Witness Name: Graham Stewart
Statement No.: 1
Exhibits: [XXXX]
Dated: 22 May 2024

THIRLWALL INQUIRY

WITNESS STATEMENT OF GRAHAM STEWART

I, GRAHAM STEWART, will say as follows: -

1. My full name is Graham Stewart. My undergraduate training was at The University of Edinburgh qualifying with MBChB in 1982. I obtained MRCP(UK) in 1988 by examination and FRCPCH in 1996 at the formation of RCPCH. I was subsequently elected to FRCP(Glasgow)

2. My pre-registration house officer posts were completed at The Lewis Hospital Stornaway (surgical) and the Victoria Hospital Kirkcaldy (medical) leading to full GMC registration in August 1983.

3. Thereafter I initially set out to train as a general practitioner on the West Cumbria GP Vocational training scheme completing 6 months as a GP trainee and Senior House Officer posts of six months each in Geriatric Medicine, Obstetrics and Gynaecology, Paediatrics and Psychiatry in the West Cumberland Hospital Whitehaven. During my paediatric senior house officer post I decided that I would like to train as a paediatrician.

4. In February 1986 I moved to Glasgow to work as a senior house officer in Paediatrics in the Royal Hospital for Sick Children, Yorkhill, Glasgow. I moved to a paediatric registrar post in Raigmore Hospital, Inverness in October 1986. Whilst in Inverness I obtained MRCP(UK) in October 1988 and moved back to the Royal Hospital for Sick Children as a paediatric registrar in February 1989. I became a research fellow in 1990 and a senior registrar in 1991.

5. I was appointed consultant paediatrician with a special interest in neonatology to the Royal Alexandra Hospital, Paisley and took up this post on 1st March 1994. My main clinical duties were in Paisley but I also worked in Vale of Leven Hospital and conducted outpatient clinics in rural parts of Argyll and Clyde.

6. Argyll and Clyde Health Board was subsumed by the formation of NHS Greater Glasgow and Clyde and I had clinical and clinical management roles in the Royal Hospital for Sick Children Glasgow and subsequently in the Royal Hospital for Children Glasgow, which opened in 2015.

7. From 1996 I held a number of clinical management posts, In Argyll and Clyde Clinical Director Obstetrics Gynaecology and Paediatrics, Clinical Director Child Health. In NHS Greater Glasgow and Clyde, Clinical Lead, General Paediatrics, Clinical Director Medical Paediatrics and finally in 2014-2015 Clinical Adviser to the New Children's Hospital Project Board. These posts included responsibilities for clinical governance, risk management and service development planning and redesign.

8. NHS Greater Glasgow and Clyde was asked to review Children's Services in the Western Isles in 2011 with a view to developing a networked service. I led that review with support from 2 clinical colleagues.

9. At the time of the COCH review I was a consultant paediatrician employed by NHS Greater Glasgow and Clyde.

10. I applied to become a reviewer for The RCPCH Invited reviews service in June 2013.

11. I was a Subject Matter Adviser to Healthcare Safety Investigation Branch in 2019-21.

12. I was an examiner and senior examiner for RCPCH.

Safeguarding of babies in hospitals

13. I have never, as far as I recall, had specific training on what to do where abuse on the part of a member of staff towards babies or children in hospital is suspected.

14. If I had required advice on this topic I would have involved consultant colleagues specialising in Child Protection.

Invited Reviews Service

15. The Invited Reviews service of the RCPCH is provided to assist clinicians and managers in delivering/developing high quality safe services for children and families. The review team is independent and objective. Any recommendations should be supported by evidence. Reviews may be commissioned for a number of reasons. Service redesign and merging of clinical services for reasons of safety and sustainability is a recurring theme. Reviews can assist organisations where relationships between clinicians and managers have become difficult or where relationships within clinical teams are strained.

16. Case note reviews are an in depth study of an agreed number of individual cases. To conduct a case note review access to complete sets of medical and nursing records is required. These notes should be studied in detail in order to provide an independent opinion on case management. Case note reviews may focus on a single case allowing time to study all clinical information before a planned visit to meet staff. Case note reviews may involve interviews with families including bereaved families.

17. Interviews are undertaken during the review visit giving staff members an opportunity to express their views in a supportive and confidential way. The review team seek information from stakeholders from different staff groups and from service users. At times the review team will have open meetings with the general public.

18. Service reviews will look at the clinical service, clinical governance, risk reporting and risk management, clinical guidelines, medical and nursing staffing levels and rotas, opportunities for education and training, networking with regional centres, morbidity and mortality meetings relationships with other parts of the organisation and with other organisations e.g. tertiary centres and regional services. These areas can be benchmarked against current national professional guidelines allowing the review team to develop a number of recommendations for the commissioning client.

19. I do not know if case note review was offered by RCPCH in 2016.

Membership of a review team

20. After applying to become a reviewer the RCPCH, I attended a one day training event along with written information. The training event included how the invited review

service worked and the process of invited reviews. It included advice on interviewing and skills to use to get the most out of interviewees. Equality and diversity was covered and there were tabletop exercises/mock reviews. Refresher training is provided at intervals.

21. The lead reviewer is involved in the planning process with the RCPCH team member. At this stage terms of reference are agreed between the RCPCH team member and the commissioner of the review. In the pre-review meeting the lead reviewer will agree with other members of the team areas of expertise of each team member and therefore their areas of questioning or perhaps interviews where a particular team member may lead the questioning. During the review the lead reviewer chairs the meeting ensures that the team are introduced to the interviewees and gives interviewees an opportunity to introduce themselves and explain their role in the organisation. The lead reviewer ensures that all of the team get the opportunity to ask questions and any follow ups that arise during discussion.

22. The lead reviewer should deliver the immediate informal feedback to the commissioners of the review. The RCPCH team member will produce a draft report with assistance from the lead reviewer and from the remainder of the team.

23. In most interviews the lead reviewer will open the questioning. The second clinician may have different, specific areas of expertise and areas of questioning agreed before the interview. After the lead reviewer has finished the second reviewer will explore their agreed area but also can ask follow up questions arising from the answers already give by the interviewee. At times it can become clear that it would be helpful for the review team to meet people not originally scheduled for interview. The second clinician, and/or another team member, may undertake these interviews whilst the lead reviewer continues with scheduled interviews.

24. Depending on the scope of the review a team member from another discipline may be essential for example if reviewing women's and children's services it would be appropriate to have the expertise of an obstetrician/gynaecologist and/or a midwife.

25. All reviews I have taken part in have had a senior nurse on the team to advise on professional aspects of nursing and for their knowledge of agreed national standards for staffing, training and education etc.

26. The lay reviewer may have significant experience as a service user / parent and they bring a different viewpoint regarding services and how they should be delivered.

Remuneration for the role

27. While working for NHS Greater Glasgow and Clyde my medical director gave me professional leave to assist the college with review visits. The RCPCH remunerated my employer. I also did some quality assurance work for the invited reviews service in my own time and was remunerated directly. After I retired I assisted with perhaps one further review and was remunerated directly by the college.

Understanding of the process by which an invited review is undertaken

28. My understanding of the review process is that RCPCH reviews service is approached by a senior manager in an organisation usually medical director or chief executive. The RCPCH will then advise if the invited reviews service is appropriate or whether difficulties should be resolved internally eg HR processes or with assistance from other external bodies eg the general medical council.

29. The commissioner and the RCPCH team member will discuss the type of review, what the organisation wish to achieve and they will then agree the terms of reference. The draft terms of reference would be discussed with the lead reviewer and subsequently with review team members once a team has been established.

30. In preparing for a review visit, the RCPCH team would provide the organisation with a relatively standard list of documents required to assist in preparing for the review. These would include services delivered by the organisation including activity data. Relationships with other organisations such as regional centres and transport teams. Medical and nursing staffing information including staffing complement, vacancies, use of locums or agency staff and examples of medical and nursing rotas. Clinical governance information including the organisation's clinical governance structure. RCPCH would want to see examples of minutes of clinical governance meetings and of morbidity and mortality meetings and action plans arising from these meetings.

31. Once the initial documentation has been received it is shared with reviewers who can then suggest additional information which may be of assistance.

32. The purpose of the review visit is to learn as much as is possible about the organisation and the clinical teams and their service as is possible in the time available. During interviews the chair should allow all team member and the interviewee time to ask and respond to questions while keeping as closely to the schedule as possible.

33. Other members of the team will focus on their particular area of expertise and any follow up questions arising from answers. The interviewee should also be given the opportunity to ask any questions. During other parts of the visit, walk rounds etc it is often possible to engage informally with staff to gain further insights into the service.

34. The written report should provide a clear description of the service and should logically address the terms of reference. It should be constructive and clear. The report should provide a number of recommendations and give some time scale for achieving each of the recommendations (some are more urgent than others). The recommendations should be supported by evidence e.g a recommendation to increase nursing or medical establishment would refer to national agreed staffing guidance from the appropriate professional body.

35. The report belongs to the commissioner who is responsible for determining the audience but it should be written with the expectation that it would be shared with stakeholders in all staff groups and possibly the general public. RCPCH encourages commissioners to share the report widely. The college does not have responsibility for actioning recommendations this is a decision for the commissioning organisation. My understanding is that the RCPCH team would have follow up discussion/meetings with the client sometimes involving reviewers.

Escalation Policies/guidance 2016

36. At the time of the COCH review, I would have had access to:

    a) The January 2016 handbook for reviewers [INQ0012822]

    b) The August 2016 Guide on Invited Reviews [INQ0010214]

    c) The Role of the Lead Reviewer document (understood to be dated April 2016) [INQ0012828]

37. I was not aware of a separate escalation policy in 2016 but there was a section in the 2016 Guide.

38. The August 2016 guide contains information to assist reviewers, lead reviewers and RCPCH invited review team members. If serious concerns regarding patient safety arose the reviewers could discuss with the medical and/or nurse director what action they may consider.

39. COCH had taken action with the aim of addressing patient safety. A member of staff had been removed from the service and the trust board had downgraded the service from a local neonatal unit.

40. As far as I am aware, RCPCH was not aware of the removal of the member of staff before the review visit. The change in unit status was in the public domain.

41. In an invited review where allegations of criminality arise once the visit is in progress the advice at that time was to continue the review in relation to its original remit. At the COCH the review team continued with the review but did not investigate or address any issues relating to the individual member of staff after the interviews with medical and nurse director, non exec director, consultant medical staff and senior nurses. They were the only groups of staff party to the concerns about criminality. Advice on how to proceed would be given by the lead reviewer and member of RCPCH invited review team.

42. That discussion took place with the review team, lead reviewer and RCPCH head of reviews.

43. The college developed the invited review process in 2012. I am not sure how many guides for reviewers were written between 2012 and 2016. The guidance has been updated at least in 2018 2022 and 2023. As experience is gathered from RCPCH and other colleges the guidance has become considerably more comprehensive and is now more than double the length of the 2016 guidance with a separate 19 page guide to the escalation process. The section on governance of reviews and the college structure supporting that is more detailed. The structure of a pre-meeting is much more clearly defined. The guidance regarding expected follow up following a review with involvement of the review team and the client is much more detailed.

44. My understanding is that escalation now includes obtaining advice to adjourn a review rather than in 2016 complete the review adhering to terms of reference if

information comes to light which, if it were known to RCPCH prior to the visit may have resulted in a decision not to proceed with the review. There is a clear line of escalation from the lead reviewer and head of reviews to the programme board and senior college officers.

Experience as a Reviewer and wider experience

45. Prior to the Countess of Chester review I think I had contributed to two service review for RCPCH and also one service review conducted by my health board at the request of Western Isles Health Board.

46. I attended the RCPCH one day training course before undertaking any reviews for RCPCH. I know that I attended refresher training run by RCPCH but I cannot recall the date. That refresher training may have been after the COCH review.

47. I had not received specific training regarding safeguarding issues arising during a review.

48. During training from RCPCH escalation of serious concerns was discussed and escalation would normally be to the medical director of the commissioning organisation.

49. I had not previously undertaken a review where unexpected or unexplained deaths were involved or where the terms of reference required consideration of reasons for increased mortality. I had not undertaken a review where there were allegations of criminality or where escalation to an external body or where the report had been shared with an external body.

50. If difficulty was encountered I would have sought advice from the lead reviewer or RCPCH head of reviews.

51. At the time of the review I had access to the January 2016 handbook for reviewers, the August 2016 Guide on Invited Reviews and the Role of the lead reviewer document April 2016 and was familiar with those documents

52. In approximately 2004 following a service reconfiguration in Argyll and Clyde where three consultant led maternity units merged there was an apparent increase in perinatal mortality numbers. Our public health team and information and statistics division of the NHS Scotland conducted an external review to consider if the apparent

rise related to service reconfiguration. They concluded service reconfiguration was not a factor. Perinatal mortality figures thereafter returned to previous levels.

53. I have no experience of concerns of criminal conduct of staff towards patients and investigation of those matters.

Selection for the COCH review team

54. I was asked by Sue Eardley head of invited reviews at RCPCH if I was available to contribute to the COCH review. I am not able to recall the exact date. I was not the lead reviewer.

55. The background information that I was given related to the downgrading of the neonatal unit at COCH from a level two to a level one unit following a possible increase in mortality. The aim of the review was described in the terms of reference. To determine if the service was compliant with professional standards, to look at staffing, leadership, team working, risk management, and governance. To explore relationships with neonatal network and transport teams and to look for identifiable common factors which might explain the apparent rise in mortality. Also to look at the steps that should be taken before consideration of returning to level two status.

Contract for the invited review

56. I do not recall if this was the first time I saw the terms of reference.

57. I do not recall any discussion of the terms of reference.

58. The scope of work required was similar to other reviews. I do not recall having concerns about being able to address the terms of reference.

59. In 2016, I was a member of the British Association of Perinatal Medicine (BAPM). As a district general hospital neonatologist I was working in a similar environment to the consultant team in COCH. The most preterm infants would be delivered in regional centre or transferred there soon after birth. In a DGH setting at that time consultants looked after both general paediatrics and neonates when on service and covered both inpatient wards and their neonatal unit when on call. My experience and the

clinical challenges of the job therefore would be similar to the team of consultants in Chester.

60. Discussions about the methodology of the review would normally be undertaken by the RCPCH invited review lead. I do not recall any discussion that the methodology would be different from other reviews.

Arrangements for the Review

61. The RCPCH review team was responsible for the arrangements for the review. I had no discussion with David Milligan directly as far as I recall. I was included in email circulation from Sue Eardley regarding previsit documentation and may have had emails about the schedule and required interviewees. I do not recall a pre meeting or call but some of the team met informally over dinner the evening before the review commenced. I do not recall the details or attendees at dinner on the evening before the visit.

62. I do not recall making any recommendations as to arrangement for the review.

63. Huddle is a secure document store which provides shared access and allows collaborative working. This was the first time I had access to documents from COCH.

64. In the terms of reference we were being asked to look for common factors that might be responsible for the apparent increase in mortality. The mortality reviews had been carried out by the paediatric team in COCH and network members and may have provided clues to evidence for common factors.

65. The transport service for the region was provided by three separate teams. There were concerns regarding availability, staffing, response times and issues of communication, There was a lack of consultant availability to deliver a consultant led service out of hours.

66. My understanding of the urgency for the report was that the service had been downgraded and this would result in pregnant women being transferred to other units for delivery with knock on effects for the other units in addition to the loss of local service. The terms of reference for the review included the steps that must be taken before considering delivering a level two service.

67. My practice was to review all the documents deemed helpful and any others that I thought were of relevance. I do not recall which documents I reviewed ahead of the visit.

68. I believe that "MA" referred to in an email from Sue Eardley email is Melissa Ashe who collated and read data provided by COCH. As far as I recall I did not contribute to a version of these tables.

69. I did not prepare a written analysis of the documents I considered but may have made notes for my personal use in the review. These notes would not have been shared.

70. Following consideration of these documents I was not convinced of statistically significant increased mortality but the review team would explore that further during the visit. In the previsit data there were a number of cases briefly described including some unexpected deaths and collapses but there was not enough detail to draw any conclusions or elicit any common factors.

71. I do not recall any specific concerns regarding the neonatal service nor any nursing concerns arising from the previsit data.

72. I did not take any other steps in preparing for the visit.

Nursing Concerns

73. Prior to the review visit on 1st September 2016 I had not been told that the clinicians at COCH had raised concerns about Lucy Letby. I had not been told and was not aware that the clinicians had discussed or requested involving the police.

74. If I had been aware of the concerns about Lucy Letby I would have questioned whether the invited review process was appropriate. The terms of reference did not include any suspicion regarding a member of staff. I would have sought advice form the lead reviewer, head of reviews and / or other senior college officers. I would have advised COCH that if any criminality was suspected that the police should be involved.

75. In preparation for the review I would have looked at staff rotas in terms of numbers. I did not identify any correlation between Letby and the deaths.

76. I did not see any comment by David Milligan that "*we have much of the workload data I was looking for plus a more in-depth analysis of what happened with the index cases but a number of questions arise from that, not least that one individual appears to have been present for all but one of them*" or discuss this issue with David Milligan or anyone at RCPCH before the review visit.

77. I do not recall any discussion about Letby and therefore do not recall any comments or views about Letby. I had no knowledge or discussion about Letby prior to the visit.

Visits and Interviews

78. I have had the benefit of reminding myself from the following:

[INQ0010124]: Eardley's handwritten notes of 01.09.16.

[INQ0010125]: Eardley's handwritten notes of 02.09.16.

[INQ0010121]: Handwritten notes of 01.09.16 interview with Letby.

[INQ0010122]: Handwritten notes of 02.09.16 interview with nurses.

[INQ0010119]: Handwritten notes of interview with Jacqueline Morgan.

[INQ0010120]: Handwritten notes of interview with parents on 02.09.16. [INQ0010123]: My typed note.

[INQ0010118]: Typed notes of interview with Carol Jackson on 14.09.16.

Also, typed transcripts of the handwritten notes prepared by the RCPCH:

[INQ0014600] Transcript of Jacqueline Morgan interview notes.

[INQ0014601] Transcript of parents' interview notes.

[INQ0014602] Transcript of Letby interview notes.

[INQ0014603] Transcript of nurses' interview notes.

[INQ0014604] Transcript of Eardley's 01.09.16 interview notes.

[INQ0014605] Transcript of Eardley's 02.09.16 interview notes.

79. To the best of my knowledge, I was present at the following interviews (this is taken from notes from review team members).

a) Mr Ian Harvey and Mrs Alison Kelly

b) Consultant Paediatricians initially Dr Brearey and Jayaram then joined by Drs Gibbs, Holt, Saladi and Drs V and ZA

c) Emma Jayne Punter and Gill Mort

d) Kathryn de Beger occ health

e) Dr Howie Isaac and Karen Milne

f) Dr Rajiv Mittal

g) Trainees Drs Mayberry, Bohwmik, Loughnane, Stratford, Fairclough, Kames, Burke and Thorne

h) Neonatal band five nurses Ashleigh Hudson, Siophie Ellis Bernie Butterworth Nurse Z

i) Colin Morgan Julie Maddocks

j) Sharon Dodd

k) Andrew Higgins

l) Ruth Millward Anne Marie Lawrence

m) O& G cons Jim McCormack, Sara Brigham

n) Carol Jackson transport lead (interview by conference call 14/09/2016

79. I was not present at the following interviews

a) Jackie Morgan Neonatal Network Manager

b) Lucy Letby

c) Parents

d) Nurse Practitioners Yvonne Farmer, Eirian Powell, Anne Murphy, Yvonne Griffiths

e) Ian Harvey and Alison Kelly 02/09/2016

80. As with all of my evidence taken from reading meeting notes by me and other members of the review team, some of the comments made may relate to the thoughts of reviewers rather than what was actually said by interviewees.

Interview with Harvey and Kelly 01/09/2016

81. Exploration of the detail of the deaths as opposed to common factors as mentioned in the terms of reference would require a case note review and this was not in the terms of reference and would not have been possible for the number of infants in a 2 day review. I do not recall who raised this.

82. The medical director then spoke about the concerns raised by the paediatricians regarding correlation of one nurse and the deteriorations of infants. He told us that the consultant paediatricians said collapses did not follow a normal pattern and that the infants did not respond to resuscitation in the normal way.

83. He told us that other than Letby's presence there were said to be no factors in her background and that her colleagues thought highly of her. He had spoken with a non exec director who was formerly in the police.

84. I am not able to recall who talked bout the tipping point regarding calling the police.

85. My understanding was that the trust was looking for an opinion / advice on how too proceed. It was my opinion that the review team did not have sufficient time to conduct a case note review and did not have the forensic skills to determine whether or not there was any evidence of criminality.

86. A full case note review by a clinical neonatologist and by a neonatal pathologist may have provided evidence of criminality studying each case in detail looking at clinical and any pathological findings.

Brearey and Jayaram interview

87. In the interview with Steve Brearey and Ravi Jayaram some details about a number of the cases were discussed. Cases were investigated initially internally by Brearey.

A number of the infants appeared to have collapsed without any warning and failed to respond to normal resuscitation measures. By early 2016 a table top review was arranged with external input. An analysis of nursing observations prior to collapse was undertaken but no pattern was found. Post mortem examinations did not provide a cause of collapse and death. The investigations identified learning points but no common factors in the collapses and deaths. From memory the consultants described sudden onset of skin mottling which was relatively transient and different from the mottling one sees in circulatory collapse this apparently occurred in a number of the cases and was seen by a number of the consultant team.

88. Steve Brearey and Ravi Jayaram went on to tell the team that given the lack of answers from the above investigations and case reviews they went on to question if there was something they were missing in terms of staffing environment etc. My memory is that the consultants had become aware that one nurse was present at times when infants collapsed. They raised their concerns with the Medical Director and Nurse director and the nurse was moved to day shifts. We were told that the collapses at night appeared to stop but that collapses happened in the daytime. We were told that all seven consultants began to think the same thing. The nursing managers had no concerns about the nurse and were described as defensive.

89. From memory Ravi Jayaram raised the possibility of air embolism as a mechanism, for some of the collapses. I have never seen an infant suffer from air embolism and I do not think any other team members had seen air embolism.

90. From studying the notes it appears that the collapse of the two triplets led to the consultants telling management that they wanted Letby off the unit until investigations were resolved.

91. In the interview with Steve Brearey and Ravi Jayaram we were told that obstetricians and paediatricians were concerned that a member of staff may be causing the collapses. I described that in my note as foul play. I do not recall if that phrase was used by either of the interviewees or if it is my interpretation of what they were telling us.

Meeting with Dr V Gibbs Saladi Holt Dr ZA

92. We were told in the interview with Jayaram and Brearey and again in this meeting about several infants who suddenly developed an unusual pattern of mottling. My notes contains three phrases in quotation marks regarding mottling. I did not ascribe these to any individual at the time and cannot recall which consultant or consultants made these comments.

93. Sue Eardley's notes again relate to the consultants concern regarding this unusual mottling occurring during the collapses. The consultants were clear that this was not something they had seen before and that they could not explain. They were clear that the infants did not respond in the usual way to resuscitative measures.

Response to the concerns expressed

94. At the first coffee break on the 1st September after we had been informed of the concerns raised by the consultant paediatricians I expressed the view that the commissioners of the review had not been honest and transparent with RCPCH and that it may be better to leave at that stage. This was discussed as an option and it was subsequently agreed that the review could continue but would closely follow the terms of reference and could include recommendations regarding how to progress.

95. I was shocked when we learned about the allegations about a single member of staff from Harvey. I thought that the trust had not been open and honest about their reasons for the review and had not been open and honest while discussing terms fo reference. I thought that t we were being expected to assist in resolving an extremely complex situation.

96. I do not recall whether it was at that time or later on reflection that I considered whether or not our review activities might be prejudicing a future police investigation. Although the unexplained collapses appeared to have stopped since Letby was taken off the unit and the service was downgraded it was possible that the she was innocent and that someone else was responsible for harming infants.

97. As above I expressed my concerns and at least questioned whether or not we should abort the review. As far as I recall the lead reviewer and head of invited reviews expressed the opinion that we could continue with the review strictly adhering to the

terms of reference and providing some recommendations that may be helpful for the trust in terms of staffing, clinical governance, and the need to commission an external case note review. None of the remaining interviewees other than trust execs consultants or senior nurses were aware of the concerns about a specific staff member and our interviews would follow strictly the terms of reference. I do not recall the views of Alex Mancini and Claire McLaughlan. I am not aware of any advice being sought from RCPCH management.

Interviewing Letby

98. I do not know who added Letby's name to the manuscript. My recollection is that members of the review team were concerned that Letby had been moved from clinical duties and it was not clear what HR process, if any, had been used and what personal support was being provided for her by her employer or by her professional body.

99. I do not recall who decided she should be interviewed.

100. I have not been involved in reviews involving an interview of a member of staff who was suspended or suspected of criminality.

101. I do not recall expressing a view of the appropriateness of interviewing Letby nor did I seek advice from RCPCH for this. In terms of the RCPCH statement I certainly had no experience of this sort of interview taking place.

102. My recollection is that the review team believed that Letby was potentially vulnerable having been removed from clinical duties and that a more formal interview with the whole team would have been more difficult for her. The review team also had a schedule to complete and it was not unusual in reviews for the team to divide in order to interview additional members of staff. I do not recall who made the decision. McLaughlin and Mancini both had a background in nursing at a senior level and therefore experience of dealing with colleagues undergoing HR processes.

103. In the notes that refer to "big concern about Lucy", my recollection is that this relates to the lack of clarity from the trust as to what HR process had been used to move her away from clinical duties without full transparency and how the trust was going to resolve that.

104. I was not present at that meeting and cannot comment further. I was not aware of any request by Letby for an "off the record" discussion with the reviewers.

Higgins Interview

105. I do not recall detail of this interview but from the notes available it is clear that police involvement had been considered by the trust board and that this had involved long debates and that they had decided that an external review may assist in deciding whether or not to go down that route. It is clear from the notes that the trust had taken legal advice but not what that advice was.

Verbal feedback

106. The feedback session at the end of the second day was attended by Harvey and Kelly and I think Chambers. The review team were present except Dr Milligan who had to leave early.

107. The verbal feedback was given by me and included the view that any concerns of criminality should be addressed by involving the police.

108. Other ares of feedback were as follows from my notes.

a) An independent case review should be undertaken and college could assist in suggesting people who may be able to carry out such and investigation

b) An appropriate HR process should be agreed by the trust regarding Letby.

c) The neonatal during team appeared strong and supportive

d) Obstetric and paediatric consultant teams appeared to have good relationships and were cohesive.

e) The trainees were content with training being provided and relationships with the deanery were good.

f) There were good links with the neonatal network and the transport service.

g) The safeguarding team were committed with evidence of innovative practice.

h) A number of recommendations would be contained in the report regarding:

i. transport the network and patient pathways

ii. compliance with professional standards

iii. leadership and strategic leadership at executive level

iv. support for staff

v. maintaining skills of the neonatal team medical and nursing

vi. governance processes

i) Parents gave positive feedback

j) Many, many members of staff passionate and committed to COCH

109. As explained in other answers a case note review is a lengthy process requiring study of all medical and nursing notes and an analysis in order to ascertain if any difference in care may have delivered a different outcome.

110. From the information available to us and the interviews with the medical staff it was my opinion that a some of the deaths were not expected and given the negative investigations and reviews some of the deaths remained unexplained.

111. In the feedback session on the 2nd September I gave verbal feedback and this included involving the police. As I recall in one meeting perhaps earlier in the review Harvey referred to a non exec board member who was a retired senior police officer who had advised that there was not enough evidence for the police to conduct an inquiry. (Eardley's note of meeting in the morning of 01/09/2016 refers to this) I do not recall if he expressed a view about police involvement at the feedback meeting.

112. I do not recall any discussion about the review team directly involving the police. I understood that If the police became involved a formal process of investigation may follow led by officers with experience of forensic investigation.

113. I was aware that a police investigation would have negative implications for the trust. It would be very difficult for the trust in terms of managing families of children looked after at COCH past and present, providing support for staff involved in a police investigation and managing the public interest in any police investigation. I was already aware of concerns about reputational damage regarding the downgrading of the unit.

114. An independent case note review may have provided common factors in the collapses and deaths of infants which had not been discovered by the case reviews conducted internally and with support from local network. This may have helped the

trust decide how to progress and may have resulted in the police becoming involved. A review of post-mortem evidence by a forensic pathologist may have contributed to this. I recall questioning whether or not a clinical neonatologist would be in a position to comment on potential deliberate harm such as air embolus. I do not recall any other discussion regarding escalation and as stated there was no written guidance regarding this from RCPCH at that time.

115. In terms of patient safety in the relatively short period since Letby had been removed from clinical duties and the unit redesigned as a level one there had been no unexpected deteriorations and collapses.

116. I was not involved in drafting the letter sent to the trust on 05/09/2016 and did not see that letter as far as I recall. Any discussion about recommendations to make in that letter would have taken place at the end of the review on 02/09/2016. The letter does reflect the reasons for Letby's removal from the unit. Allegations were made by one member of staff, Brearey the neonatal lead, with support from medical colleagues.

117. My recollection is that Letby had been removed from clinical duties without any clear process as to how this could be managed in the longer term and what HR processes would be involved. This was not in the terms of reference which contained no information about any allegations being made about any member of staff.

118. I do not recall discussion regarding the definition of unexpected deaths during the review visit. I do not recall seeing the information provided by the CDOP following the review visit but having read it I do not think it contributes to the review report.

119. Other information gathered

120. The interview with Carol Jackson allowed triangulation of the concerns raised during the visit regarding communication with the transport team, time for the team to be able to respond and lack of 24/7 consultant availability

121. I was not involved in the interview with Nim Subhedar I do not know if any other members of the review team spoke to him, what was discussed, whether or not a note was taken and what the significance of any discussion was.

Following the visit and reflections

122. The RCPCH head of invited reviews was responsible for drafting the report with input from the lead reviewer. The draft report was circulated and the review team were asked to provide any comments, answers to questions raised by Eardley and contribute to draft recommendations. This would have been done electronically. I do not recall meetings or discussions relating to preparation of the report. I do not recall the number of drafts of the report I considered.

123. The reference to Stepping Hill in correspondence refers, I assume, to events at that hospital where a member of staff was found to have harmed patients. I do not know who wrote it.

124. I do not know who removed the wording [Lucy Letby's move to an alternative post] *was apparently due to the risk of the consultants approaching the police with the allegations"* nor do I know at whose request.

125. I do not recall the reasons for my comment about Brearey being a possible clinical director if Ravi moved away from a clinical management role.

126. The neonatal admission rate at approximately 17% was considerably higher that one would expect in a DGH neonatal unit with separation of infants from mothers. In correspondence it is noted that the admission rate had fallen by the time of the review and in other data the admission rate was under 10%

127. There were a number of issues relating to the neonatal transport service, staffing, organisation and response times. One of these was consultant availability for transfers out of hours.

128. Commenting on the neonatal environment we were aware that the unit required upgrading and that fund-raising was already being undertaken support that upgrade. Neonatal environment space, direct visibility and central monitoring can all impact on patient care and outcomes.

129. Quality assurance is to ensure that the report is logical and reads clearly so that someone who had no prior knowledge of the review would understand the reasons for the review the areas explored and the evidence provided in the report to support the recommendations.

130. I am not aware whether or not Dr Dorling undertook quality assurance. I had no discussion with him and am not aware of any comments made by him.

131. I think Dr Wilson made some comments that relate to the lack of HR process in removing Letby from clinical duties although I do not know what was meant by his other comments.

132. I did not receive the comment made by Dr Shortland in relation to Grantham. I am aware that in Grantham a member of staff harmed patients and similar allegations were being made at COCH.

133. I am not aware which version of the report was provided to Dr Shortland or whether it contained the references to requests by the paediatricians to involve the police. I had no discussion with Dr Shortland

134. I read the final version of the report and agreed with the recommendations

135. The review team agreed that there were no obvious factors which linked the deaths and that circumstances in the unit were not materially different from those which may be found in many other neonatal units within the UK. Some of these deaths could have been described as expected some were unexpected. In particular a number of the consultants noted that several of the infants had collapsed unexpectedly and had been unresponsive to normal resuscitation measures. Some of these infants were described as showing skin mottling which the consultants had not seen before.

136. Like many units in the UK the COCH did not meet professional standards in terms of staff numbers both nursing and medical. An external review identifying these issues can be helpful in increasing the resource available to units to increase the nursing complement and to consider alternative means of reaching the standards e.g training of advanced nurse practitioners, recruiting SAS grade staff, additional consultants.

137. Leadership and team working was generally thought to be good but greater involvement of nursing staff in decision making may have improved relationships. Escalation and transfer out of patients requiring care in a regional unit was not consistent and could be improved.

138. Safety, Risk and governance was an area where the team felt there should be greater standardisation of reporting and management. The trust was already aware that incident reporting in the neonatal unit was not systematic. Reviews of deaths did not

appear to use a standardised approach and did not have close links with the risk management team.

139. The review team thought the the relationships to the network were good. There were issues regarding timeliness of transport and availability of cots in regional centres.

140. The recommendations the report came from evidence gathered from data submitted and from interviews during the visit.

141. The final versions of the report do not reflect the references to potential police involvement. I assume this was thought to be too sensitive to include.

142. The report was not drafted by me and I am not able to comment on why there is any reference to a subjective view used. I do not recall any discussion by the review team whether or not the paediatricians' concerns were objective.

143. The staff rotas appeared to indicate that one member of nursing staff was on duty at the time of almost all of the events. She was a full time member of staff who frequently worked additional shifts. I do not recall if the team reached an agreed conclusion regarding this.

144. Section four attributes to the consultants a comment about gut feeling. I do not know when or if that comment was made and by whom. I was not at the interview with the senior nurses.

145. I do not recall the team discussing whether the unexpected nature of the deaths or the issue of mottling gave rise to or added to grounds for suspicion, however they did indicate a need for the detailed case review.

146. At para 3.10 the report refers to our view that the review team agreed that there were no obvious factors which linked the deaths and that circumstances in the unit were not materially different from those hich may be found in many other neonatal units within the UK.

147. I was not involved in the decision to send two reports to the trust. My understanding was that the 'confidential' report contained information that potentially could identify the member of staff who had been removed from clinical duties and that this version of the report would only be circulated to the executives involved in commissioning the review and the paediatric clinical director and the neonatal lead. I do not know if consideration was given to sharing the report with any other agency.

148. I did not know if/when the confidential report was shared with any of the paediatricians.

149. I did not make any contribution to Appendix 4. I do not know when / if this appendix was sent to the COCH.

150. From reading the redacted information available. These appear to be a collation of internal and network reviews. Incidents appear to be more common in the early hours of the morning. There are a number of different underlying diagnoses for example prematurity, intra-uterine growth retardation necrotising enterocolitis chronic lung disease, sepsis.

151. In some cases deaths may be expected and in some unexpected. There are some recurring themes such as UVC placement and fixing. There are a number of infants who have had multiple transfers and some comments about communications with transport services and decision making around transfers.

152. I had no discussion with RCPCH management or the board of trustees at the time of the review or following it.

153. I was not involved in drafting or contributing to the written update to the programme board.

154. I am not aware of the purpose of the close out form nor who completed it. I did not contribute to it. In my view follow up was required to ensure that the trust was implementing the recommendations of the review. The recommendation perhaps most likely to assist the trust was the independent case note review. I did not make any recommendations regarding follow up nor was I asked for advice regarding follow up. After the review visit to COCH I took part in a telephone interview with the transport lead and Sue Eardley as part of the review but had no other involvement in follow up. Informally I heard that the detailed case note review had been commissioned.

155. I had no further involvement with the COCH review following finalisation of the report

156. I had no involvement in the preparation of any additional reports dated November 2016. I am not aware of their purpose. I am not aware of the circumstances in which the report came to be published by COCH and had no discussions with the trust or RCPCH regarding this.

157. I did not see an email from Harvey to Sue Eardley dated 14/12/2016 [INQ0012756] attaching a letter from the paediatricians to the Trust dated 10.12.17 [INQ0012757] requesting an urgent investigation by the Coroner of all deaths and unexpected collapses, nor did I provide any comments on these. If I had seen or been asked to comment on the email from Harvey and the Consultants letter I would have noted that:

- The trust management had not shared the confidential report with the whole paediatric consultant team.
- As one might have anticipated the case note review conducted by Dr Hawdon led to a recommendation for further forensic investigation of a number of cases.
- Despite the case note review of Dr Hawdon the consultant team remained concerned regarding the unexplained deterioration of a number of infants in the period before early July 2016.

158. I did not see or make comment on emails between Dr Brearey to Professor Modi of RCPCH.

159. I would expect the employing authority to be responsible for support to all staff following reviews, inspections, inquiries, etc.

160. I was not party to the decision process to produce two reports one for restricted circulation and one which may become public. In my view all of the paediatric consultant team should have seen both versions of the review.

161. The RCPCH review service does offer follow up with the client - in this case the medical director. In this case as is stated the clinical team had difficulties in their relationship with the medical director.

162. I did not contribute to the RCPCH chronology

163. I was asked to contribute to the Crisp review of the RCPCH invited reviews service and took part in a short telephone call or conference call.

164. The review team, I think, were aware that conducting a forensic investigation was beyond our remit and ability hence our discussions with the medical director about police involvement. I agree it was not for the college to investigate the removal of Letby but I am not sure that the review did that other than to advise that an HR process should be used.

165. In retrospect I would agree that a review that requires redaction of one version of its report may have overstepped its brief but would assert that this would not have happened if the trust had been open and honest when the terms of reference were being agreed.

166. The review team considered aborting the review when the allegations about a member of staff became clear but it was felt that there was some benefit in continuing according to the terms of reference and making some recommendations about further investigation that might be helpful. The fact that the college felt the need to revise the invited review guidance demonstrates that the /complexity at COCH had not previously been considered nor included in the guidance available at the time.

167. The recommendation that a detailed case note review be undertaken follows from the reviews inability to find identifiable common factors.

168. I was not aware of a meeting between RCPCH and Brearey on 12/07/2019, nor did I speak to anyone about this. I have not seen Brearey's comments.

169. At the time of the Crisp review I expressed doubts about continuing with the review after we were made aware of specific allegations regarding a member of staff. The team as a whole agreed that there was benefit in continuing and that if we adhered to our terms of reference we could provide some recommendations that might help the trust move forwards.

170. I did not consider the contracted role nor the contract between RCPCH and COCH and did not express the view that we would let the College down if we walked out.

171. I have no recollection of a conversation regarding professional risk. In my view professional risk would relate to undertaking tasks which are not appropriate. I did not specifically consider professional risk in my contribution to the decision to continue the review.

172. As previously stated, if the allegations about a member of staff had been made before the 1st of September 2016 I would have been surprised that the College would have agreed that an invited review was the correct way forward.

173. In my view an invited review is not an appropriate means of investigating an increase in unexpected or unexplained deaths in circumstance where clinicians suspected a nurse of criminality.

174. If we had aborted the review on the morning of 1st September any other benefits arising from the review process would have been lost.

175. I do not believe it was appropriate to interview Letby.

176. In retrospect and looking at the revised RCPCH guidance there was not sufficient feedback to the RCPCH board during the review.

177. The review team advised the trust management team to involve the police if there was suspicion of criminality. There was no RCPCH escalation guidance in place at that time.

178. If the current guidance for reviewers had been in place I think that the review would have been adjourned on the morning of 1st September 2016 and the concerns escalated within the College according to the 2023 escalation guidance.

Statement of Truth

I believe that the facts stated in this witness statement are true. I understand that proceedings may be brought against anyone who makes, or causes to be made, a false statement in a document verified by a statement of truth without an honest belief in its truth.

Signed: **Personal Data**