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