SCOTTISH HOSPITALS INQUIRY

Bundle of documents for Oral hearings commencing from 19 August 2024 in relation to the Queen Elizabeth University Hospital and the Royal Hospital for Children, Glasgow

Witness Statements – Week Commencing 28 October 2024 – Volume 11

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SCOTTISH HOSPITALS INQUIRY
WITNESS STATEMENT OF
MS SANDIE ARMSTRONG AND MS BETH ARMSTRONG

WITNESS DETAILS

1. Our names are Sandie Armstrong, date of birth: [redacted] and Beth Armstrong, date of birth: [redacted]. We live in [redacted].

2. We are the daughters of [redacted] who was born on [redacted] and passed away on [redacted]. Our mum lived in Glasgow with her [redacted]. Mum was a patient in Ward 4C at the Queen Elizabeth University Hospital ("QEUH") in Glasgow where she contracted cryptococcus neoformans while she was undergoing cancer treatment.

3. During the period when these events unfolded, I (Beth) was living in Glasgow and would be regularly attending the hospital to see Mum, and Sandie was regularly [redacted] Scotland to see her.

Background

4. Our mum [redacted] was full of life. She was [redacted] but was very young for her age. She was active and lived life to the full. She travelled the world even after her cancer diagnosis and would regularly travel to [redacted] to visit Sandie and other family members. She was young in spirit, bright, intelligent and happy and would have continued to be so, had it not been for what happened. We exhibit a photo of our mum as 001. **(A50616103 - Photograph of [redacted])**

5. Mum was diagnosed with angio- immunoblastic T Cell Lymphoma in June 2016 and underwent six cycles of chemotherapy treatment from October 2016 – July 2017 as part of a Chemo-T trial. Unfortunately, she relapsed 8 months after completing this treatment and commenced on oral cyclophosphamide chemotherapy treatment in December 2017. This treatment was intended to continue indefinitely to control progression of the disease.

6. Mum was responding well to treatment until she became unwell on a trip to see Sandie in [redacted] in October 2018. She was admitted to [redacted] on [redacted] October 2018. Blood results showed that she had pancytopenia. Her oral chemotherapy was stopped and she was treated with IV antibiotics to increase her blood cells.

7. She was transferred to [redacted] for continuing treatment where a bone marrow biopsy showed findings consistent with her having a relapse of lymphoma. Steroids were commenced on [redacted] October. It was recognised that Mum needed ongoing inpatient care. She was given the choice to stay where she was or go closer to home. She told them she wanted to go back to Glasgow, so they transferred her to the QEUH on [redacted] November 2018 by ambulance and admitted her to Ward 4C which is a specialist ward for cancer patients. This was the first time Mum had ever been to the QEUH. Prior to this her regular treatment was at the Queen Victoria hospital in the haematology clinic on an outpatient basis. Mum was never transferred to any other ward during her time at the QEUH.

8. When Mum was admitted she had a continuing fever but had no further indications of having an infection. She remained on antibiotics due to her fever.

9. We recall that when she was admitted she was put in a specialist negative pressure room, which had double door entry access. We would have to put on full PPE and scrub up before we could see her.

This was because she was neutropenic. We can't recall what room number she was in. She was decanted from that room shortly after she was admitted but we can't recall dates now. We also recall that there was one point in November that she was decanted from her room on ward 4C because there was a blockage and stagnant water was sitting in the shower room.

10. The main room that mum stayed in was very near to the nurses' station, as you walked into the room the bathroom was on the right. There was a window which she couldn't open that looked out onto the flat roof outside. The roof had a lot of vegetation on it, which Teresa Inkster later told us was attracting pigeons.

11. Apart from the incident with the bathroom, the rooms Mum stayed in looked very clean. They would be cleaned daily and we didn't see any obvious red flags.

12. The medical records show that on the [redacted] November, Mum was showing signs of confusion.

13. On the [redacted] November her test results showed that her Liver function Test results (LFTs) were worsening, so her medication was stopped.

14. On the [redacted] November Mum started saying she was feeling better but by the [redacted] November her fevers had returned.

15. On the [redacted] November blood cultures were returned and we were advised that she had tested positive for cryptococcus neoformans. Antifungal treatment, Ambisome commenced and was soon combined with Flucytosine. By early December we were told her blood cultures were negative.

16. Sandie was travelling up to see Mum during the weekend that Mum was diagnosed and I (Beth) recall that [redacted], one of the Senior Staff

nurses who was excellent at keeping us informed when we weren't there, spoke to me. [redacted] asked if Sandie was coming up soon. I told her that she was on her way at that moment and [redacted] said that [redacted] wanted to speak to us both together because there had been a serious meeting with Dr Inkster, Dr MacDonald, our Mum and her [redacted]. [redacted] was concerned that we had not been present. [redacted] told us [redacted] was not clear how much of the meeting Mum and [redacted] had taken in.

17. When Sandie arrived [redacted] clarified that [redacted] couldn't emphasise the seriousness of the conversation that had happened. [redacted] told us that Mum had contracted a hospital acquired infection, this was how it was described to us. We were told that the infection that Mum had caught was a very unusual infection. [redacted] said that this was a very serious matter, and Mum should not have caught it. [redacted] told us we had a right to request a meeting and advised us to get in touch with management to request an official meeting to tell us what was going on.

18. On Thursday [redacted] November or Friday [redacted] November, the Registrar informed us (Beth, Mum and [redacted]) that the source of the infection had been identified as Cryptococcus and that the infection was known to originate from pigeons. We can't recall [redacted] name – [redacted] seemed very nervous. [redacted] told us that the anti-fungal medication, Flucytosine which Mum started taking on [redacted] November, cost [redacted] for each box that would last 5 days of treatment. Mum was on the medication for 10-14 days, after which she was told that the infection had cleared from her blood (they were no longer able to grow the cryptococcus bacteria from her blood) but said that the fungus could hide in her system for up to a year so she would have to continue to take an anti-fungal medication in oral form for the next 12 months.

19. We think but we can't be sure that it was the Registrar who told us that the infection had cleared from mum's blood.

20. Mum's records show that Staph epidermidis is also indicated in the blood cultures but this was also showing as being negative in early December. We were told that Mum was showing as no longer having Cryptococcus in early December. We don't have any recollection of being told about the Staph epidermidis.

21. Mum's health deteriorated quickly during this period - she lost the use of her legs, was having nightmares and hallucinations and at some point she was unable to speak coherently, getting her words mixed up. During this time Dr Hart [redacted]. This was a supportive conversation, and he was trying to reassure us.

22. I (Sandie) have looked up AmBisome that mum was taking. Online information advises that side effects of this drug can include confusion, abnormal thinking, chills, dizziness, nausea, vomiting, renal function abnormalities, respiratory failure and seizures amongst many others.

23. Mum recommenced chemotherapy cycle 2 on [redacted] December. Several years after Mum died, we saw in the records that on the [redacted] of December Mum's test results showed that she was antigen positive which was never discussed with either of us.. We were just told continually that her blood cultures were negative. We have also never been told what possible impact being antigen positive might have had on her health. It raises the question of why they stopped the treatment for Cryptococcus and put her on a more general anti-fungal maintenance of Fluconazole.

24. The Cryptococcus knocked her back and unfortunately she never recovered from that. She had a physio coming in every day because since contracting Cryptococcus she had lost the use of her legs. She was told that she would only be able to go home for Christmas if she

was able to walk unaided. She was determined to get home for Christmas. She tried to regain some limited mobility and [redacted] was taking her for walks in the corridor every day with the aid of a walking frame. She was trying to get up and about, this was what our Mum was like. She wanted to be told what she had to do to get better and she would do it.

25. The chemotherapy treatment stopped on [redacted] December 2018 and she was allowed to go home for Christmas day. She was quite weak at this point but was well enough to get dressed, put make-up on and have Christmas dinner with us.

26. We attended a meeting with Dr Inkster – we are not sure of the date, it may have been on 27 December. Dr Inkster explained her role and what infection control entails. It was explained to us that when there is more than one incident of an unusual infection close in time and place it would trigger an investigation, and that she would be leading the investigation. We were told that Mum had a hospital-acquired infection that comes from pigeon droppings and that they had discovered a hole in the roof on the 12th floor where pigeons were roosting in the ventilation machine room. There was also some conversation about the flat roof outside Mum's room on ward 4C that had vegetation growing and was attracting pigeons. Dr Inkster said that all of this would be looked at in the investigation. We asked about the other patient who contracted cryptococcus and she told us she couldn't discuss any details due to patient confidentiality. When we asked if the hole in the roof had been fixed, we were told that she didn't know and she would have to ask Estates.

27. We were advised she would provide us with the results following air testing they were conducting, but we never received these. I (Beth) once received a phone call from Dr Inkster to discuss the air tests while I was on a bus home from work. It was a very technical conversation so I asked if it could be put in an email. I also wanted this information in

writing so I could share it with the family, but I never received anything in writing. We read in the press that the test results were returned on 16 January 2019.

28. Mum returned to hospital on Boxing Day and her health continued to deteriorate. A meeting was organised for 9am on 1 January. Sandie was in [redacted] so it was just me (Beth) and [redacted]. [redacted] picked me up at 8.30am and we drove to the hospital and attended a meeting with Mum, Dr Hart and Dr McDonald. We were advised that there had been a clinical deterioration and that Mum was no longer responding to chemotherapy. Her treatment would stop and she would move to palliative care. Mum was stunned by this news – we all were. She was very quiet but she did ask how long she had to live – it was a big shock.

29. I knew that Mum had to process the news with [redacted] privately, so I gave them some space and left. I don't drive, I ended up in tears in the forecourt of that hospital. There were no buses running because it was New Year's Day. I had just been told my mum was going to die. I remember thinking, why did they build the bloody hospital in the middle of nowhere and beside a sewage plant? Who was going to be awake on the 1st January at 9am to help me get home? I didn't know who to phone and didn't have my purse on me to pay for a taxi. I was stranded and just felt totally helpless.

30. There were 2 subsequent meetings on 3rd and 4th January with Dr MacDonald. Dr Inkster was at one of them. When we spoke to Dr MacDonald and Dr Inkster at one of these meetings Dr MacDonald mentioned the other case near Mum's ward. I (Sandie) asked if this patient was alive or dead. They said they couldn't tell us because of patient confidentiality. So I asked if there was a problem, why was she not moved out of the ward? There was a big silence and [redacted] told us that it would have been too difficult because she wouldn't have the specialist equipment for her care. [redacted] also said that she was in a

different ward to the other patient. So I (Sandie) then said, oh right so it's not just her room, its possibly the whole ward that's been infected or maybe other wards or the whole hospital? [redacted]. We were very confused about the fact that they knew something was happening but they kept her in the same room. There was a note-taker in at least one of these meetings. We asked for the minutes after Mum's death and we were told there did not appear to be any minutes taken.

31. After the meeting on the 4th January Dr MacDonald said he wanted to talk to Mum and the family. We had to wait for Dr Hart to arrive and we had a meeting with Dr MacDonald, Dr Hart, Mum, [redacted] and both of us. At that meeting they confirmed the previous conversation from 1st January that she would be moving on to palliative care and explained what this meant. There was a discussion about whether she wanted to go to a hospice or to die at home. She was adamant she wanted to go home. They told her that they would not resuscitate her if she required it. This seemed to come out of the blue, and Mum was looking at us puzzled and asking us what we thought about this. It was the most horrific conversation we have ever had.

32. Mum passed away in hospital on [redacted].

33. Mum was never out of ward 4C despite having sustained the Cryptococcus infection. We put it to the doctors that she ought to be moved as there was a fungal infection going around, but she never was.

The Building

34. Having never been in the QEUH before, we were quite shocked by the building. It was so large and overwhelming.

35. I (Beth) would spend a long time just wondering how on earth they would keep it clean. I remember looking down on the atrium when we were waiting for the lifts. There were three lifts and quite often one of them would be out of order so you would spend a long time just staring down at this atrium waiting for the lift. I remember looking down at the atrium where coffee and tea is served and seeing these offices that look like boxes that jut out into the atrium above the food court areas. You would need a crane to come and clean those areas - it was such an odd design for a hospital. The top of the boxes were thick with dust and grime and I would wonder how on earth are they going to clean them? It makes you wonder what was in the dust that the ventilation system must have been circulating.

36. I (Sandie) remember seeing flocks of birds in great numbers circulating the waste processing plant next to the hospital on many occasions and pigeons flying around the outside area of the hospital. The foul smell from the waste processing plant was often overpowering.

37. I (Beth) recall reading a social media post where a pregnant lady posted a video of a pigeon flying around in the atrium. This was shocking as there would be no way of catching it due to cavernous nature of the space. It looked more like an airport hangar than a hospital. Also, there was often no hand sanitiser in the dispensers.

38. [redacted] would take Mum out for walks every day down the corridors to try and get her strength up, as advised by the clinical staff. Mum wanted to do everything she could to get better so remained as active as possible.

Anti Fungals and Treatment

39. We were alarmed by how fast Mum deteriorated. She started speaking nonsense, having terrible nightmares and hallucinations. This was after

she started the anti-fungals. She lost the use of her legs, she had to use a catheter and was completely bedridden. She knew she was talking nonsense but couldn't express it. We wondered about the toxicity of the drugs she was being given and whether it was causing this reaction. She had a relapse, was neutropenic, on steroids, had an infection and then she was hit with these heavy-going anti-fungals. It seemed to us that the Cryptococcus and the anti-fungal treatment significantly reduced her quality of life during this time. The chemo had to be stopped so we were asking questions about the drugs and no one gave us coherent answers. Was it dangerous? Was it going to reduce the chance of success of the chemo? We had all those questions. We also asked these questions after the SCI report **(A50257415 – Beth and Sandie Armstrong – SCI report 003 – Bundle 27, volume 13, page 26)** and after our meeting of 30/09/2020 **(A50256349 – Beth and Sandie Armstrong – Meeting with [redacted] family 30 September 2020 – Bundle 27 volume 13, page 41)** and felt we never received a straight answer.

40. The doctors were due to administer a lumbar puncture (spinal tap) but explained that Mum was not well enough to endure this so they couldn't say for certain what was going on but the cultures were negative. At the time we weren't sure why a lumbar puncture was so important but we now think they might have been looking for evidence of cryptococcal meningitis.

41. For me (Beth) there were two phases, the first phase when Mum was alive and she was going through the cancer journey. Had Cryptococcus not happened all the conversations would have been about the cancer and the treatment options. Even if the treatment was going to fail again, Mum would have had options, for example to be cared for at home where she could have been surrounded by friends and family in her final days. We would have had space to say goodbye, but instead all of the conversations were about what was going on with the

Cryptococcus and dealing with the fallout of the infection and the treatment.

42. There were all these new doctors that would come in every day and check her eyes and send her for scans. We now understand that meningitis is a condition that can follow on from Cryptococcus. We were never told that they were looking for meningitis we just suspected it later, however it was clear that Mum had symptoms of some sort of brain infection. Unfortunately, because no spinal tap or post-mortem was carried out, this is inconclusive. They told us they couldn't do a lumbar puncture because she was too weak and no post-mortem was offered or discussed. In the SCI, which we describe below, it was never explained to us that Cryptococcus could be linked to developing meningitis.

43. Mum's specialist consultant, Dr Hart, advised that she had a choice of three cancer treatments in November 2018. It was decided that she ought to go with treatment option A which was three courses of chemotherapy which go in 3-weekly cycles with a rest week in between. This started on [redacted] November 2018. Treatment was temporarily stopped because she was not well enough when they had just confirmed the cryptococcus infection on [redacted] November. Once her blood cultures showed negative she recommenced chemotherapy on [redacted] December and had 3 courses ending on [redacted] December. On Jan 1st we were told that the treatment had failed so she would go into palliative care. We asked about the other cancer treatments that had previously been discussed but were told that there were no longer options. It was a shock when we were told that the options had disappeared suddenly. A few weeks ago there were 3 different options for cancer treatment, now there were none.

44. Dr Hart was very kind and he had a good rapport with us when Mum was in hospital. The communication at one point was also very good, I (Beth) recall that they would talk to us about results coming back and

that the results would be available on a Friday morning because samples would need to grow on the petri dishes for the right amount of time. This was when Dr Hart and other senior consultants and registrars would visit so I started to take Friday mornings off work so I could be updated.

Events after 7 January 2019 - Communication

45. Mum sadly died on [redacted]. Our stepfather, [redacted] signed and collected the death certificate. The death certificate noted the cause of death as being Lymphoma. [redacted] asked the doctor whether Cryptococcus should have been included on the death certificate. The [redacted] said it should not as the cause of death was Lymphoma. We wanted to challenge this, but [redacted] was very upset and just wanted to get away from the hospital.

46. It transpires that the presence of an active Cryptococcus infection in her blood at the time of death could be conclusively proven or disproven with a post-mortem – a fact we did not know at the time. We had just been told that her blood cultures had turned negative, but we now know that the Cryptococcus antigen was still in her blood. There was no discussion or offer of having a post-mortem when [redacted] went to collect the death certificate.

47. Dr Hart reassured me (Beth) that Mum's case had been raised at a weekly haematology department meeting and that there had been a long conversation with all the Senior Consultants about the matter where it was agreed unanimously that the cause of death was lymphoma.

48. The day after our mum was cremated, the QEUH issued a press release on 18 January which told the public that a child [redacted] in the

hospital as a result of Cryptococcus, and that an “elderly” woman had also died, but her death was not linked to Cryptococcus although she had contracted the infection. This was the first we heard about the child [redacted], and we were annoyed about the press release describing my mother as elderly. She was certainly not elderly, she was very young for her age. She was active and travelled around the world even after her cancer diagnosis. It felt like there was an agenda at play, describing her in this manner. It also felt like odd timing – as the information was released to the press about the [redacted] the day after mum’s funeral.

49. The day after Mum was cremated, Dr MacDonald contacted [redacted] to tell [redacted] there was going to be a press release coming out that was going to talk about Mum. This was the point that everything switched for us from being this terrible unfortunate incident to something more sinister. The moment she was cremated and the press release came out, it felt like the hospital’s sole focus became about disproving a link between Mum’s death and cryptococcus neoformans and later on this developed into disproving a link between the building and the infection. That seemed to be their only goal.

50. A couple of things happened after the initial press release that we would like to share with the inquiry to help illustrate how the hospital began to take control of the narrative to our detriment and, we believe, to the detriment of the search for the truth. Firstly, the then Health Minister Jeanne Freeman made a statement to the Scottish Parliament which was recorded and published on the BBC website stating that an elderly woman had contracted cryptococcus at the QEUH and had subsequently died, but her death was not related to the infection. The description of our Mum as ‘elderly’, we believe, was designed to minimise the interest in the cause of her death and to discourage questions to be asked concerning a second instance of Cryptococcus at the hospital. It was shocking to us that a definitive statement was made ruling out any possible connection to the other patient who had

[redacted] cryptococcus before any investigations, including the SCI, had been concluded. We can only imagine this briefing came from the health board. I wrote to Ms Freeman to ask about this, but never received a reply.

51. We were contacted by a BBC journalist, [redacted], who was making an investigative documentary about the infections contracted by children and adults at the QEUH. I (Beth) met with her and her producer at my workplace, along with my [redacted], [redacted]. [redacted] had brought along photographs of Mum as he was so upset about how she was being portrayed in the press. When we showed the photographs to the BBC journalists they were visibly shocked. [redacted] told us that [redacted] had called the press office the day that the press release had been issued to ask about the second case of cryptococcus and [redacted] had been advised that the lady who had died was very old and very frail. [redacted] could not believe that the woman in the photographs could be described in this way – this is why [redacted] introduced our Mum's story with the photograph that we have submitted to the inquiry as exhibit 001. **(A50616103 - Photograph of [redacted])**

52. In response to the concerns we raised about what happened to Mum, we received a letter from Jonathan Best dated 10 May 2019 which we exhibit as 002 **(A50257408 – Beth and Sandie Armstrong – Letter from Greater Glasgow Health Board in relation to concerns raised following the death of [redacted] – 10 May 2019 - Bundle 27, volume 13, page 22).**

53. This letter was presented as a response to a formal complaint that in actual fact, we had never made. We had been asking the hospital questions about our mother's death which became a formal complaint without us being advised or given information about our rights. We never received any letters that indicated a complaint procedure was underway until we received this letter from Jonathan Best. We think our questions must have been lodged as a complaint by Jennifer Haynes,

the Board's Complaint Manager, because it says in the letter that if we were unhappy with this response to our complaint, we could meet with them to discuss it and if we were still unhappy we could take the complaint to the ombudsman. The reason we did not take it to the ombudsman was because we were uncertain if a complaint had been submitted and we were dealing with grief.

54. We asked if we could be assigned a Family Liaison person who could help us understand more about what had happened and answer our questions. They assigned us Jennifer Haynes, the Board's Complaint Manager. We were never signposted to any family support services at the hospital by anyone.

55. Jennifer Haynes had previously been in email touch with us and we asked how to lodge a formal complaint about how we were being treated. Mum's [redacted] wanted to as well. [redacted] had been sending emails and was creating an e-mail trail, and at one point [redacted] said [redacted] wasn't happy with the communication and wanted to know what the formal complaint procedure was. Jennifer said [redacted] complaint had already been lodged, assembled from their communications. In a phone call with Ms Haynes, [redacted] said [redacted] was not happy with that and wanted to lodge his own complaint, and Jennifer said [redacted] couldn't because once you lodge one complaint that's it. We were never told about the process and procedures for complaints. A leaflet was sent to us by Jennifer Haynes but there was no discussion about how it works – no one said to us there should have been Stage One and Stage Two.

56. I (Beth) compiled a list of questions from our family that we wanted to ask before we lodged the complaint and sent the questions to Ms Haynes. Ms Haynes said she didn't know the answers to the questions but would get back to us. She then asked if she could use our questions as a basis for a complaint. We replied that she would like answers to our questions before the family got together to compile the complaint. This back and forth continued without resolution. Our

questions were very clearly not our complaint, and this was repeatedly ignored. We never received any letters that indicated a complaint procedure was underway until we received the letter from Jonathan Best as a response to our 'complaint'. This ongoing refusal to listen to us and answer our questions and the submission of a complaint without our agreement or knowledge was hugely distressing to us at an already upsetting time. I exhibit this e-mail chain as 003

57. In this letter Jonathan Best also says that an SCI investigation was already underway and would look to understand the root causes of her death. It said they would engage with us throughout this process. This did not happen.

58. We exhibit our copy of the Significant Clinical Incident Investigation Report that took place into Mum's death as 004 **(A50257415 – Beth and Sandie Armstrong – SCI report 003 – Bundle 27, volume 13, page 26)**. This report created more questions than answers.

59. The SCI states that it was commissioned on 11 March 2019 and finalised on 6 April 2020. It was not sent to us until 28 April 2020, 3 weeks after it was finalised, and 1 year and 3 months after our mother's death. The guidelines state an SCI should be completed within 3 months of the incident.

60. We believe that the hospital failed in its duty of candour to us when producing and communicating about the SCI and we will explain why, later in the statement.

Sandie's View – SCI

61. The SCI concludes that the cryptococcus infection was not thought to have made a significant contribution to mum's deterioration and death,

rather, this was as a result of her underlying lymphoma. It concludes that issues were identified but they did not contribute to the event.

62. Antifungals: The SCI report states that clinicians noted Mum's worsening liver function on [redacted] November 2018, so she was taken off the standard anti-fungal Fluconazole. This was before they knew she had the cryptococcus infection. The review team considered whether another anti-fungal should have been considered but that *"there was an extremely low risk of such an organism infecting a patient such as [redacted]. Whilst clinicians now may be sensitized to the risk of this recurring and are more likely to consider secondary antifungal cover".* This seems like they were saying that mum did not have adequate anti-fungal protection against contracting the Cryptococcus infection, but the doctors did not think she would contract such an infection so, on balance, it was decided to take her off the anti-fungal protection because of her liver function. This may be the case but we don't understand why the SCI concludes with such certainty that *"Issues identified but they did not contribute to the event.'*

63. Side effects of antifungals: There was no discussion of the possible side effects of the cryptococcus antifungals in the SCI report. We go on to discuss this later in the statement.

64. Scans: The SCI mentioned Mum's CT and MRI scans to the head (13/11 and 16/11) because of her confusion but said no findings of concern were noted. However no mention is made of her extreme confusion after these scans were carried out. We particularly remember her speaking incoherently, making no sense at all, and having hallucinations, later on, in the week beginning [redacted] November 2018. There is also no mention of what they were specifically looking for when they did the scans, and the possibility of cryptococcal meningitis is not mentioned in the SCI.

65. Investigations: We were not given any details of investigations that had been carried out as part of the SCI , except a list of actions in the Review Process which were: review of patient records; construction of timeline; review of any relevant policies, procedure, literature. In particular, we are concerned that the construction of a timeline was not disclosed in the report, to give us an overview of mum's treatment and care.

66. Presence of infection: There is no mention that mum was antigen positive for cryptococcus when she died, although her blood cultures were negative.

67. Scope change of SCI: The SCI did not address the root causes of the infection or the source of the infection. We had not been informed that the scope of the SCI had been changed to no longer include the source of the infection. Jonathan Best said in his letter (exhibit 002) that they would look to understand the root causes in the SCI. When we received the SCI report it had changed its terms of reference and it said: "*Section 1: Terms of Reference: The initial terms of reference included consideration of the potential source of the organism but this was revised as the Board commissioned a specific review of these matters."* We were never given any further information about what the Board's specific review of these matters" was. In *Section 4 'Key Issues Identified & Lessons Learned',* it states: *"The findings from the accident causation model should be included here. What was the source of the Cryptococcus infection? Estates and Environment Considerations. The presence of Cryptococcus in the hospital environment is subject to wider review by the Board and Scottish Government."* That is all we were told - we were not given any more information about what the wider review by the Board and the Scottish Government was. They did send us the QEUH Independent Review of June 2020 but we were not told whether this was the wider review mentioned in the SCI as they did not communicate any connection with the SCI when they sent it to us. When we read the Review in June 2020 we found out it had been

commissioned in response to the two cryptococcus cases and another case at QEUH. However, the Review did not mention Ward 4C where mum was, in any of its pages and it also threw up more questions than it answered.

68. Duty of candour: We believe that the hospital failed in its duty of candour to us when producing this report, for a number of reasons: We were not notified about the SCI until it was already underway. We were not included in any conversations about the SCI process and the investigations. Details of the investigations they carried out were not disclosed in the SCI. The scope of the SCI had been changed without our prior knowledge or discussion, and investigating the source of the infection became out with the scope. The way we were told about the scope change we believe was also evasive and misleading, as we note further on.

69. In his letter of 10 May 2019 (exhibit 002) **(A50257408 – Beth and Sandie Armstrong – Letter from Greater Glasgow Health Board in relation to concerns raised following the death of [redacted] – 10 May 2019 - Bundle 27, volume 13, page 22)** Jonathan Best told us that the SCI was already underway, and when we received the SCI it states it was commissioned on 11 March. No one had contacted us in March to tell us about it or explain what it was or how the process worked, this happened only by letter two months after it had been commissioned. Contrary to his assurance in his letter that they would engage with the family throughout, no-one contacted us about the investigation until the report was sent to us on 28 April 2020. We have since found out that the report was referred to the Commissioner at some point but we were never notified about this or contacted by the Commissioner.

Beth's comments on SCI report

70. When we received the report it was distressing. We felt as though we were being blindsided. The SCI report was a whitewash, a deliberate attempt to mislead us . No one wanted to put anything in writing before we received this. When we received the agreed terms that the report would consider it was presented with the title “draft”. I questioned this but felt everything was smoke and mirrors.

SCI – Communication

71. We exhibit our copy of the cover letter from Jonathan Best of April 2020 which accompanied Significant Clinical Incident Investigation Report as 005 **(A50622700 – Beth and Sandie Armstrong – Cover letter from J Best – 28 April 2020 - see appendix)**.

72. In his cover letter with the SCI report dated 28 April 2020, Mr Best states that the purpose of the SCI report is to establish the root cause of the incident, and that is why clinical language is used. However, he then goes on to say, *"In addition, as you will see, the SCI report does not consider the source of your mother’s infection. This is because the role of an SCI investigation is to establish if there was anything related to care and treatment that had a detrimental impact to the patient. For this reason, establishing the source of the infection was out with the scope of the SCI."* We find this wording very misleading, because the purpose of an SCI is to understand root causes, not just to investigate care and treatment. Establishing the source of the infection was not out with the scope of the SCI until the scope had been changed without our knowledge, consultation or any prior notification whatsoever. In addition, we have only now discovered that, according to Dr Inkster's oral evidence to the Inquiry, the drafts of the SCI reports had been changed so they did not include any information about the ventilation system plant room.

73. We asked in 2020 why the ventilation system had not been discussed in the SCI. Jonathan Best replied in his letter (October 2020) **(A50256343 – Beth and Sandie Armstrong – Letter re SCI investigation – 13 October 2020 – Bundle 27, volume 13, page 46)** *"Although ventilation systems have received negative publicity, I can confirm that despite extensive review, no link has been found between ventilation and infections in the Queen Elizabeth University Hospital".* He then goes on to summarise Dr Hood's hypothesis which attempts to rule out a link between our mother's cryptococcus infection and one ventilation system plant room. We strongly dispute this reason for omitting a discussion of the ventilation system in the SCI. We also strongly dispute Dr Hood's hypothesis.

74. The SCI report threw up many unanswered questions for us, it had inaccurate information in it and it did not address many issues about either our mother's care or the source of the infection. We put these questions to the hospital and received a response letter from Jonathan Best in October 2020 which he sent to us after meeting with the hospital in September 2020 as exhibit 006 **(A50256343 – Beth and Sandie Armstrong – Letter re SCI investigation – 13 October 2020 – Bundle 27, volume 13, page 46).**

75. We had a Zoom meeting on 30/9/20 with senior management and clinical staff from the QEUH to discuss this report:
Scott Davidson (SD) – Deputy Medical Director, Acute Services
Jonathan Best (JB) – Chief Operating Officer, Acute Services
Alistair Hart (AH) – Consultant Haematologist
Teresa Inkster (TI) – Consultant Microbiologist
John Hood (JH) – Consultant Microbiologist
Jen Haynes (JHaynes) – Board Complaints Manager

76. Ahead of this meeting, I (Beth) prepared an agenda to try and find a way to get clear answers, which we exhibit as 007 **(A50256399 – Beth and Sandie Armstrong – Meeting with QEUH on 30 September**

2020 – Bundle 27, vol 13, page 34). At the beginning of the meeting, I read out a statement on behalf of the entire [redacted] family. The response to our statement in the meeting was that they were sorry for our loss.:

We would like to reiterate our gratitude for the excellent care mum received from the doctors, nurses and health support staff throughout her care both as an outpatient at the [redacted] and an inpatient at the QEUH. She always felt well cared for and in good hands. Our complaint is not with them, it is with the senior management of the QEUH and health board who we feel have acted in their own interests and not in the interest of patients. A lack of transparency from the hospital has damaged our confidence in them. we feel that the hospital and the SCI report has taken the approach of downplaying the seriousness of the Cryptococcus infection, its link to the known building issues and its impact on our Mum's treatment and death. We do not believe that the priority has been to investigate the source of the Cryptococcus infection to ensure that the issue is resolved so that it never happens again. Rather we feel that the priority has been to protect their own reputations.

77. At this meeting John Hood downplayed everything. We felt we were being manipulated. We had believed that in an NHS hospital, the only motivation would be to resolve the problem to prevent others from becoming sick and in our view that's not what happened. The main focus seemed to be about disproving links rather than finding out the truth.

78. At this meeting we asked if any special measures had been implemented because of the substandard ventilation. Dr Hood argued the air was fine and even if pigeons were accumulating on the roof, the spores from the droppings could not find their way in through the ventilation system. He went into great detail about a test that he had done himself with a sheet of paper that conclusively proved this. This

seemed ridiculous to us. He said there was no way we could prove that the Cryptococcus came from pigeons roosting in the hospital, and our Mum could have contracted this in the park opposite her house. This seemed highly unlikely to us, particularly as we knew that there had been two cases in close proximity in time and location in the hospital. Dr Inkster was very quiet at this meeting and did not seem to support Dr Hood's hypothesis which dominated the meeting. The notes reflect that she could not say with certainty but it was her opinion that mum probably had an acute infection, which she felt was linked to the pigeons on the QEUH site.

79. When discussing his hypothesis with us in the meeting (30.09.20), Dr Hood was basing his theory on one ventilation plant room which he said did not serve areas of the hospital that our mum or the other case were in. However, Dr Inkster told us in the same meeting that she and other colleagues had been into the plant rooms and that pigeons had been in all four of the level 12 plant rooms.

80. Since this conversation with Dr Hood we have been very upset to read other reports about the ventilation system including papers submitted to the Inquiry, that strongly dispute Dr Hood's hypothesis. In addition, since this conversation with Dr Hood, a number of expert reports have been published which point out that the air change rate and the air pressure in the rooms in Ward 4C and other wards, did not meet Health and Safety regulations.

81. I (Sandie) tried to discuss the improvement notice on Ward 4c but they denied knowing what I was talking about because I never specifically referred to the 'improvement notice' instead I referred to "special measures". When I asked about this, there was an awkward silence and everyone looked at each other. They all said they had never heard of special measures. What I had meant was the Improvement notice and I do believe that they knew that. The improvement notice has been in force since January 2019, and as a result, they were legally obliged

to install upgraded air ventilation systems, which appeared to be evidence that there was, in fact, an issue with the air. We had never been informed about the Improvement Notice on Ward 4C by the hospital so we were only vaguely aware of it and at this point we hadn't seen it **.**

82. We requested minutes of this meeting to be sent to us. What we eventually received were not accurate minutes. It was a document named 'final version' and contained additional information on Dr Hood's hypothesis that was not part of the meeting and it skimmed over much of what we had said. We complained about this and have never received a satisfactory response. This increased our mistrust of Dr Hood and the senior management of the hospital. We exhibit a copy of the meeting notes that we received after this meeting as 008 **(A50256349 – Beth and Sandie Armstrong – Meeting with [redacted] family 30 September 2020 – Bundle 27, volume 13, page 41)**.

83. After the meeting we once again had more questions than answers. One area was the SCI report which we decided to send written questions about to get them to respond in writing. After the meeting Jennifer Haynes sent us a letter from Jonathan Best which attempted to answer some of the questions we had raised about the SCI report.

84. Antifungals: There was no discussion of the side effects of the cryptococcus antifungals in the SCI report and we asked what they could have been. In his response letter Jonathan Best says: *"Whilst I realise you are worried, please be assured that her clinicians do not think these 3 medications had any specific side effects that had a significant effect on your mother. Of note, Ambisome is particularly well tolerated for a patient's overall condition in terms of side effects".* We strongly dispute that Ambisome is well tolerated, but we also want to point out that the SCI report itself says that a side effect of Fluconazole is liver toxicity, and that is why mum was taken off it on Nov [redacted] yet

Jonathan Best contradicts this and says clinicians do not think these medications had any side effects that affected our mother.

85. Negative blood cultures: His letter changes the focus of our question which was whether Mum could have still had cryptococcus in her system even with negative blood cultures. He said a *"significant part"* of her infection had been treated which changed from us being advised it was absent after treatment. This is what they had implied verbally to us by saying the blood cultures were negative.

86. During the meeting of 30/09/20 Dr Hart showed us a timeline of Mum's care and her journey. We don't know whether this was the same timeline that was mentioned in the SCI because that timeline was never disclosed to us. The first time we saw Dr Hart's timeline was when it was flashed up on screen. It said Mum was "antigen positive" on December [redacted] but this was not discussed and we didn't notice it because it didn't mention the word Cryptococcus so we didn't know what it meant.

87. Jennifer Haynes sent us Dr Hart's timeline afterwards with the letter from Jonathan Best of 13/10/20 **(A50256343 – Beth and Sandie Armstrong – Letter re SCI investigation – 13 October 2020 – Bundle 27, volume 13, page 46)**. In his letter Jonathan Best, when answering the question of whether cryptococcus could still have been in her blood when she died, still did not mention that she was antigen positive. Mr Best turned it into a discussion about whether the infection was latent or acute which was not what we were asking. Mr Best, wrote in his letter of 13/10/20: *"Negative blood cultures: As you know, we discussed in the meeting we had with you the difference between a latent infection (lies inactive or dormant in a patient) and an acute infection (a 'live' infection, where symptoms are present). We unfortunately do not know with certainty whether your mother's Cryptococcal infection was latent or acute, but we do know her blood cultures were initially positive, then became negative, which suggests*

that a significant part of the infection had been treated through the aforementioned antifungal medications". We had been led to believe up until this point that Mum had shown no signs of a live infection because her blood cultures were negative, hence she had been taken off the targeted cryptococcus antifungals and the cause of death was recorded as lymphoma. However, Mr Best was now saying that they did not know if her infection was live/acute or dormant/latent. He also says in this letter that mum's deterioration was not thought to be specifically due to her infection and its treatment …"*although this will have been part of it".* This was the first time it had been inferred that mum's infection may have been part of her decline. In addition. We were being told different things by different people and it seemed liked the narrative was constantly changing.

88. We asked if the cryptococcus could have contributed to Mum's death and Mr Best replied: *"Her blood cultures were not of concern at this time. For these reasons,* [redacted] *colleagues do not feel Cryptococcus contributed to your mother's death, and this was also the conclusion reached by the SCI investigation team based on their review of your mother's case, including her medical records."* He is again referring to the blood cultures being negative, and no mention is made of her being antigen positive for cryptococcus in her medical records.

89. If we had been told she was antigen positive we would never have agreed to have the DNR conversation with Mum but would have demanded a treatment plan. With hindsight, we should have been advised properly so we could have requested a post mortem as to establish the true circumstances into her death.

90. As we have outlined in detail in this statement, when we got the Significant Clinical Incident Review we asked a lot of questions about why was it commissioned and why was there a delay in it being released. Why were the authors not named and we pointed out that the

dates were wrong. We said we were not happy with the SCI - it was full of inaccuracies and it looked as though it had been put together at the last minute. It looked as though they had forgotten to do it and had quickly put it together. It took over a year to be written, and guidelines say it should have been written in 3 months. It included a statement that the family had been kept informed about its delay which was not true. Other questions we asked about the SCI report related to reasons it was commissioned, why it took so long and why the ventilation system and root causes had never been discussed in the report.

91. In summary, communication with the hospital has been appalling. We were put in contact with Jennifer Haynes, the Board's Complaint Manager but we never felt like we ever got answers to our questions. It felt like she was just a gate keeper and it seemed like we were not being supported to put our own complaint in. We felt like communication from Jonathan Best and others, was at times evasive and misleading. We believe the hospital failed in its duty of candour to us, particularly in terms of the SCI report and the ensuing meetings and letters. We became very fatigued by the whole process, we became burned out, hence why we did not engage with the public inquiry to begin with.

92. We have been very distressed to learn recently that there have been other cases of cryptococcus with links to the QEUH that we were never told about before. This only came to light in May 2024 in the Expert report prepared for the Inquiry by Sara Mumford and Linda Dempster. This report states that, in addition to our mum and the child, there were 5 other cases between 2015 and 2020 that suggested links to the QEUH. The fact that this was never disclosed to us is deeply shocking and distressing. It further compounds our deep distrust in the senior management of the QEUH and their evasive communication with us throughout the years since our mum's death.

Impact

Sandie

93. I believe that our mother's life was shortened by the cryptococcus infection and possibly also her treatment for it. We will never get that time back with her. In addition to feeling that loss, the rapid decline in mum's health was extremely difficult to cope with. We were advised in November that she would be back on track but at the end of December, we were told nothing else could be done. I was unable to really talk and be with my mother prior to her death, she was unable to have conversations. A lot of people would turn up to say their goodbyes, it was a chaotic time. We never had that time with her, at the end. To really talk to her and say goodbye. It was just so sudden. We never had that time with her, at the end.

94. Mum never even wrote a will until two days prior to her death.

95. We can't grieve properly and all the investigations seem to just go on and on and keep being brought up so publicly. On top of grief and loss, when you feel you are battling a system and you don't know what is true and what is not, it is disturbing and very difficult to cope with. It felt like we were being manipulated and that has added so much to our upset and strain. It's just awful.

96. Ever since Mum's death, [redacted]. It has been difficult. The pandemic followed one year after as well. Mentally, it has been the toughest time of my entire life.

97. I had to see a counsellor for over a year. [redacted].

98. I was starting a counselling diploma course in 2021 and had to drop out due to the stress of everything, keeping up with the expert reports and

developments in the media and processing the often contradictory and confusing information.

99. Dealing with evasive communications from the hospital and their subtly changing narrative around the circumstances of mum's death has been extremely upsetting and confusing.

100. Contact with the media has also been stressful. For example, I was on my way to a friend's wedding and I received a text from a journalist asking me to attend a 6pm press conference that day. I was unable to do this and it completely threw me off kilter.

101. I am a single parent and a self-employed freelancer. The stress and time-consuming nature of dealing with everything since 2019 has impacted on me in many different ways and at times I have felt completely overwhelmed.

102. I just do not consider I have had time to grieve. I really miss my mother, it has been terrible. It happened too quickly, and she suffered so much.

103. I feel terribly sad for the other families who have had to endure the pain of not knowing the truth and having to fight for answers, on top of dealing with their tragic loss and the grief.

Beth

104. As well as the grief we are experiencing, every time another report appears we are having to read it over again and again.

105. I have worked for a charity for over 15 years and I loved my job. I was the creative director of a film charity in Glasgow and was very committed to my job. During this period my health deteriorated because

it was so stressful. I was working during the day and visiting the hospital at night, arriving home late every night. The hospital is not very accessible to people without cars, and I spent much of my time waiting on buses.

106. After my Mum died I was the main point of communication for my family with the hospital. I was dealing with the press releases and emails and trying to push for answers. It felt like we were being run around in circles by the hospital. [redacted]. [redacted]. I believe this to be a result of the incredible stress that I experienced attempting to deal with the aftermath of my Mum's death and the appalling communication from the hospital.

107. I realised that if I continued dealing with all of this I was [redacted]. I decided to stop working and moved to Spain to try to get better. I was not aware of the adverts relating to the public inquiry when I was abroad and largely ignored what was going on as I had become burnt out by it all.

108. When I went to Spain, Sandie took over the communications and that resulted in her having to drop out of a counselling course that she was undergoing because it was too stressful to do it all.

109. It's not unusual to lose a Mum to cancer, it's not even unusual to catch an infection while in hospital, but what we were experiencing here was at another level. It felt as though the hospital was deliberately trying to confuse us and wear us out – it was like an episode of the twilight zone. The smoke and mirrors, the lack of trust, never getting a straight answer, feeling like we were being fobbed off, feeling like a cover-up was going on and feeling all the time like we have to get to the bottom of this for our Mum. That's entirely different from grieving for our mum.

110. We are very pro-NHS and until this happened we trusted in the NHS to protect the interests of its patients and staff. The clinical and support

staff that cared for our Mum were amazing in caring for her, and also for us, as my Mum went through her cancer journey. They were compassionate and kind. However, once we started dealing with the senior management we were met with obfuscation and disrespect. It felt as though they were taking advantage of our grief and distress to avoid any accountability for what happened to our Mum. We are appalled that these people are representatives of the NHS and they undermine the wonderful work that the clinical and support staff do every day in extremely difficult circumstances.

Hopes for the Inquiry

111. Is it appropriate to build a hospital with contractors competing to win the contracts at the cheapest price? Is it appropriate that those in positions of power have the authority to make the questionable decisions that they did regarding the quality and specifications of the building and ventilation system that was installed? Why did they accept the keys in the first place? If they need to shut down the hospital to resolve the problem then they must do that to save lives. There are no checks and balances when playing with people's lives – it's a false economy. The NHS is paid for by us and from what we have found out over the past few years, patients haven't been put first and they still aren't.

112. The senior management of NHSGCC need to be held to account for this appalling tragedy. The people at the top, the buck stops with them. We hope the Public Inquiry will remind them that they are here to serve the people of Scotland and they cannot play with peoples' lives in order to balance their budgets. If they are shown to have been negligent or to have obstructed the search for the truth they must be removed from their positions for which they have substantial salaries, paid for by the people that they were supposed to protect.

Final Comments

113. We understand that our Mum had a rare form of cancer. . Her final days should have been spent somewhere safe, with her family, not fighting a rare environmental infection that shortened her time with us. Instead, she was fighting a serious infection and undergoing invasive treatment on top of her cancer treatment and wasn't well enough to spend time with the people she loved or to properly say goodbye. This has never been acknowledged by anyone at QEUH, and we hope that the public inquiry will finally recognise the impact that this had on our Mum's life and the quality of her death.

114. We hope that this inquiry will be a force for good so that the hospital and the Health Board addresses the extremely concerning built environment issues that are still unresolved today in order to avoid any further terrible consequences to patients and their families in the future.

Declaration

115. We believe that the facts stated in this witness statement are true to the best of our knowledge, information, and belief. We understand that this statement may form part of the evidence before the Inquiry and be published on the Inquiry's website

115. The witnesses verbally introduced or provided the following documents to the Scottish Hospital Inquiry for reference when they completed their statement (Appendix A).

Appendix A

A50616103 - Photograph of [redacted]

A50257415 – Beth and Sandie Armstrong – SCI report 003

A50256349 – Beth and Sandie Armstrong – Meeting with [redacted] family 30 September 2020

A50257408 – Beth and Sandie Armstrong – Letter from Greater Glasgow Health Board in relation to concerns raised following the death of [redacted] – 10 May 2019

A50256343 – Beth and Sandie Armstrong – Letter re SCI investigation – 13 October 2020

A50256399 – Beth and Sandie Armstrong – Meeting with QEUH on 30 September 2020

A50622700 – Beth and Sandie Armstrong – Cover letter from J Best – 28 April 2020

Greater Glasgow and Clyde NHS Board

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Private and Confidential
Ms Beth Armstrong

Via email: [redacted]

Date: 28 April 2020

Enquiries to: Jennifer Haynes
Direct Line: [redacted]
E-mail: [redacted]

Dear Ms Armstrong,

I am writing to you following the completion of the Significant Clinical Incident (SCI) investigation into the death of your mother, [redacted], and I have enclosed a copy of the SCI investigation report with this letter.

Firstly, I would like to apologise unreservedly for the inordinate delay in completing the SCI report. This delay was unacceptable, and I deeply regret any added distress the lateness of receiving the report caused you and your family. We recognised the importance of the issues, and wanted to make sure that we obtained all of the information required to consider and address the serious and significant concerns, but even with that being the case, it should not have taken the length of time it did to complete the investigation and report, and for that, I am truly sorry.

I would also like to highlight to you that the purpose of an SCI investigation is to establish the root cause which led to the, in this case, very sad outcome. It is therefore written in a very factual and clinical way, so that the findings are clear, and lessons can be learned. This is therefore not the same approach we would take, for example, when writing a letter to a bereaved family, where we would still wish to be clear and factual, but would also put a lot of consideration into ensuring the tone and language was compassionate.

In addition, as you will see, the SCI report does not consider the source of your mother's infection. This is because the role of an SCI investigation is to establish if there was anything related to care and treatment that had a detrimental impact to the patient. For this reason, establishing the source of the infection was out with the scope of the SCI. Please be assured that does not mean that this matter is not very important, and is being looked at as part of a separate external investigation.

The reason I have brought these points to your attention is to assure you that despite the factual nature of the SCI report, we have not lost sight of all that you and your family have been through. I realise that some time has now passed since your mother died, and whilst time can make grief easier to cope with, I am very aware that losing a parent is a significant event in anyone's life, and this must have been even more difficult in your case, given what happened. My sincerest condolences therefore remain with you.

In normal circumstances, I would invite you to come to meet with us once you had the opportunity to fully consider the SCI report, if there was anything that you wished clarification on, or wanted to discuss. At the moment, however, such a meeting would not be possible due to the unprecedented COVID-19 pandemic, and the social distancing measures in place to help protect us all. Once the pandemic is over and some of these measures have been lifted, we would welcome the opportunity to meet with you, if you would wish to do so. Alternatively, if, once you have read the report, you wish to speak to us and feel you cannot wait until the pandemic is over, we could look at using

technology to allow for a video conferencing style meeting. If you wish to pursue either of these options, or have any questions, please do not hesitate to contact Mrs Jennifer Haynes, Board Complaints Manager, whose details are at the top of this letter.

My kindest regards go to you and your family.

Yours sincerely

Jonathan Best
Chief Operating Officer – Acute Services
NHS Greater Glasgow and Clyde

Scottish Hospitals Inquiry

Witness Statement of

Gaynor Evans (OBE)

INTRODUCTION

1. My name is Gaynor Evans.

2. My contact details are known to the Scottish Hospitals Inquiry.

3. I was employed as the Clinical Lead for the Gram-negative reduction programme in NHS England/NHS Improvement on appointment to the panel. I retired 31st March 2020 and returned to work 2nd April 2020 to support the Covid-19 NHS England/NHS Improvement national team IPC resource.

4. I was employed as part time Safety Support Advisor for IPC for NHS England /NHS Improvement and part time Senior Clinical Advisor for Clinical Governance in the Public Health Clinical Oversight Group Covid Testing Team, UKHSA (United Kingdom Health Security Agency) during the Covid-19.

5. I work as a private Independent Consultant advising on infection control and governance; within that role I was working as a member of a consortium advising and mentoring on an IPC leadership development programme. This was a commission through NHS London. to support aspiring leaders in infection prevention and control.

EDUCATION

6. I qualified as a Registered General Nurse at the Queen Elizabeth Hospital, Birmingham in 1983 and as a Midwife at Royal Shrewsbury Hospitals in 1987.

7. Post graduate education, I attained a Post Graduate Diploma in Infection Control at Glasgow University in 1997 and a PHD Module in Epidemiology and Statistical Analysis at the London School of Hygiene in 2002.

PROFESSIONAL BACKGROUND

8. Post registration, I worked across multiple sectors including acute hospital wards, school nursing, critical care and Genito urinary medicine before specialising in communicable disease and infection control within community, hospital, and public health settings form 1997 and attaining a post graduate diploma in Infection Prevention and Control (IPC) in 1998.

9. Between March 1997 and April 2000, I was appointed IPC and Communicable Disease Nurse, Dudley Health Authority area in the West Midlands, to create an IPC service for Dudley community and public health where none existed prior. In 2002 the role transitioned to Senior IPC practitioner for West Midlands Health Protection Agency (HPA) until August 2007.

10. In 2008 I was involved in an overseas engagement to Libya as part of a delegation of three invited to investigate an outbreak of infection in a large neonatal care unit in a central acute hospital while seconded to the first regional lead for IPC in West Midlands Field Epidemiology team of HPA. The report was to inform the Libyan ministers and the centre for communicable disease control in Libya and subsequently the Libyan conference in Chatham, London.

11. I was appointed as the Clinical Lead for IPC within NHS Improvement, North of England between 2023 -2016 and between November 2016 to July 2017, the Senior Quality Manager NHS England/NHS Improvement Midlands, and East Region.

12. Between August 2017 and March 2020, I was appointed to a national role as Clinical Lead for the Gram-negative reduction programme for Infection

Prevention and Control in NHS England/NHS Improvement. Nursing Directorate. In March 2020 I retired and returned to NHS 2 days later.

13. From April 2020 I was appointed as Support/Improvement Advisor (Band 9) roles within NHS England/NHS Improvement Nursing Directorate in respect of Covid 19 safety.

14. From 2021 -2023 I worked on part time basis with UKHSA as clinical governance advisor for the Covid testing team

15. 2021 to date I work as an independent consultant as IPC and governance advisor.

16. In October 2020 I was awarded the OBE for services to Infection Prevention and Control in response to the Covid 19 Pandemic.

GENERAL DESCRIPTION OF SPECIALISM

17. I commenced in communicable disease control and infection prevention and control in 1997, creating the first community and public health IPC service for Dudley Health Authority in the West Midlands. Undertaking a post graduate Diploma in infection Prevention and Control at Glasgow University in 1997-8

18. I held several senior Infection Prevention and Control and Control Specialist roles with wide ranging experience working at national, regional NHS acute and community provider organisations, integrated care systems and public health organisations within field and epidemiology teams.

19. I worked directly with senior executives with board responsibilities and with individuals, Executive Directors, IPC leads, key stakeholders at national level, regional and local healthcare systems, and teams to implement quality improvement strategies, with a focus on outbreak management, improving senior

leadership, mentorship, coaching, governance and assurance processes, patient safety and improving patient outcomes.

20. I was part of an international delegation to Libya to investigate an MRSA outbreak in a neonatal unit and advise on best practice. The delegation drafted a report for the Libyan ministry and Libyan Centre for Communicable Disease Control. I subsequently presented findings UK ministers and senior officials at the UK Libyan summit at Chatham House.

APPOINTMENT TO THE CASE NOTE REVIEW

21. I was approached by Lesley Shepherd, the HCAI (Healthcare Acquired Infections) Advisor on behalf of the Scottish Government to participate as a member the Expert Panel of the Case Note Review in respect of the QEUH (Queen Elizabeth University Hospital) and the RCH (Royal Children's Hospital) as an independent IPC practitioner.

22. I was Clinical Lead for Reduction of Gram-Negative Blood Stream Infection for NHS England. I was accordingly an independent practitioner who was in a national role and had no links to the previous investigations at the hospital. I had previous experience of reviewing infection incidents locally regionally and as part of national outbreaks.

THE PURPOSE OF THE CASE NOTE REVIEW

23. I have prepared this statement on the basis that the reader has read the Case Note Review Overview Report, March 2021 ("the Overview Report") **[A33448007 - Case Note Review Overview Report – March 2021 - Bundle 6 (hearing commencing 12 June 2023) – Page 975]** and will refer to sections with that report within this statement. I am one of the authors of the Overview Report and will adopt it as my evidence to the Inquiry.

24. The panel comprised of Emeritus Professor Michael Stevens, Professor Mark Wilcox, and myself. I had known of Professor Wilcox in a professional capacity over several years in professional capacity. He was employed by NHS England as an advisor for IPC. I did not know of Michael Stevens before we met as part of the panel in February 2020.

25. I was invited to become part of the panel as I has not prior engagement or knowledge of previous investigations at QUEH and not affiliated with anyone in Scottish Government or GGC and independent of existing investigations or reports. I have participated in previous investigations on other large and national outbreaks of infection in hospitals in the UK and a large outbreak of MRSA in a neonatal unit in Libya focussing on lessons we can learn reducing the future impact of morbidity and mortality.

26. The panel was tasked to review the medical records of all children and young people in an identified cohort of people in the care of RCH between 1.5.15 and 31.12.19. Immunocompromised children who may have been at risk because of the environment where they received care and how the blood stream infections many have affected their recovery or health outcome. The intention was to determine the number of patients affected and where there were lessons to learn for GGC and across Scotland.

27. The full details can be seen in section 2.2 of the Overview Report and included a set of questions in a brief that included:

- How many children in the cohort have been affected, when and by which organism?
- Is it possible to associate these with the environment of the RCH and QUEH?
- Was there an impact on the care and outcome?

- What recommendations should be considered not solely by GGC but wider in NHS Scotland that would improve and strengthen IPC practices for the future?

28. Professor Marian Bain, Executive Lead for IPC for NHS GGC, latterly deputy Chief Medical Officer for Scotland, acted as intermediary and link between GCC and the panel. Her role was to have oversight of the review.

29. The panel reported directly to Professor Fiona McQueen, Chair of the Oversight Board

GENERAL DISCUSSION OF HOW TO DETERMINE WHETHER INFECTIONS ARE ASSOCIATED WITH THE ENVIRONMENT

30. The second of the questions asked of the review is whether it is possible to associate these infections with the environment of the RCH and the QEUH. The panel reviewed all episodes of infection and using data available reviewed all environmental sampling from patient environment or proximity to understand whether there was an association with the same infective organism as in the environment.

31. The panel was looking for a likely source of the infections in the cohort of children and young people with cancer, leukaemia and other serious conditions caused by Gram-negative environmental bacteria, and potential associated to the environment within RCH and QUEH. We reviewed possible links between patients and environments and considered all available data when considering the environment as a potential source of bacteraemia. The principles of reaching our conclusions about the environment is detailed in section 3.6.6 of the Overview Report.

32. As explained later in this statement microbiological data alone did not allow for us to conclude any likelihood of association given the retrospective receipt of data we were able to utilise. The panel considered endogenous and exogenous

sources of infection and on occasion where patients have been away from ward environments, we considered those as a potential source of infection.

33. The panel was unable to determine with certainty any episodes were linked with an environmental source and in section 5.6 of the Overview Report we have detailed the rationale for this based on probability.

34. The environment we defined for the review includes all hospital areas the patient may have been in contact with, hard and soft furnishings including water supplies, drainage, and ventilation systems.

35. The panel reviewed all specimen results of the cohort and environment available to us to determine if we could identify an organism with the same Whole Genome Sequencing between individuals within the cohort and the environment within a set period as part of the epidemiological investigation. We were looking for the same typing and or genome sequencing between patients and or the environment to be convinced of a definite association. However, we also carried out a standard epidemiological investigation where time place and person are categorised (sees section 3.3.1 of the Overview Report).

36. In the overview report we iterate that we would expect a Root Cause Analysis to help identify why these BSI occurred in this cohort individuals. This was not instigated until late 2019 as a methodology for IMT investigation. It was used prospectively for two patients within our review. A root cause analysis undertaken by ward staff and IPC team members at the time or soon after the occurrence of the infection is helpful in identifying a cause or source of infection, multiple infections of an unusual or novel infection or where there are two or more within a short time linked by time and place. This should have been included as part of the investigations and informed PAGs and IMTs at an earlier stage and could have supported both the PAG and IMT investigation. There is now a proforma that has been created to undertake RCA for bacteraemia in haematology and oncology patients. See Section 8.2.2.2 of the Overview Report.

37. The Inquiry Team has asked me to explain the relance of Root Cause Analysis (RCA) to our work. A root cause analysis investigates the reasons why a person has developed a bloodstream infection, in this cohort of patients we have described in the background of the overview report that is it not uncommon for BSI to develop. Contributory factors that may give an entry point for infections such as a urinary catheter in situ or an intravenous catheter in situ would be reviewed as potential risk factors or an external source of infection.

38. In this review the panel was investigating using a data like that utilised for RCA to review the likelihood of BSI being to have been caused by identical (or almost identical) organisms using molecular typing or WGS that had been confirmed in the sampling of the environment, or to rule out outbreaks, recognise virulent strains and evaluate control measures and for any patterns or commonality that would link cases of infection.

39. In this cohort the Gram-negative environmental organisms we know GNE can be found in water systems, drains or showers. Investigations in my experience look for those as potential sources as a common problem and would sample the environment to determine a potential link or exclude it.

40. The panel cannot conclude a definite link with the environment only as described in section 5.6 that the criteria for definite link see footnote 66, The panel used clinical notes and available microbiological data to determine likelihood of links to the environment and challenges with retrospective data received for the maintenance and environmental specimens. We have described the criteria for our conclusions of definite, strong probable, probable, strong possible, possible, weak possible unlikely and unrelated

DATA QUALITY AND AVAILABILITY: IC NET

41. IC-Net is an electronic system used by infection prevention and control teams to manage patients with possible or confirmed infection. It works by importing data

from the Telepath system used in the laboratory. The system works by having a set of predefined organisms, known as alert organisms, installed in the system. The alert organisms can be adapted to include local alert organisms where there are additional organisms added to the alert list. If ICNet received a notification of an alert organism it initiates a notification to the IPC team. This will alert the IPC team or person responsible for the site to instigate an investigation and advise on the management of the patients and any risks to them or others. There is a set of questions for in the investigating IPC professional. This is recorded in the ICNet system and can be closed if there are no ongoing concerns or risks of transmission to others. The National Infection prevention and control manual contains a nationally agreed minimum alert organism list for organisations to follow and investigate in adverse situations. There was agreement in March 2020 for the Panel to access IC-Net but this was still not in place by August 2020.We were advised we did not need direct access as the IPCT team would pull out the information on patients as required , For the initial five extracts there were gaps where potentially relevant information was missing and we discussed if this was because it was not available or did not exist and so pursued the route of direct contact with GGC. This was resolved by GGC Executive. Once able to review the system it was apparent that it did not have evidence of any modification to the minimum list even by 2019 although the panel had been advised by GGC that there were then increasing bacteraemia episodes. It did not import the information of some episodes of infection, and therefore early interventions by IPCT was not initiated as we would have expected This description is covered in section 3.5 and in sections 8.1.3, 8.3 and 8.4.2 of the overview report.

42. It would be usual practice, in my experience, for Microbiologists and the infection control teams to discuss alert organisms on a regular basis. This was not the practice in GGC and there was no verbal communication or regular meetings between IPC teams and microbiologist because of a prior complaint between the teams and Jane Grant discusses this issue in her letter dated 1st March 2021

MANAGEMENT OF INCIDENTS

Incident management Team (IMT)

43. The panel utilised the data available for reviewing how incidents were managed in real time. The process used by GGC is contained within a standard operating procedure for outbreaks of communicable disease or alert organisms in healthcare premises which lays out the process for identifying and managing a potential outbreak and instigating a formal investigation. Further detail of how the SOP details the process is in the section 8.2. of the Overview Report.

44. In September 2020 we requested and received minutes from Problem Assessment Group (PAG) the initial part of the SOP process, (this was latterly added to the SOP in 2019), and Incident Management Team (IMT) meetings. There did not appear to be any consistent approach to the IMT process, consistent action logs or how data related to IMT minutes were located and stored. IMT minutes did not always give a full situation report or hypothesis to prove or disprove. We observed where an action was suggested in the minutes there was no responsible person identified and no consistent timeline of actions and or implementation for the timespan of the IMT. In some cases, the minutes reflected juxtaposed assessment of the occurrence of a GNE outbreak. In some IMT notes we found evidence of environmental sampling being requested at a specific location, however there was no further follow up or report of the sampling outcomes. We attempted to cross reference these requests with environmental sampling data but insufficient location detail did not allow us to substantiate the link between the environment more than a probable link see example 8.1 in the overview report as an example. Where there was an action log for an incident meeting, and this was limited, there was no evidence of governance or oversight around the implementation of actions arising from IMT meetings. Of additional concern to us was the delay in the instigation of an IMT from an initial PAG. Examples of where we had concerns are specified in examples 8.3 of the Overview Report where the PAG was held on 18/5/2018 after 4 specimens had isolated Enterobacter cloacae, but an IMT did not take place until 29/5/5/2018

when a further isolate had been identified when the IMT was suspended despite HIIAT score of amber and reinstated on 4/6/2028 when drain swabs in ward 2A isolated that organism. It was discontinued again on 21/6/2028 with outstanding actions and met again 5/9/2028 when there had been further 2 samples with the bacterium isolated. Examples are detailed in sections 8.3 and 8.4 of the Overview Report. Detail can be seen in example 8.1 section 5.4 and 8.1.4 of the Overview Report

45. At the end of any IMT, there should be a final report to say what conclusions had been drawn as per the GGC SOP. Some of the IMTs were stopped before they had concluded their actions to reconvene if there were more cases. In one example there were two more cases, but a renewed IMT did not manifest. The IMT process and the assurance process had no consistent approach to how it was managed. This did not give the panel confidence in the system and process to manage the outbreak to its conclusion. Due to the inconsistencies and lack of clear evidence of investigations i.e. no consistent evidence of environmental healthcare infection incident assessment tool risk assessment (HIIAT), ward audit or hand hygiene presented as part of IMT investigations the records were not a detailed picture of the management of an outbreak or incident. They did not give the panel confidence in the outbreak management process in conjunction with the challenges of the data quality for environmental sampling. Section 5.4 and 8.2 of the Overview Report.

46. When reviewing the IMT minutes additional attachments such as supplementary reports such as water or environmental sampling results were not supplied. We did request additional documentation that we expected to be included with IMT minutes. We did not receive agendas for these meeting that would link to the minutes and we concluded that verbal updates may have been reported but not documented within the minutes. As a consequence the minutes were not always helpful retrospectively to give an evidence trail of management and actions. The IMT attenders were named but no job role to identify what part they may have taken or if the meeting was quorate or included the appropriate skill mix of staff.

An example of the challenges is demonstrated in example 8.5 of the Overview Report It was difficult to interpret how requests for environmental samples were agreed, implemented, reported, and recorded as it does not appear within the IMT notes .

47. As set out in Example 8.6 the panel was concerned there was a lack of clarity about what was expected to be reported to the GHGC Board. In that example we record how although the GGC board was informed of 2 cases of BSI over 8 days, subsequently confirmed as different types, it was not appraised of the death of one of those children. This shows an inconsistency of approach and may represent an organisational culture focused on process.

ENVIRONMENTAL AND MAINTENANCE SAMPLING

48. To give context to the subject matter, maintenance, and repair of the any hospital building and the fixtures and fittings is normal. See Section 5.2 of the Overview Report. Whether this is from internal or contracted services any maintenance works give rise to increased risk of infection originating from within the environment, we use an example of a blocked sink or shower drain. A risk assessment using HAI SCRIBE should be undertaken to identify and mitigate the risk whenever maintenance work is carried out.

49. To determine risk and identify any recurring maintenance activity within the ward 2A and 2B and subsequently 6A and 4B the panel reviewed maintenance data shared with the team. The scrutiny of the large data base was challenging because of the volume and the initial format did not allow us to identify a specific location for the work. Works were identified by ward and subject, e.g. drain rather than individual room within that ward. A drain may be that of a handwash sink or bathroom, ensuite sink, dirty utility, shower, kitchen sink as an example. The detail of the work was not specific neither was the date. It was apparent from the number of maintenance records for the paediatric haematology/oncology there were high numbers of interventions in particular drainage, water, and chilled

beam interventions. We cannot qualify if these were excessive compared to the rest of the site as we did not have the data and capacity to explore further.

50. When patients moved from Ward 2A and B to Wards 6a and 4b, in the data supplied, the maintenance teams were still recording work done in 6A and 4B as relating to Ward 2A. When we scrutinised the maintenance records, we could not ascertain if we are looking at Ward 2A works or Ward 4b works

51. There was criticism from GGC that we were late in requesting data. This was not the case. There were several requests before we elicited a response, which impeded the IPC review of the process. It necessitated additional IPC expertise to support the interrogation of the volume of data adding to the challenge of the completion date.

52. Sampling from the environment is helpful in establishing a common source of infection particularly where the two or more cases appear around the same time in proximity or within the same room consecutively. In our investigation this could be complex as patients undergo frequent moves from bay or ward or department. The likelihood of finding a positive sample from the environment is dependent on the rigour and frequency with which sampling is undertaken. A cautious approach should be taken with negative sampling where the environment has been a possible source of the bacterium as factors such as recent cleaning or disinfection or flushing the taps regularly can affect the sample. Sampling and not finding an organism does not mean the bacteria was not there at some point but it was not in that sample. When we did receive sample results from the environment, we were not always able to establish which location they came from and therefore unable to utilise the data to establish a definite environmental link to cases of BSI with the same or very similar results. It was not readily available or timely forthcoming when it was requested. Results appeared infrequently and scrutiny demonstrated it was unclear what organisms had been sampled for, a single pathogen or all. See section 5.4 and 8.3.1 of the Overview Report.

53. There were multiple problems following up results which impeded our investigations, either there were no results or no samples we could identify linked to a specific clinical environment or the labelling was inadequate to determine the original location of the specimen. This added to requests for clarification and delayed timescales in being able to determine if an established process has been followed. Section3.6.6 overview report

54. The impression I had was that the location information was not recorded, rather than it being a case of it being recorded and then failing to pass the details on to us. The panel conclusion was that there was no systematic approach to environmental sampling. See section 5.4 of the Overview Report.

55. This lack of detail proved to be a huge constraint on our ability confirm the environment as the source of infection despite this being a likely hypothesis. Section 5.2 of the Overview Report.

CLEANING AND STANDARD IPC MEASURES

56. Effective cleaning and IPC practice contribute to patient safety and quality of care. As part of our review the panel and clinical team reviewed cleaning standards and the IPC practices in place at the time of the GNE bacteraemia occurrence.

57. The IPC audit of the practice and the environment is assessed against set criteria for the environment and the standard infection control precautions. These are specified in the NIPCM for Scotland, a detailed description of which is included in section 5.3.1 of the Overview Report

58. The IPC audits based on the NHS GGC audit tool were available for the period between 2015 and 2017 with the SIPC audits appearing in 2017. In addition to audits, we reviewed data from domestic and estates and facilities audits. Our findings were that there was a flaw in the system as an audit may have an overall score of 91% but have significant failings in environmental score and equipment.

However, a reaudit would not take place for 12 months. We have detailed this in section 5.3.1 as this does not suggest there was an obvious improvement pathway where there were failings in specific area. See the table 5.2 overview report. The documentation did not give sufficient evidence for us to be assured that improvement has been implemented or sustained. However, the responsibility lies with the nursing manager and it was not apparent how actions were implemented or where any governance and assurance was in place. See Section 5.3.2 of the Overview Report.

CASE NOTE REVIEW CASE DEFINITION

59. The selection criteria for inclusion in the review were drafted and agreed by the core project team, approved by the oversight board, and set out in a protocol document. Given the concerns raised at the time regarding the possibility of contamination of the environment (including water supply and or ventilation) with Gram- negative microorganisms the process of defining environmental contaminants in the first instance and starting with those infections appeared a sound scope. A flexible approach was agreed to include other patients where there was no proven bacteraemia (blood steam infection) and one patient was included in this group at the family's request. The data set for patients has been used in a previous review by Health Protection Scotland (2019). See Section 3.2.1 of the Overview Report.

60. To account for multiple infections in a single child we chose to include any positive blood culture of a Gram -negative environmental single bacterium not seen in the previous 14 days. In line with standard laboratory practice, we exclude repeated results of the same bacteria occurring within 14 days as this may be attributed to a prior infection not yet cleared from the blood stream. An episode (or case) of newly identified bacterium/bacteria in a blood sample with the potential for an environment source which has not identified in the previous 14 days is classified as a new episode of infection.

THE CASE NOTE REVIEW PROCESS AND SUPPORTING TEAMS

61. The CNR process is laid out in figure 3.2 on page 40 of the Overview Report. The figure demonstrates the breadth and sources of data which were reviewed, collated, and analysed as part of the CNR.

Paediatric Trigger tool (PTT)/Clinical team

62. The PTT work was led by Honorary Professor Patricia O'Connor and supported by Professor Peter Davey. It was reviewed and collated using the tool collated the information provided by GGC. The data can be found on page 40 of the case note review figure 3.2. The PTT team assimilated the data for each child or young person for the panel to review the patient journey. The use of the PTT is discussed in sections 3.4.2 and 3.4.3 of the Overview Report and the process of identifying impact on the patients is discussed in section 3.6.7 of the Overview Report. The PTT team used a systematic process to extract data from the clinical notes and other available data of an agreed cohort of patients against criterion within the PTT trigger tool. The trigger tool is a method for identifying adverse events (AE) in the treatment of patients. The aim of using the PTT was to create opportunities to learn from AE by identifying all triggers and describe the rate and severity of harm of hospitalised children in the cohort. Comparing it to evidence from published studies the use of the PTT was a method of creating consistency in a tool that has been used so everybody had that same critical eye. Published reports indicate that there is a 10-fold greater rate of AE identified through a trigger tool than in a reporting system alone. The is a UK developed tool (2013) adapted for use with this review. The use was agreed as part of the methodology. We used both the PTT and the Datix reporting system used by GGC to ensure all data was considered as part of the data synthesis. The work of the EP would have been protracted and not have had the same level of consistency without an investigative tool. Sections 6.4.1, 6.4.2, 8.6, 8.6.1,8.6.2 of the Overview Report.

63. The PTT and clinical teams were crucial to obtaining accurate information. Their initial review and methodical presentation of data where it was available or

identification of where there were significant gaps or partial availability, enabled the panel to ascertain where additional information was required or where there were significant challenges to our requests for transparency and data sharing.

Epidemiology

64. Epidemiological data analysis and timelines were supported by Dr Fiona Murdoch Lead Healthcare Scientist, National ARHAI Scotland (clinical and epidemiological data lead; data analysis and presentation and Jane McNeish Senior Nurse epidemiologist and national antimicrobial resistance, healthcare associated infection (ARHAI) Scotland and Professor Perter Davey. The data set provided were utilised by the panel review each case of infection.

Data Synthesis and Literature Review

65. Dr Julie Aitkin Scottish Clinical Leadership Fellow with the Scottish Government supported data synthesis and undertook a literature review.

Infection Prevention and Control Clinical Support

66. Linda Dempster Infection Prevention and Control Advisor Safety Support for NHS England /NHS improvement supported with advice on IPC records, IMT, Audit and PAG practices. Haley Kane Infection Control Manager Scottish National Blood transfusion Service supported with GGC IC Net analysis and Telepath records to provide data to the panel.

67. The panel met to with clinical teams/PTT to discuss the data, clinical notes, PTT and data synthesis completion and where additional information would be required. This was part of data gathering not to be confused with role of the panel to review investigate and draw conclusions from the data set.

The Panel

68. The three panel members, Professor Michael Stevens and Mark Wilcox and myself met to review the individual patients and episodes of infection. The

meetings were held independently of other support teams to allow us to discuss and challenge the data set and outcomes. This occurred at least twice for each patient and sometime more frequently if we considered additional information was needed. The outcomes were the consensus of the panel after all routes of information had been exhausted and using agreed methodology. Our decisions reflected a balance of probability considering all the data we had available, the complexity of the cohort of patients and the ability of infection to originate from with the patient (endogenous) or exogenous (from the environment in hospital or elsewhere). See Section 5.6 of the Overview report.

REVIEW OF PAEDIATRIC HAEMATOLOGY DATA 2019 - HEALTH PROTECTION SCOTLAND REPORT

69. The HPS 2019 report is discussed in section 8.2.3 of the Overview Report. The authors looked at the data to determine whether the number of infections at RHC was excessive when compared with two other paediatric units, Royal Hospital for Sick Children in Edinburgh and Royal Aberdeen Children's Hospital. The principal methodology used was the creation of Statistical Process Control (SPC) charts which were used to explore the data.

70. There were periods when there was an upward shift outside the upper warning limit and outliers outside the upper control limit in SPC of bacteraemia identified in the data since the move to the new site. There did not appear to be any consistent messages from the report. We have stated that we agreed the data set provided an accurate reflection of NHS GGC situation, but the SPC variations alone did not provide clarity or significance and we agree with caution expressed in analysis of some subsets if data is justified.

71. In terms of my concern about the use of SPC charts, (Section 8.2.2.1 of the Overview Report), SPC charts should be used with caution when dealing with small numbers to monitor trends over a time, as the data can be misinterpreted.

HPS also noted this in their report when using small numbers, although they had suggested use of SPC charts. Section 8.2.3 of the Overview Report.

THE CASE NOTE REVIEW METHODOLOGY

72. The selection criteria for cases to be included in the review were drafted and agreed by the core project team details of which can be found in section 3.2 of the overview report

73. The Case note review was initially a three-month time span for delivery. Widening the scope of the review would have changed the initial focus and expanded the time frame considerably.

74. The decisions of the panel were based on all data available (See section 5.6 of the Overview Report) from the evidence (data synthesis) for each individual case, the quality of the data provided and previous investigative experience of the panel and published literature. Lack of episodes being classed as Definite (association to the environment) reflect the stringent criteria we agreed prior to the review. There were many inconsistencies in the provision and quality of data within the environmental sampling (section 5.4) and water system sampling (section 5.5.2) As microbiological results were not sufficient to establish a conclusion, we considered all clinically relevant information in our conclusions and recommendations.

75. It was not possible to give an confirmation of the source of the BSI an infection, for multiple reasons; either the data was unavailable in a form we were able to analyse readily such as maintenance data, or information was conflicting such as IMT records where there are opposing opinions as to whether a GNE outbreak exists, or it did not exist such as environmental sampling or where it did exist was not sufficiently detailed to allow the panel to associate the specimen with cases of BSI . We utilised as far as practicable all the provided data that was available to us.

76. Whole Genome Sequencing is described as a “state of the art” method of fingerprinting microorganisms. This has latterly been introduced into GGC. Professor Wilcox as the microbiologist has an expert knowledge of the methodology and its use in outbreak management would be a more appropriate person to describe this in detail. It is not my area of expertise to describe the methodology but I am aware of its purpose in determining potential links between environmental specimens and cases of infection in patients

77. The typing data we received was made available in December 2020, nearing the end of the review. There were some factors which confounded or limited reliance upon the data. The data supplied included all data for all ages of patients for GGC during a period 2015-2019. It was supplemented by whole genome sequencing for specific bacteria. The typing data was not routinely uploaded to the Telepath system. We found there was no easy way to obtain the typing results for individual specimens without a systematic recording process and no electronic reporting system in place at GGC and an it was not possible to search for linked typing samples. Section 8.3.2 of the Overview Report. Without this capability we could not draw an association between location and patient episodes of BSI.

78. The Whole Genome Sequencing study was carried out specifically on three organisms, Enterobacter, Stenotrophomonas (84 isolates, 15 from patients in the review, 59 environmental strain and ten from other patients) and Cupriavidus (263 isolates). Only 18 samples were included in this review, one patient being from ward 2A but the date of the specimen does not match the infection date for either patient in the group of patients we considered or for whom we were provided with data for). There did not appear to be a methodical way or process for sampling or recording the results.

79. The IMT meetings suggested that WGS was requested but there were no results we could identify as corresponding to the IMT meetings. It was frustrating as we did not know which positive cultures or environmental cultures had been

requested for WGS. It was not recorded as far as we can ascertain from our investigation, on their laboratory reporting systems or in IMT records. (Section 5.4 overview report). Without the confirmation of a WGS match for a blood culture and environmental sample we are unable to conclude a Definite link. It does not mean it did not exist.

EXPERT PANEL REVIEW

80. The panel has described in section 3.6.4 of the Overview Report that using the balance of probabilities the conclusions we reached in reviewing each case or episode of infection were more likely to apply than not and so yes more than a 50% likelihood when we grouped ‘Strong Possible’, ‘Probable’ and ‘Strong Probable’ as being in a “most likely” group of 37 cases (see Table 5.4).

ROOT CAUSE ANALYSIS

81. Root cause analysis (RCA) offers a structured approach to the investigation of patient safety incidents and facilitates organisational learning. RCA is a systematic investigation of an event identifying the cause of an untoward incident to develop solutions to mitigate for the cause.

82. An example in this instance would be to investigate the cause of a BSI. To investigate how microorganism had opportunity to enter the blood stream e.g. via an indwelling device (such as an intravenous line)? The questions would be asked about how the line was managed; did the staff record the management, was there a lapse in the recognised management, was there a deviation from normal practice? Is practice current evidence-based practice?

83. We used the available evidence from patient notes, IPC audits, hand hygiene compliance and patient timelines for movement, environmental sampling to identify any environmental associations where available and line management to determine any place there might have been opportunities for improving the

management and recordings system. We used this for all episodes of infection to determine lapses in care and/or good practice.

84. We have recommended a systematic and structured approach to the investigation of all future bacteraemia using Root Cause Analysis Methodology, see sections 3.4.1. 8.2.2.2 and footnote 33 of the Overview Report.

THE STANDARD INFECTION PREVENTION AND CONTROL ASSESSMENT TOOL

85. The Standard Infection Prevention and Control (SIPC) Assessment Tool is a systematic tool used to assess compliance to IPC practices, policies, and standards. This is different to the HIIAT audit tool used as a risk assessment tool as part of the SOP for management of outbreak of communicable disease.

86. SIPC is an audit used at ward level that assesses compliance to evidence of cleanliness, hand hygiene, intravascular catheter (line care), or whether environmental issues that would impact on patient safety and quality of care. It identifies any IPC risk factors for that area at the time or any elements of good practice we could learn from. The results from the SIPC assessment tool use in a ward environment would indicate areas for improvement by ward managers. Of concern is that there was no apparent governance or oversight of improvement implementation. As discussed previously and in section 5.3 and 5.3.1 of the Overview Report, the responsibility for the improvement was at nursing lead for the ward. Due to the RAG rating system applied (Red, Amber, Green, Gold) a score above 80% despite significant failures of compliance in areas such as environment could result in no reaudit for 12 months There was contemporaneous follow up by the IPC team to monitor improvement. Non-compliance around poor cleaning and the condition of the environment may suggest a probable or possible contribution to a cause of infection but will not determine a definite cause without sampling and typing results. Of interest to the panel was the compliance to environmental standards for IPC. Some of these could be as low as 67% and for equipment cleanliness and integrity 75%. Non -

compliance in these two criteria raised the risk of potential environmental contamination and when reviewing possible association between BSI and to the environment we would review the state of repair, integrity, and severity of failure as contributory factors in environmental contamination. We would expect to see an implementation plan and reaudit to ensure the compliance is improved and shift the focus from the score to risk assessment.

87. There are some areas in which you would expect to have a significant weighting. If you do an audit using your standard infection prevention tool, and you look at the environment, and the parts of the environment only score 60 per cent but everything else is okay, then that would be high. This would pass your overall score, but there is no weighting to say you need to go back and check whether that environment is clean, because your overall score will say that you have done well overall. The whole purpose of an audit is around improvement, and that is where the lack of governance and assurance fell short to demonstrate improvement and have oversight of the changes.

88. This is significant because a score of 67 % is below a pass for the audit. We should be asking, 'What did you do, what did you improve, what did you go back and improve?'

89. There are some examples in their enhanced audit where ward managers developed an improvement plan, but there was no governance or assurance oversight, and it was the responsibility of ward managers to make sure that improvement was overseen. In an audit six months later, the audit score is still the same, then the improvement has not been implemented and the purpose of the audit becomes a tick box exercise. An audit appeared to be the end of, rather than the beginning of the process.

90. I would have expected utilisation of IPC expert knowledge when undertaking an audit. Were they using any other evidence that they knew about that environment or about that ward to make some decisions and to make some improvement? There was no documented evidence of improvement that the panel were shown.

DATASETS RELEVANT TO HOSPITAL ACQUIRED INFECTION REPORTING

91. All the data sets listed within the Overview Report amass to give a slightly different picture of an individual infection. Some, which are for surveillance purposes, could be specific infections within a determined list. Others are a complete illustration of all infections and those such as IC-Net and Telepath can pull infections from a predetermined list and keep a record of advice and management of IPC team or microbiologists' interaction with clinical staff caring for a patient.

92. This approach worked well and consistently in our review of cases based on the available evidence. We reviewed each of the episodes of infection at least twice to ensure we had included all available data which would allow us to draw conclusions about possibility and probability. The panel approach has been based on probability and the likelihood of it happening is greater than not.

93. Other data sets utilised track the location of patients as they move from different locations around the hospital during their care; unfortunately not always to specific bed level. Using a matrix approach of all these data sets for an individual patient can give us a comprehensive picture of what was happening to that person, where they were, and if other cases overlapped in time and place.

94. These combined are routinely used to manage outbreaks by looking for time, place, person links and where there is sampling data available from environments or water, link these to patients with specific or matching microorganisms or unique infections.

95. When we put all the datasets together, it became a data mapping exercise to see where people had been. We would look at one individual and identify where they were physically for various parts of their treatment and then putting a line through when there was an intervention, so we could see at what point in time it happened. We used a timeline to demonstrate this.

96. If you do that for everybody, and put it all into a timeline, you can observe on a particular day, area, week, when you might have simultaneous infections or that the drain was blocked twice or the ventilation was not working. You can observe whether patients in the same room acquired the same infection within days of each other. That is what you would do with any sort of outbreak or incident, you would look to see if there is any overlap by time, place, person, for any of those datasets. We would normally do this as a timeline chart or table like Gantt chart Timelines were created using data visualisation software (Tableau 2019.1). Section 3.3.3 of the Overview Report.

CONCERNS ABOUT THE USE OF DATA SYSTEMS BY GGC

97. In chapter 8 of the Overview Report the challenges the team experienced relating to data provision or quality are described. The chapter gives an overview of and context to the difficulties of investigating the GNE bacteraemia episodes. Both the Panel and NHS GGC have acknowledged that the Covid-19 pandemic had implications for data gathering and analysis. Jane Grant refers to these challenges in her letter dated 1st March and in the NHS GGC response to the draft case note review.

98. The team experienced delays in response to requests for access as part of the information sharing agreement and suspension of access following contract extensions despite advance notice. Details can be found in section 8.1.1 of the Overview Report.

99. Data for the Review team was requested in April 2020 relating to environmental microbiology sampling and facilities and maintenance data. The relevance has already been discussed and is detailed in section 5.2, 5.4.and 5.5 of the Overview Report.

100. Environmental samples initially arrived on 11th May 2020 for water samples only, not drain samples and were incomplete or had no sample results attached from the water sampling contractor.

101. Maintenance data provided initially was via HAI SCRIBE risk assessment tool record, however as we required linking works to the investigation we were provided a data set on 1st June 2020. Again, this was of limited value for our use. it was not possible to identify which toilets, sink and or drain repairs had been made on ward We explain this issue in detail at section 8.1.2. of the Overview Report.

102. I have previously mentioned concerns about the recording of data by GGC. To expand on that, some of the data sets we were provided with were incomplete or mislabelled, for example, after Ward 2A had been closed, this identifier was still being used when ward location has moved to Ward 6A, so trying to place a specific child in a specific location became confused. The Overview Report in Chapter 8 discussed these in detail

103. Most of our concern was that data was not collated in a systematic way, either for them to retrieve information, or for us to interrogate.

104. When we requested data, it was not presented in a systematic, timely and/or chronological format for the most part. This contributed to delays and extended timeframes in which to try to piece together fragmented/ incomplete details.

NHS GGC RESPONSE TO THE CASE NOTE REVIEW

105. The panel received the response prepared by NHS GGC in response to the draft of our Overview Report on 1/3/2021. The Panel considered all the points noted including the attached documents and responded with the document titled, “Case Note Review Team Rebuttal of GGC Consultation Response.”

106. The GGC response to the overview report was of considerable detail, their rationale, and explanations for why the situation arose appeared to rely heavily on Health Protection Scotland (HPS) report from November 2019. As part of the rebuttal response, the panel agreed to add a short section discussing our analysis of the overview report on the HPS report (section 8.2.3) Our key observations were that we did not find the report to have clear messages of reassurance; and that the clarity of recommendations for the future were most helpful and similar to some of those that we have made within the Overview Report. We reiterated this in our summary of the HPS report in Chapter 8 of the Overview Report

107. Following a teleconference with NHS GGC on 4th March 2021 to discuss the draft Overview Report and NHS GGC response, Jane Grant sent a second letter on 5th March 2021 to Professor Stevens as chair of the Expert Panel with further requests to acknowledge in our report that improvements had been made to reduce infections related to central line associated bloodstream infection (CLABSI). This is included in the section 8.8.3 conclusion of the Overview Report. In the rebuttal response we iterate we are happy to include references to where we had found good practice.

108. With the help of my notes I recall the telephone call. NHS GGC was represented by Jane Grant, Chief Executive, Jennifer Armstrong, Medical Director (MD), Scott Davidson deputy MD, William Edwards and Elaine Vanhagen, Head of Board Administration and Corporate Governance and the Panel members. The discussion was intense and, to me, defensive in discussion giving contrary examples to those in the Draft Overview Report. There was discussion around the delivery dates and requests for data and examples of good practice were referred to by NHS GGC. This was an uncomfortable meeting and did not resolve the expectations of NHS GGC in amending the draft report outside the areas we identified within our rebuttal document to GGC.

109. Within the rebuttal response to NHS GGC the responses we have made are to the best of my knowledge factual, regarding timelines and data requests or receipt. Where we considered the challenge was valid, we reviewed wording or added additional clarity to the final version of the Overview report. The NHS GGC response to the Draft Overview Report was extensive with over 60 pages of commentary.

110. The Panel did make changes for clarity, to references and to credit good practice throughout. The Panel did not concede that all points had validity and there were outstanding discussions for the accuracy of timelines for which we had confidence we had recorded accurately. The changes did not alter the context or recommendations of the Overview report.

111. Criticism of the CNR's methodology by the GGC could have been raised earlier in the review as a point of concern. Responses appear to be a defensive approach to override the CNR findings with emphasis on the credibility of the HPS 2019 report conclusions.

112. NHS CCG challenged the methodology the review worked with, which was agreed at the onset of the review in February 2020. There had been regular conversations between Prof. Mike Stevens and the clinicians (doctors working in paediatric haematology, oncology) caring for the patients. Concerns could have been raised during those conversations with Professor Stevens during their meetings or indeed raised via email. Professor Bain was acting as the intermediary all the way through; it would have been pertinent to have raised concerns at the beginning or as they arose. In the letter to us dated 1 March 2021 from Jane Grant, it is noted that the GGC believe that the CNR indicates that the Health Board should have approached the issues they were facing in a different way, despite following advice and guidance from national experts and agencies. . The tone of the correspondence from GGC was defensive; apportioning responsibility to other organisations when they have a large cohort of internal expertise at their immediate disposal.

113. Some of the information contained within the letter could have been shared with the panel at any point during the review and opportunities to explain complexities with internal staff should not impact on patient information and professional processes. We discussed this response as a panel.

114. Some of the data that was shared we had to ask for several times, and we have stipulated this with dates in the overview report in Chapter 8. NHS GGC response was defensive, stating that they either did not have it in the correct format, or there were resource implications due to Covid 19 response or it did not exist or GGC did not understand the request. This was discussed by William Edwards during the telephone call with NHS GGC on 4th March 2021 and it was noted at the time that our recommendations would help with change in future.

115. It is difficult to see as an external reviewer how it was that GGC did not follow through their own SOP and practices. This is especially the case given that GGC were unable to proffer an alternative evidenced account beyond its the reliance on HPS 2019 report for the origin of the high number of cases of GNE bacteraemia or making change to their laboratory and sampling practices for 5 years. It should also be noted that in her letter of 1st March 2021 Jane Grant refers to approximately £6 million expenditure “to deal with the matters associated with water”. The relocation of 2 wards and complete renovation would also suggest the organisation considered an environmental source credible. However, despite concerns that the water was being discussed as a possible source of infection, routine water testing did not commence until 2018 when the building was handed over to NHS GGC in 2015. In section Overview Report 5.5.2 we have raised concern about the absence of water sampling from the time of handover. Although water testing has been implemented in augmented care (enhanced care) units by the NHS in England since 2012, this was not adopted in Scotland. Previous reports commissioned have identified the same issues with water safety within their findings.

CONCLUSIONS

116. In terms of conclusions, the Panel was able to conclude only 8 of 118 episodes of infection were unrelated to the environment. I have already discussed why we were not able to say that any episodes of infection were definitely related to the environment (see Section 5.6) but that the remaining episodes either probable or possibly associated with the environment.

117. We have noted in footnote 67 on page 69 of the Overview Report that GGC reported they were able to link one of the three cases of Mycobacterium Chelonae to the environment. Referring to section 8.4.1 of the Overview Report, we determined that the data provided for one of the cases dating back to 2016 was insufficient for us to confirm the case was linked to the environment. On page 69(section 5.6) of the Overview Report, we state, “Microbiological information alone was insufficient for us to reach our conclusions and we also looked carefully at clinically relevant material”

118. The inconsistencies in data availability, quality and the challenges NHS GGC had identifying, collating, and sharing with the Panel asks the question: how did the organisation use the information in their own investigations?

119. We were not assured that there were adequate systems in place to monitor the environment and the risks, especially around water safety between 2015 and 2018 and. As an IPC Professional I found it surprising that there was no evidence of water testing at the building handover, you would want to know that all the testing in order before you take over ownership.

120. There was insufficient consistent data relating to routine water system sampling (which was not commenced until 2018), so there was insufficient data with which to build a profile of any existing issues with water quality. There was also variability in environmental sampling throughout the investigation, sometimes specimens were taken, sometimes they were not, or there were no results available to GGC or ultimately to us.

121. NHS GGC must have highly suspicious that environmental risks existed to have completely relocated and renovated at great expense wards 2A and 2B a commitment not taken lightly.

122. Typing was not systematically recorded or available and therefore the clinical evaluation was needed to complete a more cohesive picture of the environment and the investigation that had been undertaken.

123. I have not personally seen or heard of anything that would indicate the position of implementation of the Panel's recommendations at GGC or the wider health economy in Scotland.

DECLARATION

124. 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.

Appendix A

A43293438 – Bundle 6 – Miscellaneous Documents

Scottish Hospitals Inquiry
Witness Statement of
Professor Mark Wilcox

Professional Background

1 I am Professor Mark Wilcox. I am Professor of Medical Microbiology at the University of Leeds where I hold the Sir Edward Brotherton Chair of Bacteriology and a consultant microbiologist at Leeds Teaching Hospitals NHS Trust. Since 2020 I have held the post of National Clinical Director Antimicrobial Resistance and Infection Prevention & Control at NHS England. I currently work three days a week. Two of those three days are at NHS England with the remaining day split between my university role where I run a research team focusing on healthcare associated infection and my role at the Leeds Teaching Hospitals Trust which is a research post. I am the lead for Clostridioides difficile infection for what was Public Health England and is now the UK Health Security Agency. My research interests are multiple aspects of Clostridium difficile infection, diagnostics, antibiotic resistance and the gut microbiome, staphylococcal infection, and the clinical development of new antimicrobial agents.

2 Between 1981 and 1986 I attended Nottingham University Medical School, where I gained a Bachelor of Medicine with First Class Honours Class in 1984 and a Bachelor of Medicine and Bachelor Surgery with Honours in 1986. I also have post-graduate qualifications, gaining Doctor of Medicine (Microbiology) in 1990 and FRCPath (Microbiology) in 1992. In 2024, I was awarded ab OBE for services to Infection Prevention and Control, primarily during the COVID-19 pandemic.

3 I have held multiple senior posts within Microbiology, both in Leeds and nationally, including:

1993-95	Consultant Microbiologist, Addenbrookes' Hospital Cambridge.
1995	Senior Lecturer & Consultant Microbiologist, Department of Microbiology, University of Leeds & Leeds Teaching Hospitals Trust (LTHT).
2001-16	Head of Microbiology for LTHT.
2003-08	Director of Infection Prevention & Control/Lead Infection Control Doctor for LTHT.
2004	Professor of Medical Microbiology (University of Leeds).
2005-16	Head of Unified Clinical Microbiology Service for Leeds, including former Leeds HPA diagnostic services.
2006-12	Clinical Director of Pathology for LTHT.
2007	Established and led *C. difficile* Ribotyping Network for England (CDRN, including N. Ireland).
2008	Lead on *C. difficile* for Health Protection Agency (HPA) in England (now Public Health England).
2011	Expert Advisor on Healthcare Associated Infection to the Department of Health (England).
2016	Head of Microbiology Research & Development, LTHT.
2017	Medical Advisor to National Infection Prevention & Control Lead (NHS Improvement), England.
2018	Infection Lead of the Leeds NIHR Diagnostic Technologies Medical Technology and In Vitro Diagnostic Co-operative at LTHT.
2022	Lead of Antimicrobial Resistance and Infection theme of Leeds NIHR Biomedical Research Centre.

4 My main area of interest from a clinical and academic perspective is infection prevention and control and healthcare associated infections, which is the discipline of trying to minimise infection risk for patients within a healthcare setting. Within infection prevention and control clinicians can hold various levels of responsibility, such as an Infection Control Doctor and Director of Infection Prevention and Control, and I have held the full range of such roles

during my career. Prior to the pandemic I was the medical advisor to the Chief Nurse in England and that metamorphosised into becoming National Clinical Director for Infection Prevention and Control and Antimicrobial Resistance. During the pandemic, Sir Patrick Vallance invited me to chair one of the subgroups of Scientific Advisory Group for Emergencies (SAGE) on minimising the risk of infection and acquisition of COVID in hospital; this role meant that I joined SAGE as well. I was a member of SAGE from May 2020 until its dissolution.

5 I have attached at Annex B a resume outlining my National and International responsibilities where I have worked or taken the lead on a number of committees and advisory boards over the years.

6 I have never worked for NHS Greater Glasgow and Clyde (NHS GGC), as a consultant, and this statement relates to my contribution as part of the Case Note Review (CNR) team, which was established in January 2020 to examine individual cases of infection at the Queen Elizabeth University Hospital (QEUH). As part of the CNR Expert Panel, I examined the case notes of those children and young people in the paediatric haemato-oncology service in the RHC and the QEUH from 2015 to 2019 who had a bacteraemia caused by a Gram-negative environmental microorganism (and selected other bacteria, as identified in laboratory tests).

7 I have prepared this statement on the basis that reader has read the Case Note Review Overview Report, March 2021 (“the Overview Report”) and will refer sections with that report within this statement. I am one of the authors of the Overview Report and will adopt it as part of my evidence to the Inquiry.

8 My recollection is that I was first contacted about the Case Note Review in January 2020. I cannot now recall if the emails were preceded by phone calls. I was contacted via email and asked if I would be willing to join a panel of independent experts for a case note review and provide infection and prevention control advice, specifically medical microbiology aspects of advice. I am not sure of the process for my selection to the Expert Panel and I was

not interviewed. I was given the contact names of some individuals who I could talk to and get an idea of what was involved, as I did not know anything about NHS GGC and what had gone on. I spoke to a couple of individuals by phone or over email, with Lesley Shepherd being one of them, to understand what was involved, because it was obviously an unusual scenario, but I was not aware of there being a formal process of me being vetted. It never felt like that at any stage.

9 The Expert Panel of the CNR comprised me, Professor Mike Stevens (panel lead) and Gaynor Evans. Within the CNR team there was also a core clinical team. They were Professor Peter Davey, who was involved in acquiring data and discussing aspects of our findings and Professor Marion Bain, a director of infection and prevention control, who was the link between the panel and NHS GGC. There were other individuals contributing, but the Expert Panel was just the three of us.

10 The respective roles of the Expert Panel and various support teams are described in the CNR Terms of Reference. The Expert Panel was responsible for a) agreeing, within the scope of these Terms of Reference, the definitions used to select patients for the review, the scope and direction of the data collection and the methodological tools required; b) overseeing and interpreting the analysis of data obtained and developing the Final Report (and, in discussion with Professor Bain, the provision of any agreed interim reporting);c) progress reporting to relevant audiences, including the RHC/QEUH staff; and d) providing reporting to individual patients and families. It should be noted that despite the existence of support teams, the conclusions in the CNR report are those of the expert panel.

11 The Clinical Team was responsible for: a) undertaking the data collection, storage and submission of case note review material to the Expert Panel; b) resolving data/sampling issues with Professor Bain, the Support Team and the Expert Panel; and c) supporting the analysis and reporting of the Case Note Review through the Expert Panel.

12 The Support Team was responsible for: a) resolving practicalities and resourcing issues with Professor Bain, Professor Stevens and Dr O'Connor; b) undertaking key communication and engagement functions with Professor Bain; c) developing and maintaining the Review workplan; e) providing secretariat and related functions to the Expert Panel, and f) ensuring submission of Final Report to the Cabinet Secretary and publication.

13 There was also a specialised PTT (Paediatric Trigger Tool) Team. The intention of using an adapted Paediatric Trigger Tool in the study of NHS GGC is not to determine preventable or non-preventable harm but to create opportunities to learn from the triggers and adverse events identified. It forms only part of the overarching case review process, and it is anticipated the information from the PTT will underpin the epidemiological and clinical outcome review and the contextual organisational data and reports. The PTT methodology will examine harm in the processes of healthcare in the group of patients selected for case note review and its objectives are to contribute to the overall aim of the case note review by identifying all triggers and adverse events in the cohort of patients identified by the epidemiological review using an adapted PTT; and by describing the rate and severity of harm occurring in hospitalised children in the cohort group.

14 Professor Bain was the Expert Panel's link to NHS GGC. Her role is also set out in the Terms of Reference for the CNR: 'As Executive Lead for infection prevention and control within NHS GGS, as appointed by Professor McQueen, Professor Bain will have oversight of the project as a whole. She will be responsible for its progress and reporting to Professor McQueen, including advice – provided by the Expert Panel and other members of the team below – for any necessary change in key elements of these Terms of Reference.' She was also responsible for communications with patients/families, along with Professor Craig White.

15 The Oversight Board provided professional oversight, holding the core team to account for progress and delivery, together with identifying risk and resolving any problems with sampling or data. The Board was helpful in addressing some of the obstacles we encountered in obtaining data/information. The Oversight Board did not influence the conclusions of the CNR team. Instead, it oversaw our progress in obtaining and reviewing the data necessary to make our assessments and draw our conclusions. The Expert Panel was responsible for providing a Final Report to Professor Bain and the Oversight Board.

CNR and Terms of Reference (ToR)

16 Prior to the commencement of the CNR the panel was provided with an outline of the case criteria and case definitions. The outline case criteria and definitions were sent to us by Philip Raines or Jim Dryden (QEUH Support Unit, Scottish Government), and were set out in an 'Epidemiological Protocol' (February 2020 v0.1; Health Protection Scotland & NHS National Services Scotland). We made some very minor modifications to tighten those up, so they were logical and that they were explained in the report with nothing else to add. We had access to other reports that outlined some other epidemiology of wider bacteraemia, such as Gram-positive organisms. That, for me, underscored the sense in focusing on the so-called environmental Gram-negative bacteraemia. By "so-called" environmental Gram-negative bacteria I mean GNBs which can be found in or recovered from various sites in the environment and can survive well outside animal or human habitats.

17 I have been asked by the Inquiry if the CNR team considered the possibility of taking account of positive blood cultures from other parts of the hospital, which might have been relevant to a more extensive pattern of concern outwith the Schiehallion unit. We discussed this, but our remit concerned this particular group of vulnerable individuals. To my knowledge, there were no similar potential signals of an environmental source elsewhere. Given the nature of these individuals, they are hyper susceptible. The air we breathe has

fungal spores in it, and that is why some bread will turn green eventually, because the fungal spores land on the bread. The fungal spores that we breathe in cause us no harm whatsoever; however, someone with a very depleted immunity, such as bone marrow transplant patients, who breathe in exactly the same air as us can develop a fatal infection. So, they amplify, if you like, bacteria that in this case may well cause no harm in other individuals. To look for potential environmental sources of infection, it was logical to understand the patterns and timings of the clusters of bacteraemias and the types of bacteria involved.

18 I have been asked to explain how we reached the conclusion that there were no potential signals of an environmental source elsewhere. This was my assumption and was formulated from what we were told initially and the focus on bacteraemias caused by Gram-negative environmental bacteria. We were not, to the best of my recollection, given assurances regarding the absence of unusual potentially hospital associated infections outside the Schiehallion Unit patient cohort. I do not recall being made aware of ‘a series of up to six Cryptococcus cases found in patients in the hospital between 2018 and 2020’. Had this occurred, I would have considered such a series to be unrelated, in terms of specific source(s), to the bacteraemias caused by Gram-negative environmental bacteria. This is because the habitats and mode of transmission of Cryptococcus differ from those associated with Gram-negative environmental bacteria.

19 Our remit was limited to Schiehallion patients. Immunocompromised patients are more susceptible to developing infections caused by certain bacteria (including Gram-negative environmental bacteria). Thus, our remit to focus on these patients and these bacteria was logical. We did briefly discuss the merits of expanding beyond these, but we stuck to our original brief.

20 I have been asked by the Inquiry if I could provide a layman’s explanation of the case definition as outlined at Section 3.2.2 in the Overview Report. The focus here was on potentially environmental Gram-negative bacteria, which are split into two broad groups based on a simple staining technique. They

either retain the stain, in which case they are Gram-positive, or they lose the stain when challenged, in which case they are Gram-negative, Gram being the surname of the bacteriologist who devised this technique. The reason bacteria are either Gram-positive or Gram-negative is because of the fundamental difference in the outer coating of the bacteria. That outer coating and the other characteristics of the bacteria fit in with this Gram stain property. If the bacteria are Gram-negative, they are more likely to thrive in wet, moist conditions as opposed to Gram-positive bacteria, which will survive happily in dry, arid conditions. So, the CNR was focusing on Gram-negatives, which needed to have been recovered from blood cultures. They are detected by a conventional technique where you heat the blood, you incubate at 37 degrees centigrade and see whether you manage to amplify the small numbers of bacteria in a blood sample to larger numbers, which create a positive signal in that blood culture. We wanted a deduplication process. If someone tested positive today and then tomorrow and maybe in 10 days' time, you would count that really as one episode. So, it is a persistent bacteraemia, and it is one episode rather than counting that as three.

21 We used a 14-day period to deduplicate the records for the CNR, which means that any bacteraemia occurring within 14 days were counted as one episode. Outside of that, if I get bug X today, and then in four weeks' time bug X again, that is two different bacteraemia, because you should have really cleared that bug from your blood. If it returns, it could be the same episode, but it also equally could be you that could have reacquired it. That is the basis on which we were selecting cases, Gram-negative potential environmental source bacteria in blood cultures causing so-called bacteraemia deduplicated. We set some exceptions; the most obvious ones were that post-mortem samples were excluded. They are not commonly taken, and they can be misleading. We did not want contaminations or samples from other sources such as faecal samples.

Infections and Association

22 I have been asked by the Inquiry what is meant by “association” when looking at infections and causation. In the Overview Report we did not define, using our criteria, any definite relationships between the environment and bacteraemia in children, but a relatively large number of probables, the highly probables, highly possibles and so on. The term “association” is qualified by those grounds of probability, and, in infection prevention and control terms, the key here is any clustering in time and place. The more clusters of cases that you get that appear similar, or the more cases in a cluster that appear similar, in this case caused by the same bug, in time over a number of years, maybe a few weeks or months, and in the same place, then the greater the likelihood that the association is real and that there is potentially a common cause. We were looking to see whether there was a pattern of infection that could be associated with the environment, rather than establishing whether infection was caused by the environment. Our aim was to determine a timeline for each of the cases; characterise the cases in terms of time, place and person; and – where possible- to describe the cases in the context of environmental risks and incidents.

Infections and the Environment

23 I have been asked by the Inquiry if the CNR team were looking to establish whether an infection was caused by the environment, or whether there was a pattern of infection that could be associated with the environment. I have been involved in numerous roles, at both local and national level, attempting to establish links and associations and causality in the chain of infection, and looking at both of these areas. My initial approach will be to look for evidence of, let us say, clustering in time and place; these are the cardinal features, which suggest an association. Then one looks for causality, because of course if there is causality, it could be in one of two directions. If you find a bug in a sink, and you find a bug in a patient, you may conclude that they are the same bug; however, you need to establish did the patient put the bug in the sink, or did the bug come from the sink? So, the likelihood that it is sink to

patient increases the greater the size of the cluster in time and place sharing that association.

24 The organisms that we were looking at are generally water-associated or can be water-associated. It does not mean you only find them in water. You can also find them inside people, particularly as part of the bacteria forming the gut, the gut microbiome, or gut bacteria. In the CNR report, we refer to endogenous infections, which are bugs already in or on a person that then go somewhere else within that person and cause an infection - in this case, into the bloodstream. By contrast exogenous infections is where a person may acquire the same or similar bugs from other sources. It was those exogenous possibilities that we were particularly focused on, while not ignoring the chance that they could be endogenous infection as well. The chances of a cluster of cases all caused by the same or similar bug occurring in time and place endogenously decreases, and you start to think, “Well, hold on, it’s more likely to be exogenous,” and we refer to that time and again within the CNR findings.

25 There are many potential sources of bacteria or viruses in the environment, the air we breathe, things we touch, and water sources are probably three of the most common. The hands of patients and/or healthcare workers, or visitors and friends, can act as links between those potential sources or “reservoirs” of infections. These organisms would not normally be thought of as airborne organisms. They MAY splatter from droplets, but they are not airborne in the way that a respiratory virus such as COVID-19 or influenza is transmitted. As part of the review, we focused on primarily water sources or intermediary surfaces. In this context, the “environment” here refers to the physical, biological, and chemical factors external to the patients.

26 I have been asked by the Inquiry how the supporting teams approached the analysis of causation, including identifying causal criteria. The extended team did not play a key part there. The key decision-making around causality was between the three of us in the panel. It did not mean that they could not provide input by identifying information that we might not be aware of or

adding context via records that we had not seen. The actual decisions of something being possible, likely or this is highly probable, was the responsibility of the three of us. In terms of the definitions themselves, they contributed to those definitions, but the final decision about the acceptability and robustness of the definitions was that of the Panel.

Use of the Paediatric Trigger Tool (PTT)

27 As highlighted in the Overview Report at section 3.4.2 a trigger tool is a method for identifying adverse events (AE). In adults, the rate of detection of AE with a trigger tool is typically ten-fold greater than the rate detected through spontaneous reporting systems. Similar results have been reported with paediatric trigger tools in general wards and neonatal intensive care units.

28 In 2014, the UK PTT was developed with the support of clinicians in nine hospitals across the UK in order to detect AE in paediatric care provided in district general hospitals, acute teaching hospitals and specialist paediatric centres. The PTT was used for the CNR not to determine preventable or non-preventable harm, but to create opportunities to learn from the various AE identified.

29 I have been asked by the Inquiry the significance of the paediatric trigger tool, which is referred to multiple times within the CNR report. I think it is a confusing concept, and I had never come across it prior to this review. It is a system simply for determining whether there has been an actual or potential adverse event and seeks to establish what has been the impact of that event. It is a tool that was devised around the care of children specifically, so whilst I have treated children throughout my career, it has not been a particular focus of mine, which is probably why I have not come across it.

30 There are other ways of assessing whether there has been an adverse event, such as for example in Datix reporting. The Datix system is a widely used system in the NHS regardless of which country you are in and whether the people affected are young or old. It was suggested from the outset that the PTT could be a useful way of assessing adverse events. There is a component in the report, where we talk about the impact of these bacteraemia seen as adverse events. The tool was useful there, but we could have used other tools. I recall some discussion early on about concerns being raised by NHS GGC over the use of the paediatric trigger tool. I cannot remember the basis for those concerns; however, I do not think it really matters whether we used the PTT or some other tools/methods because what we were doing was trying to ascribe a likelihood to the environment being the source of a bacteraemia.

31 Within the CNR report we did say, “regardless of whether there was a likelihood, what was the impact?” with particular interest where we thought there was an environmental source. If you follow that train of thought, the utility of the paediatric trigger tool is not core to our purpose. It is secondary to that; however, I am not saying it did not have some value.

Methodology

32 I have been asked by the Inquiry how the methodology evolved during the CNR, and whether the decision was a done collectively or did someone take the lead. It was very much a collective decision. Gaynor and I have more relevant closer skill sets than Mike did as he was a lifelong paediatrician with an interest in infection, whereas Gaynor and I are infection specialists. Our relative skills were quite complementary in terms of defining what we believe was a case, defining the terms of our investigation and what we felt was reasonable or unreasonable to attempt to do and what we did not think was reasonable to attempt. I do not recall there being any fundamental disagreement or challenge of what we decided.

33 There is no set methodology that one must use to investigate a putative series of transmission events, but there are a certain series of core principles. I have already alluded to time and place, cluster analysis. I could go on about the detailed typing and fingerprinting attempts, and the drawbacks with those or the surveillance in general about the robustness of the investigation tools that we used. I do not mean paediatric trigger tool; I mean the actual incident management team meetings and processes and so on. There are different ways of investigating an outbreak or a series of outbreaks transmission events, but the core principles remain the same. We were confident that we used those core principles appropriately.

34 I have been asked by the Inquiry if the overall analysis is based on circumstantial evidence, defined as a combination of circumstances that are more likely or not to point to an infection episode having been caused by the built environment. In the absence of definitive proof- which in this case would be provided by bacterial typing or fingerprinting methods that matched, as close to certainty as possible, a bug in water with a bug in patient's blood - we were left with making decisions based on grounds of probability. We were using facts on where bacteria were found, how frequently they were found both in patients and in environmental samples, and then making judgments based on how complete investigations were. From my lay understanding of the term "circumstantial," I think I would agree with that, but underlying the decisions we made about the balance of probabilities was a considerable degree of expertise in the likelihood of association and indeed causality.

35 Whole genome sequencing is one of multiple methods that can be used to fingerprint a microbe, in this case according to the make-up of its nucleic acid (DNA or RNA). Typing methods, in addition, assign a type (e.g. name or number) to the output of the fingerprinting method. If it were simply looking at 84 patients and 112/118 bloodstream infection/ bacteraemia episodes all in isolation, it would be extremely difficult to have any confidence in saying what the source of that individual bacteraemia was. If, however, you note that there have been eight bacteraemias caused by an organism with the same species name, characterised to species level, within a handful of months, then either

side of that handful of months no more such bacteraemias, and these patients are all situated and managed in the same place, same ward, then the grounds of probability are very much in favour that there is a common source there. So, yes, it can be circumstantial if we then say that we believe, for other reasons as well, that the environment is a likely source. However, those circumstances that underscore the circumstantial decision are quite powerful in epidemiological terms. A fundamental part of what we do when we investigate transmission events or potential transmission events is the power of the epidemiology, and how supportive it is.

36 If we go back to the pandemic, you would ascertain whether you are a contact and you get pinged, and you are advised to isolate. If you then become COVID-19 positive within a few days, the inference is that it is related to that ping, but obviously that may not have been the case. That is a more circumstantial, less robust association than what we were looking at here, i.e. well-defined time and place associations. So, it is the degree of circumstantial evidence we are discussing here. The more infections of the same type, caused by related microbes, occurring in the same place, and linked in time, the greater the chance that those infections are linked to each other and that the environment could be the source of infection.

37 I have been asked if there was any weighting applied to particular circumstances. I would say probably not, as if we had weighted one line of evidence, we would have to define that and refer to it in our reports. It was almost like ticking boxes of probability. We neither defined nor weighted them, and this approach is standard practice in an epidemiological investigation such as ours.

38 Regarding the possibility of outside environmental sources as described in section 3.6.3 of the Overview Report, we had a detailed timeline for each patient; their date of admission, their date of discharge, their date of re-admission, because very often there would be multiple admissions. We sought to establish when the bacteraemia developed in relation to the person entering the potential risk environment. If you develop something such as

bacteraemia or diarrhoea on day one, two or three, it could well be related to what happened before you entered the hospital. If it is beyond that and this keeps on happening with these bacteraemias, as it did, then that increases the likelihood that it has something to do with being in hospital. That does not necessarily mean that the source is definitely the environment of the hospital, because it could be something that is done to the patient. They could have received a medicine that makes their immune system more depleted, which can happen, and it could be that which increases their risk of endogenous infection. Then there is the clustering, which I referred to earlier, which asks the question, “Why would you get a run of endogenous infections with the same bug? That does not seem plausible.”

39 I have been asked by the Inquiry to identify the recognised methods for demonstrating a causal relationship to a standard scientific certainty and whether there are methods that can be used to demonstrate a definite relationship or to definitely exclude a relationship. There are different levels. You can start off with simply saying, “This is a Gram-negative bacterium,” and you get a series of Gram-negative bacteria, and you want to know, “Are they related?” The next thing you would do is name and speciate those organisms, for example, Stenotrophomonas maltophilia. So, we are now dealing with eight bacteraemias all caused by Stenotrophomonas maltophilia. The next question is, “Are those the same Stenotrophomonas maltophilia or very closely related, or are they different?” Bacteria multiply very quickly and so you can get changes in the DNA as you move from this bacterium to its progeny and to the progeny of those progeny. All of this is happening every 20 minutes, with the bacteria multiplying, so there are limits. There is a drift, and that needs to be considered when you apply a typing or fingerprinting method to, in this case, Stenotrophomonas maltophilia to work out if tomorrow’s Stenotrophomonas maltophilia or, indeed, the ones three weeks away related to the ones three weeks previously.

Whole Genome Sequencing

40 There are many different typing and fingerprinting methods, but the more robust methods are based on looking at the DNA in those bacteria. The ultimate fingerprinting method that we have at our disposal is called, “whole genome sequencing,” where you basically read the whole genetic code in a bacterium, and then you compare that genetic code with genetic code of other bacteria. Again, you have to set limits because to expect the genetic codes to be identical is too stringent and depending on the bacterium and experience of looking at bacteria, they clearly are related because you culture them yourselves and look how much they drift or you put them into an animal and see how much they drift in genetic code. That is the ultimate technique, and that ultimate technique was applied post-hoc, not real time, to my understanding, but post-hoc to some of the bloodstream isolates from some of these individuals.

41 We deal with this in the CNR report at section 8.3.1. No-one appears to have said, “Let’s type everything we’ve got, all the isolates causing all these bacteraemias, and type all the isolates that were recovered from environmental sources.” The difference between typing and fingerprinting is semantic; for all intents and purposes the words can be used interchangeably. There was no systematic use of typing, either in real time or after the event. Of even greater concern, and this is detailed in the report, the sampling of the potential environmental sources was not systematic. If you have not sampled the water in a repeated way, you cannot confidently exclude the water as the source. If there is an ad hoc process to sampling the water, not only when you do it, but what you look for when you have got that water sample, then it is perhaps not surprising that we were unable to produce definitive matches of bacteria in blood with bacteria in a water source.

42 We were provided with reports of the sequencing that was done in 2021, but this was only at a late stage in our investigation. We had more than one meeting to discuss the post-hoc whole genome sequencing results that had been obtained. We highlighted that these were incomplete, and the answer was, “Well, these are all the ones that were available.”

43 There is a routine practice for when you grow bacteria from critical samples and blood cultures, which is that you store all the positive bacteria recovered, not least so that one can go back and retrieve them if there is a subsequent need. In this case we are only talking five years or so down the line, so I would expect, had there been a systematic storage process in place, which there should have been, that all the bacteria would still be in that store five years down the line. It would appear not, from the fact that not everything that one would have liked to have been typed was typed.

44 Let’s say you type five bacteria, and you cannot find a match in three of those five, but the two that are missing could have matched to any one of those three that you do have information about, and both of them could match to one of those three, or one of them could match to one of them. So, you are then left with, “Okay, you have done some typing; not found any matches, but you have not excluded by any means the possibility of a link.” That is just with the isolates that you have got from the blood cultures. If you have not got any isolates that you can include in that typing exercise from water samples, then we are not saying there can only be one Stenotrophomonas in water that would cause Stenotrophomonas whenever it occurred in a patient. There could be 20 different Stenotrophomonas species in the water, of which only three ever get into patients, so it is complex. Because of the incompleteness of all those levels then it is not surprising, sadly, that we were unable to produce case examples that match the definition of definite. The level of certainty with which WGS can rule in or rule out matches between human and environmental isolates depends on how comprehensive/extensive are the collections of available isolates.

45 I have been asked by the Inquiry if I found it surprising that complete typing was not done, and that level of sampling was not what I expected. Let me deal with the sampling first because that, perhaps for me, is the most surprising. There was a lot of noise in real time within NHS GGC about the environment, and especially on the quality of the water. There were lots about reports and concerns, incident meetings, lots of interventions that were put in place by NHS GGC to attempt to mitigate water-associated risks. All those together say that in real time, there were question marks, at the very least, around water quality. With that you need to then ask why there was not a robust systematic investigation process, surveillance process, sampling process in place to assure or describe what was happening with respect to water. Not least because you put in these expensive system-wide interventions, and unless you are sampling systematically before and after the intervention, you cannot know how effective that intervention has been.

46 For example, one of the interventions was the chlorination of the water system by the addition of chlorine dioxide. If you are simply going to wait to see whether there are more or less infections in patients, then that is a very blunt tool to do that. I would have expected to see a systematic sampling process, sampling key parts of the system rigorously in a set schema, and how you then process those samples. In other words, “What did you look for in those samples?” Did you simply count the total number of bacteria, or did you simply look for “bug X,” and you were not bothered in bugs A to Z apart from bug X? This appeared to be happening with very large numbers of samples, and I believe we saw all the records that were available.

47 The lack of use in real time of definitive fingerprinting methods and whole genome sequencing, is less surprising, because it is an evolving methodology, and was evolving through the time in which these events were going on. The ability to use whole genome sequencing through much of that decade was largely down to reference laboratory capacity rather than being used routinely in each and every hospital. NHS GGC, just like many of the laboratories, were referring bacteria to a reference laboratory (Colindale). The Colindale laboratory is part of UK Health Security Agency (formerly Public

Health England). It provides reference (expert) laboratory services, in particular to identify and type or fingerprint microbes.

48 Where Colindale did have that capability, which perhaps was not as robust and discriminatory as whole genome sequencing but not far off, NHS GGC were doing it in an incomplete fashion. The laboratory was not referring all the isolates and, of course, if you are not sampling systematically, then you are using a needle-in-a-haystack sampling approach. The chances of finding matches are diminished. So, I was less surprised about that, but still surprised that there was not a greater attempt to make these matches. As soon as you make just one match, which is not easy to do this because of all the difficulties of finding bacteria in water sources, but if you did find a match, then that is absolute proof that there is a problem, and you have to focus everything on it and consider closing units and moving, and that is what happened. There was concern about this, but the concern about the putative source of these bacteria was not matched, to my mind, by the robustness of the investigation of these putative sources.

49 Water environmental microbiology is technically demanding. It is key to have a systematic sampling scheme in place in order to increase the chances of identifying contaminating bacteria, which may only be found sporadically (from time to time) in a water source(s). Such a scheme should include the collection of appropriately collected (to minimise the chance of contamination during collection) water samples in adequate volumes, taken from sites that are truly representative of the water system under investigation. Also, when processing the water samples, there are a variety of microbiological methods that can be employed, some of which aim to count overall numbers of bacteria present, and others that can target/identify whether specific bacteria of interest are present.

50 It is always difficult when you look back because we were not there in real time. The best thing we had to go on, having realized that this was what happened, was the IMT minutes. Oddly, they did not highlight this as an issue. Had I sat in one of those IMTs, I would have been banging the table, saying, “We need to do it this way. The sampling techniques need to be like this, and

then we need to type everything that moves." I am not saying there was never any reference to the need to match bacteria, but the drum was not banging very loudly.

Categorising the likelihood of an environmental source for an infection

51 In considering the likelihood of the hospital environment as the source of each bacteraemia, we took into account all available patient, clinical, infection prevention and control, microbiology, local investigations (including Datix and IMTs where available) and hospital environmental data- everything which was provided to us. This is described in section 3.6 of the Overview Report. The standard epidemiological way of determining causality of, and potential links between infections is according to 'time, place and person' information.

52 I have been asked by the Inquiry how the approach of determining causation, based on whether a causal link was more likely than not, map onto the descriptors of the likelihood adopted by the expert panel. A" strong possible' and above represents a greater than 50 per cent likelihood, and we categorised the 'strong possibles' alongside the 'probables,' of whatever strength. On the balance of probabilities, to my understanding, it means more than 50 per cent.

Datasets

53 I have been asked by the Inquiry if I can explain what the various processes and datasets relevant to HAI reporting are supposed to do and how they link together to help identify infection risk and link.

54 The CNR report refers to statistical process charts (SPC). Based on observations over a long period of time, you assess a threshold which you believe is the natural baseline occurrence of a certain event, in this case the bacteraemia caused by a particular bug. You look over several years and you

see that, this particular bug, bug X, occurs once a year causing a bloodstream infection. There is a mathematical way of ascribing limits around that threshold of 1 per 12 months. Those limits, looking at the line above and below, is the line above we are interested in, the limit above. Once that is exceeded, that sets an alert that there is a potential issue here. You could not really set a statistical process chart for every possible bug causing every possible infection, as you would have charts coming out of your ears. In reality you use an SPC process in real time for particular bugs of interest.

55 SPC charts are not infallible. As with all tools / techniques to investigate possible (genuine) increases in infection incidence, it is important to examine the raw (time / place / person) data to identify potential clusters/outbreaks. Thus, SPC charts should be seen as an adjunct to rather than the key determinant of investigations of potential increases in the incidence of infection.

56 MRSA and Clostridium difficile were particular bugs of interest in the early 2000s, so we had national targets for these, and organisations will have used statistical process charts to track the occurrence of those bugs. It would be uncommon to use that process for, in this case, Gram-negative bacteria of potential environmental source. Instead, you would use a common-sense approach to thinking, “I would expect to see this organism uncommonly.” When I see eight episodes of Stenotrophomonas maltophilia, for example, occurring within four or six months I would consider these to be clusters. Those are quite powerful analyses, just to say, “Investigation is warranted here.” Investigation is mandated to keep patients safe. We start off with a basic epidemiological look-see to look at that for the evidence of clustering in time and place, and then we spread the net further to look for putative sources.

57 I have been asked by the Inquiry if the CNR panel had concerns over the use of the systems by NHS GGC and the breaching of upper limits. We were not expecting that for each and every bug there would be prescribed limits; however, it is standard practice to review infections in real time and look for potential clustering and potential common sources or common causes. The

panel were not assured that that process was robust enough, either in terms of when it occurred in response to this time-place clustering or how it occurred. We saw several examples of incident management meetings where the actions set in one meeting would not be reviewed in the next meeting, or any written evidence that they would be reviewed at a later date. The whole point of an Incident Management Team is recognising a potential incident and setting actions. The first thing you do at the next IMT meeting is to review those actions and ensure they have been followed through. We found multiple examples where that robustness of process was not followed.

58 I have been asked by the Inquiry whether, where the necessary datasets are available but the reporting from the laboratory does not confirm a relationship, it means that a relationship is excluded, or whether it means no more than a relationship has not been proved to a desired standard of certainty. I would say that it is absolutely the latter. Finding a match is not a simple process at all; you have to try hard in terms of how frequently you are sampling, how assiduously one is looking for bacteria in those samples, and then how robust are the typing methods used. Each one of those can fundamentally flaw the process.

59 I have been asked by the Inquiry if there are recognised methods for excluding a link. I would say that, had there been a systematic process in place for both sampling in time and place and the way those samples were processed and then the way any subsequent bacteria that were recovered were then typed/fingerprinted, that would have been the desired way of doing things. All one could then potentially argue about is, well, “How frequently are you sampling? You are only doing it monthly, I would have preferred to see it weekly or daily,” or whatever. I am stretching the point for effect. Those tests about robustness of frequency, time and place sampling were not, to my mind, met. The methodology about what was looked for, the systematic process, was not met. The typing process was not met; therefore, it did not meet the ideal for each of those three pillars if you like.

NHS GGC Response to CNR

60 I have been asked by the Inquiry for my thoughts on the document which was prepared by GGC in response to our final draft of the Overview Report. We took this very seriously and we complied a document titled, "*Case Note Review Team Rebuttal of GGC Consultation Response*". My overall impression is that I felt it was defensive rather than constructive. There seemed to me to be an attempt to highlight the lack of definitive proof that we had been able to highlight about the environment as a source of infections, as opposed to accepting the weight of evidence and the balance of probabilities about such sources. Admittedly you would expect an organisation faced with a critical report to defend itself, but I have been in multiple situations where one issues a report and then there is a rebuttal, and I felt it was more defensive than I would have thought necessary. It did not accept the weight of evidence that we produced highlighting both the likely associations with the environment and the deficiencies we had highlighted in process about investigating the bacteraemias.

61 It felt as if the NHS GGC's prime aim was to defend as opposed to learn. I have spent four decades working in the NHS and the culture has changed markedly from when I first started working in the NHS to how it is now. It has changed for the better, to being open and encouraging criticism or critique so that one can learn and improve. I felt that the NHS GGC approach was less attuned to practice today about accepting criticism and how one uses that criticism and critique compared with how it used to be. Way back when I first started, it was like that, but it certainly was less attuned to what I have become accustomed to. As a result of the response by NHS GGC, a number of very minor changes were made to the panel's draft report.

62 Had I been a senior manager at NHS GGC throughout the process, I would have made it an imperative for me to understand what the terms were of this next process, what the terms were, the objectives, I would have striven to get as much information as I could, and then tried to steer, dare I say, "correct," any deficiencies I felt or omissions in the process. I did not recall that taking

place and it felt more like a reactive process, responding to our report, the meeting, and the draft and so on, rather than a proactive response.

63 Within the Overview Report we had highlighted the issue of typing evidence and in particular queried the typing evidence that, according to NHS GGC, showed that the Stenotrophomonas cases were not linked to each other or the water system. We came to the view that this was an example of NHS GGC using Whole Genome Sequencing as a method of excluding a link rather than establishing it. Of course, NHS GGC were critical of this, but for me it seemed they were concentrating on the information they had to refute a potential link. However, that information was flawed in terms of its robustness on each of those three pillars that I referred to and there was no acknowledgement of that lack of robustness in that attempt to refute the links. When you read their report, you can clearly see a defensive approach to this, you see zero next to "definite cases" that fulfil the definition of, "The environment is the proven source." Then you say, "Well, you have been unable to come up with 'definite' and look, this is our typing evidence. We are agreeing with that. There are no 'definites'," as opposed to, "One in three of the cases, based on the grounds of probability, were linked to the environment." The lack of "definites" does not rebut those one in three cases.

64 I have been asked by the Inquiry for my thoughts on NHS GGC response, in particular their comments stating that the CNR ought to have considered additional comparison data from similar units and trends in infection along the years. I would respond by saying that we did not need to go and look at what was happening in a range of other hospitals. Faced with the epidemiological data that showed clear clustering in time and place of these bacteria, it was not relevant what was going on elsewhere. If I found the same thing in another hospital, then they have an issue, but it may be a completely different issue, and I do not need to look there. The epidemiology stands on looking within this institution, or place, or this limited number of places within this institution. The Expert Panel were not saying, "There's been an increase overall in Gram-negative environmental bacteraemia." That might be the case, but that was not our remit. Our task was to match a potential environmental source to each

individual episode. Therefore, looking at what was going on in other hospitals was not necessary.

65 From their response, NHS GGC's position was that there was no baseline for infection. The onus here is on them to make clear what they mean by that, but if what they mean is that we did not look far enough back in time to establish a baseline, then I would refute that. We have five years' worth of data; if you plot what is going on in the x-axis for five years and suddenly there is a peak here and then there is a peak there, your baseline is there. You have enough data in that five-year period to be able to spot clustering in time and place, because a five-year period provides, effectively, a running baseline.

66 I have been asked by the Inquiry for my thoughts on a letter dated, 1 March 2021, from Jane Grant in which she states, that "NHS GGC believe that the CNR indicates that the health board should have approached these issues they were facing in a different way, despite following advice and guidance from national experts and agencies." I recall the Expert Panel being a bit confused by that statement. I think we understood what was being said was that "we did what we were told, so if this report's saying that we shared something different, that is not our fault, because we did what we were told." I do not know precisely what Health Protection Scotland (HPS), told NHS GGC to do in detail. We reviewed the information that we had, whether that was the incident management reports, the clinical way of reporting the infections, the typing, the sampling, whatever. Either the advice they got previously was incomplete or they were just told that "everything's hunky-dory, just continue," which seems incredible given the number of reports and the consistent levels of concern that were expressed. A lot of what we were referring to are basic measures to minimise risk, either from the point of view of how you investigate infection clustering in time and place and/or carrying out surveillance, water sampling, etc, based on how you would carry out an IMT and a follow-up to an IMT and so on. I do not know what level of detail other organisations and bodies went into, but all we can look up is some product of what happened. I do not think it is fair to take a defence line that might be, "We did what we

were told," because I cannot believe they were told the things that we put in our reports because, if they were, then they did not do them.

67 We took the decision at the outset that we would not review other reports, as we did not want to be biased by what had been said. Obviously, we knew there were concerns about the environment and potential infection sources, but had we read reports that kept saying the same thing or lines of evidence, I think that would have naturally swayed us. So, we did not do that. I have not, after carrying out our investigation and writing our report, gone back to see what was agreed and disagreed. To my recollection, there was only one other report in detail that we referred to, but we did that post investigation as we were writing our report. So, what was said or not said, what was done or not done, was not part of our remit. Our remit was to review a cohort of bacteraemias, and we did that.

CNR Conclusions

68 I have been asked by the Inquiry the extent to which the expert panel's ability to come to findings was restricted by the limits of the datasets. I feel that the process took longer than it needed to have taken. Obviously, the pandemic drastically affected the initial predicted timescale, and we acknowledge that in the report. But undoubtedly the difficulties in obtaining complete datasets delayed us, as it meant we had to go around the process again. We had to review every patient twice, and sometimes more than twice because we were getting new information after we had done the first review. We have to assume that we were eventually given all the information that we requested, and that there was available. We could have done with more, if a major part of the criticism was that we did not dig enough. If the question is, "How were our conclusions affected by the information provided?" I think our conclusions came late compared to when they should have been made, but the substance of our conclusions stand.

69 In regard to those limitations, I have been asked what evidence was available in the 'Most likely' group (as described in section 5.6 on page 69 of the Oversight Review) that was absent in the remaining 'possible' cases. More often than not, the "Most likely" classification was not given when there was more information available than for the ones where there is not enough information. Rather, it was the weight of evidence based on time and place, based on similar organisms recovered from water. It is the ticking of those boxes that strengthens the balance of probabilities, as opposed to there being an absence of data. There is no straight-line association between how much information is provided and the degree of likelihood of association, but it is a contributory factor.

70 We had strong opinions based on the evidence available, and there was consensus. The Expert Panel was just the three of us and I cannot recall any instances where we had two versus one. It was, to the best of my knowledge, all three of us in agreement.

71 I have been asked by the Inquiry what evidence would lead to the conclusion that a case was unrelated; was there insufficient evidence to prove even a possibility of a link or was there evidence that positively excluded the link? On reflection I would say it was probably a bit of both. For example, if we get an environmental-type, Gram-negative organism occurring within 24 hours of admission to hospital then the likelihood is that someone has acquired that organism from the water. For it to be from the hands of a healthcare worker, or a contaminated intravenous line, all within 24 hours, is stretching the bounds of probability. That would be a good example where the basic epidemiology would say, "This is unlikely to be hospital acquired," using a 48- to 72-hour window of community association. There could also be an organism you see once, and once only, in a patient's blood, and you do not see it at all in any of the albeit incomplete surveillance data. During the CNR there was one case where we were unable to determine causation. I cannot remember which particular bug it was, but we just did not have enough information available in the timeline. There were some key bits missing and, therefore, to guess those would have would have clearly been inappropriate.

So, some of those basic tenets of when it satisfied time and place and likelihood of community source, for example, were missing.

72 I have been asked by the Inquiry if I am aware of NHS GGC reporting that they were able to link one of the three cases of mycobacterium chelonae to the environment, and if this was achieved because of whole-genome sequencing or Variable Number Tandem Repeat- VNTR. My recollection is that this was based on VNTR typing, where they saw that match. If all that had been done here, there would have been no whole-genome sequencing available and we would just be fingerprinting. There are a few examples of successful defence saying that fingerprinting is not enough to match a criminal to an offence. So, it was not, from recollection, whole-genome sequencing based that provided a match.

73 Whole genome sequencing (WGS) and Variable Number Tandem Repeat (VNTR) methods are both based on the DNA content of the microbe. They use different ways to look at the fine detail of the DNA sequence (code). WGS can provide more information/detail about the DNA code than VNTR and so may be more suited to determining a rule in/rule out for matching microbes; however, this is not always the case. Both methods are generally accepted as being proficient at ruling in/ruling out matches between microbes.

74 Within the NHS GGC response to the CNR they indicate that the CNR expert panel finds it hard to accept NHS GGC's challenge to its findings on causation. During the five-year timeline from which we were working, a number of significant interventions took place. This included ward relocation, which is a major decision, chlorination of water systems and additional extra decontamination and so on. It is hard to believe these measures were taken unless NHS GGC seriously entertained the possibility that the water was a potential source of infection for patients. To then say, "Ah, but there's no definitive proof because there are no cases that match your case definition here, and we did some post-hoc whole-genome sequencing based on incomplete datasets, therefore quid pro quo;" there is a lack of logic there. There is one set of arguments being used to take these very big, significant

decisions and a different set of logic to say, “Ah, yes, but the environment” you know, “there is no proof here.” The grounds of probability, for me, suggest there is ample concern that the environment was linked to a substantial number of these bacteraemias. To say that there is no definitive proof, I think, is ignoring a large part of the evidence story here. The question for NHS GGC would be why you would undertake such significant measures and spend likely large amounts of money if you did not think there was a problem.

HAI Monitoring and reporting

75 During our review we engaged with a number of key staff involved in IPC at NHS GGC who advised us that they had been denied access to water sampling and testing information despite multiple requests. This information was coming from whistle-blowers, with whom we met on more than one occasion. Clearly, we had to be careful about what we were told, and what we said in those meetings, and I believe we were careful. I know that, by the very nature of whistleblowing, it is potentially one side of the story, but some of the things we were told made us feel very uncomfortable about what allegedly took place. This was one of those things. If I was Infection Control staff which this person I am referring to was, and part of my responsibilities is to reduce infection risk to patients to a minimum, and I am denied access to basic, information, it would make my job untenable. I would want to know why am I being denied this? Is there something wrong with these data? Has it turned up something that no-one wants to tell me? Is the data incomplete such that I would want things done in a different way? Would I be critical of individuals? Would I be critical of managers? Am I protecting someone or something? I have never come anywhere near to experiencing this in my career. I might have to ask twice on occasions for such information, but I have never been denied.

76 This made very uncomfortable reading of the situation. Obviously, we do not know what the reasoning might have been, but I cannot think of a valid reason why multiple requests were denied, not just to an interested party but to someone who could not fulfil his or her role adequately. It is not difficult to say, “We haven’t got the information you’re asking for,” or, “It’s written in double Dutch, and we’ve got no-one who can translate double Dutch.” I am being facetious but why would that exist? It is fundamental to enable this person and the rest of the IPC team to minimise risk to patients, so I cannot think of a valid reason why multiple requests would be denied.

Declaration

I believe that the facts stated in this witness statement are true to the best of my knowledge, information, and belief. I understand that this statement may form part of the evidence before the Inquiry and be published on the Inquiry’s website.

Appendix A

A33448007 – Bundle 25– QEUH Case Note Review report March 2021

A43237055 – Bundle 25 Case Note Review team- rebuttal of NHSGGC response.

Appendix B- CV

International Responsibilities (selected)**:**

1. Delivered >140 invited lectures at international meetings between 2002-19.
2. Editorial Advisory Board Member Clinical Infectious Diseases, 2020-
3. Non-Executive Director, Phico Therapeutics, 2018-.
4. Member of Scientific Advisory Board of AiCuris, 2018-.
5. Member of Wellcome Trust CARB-X panel on novel antimicrobials 2017.
6. Co-Lead of EU Innovative Medicines Initiative’s COMBACTE-CDI consortium, 2017-.
7. International Advisory Board for Lancet Gastroenterology & Hepatology, 2016-18.

8. Panel member for MRC UK-China Antimicrobial Resistance Partnership Initiative, 2016.
9. Member of Scientific Advisory Board EU Innovative Medicines Initiative's COMBACTE-NET consortium, 2015-.
10. Expert Panel for Swedish Medical Research Grant applications (all medical specialties), 2015-20.
11. Chair of global publication committee *C. difficile* monoclonal anti-toxin antibody studies (Merck), 2015-18.
12. Consultancy advice / lead clinician for phase 3 studies roles for the development of multiple novel antibiotics including linezolid, tedizolid, tigecycline, ceftaroline, dalbavancin, ceftaz-avibactam: 2000-17.
13. Chair of expert group/publication (*C. difficile* infection in Europe) on key issues for healthcare policy makers across Europe (2012-).
14. Lead of pan-European *C. difficile* surveillance projects (diagnosis, EUCLID; resistance, ClosER) (2012-).
15. International Editorial Board, Journal of Hospital Infection (2011-).
16. Editorial Board Infectious Diseases in Clinical Practice (USA) (2010-).
17. Invited member of *Clostridium difficile* guidelines working group for Infectious Disease Society of America (2010-). 2010 guidelines published: 2016/17 guidelines in progress.
18. Global Scientific Advisory Board for cadazolid, Actelion (2009-18).
19. Advisor to Wellcome Trust's Technology Transfer Strategy Panel (2008-).

National Responsibilities (selected)**:**

1. Clinical advisor to Centre for Health Economics, University of York for the (UK NICE) evaluation of the value to the NHS of ceftazidime with avibactam and cefiderocol for treating severe aerobic Gram-negative bacterial infections (2020-21).
2. Expert advisor to NICE for update of CDI treatment guideline (NG199, July 2021) 'Clostridioides difficile infection: antimicrobial prescribing' 2020-21.
3. Member of two SAGE sub-groups (Hospital-Onset COVID-19 Infection; and Environment & Modelling) and chair a working group (Hospital Environment) of the latter. The Scientific Advisory Group on Emergencies (SAGE) gives advice to the UK government on SARS-CoV-2 / COVID-19 (2020-).

4. Co-chair of Technical Validation Group for COVID-19 diagnostics for UK/NHS use (2020-).
5. Invited Expert by NHS Scotland to participate in Case Review for the Queen Elizabeth University Hospital (Glasgow) (2020-21).
6. NHS AMR Programme Board (2019-).
7. Expert advisor to NICE antimicrobial evaluations project, Univ. of York (2021-).
8. Expert advisor to NICE panel for guidelines on treatment of C. difficile infection (2020-21).
9. Chair of Public Health England sub-group to update guidelines on treatment of C. difficile infection (2018-19).
10. Chair of PHE sub-group to review delivery of C. difficile typing/fingerprinting in England (2018-).
11. Technical Advisor to Policy Research Unit in Economic Evaluation of Health & Care Interventions: 'Framework for Value Assessment of New Antimicrobials.' (2017-18).
12. Newton Prize reviewer (2017-19).
13. NIHR DH/NHS Capital Funding Antimicrobial Resistance review panel (2017).
14. Member of the Medical Research Council Infections and Immunity Board, 2017-21.
15. Chair of Public Health England Rapid Review Panel, 2014-.
16. Deputy Chairperson of Antimicrobial Resistance & Healthcare Associated Infection (ARHAI) (2011-18).
17. Chair of ARHAI sub-groups on HCAI surveillance (2012-14); Surgical site infection Surveillance proposals (2013-14); revised MRSA screening in NHS (2013-14); Antibiotic prescribing diversity (2014-).
18. Expert Advisor to EPIC3 project: Evidenced-based Practice Infection Control guidelines (2012-13).
19. Expert Adviser to National Institute of Clinical Excellence, NICE guidelines (Broad spectrum antibiotics and *C. difficile* infection risk, 2015; Infection Control, 2014; faecal transplantation, 2013-14); evidence summaries (fidaxomicin, 2013; fosfomycin, 2014; telavancin 2014).
20. Advisor on healthcare associated infection diagnostics for Technology Strategy Board (2009-10).

21. HPA (PHE) Healthcare-associated Infection & Antimicrobial Resistance Programme Board (2008-).
22. HPA (PHE) Regional Microbiology Network Lead *C. difficile* infection (CDI) (2007-).
23. Appointed as member of ARHAI - advisory committee to the Department of Health (2007-). Lead for CDI.
24. Lead Examiner for Royal College of Pathologists (MRCPath) Medical Microbiology Practical Examination (2001-02, 2005, 2008, 2010, 2013). Assisted in re-design of MRCPath Part II examination. Lead for setting of Scientific Paper Evaluation questions - MRCPath Part II (2004-).
25. Lead / UK Investigator 15 clinical trials of new anti-infective drugs (1999-). Advisor on trial design/results/ registration issues.

Research Awards: In the last 5 years ~[redacted].

Selected Research Grants:

1. Biological Research Centre, Leeds. One of six theme leads – Infection and Antimicrobial Resistance. NIHR (2022-27) ~[redacted] (Theme Lead).
2. Mechanisms of spore engulfment in C. difficile. Medical Research Council (MR/V032151/1) (2021) - ~[redacted] (Co-Investigator).
3. Reducing the infectivity of SARS-CoV-2 on PPE gowns used in healthcare environments. Engineering and Physical Sciences Research Council (EP/V056921/1) (2021) - ~[redacted] Lead
4. Detection of SARS-CoV-2 in faeces. JP Moulton Foundation (2020) - [redacted] (Lead).
5. Health Protection Research Unit in Healthcare Associated Infection. NIHR 2019-24 - [redacted] (named academic partner to U of Oxford/PHE).
6. Transforming Antimicrobial Research with Gut model Evaluations for Therapies and Diagnostics (TARGETED AMR). NIHR (200633) (2019-21) - [redacted]) (Lead).
7. Development and Validation of in vitro Healthy and Dysbiosis Human Microbiota Models to Facilitate Early Phase Antimicrobial Development. Centers for Disease Control. (2018-19), [redacted] (Lead).

8. Combatting Bacterial Resistance in Europe – Clostridium difficile Infections (COMBACTE-CDI). European Union Innovative Medicines Initiative (2017-) – [redacted] in kind EFPIA contribution (Co-Lead).
9. Multisite study of environmental contamination in hospital washrooms according to hand drying method. European Tissue Symposium. (2017-) - [redacted] (Lead).
10. Accelerating development of infection diagnostics for patient management and reduction of antibiotic misuse. MRC. (2016-), [redacted]. Co-app.
11. Principal/UK Investigator 14 clinical trials of new anti-infective drugs, 1999-2015.
12. Novel test for rapid bacteraemia detection. Spectral Platforms (2015-), [redacted]. Lead.
13. Health Protection Research Unit (Oxford), HCAI & AMR. NIHR (2013-16), [redacted]. Co-app.
14. Antibodies to treat severe CDIs. TSB (2013-16), [redacted]. Co-app.
15. WGS for patient care/surveillance. HICF, Wellcome/DoH (2013-16), [redacted]. Co-app.
16. Pan-Europe CDI surveillance (Co-Lead), resistance (Lead), diagnosis (Lead). European CDC [redacted], Astellas [redacted], Astellas [redacted] (2010-14).
17. Modernising Medical Microbiol via WGS. NIHR (2009-13), [redacted]. Lead on C. difficile. Co-app.

Invited Oral Presentations: >250, including >100 international.

Publications: 13 Books, 25 Chapters, ~600 Publications, >300 Abstracts.

Scottish Hospitals Inquiry

Witness Statement of

Professor Michael Stevens

Personal Details

1. My name is Professor Michael Stevens. I am retired but continue to hold the role of Emeritus Professor of Paediatric Oncology at the University of Bristol. My last clinical role prior to retirement was as a Consultant Paediatric Oncologist at the University Hospitals Bristol NHS Foundation Trust and the Bristol Royal Hospital for Children.

2. I have prepared this statement on the basis that reader has read the Case Note Review Overview Report, March 2021 ("the Overview Report") **[A33448007 – Case Note Review Overview Report (March 2021) - Bundle 6, Page 975]** and will refer sections with that report within this statement. I am one of the authors of the Overview Report and will adopt it as part of my evidence to the Inquiry.

3. Once we had completed our draft report NHS GGC provided us with a lengthy document as a response to our final draft. We took this very seriously and we complied a document titled, "*Case Note Review Team Rebuttal of GGC Consultation Response*" **[A43237045 – CNR Team Rebuttal of NHSGGC Consultation Response - Bundle 25, Page 157]**. We took each of their points in turn and where necessary queried or challenged what they said. We did make some changes to our draft document based on the response to some of the things they said but we did not change the overall conclusions, it was simply changes in order to clarify matters. This document was not shared with anyone apart from our team.

Professional Background

4. I completed my undergraduate degree in medicine at the University of London in 1974 and graduated with an MB BS (with distinction). I went on to obtain the MRCP (UK) in 1976 and accreditation for training in Paediatrics in 1982 and in .

Paediatric Oncology in 1986. I was appointed FRCP by the Royal College of Physicians, London in 1992. In 1997 I was appointed a Fellow of the Royal College of Paediatrics and Child Health and awarded Fellowship of the Royal College of Radiologists in 2003.

5. Paediatric Oncology is broadly divided into professionals who look after children with blood diseases including leukaemia and those that look after children with what are understood colloquially as solid tumours. I had a special expertise and interest in the management of children with soft tissue sarcoma.

6. Despite the majority of my career focusing on children with solid tumours I gained comprehensive clinical experience across the board and have experience of looking after children across the breath of children's cancers across my clinical practice. When I first became a consultant in the UK, I undertook the care of children with leukaemia for several years but as my degree of specialism grew, I stopped taking primary responsibility for leukaemia. It should be noted that when undertaking weekend or night work or when on call for ward supervision I was responsible for all patients, so I was involved consistently with patients with leukaemia despite not being primarily responsible for their treatment.

7. I have been involved in a number of significant reviews which are detailed in my professional CV which is appended to this statement. I have also undertaken a number of reviews about patient management for the NHS, both within my own hospital and others. I have experience of the detailed investigation of individual patient management as well as far larger scale reviews of service delivery policy and the practical implementation of health service strategy both in the UK and abroad.

Appointment to the Case Notes Review Expert Panel

8. On 11th December 2019 I received a telephone call from the Chief Medical Officer for Scotland, Catherine Calderwood. She explained, in brief, the emerging situation at NHS Greater Glasgow & Clyde Health Board (NHS GGC) and the recent establishment of an Oversight Board by the Director-General of Health and Social Care consequential on the escalation of the health board to Level 4

of the NHS Scotland Performance Management Framework. She explained that one of the work streams within the role of the Oversight Board was likely to be a need for a review of cases. No more specific information was provided at this point. She stated that she had received a recommendation that I would be a suitable person to undertake that review and that they wished someone from outside Scotland to undertake the role. I said at that stage that potentially I would be interested but there was clearly more to discuss.

9. Around a week after my initial conversation with Catherine Calderwood I was invited to a telephone conference involving Fiona McQueen, who was the Chief Nursing officer at the time and the chair of the Oversight Board, together with Philip Raines who was a civil servant in the Chief Nurse's office. Professor Marion Bain was also in attendance and her role was to have executive oversight of the Case Note Review together with Catherine Calderwood. They provided me with more detail of what the Case Note Review was hoped to achieve, I was asked questions and asked to submit a CV. I was asked to ensure that I was available for meetings in mid-January 2020 and subsequently travelled to Edinburgh for a succession of meetings.

10. The last meeting was with Fiona McQueen and Jeane Freeman who was Cabinet Secretary for Health at the time when I was offered the role. This was the only time that I met Ms Freeman. I did have a few meetings with Fiona McQueen, but she left her role before the end of this process and a new Chief Nursing Officer was appointed. We had very little direct contact with anyone other than Marion Bain and Phil Raines. We were aware that others were being kept up to date with the progress of our work.

11. I had been provided the names of Professor Mark Wilcox and Gaynor Evans and told that the three of us would be working together. I did not know either of them prior to meeting them on 24th February 2020, and I was not involved in either of their appointments. I was relieved that people had been identified with their skills because it was apparent to me from the outset that this review could not be conducted by a clinician alone and that input was necessary from microbiology and infection control expertise. I was not asked for advice or suggestions on recruitment, and I would not have been able to give any on the roles that Mark

and Gaynor took up.

Composition of the CNR Team

12. There were four component parts to the CNR Team. First, there was the Expert Panel which comprised of myself, Mark and Gaynor.

13. The second team was led by Pat O'Connor and included Professor Peter Davey from the University of Dundee. We initially referred to them as the "ground team". They would extract information from all the clinical records for us and provide information about patients who had infections. Pat O'Connor and Professor Peter Davey were absolutely central to the search for relevant clinical information and passing it on to us.

14. Pat O'Connor and Peter Davey were initially appointed to implement work on the Paediatric Trigger Tool ("PTT") referred to in Figure 3.2: Case Note Review Process Map and elsewhere in the report. The term 'ground team' was used only at the very beginning of our work and related to their responsibility for accessing clinical records 'on the ground'. We subsequently referred to them as the PTT team. When first considering how our work would be carried out (prior to the constraints imposed by the Covid pandemic), I had assumed that I would have played a greater role in evaluating data from clinical records at source by visiting Glasgow. In the event, this was not possible and we therefore relied on the PTT team (so called as they were responsible for this component of the Case Note Review) to collect the data we needed from clinical records. The work of the PTT (and of the HPS) team is further described in 3.6 and, more specifically, in 3.6.2.

15. The third team were from Health Protection Scotland (HPS) who subsequently changed their name to ARHAI. This mainly comprised of Fiona Murdoch, Lead Healthcare Scientist, and Jane McNish, a nurse epidemiologist. Their role was the management of other aspects of clinical information.

16. Where the Overview Report describes the work of the Clinical Team at 2.6.2 it is referring to both the ground/PTT team and the team from HPS. Pat O'Connor's team extracted clinical information from case notes and patient records and then

Fiona Murdoch's team collated and presented to us the microbiological data relating to the patients in the cohort. The HPS team also took on other tasks such as generating information about where in the hospital the patients had been nursed so we could ascertain which ward patients were in at the time of their infections or immediately prior thereto. The HPS team were also responsible for helping us manage the information received from NHS GGC about environmental sampling..

17. The fourth team was the secretariat or support team as described at 2.6.3 of the Overview Report. This was made up of Marie Brown and Emma McKay. They organised our meetings, managed our workplan, documents and records, and undertook other administrative tasks.

18. The core project team consisted of all members of the Case Note Review teams with Professor Bain and other members of the Oversight Board. It met about once a month and there would usually be around 8 or 9 individuals in attendance. It was from these meetings that information was passed back to the Oversight Board. During these meetings we would discuss supplementary verbal and written reports and provide feedback. We did not keep formal minutes, but an action log was kept where we noted outcomes or progress reports.

19. The Case Note Review was one of the various components of the work of the Oversight Board. Professor Marion Bain, in addition to chairing our core project team meetings, also held responsibility for the oversight of the governance aspect of the ongoing management of infection in NHS GGC. Professor Bain was our direct line of report. She did in the early days have a lot of dealings with NHS GGC as she used to go and work in the organisation regularly. This meant she was in a good position to guide us in understanding where the information we required could be sought. Phil Raines on the other hand, was our 'go to' person at the outset of our work and provided day to day advice about our review in relation to the wider work of the Oversight Board.

20. We were essentially responsible to Professor Bain for progress of the review and if there were significant decisions to be made. For example, in the Summer of 2020 we were unable to sustain meetings because Gaynor and Mark had

significant responsibilities for COVID management in England. We therefore required to stop our work for a short period. The decision as to that was taken together with Professor Bain.

21. I visited the Royal Hospital for Children in Glasgow in early February 2020 and met with some of the members of the Infection Prevention and Control team. I then attended a meeting with Pat O'Connor in Edinburgh. The panel met for the first time on 24th February 2020. Unfortunately, Covid struck shortly after, and we needed to move all our work online. I think we managed this very successfully.

The Risk of Infections to Children with Malignant Disease

22. The generality of the Case Note Review was about infections in children with malignant disease, i.e. Leukaemia and cancer. There were also a small number of children included in our review who had non-malignant but serious blood disorders, for example Aplastic anaemia and severe Haemophilia. There is typically a higher risk of serious infection for those having bone marrow transplantation but in reality, that risk confronts all children being treated with chemotherapy.

23. A large component of the work of an oncologist is supportive care. In cancer care you use potentially lethal doses of drugs and then salvage the patient from the side effects of those drugs in the hope that they will have a damaging effect on the disease. Supportive care is generally the management of infection, nutrition and transfusion requirements. It comprises of a huge component of the work. All oncologists and haematologists have a day-to-day responsibility for the management of children with infections. There are certain types of unusual or persistent infections for which you would seek advice from microbiologists and in some cases infectious disease colleagues. The management of infection is part of the bread and butter of our role, and we have protocols in place for the management of infection.

The Terms of Reference

24. The Terms of Reference ("TOR") of the Case Note Review are set out in chapter 2 of the Overview Report. They were not set by the Expert Panel. They were determined at an early stage in the project. Although I was involved in discussions about aspects of the approach to be taken by the Case Note Review from January 2020, draft TOR for our work were provided prior to the first meeting of the Panel (held in Edinburgh on 24 February 2020) by Phil Raines. The TOR as reproduced within chapter 2 of the Overview Report are substantially unchanged from that draft. I recall that we discussed them and made some suggestions and they were accepted at that meeting. I do not think we (the CNR Panel) significantly influenced them. We may have refined the language to a degree but did not fundamentally alter them.

25. A key question asked in the Terms of Reference (set out in Section 2.2 of the Overview Report) was the extent to which it is possible to associate the infections identified in patients within the CNR with the environment of the RHC and QEUH. I have been asked about the word "associate" and what it means in this context. I can confirm that this does not mean the same as "caused by". "Association is not causation" is a key mantra in epidemiology. Merely because something happens at the same time or alongside something else does not necessarily mean that one causes the other. It can raise the question that there might be a link. We were tasked with searching for evidence that might link an infection in a patient with a source of that same infection somewhere in the hospital environment. Our investigation was set up to attempt to see whether we could draw inferences between the identification of a bacteria in a child with the identification of the same bacteria somewhere in the hospital environment.

26. Due to the nature of the infections we were dealing with, we focused on the water supply and the wet parts of the hospital. We did not investigate the air supply because the nature of the transmission of infections identified for the CNR was not airborne, and we were much more interested in water supply, drains, sinks and surfaces. We were interested in where water went and how areas were being cleaned. If water is contaminated and then it is used to clean a surface, then bacteria are potentially on that surface.

27. For avoidance of doubt, the term ‘environment’ in the Overview Report refers to all surroundings to which a patient may be exposed. This may be the hospital, the home or other places in between. However, in the context of our work, given the nature of the infections and the questions of association we were asked to explore, the use of the term environment was almost always synonymous with the hospital surroundings and, because of the predilection of Gram negative bacteria for wet places, we focused on aspects of the environment relating to water (its provision, use, drainage). Water may also be present in air systems, such as air conditioning systems but distribution of Gram-negative bacteria by air flow is not a recognised risk in contrast with, for example, certain fungal infections which we were not asked to investigate. My colleagues Mark Wilcox and Gaynor Evans would be much better placed to provide a more detailed commentary on this point.

28. The most certain scenario would be to find a bacterium in a patient which we could characterise in a way that when you compared it with the same bacteria found in a water supply you could say it was the same infection. Without such certainty, if a patient was shown to be in physical proximity to an identified source of infection, you would be closer to suggesting a causation. This still involves an element of assumption regarding the environment and the child’s exposure to the environment. As our report sets out there was a lot of uncertainty and one of the reasons for this is because the environment was not being surveyed in a particularly frequent manner, and testing was not being undertaken that would allow us adequately to compare the nature of some of the bacteria that were identified in patients with the bacteria found in the environment.

29. Testing to obtain definitive proof would require a regime of testing that was able to demonstrate the presence of precisely the same bacteria in the environment of the patient as found in the patient, with a plausible means of their interaction. This would require prospective and extensive screening of all parts of the hospital environment to which the patient was exposed including, for example, areas like radiology departments, operating theatres as well as ward areas. Confirmation of bacterial similarity would require genome testing of paired samples. This is generally something that is not achievable at scale and might only be

implemented if there were concerns of the nature identified at GGC.

30. As time went on, we increasingly believed that there were sufficient grounds to be suspicious of the environment that a more robust scrutiny could have been set up to try and identify more precisely the link between infections and the environment. Steps were taken by NHS GGC to improve the water supply and sterilise the environment so presumably they believed that the environment was in some way responsible for the infections, but the data collected by them did not help to define that.

31. For avoidance of doubt, 'linked to' in the context used in our classification of infections (described in section 3.6.5 and reported in section 5.6) reflected the level of certainty about the likelihood of a hospital source for the infection. This is discussed in section 3.6.6.

32. When considering issues of potential association, it is useful to reflect on where you see a sequence of infections occurring in different children over a relatively short period of time (a cluster). This would suggest that there is something potentially in the environment- why else would half a dozen children get this particular kind of infection at the same time if there was not some kind of heightened environmental risk? The background to all this is complicated further by the fact that these children are more vulnerable to infection regardless of how risky the environment could have been. Bacteria will not always cause an infection where they are found in healthy people, they are naturally found in the body, especially the gut, but natural defences limit the likelihood of infection except when immunity is challenged.

33. NHS GGC and HPS had, as well as ourselves, managed to identify patterns of infection, and the follow up question to that is how significant those patterns were. We took the view that some of the patterns of infection were more significant than others. I believe NHS GGC in the past had been reassured that they were not outside the ordinary.

34. We provided information regarding patterns of infection in section 4.3 and illustrated by some of the Examples given in chapter 8 (particularly Examples 8.2

and 8.3) before being discussed in section 10.2 where we stated “By 2018, we suggest that simple observation should have identified a disturbing pattern characterised by the occurrence of bacteraemia caused by some very unusual microorganisms and apparent clusters of some of those more commonly encountered”. One example of an unusual pattern of infection by a bacterium not uncommonly seen in children being treated for cancer would be that of Klebsiella (described in section 4.3.3) where 8 of 9 episodes of infection identified in 2016 occurred within a 6-month period and 8 of 9 episodes identified in 2017 occurred in a 5 month period. I have worked as a consultant in two UK paediatric oncology units larger than NHS GGC where I think that the frequency and clustering of Klebsiella infection would have been considered unusual. Similar data for Enterobacter and Stenotrophomonas, other relatively common bacteria in this population, are discussed in sections 4.3.1 and 4.3.2 and would, I believe, raise similar caution.

35. An example of the occurrence of less usual infection would be Mycobacterium chelonae which favours water / water systems. Although infection in immunocompromised patients is more likely, the identification of 3 cases within the Case Note Review would raise concern.

36. Our approach to these patterns of infections was very broad. We were interested in gathering information about bacterial contamination of any aspect of the environment, although a lot of the focus was on water sampling. There are many other sources of environmental testing that can be undertaken. It is true that if you sample areas that are dirty, such as drains, you may find information that cannot be interpreted successfully. For example, if you are looking at the management of intravenous catheters in children. Those caring for them should wash their hands and therefore it is important to go into detail and discuss audits of cleanliness in terms of clinical practice and environmental cleaning as you require to address every possibility of how a bacteria could get from one part of the environment into a patient. The patient’s environment obviously includes outside the hospital and on occasion we required to consider whether or not infections arose from their own environment. We did identify one patient where we considered that the infection had not arisen within the hospital at all.

37. If it was established there was contamination of water, it would raise a concern about the bacteria in the water supply spreading to other parts of the environment. Again, though it is important to recognise that bacteria are very often present in the human body so contamination could come from toilet use and such like and not necessarily contaminated water supply.

38. It was difficult to determine which particular aspect of the environment was the likely source where we considered there was a likely link with an infection in a patient. As indicated, we focused our attention on aspects of the environment relating to water (its provision, use, drainage) but the data available from surveillance at such sites was very limited.

39. We believed there were circumstances where certain bacteria may have more likely arisen endogenously (i.e. within the patient him/herself). For example, where we saw clear evidence of diarrhoea or other indications of gut damage in the presence of a bacterial infection, we considered the possibility that the source was endogenous via gut translocation rather than via contamination of the external environment.

Possible Ways Infections Could Occur

40. We tried to think of all possible ways in which infection could occur, be disseminated, or even prevented. As discussed in part 5.2 of the Overview Report one of the areas we looked at was issues surrounding maintenance, either undertaken routinely or because equipment or system needed to be repaired. This is because such activity may disrupt the environment and potentially disseminate contaminated sources. Issues such as blocked sinks or pooling of water from blocked sinks would be routinely reported to maintenance to fix. One of the frustrations we encountered when looking at maintenance logs was, for example, that a plumber would be called to a specific ward to deal with a blocked sink but there would be no record kept about which sink it was. When it came to trying to link those kinds of interventions to individual patient infections it became impossible. We would know which ward and sometimes which bed a patient was in, but we would not know if they had been in the room where a sink

had been manipulated by plumbers that day or the day before. The information was not useful in this respect.

41. We found very few examples of where “work undertaken in close temporal and physical relationship to the care environment of a patient could be linked to the occurrence of a specific infection or to potential outbreaks” (Overview Report, section 5.2 page 60). We could make general observations for example where we know that plumbers were called to a specific ward several times in a month. We might not know why they were called so it was not very useful information, but it might suggest that there was some issue occurring. Despite that, there might not have been any infection of interest that month so no clear pattern of association. If the maintenance records had been more precise, we would have had a better chance of establishing association.

42. One of the commonest type of infections in central lines do not involve the type of bacteria we were concerned with in the review. The most common kind of infections in central line are gram-positive bacterial infections, staphylococcus particularly. These bacteria sit typically on the skin and are present in everyday life. They only become a problem under certain circumstances, and they are particularly difficult when a central line is fitted. With this in mind, we applauded the work done by the Quality Improvement Group to push down the incidence of central line infection, but the reality is, as important as that work was, it was unlikely to have any significant impact on the occurrence of gram-negative environmental bacterial infection.

43. In Chapter 9 we outlined evidence of good practice and I believe we acknowledged the work the Quality Improvement Group had done. We also indicated that we found evidence of very good documentation of central line care in the nursing records.

44. When it comes to gram-negative environmental bacterial infections, although central line care is very important to minimise the risk of contamination, it does not itself address the source of such bacteria in the environment.

Identification of Cases for Inclusion in the Review

45. This is discussed in some detail in section 3.2 of the Overview Report. The work relating to the identification of cases by HPS was largely completed prior to the first panel meeting. We were presented with a rationale for the identification of cases. HPS had looked at a number of different sources of information because there were different datasets within NHS GGC. They completed work to avoid duplication and to be as inclusive as possible to obtain the fullest possible dataset for us to look at.

46. We did talk about the datasets and the information provided to us. We were confident that all the infections were appropriately included but we do not know if there were other infections that were not in the dataset but occurred within the period of our review. We had to accept that there was a sufficiently rigorous selection of the data, but I had no reason to doubt that the dataset that was presented for us to work on was in any way inadequate.

47. The HPS report was presented in 2019 – **[A33448012** - **HPS Review of NHSGG&C paediatric haemato-oncology data October 2019 – Bundle 7, Page 214]** - before we were involved and is discussed more fully at paragraph 8.2.3 of the Overview Report. The generation of the cohort of patients was identified prior to the first meeting of the panel. We were presented with the cohort and that is what we worked from.

48. At our first meeting it was agreed that the dataset was appropriate. There were representatives from HPS there. I believe Lesley Shepherd was representing infection control.

49. Prior to the first meeting of the Panel on 24.2.20 at which the cohort of cases to be included in our review was agreed, I had participated in a couple of other discussions which included consideration of the make up of the cohort. I have notes of meetings in late January and early February at which Marion Bain was present but I have neither noted nor remember her taking a particular position. It is my recollection that HPS took the lead on this and an email received from Phil Raines on 5.2.20 (to which Marion Bain was also copied in) stated *"I will find out from HPS how it is defining the sample and provide the full detail as soon as I*

get it. My suggestion is to make that available for full discussion – and final agreement – when we all meet on Monday, 24 February".

50. We all agreed the time period, which was straightforward. The hospital opened in June 2015 and the dataset went back on one month before to ensure that if a child were transferred with an infection, it would be able to be traced back to the previous hospital. The dataset ended in December 2019 which was shortly before we started our work.

51. We did reflect on whether other cohorts or bacteria should have been included. For example, very early in our discussions we talked about fungal infections, typically aspergillus fungal infections as these are environmentally linked and do occur in haematology-oncology patients. We discussed it and pulled out some data looking at the early instance of fungal infection, but we concluded two things. Firstly that it was not likely that we would be able to ascertain that there was a link to inappropriate environmental contamination, and secondly that we were not convinced that the pattern of infections from the preliminary data we had access to was of sufficient concern. It does however appear more frequently in environments where there has been recent building work, and it is of a particular risk for immunocompromised patients. We did therefore challenge ourselves whether there were additional infections that we ought to have been considering.

52. We reflected more than once on the question whether if the environment of the hospital was in some way a risk factor for patients, should our work not have also included a scrutiny of infections in other parts of the hospital. There were two reasons for that, firstly because haematology and oncology patients were mainly managed in one area, although obviously visited other areas of the hospital and secondly as we continued our work, we heard the odd reference to concerns about Gram-negative infections occurring in other areas, specifically the NICU and PICU. We were not asked to extend our work and we did not interrogate those data. I do suppose that if you wanted to look at the environmental health of the whole hospital, a much bigger project could have been set out, but it was not what we were asked to undertake.

53. There may have been mention of a wider review in my early discussions about

the project (i.e. before the CNR) but it was pretty clear from the outset the focus was to be on haemato-oncology patients.

54. The statement in 4.3.5 about the frequency of infection was prefaced with *"whilst it is not possible to state this with certainty"*. The HPS Review of NHSGGC paediatric haemato-oncology data 2019 report **[A33448012 – HPS Review of NHSGG&C paediatric haemato-oncology data October 2019 – Bundle 7, Page 214]** discusses some of the challenges in demonstrating changes in frequency of infection over periods of time and recommends the use of aggregated data for all bacterial infections within the subgroup of interest to provide a more reliable indicator. Nevertheless, we looked at the relative frequency of individual types of bacteria within our review in relation to those most likely to be seen. As stated, Klebsiella and Pseudomonas are likely to be the most common yet the number of Enterobacter and Stenotrophomonas infections both exceeded that of Pseudomonas and, for Enterobacter, were close to the number of Klebsiella (see Table 4.2 in our report). These are small groups of data and comparisons of this type must always be considered with caution, but this nevertheless influenced our opinion.

The Use of Control Measures to Understand Infections

55. A control measure as referred in paragraph 3.3.1 of the Overview Report is anything you might do to potentially minimise the impact of an environmental risk. For example, NHS GGC chlorinated the water supply at a point in time, which is a control measure. The Health Board also instigated enhanced cleaning regimes which could also be considered a control measure. Control measures are a useful data source in an epidemiological study, for example if there is a change in the incidence of infections following on the implementation of a control measure.

56. When considering a timeline if you see a control measure that has been introduced and the infection numbers drop, it could potentially help you to conclude that the infections were more likely to be linked to the environment. For example, if there was a run of infections in a particular area of a hospital and an

aggressive programme of augmented cleaning was introduced and thereafter the frequency of infections dropped, it could be justifiable to say that there was something in the environment that was suboptimal but that had been overcome. It could be justified to say that there was a relationship between the infections previously identified and the state of the environment. It becomes more difficult when attempting to assess direct impact on patients and it is also very difficult when considering sporadic and relatively infrequent nature of these infections. The influence would be quite hard to pick up in observations. The use of 'direct impact' here is synonymous with defining the burden of the infection on the patient.

The Burden on the Patients

57. At the outset of our work, it had not occurred to me how important it was for us to be able to say something about the burden of these infections because at the beginning the focus was on that these infections had occurred and the question was, were they caused by the environment? As the work progressed, we began to realise that we had something important to say about the impact of these infections on individual patients. I took the attitude that if the infections did not matter, then why were we doing the work? In reality the infections do matter, and with our data we are able to point out the real impact on patients, whether or not the infection was caused by the environment.

Methodology

58. Our methodology is set out in Chapter 3. I suppose I took a significant lead in defining the methodology. It was a little iterative. The process therefore evolved slightly but they were essentially team decisions. I took the lead on how we were going to handle the integration of the clinical and epidemiological data. Fiona Murdoch at HPS presented the way in which she was going to provide us with her information, but we agreed on it and worked together. It was a bespoke approach and as there were different channels of information available to us, we needed to design our own approach in terms of data collection and its synthesis.

Certain elements such as the PTT and the National Framework for Adverse Events in Scotland were taken as previously defined.

59. No other methodologies were considered. I was not aware, at the time or now, of an established methodology we could have used to undertake an assessment of this nature, considering each infection in every patient. The start point was the need to extract relevant clinical and microbiological information for each episode in order to establish a clinical timeline against which we could interrogate a) whatever data were available about how the infection episode fitted within the pattern of other infections in the same group of patients and, b) whether there was useful data from the hospital environment at that time.

60. The demonstration of a causal relationship between an infection and the presence of the same bacteria in the hospital environment requires (as I discuss later) robust time/person/place data supported where possible by genomic typing.

61. The work required to obtain such data prospectively in all cases would be substantial. This is why monitoring infection rates and responding to an unusual pattern (in terms of frequency and type of infection) provides an opportunity to introduce data collection of this type when concerns are raised.

Case Definition

62. At section 3.2.2 of the Overview Report we explained the defined protocol by which blood cultures are identified for inclusion in the study. This was because the difficulty is that if a patient is infected with an organism that shows up in a blood culture, repeated blood cultures may be taken and therefore there may be sequential positive blood culture results over a period of time. The first part of the case definition was that there would be a 14-day period in which you do not recount the same infection. For example, if you had a positive blood culture and then eight days later you were tested and found to have the same blood culture, it would not be counted as a second infection. In that case an assumption would be made that it was linked to the first infection. This tries to avoid a situation where incidents are overestimated. This is an area where both Mark Wilcox and

Gaynor Evans will have an expertise.

63. “Hospital-associated infection is a positive blood culture in a patient who’s been hospitalized for 48 hours, but a healthcare-associated infection is a positive blood culture in a patient within 48 hours of admission, but who has nevertheless had contact with healthcare in the previous 30 days.” Using the same initials for both scenarios may potentially cause problems. More importantly, there is a potential that you are looking at slightly different groups of infection; one that is acquired in a patient who has already been in hospital for at least 48 hours, and one in a patient who has come into hospital, and whilst they may have had contact with the hospital as an outpatient, say, in the past month, they weren’t necessarily acquiring the infection whilst they were in the hospital. This does raise questions about the origin of the infection.

The Use of the Paediatric Trigger Tool

64. The Paediatric Trigger Tool (PTT) is explained in section 2.4.3 of the Overview and the purpose of a trigger tool in general is explained in the first paragraph of section 3.4.2 of the Overview Report. The use of the PTT in the CNR was established prior to my appointment. I think it was the decision of the Deputy Chief Nursing Officer, Diane Murray and she had a particular interest in it. I think she felt that the application of the PTT would illuminate what was happening at GGC.

65. The requirement to include the PTT in our review was made clear to me at the outset and before the CNR panel had met for the first time. I had not previously been involved in its use in my clinical career although I was aware of it as a tool for measuring adverse events in health care settings. I was unclear what its use would bring to our work and did not feel it would directly address the key terms of reference set for the CNR. This was discussed in some of my initial meetings and again at the first meeting of the Panel on 24.2.20. It seemed to me that the PTT was to be used to assess aspects of the quality of the care provided at RHC and I had acquiesced to this. However, I sought to ensure that when clinical data was collected from the patient records for the PTT, the data I had defined as

required for our clinical timeline for each patient would be collected at the same time. In the event, this worked well, especially as we came to rely heavily on Pat O'Connor and Peter Davey for the abstraction of all relevant data from clinical records and to return to these, often on multiple occasions, to answer our queries. If they had not fulfilled this role, we would have had to identify an alternative team to do this.

66. The PTT did not trigger the collection of patients into the cohort – as indicated in this question, this was undertaken by the microbiological definition reached by HPS. Little if any of the data collected specifically for the PTT was of direct use in helping us reach conclusions about any link between infections and the hospital environment.

67. Previously I had no personal experience of utilising the PTT. I initially did not understand what it would bring to achieving our terms of reference and I would say that I did initially push back on its use but I rapidly realised that the information that was required to be extracted from the case notes for the PTT actually allowed for all the information that I wanted for our data synthesis of these patients to be collected at the same time.

68. As time went by, I began to realise that the PTT had a value of its own. Pat O'Connor and Peter Davey wrote a separate detailed report about their findings, which was submitted to the Oversight Board with the expectation that it would be published at the same time as the CNR. This did not happen and I was unable to ascertain why or at what level this decision had been taken. I remain unclear whether this report has yet been made available within NHS Scotland but whilst it did not address the issues of causation in relation to infection and the environment, the findings offer useful insights into good practice in care and record keeping at NHS GGC, and into areas where improvement might be made. On that basis we decided to include the analysis of Adverse Effects experienced by the children, made possible by the work of the PTT, in our chapter on the impact of infection. My initial reservation about use of the PTT was that some of the clinical features were being scored as part of the trigger tool were potentially irrelevant to our patient population and others were so frequent that they were uninformative. I can explain my initial concerns by reference to the Paediatric

Trigger Tool Score Sheet in Appendix C of the Overview Report (at page 132). The first column is a list of possible triggers. The second allows whether the trigger has occurred to be recorded whether the incident has occurred during the period under consideration. The third column records whether or not an Adverse Event (AE) occurred, and fourth column provides for the assessment of the severity of the AE. Returning to my initial concerns trigger PG5 is 'Cranial Imaging' which is presumably a CT or MRI scan of a head or brain. If a child has a brain tumour, then multiple cranial images will be taken because it is not only essential for diagnosis but also for monitoring response to treatment. I did not think that scoring whether or not a cranial image had taken place represented an adverse effect because it did not. It was a required part of treatment. Similarly, on the next page (page 133) there is a trigger PM6 "Anti-emetic given". This is a medication used to stop being feeling or being sick. It is well known that chemotherapy can make you feel sick, so we routinely give antiemetics to patients receiving it. Children would very frequently be given an antiemetic injection prior to and for a day or two after the administration of routine chemotherapy. Also, PL2 'Transfusion' – the use of transfusion of blood, red blood cells or platelets is an integral part of the supportive care of children receiving chemotherapy. I thought it was uninformative. Some of the other things are manifestations of children who are very sick, for example PL5 refers to abnormal shifts in the serum level of sodium but these children are being monitored for these things on a routine basis. I think the intention of using the PTT was to look across a range of different cases. For example, most hospitals will take a random sample a month prior to admission and applying the PTT they will pick out patterns and be able to pick out things such as sodium levels not being correctly monitored and then respond to them. It is a tool for improving practice.

69. As our investigation and processes evolved, Pat O'Connor and Peter Davey, started analysing the data and comparing it to the data from the reporting of adverse events in Datix with NHS GGC. I recognised in this the value for NHS GGC in improving their recognition of adverse events and their use of that information to improve care.

70. The clinicians in the RHC were very exercised about the use of the PTT at the very outset and I was challenged about its use. I think I first met with them on, 3 February 2020, before the panel had even assembled. I do not have a note of individual names of who attended that meeting but there were seven or eight clinicians, predominately senior medical staff from the Oncology team in attendance. It was difficult for me at that point to justify its use because I had not used it myself before and could not rely on firsthand experience. I think they felt it was an attempt to identify that their treatment was suboptimal but in fact if you read our conclusions, we felt that the treatment that the patients received and the documentation of medical notes and the collaboration between the clinicians and the microbiologists in the management of patients was very good. We did however think there were learning points about the reporting of adverse events. The work could have been done without the PTT but it did add an extra dimension and I felt that by the use of it we offered NHS GGC helpful insight in that they probably were not using their own adverse event reporting system as adequately as they might and that there were other ways in which they could look at their adverse event data. I do not believe we were unduly critical of them in any way.

71. We did have ongoing meetings with the clinicians themselves and there is a timeline that starts on page 129 of the report where it shows when the meetings with clinicians took place. They had a meeting with the CMO on 3 March 2020 where I believe they articulated concerns about our work. They were really concerned about what we were going to do and felt that their own clinical practice was in the firing line. The timeline dates the other meetings I had with them throughout the year. I am hoping the issue is settled in terms of the clinicians, I could not share any information with them until the report was produced. It was not until they had the opportunity to read the report that they could reassure themselves. My sense was by the end of the process that they were more grateful for the review than they thought they would have been.

72. In summary regarding the PTT, at the beginning I was challenging about the use of it but then I became agnostic and by the end I believed it actually did add an additional dimension of value to the work of the review. I do not think it illuminated the enunciation of our core terms of reference which was whether

there was an environmental risk to the cause of infection. It did however look at potential impacts on patients and the work that Pat O'Connor and Peter Davey did allowed us to produce the chapter 6 on the burden on the patients.

The Expert Panel Review Process

73. Expert Panel Review Process is the heart of the CNR. We created a systematic approach to the capture, scrutiny and summation of the data available in every case. We sought to achieve and record, in a structured way, a consensus view as set out in the Conclusions record sheet in Appendix D (page 136) and described in section 3.6 of our report.

74. This was an approach created for the CNR - I know of no other similar investigation that has used the same process, but it has similarities to the approach that may be used in a Root Cause Analysis.

75. Figure 3.6: Case Note Review Process Map can be found at part 3.6 of the Overview Report and shows how we looked at each of the 120 episodes of infection. Each of these episodes was looked at and the starting point was essential the extraction of basic information. A key stage before Full Panel Meetings was Data Synthesis. Appendix D (page 134) shows the Data Synthesis Template which on we identified things that we thought were important to know about. These were a series of data items and the first stage was to try and pull out the information that helped populate that data synthesis template. A separate Data Synthesis Template was completed for every infection in each patient.

76. The HPS team provided us with information. For example, dataset item 19 was date of admission and 23 would be date or dates of previous attendance, 25 ward and bed location. This was provided for each of the patients. We were told where the patient had been admitted from and we were shown which beds the patients went to. A visual tracker was established using software which allowed us to see how the patients moved around the hospital.

77. The PTT team who were working on the clinical records pulled out information to provide us with more of a narrative of care. They would indicate things like "Child

attended the day unit with a history of fever for 12 hours" or "Was referred from Fife with a fever". They would describe something about the child's condition, their temperature, where the infection was thought to be and when antibiotics were initiated. The HPS team had access to antibiotic prescribing data too so from those two sources we created a stream of information which then had to be integrated. This was essentially my task - I think I was the most suited as it required clinical knowledge of patient care.

78. For every infection episode I extracted information and populated the data synthesis template. I also created a corresponding timeline to ensure there was a chronology to events.

79. We created a data synthesis and clinical timeline for every episode. I used to meet with Pat O'Connor, Fiona Murdoch, Jane McNeish, Marie Brown and Emma Mackay each week. We would clarify points and I would ask them questions about things I did not understand. I would ask them to go back to the clinical record or clarify something such as where a patient was nursed or when antibiotics were given or stopped.

80. By a process of iteration, it took a bit of time, but we were able to create a report which we thought was sufficient comprehensive to take to a full panel meeting. At that meeting Gaynor, Mark and I would sit down and look at the reports and discuss what we thought was going on, on the basis of that information.

81. The next step in the process involved completion of the second part of the Data Synthesis Template – Summary. This can be found on page 135 of the Overview Report. This was very much expanded when populated with information. We would summarise the clinical situation. We would look to see, for example, whether the patient had evidence of damage to the bowel because that is a possible way in which patients might acquire infections of this kind. We would then look at the Tableau timeline. Tableau is the description of the software we used, essentially it is a timeline from which we could see if there were any clustering of other patients with similar infections. We started adding information from other hospital systems including what responses were from microbiology and the Infection Control team. We looked at the ICNet and Telepath data bases

and at relevant IMT and PAG minutes to see what the response of the organisation had been at the time. We also looked at environmental information - for example where water samples were taken and where swabs of surfaces were taken – and at maintenance and building activity and at cleaning records. We interrogated the Datix system, which is about adverse event reporting, and finally sought to identify whether there was any other relevant information available. Parents also had the opportunity to send us information, and some did.

82. If we identified any clustering, we would then ask ourselves what this might mean. We would look at the information provided by the Infection Control nurses and by the microbiologists to see whether they had made any observations, particularly at observations recorded in the Incident Management Team minutes and the Problem Assessment Group minutes. We would assess whether these gave us an insight into whether there were concerns about environmental hazards that could point us in that direction. We would then look at the evidence of any surveillance cultures. We did make the point that there really was not very good, useful data but there was some. We would look to see if there was anything around that information that would help us. We have already covered the issue about maintenance activity and how difficult that was, but we nevertheless looked at all those things for each patient and tried to draw them together.

83. In reference to second paragraph of Overview Report – Para 3.6.6; this suggests that particular weight was given where a cluster of episodes (understood to be a number occurring within a short period of time) was found to have occurred involving the same bacterium and different patients. The presence of a cluster of similar infections affected our assessment of the probability of an environmental cause

84. Taking all the information together , we then populated the Summary component of the Data Synthesis Template. We asked ourselves all these questions and then tried to answer whether it is possible to link the infection episode with the environment. We then moved to the Conclusion pro forma which can be found on page 136 of the Overview Report. It was not possible to do that with clarity at

one sitting for most patients, we had multiple review meetings, sometimes up to six. We would keep bringing patients back to the panel meetings until we were satisfied that we had as much information as was available and that we had achieved maximum benefit from all the information available.

85. As the process matured, we got better at being able to challenge information, we would ask for things to be double checked or ask for further data items. We got more sophisticated not only in terms of integrating information but also challenging.

86. The whole case note review process was about creating a data synthesis in a clinical timeline and integrating it with all the other sources of information in the red box on the left in figure 3.2 and the having a discussion, sometimes on many occasions, to achieve a final outcome. We did not have any patient identifiers; all the work was done without any knowledge of who the patient was.

Categorising Likelihood of an Environmental Source for an Infection

87. In section 3.6.6 we discussed how we categorised likelihood of an environmental source for an infection. We decided to categorise episodes into one of four levels of likelihood that the hospital environment was a source of a bacteraemia: Unrelated, Possible, Probable or Definite. This approach is discussed further in Chapter 5, section 5.6. In some cases, we thought we might be unable to determine likelihood because of inadequate or conflicting data. The allocation of these descriptors inevitably represented a position taken along a continuum of certainty and, for the two largest groups (Possible and Probable) we attempted to refine our position by further extending our categorisation into Weak Possible, Possible, Strong Possible, Probable and Strong Probable groupings. We did not feel we were able to distinguish between Probable and Weak Probable.

88. In regard to the categories or terms used in Para 3.6.5 and 3.6.6, there is no distinction in meaning between “Confirmed” and “Definite”. Although we had used ‘Confirmed’ on the Data Synthesis template, as we were finalising our assessment via the process of the second review we undertook for all patients,

we chose to use the term ‘Definite’. I don't think any great significance derives from this but I recognise there is a potential for confusion. Although we had initially used 5* descriptors in our final outcome reports (section 3.6.5) as the project progressed, we came to see that this was insufficiently granular. The report describes the sub-categorisation of ‘Possible’ and ‘Probable’ to create the final list of 8* categories used in section 5.6 and Table 5.3. [* means that there are 5 or 8 categories if one includes ‘Unable to Determine’]

89. I do not think it would be fair to say that our final conclusion was circumstantial. We had a lot of different sources of information. One particular piece of information did not allow us to be absolutely certain in our conclusions. What we have tried to describe is how our judgements were made after considering all the different kinds of information available to us. We looked at all the circumstances that were capable of being connected to a particular episode of infection to come to our conclusions. We worked on the basis that the more the various pieces of data available pointed to a particular conclusion, the stronger the conclusion.

90. In Section 3.6.6 at the top of page 44 there is a paragraph that sets out reasons why we thought some cases were not related to the hospital environment. We then went on to talk about some of the factors that helped us point more towards reaching a conclusion that they might be related to the hospital environment. We referred to some of the difficulties about the frequency with which some of the environmental testing was done and how difficult it was to link to it. It is important to remember that association does not infer causation. I recall one of the criticisms made by GGC in their critique of our draft report in which, in reference to section 3.6.6 of the report, they wrote to us as follows:

> *“A key omission for context; there is no reference to published literature on the methodology utilised by the panel given that causality is assessed using the Bradford-Hill criteria (J Roy Soc Med 1965:58:295-300) as any observed association may in fact be due to the effects of one or more of the following: chance (random error) ; bias (systematic error) ; or confounding”*

and they offered reference to a teaching resource (the significance of which we were uncertain). We reviewed this section of the draft report in response to

GGC's comments but felt that our text had adequately set out the caveats that applied to our conclusions. The only significant addition to the text in its final form was the addition (at the end of paragraph 7 of section 3.6.6) of the sentence starting *"Given our remit, we focused on potential hospital sources of infection…. This* goes on to acknowledge the possibility of infection acquired outside the hospital environment.

91. I have been asked to explain how we assessed infection arising outside the hospital environment. Clearly it is difficult to be absolutely certain in making this distinction but we relied on our assessment of the type of infection and the strength (or otherwise) of the opportunity to acquire infection in hospital. For example, one patient who had a chronic blood disease, but unlikely to have been significantly immunocompromised and largely only ever treated as an outpatient, had three episodes of infection with an unusual bacterium (Elizabethkingia). This is widely found in the natural environment and although it has sometimes been described in relation to hospital acquired infection, its finding in that context would be unusual. We felt the clinical circumstances were much more likely to link to infection acquired at home – indeed this was the conclusion of the clinical team caring for the patient at the time.

92. I would not say that there was differential weighting to factors because the exercise involved considering all available factors in any situation. Our conclusions were not driven by the number of factors. Clustering is quite important, but we did not give any formal weighting to one factor or another. We truly attempted to integrate our knowledge of the patient, our knowledge of the behaviour of the individual bacteria and the environment. Some of those elements were incomplete but we used what we had.

93. It was recognised that the possibility of outside environmental sources could not be very easily addressed unless we received some specific information.

94. An 'outside environmental source' means the possibility that the identified bacterium was acquired somewhere outside GGC. In most cases this would have been the patient's home environment but for some patients, care was delivered in other healthcare settings about which we had no information.

95. Root Cause Analysis is essentially what we were doing. We were tracking the evolution of each infection and then trying to fit around it all the possible influences. That is essentially what the approach involves; you say something has happened then you consider all the possible influences on what it has happened and what the outcome was. One of our recommendations to NHS GGC was that this approach should be used by them, and it came as a surprise to us that they did not have a more systematic approach to Root Cause analysis. They did tell us about it, but it was only introduced in late 2019 which was the end of the period of our review. There was very little information from Root Cause Analysis available for us to draw on. If it had been used at a much earlier stage, then it may have provided us with more pertinent information and, more importantly, I think it would have systematised their response to the issue.

96. Root Cause Analysis is not unique to healthcare settings and may be delivered in different ways, but the fundamental approach is to consider an adverse situation / event and look at all possible factors that may have contributed to its occurrence and its outcome. By way of example, I attach [see Appendix] a template I had used previously at my own hospital. This is not the only framework one can use, and I assume GGC had their own, but the value of an RCA framework is that it offers a consistent and systematic approach to investigation and requires the identification of recommendations and actions for the future. We refer to GGC's own policies with regard to the use of RCA in section 3.4.1 and, in section 8.2.2.2, we discuss how we identified RCA utilised in two of the patients included in our review and comment on the development of the template used. I regret I am unable to retrieve this from my records.

The Standard Infection Prevention and Control Assessment

97. On page 44 at 3.6.6 we explain that standard infection prevention and control assessment reflected that "In routine practice, such a conclusion (that the environment was likely the source) would be made until or unless it was possible to confidently arrive at an alternative hypothesis for the cause or source of infection". This means that if one found an infection to be of a potential environmental origin, one would make the assumption that it came from the

environment unless it was possible to demonstrate that there were adequate infection prevention control measures in place and/or there was an alternative reason. Starting from a position of concern about the environment you then should ask whether everything that could usefully be done to prevent infection had been done and if so, had it been done properly. If you conclude that an environment had been managed properly in terms of infection control, then you would reduce your suspicion that the infection arose from the environment.

Approach to Causation

98. In terms of our approach to causation, this represented a gradient of increasing certainty. It was because of this that we decided to group the Strong Possible, Probable and Strong Probable groups together within the category of 'most likely'. Table 5.6 shows that by doing so we included only 4 cases of Strong Possible (and 3 cases of Strong Probable). By restricting ourselves to the inclusion of only those that were identified as Probable or Strong Probable, our conclusion would have been that 28.2% of the whole group fell into the 'most likely' group rather than the 31.6% we gave in our report. I suggest that this does not represent a significant difference in our overall message.

99. When looking at recognised methods for demonstrating a causal relationship there are statistical methods you could apply. Looking at the issue very simply, if you have two populations of patients, and one had been exposed to an abnormal water supply but the other had not, and then you look at the frequency of an event – say an infection in both populations – you could do a statistical test to prove that the number of infections was greater in one population than the other. On completion of the statistical test, it would allow you to come up with a statement that on the balance of statistical probability, the exposure of this population to this abnormal water supply meant that they got infections while other people did not. The difficulty there is that you have to be sure that there are no confounding variables. You also have to have enough patients in the analysis because it cannot be done reliably with small numbers of patients. I think in our setting it was very difficult to use statistical information to give any

kind of meaningful conclusion. I do not know if there is a method available to establish a causal relationship in such a setting. The process of causal inference is complex, and arriving at an inference of causal or non-causal nature of an association is a subjective process. It comes down to judgment. If we had been able to apply a test and say that the link is definitely caused by the environment it would have been a much easier piece of work.

100. It is perfectly possible to undertake a statistical comparison between two groups when those groups are clearly defined and are otherwise comparable in terms of possible factors which may distinguish them. In the case of our work, we had no comparative population. It will be interesting to see a comparative study with another group of patients from elsewhere but the validity of any conclusion reached will need to be assessed. It may also be relevant to point out that staff at GGC had themselves suggested a link between infections and the environment – see, for example, the text of our Example 8.4 on page 90 of the report.

The Support and Literature for the Approach Taken by the CNR.

101. One of the criticisms that was levelled at us by NHS GGC in response to our draft report was in respect of lines 828-829 of the draft which related to paragraph 3.6.6 of the Review. According to NHS GGC: “A key omission for context is no reference to published literature on methodology used by the panel, given that causality is assessed using the Bradford Hill Criteria”. We responded by saying that we believed that it was implicit in our approach.

102. There is a whole science behind infection prevention control and environmental infections. Time, place, person approach is standard practice if you are asked to investigate an outbreak of infection.

103. Bradford Hill was a very distinguished occupational physician and statistician in the 1960s. He published a piece of work which talked about the criteria that you might use to try to associate a factor (not necessarily an environmental factor) with a specific disease. He talked about the strength of association, the consistency of the association, how specific the association was – the temporal

relationship. These remain broad principles but as times have moved on they can and have been challenged.

104. I don't think we are challenging the work of Bradford-Hill but merely pointing out that whilst the principles of his observations about association remain important, they have been challenged. Indeed, this is referred to in the reference provided by GGC quoted and commented on at paragraph 93 of this statement.

105. In saying that, I do think we were doing exactly what he set out. He said that you have to think about all these different things and the web reference that NHS GGC provided us in their letter addressing our report in this section refers to a teaching session on the Bradford Hill criteria. It simply talks about them and says that these were historically important. The conclusion of the link states, "The process of causal inference is complex, and arriving at a tentative inference of a causal or non-causal nature of an association is a subjective process". We recognised that and integrated the information that was made available to us and then made a judgment on it. We have been quite upfront about the fact that the review is our judgment.

106. I hope we have demonstrated how much information we carefully considered and how we used it. It will be for others to judge whether it stands up to scrutiny but clearly NHS GGC did not feel that what we did stood up to their scrutiny. However, I stand by what we did and our conclusions.

Case Note Review Concerns About Use of Systems by GGC

107. Our concerns are captured in Chapter 8. We talk at some length about NHS GGC's management, investigation and reporting of infection episodes. We discuss the availability of data, its quality and our access to information systems in general. We had difficulty with the environmental microbiology and facilities and maintenance work data and the lab information systems. We wrote at length about the problems were and attempt to illustrate it in the review. We were particularly critical of the fragmentation of their approach to the IMT meetings. Each investigation of an infection or a series of infection seemed to stand alone,

and nobody raised the point that the same issue had been discussed a few months ago or asked the question as to why they were not linking back to what had been discussed previously. We also had concerns about bacterial typing.

108. Our concerns about bacterial typing are discussed in section 8.3.1 of our report. We recount challenges with the documentation and detail of results, and the lack of any system to allow results to be aggregated, linked or searched.

109. We had concerns about clinical records, not what the medical or nursing staff wrote but their organisation. It is not a unique problem to NHS GGC, but electronic patient records have evolved in a way which is not always completely intuitive in terms of how you go about finding information, it is not always necessarily chronological.

110. A summary of our approach to/ concern about the clinical records is described in section 8.4 of our report. I can amplify this by referring to the separate report by the PTT team **[A48184781 – A Paediatric Trigger Tool Review of Patients a the Royal Hospital for Children in NHS Greater Glasgow and Clyde – Report by Dr Patricia O'Connor, University of Stirling and Prof. Peter Davey, University of Dundee – March 2021 – Bundle 25, Page 304]** which, in section 4.3, sets out how the medical records were arranged and the challenges of identifying data within them.

111. We deal with the use of SPC charts at 8.2.3 in our report, on p88. We say that we had reservations about the reliance on SPC methodology. It is a perfectly respectable methodology but there are concerns about trying to apply it in situations where there are a relatively small number of incidents. It is a way of looking at trends of occurrence of events over periods of time, and the trend is much more tightly defined if you have lots of things happening. It is just like trying to draw a line through a series of data points, lots of points means you can get a much straighter and convincing line. If the data points are all over the place, it's much more difficult. We said two things, one that you need a baseline for SPC because what you are trying to do is to compare what is happening now with what happened in a previous period. The second thing is that we thought the numbers for this approach were small.

112. We took a simple approach. We just looked at timelines. We stretched out all these infections and asked what was "going on here?". We give an example in a box (Example 8.2 on page 88) looking at a bacteraemia called Klebsiella. Klebsiella is a relatively common infection in these patients, so it is not so unusual. We however pointed out that just under half the infections that were identified in the review occurred in a period from June to November 2016 and then again in 2017. It was a clear clustering and as we have acknowledged a cluster does not tell the whole story, but it does ask the question if the infections should be looked at or taken more seriously. I think NHS GGC were reassured by the SPC analysis and we just think that analysis was probably inappropriate and that they put undue confidence in it.

113. You do not know what a Statistical Process Control (SPC) analysis means unless it is compared to something before. The first time you do an SPC analysis you are asking what is going on but if you want to observe a change then you have to compare what is happening now with what happened before but there was no comparison with what was happening before in this case. We wrote, "it can be argued that the use of data for the instance when the hospital was located in Yorkhill merely swaps one environmental baseline for another". The trouble was it was not the same environment, so the baseline was not really applicable. If you open a new hospital, you do not have a baseline, so you have to use another way of saying "I am not sure this is right".

114. There was an issue about alert lists or the microbiology alert system. ICNet is one of the IT systems that is used to record positive microbiology results. It has the facility by which you can add an alert for a specific bacterium so that, if an infection with that bacterium is identified in the future, the system automatically triggers a notification to the Infection Prevention Control team. We went into a bit of detail about this in our report. This can be found on page 96 in the section numbered 8.4.2. [I regret this was erroneously mis-numbered and should have been numbered 8.3.2]. Our Examples 8.2 (on pages 88 & 89) and 8.7 (on page 97) are also relevant. NHS GGC told us that the alert list had been extended to include a broader group of infections but this did not seem, from the data we examined, to have been the case.

Whole Genome Sequencing as a Tool

115. Bacterial typing data is Professor Mark Wilcox's area, and he will be able to talk to the limitations of bacterial typing. The important thing to understand is that you might have an infection with a bug like Pseudomonas. Its subtype is aeruginosa and there are half a dozen patients who are infected with Pseudomonas aeruginosa – can it be said it is the same infection? At certain level it is the same infection but within pseudomonas aeruginosa there are further subtypes and sub-characteristics. Not all Pseudomonas aeruginosa infections are exactly the same. That is reflected in the genetics typing and looking at genetic characteristics. If you take 100 isolates of Pseudomonas aeruginosa infection and subject them to bacterial typing they would not all be exactly the same. There would be a great deal of overlap and there are variations within the behaviour of Pseudomonas aeruginosa infections which would be reflected in subtle and sometimes not so subtle differences in their genetic makeup. Genotyping is looking at the genetic building components of the bacterium and comparing them.

116. If there is a Pseudomonas aeruginosa found in a water sample and the same is found in the patient, you would be looking for a very close degree of similarity between the two before you could be confident of a match. They would not necessarily be absolutely identical, but they would be close. Bacteria evolve so when it spreads from one person to another, the bacterial itself may subtly change its genetic make-up. There are rules about what you would call a close match and what is not a close match and that again is Mark's area of expertise. The ideal situation is where you find a bacterium in the environment which is a close enough match to that in the patient, you can say it is the same bacterium.

117. The HPS and PTT team were not involved in collecting the bacterial typing data. Bacterial typing is laboratory information and came from the microbiology labs. The PTT and HPS teams provided us with more conventional data about admission dates, antibiotic information and operation and culture dates and such like. We established right at the beginning a pipeline for getting all the

information, but it was only relatively late in the process that we were able to get information about genotyping from NHS GGC.

118. NHS GGC criticised us in in their response to our draft report for ignoring the value or diminishing the value of the work completed on genotyping. The problem we had is that most of the patients we reviewed did not have genotyping done. NHS GGC provided us with a lot of information about genotypes from other infections that were not included in our review. This is discussed at the bottom of Page 95, going into 96 of the Overview Report. To be fair, genotyping of bacterial infections is not standard practice and it would not be done for every infection because it is expensive and time-consuming. I think our position would be that, had it been recognised there was a problem, a systematic approach to evaluating infections using genotyping could have been implemented at a much earlier point. I think it would be fair to describe the typing data we received as patchy both in terms of samples both from patients and the environment.

119. The point is that whilst it would be unreasonable for bacterial genotyping to be applied in a widespread and non-specific manner, once it became clear that there was a problem, a programme of genotype testing could have been introduced selectively to ensure that specimens from the patients affected were compared both with each other (where bacteria were the same) and with those obtained from (augmented) surveillance of the environment (where positive findings were identified).

120. The limits of sensitivity are discussed on page 100 in respect of the lack of complete data about the location of patients within the hospital. Whole Genome Sequencing is a way of looking at all the genetic information with bacteria, so essentially, it is a genetic fingerprint of the bacteria. It identifies what I have mentioned already that first of all that the genetic code within bacteria can evolve and mutate so that things change. As the bacteria reproduces itself and spreads, it evolves and mutates.

121. There are degrees of difference. Rules are applied differently by different people in relation to how closely similar bugs need to be for you to believe that they are essentially the same bug. There is a measure of genetic difference called single

nucleotide polymorphism (SNP). Essentially if you imagine a series of building blocks and each building block is an SNP many people would say that if there is anything more than about a 25-building block difference in the sequence of gene information then you are moving away from this being a similar strain of bug. Again, this is an area for Mark but I would bring your attention the following paragraph towards the foot of paragraph 95 in the Overview Report, "It is likely that bacteria found in environmental locations may exist as multiple types and it may be best to say that whilst a demonstration of a close relationship between a patient specimen and an environmental isolate is strongly indicative of a relationship, the reverse does not necessarily apply". We tried to make the point in the report in a number of places that the absence of a proven connection does not eliminate the possibility that the connection is there.

122. Our main frustration was that it appeared to us that the testing carried out was somewhat hit or miss. We could not work out what the rationale behind the water-testing regime was. Samples were not taken from every tap once a month, for example. I do understand that there are substantial resource implications here but if NHS GGC believed they had a problem, which I am not sure they all did, they could have been much more systematic about applying these techniques.

123. As discussed on pages 95 and 96 of the report, whole genome sequencing was only carried out on three groups of isolates: *Enterobacter* spp., *Stenotrophomonas* spp. and *Cupriavidus* spp. We did not have any other typing data. My understanding is that this methodology is easier to carry out on some organisms than on others. There may be different clinical priorities for doing it under different circumstances. We were particularly interested in Stenotrophomonas for example and 84 genotypes had been done on it. 15 were isolates from patients in our review but there were also 10 other patients and 59 environmental strains. Five of the children in our series were not included and I do not know whether it was done for them and was not successful but an incomplete set of data limits your ability to draw conclusions from it.

124. I recognise that GGC placed a lot of emphasis upon the use of this typing showing that there was not a link with infections but again it comes back to earlier

discussions, merely because they did not demonstrate a link does not mean to say a link was not there, firstly because the environmental sampling was incomplete and secondly because not all the patients were typed.

125. I do not know why NHS GGC limited the isolates to just three groups. There may have been other bacteria that they were working on that were not relevant to our investigation. They may well have been looking at other bacteria for other reasons. They appear to have set greater stock on the work they did than we could understand.

126. GGC told us that they had identified definitively two infections, one *Cupriavidus* and the other was a *Mycobacterium* which was included in our review. Our position was that it was not the end of the story, because there were challenges in sampling did not mean that we could assume there were only two. I think we felt like we were being told by GGC that they had done this work and that there were only two environmentally associated cases of infection and therefore by inference the environment was not much of a problem. Our position was that we did not accept that the environment being a problem could be excluded as a possibility.

127. There were two cases of Cupriavidus (a relatively unusual organism) in the Case Note Review series and both infections occurred within 4 months of each other in separate patients on Ward 2A between September 2017 and January 2018. A subsequent report from HFS technical water investigations confirmed water testing positive for the bacterium from multiple outlets on the ward. Seven samples taken from the environment on Ward 2A were included in the GGC's WGS data on Cupriavidus, as was one sample from a patient. However, the environmental samples were taken between November 2019 and January 2020 (long after the infections in the two patients in our review) and the date of the patient sample (February 2018) did not match the date of the infections in the patients in our review. We therefore did not consider these results informative. Coincidentally, we were aware that there was a link established between a sample from a tap in the Aseptic Dispensing Unit in pharmacy with a Cupriavidus infection in a patient in 2016 but this patient was not part of our review and I do not know if this link was established by WGS.

128. GGC also indicated that they had established a relationship between a patient (included in our review) with Mycoplasma chelonae and samples from the water system. We identified the environment as the source of this patient's infection as 'Highly Probable' and made the following note in our data analysis: "there is close temporal relationship with isolates from water samples in Ward 6A although the IMT concluded that the exposure was with water supply out with Ward 6A. The organism was isolated from a swab at the site of the patient's central line, which had been the location of a sterile abscess arising 3 months earlier within 6 weeks of the line insertion in Theatre 6. Filters had not previously been fitted to taps in theatres at that time".

129. In summary, I felt we were being told by GGC that they had only identified links to the environment in 2 cases and that, on that basis, the likelihood of wider environmental causation was small. Our position remained that the data were limited and that the inadequacy of environmental sampling and the very limited number of samples from patients in the case note review subjected to WGS could not exclude this as a possibility in others.

130. With regard to NHS GGC's critique of our draft report, we made it clear we would review their comments, but we would not be issuing them with a written response. Overall, the submission received from them was a very significant piece of work. The document they sent us was 70 pages long and contained something like 28 embedded documents and, in the timescale that we had put aside for taking on board stakeholders' comments, it was difficult for us to respond to this. We felt under pressure to modify the nature of some of our comments and I did wonder whether the purpose of giving us this much feedback was to overwhelm us. Nevertheless, we took all their comments seriously and I generated a provisional response and shared it with my colleagues before we agreed if and where we were going to make changes to our report.

131. In response to a criticism by NHS GGC in respect of lines 868 onwards in our draft report, stating that species level clustering is not evidence of transmission, we clearly identified the other factors we included in making our assessment and we held it to be indirect evidence of transmission. With specific reference to the issue of bacterial typing technology, we considered that we had commented on

the typing information and the limitations of the data provided and, crucially, how such limitations relate to the sampling of the environment. We do not believe we dismissed the typing data, rather, we critiqued its value as evidence. Essentially we felt GGC were saying that just because you get infections that happen at the same time does not mean to say they are environmentally caused, we believed that the simultaneous/temporally linked incidence of cases of infection is one factor providing indirect evidence of a common environmental source. We believe that 'clustering' of similar infections in different patients provides one piece of evidence that you should consider in determining whether there could be an environmental origin.

Meeting with GGC Following the Draft Report

132. In terms of the letter from Jane Grant **[A35308833 – Letter from Jane Grant to Prof Stevens 1 March 2023 – Bundle 25, Page 151]**, the timeline went that we sent the draft report out to all stakeholders, including NHS GGC on 22 February 2021 and that this letter was generated on 1 March. We agreed to a meeting with them on 4 March and Jane Grant asked for a one-to-one phone call with me the day before the meeting. She wanted, perfectly reasonably, to agree how the meeting was to be handled and we agreed the process beforehand. I did however feel that I was under pressure in that call to adjust our report on the basis of her concerns.

133. We had the meeting and all three of us were present together with a number of individuals from NHS GGC. They made the case that we should change certain things in our report, but we gave no undertaking that we would although we agreed that we would consider what they had said. I received a second letter from Jane Grant on 5 March, I thought this slightly strangely, given we had met the day before. That letter said that our report was going to cause disquiet amongst patients and staff and asked if we could include in our report a statement of reassurance about the current situation, i.e. that we now thought the environment at NHS GGC was safe. I took advice from my colleagues and we agreed that it was not in our terms of reference to assess the current state of

the hospital. Indeed, we were in no position to do so as we had been reviewing retrospective data up to a period almost 18 months before that conversation took place.

134. I feel that there was a concerted effort to get us to see NHS GGC's point of view. They challenged us on certain points and had issued a very comprehensive rebuttal document to our draft report.

135. NHS GGC made the point that they were taking advice from various people throughout. My response was, however, that if you are confronting a problem which is not resolved after following standard advice or policy then you have a responsibility to think about things in a different way. I was not convinced that what they put forward was an adequate explanation. We ourselves came to the conclusion that there was a problem and it seemed to us that they had acted because they also thought there was a problem. In effect NHS GGC had acknowledged the problem: they had shut a ward, chlorinated the water supply and spent an awful lot of money on remediating the environment and yet were not collecting data that we thought they should have realised would have been helpful to monitor the outcome of those actions. Regardless of the advice they were getting, if they believed they had a problem then one would ask "why were they not thinking about the problem in a different way and why did they not adequately monitor the consequences of the changes they had made"

136. Regarding the Oversight Board report, I received a copy but I am not familiar with its content beyond that which related to the Case Note Review. I believe NHS GGC tried to respond to the report by suggesting there was no obvious difference in patterns of infection between GGC and the other paediatric oncology units in Scotland at Aberdeen and Edinburgh. We made a few observations in our report (section 8.2.3) about this, concluding that the October 2019 report from HPS on Paediatric Haemato-Oncology Data did not offer "any message of either reassurance or concern about past events". We also pointed out that the Glasgow unit was significantly larger than the other two. The Aberdeen haematology-oncology service, in particular, is so small that it would be very difficult to see patterns because of the likely frequency of events.

Limitations to the Review

137. I have been asked to what extent our findings are restricted by the limitations in the datasets with which we were provided. Our position is outlined in section 5.5.2 of the Overview Report which relates specifically to the water sampling. In terms of WGS I think the situation was more that NHS GGC seemed to feel that they had the data that essentially established that there was not a problem whereas we did not think that was the case. We certainly found the lack of data about environmental sampling frustrating. It might be asked "would you expect to get this information from other hospitals under routine circumstances?" to which my response would be that these were not routine circumstances and, once they had identified that there was a problem, they should have carried out their investigation of its cause in a much more systematic way.

138. There were other challenges in how the information as presented to us, particularly the information about maintenance work and facilities management. It was extraordinarily difficult to work with these data until they were revised. I know that NHS GGC felt that we did not ask for information until late in the process, but I believe we did ask for it early on, although we asked for more of it later. There was a considerable sense of dissatisfaction throughout the review process about the availability of information from NHS GGC, the way in which information was provided to us, and our ability to use the information given to us. I think if you are struggling to understand information as provided to you, you have to ask the question about whether it has been adequately presented.

139. I think the quality of data avaliable did influence our ability to reach findings. It was not just that data was missing (there is an example of this on page 86, Example 8.1) but it was also that we were not terribly confident about some of the information provided to us.

140. The illustration offered by Example 8.1 is a relatively simple issue, yet one which challenges the adequacy of GGC records. We read in IMT minutes (23 March 2018) that water samples were positive for Stenotrophomonas (the infection under consideration in the patient being discussed) yet although we

subsequently identified a positive water sample in the data provided by GGC, its location was not recorded. How then can we be sure that what was recorded and believed true by the IMT was in fact the case? Our reservations about the adequacy and presentation of data taken from environmental sampling and records of maintenance work undertaken in Wards 2A/2B/6A are discussed further in section 8.1.2 of our report.

141. We felt more confident with the information that we derived from clinical information and the temporal proximity of other infections of the same type. Chapter 5.6 deals with likelihood that infections were linked to the hospital. At the top of page 69 we have stated that the lack of any episodes being classified as definite reflects the tight criteria we believed that we needed to reach that point. We have stated, “Decisions at this level were influenced by the inconsistency with which our own data could be informed by data systematically investigating the microbiological environment, the water system and the likelihood that, by using typing methodologies, different bacterial isolates were linked. Microbiological information alone was insufficient to reach our conclusions, and we also looked carefully at clinically relevant information.”

142. Section 3.6.6 of our report may usefully illuminate what we were trying to articulate on page 69 as part of section 5.6. It shows, I hope, that we defined, at the outset, what we thought our criteria should be in agreeing the likelihood of environmental origin, and that we had given thought to the constraints on environmental sampling and genotyping. In the event, we were limited in what we could gain from such data and had to rely more on our interpretation of clinical circumstances and the clustering of similar infections.

143. In this context an example of clinically relevant information would be that a child who has been in hospital for several weeks and then develops an infection. Under those circumstances you can be very much more confident that you are not looking at the impact of the environment outside the hospital.

144. I think one needs to assess all elements of the ‘environment’ when considering risks of this nature and that even if some or all of the elements on which we commented in sections 5.2-5.5 had been more effective / informative, we would

still have taken a holistic view in delivering the conclusions offered in section 5.6.

145. We were very conscious throughout our work that we needed to avoid the criticism of having seen causation in correlation and, if anything, I think we often erred on the cautious side in reaching our conclusions for individual patients. Perhaps this illustrated by the fact that we felt unable to identify any patients as having a 'Definite' link to the environment, and scored only 3 as having a 'Strong Probable' link?

146. I have been asked to what extent was the CNR team's ability to answer the second of the four questions asked of the CNR team in its TOR (as set out on page 25 of the Overview Report to the end of section 2) impaired by the limitations in data retained and provided by NHS GGC in respect of maintenance of the built environment, cleaning and SICP, hand hygiene and environmental microbiological surveillance. I would argue that our work was significantly impacted by the limitations in data retained and provided by NHS GGC in respect of maintenance of the built environment, cleaning and SICP, hand hygiene and environmental microbiological surveillance.

Discussion of our Conclusions

147. In respect to whether it was possible to link each infection episode with the environment of the QEUH/RHC the 'most likely' group was a merging of those infections we had initially assessed as "strong possible," "probable" and "strong probable." It was a subjective judgement and we recognised it as a potential criticism of our work. We had stated (section 3.6.6 of the Overview Report) that we did not feel we were able to distinguish between 'probable' and 'weak probable'. We could have just used our original review scale categories of "unrelated," "possible," "probable," "definite," but we put in those intervening steps as we ultimately felt that the difference between "possible" and "probable" was too big a gap. Our final categorisation involved repeated discussion of each individual case with outcomes finely balanced according to the circumstances identified.

148. There were eight cases that were considered unrelated and that was because we felt the evidence was strong enough to exclude a link. If there had been insufficient evidence, they would have been in the unable to determine box. These were predominantly, if not exclusively, patients who had clear evidence of gut toxicity. Chemotherapy frequently damages the gut; it makes the mouth sore, and it can also damage bowel. Because the bowel is such a big repository of bacteria, once damaged the bowel becomes 'leaky' and bacteria can pass into the bloodstream very easily. So, where we saw children with positive blood cultures who were sick with bowel problems, typically as a result of chemotherapy, then we tended to say, "The likelihood is that this was an intrinsic infection that came from a damaged and leaking bowel." Therefore, under such circumstances we were as confident as we could be that that was not related to the environment.

149. At the end of section 8.4.1 on page 96 we have stated that NHS GGC told us it was possible to link the environment with infection using Whole Genome Sequencing in only two patients (one with *Cupriavidus* spp, who was not included in our review, and the other with *Mycobacterium chelonae*), but we never saw those data and on that basis did not record the *Mycobacterium chelonae* case as a definite but as a Strong Probable.

150. We may have seen the relevant WGS data on Cupriavidus as this formed one of the three groups of bacteria that were studied by GGC but we did not see the data on the patient with Mycobacterium chelonae – specifically, we found no reference to microbiological fingerprinting/genetic sequencing tests on any sample of M. Chelonae in the datasets provided to us by NHS GGC.

151. In expanding my view on the response of GCC to the issues identified within the paediatric haematology oncology patients, I would reflect on what we wrote in the last paragraph of section 10.2. This was an organisation which argued that there wasn't proof of an environmental link to patient infections yet took substantial measures to address the possibility that there was and then failed to establish systems to adequately monitor and collect data to assure the safety of the patients.

152. In relation to clustering we have commented at the end of section 4.3.5 that, "There is evidence for both increased frequency of specific gram-negative bacteraemia and episode clustering in time and place. Neither phenomenon proves that some of the bacteraemia had hospital environment sources, but the observations are consistent with this hypothesis." What this means is that SPC charts are perfectly respectable methodology, but they were we believed in this case probably inappropriately applied and that a much simpler approach, just looking at a timeline and looking visually at the clustering of infections could have been a much more useful tool in terms of suggesting that something was not quite right. We pointed out in paragraph 4.3.5 that some of these bacteria are quite common in this population of patients. However, for infections caused by bacteria such as enterobacterium Stenotrophomonas, they are relatively uncommon and to see those cases clustering in time and in space, because it is the same part of the environment, suggests that something is not quite right. So, we are saying this does not prove they had a hospital environment source, but the observation will be consistent that this was the cause.

153. In section 4.3.5 we are pressing the point that simple analysis of patterns of infection can be as important as what may be considered as more sophisticated methodologies. SPC charts have their place and offer a way of visually interpreting trends that may not be apparent when looking at basic data but they are also less sensitive when sample sizes / numbers of events are small. The HPS report in 2019 **[A33448012 – HPS Review of NHSGG&C paediatric haemato-oncology data October 2019 - Bundle 7, Page 214]** included various SPC charts and made this comment "The SPC charts included in this report describe that there has been instances of variation outside what would normally be expected in this patient population, the latest was a breach in the upper warning limit for Gram-negative blood culture episodes in September 2019. The characterisation of these cases alongside understanding in the context of environmental microbiology is critical to understanding and managing risk". In other words, one has to take a broad view and be sensitive to the possibility of a problem – how much better to prove that there isn't a problem by enhancing surveillance and monitoring further infections than to dismiss the possibility and be found to be wrong.

154. The point was made in the NHS GGC response to our draft report that "Clustering is not evidence of transmission events." And our response was, "No, it isn't, but it suggests it." It suggests it could be; it raises the question. My overriding thesis is how many hints did this team need to believe that something was not quite right, especially when they spent several million pounds on remedying something which they said was not a problem?

155. More typing would have helped but as important would have been the approach to environmental sampling. For example, if you have a cluster of Stenotrophomonas infections and you had systematic water sampling, and you picked up the Stenotrophomonas in the water during that period, then you could use typing to ascertain the closeness of the relationship. But even without the typing, you would have a very good shot at saying, "You have got Stenotrophomonas in the water at a time that you are having what appears to be a cluster of infections. How can you ignore the possibility that one caused the other?"

Meeting Dr Peters and Dr Inkster

156. We did have a meeting with Christine Peters and Teresa Inkster. We deliberately did not meet with them until right at the end of the process. We knew they had a lot to say and a lot of knowledge. We did not however, want it to seem that we had been unduly swayed by their views, until our work was complete. We did not meet them until end of January 2021.

157. In the second paragraph of page 67 we did report that we had been told that some key staff were denied access to water sampling/testing results despite multiple requests". Our source was Dr Peters, I think. She was concerned about the safety of the water system and the testing of water. Even after our report was complete and our work finished, she contacted me because she had been asking for access to data within GGC. She was told that the information was not available to her, and she had to get my permission as the lead for the Case Note Review to access it. This struck me as absolutely bizarre because this was shortly after we finished our work or as we were finishing it. I wrote to Jane Grant

and said I could not understand why access to information was blocked to somebody who works within the health board. So, we knew, first-hand, that access to certain information was restricted in some way and that Christine Peters had been trying to get access to water sample results and had not been allowed to have them.

Conclusion

158. I do not know whether NHS GGC followed any of our recommendations or not. I would have very much liked to have known what the status of their response had been. They did suggest that some of the things we had raised had already been fixed. The disappointment for me was that the Oversight Board appeared to change in function within a fairly rapid period of time after the submission of our report. I do not know whether any of the recommendations we made have been or will be fully implemented and it was not made clear to me who was going to monitor this. This did not seem to be a very robust conclusion to a substantial piece of work – we made over 40 recommendations but have never had a clear understanding of who was going to monitor the response or the implementation of any change.

Declaration

159. 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.

160. The witness was provided access to the following Scottish Hospital Inquiry bundles/documents for reference when they completed their questionnaire/ statement (Appendix A).

161. The witness introduced/provided the following documents to the Scottish Hospital Inquiry for reference when they completed their questionnaire/ statement (Appendix B).

Appendix A

A43293438 - Bundle 6 – Miscellaneous Documents

A49585984 - Bundle 25 - Case Note Review Expert Panel, Additional Reports and DMA Canyon

A43909077 - Bundle 7 – Written Reports prepared by Health Protection Scotland (HPS), Health Facilities Scotland (HFS) and Antimicrobial Resistance and Healthcare Associated Infection (ARHAI)

Appendix B

A43030605 – CV Professor Mike Stevens

Professor Michael Stevens

Curriculum Vitae for Scottish Hospitals Inquiry

March 2023

PERSONAL DETAILS

Full Name : Michael Charles Garston STEVENS

Date of Birth : [redacted]

Nationality : British

Contact details : [redacted]
Mobile: [redacted]
Email: [redacted]

UNDERGRADUATE EDUCATION

Undergraduate Studies University of London
St Mary's Hospital Medical School
(1968-1974, with external research year 1972-73)

Qualification: MB BS (with distinctions) (1974)

POST GRADUATE QUALIFICATIONS

MRCP (UK) 1976

Accreditation in Paediatrics (Joint Committee on Higher Medical Training) 1982.

MD, University of London, 1983.

Accreditation in Paediatric Oncology (Joint Committee on Higher Medical Training) 1986.

FRCP (London) 1992

FRCPCH 1997

FRCR 2003

CURRENT POSITION:

Emeritus Professor of Paediatric Oncology, University of Bristol

GMC Registration: [redacted] – Voluntary erasure from Register May 2022

Medical Defence Union Membership: [redacted] – Inactive membership

EMPLOYMENT HISTORY (most recent first)

July 2021	Retired
January 2020 July 2021	Lead, Independent Expert Panel, Queen Elizabeth University Hospital /Royal Hospital for Children, NHS Greater Glasgow and Clyde Case Note Review for QEUH/NHSGGC Oversight Board
September 2001 - September 2021	Consultant Paediatric Oncologist, University Hospitals Bristol NHS Foundation Trust / Bristol Royal Hospital for Children (part time from March 2015)
September 2001 - March 2015	CLIC Professor of Paediatric Oncology, University of Bristol (& then Emeritus Professor)
December 1985 - August 2001	Consultant Paediatric Oncologist Birmingham Children's Hospital NHS Trust
June 1985 - November 1985	Member of Staff, Division of Haematology/Oncology, The Hospital for Sick Children, Toronto, Canada Assistant Professor, Department of Paediatrics, University of Toronto.
September 1984 - June 1985	Terry Fox Clinical Training Fellowship Division of Haematology/Oncology, The Hospital for Sick Children, Toronto, Canada.
January 1984 - September 1984	MRC Clinical Research Fellowship, MRC Laboratories, University of the West Indies, Kingston, Jamaica.
January 1983 - December 1983	Clinical Fellow, Division of Haematology/Oncology, The Hospital for Sick Children, Toronto, Canada.
September 1980 - December 1982	Senior Registrar, Department of Paediatrics, John Radcliffe Hospital, Oxford.
October 1978 - September 1980	MRC Clinical Research Fellowship MRC Laboratories, University of the West Indies, Kingston, Jamaica.
October 1977 - October 1978	Tutor (Honorary Registrar), Department of Child Health University of Manchester.
August 1977 - October 1977	Locum Registrar, Paediatrics, Radcliffe Infirmary, Oxford.
January 1997 - July 1977	Senior House Officer, Neonatal Paediatrics, John Radcliffe Hospital, Oxford.
August 1976 - January 1977	Senior House Officer, General Paediatrics, Radcliffe Infirmary, Oxford.
August 1975 -	Senior House Officer, General Medicine,

July 1976	Radcliffe Infirmary, Oxford.
January 1975 - July 1975	House Surgeon, General and Paediatric Surgery, St Charles Hospital, London, W10.
June 1974 - December 1974	House Physician, General Medicine, St Mary's Hospital, London, W2.

August 1972 - July 1973	Wellcome Trust Undergraduate Research Fellowship, Tropical Metabolism Research Unit, University of the West Indies, Kingston, Jamaica.

SIGNIFICANT NHS CLINICAL MANAGEMENT & LEADERSHIP POSITIONS

Birmingham Children's Hospital

- Clinical Director, Haematology & Oncology (1990 – 1998).
- Medical Director (1998 – 2000)

University Hospitals Bristol NHS Foundation Trust / Bristol Royal Hospital for Children

- Chair, Paediatric R&D Group (2002 - 2005)
- Lead Clinician, Paediatric Haematology Oncology & BMT (2006 –2008)
- Chair, Advisory Group for Teenage & Young Adult Cancer (2008 – 2009)
- Trust Interim Director of Research & Development (2009 –2010)

NHS South West

- Chair, South West England Children's and Young Persons Cancer Services Group (2002 – 2003, 2005 – 2009)

UK ACADEMIC MANAGEMENT & LEADERSHIP POSITIONS

Birmingham Children's Hospital

- Co-Director, West Midlands Regional Children's Tumour Research Group, (1986 -1999).

University of Bristol

- Director, South West Children's Cancer Research Registry (2001 – 2020)
- Head, Academic Unit of Child Health, Faculty of Medicine and Dentistry (2002 – 2005)
- Director, Institute of Child Life and Health, Faculty of Medicine and Dentistry (2004 – 2008)
- Chair, Medical Education Committee, Faculty of Medicine and Dentistry (2005 –2011)
- Chair, Bristol Cancer Research Strategy group (2008 – 2011)

NATIONAL PROFESSIONAL & ACADEMIC LEADERSHIP POSITIONS

UK Children's Cancer and Leukaemia Group

- Group Chair (1997 – 2000 & 2008-2011).
- Sub Group Chair: Soft Tissue Sarcoma Group (1989 – 1994); Late Effects Group (1993 – 1996); Education and Training Committee (1994 – 1998); Epidemiology and Registry Group (2002 – 2015); Clinical Research Governance Group (2003 - 2005)
- Cancer Research UK appointed lead for CCLG national reconfiguration project (2008-2011)

UK Commission on Human Medicines

- Member, Haematology & Oncology Expert Advisory Group (2006 - 2009)

- Member & Vice Chair, Paediatric Medicines Expert Advisory Group (2007 - 2013)

Medical Research Council

- Member, Leukaemia Clinical Trials Data Monitoring and Ethics Committee (2003 - 2014)
- Chair, UKALL R3 Data Monitoring Committee (International clinical trial for children with relapsed leukaemia), (2003 – 2013)

NHS / NHS England

- Cancer Referral Guidelines Steering Group (1999 – 2002)
- National Cancer Action Team Advisory Group for the Implementation of NICE Guidance on Improving Outcomes for Children and Young People with Cancer (2005 - 2012)
- NHS Information Authority. National Cancer Dataset Steering Group (2000 – 2008)
- National Cancer Intelligence Network: Chair, Children Teenage & Young Person's Clinical Reference Group (2008 – 2013)
- NHS Improvement / National Cancer Survivorship Initiative: Children's & Young People Workstream Steering Group (2010 – 2013)
- NHS Improvement / NHS Improving Quality: National Clinical Adviser CYP Cancer Survivorship & Transition (2012 - 2014)
- NIHR Cancer & Nutrition Collaboration: Executive Committee & Chair CTYA Working Group

INTERNATIONAL PROFESSIONAL & ACADEMIC LEADERSHIP POSITIONS

European Paediatric Soft Tissue Sarcoma Group

- Chair (2000 – 2013)

European Cancer Organisation

- Board Member (2002 – 2008), Treasurer (2003 – 2008)

International Society of Paediatric Oncology

- Chair, Soft Tissue Sarcoma Studies Committee (1993 – 2005)
- European President (2000 - 2003)

UK EXPERT ADVISORY APPOINTMENTS

- Chair, London Paediatric Oncology Review. NHS England (2014 – 2015).
- Chair, Independent Expert Panel for Case Note Review. Queen Elizabeth University Hospital / Royal Hospital for Children, NHS Greater Glasgow and Clyde. January 2020 – June 2021.

INTERNATIONAL EXPERT ADVISORY APPOINTMENTS

External Reviews

- External Reviewer, Department of Paediatric Oncology, Institut Gustave Roussy, France: (1996).
- Report on national provision of children's cancer services in New Zealand. Government of New Zealand: (1999).
- External reviewer, Department of Paediatric Haematology & Oncology, University of Toronto and Hospital for Sick Children, Toronto: (2009)

Academic Appointments

- Jordan University of Science & Technology: External Examiner (2011-2012)

- External assessor for academic promotions at: University of Otago, New Zealand (2009); University of Toronto, Canada (2009); St Jude Children's Research Hospital, USA (2011); University of Florida, USA (2013); Israel Institute of Technology (2014); University of Leeds (2019)

SCIENTIFIC ADVISORY & ACADEMIC STEERING COMMITTEES

United Kingdom

- University of Birmingham, Department of Epidemiology. Steering Group for British Childhood Cancer Survivors Study (BCCSS) (1998 – 2013). Funded by Cancer Research UK.
- University of York, Social Policy Research Unit. Steering Group for project "Care and Support Needs of Children with Cancer and Leukaemia and their Families" (2002 – 2004). Funded by Cancer & Leukaemia in Childhood (CLIC).
- University of York, Epidemiology and Genetics Unit. Oversight Committee for the United Kingdom Children's Cancer Study (UKCCS) (2006 - 2009). Principal funding by the Leukaemia Research Fund
- University of Oxford, Department of Paediatrics. Scientific Advisory Committee for the Childhood Cancer Research Group (CCRG) (2006 – 2013; Chair from 2009).
- NIHR Medicines for Children Research Network, South West, Steering Group (2007 - 2011)
- University of the West of England, School of Psychology. Steering Committee for the Centre for Appearance Research (2008 - 2015)

International

- Cochrane Childhood Cancer Group (Amsterdam, The Netherlands). Member of Editorial Board (2006 – 2015)
- European School of Oncology (Milan, Italy). Scientific Committee. (2007 – 2014)
- Chair, Independent Data Monitoring Committee for Paediatric Hepatic International Tumour Trial (PHITT) (2017 - current)

EDITORIAL & OTHER ACADEMIC ACTIVITIES

Grant reviewer – including:

- Auckland Medical Research Foundation, New Zealand; Cancer Research UK; Cancer Research Trust New Zealand; NIHR Research for Patient Benefit programme; NIHR Senior Research Fellowship Programme; ODAS Foundation, The Netherlands)

Journal Reviewer - including:

- Annals of Oncology; Blood; Cancer; European Journal of Cancer; JAMA Paediatrics; Journal of Clinical Oncology; Lancet; New England Journal of Medicine; Pediatric Blood and Cancer; PLOS One.

Editorial Boards

- Member, Editorial Board, Medical and Pediatric Oncology (now Paediatric Blood & Cancer, 2001 - 2003)
- Paediatric Editor, European Journal of Cancer (2005 - 2010)

RESEARCH SUPERVISION

Post Graduate Degree Supervision :

- 1987 – 1989 Dr D Smith. Nutritional status of children with malignant disease. MD, University of Cambridge (Awarded 1991).

- 1989 - 1990 Ms J Lees. Eating behaviour of children with cancer. MSc (Clinical Psychology), University of Birmingham (Awarded 1991).
- 1990 - 1991 Ms C Evans. Adaptation behaviour of siblings of children with cancer. MSc (Clinical Psychology), University of Birmingham (Awarded 1992).
- 1995 - 1998 Dr H Traunecker. The biology of drug resistance in human sarcoma cell lines following a brief exposure to doxorubicin. PhD, University of Birmingham. (Awarded 1999)
- 1999 – 2001 Dr H Jenkinson. The epidemiology and molecular genetic basis for second malignancy after treatment for cancer in childhood. PhD University of Birmingham. (Awarded 2002).
- 2002 -2006 Dr ML Yeap. Growth and metabolic consequences of treatment for childhood leukaemia. MD, University of Bristol (Awarded 2009)
- 2002 – 2006 Dr A Penn. Health related quality of life after diagnosis of childhood brain tumour. PhD, University of Witwatersrand, Johannesburg, South Africa (Awarded 2013)
- 2007 – 2009 Dr N Davis. Cardiac and metabolic risk factors after bone marrow transplantation for childhood leukaemia. PhD, University of Bristol (Awarded 2013)
- 2010 – 2014 Dr C Wei. Mechanism of Impaired Glucose Tolerance in Survivors of Childhood Leukaemia treated with and without Bone Marrow Transplantation. MD, University of Bristol (Awarded 2014)

External Examiner For Postgraduate Degrees :

- University of Newcastle upon Tyne, 1995. (PhD Examiner).
- University of Leeds, 1997. (MD Examiner).
- University of Liverpool, 1998. (PhD Examiner).
- University of London, 1998 (PhD Examiner)
- University of Amsterdam, 2004 (PhD Examiner)
- University of Birmingham, 2008 (PhD Examiner)
- University of Oxford, 2010 (DPhil Examiner)
- University of Leeds, 2013 (MD Examiner)
- University of Amsterdam, 2015 (MD Examiner)

TEACHING LEADERSHIP

Undergraduate education

- Chair, Medical Education Committee (Oversight of MB ChB Programme: Governance & Standards), University of Bristol (2005 – 2011)

Postgraduate medical education

- Faculty, European School of Oncology / International Society of Paediatric Oncology postgraduate courses (1996 x2, 1997, 2003, 2004)
- Faculty, FECS / AACR / ASCO International Workshop on Methods in Clinical Cancer Research, Switzerland (2002, 2003, 2004)
- Co-Founder & Chair of European School of Oncology / SIOP Europe Master Class in Paediatric Oncology held in: Orta, Italy (2006); Ascona, Switzerland (2008); Castel Gandolfo, Italy (2010); Castel Gandolofo, Italy (2012); and Lujbljana, Slovenia (2014)
- Faculty, University of Amsterdam School of Paediatric Oncology, residential Master Classes (2007 & 2009)

WORK WITH CHARITABLE ORGANISATIONS

Trusteeships

- Society of Parents of Children with Cancer (West Midlands Regional Parents Support Group), (1989 – 2001).
- Trustee, Joshua Gilbert Rhabdomyosarcoma Appeal (national charity for research in rhabdomyosarcoma), (1995 – 1997).
- Trustee, Lisa Thaxter Trust (national charity for childhood cancer support and research), (1996 – 2006).

AWARDS:

1974 – Distinctions in Surgery and in Obstetrics & Gynaecology, Final MB BS, University of London

1981 - Golden Stethoscope Award – annual award from the clinical medical students at Oxford University for their most revered teacher

2001 - NACCPO Award from the National Alliance of Children's Cancer Parents Organisations, for services to children with cancer and their families

2017 – Macmillan Cancer Support – National Innovation Excellence Award

PUBLICATIONS

Book Editorship

Cancer in Children: Clinical Management. Oxford University Press
5th Edition. (Eds. Voute PA, Barrett A, Stevens MCG, Caron HN. (2005)
6th Edition. (Eds. Stevens MCG, Caron HN, Biondi A) (2012)

Book Chapters (n= 12)

Major themes: undergraduate medical education; rhabdomyosarcoma and other soft tissue sarcomas of childhood; late effects of childhood cancer treatment

Peer Reviewed Journal Publications (n >150)

Major themes: children's blood disease and cancer including work on: sickle cell anaemia; soft tissue sarcoma; brain tumours; patterns of cancer survival; late consequences of treatment; nutrition; time to diagnosis

Scottish Hospitals Inquiry

Witness Statement of

Dr James Walker

WITNESS DETAILS

1. My name is James Taggart Walker. My occupation is as a public health microbiologist.

2. This statement is specifically in relation to the meeting that took place at Queen Elizabeth University Hospital (QEUH) on site on, 5 June 2014, which was entitled the “Special Meeting held in the Labs FM Block- at the South Glasgow Hospital to discuss and resolve issues with Optitherm taps installed in the Hospital.”

BACKGROUND

3. I worked for Public Health England as a public health microbiologist for approximately thirty years. During that time, I attended various training events and society conferences.

4. I was a member of the Public Health England Biosafety team in 2012 operating as a public health senior research microbiologist, investigating the infection outbreaks in various hospitals in Northern Ireland [December 2011/April 2012 and intermittently until the publication of the **(DHSC Health Technical Memorandum, HTM 04-01: Safe Water in Health care Premises. Part C: Pseudomonas Aeruginosa – Advice for Augmented Care Units)** and scientifically peer reviewed manuscript namely **(JT Walker and others. Investigation of Healthcare-Acquired Infections Associated with Pseudomonas Aeruginosa Biofilms in Taps in Neonatal Units in Northern**

Ireland (2014) 86 J Hosp infect 16) in relation to microorganisms focusing on *Pseudomonas aeruginosa*. Other reports were produced following investigations by other teams of experts **(RQIA Independent Review of Incidents of Pseudomonas Aeruginosa Infection in Neonatal Units in Northern Ireland – Interim Report – 31 May 2012 – Bundle 18 – Volume 2 of 2 – Document 85)** which concluded that the outbreaks of infection of Pseudomonas aeruginosa, which occurred in the neonatal units at Altnagelvin and Royal Jubilee Maternity Hospitals, were linked to contaminated tap water in the intensive care rooms of the units.

5. The main conclusion that we drew from this exercise was that the potential for microorganisms in the built environment to cause infections in patients was underestimated. We have learned over the years that the risks from the built environment, including from the air, the water and various surfaces are important especially in relation to those individuals who are immunocompromised.

6. Some individuals from Public Health England were invited by the Department of Health to become part of a guidance writing team [2012 through to 2014] in order to provide a new document regarding the risk of *Pseudomonas aerugin*osa in augmented care units. I was on that panel. There would also have been representatives from the devolved nations. I cannot remember exactly who was involved in this guidance writing team, but there were a wide range of expert participants.

7. We wrote that guidance in relation to taps covering many aspects of tap engineering, including the components of the taps, and also making recommendations as to the fitting/removal of components in relation to safety of the water **(DHSC Health Technical Memorandum, HTM 04-01: Safe Water in Health care Premises. Part C: Pseudomonas Aeruginosa – Advice for Augmented Care Units).**

8. Since I ceased working for Public Health England in 2019, I have started a small consultancy, Walker on Water in the same year. In this capacity I currently work for one other client. I also occasionally consult with water companies and

hospitals. My main focus at the current time is my work as an expert with the Scottish Hospitals Inquiry.

9. I was the Chair of the Central Sterilisation Club (2021 – 2024) and am a Fellow of the Royal Society of Public Health, and a member of the Water Safety Management Society and HealthCare Infection Society.

Involvement with the QEUH and the meeting 5 June 2014

10. Prior to attending the meeting in question, I had had no direct involvement in any capacity with the Queen Elizabeth University Hospital (QEUH) or with any of its staff members related to the water system at QEUH.

11. I first became involved with the QEUH in June 2014 when I was working for Public Health England shortly after we had been involved in investigating a number of outbreaks including those in Northern Ireland associated with water system components.

12. Public Health England was at that time [2012-2014] in the process of working with the Department of Health in writing guidance, **(DHSC Health Technical Memorandum, HTM 04-01: Safe Water in Health care Premises. Part C: Pseudomonas Aeruginosa – Advice for Augmented Care Units)** as mentioned above.

13. I was invited to attend the meeting at the QEUH by way of an email in order to provide information as a Public Health England representative in relation to our experiences and learning in the context of our investigations in respect of the above-mentioned Northern Ireland infection outbreaks. I cannot remember who it was that sent me the initial invitation to speak at the relevant meeting at the QEUH.

14. Public Health England had been involved in the Northern Ireland hospital infection outbreaks from a very early stage [December2011/ January 2012)], both in providing advice and as well as conducting investigations in using its research

and scientific laboratory capabilities to assess a large number of plumbing components removed from the hospitals' water distribution systems under what might be described as almost forensic conditions.

15. The meeting in question was held in the Laboratory FM Block at the South Glasgow Hospital on the QEUH site. In attendance at the meeting were representatives from the NHS GGC Departments of Estates, Infection Control, and senior Management as listed on the meeting minutes. The meeting was chaired by Ian Stewart of Health Facilities Scotland. In attendance were Lisa Richie (HPS);Paul Southworth (HPS);Alan Gallagher (NHS GGC); Ian Powrie-(NHS GGC);Jim McFadden (JMcF); Jim McFadden (NHE); Gerry Cox(Golden Jubilee Hospital); Iain McInally (NHS Ayrshire & Arran); Jimmy Walker (PHE); Ian Storrar (HFS); Angus Horne (Horne Engineering Ltd); and John Horne (Horne Engineering Ltd). Apologies received from Eddie McLaughlan and Geraldine O'Brien. There was no affiliation for Eddie McLaughlan and Geraldine O'Brien in the minutes of the meeting. These were the types of people you would expect to find in a water safety group.

16. I had been invited to the meeting as a representative of Public Health England to share information and learning at QEUH with staff in respect of PHE's involvement in the Northern Ireland hospital infection outbreaks and investigations **(JT Walker and others, 'Investigation of Healthcare-Acquired Infections Associated with P. Aeruginosa Biofilms in Taps in Neonatal Units in Northern Ireland' (2014) 86 JHI 16.)** This was particularly relevant in respect of the Optitherm Horne taps that contained plastic outlets that had already been procured for use by NHS GGC. The duration of the meeting was approximately two hours.

17. At that meeting I gave a Power Point presentation in relation to our investigations into contamination of plumbing components found in a wide range of different taps across a number of hospitals in Norther Ireland. I explained that the investigations, which I was personally involved in conducting, included the microscopic visualisation of microorganisms found on the surfaces of many different water system components as well as the microbiological recovery of live

organisms for enumeration and typing. I also provided background information about Pseudomonas aeruginosa – which the investigation team found to be growing on the plumbing components under investigation. I described the investigation team as having a background knowledge of microbiology and plumbing components (though the latter to a lesser extent), and how it was established that particular structures were found to be positive for microorganisms from inlet components (strainers) to outlet components (flow straighteners) of various water system structures. I also discussed the implications of the plumbing components testing positive for microorganisms which had infected the patients as P. aeruginosa isolates recovered from tap biofilm from three taps at one hospital had VNTR (Variable Number Tandem Repeat) profiles, which are techniques used to compare isolates form water and patients, that were typed as being indistinguishable from the strain found in both patients and tap water from that hospital **(JT Walker and others, 'Investigation of Healthcare-Acquired Infections Associated with P. Aeruginosa Biofilms in Taps in Neonatal Units in Northern Ireland' (2014) 86 JHI 16.)**. In particular how organisms which had been identified on such components had been shown to relate specifically to those organisms recovered from patients.

18. It was very clear to me, and the investigation team, that the taps and the contaminated water were the most likely exposure route and transmission risk to the children in the hospitals in Northern Ireland, and this is what I wanted to get across to the team in Scotland.

19. I gave my presentation based on my experience as a water microbiologist and a biofilm expert of 25 – 30 years standing. The findings were that a number of tap outlet fittings which had a large surface area to volume ratios. were heavily contaminated with microbial organisms that were typed as being indistinguishable from the clinical strains. It was striking how much material (biofilm) was attached to the components. Such microbial colonisation would present an infection risk to patients if the risk were not monitored and effectively managed.

20. Inside the taps on the metal components there can sometimes be quite rough areas. The rough areas can become filled with debris. The rougher the area is

the more debris can become attached. Prior to the water coming into a tap there is a component called a strainer (which is a little mesh). The mesh is there to protect the water quality. However, debris and particulate matter in the water system will attach to that mesh and biofilm can build up on the strainer and thereby contaminate the rest of the tap. Further, people washing their hands which may be contaminated from a variety of sources may then contaminate the outlet tap components. This is made possible by the components having large surface areas to volume ratios which encourages microbial growth.

21. After I had given my presentation Angus and John Horne of Horne Engineering Ltd (the sole provider of taps to the Hospital) gave a presentation in relation to its taps which had already been procured by the QEUH and which had been engineered to prevent microbial contamination. They used videos and smoke graphics to demonstrate how they believed that Horne tap components would not become contaminated in use i.e. if the tap was full of water the smoke would not enter the tap outlet fitting. They likened the smoke to air containing bacteria i.e if the air could not enter the tap, then neither could the bacteria. They used videos and smoke graphics to demonstrate how they believed that Horne tap components would not become contaminated in use. That is, if the tap outlet was full of water, then smoke would not enter the tap outlet fitting. Conversely if the tap outlet did not contain water, then the smoke would enter the tap body and hence contaminate the tap body. They also explained how the outlet fittings in their taps would be less likely to become contaminated because of the nature and design of the mesh material and due to the retention of water within in the spout of the tap i.e. they believed they had designed a tap and outlet fitting that would not become contaminated with waterborne pathogens but were not able to provide any microbiological evidence from laboratory studies to support these claims.

22. Such companies often have their own hypotheses based on their own engineering and design without having carried out a microbiological study. I could not see any evidence of scientific reasoning to why the Horne taps in question with the large surface area to volume ratio of their outlet fittings would not become microbiologically contaminated.

Outcome and Decision

23. My task as an external expert in this field (water microbiology and biofilms) was to explain the risks associated with tap components in the context of what we had learned during our investigations of the hospitals in Northern Ireland, and in particular the extremely high risks posed in relation to immunocompromised groups of patients **(JT Walker and others, 'Investigation of Healthcare-Acquired Infections Associated with P. Aeruginosa Biofilms in Taps in Neonatal Units in Northern Ireland' (2014) 86 JHI 16. (DHSC Health Technical Memorandum, HTM 04-01: Safe Water in Health care Premises. Part C: Pseudomonas Aeruginosa – Advice for Augmented Care Units) (Jacqui Wise, Three Babies Die in Pseudomonas Outbreak in Belfast at Neonatal Unit (2012) 344 BMJ e5920) (RQIA Independent Review of Incidents of Pseudomonas Aeruginosa Infection in Neonatal Units in Northern Ireland – Interim Report – 31 May 2012 – Bundle 18 – Volume 2 of 2 – Document 85)** My ultimate advice was to remove the outlet components from the taps in the wards accommodating immunocompromised patients who are particularly vulnerable to infection.

24. In the light of my presentation and that of Horne Engineering's, a decision had to be made as to whether or not use the Horne taps that had been procured for the whole of the Hospital, and if so where they should and should not be used. Various options were considered during the course of the meeting. They were 1. to fit the taps as procured (even though it had been concluded during the NI investigations that such taps with large surface area to volume ratios readily accumulated microbiologically contaminating material (biofilm) in the absence of proper maintenance, 2. to fit the taps in the Hospital and remove the outlet fittings or 3. to purchase new taps for the wards/rooms that accommodated clinically vulnerable/immunocompromised patients only.

25. The attendees unanimously agreed at the meeting that they would proceed with taps as fitted/to be fitted as purchased.

26. “That unanimous decision was based on earlier guidance (Scottish Health Technical Memorandum 04-01: The control of Legionella, hygiene, ‘safe’ hot water, cold water and drinking water systems Part A: Design, installation and testing 2008) i.e. the taps that had been installed within the new build development had complied with guidance at the time of its specification and briefing and that as the hospital was in the process of being commissioned it should be regarded as being in the “retrospective” category, and not “new build”. Therefore, those representing NHS GGC decided that the guidance in the Scottish Health Technical Memorandum 04-01: Water safety for healthcare premises Part A: Design, installation and testing 2014 i.e. “Rosettes, flow straighteners and aerators have been found to be heavily colonised with biofilm but their removal can create turbulent flow at increased pressure resulting in splashing of surrounding surfaces and flooring. Current advice is that they should be removed but this should be subject to risk assessment” did not apply in these circumstances”.

27. I know from my own perspective I felt disappointed with that decision. Following discussion those present took the decision that (i) the taps would stay in place and (ii) that risk assessments based on commissioning procedures, operational management, seasonal influences and personnel involved may reduce the risk of P. aeruginosa contamination and patient infections and that this risk assessment strategy would be sufficient to protect patients. I just felt that they had not taken on board the risk to patients. My whole reason for attending the meeting was to present the background work that we had carried out in Northern Ireland in connection with the infection outbreaks and infant deaths (which were publicised widely) and to explain the above-mentioned Department of Health England guidance in the context of risk to patients and users. This guidance is universally applicable and is not simply confined to any one country in the same way that outbreaks can occur widely across countries.

28. I was left sitting in the position thinking that I was not sure that I had done my job well enough here for them to appreciate the risk of these components to people who were going to be in these hospitals.

29. Emails of a general nature were exchanged between myself and various individual staff members in relation to potential contamination risks, but I cannot remember whether these were sent before or after the meeting. I cannot confirm any details of any of these emails as I no longer have access to my PHE emails.

30. It seemed to me that the overall understanding by the attendees was that there would not be a microbial risk in respect of installing the Horne taps as they seemed to believe that any inherent risk could be managed. I was not sure that there was an understanding of the microbial risk of the water to the patient had actually been accepted by the attendees.

31. The unanimous decision to accept the use of the taps for the Hospital in question was my disappointing ‘take away’ from the meeting.

32. Here we are today eleven years post the Northern Ireland investigations and multiple publications demonstrating water microbiology associated with taps, and outlet fitting as being an issue in terms of infections and patient fatalities.

33. My ultimate advice was given through my presentation. It was the responsibility of the attendees to take forward their decision as they saw fit in the light of the information provided to them.

34. The cost in relation to the taps was not considered during the course of the meeting.

35. I cannot remember precisely how the decision to use the taps was arrived at, but the decision was made at the meeting there and then, taken forward by the Chair.

36. Having presented on what I thought the real microbial risks were in relation to the tap components and in the context of the lack evidence from the Horne company, it was, I thought, an unusual way to make such a decision. At the end of the day the attendees made that decision to base patient safety on risk assessments

during that meeting and had their own reasons for doing so. I was not party to those reasons - financial or contractual.

37. 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.

SCOTTISH HOSPITALS INQUIRY

Bundle of documents for Oral hearings commencing from 19 August 2024 in relation to the Queen Elizabeth University Hospital and the Royal Hospital for Children, Glasgow

Witness Statements – Week Commencing 28 October 2024 – Volume 11

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