agreed at IMTs. Whether we can link patients' infections to the environment is a specialist area and is not straightforward. It is easy to assume that, if an organism is identified in a patient and is then isolated from the environment, the two are linked. However, this is not necessarily the case. There are different strains of bacteria, and bacteria mutate. There were a number of cases where a link between an infection and the hospital environment was considered or explored, but I believe there was only one case where there was sufficient evidence to confirm the link. This was a case of mycobacteria in a patient where the organism was isolated from both the patient and pre-filter water and sequencing suggested a link.

251. There were other cases where a link was suspected, but where I am told that further investigation and sequencing excluded this. Colleagues in microbiology would be better placed to provide this information.

Prophylactic Medication

252. There was an increase in the prescribing of prophylaxis at RHC at times of increased risk. This was appropriate care and was done in the best interests of patients and for their protection against infection from gram negative bacteraemia or fungus. The IMTs record discussion around starting and stopping prophylaxis in response to perceived environmental risk. Prophylaxis was given in our Unit either as per protocol or on the advice of or recommendations from IMT / Microbiology or IC, and for the period of risk only.

253. Ciprofloxacin was given to patients with central lines to address the risk of gram-negative bacteraemia. Ciprofloxacin is an oral antibiotic which is effective against gram-negative bacteria. It was given to children with central lines in situ during the period when the incidence of gram-negative organisms was causing concern. It was given on the advice of IMT/ microbiology/IC. Previously we would have restricted our use of Ciprofloxacin to very high-risk patients with very poor immunity who tolerate sepsis poorly e.g. Infant ALL, DS ALL, post-transplant. However, there is now a new national trial whereby Ciprofloxacin will be offered to all patients with ALL as part of a randomised study. The fact that this trial has been approved means that several experts have agreed that it is safe and appropriate to do so, which might help understand the context around the use of Ciprofloxacin.

254. Some parents reported that their child was experiencing gastrointestinal side effects, predominantly diarrhoea, whilst on Ciprofloxacin. I raised this at an IMT. A small group was established which included haemato-oncology clinicians and Infection Disease doctors to re-examine the risk / benefits. A step-down approach was recommended with a change to Taurolock which is now our current practice. Taurolock is installed into the central line and a few patients have had severe reactions. Nothing we do is without risk.

255. Antifungals were given around the time of the cladding work and after detection of Cryptococcus. Antifungal prophylaxis is routine in some protocols/diseases/settings.

256. It was more common for children with leukaemia to receive prophylaxis because they had central lines, received steroids and had profound and prolonged neutropenia. Most children with solid tumours did not have these risk factors. It is not true to say that parents were not told that their child was receiving prophylaxis.

257. As I mentioned above, at IMT on 6 September 2019 - **A36591637 – IMT Water Incident Minutes – Ward 6A – Gram Negative – Paediatric Haem Onc – 6 September 2019 – Bundle 1 – page 354** – a group was established to look at the need for prophylaxis and this included Infectious Disease representation. This group was set up because of concerns of side effects with Ciprofloxacin. I was not directly involved in the group, but I have seen the minutes of a meeting held on 24 September 2019, the aim of which was to review the prophylaxis strategies against gram negative bacteraemia and fungal infections among paediatric haemato-oncological patients. At this point the side effects had been reported by the families. The minutes record discussion around the use of Ciprofloxacin prophylaxis at that time and acknowledge that whilst Ciprofloxacin was used as standard in certain patient cohorts to reduce the risk of non-environmental gram-negative infection, its usage was more widespread amongst paediatric haemato-oncological patients to mitigate environmental risk. It was agreed that there was a need to balance the potential for Ciprofloxacin side effects and the generation of further resistance against its efficacy in preventing infection.

258. It was agreed that further environmental sampling data was needed and a possible step-down approach to the usage of Ciprofloxacin prophylaxis in select patients would be considered in light of that data. The sampling would have been for gram-negative bacteraemia. A step-down approach is when you remove the treatment from patients at lesser risk.

259. The minutes of this meeting also summarise the background and chronology in relation to the widespread usage of anti-fungal prophylaxis. It was agreed at the meeting that there was potential to specify which patients require antifungal prophylaxis more clearly and that this would also be reviewed after further environmental sampling data was made available. I cannot remember the specific details or timings thereafter, but I recall that a step-down policy was initiated in respect of Ciprofloxacin and antifungal prophylaxis at some point following this meeting. IMT minutes record that I regularly raised concerns in relation to the side effects of Ciprofloxacin and antifungals if given long term.

Communication related to Prophylaxis

260. Decisions in relation to prophylaxis were made at IMTs and then communicated to clinical staff on the ward, who were responsible for prescribing the medication in accordance with those decisions. Each Consultant discussed the prescription of prophylactic medication to their patients with each family. I cannot remember what information the communications team or management produced in relation to prophylaxis but there is a note in the IMT minutes for 16 March 2018 - **A36690477 – IMT Water Incident Minutes – Ward 2A and 2B – Water Contamination – 16 March 2018 – Bundle 1 – page 66** saying that patients should be told that prophylaxis was to be given "*just as a precaution due to issues with the water supply*". For me it's splitting hairs, but it's a question of what you mean by a precaution. In my mind, a precaution is quite an unlikely event or a not very serious event. I felt it wasn't the best word to use in this situation because we had serious concerns about the risk of infection. I do not think I used the word "precaution" when discussing the issue with parents despite the IMT's instruction on this. I believe I told parents that we recommended that their children receive prophylaxis (most often Ciprofloxacin) to reduce to reduce the risk of infection. This was accurate.

261. It's my recollection that the parents of the children were told that the medication was being given due to concerns about infections which were potentially linked to the environment, and we were recommending that they receive prophylaxis.

262. These were parents well educated in their child's treatment, who knew exactly what medication their child received. If there was a new medication, they would ask what it was for. There would have been no merit in not explaining this to them. I have no knowledge of there being any withholding of information about the prescription of prophylactic medication from patients/ parents.

COMMUNICATION

Treatment

263. There are key aspects of the duty to communicate effectively with patients generally and with paediatric haemato-oncology patients specifically. At diagnosis parents have a detailed discussion with their consultant about all aspects of treatment, side effects and outcome. This is accompanied by written information which is usually provided as a Parent and Patient Information Sheet including information about clinical trials, MacMillan and Children's Cancer and Leukaemia Group (CCLG). Wherever possible patients and parents are given time to read this information before consent for treatment is taken. In the event of relapse or any other event which requires a change in treatment, the same process is followed. Honesty is important. Information will also be given by nursing staff, particularly Outreach Nurses visiting families at home.

Clinical Governance

264. If something has gone wrong during care or treatment, patients and families will be told what has happened and an explanation given. This will be recorded in the case record. It is likely that a DATIX will be raised, and the issue discussed at the Clinical Governance Meeting.

265. DATIX is a reporting system that is used by GGC to report clinical incidents. Any clinical incident can be reported by any member of staff. These reports are discussed at our clinical governance meeting, and those related to transplant are discussed at the HSCT Quality Management meeting. Their significance is graded as minor, or no consequence, or significant.

266. DATIX reports are escalated to the Trust Clinical Governance group who should be able to detect a trend. What is most important is that they can be used as learning points and outcomes should be disseminated throughout the department.

Duty of Candour

267. GGC has a Duty of Candour policy which stipulates the time frame for Duty of Candour disclosures to families. I personally have never received any training in Duty of Candour; however, I have completed a LearnPro which is online learning.

268. I think that we are good at meeting the Duty of Candour guideline. In retrospect, we were probably not good at recording what we said to families. We now over- record. We have a handover at lunchtime every day, but on Friday, we have an extended handover which microbiology attends, and where we review all positive blood cultures, any lines removals and any complaints. We confirm that parents have been informed of any positive blood cultures, and that this discussion has been documented in the child's case record.

269. Duty of Candour was discussed at the IMTs, and it was always clearly decided who would inform the parents of any new infection. Parents met their consultant and the Lead ICD +/- a manager and were told which infection their child had and the likely source if known.

Whistleblowing

270. If I have any concerns regarding wrongdoing, failure or inadequacy within the hospital, there are procedures in place to report this. For example, with formal whistleblowing, there is a GGC Whistleblowing Policy, which can be found on the website. I am not aware of any other procedures. There were opportunities to raise concerns at IMT's and other meetings with management.

Communication and Infection

271. The main communication from management to clinical staff regarding infection risk was in the form of written statements from SMT following IMTs. The written statements were a script to be followed by clinical staff when communicating with patients.

272. The communication between management and patients was done via clinicians, using the scripts issued following IMTs.

273. Communication from management to media was sometimes agreed at IMTs when a Press statement would be prepared, but I don't remember having access to any.

274. I don't remember receiving any pre-broadcast advice regarding the BBC programme, Dispatches. I think that we received an email alert that the programme would be broadcast.

Facebook

275. There are two Facebook pages that relate to the Schiehallion Unit. One was set up by GGC as a result of discussion at an IMT regarding positive communication with patients and families. I understand that useful information has been posted on the Facebook page, but the majority of traffic is between parents. The FB page is administered by the GGC and Coral McGowan manages and screens the content. Clinical staff have no access to the page.

276. There is a second Facebook page which is run by parents. I understand that the content on that page is not always constructive and at times has been very damaging to staff and parent relationships. I have been asked by staff to stress how destructive this FB page has been. We don't have access to it, although some staff have seen some of the posts.

277. My view is that all Facebook pages are unhelpful. You can write anything you like on Facebook with no consequences. Some of the postings have not been acceptable.

Information from external bodies

278. I am not aware of any instructions or information from bodies external to GGC apart from a representative of Health Protection Scotland (HPS), Annette Rankin, at IMTs. Information was escalated to SG.

279. Early in 2018 when the water incident was first recognised, Eddie Doyle, who is the Medical Director in Edinburgh, and someone else whom I cannot recall visited us on behalf of SG to see how we were coping. That was probably the most supportive event that we had at the time.

280. I am aware that there was a meeting between the parents and Jeanne Freeman, but staff were not present at those meetings.

281. I know that Anwar Sarwar has had a lot of influencewith the families and still has. We are not involved, and he has never approached any clinical staff.

282. Jeanne Freeman came to meet us once in Ward 6A. I think this was after she had met with the families.

Other Reviews and Change

283. I have provided oral evidence to the Independent Review and provided evidence to the Health and Safety Executive (HSE) Investigation. I have had no involvement with the Oversight Board.

284. I have found engagement with all investigations and inquiries stressful and time consuming. I do accept that I have a responsibility to provide evidence as honestly as I can, but even remembering much of the information is difficult. So much happened and much of it was over 4 years ago.

285. Whilst at Yorkhill our department enjoyed a reputation as one of the best in the UK. However, the relentless bad publicity over the past 4 years related to the environmental problems is known nationally and indeed internationally. There is a national shortage of Paediatric Haematologists and Oncologists with many posts unfilled. The last three trainees in Glasgow have all taken Consultant posts out with Glasgow. Staff are demoralised and there is an atmosphere of a broken department staffed by broken people. I think that it will take at least 5 years after the Public Inquiry for the reputation to recover, if it can recover. There is no doubt that relationships between staff and families have been severely damaged.

286. I have seen some change because of these reviews. With HAI reporting procedures, every episode of gram-negative bacteraemia has a root cause analysis and may trigger a PAG or IMT. Communication has changed. Patients and families are told that their child has had a HAI and given the name of the organism. If there is a cause identified patients and families will be given this information. Their consultant will be involved in the discussion and he or she may be joined by IC. This is documented in the case record. Whilst this process was in place from at least 2018, I believe there has been a change in terms of the documentation of such discussions. These are now very carefully documented in the case notes to keep a record that the duty of candour obligations have been fulfilled within the appropriate timescale. Once a week all positive blood cultures and line removals are presented at a departmental meeting and reported to management.

287. Encouragement to raise issues hasn't changed much as we have always raised issues. This is done at a departmental meeting which management often attend. I don't think that we have had any concerns to raise recently.

288. There have been positive changes in the way that we engage with the IC team. We have a Schiehallion Unit meeting and a Clinical Governance meeting which is attended by the ICD and a microbiologist, but we have always had good communication with microbiology.

289. Estates are more proactive.

290. There is always room for improvement, but I think that Infection control issues are very tightly controlled.

CLOSING STATEMENT

291. An £8-11 million refurbishment has taken place which has required a decant of clinical services for 3 and a half years. We are told that the Unit has the optimal ventilation system and that the water supply is as clean as can be achieved.

292. The floor plan remains inadequate for a comprehensive and inclusive service, but staff are adapting. Management has recognised the need to accommodate staff close to patients. The transplant patients are the most vulnerable and the associated staff have been accommodated in close proximity. Pharmacy have been given improved facilities. A staff room has been provided. A facility has been provided for 8–12-year-olds.

293. . The reputation of the Unit has been severely damaged with a demoralising effect on staff. However, relocation to wards 2A and 2B has increased accommodation and emphasis on training and education has helped.

294. It would be helpful to include clinicians during the planning stage for any new healthcare facility.

295. As difficult and as unbearable as the last 3 and a half years have been, as a multidisciplinary team we all recognise that we are privileged to look after this group of children and engage with their families at the worst time in their lives. I chose the name Schiehallion for our Unit to symbolise the uphill struggle that these families face. We are now back in our refurbished Unit and this summer will climb our mountain as we did in other years before this problem. Those who can walk up the steep but broad path will do so with staff, family and f riends and those who can't will spend the day in the field at the bottom catching tad poles in the stream, having their faces painted, having a massage, or toasting marshmallows on a bonfire because that is what we are about.

296. I believe that the facts stated in this witness statement are true. I understand that this statement may form part of the evidence before the Inquiry and be published on the Inquiry's website.