THE THIRLWALL INQUIRY

CLOSING STATEMENT ON BEHALF OF THE FAMILIES OF

CHILD A, B, I, L, M, N & Q

('FAMILY GROUP 1')

SECTION (1) – INTRODUCTION

1. This closing statement is provided by the families of Children A, B, I, L, M, N and Q (Family Group 1). In the first paragraph of their opening statement to this Inquiry, the Families said that:

   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. These fundamental questions have been explored exhaustively during the Inquiry's oral hearings – during which many witnesses, from both within and outside the COCH, have been pressed on their knowledge, decision-making, and actions.

3. As we set out and develop in the body of this statement, the answers are now clear:

   a. The paediatric consultants and the NNUs managers failed to prioritise patient safety and notify the police at the end of June or in early July when they first became concerned that Letby might have killed babies on the unit – a failure which became more acute and chronic as months passed and further babies were harmed and died.

   b. They failed to initiate safeguarding procedures designed for immediate implementation when deliberate harm may have occurred.

   c. They failed to investigate the deaths and collapses of babies on the unit using the applicable systems: Sudden Unexpected Death in Infancy and Childhood ('SUDIC'), serious incident investigations, and Datix.

   d. They failed, for many months, to escalate their concerns and growing suspicions to the COCH's Executives, or to any of their internal governance committees, in clear and urgent terms.

   e. When the Executives were told of the consultants' concerns and suspicions about Letby, they too failed to notify the police or initiate safeguarding procedures.

   f. They refused to accept and investigate the consultant's concerns and suspicions, embarked on protracted investigations to find alternative causes, and pressured the consultants to back down and keep quiet.

   g. They misinformed and misled the Board of Directors – which, even when it was better informed, failed to challenge the Executives and ensure that they notified the police.

   h. No one was open, transparent and candid with the Families about any of these concerns, suspicions, decisions and investigations – on the contrary, critical information about their children was deliberately withheld from them.

i. COCH also deliberately withheld information from NHS England and the Senior Coroner for Cheshire – keeping him ignorant of the consultants' concerns and suspicions both during and after Child A's inquest.

4. Many of COCH's most senior witnesses, including the consultants, have now accepted personal responsibility for their part in these failings. But the Executives have not done so. Their lack of insight into their own mistakes is both remarkable and shameful. Throughout the hearings, they consistently sought to defend their actions and to deflect blame onto others. And they are now attempting, opportunistically, to suspend the Inquiry's work pending Letby's third attempt to appeal her convictions – a bold and misguided move that the Families will address in their oral closing statement.

SECTION (2) – WHAT WENT WRONG

5. In **PART (A)** of this section on **what went wrong at the COCH between 2015 and 2017** we set out the **principles and procedures that should have been applied** and the **steps that should have been taken** from the point that there was an increase in mortality and unexpected collapses at the COCH.

6. **PART (B)** comprises a table of the **key failings and inflection points** in the chronology of events, at which we say there were opportunities to act differently and opportunities for intervention that would have prevented Letby from harming and murdering more babies.

7. The Families' position is that the possibility that Letby may have harmed babies should have been viewed as a patient safety and safeguarding issue at the end of June/beginning of July 2015. There should have been an immediate safeguarding referral to the COCH's safeguarding team and onwards to the LADO and LSCB. There should also have been a direct referral to the police. Letby should have been excluded from the NNU immediately pending investigation.

PART (A)

Failure to put patient safety first

8. We begin with patient safety because that is the principle that should have guided all decision-making from June 2015. It is, or should be, uncontroversial that those working in and running a hospital should not take unnecessary risks with the lives and safety of neonates, the most vulnerable of all patients. The safety of babies should have been the number one and overriding priority and watchword at all times in the COCH.

9. We do not examine in detail the multiple systems of assurance, reporting and improvement mechanisms that are part of the day-to-day operations of NHS providers, and which aim to improve patient safety. Nor do we consider the complex ecosystem of healthcare organisations and regulatory bodies with responsibilities that include patient safety. Instead, we concentrate on patient safety as a principle – and advance three key points.

10. **First**, with a properly engrained patient safety culture, the safety of babies should have outweighed any concerns about the reputation of the COCH or any individual staff members. It should have prevailed over nervousness about upsetting Letby[1] or her nursing managers such as Eirian Powell and Karen Rees. It should have eclipsed human resources processes, which were blindly and unthinkingly operated, and any concern, real or false, that contacting the police would lead to the NNU being disrupted and turned into a crime scene (as was Stephen Cross' warning at the end of June 2016)[2].
11. **Second**, a properly engrained patient safety culture would and should have brought greater curiosity and urgency to understanding what was happening on the NNU from June 2015. Sir Robert Francis KC said that health is, by definition, a risky business. Safety, in the sense of avoiding harm to patients, should be the priority. Most risks are avoidable and so safety culture requires people to be thinking about it all the time and "*when things for instance go wrong, there needs to be this persistent curiosity about why they went wrong, what the answer to it is, and how we can avoid doing it in future….it's got to be everyone's business"*[3].
12. The paediatricians and senior nurses in the NNU did not exercise persistent professional curiosity to understand the reasons for the increased mortality. They did not proactively record and investigate the reasons for unexpected and unexplained collapses when the babies survived. While the Families accept that Dr Brearey and subsequently other paediatric consultants did recognise the increase in mortality, their response to this and further deaths and collapses lacked urgency, was unsystematic, and failed to examine the whole picture. For example, Child B's collapse was not considered alongside the deaths of Child A, C and D, despite her also having a rash; and the collapse of Child M, which alarmed Dr Jayaram, was not investigated or linked with the mortality cases.
13. However, the most notable and unforgiveable lack of curiosity came from outside the paediatric consultant group, specifically:
    a. The nursing managers: Eirian Powell, Yvonne Griffiths, Anne Murphy, Karen Townsend, Karen Rees and Sian Williams;
    b. The Executives: Tony Chambers, Ian Harvey, Alison Kelly and Sue Hodkinson; and

[1] James Wilkie's evidence was that, the day after the first extraordinary board meeting on 14 July 2016 when it was agreed that Letby would return to work on the NNU with supervision, he went to speak with Alison Kelly because he was unhappy with this decision. He said his impression from speaking with Ms Kelly was that she was concerned about the impact that removing Letby would have on the individual. Mr Wilkie said, rightly in our view, "*I took the view that patient safety trumped any concern of an individual member of staff's feelings*" [Wilkie/ wk12/ day1/ p175/ ln 11 – p176/ ln 8]

[2] Stephen Cross was unable to give oral evidence. Had he done so, we would have put to him (via CTI or directly) that his advice was wilfully alarmist, that as a former police officer he knew it was wrong, and that he misled the meeting with a view to stopping the police from investigating Letby's alleged crimes. For the warning given by Stephen Cross, see [McCormack/ wk5/ day2/ p66/ ln13 – p67/ ln24] and [Saladi/ wk4/ day4/ p95/ ln19-25].

[3] [Francis KC/ wk4/ day1/ p33/ ln10 – p34/ ln12]

c. The safeguarding professionals: Ruth Millward (Head of Risk and Patient Safety), Dr Rajiv Mittal (Designated Doctor for Safeguarding), and Dr Howyada Isaac (Named Doctor for Safeguarding).

14. **Third**, with a properly engrained patient safety culture, the possibility of deliberate harm being caused to patients will always be kept in mind. As soon as there was such concern or suspicion at the COCH that Letby may have harmed babies then the focus should have been on keeping babies safe, and on the risks Letby may have still posed, rather than waiting until there was more definitive proof of deliberate harm[4].
15. In our submission, the Executives catastrophically failed to hold patient safety as their watchword. This was seen in Tony Chambers' evidence:

> "*Q: You viewed it in fact as a hypothesis and not a risk. You viewed it through the prism of a hypothesis, it is possible these babies may have been killed deliberately, but you didn't see it as a risk; is that fair?*
>
> *A: I think that might be a reasonable way of describing -- describing it. I -- as I said before -- at the end of my last evidence, that all evidence to date at that time pointed to unexplained deaths being more likely to be caused by a multi-factorial set of issues rather than a single act or individual. I don't think that was -- if that is a hypothesis then I accept that*[5]".

16. The oral opening statement made on behalf of the Executives included the following:

> "*We are confident that, having heard the evidence, the Inquiry will have a better understanding of the following five factors.*
>
> *One, at all times, patient safety was prioritised*[6]".

17. The Families could not disagree more with this assertion, most particularly as it relates to the Executives and senior managers represented in that group. It was patently wrong before any oral evidence was heard. It is now utterly contradicted by the evidence adduced since September 2024. Patient safety was wilfully ignored by the Executives.

Failure to follow basic safeguarding principles and procedures

The principles and procedures

18. 'Working together to safeguard children: a guide to inter-agency working to safeguard and promote the welfare of children' (March 2015. 'Working Together') contained the following:

a. "T*he child's needs are paramount…*[7]";

[4] [Francis KC/ wk4/ day1/ p119/ ln6-12]

[5] [Chambers/ wk11/ day 3/ p205/ ln2-14].

[6] [Opening submissions Former Executives/ wk1/ day4/ p5/ ln18-21]

[7] [INQ0014575_0008, §12]

b. "A*ll professionals who come into contact with children and families are alert to their needs and any risks of harm that individual abusers, or potential abusers, may pose to children[8]";*

c. *"All professionals share appropriate information in a timely way and can discuss any concerns about an individual child with colleagues and local authority children's social care"*[9];

d. *"Ultimately, effective safeguarding of children can only be achieved by putting children at the centre of the system, and by every individual and agency playing their full part, working together to meet the needs of our most vulnerable children*"[10];

e. *"Safeguarding is everyone's responsibility: for services to be effective each professional and organisation should play their full part"[11];*

f. "*Effective safeguarding systems are child centred. Failings in safeguarding systems are too often the result of losing sight of the needs and views of the children within them, or placing the interests of adults ahead of the needs of children*"[12];

g. "*Fears about sharing information cannot be allowed to stand in the way of the need to promote the welfare and protect the safety of children. To ensure effective safeguarding arrangements:*

h. *No professional should assume that someone else will pass on information which they think may be critical to keeping a child safe. If a professional has concerned about a child's welfare and believes they are suffering or likely to suffer harm, then they should share the information with local authority children's social care"[13]*.

19. Dr Joanna Garstang added to these principles, saying that it was one of the key mantras of safeguarding that no child has ever died because people shared too much information and that it is always better to share information. Protecting children is the fundamental responsibility and not the adults or organisations, and children should always be kept at the forefront[14].

20. Critically, Chapter 2 of Working Together also stated that all NHS organisations were required to have:

> "*clear policies in line with those from the LSCB for dealing with allegations against people who work with children. Such policies should make a clear distinction between an allegation, a concern about the quality of care or practice or a complaint. An allegation may relate to a person who works with children who has:*
>
> - *Behaved in a way that has harmed a child, or may have harmed a child;*
> - *Possibly committed a criminal offence against or related to a child; or*

[8] [INQ0014575_0008, §12]

[9] [INQ0014575_0008, §12]

[10] [INQ0014575_0008, §13]

[11] [INQ0014575_0009, §14]

[12] [INQ00014575_0009, §20] Dr Garstang agreed this was an important principle [Garstang/ wk3/ day4/ p132/ ln12-13].

[13] [INQ001475_0017, §24]

[14] [Garstang/ wk3/ day4/ p133/ ln23 – p134/ ln5]

- *Behaved towards a child or children in a way that indicates they may pose a risk of harm to children"* [INQ0014575_0054, §4].

21. The COCH's own 'Speak Out Safely (Raising Concerns about Patient Care) and Whistleblowing Policy' ('SoS policy') dated November 2013 adopted the same language as Working Together [INQ0003012], stating:

> "*If there is a concern raised or an allegation made about a person who works with children, whether a professional, staff member, foster carer or volunteer that they may have:*
>
> - *Behaved in a way that has harmed a child, or may have harmed a child*
> - *Possibly committed a criminal offence against or related to a child or*
> - *Behaved towards a child or children in a way that indicates s/he is unsuitable to work with children,*
>
> *Then the process outlined below should be followed…*" [INQ0014171_0009].

22. This was repeated in the Trust's disciplinary policy (dated 24 November 2011) [INQ0002879_0120].
23. The COCH Safeguarding policy also advised staff what to do if their concerns were not acted on:

> "*If at any point a member of CoCH staff feels that their concerns about a child are not being acted upon appropriately they must discuss this with the safeguarding children team who will take responsibility for ensuring the case is appropriately managed within the CoCH*" [INQ0003250_0030][15].

24. Dr Garstang's evidence was that the language in Working Together meant:

> "*…that you only have to have concerns that it might have happened. You don't need to prove -- it's not up to you to prove it before making a referral. Certainly -- I mean I have --these cases -- it's obviously very difficult when there's concerns that it might be a staff member who has harmed or might have harmed a child, so you would expect that there would be discussions within that healthcare organisation with the Trust's safeguarding team and getting advice from them, but if there was any doubt they would make that referral to allow a proper investigation. It's not up to an individual organisation to do the investigation themselves because you have only got that one element of the picture. The other agencies may have much more information*"[16] .

25. When asked what she would do if she had concerns about a staff member, she said:

> "*…these are really difficult situations, but you have to bear in mind that your duty is always to your patient, even if that – or to safeguard children and even if that child has died, it's still a safeguarding matter because other children are potentially at risk*"[17].

[15] The 2013 Safeguarding policy contained the same wording [INQ0014163_0027, §5].

[16] [Garstang/ wk3/ day4/ p137/ln24 – p138/ ln13]

[17] [Garstang/ wk3/ day4/ p185/ ln24 – p186/ ln4].

Individual failures at the COCH

26. As soon as there were concerns that Letby had or may have harmed babies, this should have been viewed as a safeguarding issue and standard safeguarding responses followed to the letter. The safety and welfare of babies should have been paramount and put well ahead of the Letby's perceived needs. That was everyone's responsibility. The evidence demonstrates there was a complete failure by the consultants, NNU and nursing managers, and the Executives (Ian Harvey Alison Kelly, and Tony Chambers) to consider and apply basic safeguarding principles.

27. The oft-repeated evidence from clinicians, senior managers and Executives was that their safeguarding training did not focus on healthcare practitioners causing harm to children and that they did not think of this as a "safeguarding issue" needs to be viewed against the fact the Trust's own SoS and disciplinary policies expressly identified the possibility of staff causing harm, and expressly set out a process to be followed. Certainly, senior managers (including HR personnel such as Sue Hodkinson and Dee Appleton-Cairns) and the Executives should have been aware of these policies.

28. As soon as anyone at the COCH held concerns or suspicions that Letby may have deliberately harmed babies, they should have contacted members of the COCH's safeguarding team and/or managers. That would have included Dr Isaac[18]. It is likely that Alison Kelly, as the Board lead for safeguarding would also have been informed sooner than she was. The safeguarding team should have made an immediate referral to the LADO or encouraged and supported the consultants to do so. This is supported by:
    a. Working Together: "*Any allegation against people who work with children should be reported immediately to a senior manager within the organisation"* [INQ0014575_0054, §7] and "*[l]ocal authorities should…have designated a particular officer, or team of officers (either as part of multi-agency arrangements or otherwise), to be involved in the management and oversight of allegations against people that work with children"* [INQ0014575_0054, §5].
    b. The SoS policy: "*The member raising the concern should first discuss this matter with the Professional Head / Lead Clinician or Head of Service for their Division (named senior officer). These managers will have responsibility for allegations management and will liaise with the LADO within the children's safeguarding unit, Local Authority,* INQ0014171_0009]. See also the Trust's disciplinary policy [INQ0002870_0120]
    c. Dr Garstang: a healthcare professional with concerns about a member of staff harming children should go to the safeguarding team in the organisation. She said she would not

[18] Dr Isaac's evidence that, if there were safeguarding concerns, she should have been told [Isaac/ wk10/ day1/ p207/ ln5-12]. Paul Jenkins' (the LADO) commented, "*One matter about the [Letby] issue that I am curious about, is why the consultants went to the Director of Nursing (Alison Kelly), rather than the safeguarding team and the designated lead in the hospital? I would normally expect them to take that route. I feel there is probably some learning for the hospital there*" [INQ0017823_0013, §57].

expect a paediatrician on the ward to directly call the local authority, but the safeguarding team should support or encourage the paediatrician to make the referral[19] .

29. In addition:

    a. The local guidance in the Pan-Cheshire Child Death Overview Panel protocols stated that (in the context of child deaths):

        "*Where, at any stage, a child may have been or likely to be harmed, there will need to be interagency child protection and/or criminal investigation led by the police"* (underlining in original) [INQ0010095_0011];

    b. The evidence of Paul Jenkins (the LADO at the time, employed by Cheshire West and Cheshire Council) is that:

        i. The LADO does not conduct investigations. The LADO oversees and directs investigations done by others [INQ0017823_0001, §5].

        ii. Letby's offending involved the murder of children and "*is therefore a safeguarding issue which should be reported to a LADO*" [INQ0017823_0004, §19].

        iii. He would have expected the consultants to escalate their concerns internally and, if not satisfied with the response, then to go to the LSCB. Good safeguarding relies on there being a culture in which practice around children can be challenged and he would expect to see a "*culture of challenge*" in the COCH [INQ0017823_0007, §34].

        iv. "*…it is my view that once hospital employees started to suspect an individual, a LADO referral should have been made*" [INQ0017823_0016, §71].

    c. Alison Kelly agreed that, if this had been considered a safeguarding concern, then a LADO referral would have been made. Through that, the police would have been notified as part of the multi-agency approach[20] .

30. The consultants did not need the Executives' permission or approval to make a safeguarding referral. Nor did members of the COCH's safeguarding team. Dr Garstang was clear about this:

    "*What I would not expect is any management involvement in that, that you absolutely do not need management permission to make a referral through LADO. Out of courtesy of course you would let management know, but it's not their decision whether that -- a safeguarding referral is made or not*"[21].

31. Dr Brearey said that the consultants thought engaging with and persuading the Executives to contact the police was the right thing to do[22]. This was wrong. Once they adopted that approach,

[19] [Garstang/ wk3/ day4/ p185/ ln24 – p186/ ln12]

[20] [Kelly/ wk11/ day1/ p12/ ln8-16]

[21] [Garstang / wk3/ day4/ p186/ ln13-18]

[22] [Brearey/ wk10/ day2/ p138/ ln6-19].

neither the Executive or the Board should have applied the 'brakes' at any point to the consultants or anyone else wanting to contact the police. Yet that is precisely what happened in June/July 2016.

32. All of COCH's Executives and senior managers failed to follow safeguarding processes. But particular opprobrium attaches to Alison Kelly, Executive Safeguarding Lead at the COCH, for her abject and repeated failures to ensure appropriate safeguarding responses were initiated:

    a. Alison Kelly either did not read or did not properly read the Thematic Review when it was sent to her on 15 February 2016.

    b. She delayed meeting with Dr Brearey until 11 May 2016;

    c. In the context of the meeting on 11 May 2016 between Ian Harvey, Alison Kelly, Dr Brearey, Anne Murphy and Eirian Powell, she was asked:

        "*Q: Now, within safeguarding, where there is a concern that somebody may be causing harm, in this case to babies, is it ever appropriate as an action plan just to wait and see if the harm is caused again from a safeguarding perspective?*

        A: From a safeguarding perspective, no, that wouldn't be appropriate. However, I had assurance at that meeting from my senior nursing team that there were no concerns with that individual at that time"[23].

        She went on to accept that the reassurance she was being given by her nursing team related to Letby's competence.

    d. Alison Kelly had a responsibility to raise safeguarding at this meeting but failed to do so. She gave evidence that, "*[l]ooking back, and reflecting on that meeting, there should have been a safeguarding conversation. But it never came up and I never approached it as a safeguarding issue*"[24]. When asked if her actions at the meeting on 11 May 2016 would have been different had she viewed this as a safeguarding concern, she said her "…*actions <u>may</u> have been different. But we didn't have a safeguarding conversation…*" (emphasis added)[25]. Either this was a disingenuous response, or Alison Kelly was not fit to be the COCH's safeguarding lead.

    e. She attended a meeting on 7 July 2016 with, inter alia, NHS England and the CCG. Her own notes record "*safeguarding referral*" [INQ0004320]. In evidence Alison Kelly said she could not remember the conversation, but this would suggest that safeguarding was either discussed at this meeting or was in her mind. She failed to inform these organisations that, just a matter of days before, the consultants had said they believed Letby had deliberately harmed babies in the NNU[26].

[23] [Kelly/ wk11/ day1/ p9/ ln16-24]

[24] [Kelly/ wk11/ day1/ p12/ ln17-24] See also [Kelly/ wk11/ day1/ p13/ ln16-22].

[25] [Kelly/ wk11/ day1/ p10/ ln21-24]

[26] [Kelly/ wk11/ day1/ p25/ ln3-22]

f. Shortly after this, she had a call with Gill Frame from the LCSG[27]. There is no evidence that she informed the LCSG about the consultants' concerns. Even at this point, her evidence was that "*…at the time nobody, including myself, was looking at it through a safeguarding lens"*. She said she was informing the LCSG as part of the COCH's "*communications plan*" linked with the NNU being downgraded[28].

33. Throughout the period from February 2016 to May 2017, Alison Kelly failed to recognise that suspicions that a nurse was murdering and harming babies was an obvious safeguarding issue[29]. At no time did she speak with her safeguarding colleagues or bring the issue to the COCH's Safeguarding Strategy Board. Her evidence was that she did not think of the increase in deaths as a safeguarding concern "*because it did not fit within the usual categories of safeguarding concerns that we typically dealt with. It was more of a concern about a clinical trend…as opposed to an isolated safeguarding concern"* [INQ0107704_0040, §123]. This is simply unsustainable.
34. Even after the police were notified, it appears she still failed see the safeguarding issues. In March 2018, 9 months after the police commenced their investigation, she had to be asked to make a LADO referral. When she eventually made did so it was inaccurate, inadequate, and misleading in multiple ways. She even failed to inform the LADO that Letby had been going to Alder Hey Hospital since March 2017[30].
35. Ian Harvey's evidence was that Alison Kelly did not give him any advice about what to do from a safeguarding perspective when there were concerns about deliberate harm to babies[31]. Both Harvey and Tony Chambers also said they would have looked to her for advice on whether the circumstances raised a safeguarding issue[32]. She should have prioritised her Executive safeguarding role over all other aspects of her role. Dr Garstang was asked about a board member wearing "*a number of hats*" and said:

    "*…because safeguarding is always your first principle anyway, but they are sitting on the board as they are wearing a safeguarding hat on the board. I mean, I suppose sometimes people may have two roles but fundamentally safeguarding comes first*"[33].

Systemic failures at the COCH

36. There are many examples of staff at the COCH not knowing what safeguarding covered and the processes it entailed. In addition to the evidence referred to above, we point to:

    a. Dr Gibbs, a very experienced and senior consultant, said he thought he knew the steps to take if he was concerned about a colleague deliberately harming patients or criminal activity, although could not remember if this was part of safeguarding training. He said that he

[27] Note in Alison Kelly's notebook at [INQ0106930_0125].

[28] [Kelly/ wk11/ day1/ p6/ ln6 – pg18/ ln10]

[29] [Kelly/ wk11/ day1/ p5/ ln12-20]

[30] Referral at [INQ0013064]. See questions put to Alison Kelly about the referral at [Kelly/ wk11/ day1/ p33-42].

[31] [Harvey/ wk11/ day4/ p88/ ln6-15]

[32] [Harvey/ wk11/ day 4/ p88/ ln6-15]; [Chambers/ wk11/ day3/ p203/ ln5-7]

[33] [Garstang/ wk3/ day4/ p187/ln14 – p187/ ln24]

assumed this would be done in the same way as raising performance problems, i.e. to a line manager/ supervisor. He said he would not have considered speaking to the safeguarding team about concerns about a nurse[34]. This way of thinking reveals a focus on the adult staff member, rather than putting the babies and risk management at the centre of the response.

b. It is not even clear if Dr Isaac, the Named Doctor for Safeguarding, immediately recognised a safeguarding issue when she first learnt in November 2016 that Dr Brearey was concerned Letby had murdered babies[35]. She certainly did not respond appropriately to such a serious safeguarding concern[36]. She seemed to think instituting a proper safeguarding response was the responsibility of others[37].

c. Dr Mittal, the Designated Doctor for Safeguarding, also did not recognise an ongoing safeguarding issue when he attended the meeting on 27 April 2017, with Hayley Frame, Detective Chief Superintendent Wenham, and others[38].

37. Such ubiquitous failures point to major deficiencies in the management of and training on safeguarding, at multiple levels. Many healthcare professionals at the COCH gave evidence that their mandatory safeguarding training was concerned with harm or potential harm from family members or carers, but did not cover harm from a member of staff[39]. This recollection is supported by the available contemporaneous training documents, which do not contain references to harm by staff[40]. However, Sharon Dodd, who had had level 1, 2 and 3 safeguarding training and who delivered safeguarding training at the COCH, said that the training "*absolutely*" made reference to cases such as Beverley Allitt and Harold Shipman:

"*…Actually, as part of delivery of training we would include relevant serious case reviews and relevant information that we would impart to people that we were training. But also we would*

[34] [Gibbs/ wk4/ day2/ p29/ ln5 – p31/ ln2]

[35] On 22 November 2016, Dr Isaac met with Dr Brearey to conduct his appraisal. She accepted that, in this meeting, Dr Brearey was telling her he was worried a staff member had murdered babies. She said, "*[s]o at that time it wasn't regarded as safeguarding and I suspect that's why my colleagues haven't approached me as safeguarding lead*". She went on to say that safeguarding is about children who are alive, and Letby had been removed from the NNU [Isaac/ wk10/ day1/ p210/ ln20 – p213/ ln2]. To be clear, Dr Garstang's evidence on the child-centered approach of Working Together was that, "…*for child death you still take it that even though a child has died they have the right to have their death investigated fully, the right that we learn from their death and also you're thinking of future children's rights to not die from the same thing"* [Garstang/ wk3/ day4/ p131/ ln14-19].

[36] Dr Isaac's draft letter to Alison Kelly sets out a confused understanding of the threshold for taking action in response to a safeguarding concern - she refers to the balance of probabilities [INQ0102620_0022]. In oral evidence, Dr Isaac appeared to clarify that only "*concerns*" were needed in order to raise a safeguarding issue and seek a safeguarding investigation, whereas the balance of probabilities would be applied to decision-making after an investigation had taken place [Isaac/ wk10/ day1/ p197/ ln4 – p199/ ln3].

[37] As one of her 'excuses' for not acting on the information from Dr Brearey, she said that concerns about Letby murdering babies had *"already been escalated to the highest level. The senior manager, the top, you know, in the hospital were already aware of it and Lucy Letby had already been removed from the neonatal unit*" [Isaac/ wk10/ day1/ p212/ ln16-21]. She also said that Dr Brearey, speaking in his appraisal, was not "*referring to me for…a safeguarding process to be followed*" [Isaac/ wk10/ day1/ p215/ ln6-9].

[38] [Mittal/ wk10/ day3/ p131/ ln2 – p135/ ln8] and meeting note at [INQ0005461]

[39] See, for example: Dr ZA [ZA/ wk5/ day1/ p12/ ln8-14]; Dr V [V/ wk5/ day1/ p86/ ln11-17];

[40] On our own review of the training documents on safeguarding that have been provided to the Inquiry by the COCH, we have not seen reference to Allitt or Shipman. Documents: [INQ0108338], [INQ0108339], [INQ0108340], [INQ0108341], [INQ0108342], [INQ0108343], [INQ0108344], [INQ0108346], [INQ0108348] and [INQ0108349].

be receiving that training from other areas, certainly the LSCBs to deliver a lot of training around, you know, serious case reviews that were relevant.

Q: You say "serious case reviews", but very specifically were you trained and referred to the case of Beverley Allitt?

A: Absolutely, yes."[41].

38. Although Ian Harvey and Tony Chambers both said they would have looked to Ms Kelly for advice on whether the circumstances raised a safeguarding issue[42] [43], this does not absolve them of personal responsibility for failing to initiate safeguarding procedures. Working Together stated, "*[t]his statutory guidance should be read and followed by… senior managers within organisations who commission and provide services for children and families, including…professionals from health services…All relevant professionals should read and follow this guidance so that they can respond to individual children's needs appropriately.*" [INQ0014575_0007, §6-7]

Failures by external persons and organisations

39. There were also failures by external bodies and professionals to recognise that concerns about Letby harming babies were a safeguarding matter.

40. RCPCH: Before the RCPCH review on 1-2 September 2016, Sue Eardley was aware of the increase in neonatal mortality and of the consultants' concerns about the association with a member of staff and suspicions that she had deliberately harmed babies[44]. The other RCPCH reviewers knew this on 1 September 2016, the first day of the review. Indeed, they discussed amongst themselves potential methods by which staff could cause deliberate harm to babies[45]. No one from the RCPCH appears to have identified a safeguarding concern that mandated a safeguarding response. This is despite Sue Eardley's experience of working in safeguarding and the review panel including a neonatologist, a paediatrician and a neonatology nurse.

41. NMC: Alison Kelly spoke with Tony Newman at the NMC on 6 July 2016, telling him that some clinicians were concerned a nurse "*may pose a serious risk to public safety*" (although it was said that "*no evidence*" was available). She said that the Executive team was due to meet that day to decide if Letby should be reported to the police [INQ0002964_0003]. It is the Families' understanding that the NMC did not, thereafter, advise the COCH that this was a safeguarding issue and took no steps itself to raise a safeguarding concern.

42. Grievance Chair: Annette Weatherley, Deputy Nurse at the University Hospital, South Manchester at the time, did not identify a safeguarding issue.

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[41] [Dodd/ wk10/ Day1/ p5/ ln15 – p6/ ln5]

[42] [Harvey/ wk11/ day4/ p88/ ln6-15]

[43] [Chambers/ wk11/ day3/ p203/ ln5-7]

[44] [Eardley/ wk8/ day4/ p135/ ln4 – p138/ ln12]

[45] See, for example: Eardley's witness statement [INQ0101348_0031, §124]; [Eardley/ wk8/ day4/ p183/ ln14 – p184/ ln21].

43. BMA: Dr Jayaram took advice from the BMA in relation to Letby's grievance. He communicated the concerns that Letby had caused deliberate harm to babies [see e.g. INQ0004356_0002-3]. To our knowledge no one at the BMA advised Dr Jayaram to think about a safeguarding issue.

Concluding comments

44. The inability or unwillingness on the part of staff at the COCH and in multiple independent institutions to identify a safeguarding issue is astonishing. Even if training for the professionals concerned did not expressly identify harm or murder by healthcare staff as a specific category raising safeguarding concerns, or include a case study on this, they should have identified and applied first principles. That is so even if the circumstances were novel or difficult to comprehend. Too much attention was given to the rights and needs of the potential perpetrator, i.e. Letby. Woefully insufficient attention was given to the babies, meaning that there was not a "*child-centred*" approach. Working Together cautioned against this:

> "*Effective safeguarding systems are child centred. Failings in safeguarding systems are too often the result of losing sight of the needs and views of the children within them, or placing the interests of adults ahead of the needs of children"* [INQ0014575_0009, §20].

45. The widespread failure to recognise and follow basic child protection principles – both inside and outside the COCH – demonstrates the type of deep-seated and unhelpful mindsets, biases, and defensive values that Professor Dixon-Woods identified in her evidence[46]. Whatever local training had been given on safeguarding, it was insufficient to counter these factors when staff were confronted with the difficult and transgressive reality of Letby's offending.

Failure to notify the police

46. Once a fair-minded and experienced paediatric consultant or group of consultants held genuine, that is not irrational or malicious, concerns that Letby was deliberately harming babies, it was imperative that the police were contacted straightaway. This should have been done directly or through existing multi-agency arrangements. The responsibility for notifying the police also vested with everyone else – including managers and Executives – who held or was aware of concerns about Letby and it arose repeatedly from late June 2015 to May 2017 (see the table of specific failings below). It would have been reasonable for the consultants and junior managers to allow a

[46] See, for example, from Professor Dixon-Woods: "*A further challenge in detecting warning signs is that normal human and organisational sensemaking tends to favour plausibility and coherence, particularly when a pattern is complex, rare, difficult to discern, or lacking in strong signals. These processes may mean that people reach (sometimes prematurely) for the most credible or easiest explanation, rather than the most discomfiting one. Some events, particularly initially, may be easily "explained away" as attributable to issues of staffing levels, acuity of patients, process defects, or ambiguities about whether an error or other incident really occurred and how it should be understood (see above comments on voiceable concerns)*" [INQ0102624_0019]. "*What can happen is that the people who are responsible for taking action judge them [warning signs] inappropriately and that may happen for a reason, so for normal human sense-making. They may not recognise the pattern, they may classify it as something else and when they classify it as something else, for example as some sort of interpersonal dispute or a HR issue, they enter into something called cultural entrapment which is very difficult to escape from. They keep understanding the issue in the same way, they keep applying the same actions and its not disrupted unless something happens…Where it becomes pathological is when…that is overlayered with denial, defensiveness, inability to accept challenge…*" [Dixon-Woods/ wk3/ day4/ p33/ ln16 – p34/ ln21]. See also [INQ0102624_0021, §4].

member of the Executive team to contact the police. But if the latter were unwilling to do so immediately, then it was incumbent on the former to do so themselves.

47. Many witnesses accepted this basic failing in their oral evidence to the Inquiry – in particular:

    a. Dr Brearey acknowledged that he or someone else should have taken action from the moment that Letby was suspected or harming and killing babies. This should have comprised external help, not further internal investigations, meetings, notes and reviews[47].
    b. On 29 June 2016, Dr Saladi emailed his consultant colleagues suggesting that the police should be contacted and saying, "*I believe we need help from outside agencies, who can deal with suspicion… We should not have had any reason to be suspicious in the first place, once we have reason to be suspicious we need to take appropriate action…*" [INQ0003112_0004].
    c. Dr Jayaram said "*we shouldn't have had to have waited for permission to go to the police. We should have just gone*"[48].
    d. Dr McGuigan's email to his consultant colleagues on 26 March 2017 accurately summed up the position: "*[m]y opinion is that this can never be investigated properly without a police led investigation…. I think the events you have described to me are extremely unusual. Ultimately, you suspect a crime has been committed and I think there is an obligation to report this to the police, whether or not your managers agree."* [INQ0101093_0002].
    e. Eirian Powell accepted that, when professionals raised suspicions that could not be excluded and were not obviously malicious, the police needed to be called and that should have happened as soon as those suspicions were articulated[49].
    f. Alison Kelly accepted that keeping an open mind meant she needed to recognise the possibility of deliberate harm as suspected by Dr Brearey and the only option in those circumstances was to trigger safeguarding processes or call the police[50].
    g. Sian Williams recalled telling Alison Kelly and Karen Rees that they needed to go to the police[51] – though none of these three very senior nurses actually did this.
    h. Karen Rees recognised that it was the responsibility of everyone involved to call the police as soon as suspicions became apparent and when it was clear that these could not be handled internally[52].
    i. Ian Harvey accepted that, at the point discussions about whether a member of staff has killed babies and speculating about the mechanisms of murder, the only option was to contact the police. He said it was one of his regrets that he did not contact the police in June/July 2016[53].

[47] [Brearey/ wk10/ day2/ p256/ ln23 – p257/ ln9]

[48] [Jayaram/ wk9/ day3/ p257/ ln10-12]

[49] [Powell/ wk6/ day4/ p195/ ln8-21]

[50] [Kelly/ wk11/ day1/ p260/ ln6-18].; See also [Kelly/ wk11/ day1/ p261/ ln7 – p262/ ln1]

[51] [Williams/ wk8/ day2/ p44/ ln14-19]

[52] [Rees/ wk7/ day1/ p215/ ln19 – p216/ln5]

[53] [Harvey/ wk11/ day4/ p194/ ln18 – p195/ ln9]

j. Dr Isaac accepted that Executives and healthcare professionals did not have the skills of equipment to investigate very serious criminal offences, and this was exactly the kind of circumstances when external assistance was needed. Local multi-agency safeguarding arrangements should have been used, which included the police[54].

48. The COCH were right to investigate potential non-transgressive causes for the deaths and deteriorations, e.g. clinical causes, staffing levels etc. But this should have been done simultaneously alongside a proper response to the concerns about criminal conduct, which mandated police involvement. A patient safety investigation was not a substitute for a safeguarding investigation or direct contact with the police.

49. In her questions to Tony Chambers, leading counsel for the Executives sought to present events and decisions in June/July 2016 as an 'either/or' situation: either investigate non-transgressive causes or take safeguarding steps and contact the police. Tony Chambers agreed and stressed that they had taken steps to make the unit safe by downgrading it and (eventually) removing Letby. He said "…*there wasn't absolute clarity of what the causes of the unexplained increases in harm were. There was definitely concerns being raised around the conduct of one individual but there was also serious concerns being raised around the demand, the acuity and the care on the unit*"[55]. But it was precisely that lack of clarity that mandated immediate investigation of all possible causes, i.e. deliberate harm as well as any inadequacy in the medical care or systemic failing/s.

50. Ian Harvey took responsibility for commissioning and managing the external investigations into the increased mortality in the NNU, specifically the RCPCH review and the subsequent reviews by Dr Jane Hawdon and Dr Jo McPartland (addressed in more detailed in Part B below). It is clear from his evidence that he considered it appropriate to investigate clinical and systemic causes before considering criminal conduct, based on his and the other Executives' assessments[56] that the 'evidence' of criminal conduct was weak and so deliberate harm was unlikely to be the true cause of babies' deaths:

> *"I felt at the time that we were following what was a logical progression of investigation, based on the situation that we had been presented with and, based on the information that we, we were being provided by both the reviewers and other experts and, at the time, it felt like the right and logical process to -- to follow*"[57].

51. This approach was entirely wrong. The major murder investigation initiated in May 2017 was started with the exact same information that was available the previous year. Any rational non-malicious suspicions of criminal conduct should have been sufficient[58]. In any event, none of the Executives,

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[54] [Isaac/ wk10/ day1/ p225/ ln18 – p227/ ln6]

[55] [Chambers/ wk11/ day4/ p31/ ln10-17]

[56] See also the oral evidence of Alison Kelly [Kelly/ wk11/ day1/ p96/ ln9-21].

[57] [Harvey/ wk11/ day4/ p96/ ln14 – p97/ ln11]

[58] Detective Superintendent Wenham said that, if a clinician had expressed concerns about a number of unexpected deaths and had a suspicion that a member of staff may be harming children, he would have listened, gathered further information. He also said that the police should have been contacted earlier [Wenham/ wk10/ day3/ p188/ ln17 – p189/ ln3 and Wenham/ wk10/ day3/ p191/ ln11-15].

including Ian Harvey, had the experience, skills or knowledge to determine whether the babies had been murdered. That was for the police with the assistance of forensic medical experts.

Failure to articulate suspicions about Letby with sufficient clarity

52. In the Families' oral opening statement it was acknowledged that the paediatric consultants deserved the gratitude of the Families for being the first to identify Letby as the connecting factor between the unexpected deaths and subsequently the person who deliberately harmed their babies. It was also recognised that they had "*acted with tenacity and courage in the face of difficult and defensive managers*", including under the threat of professional consequences[59].
53. After hearing the consultant's evidence and the evidence of Tony Chambers, Ian Harvey, Sue Hodkinson, Dee Appleton-Cairns, and Karen Rees, it is clear that the "*difficult and defensive*" managers does not adequately characterise what they ultimately faced – which was bullying, threats, manipulation, and a consistent lack of integrity. Nevertheless, it was imperative that the consultants, initially Dr Brearey, then Dr Jayaram and others, articulated their concerns clearly and formally, and did so as soon as they held such concerns.
54. Dr Brearey accepted that he should have named his concerns and suspicions, when they grew, in the clearest and most explicit terms. He accepted that, by preparing a Thematic Review that did not mention Letby (other than in the appendix), and by sending emails with phrases like "…*we still need to talk about Lucy*" [email at INQ0003114], this was "*all euphemistic…all implicit and it needed to be clear and explicit and it never was*". He stated:

    "*Yes, and you know, if I was writing a guideline for how to do this for future doctors…I would be happy to include that. But…with the environment in the Trust and the feeling of the nursing staff and the lack of worry anywhere else in the organisation then, I felt I had to be categorical…*"[60].
55. COCH's senior managers and Executives repeatedly told the Inquiry that the consultants never properly explained their concerns, a failure that they relied on to justify their decision not to take more decisive action, including not calling the police immediately. This was a notable feature of Alison Kelly's oral evidence and repeated many times (e.g. "*concerns, yes, but they never articulated what that was"*[61].
56. However, this is an empty and unsatisfactory excuse. It was the Executives' job to proactively find out precisely what the consultants' concerns were. There is no reason to think the doctors would have been anything other than transparent about why they suspected Letby. The basis for their suspicions was not a secret or difficult to explain. It was articulated in the Thematic Review (see further below). It was also the Executives' job to bring objectivity and fresh judgement to what was obviously a very difficult situation for the consultants – who, again obviously, were struggling to come to terms with their own suspicions about a close and valued colleague and finding it difficult to articulate those suspicions using language that reflected their awful reality.

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[59] [Family Group 1 Opening Submissions/ wk1/ day3/ p14/ ln14-24]

[60] [Brearey/ wk10/ day2/ p251/ ln6 – 22]

[61] [Kelly/ wk11/ day1/ p15/ ln23-24]

57. Further, even when the consultants did expressly articulate their concerns about serious criminal conduct, with supporting reasons, at the end of June 2016, the senior managers and Executives failed to respond appropriately. Dr Jayaram, for example, told Karen Rees on 24 June 2016 that the consultants were concerned about the possibility that Letby was responsible for the deaths, including that she was intentionally harming babies [INQ0107962_0058, §398][62]. But no action was taken to remove Letby from the NNU, initiate safeguarding procedures, or contact the police.
58. Later, in a meeting on 29 June 2016, attended by Tony Chambers, Ian Harvey, Alison Kelly, Lorraine Burnett, Stephen Cross, Dr Brearey, Dr Jayaram, Dr Saladi, and Dr Jayaram, the consultants clearly outlined their concerns that Letby had murdered babies on the NNU. Dr Brearey described how babies were stable/improving, then suddenly deteriorated, but did not respond to resuscitation as they should. He explained the unusual timing of many of the deaths, between midnight and 04.00, when Letby was working. He stated that a baby (Baby I) had survived and improved in Arrowe Park, then returned to the COCH and deteriorated [INQ0003371_0001]. The unusual nature of the deteriorations and collapses was also described by Dr Saladi [INQ0003371_0002]. Dr Jayaram even asked how Letby might be harming the babies, "*how? Canular. Air embolism?"* [INQ0003371_0002]. The possibility of criminal activity was openly discussed, including by Tony Chambers [INQ0003371_0002-3]. But again, at this and similar meetings at this time, the Executives failed to recognise that contacting the police was the only sensible option.

Failure properly to heed the consultants' suspicions

59. The Executives and senior managers should have carefully listened to the consultants' concerns and suspicions about Letby, taking them seriously and at face value. It was not the consultants' responsibility to prove how Letby was harming babies, to produce eye-witness evidence of harm, or to persuade the Executives that she was guilty of murder. Again, as the Families said in their opening oral statement, absent obvious malice or irrationality, the authority, experience and (by June 2016) unanimity with which they spoke should have been sufficient. It should have led to prompt contact with the police, whether directly or through the safeguarding processes.
60. The information contained in Dr Brearey's Thematic Review did, in fact, provide support for the consultants' concerns about Letby, specifically the unexpected and (for the most part) medically inexplicable circumstances of the collapses and deaths, the unusual lack of responses to resuscitation efforts, Letby's consistent presence when the babies died, and the timing of many of the arrests. However, the Review was effectively ignored from the middle of February to May 2016. The consultants' professional opinions were given no real weight, and markedly less weight than the views of nurses such as Eirian Powell, Anne Murphy or Karen Rees, or non-specialist clinicians such as Ian Harvey. The consultants were then kept on the sidelines while Ian Harvey 'managed' his own investigations and analysis. The RCPCH report that included commentary about Letby was

[62] Karen Rees has given evidence that Dr Jayaram alleged to her and Karen Townsend that he and Dr Brearey thought Letby was purposefully harming babies on the NNU [INQ0014005_0002] and [INQ0102038_0008-9, §28 and 31].

kept from them. They were not invited to the second extraordinary Board meeting on 10 January 2017[63].

61. The Executives and senior managers did not see the consultants' professional judgments as being capable of amounting to supporting evidence:

    a. Tony Chambers' evidence, even in November 2024, was "*…what we had…was gut feelings and nothing was presented in a very explicit way that would make you feel this was the only explanation*"[64] The formal minutes of meeting on 22 December 2016 between Executives, Letby and Letby's parents record Tony Chambers as saying: "*We are within our rights to phone the police, but we didn't believe it…If we believed it was a criminal issue, we would have phoned the police…*" [INQ0002913_0002 and 3].

    b. Alison Kelly stated in her witness statement that: "*[t]here was ample opportunity for the consultants to furnish us with information about why they suspected Letby may be involved with the deaths and also to agree the actions to be taken. They provided us with nothing more than a feeling of general disquiet"* [INQ0107704_0095, §310]. In oral evidence, she asserted that in June 2016 the Executives "*[o]nly had… the say-so of the paediatricians. We had no actual evidence as in nobody could see her do anything. There was broadbrush statements. There was no evidence provided to us at that time*"[65]. In a drawn out and unattractive exchange with CTI, she repeatedly denied that the consultants' expert view amounted to evidence. She eventually appeared to accept it did but said, "*at the time I didn't take that as evidence*"[66].

    c. Sue Eardley's evidence was that Alison Kelly, "*was particularly supportive of Letby and in my recollection quite dismissive of the allegation*"[67]. Alex Mancini, part of the RCPCH review team, also said the attitude of Alison Kelly and Ian Harvey was "*disbelieving*"[68].

    d. Dee Appleton-Cairns' views are recorded in file note of a telephone call with Ian Pace on 5 July 2016, which stated "*Dee is satisfied that there are no malicious issues involved.*" In her oral evidence, she said that she could be satisfied of this because the clinical team, Ian Harvey and Alison Kelly, had been through matters and had given her these assurances[69].

    e. Sian Williams said in her statement that, "*I felt that the Executive team were clear in their minds that the deaths were due to poor care and that Letby was not deliberately harming babies…"* [INQ0101320_0014, §83].

    f. Dr Brearey's evidence was that in meetings Karen Rees would raise her voice from across the table, telling him there was no evidence. He said she did not understand this, as the evidence was in the Thematic Review and he thought that was enough to escalate things to another

[63] [Nichol/ wk12/ day1/ p75/ ln5-22].

[64] [Chambers/ wk11/ day4/ p3/ ln16-19].

[65] [Kelly/ wk11/ day1/ p35/ ln7-10]

[66] [Kelly/ wk11/ day1/ pp35-36].

[67] [Eardley/ wk8/ day4/ p142/ ln13-22]

[68] [Mancini/ wk9/ day1/ p134/ ln16-23]

[69] [Appleton-Cairns/ wk8/ day2/ p194/ ln15 – p196/ ln13]

level: "*you know, you didn't have to witness somebody pulling a tube out or, you know, injecting something to have enough evidence to go to the police. I felt we had enough concern evidence at that stage to do it and clearly Karen with her limited understanding of neonatology felt otherwise*"[70].

62. Dr McGuigan summed up the overall state of affairs:

> "*You'd have thought that it would be relatively easy for a Consultant to speak up within an organisation because they're people who have a relative amount of power within an organisation. You'd have thought that when all of the Consultants within a particular specialty are trying to say something that that would be relatively easy to have that voice heard, but that's not how it appeared to me looking back at the experience that happened over that period*"[71].

63. Not only did the Executives dismiss the consultants' concerns without due consideration, they also questioned their honesty, integrity and professionalism. In one of many low points in the evidence from Executives and senior managers, Karen Rees said she thought that Dr Brearey and the consultants raising concerns that Letby may have been killing babies in June 2016, "*was personal. Rightly or wrongly, I admit at that time I thought there's a personal issue going on here*"[72]. She continued:

> "*My question: why did Steve Brearey not give me something else?*
>
> *Q: They have given you that they thought she may be deliberately harming babies. What more did you want? Did you need the mode of attack, what did you want? How could they give you that without the pathology, forensics that were required?*
>
> *A: I don't know. I just – because I thought they are not willing to give me anything else to support my decision whether to exclude or remove, I honestly thought it was personal and perhaps I was slighted by that*"[73].

64. Nevertheless, although Karen Rees said she thought the consultants had something "*personal"* against Letby,[74] she did not approach or challenge them about this to ascertain if it was in fact the case[75].

65. Tony Chambers demonstrated a similar combination of scepticism and lack of curiosity when he sought to explain why he too did not believe the consultants*: "I was minded by the fact that if there genuinely – it was genuinely felt that this was deliberate harm by this individual, I am absolutely confident that the professionals, the doctors, would have alerted these [safeguarding and SUDIC] processes themselves, either directly to the police or they would have gone through one of those*

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[70] [Brearey/ wk10/ day2/ p141/ ln6-17]

[71] [McGuigan/ wk5/ day2/ p137/ ln9–17]

[72] [Rees/ wk7/ day1/ p143/ ln1-4]

[73] [Rees/ wk7/ day1/ p147/ ln19 – p148/ ln5]

[74] Karen Rees said that she thought that Dr Brearey and the consultants raising concerns that Letby may been killing babies, "*was personal. Rightly or wrongly, I admit at that time I thought there's a personal issue going on here*" [Rees/ wk7/ day1/ p143/ ln1-24].

[75] [Rees/ wk7/ day1/ p212/ ln24 – p213/ ln21]

mechanisms…"[76]. Again, this evidence shows a complete lack of judgement, logic and credibility. It was the Chief Executive's job to ensure that proper governance procedures were followed, not to allow them to be ignored and then draw false inferences from that fact.

Freedom to speak up / whistleblowing

Policy framework

66. From November 2013 onwards, COCH had a dedicated policy for speaking up safely and whistleblowing: 'Speak out Safely (Raising Concerns about Patient Care) and Whistleblowing Policy' [INQ0014170][77]. It was said that COCH was "*committed to achieving the highest possible standards of patient care and the highest possible ethical standards in public life in all of its practices.* To achieve these goals, COCH committed to not only encouraging freedom of speech but to also "*encourag[ing] staff to use internal mechanisms for reporting any malpractices or illegal acts or omissions by its staff or former staff.*" [emphasis added].
67. The policy provided that staff concerns would be "*fully investigated*" and, where the concerns raised related to patient care, these would be "*dealt with seriously, promptly…*". It emphasised that no "*recriminations will follow reports which are made in good faith about low standards of care or possible abuses*." This was because COCH's core values required that patients were put at the heart of everything they did. It was therefore clear that, at the relevant time, COCH sought to implement a culture that was open and transparent in relation to patient care and safety. This was line with a national cultural shift that was precipitated, in part, by Sir Robert Francis KC, who led the Inquiry into the Mid Staffordshire NHS Foundation Trust scandal, and determined that patient safety and staff welfare had not been prioritised as they should have been.
68. The policy also provided that where concerns were raised in relation to patient safety matters, staff did not need to "*prove [that] the facts or allegations being disclosed are true, or that they are capable in law of amounting to one of the categories of wrongdoing.*" This was also reflected in the Whistleblowing Guidance for Workers and Employers in Health and Social Care, dated April 2014, which stated that "*if you believe that something is wrong, you do not need proof. Speaking out early could stop the issue from becoming more serious, dangerous or damaging*" [INQ0016686_0009]. Indeed, the Guidance went further in relation to concerns relating to patient safety "*…it is not the worker's responsibility to investigate or decide if abuse has happened, only to make sure that the appropriate agencies are told about their concerns or suspicions.*" [INQ0016686_0008].

[76] [Chambers/ wk11/ day3/ p203/ ln10-15]. Karen Rees expressed similar thoughts and judgments: "*Q: …what really should happen though is if somebody, the senior doctor, says to you in good faith: I think this nurse may be murdering babies, is that you should call the police, shouldn't you? A: On hindsight perhaps I should, but then I questioned as to why neither Consultant did that also. If they were so convinced, why did they not? But I acknowledge yes, yes"* [Rees/ wk7/ day1/ p198/ ln25 – p199/ ln 7].

[77] In January 2016, COCH reissued this policy [INQ0014171], in almost identical terms to the 2013 version.

Staff responsible for its implementation

69. COCH's executive team, including Tony Chambers, Ian Harvey and Alison Kelly, were or should have been aware of the clear and unambiguous terms of these local and national policies and the protections that they afforded to staff who reported concerns. Mr Harvey and Ms Kelly were named as '*Designated Officers*' under the policy and each acted as a first point of contact when it came to staff disclosing concerns.

70. There were a number of other '*Designated Officers*' named in the policy, including Sue Hodkinson and Hayley Cooper. Their duties and responsibilities included arranging an initial interview with the person making the disclosure, reassuring them about the protections that their disclosure provides, and explaining the timescales for possible actions. Designated Officers were responsible for managing the investigation which was to be completed as quickly as possible. Anyone with information or evidence to assist the investigation was to be contacted and a recorded interview undertaken.

Failure to follow the policy

71. The concerns raised by the paediatric consultants that Letby may have harmed children were based on their individual and collective professional opinions, informed by many years of experience in the provision of neonatal care. They fell squarely within the terms of COCH's policy, which was sufficiently wide to encompass patient safety issues and the possibility of deliberate harm caused by a member of staff.

72. Throughout 2015 to 2017, COCH senior management and Executives – including Tony Chambers, Ian Harvey, Alison Kelly, and Sue Hodkinson – failed to recognise that the policy was applicable or needed to be engaged in relation to the concerns that were being raised regarding the increase in sudden and unexpected neonatal deaths and the association with Letby who could be deliberately harming the babies.

73. This led to two catastrophic consequences: First, the consultants' concerns did not receive the prompt and robust response and investigation that they warranted given their obvious gravity. Second, the consultants themselves were personally criticised and threatened with disciplinary and professional sanctions. Both these outcomes contributed to the overall failure to protect children on the NNU from harm and the failure to refer the suspicions about Letby to the police at the earliest opportunity.

Misuse of Letby's grievance investigation

74. The first time that the COCH management appears to have considered the relevance of the Speak out Safely/Whistleblowing policies appears to be in an email sent by Ms Appleton-Cairns to Ms Kelly and Ms Hodkinson on 21 September 2016, after Letby had raised her grievance against COCH and many months after the consultants had first spoken up. Ms Appleton-Cairns stated "*[a]s part of this [Letby's grievance] we were going to ask Ian to speak to SB [Stephen Brearey] and ask him to formally voice his concerns under Speak Out Safely. I think we need to do this in parallel – any thoughts?*" [INQ0002976_0002]. Neither recipient answered this basic question, despite both

being a Designated Officer under the policy and capable of answering it. The Inquiry was not given any cogent or credible explanation for this failure by the relevant witnesses. As a result, the consultants' concerns were never properly considered, and more importantly, protected under the policy, leaving them to face direct personal and professional criticism and to be threatened with possible referral to their regulatory body.

75. Instead of investigating the consultants' concerns seriously and promptly, as required by its own Speak Out Safely/Whistleblowing policy, COCH's senior management and Executives permitted Dr Green, who led Letby's grievance investigation, to determine their validity. This was wholly inappropriate and a task for which Dr Green was ill-equipped and unqualified to carry out. In his final draft report, submitted on 22 November 2016, Dr Green wrongly concluded (whether informed by COCH management or simply assumed) that the "*concerns raised by the Consultants, in particular [Dr Brearey]…were raised through the appropriate channels in line with both the Trusts Speak Out Safely Policy and the guidance proffered by the General Medical Council (i.e. through the Executive team).*" It is not clear what the evidential basis of this conclusion was, other than second/third hand hearsay without foundation. If Dr Green honestly believed this to be the case, he would not have gone on to conclude that "*…I do not find that the consultants concerns, when reiterated to the Executive team were "clear, honest and objective...*" as the consultants' disclosures would have attracted protection against recrimination [INQ0002883_0014].

Misrepresentations to the Board and others

76. On 26 January 2017, Mr Chambers chaired a meeting between the consultants and the Executive Directors Group during which he claimed "*…that the Speak Out Safely process had been professionally managed…*" [INQ0003523_0002]. However, up to this point, there had been no discussion about the consultants' concerns having been dealt with under this policy. Indeed, it was not until 20 February 2017 (almost a month later) that the Speak Out Safely Committee discussed the consultants' concerns in a meeting at which it was decided that the concerns were <u>not</u> to be formally recorded under the Speak Out Safely policy [INQ0098375_0003][78]. This is yet another example of a member of the Executive team deliberately misrepresenting facts to justify their views/stance in relation to the consultants' concerns and support for Letby's return to the NNU.
77. A further misrepresentation occurred in a meeting on 15 March 2017 between Ms Hodkinson and Dr Jayaram, in which they discussed his concerns regarding the mediation process that he had felt compelled to engage in because of Letby's grievance process. During this meeting, Ms Hodkinson indicated that the concerns raised by the consultants in relation to the sudden and unexpected deaths on the NNU and the association with Letby had been "*treated under the [Speak Out Safely] policy.*" [INQ0003219_0002]

[78] The accuracy of these minutes was later called into question at the Speak Out Safely Meeting held on 24 April 2017 [INQ0098434/INQ0098376] when the group were unable to recall whether at the previous meeting they had agreed not to formally log concerns raised about neonatal mortality. Of course, the Inquiry will note that this was in light of the police having been contacted at this stage and therefore may feel there was an element of backtracking by the group.

78. Sue Hodkinson could not have believed in the truth of this statement at the time as she had not received any formal confirmation (further to Dee Appleton-Cairns' email sent on 21 September 2016[79]) that the consultants had been asked to raise their concerns under the Speak Out Safely policy. Ms Hodkinson would also have been aware that the Speak Out Safely Committee had decided against registering the concerns under the policy. In the absence of any cogent factual basis for her to make such a statement to Dr Jayaram, the most likely motivation was to provide false reassurance to him and (through him) the other consultants that COCH that they would be protected under the policy.
79. Part of the problem with the Speak Out Safely policy and process at COCH between 2015-2017 was that the Designated Officers do not appear to have been provided with any specific training, guidance or support in relation to recognising when someone is making a protected disclosure under the policy, how this should be communicated, and what to do to investigate/escalate matters. This was most acutely set out in the following two examples:
80. **First,** Dr Chidgey-Clark, the National Guardian, told the Inquiry in her written witness statement:

> "*The NHS Contract required Freedom to Speak up Guardians to be nominated from October 2016. In the same month, according to office records, we received an email from CoCH to confirm that they had appointed 'Speak Out Safely Designated Officers.' This did not correspond directly to the appointment of a Freedom to Speak Up Guardian…The only individual from this group that was confirmed to have attended and completed the Freedom to Speak Up Guardian foundation training available at that time was Hayley Cooper. She attended this training on 23rd June 2017. JCC/31 [INQ0014089] For context, the first foundation training for Freedom to Speak Up guardians was launched in May 2017. My office can confirm that Sue Hodkinson also then attended Freedom to Speak Up Guardian training on 6th September 2017. JCC/32 [INQ0014090] In December 2017, my office has found records stating that Ian Harvey and Alison Kelly were listed on the directory as Freedom to Speak Up Guardians. JCC/33 [INQ0014091] However, after detailed searches, we do not have records that they attended training…*" [INQ0014485_0019-0020, §§89-92].

81. This demonstrates the lax attitude towards training on the part of senior managers who had responsibilities as Speak Out Safely Guardians and Designated Officers.
82. **Second,** Yvonne Griffiths, who was one of the Designated Officers under the policy at COCH, told the Inquiry in her oral evidence that it was usual for concerns not to be discussed between the Designated Officers at meetings and that certain information would not be shared with her[80]. This illustrates a remarkable lack of professional judgment on the part of the committee – whose members should have been privy to all relevant information/background to concerns raised by members of staff so that they could quiz or challenge the steps being taken and to suggest escalation where appropriate. The tone of Ms Griffiths' evidence about her role as a Designated

[79] [INQ0002976]

[80] [Griffiths/ wk8/ day3/ p12/ ln23 - p14/ ln14]

Officer (and later Guardian) was that she was often overlooked/sidelined when it came to discussions about patient safety concerns and that she was simply there to make up the numbers.

83. The danger of Speak out Safely Guardians being from the senior management and executive level, or not being independent, was highlighted by Dr Gilby in her oral evidence to the Inquiry:

> "*Q…Then you continue at paragraph 120: "Somewhat unusually, the Freedom to Speak Up Guardians at the Trust were mainly Executive officers -- I recall that Sue Hodkinson (the Human Resources Director) and Alison Kelly ... were amongst them." What was your experience or expectation, then, as to where the Freedom to Speak Up Guardians would come from in the Trust or any Trust?*
>
> *A. Well, my previous experience of the Freedom to Speak Up process had been at Wirral University Hospitals, where the Freedom to Speak Up officers were independent from the Executive and the board. There were Freedom to Speak Up champions on the board, both Non-Executive and Executive, but…staff were…able to go to someone who was completely independent from the leadership of the organisation to raise a Freedom to Speak Up concern, which makes sense…ultimately, the line management route leads to the Executive and the board. So it was counter-intuitive that the people who were hearing Freedom to Speak Up concerns were the top of the line management tree. And there was a process already started, when I arrived, to recruit a Freedom to Speak Up Guardian who -- it would be their sole role in the organisation on a part-time basis. And it was made very clear to me that the intention was that that would be one of the HR team who reported to Sue Hodkinson and her deputy, although we were interviewing several people but a decision had been made in advance of the interviews*."[81].

84. The lack of independence of any of the relevant Designated Officers and Guardians at COCH was a further impediment that prevented the consultants' concerns about patient safety being treated objectively and investigated appropriately in 2015-2017.

Failure to act on instances of suspicious conduct and incriminating information

85. After Child K's collapse on 17 February 2016, Dr Jayaram should have informed his consultant colleagues, the NNU's manager, and the Executives of Letby's extraordinary indifference to the child's dislodged tube and deterioration. That information was important and should, at least in theory, have led to the consultants' concerns being taken more seriously. However, again it is notable that when even Dr Jayaram did report it to Executives in March 2017, they failed to take appropriate action (see notes of Executives' meeting on 16 March 2017 [INQ0003344_0003][82].

[81] Further Evidence Hearing/24.2.25/ p81/ ln17-p.83/ ln.5].

[82] Tony Chambers said that he went to speak to Dr Jayaram about his (late) disclosure of this information but in fact did not ask him directly about what he had seen. His explanation for this seemed to be that he did not want Dr Jayaram to feel "*in any way coerced*" [Chambers/ wk11/ day3/ p125/ ln20 – p129/ ln6]. In his witness statement, Chambers asserted that, had he known of certain matters, including what Dr Jayaram witnessed with Child K, "*I would have done to the police with my concerns immediately"* [INQ0107708_0182, §664-665]. That is demonstrably not true.

86. As the consultants acknowledged in their oral evidence, they and their colleagues also missed or misinterpreted the abnormal blood results of Child F on 13 August 2015 and Child L on 14-15 April 2016, which indicated that the babies had been given endogenous insulin for which there was no medical requirement and no prescription[83]. These were very significant failures on the part of the medical staff to identify and act on powerfully incriminating evidence. Both were major missed opportunities to prevent Letby from harming or killing more babies.

Failure to follow existing systems of reporting and investigation

87. As we have indicated above, there were existing systems and processes that could and should have been used, and that would have led to multi-agency involvement, including the police at a much earlier stage. It is our submission that the lives of babies would have been saved, and Letby would have been stopped from harming other babies.

SUDIC

SUDIC should have been used following in-patient neonatal deaths

88. The system or process that should have operated first in time is the SUDIC process[84]. That should have been initiated after Child A's death on 8 June 2015. It should then have been used in response to all sudden and unexpected baby deaths at the COCH[85]. Doing so would have removed some of the arbitrariness of the internal COCH reporting and investigations. It would have resulted in an independent and systematic investigation of the deaths. Dr Garstang explained that a SUDIC is a "*marker for a sudden death that needs detailed investigation"*[86]. Importantly, the police would have been involved immediately after each sudden and unexpected death.
89. Working Together contained a section headed "*Action by professionals when a child dies unexpectedly"* [INQ0014575_0085]. Under this section:

    a. An unexpected death was defined "*as the death of an infant or child which was not anticipated as a significant possibility for example, 24 hours before the death; or where there was an unexpected collapse or incident leading to or precipitating the events which lead to the death*" [INQ0014575_0085, §12].

    b. "*The designated paediatrician responsible for unexpected deaths in childhood should be consulted where professionals are uncertain about whether the death is unexpected. If in doubt, the processes for unexpected child deaths should be followed until the available evidence enables a different decision to be made*" [INQ0014575_0085, §13]. Dr Garstang reiterated this saying, "…*if in doubt, start: you can always stop*"[87].

[83] See section (3) below; §232-237

[84] The submissions focus on the SUDIC process. We do not understand there to be significant differences in the Welsh PRUDIC process.

[85] For Child C, there was a CDOP initial strategy meeting but the SUDIC processes were not used. It appears there was some overlap in the forms used [Gibbs/ wk4/ day2/ p57/ ln7 – p58/ ln5]

[86] [Garstang/ wk3/ day4/ p124/ ln7-8]

[87] [Garstang/ wk4/ day4/ p146/ ln19-20]

90. The 'Pan-Cheshire Guidelines for the Management of Child Deaths, including SUDIC', dated April 2015 and July 2015 contained the same definition of an unexpected death (April 2015 [INQ0014580_0003, §1.7] and July 2015 [INQ0014582_0003, §1.7] (the 'Pan-Cheshire Guidelines').

91. In 2015/16, where there had been a sudden and unexpected death of a neonate:

    a. Working Together stated that "*the consultant clinician… should inform the local designated paediatrician with responsibility for unexpected deaths [Dr Mittal] at the same time as informing the coroner and the police. The police will begin an investigation into the sudden or unexpected death on behalf of the coroner. The paediatrician should initiate an immediate information sharing and planning discussion between lead agencies (i.e. health, police and local authority children's social care) to decide what should happen next and who will do it*" [INQ0014575_0085, §15].

    b. The police should commence an investigation on behalf of the Coroner [INQ0014575_0085, §15].

    c. NHS England should have been notified of the death [INQ0014575_0087, §19].

    d. The Pan-Cheshire Guidelines (April and July 2015) stated: *"[i]nvestigation of a SUDIC case is a multi-agency task and all the professionals who are involved in the case are inter-dependent for sharing of information with the proficient level of expertise*" [INQ0014580_0004, §1.8 and INQ0014582_0004, §1.9].

    e. The Pan-Cheshire Guidelines also provided for a multi-agency response, with police and local authority involvement (see flowcharts at [INQ0014580_0008-9] and [INQ0014582_0009]).

    f. There should have been prompt multi-agency discussions and rapid response meeting, i.e. a multi-agency meeting within 72 hours – 5 days after the baby's death. This would have been chaired by a police officer, a senior investigating officer. The purpose of such discussions and meeting included gathering and sharing information to identify the cause of death and/ or those factors that may have contributed to the death and identifying any risk factors or suspicious circumstances [see INQ0014580_0011, §2.3-2.3.11 and INQ0014582_0010-11, §2.3-2.3.10].

    g. Importantly, under the July 2015 version of the Pan-Cheshire Guidelines (the relevant version), a final multi-disciplinary case discussion should have been held as soon as the final post mortem results were available [INQ0014582_0011, §2.3.11][88]. In a case such as Child A's, that would have meant a multi-disciplinary meeting with police attendance in late December 2015 or early January 2016, at a time when Drs Brearey, Dr Jayaram, Dr Gibbs and Dr Newby already had suspicions about Letby deliberately harming babies.

[88] The same applied under the April 2015 Pan-Cheshire Guidelines [INQ0014580_0012, §2.3.11].

h. The Pan-Cheshire Guidelines also anticipated discussion with the Coroner and the family[89].

92. The oral evidence has demonstrated that healthcare professionals at the COCH, and more widely in the NHS, did not understand that SUDIC processes applied to the unexpected death of a child in hospital, and that they did not apply those processes rigorously.

93. **First**, Working Together indicated the immediate steps that should have been taken in the event of the unexpected death of a child, or where professionals were uncertain about whether the death was unexpected [INQ0014575_0085-86] (see above). No exception was made for the death of a baby who died in hospital and who had never been discharged. Dr Garstang, community paediatric consultant and expert on the investigation of unexpected child deaths, indicated that the language of Working Together "*would imply that unexpected child deaths in hospital should be investigated the same as unexpected child deaths occurring the community*" [INQ0017975_0008–9, §3.7].

94. **Second**, the April 2015 version of the 'Pan-Cheshire Guidelines for the Management of Child Deaths, including SUDIC' expressly stated (underlining added):

> **"***This guidance should be used for the sudden and unexpected death of a child under the age of 18 years irrespective of place of death:*
>
> - *At home or in the community*
> - *In the hospital Emergency Department <u>or in the Ward</u>*" [INQ0014580_0003, §1.4].

95. Identical language was used in the July 2015 version of this document [INQ0014582_0003, §1.4] and both versions of these Pan-Cheshire Guidelines contained flowcharts setting out the pathway after a "*child death in hospital/ community*" [INQ0014580_0010 and INQ0014582_0009].

96. **Third,** the COCH's policy on 'Safeguarding and Promoting the Welfare of Children' ('COCH Safeguarding policy', dated September 2015) stated[90].

> "*The sudden unexpected death (unexpected in 24 hours prior to death) of a child under the age of 24 months, irrespective of the place of death…A SUDIC should be managed in accordance with the SUDIC guidelines…*" [INQ0003250_0033, §6].

97. The predecessor to the COCH Safeguarding policy (October 2013) used the same definition [INQ0014163_0029, §6].

98. **Fourth,** several witnesses accepted in their oral evidence that the SUDIC process should have been used for in-patient neonatal deaths, including: Dr Jayaram[91], Dr Holt, although she considered that the way in the policy was written leant more towards deaths in the community[92], Dr Mittal (the

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[89] See, <u>for example</u>, the April 2015 Pan-Cheshire Guidelines [INQ0014580, §§2.3.1 – 2.3.11 and §2.4] and the July 2015 Pan-Cheshire Guidelines [INQ0014582, §§2.3.1 – 2.3.11 and §2.4]. Working Together also stated that a member of hospital staff should have been allocated to remain with the parents and support them during the SUDIC process [INQ0014575_0086, §§15 and 17].

[90] The predecessor policy, 'Safeguarding and promoting the welfare of children and child abuse management', dated October 2013, contained the same definition [INQ0014163_0029, §6].

[91] [Jayaram/ wk9/ day3/ p9/ ln24 – p10/ ln2; p11/ ln12-21; p19/ ln16-23]

[92] [Holt/ wk4/ day4/ p140/ ln12-25]

designated doctor for safeguarding and child death)[93], Sharon Dodd (the named nurse for safeguarding at the CoCH)[94] and Dr Saladi, although he unfortunately appeared to misunderstand what the SUDIC entailed[95].

99. However, many witnesses identified a discrepancy between the formal policy and its practical application. Dr ZA accepted that the SUDIC process was applicable to hospital deaths, but explained that this was not the practice and culture at the time[96]. Dr Brearey said was that he understood the SUDIC guidelines as "*predominantly"* written for children or babies who had died unexpectedly from a community home setting rather than a hospital setting, and then death on the NNU was even more detached from this[97]. Dr McGuigan said he could not think of any examples of a sudden unexpected death of an in-patient that had led to a joint agency response (the current term for a multi-agency response), but recalled training as a registrar which made clear that it should[98]. Dr Rackham, clinical lead at Arrowe Park Hospital at the time, said that: "*Our experience was that that policy existed but that it wasn't…always enacted for babies who die in a hospital but in certain cases it would be*"[99]. Dr Gibbs said that, in 2015/16, he did not understand it applied[100]. Dr Newby said that she did not understand that SUDIC processes applied to in-patient neonatal deaths[101].

100. Dr Kingdon (President of the RCPCH from May 2021 to March 2024) said she was not surprised that Dr Brearey and the consultants did not think about activating the SUDIC processes, although her evidence was not that it was inappropriate (double negative in her evidence)[102]. This seemed to be on the basis that babies on a NNU are not, as a group, normal healthy babies and so their deaths may not be unexpected[103]. However, the evidence of the treating consultants at the COCH is that most of the babies murdered by Letby were considered to be stable and that, as a matter of fact, their deaths were judged to be sudden and unexpected. We invite the Chair to conclude the SUDIC process did apply and should have applied to those babies.

101. If the SUDIC process had been commenced for each baby, then the designated paediatrician would have been fully aware of each death, as would the local authority and police. Dr Garstang gave important evidence about the value of police involvement in the SUDIC process. She said:

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[93] [Mittal/ wk10/ day3/ p86/ ln1-3, and p87/ ln8-16]

[94] [Dodd/ wk10/ day1/ p45/ ln7-21],

[95] [Saladi/ wk4/ day4/ p55/ ln7-14]

[96] [ZA/ wk5/ day1/ p15/ ln1-4]

[97] [Brearey/ wk10/ day2/ p3/ ln13-25]

[98] [McGuigan/ wk 5/ day2/ p83/ ln23 – p85/ ln3]

[99] [Rackham/ wk11/ day2/ p253/ ln5-23]

[100] [Gibbs/ wk4/ day2/ p33/ ln2-7]

[101] [Newby/ wk4/ day4/ p15/ ln12-19]

[102] [Kingdon/ wk13/ day2/ p181/ ln3-7]

[103] [Kingdon/ wk13/ day2/ p179/ ln9 – p180/ ln7]

"*…the police you work with are…specialist child abuse police officers, so they've got a very good handling of child abuse and neglect and they will – I mean, we all offer each other challenge. They will sort of challenge paediatricians sometimes, have we thought appropriately of safeguarding, or we may challenge the, But I think also it means that…if you do have soft concerns about something, you're not having to pick up the phone to somebody you have no relationship with or you don't know that actually they're already a part of your core team so it's very easy to have those discussions*"[104].

102. In conclusion, the SUDIC process should have been used in response to each of the baby deaths under this Inquiry. This would have changed events, leading to Letby being removed from the NNU sooner and an earlier police investigation. Others, including the designated paediatrician, the local authority and specialist police officers would have had an overview of the frequency and nature of the unexpected deaths at the COCH. The Coroner would have viewed the increasing number of deaths in the context of being SUDIC deaths. The consultant body would have had existing and easy access to external agencies and professionals with experience in safeguarding issues and investigations. They would not have considered it to be such a huge step to speak with external professionals, including the police, about their concerns. There would have been external and independent investigation of the deaths.

Systemic failures to apply SUDIC

103. The repeated failure to apply SUDIC to the deaths in the NNU at COCH is indicative of wider systemic failures:

a. At a national level, training on the SUDIC and communication/education about the applicability of SUDIC processes were inadequate;

b. At a local level, training on the SUDIC and communication/education about the applicability of SUDIC processes were inadequate; and

c. Healthcare professionals, particularly doctors, did not make themselves aware of the SUDIC policies and processes that applied.

104. **First,** the evidence points towards a lack of training, communication and education at a <u>national level</u> on the applicability of SUDIC processes to in-patient neonatal deaths. The Inquiry has the evidence of Dr Rackham and of Dr McGuigan before he joined the COCH, and evidence as to the practices at the COCH. Dr Kingdon's evidence was that: "*up until very recently the teaching and our curriculum has not highlighted Sudden Death in Infancy and Childhood well enough. That has been remedied because we have an outcomes-based curriculum which is very easy to update, so that has been updated*"[105]. However, this was contradicted by Dr Mittal's evidence that the non-use of the SUDIC process for hospital deaths remains a national problem[106].

[104] [Garstang/ wk3/ day4/ p169/ ln11-23]

[105] [Kingdon/ wk13/ day2/ p173/ ln15-24]

[106] [Mittal/ wk10/ day3/ p84/ ln23 – p85/ ln6; p85/ ln14-19]

105. **Second,** at a local level, training on the SUDIC and communication/education about the applicability of SUDIC processes was inadequate. This is divided into two parts.

106. At the COCH: As set out above, many clinicians did not properly appreciate that SUDIC processes should have applied to in-patient neonatal deaths. First and foremost, it appears the COCH did not make them aware of this. Dr Mittal's evidence was that, at the time there was no named doctor for child death at the COCH. He was the designated doctor but was not employed by the COCH in this role. He said that he was delivering ad hoc training to paediatricians and consultants in the hospital, but could not remember when such training was held[107]. He accepted personal responsibility for not ensuring that this took place but emphasised how little time and funding he had for this aspect of his work[108].

107. Dr Gibbs' evidence was that he did not remember his attention being drawn at the time to the section of Working Together that dealt with SUDIC. He referred to the "*enormous number of guidelines in all different aspects of our speciality*"[109]. Based on simply the snapshot of guidelines and policies considered in this Inquiry, the Chair may have some sympathy for this. That is precisely why there needed to be training and education on SUDIC, delivered in the COCH (either by Dr Mittal or under his direction).

108. The fact that no healthcare professional working on the NNU spoke with Dr Mittal about the unexpected deaths is also telling.[110] Working Together stated that "*designated professionals, as clinical experts and strategic leaders, are a vital source of advice to the CCG, NHS England, the local authority and the LSCB, and of advice and support to other health professionals*" [INQ0014575_0057, §17].

109. We still do not know why Dr Mittal was not informed, or why Dr Mittal did not himself see that he should speak with the consultants working on the NNU about the number and nature of the deaths. His evidence was that all the 'Form As' came to him and "*in hindsight*" he should have noticed the increase in mortality[111]. He said he became aware in September 2016 of the increase in mortality, but the Chair will note that this did not catalyse sufficient professional curiosity to prompt him to speak to the consultants[112].

110. In oral evidence, Dr Mittal accepted that an email to him from Dr Gibbs dated 28 September 2015 (about another neonatal death) was a sufficient prompt for him to be curious, as designated doctor, and speak with the consultants about what was happening on the NNU[113]. He also accepted that he was aware of the NNU downgrade in July 2016 and that should have prompted him to speak

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[107] [Mittal/ wk10/ day3/ p89/ ln11-25 and p90/ ln5-15]

[108] [Mittal/ wk10/ day3/ p91/ ln2 – p92/ ln1]

[109] [Gibbs/ wk4/ day2/ p32/ ln2-5]

[110] Dr Mittal said that none of his colleagues at the COCH asked him whether the SUDIC protocol applied to any of the deaths they dealt with [Mittal/ wk10/ day3/ p87/ ln1-20].

[111] [Mittal/ wk10/ day3/ p102/ ln15-22]

[112] [Mittal/ wk10/ day3/ p103/ ln24 – p104/ ln1 and p104/ ln18 – p105/ ln19]

[113] Email at [INQ0103110], [Mittal/ wk10/ day3/ p105/ ln20 – p107/ ln4].

with his colleagues[114]. He was also aware, in early 2017, that Dr Isaac considered sending a letter to Alison Kelly. He acknowledged this was a 'red flag' "*in hindsight*". But he did not find out if the letter had been sent and he did not follow-up at all with Dr Isaac. He did not speak with the consultants to understand their concerns. It was put to him that this was a "*significant failure on your part, not to intervene at that time*. He said "*I would say, yes, I should have intervened at that time*"[115]

111. At the area level: As stated, Dr Mittal was employed by the CCG as designated doctor. He accepted that he had a responsibility to ensure that everybody within his CCG area, including staff at the COCH, understood that the SUDIC process should be followed for in-patient neonatal deaths[116]. As a matter of fact, they plainly did not.

112. In addition, all the murdered babies had been referred to a CDOP, but it appears that no CDOP picked up that the SUDIC process had not been used for the unexpected deaths. There was a lack of understanding of SUDIC processes at the CDOP level, and a lack of rigour and diligence being applied. For example:

a. At a Pan-Cheshire CDOP meeting on 16 September 2016 (Dr Mittal chaired this meeting) a recorded action was, "*item to be added to the November meeting asking if the panel consider that unexpected deaths in Hospital should be referred for RR [rapid response] meetings*" [INQ00178115_0002]. However, Dr Mittal's evidence was that the wording used in the minutes did not reflect the position that it was clear that the SUDIC process applied to in-patient neonatal deaths and the discussion was about raising awareness of this[117].

b. At the meeting on 20 November 2016 (which Dr Mittal attended), the recorded discussion was:

> "*Should a rapid response meeting be held each time there is a sudden unexpected death within a hospital. The meeting felt that the response should be on a case by case basis and the safeguarding doctor should be involved in the discussion with the designated doctor and a rapid response should be arranged if deemed appropriate. The meeting felt this process should be reflected in our procedures with clarification of best practice.*
>
> *Action: Ensure that…when the Pan Cheshire procedures are reviewed sudden un-expected death in hospitals are identified.*
>
> *Action: A letter to be sent to hospitals reminding them of the procedure and a requirement for a discussion between key professionals needs to take place*" [INQ0017817_0002].

c. At the meeting on 24 March 2017 (which Dr Mittal attended), the cluster of deaths at the COCH was discussed for the first time. The minutes record:

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[114] [Mittal/ wk10/ day3/ p109/ ln1-6]

[115] [Mittal/ wk10/ day3/ p116/ ln7 – p120/ ln24].

[116] [Mittal/ wk10/ day3/ p92/ ln2-8]

[117] [Mittal/ wk10/ day3/ p93/ ln13 – p97/ ln10]

> "*The panel discussed SUDI deaths within hospital and whether it was felt that deaths are not always treated with the same concern. It was agreed that a discussion between professionals should always occur and if there was a concern over the death the SUDIC protocol should be followed. The panel is aware that on a number of occasions the rapid response process is not followed. [Gill Frame] suggested that the SUDI process for hospital deaths should be identified within the guidelines*" [INQ0012008_0003].

113. It is clear that even the CDOP's collective understanding of SUDIC was wrong – initiating it was not dependent on whether there was a "*concern"* and was not down to the discretion of professionals. Sharon Dodd agreed with this[118]. It was a mandatory process, to be used where the death was sudden and unexpected. She said that, at this the time, "*we were concerned that the SUDIC wasn't followed because of lack of knowledge and lack of education primarily and it was after that that we did some training around use of the SUDIC protocol*"[119], [120].

114. **Third**, there was a general, systemic, failure on the part of healthcare professionals, particularly doctors, to familiarise themselves with SUDIC policies and processes. This was contrary to the Pan-Cheshire Guidelines, which expressly stated that: "*[i]t is essential that every professional involved in a…(SUDIC) case must be fully aware of the guidelines and should keep meticulous records"* [INQ0014580_0003, §1.5 and INQ0014582_0003, §1.5]; and to the COCH Safeguarding policy (see §6 on SUDIC), which stated that, "***All Trust employees must comply with this generic policy…***" (bold in original) [INQ0003250_0014, §2].

Serious incident reporting

Serious incident investigation

115. The Serious Incident Framework applicable at the time stated in paragraph 1 that [INQ0009236_0013]:

> "*In broad terms, serious incidents are events in healthcare where the potential for learning is so great, or the consequences to patients, families and carers, staff of organisations are so significant that they warrant using additional resources to mount a comprehensive response…Serious incidents can be isolated, single events or multiple linked or unlinked events signalling systemic failures…*".

116. From the June 2015 onwards, there were repeated failures at the COCH to initiate serious incident ('SI') investigations in response to the collapses and/or deaths of babies in the NNU:

    a. Child A: Child A died on 8 June 2015. His death was reported on Datix as "*sudden and unexpected deterioration of death…*" [INQ0000016_0001]. The SBAR analysis recorded "*At present, there is no explanation for sudden cardio respiratory arrest…The*

[118] [Dodd/ wk10/ day1/ p51/ ln9-15]

[119] [Dodd/ wk10/ day1/ p51/ ln25 – p52/ ln4]

[120] In addition, while it is not clear which guidelines the CDOP was referring to, there already were Pan-Cheshire LSCB 'Guidelines for the Management of Child Deaths, including SUDIC' which, as set out above, expressly stated the SUDIC processes applied to deaths in hospital, including on the ward.

initial PM findings did not give any answers" [INQ0000016_0005]. His death should have been investigated as a serious incident from the outset or after the post mortem was unable to identify why he died.

b. Child A, Child C and Child D: Child C died on 14 June 2015. Child C's death was also reported on Datix as "*sudden deterioration of an infant following full resuscitation*" [INQ0000111_0001]. No SBAR was completed on the Datix [INQ0000111_0004-5]. Child D died on 22 June 2015. Child D's death was also reported on Datix. [INQ0000766]. No explanation for the death was given. Again, no SBAR was completed [INQ0000766_0007]. The cluster of deaths of Child A, Child C and Child D between 8 and 22 June 2015 should have prompted an SI investigation.

c. Child B: Child B collapsed without medical explanation on 10 June 2015.Her collapse should have been included in the group SI investigation of Child A, Child C and Child D.

d. Subsequent children: From June 2015 onwards, all unexpected collapses of babies that triggered emergency resuscitation should have been combined with the existing SI investigation into the multiple deaths and collapses or been separately treated as serious incidents.

117. The Families whom we represent therefore agree with the criticism made by NHS England in its written opening submissions:

"*On the basis of what is known currently, it appears to NHS England that the failure of the hospital to report each incident of unexpected collapse or death as a Serious Incident in 2015-2016 and/or an earlier report of the unexpected increase in overall morbidity and mortality could have been a missed opportunity to enable NHS England (and others) to have been alerted while LL was still on the unit.*

Further, and while NHS England has no desire to add to the suffering of the families by speculating about what might have been, the Inquiry might explore further whether — based on the action taken following the declaration of a Serious Incident in June 2016 —this could have been a missed opportunity through which LL's offending could have been stopped at an earlier stage" [INQ0107952_0006-7, §34].

118. The evidence adduced by the Inquiry indicates that some of the medical and nursing staff recognised from early on that there were potentially connections between the deaths that required investigation. On 23 June 2015, Dr Gibbs emailed the consultants to report that Dr Lambie, a registrar, had come to speak to him. It is worth setting out the body of this important email:

"Rachel Lambie came to speak to me this morning…to say that the Registrars are very concerned about the recent neonatal deaths and collapses Child B where all the infants showed a strange purpuric looking rash (that probably wasn't true purpura). However, I pointed out that Child C who also died did not have this rash – but its true that Child A, Child B and the recent death, Child D, did show a similar strange colour change on 'collapsing'. Rachel also said that

'all' the neonatal nurses are very worried. They feel we 'ought to be doing something' and also asked what else different the Registrars can do.

I explained that we were looking into this worrying spate of deaths (and Child B's collapse) but at the moment couldn't identify a unifying cause. For now, I didn't feel that the Registrars can do anything differently.

Although I've mentioned 'we' are looking into this. I'm not sure exactly how this is being done (but I didn't say this to Rachel)….I think a meeting would be useful, even if we have no answers – just to let the nurses air their concerns and to show we are concerned…" [INQ0025743].

119. Dr Gibbs queried what was being done to investigate events. The response should have been an SI investigation, failing which Dr Gibbs should have initiated one himself.

120. On 2 July 2015 there was a SI Panel meeting to review the deaths of Child A, C and D. Child B was not on the agenda. She should have been. No SI investigation followed, save an individual SI for Child D. This was despite the cluster of unusual deaths and there being no explanation for the unusual rashes that were leaving the registrars "*very concerned*" and the neonatal nurses "*very worried*". Mother A reasonably and sensibly pointed out, "*That rash could have been absolutely anything…*"[121]. She also said that, had she been told about Child A's rash, she "*would have demanded that something was done…for some—consultant to tell me they had never seen this before, that indicates that something is seriously wrong. Seriously wrong. And…it wasn't just a one-off; it happened with Child A and then the very next day with Child B….That, to me, indicates that something is wrong and it should have been looked into"*[122].

121. According to Ruth Millward, Head of Risk and Patient Safety at the COCH at the time, "…*it would have been appropriate for the hospital to have reported the overall increase in neonatal death that occurred in June 2015 as a serious incident. That would have then triggered a comprehensive investigation into the increased mortality rate at a much earlier stage…*" [INQ0101332_0056, §260][123].

122. Dr Brearey was the consultant present at the meeting on 2 July 2015 and the evidence suggests that he did not properly appreciate the nature, and commonality, of the rashes. When asked about whether there should have been a serious incident into the cluster of death, which would have captured the theme of the rashes (which turned out to be important), he agreed that was a "*reasonable thing to say in retrospect*" but went on to say, "*…I don't think the description of the rashes in the case notes when I was reviewing them were did enough to really trigger my concern and clearly the email as well didn't do that…"* [i.e. the email dated 23 June 2015]. See also Dr

[121] [Mother A and B/ wk2/ day1/ p36/ ln4-5]

[122] [Mother A and B/ wk2 /day1/ p49/ ln13-24]

[123] In oral evidence she said that the three deaths could have been considered as an SI, with a collective review of the deaths and more of a "*systems process review"* of the NNU than a SI review of Child A and C [Millward/ wk8/ day1/ p151/ ln22 – p152/ ln10].

Brearey's review on 1 July 2015 of Child A's death, which does not refer to his rash at all [INQ0002042_0777].

123. If there had been an SI investigation, including into the rashes, this would have brought them to greater prominence, which in turn would have made it easier to identify the connection with later babies who had similar rashes. It is also likely that Letby as a common theme between all four babies would have been formally recorded earlier. NHS England would have been informed (via STEIS) [INQ0009236_0008].

124. Critically, the parents of these children would also have been involved in the SI process, which would have afforded them the opportunity to provide information and to ask questions and insist on candid answers. The SI Framework stated, "*[t]he needs of those affected should be the primary concern of those involved in the response to and the investigation of serious incidents. Patients and their families/ carers…must be involved and supported throughout the investigation process* [INQ0009236_0008].

The use of Datix

125. Alongside the SI investigation process, it should have been recognised from June 2015 onwards that staff needed to complete Datix forms for all unexpected and unexplained deteriorations not leading to death. This would have created a bank of information and data that would have been highly valuable for the purposes of analysing the number and frequency of deteriorations, what was causing them, and whether there were similarities between non-fatal and fatal cases.

126. On 16 May 2016, Dr Brearey sent a much-belated email to the consultants, Eirian Powell and Anne Murphy saying [INQ0005721]:

> "*Eirian and Anne and myself met Ian Harvey and Alison Kelly last week to discuss the rise in neonatal mortality last year…Naturally, we will be keeping close eye on things in the immediate future. If you do come across a baby who deteriorates suddenly or unexpectedly or needs resuscitation on NNU, please could you let me and Eirian know. We will keep a record of these cases and review them as soon as practicable"*.

127. This guidance was inadequate for several reasons. It should have been given many months earlier. It should have been stronger in its exhortation that deteriorations must be reported. Instead of requesting staff to feed into an improvised reporting process with potentially incomplete or inconsistent types of information, it should have been clear that all deteriorations should be reported using the Datix system, which was designed to capture such information for the purposes of identifying and managing risks.

128. Dr Brearey was asked whether he connected the worrying collapse of Child M on 9 April 2016 with already existing concerns about Letby. He said no, but could not explain why. He said, "*but certainly that was a moment…there was an opportunity to link some events like that"* [Brearey/ wk10/ day2/ p242/ ln5-18]. He also said that he could not remember when he started to think about morbidity cases in addition to mortality cases, but it was around that time (i.e. April/May). He

accepted that "*… it was very hard to get a grip of the morbidity cases…and yes, certainly that was a missed opportunity*"[124].

129. Conflicting evidence has been given about the attitude of NNU staff towards reporting incidents on Datix. Anne-Marie Lawrence's evidence was that the NNU staff did not approach the Datix reporting in an open and transparent way, and that, "…*they would only report an incident if they felt it was avoidable or there had been an obvious omission in care*" [INQ0102759_0005, §26]. She said this applied to every person working on the NNU (from May 2016, when she started working with the NNU). She felt some staff purposefully held back on reporting incidents until this had been discussed with others, and that included the whole consultant body [Lawrence/ wk7/ day2/ p185/ ln14 – p199/ ln13]. She thought the neonatal team considered incident reporting to be punitive[125].

130. By contrast, Dr Brearey said:

> "*…I was the neonatal Risk Lead so it was my job to encourage a healthy, risk aware [NNU] and I was trying my very best at that and I think I was relatively successful"*[126].

131. In practice, not a single Datix was completed in respect of babies who deteriorated/collapsed but did not die. Child I's collapses which proceeded her death did not result in a Datix.[127] So, while different staff purported to have different understandings of the Incident Reporting Policy, the outcome was strikingly consistent – these events were not recorded and their significance was lost. They did not get considered at the Neonatal Review Group (which was or should have been provided with a list of the NNU Datixes)[128].

132. Notwithstanding this, the CQC was positive about the incident reporting in children's services, finding that "*incidents were reported appropriately"* [INQ0017433_0108]. It is not clear how it came to reach this conclusion. Such a sweeping finding is undermined by the evidence adduced by this Inquiry and raises serious questions as to the depth and probative value of the CQC's inspection insofar as it related to the NNU. Again, we point towards the disparity between the existence of systems and processes and the quality and consistency of those systems and processes in practice.

133. The failure to use Datix consistently was another missed opportunity to recognise earlier the number, nature and frequency of babies' deteriorations in the NNU and then to interrogate whether Letby was a common factor. This was consequential: proper reporting would have added to the concerns about Letby and should have formed part of the safeguarding investigations that then took place.

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[124] [Brearey/ wk10/ day2/ p243/ ln10-17].

[125] [Lawrence/ wk7/ day2/ p221/ ln1-13]

[126] [Brearey/ wk10/ day2/ p21/ ln25 – p22/ ln3]

[127] See table produced by ILT, which brings this information together at [INQ0108517]. Some Datixes were generated but these did not relate to a deterioration/ collapse.

[128] The COCH's oral opening submissions included: "…*we accept that the available evidence suggests that non-fatal collapses were not or not consistently reported on Datix"* [COCH Opening Submissions/ wk1/ day3/ p70/ ln19-21].

Systemic failures to report incidents

134. We address two systemic issues: lack of clarity on what incidents should be reported – leading to the inconsistent application of the policy, particularly the non-use of Datix (set out above); and inadequate risk management and support provided to the NNU. We do not know the extent to which these problems would have been seen in other hospitals at the time (or now).

135. **First**, lack of clarity and inconsistent application of policy: the COCH's 'Policy for Reporting of Incidents' ('Incident Reporting Policy') stated that the following should be reported [INQ0010022][129]:

e. Incident: "*an event or circumstance which could have resulted, or did result, in unnecessary damage, loss or harm to patients, staff, visitors, members of the public*" and gave a number of examples.

f. Near Miss: "*a near miss incident, event or omission that fails to develop further, whether or not compensating action was taken, and does not cause injury, harm or ill-health. Such incidents may still have the potential to result in serious consequences e.g. prosecution*".

g. Never events.

136. During the hearings, questions were asked about what amounted to an "*incident*", particularly the role of the word "*unnecessary*", whether preventability was a precondition to an event being an incident, and whether any harm needed to be caused by the NHS[130]. Different witnesses interpreted the policy differently. Debbie Peacock observed that there as a degree of ambiguity about what needed to be reported[131]. That is obviously undesirable. On the facts of this Inquiry, a consequence was that it was not sufficiently clear that the unexpected and unexplained deterioration of an individual baby who did not due should have been reported on Datix.

137. Given the ambiguous terms of the Incident Reporting Policy, it is perhaps unsurprising that staff in the COCH did not apply it in a consistent way. For example:

a. Eirian Powell's evidence was that all collapses leading to resuscitation were or should have been recorded on Datix[132].

b. Debbie Peacock disagreed with Eirian Powell, saying that a collapse requiring resuscitation did not need to be recorded on Datix unless "*there was something untoward happened during the resuscitation*"[133].

c. Dr Gibbs said he would not complete a Datix for the sudden and unexpected collapse of a baby who then recovered. He said this was, "*because you had to identify what was the*

[129] The date this document was created is not clear.

[130] See, for example: [Peacock/ wk7/ day2/ p92/ ln20 – p97/ ln22] and [Lawrence/ wk7/ day2/ p201/ ln5 – p208/ ln12].

[131] Debbie Peacock was the Risk and Patient Safety Lead working with the NNU from December 2013 – February 2016 [Peacock/ wk7/ day2/ p98/ ln24 – p99/ ln4].

[132] [Powell/ wk6/ day4/ p183/ ln2-19].

[133] [Peacock/ wk7/ day2/ p95/ ln8-13]

problem, a medication error, a lack of equipment, a staffing problem that led to that episode". It was his understanding that a Datix form presupposed being able to identify something that had gone wrong[134].

d. Dr Brearey's evidence was that he thought the staff were all aware of the requirement to report a Datix incident, "*no matter how significant, whether they felt any problem with the care of the baby might have been compromised*"[135].

e. A 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].

f. 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].

138. The Incident Reporting Policy needed to be unambiguous in its wording to prevent inconsistency of understanding and application. But in any event the existing policy, even though ambiguous, should have been interpreted in an inclusionary and cautious way. All events involving unexpected or unexplained patient outcomes should have been treated as incidents under the policy and reported. One of the reasons for reporting incidents was to learn lessons. In circumstances (as frequently arose at the COCH) where the reason for a baby's deterioration was not known, then it would not have been possible to know whether an "*incident*" had occurred or whether there were lessons to be learnt.

139. **Second**, inadequate risk management support provided to the NNU: we make only brief submissions on this issue. The Chair has heard evidence about the heavy workload on the consultants, made heavier by Letby's criminal actions. Sufficient, trusted and good quality support from the Risk and Patient Safety team was needed. At periods in 2015/16 this was lacking. These submissions do not seek to adjudicate on the working relationship between Dr Brearey and Anne-Marie Lawrence. Instead, they simply draw attention to the gaps in support after Debbie Peacock left in February 2016, including the fact her replacement, Janet McMahon, was performing two roles. This should not have been sanctioned by Ruth Millward or the COCH Executives at a time when the NNU mortality had increased and the Thematic Review had been sent to the Executives.

140. The Chair will recall Dr Brearey's email, dated 15 July 2016, about Ms Lawrence's competence and support [INQ0006769]. Ms Lawrence's comments on this included that the Risk and Patient Safety team at the COCH was one of the most "*under resourced Risk and Patients Safety teams"* she had known. She said, even-handedly, "*…it would be fair to say [Dr Brearey's] got a point because there were some absolute gaps in the service"*[136].

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[134] [Gibbs/ wk4/ day2/ p21/ ln15 – p22/ ln5]

[135] [Brearey/ wk10/ day2/ p21/ ln20 – p22/ ln6]

[136] [Lawrence/ wk7/ day2/ p252/ ln12-22]

141. Dr McGuigan also commented that when he started at the COCH in January 2017, the governance support was:

> "…*minimal and insufficient. Investigating incidents thoroughly and effectively requires time and resources. Consultants are busy, with lots of their time taken up by clinical work. My understanding is that consultants at the time were trying to find the time to process and analyse what might be behind the increase in neonatal collapses….More effective governance structures at the time, including a neonatal risk lead with job-planned time for managing risk and increased support from governance nurses and midwives could have led to a better and quicker understanding of what was happening*" [INQ0101097_0012, §64][137].

142. We acknowledge that it is difficult to be precise about the difference that more or better support from the Risk and Patient Safety would have made, but in the Families' submission this is one of a constellation of factors and shortcomings that probably contributed to Letby being able to continue murdering and harming babies for over a year, and then to the delay in contacting police.

Failure to be open, transparent and candid

The duty

143. The Health and Social Care Act 2008 (Regulated Activities) Regulations 2014 came into force over a decade after the Bristol Royal Infirmary Inquiry report in July 2001 and a year following the Mid-Staffordshire Inquiry report in February 2013. Regulation 20 sets out the 'Duty of Candour' and requires NHS Trusts in England to act in an open and transparent way in relation to the care and treatment of patients.

144. A 'notifiable incident' is defined in Regulation 20(8) as any unintended or unexpected incident that occurred which in the reasonable opinion of the health care professional, could result in, or appears to have resulted in (a) the death of the service user, where the death relates directly to the incident rather than to the natural course of the services user's illness or underlying condition, or (b) severe harm, moderate harm or prolonged psychological harm to the service user.

145. Alongside the statutory duty, a professional duty also exists covering individual doctors, nurses and midwives (see, for example the GMC's *Good Medical Practice* at [INQ0007314_0013] which requires a doctor to take prompt action if they think that patient safety or dignity is or may be seriously compromised on account of concerns regarding a colleague who may not be fit to practise and may be putting patients at risk. In such circumstances advice must be sought from a colleague, defence body or GMC). These duties have the same underlying purpose: to put patients and parents first and to be open and transparent where something is believed to have gone wrong and there is information in the possession of healthcare professionals that patients and their families should be told.

[137] See also Dr McGuigan's oral evidence [McGuigan/ wk5/ day2/ p98/ ln22 – p99/ ln20].

146. COCH's Speak Out Safely policy 2013 [INQ0014170_0003] provided that where the concern raised by a member of staff involved a patient safety incident, the 'Being Open' guidelines applied. Within these guidelines, COCH made the following commitments to its patients (insofar as is relevant to the Inquiry):

    a. To explain, openly and honestly, what has gone wrong;

    b. To describe what is being done in response to the mistake; and

    c. To give updates on the results of any investigation.

147. What makes COCH's repeated failures to undertake its obligations under the duty of candour even more extraordinary is that it had produced a leaflet called 'Duty of Candour Responsibilities – Information for all staff' [INQ0014137], which specifically provided instructions in relation to what staff should do to comply with their duty of candour. It required staff to tell someone if they had been involved in or observed a situation where a patient *may* have been or had the potential to be harmed. Staff were required to report the actual or potential incident on Datix so that others are informed as to the level and type of investigation that is necessary to ascertain what/how/why something had happened and to learn so that it does not happen again.

148. The leaflet also contained a table of examples of incidents ranging from moderate harm e.g. fractures, to severe e.g. amputation and death. For COCH to comply with their duty of candour obligations, they were required to inform patient/their families within 10 working days of a review which is to be undertaken into the incident and the outcome of final investigations are to be shared within 10 days of it having been approved under Governance arrangements.

149. Sir Robert Francis KC stated that openness, transparency and candour were in reality different aspects of the same thing. His definition of 'openness' was the proactive provision of information about performance, negative as well as positive both internally and externally[138]. Sir Robert defined 'transparency' as "*the provision of facilities for all interested persons and organisations to see the information they need properly to meet their own legitimate needs in assessing the performance of a provider in the provision of services*."[139] He went on to state that one of the underlying features of openness and transparency is that the information provided had to be true and accurate[140].

Failure towards the parents

150. The evidence adduced by the Inquiry indicates that between June 2015 and June 2016, an increasing number of babies in the NNU at COCH began to collapse and die suddenly and unexpectedly. Many of them failed to respond normally to resuscitation efforts. This led to concerns on the part of the paediatric consultants that there were unidentified common causes between some

[138] [Francis KC/ wk4/ day1/ p50/ ln15-21]

[139] [Francis KC/ wk4/ day1/ p51/ ln6-12]

[140] [Francis KC/ wk4/ day1/ p51/ ln13 - p52/ ln4]

or all of the deaths and, following internal attempts to identify those causes, to their belief that there was a real possibility that a member of the nursing staff had deliberately killed the babies.

151. All of these facts were deliberately kept from the parents of the babies who died or collapsed, even as it gathered momentum and precipitated a breakdown between the consultants and the hospital's management and Executive. It was also kept from the parents of babies who were not harmed but were on the NNU when other babies were killed; and from the parents of babies who were admitted to the unit over the same period, unaware of what had happened to other patients.

152. Ms Millward, who as Head of Risk and Patient Safety has responsibility for overseeing matters relating to the statutory duty of candour, told the Inquiry in her oral evidence that when it came to parents of Baby O and P, she believed that the duty of candour should have been handled by 'someone more senior'[141]. However, she was unable to explain why the box relating to the duty of candour on each of the Datix forms pertaining to the indictment babies were blank[142]. These should have contained clear information about what the families were told, when, by whom and more importantly, what they were told about the steps being taken by COCH to investigate concerns being voiced about how the babies might have died.

153. It is wholly contrary to Regulation 20 and the principles underpinning it that COCH withheld such significant information from parents. They had the right to be notified that their children were or might have been harmed, so that they could understand the truth of what happened and could seek accountability for any criminal or negligent conduct that occurred. Parents also had the right to be notified of any information that bore upon the safety of the unit to which they were entrusting their children, so that they could make informed choices about whether to opt for treatment at a different, safer, hospital. They should have been given this information, in person and in writing, by the consultants who had (or were due to take) primary responsibility for their babies' care.

154. Similarly, the parents of babies on the unit had the right to know that in 2016 COCH intended to commission the RCPCH to review the NNU and subsequently external doctors (Dr Hawdon, Dr McPartland) to review the records relating to some of individual deaths. This information should have been given to them, in person and in writing, by their treating consultants or by COCH's most senior doctor or manager, Mr Harvey or Mr Chambers. Again, it is an egregious breach of the duty of candour that it was not provided to grieving parents who either did not know, or were under misapprehensions as to, why their babies had died. Non-disclosure and delayed disclosure of significant information about internal and external investigations only added to their already immense distress.

155. A carefully managed process should have been planned and implemented from the start, whereby all parents were given significant relevant information – about their children and about the NNU generally – as soon as reasonably practicable and at each investigatory milestone. Dr Holt made direct reference to the statutory duty of candour wrote in an email she wrote on 5 July 2016,

[141] [Millward/ wk8/ day1/ p188/l n18 - p189/ ln2]

[142] [Millward/ wk8/ day1/ p214/ ln1-12]

stating that the families of the babies who have died "*…deserve appropriate information…I don't think that we should send the without some explanation as to why these changes [downgrading of the NNU] are being made*". She then reiterated the importance of candour by referring to the CQC's guidance on candour "*Providers must promote a culture that encourages candour, openness and honestly at all levels. This should be an integral part of a culture of safety that supports organisational and personal learning. There should also be a commitment to being open and transparent at board level, or its equivalent such as a governing body.*" [INQ0002693_003-4]. It should therefore have been clear to all at senior management and Executive level that the need to be open and transparent with families was paramount. Dr Holt described the failure to ensure this happened as "*cruel*"[143].

156. As well as the need to provide the parents with essential information about what happened to their baby/babies on the NNU, this information should have also been provided to them in a form that they could understand. So, for example, parents should not have been given Dr Hawdon's report, which was written in a compressed format and full of medical terminology, without a clear covering explanation of its findings and their significance. Dr Hawdon herself accepted in her witness statement to that "*…It is my personal opinion that the case review reports alone would have been difficult for families to understand and could have added to confusion and grief.*" [INQ0099063_0022 §109]. It took until after the *Sunday Times* published its article about the increase in neonatal deaths on 3 February 2017 [INQ0003099/INQ0003100] for COCH to undertake serious attempts to contact the families and inform them about what had been going on over the previous 1½ years.

157. Mr Harvey admitted in his written statement that "*In short, I think we got this [communication with families] wrong. Families were let down and the communication we had with them should have been better…Families did not receive the support they should have.*" [INQ0107653 §839]. However, he was unable to explain why the duty of candour had not been complied with[144], even though it was specifically mentioned in an email dated 4 March 2016 in relation to the Thematic Review [INQ0008927]. He was also unable to provide a satisfactory explanation for why he misled Dr Hawdon in relation to having obtained prior permission from families in relation to the provision of medical records to her.

158. On 8 September 2016 Dr Hawdon asked Mr Harvey whether COCH were "*seeking parental consent to release records?*" Mr Harvey replied "*Re parental consent, we had informed parent ahead of the review that it was occurring*". In her oral evidence to the Inquiry, Dr Hawdon was asked why it was important that parents' consent had been obtained by Mr Harvey before she reviewed the medical records of the babies. She responded "*it's vital that no -- no parent should know that the care of their baby is being reviewed by an external person without them being informed*"[145]. In a follow up question when Dr Hawdon was asked to clarify her answer, she said "*The baby is their*

[143] [Holt/ wk44/ day 4/ p149/ ln 4-5]

[144] [Harvey/ wk11/ day5/ p122/ ln1-8]

[145] [Hawdon/ wk9/ day2/ p44/ ln11-13]

baby and all matters related to their baby are important to them."[146]. The exchange between CTI and Mr Harvey on this issue warrants close consideration[147]. It is readily apparent that he lied to Dr Hawdon about having parental consent before sending her the medical records of the babies she was being asked to review.

159. In **Section (2)** below, we address specific failures by consultants and the Executives at the COCH to be open, candid and honest with Parents A and B in the context of coronial proceedings arising from Child A's death.

Failure towards external persons and organisations

The Coroner

160. There was a catastrophic failure to be open and honest with the Coroner, a judicial officer with important responsibilities for investigating unexpected deaths. Child A's inquest was conducted and concluded on partial and misleading information. If the Coroner had been aware of the consultants' suspicions, he would have contacted the police immediately. This failure was not remedied when COCH Executives met with the Coroner(s) in February 2017. We make further submissions in Section (3) below on the information provided to the Coroner in the context of Child A's inquest.

The CQC

161. There was also a failure to be open and transparent with the CQC, who inspected COCH between 16-19 February 2016. Mr Harvey at the very least (though also Ms Kelly) were aware that there had been an increase in neonatal mortality on the NNU between June 2015 and February 2016 and that these deaths were sudden and unexpected with a nurse being present at the majority of these collapses. The CQC was not told of this fact.

162. There was no cogent explanation provided by any of the executives or senior management as to why this was the case. This was most vividly demonstrated in the oral evidence given by Mr Chambers. He was taken by CTI to a meeting that had taken place with the CQC on 17 February 2017 [INQ001445], it was put to him that there was key information that the executives who attended possessed, which the CQC should have been informed about e.g. the fact that Dr Hawdon believed that four of the deaths that she had investigated remained unexplained and unexpected as well as the consultant paediatricians continuing to harbour concerns about Letby. Mr Chambers' justification for not providing the CQC with all the relevant details was that a balance had to be struck "*between the duty of candour to whoever whether that's the family or to or external partners, regulators and so on, and the duty of care to an individual and that's a very difficult balance to tread*…"[148]. This again demonstrates the failure of management at COCH to make the correct qualitative distinction between patient safety and safeguarding concerns, which should have been

[146] [Hawdon/ wk9/ day2/ p44/ ln15-16]

[147] [Harvey/ wk11/ day5/ p23-25/ ln3-25]

[148] [Chambers/ wk11/ day3/ p123/ ln5-8]

their paramount concern, and their obligations towards an individual member of staff, which are primarily human resource related and could not outweigh the former.

NHS England

163. COCH and its executives also lacked openness and transparency in their dealings with NHS England. The oral evidence given to the Inquiry by Mr Chambers best demonstrates the point. Mr Chambers had said in his evidence that he believed COCH had been open and transparent with the Coroner and the regulators[149], but he knew full well that such a sweeping statement was disingenuous/false, for a number of reasons.

164. **First**, it is contradicted by the evidence provided to the Inquiry by NHS England in its opening submissions [INQ0107952_005-006, §§25-28] and thereafter through Sir Stephen Powis, who told the Inquiry in his first witness statement that:

> "*…it seems that neither NHS England nor the Legacy Bodies were aware of any specific concerns about the safety of neonatal services at the Hospital until the last day of the First Relevant Period, 30 June 2016. This was the day when the Countess of Chester Hospital reported two Serious Incidents relating to neonatal deaths via the Strategic Executive Information System. It was also the day that LL worked her last shift on the neonatal unit. However, NHS England was not aware of this at the time and was not informed that there were any concerns about a particular individual or the identity of this individual (LL) until much later, in March 2017.*" [INQ017495_0112 §§447-448].

165. **Second**, given the significance of the concerns raised by the consultants and the obvious patient safety/safeguarding concerns, the justification by Mr Chambers as to why NHS England were not informed earlier lacks credibility or cogency. He told the Inquiry in his oral evidence that "*…what we thought we were doing was trying to explain the causes of increased unexplained mortality…*" before informing NHS England. When put to him that there was a clear expectation on the part of a regulatory body that they would be informed about serious concerns relating to patient safety/safeguarding, especially concerning deliberate harm, he vaguely responded that NHS England were informed of concerns regarding increased neonatal deaths in 2017[150]. He ignored the fact that this was only after Letby had been removed from the NNU and that it was not until March 2017 that NHS England were notified of the consultants' concerns that she was connected to the deaths. Even when directly asked by CTI: "*[d]o you accept that NHS England should have been told about the concerns that a single nurse was responsible for the increase in deaths when those concerns arose?*", Mr Chambers said rather surprisingly said "*the answer is I don't know, it's just that balance between candour and duty of candour and duty of care. I -- whether we got that balance wrong, I'm not sure at that time whether we had got the balance right*."[151].

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[149] [Chambers/ wk11/ day3/ p208-211/ ln22-25]

[150] [Chambers/ wk11/ day3/ p210/ ln19-21]

[151] [Chambers/ wk11/ day3/ p211/ ln3-11]

The NMC

166. The COCH also failed to inform the NMC of the consultants' concerns that Letby had been harming children even after Letby was finally removed from the NNU at the consultants' insistence in June 2016. As the Director of Nursing, Alison Kelly should have taken this step as soon as she was aware of such grave concerns and the safeguarding risk that Letby presented to other patients, both at COCH and elsewhere (should she have moved to another hospital). She was unable to defend her consistent failure to do so[152]:

> *Q: I mean, do you agree in terms of an overview here because we are seeing this emerging time and time again that consistently what other external bodies are being told is everything but the Consultants' concerns, do you think that's a fair characterisation of the period up until the end of May -- end of April 2017?*
>
> *A: I think we were really clear in the communication plan in July 16 that we told all of our regulators about an increase in mortality.*
>
> [Question repeated]
>
> *A: I think looking back then we should have perhaps mentioned that as well at the time. However, we were really keen to fully understand what was going on. But perhaps those Consultant concerns should have been mentioned in the beginning.*

Concluding comments on COCH's failure to comply with duty of candour

167. The COCH Executives offered no clear or credible explanations for such major failings to comply with the hospital's duty of candour – to parents and to external persons organisations. This leads inexorably to the conclusion that the consistent withholding information was not simply an oversight, but a deliberate and concerted attempt to avoid adverse repercussions for the Trust, including demands for more information and answers, the involvement of Coroner and the police, public concern, and unwelcome interventions from the CQC, NHS England and the NMC.

Failure of basic governance

168. Counsel to the Inquiry provided a detailed outline of the governance structure at COCH in Chapter 3 of their opening statement[153]. Below we summarise some of the ways in which governance structures failed in response to Letby's actions. This is again indicative of a failure of senior leadership at Executive and Board level – whose responsibility it was to ensure that governance structures were in place and are operating effectively. Dr Susan Gilby summarised the position in her statement:

> "*More concerning, however, was the Director of Corporate and Legal Affairs' seeming absence of knowledge regarding good governance in NHS bodies, and the fact that he appeared oblivious to the significant gaps in the Trusts governance structures systems and processes –*

[152] [Kelly/ wk11/ day1/ p95/ ln14 – p96/ ln21]

[153] Counsel to the Inquiry Opening Statement/ wk1/ day2/ p1/ ln12 – p47/ ln8

including the fact that there was no governance framework, nor a governance handbook. Both I regarded as fundamental…I repeatedly asked to see the governance framework documents and governance handbook. It was some weeks before Claire Raggett (at the time the[sic] Stephen Cross's associate/assistant) told me, tearfully, that she had been instructed not to reveal to me that they didn't exist...I came to the realisation that fundamentals of governance were absent in the organisation…"[154].

Women and Children's Care Governance Board

169. Between 18 June 2015 and 20 April 2017, there were thirteen Women and Children's Care Governance Board (WCCGB) meetings[155]. Neonatal mortality was discussed on ten occasions (as highlighted in the footnote below). Most of these discussions about neonatal deaths focused on the individual deaths of the babies presented at the meeting. There was no general oversight or connection made with earlier deaths that had been presented. For example, at the meeting on 22 October 2015 it was noted that there had been three '*unexpected*' deaths on the NNU. However, this important theme/cluster of deaths was ignored or at best diluted by discussion of other neonatal incidents, most of which were explained clinically.

170. There is no explanation as to why the cluster of three deaths on the NNU in a short space of time did not give rise to further discussion/consideration as to the circumstances and details to ascertain whether there were any patient safety/safeguarding issues. This was especially important as by this time, Dr Brearey and the other consultants were clearly concerned about the sudden and unexpected collapses as well as the association with Letby.

171. Eight months after the above meeting, the WCCGB met on 16 June 2016 and discussed the Thematic Review dated 8 February 2016, which had considered neonatal mortality on the NNU between 2015 and January 2016. The notes of the meeting state that an '*obstetric*' (as opposed to a neonatal) thematic review had not identified "*any common themes or identifiers that might be responsible for the rise in mortality in 2015…There was no common theme identified in all the cases.*" [INQ0003212_0005]. This was clearly wrong, and it is not clear why the meeting was unaware of the Thematic Review of February 2016 and instead had relied on the obstetric review, which in the main considered still-births and was irrelevant for the purposes of understanding the increased mortality in the NNU.

172. At no time during any of the WCCGB's meetings was the association between the sudden and unexpected deaths that had occurred on the NNU and Letby discussed or considered, even though this concern was in the minds of the paediatric consultants and nursing managers throughout 2016. No explanation for this was provided by any of the witnesses who attended these meetings.

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[154] [INQ0101076_0012 §§67-69].

[155] 18 June 2015 [INQ0004235], 30 July 2015 [IN00004240], 22 October 2015 [INQ0003223], 19 November 2015 [INQ0004271], 18 December 2015 [INQ0003224], 14 January 2016 [INQ0004293], 21 April 2016 [NQ0004303], 16 June 2016 [NQ0003212], 19 June 2016 [NQ0003214], 21 July 2016 [INQ0003213], 26 January 2017 [INQ0004388], 23 February 2017 [INQ0004398] and 20 April 2017 [INQ0004416].

Safeguarding Strategy Board

173. There was also a fundamental failure of internal governance and external regulatory oversight. The COCH had a Safeguarding Strategy Board, chaired by Alison Kelly. Ruth Millward, Dr Mittal and Dr Isaac also attended/sat on this Board. This was tasked with expansive duties, including ensuring systems, processes and reporting mechanisms were in place to detect, prevent and respond to concerns about abuse or neglect; and ensuring the COCH reported safeguarding concerns to external agencies [terms of reference at INQ0102620_0017-18].

174. It is plain from the evidence however that the Safeguarding Strategy Board utterly failed to achieve what it was supposed to achieve. It performed no role at all in identifying, discussing or responding to concerns about Letby. Tellingly, the increase in neonatal mortality (and police investigation) was not even mentioned in the papers for this Board until November 2017 [see Safeguarding Children Annual Report 2016/17, dated July 2017 in papers for November 2017 board meeting at INQ00063741_0161, §11.5]. These failings wholly undermine the CQC's findings in February 2016 that the COCH had safeguarding policies and procedures in place and staff, were aware of their roles and responsibilities, and knew how to raise matters of concern appropriately.[156] The mismatch between the internal reality and the external assessments clearly demonstrates the inadequacy of the way in which governance is scrutinised by the CQC.

175. The SSB reported directly to QSPEC, and its function was to ensure that safeguarding was a strategic objective within COCH and provide strong leadership and divisional accountability by making safeguarding integral to care. It was also responsible for ensuring that COCH reported safeguarding concerns to external agencies[157].

176. Between 23 July 2015 and January 2018, there were seven SSB meetings[158]. Neonatal mortality was discussed on only two occasions during this entire time (as highlighted in the footnote below) and, even then, it was limited to Alison Kelly providing an update on preparations for the CQC inspection which was due to take place in February 2016 and the internal processes for reporting baby deaths in May 2017. The *increase* in neonatal mortality was not mentioned in the papers for this Board until November 2017 some 6 months after the police were contacted. The consultants' concerns were not considered further at these meetings or indeed the link association with Letby and her suspected deliberate harm of babies on the NNU.

Quality, Safety and Patient Experience Committee

177. Between 20 July 2015 and 18 April 2017 there were eighteen QSPEC meetings[159]. Neonatal mortality was discussed on six occasions (as highlighted in the footnote below). Once again, at no

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[156] CQC inspection in February 2016, publication of report on 29 June 2016 [INQ0017433_0110].

[157] [INQ0102620_0017-18].

[158] 23 July 2015 [INQ0104180], 25 September 2015 [INQ0104181], 27 November 2015 [INQ0038309], 15 April 2016 [INQ0043309], 11 May 2017 [INQ0069016], 30 November 2017 [INQ0063741] and 29 January 2018 [INQ0076762]

[159] 20 July 2015 [INQ0003211], 21 September 2015 [NQ0004243], 19 October 2015 [N00003210], 16 November 2015 [INQ0004268], 14 December 2015 [INQ0003204] (although it was purported that the report presented related to neonatal mortality, this was in fact incorrect and only covered still births), 18 January 2016 [N00004296], 15

time during any of these meetings was there discussion of the consultants' concerns about the increase in sudden and unexcepted deaths on the NNU and their suspicion that Letby had deliberately harmed babies. This was an incredible omission by senior managers and the Executives who attended these meetings – such as Ian Harvey, Alison Kelly, Tony Chambers, Karen Rees, Sue Hodkinson and Ruth Millward – who provided briefings to other senior personnel at COCH, such as the Chairman of the Board, Sir Duncan Nichol.

The Trust Board

178. Between 26 June 2015 and 2 May 2017, there were thirteen Board of Directors meetings[160]. Neonatal mortality was discussed on eight occasions (as highlighted in the footnote below). Although the initial cluster of neonatal deaths on the NNU was noted at the meeting on 26 June 2015, there was then no further discussion or consideration of these and subsequent deaths until 7 July 2016. This was despite the fact that the number of deaths continued to increase, the consultants' developed persistent concerns that Letby was responsible, the Thematic Review reported in February and March 2016, and Letby was moved in April 2016 to working on day shifts for closer supervision.

179. These were all essential and important facts that required consideration, discussion, and monitoring at the most senior level. Sir Duncan Nichol told the Inquiry in oral evidence that the Board should have been alerted from an early stage after the consultants had raised concerns about the increase in neonatal deaths and that a cluster of deaths should have been referred to QSPEC[161]. However, he and the non-executive directors did not initiate appropriate action even when they were told of those concerns and suspicions in late June and early/mid July 2016. From that point onwards, they should have taken grip of the issue and of the Executives' response:

    a. They should have insisted on being briefed comprehensively on what had occurred and the basis for suspecting Letby[162].
    b. They should have asked to hear from the consultants directly.
    c. They should have asked for copies of the internal and external investigations that had taken place.

February 2016 [NQ0003205], 21 March 2016 [INQ0004300], 16 May 2016 [IN00004304], 20 June 2016 [INQ0004309], 15 August 2016 [INQ0003176], 19 September 2016 [INQ0003178], 17 October 2016 [INQ0004347], 21 November 2016 [INQ0004363], 16 January 2017 [INQ0004381], 20 February 2017 [INQ0003179], 20 March 2017 [INQ0003180] and 18 April 2017 [INQ0003177].

[160] 29 June 2015 [INQ0003203 and INQ003381], 7 July 2015 [INQ0014812], 1 September 2015 [INQ0014813], 2 February 2016 [INQ0015531], 3 May 2016 [INQ0014816], 5 July 2016 [INQ0014817], 13 July 2016 [INQ0003365], 14 July 2016 [INQ0004216], 6 December 2016 [INQ0107708_0114 § 401], 10 January 2017 [INQ0003514], 7 February 2017 [INQ0014821], 16 March 2017 [INQ0003344] and 2 May 2017 [INQ0004221].

[161] [Nichol/ wk12/ day1/ p38/ ln13-17].

[162] James Wilkie said that if, on 14 July 2016, he had known everything he knows now, he would have insisted Letby was removed from the NNU and insisted on going to the police [Wilkie/ wk12/ day1/ p200/ ln9-18].

d. They should have questioned whether the Trust's safeguarding, whistleblowing, and duty of candour[163] policies had been followed; and insisted that any non-compliance be remedied immediately.

e. Most importantly, they should have challenged the Executives' decision not to call the police and have insisted that they be notified.

180. Sir Duncan Nichol accepted in his oral evidence to the Inquiry that the biggest failure on his part was not inviting the consultants to attend the extraordinary Board meeting on 10 January 2017. This should in fact have occurred six months earlier. But had it occurred in January, the consultants would have been able to explain their concerns and suspicions about Letby, and their views on the inadequacy of the RCPCH report in relation to answering their concerns.[164] This was vitally important as he (and no doubt other Board members) had not appreciated that the RCPCH report had not considered let alone excluded the association with or involvement of Letby in the sudden and unexpected collapsed of the babies on the NNU[165]. He also felt that he was misled by Mr Harvey into believing that Dr Hawdon had completed the work she was asked to carry out, whereas in fact she had indicated that she was unable to do so and therefore unanswered questions remained as regards the causes of the deaths of multiple babies[166].

Leadership and culture

Good leadership and culture

181. Professor Dixon-Woods told the Inquiry that:

"*a uniting feature across the many (over 100) investigation and inquiry reports into major NHS failings over several decades is the significance of culture, sometimes as directly implicated in egregious conduct (e.g. abuse, reckless or criminal or otherwise transgressive behaviours) and sometimes as enabling poor quality and safety, misconduct, and unacceptable behaviour to go undetected, tolerated, or unaddressed for too long.*" [INQ0102624_0012 §3.1].

182. However, she went on to say there is no standard definition of '*culture*' and there is no single consensually agreed way of measuring or assessing it. In part, this is because the notion of culture encompasses behaviours, attitudes, practices and basic assumptions that people share about their work and the values that guide them.

183. Though '*culture*' is difficult to define, the concept of a healthy culture is often described as a setting whereby there is openness, collaboration, mutual respect and support and a consistent drive to maintain high standards of efficiency and effectiveness. When all within an organisation are striving to achieve the same goal(s) and can find a sense of purpose, belonging and direction from senior managers, it is said that there is healthy culture at play.

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[163] Sir Duncan Nichol said that after the Board became aware of the concerns about increased mortality and specific suspicions about Letby: "*The Families were not in the big picture. We didn't exercise appropriate duty of candour towards the Families and that was …a failure. A serious failure*" [Nichol/ wk12/ day1/ p136/ ln17 – p138/ ln8].

[164] [Nichol/ wk12/ day1/ p75/ ln5-19].

[165] [Nichol/ wk12/ day1/ p76/ ln20 - p77/ ln6].

[166] [Nichol/ wk12/ day1/ p79/ ln18-22].

184. Conversely, bad culture is often only identified when something significant has gone wrong. Those who drive a bad culture, such as one where factions exist and work against each other, can be good at hiding the real impact of their shortcomings until a serious incident arises. Promoting and encouraging a healthy culture within the healthcare sector is therefore about more than producing detailed and complex policies and requires routine robust monitoring measured against specific criteria to ensure that a healthy culture is fostered and maintained.

185. At §9.2 of her written evidence to the Inquiry, Professor Dixon-Woods summarised the qualities of an effective senior manager in the healthcare sector[167]:

a. Clear about the values that drive them, and demonstrate value congruence — what they say is aligned with what they do;
b. Articulates and reinforces the expected behaviours and standards of conduct on a daily basis through role modelling and through leading by example;
c. Works effectively as part of a senior team, with clear goals that are shared with others and aligned with the mission and vision of the organisation;
d. Effective in shaping an environment where colleagues feel valued, supported, and satisfied in their work;
e. Consistently demonstrates a commitment to equality, diversity and inclusion;
f. Demonstrates leadership inclusiveness, defined as "words and deeds exhibited by leaders that invite and appreciate others' contributions";
g. Demonstrates and values good management practices, including in relation to people, operations and planning;
h. Manages conflict effectively, using skill in having difficult conversations;
i. Demonstrates "problem-sensing" rather than "comfort-seeking" behaviours;
j. Exercises good judgement in selecting priorities for attention and action;
k. Accepts and offers challenge constructively;
l. While demonstrating civility and respect, capable of being firm and persistent when faced with problematic conduct and transgressive behaviour;
m. Commits to optimising structures, including staffing, skill mix, environment and equipment, in so far as resources allow. Where it is not possible to address them, the reasons are made clear to staff and patients, as are the mitigations put in place.

186. Sir Robert Francis KC identified similar leadership qualities in his written evidence[168]:

a. Probity;
b. Courage;
c. Openness and candour;
d. Listening and learning from patients and colleagues;
e. Inspiration and motivation of colleagues;

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[167] [INQ0102624_0095].

[168] Sir Robert went on to state that "*Needless to say, all these attributed, even if present in an individual, require energy, commitment, compassion and empathy. Success also requires the ability to empower the staff individually and collectively to implement a shared vision and strategy*" [INQ0101079_0078-79, §9.15-9.16].

f. Ability to be viewed as a role model;
g. Ability to create and communicate vision and strategy;
h. Understanding of how to prioritise and protect patient safety and provision of fundamental standards within available resources;
i. Willing to challenge; and
j. Ability to judge and analyse complex issues.

Leadership and culture at COCH

187. The preceding paragraphs of this statement have catalogued what went wrong at the COCH between June 2015 and May 2017. It is a catalogue of multiple failings by many people, individually and collectively, over a long period of time. We do not seek to summarise them all here, but they include a woeful disregard for patient safety, safeguarding requirements, whistleblowing procedures, and the duty of candour. This demonstrates a woeful lack of rigour in the way that governance was implemented by the Executives and overseen by the Trust Board.

188. Primary responsibility for those failings ultimately vests with the Chief Executive, Tony Chambers, and his Executive Team. As the leaders of the organisation, when faced with concerns and suspicions about serious criminal conduct by a member of their healthcare staff, they should have approached the situation with independence and objectivity, exercised clear-headed judgment, and followed their own policies, which were designed to assist, not hinder, an effective response to a difficult situation. Instead, the opposite occurred, and the invaluable qualities identified by Sir Robert Francis and Professor Mary Dixon-Woods were absent – with the result that Letby continued to harm and kill babies until June 2016 and her crimes then went uninvestigated by the police for a further 11 months.

PART (B)

189. The table below sets out the **key failings and inflection points** in the chronology of events, at which we say there were opportunities to act differently and opportunities for intervention that would have prevented Letby from harming and murdering more babies.

June 2015	**SUDIC processes should have been commenced in relation to Child A, Child C and Child D**. This would have led to local authority and police involvement. The Coroner and NHS England[169] would also have been informed of all three deaths. By 22 June 2015, Dr Brearey and Eirian Powell had already identified that Letby was present for all three deaths[170].

[169] Professor Sir Stephen said that if a cluster of deaths had been reported as an SI in June 2015, then he was confident it would have triggered the "*same level of inquiry and curiosity from Commissioners that occurred a year later*" [Powis/ wk15/ day4/ p109/ ln4-8].

[170] Dr Brearey set this out in an email on 22 June 2015, sent to Dr Jayaram, Eirian Powell, Dr Newby, Dr Saladi, Debbie Peacock and Dr Davies [INQ0003110_0001].

End June / early July 2015	**Additionally, an SI investigation should have been commenced into the deaths of Child A, Child C and Child D, and the deterioration of Child B; and the cluster of events should have been escalated to WCGB, QSPEC and the Trust Board**[171]. Dr Brearey's oral evidence was that, at the meeting on 2 July 2015, he had a "*concern that there might be somebody harming babies"*[172,173]. As part of the SI investigation, analysis of the staff who could have harmed the babies would have identified Letby as the common theme. Eirian Powell's evidence pointed towards an early discussion with her nursing colleagues, possibly shortly after June 2015, about the possibility of deliberate harm being caused to the babies[174]. **As soon as it was suspected that someone may have deliberately harmed a child on the NNU, there should have been an immediate safeguarding referral to the COCH's safeguarding team and onwards to the LADO and LSCB, *and* a direct referral to the police. The paediatric consultants, the unit's managers, the COCH safeguarding team and/ or the COCH's Executives should have ensured these steps took place.** **Having identified Letby as the member of staff potentially responsible, she should have been excluded from the NNU immediately pending investigation.**
Based on the evidence explored in detail at this Inquiry, this was the first timepoint at which appropriate actions and interventions would have saved babies from harm from Letby. Each subsequent baby would have avoided harm[175]. **This important point applies throughout – but is not repeated – in the chronology below.**	
Early August 2015	**Child E's death should have been added to the existing SI investigation, and reported to the WCGB, QSPEC and the Trust Board. SUDIC processes should have been commenced.**

[171] We do not set out every meeting at which increased mortality or collapses on the NNU should have been discussed at the WCGB and/ or QSPEC. However, these matters should have been regularly and frequently revisited by these bodies.

[172] [Brearey/ wk10/ day2/ p61/ ln22-23]

[173] Dr Brearey originally said "*suspicion and concern"* but then changed his language to "*concern*" [Brearey/ wk10/ day2/ p61/ ln5-23]. See also Dr Brearey's evidence that, at the meeting on 2 July 2015, Letby was raised as a "*commonality*" and "*the worst"* was in the back of his mind [Brearey/ wk10/ day2/ p248/ ln5 – p249/ ln5]. He was also asked, "*[e]ven…at the meeting of the Serious Incident back in July when you said "oh no", a causal link was made that somebody could be doing this… in bad faith?"* He said "*yes*" [Brearey/ wk10/ day2/ p80/ ln3-8].

[174] [Powell/ wk6/ day4/ p189/ ln8 – p190/ ln6] Her evidence about the exact timings was not entirely clear.

[175] We are aware of police investigations into whether Letby had harmed babies before June 2015, but evidence on this has not been examined in this Inquiry. This 'causation' point is therefore made without knowing whether harm to Child A, B, C or D could have been prevented.

	This should have been done even if clinicians thought there was a likely medical explanation for the death. The SI investigation would have formally recorded that Letby was on duty again.
13 August 2015	**The significance of Child F's abnormal blood results (extremely high insulin levels and very low C-peptide levels) should have been recognised by Dr ZA and the possibility of deliberate harm recognised.** **There should have been an immediate safeguarding referral to the COCH's safeguarding team and onwards to the LADO and LSCB, *and* a direct referral to the police. The paediatric consultants, the unit's managers, the COCH safeguarding team and/ or the COCH's Executives should have ensured these steps took place.** **A SI investigation should have been commenced, or this event should have been added to the existing SI investigation.** **Having identified Letby as the member of staff potentially responsible, she should have been excluded from the NNU immediately pending investigation.** Dr ZA's evidence was that she discussed, with the SHO, the possibility of exogenous insulin. She said they checked that insulin had not been prescribed to someone else on the NNU – it had not. However, she "*dismissed*" the possibility of deliberate administration of insulin and considered this to be "*fantastical and unlikely*"[176]. She accepted that she should have completed a Datix and discussed this with Dr Brearey, Dr Jayaram and Eirian Powell[177]. Dr Gibbs' evidence was that it was "*a collective failure on the part of [the] Paediatric team to have not recognised"* the significance of these blood results [INQ0102740_0048, §157]. We agree with this, but also submit it was an individual failure on the part of Dr ZA. We invite the Chair to accept Dr Gibbs' evidence that "*this was serious failure because had we realised that Child F had been administered insulin when this was not indicated (and had not been prescribed to him), then this should have raised immediate and serious concern either about possible deliberate harm on the NNU or that there were seriously deficient procedures and*

[176] [ZA/ wk5/ day1/ p36/ ln2-24]

[177] [ZA/ wk5/ day1/ p40/ ln18-19, p41/ ln1]

	practices on the NNU that led to insulin being given to a patient accidentally" [INQ0102740_0048, §157][178]. It is likely that the possibility of deliberate harm would have been identified. That should have led to a safeguarding referral to the LADO and LSCB and to a separate referral to the police. It is also likely that this information would have been combined with the ongoing SUDIC processes and SI investigation. Letby would have been excluded from the NNU. **There should have been an immediate safeguarding referral to the COCH's safeguarding team and onwards to the LADO and LSCB, *and* a direct referral to the police. The paediatric consultants, the unit's managers, the COCH safeguarding team and/ or the COCH's Executives should have ensured these steps took place.** **A SI investigation should have been commenced, or this event should have been added to the existing SI investigation.** **Having identified Letby as the member of staff potentially responsible, she should have been excluded from the NNU immediately pending investigation.** Dr ZA's evidence was that she discussed, with the SHO, the possibility of exogenous insulin. She said they checked that insulin had not been prescribed to someone else on the NNU – it had not. However, she "*dismissed*" the possibility of deliberate administration of insulin and considered this to be "*fantastical and unlikely*"[179]. She accepted that she should have completed a Datix and discussed this with Dr Brearey, Dr Jayaram and Eirian Powell[180]. Dr Gibbs' evidence was that it was "*a collective failure on the part of [the] Paediatric team to have not recognised"* the significance of these blood results [INQ0102740_0048, §157]. We agree with this, but also submit it was an individual failure on the part of Dr ZA. We invite the Chair to accept Dr Gibbs' evidence that "*this was serious failure because had we realised that Child F had been administered insulin when this was not indicated (and had not been prescribed to him), then this should have raised immediate and serious concern either about possible deliberate harm on the NNU or that there were seriously deficient procedures and*

[178] Dr Gibbs' statement prefaced this evidence with "*[w]ith hindsight…*" [INQ0102740_0048, §157]. We do not accept this apparent caveat.

[179] [ZA/ wk5/ day1/ p36/ ln2-24]

[180] [ZA/ wk5/ day1/ p40/ ln18-19, p41/ ln1]

	practices on the NNU that led to insulin being given to a patient accidentally" [INQ0102740_0048, §157].[181] It is likely that the possibility of deliberate harm would have been identified. That should have led to a safeguarding referral to the LADO and LSCB and to a separate referral to the police. It is also likely that this information would have been combined with the ongoing SUDIC processes and SI investigation. Letby would have been excluded from the NNU. Even if Child F's abnormal blood results had not been identified, it is our submission that, by this point, the consultants, the unit's managers and Debbie Peacock should have identified Letby as a common theme in the deteriorations. This information should have been combined with the SUDIC processes and SI investigation.
7 September 2015	**Child G's repeated collapses should have been recorded on Datix. These events should have been added to the existing SI investigation.**
21 September 2015	**Child G's further deteriorations should have been recorded on Datix. These events should have been added to the existing SI investigation.**
26 September 2015	**Child H's sudden collapse, requiring resuscitation, should have been recorded on Datix. This should have been added to the existing SI investigation.**
30 September 2015	**Child I's collapse should have been recorded on Datix. This should have been added to the existing SI investigation.**
13 October 2015	**Child I's further collapse should have been recorded on Datix and Letby as identified a common theme in her collapses. This should have been added to the existing SI investigation.**
23 October 2015	**Child I's death on 23 October 2015 should have been added to the existing SI investigation, and reported to the WCGB, QSPEC and the Trust Board. SUDIC processes should have been commenced.** **Eirian Powell's first version of the "*Neonatal Mortality Review for 2015*", which identified Letby as a common theme in the deaths on the NNU, should have led to urgent meetings with Alison Kelly and/or Sian Williams[182].**

[181] Dr Gibbs' statement prefaced this evidence with "*[w]ith hindsight…*" [INQ0102740_0048, §157]. We do not accept this apparent caveat.

[182] See the Review at [INQ0003189] and Eirian Powell's covering email at [INQ0003106]. In that email she also wrote: "*Just to say that I have discussed the above [i.e. the Review] with Anne Murphy and on reflection it was decided to leave this until Monday. Alison Kelly was not in the hospital and Sian had just left as was not well.*" The evidence suggests such a discussion with Alison Kelly and/or Sian Williams did not occur and is confirmed in Eirian Powell's witness statement [INQ0108000-0033 § 115]

From end October/ beginning November 2015	**There should have been an immediate safeguarding referral to the COCH's safeguarding team and onwards to the LADO and LSCB, *and* a direct referral to the police. The paediatric consultants, the unit's managers, the COCH safeguarding team and/ or the COCH's Executives should have ensured these steps took place.** **Having identified Letby as the member of staff potentially responsible, she should have been excluded from the NNU immediately pending investigation.** Dr Brearey's evidence was, by the time of Child I's death "*there was considerable concern*" of deliberate harm [Brearey/ wk10/ day2/ p79/ ln24 – p80/ ln2]. He said that Child I's collapses and death "*was certainly a significant moment that raised [his] level of concern quite considerably*" and set "*a few alarm bells going*"[183]. For Dr Jayaram, it was early November 2015, after Child I's death, that he "*became concerned for the first time that Letby could somehow be causing inadvertent or even deliberate harm*." He recalled, "…*several informal 'corridor conversations' between Consultants at this time. I cannot recall who amongst us was the first to articulate possibility of Letby causing inadvertent or deliberate harm but when expressed openly it became clear that I was not the only Consultant with these concerns."* [INQ0107962_0045, §294-5]. He said that in November 2015, the possibility of Letby causing deliberate harm was discussed but he "*kind of tried to shut it away really…*"[184]. Dr Jayaram thought that Dr Newby and Dr Gibbs may have been part of the "*informal corridor conversations*"[185]. Dr Mittal, as designated doctor for child deaths, or other consultants would also have been able to speak with a police officer through the operation of the SUDIC processes. Letby should have been removed from the NNU.
End November 2015	**Child J's multiple collapse should have been recorded on Datix. These events should have been added to the existing SI investigation.**
December 2015	**The QSPEC meeting on 14 December 2015 and WCGB meeting on 18 December 2015 should have requested a comprehensive report on increased the mortality and collapses on the NNU and have been provided with any existing reviews.**

[183] [Brearey/ wk10/ day2/ p71/ ln11-16 and p72/ ln1-2]

[184] [Jayaram/ wk9/ day3/ p197/ ln13-23]

[185] [Jayaram/ wk9/ day3/ p35/ ln12 – p36/ ln3].

	At these meetings Dr Brigham's November 2015 review was presented (misleadingly titled 'Review of neonatal deaths and stillbirths at Countess of Chester Hospital – January 2015 to November 2015)[186]. Both bodies should have recognised that this review did not give reassurance about events on the NNU. However, as set out above, it is our submission that both the WCGB and QSPEC should already have been aware of increased mortality on the NNU and the association with Letby.
Late 2015/ early 2016	Both Dr Newby and Dr Gibbs gave evidence indicating it was late 2015/early 2016 when they started to become concerned about Letby's association with deaths and collapses. Dr Newby's evidence was that "*as 2015 went on and into 2016, the thought that something awful could be happening…solidified in people's minds*"[187]. She also said it was the beginning of 2016 when "*things really coalesced in terms of the index of suspicion or concern"*[188] Dr Gibbs placed the timing between the end of 2015 and the Thematic Review[189]
8 February 2016	There was a meeting to carry out a review of neonatal mortality for 2015 to January 2016, which led to the Thematic Review document. This Thematic Review should not have been produced as it was. Instead, the recognised SI process leading to an SI investigation should have been used (as it should from June/July 2015 onwards)[190]. However, if a thematic review was to be conducted, then this should have happened in late June/early July 2015.
15 February 2016	**On the basis of the Thematic Review taking place, Executives should have arranged an urgent meeting with Dr Brearey and the other paediatric consultants following receipt of this document – regardless of whether there was an express request for such a meeting.**

[186] QSPEC meeting minutes at [INQ0003204] and WCGB meeting minutes at [INQ0003224]. Alison Kelly and Sir Duncan Nichol attended the QSPEC meeting.

[187] [Newby/ wk4/ day4/ p34/ ln19-22]

[188] [Newby/ wk4/ day4/ p36/ ln18-23].

[189] [Gibbs/ wk4/ day2/ p81/ ln8-25] See also [Gibbs/ wk4/ day2/ p85/ ln7-19].

[190] The RCPCH review found that the "*review of deaths carried out by the (neonatal lead) consultants that, together with two additional deaths, triggered the unit's reconfiguration in July 2016 did not use a recognised RCA process nor did it involve the governance lead/ risk manager. The staffing grid in particular was not validated"* [INQ0002457_0018, §4.48].

	Dr Brearey and/or the consultants should have told the COCH Executives, clearly and explicitly, in writing and in person, that they suspected that children were being deliberately harmed and killed by Letby. **There should have been an immediate safeguarding referral to the COCH's safeguarding team and onwards to the LADO and LSCB, *and* a direct referral to the police. The paediatric consultants, the unit's managers, the COCH safeguarding team and/ or the COCH's Executives should have ensured these steps took place.** **Having identified Letby as the member of staff potentially responsible, she should have been excluded from the NNU immediately pending investigation.** Dr Brearey sent the draft Thematic Review to Ian Harvey and Alison Kelly on 15 February 2016. This identified that Letby was on duty for all the deaths[191]. Dr Brearey should have stated explicitly that it required their immediate attention because of the concern that Letby was harming babies. Whether or not he did so, the Executives had sufficient information to take immediate action based on the Thematic Review alone. Both Ian Harvey and Alison Kelly were aware there had been an increase in neonatal mortality and should have read the Review immediately and carefully[192]. In her oral evidence, Karen Rees acknowledged that, by 24 June 2016, she had known for at least six months or so, that there were concerns about Letby possibly harming babies (i.e. the start of 2016, or even late December 2015)[193]. Dr Brearey's evidence was that most of the information that was subsequently set out in the consultants' report in May 2017 was contained in the Thematic Review and that, from his perspective, the Executives had

[191] Email at [INQ0003140] and Thematic Review at [INQ0003217].

[192] Alison Kelly did not recall even reading the Thematic Review, or reading it "*in detail*", when it was sent to her in February 2016, appearing to rely on it being a draft report as justification [Kelly/ wk11/ day1/ p71/ ln25 – p73/ ln25]. In her witness statement, she did not explain that. She said she did not think she would have considered the "*detail of the appendices to the report*", essentially because she received so many emails and Dr Brearey had not communicated any sense of urgency or concern [INQ0107704_0065, §210]. In our submission, it is likely Kelly did not read any part of the Thematic Review at this time as she told the Inquiry she met with the CQC and "*generally had not realised* Alison Kelly certainly did not tell the CQC about the increase in mortality on the NNU. It would appear that Ian Harvey did read the document but did not see it as concerning at the time, although he also appeared to accept he should have been more worried about the content [Harvey/ wk11/ day4/ p127/ ln24 – p133/ ln16]. In his statement he said that the tone and content of Dr Brearey's covering email did not cause him any concern [INQ0107653_0025, §111].

[193] [Rees/ wk7/ day1/ p210/ ln1-5]

	sufficient information to take immediate action from the time of the Thematic Review[194]. Dr Jayaram also expressed the view that there was "*enough in the Thematic Review* [for Executives] *to acknowledge that the association was significant*"[195]. Dr Brearey's evidence is that he did request an urgent meeting with Ian Harvey and Alison Kelly in early 2016 [INQ0103104_0018, §123]. His email has not been located. Whatever the position, it was incumbent on him to take every available step he could to secure an urgent meeting, and incumbent on the Executives to ensure that one took place urgently. If Dr Brearey Dr Jayaram, or the other consultants felt impotent, they should have sought support from the COCH safeguarding team[196].
17 February 2016	**Dr Jayaram should have recorded and reported that he found Baby K deteriorating with a displaced endotracheal tube and that Letby was present but not intervening.** **There should have been an immediate safeguarding referral to the COCH's safeguarding team and onwards to the LADO and LSCB, *and* a direct referral to the police. The paediatric consultants, the unit's managers, the COCH safeguarding team and/ or the COCH's Executives should have ensured these steps took place.** **Having identified Letby as the member of staff potentially responsible, she should have been excluded from the NNU immediately pending investigation.** **A SI investigation should have been commenced, or this event should have been added to the existing SI investigation.** Dr Jayaram's evidence was that he was outside Child K's room, "*but by this stage I had significant discomfort…and I just felt uncomfortable knowing that Letby was in the room. And actually I was convincing myself that I was being completely irrational and ridiculous and so I got up and went in to make sure everything was fine….I didn't walk in and see anything happening. What I walked in was to find a baby clearly deteriorating and then when I went to*

[194] [Brearey/ wk10/ day2/ p259/ ln4 - p260/ ln14]

[195] [Jayaram/ wk9/ day3/ p199/ ln23 – p200/ ln6]

[196] Dr Jayaram's evidence was that, "*as time went from February 16 onwards, there was an increasing feeling between all of us that, however unlikely, unwanted, abominable the thought of Letby causing deliberate harm could be, that elephant in the room was becoming bigger and bigger and we…felt completely impotent to know how to deal with it"* [Jayaram/ wk9/ day3/ p41/ ln11-17].

	assess Baby K, the endotracheal tube was dislodged but importantly, the nurse was looking after the baby, who I believe by this stage would have flagged up this deterioration…its likely a tube problem, not responding at all. And at that time, my priority was to resuscitate Baby K, which we did successfully. I will take this with me to my grave, I at that point thought: well, how has that happened? How in isolation in that if nothing else had happened before or after, I would have probably thought nothing more of it. But was it just coincidence that this baby who had been stable to this point in the period where the nurse looking after the baby and Letby was supervising the baby, this event happened?"[197]. Dr Jayaram did not report this to anyone at the time. He accepted that "*in retrospect"* he should have completed Datix "*because even if there's accidental tube dislodgement it probably should be Datixed because then you look into why the tube may have dislodged. But I didn't"*[198].
16 – 19 February 2016	**During the CQC's inspection visit, its inspectors should have been informed of the increased mortality on the NNU and the concerns that Letby was responsible[199].**
20 February 2016	**SUDIC processes should have been commenced in response to Child K's death.** This would have led to local authority and police involvement. **The death should also have been added to the existing SI investigation.**
March 2016	**Continuing major patient safety failings as per 15 February 2015.** On 17 March 2016, Eirian Powell emailed Alison Kelly asking to arrange a meeting to discuss the findings of the Thematic Review. Her email pointed

[197] [Jayaram/ wk9/ day3/ p37/ ln22 – p38/ ln25]

[198] [Jayaram/ wk9/ day3/ p203/ ln17-22]

[199] Ian Harvey's oral evidence was that he was confident that he shared the Thematic Review with the CQC ahead of the CQC visit in February [Harvey/ wk11/ day4/ p105/ ln8-11]. Alison Kelly seemed to deny that she should have told the CQC about increased mortality, saying "*it wasn't clear that there had been an increase in mortality*" and that there was not a "*clear picture*" at the time of the CQC's inspection. Later she admitted she had not realized, at the time of the CQC inspection, that there had been an increase in mortality [Kelly/ wk11/ day1/ p73/ ln5-18 and p74/ ln4-8]. Elizabeth Childs, Chair of the CQC inspection in February 2016, agreed that the CQC inspection had not identified any concern about an unexplained spike in neonatal deaths and Letby's association with this. She said she had not seen a copy of the Thematic Review. She said that she should have been told about concerns about the increase in mortality on the NNU [Childs/ wk9 / day4/ p145/ ln22 – p147/ ln10 and p164/ ln22 – p166/ ln1]. Helen Cain, a CQC inspector, said that she would have expected to have seen the Thematic Review in advance of the inspection, that she was unaware about any increase in neonatal mortality or concerns about this. She was also unaware of any concerns about deliberate harm by a member of staff [Cain/ wk9/ day4/ p38/ ln23 – p40/ ln11; p42/ ln9-14; and p59/ ln120 – p60/ ln19]. Dr Odeka's evidence was that he expected to be told about unexpected and unexplained deaths and such deaths would be a "*red flag*" and that the CQC should have been told about the increase in neonatal mortality [Odeka/ wk9/ day4/ p91/ ln17 – p92/ ln19].

	out the high mortality and that a particular nurse was a commonality (as well as a doctor, but less so) [INQ0003089]. On 21 March 2016, Eirian Powell sent the Thematic Review to Alison Kelly[200]. We submit that the Chair will need to make findings of fact as to whether Alison Kelly read the Thematic Review at all, either in February 2016 or after it was sent in March 2016[201].
9 April 2016	**A Datix should have been completed after Child M's collapse. This should have been added to the existing SI investigation.** **Continuing major patient safety failings as per 15 February 2015.** Dr Jayaram observed Child M had unusual blotches similar to those on Child A and Child B [INQ0001982_0011 – 12]. He discussed the blotching with Dr Brearey[202]. Dr Jayaram's oral evidence was, "*[a]gain, I hadn't at that point, although myself and colleagues were – had begun to wonder about the possibility of Letby deliberately doing something, we hadn't really started actively thinking about what might be being done*"[203]. A Datix should have recorded the unusual rash and that Letby had been present at his collapse.
14-15 April 2016	**Continuing major patient safety failings as per 15 February 2015.** **The significance of Child L's abnormal blood results should have been recognised by the NNU clinicians.** **As before, urgent steps should have been taken to trigger safeguarding processes and contact the police. Letby should have been excluded from the NNU.** The possibility of exogenous inulin having been administered to Child L should have been recognised as soon as the results were received and reviewed by a member of the clinical staff. Again, Dr Gibbs' evidence was that this was a "*collective failure on the part of us Paediatricians*" and that *"our failure to recognise the potential significant of the insulin results in Chid L (just as earlier in Child F) meant that an important opportunity was missed to identify, and thus try to prevent, harm to patients in the NNU*" [INQ0102740_0077, §268]. Again, we agree with this. This was a serious failure. It is likely that the possibility of deliberate harm being caused would have been identified. That should have led to a

[200] Email at [INQ0003089] and Thematic Review at [INQ0004538].

[201] The Chair will recall Ms Kelly's attitude that she was very busy and, if someone had something urgent to tell her, they should come to her office or call her [Kelly/ wk11/ day1/ p98/ ln1 – p104/ ln11].

[202] [Jayaram/ wk9/ day3/ p44/ ln2-21]

[203] [Jayaram/ wk9/ day3/ p7-11]

	safeguarding referral to the LADO and LSCB and to a direct referral to the police. It is also likely that this information would have been combined with the ongoing SUDIC processes and SI investigation. Letby should have been excluded from the NNU. On 14 April 2016, Eirian Powell emailed Alison Kelly seeking her thoughts on the Thematic Review and sending a further copy of the document to her [INQ0003089_0001]. Alison Kelly should have carefully read this document (if she had not done so already, as she should have done).
May 2016	**Continuing major patient safety failings as per 15 February 2016.** Alison Kelly cancelled the planned meeting on 4 May 2016. In response, Dr Brearey informed her that there was "*a nurse on the unit who has been present for quite a few of the deaths and other arrests. Eirian has sensibly put her on day shifts…*". Alison Kelly's subsequent emails indicate, in our submission, that either she had not read the Thematic Review, first sent in February 2016, at all or had only skimmed it. They also show that she had not paid heed to Eirian Powell's email dated 17 March 2016. Alison Kelly wrote, "*…if there is a staff trend here and we have already changed her shift patterns because of this, then this is potentially very serious…*" [INQ0003138_0001]. Alison Kelly should have arranged a meeting before 11 May 2016. On 11 May 2016 there was a meeting between Ian Harvey, Alison Kelly, Dr Brearey, Anne Murphy and Eirian Powell[204]. Dr Brearey's evidence is that he made it clear that he and all his colleagues were concerned and worried about the association with Letby. He also felt these concerns were given more weight by the fact Letby had been moved in April onto day shifts, and there had been no collapses or deaths at night from that point. However, Anne Murphy and Eirian Powell forcibly said there were absolutely no concerns about her. In her 'Neonatal Unit review 2015-16, Ms Powell had made clear her and the nursing managers' position: '*There is no evidence whatsoever against LL other than coincidence*' [INQ0003243_0001]. CTI asked Dr Brearey: "*What action did you think was necessary to make the unit safe at this point?...* *A:…I thought that the Executives should have been discussing it outside the hospital with – with experts, whether that be safeguarding experts or*

[204] Alison Kelly's note of the meeting is at [INQ0003181].

	the police or NHS England, whoever. It just felt like so much of a significant concern that doing nothing didn't seem to be an option"[205].
Early June 2016	**Continuing major patient safety failings as per 15 February 2016.** **Child N collapsed on 3 and 15 June 2016. Both collapses should have resulted in Datixes being completed, which should have identified Letby's presence. These should have been added to the existing SI investigation.**
End of June 2016 to May 2017	**Continuing major patient safety failings as per 15 February 2016.** **SUDIC processes should have been commenced in response to Child O's death on 23 June and Child P's death on 24 June 2016. These deaths should also have been added to the existing SI investigation.** **Child Q's deterioration on 25 June 2016 should have been recorded on Datix. This should also have been added to the existing SI investigation.** After the deaths of Child O on 23 June and Child P on 24 June 2016, the consultants insisted that Letby be excluded from the NNU on the grounds of protecting patient safety[206]. There were also multiple meetings and communications between and amongst the consultants, senior managers and Executives. The possibility that Letby had murdered the two babies and other children was openly discussed, including potential mechanisms of harm. So too was calling the police[207]. It is extraordinary that basic good judgment was not exercised by the Executives in those meetings and that the police were not called immediately. Instead, over a period of several months a pointless and protracted process of independent investigation – the RCPCH service review and the consequent reviews by Dr Jane Hawdon and Dr Jo McPartland – was embarked on with the approval of Tony Chambers, Ian Harvey, Alison Kelly and other COCH Executives. In the meantime, the consultants were

[205] [Brearey/ wk10/ day2/ pp126 – 29]

[206] Dr Brearey email 28 June 2016 [INQ0003116]. Even then, Karen Townsend took the view that Letby should remain on the day-shift until she went on holiday [INQ0003116].

[207] Documents at [INQ00098325], [INQ0003116], [INQ0003112], [INQ0005749], [INQ0003371], [INQ0003360] and [INQ0003362]. The meeting note on 29 June 2016 includes Dr Jayaram saying, "*How? Canular air embolism?...*" (sic) [INQ0003371_0002]. In oral evidence Dr Jayaram said that he was raising serious concerns about Letby being associated with and possibly causing the collapses of deaths of some of the babies [Jayaram/ wk9/ day3/ p207/ ln23 – p208/ ln6]. He also agreed that, in this meeting, he was speculating about the mechanism of murder; possibly air embolism and via a cannula or some other mechanism" [Jayaram/ wk9/ day3/ p234/ ln8-11]. After this he located the Tanswell and Lee paper. A note dated 29 June 2016 includes, "*[s]ufficient level of concern that illegal activity in [appears to be NNU]*" [INQ0003360].

	effectively sidelined and muted, Ian Harvey having told them that "*All emails cease forthwith*" [INQ0003112]. These reviews were initiated and tightly controlled throughout by Ian Harvey in a way that is deserving of serious censure: 1. He deliberately decided not to instruct the reviewers to address the most important and pressing issue, the possibility that the babies had been killed by Letby, which in any event he knew was beyond their competence, as the reviewers themselves ruefully acknowledged in their oral evidence[208]. 2. He deliberately excluded the consultants from the process of instruction – which was indefensible given the gravity of the suspicions/concerns that they had raised and their direct knowledge of the care given to the babies who had died (but from his perspective a necessary step to prevent the inclusion of criminal conduct). He also withheld the consultants' views about deliberate harm from Dr Hawdon[209] and Dr McPartland[210]. 3. He then controlled the content of the reviewers' reports. He removed explicit references in the RCPCH report to the consultants' 'allegation' about the link between Letby and the deaths[211]. While the RCPCH had provided a report with information about Letby in green text, it was ultimately Harvey's decision to remove that and have two different reports[212]. He doctored Dr Hawdon's report (without discussion or

[208] See, for example: Sue Eardley accepted that, after Ian Harvey raised concerns about potential murder, the only appropriate course was for the RCPCH to say it could not undertake the review and that the only organisation equipped to investigate was the police [Eardley/ wk8/ day4/ p233/ ln9 – p234/ ln9]. She also agreed that, with hindsight, the RCPCH was being used by Ian Harvey in a way which was not appropriate for an independent review [Eardley/ wk8/ day4/ p235/ ln11-17]. Alex Mancini agreed that when the RCPCH review team was discussing "*potential methods of murder*" it was a clear signal that the review had to stop and was inappropriate [Mancini/ wk9/ day1/ p146/ ln5-10].

[209] Dr Hawdon's evidence was that she was not told that a member of staff was associated with most, if not all, of the deaths she had been asked to review or that a member of staff had been removed from the NNU. In her view she should have been told if there was a concern about criminality [INQ0099063_0010, §24]. Her evidence was that, if she had been aware and based on her findings, she would have contacted Mr Harvey and urged him to following "*appropriate Trust safeguarding and governance processes*" [INQ0099063_0012, §32]. Dr McPartland was also not told about the consultants' concerns or that a member of staff had been removed from the NNU due to her being a common factor between the deaths. In her view, "*I should have been provided with this vital information; it would have indicated to me that this was a potential criminal case that required the involvement of the Police and a forensic pathologist, and a formal independent pathology review rather than an informal "follow up discussion" as suggested by Mr Harvey, based on a few brief paragraphs of information*" [INQ0102015_0031, §111].

[210] Dr McPartland states at [McPartland/ wk9/ day2/ p10/ ln20-22] "*The suspicion of criminal intent was certainly not raised to me and I did not read criminal intent into the detailed forensic case note expression*"

[211] Unredacted RCPCH report [INQ0002457_0008-10, §§3.12-3.13 and opening part of §4].

[212] See [Eardley/ wk8/ day4/ p214/ ln19-24], [Harvey/ wk11/ day5/ p8/ ln1-10 and p8/ ln23 – p9/ ln3].

permission) so that Child D was moved out of the "unexplained category" of deaths[213].

Finally, and perhaps most egregiously given Ian Harvey's manipulation of the review process, he and Tony Chambers misrepresented the reviewers' findings to the COCH Board, stating that they effectively disproved the consultants' concerns and thereby exonerated Letby[214]. The same false message was communicated about the outcome of Letby's grievance[215].

Throughout this period, the Board members never heard directly from the consultants themselves, both about their concerns and their views on the value of the investigations that had been conducted. In a properly functioning trust, this would have been seen as essential. At COCH the opposite was the case: the consultants and the Board needed to be kept apart to protect the Executives' strategy of avoiding police involvement and external investigation of multiple potential murders.

The clear inference that must be drawn from the actions summarised above is that the true purpose of the reviews was not to accord credence to the consultants' suspicions about Letby and investigate them robustly, but to proactively seek alternative non-criminal causes for the babies' death (including poor care by the consultants themselves). The intention or hope was that the various reviews would provide irrefutable, independent support for the Executives' true and unanimous view that the consultants' concerns were in fact baseless and vexatious.

When this did not happen, and despite the false spins that Ian Harvey and Tony Chambers repeatedly attempted, the Executives' plan ultimately derailed. The consultants could no longer be appeased and became increasingly and rightly aggrieved by the inconclusive and secretive reviews, the inaction of the Executives, the criticisms made against them during Letby's grievance procedure, and the threat of referral to the GMC. Only

[213] Statement of Dr Hawdon [INQ0099063_0014, §§47 and 53].

[214] See, for example, Ian Harvey's paper, *Review of Neonatal Services at the Countess of Chester Hospital NHS FT*, which was presented to the extraordinary meeting of the Board on 10 January 2017 [INQ0003518]. One of its recommendations was to '*Support the Executive in assisting the staff member's return to work on the Neonatal Unit - the reviews having found no evidence of a single person's culpability — and in implementing the recommendations of the "grievance" investigation.'*

[215] See, for example: James Wilkie's evidence was that at the extraordinary board meeting on 10 January 2017, *"the whole outcome of the Royal College report was framed in a way that the inference that I drew was that basically Letby had been exonerated, right. I did not know at that point that they had not looked at those issues…*" [Wilkie/ wk12/ Day1/ p182/ ln12-18]. The minutes of this meeting on 10 January 2017 record that Ian Harvey explained that Dr Hawdon's reviews, "*…very much reinforce what is in the [RCPCH] review, it comes down to issues of leadership, escalation, timely intervention and does not highlight any single individual*" [INQ0003237_0002]. They also record that Tony Chambers said the grievance exonerated Letby [INQ0003237_0006]. Consistent with the above, handwritten notes of an Executive Directors' Group meeting on 11 January 2017 record "*apology letter. Making explicit review exonerates Lucy"* [INQ0004380_0001].

	then, reluctantly and boxed into a corner, did the Executives decide to contact the police. All of this process was facilitated by a weak and incurious Board – which should have been proactive in demanding to understand the precise nature of the consultants' concerns about Letby, insisted on being fully and fairly briefed on all the available information and views, challenged the Executives' biases and scepticism, rejected the Executives' decision to focus solely on non-criminal explanations, and insisted that the LADO and the police be notified immediately.

SECTION (3) – THE EXPERIENCES OF THE FAMILIES WE REPRESENT

Introduction

190. Each of the parents we represent had his or her own highly personal experience of events at the COCH and what subsequently unfolded. The Chair, in dedicating Part A of the hearings to the Families, has recognised this. We invite the Chair, everyone involved in this Inquiry and indeed the public, to return to the transcripts of the evidence given so generously and powerfully by Families. This includes the victim impact statements prepared in the criminal trials. The human suffering that the Families have endured and continue to endure must not be forgotten amongst arguments about systems, processes, governance and culture.

191. In this section, we make submissions for and about each individual Family we represent and therefore, for and about each individual baby. Before we do so, however, we make two points that are common to the Families we represent.

192. First, Mother A and B told the Chair that staff should have put themselves in her shoes[216]. The Chair described this as an insightful observation and one that she would consider as witnesses explained how they behaved at various stages[217]. If clinicians, managers and Executives had truly thought about putting themselves in the parents' shoes, events would have been very different[218].

[216] [Mother A and B/ wk2/ day1/ p46/ln1-3]

[217] [Mother A and B/ wk2/ day1/ p55/ ln14-18]

[218] We acknowledge Dr Holt's evidence about her discomfort with the COCH's planned press release covering the NNU's downgrade. She said she could imagine how awful it would be for families to learn about increased mortality rates from the press and she thought it would have been most appropriate and kindest to speak with families. She added, "*…I think the bottom line is that people who have accessed the NHS deserve honesty and we are allowed not to have all the answers at that time but they deserved to know there were some suspicions around whether the deaths were natural and could be explained by medicine or not"* and, "*[t]he death of each and every baby needed to be scrutinised to understand whether they were unexpected…"* and that the level of communication with grieving parents was "*cruel and I think we should do better*" [Holt/ wk4/ day4/ p148/ ln1 - p149/ ln5].

Communication with the Families would have been very different. Families would not have been treated as an after-thought, or kept in the dark, or misled[219].

193. Second, and linked with this, all the Families involved in this Inquiry have the shared experience of people in positions of relative power withholding information from them about their most loved and treasured babies. As parents, they were entitled to know what had happened or may have happened to their babies. They were entitled to know when their babies' death or deteriorations were being examined and investigated. They were entitled to know when their babies' medical records were being sent to others. They were entitled to know there were concerns about the cause of their baby's death or deterioration. They were entitled to see the full version of the RCPCH report. Mother A and B's evidence on this was, "*[w]e had a right to know…they are our babies.*"[220]. She is right.

Child A and Child B

General

194. Letby murdered Child A on 8 June 2015.

195. The Inquiry heard evidence from Mother A and B that 2015 was going to be the "*best year*" of their lives. They were going to be parents to a little boy and girl. "*Everything was perfect*". But "*what should have been the happiest time of our lives became our worst nightmare*"[221]. The Chair will recall the heartbreaking evidence that Parents A and B never got to hold their little boy, Child A, while he was alive[222]. Mother A and B said that although their family has a gaping hole where Child A should be, there is a constant shining light in Child B[223].

196. The Chair will understand that the impact of objectively traumatic events (like the death of a child) can be worsened by the insensitive words and actions from others or, to use Mother A and B's words, by healthcare professionals not putting themselves in a parent's shoes. She described insensitive and inconsiderate treatment and attitudes after Child A died (was murdered). For a short period, she was given uninterrupted time to be with Child B. But that quickly changed and she felt herself being told to leave. Her evidence reveals healthcare professionals not having the empathy or insight to understand that she needed to be with her surviving twin baby. She felt like she and Father A and B were not given "*any respect as the parents*"[224]. And for them, this had real-world consequences. The first time Mother A and B left Child B, Letby attacked her[225].

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[219] The Chair will recall Sir Duncan Nichol's candid admission that, "*The Families were not in the big picture"* [Nichol/ wk12/ day 1/ p138/ ln3-5].

[220] [Mother A and B/ wk2/ day1/ p53/ ln18-24]

[221] [Mother A and B/ wk2/ day1/ p2/ ln16 – p3/ln4]

[222] [Mother A and B/ wk2/ day1/ p2/ ln24-25]

[223] [Mother A and B/ wk2/ day1/ p4/ ln1-2]

[224] [Mother A and B/ wk2/ day1/ p32/ ln21-22]

[225] We note that other Families also felt that staff at the COCH did not respect their grief. See e.g. [Mother C/ wk2 / day1/ p92/ ln6-9].

197. She also described how, in the following weeks when Child B remained on the NNU and she returned to see and care for her baby, she felt that some staff did not think about or understand how traumatic that was, to return to the place her other baby had died[226].

198. Despite Child A's death being unexpected and unexplained, Mother A and B's evidence was that she felt like no one was looking for an explanation into why he died. The lack of answers, and (justified) feeling that Child A's death was not being properly investigated, obviously carried extra weight when Child B had also collapsed, without explanation. Her evidence is worth setting out:

> "*…it just felt really half-hearted and that's what I wanted to say: we are human beings and we'd lost our child, and at no point did I think that anybody was trying. I think it was just a case of: he was a patient. He died. That's the end of it. Move on. I don't think that they ever tried to understand how it was affecting us, and the fact that we never had a reason – to me, it was really important for them to try and do everything they could to give us a reason and to me, they just didn't care….I just didn't even feel like they thought of us as people, that they thought of Child A as an actual baby that had died. It was just a patient*"[227].

199. Child A's sudden and unexpected death should have been thoroughly investigated, with external and therefore independent input, through the SUDIC process[228]. An SI investigation should have been undertaken. This is supported by NHS England's opening submissions[229]. Under the SI Framework, an SI had to be declared in circumstances of:

> "*Acts and/ or omissions occurring as part of NHS-funded healthcare…that result in:*
>
> - *Unexpected or avoidable death of one or more people…"* [INQ0009236_0014].

200. Preliminary post-mortem results did not identify any significant pathology capable of explaining Child A's death. On 1 July 2015, Dr Brearey reviewed Child A's death and did not identify an explanation for it [INQ0002042_0777]. Initially there was some consideration of whether Mother A and B's health condition could have contributed to the death. But advice from haematology experts, including from Great Ormond Street Hospital, was that her health condition was unrelated to Child A's death [INQ0000721_0003-6][230]. At the meeting on 2 July 2015 there was no explanation for Child A's death and the final post mortem report was outstanding. When it became available in December 2015, it did not identify a medical cause of death, but this did not prompt a SI investigation.

201. Alternatively, the death of Child A and the unexpected and unexplained collapse of Child B should have been made part of a SI investigation into the cluster of neonatal collapses/deaths in June

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[226] She did acknowledge that a "*few of the nurses were brilliant*" [Mother A and B/ wk2/ day1/ p33/ ln20].

[227] [Mother A and B/ wk2 / day1/ p32/ ln2-15]

[228] Note also Mother A and B's evidence: "*I would hope that a formal process is implemented to thoroughly investigate any unexplained death, carried out by independent, impartial professionals that are in no way associated with the staff involved. This should lead to a mandatory formal meeting held between the consultant and the parents of the deceased after any infant death to discuss, in detail, the cause of death*" [INQ0107026, §113].

[229] [INQ0107952_0007, §34].

[230] Dr Jayaram agreed that this and other causes were ruled out clinically [Jayaram/ wk9/ day3/ p242/ ln17-22].

2015. There was no joined up thinking as between Child A's unexplained and unexpected death, and Child B's unexplained and unexpected deterioration.

202. If an SI investigation had been commenced, Parents A and B would have been able to participate in that investigation. They would have learnt that Child A had a rash similar to Child B's[231]. Mother A and B said that, if she had known about Child A's rash, she, "*would have demanded that something was done*"[232]. Having heard from Mother A and B, we submit the Chair should accept this. She also said that, if she had known about an unexpected increase in mortality on the NNU, then maybe it would have been easier for them to push for something more to be done[233]. We submit the Chair should find that Mother A and B would have pushed the COCH to investigate what was happening on the NNU.
203. The reason why a SI investigation into Child A's death was never done remains unclear (of course the Thematic Review and other investigations were done, but kept secret from Parents A and B and the other Families). The question of whether there should be a SI investigation into Child A's death remained on the agenda at the COCH right until his inquest (see correspondence between the COCH legal team, the Risk and Patient Safety team, and the SI Panel notes)[234].
204. The Chair is aware that the Coroner and the Family believed that a SI investigation would be undertaken and provided to them in advance of the inquest. On 11 August 2016, the Coroner emailed the Family's solicitor saying, "*I share your frustration and that of your clients. Of particular importance to the inquest is the SUI which although promised has yet to be completed*" [INQ0002042_0171]. The Family's solicitor wrote to the Coroner on 28 September 2016 stating, "*[w]e were told in August 2016 that this investigation was ongoing and we would be provided with a Serious Untoward Incident report*" [INQ0002042_0155][235]. Instead, the COCH provided the briefest of information about Child A, dated 1 July 2015 [INQ0002042_0777]. It is notable, in our submission, that this was the COCH's approach at a time when Stephen Cross, Ruth Millward and the Executives were fully aware that the consultants suspected Letby had murdered Child A. This, combined with how the inquest was conducted, is evidence of a cover-up.
205. Ironically given Mother A and B's feelings that no one was looking into Child A's death, clinicians were looking into the reasons for his and other deaths. Subsequently, Executives set in train a

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[231] The Chair will recall that Child A's rash was not recorded in the notes. There was no debrief after his death. The rash identified by Nurse T and the doctors was therefore not properly recorded (although it was noted in Dr Gibbs' email dated 23 June 2016 [INQ00025743]).

[232] [Mother A and B/ wk2/ day1/ p49/ ln13-15

She also said that, if the cause of the rash had been properly investigated then, "*[t]hey could have maybe stopped this sooner…"* [Mother A and B/ wk2/ day1/ p41/ ln10-11]. We submit she is correct.

[233] [Mother A and B/ wk2/ day1/ p50/ ln4-7]

[234] See, for example, the legal report for the SI Panel meeting on 17 February 2016 included, in relation to Child A: "*Decision on format of investigation to be decided as SUI Panel. Coroner has recommended consideration be given to a SUI report. Discuss at SUI Panel following review on 8.2.16"* [i.e. the Thematic Review] [INQ0102364_0042]. The legal services report prepared for the SI Panel meeting in August 2016 included, *"Format of NNU investigation thought to be equivalent of a SUI*" [INQ0008587].

[235] See also Josh Swash's file note dated 27 September 2016: "*Spoke to Mag @ Coroner's Office, urgently requiring the SUI report for Child A was expecting it by Friday 23rd*" [INQ0008943].

series of 'behind the scenes' investigations. This was all done in the shadow of suspicions about Letby. [236] Parents A and B were completely unaware of this[237]. They had no opportunity to feed into these investigations. They did not know about the RCPCH review until a phone call from Sian Williams to Mother A and B on 3 February 2017, prompted by the media contacting the COCH about the RCPCH report. They were not told there was a confidential version of the report. Mother A and B's evidence was that, if she had been told about concerns that a member of staff was involved, she would have been on the telephone to the police every day[238]. She said that, if she had been aware that the hospital had sought an independent review of the deaths, "*I'd like to have been more involved. I'd like them to have spoken to us. Because maybe we could have shed some more light on it"*[239].

Child A's Inquest

206. Parents A and B were aware of one investigation being undertaken into Child A's death: his inquest. That was held on 10 October 2016 and was the only concluded inquest into the neonatal deaths at the COCH from June 2015.This is a significant event and we ask that the Chair address it in her report.

207. Below we set out only a brief chronology, from August 2016, in relation to the coronial proceedings and the COCH's subsequent contact with the Coroner. We do not repeat the preceding chronology save to stress the Executives', including Stephen Cross's, knowledge of the consultants' suspicions.

    a. 3 August 2016: Stephen Cross' notes of an Executives' meeting, attended by (inter alia) Tony Chambers, Ian Harvey, Alison Kelly and Stephen Cross, state:

    "*Child A inquest: [statements] need to be reviewed by IH & AK – Coroner pushing for [statement]* [INQ0007197_0138].

[236] This began very early indeed. For example, by mid-February 2016, Dr Jayaram already had concerns that Letby was deliberately harming babies. And yet he wrote a letter to the Coroner, dated 10 February 2016, responding to specific questions put by Child A's parents, but making no reference to increased mortality of the NNU or concerns about the reasons behind this [INQ0000020]. This was just two days after the Thematic Review meeting.

[237] Ian Harvey was not sure if the Coroner was sent the Thematic Review [Ian Harvey/ wk11/ day4/ p122/ ln20-25]. An email from the COCH to the Coroner's officer, dated 19 August 2016, attached a document headed "*NNU Mortality Thematic Review 2015 – Child A"* and the email included: "*Please note, the NNU mortality Thematic Review has been redacted due to other patient's confidentiality"* [INQ0050707]. In our submission, it is not therefore clear what was sent to the Coroner but it is unlikely that the whole review was sent. The Coroner's later correspondence about the brevity of the documents provided by the COCH supports this [e.g INQ0002042_0171]. The Thematic Review was not in the inquest bundle for Child A or Child D [INQ0002042] and [INQ0002045]. Certainly Parents A and B were not provided with the Thematic Review.

[238] [Mother A and B/ wk2/ day1/ p51/ ln13-18]

[239] [Mother A and B/ wk2 / day1/ p52/ ln15-21]

Ian Harvey's evidence was that it would be unusual for him to review inquest witness statements or, indeed, for anyone to speak to him about the inquest of a baby[240]. He did not remember reviewing statements in Child A's case[241].

It is reasonable to infer that Harvey and Kelly took this unusual step exactly because of the known sensitivities of Child A's inquest and the significant risk that this presented to the Executives' strategy of avoiding external knowledge and investigations of the paediatric consultants' concerns that Letby had murdered babies – including Child A.

b. September 2016: Louis Browne, then a very senior junior barrister, was directly instructed by the COCH. Stephen Cross had worked with him before. The instructions sent to Mr Browne have not been located.

c. 8 September 2016: there was a pre-inquest conference with Louis Browne. Josh Swash's notes of this meeting record discussions about whether the 'nurse' was involved in Child A's care and an action to check this, which was then done [INQ0108406_0003-7][242]. The notes also recall what appears to be advice from counsel that, if the nurse was involved, this should be disclosed to the family and also "*+ spike in deaths, not just nurse = DISCLOSURE*". The notes also record that the postmortem had not concluded that the central line was related to the death and again, what appears to be advice of, "*[a]s long as we as team don't contradict these findings, there shouldn't be a problem"* [INQ0108406_0003].

d. 27 September 2016: Josh Swash emailed Louis Browne about Child A's inquest. The email included:

> "*Finally, following on from our conversation prior to the pre-inquest meeting on the 8th of September surrounding the nurses involvement in the care of Child A, having investigated the records, I can confirm she was involved in the care of Child A. Stephen has suggested that it would be helpful if he could have a conversation with you regarding this issue this week, if possible?"*
>
> Mr Swash also forwarded the email to Ian Harvey and wrote:
>
> "*Stephen Cross has asked me to forward this email to you which I have today sent to counsel regarding the above inquest, and you will note that the nurse that has recently been moved out of the neonatal unit was involved in the care of Child A. You will note that Stephen is going to speak with counsel about disclosure to the Coroner on this matter*" [INQ0052593][243].

This information was not disclosed to the Coroner. It is unclear whether a conversation about disclosure subsequently took place between Louis Browne and Stephen Cross. But it is clear that disclosure of information about the nurse, who was identified in the notes as Letby, was

[240] [Ian Harvey/ wk11/ day4/ p79/ ln11 – p80/ ln8 and p176/ ln10-11]

[241] [Harvey/ wk11/ day4/ p123/ ln21 – p125/ ln20]

[242] There is a reference to nursing notes on 9 June 2015 [INQ0108406_0007]. Child A died on 8 June 2015.

[243] See also Josh Swash's notebook at [INQ0108406_0008].

never provided to the family; and Louis Browne does not appear to have taken any steps to check this and ensure that disclosure was given.

e. 6 October 2016: A second pre-inquest conference took place, attended by (inter alia) Stephen Cross, Louis Browne, Dr Jayaram and Dr Saladi. Josh Swash's note records that Dr Jayaram said, "*still to this day Ravi doesn't know why this happened. In 27 yrs of paediatrics never seen this kind of situation*" [INQ0108406_0011][244]. Dr Jayaram does not remember the nurse being discussed at this meeting and he did not articulate his concerns about Letby[245].

f. 6 October 2016: Stephen Cross informed the Coroner that the COCH was awaiting a report from RCPCH but that the RCPCH review team had, "*indicated that they were entirely satisfied with the care within the NNU and raised no concerns whatsoever, however, they recommended that a detailed forensic case note review of each of the deaths from July 2015 should be undertaken… I have instructed Louis Browne…and he is fully aware of the review and Dr Jayaram…is also fully aware of this matter…* [INQ0002042_0187]. Stephen Cross sent to Louis Browne this email and the letter of instruction to Dr Hawdon. He did not send the Coroner her letter of instruction. The terms of that letter included that the RCPCH review team agreed that the pattern of recent deaths and mode of deterioration appeared unusual and that the review should consider rare conditions such as air embolism and details of all staff with access to the NNU from four hours before the death (which, of course, Dr Hawdon could not assist with) [INQ0003101]. Mr Rheinberg told the Inquiry that the information contained in the letter of instruction to Dr Hawdon would have been "*extremely helpful*" when approaching Child A's inquest[246].

g. 10 October 2016: Child A's inquest took place[247]. Nether Dr Jayaram nor Dr Saladi informed the Coroner about the suspicions about Letby and the possibility that she had killed Child A – notwithstanding that they had discussed this openly at meetings in late June 2016, including the possibility that he had been injected with air [INQ0003371_0002]. Dr Jayaram was asked to assist the Coroner with possible causal factors. He said there was a potential issue with staffing and that what happened to Child A made no clinical sense to him.

h. Stephen Cross and the Executives did not tell the Coroner about suspicions about Letby before, during or after the inquest. Louis Browne did not inform the Coroner about Dr Hawdon's review or that he knew the COCH was looking into a single nurse's attendance at a number of deaths, including Child A's. He did not check that the family and their representatives had been given this information in advance (in accordance with his earlier advice). Mr Rheinberg's evidence was that, so far as he was concerned, "*there was not a*

[244] See also Stephen Cross' notebook which makes no reference to Letby [INQ0106816_0057-58].

[245] [Jayaram/ wk9/ day 3/ p238/ ln20 - p240/ ln8].

[246] [Rheinberg/ wk12/ day5/ p66/ ln23 – p68/ ln12]

[247] See Josh Swash's handwritten note of the inquest [INQ0108406_0015-27]; COCH attendance note [INQ0008944]; and Pryers' attendance note [INQ0107909]. See also the record of inquest [INQ0002042_0018].

whisper of any suspicion"[248]. This is impossible for Child A's parents to understand given what the COCH, its witnesses and its legal representatives knew. It should not have happened.

208. On behalf of Parents A and B, we made the following criticisms:

a. Stephen Cross and the COCH Executives deliberately withheld from the Coroner relevant information going to the possible cause of Child A's death. Put simply, they engineered a conscious and intentional cover-up.

b. Louis Browne did not act with the professionalism to be expected of independent counsel. He said he was sure he was not told about a suspicion that Child A might have been deliberately harmed[249]. However, he accepted he probably was told there was a nurse who had been on duty for a number of the deaths, including Child A's. It was therefore incumbent on him to ask for clear and comprehensive information about the possible involvement of the nurse in the death of Child A and whether there was any suspicion of negligence or deliberate harm. It is recorded that he advised (rightly) that disclosure of some information about the nurse should be given to Parents A and B, but he then simply assumed that this had been done and he never checked the position with Stephen Cross or Josh Swash[250]. He continued to assume this at the inquest, despite the obviously anomalous fact that the issue of the nurse was never raised by legal representatives for Parents A and B or by the Coroner himself, and no one questioned any of the hospital's witnesses about her.

c. In short, Mr Browne appears to have chosen not to apply his mind to, or ask questions about, the exact relevance of this nurse to Child A's death. In doing so, whether unwittingly or not, he facilitated his client's strategy of withholding significant information in its possession and allowing the family and the Coroner to be misled during court proceedings.

d. Louis Browne also advised witnesses (as per his standard advice) that they should not speculate when giving evidence[251]. This may have fortified Dr Jayaram's decision not to ventilate his suspicion that Letby had injected air into Child A or killed him by other means. The Chair may wish to consider the impact of this type of blanket advice and whether it is proper advice to give in circumstances where the cause of death is unclear and/or there is a suspicion of criminal conduct.

e. Dr Jayaram and/or Dr Saladi should have told the Coroner about their and their consultant colleagues' suspicions. Dr Jayaram said he thought that Stephen Cross had informed the Coroner, but the factual basis for this is unclear and the Chair may think it is a result of wishful thinking. However, he expressly accepted that he should have told the Coroner that a member of staff may have been responsible for Child A's death, even if the Coroner was aware of the

[248] [Rheinberg/ wk12/ day5/ p24/ ln4-6]

[249] [Browne KC/ wk12/ day3/ p62/ ln10 – p63/ ln1]

[250] [Browne KC/ wk12/ day3/ p74/ ln8-20]

[251] [Browne KC/ wk12/ day 3/ p31/ ln24 – p32/ ln14]

consultants' concerns[252]. Both doctors failed to comply with their professional obligations under Good Medical Practice and thereby misled the court[253].

209. The sum total was that there was a catastrophic failure to be open and honest with the Coroner and Parents A and B[254]. Executives, doctors and the hospital's legal representatives allowed the Coroner to conduct and conclude Child A's inquest on partial and misleading information – without any knowledge whatsoever of the consultants' suspicion that Letby had murdered Child A and other babies. If the Coroner had been made aware of these suspicions, it is unquestionable that he would have contacted the police immediately[255]. Not to have done so would have been wholly contrary to his statutory and ethical duties as a Coroner.

210. This failure was not later remedied by the COCH when Stephen Cross and Ian Harvey met Mr Rheinberg on 8 February 2017 and then with Mr Rheinberg and Mr Moore on 15 February. While the evidence suggests that certain documents were provided on 15 February 2017 [INQ0008622], we submit that specific concerns that Letby had deliberately harmed babies were simply not communicated during these meetings[256]. When Mr Moore was asked about whether Ian Harvey and Stephen Cross told them on 15 February 2017 that there was a concern that a member of staff may be responsible for deaths, he said:

> "*There was no mention whatsoever of anything of that kind. If there had been, the outcome of this meeting would have been very different, I assure you. Mr Rheinberg is a very experienced, diligent and thorough Coroner and I have no doubt that he would have contacted the police probably before Mr Harvey and Mr Cross had left the room"*[257].

211. The Chair is invited to find that Stephen Cross and Ian Harvey did not at any time tell the Coroner and Parents A and B of the consultants' suspicions about Letby. This was a deliberate and cynical

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[252] [Jayaram/ wk9/ Day3/ p246/ ln11-14 and p247/ ln3-7].

[253] See the GMC's Good Medical Practice (2013-2024):

> "*You must be honest and trustworthy when giving evidence to courts or tribunals. You must make sure that any evidence you give or documents you write or sign are not false or misleading.*
>
> *a. You must take reasonable steps to check the information is correct.*
>
> *b. You must not deliberately leave out relevant information.* [INQ0007314_0025, §72]

The GMC document, 'Acting as a witness in legal proceedings' (2013) states that a doctor's duties to the court apply in inquests (https://www.gmc-uk.org/-/media/documents/gmc-guidance-for-doctors---acting-as-a-witness-in-legal-proceedings_pdf-58832681.pdf).

[254] Mr Rheinberg's evidence is that he "*absolutely*" would have expected the COCH to have raised the consultants' concerns with him prior to Child A's inquest and it was "*horribly disappointing*" that this was not done [Rheinberg/ wk12/ day5/ p59/ ln11 – p61/ ln10].

[255] [Rheinberg/ wk12/ day5/ p63/ ln4- p64/ ln8]. See also Mr Rheinberg's evidence that, more generally, he went to the police "*with any suggestion of criminality….* [he referred to correspondence he would receive as Coroner] *some will allege criminality, no matter how extraordinary or however unlikely….All such communication was sent to the police for investigation with the instruction that I was to be informed…as to the result of that investigation. So there would be no case of me withholding such information such as that from the police…*" [Rheinberg/ wk12/ day 5/ p77/ ln5-21].

[256] In his witness statement, Mr Rheinberg said that, prior to his retirement in March 2017, he had "*not the slightest inkling or suspicion that anyone had deliberately harmed the children*" [INQ0017842_0026, §84]. Mr Moore's witness statement also stated that there was never any mention by the COCH of suspicions on concerns that an individual had been responsible for the death of babies [INQ0101346_0010, §43].

[257] [Moore/ wk12/ day3/ p136/ ln14 – p137/ ln3]

strategy to avoid outcry on the part of the parents, public scandal, criticism by regulatory bodies, the inevitable initiation of a police investigation, and the associated exposure of COCH's long-term machinations to protect itself and Letby.

Child I

General

212. Letby was convicted of murdering Child I on 23 October 2015. The Inquiry has heard the moving written evidence from Mother I (Father I is still too traumatised to speak about the events that unfolded at COCH in 2015)[258]. She told the Inquiry that she and Father I were delighted to be expecting a new addition to their family. Mother I's previous pregnancies had all been uneventful and she expected that this time would be no different. Mother I's waters broke at 25 weeks and thereafter she was kept under medical supervision. Child I was born at Liverpool Women's Hospital in August 2015 weighing 2lb 2oz. Despite her prematurity and small size, she was doing well and did not require high level intensive care. She was therefore transferred to COCH on 18 August 2015 as part of a step-down process towards discharge.
213. Mother I quickly became aware of the level of different in care and service between Liverpool Women's Hospital and COCH, with the latter being more inconsistent and chaotic due in part to a shortage of staff on the NNU. Notwithstanding this, Child I continued to improve and was feeding well and gaining weight.
214. Warning signs began to appear in early September 2015 when Child I starting to become poorly with suspected Necrotising Enterocolitis ('NEC'). She was transferred to Liverpool Women's Hospital on 6 September 2015 for further assessment. However, the potential diagnosis of NEC was dismissed by doctors at Liverpool Women's Hospital and Child I began to immediately improve away from the NNU at COCH. Mother I described how within a short space of time Child I had gone from being fully ventilated (at COCH) to requiring no ventilation and feeding well (at Liverpool Women's Hospital)[259]. Given her rapid improvement, Child I was transferred back to COCH and placed in Room 3, which was a room for babies who were deemed to be ready for discharge.

30 September 2015

215. On 30 September 2015, Mother I had changed Child I before leaving for the day, when she came into contact with Letby. Letby told her that she would keep an eye on Child I due to her stomach looking a little swollen. Approximately an hour and a half after leaving COCH, Mother I received a phone call asking her to return to the NNU as Child I had collapsed. She witnessed Child I's successful resuscitation. However, Child I's collapse puzzled doctors as she had been doing well and there did not appear to be any medical reason for her sudden and unexpected collapse. Shortly after this collapse, Child I improved rapidly and progressed such that she was able to be bathed for the first time by Mother I.

[258] [Mother I/ wk2/ day2/ p73/ ln19 - p142/ ln25].

[259] [Mother I/ wk2/ day2/ p91/ ln15-20].

13 – 15 October 2015

216. In the early hours of the morning on 13 October 2015, Mother I received another dreaded phone call from COCH telling her to attend the NNU urgently as Child I had collapsed again. When she arrived, she was informed by medical staff that this collapse had been more severe than previously, and she had had to be resuscitated at least 7-8 times because she was 'flatlining'. Child I was thankfully stabilised with intensive resuscitation techniques adopted. This collapse once again puzzled doctors because Child I's stomach had not been noted to be swollen, she was simply found to not to be breathing.

217. Child I continued to suffer a number of collapses over the weekend, each time requiring prolonged resuscitation. These sudden and unexpected collapses were occurring predominantly at night. Child I's condition was so dire that Mother I and Father I christened her on 15 October 2015 just in case she did not survive the coming days. Indeed, on that day, Child I suffered a further collapse and was transferred to Arrowe Park Hospital. As soon as she arrived at Arrowe Park (as with the collapse on 30 September 2015), Child I's condition began to quickly improve and clinicians could not understand why she had been transferred. Child I was transferred back to COCH after only two days.

218. By now there was a clear pattern emerging when it came to Child I's sudden and unexpected collapses and rapid (some may say remarkable) improvement when transferred out of COCH to another hospital.

Events Leading to 23 October 2015

219. On her return to the NNU, Child I continued to progress and Mother I was advised to bring some clothes for her in anticipation that she would be discharged in the near future. On the evening of 22 October 2015, Mother I and Father I left the NNU at approximately 10:30pm. Letby was working on the night shift. Approximately two hours later, Mother I received a phone call to say that Child I had collapsed yet again. When they arrived, they again witnessed Child I being resuscitated, though this time it was proving more challenging than previous occasions. Dr Gibbs was the consultant leading the resuscitation efforts. Tragically, after at least 20 minutes of resuscitative attempts, Child I was pronounced dead in the early hours of 23 October 2015. She was handed to Mother I. Her pain at this moment is unimaginable, she had witnessed her premature baby girl beat many odds and thrive to the point that she was ready for discharge, but each time that this outcome was beginning to be a reality, she would suddenly and unexpectedly collapse. Mother I aptly described her and Father I's emotions when she said, "*a part of us died with her*"[260].

220. Dr Gibbs informed Mother I and Father I that Child I had been a full-term baby and that she should not have collapsed and died as she did. Dr Gibbs failed to inform them that similar incidents had occurred in the months before and that clinicians had already raised and discussed concerns about the increase in not just mortality on the NNU but also other sudden and unexpected collapses that

[260] [Mother I/ wk2/ day2/ p112/ ln6-10].

did not result in death. Yet further, Dr Gibbs did not inform Mother I and Father I that clinicians were concerned that there may have been an association with a particular member of staff and that steps were being taken to consider what to do. Mother I and Father I strongly believe that Dr Gibbs, or another clinician or senior manager, owed them a duty to be open, honest and transparent regarding the issues being experienced on the NNU at that time. It has been said a number of times during the Inquiry, that Child I's death was a turning point in this tragic chronology, but Mother I and Father I believe that the turning point was much earlier and strongly believe that had action been taken in the months before her death, Child I would still be alive today.

221. Instead of leaving COCH with a beautiful baby girl, Mother I and Father I left COCH on 23 October 2015 with a few bags of belongings and her handprint. The emptiness they experienced is beyond words.

Subsequent Events

222. The only support Mother I and Father I were given was a leaflet suggesting what was available to them. In these times of immense grief, such a leaflet was meaningless. There was no proactive follow up to see how they were coping or a repeat offer of support by COCH. Mother I was solely reliant on the support and assistance provided through her GP, whereas Father I shut himself off emotionally from the whole experience and continues to do so to this day. He has struggled to deal with any aspect of the loss of Child I. As Mother I said in her evidence to the Inquiry, "*My husband has not spoken to anyone at all, he really struggles talking about anything and I do worry about him*"[261]. He blamed the clinicians for what happened to Child I from the very start. This was a source of conflict between him and Mother I who naively believed that COCH had been open, honest and transparent with them and had done all they could to protect Child I whilst she was being cared for on the NNU. Mother I even raised money for the NNU as part of Child I's funeral process.
223. No formal coronial process was undertaken into Child I's death as her post-mortem suggested that she had died of prematurity. This is something which Mother I never fully accepted, but felt there was little that she was able to do. Mother I and Father I were not informed or aware, until February 2017, that in the summer of 2016 the COCH asked the RCPCH to undertake an investigation into the increase in neonatal deaths in the NNU, which included Child I. They were equally not informed or aware, at the time, that COCH had instructed Dr Hawdon and Dr McPartland to carry out a more forensic investigation into Child I's death. Finally, they were not informed or aware that despite these numerous investigations, Child I's death remained unexplained.
224. COCH first attempt at contact with Mother I and Father I regarding the above matters was on 8 February 2017 only after the *Sunday Times* had published its article highlighting the concerns that had been raised by the consultants. Even then, they were only provided with the 'redacted' RCPCH report, which did not allude to the concerns/association with Letby that had been raised by the consultants. When Mother I contacted COCH to ask whether the review related to Child I and what

[261] [Mother I/ wk2/ day2/ p133/ ln17-19].

the relevance was, she was told that it was simply a service review and there was nothing to be concerned about. This was a blatant lie in light of what COCH knew at the time regarding the concerns raised by the consultants and consistent with the experience of other families when it came to (the lack of) open, honest and transparent communications with COCH.

225. It was a further 15 months later that Mother I and Father I were made aware of the serious concerns relating to the death of babies on the NNU and that Child I's care and death were part of these concerns. Such notification was not by COCH, but by the police on 11 May 2017. It was only once Mother I and Father I had obtained Child I's medical records via their solicitor that they discovered the surprising and shocking fact of quite how much Letby had cared for Child I during her stay on the NNU.

226. Mother I was candid in her views about COCH's blatant lack of openness and honesty when she said:

> "*I had Doctors and staff telling us that our baby's collapses and condition were 'normal' but it turns out it wasn't normal! Staff at the Hospital already had concerns about babies being unwell and about Lucy Letby well before our baby died. I, hand on heart, believed everything they said to me at the time and now I am so angry that they were not being honest. I feel lied to and that they were just covering their own backs. Even the receptionist I spoke to about the report downplayed it and said it wasn't important and it was basically for 'training'. I felt totally blinded by all their lies and cover ups. My husband isn't surprised though. He always believed something had gone wrong and the Hospital was responsible for our baby's death.*"[262]

227. Mother I strongly believes that the failures at COCH were universal from the nursing staff, to the doctors to the senior managers. Her baby and others would have been saved if action had been taken earlier to investigate the increase in neonatal deaths and Letby had been removed from the NNU whilst these investigations were being undertaken. Her views were summarised in the following passage from her evidence:

> "*I believe that Doctors and nursing staff should have acted earlier, and those in positions of authority at the Hospital (i.e. the management at the Countess of Chester Hospital) should have listened to them instead [of] trying to create their own narrative that Lucy Letby was a victim of bullying and harassment. Someone should have investigated the concerns fully at the time…babies died because someone in an office being paid hundreds of thousands of pounds didn't want the Hospital to look bad if they shut the Neonatal Unit down while they investigated why so many babies were deteriorating when they should have been thriving. Covering up failures, inadequacies and deliberate harm was valued far higher than the life of a baby whom they should have protected unconditionally*"[263].

228. Child I's death has had a devastating impact on her entire family. Mother I and Father I separated for a while as they could not deal with the tragedy that had unfolded. Their other children also

[262] [Mother I/ wk2/ day2/ p129/ ln3 – p130/ ln1].

[263] [Mother I/ wk2/ day2/ p136/ ln12 - p137/ ln5].

suffered greatly and gave up activities that they had previously enjoyed. Their eldest child stopped speaking due to the impact that the loss of her baby sister had on her[264]. Their trauma will be life-long. Child I would have been 10 years old this year, instead of watching her grown and play, the family suffer with grief each and every day and will forever keep asking 'why?'. Such events should never be allowed to happen again and Mother I and Father I hope that this Inquiry will produce a serious of robust and workable recommendations to ensure that families like them do not suffer due to incompetence, inadequacies and deliberate attempts to suppress information and evidence when things have gone wrong.

Child L and M

General

229. Child L and Child M were twins. Letby attempted to murder both babies between 9-11 April 2016.

230. The impact on the family has been profound. Father A's physical and mental health has suffered. Shortly before the criminal trial he suffered a seizure for the first time in his life, in front of his twins. He has explained that the stress and strain of these events has been "*unbearable at times*" and he has struggled with his mental health. He described how he cannot get the image of healthcare professionals doing CPR on Child M out of his mind. He experiences flashbacks. He has had to take time away from work, sought out counselling and has taken anti-depressant medications[265].

231. Parents L and M were unaware of the RCPCH and Hawdon reviews. The first they knew about any concerns surrounding their babies' care was when police knocked on their door in 2019[266]. Even then they received no information from the COCH. All information came from the police. At the criminal trial they continued to learn much new information about what had happened[267]. This should not have happened.

Child L

232. In Section 2 above, we made submissions about the very significant failure on the part of medical staff at the COCH to identify and act on Child L's insulin and C-peptide results. These were available to the COCH laboratory on 14 April 2016 and written by hand by a junior doctor into Child L's medical records at 09.30 on 15 April 2016 [INQ0001169_0021].

233. Prior to that, Liverpool Clinical Laboratories had telephoned the COCH laboratory with Child L's results. The fact of this call indicated that the results were "*urgent, unexpected or unusual"*[268]. The recorded advice from the Liverpool laboratory was that the results were "*[d]ifficult to interpret without glucose but may be inappropriate if patient was hypoglycaemic at the time of collection*" [INQ0098712_0006, §12 and INQ0001176]. After receiving the results, Dr Bowles, consultant

[264] [Mother I/ wk2/ day2/ p132/ ln10-15].

[265] [Parents L and M/ wk3/ day2/ p4/ ln5 – p5/ ln17]

[266] [Parents L and M/ wk3/ day2/ p16/ ln23 – p17/ ln15]

[267] [Parents L and M/ wk3/ day2/ p19/ ln1-6]

[268] [Bowles/ wk5/ day3/ p93/ ln3-10].

chemical pathologist at the COCH, does not recall if she spoke to a doctor on the NNU about them[269]. There is no note in Child L's clinical records recording that a conversation. If Dr Bowles did not speak with a doctor, then she should have. If she did, then either doctors on the NNU failed to respond appropriately, or there were shortcomings in the information Dr Bowles communicated.

234. Later, on 15 April 2016, Dr U made an entry in Child L's records (about ultrasound imaging) but did not pick up the abnormalities in the results recorded that morning. On 16 April 2016 at 09.00, a senior registrar (Dr S) saw Child L on a ward round but did not pick up the abnormalities. On 17 April 2016, Dr Jayaram recorded that Child L's hypoglycaemia had resolved [INQ0001169_0021-24]. He did not identify the abnormal blood results.
235. Child L's parents were totally unaware that Child L was or had been hypoglycaemic and had received treatment for this[270]. If they had been told, they could have asked questions about Child L's hypoglycaemia, including about the results of blood tests. It may be that answering such questions would have prompted doctors to reflect on the abnormal results.
236. In any event, Child L's parents should have been kept informed about their baby's condition and his treatment. Even after COCH clinicians reviewed laboratory results in August 2018 and it was clear that Child L's insulin and C-peptide results were "*abnormal and suggestive of exogenous insulin",* Child L's parents were still not informed[271]. This was unacceptable.
237. Below, we submit that access to and usage of insulin must be more closely controlled. Parents L and M support this: "*…for us, without doubt, [insulin] is a drug that needs tighter control and supervision given the harm it can cause*"[272].

Child M

238. Letby attempted to murder Child M on 9 April 2016. Child M was resuscitated for an extended time and Dr Jayaram had a conversation with Father M about stopping the resuscitation efforts [273].
239. During the resuscitation, Child M displayed unusual patches and discoloration on his skin, witnessed by Dr Jayaram. His parents were not told about this, learning about it for the first time during the criminal trial[274]. As we have submitted above, a Datix should have been submitted about Child M's unexpected and unexplained collapse and the blotching/ discoloration. It was not. No investigation at all was done.
240. The lack of investigation is incomprehensible to Parents L and M, who have said, "*[g]iven the rarity of the skin discoloration, I do not understand why more steps were not taken to consider the cause or a discussion about it amongst the doctors, or with other doctors on a wider scale. If there had been, there may have been more weight to the suspicion that this was purposefully caused. Given*

[269] [Bowles/ wk5/ day3/ p106/ ln25 – p107/ ln14]

[270] See, e.g. [Parents L and M/ wk3/ day2/ p4/ ln15-17; p13/ ln20 – p14/ ln20; p15/ ln9-11].

[271] [Brearey statement, INQ0001218_0004 and Parents L and M/ wk3/ day2/ p15/ ln12-25]

[272] [Parents L and M/ wk3/ day2/ p20/ ln3-5]

[273] [Parents L and M/ wk3/ day2/ p10/ ln2-5]

[274] [Parents L and M/ wk3/ day2/ p10/ ln14-20].

how unusual it was, I really don't understand why it was not taken further by the clinical staff"[275]. The Chair will note how this chimes with Mother A and B's feelings about the lack of urgent and formal investigation into the unusual rashes seen on her twins.

241. The lack of information given to Parents L and M and the lack of investigation and action are made even more incomprehensible by the fact Dr Jayaram was troubled by Child M's collapse, and his and others' suspicions about Letby harming babies had been forming and coalescing for many, many months. Dr Jayaram said in his police statement, "*…this occurred at a time when other incidents were occurring, a time when realisation was beginning to dawn on me and so I added Child M to my list of suspicious incidents*" [INQ0001296_0003]. Simply adding Child M to a "*list*" of suspicious incidents was completely inadequate.

242. Despite this, Parents L and M were not made aware of any concerns about Child M's (unexplained) collapse. Parents L and M said that they were told that this was normal for premature babies[276]. This was not true and it was an unacceptable breach of trust. It was put to Dr Jayaram that candour required him to, at least, alert Parents L and M to the possibility that there was an explanation into the collapse that needed to be looked into, including deliberate harm. Dr Jayaram said he did not disagree[277]. We put it higher than this – that information should have been provided to Parents L and M. They experienced the trauma of seeing their tiny baby being resuscitated and thinking he would die. Information about their baby's condition was then withheld from them. Like other parents, they were kept in the dark and misled by staff at the COCH.

243. In addition, Letby should not have been working on the NNU at all by this point and therefore neither Child L nor Child M should not have been harmed by her.

Child N

244. Letby was found guilty of attempting to murder Child N on 3 June 2016. They jury could not reach a verdict in relation to attempted murder on 15 June 2016.

245. Like other parents, Mother N described the horror of seeing her tiny baby suffer, and the lasting impact of this:

> "…*The day we were called to the NNU [15 June 2016] was the worst day of our lives, from waking up that morning being prepared to take home our son to the utterly catastrophic scene we arrived at has left a lasting imprint on us, seeing our tiny baby fighting for his life, medics*

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[275] [Parents L and M/ wk3/ day2/ p20/ ln21 – p21/ ln4]

See also the evidence that, "*unusual, rare or unexplained symptoms in a baby should be openly discussed with all the team on the unit and research taken further if the cause remains unexplained"* [Parents L and M/ wk5/ day3/ p21/ ln5-8].

[276] [Parents L and M/ wk3/ day2/ p3/ ln17-20]

See also that "*[Dr Jayaram] explained to us that these things can happen with premature babies"* [Parents L and M/ wk5/ day3/ p10/ ln9-12].

[277] [Jayaram/ wk9/ day3/ p249/ ln4-9]

doing CPR on his tiny body and not knowing if he was going to live or die with no obvious cause"[278].

246. Mother N told the Inquiry that she relives this day, every day. She described how these events have caused "*massive trust issues*". She feels like they could not keep Child N safe in hospital and, "*as parents it's your duty to protect your children and this was taken away from us when he was in a place where he should have been at his safest*"[279]. Consequently, Parents N have been extremely protective of their child. She explained that fear has stopped her having another child[280].
247. By June 2016, Letby should not have been working on the NNU at all and therefore Child N should not have been harmed by her. Parents N should not have experienced what they experienced. They should not continue to carry what they carry.

248. Many of the same themes arise in the evidence of Parents N. They were not informed at all about their child's deterioration on 3 June 2016, when he desaturated overnight, requiring 100% oxygen [Child N's medical records, INQ0000579_0015-16]. They should have been informed[281]. Parents N only learnt about this a short time before the criminal trial[282]. Father N said, justifiably, "*I find this disgusting. As parents we have an absolute right to know what was happening to and with our son*"[283].
249. In a similar vein, Parents N were not contacted when Child N had been unwell in the early hours of 15 June 2016[284]. After Child N had suffered serious deteriorations on 15 June, they never understood what had happened or why. They never felt like they were given a proper explanation for the cause of Child N's bleed, his collapse or the chronology of events[285]. No Datix was completed and no investigation was done. They were left feeling helpless and in the dark.
250. They had no idea that the RCPCH or Hawdon reviews had been undertaken. They only learnt from the police that there was a (police) investigation into unexpected collapses at the COCH or that there were concerns about Child N's deteriorations in June 2016[286].
251. Like Mother A and B, Father N felt disempowered as a parent by the staff and atmosphere on the NNU. He felt that they were not entitled to hold their own child and did not feel welcome on the unit[287].
252. Finally, we remind the Chair of the strength of feeling that Parents N have about Dr U and nursing staff, including Letby, using Facebook and private mobile phones to message each other about

[278] [Mother N/ wk3/ day2/ p25/ ln5-12]

[279] [Mother N/ wk3/ day2/ p26/ ln10-21 and p28/ ln4-7]

[280] [Mother N/ wk3/ day2/ p29/ ln2-6]

[281] Dr Brearey accepted this [Brearey/ wk10/ day 2/ p243/ ln21 – p244/ ln3].

[282] [Father N/ wk3/ day2/ p68/ ln19-21]

[283] [Father N/ wk3/ day2/ p56/ ln12-14]

[284] [Father N/ wk3/ day2/ p58/ ln11-15]

[285] See e.g. [Mother N/ wk3/ day2/ p42] and [Father N/ wk3/ day2/ p63/ ln6-8].

[286] [Mother N/ wk3/ day2/ p39/ ln2-13 and Father N/ wk3/ day2/ p67/ ln11-13]

[287] [Father N/ wk3/ day2/ p50/ ln24-25 and p56/ ln2-3]

babies under their care and about their medical conditions. This includes Child N[288]. This was entirely inappropriate and showed a flagrant disregard for the privacy of these vulnerable babies and their parents. Dr U accepted that this should not have happened[289].

Child Q

253. Child Q collapsed on Saturday 25 June 2016. The jury was unable to reach a verdict on a charge of attempted murder.

254. We invite the Chair to revisit Mother Q's police witness statements as she did not prepare a separate Inquiry statement [INQ0001542 and INQ0001582].

255. In her victim impact statement, Mother Q powerfully explained the impact of these events. She had lost another child in 2015 and because of this, she was terrified before Child Q was born. She said she had the joy of another baby in Child Q but wonders when she can just enjoy her life, "*it's just trauma after trauma*." These events have caused her "*massive anxiety with a lot of health professionals".* If she has to go to hospital, she struggles to breathe. She said, "*I am in constant state of worry and panic, I'm hypervigilant with [Child Q] and it is so draining for me*". She explained, "*Child Q is such a special little child he brings me immense joy but I know the pain in the background will always be there*". Mother Q worries about the day when she will have to explain to Child Q what happened [INQ0001582_0002-3].

256. Again, in our submission Mother Q should never have experienced this trauma and the associated anxiety. Child Q should not have to learn about what happened at the COCH. Mother Q has said, "*[o]ne thing I really struggle with is this had been going on for such a long time and Child Q was the last one if she would have been caught before, this wouldn't of happened to Child Q*" [INQ0001582_0001]. Mother Q's sentiments are correct. Letby should not have been on the NNU by June 2016. She certainly should not have been left working on the NNU after the deaths of Child O and Child P on 23 and 24 June 2016. Executives and senior managers either failed to or refused to take Letby off shift[290].

257. In common with other parents in this Inquiry, at the time Mother Q was not even told that Child Q had deteriorated (desaturating, vomiting and needing suction and oxygen) [INQ0001582_0002]. Mother Q's evidence to the police was that "*I think that they played everything down to protect the parents and prevent panic, but I feel this was not fair to us as we needed to know what was happening to our child. When you are at the hospital, nothing is in your control – you don't have your baby there to feed. You're reliant on them…*" [INQ0001542_0003]. This is yet another example

[288] See e.g. [Mother N/ wk3/ day2/ p43/ ln20 – p44/ ln4; p44/ ln19-23; p46/ ln18-20] and [Father N/ wk3/ day2/ p70/ ln23 – p71/ ln1].

[289] [U/ wk5/ day 1/ p240/ ln1-19]

[290] For example, it was put to Karen Rees that she had refused, on 24 June 2016, to take Letby off the shift the following day and, as a consequence, she attacked Child Q. Karen Rees agreed with this [Rees/ wk7/ day1/ p202/ ln11-14]. Alison Kelly took no steps to check that Letby had been taken off the NNU [Kelly/ wk11/ day1/ p127/ ln22 – p128/ ln3].

of parents not being informed about the condition and treatment of their babies, and parents being and feeling sidelined.

Conclusion

258. We began this section of submissions by stressing each Family's highly personal experience of the events at the COCH and what subsequently unfolded. However, as demonstrated, there are a number of common themes in how the Families we represent were treated. One important theme is a lack of compassion and candour by clinicians, senior managers and Executives at the COCH. NHS England's written opening submissions stated the following, which we endorse [INQ0107952_0013, §60]:

> "*Compassion and candour should be the touchstones for all engagement, including information sharing, with parents of neonatal babies. Neonatal care can be especially stressful and daunting for parents. Kindness, compassion and an emphasis on ensuring that the voices of mothers and their families are heard are essential in ensuring personalised care*."

259. These touchstones of compassion and candour were not applied at the time as they should have been, with real and lasting effects.

260. The evidence that the Families have heard and seen in this Inquiry, much of it exploring issues not traversed in the criminal trials, has added yet more pain, distress and, at times, utter disbelief to their experience. There has been an ongoing lack of compassion and candour from some, most notably the senior managers and Executives. In opening and on behalf of the Families we represent, we asked that each CP and every witness should be transparent, honest, constructive and reflective when giving evidence. We said that responsibility had to be accepted where it was justified.

261. Some witnesses have heeded that request. Unfortunately, many others have not, again most notably the senior managers and Executives at the COCH. When they came to give evidence, they maintained their denials and deflections and still have not accepted their personal responsibility for what went wrong at the COCH. At the start of the hearings in September 2024, they expressly welcomed the opportunity to "*tell [their] story*".[291] In purporting to tell their story, they have demonstrated an ongoing and painful lack of insight and reflection that was and is inappropriate in leaders and registered (or formerly registered) healthcare professionals. There has been an ongoing failure to meet the touchstones of compassion and candour.

262. Finally, in relation to the Families we represent, we return to evidence given by Mother A and B who said, "*and all we want to do is find out what happened, and we never want it to happen again*"[292]. On the second part of this aspiration, we turn to submissions on recommendations.

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[291] See the opening statement made on behalf of the Executives [INQ0107955_0002, §4]. We observe that the Families still do not know which senior managers and Executives have aligned themselves with this position. The written opening statement was said to be on behalf of Ian Harvey, Alison Kelly, Tony Chambers and Sue Hodkinson, but proceedings have shown that others share the same legal representation. This in itself is not transparent.

[292] [Mother A and B/ wk2/ day1/ p46/ ln18-20]

SECTION (4) RECOMMENDATIONS

Introduction

263. In this section, the Families draw on their analysis of what went wrong at COCH and why Letby was able to continue harming babies with impunity, together with the suggestions and recommendations made by some the witnesses gave evidence to the Inquiry.

264. The Families' 12 proposed recommendations are naturally focused on the issues that are of greatest concern to them, though it is appreciated that the Chair, and other Core Participants, may feel that there are additional recommendations that would prevent what occurred at COCH from arising in the future. These will be addressed, as necessary, in the Families' oral closing statement.

(1) Mandatory reporting of the possibility of deliberate harm by a healthcare professional

265. The repeated failures of individual healthcare staff at COCH to exercise good judgment in response to the concerns/suspicions about Letby indicates that existing policies and training on patient safety and safeguarding may be ineffective when confronted by extreme transgressive conduct. Objective, sensible, decision-making was overridden by countervailing, rational and irrational, motivations – as set out in Section (1) of this statement[293].

266. There is no perfect solution for this. But one important and invaluable step would be for the DHSC and/or NHS England to publish a single, short, document that clearly and unambiguously sets out the steps that must be taken immediately when information arises indicating that a healthcare professional has or may have deliberately harmed a patient[294]. This would apply to any and all concerns, suspicions, or allegations of deliberate harm unless they are demonstrably irrational or malicious.

267. The policy would require all those working in a healthcare organisation who become aware of information, concerns, or suspicions of potential deliberate harm, whether directly or indirectly from others, to take ownership of the situation and initiate immediate referrals to their safeguarding team, to LADO and LSCB, and to the police. These responsibilities would be mandatory – both as contractual terms of employment for all staff and as a paramount professional obligation under the guidance issued by practitioners' regulatory bodies. Some examples of professional guidance in place that can and should be strengthened include:

    a. The GMC's Good Medical Practice:

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[293] See also the written and oral evidence of Professor Mary Dixon-Woods [INQ0102624 and Dixon-Woods/ wk3 / day4/ p2/ ln 14 – p 109/ ln4].

[294] This recommendation is supported by Professor Dixon-Woods when she gave oral evidence to the Inquiry [Dixon-Woods/ wk3/ day4/ p6/ ln 15 – p 8/ ln 25].

Dr ZA told the Inquiry in her oral evidence that if there had been a policy/protocol whereby the medical professionals were obliged to contact the police if they suspected deliberate harm had taken or was taking place, then the consultants would have been empowered to take this step without fear of repercussions from the executives and senior managers at COCH [ZA/ wk5/ day1/ p79/ ln17].

Dr Jayaram, Ms Williams and Professor Bowers KC all shared the same view [Jayaram/ wk9/ day3/ p188/ ln18-22], [Williams/ wk8/ day2/ p88/ ln22-25] and [Bowers/ wk12/ day4/ p75/ ln14-24] respectively.

The 2013 version of Good Medical Practice [INQ0007314_0013] set out the professional standards applicable to doctors during the period 2015-2017. It required a doctor to take prompt action if he/she thought that patient safety, dignity or comfort is or may be seriously compromised. It also provided that if a doctor had concerns that a colleague may not be fit to practise or may be putting patients at risk, he/she should seek advice from a colleague, defence body, or the GMC. Where concerns still remained, the doctor was required to report matters in accordance with GMC guidance and workplace policies.

In light of the events that occurred at COCH between 2015 and 2017 and the failure of the organisation and the Executives to adequately investigate the consultants' serious patient safety concerns, it might have been expected that the GMC would review and clarify its guidance to doctors regarding raising concerns. However, the latest version of the guidance, dated 2023 and last updated in December 2024[295] simply repeats the same wording as the 2013 guidance without any further elaboration.

Good Medical Practice should make clear that if doctors believe that their concerns are not being adequately listened to or investigated, they *must* contact the police directly and immediately. Such an instruction is simple and effective to ensure that doctors are not criticised for contacting the police without first waiting for their employer to investigate matters in an ineffective and prolonged fashion when patient safety requires immediate and decisive action.

b. <u>The NMC's Code of Professional Standards</u>

This was published in 2015 and updated in October 2018 [INQ0002419]; and remains applicable today. It imposes on nurses a duty to act promptly if they believe there is a risk to patient safety or public protection. This included sharing information if they believe someone may be at risk of harm. It requires nurses to acknowledge and act on all concerns raised to them, to investigate and escalate those concerns (§16.4). It also provides that a nurse should not obstruct, intimidate, victimise or hinder in <u>any way</u> a colleague or member of staff who wants to raise a concern (§16.5) [INQ0002419_0017].

This guidance is also supplemented by the Raising Concern guidance published by the NMC which was last updated in January 2019 [INQ0002567]. However, as with the GMC guidance, the NMC guidance to nurses does not provide any advice about raising concerns directly with the police if nurses believe that they are unable to raise concerns within their organisation or indeed with their regulator, or they feel that the latter are not taking prompt action to protect patient safety.

Despite a number of previous Inquiries which dealt directly with patient safety and the notion of deliberate harm (Allitt and Mid-Staffordshire for example), the guidance for nurses on the raising of concerns has remained the same since 2015. More robust and clear guidance is

[295]This document can be found on the GMC website [www,gmc-uk.org/professional-standards/the-professional-standards/good-medical-practice].

required, which would be akin to those of doctors and senior managers regarding prompt action when matters of patient safety are raised to ensure patients are safeguarded until the outcome of adverse events are ascertained.

268. The above policies, once revised, should be comprehensively and regularly publicised across UK hospitals and other healthcare institutions (including GP practices). This should be supplemented by training for all healthcare professionals – up to and including board members and NEDs who may not be medically trained – on the need to apply basic patient safety and safeguarding principles to every situation where there is a possibility that a patient may have been deliberately harmed by a staff member.

269. The training should make clear that the unthinkable must always be thought[296]. This was a key lesson from the Allitt Inquiry[297], but one that appears to have been swept away in the endless avalanche of policies and changes that have been imposed on the NHS over the last 30 years. The Inquiry is reminded that Professor Bowers KC, in his written witness statement, provided that employment policies could be improved to ensure the safety of patients by having a protocol for determining when employers should refer matters of patient safety to the police, together with appropriate training on when such referrals should be triggered [INQ0106946_0015].

270. Professor Bowers KC added to this in his oral evidence to the Inquiry when he said:

> "*I think that everybody…would benefit from a protocol of those things that you would look for in deciding whether to refer to the police. I mean, the only thing that I could find was in the guidelines for conduct of formal investigations, it talks about the deliberate harm test, flowcharts says in this case consider referral to police and disciplinary regulatory body. I think it…could be much clearer, not…buried away in an Incident Decision Tree. I mean, I know that there is a great reluctance to refer to the police a) because of the reputational damage perceived to the employer; and b) because it's likely to take a very long time for the police to deal with something, which means that discipline procedures would often be put on hold while the police investigate. But yes, I do think a protocol is important. I'm not sure whether Clothier looked at this in the Clothier Report because this came up in the Beverley Allitt case as well*."[298]

(2) Control of insulin

271. Insulin is readily available in hospitals and is routinely administered to patients. It was therefore relatively easy for Letby to obtain and use it to attempt to kill Child F and Child L in the NNU. Beverley Allitt and Victorino Chua had previously killed child and adult patients in this way.

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[296] See Dr Jayaram's oral evidence on the importance of training and thinking the unthinkable [Jayaram/ wk9/ day3/ p188/ ln3-22 and p190-191/ ln1-23]. See also the oral evidence of Ms Hudson [Hudson/ wk5/ day4/ p107/ ln 21 - p108/ ln 9]; Ms Lawrence's oral evidence [Lawrence/ wk7/ day2/ p189/ ln18 - p190/ ln12]; and Ms Eardley [Eardley/ wk8/ day4/ p106/ ln17-22].

[297] Clothier Report at [INQ00017497].

[298] [Bowers KC/ wk12/ day4/ p75-76/ ln14-11]

272. There is therefore an overwhelming case for the access to and the administration of insulin on neonatal units to be restricted and more effectively controlled[299]. There is an equally strong case for the presence of exogenous insulin to be flagged in blood results as requiring the immediate attention of the treating consultant. Raised insulin and low C-peptide level in a baby being cared for on the NNU should be classified as a 'never event', which would mandate an urgent serious incident review in all cases[300].

273. Obtaining and checking blood results should also be routinely part of the handover process so that they can be properly considered and chased if not received in a timely manner, avoiding delays which could be harmful[301].

(3) CCTV

274. CCTV should be introduced into all neonatal units in the form of individual cameras in each cot/incubator, comparable to commercially available cot cameras. This would enable real-time monitoring and recording of the interactions that medical staff have with the babies in their care. It would also allow parents to monitor their babies when they were not present at the hospital.

275. CCTV will not stop every offender or catch every malevolent act, but it is likely to have a significant deterrent effect (and evidential value) and is therefore a necessary and proportionate step to prevent serious harm being inflicted on future patients[302]. Concerns about the dignity and privacy of patients and their families would be ameliorated by providing families with secure and restricted access only the cameras monitoring their babies. Steps could also be taken to ensure that only limited areas are covered by CCTV, so that if mothers wish to breastfeed or otherwise spend private time with their baby, they can utilise specific areas on the NNU to allow for this to take place.

276. In support of Recommendation 2 above, CCTV could also be extended to cover drug dispensary areas within the hospital so dispensing insulin can be monitored at all times to deter and catch malevolent use[303].

(4) Duty of candour

277. The duty of candour and the underlying principles of openness, candour and transparency, are vital to the fair and effective function of the NHS[304]. They were profoundly and repeatedly breached by

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[299] Nurse T in her oral evidence to the Inquiry supported the close control of insulin as a 'prescribed drug' as it was still stored within hospital departments without any stock balance [Nurse T/ wk6/ day1/ p67/ ln8-14]. This was also a view shared by Dr John Gibbs [INQ0102740_0145] and Dr Stephen Brearey, [Brearey/ wk10/ day2/ p66/ ln22 - p67/ ln9].

[300] See the oral evidence of Dr Stephen Brearey [Brearey/ wk10/ day2/ p66/ ln22 - p67/ ln9].

[301] See the oral evidence of Dr Ravi Jayaram [Jayaram/ wk9/ day3/ p24/ ln1 - p26/ ln6].

[302] Its provision in NNUs is supported by the RCPCH, who stated in their opening submissions that it was likely to offer significant benefit for patient safety and care quality [RCPCH Opening Submissions/ wk1/ day3/ p129/ ln15-21]. Ms Tomkinson recognised the security and deterrent effects of having CCTV on NNUs [Tomkinson/ wk15/ day1/ p17/ ln 21 - p18/ ln6].

[303] [Powis/ wk15/ day5/ p202/ ln13 - p219/ ln18].

[304] [Francis report at INQ0010493].

staff at the COCH (at set out in Sections 2 and 3 above) and there is good reason to conclude that they still routinely ignored, inadvertently or deliberately, across large parts of the NHS The existing legal and professional obligations may also be construed narrowly – and wrongly – to avoid providing important information to parents and patients about potential harm where that information is based on opinions, concerns or suspicions that are uncertain or have not been fully investigated.

278. The legislation governing the duty therefore need to be strengthened so that:

a. It captures the type of information set out in the paragraph above (i.e. the type of information in the possession of the paediatric consultants and managers at the COCH); and

b. There are significant consequences for organisations whose staff fail to comply with their duties, such as loss of funding, removal of managers or downgrading of units/departments[305].

(5) Whistleblowing

279. The legal protection currently afforded to whistleblowers is sufficient in principle[306]. However, there is presently no legal duty on employers to consider and investigate the disclosures that made[307]. In the context of healthcare, this means that hospital managers can ignore serious concerns with impunity – which is clearly unsatisfactory.

280. It should be mandatory for healthcare institutions to investigate all protected disclosures that raise significant concerns about patient safety, including the possibility of deliberate harm by a staff member. There should also be standard disciplinary/contractual and professional sanctions for any manager who fails to comply with their duty to protect a staff member who makes a protected disclosure.

(6) SUDIC

281. The evidence addressed in Section (2) above points towards a lack of training, communication and education at a national level on the applicability of SUDIC processes to in-patient neonatal deaths. Although Dr Kingdon gave evidence that this had improved, in that teaching and the curriculum focused more on SUDIC, we note Dr Mittal's evidence that the non-use of SUDIC processes for hospital deaths remains a national problem[308].

282. The importance of SUDIC processes being used consistently calls for a review of national and local guidance documents to ensure they clearly articulate that SUDIC processes apply to in-patient neonatal deaths, and such deaths are not excluded simply because the neonate has never been

[305] Sir Robert Behrens CBE told the Inquiry that the duty of candour does not work and is in urgent need of review and replacement with a stronger version of the principle underpinned by legislation, which contains consequences for organisational failures to adhere to the duties imposed to be open, fair and transparent with patients/their families [Behrens KC/ wk13/ day1/ p47/ ln13-19]. This view was also supported by Mr Vineall in his oral evidence to the Inquiry [Vineall/ wk15/ day3/ p85/ ln11-25] and [Vineall/ wk15/ day3/ p182/ ln17 - p183/ ln14].

[306] As Professor Bowers KC told the Inquiry [Bowers KC/ wk12/ day4/ p66/ ln7-18]

[307] [Bowers KC/ wk12/ day4/ p67/ ln5-8]

[308] See [Kingdon/ wk13/ day2/ p173/ ln15-24] and [Mittal/ wk10/ day3/ p84/ln 23 - p85/ ln6 and p85/ ln14-19].

discharged from hospital. Alongside this, there should be improved training and education provided to healthcare professionals working with neonates on the applicability of SUDIC processes.

(7) Internal reporting and investigation of patient safety incidents

283. In 2015/16 there was both inconsistent and inadequate use of Datix to report the unexplained and/or unexpected deterioration of babies. In addition, investigations were not commenced when they should have been. It is hoped that the Patient Safety Incident Response Framework [INQ0009265] and the ethos behind it will lead to these issues being addressed in the NHS.

284. However, the Families continue to have concerns about the definition of a patient safety incident, i.e. "*patient safety incidents are unintended or unexpected events (including omissions) in healthcare that could have or did harm one of more patients*" (emphasis added) [INQ0009265_0002]. This envisages actual or potential harm caused by an unintended or unexpected event. Unexpected harm or potential harm, in and of itself, does not appear to amount to a patient safety incident. Instead an event, presumably meaning an act or omission, needs to be identified. This leaves unaddressed one of the problems that occurred in 2015/16 – unexpected and unexplained clinical conditions occurring without events leading to harm being identified, leading to Datix forms not being completed and SI investigations not being commenced.

285. Professor Sir Stephen Powis told the Inquiry in his oral evidence that:

> "*…one of the aims of this policy was to drive much more towards thematic reviews, so bringing together an understanding of the incidents that were occurring frequently in an organisation rather than unconnected investigations on single incidents and in implementing this framework, Trusts have been asked to and have done that thematic analysis of their overall patient safety profile, therefore to drive where improvements need to be made. So I think this would firstly have supported a much more thematic approach at the Countess of Chester. There were thematic reviews introduced but I think at the time or done at the time by lead, one of the lead paediatricians there. But I think this would have set out a stronger framework for doing those thematic reviews once there was concern around a series of deaths and other incidents of harm. I think secondly this policy is, again as I have mentioned, driving much more towards involvement of patients, carers and others affected by incidents and I think that is one of the things that was missing in the Countess of Chester, the input from those who had been affected. And I think that would also drive curiosity and a greater depth of learning and understanding of incidents*."[309]

With respect, this does not address the problem we have identified above with the definition of a 'patient safety incident'.

286. The application of the Framework states that it "*…promotes a proportionate approach to responding to patient safety incidents by ensuring resources allocated to learning are balanced with those needed to deliver improvement*" [INQ0009265_0003 and _0006-7]. This is vague language that could well allow a healthcare organisation to justify inaction and limited investigations

[309] [Powis/ wk15/ day4/ p113/ ln2 -p114/ ln. 2].

on the basis that to do more would be disproportionate to the resources available. Resources should never be used as an excuse to blunt the actions necessary to ensure patient safety and safeguarding. Therefore, the Framework requires further clarity and strengthening, to make clear that the sudden, unexpected and/or unexplained death of neonates should immediately be identified as a patient safety incident, and to set out the investigations that must then take place.

(8) Collection and use of real-time data

287. There have been improvements in effective real time data collection and monitoring since 2015/16. However, there is still work to be done. This was acknowledged by NHS England in its opening statement to the Inquiry "*NHS England has set out in its corporate and this Opening Statement the areas in which it is currently working to improve patient safety. These include in particular…More effective and real time monitoring. The work arising from the Reading the Signals Report is ongoing and the Perinatal Quality Surveillance Model will provide mandated governance in relation to both the MBRRACE-UK real time monitoring tool and MOSS (which is still in the process of being developed for maternity care)[310]. There is also ongoing work with the National Guardian's Office to enhance data reporting and monitoring.*" [INQ0107952_0029 §149].

288. In his oral evidence to the Inquiry, Dr Brearey said that MOSS and MBRRACE should run together for better neonatal triggering, as there was a need to include pre-term babies and babies over 28 days old as it was only currently useful for maternity units; and the MBRRACE real time system lacks any tools to interpret the data[311].

289. Professor Sir David Spiegelhalter told the Inquiry in his oral evidence that:

> "*There is the possibility of multiple indicators, you don't need just a single monitoring system, but you might combine common outcomes as has been done or combine outcomes into what's known as the basket, but just a pooled measure and that's been done in MOSS. The importance of using cumulative data both to identify long-term trends and sudden shifts in performance, setting explicit thresholds, usually two thresholds, an alert and an alarm threshold, which would identify different levels of unusualness and would trigger different management actions*."[312]

290. Such a combined data system would be extremely useful. However, it is not clear the extent to which the current healthcare computer systems, such as Badgernet, are capable of working across a number of different systems/programmes to capture the real-time data that is crucial for the raising of 'alerts' that require action. The Inquiry is invited to consider the evidence it has heard with a view to making a recommendation that requires a compatible and comprehensive system of data input and analysis that triggers the need for a response. This would avoid what occurred in

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[310] "*Dr Murdoch explains at paragraph 41 of her statement that the Maternity and Neonatal Outcomes Group considered whether to extend MOSS to include all neonatal deaths, but this was not deemed necessary as the MBRRACE-UK real time monitoring tool has this function. For this reason, both MOSS and the MBRRACE-UK real time monitoring tool will be used together, using the same guidelines and governance, to enhance safety signal system use and interpretation. See INQ0107010_0013*"

[311] [Brearey/ wk10/ day2/ p191/ ln25]

[312] [Spiegelhalter/ wk15/ day3/ p25/ ln 15 - p26/ ln1]

COCH, namely ill-informed judgments being made about having to determine whether there had been an increase in neonatal deaths before deciding what needed to be done.

291. The Inquiry is referred to the exchange between the Chair and Sir David regarding intra-operability of medical systems as an example of the challenges which any recommendations face to ensure consistency in approach to data input and analysis[313]. Mr Vineall gave evidence to the Inquiry that there were currently no plans or intention of integrating systems that would capture and analyse real-time data across the NHS/healthcare sector to trigger the need for actions/investigations[314]. This is extremely concerning to the Families, given that Mr Vineall accepted that there was more that needed to be done on this issue.

292. Sir David was fully supportive of taking out discretionary judgment being exercised in circumstances where concerns/triggers are raised by the data:

> "*…I think having a statistical system in place to trigger something, not only does it happen fast, but in a way it avoids a lot of argument because, you know, it's gone, it's been pre-designed, these are predetermined thresholds that have been set, there are standard operating procedures. It is almost no longer a matter of discussion: sorry, that's happened, this is what now must take place. And I think that's a considerable advantage*"[315].

(9) Reporting to the CQC, NHS England, and the Coroner

293. The CQC and NHS England were not informed by the COCH about the increased infant mortality in the NNU, or about potential deliberate harm by Letby, until many months after concerns arose internally. Thus external scrutiny and intervention were avoided for a protracted period.

294. There should therefore be an explicit duty written into NHS trusts' contracts that the CQC and NHS England must be informed immediately of any unexpected rise in patient deaths in a particular unit or department, or (as per Recommendation 1) any information that indicates that a healthcare professional has or may have deliberately harmed a patient. Trusts should also be obliged to inform those bodies of any decision to commission external reports or reviews to investigate either of those matters[316].

295. Finally, NHS trust should have an explicit written duty to inform local Coroners of the above matters – with the caveat that the notification of concerns about deliberate harm should only be made in the context of a patient's death[317].

(10) Regulation of senior management

296. Leaders and board members must live and breathe professional, ethical, values when running a healthcare organisation. They must prioritise patient safety and be open, transparent and candid

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[313] [Spiegelhalter/ wk15/ day3/ p67/ ln 18 - p68/ ln21]

[314] [Vineall/ wk15/ day3/ p92/ ln 25 - p95/ ln15]

[315] [Spiegelhalter/ wk15/ day3/ p54/ ln 8-16]

[316] This type of duty was proposed by NHS England in its opening submissions [NHSE Opening submissions/ wk1/ day4/ p65/ ln1-22].

[317] This was endorsed by Nicholas Rheinberg, former Senior Coroner for Cheshire [Rheinberg/ wk12/ day5/ p79/ ln14-23].

where required[318]. They must also exercise professional curiosity and sound, objective, judgement when matters of patient safety/safeguarding are reported to them. They must keep an open mind when appraising unwelcome information and not make assumptions about events that they have not properly understood or investigated.

297. The events at the COCH between 2015 and 2017 exemplify how the absence of these qualities can have devastating, fatal, consequences. This must not happen again when, as is sadly inevitable, the next healthcare crisis materialises. Its leaders should know that they need to respond swiftly and decisively to protect patient safety. They should recognise that if they do not do so they will face significant personal consequences, not be put on leave pending reassignment to another institution.

298. There is a clear and compelling need for NHS trust executives (i.e. senior managers) and board members to be regulated independently of the existing bodies that regulate those who are registered healthcare professionals. Regulation of NHS managers was a Labour manifesto commitment and should be followed through. The management and oversight of hospitals is a different responsibility to treating patients and requires different skills, priorities, ethics and judgments. It needs a dedicated, specialist, body that can (1) set the standards and code of conduct that are required of managers – including the primacy of patient safety and safeguarding, (2) provide guidance and support to managers when required, and (3) hold managers account when they fall short[319].

299. Standards for healthcare managers should identify protecting, promoting and maintaining patient safety as the overriding principle. In common with other healthcare regulators, the overarching objective of the new regulator should be the protection of the public, which should include protecting, promoting and maintaining patient safety.

300. The new healthcare executive regulator will need to support and be supported by the CQC and NHS England, to set, monitor and improve management standards nationally. A career development framework and training for those working as senior managers or aspiring to this will need to be implemented[320]. The CQC will need to be more robust in the way that it satisfies itself that executives and board members are performing satisfactorily – by sampling appraisals during their inspections[321] and looking more closely at the governance of patient safety, safeguarding and the duty of candour.

301. We also submit that the Inquiry should fully endorse and repeat the recommendation made by Tom Kark KC in his report 'A review of the Fit and Proper Person Test' that:

> "*Requiring the identification and definition of what is regarded as 'serious misconduct' justifying barring. This should focus upon deliberate of reckless but not inadvertent behaviour. Apart from*

[318] See Sir Robert Francis KC's oral evidence to the Inquiry [Francis KC/ wk4/ day1/ p73/ ln1-24, p151/ ln 21 – p152/ ln20].

[319] See Sir Robert Behren and Professor Smith's oral evidence to the Inquiry [Behrens/ wk13/ day1/ p39/ ln15-24] and [Smith/ wk14/ day3/ p87 /ln 21]

[320] Evidence of Tracy Bullock, former CEO Mid Cheshire NHS Foundation Trust [Bullock/ wk14/ day3/ p80/ ln2-20]

[321] See Tom Kark's oral evidence to the Inquiry [Kark KC/ wk15/ day4/ p16/ ln4]

obvious misconduct such as dishonesty and crime, we think there should be a focus upon behaviour which suppresses the ability of people to speak up about serious issues in the health service, whether by allowing bullying or victimisation or those who 'speak up' or blow the whistle, or by any form of harassment of individuals. There should be a focus on discouraging behaviour which runs contrary to the duty of candour, so any deliberate suppression or falsification of records of relevant information should be regarded seriously. Further, serious misconduct should included reckless mismanagement which endangers patients." [INQ0012637_0020 §1.8(f)]

(11) Social media and personal communications

302. The Families believe strongly in the need for guidance to be provided to all healthcare professionals about the use of social media and other electronic platforms, such as text, WhatsApp and Facebook Messenger to discuss confidential matters relating to patients. This was explored with Ms Herniman on behalf of the NMC who accepted that their guidance may require further review[322].

(12) Effective implementation of recommendations

303. There is no single body that collates and monitors the recommendations made by statutory and non-statutory public inquiries, and other forms of external investigation, for the improvement of patient safety and safeguarding generally within the healthcare sector[323]. Recommendations are therefore routinely ignored or allowed to be forgotten, with little corporate or political memory as to why they were made in the first place and why they have not been implemented[324].

304. A new unit within the central UK Government structure should focus on collating and categorising recommendations, reducing duplication and banding them into key areas/topics/concerns and levels of significance. This would ensure that policymakers remained aware of the most significant outstanding recommendations – those that (1) are most urgent, (2) would prevent catastrophic events, (3) have the greatest general effect, (4) be most cost-effective, and (5) would most readily simplify and unburden the working lives of practitioners on the ground[325]. Furthermore, the Inquiry may wish to consider the extent to which the Chair would wish to remain involved in the review and progress made with implementation of the Inquiry's recommendations and where appropriate the steps that should be taken to hold those tasked with implementation to account[326].

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[322] [Herniman/ wk14/ day2/ p147/ln 17 - p149/ ln 18]

[323] See Sir Robert Behren's oral evidence to the Inquiry [Behrens/ wk13/ day1/ p40/ ln7-24].

[324] A notable example of this is the recommendation for a medical examiner system. This was made by three inquiries – the Shipman Inquiry, the Mid Staffordshire Report, the Morecambe Bay Investigation – but was not taken forward by any Government until Chancellor of the Exchequer, the Rt Hon Jeremy Hunt MP, who happened to be a former Health Secretary, provided the political will and secured the necessary financing.

[325] Mr Hunt, in his oral evidence to the Inquiry, suggested a traffic light system to catalogue the importance of recommendations so that focus is placed on the most urgent and then one can work one's way down the list [Hunt/ wk14/ day3/ p193/ ln1-8].

[326] This is a point that the Families made in their written opening statement [INQ0107950_0029 §129].

SECTION (5) – CONCLUSION

305. The Families have faith that the Inquiry's report will identify what went wrong at the COCH and will make clear and robust recommendations to the Government on how to prevent such events from recurring. They dearly hope that something good will come from their personal tragedies.

306. As this closing statement is made before the Families have seen the statements of the Inquiry's other Core Participants – including NHS England, the COCH, and the Executives – they will respond, as necessary, to the positions taken in those statements during their final oral statement.

307. In the meantime, the Families wish to thank the Chair and her counsel, solicitor and administrative team for the diligence with which they have conducted this complex Inquiry. Hearing and reading the evidence has understandably been extremely difficult for the Families. But it has been made easier by the respect and sensitivity with which the Inquiry has treated them and the rigour that has been brought to bear on the evidence.

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4 March 2025