IN THE MATTER OF

THE THIRLWALL PUBLIC INQUIRY

OPENING STATEMENT ON BEHALF OF

IAN HARVEY

(former Medical Director of the Countess of Chester Hospital)

ALISON KELLY

(former Director of Nursing and Quality of the Countess of Chester Hospital)

ANTONY CHAMBERS

(former Chief Executive of the Countess of Chester Hospital)

SUSAN HODKINSON

(former Director of People and Organisational Development of the Countess of Chester Hospital)

Introduction

1. This written Opening Statement is made on behalf of Ian Harvey (former Medical Director of the Countess of Chester Hospital), Alison Kelly (former Director of Nursing and Quality of the Countess of Chester Hospital), Antony Chambers (former Chief Executive of the Countess of Chester Hospital) and Susan Hodkinson (former Director of People and Organisational Development of the Countess of Chester Hospital) in accordance with the approach set out by the Inquiry Legal Team ('ILT') in its 'Note on Core Participant Opening Statements', dated June 2024.

2. Before we turn to the matters about which we have been specifically asked to address by the Public Inquiry we wish to express, once again, our deepest condolences to the families of the babies harmed so cruelly by Lucy Letby ('Letby'). There is not a day that goes by when we have not thought about the trauma that the families have gone through and continue to go through. We recognise and pay tribute to their dignity and courage.

3. We hope, as no doubt do all Core Participants, that this Public Inquiry will fulfil its Terms of Reference fully and, through the evidence it has gathered and the evidence it will call, for the first time produce a comprehensive account of what happened at the Countess of Chester Hospital ('the Hospital'), so that the right lessons are learned, and real change is implemented where needed. We fully expect the Public Inquiry to do so unblinkered by hindsight bias.

4. This Public Inquiry has provided us with the first real opportunity to tell our story. We are grateful for this opportunity. We have made and will continue to make every effort to assist this Public Inquiry, and the families, in understanding what we knew, when we knew it and what informed our decision making.

5. Set out below are our responses to the questions posed by the Public Inquiry. In some instances, the original questions are generic or are directed to those who still work at the Hospital. Some appear to be directed to an organisation. We have responded in a way which we believe is of assistance to the Public Inquiry in its investigation of its Terms of Reference. Inevitably, given the limitation as to the purpose of this document, what is set out below should only be viewed as a summary response. Equally, whilst we were all part of a Senior Management Team, we each had our own specific roles, experiences, interactions and perspectives. We have provided detailed witness statements running into hundreds of pages, referencing many exhibits, covering a period of several years in order to assist the Public Inquiry. We invite the Chair to consider this summary document in the context of that detailed and specific evidence.

A. Knowledge about Suspicions and Concerns

6. The first time that concerns about Letby were raised with Senior Managers, that is Alison Kelly and Ian Harvey, was at the end of June 2016 after the sad deaths of Child O and P (on Thursday 23 and Friday 24 June 2016), the last of the babies murdered by Letby.

7. There were numerous meetings held throughout the following weeks between Doctors, Nursing Staff and Senior Managers. This included Ian Harvey, Alison Kelly, the Director of Corporate and Legal Services, Stephen Cross, and Antony Chambers, as well as meetings of the Hospital Trust Board. The purpose of these meetings was to try and understand the nature of these concerns in the context of the mortality rates on the Neonatal Unit ('NNU') and what action should be taken to keep the NNU safe. Keeping the NNU and its patients safe was always our primary, motivating factor.

8. The increase in mortality rates on the NNU was a matter about which Ian Harvey and Alison Kelly had already been made aware. This had resulted in a number of reviews and investigations which had been carried out in 2015 and 2016. These included Serious

Incident Panel Investigations[1]. There had also been a review titled, 'Neonatal Deaths and Stillbirths for the period January 2015 to November 2015' [INQ0003589] conducted by Consultant Obstetrician and Gynaecologist, Dr Sara Brigham, and a Thematic Review led by Consultant Neonatologist and Clinical Lead for the NNU, Dr Stephen Brearey [INQ0003217]. Issues were flagged within these reviews concerning elements of care e.g. delayed cord clamping and CTG interpretation [INQ0003575]. Actions were subsequently identified in order to remedy these issues. However, during the course of these reviews and investigations there was no suggestion of any concerns that the increase in mortality rates was connected to any unnatural event or the result of foul play. Furthermore, there were no concerns raised in relation to the conduct of any member of staff, including Letby.

9. On 11 May 2016, there was a meeting between Ian Harvey, Alison Kelly, the Manager of the NNU, Eirian Lloyd Powell, the Manager of Children's Services, Anne Murphy, and Dr Brearey [INQ0003181], [INQ0015537] in which the Thematic Review was discussed. Dr Brearey, Dr V (Consultant Neonatologist), Dr Nim Subhedar (Consultant Neonatologist at the Liverpool Women's Hospital), Eirian Lloyd Powell, Anne Murphy, Laura Eagles (Senior Nurse Practitioner) and Debbie Peacock (Risk and Patient Safety Lead) had all been involved in the Thematic Review exercise which had involved careful consideration and scrutiny of each neonatal death in order to identify any areas of concern.

10. The Thematic Review did not find any common themes in relation to the deaths but identified some care issues (including umbilical venous catheters and transport issues). It was noted that the cases involved some very sick babies which exacerbated the situation and may have contributed to the deaths.

11. The meeting was noted, by Dr Brearey, to have been helpful and informative [INQ0005721], and an Action Plan was agreed by all at the meeting. This included action to be taken by those directly responsible for the management of the NNU. There was to be a review of any further babies who suddenly collapsed or deteriorated and a further deep dive into the neonatal deaths which had taken place. It was agreed that a follow up meeting would be convened after a period of two months, that is in July 2016, to review the situation. It was clear to Senior Managers in attendance at the meeting that careful consideration had been given to each of the cases including by specialist clinicians in neonatology. All of the actions going forward were considered appropriate and proportionate.

---

[1] Deaths of Child A, Child C and Child D Serious Incident Panel [INQ0003530], Serious Incident Panel Meeting regarding Child E [INQ0002659], Level 2 Root Cause Analysis Investigation Report regarding Child D [INQ0014204].

12. As can be seen by a consideration of the Thematic Review documents and the record of the subsequent meeting, no concerns were raised about the deaths being unnatural or suspicious, nor were any concerns raised in relation to Letby other than in relation to her wellbeing. Senior Managers were aware that Letby had been on shift when a number of the deaths had occurred. However, it was understood that she was a specialist practitioner and, therefore, because of her skills and training, more likely to be looking after the sickest infants on the NNU, often on her own. In addition to this, her willingness to work overtime when the acuity or unit was over capacity meant that she was on shift on a more frequent basis than other nursing practitioners. Senior Managers were made aware that Letby had been moved to day shifts for three months and had understood from what they were told that this was due to work related stress. Senior Managers were also told that there were no known performance management issues or complaints against her, and that she was considered by nursing colleagues to be a diligent nurse with excellent standards.

13. The picture changed at the end of June when concerns were raised, for the first time, to Senior Managers by Dr Brearey (who had been present at the 11 May 2016 meeting), and Dr Ravi Jayaram (Paediatrician and Clinical Lead for Children's Services), about Letby being connected directly to the deaths.

14. There were numerous meetings throughout the remainder of June and July attended by Senior Managers and Consultants. Aside from the link between Letby's shift pattern and the deaths, nothing specific was ever articulated by either Dr Brearey or Dr Jayaram, or any other Consultant, to identify the wrongdoing by Letby. For example, there was never any suggestion that any Consultant had witnessed an event involving Letby that raised suspicion about her behaviour towards any of the babies on the unit. There was nothing raised about any concerning test results. There was nothing raised about a failure in the care that Letby had given to any of the babies to indicate that her conduct had, or might have, contributed in any way to the deaths on the NNU. The undefined concerns of the Consultants were not shared by nursing staff. Indeed, the NNU Manager, Eirian Lloyd Powell, was firmly of the view that Letby was a good and competent nurse.

15. In addition, at this stage it appeared that there was also a Doctor who had been on shift at the time of several of the incidents.

16. Coroner's Authorisation Form 1 had been issued in relation to all seven cases in which babies had died. The Coroner had, therefore, been alerted and had the opportunity to investigate. No concerns or issues had been raised.

17. Whilst the concerns about Letby remained undefined, nevertheless, Senior Managers still took action to better understand what was going on and to ensure that the NNU was safe.

It was felt important, from the outset, that an open mind was preserved about the cause of the increase in deaths and that all potential factors ought to be considered. Incidents or issues within wards or units were, from experience, almost always complex and multifactorial in terms of cause. This was rather than there being one single factor or, indeed, actor. It was undoubtedly the case that the picture with regards to the NNU and its problems was a complicated one. As indicated above, the NNU and how it was being managed was not without issue. This much had been identified by the reviews which had recently been carried out. The aim of the Senior Management response was, primarily, to ensure that the NNU was safe. There was also now an urgent need to understand what was happening on the unit and what needed to be improved to keep the babies safe. This had to be done through both external and further internal reviews and data gathering.

18. The following is a summary of the key actions that were taken in June and July 2016 in order to better understand the raised mortality levels and to keep the babies on the NNU safe:

    a. The unit was redesignated as a Level 1 Special Care Unit which meant that it would no longer be looking after very sick babies (that is, those born under 32 weeks).

    b. A review was commissioned from the Royal College of Paediatrics and Child Health ('RCPCH') (see more detail below).

    c. An internal review and information gathering exercise was undertaken by a team of individuals as part of a Silver Command type operation led by Stephen Cross, the Director of Corporate and Legal Services (see more detail below).

    d. The Coroner, the Nursing and Midwifery Council ('NMC') and the Care Quality Commission ('CQC') were appraised of the concerns in relation to the increased number of deaths.

    e. A Communications Plan was developed which included the setting up of a control room to handle calls with bereaved parents.

    f. Letby was redeployed off the unit into a non-patient contact role.

    g. An Extraordinary Board Meeting was held on 14 July 2016.

19. A key objective of the Silver Command operation was to collate more detailed information about each of the deaths and collapses which had occurred and the possible contributory factors, as well as looking at the staff involved and an analysis of the skill mix.

20. There was some concern about the data validation exercise in relation to the number of deaths, trends and staffing as the data was being gathered from three different databases, none of which were neatly aligned[2] [INQ0003174], [INQ0004319].

21. Some of this information was used to inform a list of clinical reviews to be undertaken by Dr Gibbs (Consultant Neonatologist) and Anne Martyn (Ward Manager, Children's Unit) who would look at the clinical records for all the babies who had collapsed and been transferred out of the Hospital.

22. Furthermore, Ian Harvey was tasked with carrying out a review of the NNU in terms of activity levels and the nature and number of admissions over the relevant period [INQ0003361/2]. This was not a clinical review of each death but an overarching service review. The purpose of this task was to identify if there were any potential issues contributing to the rise in neonatal mortality such as an increase in acuity.

23. It was felt that this work, combined with the independent RCPCH review, would be capable of providing sufficient levels of information to enable the Senior Management team to further consider the concerns raised about the increased mortality rate and also the as yet unspecified and unevidenced concerns about Letby.

24. At this time, the Senior Management team had to balance the primary need to ensure that the NNU was safe with the need to be fair and have regard to the welfare of Letby. In addition to these aspects of responsibility, the Senior Management team had to be mindful of the impact on the whole unit, and the Hospital, of the action being taken.

25. To be clear, Letby was off duty on 30 June 2016 and on scheduled annual leave for 14 days at this time [INQ0003361], returning on 14 July 2016. As such, there was no risk to patients in this course of action being taken.

26. On her return from annual leave on 14 July 2016, Letby was never again deployed in a patient facing context. Whilst there was some discussion about her return to the clinical environment during the period that investigations continued, this would only ever have been contemplated whilst she was under the direct supervision of another nursing professional. In the event, this could not be accommodated. Therefore, the decision was taken to place her in an administrative, non-clinical setting.

27. As a result of the work undertaken as part of Silver Command, a Position Paper was drafted by the Head of Risk and Patient Safety, Ruth Millward, and co-authored by Ian Harvey and Alison Kelly. It focused on the significance of any increase in mortality, an

---

[2] There was the Badgernet system (used by the NNU), the Meditech system used by the rest of the Trust and the Datix system.

evaluation of activity levels on the NNU, and an evaluation of certain measures of activity (such as the condition of the babies)[3]. It was a detailed document that looked at Datix reporting and the information relevant to the NNU in the risk registers. It was noted that the departmental Risk Register contained 15 risks of which four had been scored as "high/red". These included pseudomonas risk, the availability of the Neonatal Network transfer team and two risks associated with the availability of medical staff.

28. There was a section within the Position Paper on Neonatal Deaths and Sudden Deterioration. Of the four neonates who suddenly deteriorated during the period January to June 2016 (including Child M, Q and N), none had been reported via the Datix reporting system. Therefore, these cases required further case review[4].

29. In addition, the Position Paper noted that the review had identified "*that the NNU staffing numbers were below BAPM recommendations ... at the time of 7 of the neonatal deaths (out of 11...)*".

30. The data also revealed 11 incidents reported by neonatal staff from June 2015 to March 2016 regarding staffing and acuity concerns.

31. The Position Paper concluded that there had been a steep change in mortality levels since June 2015. There was increased activity and total care days for some months in 2015/16 and evidence of increased acuity in the second half of 2015 which were considered to be contributory factors. Staffing levels were also below recommended levels which was a national problem due to a shortage of doctors and nurses in the field. The outcome of the work undertaken did not provide a clear and definitive answer to what had been contributing to the increase in deaths. It was, however, an important step forward in identifying possible shortfalls with the care provided.

32. In addition to the above, on 28 June 2016, enquiries were made with the Royal College of Paediatrics and Child Health ('RCPCH') in respect of the commissioning of an independent review [INQ0009599]. It was explained to the RCPCH that concerns had been raised by Neonatology Consultants about an increase in the number of deaths on the NNU and that reviews to date had not identified any common causes, but there were concerns that one member of staff was disproportionately associated with the cases which is why a comprehensive and independent review of the NNU service was needed. A scoping request was completed [INQ0009590], and a draft review proposal prepared by the

[3] There was also a summary presentation prepared of the Position Paper [INQ0002837].
[4] This was consistent with the information previously shared by Ruth Millward about the lack of Datix recording by the NNU for near miss incidents.

RCPCH. There were then discussions with Ian Harvey before the proposal was finalised [INQ0009595].

33. Although the draft Terms of Reference do not make express reference to Letby (or a particular member of staff), the Consultants' concerns about a member of the nursing staff were relayed to the RCPCH. Contained within the draft Terms of Reference is the direction, "*Are there any possible common factors linking the recent neonatal deaths?"* This was drafted in a purposefully wide way and expected to include any potential linking factor(s), including staff[5]. As can be seen in the paragraph below, it is recorded that the RCPCH spoke to the Consultants during their visit to the Hospital in September 2016.

34. It is clear from the Crisp QI Report entitled 'External Review of the RCPCH Invited Reviews Service'[6], dated March 2021, that the Consultants expressed concern about Letby's involvement in the deaths to the RCPCH [INQ0010177/24].

35. The RCPCH conducted a two-day visit on 1 and 2 September 2016 and carried out a number of interviews of staff including with the Consultants and Letby [INQ0009597], [INQ0010124], [INQ0010125], [INQ0010121], [INQ0010122], [INQ0010119], [INQ0010120] and [IN0010123][7]. On 5 September 2016, the RCPCH sent its recommendations [INQ0003120] to Ian Harvey. In summary, the RCPCH recommended:

    a. That immediate steps be taken to formalise the investigation being undertaken in respect of Letby, including what the allegation was and what the process would be to investigate it. The RCPCH letter suggests that this was a Human Resources issue.

---

[5] At paragraph 2.7 the document states: "*the issue is very sensitive and needs to be resolved as soon as possible in order that the service and clinical morale is not undermined by the distressing series of events*". I think the term "*very sensitive*" applied in respect of the deaths of babies and the potential involvement of Letby. Ian Harvey, Para 240.

[6] Crisp QI Ltd were commissioned by the RCPCH to undertake an external review of the RCPCH Invited Reviews programme, the purpose of which is to assure patient safety and improve the quality of care in child health services. The programme responded to requests from healthcare organisations for independent expert review of aspects of their paediatric and child health services. At the date of the Report, the RCPCH Invited Reviews programme had been running for over nine years and had undertaken around 100 reviews. Crisp QI's review was commissioned in recognition that it is good practice to periodically review an established programme of work, to ensure that it is fit for purpose, and meets current needs and the corporate objectives of the RCPCH. The Crisp QI review utilised qualitative research methods: reviewing the documentation supporting the programme, interviewing a wide range of stakeholders, and carrying out an analysis of findings set against the context of current issues and pressures for child health services.

[7] [The Crisp QI Report [INQ0010177/24] notes that: "*Quite early on the first day, in an interview with the paediatric consultants, they expressed very clear concerns about possible involvement of a member of the nursing staff in the unexpected deaths of seven babies… The Lead Reviewer stated that when the Medical Director was presented with the review team's concerns, he was reluctant to involve the police at that point and the review team did not press him on this."* This was on account of the fact that we had already discussed the concerns raised by the consultants and that the decision to contact the police was on hold pending the reviews [INQ0010124]].

b. That there be a detailed forensic case note review of each of the deaths since July 2015, ideally using at least two senior doctors with expertise in Neonatology/Pathology in order to determine all the factors around the deaths. The RCPCH recommended that the investigation include five elements which were outlined in the letter.

36. Whilst the covering letter described the pattern of deaths and mode of deterioration as "*unusual*" and in need of further enquiry, the RCPCH team never stated that they were concerned about possible unnatural causes or criminal activity or raised any concerns about Letby's involvement. On the contrary, in the summary meeting with the RCPCH at the conclusion of their review on 2 September 2016, the Review Team raised some concerns such as issues with staffing levels and sought to highlight that they felt that Letby had been mismanaged and had a strong case for a grievance procedure [INQ0010124].

37. On 18 October 2016, the RCPCH provided their draft report to Ian Harvey [INQ0003403] and [INQ0005273]. The findings of the RCPCH review included the following:

    a. The Review team were told that Letby was an enthusiastic, capable, and committed nurse who had worked on the unit for four years. Her nursing colleagues were reported to think highly of her and there were apparently no issues of competency or training.

    b. The Consultants explained that their allegation was based on Letby being on shift on each occasion an infant died (although not necessarily caring for the infant) combined with a '*gut feeling*'. There was no other evidence to link Letby to the deaths.

    c. The unit was non-compliant on nurse and medical staffing levels, environment and accommodation for parents, support from the community neonatal team and postnatal follow up.

    d. No annual report had been prepared for the NNU which should bring together key issues and analysis for the attention of Senior Managers, the network and commissioners. This was a clinical leadership responsibility (including Dr Brearey).

    e. Leadership at Trust level appeared to be somewhat remote from the day- to-day issues taking place within the unit. Consultants felt they were '*victims of [their] own success*' and were not on the radar of the Executive Team although there were links through governance arrangements in terms of reporting and incident management.

f. Since the temporary redesignation, staff reported feeling calmer and more confident and morale/sickness levels had improved.

g. The Trust had a clear policy for reporting incidents and there is a Women and Children's Care and Governance Board which considers all incidents and reports. However, attendance at these meetings by medics was not high. This group fed into the Quality, Safety and Patient Experience Committee ('QSPEC') and risk issues could also be considered by the Corporate Directors Group. There was also a Serious Incident Panel and a Mortality and Morbidity Panel which reviewed incidents and unexpected deaths.

h. Only 10 of the 13 deaths were reported as incidents on the neonatal incidents summary. Other areas of the Hospital reported well but the NNU had for some time been less systematic in reporting.

i. Some of the deaths were reported on the Risk Register and the Review Team noted that some were recorded with '*green – low risk of harm status*'.

j. For the cluster of 13-14 deaths being considered in the review, not all were reported to the Pan-Cheshire Child Death Overview Panel ('CDOP'), as some patients were resident in Wales. The CDOP did not appear to be alert to the cluster of deaths. For at least some, there should have been a Rapid Response Meeting.

k. In terms of the deaths, the Consultants had explored a number of factors themselves but not in a systematic way and not following sound governance and root cause analysis processes and the involvement of the Network Clinical Governance Group has been relatively supervisory, working on summaries of cases rather than examining each case in detail.

38. In terms of recommendations, these were as follows:

a. A detailed case note review should be conducted prioritising the deaths that were considered unexpected, to include obstetric and pathology/postmortem indicators, nursing care and pharmacy input.

b. The Trust should ensure there are clear, swift, and equitable processes for investigating allegations or concerns which are followed by everyone.

c. An annual report should be prepared for the unit which is disseminated to the Board and network stakeholders.

d. Two additional Consultant appointments must be in place before any consideration can be given to possible redesignation as a Level 2 unit.

e. There should be a Children's Champion on the Board.

f. The response to neonatal death/near miss investigations should be strengthened to normalise the reporting culture, including risk and governance staff.

g. Procedures for the involvement of more senior advice should be strengthened, and guidelines for Consultant presence on the Neonatal Network should be developed.

39. The Senior Managers never closed their minds to the involvement of the police. However, there was nothing in the report to indicate that this was being suggested or supported at this stage.

40. There were a number of concerning issues identified with the management of the NNU which needed action and improvement. However, the report provided a level of reassurance that the situation was being managed reasonably and appropriately.

41. A final report was provided on 28 November 2016 [INQ0009618], [INQ0009619] and [INQ0009620], which was, in substance, the same as the draft report which had been received on 18 October 2016 [INQ0005273]. In addition, the RCPCH Review Team also provided "*Observations additional to the RCPCH review of Neonatal Services*" [INQ0006033] within which the Review Team stated, "*The neonatal lead, in an effort to be thorough and explore all possibilities had identified that one nurse had been rostered on shift for all the deaths although the nurse had not always been assigned to care for that specific infant. Subsequently the paediatric lead and all the consultant paediatricians had become convinced by the link. Although this was a subjective view with no other evidence or reports of clinical concerns about the nurse beyond this simple correlation an allegation was made to the Medical Director and Director of Nursing*." They also said: "*The consultants explained that their allegation was based on the nurse being on shift on each occasion an infant died (although not necessarily caring for the infant) combined with `gut feeling`. There was no other evidence or history to link Nurse L to the deaths, and her colleagues had expressed no concerns about her practice*." Again, these observations did not suggest that the Review Team in any way held concerns about Letby, nor that they had identified any evidence of wrongdoing.

42. Whilst the RCPCH Review Team had been given detailed information about the babies and documents including post mortems, it was understood that they nevertheless felt that more of a deep dive needed to be done. They gave the names of four individuals with the "*appropriate expertise and experience*" who would be able to undertake this work [INQ0005395]. Attempts were made by Ian Harvey to contact all four individuals. Unfortunately, two were unavailable to assist at the time and the third was uncontactable. Ian Harvey was able to engage one of the individuals identified by the RCPCH, Dr Jane

Hawdon, a Consultant Neonatologist, who was available to carry out the work immediately. It was decided to proceed with her to ensure that the work was carried out as quickly as possible. Depending on her findings, consideration would then be given as to whether a further review or a different course was required. Dr Rennie, one of the RCPCH's recommended reviewers, had offered to conduct a second review of any cases about which Dr Hawdon raised a concern. Whilst this was not a complete fulfilment of the RCPCH's proposal, it seemed to be a pragmatic way to progress matters. Neonatology is a very specialised field and there is a limited pool of clinicians qualified to undertake this kind of review. Owing to the need for independence, it could not be undertaken by Consultants at the Hospital, Consultants belonging to the local neonatal network, or either of the neonatologists involved in the RCPCH review. This eliminated a number of clinicians from an already limited pool. The RCPCH was informed of the Trust's approach on 23 September 2016 and expressed agreement that this seemed to be a good plan [INQ0005395/1].

43. Dr Hawdon produced an "*Advisory medical report*" dated October 2016. Dr Hawdon's report does not identify any common theme running through each of the cases reviewed. There were a number of deaths which Dr Hawdon felt were explained and could have been prevented with different care. Dr Hawdon identified major or significant suboptimal clinical care in 14 of the 17 cases, which was concerning, and pointed to issues with clinical management. Of these 17 cases, nine were later made the subject of charges against Letby. There were, however, some cases where Dr Hawdon felt further review work could be undertaken as they were unexplained and copies of post mortem reports were noted as being required.

44. Subsequently, on 25 November 2016, Dr Hawdon emailed Ian Harvey [INQ0003102] providing the following opinion:

    a. In the case of Child O, subject to a histopathology review, the collapse and death remained unexplained;

    b. In the case of Child P, subject to a histopathology review, the collapse and death remained unexplained;

    c. In the case of Child A, the cause of death was unexplained;

    d. In the case of Child D, the cause of death was pneumonia and that a delay in antibiotics may have contributed;

    e. and, "*As before, I recommend expert perinatal pathology review*".

45. This email did not comment on Child I, who had also been identified as an unexplained death [INQ0006862 at page 55].

46. Following on from this, Dr McPartland, a Consultant Pathologist at Alder Hey Hospital, was asked to carry out a forensic review of the deaths of Child I, Child O, Child P and Child A [INQ003136].

47. On 25 January 2017, Dr McPartland provided her report which contained a detailed clinical explanation of each case. She concluded as follows:

    a. Child A's death remained unascertained, but it was noted that there was no evidence of air embolism.

    b. A cause of death was attributed to Child O, but it was noted that the initial cause of the collapse was unexplained.

    c. Dr McPartland did provide a cause of death for Child I and noted significant abnormalities in the organ systems.

    d. It was noted that the cause of death for Child P could be submitted as unexplained/unascertained and that this was a subjective decision that would vary between pathologists. She recommended that the family be referred on to discuss potential genetic causes of sudden unexpected postnatal collapse.

48. Once Senior Management started to receive feedback from the external investigations via the RCPCH and Dr Hawdon, and later Dr McPartland, there were significant alarm bells ringing in terms of how the NNU was being managed and the care being given.

49. None of the independent experts pointed towards criminal wrongdoing.

50. The Senior Management Team gave considerable thought to whether or not the police should be informed Throughout the review and investigative processes, it was felt collectively that there was a responsibility to clinically investigate the concerns as far as possible before going to the police. It was felt that the Hospital had to be clear about the facts first, in the absence of which, it was difficult to see what the police would be asked to investigate. However, if at any point anyone had said anything which indicated that there was, or may have been, criminal acts on the part of Letby or anyone else which had caused or contributed to what was happening in the NNU, then the matter would have been referred to the police. But as referred to above, reviews and investigations were consistently identifying issues with the care provided within the NNU.

51. For the avoidance of any doubt, Senior Managers were never told of the following:

a. That, in August 2015, following an unexpected deterioration, there was evidence to show that Child F had been given a pharmaceutical form of insulin [INQ0010283/transcript p52] in a context in which no other babies were receiving insulin at the time. It is understood from reviewing the evidence disclosed as part of this Inquiry that no further action was taken by clinicians [INQ0010283/transcript p10-11]. It is impossible to overstate the importance of this result. In excluding accidental administration, the only alternatives are either a negligent mistake or a malicious act in harming a baby. If the proper governance processes had been followed, the outcomes of these enquires would have been reported to a Consultant. We understand that the junior doctor who received the results did report them to the Consultant Dr ZA, who, after excluding accidental administration, took no further action. This should have been clinically investigated. It should have been recorded in Datix. It should also have been reported to the Women and Children's Governance Board and the Risk Team. None of this was done. This was significant information that would have altered the picture and affected the subsequent actions created.

b. That, on 17 February 2016, Dr Jayaram witnessed Letby standing next to Child K's cot as the baby's condition was rapidly deteriorating and that he believed that Letby could see the baby was desaturating but was doing nothing to help the baby. Neither were they told that the baby's condition deteriorated on two further occasions over the next few hours and, on both occasions, the baby's breathing tube had been dislodged. This was crucial information and direct evidence of wrongdoing by Letby which was only disclosed by Dr Jayaram, for the first time, on 15 March 2017 during a meeting with Susan Hodkinson [INQ0003219].

52. The Senior Managers relied on clinicians to record and report clinically significant events, as well as raise concerns in relation to their patients, in accordance with long established processes. Senior Managers were not, and could not, have been aware that a number of objective abnormal clinical findings were either not detected or not reported or recorded. Nor were they aware that '*near miss incidents*' were not being recorded or escalated by the NNU and, in particular, that unexplained collapses which had not resulted in harm had not been recorded via Datix as they should have been [INQ0015537, INQ0003371]. There were no individual case reviews for these cases[8]. Neither were these incidents being recorded as Serious Incidents or Never Events on a database known as the Strategic

[8] There were believed to be 5 near misses, with a sudden and unexpected deterioration. There was a Trust policy in place, "Policy for the Reporting of Incidents", which set out the processes for reporting and investigating incidents.

Executive Information System (StEIS). This database was used for Serious Incidents which required investigation or significant events and included the unexpected or avoidable death of a patient. External agencies such as the CQC, the Clinical Commissioning Group ('CCG') and NHS England ('NHSE') had access to StEIS, thereby being alerted to such incidents.

53. The significance of not following established governance systems cannot be overstated. The fact that there were no such reports made meant that the monitoring of the NNU by the Neonatal Incident Review Group (reporting into the Women and Children's Care Governance Board as part of the divisional management structure), the Risk Management Team[9] and the Senior Management Team, crucial to identifying issues and trends, could not and was not taking place. If the proper governance processes had been followed this would have significantly affected the understanding of and response to events[10].In other words, effective clinical governance is highly dependent on the quality of data and information, and the incident reporting fed into it. Without this being done, the checks and balances were prevented from taking place.

54. Notwithstanding the extensive review work conducted, questions remained unanswered and by March 2017 it was felt that further review work would not bring clarity to the situation. In particular, the Consultants were now making it plain that only investigation by the police would suffice [INQ003150] and [INQ0014281].

55. At this stage the Trust sought legal advice about approaching the police. In hindsight, whilst done with the best intentions, this was unhelpful and led to a delay in speaking with the police representative on the Child Death Overview Panel ('CDOP'), Superintendent Nigel Wenham, until 27 April 2017 [INQ000337] [INQ0005461].

56. A meeting was requested by Ian Harvey and was arranged for 27 April 2017. Stephen Cross, Dr Jayaram and Dr Holt (Paediatrician) were also in attendance with Ian Harvey [INQ0003337]. In the course of the meeting, Ian Harvey explained that the view had been reached that the Hospital had taken its own investigations as far as it could which is why Superintendent Wenham was now being approached to explore the concerns being raised. Dr Jayaram explained that the Consultants remained concerned about the collapses and the association of one member of staff and indicated that the Consultants

---

[9] The Risk and Patient Safety team at the COCH who would review incidents logged onto Datix. They would follow the NHS Serious Incident Framework in terms of categorising the incidents and determining what level of investigation was required.

[10] When reviewing the documentation there was a noticeable difference in the incident reporting of nursing and medical staff, it being much more frequent with the former group. There was also a difference in reporting and governance when the neonatal team is compared to the obstetric team, the latter seeming to be much more disciplined in their reporting and approach to dealing with incidents.

were uncomfortable that not enough had been done "*on that one person or any other*". Superintendent Wenham indicated that he would speak to the Chief Constable about the concerns raised and provide guidance as to how the matter should be reported to the police.

57. On 5 May 2017 there was a meeting at Cheshire Constabulary Head Quarters which Ian Harvey, Antony Chambers and Stephen Cross attended [INQ0003077]. The purpose of the meeting was to discuss the background of the referral to the police and to determine how to report into the police. It was explained that the Consultants felt that of the 13 deaths, five could be explained but in eight cases they felt that the collapse or death could not be explained. The reviews conducted by the RCPCH and Dr Hawdon were outlined. It was explained that the Trust had received legal advice that there was no evidence of criminal activity but that the Consultants had explained they were not satisfied and that they felt nothing short of a police investigation would satisfy them that some of the deaths were not due to unnatural causes. It was explained that there was a notable high statistical relationship between Letby and babies deteriorating on the unit, but no other evidence.

58. On 12 May 2017, a further meeting took place with Cheshire Constabulary [INQ0003076] which was attended by Assistant Chief Constable Darren Martland, Detective Superintendent Paul Hughes, Superintendent Wenham, Head of Legal (Cheshire Police) David Bryan, Antony Chambers, Stephen Cross and Ian Harvey.

59. Assistant Chief Constable Martland said that "*there is nothing in the reviews, as a non-clinical expert, as to the direct allegation or suggestion of significant negligence or act that could constitute as a criminal act*". In addition, the police said "...*This is uncomfortable as there is no specific allegation at this point to suggest a criminal act. We do not have any reasonable grounds to suspect or believe this may have been the case*". It is understood that by this point there had been a number of meetings with the police, including with some of the Consultants and also that key documents had been shared with the police.

60. The Senior Managers believe that, given the information with which we were provided, and the need to maintain an open mind about possible causes of the mortality rates on the NNU, we acted appropriately at the time. We believe that we made every effort to investigate and understand what was going on in the NNU. We were motivated, always, by the primary objective of ensuring that the NNU was safe for patients.

B. Information Sharing with Parents

61. The Duty of Candour required us to be open and honest with the families of the babies who had died or had suffered a collapse, regardless of the circumstances. We have all reflected deeply on the communications that we had with them. At the time we believed

we were providing the right level of information at the right time. We wanted to make sure that what we were saying was clear and accurate. In hindsight, we should have communicated far better than we did. We were all painfully aware that the families had gone through the most unimaginably devastating experience of losing a beloved child and that we could potentially make this worse by sharing information that was inaccurate or incomplete. We were very aware that every contact or communication from us caused huge distress and we wanted very much to avoid making contact with the families unless we had something of substance to report to them. This was an extremely difficult situation because whilst we had an absolute desire to share everything possible and appropriate, there were times when we did not actually know very much and we were working on the basis of '*gut feelings'*. But we appreciate that this resulted in long periods of silence as the various reviews took their time to progress and would have left families feeling as if they were being kept in the dark. For this we are deeply sorry. The families should have had more support. We should have appointed a single point of contact early on so that families could contact us at any time with any queries or concerns. The additional benefit of this would have been the appointment of someone who could offer support and help, someone who could get to know the parents and how, and when, they would prefer to be contacted.

C. Support for Parents of Babies in Hospital

62. We were not involved in or aware of any issues in relation to the bereavement support provided to parents of babies who died at the Hospital in 2015-2016 or thereafter. Nor were we told of any complaints at any time.

63. We are not aware of what the current practice is in terms of bereavement support. However, we would note that this is a particularly difficult and sensitive area that will be unique to each grieving family. No doubt bereavement specialists will be in the best position to comment on whether and how the current practice can be improved.

D. Advice and Help

64. If a medical professional has concerns about the safety of their patients, advice and help in the first instance ought to be sought within the hospital context in which they work to best ensure patient safety in a timely fashion. Within each Trust there are, as there were in the Hospital, established reporting and governance processes which, if followed and implemented, can and will respond to concerns and identify significant or worrying trends in relation to the safety of patients including neonates and babies The difficulty as indicated above comes when data is not being shared, recorded or flagged and therefore not identified or escalated, e.g. near misses or unexplained collapses. Notwithstanding the backdrop of limited resources, we believe that further training is required to ensure low

levels of tolerance and high levels of reporting when an unexpected or unexplained medical event occurs.

65. In situations where a clinician has either reported concerns and these have not been acted on, or they feel unable to raise concerns, advice and help is available through the General Medical Council ('GMC'), the Royal College of Nursing ('RCN'), the NMC and the RCPCH. There is a plethora of existing information on safeguarding of babies, children and young people via training and policies available through these organisations. That being said, there was not any specific guidance for practitioners on routes for escalation in circumstances where criminal activity within the hospital context is suspected.

66. In addition, the CQC already provides scrutiny in this area as well as NHSE and the CCG. In this case, all of these external organisations were notified and consistently updated.

67. The potential and power to scrutinise by external organisations already exists. If there is an issue then it lies with the information provided to these organisations and action taken thereafter. Any additional arrangements need to be developed with care so as not to duplicate, cause confusion and unnecessarily burden the systems already in place.

E. The Board, its Role and Skills

68. Following the concerns about Letby being raised as described above, the Board of Directors were kept updated as and when developments occurred. Indeed, the Chair, Sir Duncan Nichol, along with Antony Chambers and members of the Senior Management team attended a number of meetings including with Consultants about next steps[11]. Key meetings of the Board were as follows:

69. On 13 July 2016, there was a private Board meeting [INQ003365] during the course of which an update was given to the Board in relation to the increased mortality rate. The next day an Extraordinary Board Meeting was called [INQ0004216], [INQ0003238] with Dr Brearey and Dr Jayaram present to update the Board on the rise in mortality and the actions that the Trust had taken to date and were taking going forwards to ensure the safety of the NNU. There was an overview provided of the review work carried out and the need "*to understand what had changed, what this meant in terms of staffing, to understand the clinical context of all the babies' deaths over a longer period and to also commission an independent review on the neonatal services*". It was confirmed that the admissions criteria for the unit had been changed, a deeper dive on the data undertaken, meetings held with the clinicians, and it was noted that there were "*further areas to be looked into after this review*".

[11] [INQ0003361], [INQ0004314].

70. In terms of whether criminality was considered, it is recorded in the notes that James Wilkie, a Non-Executive Director, said "*he wanted to better understand what are the critical issues that mean it is not appropriate to engage the police as he could see disquiet*". He is also recorded as saying "*he accept[ed] that [there is] no evidence to say [it] is due to an individual but there is no evidence to say the contrary...*". The justification at this time for not involving the police was that, with the exception of an increased mortality rate and a concern given the nature of the babies who died, there was no evidence of wrongdoing to take to the police, hence all the review work which was underway was in order to gather more information. The expectation was that this would identify the issues and provide guidance. In the meantime, a number of actions had been taken to manage the potential risk to patient safety. Antony Chambers noted that "*that there will be weekly monitoring on neonatal services at the EDG.*" This was a reference to the Neonatal Dashboard which had been set up as a result of the concerns being raised. Such monitoring equated to a weekly review of the latest figures from the unit in terms of admissions, acuity, transfers out, staffing levels and serious incidents.

71. On 10 January 2017, there was an Extraordinary Board Meeting [INQ0003237, INQ0003332] in which Ian Harvey presented a paper on the outcome of the various reviews of the NNU completed to date [INQ0003518].

72. On 7 February 2017, there was a Board of Directors meeting [INQ0004393 and INQ0014821/4] in which an update about the NNU was provided by Antony Chambers which was recorded as follows: *"the Board will be aware that in July 2016, clinicians raise concerns regarding an increase of deaths in the neonatal unit. The unit changed the admission criteria and the Trust invited the [RCPCH] to undertake a review. The RCPCH suggested a more in-depth independent review be undertaken which had been completed. The independent case review highlighted some areas for improvement but did not identify a single causal factor or raise concerns regarding unnatural causes".*

73. On 13 April 2017, there was an Extraordinary Board Meeting at which Simon Medland KC attended. This was in order for him to provide and discuss his advice in relation to whether to report the matter to the police. The Board had received the minutes from his meeting with the Paediatricians. During the meeting it was noted that Simon Medland KC said that, "[The] *Consultants take the view that they're not militant or agitating for the matter to go to the police but they cannot see anyone else who might investigate….All of us around the table agree that if there is clear evidence of a crime you would want to go to the police straight away*". He also confirmed that, in his view, "*there is no evidence of a crime*". Then he raised the option of approaching the police member of the CDOP.

74. On 2 May 2017, there was an Extraordinary Board Meeting [INQ0004221]. Ian Harvey reported that following the RCPCH review, they had met with the Consultants, and it was clear that they were unlikely to be able to get to the point of being able to meet with the parents to explain the review work. Ian Harvey noted he had met with the CDOP and Superintendent Wenham together with Dr Holt and Dr Jayaram. The feeling was that the next step was police investigation. There was reference to a further meeting with the police on 15 May 2017 (this meeting actually went ahead on 12 May 2017).

75. The Board had oversight of the clinical and corporate governance, with Non-Executive Directors chairing the relevant committees. In our view, there was varied experience across Board members (including a Chair who had previously been CEO of the NHS). As a collective, the Board had the relevant skill set to oversee both clinical and corporate governance.

F. Management in the NHS and Regulation.

76. As Senior Managers, we feel that we made reasonable decisions given the exceptional circumstances of this case. We were held to account by the Board and by the CEO. On reflection, we felt like we were taking appropriate steps having regard to the issues and the information with which we were provided. It is crucial to understand that the responsibility to keep babies safe is shared by everyone. From those who work on the ward all the way to the Board. The leadership model at the Trust was based on the 'triumvirate' model of management with three inter-professional medical, nursing, and managerial leaders working together. Within each unit and department, the leadership team was based on this collective leadership model, and this was mirrored at Board level with representatives from each of the three disciplines.

77. Trust Boards and Executive Teams are reliant on the governance, escalation and risk reporting processes that are in place to be able to know what is happening within the organisation. Clinicians are in the unique position of being able to identify if there is something concerning about a clinical presentation or if the conduct of other clinicians or staff is a concern. Such concerns must be reported/escalated in order for governance processes to work effectively and for Senior Managers to be able to make decisions on the basis of all the relevant information and data. As the evidence has shown here, the Datix system was not being used appropriately, concerns were not being flagged within QSPEC, and concerning test results and witnessed behaviour was not reported. Individual accountability of clinicians involved in the management of vulnerable babies needs to be reinforced and strengthened through training and professional standards.

78. It is difficult to see how regulation of Senior Managers would have helped in this scenario. The systems and processes were in place but were not being followed.

G. Culture

79. From our collective experience of working within the Countess of Chester Hospital, the culture of neonatal units is quite insular. Due to the nature of their highly specialised work, they can appear to be somewhat separated from the wider organisation. Neonatal units operate as part of networks. As such, their activity and performance data should be both site and network specific. It seems to us that there needs to be greater effort to link these services with maternity and children's services. Strengthening governance, in line with maternity services, would be beneficial in ensuring that work on the neonatal units is integrated into the organisational governance framework. By doing so, this would help to encourage use of the established systems of reporting, investigation and learning. The overall outcome of this may well be that trends ought to be easier to identify.

H. Reflections and Recommendations

80. We welcome the opportunity to provide input to the Public Inquiry in respect of the recommendations which it may make in due course. We await the conclusion of all oral evidence and completion of disclosure and review of all the written evidence before we provide any detailed reflections on recommendations. At this early stage, however, we would note that what is apparent to us, on reflection, is that the reporting culture on the NNU and the lack of Datix reports being submitted for deaths and unexpected collapses was a key factor in relation to why these cases were not flagged or escalated in the way that they should have been during 2015 and early 2016. Furthermore, the lack of reporting on StEIS also meant that external agencies were not being made aware of the rise in deaths and unexpected collapses. We also suggest that there be guidance published for individuals and organisations for the reporting of suspected criminal activity within a hospital setting. This would provide a clear road map for practitioners to follow leaving no doubt as to the correct procedure to use in these rare but serious circumstances.

81. The Inquiry asks for our current position on CCTV observation of neonates in hospitals. A system already in force is that of tele-tracking which is the use of smart badges and smart labelling of equipment including cots. We agree that in combination with this system, the use of CCTV in neonatal wards would assist in monitoring the risk to babies from bad actors. The mere presence of CCTV ought to dissuade those who have an intention to harm from doing so. However, although this risk would be reduced, it would not be entirely removed.

Conclusion

82. The Senior Management Team collectively welcome this Public Inquiry. We have complete faith in the process. This will be the first time that the story of what took place at the Hospital will unfold on the basis of the evidence of what took place.

83. The circumstances of what happened as events developed in 2015, 2016 and 2017 were unique, challenging and complex. The Senior Management Team understand that, having gathered the evidence and then heard testimony from those who are able to assist with what was actually happening at the time, the final story will be written by this Public Inquiry in its report. We believe that the Chair and the Inquiry Legal Team will ensure that this Public Inquiry conducts its investigation and hearings free of hindsight bias. We fully expect that decisions taken, and actions followed, will be put into their proper context and analysed in a dispassionate and measured way.

84. At the heart of this process is the expectation that lessons will be learned which is, we are certain, a goal shared by all Core Participants. This is to ensure that, as far as it is possible to do, that there can never be a repeat of what happened here.

85. We have collectively worked in the healthcare setting for many, many years and have never come across such criminal behaviour before in any of our roles. The vast majority of professionals with whom we have worked are motivated with the highest of aims. They come to work every day, often in difficult circumstances, to help save lives. They do so by working long hours in the most challenging of environments. There is a tremendous amount of trust within the NHS between professionals which we know will be acknowledged by the Inquiry.

86. We have however all been deeply affected by what happened the Hospital. Whilst we do not suggest, in any way, parity with what the families of those killed and harmed by Letby have experienced, it has been the most significant event of any of our professional lives. Not a day goes by when we don’t think about what happened. We all chose to work in the NHS to help deliver exceptional care to patients and to save lives. That a nurse could be responsible for these heinous crimes is profoundly disturbing. It is not something that any of us ever expected to be happening on the neonatal ward of the Hospital, it being so against the natural order of what was contemplated or foreseen.

Kate Blackwell KC

Alexandra Tampakopoulos

2 Hare Court

Temple

London

EC4Y 7BH

30 August 2024