THE THIRLWALL INQUIRY

OPENING STATEMENT ON BEHALF OF THE FAMILIES
OF CHILD A, B, I, L, M, N & Q
(Family Group 1)

A. INTRODUCTION

1. This opening statement is provided on behalf of the families of Children A, B, I, L, M, N and Q (Family Group 1). They want to know how Lucy Letby (Letby) was allowed to harm as many as 18 babies before she was finally removed from the neonatal unit (NNU) at the Countess of Chester Hospital (CoCH) and why so many in positions of responsibility at the CoCH refused to accept that there were issues surrounding patient safety within the NNU for so long. They want to know why it took the CoCH nearly two years from four babies being harmed in quick succession in June 2015 (Children A, B, C and D) to the police initiating a criminal investigation in May 2017.

2. This statement has been prepared before the Families whom we represent have had an opportunity to consider the opening statements of Counsel to the Inquiry (CTI), other Core Participants (CPs), and crucially before they have had sufficient time to consider all of the key factual witness statements. Further points will therefore be made in the Families' oral opening statement.

3. The Families fully support what was said by the Chair in her written ruling on livestreaming/live links dated 24 May 2024:

> "*[t]his inquiry is of profound public importance. The Terms of Reference require an examination of matters of deep public concern. This will include close scrutiny of many events, the conduct of people involved and the decisions they made – as well as consideration of broader issues affecting the NHS.*"

4. The facts and issues to be investigated in this Inquiry are of deep concern to each individual family whose baby or babies were killed or attacked by Letby at the CoCH. Two of the families we represent lost a child at the CoCH. As the Secretary of State said in a Ministerial Statement about this Inquiry on 4 September 2023, "*Losing a child is the greatest sorrow any parent can experience".*[1]

5. But beyond the families whose lives have been devastated by the events at the CoCH, the facts and issues in this Inquiry are also of profound concern to every family who has used or will use NHS maternity and paediatric services, as well as the wider public. All must be able to have confidence that patient safety is at the core of every action and decision taken by professionals.

6. Sadly, the Families whom we represent have had their lives and confidence in medical services shattered. Their babies were born, harmed and in some cases died between 2015 and 2016. Only now, nearly a decade later, are they starting to learn of the excruciatingly drawn-out failings by the senior managers and those in positions of responsibility at the CoCH – who failed to take decisive and timely action to comprehensively investigate the unexplained and unexpected

[1] Ministerial statement, 4 September 2023: https://hansard.parliament.uk/commons/2023-09-04/debates/B18741EB-DC54-40D6-98B8-76FB066FFB26/CountessOfChesterHospitalInquiry

deaths and deteriorations of vulnerable babies being cared for on the NNU. Such action could have stopped Letby killing or harming more babies.

7. The Families whom we represent are also learning more about the reluctant and grudging manner in which the CoCH finally requested a police investigation into unexplained deaths and harm caused to babies on the NNU.[2]

8. Letby was arrested in July 2018, and a new chapter of heartache opened for the Families as they began to learn, for the first time, more details of what had happened to their babies on the NNU. Whilst it is accepted that there is need for some confidentiality where there is a criminal investigation, the strategy adopted by the CoCH to brush off concerns regarding patient safety and failing to share key information with the Families of the babies concerned is inexplicable and unjustified.

9. The first criminal trial started in October 2022 and lasted approximately 10 months. The trial provided some answers about what happened to the babies Letby murdered or attempted to murder, but unanswered questions remain. Letby was sentenced in August 2023 to multiple concurrent life terms. She refused to attend Court for sentencing. Her application to appeal was dismissed by the Court of Appeal in May 2024. The second criminal trial concluded with a further conviction in July 2024, and she was sentenced to a further concurrent life term.

10. The children harmed/murdered by Letby are, or would now be, 8 or 9 years old. It is only now that their Families are able to witness those professionals who were present at the CoCH over the relevant period finally being held accountable in public for what happened there from June 2015.

11. The evidence the Inquiry will receive in Part A about the babies involved, their Families, and the human suffering they have endured must sit right at the heart of this Inquiry. It must motivate every question asked of witnesses. It is imperative that each of the CPs and every witness fully commits to being transparent, open, honest, constructive and reflective when giving evidence or in their submissions. This principle applies especially to those in leadership and management roles. Responsibility must be accepted where that is justified. The Chair's clear message to CPs and witnesses was that she expects candour (see ILT note on content of opening submissions at §9 and §§34). Anything less would be a grave insult and will compound the suffering of the Families whom we represent.

12. When sentencing Letby on 21 August 2023, Mr Justice Goss referred to pre-meditation, calculation and cunning in her actions. He said she knew that the "*last thing anyone working in the unit would or did think was that someone caring for the babies was deliberately harming them*"

[2] See, for example, the witness statement of Detective Chief Superintendent Wenham, which explains the timeline between the Pan Cheshire Child Death Overview Panel, on which he sat, first being told of the unusually high number of deaths on the NNU on 24 March 2017, and decision by Chester Constabulary on 2 May 2017 to secure a letter from CoCH inviting the police to investigate events at the NNU [INQ0102367].

(§5). The Families whom we represent hope that witnesses and institutions provide their best evidence on what was and should have been known at the relevant time and what was and should have been done at the time in response – as opposed to applying the caveat of hindsight and thereby evading responsibility. Any views on what could and should be different in the future is also of equal importance. The evil and cunning of one individual does not expunge operational or system failures. And, as the public knows, the NHS has been here before, with Beverley Allitt.[3]

B. THE CONCERNS OF THE GROUP 1 FAMILIES

Failures to inform Families of significant medical deteriorations

13. The Families whom we represent have a general concern about the CoCH's lack of transparency in respect of the high number of unexpected and unexplained deteriorations and deaths that occurred in the NNU. Concerns about high mortality were raised by Dr Brearey, Clinical Lead at the NNU in a meeting with Eirian Powell, Neonatal Ward Manager, as early as 22 June 2015 [INQ0003110].

14. Some of our Families also have more basic and specific concerns, namely that they were not even told at the time that their own babies had deteriorated or had been seriously unwell. They had the right to be given this information. Withholding it from them deprived them of the ability to ask further questions about the possible causes of these episodes.

15. Child I was born on [PD] August 2015 at Liverpool Women's Hospital (LWH). She was transferred to the NNU at the CoCH on 18 August 2015. On 30 September 2015 she collapsed vomiting and suffering a desaturation and a fall in her heart rate. Letby had injected air into her stomach via her nasogastric tube. On 13 October 2015, she suffered a further collapse as a result of Letby again injecting air into her stomach via her nasogastric tube. Baby I suffered two final collapses on 23 October 2015, the latter being fatal. On this occasion, Letby had injected air into her bloodstream. Letby was convicted of her murder based on a culmination of incidents resulting her death. Baby I's parents were not informed of any meetings or discussions surrounding her unexplained/unexpected collapses or that Datix reports had been created. No Inquest was held into Baby I's death, meaning that her parents were not provided with any answers as to what had happened to cause her catastrophic demise and ultimate death when she had been otherwise progressing well and was almost ready to be discharged.

16. Child L: Letby was found guilty of attempting to murder Child L on 9 April 2016, by insulin poisoning. Because of her actions, Child L had periods of low blood sugar which required treatment [see medical records from INQ0001169_0011]. Child L's parents were not told about this at the time. They were not informed there were any concerns about Child L while he was in

[3] Sir Robert Frances KC sets out the recommendations made in the Clothier Inquiry in his report [INQ0101078_0048ff].

the NNU, or changes in his condition. It was only at the criminal trial, many years later, that they heard how Letby had set out to harm their baby.

17. Child N: Letby was charged with attempting to murder Child N on 3 June 2016 and twice on 15 June 2016. She was found guilty in relation to the attempt on 3 June 2016. The jury could not reach verdicts in relation to 15 June 2016. In the early hours of the morning on 3 June 2016 Child N's oxygen saturations dropped very low, to 40%. He was mottled and dusky coloured and needed 100% oxygen [INQ0000579_0015]. This resulted from Letby trying to murder him. And yet NNU staff at the CoCH did not even tell the parents that this profound desaturation had occurred. Child N's father says in his witness statement: "*We were not told about this deterioration. We did not know Child N had had problems overnight on 3 June. I find this disgusting. As parents we have an absolute right to know what is happening to and with our son*" [INQ0107146].

18. Child Q: Letby was charged with attempting to murder Child Q on 25 June 2016. That morning Child Q's alarms sounded, he vomited and desaturated and had bradycardia. He was mottled. He was treated with a Neopuff [INQ0001522_0018]. However, in her police statement, Child Q's mother says she was not told of any issue with Child Q. Her evidence was that Father Q was told their baby had a chest infection but at no point were they told he had had a collapse [INQ0001542].

19. There are other examples of information about their babies' condition not being communicated to the Families. Letby murdered Child A and attempted to murder Child B. Their mother's evidence is that it was only at Child A's Inquest that she heard staff had seen mottling or blotching on Child A's skin, similar to that seen when Child B collapsed. She had been completely unaware of this [INQ0107026, §82]. Letby attempted to murder Child M. His parents were also not told that staff had seen unusual patches and discoloration on his body when resuscitating him [INQ0107025, §29].

20. It is not clear to the Families whom we represent whether information was deliberately withheld from them, or whether it was a case of healthcare professionals not turning their minds to what parents would want to know about the vulnerable babies they had entrusted to the NNU's care. These factual questions need to be explored, along with whether there was a culture of failing to update families about their children.

Failures to report and investigate when babies died or deteriorated unexpectedly

21. The evidence seen to date suggests that the CoCH only internally reported and investigated some of the babies who had died. Some deaths which should have been reported and investigated were not. Even where deaths were reported and investigated, the wrong processes involving the wrong boards, committees and people were used. In addition, the evidence considered to date suggests that external processes were not properly utilised after babies died,

e.g. Sudden Unexpected Death In Childhood (SUDIC) and the Child Death Overview Panel (CDOP). That appears to be the position for Child A. The wider concern that the consultant paediatricians did not comply with or value the reporting procedures is addressed below. The statement of Ruth Millward, Head of Risk and Patient Safety at the CoCH at the time, is telling on all of these points [INQ0101332].

22. The evidence seen to date also suggests that there was no adequate or thorough reporting or investigation in the NNU when babies deteriorated but did not die. Use of the Datix system was patchy and inconsistent. It seems reporting depended on whether a clinician concluded there had been a clinical incident.[4] The Inquiry is asked to examine whether this accorded with proper practice at the time.[5] The Inquiry is also asked to consider whether this practice should have changed when concerns about unexplained high incidences of mortality on the NNU were identified from late June 2015, and whether this would have made a difference to the harm suffered by other children thereafter.

23. Children A and B were twins. Child A died on 8 June 2015. Child B collapsed on the night of 9/10 June. The death of Child A was unexpected and remained unexplained until Letby's arrest and then conviction. Child B's collapse was also unexpected. Both babies had a similar presentation and yet it appears there was no investigation at the CoCH into Child B's unexpected and unexplained deterioration.[6] Dr V was the consultant who attended Child B's collapse but appears to have done nothing to prompt an examination of what had happened [INQ0102068, §§36-38]. The high point of investigation and comparison appears to have been an acknowledgement in July 2015 that "*twin 2* [child B] *had similar difficulties, now recovered and ready for home*" [INQ0000016_0006].

24. On 5 September 2016 the Royal College of Paediatrics and Child Health (RCPCH) wrote to Ian Harvey, Medical Director at the CoCH, stating that the "*pattern of recent deaths and the mode of deterioration prior to death in some of them appeared unusual and needs further enquiry to try to explain the cluster of deaths*" [INQ0003120]. The RCPCH recommended that the CoCH conduct a detailed forensic case note review which should include "*consideration of any other 'near miss' cases with similar chronology/presentation where the child survived"* [INQ0003120].

25. Even then, it appears Child B's deterioration was not investigated.[7] There was no investigation into Child I's various unexplained and unexpected deterioration before she died on 23 October

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[4] See Dr Gibbs' statement dated 1 July 2024 at §11 [INQ0102740].

[5] E.g.: The published RCPCH report cites the following from BAPM *Guidelines for the Investigation of Newborn Infants who Suffer a Sudden and Unexpected Postnatal Collapse in the First Week of Life* (2011) [INQ0001954_0018].
"*All infants who suffer a sudden and unexpected cardiorespiratory collapse within the first week of life should undergo comprehensive investigation to determine the underlying cause."*

[6] The obstetric secondary review report did not even mention Child B's deterioration [INQ0014200].

[7] Dr Hawdon was asked to consider 4 'near miss' cases, but these did not include Children B, F, G, L, M, or N [INQ0003328].

2015 despite the fact that she suffered three significant and unexplained collapses against the background of general improvement in her condition.[8] There was no investigation into Child L or M. There was no investigation into Child N's deteriorations on 3 June or 15 June 2016. There was no investigation into Child Q's deterioration.[9]

26. The Inquiry is invited to consider what events or deteriorations should have been reported and investigated, and also whether, if there had been better reporting and investigation of deteriorations when a baby did not die, concerns about Letby would or should have crystallised sooner, with further deaths and harm being prevented.

Failures to inform Families of the concerns about the NNU

27. The Families whom we represent were kept in the dark about the extremely serious concerns that were raised by consultant paediatricians about increased mortality on the NNU (noting that Children A and B were born at the start of this period of increased mortality). They are understandably concerned that they knew nothing about the suspicions held by the paediatricians that there may have been a link between a member of staff and the increased mortality, and that these concerns intensified over time. They were kept in the dark when the CoCH asked various external reviewers to look into the NNU and, in some cases, to look into the circumstances of their baby's deteriorations and deaths.

28. The Families were not consulted or even informed when the RCPCH review was commissioned and undertaken. When the RCPCH report was made available to the Families, they did not know there was a confidential and fuller version that reported the consultant paediatricians were "*convinced*" by a link between Letby and the deaths. The first they knew that there was serious concern about the care provided to their babies was when they were contacted by police during the criminal investigation This has seriously eroded their trust in the healthcare profession and the NHS.

29. The Inquiry is invited to reach conclusions about what Families should have been told, when, and by whom. For example, the view of Dr Holt (consultant paediatrician at the CoCH) was that bereaved Families should have been contacted before the CoCH issued a statement about the NNU being downgraded, told there were concerns about their baby's death potentially being unnatural, advised about the inquiries being undertaken, and told about accessing support [INQ0101112 at §32].

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[8] Datix reports were completed for 30 September 2015 [INQ0000458], 13 October 2015 [INQ0000456] and 23 October 2015 [INQ0000457], none were of any assistance as regards why Baby I collapsed and ultimately died.
[9] A Datix was completed in relation to child M on 13 April 2016, but it does not appear to be relevant. [INQ0001287]. A Datix was completed in relation to Child N on 29 June 2016 but that related to a prescription error [INQ0000582]. A Datix was completed in relation to Child Q in June 2016 but that related to postpartum haemorrhage [INQ0001540].

30. There is also concern, not just that Families were kept in the dark, but that the CoCH Executive team provided misleading information about what the Families were told. Just two examples are given here for illustration.

31. **First**, when Dr Hawdon was asked in September 2016 to undertake her review of individual babies' cases, she asked "*[a]re you seeking parental consent to release records*" (i.e. the babies' medical records)? Ian Harvey replied on 8 September 2016: "*re parental consent, we had informed parents ahead of the review that it was occurring*" [INQ0003123]. This does not accord with the recollection of the Families of Child A, I or Q (the babies of the other Families we act for were not part of Dr Hawdon's review). The Inquiry will no doubt ascertain whether consent was sought from the other Families.

32. **Second**, at the start of February 2017 the CoCH appears to have provided a responsive statement to the *Sunday Times* about the RCPCH review [INQ0003100, marked "*final copy*"]. This statement contains a quote, again from Ian Harvey: "*We have done all we can to keep parents informed and our clinical teams will be contacting them ahead of the review being published to make sure a copy of provided for them.*" The CoCH is asked to provide evidence of having done all it could "*to keep parents informed*". Again, this does not fit with our Families' recollections. Indeed, it is noted that the Father of Children O, P and R informed the CoCH on 8 February 2017 that the CoCH had not contacted him at all since the death of his children (in June 2016) [INQ0012633, p9].

Missed opportunities to identify the inappropriate administration of insulin

33. It is of significant concern that healthcare professionals at the CoCH failed to identify the significance of and act on Child F's insulin and C-peptide results in mid-August 2015, and again Child L's insulin and C-peptide results in April 2016. This is particularly serious given the need, which became more pressing as time went on, to ascertain why so many unexpected collapses/deaths were occurring. According to Dr Gibbs, Child F's results should have raised immediate and serious concerns about either possible deliberate harm being perpetrated on the NNU, or seriously deficient procedures and practices on the NNU that led to insulin being given accidently [INQ0102740, §157]. Dr Gibbs describes this as a "*collective failure on the part of the paediatric team*". The Inquiry is asked to scrutinise what happened and why, as the importance of what Dr Gibbs calls a "*collective failure*" cannot be overstated. There appear to have been missed opportunities to identify that deliberate harm was being caused to babies. At the very least there were missed opportunities to conduct a thorough investigation into what had happened and to gather objective evidence that could have been considered alongside the growing concerns about Letby's actions and the position of the hospital's medical director, Ian Harvey, and others that there was no evidence that Letby had harmed anyone.[10]

[10] See, for example, Ian Harvey's statement at §54 (INQ0107653_0012).

34. Dr Gibbs' evidence is that Child L's blood results "*indicating probable administration of insulin to Child L were not interpreted correctly at the time. Again, an indicator of possible deliberate harm on the NNU was overlooked…"* [INQ0102740, §80]. He accepts, albeit said to be with the "*benefit of hindsight*", that there was a "*collective failure….to not have realised that the blood result in Child L indicated that he was likely to have been given insulin when this was not indicated and had the potential to cause serious harm and even death"* [§268].

35. This evidence will be alarming to Child L's parents. But it is likely to also be deeply distressing to the Families of all those babies murdered and harmed by Letby after she had attempted to murder Child L.

The Inquest into the death of Child A

36. Child A died on 8 June 2015. His Inquest was held on 10 October 2016. The CoCH was legally represented, including by a barrister of some seniority. By the time of the Inquest, the CoCH consultant paediatricians had for many months been raising concerns about the increased mortality on the NNU and also about Letby's potential role in this. This was known by senior management, the Executive Team and the Trust Board. The paediatricians had also asked for Letby to be taken off the NNU (June 2016). Ian Harvey had commissioned the RCPCH to undertake an invited review. It appears the CoCH Executive Team had informed the RCPCH that the consultant paediatricians were "*convinced*" by the link between Letby and the deaths [INQ0009618, §3.11-3.12]. In September 2016, it appears Dr Jayaram had a meeting with Ian Harvey in which he acknowledged the paediatricians' concern "*over foul play*" and communicated that the Trust Board was aware that that the matter of deaths in the NNU "*may end up with the police being involved*" [INQ0003118].

37. Given all this, the Inquiry is invited to consider the adequacy of information that the CoCH and its lawyers provided to the Coroner before and at Child A's Inquest. Stephen Cross, Director of Corporate and Legal Affairs at the CoCH, wrote on 3 April 2017 that "*HM Coroner for Cheshire has been kept fully informed of this matter from the beginning…*" [INQ0003226]. In the same document, Stephen Cross also wrote "*[t]he Trust has demonstrated that it has taken the concerns seriously and has been open and transparent with the Coroner, its regulators, parents and the public.*" The Families whom we represent struggle to accept this.

38. Mother A has expressed her disquiet that the CoCH viewed Child A's Inquest as needing high-level advice and input [INQ0107026, §78]. The documents show that both Alison Kelly and Ian Harvey intended, in August 2016, to review the statements prepared for the Inquest [INQ0007197]. Why did they want to do that? Was that usual? The healthcare professionals' Inquest witness statements were entirely silent on to the increase in mortality in the NNU or the

suspicions of a link with Letby.[11] Both Dr Jayaram and Dr Saladi gave oral evidence at the Inquest [INQ0008944 and [INQ0107909].

39. At the time of writing, we have not seen a transcript from the Inquest and so it is not known exactly what questions were asked or answers given. But it appears that Dr Jayaram told the Coroner that he could think of nothing that could explain Child A's sudden deterioration, despite his and the other consultants' concerns about Letby. Dr Jayaram was also asked if he had encountered cases similar to Child A's and he explained there had been several similar cases on the NNU. As a result, a review was taking place but, according to Dr Jayaram, the preliminary findings of that review did not suggest a link between the cases or any major issues with the care in these cases [taken from the Inquest attendance note prepared by the CoCH, INQ0008944].

40. The Inquiry is asked to explore in detail whether, with this kind of vague and incomplete evidence, the hospital and its staff fulfilled their professional and legal obligations to be candid and open with the Coroner.

41. In addition, at the end of January 2016, the Coroner had informed the CoCH that he believed the CoCH should consider doing a 'Serious Untoward Incident' review [INQ000882]. Child A's parents had expected to see a full investigation report into Child A's death before the Inquest. This was never provided and lawyers for Child A's parents wrote to the Coroner on 28 September 2016 to express their unhappiness about this [INQ0002042]. It appears the CoCH never did a Serious Incident investigation or report. Why? Given that Child A's death was unexpected and unexplained, why was it not investigated as a Serious Incident? Did the CoCH deliberately withhold relevant information from the Coroner?

42. Sir Robert Francis KC's expert report prepared for this Inquiry states (in relation to the Mid-Staffordshire NHS Foundation Trust Public Inquiry):

> "*One of the more concerning features of what happened at Stafford Hospital was a censoring of an adverse opinion which a member of the consultant staff wanted to offer to the coroner. I thought it essential that trusts should disclose all apparently relevant information to coroners in the case of reported deaths and allow the coroner to decide what use to make of it*" [INQ0101077, §8.31.2]

43. The Inquiry will wish to investigate further the evidence Dr Jayaram gave about Child A in the criminal trial that, at the time of the Inquest, the consultant paediatricians had already begun raising concerns about the association with Letby and were being told that they "*really shouldn't be saying such things and not to make a fuss…*" [INQ0010268_0046].

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[11] See Dr Jayaram's statement, dated 24 July 2015 [INQ0008810]; Dr Saladi's statement, dated August 2015 [INQ0008812]; Dr Davies' statement, dated 21 January 2016 [INQ0008819]; Dr Jayaram's follow up letter, dated 10 February 2016 [INQ0008845]; Dr MacCarrick's statement, dated 1 March 2016 [INQ0008867]; Dr Harkness' statement, dated 11 July 2017 [INQ0008931]; and Dr Wood's statement, undated [INQ0008947].

The lack of answers for some Families

44. In the criminal proceedings the jury was unable to reach a verdict in relation to:

    a. Counts 18 and 19: 2 counts attempting to murder Child N on 15 June 2016; and

    b. Count 22: attempting to murder Child Q on 25 June 2016.

    (The Inquiry is aware that other Families are in the same position of having not guilty verdicts in relation to their children.)

45. This means that the Families of Child N and Child Q still do not know what happened to their babies. There is a lacuna that needs to be filled.

46. The questions annexed to Part A of the terms of reference do not ask what happened to each of the babies. The Families of these babies should not leave this Inquiry, nearly a decade after events at the CoCH, still without answers and still without closure.

C. PATIENT SAFETY

47. The patients who needed to be kept safe by the CoCH were premature babies, the most vulnerable members of our society. They were failed by individuals, institutions and the healthcare system as a whole. After they were harmed by Letby, they continued to be failed. Even in July 2016, after many babies had died and many others had been harmed, and after consultant paediatricians had clearly communicated their concerns about Letby, nursing staff remained unconvinced and defensive, and executives at the CoCH refused to contact the police and concluded that their planned actions, i.e. a protracted external review process, were "*proportionate*" [INQ0003365]. No doubt the Inquiry will want to ask these witnesses what the planned action was proportionate to – the risk of yet more babies dying or unexpectedly/dangerously deteriorating? If so, such consequences demanded the most urgent and effective intervention possible to safeguard patient safety.

48. The purpose of this section is to highlight some key patient safety issues and apparent failures, which the Families whom we represent ask that the Inquiry fully investigate.

Inadequate reporting and monitoring

49. The Inquiry is asked to establish, for each baby, exactly what deaths and deteriorations were reported, under what processes, and what investigations took place. It is also important to consider whether the CoCH policies and procedures represented standard practice in the NHS. Would the outcome for some babies have been different with better reporting, investigation and oversight? Was there a lack of urgency and rigour in establishing why each one of the unexpected deaths and deteriorations had occurred? Why wasn't Letby's potential involvement directly

investigated with a view to answering the consultants' serious concerns and ending the resulting divisions both in the unit and between the consultants and the managers?

50. It already seems reasonably clear that some deaths and deteriorations were not reported or investigated as they should have been, both internally and externally. Why was this? Did clinicians and others appreciate the importance of reporting and investigations? If so, were they being consciously circumvented? Ruth Millward has suggested the neonatal team "*did not value the reporting process*" and has observed that, despite growing concerns about neonatal mortality and the consultants believing some of the deaths were unexplained, not all of the deaths were reported as 'incidents' [INQ0101332, §45]. Was the onus solely on the consultants to trigger and use the conventional incident reporting systems such as Datix? Should other staff members, including managers and executives, have done so once concerns were raised? Did the absence of formal reports justify inadequate investigation given that knowledge of incidents on the NNU became widely known via other means?

51. The RCPCH report recommended that the CoCH should *"[s]trengthen the response to neonatal death/near miss investigations to normalise the reporting culture, include risk and governance staff, involve a wider group including maternity and external scrutiny, demonstrate completion of actions and clarify senior management oversight"* [INQ0001954, §4.4.9].

52. We represent two babies who died. We also represent five babies who survived. To our knowledge there was no reporting of the incidents involving the latter, which means there was no investigation of what happened or why, which at its most basic means there was a missed opportunity to identify yet more occasions to stop Letby from harming babies sooner (see the failure to respond to Child F and Child L's insulin and C-peptide results).

53. These missed opportunities were only recognised by the CoCH at a late stage. The note of a meeting on 29 June 2016 records "*inconsistent Datix reports... Unexplained collapses – perhaps [should] Datix. Lot of complexity around reporting – tricky to get oversight"* [INQ0003371]. This meeting was attended by Tony Chambers, Alison Kelly, Ian Harvey, Dr Jayaram Dr Brearey, Dr Saladi and others. On 13 July 2016 an Executive Team meeting took place and the notes record "*[n]ear miss incidents were not escalated, no Datix of individual care review. We understand there are 5 near misses, with a sudden and unexpected deterioration*" [INQ0004317].

54. The Inquiry may wish to consider whether the harm caused to some of the babies by Letby could have been prevented if there had been a functioning mandatory reporting mechanism for <u>all</u> events involving unexpected or unexplained patient outcomes.

55. Clarity is also needed about what deaths should have been reported to external organisations and bodies. There are already some striking examples of gaps. For example, in February 2017, when the Senior Coroner was informed of certain deaths of concern at the CoCH, he stated that a number of those deaths had not been reported to his office [INQ0002048]. The RCPCH's report

sets out concerns that the CDOP did not appear to be alert to the cluster of neonatal deaths at the CoCH [INQ0001954, §4.4.25]. This is supported by the evidence of former Detective Chief Superintendent Wenham, who attended the Pan-Cheshire CDOP. Prior to 24 March 2017, he says he was unaware of any increase in deaths on the NNU or any other concerns [INQ0102365, §§34-35]. In March 2017, members of the CDOP asked why it was not notified by the CoCH of the situation [INQ0013059].

56. More generally, the evidence disclosed to date suggests a rudimentary and amateurish approach to data collection and analysis by the CoCH. It took consultant paediatricians working on the NNU to 'spot' the increase in mortality. Periodically, the counting of deaths appears to have been updated by Eirian Powell, the NNU ward manager. Ruth Millward describes three different systems in place for recording mortality, with each giving different figures [INQ0101332, §158]. Given this confusing process, it is no wonder staff at the CoCH were not spotting, in a consistent way, the unexpected/unexplained deteriorations, and identifying similarities between them. The Inquiry is asked to investigate whether the CoCH's approach represented reasonable practice at the time, and whether there should have been a different system in place that could have identified patterns and strengthened the evidence for concern and action.

Inadequate debriefs after deaths and deteriorations

57. Debriefs after deaths and significant events give healthcare professionals the opportunity to discuss what happened and why, and recommend changes where necessary to avoid repeat incidents.

58. When interviewed as part of Letby's grievance, Yvonne Griffiths, the NNU Deputy Ward Manager, said "*we have a briefing after every death and go over all the facts*" [INQ0003167]. The published RCPCH report asserted that a team debrief was organised almost immediately following an incident to reflect on the situation and provide support and learning [INQ0001954, §4.3.5].

59. The above is inconsistent with the witness statements disclosed by the Inquiry to date which tend to suggest that there was no debrief after every death. This is either because witnesses say it was not usual practice to have a debrief or that these were 'rare' (e.g. Nurse T [INQ0018004] and Nurse X [INQ0017827]), or because nursing staff had no recollection of debriefs or debriefs being the norm.[12]

60. The Inquiry is asked to investigate what debriefs in fact took place after each death, and whether regular debriefs could have led to a different outcome for some babies.

[12] *Examples* are: Nurse Thomas: no debrief after Child I died [INQ0017280]; Nurse Z, no debrief after Child G deteriorated, or after Children O and P died [INQ0017440]; Nurse O'Brien: no debrief after Child P died [INQ0017837]; Nurse Eagles: no recollection of debriefs after Children A, B, I or J deaths or deteriorations [INQ00017489].

Lack of urgency and priority given to patient safety

61. One of the most shocking elements of what occurred at the CoCH is the lack of urgency with which the Executive Team acted so as to prioritise patient safety ahead of everything else.

62. At its most simple, when concerns were raised by Dr Brearey on 22 June 2015 about the deaths of Child A, Child C and Child D in close succession, a comprehensive investigation should have been carried out. That investigation should have included Child B. Ruth Millward says that it would have been appropriate to report the increase in neonatal deaths in June 2015 as a 'Serious Incident', leading to a comprehensive investigation [INQ0101332, §260].[13] At this time, Dr Brearey and Eirian Powell had identified that Letby was the only staff member present at all three deaths. It should have identified that she was also present at Child B's deterioration. Her presence, as a common factor, should have formed part of the investigation. For the Families, it is difficult to understand why, at this early stage, no consideration was given to stopping her having unsupervised access to babies on the NNU until such time as her actions or omissions could be safely excluded as a causative factor.

63. The Families whom we represent ask that the Inquiry closely scrutinises the actions and inactions of the Executive Team at each step in the chronology to reach a conclusion on whether some of the deaths and harm could have been prevented. For present purposes, the Families draw attention to a small number of issues identified from the documents reviewed to date.

64. **First,** there is evidence that, towards the **end of October 2015**, Dr Brearey contacted Eirian Powell saying that they needed to "*talk about Letby*". At this point Dr Brearey had counted seven deaths from June to October 2015 (i.e. more deaths than on the indictment) [INQ0006890, §23]. Eirian Powell's responded to say it was "*unfortunate*" that Letby had been present for each death, but each baby's death had a different cause. The relevance of each death having a different medical cause is not understood – each baby had died and more babies were dying than expected. By 19 January 2016, Eirian Powell had conducted a further staffing analysis which showed once again that Letby was present for all the deaths of concern [INQ0006890, §28].

65. **Second,** there is evidence that Dr Brearey tried, **from February 2016,** to arrange a meeting with Ian Harvey and Alison Kelly to discuss the increase in neonatal mortality and the February 2016 Thematic Review into deaths on the NNU. Despite the seriousness of the subject matter, it seems that the Executive Team did not meet with Dr Brearey until 11 May 2016, three months later [INQ0006890 §34-36 and 43]. In the interim:

    a. Dr Brearey had told Eirian Powell "*I think we still need to talk about Lucy…*" (we believe this was in March 2016) [INQ0003114].

[13] Dr Newby's evidence is that she would have expected all unexpected deaths to be discussed at the Serious Incident review group, especially when there was a spike in mortality [INQ0101317, §66].

b. On 17 March 2016, Eirian Powell emailed Alison Kelly asking for a meeting to discuss:

> "*1. High mortality – 8 as opposed to our normal 2 to 3 per year.*
>
> *2. A commonality was that a particular nurse was on duty either leading up to or during. (this particular nurse commenced working on the unit in January 2012 without incident).*
>
> *3. A doctor was also identified as a common theme however not as many as the nurse.*
>
> *Despite reviewing these cases there was nothing obvious that we were able to identify – therefore your input would be valued.*
>
> *I have been informed Ian Harvey is aware that we have had a thematic review"* [INQ0003089].

c. On 21 March 2016, Alison Kelly asked Eirian Powell to send the Thematic Review to her and then a meeting could be arranged. Eirian Powell sent the review that same day [INQ0003809].

d. Around 7 April 2016, Letby was put onto day shifts only. The reasons for this needs to be carefully examined by the Inquiry.

e. Despite the seriousness of the subject matter, on 14 April 2016 Eirian Powell had to chase Alison Kelly for her thoughts about the thematic review [INQ0003089].

f. It seems a meeting was eventually planned for 4 May 2016 between Ian Harvey, Alison Kelly, Dr Brearey and Eirian Powell. But on 3 May Alison Kelly cancelled this long overdue meeting, without suggesting a new date [INQ0003138].

g. On 4 May 2016, Dr Brearey emailed Alison Kelly to say there was a nurse who had been present for "*quite a few of the deaths and other arrests. Eirian has sensibly put her on day shifts only at the moment, but can't do this definitely…*" [INQ0003138].

h. Despite Eirian Powell's email 6 weeks earlier, on 17 March 2016, Alison Kelly then wrote on 4 May:

> "*Aah!! Can you please look into this with Anne M/ Eirian – if there is a staff trend here and we have already changed her shift patterns because of this, then this is potentially very serious!!*
> *I will check the report they sent through – I did not notice there was a staff trend!!"* [INQ0003138].

i. On 6 May 2016, Alison Kelly forwarded Dr Brearey's email of 4 May 2016 to Ian Harvey, commenting that Dr Brearey's comments "*alarmed*" her [INQ0005724].

66. Had Alison Kelly taken the time to read Eirian Powell's email of 17 March 2016, in which she expressly said that a nurse was a "*commonality*" for all the deaths? Even if Alison Kelly had not picked this up, was the increase in the number of babies dying on the NNU not sufficient to get her attention and the attention of the Executive Team? Why were the Executive Team not sufficiently engaged and interested to come to an earlier meeting? What does this say about the priority given to patient safety at the CoCH?

67. The meeting between clinicians and the Executive Team, first requested in either February or March 2016, finally took place on 11 May 2016. In the interim, Letby attempted to murder Child L and Child M (and possibly also Child K – though the dates are not clear).

68. The meeting was attended by Ian Harvey, Alison Kelly, Anne Murphy (Lead Nurse for Children's Services), Eirian Powell and Dr Brearey. It is apparent from the notes that Letby was discussed. The plan included the review all babies who deteriorated, to keep Letby on day shifts, to again review deaths that occurred at night, and to meet again **in 2 months' time** (i.e. around the time Letby was due to go back on night shifts). It seems there was no plan to review deteriorations that had already happened, e.g. Child B, Child M.

69. This lacklustre response is incomprehensible given what had already happened to many babies and the ongoing risks to babies' safety. The Inquiry is asked to examine the lack of urgency from the Executive Team and the apparent lack of appropriate concern for the safety of neonates on the NNU.

70. **Third,** on **Friday 24 June 2016**, Dr Jayaram met Karen Townsend, Director of Urgent Care. He raised concerns about Letby. Thereafter, Karen Townsend called Karen Rees, Head of Nursing in Urgent Care. Karen Rees then spoke with Dr Jayaram and Dr Brearey in person. Dr Brearey is said to have told Karen Rees that the paediatricians felt that Letby was "*purposely harming babies*", but also refused to explain why they had concerns or share the contents of what he called the "*drawer of doom*" [INQ0003057_0004-5]. (Dr Brearey does not address the existence or content of this drawer in his statement to the Inquiry [INQ0103104].) Karen Townsend contacted Alison Kelly and told her this [INQ0102038, §§33-34].

71. According to Karen Rees, Dr Brearey also called her at home that evening [INQ0003057]. He cautioned that Letby was on duty that weekend, that one of the triplets had died, and Letby had been looking after that baby. Dr Brearey wanted to know what Karen Rees was going to do. According to Karen Rees she got cross with Dr Brearey, asking what he was doing ringing her at home. She said she did not know what decisions others had made after she had left work and Dr Brearey should speak with others [INQ0003057_06]. Dr Brearey states that Karen Rees was not prepared to act on his concerns and said that Letby was safe to work [INQ0103104, §242; INQ0006890, §52]. Letby had murdered Child O on 23 June 2016 and Child P on 24 June 2016. She then worked on the weekend that Child Q deteriorated and required resuscitation.

72. It is entirely appreciated this is one incident in a long and drawn-out chronology, but it is a striking and perhaps telling example. The Director of Urgent Care, the Head of Nursing in Urgent Care and the Director of Nursing were aware of serious concerns about Letby and about her working that weekend – but they chose to ignore these warnings, which allowed Letby to continue harming babies in the NNU.

73. **Fourth,** There is evidence that, over **27-28 June 2016**, Dr Brearey told the Executive Team that a group of clinical staff wanted Letby removed from the NNU [e.g. INQ0006890, §54-56 and INQ0003116]. And yet managers and executives decided that she should continue to work on the NNU, despite the paediatric consultants' concerns that this may not be safe [INQ0003275 and INQ0003116]. It is extraordinary and inexcusable that their concerns were not given the attention and respect they warranted, and that immediate action was not taken to act on them.

74. On 29 June 2016 Dr Jayaram emailed Ian Harvey, Alison Kelly and others. He wrote:

> "[Dr Brearey] *and I are trying to meet with senior executives ASAP to discuss* [the issue of contacting the police]. *However they do not seem to see the same urgency as we do…*" [INQ0003122].

Ian Harvey replied, saying:

> "*…this is absolutely being treated with the same degree of urgency – it has already been discussed and action is being taken.* ***All emails cease forthwith***…" [INQ0003112].

75. The Inquiry is asked to examine exactly what action was being taken and whether this was adequate to protect patient safety on the NNU given the (at that stage potential) gravity of what was suspected? The Inquiry is also asked to explore the culture and working relationships that led to the Medical Director telling clinicians to "*cease*" communications on this most pressing of concerns. Emails are one of the most effective means for healthcare professionals to communicate internally with each other and good contemporaneous record-keeping is a basic, axiomatic, principle of medicine. Was Ian Harvey worried that such communications would in due course expose him and others to the accusation of failing to act sooner and more decisively? The Families ask the Inquiry to test the plausibility of his statement to the contrary (INQ0107653, §203).

76. **Fifth**, as the Inquiry knows, senior management and the Executive Team wanted to get Letby back working on the NNU as late as **March 2017**. How could that even have been considered?

77. There are many more examples that will no doubt be explored by the Inquiry. But Dr Jayaram, in an email dated 12 February 2017 to Dr Gibbs and Dr Brearey, put the position clearly:

> "*A whole body of consultants raising concerns that patient safety is potentially being compromised and concerns are being ignored could be very powerful*" [INQ0003108].

78. The evidence reviewed to date does not paint a picture of patient safety being the first priority at the CoCH. On the contrary, it suggests that the safety of premature babies on the NNU was a second order concern among senior management, the Executive Team and the Trust Board. The Inquiry must thoroughly examine whether senior managers and leaders at the CoCH prioritised the avoidance of reputational damage, to the Trust or to Letby herself, or financial consequences over the safety of the babies in their care.

79. For example, it is not clear what risk registers were maintained at Trust or directorate levels. The ILT appear to have identified July 2016 as the first time a risk register referred to increased mortality on the NNU (the urgent care risk register [INQ0004657]). How that risk was phrased may be telling: "*potential damage to reputation of neonatal service and wider Trust due to apparent increased mortality within the neonatal unit*". This is **not** directed at the risk of more babies dying or deteriorating. It is concerned with the risk of reputational damage to the Trust **from** increased mortality rates.

80. When she was interviewed on 1 July 2017, Karen Rees said that Alison Kelly was reticent about going to the police and "*I suppose the impression that we got was there was an issue about the trust reputation and they were trying to handle it internally….*" [INQ0003057_0018]. Dr Jayaram is recorded (on 15 March 2017) as saying he felt the Trust Board was more worried about an employment claim than patient safety [INQ0003219]. Dr ZA felt that the Trust's reputation was more important than patient safety [INQ0099097 at §96]. Ian Harvey himself said in November 2016 that "*they [the police] would have left a bomb site if they had come in. I am more and more sure it was right not to call the police as things have progressed*" [INQ0003156]. A note of a meeting on 29 June 2016, attended by Tony Chambers, Alison Kelly, Ian Harvey and others, records "*must not define our future*" [INQ0003371]. On 26 January 2017, Ian Harvey told a meeting that there was a "*need to draw a line under the 'Lucy issue'*" [INQ0003523].

81. Unfortunately, the Families whom we represent do not have the choice of 'drawing a line under the Lucy issue'.

Unexplained clusters of unexpected deaths

82. This section focuses on how clinicians, managers and the Executive Team approached the clusters of deaths on the NNU. Later in this opening statement, comment is made about the proliferation of reviews that were conducted over months and even years, all of which led nowhere.

83. It appears from the evidence that the paediatric consultant group, and Dr Brearey in particular, was concerned about:

    a. A higher than usual number of unexpected/unexplained mortalities on the NNU (and, to a lesser degree, deteriorations);

b. The deaths often happening in babies who had been stable;

c. Deteriorations and deaths occurring without warning signs, when warnings signs would have been expected;

d. Babies were not responding to appropriate resuscitation; and

e. Some of the babies displayed mottling/an unusual rash.

84. At its simplest, there was a cluster of deaths that was unexplained, and which therefore needed explaining. In cases where a medical cause of death was identified, that did not always clarify the underlying reason for the deterioration. The paediatricians were, initially tentatively and later with more force, suggesting Letby as the possible underlying reason for the cluster of deaths, or at least the common thread between the deaths.

85. For a very long time, it seems that senior nurses and the Executive Team did not treat this as a serious possibility. But no other valid reason or explanation was being identified or offered. It almost became a 'line to take' that there was no common theme identified in all the cases.[14] It is difficult to understand how this position could have been adopted and repeated – there was a known common theme, and it was Letby. That was identified as early as 22 June 2015 [INQ0003110]. Letby continued to be a common theme, and this continued to be known. Her involvement in the unexpected/unexplained deaths/deteriorations could not be discounted without first investigating all possible explanations for these unusual events.

86. Equally, if Letby was not a common theme that needed to be taken seriously and explored, then what was the working hypothesis for the cluster of deaths and was it reasonable? The consultant paediatrician group posed this question in a letter dated 30 January 2017 [INQ0003095]:

> "*Although it was made clear that the Trust Board has drawn a line under this issue, we would be grateful for written clarification on:*
>
> - *The Board's understanding of the reason for the increased number of unexpected and unexplained deaths on the NNU between June 2015 and July 2016…".*

87. The Inquiry is invited to carefully scrutinise whether there were reasonable alternative explanations for events on the NNU, and what these were. The Inquiry is also asked to explore why the presence of Letby as the common theme was ignored or minimised and the impact of this on the safety of babies in the NNU. The protection of the Trust's reputation and finances have

[14] See for example: the minutes of the CoCH Women and Children's Care Governance Board recorded on 16 June 2016 that "*there was no common theme identified in all the cases*" [INQ0003212_0005]; Alison Kelly emailed the Care Quality Commission on 30 June 2016 explaining that the CoCH had identified an increase in neonatal deaths in respect of which "*the reviews* [had] *failed to identify any cause or common theme*" [INQ0017411].

already been identified as factors, mitigating against escalation of concerns being expressed by paediatric consultants.

The proliferation of inconclusive reviews

88. An important element of a system that safeguards patient safety is the timely and effective internal and external investigation of events that have caused or could cause harm. The Families whom we represent have real concerns about the sheer number of investigations that were done or planned, about the CoCH's delay in seeking a comprehensive external investigation, and about the scope and terms of the external investigations that were eventually commissioned. There are also concerns about how the outcomes of investigations were interpreted, presented and used by the CoCH.

The number of investigations, reviews and reports

89. **First**, from June 2015 onwards, there were a very large number of investigations, reviews, reports. None answered the critical question of why so many babies were unexpectedly deteriorating and dying on the NNU or whether Letby was or was not the cause. On 29 June 2016, Dr Saladi emailed Ian Harvey and Alison Kelly to say "*[w]e have investigated these deaths as much as we can, which included seeking clinical input from outside… further outside clinical input is unlikely to shed more light on the relevance of [LL being a constant presence].*" He recommended that the CoCH should proactively seek the input of the police "*before we are forced to because of further deaths*" [INQ0003112]. And yet the CoCH determined that yet more investigations and reviews be carried out by healthcare professionals and institutions. Even in March 2017, the Executive Team were saying a further in-depth review was needed [INQ0003344].

90. The Inquiry is invited to consider the proliferation of investigations, reviews and reports that were commissioned and prepared, to assess how effective they were, and what further reviews achieved when they didn't consider the critical questions set out above. The Inquiry is also asked to consider why the possibility that a staff member was deliberately harming babies on the NNU was never directly and definitively addressed by any of the investigations, reviews, reports commissioned by the CoCH? Is it really the case that only when there is a police investigation can such a question be answered? What cultural, legal and other systemic factors prevented it from being confronted?

Delay in commissioning an external investigation

91. **Second,** there are concerns about the delays in the CoCH commissioning an external investigation. Should the RCPCH, or another external organisation, have been asked to conduct an investigation earlier, particularly where there was a cluster of neonatal deaths and

deteriorations?[15] What were the appropriate criteria, locally and nationally, for such an investigation to be triggered? Were they followed?

Scope and terms of investigation

92. **Thirdly,** even when the RCPCH was commissioned to undertake a review of the NNU, the scope of that investigation was inadequate. It was, in reality, a service review of the NNU as the RCPCH was not able to investigate the unexplained/unexpected death/deterioration of individual babies. This was a fundamental mistake by the Trust and more than just miscommunication (as Ian Harvey terms it [INQ0107653, §353]). In fact, after conducting its review, the RCPCH agreed that the pattern of recent deaths and mode of deterioration prior to death appeared "*unusual*" and needed further enquiry to try to explain the cluster of deaths. It said that it was not possible within the terms of reference agreed with the CoCH, and then recommended a "*detailed forensic casenote review of each of the deaths since July 2015*" [INQ0003120]. Does the use of the word "*forensic*" implicitly acknowledge the possibility that crimes had been committed?

93. It is also not clear exactly what information the CoCH provided to the RCPCH about Letby. This would have been relevant to their audit of the service level being provided by the NNU and may well have resulted in an escalation of concerns about the unexpected and unexplained increase in neonatal deaths and deteriorations. The Inquiry is asked to explore this in evidence, as well as when that information was provided (the RCPCH's letter dated 5 September 2016 suggests the reviewers may have been told on day 1 of their review [INQ0003120]).

94. After yet more delay, the CoCH commissioned Dr Hawdon to undertake a case note review intended to supplement the RCPCH review. The value of that review was dependent on the selection of the babies, the quality and adequacy of the information provided, and the questions that were posed to Dr Hawdon. Here too, it would appear the CoCH failed. Dr Hawdon was not asked to review many of the babies who would ultimately appear on the criminal indictment, including Baby B and Baby M. While she was asked to report on "*details of all staff with access to the unit from 4 hours before the death of each infant. Ancillary and facilities staff should be included*", it is not understood how the CoCH expected her to be able to do that. It is not known if she was told anything about the mottling/rash being observed on some babies (other than that recorded in their medical records). It is not known what, if anything, she was told about Letby.

95. Dr Hawdon's letter to the CoCH, dated 29 October 2016, points towards a disappointing lack of care taken by the CoCH when instructing her to undertake this potentially important case review [INQ0003358]. She complained about the medical records that were provided to her, said she did not have capacity to do the task she was asked to do, pointed out that she could not detail

[15] It is noted that that the CQC *Learning, Candour and Accountability: A Review of the Way NHS Trusts Review and Investigate the Deaths of Patients in England*", December 2016, recommended "*where serious concerns about a death are expressed, a low threshold should be set for commissioning an external investigation*" (https://www.cqc.org.uk/sites/default/files/20161213-learning-candour-accountability-full-report.pdf at pg 63) [INQ0010511 and INQ0010536].

the staff with access to the unit, and made clear that she could only consider the babies where notes had actually been provided. She asked for more information and documents.

96. Ultimately, through no fault of her own, Dr Hawdon was unable to fulfil the instructions from the CoCH. Her report also did not fulfil what the RCPCH had recommended. Her conclusions did not change the sum of knowledge. The consultant paediatrician group at the CoCH continued to say that the rise in deaths on the NNU had not been fully investigated. Letby's actions continued to go unexamined.

Misinterpretation and misrepresentation of reviews

97. **Fourth,** there are concerns about how the Executive Team chose to interpret, present and use the findings of various investigations and reviews. The Families believe that none of these excluded or even purported to exclude Letby as the underlying cause of unexpected/unexplained deaths and deteriorations on the NNU. None of these identified an alternative reason or reasons to explain these events on the NNU.

98. Notwithstanding this, Ian Harvey informed the Trust Board on 10 January 2017 that "*[t]he case reviews very much reinforce what is in the review, it comes down to issues of leadership, escalation, timely intervention, and does not highlight any single individual… There was an unsubstantiated explanation that there was a causal link to an individual, this is not the case and the issues were around leadership and timely intervention*" [INQ0003514]. What Ian Harvey did not say was that RCPCH were not considering individual cases or members of staff as part of its instructions. Did Ian Harvey knowingly misinterpret or misrepresent the various investigations and reviews to the Trust Board? The consultant paediatrician group, when referring Ian Harvey to the General Medical Council, believed that he had indeed misinterpreted the RCPCH service review to suggest its findings and recommendations were associated with the cause of the deaths and sudden collapses, and had mislead the Trust Board in his interpretation of the RCPCH report and Dr Hawdon's report [INQ0006999_0004].

99. Stepping back from the detail, the Inquiry is invited to closely examine the role that internal and external healthcare investigations and reviews play and should play in safeguarding patient safety. This should include when they should be triggered, how and by whom terms of reference are set, how swiftly they should report, how findings should be used, and what to do when investigations and reviews do not yield answers.

Culture

100. The culture within a hospital, a Trust, and the NHS as a whole, is critical to patient safety. The evidence reviewed to date raises a multitude of questions about the culture at CoCH. The Inquiry is asked to carefully build a picture of the culture at the CoCH and more widely, and how that contributed to harm caused to the babies harmed by Letby, and to the actions and inactions from

June 2015 onwards. We make a small number of points about the culture that appear to be demonstrated in the documents.

101. **First**, as noted above, there appears to have been an apparent priority given to reputation management, avoiding financial consequences, or even avoiding disruption, rather than patient safety.

102. **Second**, it is notable that the doctors on the NNU were effectively 'policing' the nurse, Letby. Her own nursing colleagues and managers did not identify or accept any anomalies or concerns. On the contrary, Letby's nursing managers were vigorously defending and supporting her. Did the schism between the senior doctors and the senior nurses reflect a longstanding cultural division, and a historical but ongoing imbalance of power and status, between the different branches of the healthcare professions? If so, did these factors cloud the judgment and objectivity of those involved?

103. Whatever the position, and despite the generally positive findings of the RCPCH review [INQ0001954], the relationships and teamwork between the disciplines were poor when it came to addressing the critical question of why there has been such an unexpected increase in mortality in the NNU. According to Dr Brearey, after a meeting on 11 May 2016 at which he (again) expressed concerns about Letby, Eirian Powell was "*very defensive of Nurse A…and raised concerns about some doctors on the Unit*" [INQ0006890, §§44-45]. Karen Rees, in September 2016, expressed her "*serious reservations"* about a decision not to allow Letby back to work on the NNU [INQ00026860]. The views expressed by Ms Rees will need to be explored with her and other nursing witnesses, but attention is drawn to this part of her email:

> "*There is also the impact, not only for the NNU but for the rest of the organisation and the message that this sends out – a Clinician is being listened to and supported, with potentially devastating consequences for a nurse. How are the nurses on the NNU going to react? I have already witnessed that senior nurses on that unit, do not even want to answer the telephone to that particular Consultant, who is making these allegations and making clear of his personal view*" [sic].

104. The revelation of this degree of dysfunction within the NNU is astounding and distressing for the Families who trusted staff at the CoCH and its NNU to look after their premature and vulnerable babies. It points towards pettiness, in-fighting, and a failure to understand that the safety of babies should be the overriding priority of everyone working on the NNU and in the CoCH. The suggestion that senior nurses did not want to answer the telephone to a consultant raises yet more concerns about the safety of babies on the NNU.

105. The Families whom we represent need to understand if there was a closing of ranks amongst nursing staff that obfuscated what Letby was doing or delayed her being stopped or detected. They need to understand whether there was a lack of professional curiosity and objective

judgment amongst the nurses and nursing managers to examine why babies were dying and collapsing. They need to know if nursing leaders were blinkered and weak. They need to know if poor relationships between doctors and nurses in the NNU, and also between doctors and senior managers and the Executive Team, contributed to the delay in removing Letby from the NNU and the delay in contacting the police. The Inquiry will wish to explore and test Nurse T's very negative evidence about the culture on the NNU and offered the view that the relationship between the unit manager and consultants may have contributed to the response from management and how concerns about Letby were managed [INQ0018004].

106. **Third**, it will be important to understand the working environment and culture within the NNU and whether there was a supportive environment for raising concerns. The treatment of Dr Brearey (including a thinly veiled threat of referral to the GMC if he did not mediate with Letby[16]) and his consultant colleagues would tend to suggest there was not. Several of the consultant paediatricians have provided evidence that they felt bullied and intimidated by the Executive Team and were fearful of losing their jobs if they continued to pursue their concerns about Letby (e.g. Dr V [INQ0102068, §172]; Dr ZA [INQ0099097, §85]. Did staff have sufficient training and understanding on how to report concerns about colleagues? The factual witness statements seen to date from nurses on the NNU again suggest they did not.[17] Why did the consultant paediatricians not reliably use the existing systems for reporting and investigating deaths and unexpected deteriorations, or the existing governance structures? Effective safeguarding of patient safety relies on well-trained, alert, curious and supported staff who are capable of and prepared to recognise and escalate concerns without hesitation.

107. **Fourth,** while events from July 2016 post-date the harm caused to the babies at the heart of this Inquiry, these events nevertheless reveal the culture at the CoCH and the ongoing patient safety failures. These events also contributed to the damage inflicted on the Families. The Inquiry is asked to closely scrutinise the extraordinary timeline and disconnect between the clinicians, nursing managers, the Executive Team, and the Trust Board.

108. **Fifth**, did the failure of NNU's staff and managers (other than its consultants), and CoCH's senior managers, to recognise that the Letby was the only plausible cause of the NNU's increased mortality rate reflect a cultural of unwillingness to accept malevolence and criminality on the part of a professional colleague? Was there a culture of denial, defensiveness and suppression of information? Murders by healthcare workers are mercifully rare and hospital staff cannot be expected to work in a culture of suspicion where anyone might be a killer. But rare events still happen, and when legitimate suspicions arise, staff are expected to maintain their objectivity and to confront and interrogate facts objectively and scientifically, without bias or pre-judgment. This did not occur in 2015 and 2016.

[16] [INQ0003104].
[17] E.g: see Nurse T [INQ0018004, at §63]; Nurse Baden [INQ0017162]; Nurse Thomas [INQ0017279].

Patient safety: conclusion

109. The Chair of the Infected Blood Inquiry, Sir Brian Langstaff, recently found:

> "*The first, and most important lesson, is that the first, and paramount consideration should always be safety. What happened would not have happened if the safety of the patient had been paramount throughout*".[18]

He concluded that risk needed to be better understood, that certainty should not be confused with whether "*there is a real risk calling for a response",* and that a response to risk "*should be prompt*". He also concluded that "*candour is essential in the relationship between clinicians and patients*".[19] The Chair of this Inquiry may think that the same principles apply here.

110. Of course, there have been many Inquiries into aspects of the health service which have found and recommended that the patient should be put at the centre of everything the NHS does, and there must be transparency and openness in the NHS. And yet these basic and fundamental principles repeatedly fail to guide decisions and actions in the NHS. It is hoped that the Chair will seek to understand why, and what more can be done to protect patients and their families.

D. GOVERNANCE

111. It is hoped the Inquiry will explore what good governance should have looked like in 2015-2017, the extent to which this was achieved both internally at CoCH and externally, and whether better governance would have made a difference to the babies and their Families. It is hoped that the Inquiry will scrutinise the strength or weakness of leadership at the CoCH.

112. It has been difficult to piece together how staff, managers and leaders at the CoCH were being held accountable for ensuring high standards of clinical care and patient safety. It is not clear what frameworks were in place to prioritise patient safety and take reported concerns seriously. But the impression reached to date is that governance at the CoCH was weak, opaque, paralysed by indecision, and at times shambolic. There was insufficient professional curiosity and challenge. It is not even easy to understand what information was provided to boards and committees at different times, in part because minutes are poorly drafted and/or very brief. There is also a clear sense that governance arrangements, which should have created some accountability for patient safety and the quality of care, were not properly used. It is not known if this was intentional, due to not understanding the complex and ambiguous systems in place, or for other reasons. Ruth Millward has said that the governance arrangements were not sufficiently robust to ensure that the voice of the NNU was heard at divisional and executive level meetings. But she also says that consultant paediatricians were "*actively working around the governance arrangements that were in place…*" and this meant that "*there was a lack of transparency,*

[18] https://www.infectedbloodinquiry.org.uk/sites/default/files/Volume_1.pdf §1.4.
[19] Ibid §1.4.

monitoring and professional challenge around the increase in mortality on the [NNU] at divisional and executive level meetings…" [INQ0101332, §262].

113. The following issues are highlighted.

114. **First,** as above, what were the governance structures in place at the time and how did they work? Why did they fail to detect and prevent Letby's actions for so long? Did the confusing number of committees and boards serve to deter or frustrate the reporting of increased mortality and associated concerns as opposed to escalate and respond to them? What were the reasons for, and implications of, the RCPCH's findings that [INQ0001954, §4.4 and §4.3.7]:

    a. "*There did not… appear to be sufficient join[ed] up between the neonatal unit, obstetrics and the Trust's risk management system to deal proactively with the increased mortality*"; and

    b. "*Leadership at senior Trust level appeared to remote from the day to day issues taking place at the unit…*"?

115. **Second,** it would appear that information about increased mortality on the NNU (and the potential reasons for this) should have been considered at the Women and Children's Care Governance Board ('WCCGB'), the Quality, Safety and Patient Experience Committee ('QSPEC'), and the Trust Board. But it is not at all clear what information was provided to these bodies, what was discussed, and when?

116. For example, it is not clear when the issue of increased neonatal deaths was even brought to the QSPEC for the first time. This may have happened on 14 December 2015, around 6 months after the increase was first noted, but even that is ambiguous [INQ0003204]. In any event, the minutes from this meeting do not record that the QSPEC was informed that Letby was a common thread between the neonatal deaths. After this, it appears that the issue of increased neonatal mortality was not even discussed at the QSPEC meetings in January, February, March, April, May or June 2016 (the minutes for July 2016 have not yet been located).[20] This is despite Letby being taken off night shifts in April 2016. It seems that the February 2016 Thematic Review into deaths on the NNU was not even discussed at the QSPEC (or the Divisional Governance Group for Urgent Care).[21] Ruth Millward's evidence is that it would have been appropriate for concerns about increased mortality on the NNU to have been escalated to the QSPEC [INQ0101332 at §24]. Ian Harvey, Alison Kelly, Sian Williams. Tony Chambers, Karen Rees, Sue Hodkinson and Sir Duncan Nichol appear to have been members of the QSPEC.

117. The increase in neonatal deaths appears to have been tabled more often at the WCCGB meetings. But the Inquiry is invited to establish what information was provided to the Board and

[20] Minutes at: 18 January 2016 [INQ0004296], 15 February 2016 [INQ0003205], 21 March 2016 [INO0004300], 16 May 2016 [IN00004304], 20 June 2016 [INQ0004309] June 2016 [INQ0004309].
[21] See Ruth Millward's witness statement at §261 [INQ01010332]. She says it should have been.

when; what, if any, scrutiny the Board gave to the reasons for the increase in mortality; what the Board was told about the association with Letby; and what action the WCCGB took. The February 2016 Thematic Review was received at the WCCGB on 16 June 2016 and Dr Jayaram attended this meeting. The 'line to take', that no common theme had been identified in all the deaths, was recorded in the minutes [INQ0003212_0005]. Based on the minutes of this meeting, there was no meaningful discussion about the NNU, and Letby as the common theme does not appear to have been discussed, despite her being taken off night duty two months earlier. No action was taken. What role should this Board have played in clinical governance and patient safety?

118. **Third**, the Inquiry is asked to investigate exactly when the increase in neonatal mortality was communicated to the Trust Board, when the Board was told that Letby was the only identified common feature in the deaths, and when the Board was told that consultant paediatricians suspected Letby was harming babies. On 14 July 2016, there was an extraordinary meeting of Trust directors. The minutes of this meeting tend to suggest the Board was already aware of the increased mortality on the NNU, and that there had been "*considerable disquiet about an individual*" [INQ0003238]. What precisely did Board members know and when? What challenge was provided? What action was to be taken?

119. At the same meeting, the minutes record that Ian Harvey "*highlighted an issue around the rota allocation of medical and nursing staff on shift before and when babies deteriorate. There are a number of staff who appear more frequently and one member of staff in particular…".* Then the minutes say "*Dr Jayaram stated that what he was to say next was confidential and not to be minuted.*" What exactly did he say? Why was this being hidden? Was this request reflective of a culture of secrecy, or the consultant paediatricians' fear and mistrust of systems of reporting and governance? Why did the Board not decide to contact the police? How could the Board have possibly decided that Letby should return to the NNU to work under supervision? Was the reality that the Board did not believe what they were being told about Letby?

120. The Trust Board did not formally invite a criminal investigation until, at the police's request, the Chief Executive wrote to the Chief Constable of Cheshire on 2nd May 2017 [INQ0102319] and the criminal investigation, Operation Hummingbird, was then opened on 15th May 2017. (It will be important to establish the precise timeline of meetings, communications and decision-making by COCH and the police.) This delay will be incomprehensible to the Families. What information was being provided to the Board about the consultant paediatricians' ongoing, and increasingly robustly expressed, concerns? What did the Board members understand their role to be? What challenge did they offer to Executive members such as Mr Harvey? Why was the safety of neonates not the Trust Board's overriding concern? Why did Board members not insist on more candour and transparency with Families about enquiries into the mortality increase on the NNU? Would they have taken the same approach if it was their children who had been harmed or were at risk?

121. There are doubts about whether Ian Harvey provided accurate information to the Trust Board. On 10 January 2017, he is recorded as saying:

> "*There was an unsubstantiated explanation that there was a causal link to an individual, this is not the case and the issues were around leadership and timely intervention…Mr Harvey said that when thinking back to activity one alarm bell was how many cots the unit had over their allocation, the number of low birth weight and gestation babies and this strengthens the case that it was due to the intensity of the numbers of babies coming to the unit"* [INQ0003514].

122. It is not known what review or investigation Ian Harvey, an orthopaedic surgeon, was relying on to inform the Board that the increased neonatal mortality was due to the intensity of the numbers of babies coming to the unit. He will need to be asked to explain this. In March 2017, Dr Jayaram said that Ian Harvey had misled the Trust Board [INQ0003219]. This assertion was repeated when the consultant paediatrician group referred Ian Harvey to the GMC [INQ0006999_0004].

123. The current evidential picture points towards a complete failure by the Trust Board to obtain proper input from the consultant paediatricians, to exercise independent judgment, to hold the CoCH to account, to foster a culture of openness and insight,[22] to assure itself that risks to premature babies were being appropriately managed and mitigated, and to ensure high standards of health care were being delivered to the public.

124. **Fourth,** given these apparent failures, the Inquiry is invited to consider whether the CoCH Trust Board had an appropriate skills mix, and properly understood its role and responsibilities.[23]

125. **Fifth,** the evidence considered to date strongly points towards an alarming disconnect between clinicians and the Executive Team. The Inquiry is asked to examine whether this directly or indirectly led to harm to babies, harm to Families, and ultimately damage to public confidence. The drawn-out and tortured chronology of clinicians raising concerns and the Executive Team's and Board's response will need to be scrutinised. But it is also clear that clinicians felt they were not being listened to, that the Executive Team was making decisions without clinical input, that the Executive Team was keeping information from them, and that their concerns about patient safety were being ignored [emails in September 2016 and February 2017: INQ0003133 and INQ0003108].

126. **Sixth,** the Inquiry is asked to examine the safeguarding arrangements and oversight in the CoCH, including at Board level; whether there were clear processes for identifying safeguarding issues

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[22] Recommendation 8 of the Mid-Staffordshire NHS Foundation Trust non-statutory inquiry was that "*The Board should give priority to ensuring that any member of staff who raises an honestly held concern about the standard of safety or safety of the provision of services to patients is supported and protected from any adverse consequences, and should foster a culture of openness and insight*" [INQ0101077, §7.6].

[23] See, for example, Dr Jayaram's concerns, expressed on 15 March 2017, that the Trust Board did not have a neonatologist taking Board members through the review [INQ0003219].

and sharing these with other professionals and the local safeguarding children board; and whether the CoCH had any policies directed at dealing with allegations against staff members, from a patient safety rather than an employment law perspective. The evidence reviewed suggests a conspicuous absence of consideration and application of established processes for safeguarding children – processes that are specifically designed to prioritise the protection of children from harm.

E. THE INQUIRY'S RECOMMENDATIONS

127. Some of the Families whom we represent have made preliminary suggestions as to what should be different in the future, and we respectfully refer the Chair to their witness statements in this Inquiry. We will return to the issue of recommendations in future submissions. At this early stage, we say only the following.

128. **First**, one of the recommendations made in the Infected Blood Inquiry to prevent future harm to patients was:

> "*That a culture of defensiveness, lack of openness, failure to be forthcoming, and being dismissive of concerns about patient safety be addressed by [additional measures to strengthen the duty of candour], and also by making leaders accountable for how the culture operates in their part of the system, and for the way in which it involves patients.*"[24]

We do not advocate duplication of recommendations, but it seems clear that the substance of this recommendation is also highly pertinent in this Inquiry. The Chair is invited to reflect on whether more can and should be recommended on the facts that she is inquiring into.

129. **Second**, the making of recommendations by an Inquiry Chair is different from the recommendations being accepted and even more different from the recommendations being implemented. The Chair is asked to consider methods by which she may wish to review the progress towards implementation of any recommendations she makes, and how those responsible for implementation can be held to account.

CONCLUSION

130. It forms no part of this Inquiry to investigate what motivated Lucy Letby to commit such heinous crimes against the children in her care. She has refused to accept her guilt, so the public may never receive an explanation. But the Inquiry does have the vital task of determining whether the professional staff around Letby – the doctors, nurses, managers, executives and Board members at the CoCH – responded appropriately to the suspicion that she was assaulting and murdering babies in her care. That suspicion could not have been more serious. It required the most urgent and robust response. The documentary and witness evidence so far obtained by

[24] https://www.infectedbloodinquiry.org.uk/sites/default/files/Volume_1.pdf §1.5, recommendation 4(b).

the Inquiry indicates that this did not occur. Instead, there was denial, delay and confusion, which allowed Letby to go unchecked and put more patients' lives at risk – with devastating consequences. The Families whom we represent expect all witnesses who give oral evidence over the next four months to be open and candid about why this occurred and for those responsible to accept the personal part that they played in these awful events.

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30 August 2024